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Medical Center
16111 Plummer Street
Sepulveda, CA 91343

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October 24, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, D C. 20555

Dear Mr. Secretary,

I wish to express my very strong support for the recent Petition for Rulemaking filed jointly by the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP). I am the Chief, Nuclear Medicine Service at the Veterans Administration Medical Center in Sepulveda, California. The April 1987 revision of 10 CFR 35 interferes with both the practice of medicine and pharmacy. It prevents the delivery of optimum patient care diagnostic studies and therapeutic modalities. I sincerely believe that this interference with the practice of medicine and pharmacy, violates the NRC's stated policy against such interference, is probably illegal, and is certainly misguided.

Our Medical Center was visited in April 1989 for a prelicensing orientation by two representatives of NRC Region V. The question of the onerous new regulations was raised by me and we were informed that the commissioners are very upset by the number of medical mis-administrations around the country and that they believe that if a similar amount of radiation was delivered to a similar number of people by a leak from a nuclear power reactor, they would have a major crisis. I have great difficulty believing that the commissioners have such a naive belief, though I would not be surprised to see some of the media try to equate such medical exposure to radiation exposure from a nuclear power plant or weapons factory. Whatever the radiation exposure from a medical mis-administration, that's it. There is no additional radiation exposure or immediate risk. Radiation exposure from a power reactor or weapons factory is not merely radiation exposure of an individual, but is a danger signal and a warning of possible impending catastrophe! It is the real risk of a catastrophe that makes radiation exposure at a power plant so ominous and a news worthy event.

The recent revision of 10 CFR 35 special provisions for the practice of medicine and pharmacy under a broad licensed program. We have operated an extensive "in house" radiopharmacy program under our broad license for about 20 years. Most radiopharmaceutical kits are made and tested "in house". The FDA has budget problems like everyone else and will not accept physician sponsored IND's for "in house" preperations of commonly used products. Thus, our radiopharmacy program

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will have to cease and all materials will have to be purchased from commercial vendors at an estimated additional cost of $40,000 per year. We would also have little justification to retain our radiopharmacist and would then be unable to continue many of our efforts to deliver high quality patient care at the lowest possible radiation exposure to our patients. We performed about 200 SPECT brain scans using N-isopropyl-p-iodoamphetamine labeled in our laboratory with a much higher purity I-123 than was commercially available at that time. This resulted in the 200 patients receiving only about 1/2 of the radiation exposure that would have been received from the commercial version of this agent. I suspect that this reduced radiation exposure dose from our hospital's "in house" radiopharmacy program more than balanced out the increased radiation exposures from all of the medical mis-administrations on the entire west coast. If we have no "in house" radiopharmacy program, we will have no radiopharmacist, and no radiopharmaceutical research. The loss will also have a serious adverse impact on our residency training program.

The Nuclear Regulatory Commission can significantly improve the radiation protection of the general public, by urging amendment of the Atomic Energy Act of 1954 to include NRC regulation of accelerator produced isotopes, rather than imposing more restrictions on the medical use of by product material. The changes in 10 CFR 35 proposed by SNM and ACNP will correct most or all of the current deficiencies.

Sincerely yours,

Marvin B. Cohen

Marvin B. Cohen, M.D.
Chief, Nuclear Medicine Service
Professor, Medicine & Radiology, UCLA