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Osteoporosis & Endocrine Center of Southern Nevada

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October 14, 1999

U.S. Nuclear Regulatory Commission
Greta J. Dicus, Chairwoman
016C1
Wahsington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR 20, 32 + 35
(64FR43516)

All Aspects of Adult Endocrinology
Diabetes Mellitus
Insulin Pump
Thyroid Disease and Nodules
Adrenal Disease
Osteoporosis
Pituitary Disease
Erectile Dysfunction
General Endocrinology

Advanced Testing
DXA Bone Density Testing (ISCD Certified for Quality)
Ultrasound Osteoporosis Screening
Thyroid Biopsy
Thyroid Ultrasound
ACTH Stimulation

Affiliations
International Society for Clinical Densitometry
National Osteoporosis Foundation
Endocrine Society
American Association of Clinical Endocrinologists
American Diabetes Association
Clark County Medical Society

Dear Chairwoman Dicus:

It has come to our attention that the U.S. Nuclear Regulatory Commission is meeting to consider proposals that may modify the training requirements of physicians that will be using I-131 to treat patients with thyroid diseases. We were gratified that the proposed NRC staff recommendations would not modify the current requirements. It is clear to us that the current requirements have not only served the public well, but have proven to be extremely safe. We hope that you and your colleagues will vote to maintain the status quo.

We were alarmed, but not surprised to learn that special interest groups are advocating draconian changes in the training requirements. In our opinion, these recommendations have little to do with the best interest of the patients and public to which we all have our primary responsibility. Rather, the modifications are part of ongoing turf-battles that are largely influenced by financial remuneration of the special interest groups involved. The recommendation to increase training to 700 hours is meant to secure exclusive rights to this therapeutic modality for a select few. It ignores the fact that endocrinologists have safely been administering I-131 for over fifty years.

Common sense would argue that the physician that diagnoses the thyroid disease, makes the decision to use I-131, and then assumes the care and monitoring of the patient after therapy is in an excellent position to administer the treatment itself. Few would dare to argue this point. The question relates to how much training one needs to ensure that the radioisotope is handled, stored, dosed and administered appropriately. The argument that 700 hours is the magic number implies that the current requirements are woefully inadequate. Inadequate training ultimately translates into improper use of radioisotopes and this results in specific cases in which patients or the public are inappropriately exposed to radioactive materials. We would be most interested in reviewing what

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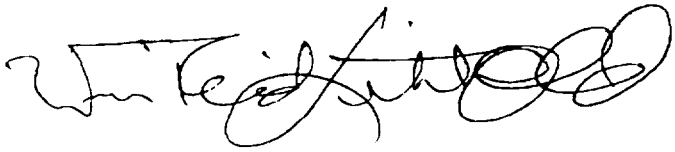
must be a lengthy list of cases in which this occurred ***as a result of*** a clinician having received only 1/9 of the necessary training that is needed to safely use I-131 (i.e.—80 hours instead of 700 hours of training).

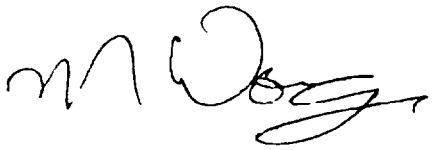
We have a system that works and has honorably served the public interest for many years. It is incumbent on the proponents any proposed modifications to offer concrete evidence as to how current regulations do not safeguard patient care and public safety. We are confident that this evidence is seriously lacking (if present then please proceed to safeguard the public interest). We encourage you and your colleagues to insist on seeing this type of evidence before fixing something that isn't broken. To do so in the absence of compelling data would not only threaten patient care, but also surrender the autonomy of the NRC to special interest groups.

Thank you for giving our views careful attention.

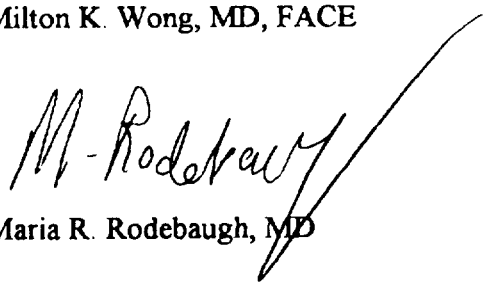
Respectfully,



W. Reid Litchfield, MD, FACE



Milton K. Wong, MD, FACE



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