February 10, 2014

Mr. Peter Crane
6545 27th Avenue NW
Seattle, WA 98117

Dear Mr. Crane:

I am responding to your April 15, 2013, letter to Chairman Macfarlane, in which you questioned the Nuclear Regulatory Commission's (NRC) regulations concerning licensees' releases of patients who have been administered radioactive iodine-131 (I-131). I understand the technical concerns that underlie your questioning of the legal, and health and safety adequacy of the current NRC regulatory approach to focus on whether the release of patients treated with radiopharmaceuticals will be exercised in a manner that protects three subsets of the public described in your letter. Those subsets are: (a) patients and their families, when patients are sent home; (b) users of public transportation, who may come into contact with newly released patients; and (c) hotel housekeepers and guests, when patients are sent to hotels.

With respect to your technical concerns, as you acknowledge in your letter, the Commission has directed that the NRC staff study the manner in which the current rule is being implemented and review data and calculations that may give indications of the doses actually being received by members of the public or that are likely to occur given certain common exposure situations, including hotels and public transportation as well as at home. Through your past interactions with the Commission, you certainly have highlighted many of the issues that prompted the Commission to direct the additional study. While I recognize your frustration with the time it will take for this study to be completed, the NRC awaits receipt of the additional information to help resolve the underlying technical concerns that you raise and to make an informed decision on any modifications to current regulations. We have heard from you and others that there may be a need for additional public interactions in this area. As such, the NRC staff is currently considering holding a public workshop in the spring or summer of 2014 to solicit the views of interested individuals and organizations.

I have reviewed the issues you described as "a legal question, or more precisely, an issue in which law and policy are intertwined." In its 1997 Patient Release Rule (62 FR 4120; January 29, 1997), and denial of your 2005 petition for rulemaking (73 FR 29445; May 21, 2008), the NRC addressed the issues of dose to a patient's family when the patient goes home, to fellow travelers if the patient uses public transportation, and to members of the public from contamination. In the Patient Release Rule, the NRC established a dose limit of 500 millirem total effective dose equivalent to an individual from exposure to the released patient for each patient release. In response to your petition for rulemaking, the NRC revised NUREG-1556, Volume 9, and issued Regulatory Issue Summary (RIS) 2008-11. This RIS was intended to inform licensees and the public about doses to children from patient contamination and the precautions licensees and patients should take to maintain the dose to children and infants as low as is reasonably achievable. The RIS also informed licensees and the public about precautions that should be taken to keep children away from any sources of patient

contamination. Additionally, in response to concerns raised by you and others, the NRC issued RIS 2011-01 in January of 2011 that emphasized to licensees that the obligation to assure the patient received adequate instructions to minimize the exposure of third parties should include a consideration of the intended immediate destination. Determining the patient's intended living and other arrangements after release is part of the process of determining whether the patient can be legally released. It is the licensee's responsibility to not release the patient if it becomes clear that close proximity to children at home, for example, will make it unlikely that the release condition will be met.

To the extent that your April 15, 2013, letter raises concerns about the potential of exceeding the 500 millirem limit in certain circumstances and whether such exposures would violate NRC requirements, the 2011 RIS provides some guidance. That communication emphasized to licensees that release to other than a private residence raised questions as to a licensees ability to fully comply with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.75(a). Further, it noted that a determination of compliance with the requirement in 10 CFR 35.75(b) to give adequate instructions to a patient "may depend on the licensee's consideration of the destination to which the patient will be released." This communication was intended to highlight for licensees the need to consider the very situations about which you have raised concerns when making release determinations. The regulations do not, however, require licensees to address in their instructions every conceivable permutation on release scenarios that could be theorized.

The concerns you raised in your recent letter largely focused on the adequacy of the NRC's regulations as implemented and licensees' compliance with those regulations. The regulations establish a valid legal framework for determining when a licensee can release a patient under 10 CFR 35.75. The regulations reflect the NRC's understanding that hospitals are not always the best place for I-131 patients to recover, and provide a minimum threshold for when a doctor can release a patient. Under our regulations, patient release determinations must be made on a case-by-case basis, considering multiple factors. Thus, the regulations appropriately allow release of patients when the minimum threshold can be met and when it is in the interest of the patient. At the same time, nothing in the NRC regulations requires release of patients. As explained in the Statement of Considerations for the 1997 Patient Release Rule, licensees have discretion on when to release patients and whether to release a patient at all.

Your correspondence raises scenarios which project a potential that a member of the public might receive an exposure in excess of 500 millirem. To date the NRC is unaware of any verified instances where this has occurred. The lack of concrete information on such circumstances is one of the bases for the Commission having directed the staff to conduct a study so that these issues can be further considered.

The issues you raise are of legitimate concern and warrant further examination, especially if there are small changes in practice that could make the possibilities of such exposures even more remote. As I have mentioned, the NRC staff is currently collecting data that can be used to determine the extent to which the public and workers could receive doses from patients.

If this information verifies that members of the public are receiving an unsafe dose from I-131 patients, the NRC will have a basis on which to take additional steps within its regulatory responsibilities and to work with other Government agencies on matters within their jurisdiction.

I can assure you that the NRC takes these issues seriously.

Sincerely,

/RA/

Margaret M. Doane
General Counsel

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Sincerely,

Margaret M. Doane
General Counsel

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