

CHAIRMAN Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Friday, December 07, 2018 7:07 PM
To: NRCExecSec Resource
Cc: CMRBurns Resource; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Subject: [External_Sender] Petition requesting enforcement of 10 CFR Part 35.390
Attachments: NRC T&E Petition 12-06-18.docx

Dec. 7, 2018

Dear Ms. Vietti-Cook:

Attached is a petition requesting NRC enforcement of 10 CFR Part 35.390.

Thank you for your attention and consideration.

Sincerely,

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

SUNSI Review Complete
Template = ADM-013
E-RIDS=ADM-03
ADD=Sarah Lopas

COMMENT (53)
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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