UNIVERSITY OF VIRGINIA MEDICAL CENTER
CHARLOTTESVILLE, VIRGINIA
22908

DIVISION OF NUCLEAR MEDICINE

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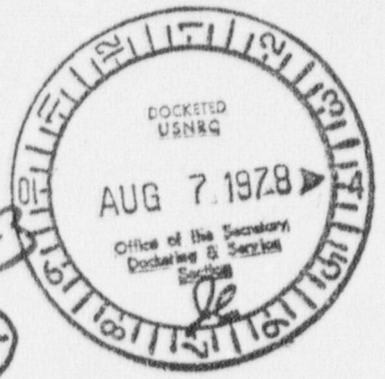

TP 102-3
(15)

Mr. Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR-35(43FR29297)

Dear Mr. Chilk:

Several points are of concern to me about the proposed rule concerning misadministration as I am a physical-chemist with 10 years of experience in nuclear medicine, I will comment on the physical and practical aspects of the proposed rule.

In §35.33 (f), (3) misadministration includes the correct radiopharmaceutical by the wrong route. Most of the radiopharmaceutical administrations are intended to be made intravenously. However, because of many circumstances including poor veins and venous collapse during administration, at least part of the dose is administered subcutaneously. Often this misadministration is not even detrimental to the reguired collection of image information, as in the case of Ga-67 imaging. I am concerned that labelling all missed injections as misadministrations may needlessly burden an apparatus intended for another purpose and unduly alarm everyone concerned. Careful technique can help to correct this source of error but cannot hope to solve it.

In §35.33 (f) (4) and (5), misadministration is defined using limits of ± 10% on therapeutic doses and ± 20% on diagnostic doses. I am concerned that the dose calibrator, the instrument used to measure the doses being administered, cannot itself be controlled to the required tolerance. The standard for dose calibrators is that they read within ± 10% for the standard sources, which should be traceable to the National Bureau of Standards sources. Depending on the design of the calibrator however, the standard source may be read acceptably while other sources, in other geometries, may not be read accurately at all. There have been several comparisons of dose calibrators suggesing that the results may be precise but not accurate. I feel it is thus a mistake to set the tolerance for misadministration too finely. I believe a statistician should be consulted for suggestions on a reasonable level of error.

Thank you for the opportunity to comment on the proposed rule.

Sincerely yours,

Barbara Y. Croft

Barbara Y. Croft, Ph.D.
Assistant Professor

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Acknowledged by card. 8/8