

April 23, 2008

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Charles L. Miller, Director /*RA George Pangburn for*/
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: DENIAL OF PRM 35-18: PETITION FOR RULEMAKING
SUBMITTED BY PETER G. CRANE

Your approval and signature are requested on both the enclosed letter to the petitioner and the *Federal Register* Notice (Enclosures 1 and 2). The notification for the Commission is Enclosure 3.

The Commission received a petition dated September 2, 2005, from Peter G. Crane. This petition was assigned Docket Number PRM-35-18. The petitioner requested that the U.S. Nuclear Regulatory Commission (NRC) partially revoke the patient release criteria rule in 10 CFR 35.75 insofar as it allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine I-131 (I-131) in their bodies. The petitioner believes that this regulation is defective on legal and policy grounds.

The notice of receipt was published in the *Federal Register* on December 21, 2005 (70 FR 75752). The comment period closed on March 6, 2006. NRC received 48 comments including 3 supplements provided by the petitioner. Fourteen comments were received in support of the petition, mostly from patients. Thirty-one comments were received opposing the petition. Commenters opposing the petition included physicians, medical physicists, radiation safety officers and several professional organizations.

The staff has considered the petition and its supporting rationale. For the reasons provided in the *Federal Register* notice and discussed below, the staff recommends that the petition be denied. The Office of Federal and State Materials and Environmental Management Programs (FSME) staff has determined that rulemaking to address the concerns raised by the petitioner is not necessary, because current NRC regulations provide adequate protection to family members and others. Additionally, the petitioner did not provide any specific data to support his request, and did not provide a sufficient basis for revoking the current release criteria.

DISCUSSION

NRC's patient release criteria are specified in 10 CFR 35.75. This regulation was amended in 1997 (Enclosure 4, "History of the Current Patient Release Criteria Rule") and authorizes the

CONTACT: Neelam Bhalla, FSME/DILR
(301) 415-6843

release of patients from licensee control if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (mSv) (0.5 rem). Prior to that time, NRC regulations required hospitalization of patients until the radioactivity in their bodies decreased to the equivalent of 30 millicuries (mCi) of I-131. The provisions of the current rule allow outpatient treatment for greater than 30 mCi of I-131 based on the licensee's determination that the TEDE to an individual from the released patient is not likely to exceed 5 mSv (0.5 rem). The petitioner requests that NRC revoke the current rule and re-adopt the release criteria that existed prior to 1997. Among other things, the petitioner asserts that the release of patients under the current rule creates an unwarranted radiation hazard to the public and patient's family, particularly children. The petitioner expresses concern about dose to members of the public during transport from patients who have been administered large amounts of I-131. The petitioner is also concerned about the risks of a patient vomiting the I-131 dosage, with resultant exposure to family members in cleaning patient vomit. In addition, the petitioner is concerned that the patients in their hypothyroid state may have trouble comprehending and remembering the guidance that is provided to them to minimize exposure to others.

The current release criteria are consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," October 1, 1970, and of the International Commission on Radiological Protection (ICRP) "1990 Recommendations of the International Commission on Radiological Protection" Publication 60. NRC's NUREG-1556, Volume 9, "Consolidated Guidance About Material Licenses: Program Specific Guidance About Medical Use Licenses," Appendix U, provides licensees with calculational methods that enable them to make a determination of the potential doses to family members as well as to members of the public. The regulations and associated NUREG-1556 guidance clearly establish that a patient cannot be released by the licensee if the dose to any other individual is likely to exceed 5 mSv (0.5 rem). As part of the routine inspection program, NRC inspectors review the licensees' calculations and verify that patients have been provided with the guidance required by the rule.

The petitioner expressed particular concern about potential exposure to children, given their greater sensitivity to radiation. In addition, one of the commenters noted that ICRP Publication 94 (published in 2004) now recommends that doses to children be limited to less than 1 mSv (0.1 rem) and notes that doses to children from patient contamination have the potential to be far greater than from external exposure. In light of this, the commenter recommended that NRC consider adding instructions in NUREG-1556, Volume 9, regarding the avoidance of exposure of children to patient contamination.

The current patient release criteria were based on the assumption that internal doses are small compared with external exposures and may be neglected (NUREG-1556, Volume 9, Appendix U). ICRP Publication 94 states that the dose to adults exposed to these patients is mostly from external radiation, but children may receive a considerable dose from contamination, especially from patients' saliva. In previous recommendations, ICRP recommended the 1 mSv/year limit for members of the public, but allowed a few mSv/episode dose limit for relatives, visitors, and caretakers. There was no distinction made for children or infants in the previous recommendations. However, ICRP Publication 94 now recommends that young children and infants, as well as visitors not engaged in caregiving, be treated as members of the public (i.e., have a dose limit of 1 mSv/year). The Commission has not taken a position on these recommendations. Recently, ICRP published a comprehensive set of recommendations in Publication 103, "The 2007 Recommendations of the International Commission on Radiation

Protection.” ICRP Publication 103 repeats the recommendations made in Publication 94 that young children and infants, as well as visitors not engaged in the caring of the patient, should be subject to the public dose limit of 1 mSv/year.

The petitioner also asserts that the 1997 rulemaking was defective because it was purportedly adopted in response to a petition from a member of the public submitted in December 1990, but was actually drafted at the request of the NRC staff, and according to NRC staff specifications. The petitioner asserts that the NRC staff’s failure to disclose this fact to the Commission in the rulemaking documents and the failure to notice this assistance in the *Federal Register* violated the Commission’s rules. The petitioner asserts that NRC staff offered inappropriate assistance to the rulemaking petitioner. However, there were neither NRC regulations nor internal policies that addressed the staff role or level of assistance that could be provided to potential petitioners at the time that the alleged staff assistance occurred.

In any event, a decision to initiate rulemaking to adopt the petitioner’s proposals could not rest on a question of staff compliance with internal NRC procedures. However initiated, the 1997 rulemaking involved broad participation with 63 commenters, including medical practitioners and medical organizations, regulatory agencies in Agreement States, public interest groups and private individuals. Moreover, the American College of Nuclear Medicine and the American Medical Association filed petitions later that were included in the rulemaking. Their independent proposals as well as the broad participation by interested parties negate the inference drawn by the petitioner that the resulting rulemaking was merely the product of staff influence. To reopen the earlier rulemaking would require evidence that alleged procedural defects substantively affected the final rule in a manner requiring that additional rulemaking be initiated. No such evidence has been brought to our attention to reach such conclusion. Thus, even assuming that the petitioner’s allegations of undue staff assistance were true, the petitioner has not demonstrated a substantive basis for reopening the earlier rulemaking or for initiating rulemaking in response to this petition.

As part of the normal petition review process, a working group (WG) was assembled to consider the issues raised in the petition and to make recommendations to the FSME’s Petition Review Board (PRB)¹. The PRB reviewed the petition and the WG recommendations for resolution of the petition. The PRB determined that the issues raised by the petitioner were extensively addressed in 1996 in “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material” (NUREG-1492) when the current rule was promulgated; and that the petitioner had not provided any specific data to refute the analysis. However, the PRB considered several options (Enclosure 5 “Regulatory Options Considered to Address Exposure to Children”) for addressing the concern regarding exposure of children raised by the petitioner. The PRB concluded that revising the guidance in NUREG 1556, Volume 9, and issuing a Regulatory Issue Summary (RIS) to the medical use licensees is the most effective option for addressing this concern.

¹The PRB consisted of: G. Pangburn, Deputy Director, FSME (Chair); J. Schlueter, former Director, Division of Materials Safety and State Agreements, FSME; D. Rathbun, Director, Division of Intergovernmental Liaison and Rulemaking, FSME; F. Cameron, former Assistant General Counsel for Rulemaking and Fuel Cycle, Office of the General Counsel; and M. Lesar, Chief, Rulemaking, Directives, and Editing Branch, Office of Administration.

The decision to deny the petition is consistent with NRC's Strategic Plan for Fiscal Years 2008-2013. The staff believes that NRC's strategic safety goal to "ensure adequate protection of public health and safety and the environment" would be maintained because the current rule is adequate to protect public health and safety from release of these patients. The decision is also consistent with the Strategic Plan's focus on Organization Excellence. Specifically, the openness objective was accomplished by soliciting and considering public comments on the petition. It is expected that denying this petition will continue to maintain the NRC's effectiveness objective because reverting to the 1997 release criteria as requested by the petitioner would place a significant regulatory burden on licensees with no commensurate benefit to public health and safety.

In conclusion, the staff finds that the arguments presented in PRM-35-18 do not support a rulemaking to revoke the patient release criteria in 10 CFR 35.75. The staff believes that additional guidance in NUREG-1556, Volume 9, and a RIS will effectively convey to the licensees the concerns expressed in ICRP Publications 94 and 103 with regard to children's exposure from released patients. The staff has prepared a RIS and revised the guidance in NUREG 1556, Volume 9, which will be issued to all medical use licensees and to the Agreement States, concurrent with the issuance of this petition resolution.

The appropriate Congressional committees will be informed of the denial of the petition.

The action does not constitute a significant question of policy, nor does it affect regulations contained in 10 CFR Parts 7, 8, or 9, Subpart C, concerning matters of policy.

Enclosures:

1. Letter to the Petitioner
2. *Federal Register* notice
3. Notice of Petition Denial
Signed by EDO
4. History of the Current Patient
Release Criteria Rule
5. Regulatory Options Considered
to Address Exposure to Children

Regulatory Issue Summary (RIS) to the medical use licensees is the most effective option for addressing this concern.

The decision to deny the petition is consistent with NRC's Strategic Plan for Fiscal Years 2008-2013. The staff believes that NRC's strategic safety goal to "ensure adequate protection of public health and safety and the environment" would be maintained because the current rule is adequate to protect public health and safety from release of these patients. The decision is also consistent with the Strategic Plan's focus on Organization Excellence. Specifically, the openness objective was accomplished by soliciting and considering public comments on the petition. It is expected that denying this petition will continue to maintain the NRC's effectiveness objective because reverting to the 1997 release criteria as requested by the petitioner would place a significant regulatory burden on licensees with no commensurate benefit to public health and safety.

In conclusion, the staff finds that the arguments presented in PRM-35-18 do not support a rulemaking to revoke the patient release criteria in 10 CFR 35.75. The staff believes that additional guidance in NUREG-1556, Volume 9, and a RIS will effectively convey to the licensees the concerns expressed in ICRP Publications 94 and 103 with regard to children's exposure from released patients. The staff has prepared a RIS and revised the guidance in NUREG 1556, Volume 9, which will be issued to all medical use licensees and to the Agreement States, concurrent with the issuance of this petition resolution.

The appropriate Congressional committees will be informed of the denial of the petition.

The action does not constitute a significant question of policy, nor does it affect regulations contained in 10 CFR Parts 7, 8, or 9, Subpart C, concerning matters of policy.

Enclosures:

6. Letter to the Petitioner
7. *Federal Register* notice
8. Notice of Petition Denial
Signed by EDO
9. History of the Current Patient
Release Criteria Rule
10. Regulatory Options Considered
to Address Exposure to Children

Distribution: EDATS -FSME-2007-0029

DILR r/f RidsEdoMailCenter RidsFsmeOd
FSME r/f EDO r/f DMSSA r/f

ML073300444

OFFICE:	DILR	DILR	DMSSA	DILR
NAME:	NBhalla	MDelligatti	JSchlueter	PBubar
DATE:	4/10/2008	4/10/2008	11/ 5 /2007	4/ 14 /2008
OFFICE:	DILR PB for	Tech Editor	FSME	
NAME:	DRathbun	Cpoland;PTressler for	CMiller (G.Pangburn for)	
DATE:	4/ 14 /2008	4/16/2008	4 /23 /2008	