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March 6, 2006

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

DOCKETED
USNRC

March 7, 2006 (10:04am)

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

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

RE: Docket No. PRM-35-18

Dear Secretary Vietti-Cook:

Thank you for the opportunity to comment on the petition for rulemaking filed by Peter G. Crane as published in the December 21, 2005 *Federal Register*, requesting the amendment of regulations that govern medical use of byproduct material concerning release of individuals who have been treated with radio pharmaceuticals. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. Within the APhA Academy of Pharmacy Practice and Management (APhA-APPM), the Section on Nuclear Pharmacy Practice is comprised of nearly 300 pharmacists involved in nuclear pharmacy.

APhA appreciates the U.S. Nuclear Regulatory Commission's (NRC) continued efforts to develop guidance for nuclear pharmacists. Although the proposal to amend 10 CFR Part 35.75 in Docket No. PRM-35-18 does not directly affect the practice of nuclear pharmacy; the petition for amendment does affect the care and treatment that patients receive from nuclear pharmacists in collaboration with other healthcare providers. APhA recommends that you deny the petition request to amend the patient release rule. The petition would not allow patients treated with radioiodine-131 (I-131) to be released from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their bodies. The current procedures established by the NRC for the release of patients containing byproduct radioactive material are adequate to protect both the patient's interest and the public health and safety of those individuals who may come in contact with treated patients. The current regulations also provide the treating physician and medical institution the authority to prevent the immediate release of a treated patient if it is not in the best interest of the patient or the public. The current regulations also help to minimize overall healthcare costs associated with hospitalization by allowing immediate release of treated patients when appropriate.

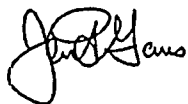
In conclusion, APhA requests that the NRC deny the petition to amend the current patient release rule. The authority to immediately release or retain a treated patient, depending on patient specific circumstances, already exists and does not need further revision.

Template = SECY-067

SECY-02

Thank you for your consideration of the views of the nation's pharmacists. Please contact Marcie A. Bough, APhA's Senior Manager of Practice Development and Research at 202-429-7540 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gans". The signature is fluid and cursive, with the first name "John" being more prominent.

John A. Gans, PharmD
Executive Vice President

cc: Susan K. Bishop, MA, Associate Director, Regulatory Affairs
Marcie A. Bough, PharmD, Senior Manager, Practice Development & Research
Stephen C. Dragotakes, RPh, BCNP, Chair, APhA-APPM Section on Nuclear Pharmacy
Practice

From: "Bough, Marcie" <mbough@aphanet.org>
To: <SECY@nrc.gov>
Date: Mon, Mar 6, 2006 7:06 PM
Subject: APhA comment letter on PRM-35-18

Please find attached the comment letter from the American Pharmacists Association (APhA)

on Docket No. PRM-34-18.

Please reply so that I know you received this email.

Thank You,

Marcie Bough

Marcie Bough, Pharm.D.

Senior Manager, Practice Development and Research

American Pharmacists Association (APhA)

2215 Constitution Ave., NW

Washington, DC 20037

(p)202-429-7540

(f) 202-628-0443

mbough@aphanet.org

www.aphanet.org <<http://www.aphanet.org>>

APhA was founded in 1852 as the American Pharmaceutical Association

CC: "Bough, Marcie" <mbough@aphanet.org>

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Subject: APhA comment letter on PRM-35-18
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