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Submitter Information

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General Comment

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Attachments

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Comments - NRC Patient Release Program-rplieto 062717

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June 27, 2017

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: (Docket ID: NRC-2017-0094; 82 FR 17465) Patient Release Program; Comments of the American College of Radiology

I am a medical physicist and radiation safety officer responding to the U.S. Nuclear Regulatory Commission's (NRC) request for comments (NRC-2017-0094; 82 FR 17465) on the patient release requirements under 10 CFR 35.75. My comments are based on nearly forty years of experience in the radiation safety of radioactive materials in diagnosis and therapeutic uses, especially in nuclear medicine under NRC licenses.

General Comments

10 CFR 35.75 establishes the criteria for any NRC or Agreement State licensee to release from its control any individual administered radioactive material for either diagnostic or therapeutic use. The licensee is required to provide the released individual or caregiver with instructions to minimize exposure to other individuals. While 10 CFR 35.75 is applicable to any administration, the focus of public interest regarding the NRC's patient release program is on radioactive iodine (I-131) therapy, which is a highly effective, noninvasive treatment option to thyroid patients for over fifty years.

The overwhelming consensus within the medical community is that the existing risk-informed, performance-based NRC patient release requirements in 10 CFR 35.75 sufficiently protect public health and safety. There is not a scientific basis or substantial patient benefit to regress to the pre-1997 patient release requirements, which called for automatic hospitalizations based on an arbitrarily established activity limit nearly forty years ago. From a regulatory perspective, returning to the older requirements would eliminate the NRC's risk-informed, performance-based approach in 10 CFR 35.75 and directly interfere with the practice of medicine by mandating hospitalization of otherwise healthy I-131 patients. This then exposes the patient to known added risks, such as hospital-acquired infections, additional patient anxiety and apprehension about the procedure, fewer healthcare facilities providing I-131 therapy, insurance coverage concerns, and significantly higher healthcare costs.

The NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) has revisited the issue of patient release multiple times since the original promulgation of 10 CFR 35.75 without significantly modifying its support for the current criteria. I totally support the ACMUI's risk analysis and recommendations over the past decade related to patient release and urge NRC to follow the its advice on this issue. I agree with the ACMUI's view that existing NRC regulatory requirements allow for effective exposure management to the general public if release instructions are followed. The content and the manner of instructing patients is under the purview of the practice of medicine and does not belong in rulemaking.

Question Responses

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

Response: The patient release requirements in 10 CFR 35.75 should NOT be revised at this time. There are no scientific or practical evidence to support regressing to the pre-1997, activity-based patient release threshold (known as the "30-mCi" rule). The current NRC patient release requirements are risk-informed and performance-based in accordance with the agency's more realistic approach to regulation. This requires the licensee to estimate exposure risk to members of the public, and allow patients capable of following appropriate instructions to minimize exposure to others in the public to be released from healthcare facilities with proper guidance.

The NRC's NUREG 1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material published in February 1997 analyzed the risks and benefits of continuing with the existing activity-based release threshold or adopting a dose-based release criteria. The NRC stated in the Federal Register (Vol. 62, No. 19 January 29, 1997) the following statements:

- "The new criteria are consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP)."
- "The NRC believes that the dose-based release limit can and will work well because the associated Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," can be used to relate the dose to the quantity of activity in the patient. The guide provides conservative estimates of activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in the final rule."

This issue was again revisited by the Advisory Committee on the Medical Use of Isotopes (ACMUI) in their report dated December 13, 2010, which provided a comprehensive review of patient release issues included the following statements:

- "The Subcommittee affirms the thorough analysis found in NUREG-1492 and its rational evaluation of the three alternatives. The NRC's final decision to implement **Alternative 3** as the patient release criteria found in 10 CFR 35.75 appropriately balanced the three fundamental radiation protection principles for use of radioactive materials in medicine." (Alternative 3 referred to the 5mSv (500 mrem) dose limit.
- "The NRC is adopting a dose-based limit rather than an activity- based limit because the dose based limit better expresses the NRC's primary concern for the public's health and safety."

Yet, again, the ACMUI addressed this issue to the NRC Commission itself on May 9, 2014. A cogent, scientific reaffirmation of the dose-based release criteria was presented by Pat Zanzonico, PhD, which also addressed associated patient release concerns.

The benefits for released patients are psychological (e.g., reduced anxiety, increased comfort, and closeness to loved ones/caregivers), health and safety (e.g., reduced risk of hospital-acquired infections), as well as financial (significantly reduced healthcare costs and, in certain scenarios, a swifter return to work). There are also positives for

healthcare providers who are able to focus limited inpatient resources on others in need of hospitalization for legitimate clinical reasons. The NRC's repeated, unsuccessful attempts to have the regulated and radiological community support a bureaucratic return to the 1980s gives an apparently inflexible attitude to accepting the scientific and practical basis for the dose-based release criteria as appropriate.

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

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? 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.

Response: No change to any patient release rulemaking is justified at this time. The current patient release regulations in 10 CFR 35.75 adequately protect public health and safety. The NRC in the Federal Register (Federal Register Vol. 62, No. 19, January 29, 1997 final rule) addressed this issue in an unambiguous manner to specifically allow for "per-release" decision-making by the licensee. In addition, it is stated, "Each patient release is to be treated as a separate event, and licensee knowledge of previous administrations is unnecessary." It is completely disingenuous or lack of knowledge of past NRC actions for the NRC to indicate that "...as written the regulation is ambiguous and the dose to any other individual from the released individual does not reflect the NRC's intent of a per-year limit and that this limit has been interpreted by others to be per release." (page 82 FR17466, April 11, 2017). NRC is very clear that their intent in 1997 was that the criteria is per release and repeat that several times. The regulated community has affirmed this continuously since then. There is no issue of "interpretation".

Part 35.75 applies to all administrations of radioactive material for each patient from diagnostic as well as therapy administrations. If a "per year" time frame is mandated, licensees would be required to accurately gather dosimetry data and engage in exchange of such data across different healthcare providers. There is no universal method for exchanging radiation dose across different healthcare providers throughout the year to demonstrate full compliance with an annual limit. Therefore, it would be unenforceable for the regulatory agency and unjustifiably burdensome for licensees to comply with 5 mSv as a "per-year" limit because the access that providers need to all pertinent data to ensure compliance does not exist.

The NRC has discussed this question several times since the initial 1997 rule change, and any effort to move to an explicit "per-year" limit has been abandoned due to the inherent compliance challenges. Until such time as healthcare providers are able to reliably, universally, and instantly access a patient's radiation dose data across all different providers, the current long-standing "per-release" application in 10 CFR 35.75 must be maintained.

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?

Response: It is appropriate to apply this same dose limit for all mentioned groups, except caregivers who should be permitted up to 20 mSv (2 rem) or more. This higher caregiver level is a current recognized practice by NRC on a case-by-case basis. Importantly, the "risk" from 500 mrem (5 mSv) or even 1000 mrem (10 mSv) is based on an extrapolation from the linear no threshold hypothesis and has been shown to be near zero or at worst negligible. Both the NRC (NUREG-1492) and the NCRP (Commentary No. 9) have noted that even with doses of 5000 mrem (50 mSv) "no harm from deterministic effects and the risk of stochastic effects is less than one (1) percent". Therefore, the risk from 10% of this dose level would be again negligible.

I supports the numerous ACMUI explorations and recommendations related to this question. The appendix of the December 13, 2010 ACMUI **Patient Release Report** explained that realistic projected doses to hotel workers are "very low" to the extent that they would be equivalent to less than a day-and-a-half, at most, of extra natural background radiation. Professional training, professional guidelines/parameters, community standards of medical care, and technical standards address numerous clinical details that are not explicitly required by NRC regulations. Important issues like potential exposure risk for young children and pregnant women are accounted for in the physician's decision-making process. Therefore, the current 10 CFR 35.75 allows for appropriate exposure management by enabling physicians to evaluate patients' unique situations and customize treatment/instructions accordingly, even where different dose limits are not specified in federal regulation for various occupations and/or demographics..

ACMUI again addressed this issue to the NRC Commission itself on May 9, 2014. It provided information on multiple studies and analysis of dose contributions to these different groups of the public demonstrating that were below recommended limits, and reaffirmed the Committee's support for the current dose-based release criteria. Doses to other individuals from released radioactive patients can be safely controlled by the current dose-based release criteria in 10 CFR 35.75.

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?

Response: This should not be a regulatory requirement but issued as "guidance", based on a requirement of the provision of simple written instructions to the patient. The current NRC regulations, guidance and information notices, as well as education and practice/procedure guidelines from the medical community adequately address concerns described in this question without added rulemaking.

On the topic of exposure to pregnant women and children, the National Council on Radiation Protection and Measurements (NCRP) No. 155, **Management of Radionuclide Therapy Patients,** which recommends that dose to pregnant women and children should ideally be limited to 1 mSv (0.1 rem)., which is an extremely low dose level that is within the variation of natural background radiation. Absolutely no evidence that doses at this

level are a health and safety concern. Professional guidelines, practice parameters, and technical standards are more appropriate than regulation to make informed decisions that account for a patient's unique circumstances at home.

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 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?

Response: No. This is adequately addressed by the current guidance available from the appropriate professional societies and NRC Regulatory Guides. The ACR-ASTRO **Practice Parameter for Communication: Radiation Oncology** states that "timely, accurate, and effective communications are critical to quality in contemporary medical practices." I agree that patients should not be unnecessarily inconvenienced and prevented from setting post-treatment plans, but a federal regulation of a specific lead time for all situations is not appropriate way to promote timely communications with patients nor is it required elsewhere in medicine where there is informed consent. There completely valid circumstances (patient convenience, long travel distances, etc.) where it may be appropriate for the patient to be informed and received a therapy in the same day.

It would be exceedingly difficult, if not impossible, for NRC or the Agreement States to enforce an explicit lead time requirement because information provided to a given patient on a specific occasion would be inaccessible by investigators after the fact. The HIPAA privacy rule and the Privacy Act of 1974 restrict government access to health information with limited exceptions.

Instead of regulating this, NRC should address the lead time question as an educational issue by providing feedback in information notices and promoting ideal lead times in collaboration with national specialty societies.

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)?

Response: As stated in the question E response, this issue is not appropriate in federal regulation. A specific time frame should not be regulated. The timing of providing instructions to patients and their household members and/or caregivers is a clinical decision and can vary from patient to patient. The lead time issue can be addressed via guidance/information notices done in collaboration with national specialty societies who develop educational materials and practice/procedure guidelines for medical professionals.

Thank you in advance for your consideration of these comments.

Sincerely,

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