

medlab



TP-810-1
Podolak

DOCKET NUMBER
PROPOSED ACTION

(21)
-35(44 FR 24023)

May 10, 1979

chemistry

S. STEFAN BJORNSON, M.D.
P. JOHN PEGG, M.D.

cytology

A. CLINTON HEWES, M.D.
FRANCIS P. PARKER, M.D.
JAMES F. REAMER, M.D.

hematology

JOHN E. BENZEL, M.D.
VINCENT DeDUCA, JR., M.D.
JOHN J. EGAN, M.D.
R. CURTIS MILLS, M.D.
CHARLES M. SMITH, M.D.

microbiology

PARK W. HUNTINGTON, M.D.
ROBERT C. KNOWLES, M.D.

nuclear medicine

ROBERT L. MECKELNBERG, M.D.
VIDYA V. SAGAR, M.D.

pathology

PATRICK F. ASHLEY, M.D.
JOSEPH V. CASELLA, M.D.
ROBERT DICKERSON, M.D.

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

RE: Petition of George B. Taplin, M.D. to amend the "Human
Uses of By-Product Material", 10 CFR Part 35.

Dear Sir:

I strongly concur with the petition of Dr. Taplin to remove the present limitations on the use of approved radiopharmaceuticals for non-listed indications. The use of the radiopharmaceutical in question, technitium 99m DTPA as an aerosol for lung ventilation scanning is quite cogent. This particular agent's use would obviate some of the most difficult problems in radiation control in nuclear medicine laboratories today that are continuing to utilize radioactive xenon as a ventilatory scanning agent. The radioactive gases require the most elaborate control systems in nuclear medicine laboratories to limit exposure to all concerned whereas the use of an aerosol markedly reduces this exposure and in particular practically eliminates the airborne contamination in the surrounding atmosphere.

It is extremely unlikely that the commercial manufacturer of the radiopharmaceutical will go to the time and expense for submitting an IND for this new application. Thus, under the present rules the chance for utilization of an improved methodology would be stifled.

Sincerely,

Robert L. Meckelberg, M.D.

cc: George W. Taplin, M.D.

RLM/nlb

307 309

Delaware Medical Laboratories, Inc • (302) 994-5764

1 PIKE CREEK CENTER WILMINGTON, DELAWARE 19808

Acknowledged by card... dlh 5122

7907090/08