

October 20, 1981

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

DODIET NUMBER (46 FR 43846)

Gentlemen:

This is in reference to the September 15, 1981 N.R.C. notice in which the commission is proposing to amend its regulations in IOCFR35 to require specific category medical licensees to measure to verify that the total activity does not exceed 10 microcuries for each radiopharmaceutical dosage with an activity of 10 microcuries or less.

While we do agree with the Commission's proposal to require all radiopharmaceutical doses to be assayed in a dose calibrator and documented prior to administration, it is not feasible to measure doses less than 10 microcuries simply because dose calibrators are not accurate to within 10% below activities of 25 microcuries.

We urge this proposed regulation change, specified in Section Part 35 - Human Uses of Byproduct Material - Requirement to measure the activity of radiopharmaceutical dosages (b), of the recent notice be deleted.

Sincerely,

Charles L. W.

Charles G. Wieland, M.D. Director of Radiology

Site Sate

Peter J. Soto, M.D. Director of Pathology

Randall G. Benson, M.D. Medical Isotope Committee Chairman

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USNRC

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