April 28, 1997 SECY-97-091

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: DRAFT RULEMAKING PLAN: REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS (10 CFR PART 20) (PRM-20-24)

PURPOSE:

To inform the Commission that the staff's draft Rulemaking Plan for amending 10 CFR 20.1301, "Dose limits for individual members of the public," to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 500 mrem (5 mSv) per year has been forwarded to the Agreement States for their comment and to provide the rulemaking plan to the Commission for information.

BACKGROUND:

The Nuclear Regulatory Commission (NRC) received a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. The petitioner requests that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public," to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 500 mrem (5 mSv) per year. The staff proposes to amend § 20.1301 to allow authorized user physicians the discretion to permit consenting adult care givers to receive up to 500 mrem (5 mSv) annually from exposure to radiation patients.

AGREEMENT STATE IMPLEMENTATION ISSUES:

This amendment would be proposed as a Division 2 matter of compatibility. As such, Agreement States could promulgate similar regulations that are at least as stringent as NRC's rule. Agreement States would not necessarily have to adopt the 500 mrem (5 mSv) annual dose limit for their regulations.

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COORDINATION:

The Office of the General Counsel has no legal objection to the rulemaking plan. The Office of the Chief Financial Officer has no objection to the resources estimate contained in this paper. The Office of the Chief Information Officer has reviewed the rulemaking plan for information technology and information management implications and concurs in it. However, the plan suggests new information collection requirements that must be submitted to the Office of Management and Budget prior to publication of the proposed rule.

L. Joseph Callan
Executive Director
for Operations

Enclosure:
Rulemaking Plan

The Commissioners

Rulemaking Plan

Response to Request for Rulemaking

10 CFR Parts 20, 35

PRM 20-24 University of Cincinnati

Regulatory Issue

The NRC received a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. The petitioner requests that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public," to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 500 mrem (5 mSv) per year.

The amendment proposed by the petitioner would provide medical licensees the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient) to receive up to 0.5 rem (5 mSv). Furthermore, the petitioner proposes excluding pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 0.1 rem (1 mSv). Finally, the petitioner suggests that compliance could be documented by issuing radiation dose monitoring devices (i.e., pocket dosimeter, film badge, TLD or electronic dosimeter) to each specified visitor.

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on the petition. Comments were received from four members of the general public. All commenters agreed with the petition. One of the commenters suggested that the previous 0.5 rem (5 mSv) dose limit for the general public be reinstated for family members and, under unusual circumstances, also permit the attending physician to authorize even higher dose limits provided the latter does not exceed the occupational dose limit.

Existing Regulatory Framework

It is acknowledged in Part 20 that there may be instances that warrant individual members of the public receiving a dose in excess of the 0.1 rem (1 mSv) limit. Specifically, under the provisions of § 20.1301(c), licensees may request NRC authorization to operate up to an annual dose limit for individual members of the public of 0.5 rem (5 mSv). However, the Statements of Consideration for the 1991 revision of Part 20 clearly indicate that this provision was intended for temporary situations to alleviate an immediate need to redesign a facility (56 FR 23375).

> "The 0.5 rem limit is intended to be applied primarily to temporary situations where operation of a facility, or the person's exposure to radiation and radioactive emissions, is

not expected to result in doses above 0.1 rem over long periods of time. For design of new installations, the 0.1 rem limit should be used. However, existing facilities may apply for NRC approval to use the 0.5 rem limit while more complete evaluation of the need for any additional modifications is performed. Such facilities may include, for example, hospitals with existing teletherapy machines that were designed, constructed, and installed to comply with a 0.5 rem annual dose limit."

The NRC has received few requests to allow care givers[1] of radiation patients to exceed the 0.1 rem (1 mSv) public dose limit. In light of the above, it is possible that licensees generally are reluctant to request such authorization, either because they do not believe the provision would apply or because of the administrative or financial burden associated with such a request. (Section 20.1301(c) requires fairly complete documentation of the circumstances of the request and the licensee's proposal to make changes so the dose limit will not be exceeded in the future). Therefore, denying this petition would restrict and possibly prohibit close contact between care givers and patients at a time when the physical and emotional support provided by such individuals is of great perceived benefit to both the patient and the care giver.

How the Regulatory Problem Will be Addressed By Rulemaking

An appropriate change in the Commission's regulations would permit authorized user physicians the discretion to permit care givers to receive doses in excess of the 0.1 rem (1 mSv) public dose limit in the course of providing physical and emotional support to radiation diagnostic and therapy patients.

Rulemaking Options

1. Deny the Petition. The petition could be denied on the basis that there are sufficient provisions within § 20.1301(c) to allow case-by-case use of the 0.5 rem (5 mSv) annual dose limit for "specified visitors" of radiation therapy patients. In fact, the NRC recently granted an amendment request to the University of Cincinnati to apply the 0.5 rem (5 mSv) dose limit to care givers of radiation patients as specified by the authorized user physician.

The advantage of option 1 is that it does not require government resources for rulemaking.

The disadvantage of this option is that access to radiation patients by care givers would be constrained by the 0.1 rem (1 mSv) dose limit of § 20.1301 unless prior authorization were requested by the licensee and granted by the NRC. The process to obtain authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv) can be time consuming and impose a financial burden on the licensee.

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[1] Care giver is any person who spends a substantial amount of time in the company of the patient on a regular basis providing physical or emotional support and comfort.

2. Grant the Petition as Requested. Amend § 20.1301 to allow authorized user physicians the discretion to permit consenting adult, nonpregnant care givers to receive up to 0.5 rem (5 mSv) annually from exposure to radiation patients and to direct the authorized user to provide instructions to care givers to minimize their doses while visiting the patient (e.g., ALARA guidance). In addition, licensees would be required to badge those care givers whose total effective dose equivalent would exceed 0.1 rem (1 mSv).

The advantage of option 2 is that it would relieve the licensee of the administrative burden and expense of requesting, on a case-by-case basis, NRC authorization to exceed the 0.1 rem (1 mSv) dose limit to permit closer contact between care giver and patient. Records of individual exposures and documentation of instructions to minimize radiation exposure would enable the NRC to verify that licensees are complying with the new provision. The patient would benefit from the less restrictive visits and additional physical and emotional support provided by care givers.

The are disadvantages with option 2. First, owing to the fact that no application for a license amendment need be made, a greater number of family members and care givers may be permitted to be in close proximity to radiation diagnostic and therapy patients. Consequently, these care givers would be subject to increased radiation exposure and an increased, albeit small, health risk. Second, the licensee would be burdened by the requirements to badge those care givers who might exceed the 0.1 rem (1 mSv) dose limit, maintain exposure records for each badged care giver, and document that ALARA guidance was provided. Third, the NRC also would be burdened with the requirement to inspect licensee records documenting care giver badging, exposure, and ALARA instruction.

3. Grant the Petition Without Exposure Monitoring. The total effective dose equivalent anticipated for virtually all care givers of radiation patients will be less than 0.5 rem (5 mSv), especially if the care givers follow the ALARA guidance. Consequently, it does not appear that the petitioner's suggested measures, beyond basic ALARA instruction, warrant the administrative burdens associated with badging care givers. Licensees already demonstrate compliance with the public dose limit by maintaining records of dose rates in unrestricted areas; they are required to post a "Radioactive Materials" sign on the patient's door and note, either on the door or in the patient's chart, where and how long care givers may stay in the patient's room.

Option 3 recommends amending § 20.1301 to allow authorized user physicians the discretion to permit consenting adult care givers to receive up to 0.5 rem (5 mSv) annually from exposure to radiation diagnostic and therapy patients. However, there would be no requirement to monitor such individuals, nor any requirement to record or report the total effective dose equivalent for each care giver. In addition to amending § 20.1301, §§ 35.315 and 35.415 would be amended to require licensees to obtain and document voluntary informed consent from care givers who may receive a total effective dose equivalent of up to 0.5 rem (5 mSv). Licensees would be required to document that the care giver received ALARA instruction. Section 20.1003 would be amended to include a definition of care giver.

The advantages and disadvantages of this option are similar to those described for option 2 except that licensees would not be burdened with monitoring and recording individual external exposures or with associated reporting requirements. The responsibility for not exceeding the

0.5 rem (5 mSv) exposure limit would rest with the licensee even though the licensee is reliant upon the care giver to adhere to ALARA guidance and time-distance restrictions, if any. Although badging and area surveys could be used to document that the 0.5 rem (5 mSv) limit was not exceeded, it is unlikely that badging itself would prevent an overexposure, and therefore badging would not be required.

4. Use a Modified Approach to Granting the Petition. Amend § 20.1301 to allow the medical licensee to permit an adult member of the public to decide for themselves, if they consent, to possibly receive up to 0.5 rem (5 mSv) while visiting a radiation patient. Amend §§ 35.315 (a)(2) and 35.415 (a)(2) to require the licensee to post on the door of the patient's room a "Radioactive Materials" sign that contains the following information: (1) where and how long an adult visitor may stay in the patient's room, (2) where and how long visitors under the age of 18 may stay in the patient's room, and (3) a list of guidelines visitors should follow to keep exposures ALARA. Licensees would have the option to not specify the location of the visitor within the room but to adjust the stay-time calculation accordingly. No dosimetry badging of visitors would be required under this option.

The principle advantage of option 4 is that this alternative would alleviate the authorized user physician of the burden of determining which members of the public constitute adult patient care givers, because responsibility for determining who can visit a radiation patient would be left entirely to the visitor. Entering the patient's room after reading the "Radioactive Materials" sign would constitute informed consent, receipt of ALARA guidance, and acceptance of time-distance restrictions. This would relieve the licensee of the burden of documenting consent to potentially receive a radiation exposure that exceeds the 0.1 rem (1 mSv) public dose limit and providing ALARA instruction and exposure restrictions to each visitor. This option also would reduce the number of inspection requirements and eliminate the need for licensees to collect information from visitors to radiation patients. Although badging would be useful to document that the 0.5 rem (5 mSv) limit was not exceeded, it is unlikely that badging itself would prevent an overexposure, and therefore would not be required.

The disadvantage of option 4 is that there would be no way to either ensure or document that the care giver read or understood the potential consequences of being in close proximity to the patient, or understood the ALARA instruction. Hence, there is a possibility that individuals could "involuntarily" receive doses in excess of 0.1 rem (1 mSv).

Preferred Option

Option 3 is the preferred option. Option 3 is consistent with ICRP, IAEA, and NCRP guidance in that it would allow voluntarily exceeding the public dose limits to assist in medical care. The licensee would be required to provide sufficient instruction to care givers to permit willing and informed consent to the exposure as well as to provide ALARA guidance. In addition, the licensee would be required to document that the care giver provided informed consent about potentially receiving an exposure greater than 0.1 rem (1 mSv) and receipt of ALARA instruction. However, individual monitoring of external radiation exposure by the licensee would not be required.

By increasing the individual dose limit for care givers to 0.5 rem (5 mSv), options 2, 3, and 4 theoretically may result in an increased risk of cancer, but this increase would be negligible.

The number of care givers who may exceed the 0.1 rem (1 mSv) limit would certainly be very small and the emotional support provided to the radiation patient may be significant. There is a small cost to NRC and the Agreement States associated with proceeding with rulemaking that could be construed as being offset by the benefit to the patient. Further, licensees would have the option to refuse to allow care givers to receive the additional dose.

Option 1 is unacceptable because it does not allow physicians to fully employ their medical judgment in the treatment of their patients. Option 1 unnecessarily restricts care giver access to radiation patients unless the licensee requests a license amendment to exceed the current 0.1 rem (1 mSv) public dose limit. Exercising this option requires time to obtain NRC approval and places a financial burden on the license just to request the license amendment. The time required to obtain authorization to exceed the public dose limit occurs when both the patient and care givers are likely to receive the greatest benefit from such access.

Option 2 is an acceptable option. It permits closer contact between care givers and patients if the individual and the treating physician agree that the potential increase in risk is justifiable. However, it imposes an additional burden of badging, ALARA instruction, and record keeping on the licensee and imposes an increased inspection burden on the NRC.

Finally, option 4 is not preferred because it lacks any means to ensure or document that care givers are truly giving informed consent to receiving doses in excess of the 0.1 rem (1 mSv) dose limit. Further, because this option, unlike options 2 and 3, would remove the licensee's active control to permit access by members of the public to radiation, it is inconsistent with current practice that reflects the NRC's position that the fundamental dose limit for individual members of the public is 0.1 rem (1 mSv), and that higher doses, while appropriate in some circumstances, are not to be permitted routinely.

Office of General Counsel Legal Analysis

The proposed rulemaking revisions would address the problem identified by the petition for rulemaking. These revisions are consistent with ICRP, IAEA, and NCRP guidance. OGC has not identified any basis for a legal objection to the rulemaking. The rule does not affect reactors, therefore the rule does not constitute a backfit under 10 CFR 50.109. An environmental assessment must be prepared for this rule in compliance with 10 CFR 51.21. There are new information collection requirements in this proposed rule, therefore, to comply with the Paperwork Reduction Act of 1980, an analysis must be prepared and the information collection requirements must be submitted to the Office of Management and Budget for approval. The final rule must be evaluated for compliance with the Small Business Regulatory Enforcement Fairness Act of 1996.

Since the proposed rulemaking plan would address resolution of PRM-20-24, the staff will need to assure that the appropriate procedural actions are taken to close the actions associated with that petition. These actions include specifically granting or denying the petition for rulemaking, either in the Federal Register notice associated with the rulemaking or in a separate Federal Register notice, and informing the petitioner of the NRC's decision. The detailed procedures for responding to the rulemaking petition are contained in Part 11 of the Regulations Handbook (NUREG/BR-0053, Rev.3).

Backfit Analysis

This amendment does not affect nuclear reactors, and backfit analysis is not required.

Agreement State Implementation Issues

This amendment would be proposed as a Division 2 matter of compatibility. As such, Agreement States would need to promulgate similar regulations that are at least as stringent as NRC's rule. Agreement States would not necessarily have to adopt the 0.5 rem (5 mSv) annual dose limit in their regulations. Therefore, Agreement States would not necessarily have to make any changes to their regulations.

Major Rule

This rulemaking does not constitute a major rule.

Supporting Documents Needed

A Regulatory Impact Analysis, Environmental Assessment, and an Office of Management and Budget clearance package will need to be developed in support of this rulemaking.

Issuance by Executive Director for Operations or Commission

This rulemaking would not fall within the authority delegated to the EDO to issue this rule in accordance with paragraph 0213 of Management Directive 9.17. It, therefore, will be forwarded to the Commission for approval.

Resources Needed to Complete Rulemaking

The estimated resources to complete this rulemaking would be about 0.5 staff years. Approximately 60 percent of this effort would come from RES and about 40 percent divided among NMSS, OSP, OE, and OGC.

In addition, contractor support funding of $50,000 would be used to assist in developing the Regulatory Impact Analysis. These resources are included in the current budget. No additional resources are anticipated to implement the rule.

Staff Level Working Group

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Concurring Official

David Morrison
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Management Steering Group

No steering group will be used on this rulemaking. The technical contacts are identified above.

Public Participation

Enhanced public participation is not needed for this rulemaking as affected individuals would be permitted to participate in the decision to increase their own exposure. Licensees will not be required to offer this flexibility, and therefore will have adequate opportunity to provide training, dosimetry, and keep records. The petition for rulemaking was published in the Federal Register. Four comments were received, and all were in support of granting the petition. A proposed rule will be published in the Federal Register and all public comments will be considered. The final rulemaking plan and the rulemaking documents will be placed on both the NRC electronic rulemaking bulletin board and the interactive Rulemaking Web Site.

Supporting documents will be available to the public through the Public Document Room, local Public Document Rooms, FedWorld, the NRC Rulemaking Web site, and through direct contact with the RES lead for this rulemaking. These mechanisms permit adequate public involvement in the resolution of the issues.

Schedule

Proposed rule to EDO	3 months after EDO approval of Rulemaking Plan
OMB Clearance	2 months after Commission approval of proposed rule
Final Rule to the EDO	6 months after proposed rule published for comment