

June 10, 2017

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Docket ID NRC-2017-0094, Patient Release Program Requirements

Dear Chairman Svinicki:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to provide comments on the Nuclear Regulatory Commission's current patient release requirements. SNMMI's more than 17,000 members set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on specific topics detailed below.

A. Development of an Activity-Based Patient Release Threshold

According to 10 CFR 35.75, a licensee may authorize the release of any individual who has a radiopharmaceutical if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv. This represents a risk-based approach which takes into consideration many aspects of the patient's specific situation. Adopting an activity-based release threshold would ignore the fact that there is substantial variation in patients with regard to their anatomy, physiology and living situation. One activity level may be reasonable for one patient and twice that may be reasonable for another. As a result, adopting an activity-based release threshold would likely be overly conservative (in order to be appropriate for the vast majority of patients) and would lead to many patients being unnecessarily retained. With proper consideration and instruction for the patient, there is no evidence that the current approach has put any individual at undue risk, and thus the SNMMI recommends its retention.

It can also be noted that the NRC's *Consolidated Guidance About Materials Licenses* (NUREG 1556, Vol 9, Rev 2) already presents methodology and justification for implementing activity based patient release, as well as measured dose rate patient release – the latter accounting for shielding by tissue. The thresholds are simply derived from 10 CFR 35.75 5 mSv public exposure limits implemented using the most conservative assumptions. In fact there are many clinical situations in which this guidance is utilized. However the NUREG 1556, Vol 9, Rev 2 document also provides guidance for calculating patient specific exposure estimates and presents this as an equal alternative option for patient release. In practice this option is also used in many clinical situations. We feel that the flexibility presented in this guidance document allows for implementing patient-centric care, is scientifically appropriate and ideal for use in our field.

B. Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals

Currently, under section 35.75(a) of title 10 of the Code of Federal Regulations (10 CFR), a licensee is allowed to release a patient if the dose to any other individual is not likely to exceed 5 mSv. This regulation has traditionally been interpreted to mean that the 5 mSv exposure limit is per release of the patient, rather than a yearly limit. Other interpretations that support a per-year limit, would be prohibitive and difficult to follow. It is also uncommon that a patient requires a second treatment within the one-year time frame. For these reasons, the SNMMI recommends the approach of a 5 mSv limit per release.

C. Appropriateness of Applying the Same Limit on Dose From Patient Exposure to All Members of the General Public

The 5 mSv limit total effective dose equivalent from exposure to a release individual who has been administered a radiopharmaceutical applies to any individual including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public. The underlying assumption is that this dose level is safe and reasonable under these circumstances. There is no evidence that having this dose level higher than that for the general public (1 mSv) has put any individual at undue risk.

Requiring practitioners to consider different dose limits for different members of the public would be complicated. However, if it is done, it should only involve pregnant women/fetus and children. Some of our members already give more stringent release instructions to limit dose to children and pregnant women since age of exposure matters (Fahey, et al). Other adults listed in the question for comment are less likely to develop ill effects of radiation exposure. In particular, caregivers have previously been studied. In at least 1 article, they have been noted to only receive small radiation doses when following appropriate instructions (Greaves, et al). For family members, it has been documented that the current instructions do well to minimize exposure (Greenlee, et al and Han, et al).

It is surprising to see the discussion of hotel workers in this list since NUREG 11-024 (issued 2/14/2011) states that having patients go to hotels following treatment is “strongly discouraged.”

D. Requirements for Releasing Individuals Who Are Likely To Expose Young Children and Pregnant Women

As discussed in above section C, there is no evidence that adjusting the total effective dose equivalent for any patient population would put any individual at undue risk. However, it is appropriate that all written instructions for those likely to exceed 1 mSv should address the risks to children and pregnant women, specifically that these populations are more vulnerable to the effects of radiation and that their exposure should be kept as low as reasonable achievable (ALARA). In consideration of ALARA, it is appropriate for the patient to maintain a distance of > 6 feet until there is reasonable assurance that the exposure is < 5mSv, based on patient specific calculations. Patients should also be counseled on the option to temporarily relocate children outside of the household in accordance with ALARA, however this is sometimes impossible.

We want the NRC to note that many members of the SNMMI already find it exceptionally difficult to admit patients to the hospital for radionuclide therapies. This is true even after writing an appropriate letters outlining the reasons why the radiation safety issues warrant hospital admission. If the regulations become stricter, the NRC should recognize potential unintended consequences. In particular, we would ask that there be a mechanism in place to require insurance companies to cover admissions performed in adherence

with NRC regulations. We do not want the patient to be placed in a risky financial situation. Importantly, another unintended consequence could be in delay in therapy with while awaiting insurance approval or potentially inability to treat a patient safely, which could be a true health hazard. In discussion of proposed changes, the SNMMI asks the NRC to consider these important points.

E. Requirement for Timely Discussion With the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning

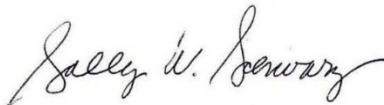
It is critical to have a timely discussion with the patient well in advance of scheduled date of I-131 administration. This is not only helpful in providing adequate logistics time to the patient and licensee to coordinate isolation but it also helps in ensuring compliance to specific preparations, such as low iodine diet. At a previous NRC call on this matter several participants expressed that it is beneficial to have at least a two week lead time to allow the patient and the families/friends prepare for isolation. Ideally, this discussion can take place in the setting of a formal consult with the patient by nuclear medicine physician. Many institutions in the country are now routinely offering this consult service and are discovering significant benefits in terms of proper preparations and planning for therapy.

F. Requirement To Ensure Patients Are Given Instructions Prior to the Procedure

Detailed instructions are paramount to ensure that the patients are in compliance after the procedure. Ideally these instructions are given to the patient during discussion and the patient/their families are allowed ample time for questions/concerns/clarifications. The written instructions detailing the same should then be given to the patient so that the patient and their families can refer to them periodically. These instructions should ideally be given in advance of the procedure (such as during consult, as elaborated in section E) and can be reiterated during the actual procedure.

As always, SNMMI is ready to discuss any of its comments with the NRC. In this regard, please contact Caitlin Kubler, Senior Manager, Regulatory Affairs, by email at ckubler@snmmi.org or by phone at 703-326-1190.

Sincerely,



Sally Schwarz, MS, RPh, BCNP

References:

NUREG 1556, Vol 9, Rev 2

NUREG 11-024

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