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SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING

DEPARTMENT OF RADIOLOGY

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Robert E. O'Mara, M.D.
Professor and Chairman

August 23, 1988

U.S. NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

Re: Proposed Rules Changes as announced in the Federal Register/Vol. 53, No. 101/Wednesday, May 25, 1988.

Dear Sirs:

I am commenting upon these proposals not in any of my "official" roles as a member of various medical organizations that deal with the use of radioisotopes and radiopharmaceuticals for diagnosis and therapy. Rather I am offering these comments to your proposed changes simply as an individual who, for 20 years, has been charged with the development of training programs for physicians and technologists who engage in the practice of Nuclear Medicine, Nuclear Radiology, and Nuclear Technology. I will comment upon these proposed changes only as they apply to the use of radioisotopes and will not comment upon your suggestions for Radiation Oncology, Radiotherapy, Teletherapy Dosimetrists and Physicists since they are areas in which I do not function.

Much of the proposed changes are based upon the reasonable desire to assure, as completely as possible, protection of the public from misuse of radioactive materials in a clinical mode. Much of the presentation deals with the misadministration of such materials. I have never seen data from any source that suggests that the misadministration of radiopharmaceuticals for diagnostic or therapeutic purposes represents a significant hazard to the general health population of this country. Such events do occur but their number, frequency, and severity are usually such that it is admirable that they are so few, especially with the large numbers of procedures performed on individuals. Often, such misadministrations are the result of human error which no amount of training or regulatory control can totally ablate. Indeed, a similar point can be made for poor interpretation of clinical studies. During a training program, one can only introduce a student to basic principles. One can then examine or test a student, as is currently done, in their knowledge and application of these principles. When out in clinical practice, it is then the student's responsibility to apply these. This becomes an individual human function in which disagreement between practitioners as to appropriateness of a clinical exam, performance and interpretation of that exam can be honestly debated. The same may be held for therapy with radioisotopes.

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At present, all training programs whether for physicians or technologists have to meet criteria set up by national organizations charged with the responsibility of supervising, examining and accrediting such programs. As an example, Nuclear Medicine residencies and Nuclear Radiology programs are under the examination and control of the respective residency review committees of the ACGME. Invariably, these requirements include training that meets the NRC requirments as a minimum. These programs are examined at intervals in great detail and accreditation either given or withheld until proper functioning is demonstrated. Finally, the graduates of such programs must then pass written and/or oral examinations given by the various Boards concerned. Such examinations include direct questioning in the areas of the basic science of radioactive materials, radiation safety and clinical application. A similar situation exists for technologists in this field. The establishment of another bureaucracy with another examination will merely add the expense of this whole procedure and result in an increase cost of medical care of unknown amounts. Unless direct evidence can be presented that the current system has failed, such a costly proposal is unacceptable.

A similar discussion can be had for the evidence of continuing education. Such courses and education efforts are documented through a variety of national organizations charged with the accreditation and evaluation of these programs. Again, if no direct evidence can be forthcoming that this system has failed the public of the United States, then my suggestion is leave it alone.

Over the years, the NRC has waxed and waned as to what basic requirements for training of the use of radioisotopes should be. Again, you are doing this both in regards to general training of individuals who wish to use these materials at any level and also for specific classes of specialities. In this particular instance I refer to individuals training to use isotopes for cardiovascular clinical procedures. It should make no difference whether one is using a single radioisotope or two or is using a wide variety of isotopes in clinical practice. The amount of basic scientific knowledge and training to insure adequacy of the safety of the general public is the same. I would strongly urge that the NRC develop a set of basic training criteria with which it is comfortable and with which the training community can handle at reasonable cost and stay with those requirements for a long enough period of time that they can be adequately assessed. At the very least, this constant waffling of the NRC as to its basic requirements makes it virtually impossible to devise a training program for individual physicians and technologists that has any continuity in time as well as effort. It also makes it extremely difficult to advise these young people as to what they should look for in training programs as they embark upon the effort to be trained to establish a career in these fields.

Finally, the establishment of individual criteria for certain specialized groups such as cardiovascular nuclear medicine procedures will lead the NRC into the path of having to establish individual training criteria for a wide variety of other specialized interests. Is the basic training requirement to provide for the public safety any different for an individual who wishes to evaluate myocardial function or cellular integrity with nuclear procedures than that of, say for example, a pulmonary physician who desires to look at the ventilatory capacity of the lung with radioisotopes? The answer is simple--absolutely not. Again, the same basic knowledge is required whether one wishes to do this type of specialized study or apply radioisotopes in a more general fashion. As an individual, I really do not care whether your training requirements add up to three months time, six months time, or even 20 years time. I do ask, as I said before, that the NRC develop a satisfactory minimum level of training requirements and stay with it in uniform application.

Finally, I should point out that under Section 35.910 you should probably include Diagnostic Radiology with Special Competence in Nuclear Radiology as an exam given by the American Board of Radiology. The same is also true for Section 35.930.

Thank you for the opportunity to comment upon these proposals.

Sincerely yours,

R. E. O'Mara

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