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CHARLES H. ROSE
1143 Peakview Circle
Boulder, CO 80302

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Mr. Roger Broseus, Health Physicist
US Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852

(301) 415-7000

Dear Mr. Broseus:

This letter is being sent to several individuals to express concerns regarding the establishment of didactic requirements for licensure as medical authorized users and radiation safety officers. These concerns are my personal concerns, however, they are shared by several professional organizations and many physicians.

This historical development of the didactic training requirements for authorized users commenced with the evaluation of Radiology Residency programs and the required didactic contact of those programs. Even though the didactic requirements included areas not directly related to radioisotope handling; i.e., the physics of x-ray production and tele-therapy dosimetry, at that time, Radiology Residents were required to have 200 hours of formal instruction and to be evaluated by examination to assure competency in the material. This was the origin of the same requirements for Nuclear Medicine Residency programs and became the standard for didactic training. The completion of boards; i.e., Radiology or Nuclear Medicine, was considered to be the criteria for evaluation of the training of these physicians as the didactic training was part of their Residency program.. The boards included questions on the didactic subjects and the completion of the Residency program, and the included didactic training, became the standard. This standard also became the origin of the NRC requirements for non-boarded physicians.

Over the decades, the Radiology Residency programs evolved and as part of the process, many and eventually all, reduced the number of didactic hours. This was unofficial but clearly recognized by everyone. The ACGME did not, and does not, evaluate the didactic (education in non-medical issues) portion of the program. Surveys performed in the mid-1990's by the American Association for Nuclear Cardiology (AANC) received written input from senior radiology residents and those surveys as well as later surveys proved that the radiology residents in ACGME training programs received

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SIGNIFICANTLY less than the traditional 200 hours of instruction. In addition, very few residents had actual evaluation of their instruction to determine competency. The "deterioration" of the training program requirements, or actual implementation was necessary according to many individuals, to permit additional clinical experience by the resident in the emerging technologies.

The Nuclear Medicine Residency programs, or most programs, maintained the standard didactic hours of instruction. By the time that the National Academy of Sciences (NAS), Institute of Medicine and the Commissions Strategic Assessment and Rebaselining Initiative (SA) evaluated the status of training in 1996, the Nuclear Medicine Residency programs were the only ACGME programs offering the assumed standard of didactic instruction. The general attitude by many states, Agreement States, was that even though Radiology did not do it, everyone else should do it. One state even concluded that the same 50 hours of instruction given each year for four (4) years of a Residency program equaled the 200 hour requirement (Texas).

About the time that it was clear to everyone that there was, is, a clear discrepancy in the training received vs. training intended. the NRC made another significant change in the application of the statutes. The NRC had been on the record, in writing, that the 500 hour clinical and 500 hour experience requirements were acceptable as concurrent training. Through significant political pressure, the policy was revised to make the requirements non-concurrent, in essence, increasing the total requirements by 500 hours (700 hours became 1200 hours). Some Agreement States changed their requirements and some did not "agree" with the NRC position.

During this time period, the NRC staff "visited" the providers of non-Residency program instruction to evaluate the didactic offerings of those programs. The results showed that like Radiology Residency programs, most of the providers did not actually provide the 200 hours of instruction, many included significant clinical content that did not fit the instructional requirements and only one actually evaluated the competency of the participants. Some programs were clearly so questionable as to be "scams" (my term not NRC) with participants only attending a few hours of class and if an exam was given, it was open book with the instructor going over the answers to "assure everyone understands the correct answer" and passes the course.

The hearings held nationwide and in Washington, in 1998/1999 concerning the training requirements revealed that the NRC did not have the desire, for several reasons, to evaluate training programs addressing the didactic requirements. When mechanisms for evaluation were presented as well as offers to provide the NRC with an examination to evaluate the competency of individuals who had purported to receive such training, the NRC declined to accept or, administer, or endorse such devices.

With the advent of the new regulations, and the creation of the new "Boards," the training again diminished not only in academic quality but in actual implementation. The NRC was informed the new "Boards" would assure that the applicant met the NRC requirements before being accepted for the "Board" examination, and the NRC accepted the "Boards." When it was later pointed out to the NRC that the "Boards" did not follow this requirement and even promoted "don't ask don't tell" (my terms), the NRC stated it was not interested.

We currently have an Agreement State that will permit licensure with no Basics of Radioisotope Handling didactic training. We have some states that will accept the new "Boards" thus some applicants with no training or perhaps, in some cases, only a few hours. The quality of the training, of course, is questionable as in many programs there is not a certification or approval process and there may be no evaluation of the participant's competency. The NRC's position is, apparently, that as long as a physician's colleague will sign a statement, no one will question the accuracy of that document. Currently, there are authorized users being added to licenses who have minimal or non-existent didactic qualifications. There are sources of didactic education that provide courses that are inadequate, even by minimal standards, whatever those minimal standards may be. The ACGME does not evaluate the education content of educational programs in the Basics of Radioisotope Handling even within ACGME approved Residency programs. The presence of Category 1 Continuing Medical Education, CME, does not indicate a level of quality as they only evaluate the medical education quality of programs. The didactic training is not medical education.

There are organizations such as the American Council of Education (ACE) that evaluate the ACADEMIC standards of educational programs. Every state has requirements for the organizations offering education in that state, or organized in that state, to meet specific state requirements. These states may administer the training programs through the Department of Education or Department of Higher Education of that state. Please be aware, however, that neither the American Council of Education or the state reviews, approves or has responsibility for Fellowship, Residency or even Basics of Radioisotope Handling programs provided by Medical schools or teaching institutions. Medical education is treated separately from academic education beyond the basic medical school level.

My suggestions are as follows:

1. The minimum standards for the hours of Basics of Radioisotope Handling should be set and enforced. Remember the minimum will become the maximum as the applicants will rise to only the minimum standard.

2. The number of hours should be sufficient to provide the participant with a working understanding of Radiation Physics, Instrumentation, Radiation Safety (including Biology) and Radiopharmaceuticals. The inclusion, in the minimum requirement, of clinical procedures, interpretation, reading sessions, etc., should be prohibited. How many hours would you require to learn the above topics including 10CFR 19, 20 and 35 and the appropriate sections of 49CFR?
3. The number of didactic hours for the authorized user and for the non-authorized user RSO didactic training should be the same. After all, the AU is automatically qualified as the RSO and some non-institutional licenses perform more procedures, including therapy, than was done in the past by active teaching hospitals.
4. The authorized user applicant should be required to provide actual documentation of the didactic training received. This should be documented by the topics, hours and evidence of competency, not just a "certificate." The applicant should be required to attest to the accuracy of the document.
5. Sources of the didactic training should be required to be licensed by the States Department of Education and be accredited by an independent academic organization; i.e., American Council on Education. This will assure at least some review of the academic integrity of the organization.

Residency programs, ACGME approved, would be exempt from this recommendation, however, all applicants requesting licensure should have to show evidence of their didactic education. The completion of an ACGME approved program should attest to the medical experience, the didactic requirement is not medical experience.

6. Completion of didactic training should include proof of attendance and proof of competency.
7. Non-traditional "Boards," those other than Radiology, Nuclear Medicine, etc., those not supported by requirements to complete an ACGME approved two (2) to four (4) year Residency program, should have to document the qualifications of their applicants prior to being accepted for the examination;

or

all applicants, even those with "Boards" should have to provide their credentials, proof that they have the didactic training and handling experience. The proof is not a colleague's statement but the actual documentation of the training.

And consider:

The training requirements no longer involve medical practice thus the "preceptor" should be the person, not necessarily a physician, who is responsible for the didactic and/or handling experience.

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The system was not working perfectly but now it is not working. The quality of some applicants training and experience has deteriorated at the same time that our national concerns for the safe handling of radioactive materials has increased. It is time to return to fundamental radiation safety and stop responding to the political posturing and medical specialty financial interest. Let's return to basics and the patients, employees and the nation will be safety.

Sincerely,



Charles H. Rose, MA, MSPH, D(ABSNM)

P.S. I have been involved with training radiologists and Nuclear Medicine Residents since the mid-1960's. I have participated in the training of over 3,000 physicians, many cardiologists to meet the didactic requirements. I am a license holder, Licensee, and RSO and developed the nation's first radiopharmacy program. I have developed and administer a closed book, 320 question examination to determine didactic competency, to over 2,500 physicians. I administer the only organization that represents, without commercial interest, nuclear cardiologists and I administer the nation's oldest and largest training program in the Basics of Radioisotope Handling. I feel that decades of experience provide an insight of knowledge that should be considered in evolving new standards.