PUBLIC 34-01216-03 030-02672

JAN 1 2 1994

St. Vincent Medical Center ATTN: Kathryn J. Royen, Ph.D., D.A.B.R. Radiation Safety Officer Senior Medical Radiation Physicist 2213 Cherry Street Toledo, OH 43608

Dear Dr. Royen:

This is in response to your letter dated December 23, 1993, requesting interpretation of 10 CFR 35.400(f).

The use of iodine-125 seeds as described in your letter dated December 23, 1993, is consistent with that listed in 10 CFR 35.400(f).

If you have any questions or require clarification on any of the information stated above, you may contact us at (708)829-9500.

Sincerely,

Original Signed By Robert G. Gattone, Jr. Nuclear Materials Licensing Section

Enclosure: 10 CFR Part 35

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December 23, 1993

U.S. N. R. C. Region III 799 Roosevelt Road Glen Ellyn, Illinois 60137

> Re: Medical Byproduct Materials License No. 34-01216-03 St. Vincent Medical Center Request for Clarification

Dear Sirs:

St. Vincent Medical Center wishes to perform Ophthalmic Brachytherapy using Iodine-125 in eye plaques sutured to the back of the eye. As you are aware, this application results in the plaque being held between tissue layers inside the skull as the eye is rotated back into proper position at the conclusion of the surgery. Strictly speaking, then, this is an interstitial use of the isotope, and our current limited-scope license should permit its use in this application. Of course the Quality Management Program for Brachytherapy currently in place at our institution would be followed in the implementation and execution of this new procedure.

However, we wish to receive validation of this interpretation of 10CFR35.400(f) from your office. Please respond by phone and letter regarding your position on this issue.

This is a new program for our institution, and patients are scheduled for surgery on January 13, and January 20, 1994. Any amendment process which you may require would have to be expedited on the basis of a medical emergency. We would appreciate your assistance, advice, and review of this matter as quickly as practicable. Please contact me, therefore, at (419)321-4044.

Thank you for your attention to this request.

Sincerely,

Kathryn J. Royen, Ph.D., D.A.B.R. Radiation Safety Officer Senior Medical Radiation Physicist

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UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

Au. 14, 1994

NOTE FOR: DOCUMENT CONTROL DESK

FROM: LICENSE FEE AND DEBT COLLECTION BRANCH, OC/DAF

THE ENCLOSED MATERIALS LICENSING DOCUMENTS ARE BEING FORWARDED FOR PLACEMENT ON THE NUCLEAR DOCUMENTS SYSTEM IN ACCORDANCE WITH MAY 21, 1984 PROCEDURES.

LICENSE FEE and DEBT COLLECTION BRANCH DIVISION of ACCOUNTING and FINANCE OFFICE of the CONTROLLER