August 1, 1997 SECY-97-177

TO: The Commissioners

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

SUBJECT: FINAL RULEMAKING PLAN: REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS (10 CFR PART 20 AND 35)

PURPOSE:

To inform the Commission of the staff's rulemaking plan for amending 10 CFR 20.1301, "Dose limits for individual members of the public," to authorize specified family members of hospitalized radiation patients, as individual members of the public, to receive up to 0.5 rem (5 mSv) per year.

BACKGROUND:

In accordance with a staff requirements memorandum dated October 9, 1996, that directed the staff to proceed with rulemaking in response to a petition (PRM-20-24) submitted by the University of Cincinnati, the staff drafted a rulemaking plan and submitted a copy of the plan to the Commission in SECY-97-091. The petitioner requested that the NRC amend its regulations to authorize "specified visitors" of radiation therapy patients (hospitalized under 10 CFR 35.75 or receiving a temporary implant under 10 CFR 35.400) to receive up to 500 mrem (5 mSv) per year, and that these individuals be provided with personal monitors to document compliance with the limit.

Under the draft plan, the staff would develop a proposed rule to amend 10 CFR Part 20 and 35 to allow an authorized user physician the discretion to permit consenting adult family members 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 family members on how to minimize their doses while visiting the patient. Furthermore, licensees would be required to obtain and document the voluntary informed consent from the family member and document that the

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family member received instruction in how to keep radiation exposure as low as is reasonably achievable (ALARA). The staff's recommended option did not include a dose monitoring requirement as proposed by the petitioner.

A copy of the draft rulemaking plan was provided to the Agreement States on May 1, 1997 for a 45-day period of review and comment. The comment period closed on June 13, 1997. Seven comment letters were received from the Agreement States.

AGREEMENT STATE COMMENTS ON DRAFT RULEMAKING PLAN:

Five States —Arkansas, Colorado, Florida, Illinois, Maine— supported the staff's recommendation to grant the petitioner's request, but without a requirement that licensees monitor radiation exposure of family members. Two States —Iowa, Washington— agreed with the granting the petition as requested by the petitioner which would require licensees to monitor each visitor's radiation exposure. These States proposed that direct reading dosimetry be used to allow "more direct control of dose" and provide a way for the visitor to monitor their exposure.

In the draft rulemaking plan, the term "care giver" was used to describe family members and specified visitors. Three States—Iowa, Colorado, Florida—expressed concern that the definition for "care giver" was too broad and could be misinterpreted to include professional health care givers (e.g., nurses) and other hospital support staff (e.g., clergy and house keeping staff). Two States —Iowa, Illinois— suggested that the diagnostic use of radioactive material should not be considered in this rulemaking because these procedures require very little patient/visitor control, and posting a radioactive materials sign on the patients' door is not required.

One state —Colorado— expressed concern that the staff's preferred option does not specifically address pregnancy and that special consideration should be given to women who could be pregnant so that an ample margin of safety is afforded the fetus.

One State —Illinois— recommended a more prescriptive revision of Part 35. Illinois proposed revising §§ 35.310, 35.315, 35.410, and 35.415 to include: (1) authorized user guidelines to determine the suitability of visitation of certain patients, (2) guidance regarding who will provide the ALARA instruction and how cumulative exposure will be tracked, and (3) methods to control the spread of radioactive material contamination (to include the potential dislodgment and loss of brachytherapy sources) inside and out of the patient's room.

STAFF RESPONSE:

While the staff agrees that there is merit in providing dosimetry to family members to monitor radiation exposure, the rulemaking plan was not amended to include such a requirement. The reason for not adding this requirement is that the potential benefit from requiring monitoring does not seem justified when compared to the burden associated with imposing such a requirement on licensees.

Staff usage of the phrase "care giver" in the draft rulemaking plan was misconstrued by half the commenters. The phrase (care giver) was not intended to be applied to occupational workers or other workers who, in the performance of their job related duties, might receive an exposure

from a radiation patient. Rather, the intent of the definition was to broadly describe family members. To avoid confusion, the phrase care giver has been replaced with the phrase "family member" in the final rulemaking plan. The staff will define the term family member as described in NCRP Commentary No. 11, "Dose Limits for Individuals who Receive Exposure from Radionuclide Therapy Patients." It states that a family member is any person who "spends a substantial amount of time in the company of the patient on a regular basis, providing support and comfort, and who the patient considers a member of their "family," whether by birth, by marriage, or by virtue of a close, caring relationship." This definition includes both blood relatives of the patient and those who might be described as "significant others."

The staff agrees that the instructions provided to family members on maintaining radiation exposure ALARA should include information to inform pregnant family members of the implication of radiation exposure of the fetus. The staff also recognizes that a specific restriction on a pregnant family member could be difficult to implement and enforce.

In general, the staff agrees with the comments from Iowa and Illinois that most patients receiving radioactive by-product material for diagnostic purposes should not be included in this rulemaking plan. For most of the diagnostic procedures described in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," the dose calculations suggest that these procedures do not have the potential to deliver a 0.1 rem (1 mSv) dose to an individual exposed to the patient. However, with certain diagnostic procedures using iodine-131 to detect thyroid cancer, the maximum likely dose to exposed individuals could reach 0.15 rem (1.5 mSv). In addition, there may be other diagnostic procedures developed in the future where the doses to family members could exceed the public dose limit. Even though most diagnostic procedures will not exceed the current public dose limit of 0.1 rem (1 mSv), the staff does not believe that excluding these procedures (or diagnostic procedures to be developed) from the rulemaking plan is warranted.

The staff agrees with comments offered by the State of Illinois that instructions to family members need to clearly describe the risks associated with radiation exposure and precautions that need to be followed. This will be addressed in revisions to sections 35.315 and 35.415.

This amendment would be proposed as a Division 3 matter of compatibility[1]. As such, Agreement States have the option to develop a similar rule if they wish.

[1] Under the new policy on compatibility of regulations, Division 3 compatibility regulations have been designated Category C regulations, but the specific requirement for compatibility remains unchanged.

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.

RECOMMENDATION:

Unless the Commission directs otherwise within 10 days from the date of this paper, I will implement the rulemaking plan and direct the staff to begin development of a proposed rule to revise the public dose limit for family members of hospitalized radiation patients.

L. Joseph Callan
Executive Director
for Operations

Enclosure: Final Rulemaking Plan

RULEMAKING PLAN FOR

REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS (10 CFR PART 20 AND 35)

Lead Office: Office of Nuclear Regulatory Research

Staff Contact: E. Vincent Holahan, RPHEB (415-6272)

Concurrences:

SIGNED 3/14/97
D. Morrison, RES Date

(memo from Carl Paperiello 4/1/97
C. Paperiello Date

SIGNED 3/14/97
W. J. Olmstead, OGC Date

(memo from Brenda Jo Shelton 3/18/97
A. Galante, CIO Date

(memo from Carl Abbott) 3/21/97
Jesse L. Funches, CFO Date

(memo from Paul Lohaus) 3/27/97
R. L. Bangart, OSP Date

(memo from James Lieberman)

3/25/97

J. Lieberman, OE Date

Approval:

L. Joseph, EDO Date

Final Rulemaking Plan
10 CFR Parts 20, 35

REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS (PRM 20-24)

Regulatory Issue

The NRC received a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. The petitioner requested 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 0.5 rem (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 family members 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 family members 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 family.

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 family members 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 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 visitors of radiation 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 visitors 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 family members 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. It would also require expenditure of NRC resources to review each request.

2. Grant the Petition as Requested. Amend § 20.1301 to allow authorized user physicians the discretion to permit consenting adult, nonpregnant visitors to receive up to 0.5 rem (5 mSv) annually from exposure to radiation therapy patients and to direct the authorized user to provide instructions to the visitors to minimize their doses while visiting the patient, e.g., guidance on keeping visitor doses as low as is reasonably achievable (ALARA). In addition, licensees would

be required to badge those visitors 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. 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 radiation therapy patient would benefit from the less restrictive visits and additional physical and emotional support provided by the visitor.

There are disadvantages with option 2. First, owing to the fact that no application for a license amendment need be made, a greater number of visitors may be permitted to be in close proximity to radiation therapy patients. Consequently, these visitors would be subject to increased radiation exposure and an increased, albeit small, health risk. Second, the licensee would be burdened with implementing and enforcing a provision whereby the authorized user physician would need to determine the pregnancy status of each visitor. Third, the licensee would be burdened by the requirements to badge those visitors who might exceed the 0.1 rem (1 mSv) dose limit, maintain exposure records for each badged visitor, and document that ALARA guidance was provided. Finally, the NRC also would be burdened with the requirement to inspect licensee records documenting visitor badging, exposure, and ALARA instruction.

3. Grant the Petition with modification. Amend § 20.1301 to allow authorized user physicians the discretion to permit consenting adult family members to receive up to 0.5 rem (5 mSv) annually from exposure to radiation patients or human research subjects. Amend §§ 35.315 and 35.415 to require licensees to obtain and document voluntary informed consent from family members who may receive a total effective dose equivalent greater than 0.1 rem (1 mSv). Licensees would be required to provide instructions (e.g., ALARA guidance) to these visitors to minimize their dose while visiting the patient or human research subject and to document that each visitor received the instruction. Section 20.1003 would be amended to include a definition of family member.

This option differs from the petition on four points. First, the licensee would not be required to issue radiation monitoring devices to visitors nor record (or report) the total effective dose equivalent for each visitor. The total effective dose equivalent anticipated for virtually all visitors of radiation patients or human research subjects will be significantly less than 0.5 rem (5 mSv), especially if the visitor follows the ALARA guidance provided by the licensee. Consequently, it does not appear that the petitioner's suggested measures, beyond basic ALARA instruction, warrant the administrative burdens associated with badging visitors. Second, visitor access would be limited to adult family members. Family member is defined as any person who spends a substantial amount of time in the company of the patient or human research subject on a regular basis, providing support and comfort, and who the patient or human research subject considers a member of their "family," whether by birth, by marriage, or by virtue of a close, caring relationship. Third, this option would not be restricted to family members of radiation therapy patients hospitalized under 10 CFR 35.75 or patients receiving temporary brachytherapy implants under 10 CFR 35.400. Rather, the authorized user physician retains the discretion to permit a consenting adult family member to visit human research subjects or

patients to whom radioactive byproduct materials have been administered for either diagnostic or therapeutic purposes. Finally, at the discretion of the authorized user physician, consenting pregnant family members would be permitted to receive up to 0.5 rem (5 mSv) annually from exposure to radiation patients or human research subjects.

The advantages 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. 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 visitors may stay in the patient's room. Responsibility for not exceeding the 0.5 rem (5 mSv) exposure limit ultimately rests with the licensee even though the licensee is reliant upon the visitor 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. Another advantage of option 3 is that the licensee is not required to ascertain the pregnancy status of a visitor, a provision that could be difficult to implement and enforce.

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, non-pregnant family members, 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 visitor 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).

Agreement State Comments on Draft Rulemaking Plan

Comments were received from seven States (Arkansas, Colorado, Florida, Illinois, Iowa, Maine, and Washington). Five States (Arkansas, Colorado, Florida, Illinois, and Maine) support the staff's recommendation to grant the petition as requested by the petitioner, but without a requirement that licensees monitor radiation exposure of family members. Two States (Iowa, Washington) agreed with granting the petition as suggested by the petitioner thus requiring the licensee to monitor each visitor (preferably using a direct reading dosimeter only) to allow more direct control of radiation exposure and provide a way for the visitor to monitor their exposure.

In the draft rulemaking plan, family members and specified visitors were described as "care givers." Three States (Iowa, Colorado, Florida) expressed concern that the definition for care giver was too broad and these states interpreted the definition to include professional health care givers (e.g., nurses) and other hospital support staff (e.g., clergy and house keeping staff). One State (Florida) stated that there are too may definitions already. In the draft rulemaking plan, reference was made to both radiation diagnostic and therapy patients. Two States (Iowa, Illinois) suggested that the diagnostic use of radioactive material should not be considered in this rulemaking because these procedures require very little patient/visitor control, and posting a radioactive materials sign on the patients' door is not required.

One state (Colorado) expressed concern that the staff's preferred option does not specifically address pregnancy and that special consideration should be given to women who could be pregnant so that an ample margin of safety is afforded the fetus.

One State (Illinois) recommended a more prescriptive revision of Part 35. Illinois proposed revising §§ 35.310, 35.315, 35.410, and 35.415 to include authorized user guidelines to determine the suitability of visitation of certain patients; guidance regarding who will provide the ALARA instruction, how cumulative exposure will be tracked, when radiation surveys should be performed on the patient's room, and when materials removed from the patient's room should be surveyed; and methods to control the spread of radioactive material contamination (to include the potential dislodgment and loss of brachytherapy sources) in and out of the patient's room.

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 the medical care of family members. The licensee would be required to provide sufficient instruction to family members to permit willing and informed consent to the exposure as well as to provide guidance in keeping doses ALARA. In addition, the licensee would be required to document that the visitor 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 visitors 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 visitors who may exceed the 0.1 rem (1 mSv) limit would certainly be very small and the emotional support provided to the radiation patient or human research subject 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 or human research subject. Further, licensees would have the option to refuse to allow visitors 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 family member 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 family members are likely to receive the greatest benefit from such access.

Option 2 is an acceptable option. It permits closer contact between family members 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 family members 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 a backfit analysis is not required.

Agreement State Implementation Issues

This amendment would be proposed as a Division 3 matter of compatibility. As such, Agreement States have the option to develop a similar rule if they wish. An Agreement State may decide that licensees should issue radiation dose monitoring devices (e.g., ionization chambers or TLDs) to each visitor. Similarly, 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
Concurring Official

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Catherine Haney
Kathryn Winsberg
Lance Rakovan
Herbert Parcover

Ashok Thadani
Carl Paperiello
Stuart Treby
Richard Bangart
James Lieberman

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