[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-10A]

American College of Nuclear Medicine;

Receipt of an Amended Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Amended petition for rulemaking: Notice of receipt.

SUMMARY: The Commission is publishing for public comment a notice of receipt of an amended petition for rulemaking which was filed with the Commission by the American College of Nuclear Medicine. The amended petition was docketed by the Commission on April 21, 1992, and has been assigned Docket No. PRM-35-10A. The petitioner, in both the original petition and in this amendment to that petition, requests that the Commission amend its regulations regarding confinement, safety instructions, and precautions used for patients receiving radiopharmaceutical therapy in amounts greater than 30 millicuries. The petitioner requests that the original petition be expanded to consider the need to allow amounts greater than 30 millicuries to be used in diagnostic studies and to add a definition of confinement.

Fed 5/18/92

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7/17/92

DATE: Submit comments by (60 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write: Rules Review Section, Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-7758 or Toll Free: 800-368-5642.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION

Background

On January 14, 1992, the Nuclear Regulatory Commission (NRC) docketed a petition for rulemaking submitted by the American College of Nuclear Medicine (PRM-35-10). The notice of receipt of this petition was published on March 9, 1992 (57 FR 8282), and a document correcting a typographical error in a reference to codified text from §35.72(a)(2) to §35.75(a)(2) was published on March 24, 1992 (57 FR 10143). On April 21, 1992, the NRC docketed an amendment to this petition. The amended petition was also submitted by the American College of Nuclear Medicine. The amended petition was assigned docket number PRM-35-10A. The amended petition supplements the original petition by requesting that the NRC consider the need to allow the use of amounts greater than 30 millicuries in diagnostic studies and add a definition of the term confinement.

The petitioner requests amendments to 10 CFR Part 35 that would clarify the requirement for confinement for ambulatory patients receiving oral or intravenous radiopharmaceuticals in amounts greater than 30 millicuries and allow patients the option to be treated on an outpatient basis if they qualify medically.

The petitioner states that the requested amendment is in the best interest of patients who require access to affordable quality care and that scientific published data support the changes requested by the petition as consistent with protection of the public as stated in 10 CFR Part 35.

Petitioner's Request

The petitioner requests the NRC to revise 10 CFR Part 35 to-

(1) Delete the requirement in 10 CFR 35.75(a)(2) that licensees may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until the activity in the patient is less than 30 millicuries;

(2) Amend §35.75(a)(2) to allow for an outpatient option instead of mandating confinement for patients receiving oral or intravenous radiopharmaceuticals in amounts greater than 30 millicuries.

(3) Allow doses greater than 30 millicuries to be used in diagnostic studies, in addition to radioisotope therapy. The petitioner believes that these doses are desirable in that many of the new Technetium 99m labeled radiopharmaceuticals available today can be performed without risk to the health and safety of the public or occupational workers.

(4) Define "confinement" to mean remaining in a hospital or a private residence.

Reasons for Petition

Section 35.75 prohibits an NRC medical use licensee from releasing from confinement for medical care any patient administered a radiopharmaceutical until certain criteria are met. One of the criteria is that the activity in the patient is less than 30 millicuries. The petitioner believes that the regulation should be clarified to allow for temporary home

confinement. The petitioner claims that with the advent of monoclonal radiolabelled antibodies and other new radiopharmaceuticals for diagnosis and treatment, outpatient diagnosis and therapy would provide efficient care and allow costs to be minimized without increased risk to the public. The petitioner also states that published scientific papers attest to the safety of outpatient radiopharmaceutical therapy in doses of up to 400 millicuries of I-131 NaI.

Conclusion

The petitioner states that if this amended petition is granted, it would benefit patients by giving them affordable quality care while allowing them to be diagnosed and treated on an outpatient basis instead of being confined to a hospital. The petitioner claims that scientific studies support the finding that diagnosing and treating patients on an outpatient basis with radiopharmaceuticals in doses greater than 30 millicuries would not create a safety hazard to the public.

Dated at Rockville, Maryland, this 12th day of May, 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.