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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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Michael Fuller
USNRC

Office of Federal and State Material and Environmental Management Programs
Division of Materials Safety and State Agreements
Mail Stop T-8 F5
11545 Rockville Pike
Rockville, MD 20852-0001

Re: Fed. Reg. vol. 76 No. 98 May 20, 2011

Dear Mr. Fuller:

I wish to make comments on Topic 2, Amending Preceptor Attestation Requirements, and on some related problems with NRC requirements for radiation oncologists as Authorized Users.

I served two terms on the ACMUI, am board certified in Nuclear Medicine, and am actively engaged in the teaching of Radiopharmaceutical Therapy to residents in Radiation Oncology and Nuclear Medicine at the David Geffen School of Medicine at UCLA.

I. Amending Preceptor Attestation Requirements

As in many academic medical institutions with Radiation Oncology and Nuclear Medicine residency programs, radiopharmaceutical therapy is the province of Nuclear Medicine, as is the case at UCLA. Radiation Oncology and Nuclear Medicine cooperate in resident education, training, and experience in the area of radiopharmaceutical therapy. I give lectures in radiopharmaceutical therapy, and then coordinate with Nuclear Medicine when therapy cases are scheduled, and my Radiation Oncology residents participate in these cases. I also administer a comprehensive examination to the residents in the area of radiopharmaceutical therapy. Passing this examination is now a requirement of our Radiation Oncology Residency Training Program.

The Radiation Oncology board now requires three cases of NaI-131 therapy for differentiated thyroid cancer (administered activities greater than 33 mCi), and three cases of parenteral beta emitter therapy

Template = SECY-067

(such as Quadramet, Metastron, Zevalin, Bexxar, SirSpheres, Sodium Phosphate-P-32, Chromic Phosphate P-32, etc.). I teach what is needed to understand these therapies, and also include the requirements in 10 CFR Part 35. **No one else in the Department knows what the residents have achieved and what their participation has been in cases.** Each year I summarize lecture attendance, case participation, and examination results to the Residency Program Director.

I therefore strongly believe that preceptor attestation is important and should continue. It is entirely possible to complete the case requirements, sit in a chair during lectures with one's brain turned off, and meet NRC's requirements for licensure. I do not provide preceptor attestation unless I believe the resident to be **competent**, even if they have met NRC's minimal requirements. The honest preceptor is the last guardian against incompetence. **For the good of patients and the public, I believe it should be maintained.**

II. Difficulties with Requirements for Radiation Oncologists and with NRC Form 313A (AUT)

For Radiation Oncology residents, the American Board of Radiology certification has two parts: written and oral. The written exam is also taken in two parts. Radiation physics and radiation biology is taken at the end of the third year (sometime in June) and the clinical part at the end of the fourth year (sometime in July). The residents need to pass those in order to be eligible for the oral exam, which is primarily a clinical competency exam. This oral exam is given one year after they complete their residency, after a year in practice, sometime in May. **So, during their first year in practice, they are only board eligible, not board certified. This means that they cannot practice radiopharmaceutical therapy during their first year in practice using the board certification pathway.**

This situation is somewhat absurd, but it becomes really problematic when a radiation oncologist takes a position in a small town where he is the solo practitioner of his specialty. For the first year, he cannot offer radiopharmaceutical therapy. This means that patients have to travel to other cities for medical therapy, and this may be difficult and expensive.

Of course, one could theoretically fill out NRC's forms documenting the 700 hours of training and experience, with 200 of those hours being in specifically defined categories. This, however, is virtually humanly impossible. Radiation Oncology residents spend at least 10,000 hours over four years in an adventure in applied radiation biology. Documenting the hours and categories of learning are ridiculous---they go on continuously, formally and informally, and no one is going to sit there and endlessly document bits and pieces of training and experience for the NRC. We are, after all, practicing medicine, not supporting blind bureaucracy. **I therefore strongly recommend that residents who pass the two written board examinations be permitted to practice radiopharmaceutical therapy as soon as they complete their residency, so long as there is preceptor attestation of competence.** It is not necessary to wait until they pass their oral boards.

The last problem has to do with NRC Form 313A (AUT). In order to practice nuclear medicine therapy using all currently approved FDA drugs, the physician really only needs 80 hours of classroom and laboratory training, and that training **must include** (italics mine) subjects listed in Part 35. However, when filling out Form 313A (AUT), **all 80 hours must be made up of those subjects.** This is against the Code of Federal Regulations, **and must immediately be changed.** While this pathway may be used to allow the physician to practice radiopharmaceutical therapy during his first year in practice, the form

must reflect the requirements in the Code of Federal Regulations, not the whims of NRC staff who made up the form.

Thank you for your attention and consideration. Hopefully you will make the necessary changes to ensure the competence of practitioners and the availability of radiopharmaceutical therapy to patients.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
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