SOUTHWESTERN CHAPTER
SOCIETY OF NUCLEAR MEDICINE
1998 - 1999

The Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Att: Rulemakings & Adjudication Staff

October 30, 1998

414

Dear Madam/Sir:

I am writing as the President of the SouthWestern Chapter of the Society of Nuclear Medicine, which is comprised of members from the states of Texas, Arkansas, Louisiana, Oklahoma, and New Mexico. We have had considerable discussion of the proposed revision to 10CFR Part 35 in the SouthWestern Chapter, and we would like to express our thoughts in this regard. Specifically:

1) We have significant concerns regarding the level of training and supervision of physicians using radioisotopes in their medical practice. We strongly recommend that a high level of training and experience be maintained by the requirements of 10CFR35. We are concerned that the proposed revision does not provide for adequate training of physicians in radiation safety and management. In addition, it is subject to abuse and misinterpretations. It is most critical that the level of training requirements be bona fide.

2) We are strongly opposed to 10CFR35.27 relating to supervision. "Supervision" is already being misinterpreted by several practicing physicians. The wording of this regulation allows large numbers of physicians not qualifying for a license to practice to all use the license of one physician with virtually no supervision. Problems include:

- Retrospectively reviewing a few percent of the cases per year per physician - not necessarily in the presence of the supervisor.
- Attending one lecture per year (not necessarily given by the supervising physician) is sufficient to represent supervision.
- One supervising physician may "supervise" 20 or more physicians, even when out of town.
- The supervising physician need not have passed any board certification in nuclear medicine nor have passed any test in nuclear medicine.
- It is possible to practice (and charge patients) as a "supervised" physician for decades without ever satisfying NRC basic qualifications for safe use of radiopharmaceuticals. Texas, as an agreement state, has no specific provision for a supervised physician.

44th Annual Meeting
March 26 - 28, 1999
Santa Fe, NM

PO Box 411106 • San Francisco, CA 94141-1106 • Phone: 415/487-9802 • Fax: 415/487-9803 • info@swcsnm.org
Website: www.swcsnm.org

D510

3) The proposed changes of section 10CFR35.27 should at least bring requirements up to minimal Accreditation Council for Graduate Medical Education (ACGME) teaching requirements for physicians, even if the total time is shorter than a residency. At any ACGME certified training institution, an individual being trained has all the cases reviewed by the teaching physician and interacts with the supervisor on all cases. There is an oral or written questioning by the supervisor. There are multiple lectures a week, and there is a final test by an ACGME approved body, with consequences for failure. If one teacher is away, another supervises. The trainee cannot bill for those services as a specialist.

   In radiology, there is an ACGME requirement of at least one staff physician per resident. The ACGME nuclear medicine teacher has passed a nuclear medicine test and is Board Certified. The training program should have goals and objectives, a curriculum, handouts, a reading list, etc. There is a time limit on getting certified. The ACGME reviews the program.

4) Any clinician who desires to become licensed in handling radioactive products should do so through an ACGME accredited program, like several other specializations in medicine. There is no pressing need to increase the number of physicians authorized to use such materials. To our knowledge, no one is denied the care they need. We recognize the valuable expertise that various clinical specialists, such as the endocrinologists, can bring to managing patients, e.g. thyroid disorders. However, we feel strongly that the superior knowledge of a physician fully trained in nuclear medicine brings valuable expertise to these patients, and is vital in quality care of our community. There is already a mechanism by which clinicians can become licensed in the use of radio-iodine and other radio-isotopes. Any further relaxation of these requirements by the NRC would be a grave error, and an act of injustice to our patients.

5) Unlike all other training, there is no punishment for failure. It may be possible to follow the letter of the law but not the spirit of the law. Any "licensed provider," as per the revisions, may not be adequately trained to ensure the safety and quality of care that our community deserves. We have all seen the disaster that occurred in the early days of mammography, before the MQSA requirements and the need for mammography certification. There were many centers causing terrible abuse to patients through poor quality, expensive examinations done on substandard equipment, and through interpretation by incompetent practitioners who felt they were competent. The intervention of the federal government put an end to this dreadful situation.

6) We are opposed to lowering the minimum requirements for radiation safety training for supervised physicians. Any change to the minimum standards of training required by 10CFR35, we feel, has to be for the betterment of patient care, and not for physicians' benefit. Otherwise, a similar situation will arise in the radioactive materials use scenario. The best interest of patients dictates that we maintain minimum standards in training requirements of physicians.

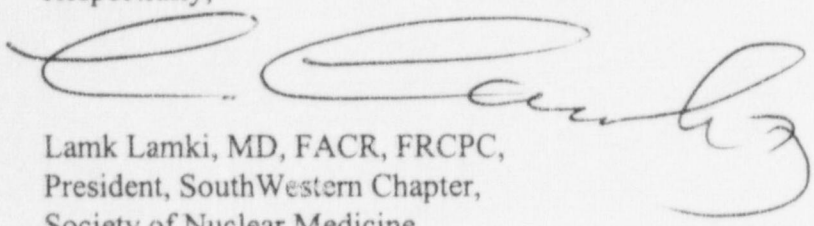
7) We applaud the NRC's willingness and desire to minimize interference with good care, cut taxpayer expenses, and in general, promote the field of nuclear medicine and other uses of radioactive materials in medicine. We feel that the changes proposed by the NRC to 10CFR35, in terms of the authorized users and supervisors, will not serve that purpose. They will cause an explosion and lead to poor quality procedures that will increase the cost of care and ill serve the patients' needs.

8) It is the strong opinion of the Southwestern Chapter of the Society of Nuclear Medicine that the NRC should not abandon the nuclear community at this critical period. A close involvement of the NRC is essential to the further growth and advancement of nuclear medicine, and patient care. It would be of questionable judgement for us to radically depart from our past, with its proven track record and with its development, stemming from close collaboration between the founding patriarchs of both nuclear medicine and the NRC. They demonstrated a great deal of wisdom that benefits us greatly today.

9) The NRC regulation should clearly separate "supervision" requirements for physicians from those requirements for supervising technologists and other assistants. Regulations that are meant for laboratory assistants are not always applicable to physicians, who should be seeking appropriate and proper training. The system is currently either misinterpreted or abused. The NRC supervision regulations have opened a huge loophole that almost completely defeats NRC minimum training requirements. The NRC may also incur a liability by allowing this.

We urge you to seriously consider the impact of inadequate requirements for physician training in both the handling of radioisotopes and lax supervision regulations. In addition, the safety requirements need to be strengthened and not loosened any further - for the benefit of our patients, as well as for cost-effective delivery of health care to our community.

Respectfully,



Lamk Lamki, MD, FACR, FRCPC,
President, SouthWestern Chapter,
Society of Nuclear Medicine