Molly C. Dwyer
Clerk of Court

Office of the Clerk
United States Court of Appeals for the Ninth Circuit
95 Seventh Street
Post Office Box 193939
San Francisco, California 94119-3939

(415) 355-8000

July 11, 2008

CA9 Docket No.:	08-72973
Agency Number:	PRM-35-18
Short Title:	Peter Crane v. United States Nuclear Regulato, et al

Dear Counsel:

Your Petition for Review has been received in the Clerk's Office of the United States Court of Appeals for the Ninth Circuit.

The U.S. Court of Appeals docket number shown above has been assigned to this case. Always indicate this Court of Appeals docket number when corresponding with this office about your case.

The due dates for filing the parties' briefs and otherwise perfecting the petition have been set by the enclosed "Time Schedule Order," pursuant to applicable FRAP rules. These dates can be extended only by court order. Failure of the petitioner to comply with the time schedule order will result in automatic dismissal of the petition. 9th Cir. R. 42-1.

The following information is being provided in an attempt to answer the most frequently asked questions regarding the appellate process. Please review this information very carefully. For convenience, we use the term "Circuit Rules" instead of "Rules of the United States Court of Appeals for the Ninth Circuit" and "FRAP" instead of "Federal Rules of Appellate Procedure."

Enclosed with this letter is an appellate processing schedule along with a case processing checklist to help you monitor the progress of your case.

Petitioners who are filing pro se should refer to the accompanying information sheet regarding the filing of informal briefs.

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

JUL 11 2008

MOLLY C. DWYER, CLERK OF COURT
U.S. COURT OF APPEALS

PETER G. CRANE,

Petitioner,

v.

UNITED STATES NUCLEAR REGULATORY COMMISSION; UNITED STATES OF AMERICA,

Respondents.

No. 08-72973
NRC No. PRM-35-18
no origin

TIME SCHEDULE ORDER

The parties shall meet the following time schedule:

Wed., August 20, 2008	Appellant/petitioner's opening brief and excerpts of record shall be served and filed pursuant to FRAP 32 and 9th Cir. R. 32-1;
Fri., September 19, 2008	The brief of appellee/respondent shall be filed and served, pursuant to FRAP 32 and 9th Cir. R. 32-1

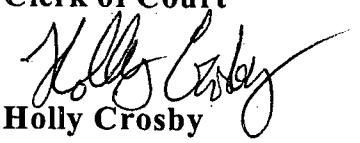
The optional appellant/petitioner reply brief shall be filed and served within fourteen days of service of the appellee/respondent's brief, pursuant to FRAP 32 and 9th Cir. R. 32-1.

Failure of the appellant to comply with the Time Schedule Order will result in automatic dismissal of the appeal. 9th Cir. R. 42-1

Appellants/Petitioners without representation of counsel in a prisoner appeal may have their case submitted on the briefs and record without oral argument, pursuant to FRAP 34(a). Within 10 days of the filing of the appellant's opening brief, parties may file a statement setting forth the reasons why, in the opinion of the parties, oral argument should be heard.

FOR THE COURT:

Molly C. Dwyer
Clerk of Court



Holly Crosby
Deputy Clerk

United States Court of Appeals for the Ninth Circuit

FILED
JUL 11 2008
MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

Peter G. Crane, Petitioner)
)
v.) Petition for Review
)
United States Nuclear Regulatory)
Commission and The United States) 08-72973
of America, Respondents.)

Peter G. Crane, admitted to the bar of this Court on September 8, 1980, but here appearing *pro se*, hereby petitions the Court for review of the United States Nuclear Regulatory Commission's denial, published in the *Federal Register* at 73 Fed. Reg. 29445 (May 21, 2008), of a petition for rulemaking on the criteria for releasing patients from radiological isolation after treatment with radioactive iodine I-131. A copy of the Commission's denial is attached.

Respectfully submitted,

PETER G. CRANE
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Seattle, WA 98117-5902
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Dated: July 8, 2008

Proposed Rules

Federal Register
Vol. 73, No. 99
Wednesday, May 21, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM–35–18; NRC–2005–0020]

Peter G. Crane; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Denial.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM–35–18) submitted by Peter G. Crane (petitioner). The petitioner requested that the NRC amend the regulations that govern medical use of byproduct material concerning release of individuals who have been treated with radiopharmaceuticals. The petitioner believes that this regulation is defective on legal and policy grounds. The petitioner requested that the patient release rule be partially revoked 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 NRC, for the reasons described in the **SUPPLEMENTARY INFORMATION** of this document has determined that the issues raised in the petition do not justify a rule change.

DATES: The docket for the petition for rulemaking PRM–35–18 is closed on May 21, 2008.

ADDRESSES: You can access publicly available documents related to this petition for rulemaking using the following methods:

Federal e-Rulemaking Portal: Go to *http://www.regulations.gov* and search for documents filed under Docket ID [NRC–2005–0020].

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Public File Area O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agency Wide Document Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into 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.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–6843, e-mail *Neelam.Bhalla@nrc.gov.*

SUPPLEMENTARY INFORMATION:

The Petition

On December 21, 2005 (70 FR 75752), the NRC published a notice of receipt of a petition for rulemaking dated September 2, 2005, filed by Peter G. Crane. The petitioner requested that the NRC revoke the 1997 amendment to 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material" (62 FR 4120; January 29, 1997, Patient Release Criteria Rule), insofar as it allows the release of patients from radioactive isolation with more than the equivalent of 30 millicuries of radioactive I–131 in their bodies.

Subsequently, during the public comment period, the petitioner filed a document dated January 30, 2006, in which he stated that after filing the petition, additional information relevant to the issue of criteria for the release of patients treated with radioactive I–131 had come to his attention and some of the comments filed warranted a response from the petitioner. In the January 30, 2006, document, the petitioner further clarified his grounds for filing the petition. In addition, the petitioner submitted an additional comment on March 6, 2006, as corrected by a submittal dated March 10, 2006. The NRC considered these documents together with the original petition.

NRC's patient release criteria are specified in 10 CFR 35.75. This regulation was amended in 1997 and authorizes the 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) (Typical natural background radiation in the United States is 0.3 rem per year). Before 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 requested NRC to revoke the current rule and re-adopt the release criteria that existed before 1997.

The petitioner believes that this regulation is defective on legal and policy grounds. The petitioner asserts that the 1997 rulemaking was defective on legal grounds because it was purportedly adopted in response to a petition from a member of the public; however, the petition was actually drafted at the request of the NRC staff, with NRC staff assistance, under NRC staff specifications. The petitioner alleges that the NRC violated its own rules because (1) the NRC staff failed to disclose in papers forwarding the rulemaking, that the staff had assisted the former petitioner by encouraging the individual to submit the petition and (2) the NRC did not mention any such assistance in its rulemaking notices in the **Federal Register**.

The petitioner supports this assertion by referring to a memorandum from the Executive Director for Operations (EDO) dated February 23, 1994, addressed to "All NRC Employees, " that discusses the requirements in 10 CFR 2.802(b), which limits the assistance that the NRC may give prospective petitioners. The petitioner states that the memorandum advised that every year after 1991, the EDO had issued an announcement to NRC employees which clarified the permissible scope of NRC staff interaction with a prospective petitioner for rulemaking. The memorandum stated that should any NRC staff assistance be provided to a prospective petitioner regarding technical or substantive issues, that assistance must be disclosed to the Commission in the

paper forwarding the rulemaking action for approval. Also, NRC staff assistance must be noticed in any public notice regarding the petition and any rulemaking that may result from the petition that is published in the **Federal Register**. The petitioner asserts that "assistance" as defined by the NRC includes encouraging a prospective petitioner to submit a petition, and that the NRC staff in its rulemaking notices in the **Federal Register** did not mention any such encouragement to the former petitioner to file the petition.

The petitioner also asserts that the release of patients under the current rule creates an unwarranted hazard to the public and patient's family, particularly children. The petitioner's safety concerns are summarized as follows:

1. Dose to family members, especially children.

The petitioner argues that patients treated for thyroid cancer with I–131 are being sent home under conditions that guarantee that family members will receive large and potentially harmful doses of radiation under uncontrolled conditions. The petitioner expresses concern for exposure to children stating that children are more radiation-sensitive than adults and argues that children deserve more protection, not less.

2. Dose to members of the public during patient transport.

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 states that by reverting to the 1997 release criteria, the exposure to members of the public will be less because patients being transported home will not be released with large amounts of radioactivity in their bodies.

3. Contamination and dose concerns due to vomiting.

The petitioner expresses concern about the risks of vomiting of the I–131 dosage, with resultant exposure to family members in cleaning patient vomit, and a loss of the administered dose to the patient.

4. Hypothyroid patients are not able to fully comprehend or remember the instructions provided to them.

The petitioner asserts that although the patients are supposed to receive instructions on minimizing exposure to others, patients may have trouble comprehending and remembering the guidance, given their hypothyroid state. The petitioner draws from personal experience and states that the severe hypothyroid state impairs a person's ability to follow safety guidelines for the protection of family members and other members of the public.

5. NRC has allowed for reduction of exposure to hospital employees and clergy members at the expense of elevated exposure to family members, and particularly, children.

The petitioner has referred to a discussion in the statements of consideration of the final rule published on January 29, 1997 (62 FR 4120) of relevant benefits and risks associated with the options of patient release and hospitalization. The petitioner asserts that the NRC acknowledged that family members of patients would receive higher doses of radiation, and justified this in part by arguing that members of the clergy who visit hospitals frequently would receive lower doses of radiation because cancer patients would be at home instead of in the hospital.

Public Comments on the Petition

The notice of receipt of the petition for rulemaking invited interested persons to submit comments. The comment period closed on March 6, 2006. NRC received 48 comment letters including 3 submittals from the petitioner. There were 14 letters in support of the petition. These were primarily from cancer patients who had been treated with I–131 and released under the provisions of 10 CFR 35.75 or the equivalent State regulations. These patients expressed concern that they had to take care of themselves. However, had they been hospitalized, they would have been taken care of by the hospital staff. Several of these commenters expressed concern about exposure to family members and others, in particular from patient vomiting.

One commenter supported the petition for a concern not cited by the petitioner. This commenter stated that the current release criteria have resulted in an increase in the number of events when radiation monitoring equipment detects radiation at municipal waste-handling facilities and that the States have to respond to these events.

Commenters opposing the petition generally included physicians, medical physicists, and radiation safety officers, as well as several medical professional organizations. These professional organizations included the American Society of Therapeutic Radiation Oncologists (ASTRO), the American Association of Physicists in Medicine (AAPM), the American Board of Nuclear Physicians (ABNP), the American Thyroid Association, the Endocrine Society, the American College of Radiology (ACR), the Society of Nuclear Medicine (SNM), the National Association of Nuclear Pharmacists, the American Pharmacists Association, and the Council on Radionuclides and Radiopharmaceuticals (CORAR).

Commenters opposing the petition stated that reverting from the current release criteria back to the 30-mCi rule would result in additional and unnecessary healthcare costs, and would unnecessarily limit access to treatment for patients who cannot afford hospitalization. Commenters opposing the petition also stated that the provisions of the current rule provide patients the comfort and convenience of being in their homes, rather than the confinement in a hospital environment.

Many physicians opposing the petition disagreed with the petitioner's assertion that the patients are released while they are a risk of exposure to others. These physicians commented that they carefully interview the patients and assess their ability to follow and understand radiation safety precautions and their living conditions at home, and then decide on outpatient treatment. These physicians also stated that they discuss with their patients arrangements to have any children in the households stay away from their homes during the initial week of their treatments. With regard to the petitioner's concern about patient vomiting, some physicians stated that they provide special instructions to the patients to handle the vomitus and prescribe anti-nausea medication, if needed. These commenters indicated that vomiting is a rare complication with these patients.

One commenter generally opposed the petition but noted the recommendations of the International Commission on Radiological Protection (ICRP), in ICRP Publication 94 (published in 2004), entitled, "Release of patients after therapy with unsealed radionuclides." The commenter stated that ICRP Publication 94 now recommends that doses to children be constrained to less than 1 mSv (100 millirem) and that doses to children from patient contamination have the potential to be far greater than from external exposure. In light of this, the commenter suggested that there may be a need for NRC to consider adding instructions in NUREG–1556, Volume 9, "Consolidated Guidance About Material Licenses: Program Specific Guidance About Medical Use Licenses," regarding the avoidance of exposure to children to patient contamination. NUREG–1556, Volume 9, Appendix U, "Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials," provides instructions to minimize exposure to family members and other members of

the public (U.2.3.1). Although these instructions include precautions to reduce the spread of contamination, the instructions do not specifically caution against avoiding exposure of children to patient contamination. Therefore, the commenter suggested that NRC revise NUREG–1556, Volume 9, to include specific guidance for patients on precautions to avoid children's exposure to radioactive contamination.

Petition Resolution

After reviewing the information provided in the petition, as supplemented, and the comments, the NRC has determined that the issues raised in the petition do not justify a rule change. The NRC believes that the current NRC regulations provide adequate protection to family members and other members of the public. The NRC's responses to the petitioner's specific concerns are provided below.

NRC Responses to the Issues Raised by the Petitioner

The petitioner 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, nor is the Commission aware of any basis for such a 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.

Dose to Family Members, Especially Children

The petitioner asserts that patients treated for thyroid cancer with I–131 are being sent home under conditions that guarantee that family members will receive large and potentially harmful doses of radiation under uncontrolled conditions. The petitioner expresses particular concern for exposure to children because children are more radiation-sensitive than adults.

The concerns related to doses to the family members and members of the public from released patients were extensively considered during the development of the current patient release criteria rule. By way of background, in 1991 (56 FR 23360, May 21, 1991) NRC published a final rule that amended 10 CFR Part 20 "Standards for Protection Against Radiation" to include a change to the dose limits for individual members of the public in 10 CFR 20.1301. The rule lowered dose limits for members of the public from 500 millirem per year to 100 millirem per year. However, the criteria for the release of patients under 10 CFR 35.75 had been based on a dose limit of 500 millirem to members of the public. When 10 CFR Part 20 was issued, there was no discussion in the supplemental information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients.

Some stakeholders were uncertain about what effect the revised 10 CFR Part 20 would have on patient release criteria and subsequently, three petitions for rulemaking were received related to this issue. One petition was received from Dr. Carol Marcus, one from the American College of Nuclear Medicine (ACNM), and one from the American Medical Association (AMA). Dr. Marcus, and the ACNM petitions requested the NRC to amend the revised Part 20 and 10 CFR 35.75 to raise the annual radiation dose limits to members of the public from 1 millisievert (0.1 rem) to 5 millisieverts (0.5 rem) from patients administered radioactive materials, and the AMA petition requested that patient release be regulated by Part 35 rather than Part 20. NRC decided to resolve all of these petitions in a single rulemaking.

In June 1994 a proposed rule was published to amend 10 CFR 20.1301(a)(1) to specifically clarify that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients released under 10 CFR 35.75. 59 FR 30724 (June 14,1994). However, the dose limits in the revised Part 20 were not changed.

In the proposed rule, the NRC also proposed to amend 10 CFR 35.75 to change the patient release criteria from 30 millicuries of activity in a patient or a dose rate of 5 millirems per hour at 1 meter from a patient, to a dose-based criteria where the TEDE to an individual from exposure to a released patient is not likely to exceed 5 mSv (0.5 rem). Under the regulations in effect before 1997, activity within a patient was measured to determine whether a patient could be released from licensee control. However, the NRC determined that this type of an approach was not dependable, in that there were variants among the isotopes that would cause variations in the dose that would result to another individual from exposure to the released patient. The NRC believed that the primary consideration in the release of patients should not be the activity within the patient, but the potential doses to other individuals. NRC concluded that basing the patient release criteria on the dose to individuals exposed to a patient (*i.e.* dose-based regulation) would provide a consistent, scientific basis for such decisions that treats all radionuclides on a risk-equivalent basis. A dose-based rule was therefore proposed that would allow consideration of case-specific factors to more accurately assess the dose to other individuals.

The final rule amending Part 20 and Part 35 to incorporate these changes was published in 1997 (62 FR 4120, January 29, 1997). In April 1997, the NRC also published a report "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG–1492). The report assessed the potential internal and external doses to individuals exposed to patients who have been administered radiopharmaceuticals and performed a comprehensive risk/benefit analysis for adopting the 5 mSv (0.5 rem) TEDE criterion for patient release. The report stated that the criterion was based on the ICRP Publication 60, "1990

Recommendations of the International Commission on Radiation Protection," and the recommendations of the NCRP in NCRP Report No. 116, " Limitation of Exposure to Ionizing Radiation." Each of these reports provided a basis for allowing individuals to receive annual doses up to 5 mSv (0.5 rem) under certain circumstances. These recommendations of the ICRP and NCRP were based on a finding that annual doses in excess of 1 mSv (0.1 rem) to a small group of people, provided that they do not occur often, need not be regarded as unduly hazardous. The dose-based release limits also used assumptions that the internal doses for individuals who may come in contact with released patients were very small compared with doses from external exposures.

The petitioner has not provided any data to refute the analysis provided in NUREG–1492. However, one commenter noted that ICRP Publication 94 now recommends that doses to children be limited to less than 1 mSv (100 millirem) and that doses to children from patient contamination have the potential to be far greater than from external exposure. The commenter recommended that NRC consider adding instructions in NUREG–1556, Volume 9, regarding the avoidance of exposure of children to patient contamination.

The NRC carefully considered this issue in reviewing the petition and reviewed ICRP Publication 94. The recommendations in the report do not explicitly state that patients should be hospitalized. However, ICRP recommends that public dose limits and dose constraints for others be observed, and be followed with optimization, realizing that procedures of optimization and their effects on individual behavior will differ among individuals and their circumstances.

In addition, ICRP recommends: "Since high absorbed thyroid dose may occur in infants and young children from contamination, and children's thyroids are very radiosensitive for carcinogenesis, this population should be restricted to the public dose limit of 1 mSv/year." The report states that although the dose to adults exposed to released patients is mostly from external radiation, children may receive a dose from contamination. Therefore, restrictions following the release of patients should focus on infants and children. Recently, ICRP has also published a comprehensive revision to its recommendations made in 1991, in ICRP Publication 103. ICRP Publication 103 repeats the recommendations made in ICRP Publication 94 that young children and infants, as well as visitors not engaged in the care of patients, should be limited to a dose of 1 mSv (0.1 rem) per year.

This recommendation represents a departure from previous ICRP recommendations, which did not make a distinction for children or infants. Therefore, NRC considered the following regulatory options for limiting the exposure to children and infants from released patients:

(1) Amend 10 CFR 35.75 to limit children and infants exposure to 1 mSv (0.1 rem);

(2) Amend 10 CFR 35.75 (b) to include special instructions if the dose to an infant or child could exceed 1 mSv (0.1 rem); or

(3) Revise the guidance in NUREG–1556, Volume 9, to include the ICRP Publication 94 recommendations and issue a Regulatory Issue Summary (RIS) to medical licensees to make them aware of the ICRP recommendations.

Option (1) Amend 10 CFR 35.75 to Limit Children and Infants Exposure to 1 mSv (0.1 rem)

NRC has determined not to change the rule to adopt a lower limit for children and infants. The NRC does not believe that such a rule change would be effective because it is difficult to meaningfully estimate the doses that may result from patient contamination. The factors involved in assessing such doses are largely indeterminate, and even assumptions are likely to be so much in error as to be meaningless. For example, the amount of iodine in the patient's saliva is highly variable even for patients receiving the same treatment, and the amount of saliva that may be ingested by a child is dependent on the details of the family's living arrangements, family habits and the age of the child, and cannot be reliably assumed to assess the dose to the child or the infant. This makes a dose-based approach to protecting children from patient contamination an impractical choice. NRC believes that an alternative approach that is more likely to provide better protection for children and infants would be for patients to take precautions to maintain the dose to children and infants as low as is reasonably achievable (ALARA). NRC therefore has determined that the instructions to the patients, as well as any guidance to physicians, should be modified to stress the need to keep children and infants away from any possible sources of contamination.

10 CFR 35.75(b) requires licensees to provide instructions, including written instructions on actions recommended to maintain doses to other individuals ALARA. Therefore, NRC determined that this guidance should be strengthened to protect children and infants from any sources of patient contamination. To achieve this goal, NRC has revised the guidance in NUREG 1556, Volume 9 and has developed a Regulatory Issue Summary (RIS) to convey to the licensees the concerns expressed in ICRP Publications 94 and 103 about doses to children from patient contamination and the actions licensees and patients should take to keep children away from any sources of patient contamination. These actions would be based on the individual patient's circumstances and may include hospitalization of the patient based on the patient's family situation. NRC will issue the RIS and the revised guidance in NUREG 1556, Volume 9, to all medical use licensees and to the Agreement States concurrent with the issuance of this petition resolution.

NRC believes that enhancing the guidance is a more efficient way of protecting children and infants than amending the regulations. In addition, in considering the disposition of a petition for rulemaking, NRC must consider whether addressing the topics raised in the petition are likely to result in a significant increase in safety or security for all affected stakeholders. As explained above, NRC does not believe that the issues raised in this petition significantly impact safety and security such as would warrant a rulemaking. Additionally, the NRC must consider the potential impact of a rulemaking on the agency's efficiency and effectiveness. NRC has limited resources for rulemaking; therefore any topic to be considered in the NRC rulemaking process must have a strong technical basis before it can be considered in the agency's prioritization process for rulemaking. In any given budget cycle, only a limited number of rulemakings can be funded. Topics with minimal safety or security impact may not reach the funding threshold. The NRC does not believe that there is a sufficiently strong technical basis to consider the issues in this petition in a rulemaking.

Option (2) Amend 10 CFR 35.75 (b) to Include Special Instructions if the Dose to an Infant or Child Could Exceed 1 mSv (0.1 rem)

NRC determined that it is not necessary to amend 10 CFR 35.75(b) to require that special instructions be provided if the dose to an infant or child could exceed 1 mSv (0.1 rem). Section 35.75(b) presently requires a licensee to provide the released individual, or the individual's parent or guardian with instructions, including written

instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA), if the TEDE to *any other individual* is likely to exceed 1 mSv (0.1 rem). The requirement that instructions be provided if the TEDE is likely to exceed 1 mSv to any other individual includes that these instructions must be provided if the TEDE to children and infants is likely to exceed 1 mSv (0.1 rem).

Option (3) Revise the Guidance in NUREG–1556, Volume 9, to Include the ICRP 94 Recommendations and Issue a Regulatory Issue Summary (RIS) to Medical Licensees to Make Them Aware of the ICRP Recommendations

As discussed under Option (1), NRC determined to revise the guidance in NUREG–1556, Volume 9, and issue a RIS to make licensees aware of the ICRP's new recommendations, and to heighten licensees' awareness of the requirements of the regulations in 10 CFR 35.75(b). NRC believes that the protection for children is best achieved through maintaining doses ALARA. NRC believes that this can be accomplished under the current patient release criteria, but that the instructions to the patients, as well as any guidance to physicians, need to be modified to emphasize the need to keep children away from any possible sources of contamination. The guidance needs to be sufficiently flexible so that the patient's physician has the option of keeping the patient in the hospital for longer periods than currently required if the patient's living conditions warrant such a decision. The NRC believes that these actions will adequately protect infants and children.

The petitioner also asserts that NRC has allowed for reduction of exposure to hospital employees and clergy members at the expense of elevated exposure to family members. The petitioner's assertion is based upon a misinterpretation of a response to a comment on the proposed rule as discussed in the Statements of Consideration of the final rule published on January 29, 1997 (62 FR 4120). Specifically, a commenter had noted that it would not be possible to maintain the same level of contamination control at home that could be maintained in a hospital. In responding to this comment, the NRC noted that the two situations were not comparable because areas in hospitals have potential for contamination from many patients, and that people who frequent the hospital, such as clergy, would therefore have the potential to be exposed to contamination from many patients. However, in the case of a released patient at home, therapeutic administrations usually occur no more than once a year and probably no more than once in a lifetime. The reference to exposure of hospital clergy to contamination from many patients was intended as an example, and was not intended to imply that removing patients from the hospital would constitute a benefit to clergy that would compensate for an additional risk to a patient's children. Rather, the Statements of Consideration in the 1997 final rule explain that NRC considered the results of studies and recommendations current at the time, evaluated the benefits to patients from being home, and concluded that doses to household members from one patient would be low, compared to increased exposure to hospital personnel from recurring administrations. NRC believes that the current rule provides adequate protection of the public and family members and minimizes exposure of hospital employees.

Dose to Members of the Public During Patient Transport

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 guidance in NUREG–1556, Volume 9, provides adequate instructions for the patient to minimize time in public places (for example, public transportation, grocery stores, and shopping centers). Also, ICRP Publication 94 concludes that patients traveling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours. From the comments received, it appears that a vast majority of the patients return home in private vehicles. Other than describing a single anecdotal account of an I–131 patient who allegedly traveled home on a bus, vomited, and exposed her husband and children to radiation, the petitioner provides no specific data in support of his position.

Contamination and Dose Concerns Due to Vomiting

In support of his petition, the petitioner expresses concern about dose to family members who clean up the patient's vomit, and a loss of administered dose to the patient. Although the petitioner describes a case that he states is known to him, the petitioner provides no specific data in support of his concern. Some physicians have commented on the petitioner's concern and stated that the incidence of vomiting in their experience is rare, and that the physicians are able to prescribe anti-nausea drugs, if needed. The same view was expressed by physician members of the Advisory Committee on the Medical Uses of Isotopes at its November 2006 meeting. In addition, some physicians stated that they provide special instructions to their patients regarding handling of the vomitus and prescribe anti-nausea drugs, if needed.

Hypothyroid Patients Are Not Able to Fully Comprehend or Remember Instructions.

The petitioner expresses concern that most patients are in a hypothyroid state and, therefore, are unable to fully comprehend or remember the instructions provided to them. The petitioner describes these patients as "sick, and quite possibly stressed, groggy, and mentally fogged, to remember the guidance and follow it." The petitioner does not provide any new or specific information in support of his concern.

The regulations in 10 CFR 35.75(b) require instructions be provided to the individual, or the individual's parent or guardian, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). In the 2002 revision to Part 35 (67 FR 20249; April 24, 2002), 10 CFR 35.75(b) was revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian, to acknowledge that it is not appropriate to provide the individual being released with instructions in some cases (*e.g.*, the individual is a minor or incapable of understanding the instructions). In addition, the regulations do not mandate the release of patients. Physicians always have the option of hospitalizing individuals based on their judgment of an individual's condition. One of the commenters, a physician, noted that at his institution if a patient is determined to be incontinent, incapable of self-care, or unable to adhere to the instructions, then the patient is treated as an inpatient.

Waste Issue

One commenter in support of the petition stated that the rule has resulted in an increase on the burden of State responders due to an increase in the alarms triggered at the municipal waste handling facilities. Although this issue was not raised by the petitioner, the NRC staff reviewed this concern. These alarms are generally triggered by any radioactivity detected at these facilities.

The commenter did not provide any data on how many or what fraction of these alarms are triggered by the wastes from these patients. With regard to the environmental pathways of radioiodine, ICRP Publication 94 states that "regarding the release of patients from the hospital, the radioiodine is in the patient where it decays or is excreted primarily in urine, and finds its way into the environment." According to the report, the impact of the released I–131 on the environment should be minimal, considering that I–131 has a relatively short half life of 8 days. The time it takes for the excreta of patients to be processed and returned to the ecosystem is relatively long. In addition, the impact of I–131 on the environment from this pathway is usually independent of whether the patient is hospitalized after treatment or released to go home.

Conclusion

The decision to deny the petition is consistent with NRC's Strategic Plan for Fiscal Years 2008–2013. NRC's strategic safety goal to "ensure adequate protection of public health and safety and the environment" would continue to be maintained because NRC believes that the current rule is adequate to protect public health and safety from the 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, NRC 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. Reverting to the 1997 patient release criteria would impose unnecessary regulatory burden and is not warranted for the protection of public health and safety. To address the petitioner's concern for exposure to children and infants, NRC has prepared a RIS and additional guidance which will be issued to all NRC medical use licensees, and to the Agreement States, concurrent to the resolution of this petition.

For the reasons cited in this document, the NRC denies this petition for rulemaking.

Dated at Rockville, Maryland, this 7th day of May 2008.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. E8–11344 Filed 5–20–08; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. AD08–8–000]

Demand Response in Organized Electric Markets

May 13, 2008.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Supplemental Notice of Technical Conference.

SUMMARY: The Commission is providing an agenda for the technical conference to be held in this proceeding on May 21, 2008, from 9 a.m. to 4:30 p.m. (EST), and detailed information regarding attendance, internet access, and transcripts. This conference will provide a forum to consider issues related to demand response in organized electric markets, as discussed in the Commission's Notice of Proposed Rulemaking which was issued on March 8, 2008 in Commission Docket Nos. RM07–19–000 and AD07–7–000.

FOR FURTHER INFORMATION CONTACT: Ryan Irwin, Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6454, *Ryan.Irwin@ferc.gov.*

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On April 10, 2008, the Commission issued a Notice (April 10 Notice) scheduling a staff technical conference in the above-captioned proceeding. As stated in the April 10 Notice, the conference will provide a forum to consider issues related to demand response in organized electric markets, as discussed in the Notice of Proposed Rulemaking issued in Docket Nos. RM07–19–000 and AD07–7–000. *Wholesale Competition in Regions with Organized Electric Markets*, 73 FR 12,576 (Mar. 7, 2008), FERC Stats. & Regs. ¶ 32,682 at P 95 (2008) (Competition NOPR). The technical conference will be held on May 21, 2008, from 9 a.m. to 4:30 p.m. (EST), in the Commission Meeting Room at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. The conference will be open for the public to attend and advance registration is not required. Members of the Commission may attend the conference.

The agenda for this conference is attached. If any changes occur, the revised agenda will be posted on the calendar page for this event on the Commission's Web site, *http://www.ferc.gov*, prior to the event.

A free webcast of this event is available through *http://www.ferc.gov.* Anyone with internet access who desires to view this event can do so by navigating to the Calendar of Events at *http://www.ferc.gov* and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the Washington, DC area and via phone-bridge for a fee. If you have any questions, visit *http://www.CapitolConnection.org* or contact Danelle Perkowski or David Reininger at (703) 993–3100.

Transcripts of the conference will be available immediately for a fee from Ace Reporting Company (202–347–3700 or 1–800–336–6646). They will be available for free on the Commission's eLibrary system and on the Calendar of Events approximately one week after the conference.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an e-mail to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

For more information about this conference, please contact:

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CERTIFICATE OF SERVICE

I, Peter G. Crane, hereby certify that on July 8, 2008, I served copies of a Petition for Review of the Nuclear Regulatory Commission's denial of a petition for rulemaking on the following parties by way of the U.S. mail:

John F. Cordes, Solicitor
Office of the General Counsel
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

July 8, 2008
Date

PETER G. CRANE