



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

September 7, 1990

The Honorable Michael Bilirakis  
United States House of Representatives  
Washington, DC 20515-0909

Dear Congressman Bilirakis:

I am responding to your letter of August 9, 1990, regarding correspondence you received on the U.S. Nuclear Regulatory Commission's (NRC's) authority over radiopharmaceutical products. Specifically, the correspondence you transmitted to NRC states, in essence, that NRC regulations unduly restrict the practice of nuclear pharmacy and medicine.

NRC's mandate to protect public health and safety includes the regulation of the medical use of byproduct material. In regulating byproduct material, NRC can limit, to some extent, the professional discretion of physicians and pharmacists. NRC must balance the hazard of the byproduct material to the patient's health and safety against the necessary exercise of professional discretion by a physician or pharmacist. Physicians and pharmacists have raised issues causing NRC to reexamine whether the appropriate balance has been maintained.

On August 23, 1990, NRC issued an interim final rule (with request for comments) (Enclosure 1) amending NRC's regulations in 10 CFR Parts 30 and 35, concerning the medical use of byproduct material. This interim rule was promulgated in partial response to a petition for rulemaking submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). That petition is mentioned in the correspondence to you.

The interim rule allows (a) medical use and commercial nuclear pharmacy licensees to depart from manufacturers' instructions (approved by the Food and Drug Administration) for preparing radiopharmaceuticals and (b) medical use licensees to depart from the Food and Drug Administration (FDA) approved package insert regarding indications and method of administration for therapeutic use of radiopharmaceuticals, provided certain conditions are met. Previously, NRC regulations did not permit these departures. This amendment allows health professionals exercising discretion within the prescribed criteria to provide diagnostic or therapeutic medical results not otherwise attainable or to reduce medical risks to particular patients because of their medical condition.

NRC believes the interim final rule amendments address the concerns expressed in Paragraphs a, b, and c of the correspondence to you.

As noted in Enclosure 1, during the three years the rule is in effect, NRC will continue to analyze the ACNP-SNM petition, the comments on the petition and on the interim rule, experience with the interim rule, and other information. Based on this analysis, NRC may propose amendments to this

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The Honorable Bilirakis

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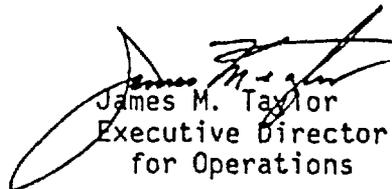
rule or to other provisions of 10 CFR Parts 30 and 35, to resolve all issues raised in the petition. The issues raised in the petition and your correspondence will be considered in the resolution of the remaining issues in the petition. As part of this process, NRC is consulting with the FDA and state boards of pharmacy to obtain their views on the resolution of the petition.

Regarding your request for background information on NRC's authority over "nuclear pharmaceutical products," I have enclosed a policy statement, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy" (44 FR 8241, Enclosure 2). This policy statement discusses NRC's role in regulating the medical uses of radioisotopes, particularly as contrasted to the role of FDA in this area. Please note that the interim final rule and certain provisions in 10 CFR Part 35 have relaxed some of the restrictions described in the policy statement.

Your correspondence will be added to the public comments on the petition for rulemaking.

I trust this reply responds to your concern.

Sincerely,

  
James M. Taylor  
Executive Director  
for Operations

Enclosures:  
1. 55 FR 34516  
2. 44 FR 8242