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Cebruary 20, 1998

Judith Anne Stitt, M.D., Chair Advisory Committee on the Medical Uses of Isotopes U.S. Nuclear Commission Office of Nuclear Material Safety and Safeguards Washington, D.C. 20555

Dear Dr. Stitt:

The American Association of Clinical Endocrinologists (AACE) and its over 2,800 members is expressly interested in the deliberations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) with respect to the Nuclear Regulatory Commission's intention to revise 10 CFR Part 35 - Medical Uses of Byproduct Material. With regard to your proposed agenda for the March 1 and 2 meeting in Rockville, Maryland, AACE would like to reiterate its position regarding the issue of current training and experience requirements to conduct certain types of treatments using radioactive materials.

Endocrinologists, both through training and experience, are the most highly trained physicians to provide integrated and cost effective care to patients with hyperthyroidism and thyroid carcinoma using I-131 therapy. Endocrinologists complete a medical residency program followed by a feliowship and extensive training and experience in treating patients with thyroid disease. They are also qualified by training and experience to handle nuclear byproduct material for medical use by virtue of formal instruction taken during the endocrine fellowship training period and comprehensive courses, such as the 80 hour course sponsored by AACE.

Considering the experience earned through such training and board certification, AACE urges the Committee to maintain the status quo regarding current training and experience requirements. If changes are made to existing standards, we recommend that Board Certification in Endocrinology & Metabolism by the American Board of Internal Medicine be required in conjunction with the physician having requisite knowledge and supervised clinical experience. The candidate for licensure should possess the knowledge and skill to:

- (i) Use of Iodine-131 for the diagnosis of thyroid disease.
- (ii) Use of Iodine-131 for the treatment of hyperthyroidism and cardiac dysfunction.
- (iii) Use of Iodine-131 for the treatment of thyroid carcinoma

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AACE is concerned that the other alternatives suggested for training and experience during the previous rule making workshops would significantly increase the barriers to licensure by unnecessarily raising the number of required training hours from 80 to 120-160 hours. This option would conflict with the NRC intention of lessening the burden and intrusion into medical practice.

I will be attending the meeting on March 1 with the intention of once again reiterating AACE's position regarding this issue. If you should need any additional information prior to this time, please contact Mr. Jay Millson, AACE Socioeconomic Director, at 904-353-7878. Once again, we appreciate the opportunity to provide the ACMUI with our comments and look forward to actively participating in the regulatory revision process being conducted by the NRC.

Sincerely,

H. Jack Baskin, M.D., F.A.C.E. President

cc: Ms. Patricia Vacherlon, NRC Bruce F. Bower, M.D., F.A.C.E. Donald C. Jones, CEO Christopher R. Seymour, Executive Director Jay W. Millson