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

November 10, 1999

The Honorable Spencer Abraham
United States Senate
Washington, DC 20510

Dear Senator Abraham:

I am responding to your letter, dated October 21, 1999, that addressed the proposed changes to the U.S. Nuclear Regulatory Commission's (NRC) regulations on medical use of byproduct material, 10 CFR Part 35, "Medical Use of Byproduct Material." In particular, you noted that the draft regulation recognizes that the continued clinical use of Iodine -131 (I-131) by endocrinologists is vital to the treatment of hyperthyroidism and thyroid carcinoma.

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. Throughout the development of the proposed revisions, the staff considered the public input, including comments from the American Association of Clinical Endocrinologists (AACE). The AACE staff has worked with the NRC staff to ensure that the endocrinologists' issues were represented at all the public meetings held during the rulemaking.

The issue of training for endocrinologists who use byproduct material to treat hyperthyroidism and thyroid cancer was specifically discussed in a Commission public meeting in June 1998. At that time, the Commission directed the staff to study the issue further. As a result, the draft final rule that the staff forwarded to the Commission in August 1999 retains the current requirements for 80 hours of training and experience for endocrinologists who use I-131 in the treatment of thyroid disease. This position is supported by the safety record of the endocrinologists using I-131 under the current requirements, which you noted in your letter.

Presently, the Commission is reviewing the staff's draft final rule and is carefully evaluating all the public comments in finalizing the revision of NRC's medical use requirements, including the training and experience requirements for users of byproduct material.

Sincerely,

William D. Travers
Executive Director
for Operations