

UNIVERSITY OF CALIFORNIA

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PETITION FILE PRM

35-18
(70 FR 15152)

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VICE PRESIDENT—FINANCIAL MANAGEMENT

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6 March 2006

DOCKETED
USNRCSecretary
US Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Rulemaking and Adjudications Staff

March 7, 2006 (10:04am)

Subject: PRM-35-18

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

The following is in response to PRM-35-18. The petitioner has requested that the NRC revoke the 1997 amendment to 10 CFR 35.75 which allows for the release of patients who have received radiopharmaceuticals, particularly I-131, in excess of 30 millicuries as long as it is documented that no individual is likely to receive greater than 500 mrem from exposure to the patient. In the petitioner's opinion, release of patients creates an unwarranted hazard. As a group, the Radiation Safety Officers (RSOs) for the University of California, including five Medical Centers, have reviewed the petition and strongly disagree with the conclusions drawn. Based on our experience in dealing with such patients, believe that his arguments are flawed. Rebuttals to four of the issues raised by the petitioner are summarized as follows:

Petitioner: Patients may have trouble comprehending and remembering the guidance given.

Response: Physicians are required to interview the patient or guardian and decide if they are competent to have outpatient therapy. If, in the professional opinion of the physician, the patient is not competent or does not understand or agree to comply, then the patient is treated as an inpatient. Instructions are given to the patient both orally and in writing. Patients are instructed to limit close contact with others and to segregate their personal belongings, clothing and bedding after treatment. Contact phone numbers are given to the patient so that questions and concerns can be answered promptly. For non-English speaking patients, interpreters are brought in. In the case of patients who are minors, the patient's guardian signs the instructions agreeing to comply.

Petitioner: Exposure to children.

Response: Patients are asked about children in the home during the physician interview. Patients can be excluded from outpatient treatment if the patient has young children that can't be taken care of by someone else or live elsewhere for the first 4 days after therapy.

Petitioner: Likelihood of vomiting and subsequent clean up.

Response: Vomiting is not a common occurrence. If a patient has a history of nausea, anti-emetics can be prescribed. As part of the oral and written instructions that are given to the patient by the Nuclear Medicine staff, directions should be given that, in the event the patient does become ill, the patient should clean up after themselves. Thyroid cancer patients are generally not debilitated and can provide self-care. If the patient is unable to provide that type of care (i.e. the patient is a minor), gloves and instructions can be given to the family member who cares for the patient. It is known in the field of Nuclear Medicine that patients who are instructed to have a light meal a few hours prior to therapy are less likely to be nauseous. In addition, while intake of liquids is encouraged with this type of therapy, excessive intake is not recommended.

Template = SECY-067

SECY-02

Petitioner: Argues that there is no emotional benefit to the patients.

Response: Most patients have recently had thyroidectomies and are very happy not being admitted to the hospital again. Most appreciate the thorough instructions that are given and the opportunity to have their questions answered prior to therapy. In our experience, few have called with subsequent questions. Additionally, parents of children being treated are very happy that their children don't have to be hospitalized.

The present modality used to treat these patients provides protection to those around them, a psychological benefit to the patient, and a benefit to society (reducing health care costs). We ask that you consider the real-world experience of those of us in the medical community who are providing these treatments and deny this request for rule making as being not based on facts or experience. If any further information or clarification is needed, please contact Linda Kroger, chair of the University of California Radiation Safety Officers Workgroup, at 916-734-7325.

Sincerely,

The University of California RSO Workgroup

Submitted on behalf of the above workgroup

Joe S. Adams, CSP
Director, Environment, Health & Safety
University of California

From: Joe Adams <joe.adams@ucop.edu>
To: <secy@nrc.gov>
Date: Mon, Mar 6, 2006 7:19 PM
Subject: docket No. PRM-35-18

The attached is submitted as per requested...

CC: Linda Kroger <lakroger@ucdavis.edu>

Mail Envelope Properties (440CD169.17E : 24 : 4478)

Subject: docket No. PRM-35-18
Creation Date: Mon, Mar 6, 2006 7:18 PM
From: Joe Adams <joe.adams@ucop.edu>

Created By: joe.adams@ucop.edu

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