



THE SOCIETY OF NUCLEAR MEDICINE

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May 11, 1983

Chairman Nunzio J. Palladino
Nuclear Regulatory Commission
Matomic Building
1717 "H" Street, Northwest
Washington, DC 20555

Dear Chairman Palladino:

The Society of Nuclear Medicine has had the opportunity to review testimony concerning 10CFR35 [relating to licensure for Human Use of Byproduct Material] which was presented at the Washington hearing on April 19, 1983. Since these proposed regulations are critical to patient welfare, we would like to submit the following comments for your consideration. In formulating our position, we involved a reference panel including experts in clinical medicine, health physics and radiation safety.

1. The regulations in general represent a major improvement over those currently existing, and will offer significant benefit to patients without compromising the safety of radiation workers and the public.
2. We believe that physicians applicants for licensing should continue to have their qualifications reviewed as a prerequisite to granting of the license. The cornerstone of competence rests with the physician's qualifications, thus providing the true basis for radiation safety in the administration of radiopharmaceuticals to patients.
3. A very important improvement in the proposed regulations is the section which does away with pre-review and approval of medical routines and procedures. Pre-approval has seriously hampered timely advances in patient care in NRC controlled states and government facilities such as the Veterans Administration and armed forces hospitals. Given a competent physician licensee, the very nature of medical routines requires that they be adjusted frequently, and such is now possible only with a formal amendment to the license. A commitment by the qualified physician licensee to follow approved procedures is all that should be necessary. Prior approval including the amendment process adds no guarantee whatsoever to the physician qualifications that approved procedures will be followed, and any appropriate deviation must be determined through the inspection process.

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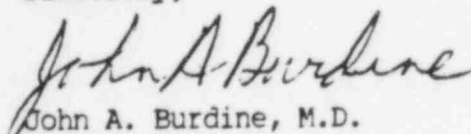
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4. The testimony from some NRC staffers grossly overstates the radiation safety problems to workers and the public in medical installations. It is obvious that the concerns from these staffers were presented in good faith, but they nonetheless provide significant misperception of the issues. The background of the individuals involved apparently has caused them to make the critical error of relating a nuclear reactor environment to the medical environment. The problems are entirely different between the two, both qualitatively and quantitatively. The radiopharmaceuticals utilized in nuclear medicine, for example, have none of the radiobiologic cancer producing potential of the transuranic radionuclides present in nuclear reactor facilities, and the quantities of radioactive material in nuclear medicine facilities are extremely small. The radiotherapy incident which apparently is one concern of a NRC staffer is a classic example where no regulations of any type can prevent lapses of competence in facilities containing qualified personnel who are thoroughly familiar with proper procedure. Fortunately, such occurrences are extremely rare.

Finally, let me emphasize that the Society of Nuclear Medicine bows to no one in its interest in protecting patients, radiation workers, and the public from inappropriate or dangerous radiation exposure. Radiation safety is of paramount importance to our 9500 physicians, medical scientists, and technologists. With the exception of our suggestion that establishment of physician competence be a prerequisite to licensing, the proposed 10CFR35 regulations are an excellent and long overdue improvement in NRC policy which will provide substantial patient benefit in the public interest without in any way compromising the human safety.

We would be most happy to provide you with any further information that you might request from our society.

Sincerely,


John A. Burdine, M.D.
President

JAB/sem

cc: Commissioner John Faherne
Commissioner James Kilburn Asselstine
Commissioner Victor Gilinsky
Commissioner Thomas M. Roberts
William J. Walker, Ph.D.