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DEPARTMENT OF NUCLEAR MEDICINE

(142)

PROPOSED RULE PR-35(43FR29297)

September 29, 1978

Robert B. Minogue, Director
Office of Standards Development
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Minogue:

I have been given the opportunity to review the proposed rule on misadministration reporting requirements by the Nuclear Regulatory Commission as published in the Federal Register, Volume 43, number 131, July 7, 1978, page 29297. I would like to take this opportunity to offer some comments on the rule.

The concept of record keeping and reporting of misadministrations of therapeutic materials is an excellent one. It is a practice consistent with good medical care and is currently employed in many medical centers. The wording of the rule suggests that misadministrations that may cause "a clinically detectable adverse affect on the patient" be reported. The administration of diagnostic radiopharmaceuticals, even misadministrations, cannot to the best of anyone's knowledge cause such an affect. If therefore, it is the Commission's intent to require only the reporting of misadministrations that can cause clinical affects, I would suggest that the wording be changed to reflect that we are discussing therapeutic administrations. I believe there would be considerable confusion in the medical community as well as possibly undue concern upon the part of patients who might undergo misadministration of diagnostic materials from which there would be no anticipated clinical affects.

Secondly, the requirement placed on the Nuclear Medicine physician to report directly to the patient or his representative, the misadministration, is poor medical practice. Since in general, physicians in Nuclear Medicine do not report favorable findings to patients, why should the restriction that they must report unfavorable results to the patient be imposed on them. It is our obligation to report our findings and actions to the referring physician who is in charge of that patient's management. Direct reporting to the patient's family or the patient himself interposes the Nuclear Medicine physician between the referring physician and the patient. There may be legitimate circumstances under which the reporting of such information to the patient would be detrimental to the patient's medical condition. The only individual who would be aware of this possible affect would be the physician in charge of the case. Therefore, I would propose that the requirements of reporting to NRC and to the referring physician be maintained. However, the direct reporting by the Nuclear Medicine physician to the patient or his representative, should be deleted from the proposed rule.

I have taken the opportunity to discuss my comments with a number of my colleagues in Nuclear Physicians of Illinois, the State organization for Nuclear Medicine physicians. I am responding as chairman for legislative affairs of Nuclear Physicians of Illinois.

Thank you very much for your attention.

Yours truly,

Robert E. Henkin, M.D.,
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