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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Ms. Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

**Re: PRM-35-18: Release of patients treated with radiopharmaceuticals
Support for the current Patient Release Rule, 10 CFR 35.75**

Dear Secretary Vietti-Cook and NRC:

As a Radioactive Materials Licensee, I share the NRC's commitment to the safe use of radiopharmaceuticals during patient care but have significant concerns regarding the recent petition seeking to amend the current regulation (10 CFR 35.75) governing the release of patients treated with more than 30 millicuries of radioactive iodine-131.

I support the current regulation and oppose the petitioner's request (Docket No. PRM-35-18) requesting the NRC prohibit the release of patients from radioactive isolation with more than 30 millicuries of radioactive iodine-131.

There is no benefit to reversing or amending the present rule (10 CFR 35.75). In fact, changing the current rule will have a negative impact on patient care and convenience as well as greatly increasing health care costs by mandating unnecessary hospitalizations for patients that pose no risk to the public health.

It is the current practice of treating physicians to conduct careful evaluations of patients and their home and work environment before exposing them to radiopharmaceuticals. This is certainly the practice here where I serve as the Radiation Safety Officer. In addition, dosimetry calculations are performed on every thyroid cancer patient before release. The total effective dose equivalent (TEDE) to any other individual from exposure to the released individual must not be likely to exceed 5 millisieverts (0.5 rem). This adherence to nuclear safety guidelines is required. (10CFR 35.75).

Radiation exposure to household members of patients who receive outpatient I-131 treatment ranging from 75 to 200 mCi of I-131 are well below the levels mandated by current NRC regulations (1). There is no compelling evidence to support the modification of the current Patient Release Rule (10 CFR 35.75). I respectfully request that the NRC continue supporting the current policy that is developed using evidence-based data and not be influenced by anecdotes.

Sincerely,

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J. Grigsby, P. Wang, Siegel, B.A. Baker, Sr., and Eichling, J.O. Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma. JAMA. 2003;289:2272-2274. 2000 only. This is certainly the best evidence available to support the current policy of treating physicians to conduct careful evaluations of patients and their home and work environment before exposing them to radiopharmaceuticals.



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