

 Washington University in St. Louis

SCHOOL OF MEDICINE

Department of Radiation Oncology

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PETITION FILE PRM 35-18
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USNRC

December 28, 2005 (11:49am)

Secretary, U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

RE: PRM-35-18

Dear Secretary:

This letter is in response to the Petition from Peter G. Crane which was published in the **Federal Register**, Vol. 70, No. 244 on December 21, 2005 in relation to the 1997 amendment of 10 CFR 35.75, "Medical Use of Byproduct Material."

Mr. Crane is requesting "that the NRC amend the regulation that governs medical use of byproduct material concerning release of individuals who have been treated with radio-pharmaceuticals" and that patients receiving radioactive iodine I-131 not be allowed "to be released from radioactive isolation with more than 30 mCi....in their bodies."

I strongly believe that the existing rule is correct and that released patients pose no danger to anyone with whom they come in contact. This amendment was approved by NRC after very extensive studies were performed and the data stringently evaluated. At that time the early release of these thyroid patients was determined as a safe procedure.

Since 1997 I have performed about 1,000 outpatient I-131 procedures (25 - 250 mCi), including children and adults, and have received neither complaints nor reports of incidents caused by accidental exposure. None of my patients reported vomiting after the I-131 administration. In addition, I have treated patients with I-131 by both the old (in-patient) and new (out-patient) methods and the patients overwhelmingly prefer the new approach because of less disruption in their lives and the great cost savings of not having to be hospitalized for several days. In my opinion, it is a medical benefit to the thyroid patient to be treated on an outpatient basis.

To further substantiate my position on this issue, I would like to suggest that the Commission consider the information in two publications that I have authored related to the safety of the 1997

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MIR Mallinckrodt Institute
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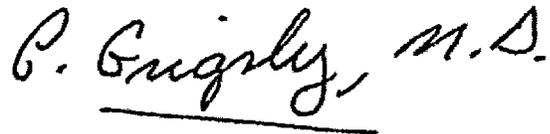
Washington University School of Medicine at Washington University Medical Center, Campus Box 8224,
4921 Parkview Place, St. Louis, Missouri 63110 USA, (314) 362-8500, Fax: (314) 747-9557, www.wustl.edu

Temolite = SECY-067

SECY-02

ruling: 1) Grigsby PW, Baker S, Siegel BA, Eichling J: New NRC patient release guidelines: Major quality of life and cost-containment benefits. *Administrative Radiology J* 1998;17(4):18-21; and 2) Grigsby PW, Siegel BA, Baker S, Eichling JO: Radiation exposure from outpatient radioactive iodine (^{131}I) therapy for thyroid carcinoma. *JAMA* 2000;283(17):2272-2274. The findings in these articles uphold the argument that this approach to treatment with radioiodine I-131 is safe and should not be changed.

Sincerely,

A handwritten signature in black ink that reads "P. Grigsby, M.D." with a horizontal line underneath the name.

Perry W. Grigsby, M.D.
Professor of Radiation Oncology,
Nuclear Medicine and Gynecologic Oncology
Director, Brachytherapy and MicroRt Treatment Center

PWG/ep

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From: "Pirkey, Elaine" <epirkey@radonc.wustl.edu>
To: <SECY@nrc.gov>
Date: Wed, Dec 28, 2005 10:07 AM
Subject: Comments on PRM-35-18

Attached is a letter from Perry W. Grigsby, M.D. regarding petition # PRM-35-18 filed by Peter G. Crane.

Elaine Pirkey
Secretary to Perry W. Grigsby, M.D.
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CC: <pgrigsby@wustl.edu>

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