NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket No. PRM-20-24]

University of Cincinnati

DOCKET NUMBER
PETITION RULE PRM 20-24
(61FR31874)

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is docketing, as a petition for rulemaking, a document dated April 7, 1996, and filed with the Commission by the University of Cincinnati. The petition was assigned Docket No. PRM-20-24 on April 15, 1996. The petitioner requests that the Commission amend its regulations to authorize specified visitors of radiation patients, as members of the public, to receive up to 500 mrem per year. In this document, the NRC is announcing the receipt of the petition and requesting public comment on the suggested amendment.

DATES: Submit comments by ~~(75 days after publication in the Federal Register)~~ September 4, 1996.

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

Pub. 6/21/96

ADDRESSES: Submit comments to the Nuclear Regulatory Commission. Attention: Docketing and Service Branch. Office of the Secretary. Washington. DC 20555-001. For a copy of the petition. write to the Rules Review Section. Rules Review and Directives Branch. Division of Freedom of Information and Publications Services. Office of Administration. U.S. Nuclear Regulatory Commission. Washington. DC 20555.

Deliver comments to 11555 Rockville Pike. Rockville. Maryland. between 7:30 a.m. and 4:15 p.m. on Federal workdays.

For information on submitting comments electronically. see "Electronic Access" under the Supplementary Information section of this notice.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar. Chief. Rules Review Section. at the same address as above or by telephone. 301-415-7163. or toll free. 1-800-368-5642. or E-mail. MTL@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Background

In §20.1301(a)(1). each licensee is required to conduct operations so that the total effective radiation dose limit for members of the public does not exceed 0.1 rem (1 millisievert) in a year. The dose equivalent must be exclusive of the dose contributions from background radiation. any medical administration the individual has received. voluntary participation in medical research programs. and the licensee's disposal of radioactive material into

sanitary sewerage in accordance with §20.2003. The current regulations state in §20.1301(c) that a licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv).

Petitioner's Request

The petitioner states that, as recommended in a report from the National Committee on Radiation Protection (NCRP 91), the proposed amendment would permit a small population of the general public to be infrequently exposed to an annual exposure limit of 500 mrem total effective dose equivalent. The petitioner presents the following specific recommendations concerning the requested amendment:

1. The individuals to whom the 500 mrem annual limit applies would be specified visitors of radiation therapy patients hospitalized under 10 CFR 35.75 or specified visitors of radiation therapy patients receiving temporary brachytherapy implants under 10 CFR 35.400.
2. The dose limit is not requested for all visitors of all radiation therapy patients hospitalized under 10 CFR 35.75 or receiving a temporary implant under 10 CFR 35.400. The dose limit would apply only to specified visitors determined by the physician to be necessary for the emotional and/or physical support of the patient (e.g., parents of children, elderly patients who need support from a familiar individual, etc.).
3. The specified visitors would be limited to adult (18 or older) non-

pregnant individuals who are members of the family or are individuals with a significant personal relationship to the patient.

4. The specified visitors would be instructed by the licensee or authorized user to maintain their exposure as low as reasonable achievable (ALARA). The instruction would emphasize the radiation safety precautions of time, distance and shielding.
5. The dose limit would apply only to dose received while the patient is hospitalized under 10 CFR 35.75 and/or receiving a temporary brachytherapy implant under 10 CFR 35.400. A personnel monitor (pocket dosimeter, film badge, TLD or electronic dosimeter) would document compliance.

The Petitioner's Proposed Amendment

The petitioner proposes that § 20.1301 be amended to permit specified visitors of radiation patients to be exposed to an exposure limit of 500 mrem total effective dose per year.

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on this petition also are available for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll-free number 800-

303-9672. Set communication software parameters as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using the ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "rules menu" option from the "NRC main menu." Users will find the "FedWorld On-line User's Guides" particularly helpful. Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS, (703)321-3339, or by using Telnet via Internet: fedworld.gov. If using (703)321-3339 to contact FedWorld, the NRC subsystem will be accessed from the FedWorld main menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC on-line main menu. The NRC on-line area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If NRC is accessed from FedWorld's main menu, the user may return to FedWorld by selecting the "Return to FedWorld" option from the NRC on-line main menu. However, if NRC at FedWorld is accessed by using NRC's toll-free number, the user will have full access to all NRC systems but not to the main FedWorld system.

If FedWorld is contacted using Telnet, the user will see the NRC area and menus, including the rules menu. Although the user will be able to download documents and leave messages, he or she will not be able to write comments or upload files (comments). If FedWorld is contacted using File Transfer Program (FTP), all files can be accessed and downloaded but uploading files is not allowed--the user will see only a list of files without

descriptions (normal gopher look). An index file is available that lists all files within a subdirectory, with descriptions of those files. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the Worldwide Web, like FTP, that mode only provides access for downloading files and does not display the NRC rules menu.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555-0001, telephone (301)415-5780; E-mail AXD3@nrc.gov.

Single copies of this petition may be obtained by written request or telefax ((301)415-5144) from the Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, Mail Stop T6-D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Certain documents related to this petition, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this petition as indicated above.

Dated at Rockville, Maryland, the 17th day of June, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 13, 1996

MEMORANDUM TO: Cynthia Pederson, Director
Division of Nuclear Materials Safety, RIII

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: ADDENDUM TO RESPONSE ON UNIVERSITY OF CINCINNATI TECHNICAL ASSISTANCE REQUEST

This is an addendum to Catherine Haney's March 19, 1996, memorandum to John Madera, subject: "Request by University of Cincinnati for Exemption from the Public Dose Limit in 10 CFR 20.1301(2)(c) [sic]." Additional alternatives available to the licensee are discussed.

In our March reply, we answered the direct question raised in the licensee's request and the Region III Technical Assistance Request (TAR). In answering the TAR, we discussed the issue with the Office of the General Counsel, and determined that the request, as written, for authorization under 20.1301(c)(2) to operate up to a limit of 500 millirem must be denied. Our stated basis for the denial was that the licensee "has not demonstrated a compelling reason to provide an indefinite exemption from the public dose limits." We noted that the conditions at the University of Cincinnati's facility do not appear to differ in any significant manner from those at other similar institutions engaged in brachytherapy or radiopharmaceutical therapy. We also discussed the significance that the licensee's request was indefinite, not temporary.

The March response should be taken only as the answer to the University of Cincinnati's January 5, 1996, request. The licensee has other alternatives to obtain higher dose limits for visitors. The licensee can at any time (including now) make case-by-case patient specific requests for exemption or apply under 10 CFR 20.2301 for an exemption from the regulations.

Patient specific requests can be made telephonically by the licensee, and can be approved or disapproved by NRC within hours, usually, by telephone or FAX. NRC's response documentation can follow a verbal NRC authorization. These types of requests are intended to be used in rare cases where immediate, authorization is needed and as such would meet the criteria for "temporary." This mechanism would be appropriate in those cases involving visitors to radiation therapy patients who may exceed the 100 millirem per year public dose limit, such as those described by the licensee (parents of children, family members to provide support for elderly patients, and so on). It is reasonable and appropriate

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415-7875

that family or other support persons of children, the elderly, the handicapped, and other persons undergoing radiation therapy treatments be permitted to exceed the 100 millirem per year annual dose limit in rare cases, when the licensee has already taken reasonable measures to keep doses ALARA. [Note that the family relationship between the visitor and the patient is immaterial in deciding whether to grant the exemption.] This is the most timely mechanism to receive temporary exemptions from the regulations, and it can be approved or disapproved rapidly.

Also, the licensee can submit a request for exemption under 10 CFR 20.2301, "Applications for exemptions." Consideration of an exemption under this provision in the regulations is not a short process, and may actually involve a Commission-level decision on the request for exemption. The licensee should be cautioned that, if it chooses this mechanism, it may take months before a final answer to their request is received. One factor affecting this issue is the generic nature of the exemption the licensee is requesting. It is the first request received by the Division to apply higher dose limits to certain groups of visitors of radiation therapy patients. Any decision on this issue would set a precedent for similar future requests by other licensees performing radiation therapy. Region III may want to note to the licensee that exemptions from the regulations, such as those filed under 20.2301, are extremely unusual. This division knows of no other cases where an exemption request under 20.2301 has been submitted.

The licensee has submitted a petition for rulemaking, dated April 7, 1996, and announced in the Federal Register on June 21, 1996 (61 FR 31874). The petition requests that the Commission amend its regulations to authorize specified visitors of radiation patients, as members of the public, to receive up to 500 millirem per year. NRC will proceed with action on the petition, but the licensee should understand that the rulemaking process can be lengthy. Once initiated, rulemaking usually takes more than a year, if the petition is deemed to have merit.

While the University of Cincinnati's original request, as written, must be denied, the licensee should not take the denial as a message that NRC will prohibit parents of children or family of elderly patients undergoing radiation therapy treatments to stay with the patient to provide emotional and physical support. On the contrary, NRC is interested in working with the licensee to authorize conditions leading to the best possible situation for the patient and the visitors, while protecting public health and safety.

Under limited conditions and in temporary situations, as permitted by the regulations, licensees can be authorized to exceed the public dose limit of 100 millirem per year. The University of Cincinnati's original request, as written, was neither limited nor temporary.

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