Chairman Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Friday, November 26, 2021 4:53 PM
To: CMRBARAN Resource; CMRWright Resource; Chairman Resource
Subject: [External_Sender] Petition to inspect Nuclear Medicine therapy T&E
Attachments: NRC T&E Petition 12-06-18.docx; NRC-answer to petition about therapy T&E .pdf

Nov. 26, 2021

Dear Commissioners:

Three years ago I submitted a petition (attached) to the NRC insisting that the NRC inspect Diagnostic Radiology and Radiation Oncology residency training programs to assure compliance with requirements for T&E in Nuclear Medicine therapy described in Part 35.390 and the Memorandum of Understanding between the NRC and the American Board of Radiology. A letter acknowledging receipt of the petition and the plan for response (attached) from Marc Dapas was received a short time later. The Inspector General and the Allegation Program of the Office of Enforcement were to be involved. **However, nothing has ever happened.** The people in the Allegation Program refused to do anything because they said that my allegation was "too vague". They did this on the telephone, not in writing. When I replied that it didn't matter where they started---all residency programs should be inspected, they refused to consider my request. They insisted that I be "more specific". So I said that UCLA's Radiation Oncology and Diagnostic Radiology residency training programs were out of compliance. They said that that made it an Agreement State problem. When I contacted my regulators in Sacramento, California, they went to their Office of General Counsel who forbid them to inspect these programs because the Memorandum of Understanding was between the American Board of Radiology and the NRC, not California, and they said that the NRC had to inspect the programs.

The Inspector General's office said that Nuclear Medicine Therapy T&E was being reevaluated, and that they would address my request once the T&E question was settled. Well, the staff gave the Commission five T&E choices, one of which was to keep the *status quo,* and that was almost two years ago. The Commission has not acted on this issue, which basically has supported the *status quo,* which was the preferred choice by far of the medical establishment. **So, why has nothing happened to my petition's request?**

What is going on is that the NRC staff and management are terrified. Their budget depends upon licensing fees. Almost all licensing fees for Nuclear Medicine therapy come from Diagnostic Radiologists and Radiation Oncologists, the NRC having nearly succeeded in destroying the specialty of Nuclear Medicine. If it were to be discovered that the NRC is in the business of essentially selling licenses to incompetent and unqualified physicians because NRC needs the money, it would make the NRC look extremely corrupt. Well, the non-medical "Medical" Section **is extremely corrupt**, and you need to change this. **I request that you insist that NRC inspectors rigorously inspect Diagnostic Radiology and Radiation Oncology residency training programs to ensure compliance with Part 35.390, not taking anyone's word for it but documenting details.**

Thank you for your attention and consideration.

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

CAROL S. MARCUS, Ph.D., M.D.

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December 6, 2018

Annette L. Vietti-Cook
Secretary, USNRC
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Ms. Vietti-Cook:

The purpose of this petition is to ensure that the NRC enforces its requirements under 10 CFR Part 35.390, Training for use of unsealed byproduct material for which a written directive is required. It appears that your inspectors do not directly ascertain whether the 200 hours of lecture and laboratory experience are met and the 500 hours of supervised experience are actually gained and rely instead on assurances from residency program directors and preceptor letters. I do not think that these assurances are necessarily accurate for many Diagnostic Radiology and Radiation Oncology residency training programs, and that the required hours need to be independently verified by the inspectors.

It is common knowledge that many radiologists who are not board certified in Nuclear Medicine do a substandard job of nuclear medicine therapy. Many do not even meet and educate their patients, telling their technologists to take care of everything. No technologist is competent to practice Nuclear Medicine, and this leads to problems. Patients are confused, receive poor quality advice, and many questions are not answered, or not answered correctly. A thyroid cancer survivors organization, which appears to be run by Peter Crane, a retired NRC lawyer, has in the past tried to fix this by regulation. Sometimes the confused patients find the "Ask the Experts" section on the Health Physics web site, and ask their medical questions there. For many years, I have been the "expert" who answers their questions. I cannot believe some of these questions. They are so elementary, yet their physicians were unable to answer them. A radiologist who receives 200 hours of lecture and laboratory experience related to nuclear medicine therapy, and 500 hours of supervised experience, would surely be able to answer these questions, or find the answer quickly. This, in part, is what leads me to believe that they are often not receiving the training and experience they claim to have received.

On Sept. 16, 2018 I put in a Freedom of Information Act (FOIA) request to the NRC to find out the actual requirements that the various medical boards agreed would be part of their residency training programs so that board certification by those boards would result in automatic acceptance by the NRC that the agreed-upon training and experience requirements were all met. On Nov. 28, 2018, I received the information. From what was sent to me, it appears that Radiation Oncology and Nuclear Medicine residency training programs agreed to all the requirements of 10 CFR Part 35.390 and that Diagnostic Radiology residency training programs agreed to the same thing with the exception that "However, at the present time we would restrict 35.390 toward the "low dose" portion of this directive to not include (G)(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131." (This is from a letter dated Dec. 26, 2000 from the American Board of Radiology to Dr. Donald A. Cool who headed the Medical Program at NRC.) Presumably a Diagnostic Radiology resident would only therefore have to participate in three cases in which greater than 33 mCi was administered and he/she would be eligible to be an AU for the larger doses of I-131 as well as those under 33 mCi. If any changes were made to the agreement between the American Board of Radiology and the NRC at a later date, they were not sent to me as part of my FOIA request. I am in possession of a separate letter sent by the American Board of Radiology to Radiation Oncology Program Directors on Apr. 4, 2006, which reiterates the full requirement for 35.390 in all Radiation Oncology residency training programs.

If NRC/Agreement State inspectors find Radiation Oncology and/or Diagnostic Radiology residency training programs non-compliant with 35.390, I suggest removing these boards from your "deemed status" list and only allowing residents who complete these residency programs to become AUs if they satisfactorily document their personal hours of training and experience at a level that satisfies 35.390.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Prof. of Radiation Oncology, of Molecular and Medical Pharmacology, and of Radiological Sciences (ret.), David Geffen School of Medicine at UCLA

Member of the ACMUI, 1990-1994

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

January 18, 2019

Dr. Carol S. Marcus, Ph.D., M.D.
1877 Comstock Avenue
Los Angeles, CA 90025-5014

SUBJECT: RESPONSE TO DR. CAROL MARCUS REGARDING ENFORCEMENT OF TITLE 10 *CODE OF FEDERAL REGULATIONS* PART 35.390

Dear Dr. Marcus:

I am writing in response to your letter to Annette L. Vietti-Cook, of the U. S. Nuclear Regulatory Commission (NRC) Office of the Secretary, dated December 6, 2018, concerning residency training programs' compliance with the training and experience requirements in Title 10 *Code of Federal Regulations* (10 CFR) Part 35.390, "Training for use of unsealed byproduct material for which a written directive is required," and the NRC's inspection and enforcement of these requirements. Thank you for sharing your concerns. We take concerns expressed by external stakeholders seriously, and as such, we have forwarded your concerns to both the NRC's Office of the Inspector General (OIG) and the NRC's Allegation Program in the Office of Enforcement. The NRC's OIG is an independent and objective unit that supervises audits and conducts investigations relating to the NRC's programs and operations. The NRC's Allegation Program deals with concerns associated with NRC requirements and wrongdoing by individuals or organizations who are subject to those requirements.

As you are aware, the NRC staff is seeking comments on the training and experience requirements for authorized users for use of unsealed byproduct material for which a written directive is required. In its October 29, 2018 *Federal Register* notice (FRN) requesting comments on the NRC staff's training and experience evaluation (83 FR 54380), the staff included specific questions about medical specialty boards. Since your comments relate closely to the FRN and are within the comment period, your letter has been forwarded for inclusion in the FRN comment docket for the staff's evaluation. This letter also confirms receipt and inclusion of your separate comment letter dated December 5, 2018, addressed to May Ma in the NRC's Office of Administration.

Thank you for your comments on the staff's 10 CFR 35.390 training and experience evaluation. We are confident that your comments, in addition to other comments received in response to the FRN, will assist us in developing the appropriate oversight and regulatory framework needed to address concerns regarding training and experience requirements.

If you have any further questions or concerns, please feel free to contact me by e-mail at Marc.Dapas@nrc.gov, or by phone at (301) 415-0595, up until January 31, 2019. After that date, please contact Andrea Kock by e-mail at Andrea.Kock@nrc.gov, or by phone at 301-415-3340.

Sincerely,

Marc L. Dapas, Director
Office of Nuclear Material Safety
and Safeguards