

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-18]

Peter G. Crane;
Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by Peter G. Crane (petitioner). The petition has been docketed by the NRC and has been assigned Docket No. PRM-35-18. The petitioner is requesting that the NRC amend the regulation that governs medical use of byproduct material concerning release of individuals who have been treated with radio pharmaceuticals. The petitioner believes that this regulation is defective on legal and policy grounds. The petitioner requests that the patient release rule be partially revoked to not allow patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine I-131 in their bodies.

DATE: Submit comments by (75 days following publication in the *Federal Register*).

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (PRM-35-18) in the subject line of your comments. Comments on petitions submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemaking and Adjudications staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at <http://ruleforum.llnl.gov>. Address comments about our rulemaking website to Carol Gallagher, (301) 415-5905; (e-mail cag@nrc.gov). Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Publicly available documents related to this petition may be viewed electronically on the public computers located at the NRC Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking website at <http://ruleforum.llnl.gov>.

Publically available documents created or received at the NRC after November 1, 1999 are also available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading--rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

For a copy of the petition, write to Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-415-7163 or Toll-Free: 1-800-368-5642 or E-mail: MTL@NRC.Gov.

SUPPLEMENTARY INFORMATION:

Background

The NRC has received a petition for rulemaking dated September 2, 2005, submitted by Peter G. Crane (petitioner) entitled "Re: Petition for Partial Revocation of the Patient Release Criteria Rule." The petitioner is an attorney who was formerly employed in the NRC's Office of the General Counsel from 1975 until his retirement from the NRC in 1999. The petitioner requests that the NRC amend 10 CFR Part 35, "Medical Use of Byproduct Material." Specifically, the petitioner requests that 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), be partially revoked.

The petitioner believes the Patient Release Criteria Rule is defective on both legal and policy grounds. The petitioner recommends that 10 CFR 35.75 be amended to prohibit the release of patients from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine-131 (I-131) in their systems. The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM-35-18. The NRC is soliciting public comment on the petition for rulemaking.

Discussion of the Petition

The NRC amended its patient release criteria in 10 CFR Part 35 in 1997 to allow the release of patients from licensee control who had been administered unsealed byproduct material if the total dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv. (0.5rem). Prior to that time, NRC regulations required

the hospitalization of patients with the equivalent of 30 millicuries or more of radioactive iodine 131 (I-131) in their systems, a dose which the petitioner believes is consistent with the International Basic Safety Standards on radiation protection.

The petitioner objects to the release of patients with more than the equivalent of 30 millicuries of I-131 in their systems. The petitioner clarifies that his objection to the patient release criteria rule is based on both legal and policy grounds. On legal grounds, the petitioner asserts that the 1997 rulemaking was “a sham” in that it was “legally tainted” by collusion between the NRC staff and a petitioner. Specifically, the petitioner asserts that a former member of NRC’s Advisory Committee on the Medical Uses of Isotopes (ACMUI) who submitted a petition for rulemaking in 1991 requesting the patient release criteria rule, submitted the petition at the NRC staff’s request with NRC staff assistance, in violation of NRC regulations.

The petitioner also objects to the patient release criteria rule on policy grounds, stating that it creates unwarranted hazards with regard to the radioactive iodine treatment of thyroid patients. The petitioner’s concern is that there is no “hard and fast limit on the amount of I-131” administered to an outpatient, and that a licensee must only perform a calculation showing that no one will receive a dose that exceeds a prescribed limit. However, the patient release criteria rule means that patients who are sick, stressed, hypothyroid, potentially nauseous, and highly radioactive are being “sent out the door,” where they may come into close contact with family members and members of the public, and although they are supposed to receive instructions on minimizing exposure, may have trouble comprehending and remembering the guidance they are given. The petitioner expresses particular concern regarding how children of released patients will be adequately protected from radiological exposure, stating that children are more radiation-sensitive than adults and deserve more protection. The petitioner also expresses concern that there is a likelihood of vomiting and that, unlike hospital staff who wear protective clothing to

protect against radiological contamination encountered while cleaning up, family members caring for patients at home will be unlikely to take such precautions.

The petitioner also claims that during the 1997 rulemaking, when the NRC gave notice of the receipt of the petition for rulemaking, it received numerous adverse comments from the ACMUI, Agreement States, and other commenters. However, according to the petitioner, the NRC proceeded to issue the proposed rule and largely ignored comments that ran counter to the NRC staff's preferred approach. In fact, the petitioner asserts that the notice of the final rule misrepresented critical comments on the release of patients with I-131 in their systems.

The petitioner states that the NRC acknowledged in promulgating the 1997 final rule that family members of patients would receive higher doses of radiation, but justified this in part by arguing that members of the clergy who visit hospitals frequently would receive lower doses of radiation as a result of patients having been sent out of the hospital, and by referring to the emotional benefit of releasing these patients. Specifically, the petitioner asserts that the NRC claimed in the final rule (see, 62 FR 4129) that although individuals exposed to the patient could receive higher doses than if the patient had been hospitalized longer, "these higher doses are balanced by shorter hospital stays and thus lower health care costs. In addition, shorter hospital stays may provide emotional benefits to patients and their families. Allowing earlier reunion of families can improve the patient's state of mind, which in itself may improve the outcome of the treatment and lead to the delivery of more effective health care."

The petitioner argues, however, that the NRC's reasoning ignored his and other thyroid patients' comments that some "patients may experience greater 'emotional benefit' from knowing that by receiving their treatment as in-patients, they are protecting their families from unnecessary radiation exposure." Moreover, the petitioner is skeptical of the NRC's rationale that releasing patients with treatment doses of radioactivity in their bodies will reduce exposure to clergy who regularly visit hospitals, or hospital orderlies.

Finally, the petitioner takes issue with other aspects that he notes constituted part of the NRC staff's rationale for the patient release criteria rule. Specifically, he contests the NRC's assertion that I-131 treatment for thyroid cancer occurs "probably no more than once in a lifetime," the NRC's implication that no harm is done by exposing family members to the exposure from just one treatment, and the implication that it is not "reasonably achievable" to keep radiation exposure to family members low by treating patients in radioactive isolation.

The Petitioner's Conclusion

The petitioner concludes that the patient release criteria rule is irredeemably flawed, as was the rulemaking that produced that rule. The petitioner therefore requests that the NRC institute rulemaking to rescind that portion of 10 CFR 35.75 that allows patients to be released from radiological isolation with I-131 in their systems in amounts greater than 30 millicuries. The petitioner requests that this rulemaking be undertaken expeditiously.

Dated at Rockville, Maryland, this 15th day of December, 2005.

For the Nuclear Regulatory Commission.

/RA/

Annette Vietti-Cook,
Secretary of the Commission.