



1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

35

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

March 6, 2006

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USNRC

March 6, 2006 (4:45pm)

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

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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

Dear Rulemaking and Adjudication Staff:

The Society of Nuclear Medicine (SNM) appreciates the opportunity to respond to the December 21, 2005, Federal Register notice regarding the petition submitted by Peter G. Crane, entitled "Re: Petition for Partial Revocation of the Patient Release Criteria Rule." In the petition, Crane requested that 10 CFR part 35, "Medical Use of Byproduct Material," be changed to partially revoke the 1997 amendment to 10 CFR 35.75, "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants" (62 FR 4120; January 29, 1997, Patient Release Criteria Rule). The partial revocation would prohibit the release of patients from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine-131 (I-131) in their body. The SNM strongly believes the Crane petition, and its proposed regulatory use of 30 mCi of I-131, is misinformed, and if taken seriously, would be a significant step backward in protecting the public's health.

Public radiation risk is directly dependant on the radiation dose to people around the patient. Of importance, while dose to people around the patient depends on the amount of radioactivity in the patient, this dependence varies from patient to patient. It is thus far preferable from a public health perspective to directly measure and estimate dose to people from the patient, rather than to assume doses based on the amount of radioactivity within the patient per se. The current standard, implemented after years of research by top nuclear medicine experts, NRC staff, and advisory committee members, follows this more appropriate approach.

Some incorrectly argue it is too difficult to calculate the radiation risk to people other than the patient, and that the NRC should revert to the blanket 30 mCi rule. Despite their claims, the existing data from studies performed by the NRC and other scientists disproves this concern, and NRC NUREG-1556, Volume 9, Appendix U, along with SNM's Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy, provide solid guidance for professionals to use in calculating radiation dose to the public. Please also see the references in the formal comment letters submitted by Jeffrey A. Siegel, Ph.D., Edward B. Silberstein, M.D., the Council of Radionuclides and Radiopharmaceuticals (CORAR), and the American Thyroid Association (ATA), among others, for scientific findings in support of the modern 10 CFR 35.75 release criteria, both in terms of scientific logic and practical implementation.

Thank you for your time and consideration. If you have any additional questions, or the SNM can assist in any way, please contact Hugh Cannon, SNM Director of Public Affairs, at 703.708.9000.

Sincerely,

Peter S. Conti, M.D., Ph.D.
President
Society of Nuclear Medicine

Template = SECY-067

SECY-02

From: "Peters Michael" <MPeters@snm.org>
To: <SECY@nrc.gov>
Date: Mon, Mar 6, 2006 2:02 PM
Subject: PRM-35-18; Comments from Society of Nuclear Medicine; Peter G. Crane Petition

Dear Rulemaking and Adjudication Staff:

Please see the attached public comments in response to the "Peter G. Crane petition" (PRM-35-18) from the Society of Nuclear Medicine (SNM).

SNM is an international scientific and professional organization of more than 16,000 members dedicated to promoting the science, technology and practical applications of molecular and nuclear imaging to diagnose, manage and treat diseases in women, men and children.

Please reply to confirm you received the SNM comments. Thank you in advance,

Michael Peters
Assistant Director of Public Affairs
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316
p: 703 708 9000 ext.1245
f: 703 708 9777
e: mpeters@snm.org
w: www.snm.org

Mail Envelope Properties (440C872E.644 : 4 : 63044)

Subject: PRM-35-18; Comments from Society of Nuclear Medicine; Peter G. Crane Petition
Creation Date: Mon, Mar 6, 2006 2:04 PM
From: "Peters Michael" <MPeters@snm.org>
Created By: MPeters@snm.org

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| SNM_comments_cranepetition_3-6-2006.pdf | | 37004 |
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