ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

September 16, 1996

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Jackson:

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) have conducted an extensive review of 10 CFR 35 and its current application to the field of nuclear medicine.[1] This review and discussion has resulted in the following proposal outlining how ACNP and SNM believe the Federal Government should approach regulations, should it retain control of radioactive material (RAM) used in medicine. It is noteworthy to point out these proposals are applicable to all RAM used in medicine, and would be an excellent proposal for Agreement States as well. We also believe that this provides the information which you requested during our meeting with you on March 25, 1996.

The development of this document has involved several paradigm shifts and a significant amount of time and effort from the members of the two organizations. We believe that this document will serve as a baseline for your agency, should it retain jurisdiction over the medical program, to develop an updated version of 10 CFR 35. This proposal should not preclude the issuance of a broad scope license or other sections of 10 CFR 33 which may need to be addressed at a later date.

The ACNP and SNM approach simplifies the current version of 10 CFR 35 and establishes performance-based regulations without detailed specifications on what should and should not be required of a licensee. The proposed regulations clearly state the ultimate performance goal to be met by the licensee and establish a level of measurement from which a state or federal entity could evaluate licensee performance. We believe that developing performanced based regulations is consistent with the discussions of the medical staff and the NRC's Advisory Committee for the Medical Uses of Isotopes. It is also important to note that this proposal does not address the field of radiation oncology. ACNP and SNM believe that the regulations necessary in that area are more appropriately addressed by other organizaitons.

We believe that commercial nuclear pharmacies should be licensed with other medical practitioners (part 35) not with manufacturers (part 32). Thus we believe that it is important that many of the suggestions in this proposal be applied to commerical nuclear pharmacies.

[1] ACNP and SNM represent over 12,000 nuclear medicine physicians, pharmacists, scientists, and technologists dedicated to the research and practice of nuclear medicine.

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Acknowledged by card 10/10/96 DMO

This proposal represents draft regulatory language of the key components that ACNP and SNM believe should be included in either state or federal regulation:

§ 35.1 (Purpose) *This section describes requirements for Authorized Practitioners and Authorized Nuclear Pharmacists and Radiation Safety officers.*

§ 35.5 (License required) *A general license shall be issued for the use of radioactive materials in medical care to: (a) any person who is an authorized practitioner in accordance with section 35.35. A general license shall be issued for the use of radioactive materials in nuclear pharmacy practice to any person who is an authorized nuclear pharmacist in accordance with section 35.40. A person shall not receive, acquire, possess, use, or transfer radioactive material under this general license unless that person has filed form NRC-313 "Application for Materials License" with the Director, NMSS, and has received a validated copy. Use of radioactive material under this general license does not exempt the licensee from any other regulatory requirements of the NRC, FDA, or the states.*

§ 35.10 (ALARA) *(a) Each licensee shall have a radiation protection program to keep worker, patient, and general public dose "As Low As Reasonably Achievable" (ALARA), and make a reasonable effort to ensure that such doses are maintained ALARA; (b) The program must include; notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of radioactive material used, occupational doses, radiation safety procedures and safety measures, and continuing education and training for all personnel who come into contact with radioactive material on a regular basis. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.*

§ 35.15 (Supervision) *A licensee may permit the receipt, possession, use, preparation, or transfer of radioactive material by an individual under the supervision of an authorized practitioner or authorized nuclear pharmacist. Each authorized practitioner and authorized nuclear pharmacist is responsible to the extent considered reasonable, for the individuals working under his/her supervision.*

§ 35.20 (Patient Release) *Authorized practitioners must conduct their practices in such a way as to give a high level of assurance that members of the general public cannot receive more than 500 mrem from a radiopharmaceutical procedure. The licensee should provide the patient or other responsible party with radiation safety guidance that will help to keep radiation dose to involved and uninvolved members of the public as low as reasonably achievable.*

The ACNP and SNM believe that the regulations proposed above represent the core regulations from which 10 CFR 35 should be constructed. There are obviously some definitions and administrative sections that need to be added to complete this part and we believe that those would become evident to the implementing body. This proposal, implemented over a period of three years, and accompanied by an immediate relaxation of many of the requirements currently contained in part 35, would create a workable system that recognizes the immense amount of education and training already inherent with the practice of medicine and pharmacy. We do emphasize, however, that these regulations should not be accompanied by excessive paperwork or recordkeeping requirements requests and that inspectors, with medical experience, would be able to evaluate the performance of a facility without undue reliance on the review of records.

ACNP and SNM hope that the Commission will give this proposal serious consideration when discussing any changes to 10 CFR 35. ACNP and SNM leadership are available to meet with the Commissioners and their staff following a review of this document and wish to continue moving forward with the process of reforming the regulation of radioactive material. Should you have any questions about this document, feel free to contact Mr. David Nichols, Associate Director of Government Relations, at (703) 708-9773.

Sincerely,

David R. Brill, M.D.
President
American College of Nuclear Physicians

Michael D. Devous, Sr., Ph.D.
President
Society of Nuclear Medicine

cc: The Honorable Kenneth C. Rogers, USNRC Commissioner
The Honorabe Greta Joy Dicus, USNRC Commissioner
The Honorable Nils J. Diaz, USNRC Commissioner
The Honorable Edward McGaffigan, Jr., USNRC Commissioner