

NRC PUBLIC DOCUMENT ROOM
UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

MAILING ADDRESS:
RADIOISOTOPE LABORATORY
CINCINNATI GENERAL HOSPITAL
CINCINNATI, OHIO 45267

DOCKET NUMBER
PROPOSED RULE 35(43FR29297)

148

November 24, 1978



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

Attn.: Docketing and Service Branch

Re: Human Uses of Byproduct Material - Misadministration Reporting
Requirements (Federal Register, Vol.43, No. 131, July 7, 1978)

Gentlemen:

This letter is being written in my capacity as consultant to the Nuclear Regulatory Commission as a result of a recent case in which a misadministration of a radiopharmaceutical occurred.

For a number of reasons I was not called in my consultant capacity for a period of about two weeks following this incident. The particular circumstances which are dealt with in the official reports rendered to the NRC concerned the fact that the wrong radioactive material was administered to a patient.

In spite of not being called during this interval the physicians involved, the hospital at which this incident occurred immediately notified the family, the various attending physicians and the administration of the hospital were immediately notified. The Regional office of the NRC was notified by phone.

My only point in bringing all of this to the attention of the Commission is to urge re-thinking of the statements on misadministration. Had this incident been reported promptly to a medical consultant it is probable that the bulk of the offending inappropriate radioactive material could have been eliminated from the patient rather promptly. By the same token, the hospital fulfilled its responsibilities in notification of the patient, his family and other appropriate individuals within the region.

It still seems to me to be a severe penalty to publicize such incidents in the public document room. Insofar as the care of an injured patient is concerned what is needed is expert medical attention rendered promptly. To this degree I would urge that the proposed regulation be reconsidered in some detail perhaps by the panel of medical consultants. The course of action which would seem to me to be most practical would be to publicize widely the availability of medical consultation through the NRC and such other consultants as the NRC consultants themselves would recommend and that the matter be handled with complete anonymity in regard to notification in the public document room.

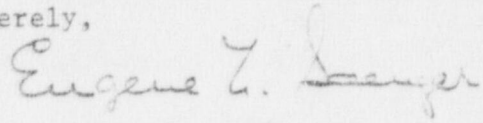
If the purpose of supervision by the NRC and the use of medical consultation is to be directed to the best possible medical care of the patient rather than administrative and/or punitive actions by the NRC such a course would seem to be most logical.

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I would be pleased to discuss this matter in greater detail if requested.

Sincerely,

A handwritten signature in cursive script, reading "Eugene L. Saenger". The signature is written in dark ink and is positioned below the word "Sincerely,".

Eugene L. Saenger, M.D.
Medical Consultant

ELS/swh

cc: Region III - NRC