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(70FR 75752)

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NATIONAL ASSOCIATION OF NUCLEAR PHARMACIES

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Rulemaking and Adjudication Staff

RE: (PRM-35-18) Peter G. Crane; Receipt of Petition for Rulemaking. Federal Register Vol. 70, No 244, December 21, 2005.

These comments concerning the Petition for Rulemaking filed by Peter G. Crane are submitted on behalf of the National Association of Nuclear Pharmacies (NANP). NANP members include nuclear pharmacies engaged in the preparation and distribution of radiopharmaceuticals used in diagnostic imaging and therapeutic applications in medicine. The NANP has an interest in ensuring that these products can be made available as needed for the delivery of quality patient care, we also have concern for the health and safety of patients, those who provide treatment and care for them, as well as the public and patient family members.

At face value it appears that the scope of applicability of the petitioner's amendment would be limited to therapeutic I-131 administered orally. NANP membership includes pharmacies that compound and prepare doses of I-131 for therapeutic administration. It has been reported[1] that in 2004, approximately 122,000 procedures were performed in the U.S. to treat hyperthyroidism, Grave's Disease and thyroid cancer using therapeutic I-131. Treatment of hyperthyroidism typically involved the administration of 2 to 30 mCi, whereas doses of 30 to 300 mCi were administered for thyroid cancer therapy. Most (85%) hyperthyroid procedures were performed on an outpatient basis as were the majority (62%) of the procedures for thyroid cancer.

The petitioner does not discuss issues that would be relevant to I-131 administered by perfusion or in other forms, including sealed sources, introduced into the body. NANP opposes the petitioner's request to amend 10 CFR 35.75 to prohibit the release of patients from radioactive isolation with more than the equivalent of 30 mCi of I-131 in their systems.

In addition, Rutar, et al. report the results of radiation exposure monitoring of family members and caregivers of those patients receiving I-131 BEXXAR therapy of non-Hodgkin's lymphoma. Family members were provided radiation-monitoring devices to directly monitor radiation exposure. Measured doses ranged from 10-409 mrem. In this and other studies, estimated and measured dose equivalents to maximally exposed individuals were below 500 mrem. Measured doses were, in most instances, lower than those predicted by patient-specific calculations, thus confirming the validity of the calculated dose predictions. Therefore, radioimmunotherapy with tositumomab and iodine I-131 tositumomab can be safely conducted on an outpatient basis.

NANP appreciates the opportunity to express comments on this Petition for Rulemaking. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,

Jeffrey P. Norenberg, PharmD, BCNP, FASHP, FAPhA
Executive Director and Chairman

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To: <SECY@nrc.gov>
Date: Mon, Mar 6, 2006 5:55 PM
Subject: PRM-35-18 Peter G. Crane Petition for Rulemaking, Federal Register Vol 70 No 244

Dear Sir/Madam,
Please find attached comments regarding (PRM-35-18) Peter G. Crane; Receipt of Petition for Rulemaking.
Federal Register Vol. 70, No 244, December 21, 2005.
Respectfully,
Jeffrey P. Norenberg

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Jeffrey P. Norenberg, MS, PharmD, BCNP, FASHP, FAPhA
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