

PDR



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

February 14, 1994

CHAIRMAN

Conrad E. Nagle, M.D.
President
American College of Nuclear Physicians

Richard C. Reba, M.D.
President
Society of Nuclear Medicine

1101 Connecticut Avenue, NW
Suite 700
Washington, D.C. 20036

Dear Drs. Nagle and Reba:

On behalf of the Commission, I am responding to your December 29, 1993 letter regarding the adequacy of the Nuclear Regulatory Commission's training and experience criteria for physicians authorized to use radiopharmaceuticals for therapeutic use in patients. The Commission appreciates your comments, but we are disturbed by your suggestion that NRC policy is ". . . producing a dangerous distribution of therapeutic radiopharmaceuticals to physicians who are inadequately qualified."

Recent NRC experience suggests that most medical misadministration errors and regulatory violations are caused by inattention to detail, ineffective management systems, and lack of training of allied health-care personnel rather than physician qualifications. If your organizations or any of their members have data to demonstrate that a dangerous health and safety situation exists, we strongly urge you to share that data with the NRC.

The adequacy of NRC's current training and experience requirements for this category of medical use was discussed with the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) during the May 1993 meeting. Although the Committee advised the NRC that the available data was insufficient to justify a change in regulatory requirements, it suggested the need for a "paradigm shift" in NRC requirements to define a minimum level of radiation safety education and validation of that education.

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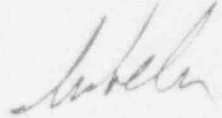
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Drs. Nagle and Reba

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NRC's Medical Management Plan includes the issuance of a new Advance Notice of Proposed Rulemaking to include redefinition of training and experience. As part of this process, NRC will solicit comments from your organizations and input from other medical groups and interested individuals.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ivan Selin".

Ivan Selin

cc: Dr. Barry Siegel