UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

December 2, 1988

MEMORANDUM FOR: Stewart D. Ebneter, Director
Division of Radiation Safety and Safeguards, RI

Douglas M. Collins, Acting Director
Division of Radiation Safety and Safeguards, RII

Charles E. Norelius, Director
Division of Radiation Safety and Safeguards, RIII

Richard L. Bangart, Director
Division of Radiation Safety and Safeguards, RIV

Ross A. Scarano, Director
Division of Radiation Safety and Safeguards, RV

FROM: Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: NOTICE OF INTENT TO REASSESS NRC REGULATIONS AND POLICY ON BYPRODUCT RADIOPHARMACEUTICALS

Several questions which may affect medical care have been raised in recent correspondence between the NRC and others regarding the human application of byproduct material. Specifically, questions regarding the scope of authority of broad licensees and nuclear pharmacies have been raised as to whether non-IND and non-NDA radiopharmaceuticals may be used in human applications, and, if so, under what conditions. There is a long history on the subject of the regulation of the medical uses of radionuclides going back to at least a policy statement issued in 1979 and possibly earlier when FDA assumed responsibility for evaluation of radiopharmaceutical safety and efficiency.

NMSS is reexamining the issues raised in the regulations and policy statements in this regard and hopes to resolve them shortly. Pending completion of this reexamination, all proposed enforcement actions on this matter, including those involving violations assessed at Severity Levels IV and V, should be referred to this Division with a copy to the Office of Enforcement before issuance in order to ensure consistent and appropriate disposition. Among the actions NMSS is considering are exemptions and the advisability of amending the regulations.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

cc: C. Kammerer, GPA