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DOCKET NUMBER
PETITION RULE PRM 35-9
(54FR 38239)

December 14, 1989

Samuel J. Chilk
Office of Secretary
c/o Docketing and Services Branch
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20555

Re: Docket No. PRM-35-9

Dear Mr. Chilk:

The American College of Nuclear Physicians and the Society of Nuclear Medicine (jointly referred to as Petitioners) recently petitioned the Nuclear Regulatory Commission (NRC) to revise certain regulations pertinent to the use of radiopharmaceuticals. See Petition for Rulemaking, 54 F.R. 38239 (1989). The American Medical Association supports Petitioners' proposed regulatory revisions, and submits these comments for consideration by the NRC in evaluating the petition.

As explained in the preamble to the proposed regulations, the NRC was historically the sole federal regulator of radioactive drugs. Approximately twenty years ago, however, the Food and Drug Administration (FDA) began regulating radiopharmaceuticals concurrently with the NRC. Since that time, the FDA's role in regulating radioactive drugs has evolved considerably and increased in scope, while state regulation has also continued. Not surprisingly, the evolution of this "concurrent but independent" regulatory authority has resulted in inconsistent requirements being imposed upon physicians represented by the Petitioners, other physicians, and their patients.

For example, the NRC's standards directly conflict with those of the FDA by recognizing only two of the several mechanisms used by the FDA to authorize the use of radiopharmaceuticals in the practice of nuclear medicine (Investigational New Drug Application and Approved New Drug Application). In addition, the NRC standards do not permit nuclear physicians and pharmacists to prepare radiopharmaceuticals that the FDA purposefully exempts from regulation.

The AMA agrees with Petitioners' assertion that the inconsistent NRC regulations interfere with Petitioners' ability to practice their respective professions. The NRC regulations hamper physicians' efforts to deliver optimal patient care by prohibiting the use of certain drugs and routes of administration. In addition, by restricting reconstitution of drugs to the manufacturer's recommended method, the NRC regulations prevent nuclear pharmacists and technologists from preparing radiopharmaceuticals in the manner a physician has determined will be most beneficial to his or her patient.

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In summary, Petitioners assert that the inconsistent and restrictive NRC standards are "causing serious problems in the optimal delivery of quality nuclear medical care and the implementation of nuclear medicine research" (54 F.R. 38241). FDA regulatory requirements for other approved drugs do not have this limiting effect, and the NRC should recognize this essential flexibility in its regulation of radiopharmaceuticals.

The inconsistent regulations imposed upon Petitioners prevent them from delivering efficient and effective patient care. Therefore, the AMA supports Petitioners' effort to obtain a consistent regulatory framework. In addition, the AMA encourages the NRC to consider carefully Petitioners' comments in support of broadening the NRC's standards, and to revise those standards as necessary to ensure that they do not encroach upon the implementation of nuclear medicine research and the delivery of the highest quality nuclear medical care.

Sincerely,

James H. Sammons, MD

JHS/da