University of
Arkansas
for Medical
Sciences

4301 W. Markham
Little Rock, Arkansas
72201

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DOCKET NUMBER
PROPOSED RULE PR-35(43FR29297)

September 29, 1978

The Secretary
U. S. Nuclear Regulatory Commission
Washington, D. C.

Attention: Docketing and Service Branch

Dear Sir/Madam:

As permitted by law and requested in the July 7 issue of the Federal Register, I would like to make the following comments regarding the proposed rule cited in FR Document No. 78-18735 affecting Title 10 Part 35.33, "Records and Reports of Misadministration".

In order to preserve some respect for the NRC's integrity and ethics, I must assume that the intent of this rule is to 1) safeguard the public (us) as consumers from irresponsible health care practices, and 2) identify the causes for misadministrations for the purpose of correcting them and preventing their reoccurrence in the future or at other sites. Both of these objectives are appropriate, needed, and worthy, in my opinion.

The manner in which the rule is stated and in light of the realities involved, I do not feel that this rule will accomplish either goal.

The reasons it will not prevent misadministrations are:

1) It is after-the-fact and there is no provision for what the NRC will do with the information compiled to correct the production, packaging, shipping, handling, administration, detection, or any number of potential causes for the error.
2) There is such variation across the country in the prescribed "dose" that a misadministration in one facility would not be so in another. Therefore, the 20% or 10% stated is effectively arbitrary and meaningless. These variations are not necessarily due to arbitrary choices in a given facility, however. The "correct" dose depends upon the patient, their condition, the instrumentation to be used, and other factors which can only be stated on a case by case basis.

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3) The definition of misadministration (". . . . other than the one intended") constitutes no definition at all.

Until or unless standardization of protocol, equipment, quality control, and training of personnel can be achieved, the efforts of the NRC in this area are futile. Far more would be accomplished by establishing equipment performance standards (realistic ones) and stipulating more concisely the competence of all personnel involved in nuclear medicine studies than will ever be accomplished by this rule. The emphasis should be on prevention not "finger pointing".

The second objective is also not met by the proposed rule. The self-incriminating nature of this rule will in no way affect the truly unscrupulous, irresponsible, or ignorant person. Only those of high moral character, with true dedication, and a sense of professional responsibility will comply with this rule. These individuals need only to become aware of a misadministration to take the proper action. This will inevitably result in smothering the flowers with shit and promoting the growth of weeds.

In a much broader sense, I question the wisdom of this rule because:

1) To my knowledge the NRC has not been given authority over accelerator produced or naturally occurring radionuclides. Both of these constitute a major source of diagnostic and therapeutic nuclides.
2) The Society of Nuclear Medicine has for sometime been compiling a registry of adverse reactions and other administration problems. These are made available to the FDA and the manufacturer.

I hope that I have conveyed a concern for and an interest in the same problems as the NRC because I am. I also hope I have conveyed my concern for regulations for the sake of regulations and not for the sake of correcting or preventing injury to the public.

Sincerely,

James F. Vandergrift, M.S.
Assistant Professor of Radiology
(Health Physics)

JFV/vv