

Victoria Morris, M.S., CHP
Radiation Safety Officer
University of Cincinnati
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Cincinnati, Ohio 45267-0591

Dear Ms. Morris:

I am responding to the petition for rulemaking (PRM 20-24), dated April 7, 1996, that you submitted to the U.S. Nuclear Regulatory Commission (NRC). The petition requests that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public," to allow specified visitors of radiation patients, as members of the public, to receive up to 5 milliSievert (mSv) (0.5 rem) per year.

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt of the PRM and requested comments by November 30, 1998. Because the petition pertained to the medical use of byproduct material, a decision was made to address the final resolution of the PRM as part of the major rulemaking action to revise 10 CFR Part 35, "Medical Use of Byproduct Material."

For the reasons specified in the enclosed Federal Register notice, we believe there is merit in granting your petition, in part. In our view, your petition was overly restrictive and we did not agree with your limitations to only allow non-pregnant adult (age 18 or older) visitors, to require documentation of radiation exposures from the patient to visitors, and to require licensees to instruct visitors.

In summary, you requested that the NRC:

- (1) provide medical use licensees with the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv (0.5 rem) (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);
- (2) exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem);
- (3) document compliance by issuing a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor; and
- (4) require licensees to instruct visitors about radiation safety.

We agree with the first request, but disagree with the second, third, and fourth requests for the reasons set forth below. Although we agree in principle with your second, third, and fourth

requests, we believe NRC regulations should be less prescriptive and more performance-based on these points.

We amended 10 CFR 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from individuals who are not to be released pursuant to 10 CFR 35.75 (e.g., hospitalized radiation patients containing unsealed byproduct material, or permanent or temporary implants of byproduct material). We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor.

In addition, we believe that the authorized user (AU) would be the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor (regardless of age) to potentially receive this additional dose, and would do so only when it is warranted. AUs have the primary responsibility for the health and safety of their patients and for determining, depending on the patient's condition, whether individuals can visit patients and if any limitations are appropriate. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

We did not grant the request in the petition (2) that NRC prohibit pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released pursuant to 10 CFR 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold.

First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 ("Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995"), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during treatment, and these visitors are likely to be willing to bear greater risk to provide that benefit.

Second, a prospective visitor's declaration of pregnancy is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

We also did not grant request (3) of the petition (that compliance be demonstrated by issuing a radiation dose monitoring device such as a pocket dosimeter, film badge, TLD, or electronic dosimeter to each specified visitor). The revised rule does not specifically require monitoring and recording of individual doses to visitors of hospitalized radiation patients however, licensees will need to ensure that doses to approved visitors are less than 5 mSv (0.5 rem).

We did not grant request (4) because safety instructions are addressed in 10 CFR 35.310 and 35.410. These sections require medical use licensees to instruct their personnel who care for patients that cannot be released in accordance with 10 CFR 35.75. One of the safety instruction topics listed in these sections is visitor control to the dose limits in 10 CFR 20.1301. As the licensee's personnel work to this performance-based objective they will instruct the specified visitors about the radiation safety precautions that you stated in your petition.

V. Morris

3

In addition, the safety precautions in 10 CFR 35.315 and 35.415 require the licensee to note on the door or in the patient's chart the location and stay time for visitors. These sections reinforce the ability of the licensee's personnel to instruct the specified visitors about time, distance, and shielding factors that will effectively limit radiation exposure from the patient to levels that are as low as are reasonably achievable.

Sincerely,

William D. Travers
Executive Director
for Operations

Enclosure: Federal Register notice for Part 35 and Part 20 rulemaking

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Sincerely,

William D. Travers
 Executive Director
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