Medical Center

54th Street and
48th Avenue South
Minneapolis MN 55417

Veterans Administration

February 10, 1988

In Reply Refer To: (618/115)

U.S. Nuclear Regulatory Commission
ATTN: Mr. John Madera
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

SUBJ: Additional information concerning the I-131 labeled monoclonal antibody study. Control number - 84611.

1. Diagnostic procedure. The patient is admitted to the hospital and placed in a private outside corner room. He has a private bath and the bed is located in the outside corner of the room. 5 to 50 mCi of the I-131 tagged antibody is given I.V. The dose is in 100 ml of saline and is dripped in over a period of 1 hour. After 24 hours, in the case of a 5 mCi diagnostic dose, the patient is taken to the Nuclear Medicine Department for a total body scan to determine the tumor uptake (the thyroid is blocked to prevent any free iodine uptake). In the case of a 50 mCi diagnostic dose, we wait 48 hours before scanning the patient.

All patients use this room on the ward with the same nursing staff. In any diagnostic dose over 5 mCi, we use standard isolation and contamination/exposure procedures. The nursing staff is supplied with pocket dosimeters and the readings are logged daily for each shift. Daily radiation readings are made at bedside, 3 feet from bed and 10 feet from the bed. These readings are logged on the outside door of the room along with the nursing instructions. Stay time for the nurse is calculated not to exceed 16 mr in an 8-hour shift.

All bedding, dishes and other articles are kept in the room until released or removed by the R.S.O. During the infusion, the drip bag is shielded to keep the outside of the room 2 mr/hr or less. The I.V. is started and monitored by a renal department assistant, who is badged and is familiar with the procedure. In the event that we do not do a therapy on the patient, he is kept in isolation and monitored until his level has dropped 10 mCi. His room is then decontaminated to background levels and it is then released to the ward.

FEB 16 1988

2. Therapy procedures: Up to this date, we have not exceeded a 50 mCi therapy dose. The same isolation and monitoring procedures are used as with the diagnostic procedure. The one adjoining room to the patients room is monitored and if above 2 mr/hr at any location we keep the room empty. In the event we have a post-therapy patient, we move him to the adjoining room and put the new therapy patient in the corner room.

3. External radiation monitoring data: External radiation ducts in and around the patients room depend directly on the physical size of the patient. We did six (6) patients this past year each with a 50 mCi therapy dose. Bedside levels varied from 22 mr/hr up to 60 mr/hr. 10 feet from the bed ranged from 1.5 mr/hr to 2.5 mr/hr. These readings were taken after the I.V. drip was completed. The urology assistant attending the patient has not received any reading on his film badge. Pocket dosimeter readings for the nursing staff have also been negative.

4. Waste disposal: Our research chemist has been doing the tagging on the antibody using the hot lab. All solid waste has been bagged and tagged for decay storage. The patient waste is in the urine. Samples of urine are collected along with blood every 4 hours for 2 days and then every 12 hours. The urine is then disposed of using the sanitary sewer system.

5. Patient release: The $T_{\frac{1}{2}B}$ for the activity is about 60 hours. We have been keeping the patient in isolation until his body burden is less than 30 mCi and exposure readings are less than 5 mr/hr at 3 feet. We will continue with these release levels. Therapy doses will exceed 150 mCi without further approval from the N.R.C.

G. M. Twite

GAYLORD M. TWITE, R.S.O.
Nuclear Medicine Service