



## DEPARTMENT OF HEALTH

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June 10, 1982

TO: Mr. Donald A. Nussbaumer, Assistant Director for State  
Agreement Programs, U.S. Nuclear Regulatory  
Commission

FROM: Dr. Leonard R. Solon, Director, Bureau for Radiation Control  
N.Y.C. Department of Health

SUBJECT: COMMENTS ON PROPOSED AMENDMENT OF TITLE 10 PART 35 OF THE CODE  
OF FEDERAL REGULATIONS TO PROVIDE EXCEPTION FROM NRC REQUIREMENT  
FOR TECHNETIUM 99m LABELED PENTATATE SODIUM FOR LUNG FUNCTION STUDIES

The proposed amendment would allow physicians to use technetium 99m labeled pentatate sodium for lung studies without regard to (1) chemical and physical form (2) route of administration and (3) dosage range. The proposed amendment would not require physicians to use the radiopharmaceutical in conformity with the product labeling and the package insert.

We have reviewed this proposal carefully. It is our opinion that the arguments furnished do not justify removing the protective restrictions on the use of technetium 99m labeled pentatate sodium which are in the best interest of the patient.

We suggest that a more detailed and convincing argument be made for exception of technetium 99m pentatate sodium from the restrictions in §35.14(b)(6) of the Code of Federal Regulations. Until this is done we must withhold support for the proposed amendment.

cc: Mr. Jack Spath, N.Y.S. Energy Office  
Dr. Karim Rimawi, N.Y.S. Dept. of Health

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