



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

(1)

November 12, 1998

The Honorable Karen Thurman
United States House of
Representatives
Washington, DC 20510

Dear Congresswoman Thurman:

I am responding to your letter, dated October 20, 1998, in which you transmitted correspondence from your constituent, Dr. Steven M. Kraft, that supported proposed changes to the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 regulations on medical use of byproduct material. In particular, he supported the proposed changes in the training and experience requirements for the use of byproduct material in diagnostic cardiology. In addition, Dr. Kraft feels that it is too early to set any definitive training and experience requirements for physicians using intravascular brachytherapy.

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 are key to the safe use of radioactive material in medicine. Therefore, the Commission has 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 intravascular brachytherapy. This important issue, among others, was discussed at a Commission public meeting in June 1998. The Commission directed the staff to study the issue further 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. These meetings took place August 19-20, 1998, in San Francisco, California, September 16 -17, 1998, in Kansas City, Missouri, and October 21-22, 1998, in Rockville, Maryland. Details of 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 meetings, invited participants who represent a broad spectrum of interests that 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 all users of byproduct material.

Sincerely,

A handwritten signature in black ink, which appears to read "William D. Travers".

William D. Travers
Executive Director
for Operations