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(53FR 18845)

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THE UNIVERSITY OF TEXAS MEDICAL BRANCH  
GALVESTON, TEXAS 77550

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MARTIN L. NUSYNOWITZ, M.D.  
PROFESSOR AND DIRECTOR

DIVISION OF NUCLEAR MEDICINE  
DEPARTMENT OF RADIOLOGY  
(409) 761-2926

Secretary of the Commission  
US Nuclear Regulatory Commission  
ATTN: Docketing and Service Branch  
Washington, DC 20555

NUCLEAR MEDICINE

THE UNIVERSITY OF TEXAS  
MEDICAL BRANCH  
GALVESTON, TEXAS 77550

SUBJECT: ANPRM-Training and Experience Criteria  
(53 FR 18845, 25 May 1988)

The following comments are provided in response to the subject ANPRM that would effect medical licensing under 10CFR Part 35. Although I am the director of a nuclear medicine residency program, these comments are provided by me as an individual, not as a representative of my academic institution or any professional organization of which I am a member or officer.

page 18850, Section 35.910: No changes are necessary. NRC may wish to consider eliminating this as a separate category, since the types of procedures addressed by this section, and the number of physicians likely to request such licensure in the future, are few and likely to be fewer in the future. The historically important studies have become obsolete or obsolescent because of abandonment in favor of an imaging study (e.g., probe renograms) or a switch to non-byproduct material (e.g., I123 for thyroid uptake).

page 18850, Section 35.920:  
Since the length of time for an integrated training program for Section 35.910 is six months, and since the procedures under Section 35.920 entail greater potential hazard to the public, it would be inconsistent to adopt a training period of less than six months. The purpose of this clinical training is to allow the trainee to gain familiarity with the day-to-day routine practice and to experience the aberrations and abnormalities that inevitably arise and learn how to cope with them. Six months may be necessary in a small, relatively low workload program. On the other hand, in busy clinics some shorter period of time may be suitable. Perhaps there should be a dual requirement of some minimum calendar time and of some minimum number of patients

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(e.g., 1000-2000 patients); if the minimum time elapses before the minimum number of patients were reached, the training period would continue until the requisite number were reached.

page 18851, column 1, Cardiovascular Clinical Procedures:

1. I strongly recommend that cardiovascular procedures not be removed from the general milieu of Section 35.920 and placed in a new section by themselves.

a. Ionizing radiation and radioactive materials are politically and publicly sensitive topics. I agree wholeheartedly that the public has a right to expect that physicians who use these tools for diagnosis and therapy are sufficiently trained and experienced so that the public will receive the benefits of the use of these tools with a minimum of risk incurred from their use. Even a cursory review of the history of medical radiation accidents will reveal that only rarely are accidents attributable to institutions and physicians who practice nuclear medicine procedures as a full-time specialty, e.g., ABNM-certified physicians with an active 100%-nuclear medicine practice. NRC has correctly been very cautious about diffusing the medical use of byproduct material to physicians other than nuclear medicine specialists or radiologists. As a result, the accident history has been enviable. Lessons can be drawn from x-ray machine history, however, which clearly show that machines in the hands of non-radiologists are likely to be out-of-repair, out-of-calibration, operated by undertrained personnel, and generally a threat to the radiation safety of the public. The most recent and glaring example is cardiologist performance of cardiac angiography; other examples include dentists and general practitioners, especially in rural areas. Any physician using radioactive material needs to be fully trained and fully experienced, conditions which rarely obtain when an individual is neither a nuclear physician nor a radiologist; licensure of other physicians should be approached with conservatism.

b. A further argument against liberalization of licensure is the potential for unnecessary studies caused by self-referral. The nuclear medicine and radiology physicians see patients only by referral, i.e., a primary care physician recommends a test solely in the best interest of the patient. If the primary care physician also operates a nuclear

medicine clinic, the temptation will exist to order unnecessary tests for the physician's financial interest, not the patient's medical interest. As pointed out in the Federal Register notice, in the hospital setting this type of behavior is monitored closely by JCAHO and other mechanisms. There are very few review mechanisms operating in the outpatient environment. The ACMUI could very well experience increased usage for resolving questions of appropriateness of studies if primary care physicians are performing studies on their own patients.

c. The definition of "cardiovascular" procedures is not given in the proposed text. By not providing a definition, the following procedures could all be construed as cardiovascular:

1. gated equilibrium cardiac imaging
2. first pass imaging for shunt quantitation
3. myocardial perfusion imaging (e.g., Tc99m isonitriles)
4. lung perfusion imaging
5. venography
6. radionuclide arteriography
7. organ perfusion/flow imaging
8. blood volume (plasma, red cell)
9. deep vein thrombosis imaging/detection

d. Participation in 50 cases and personal performance of 10 cases is grossly inadequate preparation for performing any of these cardiovascular procedures. In our clinic these numbers represent approximately one week's workload. Neither this number of cases nor two week's experience is adequate for a physician to learn how to deal with all of the machine and human problems that inevitably arise in these studies. A more satisfactory set of criteria might be 500 cases observed/100 cases performed and at least 4-6 months of supervised handling experience. I have personally supervised the training of cardiologists who wished to gain experience in nuclear medicine techniques, and they were appreciative of the extended (6 months) clinical experience at its conclusion.

e. I fully concur with the statement in Item #1, page 18846 regarding the similarity of radiation safety problems and procedures regardless of the organ system under study. I also concur with Item #3 on the same page. I would add that nuclear medicine and radiology residency programs are

accredited by the ACGME, in conjunction with the respective certifying boards, which gives reasonable assurance that the training program is of sufficient quality. Any special training program for cardiologists (or any other non-nuclear medicine or non-radiology physician) would be difficult to assess for initial or continuing quality.

f. NRC is opening a can of worms by singling out cardiologists. Soon to follow will be requests by neurologists and neurosurgeons for brain perfusion agents (e.g., Tc99m HMPAO); gastroenterologists for gastric emptying/reflux studies; renal transplant surgeons for kidney agents; the list could be extended to most medical specialties. Such a proliferation of non-nuclear medicine and non-radiology physicians will lead to increased risk to the public health due to their only peripheral interest in the supervision and performance of these studies, which would comprise just a small fraction of their daily workload.

g. NRC has a long-standing mechanism for the handling of license applications from physicians who have not received formal training in nuclear medicine or radiology, i.e., case by case review. This mechanism has been widely accepted by the medical community, and there has been no clamor for change. "If it ain't broke, don't fix it!"

page 18851, Sections 35.932 and 35.934: Radionuclide therapy is one of the increasingly important areas of nuclear medicine. The promise of monoclonal antibodies and receptors has led to great excitement about the future of radionuclide therapy. Because of the potential for harm inherent in therapeutic procedures, the requirements for classroom and laboratory training should be expanded to 200 hours and the clinical experience should be expanded to require six months and a minimum number of cases.

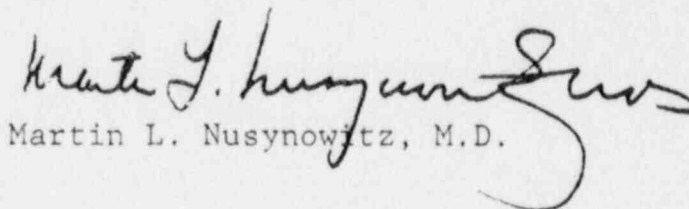
page 18853, Item #10: NRC should require that all technologists be registered or work under the direct, immediate supervision of a registered technologist. A difficult question that needs to be addressed is how to handle someone who has repeatedly failed the registry examination. Under the proposed text, this person would never have to be registered. Perhaps one solution would be to require technologists to be licensed, if their state has such a program.

The technician category should probably also include nurses and should provide for some minimal training. I

see no value in having them listed by name on a license. They should always work under the direct supervision of a registered technologist.

In conclusion, I have found the existing regulations in Part 35 satisfactory and I strongly discourage changing them in order to create special categories of licensure. The administrative difficulties of establishing appropriate criteria and the monitoring of licensee performance will be foreboding in this first instance, and they will become overwhelming as the special categories proliferate. I reiterate my support for the current, less confusing, proven method of handling special license applications.

Sincerely,

  
Martin L. Nusynowitz, M.D.