

# The American Board of Nuclear Medicine

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A Member Board of the American Board of Medical Specialties

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**(70FR75752)**

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Annette Vietti-Cook, Secretary  
Re: PRM-35-18  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

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RULEMAKINGS AND  
ADJUDICATIONS STAFF

**Re:Comments to Petition for Rulemaking Submitted by Peter G. Crane**  
**Docket No. PRM-35-18**

Dear Ms. Vietti-Cook:

We are writing, on behalf of the American Board of Nuclear Medicine, in response to The Petition for Rulemaking (PRM) submitted by Mr. Crane (PRM-35-18). This PRM requests that the NRC partially revoke 10 CFR 35.75, the "patient release criteria" rule, issued in 1997, to not allow patients to be released from radioactive isolation with more than 30 mCi of I-131 in their bodies. The American Board of Nuclear Medicine firmly supports the "patient release criteria" rule, issued in 1997 and is staunchly opposed to this PRM.

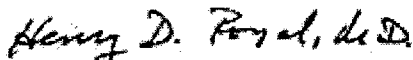
There is no justification for using the amount of radioactivity administered to a patient as the criterion for deciding whether the radiation dose to members of the public is likely to exceed 5 mSv (500 mrem). As detailed in NRC Regulatory Guide 8.39, the likely radiation dose to members of the public requires consideration of numerous factors other than simply the administered activity. The practical success of 10 CFR 35.75 has been eloquently documented in a study of 30 patients with thyroid cancer who were treated with 2.8 to 5.6 GBq (mean, 4.3 GBq [116 mCi]) (Grigsby PW, Siegel BA, Baker S, Eichling JO. *Radiation exposure from outpatient radioactive iodine (131I) therapy for thyroid carcinoma. JAMA. 2000 283:2272-4.*). The radiation dose to 65 household members ranged from 0.01 mSv to 1.09 mSv (mean, 0.24 mSv). It is clear from these data that patients with thyroid carcinoma can be safely treated with radioiodine as outpatients.


A return to the 30-mCi rule would result in additional unnecessary healthcare expenditures, and would be an unnecessary hardship for thyroid cancer patients who would much rather return to the comfort of their homes following their treatment.

The American Board of Nuclear Medicine steadfastly supports the decision of the Nuclear Regulatory Commission to replace the 30 mCi rule with the patient release criteria rule issued in 1997 and is adamantly opposed to the adoption of PRM-35-18.

Please contact us if we can be of any further assistance in this matter.

Sincerely,

  
Henry D. Royal, MD

  
Christopher J. Palestro, MD