

NOT ET NUMBER
PROPOSED RULE

(45)
PR-35(43FR29297)

August 24, 1978

chemistry

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Samuel J. Chilk, Secretary of Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

RE: Proposed rule change under Docket #7590-01
Human Uses of By-Product Material:
Misadministration Reporting Requirements

TP-3
102-3



cytology

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With reference to radio-pharmaceuticals, since distinct hazards of low-level radiation are not yet established, it would seem imprudent to needlessly worry a patient and/or his family with the suspicions of improbabilities. Any and all misadministrations, of course, should be recorded within the individual department records and steps taken within the department to assure that such misadministrations do not occur in the future. As in all other matters having to deal with the care of an individual patient, the patient's personal physician should be advised of the misadministration also, and he can then make the decision as to whether it is in the best interest of the patient to notify him or his family. The Nuclear Regulatory Commission may wish to ascertain that such records are kept by the individual department, but these should not be kept by the Commission since its records are all open to public purview. Needless to say, the unwarranted disclosure of a misadministration to a patient and/or his family could precipitate legal repercussions. This would then create an adversary position wherein the facts and known results are quite sketchy and incomplete, resulting in a legal panel or jury making decisions on emotional issues more than the facts at hand. Where direct harm can be demonstrated, then, the risk benefit ratio of the procedure has to be considered in light of the treated condition.

More data needs to be collected as to the possible harm of misadministration of radio-pharmaceuticals than we now have, and the majority of effort should be directed towards programs aimed at obviating the miscalculations, inconsistencies or aberrations that result in misadministrations.

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