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

CHAIRMAN

(2)

November 10, 1998

The Honorable Bill Archer
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Archer:

I am responding to your letter, dated September 18, 1998, that expressed concerns about proposed changes in the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 regulations on medical use of byproduct material. In particular, you were concerned that the proposed changes in the number of hours of training and experience required for using radioactive materials (I-131) for the treatment of thyroid disease would create an unnecessary burden for physicians, particularly endocrinologists.

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. The Commission has, therefore, proposed that the training and experience criteria for all users of radioactive material be risk-informed and focused on safety. Throughout the development of the proposed revisions, the staff considered the public input, including comments from the American Association of Clinical Endocrinologists (AACE). The issue of training for endocrinologists that use byproduct material to treat hyperthyroidism and thyroid cancer was discussed in a Commission public meeting in June 1998. At that time, the Commission directed the staff to study the issue further and provide a basis for its proposed 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 two meetings took place August 19-20, 1998, in San Francisco, California and September 16-17, 1998, in Kansas City, Missouri. The last meeting was held in Rockville, Maryland on October 21-22, 1998. Details of the scheduling 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 that represent a broad spectrum of interests which may be affected by the proposed rulemaking. The AACE staff has worked with the NRC staff to ensure that the endocrinologists' interests are represented at these meetings.

The Commission plans to carefully evaluate all the public comments in finalizing the training and experience requirements for users of byproduct material. If you need additional information, please do not hesitate to let me know.

Sincerely,

Shirley Ann Jackson