September 21, 1978

(100)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555 DOCKET NUMBER
PROPOSED RULE PR-35 (43FR29297)

Attn.: Docketing and Service Branch

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

Dear Sir:

The American College of Nuclear Physicians (ACNP) wishes to comment on this proposed rule concerning misadministrations.

In Section 35.33A the ACNP would agree that the licensee should notify the patient's referring physician, the patient or responsible relative and should follow such other channels as are indicated within the hospital, institution or private office in which the physician practices for notification of misadministration.

The matter of notification of the NRC Regional Office or other agency of the NRC under current regulations is unacceptable since such notification becomes a matter of public record in the Public Document Room of the Nuclear Regulatory Commission and as such simply provides the physician and institution with identity for nuisance, unwarranted publicity and suits by parties who are not injured by the misadministration or would have any claims against the physicians or hospital except for the fact of the information provided through the Public Document Room. It should be emphasized in this regard that the ACNP supports completely the proper notification of the patient, his family, the local institutional authorities and such other individuals as are party to a misadministration.

In regard to 35.33 item E, there is no objection to proper maintenance of records by a physician or an institution concerning misadministration.

Concerning item F, the definitions of misadministration are incorrect as applied to patient care. For a diagnostic dose there is no real relationship between a route of administration other than that intended by the prescribing physician and such circumstances as described in paragraph A resulting in a "clinically detectable adverse effect occuring within 24 hours or within a few days thereof". Also it is not possible to obtain a clinical effect with a 20% excessive dosage.

Under item F4, to propose a difference in amount more than 20% in a diagnostic dose is also unreasonable. Diagnostic doses of greater orders of magnitude vary in different institutions depending on the nature of the patient's clinical problem, the experience of the physician, the nature of the detecting apparatus and the information sought in the proper management of a particular case.

Similarly item F5 requiring reporting of a difference of more than 10% in a therapeutic administration is also incorrect since doses of greater than 10% have been given to patients under many circumstances without untoward results. It may be possible to generate proper criteria for definitions of misadministration but such criteria should be arrived at by appropriate review of medical experience and not by arbitrary definition.

Acknowledged by card. 10/4

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Administration of a radiopharmaceutical to the wrong patient might occur from time to time with the frequency of 1 in 5,000 or 1 in 10,000. No data are offered comparing misadministration of these drugs or other laboratory tests to patients.

In regard to therapy there has been only one incident of a serious nature regarding misadministration, that occuring at the Riverside Methodist Hospital in Columbus, Ohio. There were certainly two clearly demonstrable deaths resulting from this circumstance. There have been about 4 or 5 deaths from errors in dosage or chemical form between 1950 and 1978. The impact of such a rule for misadministration will result in the termination of the use of cobalt-60 teletherapy units and substitution of linear accelerators and similar radiation-producing sources not under the control of the Nuclear Regulatory Commission. Similarly this 10% limit is an excellent way to encourage the replacement of the more suitable cesium-137 brachytherapy sources with radium sources, again not a change in the best interests of patients or the public.

One of the major objections to this entire document is the fact that nothing is stated concerning the disposition of records to be required by the Nuclear Regulatory Commission in relation to the Freedom of Information Act. If, as noted above, such documents are placed in the Public Document Room identifying clearly the licensee, this practice will simply expose the institution to unnecessary deleterious publicity, suits for malpractice, nuisance suits and will not serve either the interest of the patient or the institution. If there is evidence of malpractice the patient is appropriately notified and protected by institutional requirements through the notification of himself or his family, the referring physician and the institution.

If the NRC persists in this course of public record keeping it is doubtful that many physicians will comply, preferring to take their chances with the situation of "misadministration" as defined under this rule rather than exposing themselves in a unilateral fashion. It is also difficult to know just exactly what the NRC would propose to do after this public notification and the degree of penalty that the NRC might assess could not be in the best service of the patient to whom the misadministration occured. It is also possible that this activity could create various conflicts with state licensure.

Therefore the present proposed rule seems entirely inadequate and should be withdrawn and re-evaluated so that patients can be properly protected without subjecting the institution and physicians to unnecessary abuse. The ACNP would be pleased to cooperate with the NRC to develop suitable recommendations for untoward events affecting patients being diagnosed or treated by byproduct materials or other radioactive substances for which the NRC has jurisdiction.

Sincerely,

Howard Dworkin, M.D., President
American College of Nuclear Physicians

Eugene L. Saenger

Eugene L. Saenger, M.D., Chairman
Commission on Governmental Affairs

HJD:ELS:swh