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U.S. Nuclear Regulatory Commission
The Honorable Chairwoman Greta J. Dicus
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Washington, DC. 20555

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Dear Chairwoman Dicus,

I write to support the NRC staff's proposed draft regulation regarding Part 35-Medical Use of Byproduct Material to maintain 80 hours of training and experience for the clinical use of I-131 for the treatment of thyroid disease. I am dual board certified in Nuclear Medicine and Endocrinology & Metabolism and hope that my opinion is valued.

My training and experience in both specialties and daily interactions with endocrinologists, nuclear medicine physicians, and radiologists have led me to several generalizations. The proper use of I-131 requires an understanding of thyroid physiology, laboratory testing, diseases of the thyroid, physical examination of the thyroid, and patient education. There is no question in my mind that the endocrinologist (or rare nuclear medicine physician with a specific thyroid interest) is better equipped for these needs than is the radiologist (and more interested). Issues specific to I-131 from a nuclear radiopharmaceutical perspective, including safety, that are not usually included in endocrinology training are currently learned during the current 80 hour requirement and appropriately practiced. The documented experience with endocrinologists is that they have managed these aspects to date without a problem.

It is generally the endocrinologist who has diagnosed the thyroid problem and/or is the physician that will provide management long term. It should be clear that for continuity of care and convenience that the endocrinologist should, therefore, be the I-131 treating physician (all else being equal). I frequently observe radiologists who request that the endocrinologist specify the dose of I-131 to be given, or refuse to treat a hyperthyroid patient because the thyroid uptake was in the normal range, or call an endocrinologist for advice about the treatment of a thyroid patient. These situations arise out of a lack of training in thyroid physiology, a lack of understanding of the entire clinical picture, and/or lack of direct management of the patient.

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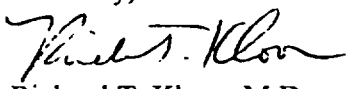
I'm concerned that the request for increased hours of training is an attempt to protect "turf", rather than an evidence based issue of safety or to benefit the patient. If 700 hours of supposed training were all that it takes to provide radioiodine to thyroid patients, then I should not be receiving the volume of calls that I get (mostly from radiologists) with thyroid related questions. However, I'm afraid it is not the number of hours that count, but rather the hands-on, face-to-face understanding one gains from obtaining a complete patient history, examination, and detailed knowledge of thyroid physiology. Radiologists are at a disadvantage as much of their work does not demand these same interventions and their routine is to not have detailed interactions with the patient or their history and they are not extensively trained in thyroid physiology. Few radiologists are truly experts in the thyroid (A check with the American Thyroid Association would document minimal representation by radiology). Yet, there has historically been reasonable money to be made by giving therapeutic I-131 (especially for the radiologist if the endocrinologist selects the patients, picks the I-131 dose, and manages the patient before and after therapy). Thus, all physicians are reluctant to give away the ability to administer therapeutic I-131.

If there were a substantiated report of increased I-131 misadministrations or other problems arising from endocrinologists' longstanding use of I-131 then I would be in favor of increased training requirements. However, my understanding is that there is not a problem with the current system and thus I see no need to revise it. 80 hours of training has withstood the test of time, and patient safety has been adequately protected under the current system.

Sincerely,



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