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

JUL 18 1985

Good Samaritan Medical Center
Lutheran Campus
ATTN: Mr. John Schwartz
President
2000 W. Kilburn Avenue
Milwaukee, WI 53233

License No. 49-00988-04

Gentlemen:

We have reviewed your letters dated June 18, 1985 and July 3, 1985 requesting an amendment to your nuclear medicine license and find that we will need additional information as follows:

1. With the addition of Dr. Richards to your license it would be possible for us to remove the "for storage only" restriction for Group VI material from your license. However, the letters and application currently referenced in your license contain no safe handling procedures, nursing instructions or source accountability system for Group VI licensed material. If it is your intent to be authorized for all of the material listed in 10 CFR Part 35, Schedule 35.100 (f) (enclosed), you will need to submit this information in accordance with Appendix L of Regulatory Guide 10.8 (enclosed). If, on the other hand, it is your intent to use only your strontium-90 eye applicator, you need only submit the information requested in Items 3, 4 and 6 of the enclosed strontium-90 opthalmic applicator guide.

2. With regard to the addition of Drs. Veluvolu and Whalen we note that they had personal participation in 15,000 and 10,000 generator elutions, respectively (ref. Supplement B, Form 313M) as well as an equal number of kit preparations. Please note that Appendix A, Section 2.b. of Regulatory Guide 10.8 request evidence of personal participation in a minimum of five procedures to elute Tc-99m and preparation of radiopharmaceuticals from Group III reagent kits. The numbers you have provided are in excessive for the time frames involved. (They imply that each physician eluted a generator approximately 100 times per week.) Please review these entries with the physicians involved and revise them accordingly.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 79286.

Sincerely,

William J. Adam

William J. Adam, Ph.D.
Materials Licensing Section

Enclosures:
1. 10 CFR Part 35
2. Regulatory Guide 10.8
3. Information to be Submitted for Strontium-90 Opthalmic Applicator

OCT 22 198

Rules for Safely Handling a Strontium-90 Eye Applicator

*1. Wear your personnel dosimeter(s) whenever you handle the strontium-90 eye applicator. Finger ring-type dosimeters should be worn with the detector on the palm side of the hand.

2. Remove the Sr-90 eye applicator from its secured storage location just before use. Do not leave it out any longer than necessary.

3. After removing the Sr-90 eye applicator from its secured storage location,

   a. Do not touch the treatment end of the applicator with your hands or other portion of your body.

   b. Always hold the applicator by its handle.

   c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.

4. If the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge or gauze dampened with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge or gauze. Do not sterilize by holding the swab or gauze in your hand.

5. During treatment, hold the patient's eye lids open with tape or other device, not with your fingers.

6. Immediately after treatment and/or resterilization, return the Sr-90 eye applicator to its storage container and to its secured location (e.g., locked cabinet).

7. Do not remove any metal or plastic inserts from the manufacturer-supplied storage container. These items are generally a part of the container's shielding. Removal of these items can lead to excessive and unnecessary radiation exposures.

*It is strongly recommended that TLD-ring or film type badges be worn when handling a Sr-90 eye applicator.

ENCLOSURE 2

APPENDIX L

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES*

1. All patients treated with brachytherapy sources will be placed in a private room that has a toilet.

2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at 3 feet (or 1 m) from the patient with sources implanted, at the patient's bedside, at 3 feet (or 1 m) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 m) from the patient on the patient's chart.

4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and attached to the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film or TLD badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient. Pocket dosimeters may be assigned in addition to a film or TLD badge.

7. At the conclusion of treatment, a survey will be performed in accordance with paragraph 35.14(b)(5)(vii) of 10 CFR Part 35 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient meets conditions for release from the hospital.

8. Instructions to Nurses

   a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. The Radiation Safety Officer should be contacted to answer any questions about the care of these patients in regard to radiation safety precautions.

   b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film or TLD badge or a pocket chamber as instructed by the Radiation Safety Officer.

   c. When a nurse is assigned to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged among nurses.

   d. Pregnant nurses should not be assigned to the personal care of these patients.

   e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.

   f. Bed bath given by the nurse should be omitted while the sources are in place.

   g. Perineal care is not given during gynecologic treatment, the perineal pad may be changed when necessary unless orders to the contrary have been written.

   h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

      Special orders will be written for oral hygiene for patients with oral implants.

   i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.

* Be sure to submit complete responses to Items 20a through 20f in addition to referencing procedures in Appendix L.

j. All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

l. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

m. Visitors should sit at least 3 feet (or 1 m) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.

n. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call _____

_____

Telephone No. (days) _____

(nights) _____

p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room, (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient, and (3) record a summary of the final survey results on the patient's chart. If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.