



Washington University in St. Louis

SCHOOL OF MEDICINE

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DOCKET NUMBER

PETITION/RULE PRM 35-18
(10FR 75752)

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

27 February 2006

Annette L. Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Rulemaking and Adjudications Staff

Re: Response to Docket No. PRM-35-18 (Peter G. Crane; Petition for Rulemaking)

Dear Ms. Vietti:

I am writing in response to the above-named petition, specifically for purposes of setting the record straight with regard to the position of the Advisory Committee on Medical Uses of Isotopes (ACMUI) on the rule (10 CFR 35.75) that represents the subject of the petition. I was chair of the ACMUI from 1990 through 1996. During my tenure, the rulemaking that eventuated in the current version of the "Patient Release Rule" was in process, and the provisions of this rule were discussed on several occasions by the ACMUI.

In his petition, Mr. Crane makes reference to the proceedings of the ACMUI meeting of 22 October 1992. He implies based on a selected item from the discussion at that meeting (taken out of context) that the ACMUI was opposed to this proposal and, that I "was worried that these protections were *insufficient*, since even 5 mCi of I-131 could pose a danger to family members." Careful review of the transcript of that meeting makes it clear that I believed it was appropriate to provide guidance to patients receiving quantities of I-131 sodium iodide requiring a written directive, so that they would be well informed about steps they could take to minimize exposure to members of their family and to members of the general public. I did not express a belief that release of patients administered this specific quantity of I-131 posed any significant safety hazard. Further review of the transcript of that meeting also makes it clear that much of the discussion focused on the potential complexity of predicating patient release in all cases on patient-specific factors. In other words there was sentiment for allowing release based on "default" retained activity levels (the mechanism that already was in place at the time) as well as for allowing release of patients with higher retained activity levels but where patient-specific factors could be used to demonstrate that exposure to members of the general public, including family members, would not likely exceed 500 mrem.

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Mr. Crane's petition fails to include any information from the continuing discussions of 10 CFR 35.75 by the ACMUI. The Committee again briefly discussed this matter at its meetings in May 1993, November 1993, May 1994, November 1994, and May 1995, and in considerable depth at the meeting in October 1995. At each of these meetings, the ACMUI assisted the staff in its assessment of the practical, clinical implication of the proposed revision to 10 CFR 35.75. The records of those meetings shows that the ACMUI was quite supportive of the proposal and of the evolving regulatory guidance that would accompany a final rule.

The ACMUI discussed this rule for the last time, during my tenure as chairman, at its meeting of 18-19 October, 1995. At the conclusion of a summary of a discussion that focused on an in-depth review of the regulatory guide, the minutes of that meeting state the following:

"Dr. Siegel stated that this rule is important for several reasons: It resolves the existing conflict between Part 35 and Part 20; it allows the release of patients with higher levels of activity than was possible heretofore; and thus has the potential to reduce the cost of care of patients treated with byproduct radionuclides.

The ACMUI unanimously agreed that the rule, with the recommended changes proposed by the Committee to the rule and to the regulatory guide, to be acted upon by the staff, and forwarded to the Commission for approval as quickly as possible."

The ACMUI gave the U.S. Nuclear Regulatory Commission sound, carefully reasoned advice over the nearly three years that it assisted in the crafting of the current 10 CFR 35.75. Nearly a decade of subsequent clinical experience (including our own extensive experience at Washington University School of Medicine) confirms that this advice has stood the test of time.

I strongly urge that the rule stand.

Sincerely yours,



Barry A. Siegel, M.D.

From: Carol Gallagher
To: Evangeline Ngbea
Date: Tue, Feb 28, 2006 9:40 AM
Subject: Comment letter on PRM-35-18

Attached for docketing is a comment letter on the above noted PRM from Barry A. Siegel, M.D., that I received via the rulemaking website on 2/27/06.

Carol

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From: Carol Gallagher

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