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Submitter Information

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General Comment

Dear Cindy Bladey, Please accept the uploaded file which contains comments on the Patient Release Program.
Thank you for the opportunity to comment.

Attachments

2017 Patient Release Letter

UNIVERSITY of VIRGINIA
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
ENVIRONMENTAL HEALTH & SAFETY

June 21, 2017

US Nuclear Regulatory Commission
Cindy Bladey, Office of Administration
Mail Stop: OWFN-12-H08
Washington, DC 20555-0001

Dear Ms. Bladey,

In response to your request for comment on the NRC's patient release requirements, we wish to submit the following comments as specified in the Federal Register Notice NRC-2017-0094 "Patient Release Program". If you have any questions I may be reached at 434-982-4917 or dps3c@virginia.edu.

Sincerely,

Deborah P. Steva

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COMMENTS ON PATIENT RELEASE PROGRAM
DOCKET ID NRC-2017-0094

A. *Development of an Activity-Based Patient Release Threshold* - Question: Should the NRC develop an activity-based patient release threshold?

1. *If so, explain why and provide a potential activity-based criterion.*
2. *If not, explain why the regulations should remain as is.*

Response: No. We do not believe there is a need to return to or develop an activity-based release threshold. We believe the 500 mrem limit to members of the general public set in 10 CFR 35.75 is adequate to protect public health. If an activity based threshold is used, some licensees may not be able to provide the needed radiation therapy to a patient due to potential complications associated with hospitalizing the patient for a specified period of time.

The existing licensing guidance for medical facilities (NUREG 1553, Vol. 9) allows licensees to use tabular values for patient release utilizing relatively conservative assumptions. Alternatively, patient release calculations, using various assumptions of uptake, occupancy, etc., based upon the patients' specific living and working conditions are acceptable and have been used successfully by many licensees. It has been noted that even with the calculation method, several assumptions and default values used for those calculations result in conservatively high estimates of dose to those who come into close proximity to these patients. Patients benefit by being allowed to return to their home environment and the public is adequately protected when licensees go through the evaluation process to estimate potential doses to the public.

Given the variability in knowledge and availability of health physics staff supporting the release program at various institutions, it would be helpful if the NRC developed a standardized spreadsheet or online program for iodine therapy patients similar to those that are currently available through various websites, e.g. RADAR, spreadsheet developed by Vanderbilt, Zanzonico, etc. which can be used by all treating facilities to successfully calculate predicted dose to members of the public from a specific therapy and generate adequate instructions for the patient to follow. Instructions for obtaining measured exposure rates at set distances from the patient and instructions on how to select and apply appropriate occupancy factors, uptake fractions, internal dose contribution and other variables which must be used in calculations should be provided as well. This would help to standardize the calculations that various institutions are using (or not using) to document that the patient will be released with adequate instruction to minimize dose to the general public. This would be particularly helpful for smaller programs which may not have health physics staff available to assist with the more complicated calculations or instruction preparation. This spreadsheet or online program should be made available and recommended for use but not required.

3. *In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.*

We are in agreement with NRCP Report 155 which states "Due to the infrequent nature of potential radiation exposures and because of the substantial benefits that accrue to the family from the patient's treatment, a radiation dose limit of 5 mSv annually for members of the

patient's family is recommended." The exposure limit set in 10 CFR 35.75 allows licensees to calculate the potential dose to family and members of the general public who may come in contact with the patient. It provides flexibility both for the treating facility and the patient. Patients who can isolate themselves from members of the public and agree to do so in writing should be given the opportunity to receive the radiation therapy as prescribed by their physician and return to a setting which is most comfortable for them. Revising 10 CFR 35.75 to an activity based threshold would remove this flexibility and would burden both hospital facilities and patients. This would also increase the radiation exposure to nurses and staff who are required to care for the patient during their stay. Allowing a patient the option of isolating themselves at home will typically reduce dose to licensee staff and members of the public if instructions are followed.

B. *Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals* - Question: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider?

Response: Yes, we believe 10 CFR 35.75(a) should be clarified. The current regulation is somewhat ambiguous regarding the time frame associated with the current dose limit. The appropriate time frame and limit would be 500 mrem (5 mSv) to members of the public and other family members per administration. Licensees should try to limit the dose to 500 mrem or less over a period of 365 days in the spirit of ALARA but it should not be a limiting requirement. There are several reasons for utilizing a per administration limit. According to our clinicians, multiple administrations of these regulated radiopharmaceuticals or permanent implants within one year are not common. Unless a patient received multiple administrations by the same licensee, it may be difficult for licensees to know if patients had received previous administrations within the past year from another institution, and all the involved details and instructions associated. (In addition, how do you define past year? Calendar year, last 365 days?). It is also difficult to know exactly how much dose members of the public actually received following any administration, only what they could have potentially received if the instructions regarding time and distance were followed by the patient.

In either case, describe the resulting health and safety benefits, or lack of benefit, to the individual being released and to individual members of the public as a result of the proposed clarification.

There are several benefits for the patient. Even in the uncommon occurrence that a patient might receive repetitive administrations within "one year", they would still have the benefits of returning to their home environment. There is less risk of acquired infections in the home environment. The patient may be able to go back to work sooner if calculations show the dose to co-workers would be acceptable. Family members may derive benefit from having their patient family member at home as well. In circumstances where there are multiple therapies within a 365 day time frame, we find that the patient and family members are more prepared for the necessary restrictions following subsequent administrations and doses to family members and public are likely less due to better preparedness and familiarity with the instructions. In addition, it would not be unreasonable to have a provision which allows a family member caregiver to

make an informed decision to be able to exceed the dose limits if there is a benefit to both caregiver and patient. While there is no direct benefit to the public, there is also no demonstrable risk to the public.

C. *Appropriateness of Applying the Same Limit on Dose From Patient Exposure to All Members of the General Public* - Question: Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?

1. If so, explain why.

Response: Yes, with a recommendation that doses to young children and pregnant women be limited to 100 mrem if possible.
Use of an appropriate spreadsheet or program allows a licensee to calculate potential doses to these various groups and generate appropriate instructions. Applying the same dose limit for all of those listed is appropriate, based upon risk. The risk associated with the difference in the two limits is too small to quantitate. A recommendation of a goal of 100 mrem for pregnant women and children is in keeping with the spirit of ALARA. A standardized specific set of instructions designed to limit internal dose as well as external dose to this set of members of the public should be required of all licensees as a means of limiting dose to pregnant women and children and as a means of ensuring that all licensees are providing at least a basic set of instructions to protect members of the general public. Calculation methods provided in NUREG 1553 Vol. 9 allow one to estimate dose contribution for dose resulting from transfer of contamination to workers or family members. Perhaps a standardized dose calculation should always include contribution for internal dose.

Concern has been raised about contamination and the possibility that hotel workers would come into contact with contamination from the patient. Based on experience here with inpatients, the sink, toilet and shower can become significantly contaminated and this contamination is not always easily removed by simple cleaning methods. There could be rare cases where certain hotels are located in close proximity to hospitals and are more heavily used by patients and their family members, potentially exposing these hotel workers to more contamination than they would normally encounter. The licensee should ask if the patient plans to go to a hotel. Using a hotel should be discouraged unless the patient agrees to and is prepared to take all the same special precautions they would take if they went home, e.g. extra toilet flushes, thoroughly rinse sink, shower after use, clean up any spills, use paper towels, disposable cups, utensils, etc. The hotel worker should be considered the same as a family member or the general public as far as potential exposure. Presumably hotel staff wear disposable gloves when cleaning these areas. As such, they should be adequately protected from contamination due to a stay by an iodine therapy patient who is compliant with instructions provided by the licensee. Again, the key here is that good instructions are provided and followed by the patient to minimize dose to the general public. Again, a set of mandated instructions would ensure certain minimal instructions are provided to everyone.

2. If not, what criterion should the NRC use for an individual group or groups? Specify the group (e.g., family members, young children, pregnant women, caregivers, hotel workers, or others) for each criterion.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.

Response: By utilizing one release criteria it makes it easier for the licensee to calculate potential dose and provide clear instructions which are easy to follow by the patient. A standardized set of required instruction ensures that all patients leave with a set of instructions that can help better protect the general public from unnecessary radiation exposure.

D. *Requirements for Releasing Individuals Who Are Likely To Expose Young Children and Pregnant Women* - Question: Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?

1. If so, explain why and describe what the requirement should include.
2. If not, explain why the requirement is not needed.

Response: A Qualified Yes, as described previously. 10 CFR 35.75 requires licensees to provide written instructions to released patients if the Total Effective Dose Equivalent (TEDE) to any other individual is likely to exceed 1 mSv (100 mrem). As described above, doses to young children and pregnant women should be limited to 100 mrem unless there is some mitigating circumstance. However, there should not be a specific requirement that doses must be limited to 100 mrem or less but there should be a specific requirement to provide a standardized set of instruction that must be included to address contact with pregnant women and children. The required instruction should also include some information on the **potential** risks associated with exposing pregnant women and children. The requirements for written instructions should include a requirement that documentation be maintained showing that the patient acknowledged by signature that they received the instructions, agreed to follow the instructions, and were provided the opportunity to ask questions. If these specific instructions are followed, the dose to young children or pregnant women should be less than both the 500 mrem limit and recommended 100 mrem.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to a young child or to pregnant woman.
Response: Patients who receive proper instructions and information are more likely to limit general public exposures to as low as reasonably achievable. That is the goal/mission of all medical licensees, to do no further harm. The NRC and Agreement States must ensure their licensees are adhering to 10 CFR 35.75 with regards to patient instructions when released

E. *Requirement for Timely Discussion With the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning* - Question: Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?

1. If so, explain why and describe what the requirement should include.
2. If not, explain why the requirement is not needed.

Response: The answer to this question is a qualified "no." We believe there should be a specific requirement for the licensee to have a patient isolation discussion with patients but the time frame should not be specified. The licensee has a responsibility to ensure that they are able to meet the requirements of 10 CFR 35.75. Not all licensees have the quality release program that larger institutions typically practice. A recommended time frame should be provided, however, it should be in the form of guidance. Just as there are other conditions for appropriate informed consent, the patient should be capable of following instructions before the treatment can proceed.

NRC and Agreement State inspectors also have a responsibility to adequately inspect licensee's release policies and procedures. Rather that regulate the patient isolation discussion, it should be a required part of licensing and guidance (e.g. NUREG-1556, Vol.9), as well as inspection procedures.

It is recommended that the licensee provide instructions in preparation and in advance to the therapeutic procedure. In the circumstance that hospitalization is required, advance determination will ensure that the dedicated I-131 hospital rooms are available and that hospital staff are trained and prepared. For the majority of patients, who are released rather than hospitalized, the patient has the opportunity to make necessary preparation for release to their home.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to individual being released, the licensee, and to the public.

Response: The timeliness of access to relevant radiation safety instructions and restrictions is critical to the patient being able to comply with the measures designed to reduce dose to the public. It is also important to the patient to be able to make alternate plans for family members, especially for infants and children, if the living conditions are not compatible with the instructions provided, e.g. do not share a bathroom, time and distance restrictions for family members, sleeping arrangements. If the patient is well prepared and knowledgeable they are more likely to comply with instructions and they will have less concern for potential harm to family members. We are seeing a greater number of patients who share a 1 bedroom apartment with multiple family members or families. In addition these same patients may have a 4 hour drive. Advance instruction is necessary to ensure alternate living arrangements can be made or arrangements are made for inpatient treatment, and that the entire family does not accompany them by vehicle to and from the treatment center, including the 4 hour ride each way. If a patient is not adequately informed of the relevant radiation safety instructions and restrictions, the licensee is placed in a position of having to refuse treatment to the person, modifying the administered dose, or releasing the individual under less than optimal conditions and potentially increasing dose to members of the public. If a patient is not adequately compliant in spite of being informed of the relevant radiation safety instructions and restrictions, that behavior may result in cancellation of the procedure.

F. *Requirement To Ensure Patients Are Given Instructions Prior to the Procedure* - Question: Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?

1. If so, explain why and provide a recommended time period for the instructions to be provided.
2. If not, explain why the requirement is not needed.

Response: The response to this question is similar to that for the previous question (E.). Yes, the regulations should specify that instructions should be given prior to the procedure but the timing, e.g. how much in advance of the administration, should be left up to the licensee. It should be recognized that a full set of instructions cannot be provided (e.g. number of days for certain activities) until exposure rate measurements are performed following treatment.

At some institutions, but by no means all, licensees provide patient information on their website as well as in written form prior to treatment. General information may also be provided by the patient's primary care or referring physician. On the internet, peer reviewed patient information is also available from reputable medical sources, such as www.thyca.org, www.throid.org, www.snmmi.org. Licensees may also refer to or recommend those sites to patients.

For those patients who undergo diagnostic scan prior to therapy, the patient can be instructed regarding the potential for receiving a therapy dose and provided with appropriate information and instructions at that time. At our institution we have a nuclear medicine staff member who serves as a patient counselor to inquire and assess the patient home and work situation through a series of standard questions in advance of the therapy appointment. They also discuss the therapy procedure and potential restrictions and instructions with the patient in advance of the therapy appointment. We also provide them with brochures and information on our website prior to the therapy dose.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released, the licensee, and to the public.
Providing the patient with clear and concise information increases the chance that the patient will be successful in following the instructions. This also benefits the public by reducing unnecessary dose. There are instances when the patient receives the diagnostic dose and therapy dose on the same day. In these cases, the licensee should not be restricted from providing necessary treatment because a specific time frame for providing advance instructions is specified in the regulations. The physician needs to retain flexibility to treat in a way they believe is best for the patient in the context of ALARA.