



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

MAILING ADDRESS: 1877 COMSTOCK AVENUE
LOS ANGELES, CA 90025-5014

PHONE: (310) 277-4541
FAX: (310) 552-0028
E-MAIL: csmarcus@ucla.edu

May 23, 2019

Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Docket ID NRC-2018-0230, Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Dear Sir/Madam:

I continue to be amazed at the terminal dysfunctionality and dangerous stupidity of the NRC staff regarding this disastrous rulemaking adventure. I ask the Commissioners to decisively end this rulemaking. The NRC staff refuses to respect the opinions of competent and qualified nuclear medicine physicians and of the ACMUI and continues to flog this rulemaking despite being informed by knowledgeable professionals that it is a grave mistake.

Instead, the Commissioners should be thinking about the size of the fine to be issued to the American Board of Radiology (ABR) for lying to the NRC about the qualifications of its physicians board certified in radiation oncology and in diagnostic radiology. I do not think it likely that there is a single residency program in the United States in radiation oncology or in diagnostic radiology that is in compliance with 10 CFR Part 35.390, yet these programs are all accredited by the ABR. Accreditation requires compliance with 35.390 as stated in ABR's memo of understanding with the NRC. The NRC needs to inspect these programs and not take the word of its residency program directors. The poor quality of nuclear medicine therapy practiced by many of these diplomates is shameful. However, the NRC staff refuses to inspect these programs because it needs the licensing fees from these physicians to support the non-medical "Medical Program" including the salaries of its ignorant bureaucrats.

The Commissioners should think seriously about ending its non-medical "Medical Program", because it no longer has any useful function. Right after WWII, when radionuclides were available for medical purposes from Atomic Energy Commission (AEC) reactors, there was a point to it. But when the American Board of Nuclear Medicine (ABNM) was founded in 1971 and formal residency programs in nuclear medicine were established, the Medical Program no longer had any purpose. In fact,

shortly after the ABNM was founded, Richard Cunningham, the NMSS Director, asked the ACMUI if he should limit licensing of any nuclear medicine activities to physicians board certified in Nuclear Medicine. The ACMUI, concerned that some competent physicians practicing nuclear medicine before the ABNM was founded, and who did not take the first board exam (essentially a “grandfathering” exam), could be denied a license to continue practice, answered that that was not a good idea. I think it was a good idea, and a grandfathering clause could have been added, but the idea died at the time.

The whole idea of licensing came about because originally all the reactors making radionuclides were owned by the AEC, and the thought was that you couldn’t just give away federal property, so they decided to license the use of radionuclides produced in the AEC reactors. Today no radionuclides for nuclear medicine come from Department of Energy (DOE) reactors, so we don’t need licensing at all. Instead, medical licensing has become a vicious monster. And, we certainly don’t need guidance documents. Any physician who can’t figure out how to comply with regulations should not be practicing nuclear medicine in the first place.

When Ivan Selin, Ph.D., Sc.D., was Chairman of the NRC, he realized how dysfunctional the non-medical “Medical Program” was, and shortly before he resigned in 1995 he offered to take language to the Congress and lobby to remove NRC’s regulatory authority in medicine. At the time I was the Chair of the Society of Nuclear Medicine (now Society of Nuclear Medicine and Molecular Imaging) and American College of Nuclear Physicians (now subsumed into the American College of Nuclear Medicine) Government Relations Committee, and he made the offer to me. I quickly wrote some draft language and contacted the President of the Society of Nuclear Medicine, who strangely refused to get involved in this opportunity. Dr. Selin left shortly afterwards, and I later learned that the President of the Society of Nuclear Medicine was looking for a federal position and didn’t want to make any waves. In 1996 the National Academy of Sciences Institute of Medicine completed its study of NRC’s “Medical Program”. Its report is called “Radiation in Medicine; A Need for Regulatory Reform”. It found that NRC’s “Medical Program” was so dangerous and worthless that it recommended that Congress remove NRC’s statutory authority in medicine and medical research. Chairman Shirley Ann Jackson then led a dishonest campaign to ignore the whole report and succeeded in doing so.

When Congress passed a law requiring that the NRC raise all its operating funds from licensing fees (except for international programs) and that funds from one program could not be used for another program, the NRC charged large licensing fees for medical licenses and tried to raise them even higher the next year. Complaints to Congress by the nuclear medicine community resulted in NRC being stopped from doing this. Instead of laying off most of the useless (and sometimes dangerous) staff, NRC went about selling more licenses, chopping up nuclear medicine into bits and pieces to optimize income. That is what NRC is doing with its present rulemaking. NRC tried to do this to radiation oncology as well, but they were politically more successful than the nuclear medicine community and killed this NRC effort. By chopping up nuclear medicine and giving large hunks to non-nuclear medicine physicians, employment opportunities for board

certified nuclear medicine physicians fell and the specialty itself is in trouble. With reimbursement cut at every opportunity in hospitals, hospital administrators insisted that diagnostic radiologists, radiation oncologists, and sometimes cardiologists do all the nuclear medicine, and then no board certified nuclear medicine physicians were hired. Meanwhile, NRC refused to inspect residency programs in diagnostic radiology and radiation oncology to find out if they were in compliance with the requirements of 10 CFR Part 35, ***because NRC could not afford to lose the licensing fees.*** This situation continues, with poor quality nuclear medicine being practiced by unqualified physicians who are not very competent. Many diagnostic radiologists expect their nuclear medicine technologists to practice nuclear medicine for them. As no technologist is competent to practice any kind of medicine, the practice sinks to the lowest level of technologist. The technologist reviews practitioner requests for procedures, decides how the procedures are done, asks technologists in other practices for procedures to do tests not currently being performed in his/her practice, carries out the tests without any meaningful supervision, gives "preliminary readings" on diagnostic procedures, and the radiologist comes in at the end of the day and signs off on all or most all of the "preliminary" readings, and bills. This is unacceptable medical practice. Board certified nuclear medicine physicians are involved in reviewing requests in the morning, changing procedures as needed, supervising technologists, and reading their own studies. There are large numbers of nuclear cardiologists who are incapable of training or supervising their technologists, and who need to hire board certified nuclear medicine physicians to interpret their scans for them.

The NRC is jeopardizing patient care in order to keep its dysfunctional bureaucracy funded.

The NRC should unbudget its entire staff in the non-medical "Medical Program", rescind all of 10 CFR Part 35, and substitute that practicing any or all of nuclear medicine requires board certification in nuclear medicine and practicing any or all of radiation oncology using radioactive material requires board certification in radiation oncology. The respective boards decide on education, training, and experience. This ensures high quality care by qualified, competent physicians. We don't need the NRC at all at this point. We don't need any licensing or NRC inspectors, either. Questionable medical practices will be brought to the attention of the state medical boards, who use board certified specialist physicians as consultants. This is done for every medical specialty and NRC contributes nothing of value here.

In every first world country, and even in third world countries like India, a physician cannot practice nuclear medicine unless he/she is board certified in nuclear medicine. The United States is uniquely stupid and uniquely bad in this respect. It is high time the Commissioners ended their non-medical "Medical Program", which has been an anachronism since 1971.

Thank you for your attention and consideration.

Sincerely,



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

Prof. of Molecular and Medical Pharmacology (Nuclear Medicine), Prof. of Radiation Oncology, and retired Prof. of Radiological Sciences, David Geffen School of Medicine at UCLA.

CHAIRMAN Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Thursday, May 23, 2019 6:10 PM
To: Cmr. Stephen G. Burns; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Subject: [External_Sender] Comments for Current Therapy T&E Plan
Attachments: NRC-expanded T&E-05-23-19.docx

May 23, 2019

Dear Commissioners:

Attached is my comment letter pertaining to NRC's request for draft approaches for addressing training and experience requirements for radiopharmaceuticals requiring a written directive. Please read it carefully, because I am asking you to end the NRC's dysfunctional Medical Program.

Thank you for your attention and consideration.

Sincerely,

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