



NEW YORK STATE ENERGY OFFICE

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DOCKETER UNIT

DEC 11 P2:41

emp

December 8, 1981

SECRETARY OF STATE
DOCKETING & SERVICE
BRANCH

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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Dear Sirs:

PROPOSED RULE - 35
(46 FR 43840)

The cognizant New York State agencies have reviewed the recent NRC proposed rule (46 FR 43840-42) which would, among other things, require specific medical licensees to measure the total activity of each radiopharmaceutical dosage, except those containing less than 10 microcuries or a pure beta-emitting radionuclide, before it is administered to a patient. While New York generally supports the proposed rule, the following comments are offered for your consideration.

As proposed, the rule would require the measurement of radiopharmaceutical dosages, even when such dosages are precalibrated by the manufacturer prior to shipment. Moreover, this rule would mean that the private practice physician who uses only small quantities of precalibrated diagnostic doses would be required to obtain dose measuring instrumentation. Our experience in New York indicates that precalibrated doses are not a significant problem since miscalibrations occur very infrequently. Consequently, we do not believe that requiring licensees to measure precalibrated doses is warranted.

The proposed rule does not appear to consider the possibly adverse situation which might arise if a licensee's dose calibration instrumentation fails or is otherwise unavailable. It would appear that under the proposed rule, the licensee would be required to suspend most nuclear medical procedures until such time as the equipment can be repaired or replaced. We believe that such a situation would result in an unnecessary curtailment of vital medical services and recommend that NRC address this possibility by incorporation of a provision allowing dosages to be calculated on an interim emergency basis.

The 10 microcurie threshold for measurement of radiopharmaceutical dosages appears to be arbitrary and artificial. In most cases, the procedure and instrumentation used to measure dosages exceeding 10 microcuries and to verify that others are below 10 microcuries will be the same. Since there does not appear to be any clear reasoning for the differing approaches, we recommend that all dosages be measured.

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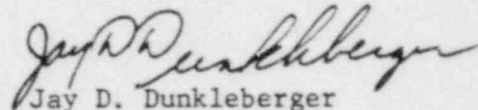
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Finally, we believe that the proposed rule should include criteria on the accuracy of the required measurements. In establishing such criteria, NRC should take into consideration the definition of a "misadministration" found in Section 35.41 of Part 35.

New York appreciates being given the opportunity of commenting on this proposed rulemaking.

Sincerely,



Jay D. Dunkleberger
Director
Bureau of Nuclear Operations

cc: Mr. Bernie Heald
Dr. Leonard Solon
Dr. Francis J. Bradley
Mr. Donald Nussbaumer