Mendiola, Doris

Subject: FW: Comment for Docket ID NRC-2015-0020, NaI-131 Pt. Release
Attachments: NRC-I-131 Pt. Release Info. 01-31-16.docx

-----Original Message-----
From: Carol Marcus [mailto:csmarcus@ucla.edu]
Sent: Sunday, January 31, 2016 6:36 PM
To: Bladey, Cindy <Cindy.Bladey@nrc.gov>; CHAIRMAN Resource <CHAIRMAN.Resource@nrc.gov>; CMRBARAN Resource <CMRBARAN.Resource@nrc.gov>; Cmr. Kristine L. Sviniki <cmrsviniki.resource@nrc.gov>; CMROSTENDORFF Resource <CMROSTENDORFF.Resource@nrc.gov>
Subject: [External_Sender] Comment for Docket ID NRC-2015-0020, NaI-131 Pt. Release

January 31, 2016

Dear Ms. Bladey and Commissioners:

Attached please find my comments on NRC's Sodium Iodide Patient Release Information Collection.

Thank you.

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

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January 31, 2016

Ms. Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Docket ID NRC-2015-0020, Sodium Iodide Patient Release Information Collection

Dear Ms. Bladey:

I wish to comment on this NRC request for information.

It is clear that many patients receiving sodium iodide I-131 (NaI-131) for whole body scans and for therapy of differentiated thyroid cancer or therapy of hyperthyroidism feel confused and apprehensive and have numerous questions that go unanswered by the physician responsible for their administered dosage of NaI-131. The Health Physics Society web site has a feature called "Ask the Expert", and for many years I have answered their questions about nuclear medicine, many of which have to do with NaI-131. I had initially been surprised that their physicians could not answer their questions. Now, no amount of physician ignorance surprises me. This is not an issue with board certified nuclear medicine physicians. It is an issue with radiologists.

It is the responsibility of the Authorized User Physician (AUP) to educate the patient about radiation safety and answer the patient's questions. Technologists do not have the education to perform this function with competence, and if forced to try to do this, tend to develop a "one size fits all" type of guidance which is scientifically without merit, and there are numerous types of questions for which the technologist cannot give intelligent advice. Many of the patients who have complained about unanswered questions have not even met their AUP. Why not, and what is going on?

What is going on is that their AUP is poorly competent. So, why is NRC selling licenses to physicians who are poorly competent?

Around 1990, Congress passed a law that required NRC to obtain all of its operating budget from User Fees (except for International Programs, which at the time accounted for about 10% of the NRC budget). In addition, User Fees from one type of licensee

could not be used to support the regulation of another type of licensee. For example, User Fees from the nuclear power industry could not be used to support the medical program. At first, the User Fees for medicine were high, and the NRC tried to make them higher still after the first year or so. Physicians complained bitterly to their Congressmen, and the NRC was told that it could not raise fees further. The NRC then had two choices. One was to unbudget numerous staff because there was no money to pay them. The other choice was to sell more licenses and make up the deficit that way. Unfortunately, but not surprisingly, NRC chose the latter course. NRC continued chopping up nuclear medicine into bits and licensing physicians who were not board certified in nuclear medicine to perform limited portions of nuclear medicine. Endocrinologists with **two weeks (!!!)** training could buy a license to perform NaI-131 procedures (the ACMUI had unanimously voted to end this practice, but were ignored). Memoranda of Understanding were sent to NRC by various boards stating that their residency training programs incorporated all the required NRC training, so that all of their diplomates were *a priori* qualified. NRC accepted these memoranda from boards representing residencies in nuclear medicine, diagnostic radiology, and radiation oncology. Diagnostic radiology residents with a supposed four month training program in nuclear medicine could do all of diagnostic nuclear medicine and NaI-131 therapy. Radiation oncologists could perform all nuclear medicine therapies with limited training. Cardiologists tried to establish a board in nuclear cardiology, but failed to convince the American Board of Medical Specialties that they were an appropriate specialty. Nevertheless, the American Society of Nuclear Cardiology ran a training program and signed a Memorandum of Understanding with the NRC that their "diplomates" were *a priori* qualified to practice all of nuclear cardiology, which was about half of all nuclear medicine studies. The United States, thanks to the NRC, has the ***lowest*** education and training requirements for nuclear medicine AUPs of any first world country, and even India has stronger requirements (board certification in nuclear medicine).

The decreased reimbursements to hospitals by the federal government, subsequently copied more or less by private insurance companies, put the squeeze on hospital administrators to save money at every opportunity. This created the perfect storm. As radiation oncologists, diagnostic radiologists, and cardiologists could be licensed to do all of nuclear medicine, who needed board certified nuclear medicine physicians? **The bulk of hospital administrators stopped hiring nuclear medicine physicians.**

While AUPs are supposed to supervise their technologists, the opposite is generally going on today in most of the United States. The radiologist expects his technologist to get a procedure from an outside institution for any test that is ordered for which no procedure currently exists in the practice, and to carry out the procedure and give a "preliminary" readout. The radiologist comes by at the end of the day (or through tele-radiology) and dictates the technologist's report and bills for it. Quality is often low.

Today, half of all the nuclear medicine residency programs in the United States have closed, and the surviving half frequently has a smaller program (fewer residents per year). About half of the surviving programs will only let in diagnostic radiologists, because those are the only ones who will get jobs afterwards.

Radiopharmaceutical research is mainly done by board certified nuclear medicine physicians, not radiologists incidentally doing some nuclear medicine. Nuclear medicine technologist training programs are mainly run by board certified nuclear medicine physicians, not radiologists incidentally doing some nuclear medicine. Research and technologist training programs will disappear as the current crop of board certified nuclear medicine physicians retire or are let go.

The NRC, in expanding the pool of paying physicians doing parts of nuclear medicine in order to increase its User Fee revenues, has decreased the quality of nuclear medicine care available to patients and jeopardized the future of the specialty in the United States.

The current plan of NRC to start telling poorly competent doctors how to practice nuclear medicine therapy and having NRC give advice to patients from a web site is completely ridiculous. **Yes, we have a problem. But this web site is not the solution.** The NRC ***is*** the problem, and it needs to stop selling licenses to poorly competent physicians. NRC's requirements for licensure are generally inadequate, and most important, there is no testing of the non-board certified physicians to see if they have mastered the necessary information. A few questions on their board exams are a joke. Back in 1994, when I was on the ACMUI, we voted unanimously to make sure that every physician who wanted to practice any or all of nuclear medicine needed to pass a comprehensive examination in basic nuclear and radiation sciences. When the new proposed medical regulations came out a couple of years later, this requirement was there. When the final regulations came out, it had mysteriously disappeared without any public discussion. The staff concocted a ridiculous reason for this, but what was really going on is that the staff knew that a huge number of licensed physicians could not pass such a test, and the User Fee revenues would plunge and with that, their jobs would disappear.

I ask the Commissioners to stop work on this web site and start work to fix the problem they have created. Please do the following:

1) Cut the number of employees in your Medical Program by 90%. Your program is a detriment to both physicians and patients. When the National Academy of Sciences-Institute of Medicine studied the NRC medical program and published its findings in 1996 (Radiation in Medicine. A Need for Regulatory Reform. National Academy Press, Washington, DC 1996), it recommended that Congress take away the NRC's statutory authority for the medical program and medical research (p.174).

2) Contract with the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and/or the American College of Nuclear Medicine (ACNM) to write an appropriate exam in basic nuclear and radiation science. Impose the exam on every physician who wants to practice any or all of nuclear medicine. The exam questions can be altered yearly.

3) Do not sell licenses to any more diagnostic radiologists unless they have completed a one year nuclear radiology fellowship.

4) Stop selling licenses to endocrinologists. They are qualified to do a nuclear medicine residency if they want to subspecialize in thyroid diagnosis and therapy.

5) Stop selling licenses to cardiologists. They are also qualified to do a nuclear medicine residency if they want to subspecialize in nuclear cardiology.

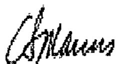
6) The requirements for radiation oncologists are probably okay *as long as they are met by the residency programs.* I think that many programs do not meet the requirements and you need the Residency Review Committees to verify that individual programs are in fact meeting the requirements. If not, they can be put on probation or opt out of the nuclear medicine therapy training program and their residents will not be able to get licenses to do nuclear medicine therapy.

7) Get rid of most of Part 35. Competent physicians merely need to practice in accordance with the standards of Part 20. They don't need to be told how to practice medicine by the NRC, and most of your regulations exist to make work for your staff and create paperwork for your inspectors, most of whom would be gone.

8) Get rid of all NRC guidance documents for the medical program. They're terrible. Competent physicians don't need your "guidance", and you would just license competent physicians. At present Appendix U, which is mainly about NaI-131 therapy, is not just wrong in multiple places, it is fraudulent. I have tried at least four times to get it fixed, but your staff and management have refused to do so. Having the same people who botched Appendix U produce more "guidance" for physicians and patients is a truly bad idea.

Thank you for your attention and consideration.

Sincerely,



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