PDR : PER
D. MOSSBURG

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

November 13, 1996

Dr. Carol S. Marcus, President
American College of Nuclear Physicians
California Chapter
Box 31
Los Altos, California 94023

Dear Dr. Marcus:

Thank you for your letter of October 16, 1996, which provides comments on a September 16, 1996 proposal by Dr. David R. Brill, President of the American College of Nuclear Physicians (ACNP), and Dr. Michael D. Devous, Sr., President of the Society of Nuclear Medicine (SNM). For your information, Drs. Brill and Devous were informed on October 21, 1996, that, since their letter was not submitted formally as a 10 CFR 2.802 petition for rulemaking and since they specifically state that there "are obviously some definitions and administrative sections that need to be added to complete this part," their letter would be docketed for later review. The draft regulatory language they submitted will be considered when the staff responds to Commission direction regarding the Strategic Assessment and Rebaselining effort, particularly Direction Setting Issue Paper No. 7, "Materials/Medical Oversight."

The staff will docket your letter and consider your comments when reviewing the ACNP/SNM letter as part of the Strategic Assessment process.

Sincerely,

Shirley Ann Jackson

Shirley Ann Jackson

1/1

DFO2

210031

ACNP

American College of Nuclear Physicians

California Chapter

Dorothy Duffy Price
Executive Director

Box 31
Los Altos, CA 94023

TEL (415) 949-1341
FAX (415) 949-1341

October 16, 1996

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

Dear Chairman Jackson:

The Executive Board of the American College of Nuclear Physicians-California Chapter (ACNP-CA) has completed its review of the letter sent to you on Sept. 16, 1996 by David Brill and Michael Devous, Presidents of ACNP and the Society of Nuclear Medicine (SNM) respectively, concerning 10 CFR Part 35. Our Executive Board believes that clarification of some of the contents of this letter is urgently needed.

During the annual meeting of both organizations in June, 1996, the following resolution was introduced: "The Government Relations Committee recommends that the governing bodies of the ACNP and SNM endorse the IOM report conclusions regarding the inappropriate regulation of the use of byproduct material in medicine (as contained in 10 CFR Part 35) and endorse the need for urgent regulatory reform. ACNP and SNM also offer their support to state and federal agencies to achieve the necessary regulatory reform". This resolution was approved by the Government Relations Committee and governing bodies of both organizations. The American Medical Association (AMA) also endorsed this need for regulatory reform and supported the immediate relaxation of the "Quality Management" rule. The Executive Board of ACNP-CA also agrees with these positions. We wish to point out that the letter of Sept. 16 from the two Presidents in no way alters commitment to the resolution stated above. It means to offer suggestions to the NRC "should it retain jurisdiction over the medical program". It does not advocate that NRC retain this jurisdiction, and we in California certainly do not wish to see NRC retain it.

In the NAS-IOM Report of 14 Dec. 95, NRC was given 12 months to end Part 35 and onerous license conditions related to it, or else it was recommended that Congress remove NRC's statutory authority in the medical (including pharmacy) areas. Nearly a year has past, and NRC has made no progress. Indeed, NRC is clearly

JACK1016.CHR

heading in the opposite direction. In a recent paper on Agreement State adequacy and compatibility, NRC has determined that all Agreement States must have essentially identical medical (including pharmacy) programs to NRC, and that all states must, curiously, repudiate their Boards of Pharmacy, regulate Nuclear Pharmacy as "manufacturing", and do so in accordance with an NRC guidance document that was due out in Dec. 1994, but has conveniently not yet appeared. The rationalization was "uniformity in interstate commerce", but surely you know that the practice of pharmacy, like medicine, is a state-regulated activity exclusively concerned with intrastate commerce. Why would NRC want to take its ill-conceived medical (including pharmacy) programs, and inflict it on everyone instead of getting rid of it at long last? And why, in NRC's recent Strategic Assessment document, does NRC in essence state that when millions of doses of radiopharmaceuticals are compounded by technologists under the supervision of physicians that this is a low-risk activity, but that when millions of doses of the same radiopharmaceuticals are compounded by nuclear pharmacists, that this is a high risk activity? This is illogical and exposes an apparent agenda at NRC to regulate the practice of nuclear pharmacy. All these activities are low risk, including nuclear medicine therapy.

The Sept. 16 letter also points out that both organizations endorse the use of "performance-based regulations without detailed specifications", but the Presidents were apparently unaware that NRC considers the Quality Management Program (QMP) to be a "performance-based regulation". In fact, the QMP is a prescriptive rule, and we do not feel that our concept of "performance standards" and those of NRC are fully compatible.

The Executive Board of ACNP-CA does not support the need for ALARA programs in medical practices as currently required in 10 CFR Part 35. All worker and public doses are already so low that getting them lower, and describing exhaustive programs to get them lower, are not scientifically defensible and are a waste of precious healthcare funding that needs to be spent instead on

clinical patient care. The ACMUI has sought to end this requirement for the past six years.

ACNP-CA does not believe that the supervision portion is needed. The licensee is responsible, and how it chooses to fulfill that responsibility is the licensee's choice.

ACNP-CA believes that the Patient Release section is unnecessary, and that it is time to return to the 500 mrem level for all medical uses. This should be simply stated in Part 20. A petition to achieve this was submitted as a 10 CFR Part 20 petition nearly five years ago.

We also wish to comment on the sections in the Sept. 16 letter relating to the training of RSO's, Authorized Practitioners, and Authorized Nuclear Pharmacists. NRC's obligation to the public and to patients and workers is to ensure that all authorized practitioners (we include pharmacists here) be licensed by NRC or an Agreement State based solely upon the ability to appropriately manage the safe handling of radioactive material. Professional competence credentialing, and qualifications for medical and pharmacy practice (privileging) are outside the radiation regulator's expertise and authority. We subscribe to the Statement on Credentialing and Delineation of Privileges, a conjoint statement of the SNM, ACNP, and American College of Radiology (ACR). We believe that NRC should leave such issues of professional practice to the JCAHO and appropriate professional medical and pharmacy groups.

ACNP-CA does not understand why the Presidents recommended a three year implementation plan in their Sept. 16 letter. The NAS-IOM said one year, and we agree with that. While it may take more time to phase in new requirements, it takes no time at all to relieve medical and pharmacy practitioners of onerous requirements.

ACNP-CA does not agree with the part of the Sept. 16 letter in which the Presidents concede that NRC needs to "add definitions and administrative sections". We are very leery of asking NRC to add anything we have not approved and reviewed when the record of the NRC in recent years has not inspired the confidence of the medical community.

In the recent Congressional Hearings on NRC's progress in compliance with the recommendations of the NAS-IOM, Congressman Michael Bilirakis (R-FL) made the point that as 90% of ionizing radiation medicine is already safely regulated by all 50 states, the 10% involving byproduct material could be absorbed easily without any need for the NRC. Of course, no state would do it exactly the way NRC has done it. This is the point made by the NAS-IOM, and with which we agree.

We would like to also point out that in NRC's Strategic Assessment document on medical programs, issued Sept. 16, 1996, the solution favored by your predecessor, Ivan Selin, in his address to the NAS-IOM, is not even included as an "option"! Chairman Selin, recognizing that each state, but not NRC, has a Board of Medicine and a Board of Pharmacy, recommended that there be a uniform national radiation protection standard, 10 CFR Part 20 (which we already have), and that all other aspects of medicine and pharmacy be left to the states because they already have their frameworks in place. State Radiologic Health entities would not regulate the practices of medicine and pharmacy at all, but would enforce the Standards of Part 20 exclusively. The ACNP and SNM agreed with this plan, and so did the NAS-IOM. We recommend that you consider its merits. Chairman Selin came to his conclusion after wrestling with the problem for three years. We believe you could save yourself a great deal of time and energy by starting where he left off.

Another curious fact about the Strategic Assessment document is that it discusses Section 81 of the Atomic Energy Act, which gives general information concerning byproduct materials, but surprisingly completely omits Section 104, the only place in the Act in which medicine is specifically mentioned. When you review Section 104, you will realize that Chairman Selin's concept is completely in keeping with the intent of the Act, but that your present program is not. The states continue to protect the public health by enforcing the safe use of all forms of ionizing radiation including the use of radionuclides produced in accelerators. They often do so with minimal regulation, the same "minimal regulation" ordered in the Atomic Energy Act which NRC has steadfastly ignored.

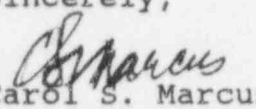
There are so many other convenient omissions and distortions in this Strategic Assessment document that we recommend that you ignore it. It was, after all, prepared by staff whose jobs are at stake if the recommendations of the NAS-IOM and those of Chairman Selin are implemented. This has at least the appearance of a "conflict of interest".

The only real question left concerns the need for a federal or national "safety net" for the states. The NAS-IOM did not think it necessary; the ACMUI felt it was needed for enforcing authorized user qualifications, but that NRC should definitely not be the group responsible. There are other groups that could be considered, and this is where our discussions should start.

We believe that it would not be necessary to change the Act to put Chairman Selin's concept in place, despite the apparent insistence of your Office of General Counsel.

Thank you for the opportunity to clarify aspects of the Sept. 16 letter submitted by our two national Presidents. Please address any inquiry to our Executive Director, D. Duffy Price, who will forward it to the appropriate individual(s).

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
Harbor-UCLA Medical Center
and
Professor of Radiological Sciences,
UCLA
and
President, American College of Nuclear
Physicians, California Chapter

cc: Commissioner Greta Dicus
Commissioner Nils Diaz
Commissioner Edward McGaffigan
Commissioner Kenneth Rodgers
Hugh Thompson, Deputy EDO

CSM:sfd