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Patient Release Program; Extension of Comment Period

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Comment on FR Doc # 2017-11027

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Submitter Information

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General Comment

Please see the attached comments submitted on behalf of the University of Colorado Radiation Safety Committee.

Attachments

UCH RSC Response to NRC 2017-0094

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June 26, 2017

Ms. Cindy Bladey, Chief
Rules, Announcements, and Directives Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Docket ID NRC-2017-0094, Patient Release Program; Request for Comment

Dear Ms. Bladey,

The University of Colorado Hospital Radiation Safety Committee appreciates the opportunity to provide comments on the patient release programs. As the NRC has indicated in Best Practice Concepts for Patient Release, "the current patient release criteria appropriately balance public safety with patient access to medical treatment."(NRC, 2017) The publication of this information notice should help licensees to improve their patient release processes within the current regulatory framework, which has been in place for 20 years. We do not believe the regulations need to be revised. Please see the responses to the specific questions in the Federal Register below.

Should the NRC develop an activity-based criterion for patient release?
The NRC should not revert to an activity-based patient release criterion. The current regulatory framework, with a requirement that the patient may only be released if the likely dose to another individual will not exceed 5 mSv, allows licensees to use simplified release criterion based on activity or dose rate, but it also allows patient-specific calculations to be made to justify that the likely maximum dose to a family member or caregiver will be below the regulatory limit. Physicians and physicists have the flexibility to work with patients to develop a plan that ensures regulatory compliance, keeps doses to others as low as reasonably achievable (ALARA) and is reasonable given the patient living situation and other considerations. Under the current system, some patients are hospitalized for radiation isolation while others can isolate in the comfort of their homes.

The return to an activity based patient release criterion would result in many more patients being forced to stay in the hospital, increasing treatment costs with no medical benefit to the patient and no demonstrable benefit to the public. At a time when healthcare costs are rising and healthcare resources are not keeping pace, allocating hospital beds to patients who do not need nursing care is difficult to justify. Access to treatment with radiopharmaceuticals would be more difficult and patients would wait longer to obtain care, which could allow cancer to spread.

There is no evidence that the current patient release criterion puts members of the public at risk. At doses below 50 to 100 mSv, the health risk is either too small to be observed or doesn't exist (Health Physics Society, 2016). The regulations should only be revised if the benefit to society from the change is greater than the associated costs (financial and otherwise).

Should the NRC clarify the time covered by the current dose limit for releasing individuals?
The current dose limit should be clarified as per-release, as was indicated when the final rule for the current regulations was released (Federal Register, 1997). It would be reasonable to publish guidance that encourages licensees to take into account previous administrations of radioactive materials when planning a patient therapy. However, the decision regarding the timing of therapies should be based on medical need.

Compliance with an annual dose limit for individuals exposed to patients released following administration of radioactive materials could be very difficult. Under the current regulatory framework, patients receiving diagnostic scans are releasable without instructions based on the activity administered using tables U.1 and U.2 in NUREG-1556, Vol. 9 Rev. 2. If an annual dose limit were implemented that would take into account all diagnostic and therapeutic administrations, a significant increase in recordkeeping would be required. Many patients receive medical care from more than one facility. Would the doses need to be tracked across multiple licensees? Would the annual dose limit be by calendar year or 365 day period?

Also, there is no evidence that the risk of health effects is greater for a caregiver who receives more than 5 mSv during one year than if the same dose is received in two separate years.

Should the NRC continue to apply the same dose criteria of 5 mSv 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?
The current criteria of 5 mSv should be maintained for all members of the public, understanding that the calculation is based upon the individual likely to receive the highest dose from exposure to the released patient. That individual is usually an adult caregiver.

The occupational limit for dose to the fetus of a declared pregnant woman is 5 mSv and there is no justification for the regulatory dose limit to the child of a patient to be set lower. According to the NCRP, "there is no harm from deterministic effects and the risk of stochastic effects is less than one percent" when the dose to a fetus or child is less than or equal to 50 mSv, which is ten times the current regulatory limit for members of the public.

However, in accordance with the ALARA principle, patients should be encouraged to follow restrictions that will keep the doses to children and pregnant women below 1 mSv when reasonable, given the financial and emotional consequences of extended restriction periods.

Changing the regulatory release criteria to ensure children and pregnant women do not receive doses above 1 mSv is likely to have a significant impact on costs and access to care for families who can least afford it. Hospitalization and childcare are expensive and many facilities do not have the capacity to provide inpatient isolation for individuals who do not require nursing care.

Licensees should also provide instructions that will keep the doses to other members of the general public, such as hotel workers, ALARA. There are times when it may be necessary for a patient to stay in a hotel following treatment and the radiation doses to hotel staff and guests are not likely to exceed

1 mSv (ACMUI 2010). However, a licensee should not be sending large numbers of radionuclide therapy patients to the same hotel.

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?

The regulations do not need to be revised because licensees are already required to consider special exposure pathways and risk factors for sensitive populations. Instructions given to patients should include specific information regarding steps to keep doses to children and pregnant women ALARA. There should not be a specific requirement to hospitalize patients who have children because the majority of our patients are able to make arrangements so they can follow the instructions we provide to keep doses below 1 mSv. Patients who cannot self-isolate are often kept as inpatients overnight or longer as necessary to keep doses to children or pregnant spouses below 1 mSv.

This is definitely an area where improved guidance should be developed and provided to licensees. However, changing the regulatory release criteria could negatively impact patient care without a benefit to the public, as discussed previously.

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?
Working with patients to ensure they have the information needed prior to the time of treatment is an essential part of good patient care. For most radiotherapy patients in our facility, we work with the patient days to weeks before the scheduled therapy to develop a plan for isolation. The concern we have with a specific requirement for the discussion is how a sufficient time will be interpreted. Individual cases will vary and the licensee should have some flexibility to meet the needs of each patient.

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)?
A time frame should not be specified. Hyperthyroid patients may require same day radioiodine diagnostic imaging and I-131 therapy. Requiring the instructions to be provided at an arbitrary time in advance could delay treatment and inconvenience patients. Physicians need the flexibility to work with patients to determine the right time for treatment, whether that is immediately or later.

Sincerely,

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