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Designator
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

APR 20 1984

MEMORANDUM FOR: Vandy L. Miller, Chief, Material Licensing Branch, NMSS

FROM: William L. Axelson, Chief, Materials and Safeguards Branch

SUBJECT: REQUESTS FOR EXEMPTION TO SECTION 35.14(b)(6) OF 10 CFR PART 35

We are forwarding the attached requests for exemptions/exceptions to Section 35.14(b)(6) of 10 CFR Part 35 from The Methodist Hospital of Gary, Gary, Indiana and The Alexian Brothers Medical Center, Elk Grove, Illinois for your review in accordance with Federal Register Notice, Volume 48, No. 25, February 4, 1983 (enclosed).

We have notified the licensee that we are forwarding their requests to you and that no exception is required for the use of technetium-99m as pertechnetate for radionuclide cystography (letters enclosed).

W L Axelson

William L. Axelson, Chief
Materials and Safeguards Branch

Enclosures: As stated

cc w/encls: D. R. Chapell, NMSS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Methodist Hospital of Gary
ATTN: Ivan Chermel, M.D.
Radiology
600 Grant Street
Gary, Indiana 46410

License No. 13-16558-01

Dear Dr. Chermel:

This is in response to your letter dated November 25, 1983, in which you request an exemption to Section 35.14(b)(6) of 10 CFR Part 35 to use technetium-99m as sodium pertechnetate and sulfur colloid for the evaluation of ventriculo-peritoneal, ventriculo-atrial, and or LeVeen shunt patency. We are forwarding your request to our Office of Nuclear Material Safety and Safeguards for review in accordance with Federal Register Notice, Volume 48, No. 25, February 4, 1983 (enclosed). Please be advised that this review may take several months; consequently, you may want to consider alternatives such as applying to the Food and Drug Administration (FDA) for acceptance of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or petitioning to the FDA Radiopharmaceutical Drug Advisory Committee to review for inclusion in the product labeling.

If you have any further questions or require clarification on any of the information stated above, please contact me at (312) 790-5625.

Sincerely,

William J. Olson

Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosure: As stated

cc w/o encl:
J. E. Glenn, RI
J. R. Potter, RII
R. J. Everett, RIV
R. D. Thomas, RV
R. Beyer, Vice President
Clinical/Professional Services

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Alexian Brothers Medical Center
ATTN: Thomas Rozek, Division Director
Professional Services
800 West Biesterfield Road
Elk Grove Village, Illinois 60007

License No. 12-12979-01

Dear Mr. Rozek:

This is in response to your application, received on October 5, 1983, in which you request an exception to the requirements in Section 35.14(b)(6) of 10 CFR Part 35 for the use of technetium-99m as sodium pertechnetate for radionuclide cystography and as macroaggregated human serum albumin (Tc-99m MAA) for assessing patency of LeVeen shunts. An exception is not required to use Tc-99m as sodium pertechnetate for cystography via catheterization of the urinary bladder, since the Food and Drug Administration (FDA) has approved the inclusion of this procedure in the product labeling for the Tc-99m generator manufactured by the Union Carbide Corporation, Tuxedo, New York, and it is our understanding that the FDA has sent a letter (August 1982) to all approved manufacturers of technetium generators and sodium pertechnetate requesting that they include the procedure for cystography in their product labeling.

As discussed in a telephone conversation between Mr. N. Lembares of your staff and Mr. R. Meyer of my staff on January 25, 1984, we are forwarding your request for an exception to the requirements to use Tc-99m for assessing patency of LeVeen shunts to our Office of Nuclear Materials Safety and Safeguards (NMSS) for review in accordance with Federal Register Notice, Volume 48, No. 25, February 4, 1983 (enclosed). Please be advised that this review may take several months; consequently, you may want to consider alternatives such as applying to the FDA for acceptance of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or petitioning to the FDA Radiopharmaceutical Drug Advisory Committee to review for inclusion in the product labeling.

If you have any further questions or require clarification on any of the information stated above, please contact me at (312) 790-5625.

Sincerely,

William J. Olson

for Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosures: As stated

cc: See Attached List

cc w/o Encl
Glenn RI Everett RIV
Potter RII Thomas RV