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DOCKET NUMBER
PETITION RULE PRM 35-18
(70FR 75752)

12 January 2006

**DOCKETED
USNRC**

January 13, 2006 (2:00pm)

Secretary, US Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20055

**OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF**

RE: Docket No. PRM-35-18

To the Secretary:

I am writing to respond to the petition from Peter G. Crane, published in the Federal Register, Vol. 70, No. 244. The petitioner requests that the 1997 amendment to 10 CFR 35.75, which addresses the release of patients treated with radioiodine-131 (I-131), be rescinded.

The petitioner requests that the NRC return to the arbitrary "rules-based" requirement that a patient's I-131 body burden be less than 30 millicuries at the time of discharge from the hospital, and abandon the 1997 "risk-based" criterion that the radiation dose to members of the public be maintained below 500 millirem (5 mSv). In the summary of his petition (p. 1), he states that:

"...the rulemaking has had precisely the adverse effects on health and safety that were predicted at the time by States and other commenters, and that were brushed aside by the NRC. Patients treated for thyroid cancer with radioactive iodine-131 are now being sent home to their families under conditions that guarantee that family members will receive larger and potentially harmful doses of radiation, under uncontrolled conditions."

Much of the remainder of the petition appears to be a reiteration of his decade-old objections to the 1997 rules change. He presents no new rationale for rescinding the rule other than vague generalities such as "giving an increased amount of radiation" to children and family members. Other than a single anecdotal account of an I-131 patient who allegedly traveled home on a bus, vomited and exposed her husband and children to radiation, he presents no data in support of his position. The petition includes no documentation of any of the "adverse effects on health and safety" that he alleges to have resulted from the rules change.

Between September 1999 and December 2005, our institution treated 163 outpatients with well-differentiated thyroid cancer using orally administered I-131 sodium iodide. These 163 patients underwent a total of 175 treatments. Our experience indicates that the implementation of the 1997 amendment to 10 CFR 35.75 has not resulted in the "nightmare" scenario presented by the petitioner. Following is a summary of our experience, and responses to some of the petitioner's other statements.

(1) How Patients Actually Get Home Following Treatment: For our 175 treatments, 20.6% of the patients traveled home alone in their private vehicles, 69.7% returned home in private vehicles on trips of less than 50 miles with other occupants, and 9.1% returned home in private vehicles on trips of greater than 50 miles with other occupants. In only one case (0.6%) did a patient intend to return home on a public conveyance

Template= SECY-067

SECY-02

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(bus or airplane).

(2) Who is Exposed in the Home: For our 175 treatments, 13.1% of the patients indicated they lived alone and 48.6% indicated they lived with a spouse or other adults, but no children. Most of the remaining households (38.3%) had one or two children in residence.

(3) Actual Radiation Exposures at Home: A study performed at Washington University (Grigsby, 2000) measured the external radiation exposure received by the family members of thyroid cancer patients who were treated and immediately released. Radiation doses ranged from 1 millirem (0.01 mSv) to 109 millirem (1.09 mSv) with a mean of 24 millirem (0.24 mSv). The maximum dose is about one-fifth of the 500-millirem release criterion. The mean dose is equal to about one month's worth of "natural background" exposure. Radiation doses in this range would not have any deleterious effects on anyone, including children and pregnant women.

(4) Vomiting: We have had no report of any of our patients vomiting after leaving the hospital.

(5) Multiple Treatments: The petitioner maintains that a single patient is very likely to undergo more than one treatment (p. 17). He cites an unnamed "expert in thyroid cancer at the University of Washington Medical Center", who estimated the recurrence rate of thyroid cancer to be "30 to 40 percent". This estimate may be too high. The experience at the Mayo Clinic with 2,444 patients over four decades indicates an overall lifetime recurrence rate of 8% at 5 years and 14% at 25 years (Hay, 2002). The experience at the Mt. Sinai Hospital in Toronto with 574 well-differentiated thyroid cancer patients indicates an overall recurrence rate of 13% (Palme 2004). A review of several studies in the literature (Witt, 2002) found recurrence rates ranging from 11.6% to 18.5%.

Of our 163 patients, 11 (6.7%) returned for a second treatment and one (0.6%) returned for a third treatment during the 6 years of follow-up. This is generally consistent with the Mayo Clinic experience. In my opinion, the petitioner exaggerates the hazard due to multiple treatments.

(6) The Linear No-Threshold Hypothesis (LNT): The petitioner states that "the implication that no harm is done by exposing family members from just one treatment is at odds with the linear no-dose-threshold theory on which all current radiation protection standards are based. (p. 17)" In fact, radiation protection standards and practices are based on the ALARA principle, not LNT. If the standards were based on LNT, we would not be releasing patients at *any* body burden greater than zero, including 30 millicuries.

(7) Capability of Patients to Follow Post-Discharge Instructions: The petitioner questions the ability of thyroid cancer patients to understand and adhere to written instructions on minimizing radiation exposure to others. He depicts them as "sick and quite possibly stressed, exhausted, groggy and mentally fogged (p. 14)." As a nuclear medicine physician who has treated dozens of thyroid cancer patients, I find this patronizing characterization to be erroneous. At our institution, patients who are determined to be incontinent of urine, incapable of self-care or unable to adhere to the instructions are treated as inpatients.

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(8) Protection of the Clergy at the Expense of Children: The petitioner maintains that NRC's justification of immediate release is in part based upon the benefit accrued to members of the clergy by reducing their radiation exposure, at the expense of increasing exposure to children and other family members of patients. Although NRC referred to the "clergy" in a single parenthetical remark in response to a comment in the final rule, the petitioner refers to a "benefit to the clergy" or "clergy protection rule" no fewer than seven times (pp. 1, 3, 4, 15, 16, 17) in his petition. When we implemented the 1997 rule change at our institution, we gave little consideration to benefits to the clergy.

The arbitrary pre-1997 "30-millicurie" rule required the hospitalization of patients who were not acutely ill solely for radiation protection purposes. The current rule benefits both the patients and health-care facilities, with no evidence of harm to family members or the public. By avoiding unnecessary hospitalizations, our 163 immediately-released thyroid cancer patients have benefited from (a) reduced personal health-care costs such as insurance co-payments and hotel bills for accompanying family, (b) avoiding hospital-acquired infections, (c) faster reintegration into the community and (d) less disruption of family life. Our institution has benefited by (a) being able to free scarce resources (radiation isolation rooms) for the patients who truly require them, such as brachytherapy implant patients, and (b) not having to divert staff resources to cover over 55 additional patient bed-days per year for I-131 thyroid cancer patients. Considering that about 10,000 Americans per year develop thyroid cancer, the benefit to society is significant.

In summary, I believe that our experience, and the experience of others, supports the continued application of the current rule. There is nothing in Mr. Crane's petition that supports rescinding the rule, and it should not be granted.

Sincerely,



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Attachment: CITED REFERENCES

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CITED REFERENCES

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Hay ID, Thompson GB, Clive S, Grant CS et al. Papillary Thyroid Carcinoma Managed at the Mayo Clinic during Six Decades (1940 –1999): Temporal Trends in Initial Therapy and Long-term Outcome in 2444 Consecutively Treated Patients. *World J. Surg.* 26:879–885 (2002)

Palme CE, Waseem Z, Raza SN et al. Management and Outcome of Recurrent Well-Differentiated Thyroid Carcinoma. *Arch Otolaryngol Head Neck Surg* 130:819-824 (2004)

Witt RL, McNamara AM. Prognostic factors in mortality and morbidity in patients with differentiated thyroid cancer. *ENT* 81:856-863 (2002)

From: Carol Gallagher
To: Evangeline Ngbea
Date: Fri, Jan 13, 2006 10:33 AM
Subject: Comment letter on PRM-35-18

Van,

Attached for docketing is a comment letter on the above noted PRM from Robert E. Reiman, Duke University Medical Center, that I received via the rulemaking website on 1/12/06.

Carol

Mail Envelope Properties (43C7C861.21E : 3 : 886)

Subject: Comment letter on PRM-35-18
Creation Date: 1/13/06 10:33AM
From: Carol Gallagher

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Security: Standard