(1)

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

CHAIRMAN

Distribution:
Callan
Travers
Thompson
Norry
Blaha
Burns
Paperiello, NMSS
DFlack, NMSS
G980488

September 3, 1998

The Honorable Jerry Kleczka
United States House of Representatives
Washington, D.C. 20515-4904

Dear Congressman Kleczka:

I am responding to your letter dated August 6, 1998, in which you expressed reservations about possible changes in the U.S. Nuclear Regulatory Commission's 10 CFR Part 35 regulations on medical use of byproduct material. In particular, you were concerned about the training and experience requirements for physicians involved in the use of intravascular brachytherapy for treatment of cardiovascular disease.

The Commission considers the overall issue of training and experience to be one of the most important issues addressed during the rulemaking. Adequately trained personnel is key to the safe use of radioactive material in medicine. The Commission has, therefore, proposed that the training and experience criteria for all users of radioactive material be risk-informed and focused on safety. At the same time, however, the Commission recognizes that the proposed rule must be adaptable to the many medical uses of byproduct material, including the use of intravascular brachytherapy. This important issue, among others, was discussed at a Commission public meeting held in June 1998. The Commission directed the staff to further study and provide a basis for its current position.

On August 13, 1998, the proposed rulemaking was published in the Federal Register for a 90-day public comment period. A series of public meetings was also scheduled during the comment period. The first meeting took place August 19-20, 1998, in San Francisco, California. Additional meetings will be held in Kansas City, Missouri, on September 16-17, 1998, and in Rockville, Maryland, on October 21-22, 1998. Details on the public meetings were published in the Federal Register on July 24, 1998 (63 FR 39763). As noted in the Federal Register notice for these meetings, the Commission, through the facilitator for the meeting, invited participants that represent a broad spectrum of interests which may be affected by the proposed rulemaking. The American College of Cardiology (ACC) staff has worked with the NRC staff to ensure that the cardiologists' interests are represented at these meetings. Representatives of the ACC and the American Society of Nuclear Cardiology were invited to participate in the public meetings.

The Commission plans to carefully evaluate all the public comments in finalizing the training and experience requirements for medical uses of byproduct material.

Sincerely,

Shirley Ann Jackson

Shirley Ann Jackson

[Originated By: D. Flack, NMSS]