June 27, 2017

ATTN: Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
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

The American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment regarding 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. The following input was compiled by the ACR's Commission on Medical Physics-Government Relations Committee, Commission on Nuclear Medicine and Molecular Imaging, and Commission on Government Relations-Federal Regulatory Committee.

General Comments

10 CFR 35.75 allows the licensee to authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). The licensee is also required to provide the released individual or parent/guardian with instructions for exposure minimization to other individuals. While 10 CFR 35.75 is widely applicable, the focus of the public interest related to the NRC's patient release program is on radioactive iodine (I-131) therapy—a highly effective, noninvasive treatment option for patients with hyperthyroidism as well as ablation of postoperative thyroid remnant and therapy of iodine-avid thyroid cancer.

The broad 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. ACR does not believe there is a scientific basis or substantial benefit to revert to the pre-1997 patient release requirements, which called for automatic hospitalizations based on activity instead of allowing physicians to make informed, customized release decisions based on circumstances and estimated risk. From a regulatory perspective, reverting to the older requirements would eliminate the agency's risk-informed, performance-based approach in 10 CFR 35.75 and directly interfere with the practice of medicine. More importantly, mandatory hospitalization of otherwise healthy I-131 patients could introduce

additional negative consequences, such as an increased risk of hospital-acquired infections for patients, additional patient anxiety and apprehension about the procedure, fewer healthcare facilities providing I-131 therapy, insurance coverage concerns, and significantly higher healthcare costs.

We note that 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 recommendations. The ACR generally supports the ACMUI's risk analysis and recommendations over the past decade related to patient release and we urge NRC to follow the committee's advice on this topic. We agree with the ACMUI's view that existing NRC regulatory requirements allow for effective exposure management if release instructions are followed.

Question Responses

A. Development of an Activity-Based Patient Release Threshold

Question: Should the NRC develop an activity-based patient release threshold?

Answer: The ACR does not believe the patient release requirements in 10 CFR 35.75 should be revised at this time, and certainly not to revert to the pre-1997, activity-based patient release threshold (known as the "30-mCi" rule). Rather, the current NRC patient release requirements are risk-informed and performance-based in accordance with the agency's more modern approach to regulation. They require the licensee to estimate exposure risk to members of the public, and allow healthy patients deemed capable enough to follow exposure minimization instructions to be released from healthcare facilities in a safe and appropriate manner.

The benefits for released patients are psychological (e.g., reduced anxiety, increased comfort, and closeness to loved ones/caregivers), health and safety related (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.

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.

Answer: The ACR does not support any patient release rulemaking at this time—the current patient release regulations in 10 CFR 35.75 adequately protect public health and safety. We note that the record-keeping discussion in NRC's January 29, 1997 final rule addressed this issue in a manner that specifically allowed for "per-release" decision-

making by the physician due to the obvious burden (without a safety benefit) of maintaining records and engaging in exchange of such data with disparate providers.

There is no universal method for exchanging radiation dose across disparate facilities throughout the year in a manner that would demonstrate full compliance with an annual limit. Indeed, healthcare facilities in 2017 are still struggling to interoperate and engage in bidirectional connectivity with disparate providers using electronic health record (EHR) technology to exchange even basic data elements, such as demographics and vitals. Therefore, it would be unenforceable for the agency, and unduly burdensome for licensees, to specify 5 mSv as a "per-year" limit due to the implication that providers would need access to all pertinent data to ensure compliance.

Indeed, this question has been discussed by NRC 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 dose data across all disparate facilities, the ACR continues to strongly support ACMUI's recommendation of maintaining a simple "per-release" application of the limits in 10 CFR 35.75.

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?

Answer: The ACR supports the numerous ACMUI explorations and recommendations related to this question. We note that 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. We also note that 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.

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?

Answer: The ACR believes the current NRC regulations coupled with guidance and information notices, as well as education and practice/procedure guidelines from the

medical community, adequately address concerns described in this question without additional rulemaking.

On the subtopic of exposure to pregnant women and children, the ACR's relevant practice parameter, *The Performance of Therapy with Unsealed Radiopharmaceutical Sources*, references 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). The ACR believes professional guidelines, practice parameters, and technical standards are more appropriate than regulation for informing medical decisions that take into account 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?

Answer: The ACR-ASTRO *Practice Parameter for Communication: Radiation Oncology* states that "timely, accurate, and effective communications are critical to quality in contemporary medical practices." While ACR strongly agrees with the notion that patients should not be unnecessarily inconvenienced and prevented from setting post-treatment plans, we would argue that federal regulation of a specific lead time for all situations is not the most appropriate way to promote timely communications with patients.

We also note that requiring a minimum lead time in regulation would be redundant with the current requirements in 10 CFR 35.75(a). The physician is already prohibited from releasing the patient if she/he believes the total effective dose equivalent to any other individual from exposure to the released patient would be greater than 5 mSv (0.5 rem). Therefore, any hypothetical scenario in which instructions are too late to be followed would trigger mandatory hospitalization if the resulting exposure to someone else would be above the limit.

Finally, 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. Even without HIPAA considerations, paperwork can be easily misplaced and/or forgotten when patients return home from the healthcare setting. The alternative would be licensee attestation of compliance for every release—but without any actual auditing capability, these attestations would be non-reviewable. 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)?

Answer: As indicated in our response to question E, the ACR does not believe that this issue is appropriately addressed in federal regulation. Rather, the lead time issue could be addressed via guidance/information notices and 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. As always, the American College of Radiology welcomes the opportunity for continued dialogue with the NRC. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director of Government Relations, at 703-716-7550 / gromanelli@acr.org, or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 703-716-7546 / mpeters@acr.org.

Sincerely,

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