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IN REPLY REFER TO: 646/115

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PROPOSED RULE PR-35 (43FR29297)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attention: Docketing and Service Branch

RE: Proposed NRC Rule 10 CFR 35.33 Records and Reports of Misadministrations.

Paragraph (a) indicates that misadministrations involving diagnostic procedures that could cause a clinically detectable adverse effect are to be reported. Paragraph (f) indicates that a misadministration may mean the administration of a diagnostic dose of radiopharmaceutical differing from the prescribed dose by more than 20 percent or simply the wrong radiopharmaceutical. In most such cases the administration of the wrong radiopharmaceutical or the radiopharmaceutical administered with a 20 percent error in the dose will not cause clinically detectable adverse effects. Most diagnostic procedures, in contrast to therapeutic procedures, will not result in detectable adverse effects on the patient. According to the definition of misadministration in paragraph (f), misadministrations of diagnostic doses are to be reported even when no clinically detectable adverse effects are likely to occur. I would suggest that item (4)(f) be excluded from the rule and that emphasis be given to the point that misadministrations to be reported include only those that could cause a clinically detectable adverse effect. Furthermore, it might be well to define what is meant by a clinically detectable adverse effect.

Sincerely,

D. P. SHREINER, M.D.
Chief, Nuclear Medicine Service

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Acknowledged by card. 8/14