St. Joseph's Hospital 350 North Wilmot Road • P.O. Box 12069 85732 • Tucson, Arizona • (602) 296-3211

DOCKET NUMBER
PROPOSED RULE PR-35 (43FR29297) (58)

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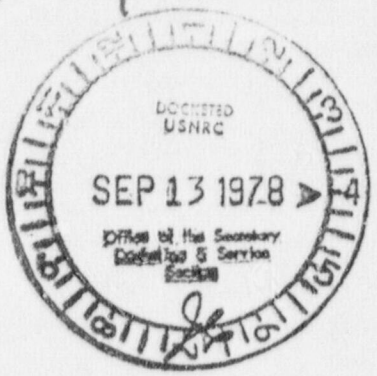

September 1, 1978

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

Gentlemen:

I am writing in response to your request for comments regarding the proposal to amend Nuclear Regulatory Commission regulation 10 CFR-Part 35. I am strongly opposed to the proposed amendment. In my opinion, this amendment is unwarranted, unnecessary, and quite possibly illegal and unconstitutional. I feel that it is unnecessary as the handling of misadministration of radioactive material is quite adequately and responsibly handled at the local level, at least in our facility. It is unwarranted as the primary effectiveness of the NRC should be in the area of dealing with qualifications, licensure, distribution of radioactive materials, and assisting development and enforcement of hospital policies rather than dealing with the problems of day-to-day medical practive. Lastly, the question of legality and constitutionality of this amendment is raised. The amendment as written certainly represents what I consider undue and inappropriate involvement in the physician-patient relationship. It should be noted that this letter refers only to radioisotope administration as utilized in the practice of nuclear medicine and does not apply to other sources of radiation.

The following are more specific comments regarding the proposed amendments. These are not to be construed as implying that alteration of the amendment based on these comments would render it acceptable to the undersigned.

At St. Joseph's Hospital, Tucson, Arizona, misadministrations of radiopharmaceuticals are fortunately rare. When they do occur, the patient and referring physician are immediately notified and appropriate arrangements made to minimize inconvenience to the patient for completion of an adequate diagnostic study. To date, a situation has not arisen where a member of the medical "team" felt that informing the patient would be harmful. On each occasion an incident report is filed with Administration for review and comment by appropriate medical and administrative authorities. This arrangement has proved entirely satisfactory; and on the two occasions in which misadministration has occurred, patient care has not been adversely effected, and corrective measures were taken where indicated. I feel that current departmental and hospital policies are fully adequate and the involvement of an additional agency would be burdensome and superfluous.

I feel the following are equally significant considerations supporting my opinion that this is a bad regulation:

1. Reporting would be necessary when a misadministration would result in a "clinically detectible adverse effect." Adverse effect is not defined, and could be interpreted within a wide range varying from direct harm to the patient at one extreme to unsuitable diagnostic results at the other extreme. This renders totally invalid any realistic criteria for reporting.

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2. It is stated a diagnostic dose of a radiopharmaceutical differing from prescribed dose by more than 20% warrants being reported. It should be noted that some radiopharmaceuticals have a prescribed dose range that varies more than 20%, e.g., Xenon 133 Ventilation Studies. Also, if a patient appears in the department later than his appointment, a precalibrated dose may be more than 20% less than the actual prescribed dose. A radiation dose less than the prescribed dose certainly could in no way be harmful to the patient even though an adequate diagnostic study could probably be obtained.

3. There is no statement in this regulation as to limitations on use of reports by the NRC. If this became public information, the potential for multiple nuisance malpraccice suits is significantly increased.

4. Adequate handling of the rare instances where this does occur are, as noted above, effectively dealt with in this facility.

The above statements represent a brief critique of the proposed amendment. Suffice it to say, I feel that Amendment 35.33 to 10 CFR Part 35 is totally unnecessary an undesirable. This would be an addition to the already overwhelming number of federal mandates with which medical facilities have to handle by increased staff time and paperwork, which invariably increase the cost of medical care as well as expanding the associated bureaucracies and tax obligations necessary to support them. If the NRC is to be reasonably appropriate and effective in meeting the objectives implied by the amendment, attention should be focused on making certain that hospital, medical and administrative authorities appropriately deal with these problems at the local level.

Respectfully submitted,

James D. Van Antwerp, M.D.
Nuclear Medicine/Ultrasound Department

JDV:mbw

cc: Robert Hastings, M.D.
President, Pima County
Medical Society