February 14, 2006

REGION 1

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RETREAT HOSPITAL

NMSBI

Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

03008485

Subject: Amendment Request License # 45-15048-01

Dear NRC:

This letter is to request an amendment to our NRC License #45-25187-01. Following the format of NRC Form 313, we request the amendment to read as follows:

- 1) This application is for an amendment to NRC License #45-25187-01.
- 2) The name and mailing address for the license has not changed: Retreat Hospital.
- 3) The address of the location for use is the same: 2621 Grove Avenue, Richmond, Virginia. 23220.
- The name of the person to be contacted concerning this amendment request is Van H. McComas, MS, Consulting Medical Physicist. You can reach him by phone at 757-876-0734 or e-mail at <u>McComasVan@aol.com</u>.

5) The Radioactive Material requested is:

- a) Iodine -125
- b) Manufacturer & Model: Bard Brachytherapy Inc. Model STM1251
- c) Form: Seal Source (seeds) for use as per 10 CFR Part 35.400.
- d) Maximum Quantity: 0.5 mCi per seed with maximum total limit on site of 1.0 curie.
- 6) Purpose of Use: Prostate Brachytherapy Manual Implants.
- 7) The Radiation Safety Officer for this license, Timothy Taylor, MD will not change, however radiation safety for this project will be overseen by Van H. McComas, MS. Mr. McComas is ABR Certified in Theraputical Radiological Physics and is named on NRC license 45-25187-01 as both the Radiation Safety Officer and the Authorized Medical Physicist.
- 8) Training:
 - a) The Authorizer User for this amendment request is Bernard Tisdale, MD. Dr. Tisdale is listed as both the Radiation Safety Officer and an Authorized User for

138445 NECONGRI MATERIALS-602

2621 Grove Avenue Richmond, VA 23220/ T 804.254.5100/ F 804.254.5187/ www.retreathospital.com AN HCA RICHMOND HOSPITAL

10 CFR Part 35.400 on NRC license 45-25582-01. Dr. Tisdale is ABR Certified and meets the requirements in accordance with 10 CFR Part 35.490.

- b) Training for individuals working in or frequenting restricted areas, as well as Operating Room staff, nursing staff for recovering patients, ward nursing staff for patients who must remain in the hospital, and Nuclear Medicine staff who will handle this material will be trained by the medical physicist in accordance with 10 CFR Part 35.410. (See Attachment 1, Sample Training Form).
- 9) Facility and Equipment:
 - a) Attachment 2 (Second Floor) show the area of storage and use. The radioactive seeds will be received into Nuclear Medicine's Hot Lab (noted on Attachment 2 and 3) for wipe test, surveys, inventory, and assay.
 - b) Seeds will be assayed in accordance with 10 CFR Part 35.432. At least 10% of the seeds received will be assayed by the manufacturer. Two seeds from the same batch will be assayed by the medical physicist and compared to the manufacturer's calibration and assay report. (See Attachment 4, Sample Assay & Inventory Fcrm).
 - c) Seeds will arrive from the manufacturer shielded and sterilized. This will reduce the exposure to staff handling the seeds for assay and reloading.
 - d) The medical physicist will transport the sterilized seeds to the Endoscopy Room (Attachment 5, Third Floor) for the implant procedure. The patient will recover in the recovery room (attachment 6) located down the hall from the procedure room. Appropriate surveys of the patient will be performed at the end of the implant procedure in accordance with 10CFR Part 35.404 (see Attachment 7, Sample Survey form).
 - e) Unused seeds will be returned to the Hot Lab for decay in storage. Source accountability will be maintained in accordance with 10 CFR Part 35.406. (See Attachment δ, Sample Waste Form).
 - f) The survey equipment for this project will be:
 - i) Model 451P survey meter.
 - ii) Model 14C G-M counter.
 - iii) Model 44-9 pancake probe for the 14C.
 - iv) The Inspector Digital G-M detector.
- 10) The Radiation Safety Program will remain in effect for this license. Additions to the current program will include personal dosimeters (TLD or film badges) for staff handling or in the area where the seeds will be used or stored. For patients receiving the radioactive material implant we will adapt procedures outlined in 10 CFR Part 35.415. Although the expected exposure rate from the patient will not be significant, radiation surveys will be conducted of the exposure from the patient, the patient will

be separated from other patients in the recovery room and ward room, and appropriate caution signs will be utilized.

11) All unused seeds will be stored in the Nuclear Medicine Hot Lab and labeled "Decay-in-Storage." If the activity of the decaying seeds plus the seeds for implant begins to approach the one curie limit, then the decay-in-storage seeds will be package for return to the manufacturer for waste disposal.

If you have any questions regarding the amendment, please call Van McComas at the phone number referenced above. I can also be reached at (804) 254-5353. Thanks for your assistance.

Sincerely, ulit

Erica Gulrich Assistant Administrator Retreat Hospital

Attachments:

- 1. Sample Training Form
- 2. Second Floor/ Nuclear Medicine
- 3. Second Floor/ Hot Lab
- 4. Sample Assay/ Inventory Form
- 5. Third Floor/ Endoscopy
- 6. Third Floor/ Recovery Rooms
- 7. Sample Post Survey Form
- 8. Sample Waste Log

Radiation Safety Training Prostate Seed Implants Retreat Hospital

I. Definition of Radiation

- a. Transfer of energy
- b. Photons wave packet that act like a particle (x-rays, γ -rays)
- c. Particles charged (alpha and beta) and neutral (neutrons)
- d. Common types of radiation
 - i. Heat
 - ii. Light
 - iii. Microwaves
 - iv. X-rays and y-rays
 - v. Cosmic rays
 - vi. Radio-waves

II. Radiation Terminology

- a. milli-Roentgen (mR): unit of exposure
- b. Rad: unit of absorbed dose (still used by laymen)
- c. Gray or centi-Gray (cGy): newest unit of absorbed dose (1 cGy = 1 rad)
- d. REM (Sv): unit of dose equivalent (1 cGy of x-rays = 1 Sivert)
- e. Half-life (T½): amount of time required for radioisotope to decay to $\frac{1}{2}$ its original activity.
 - i. I-125 T $\frac{1}{2}$ = 60 days
 - ii. Pd-103 $T\frac{1}{2} = 17$ days

III. Radiation in Medicine

- a. Diagnosis of illness
- b. Treatment of cancer
- c. Medical Research
- d. Sources of Medical Radiation
 - i. Diagnostic X-rays (CT scanner, C-arm fluoroscopic, X-rays)
 - ii. Nuclear Medicine (body scans)
 - iii. Radiation Therapy (linear accelerators, radioactive "seeds")
 - iv. Mobile units (portable x-rays, portable CT units)
 - v. Laboratories (low energy x-rays or isotopes)

IV. Radiation in Nature

- a. Background: made up from terrestrial, cosmic, and internal sources.
- b. US average around 200 mrem per year.
- c. Background radiation depends some on location. (VA around 45 mrem per year where CO is 120 mrem per year).
- d. Average radiation worker is exposed to an amount equal to the background radiation per year.

V. Biological Effects

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- a. Threshold (non-stochastic)
 - i. Cataracts (200 cGy single dose to eye)
 - ii. Skin erythema (1,000 cGy single dose to area of skin)
 - iii. Hair loss (4,000 cGy single dose to area of skin)
 - iv. Death LD50/30 (500 cGy whole body without medical attention)
- b. Chance (stochastic)
 - i. Cancer
 - ii. Genetic effects
 - iii. Effects of the embryo/fetus

VI. Typical Exposures to Patients

- a. Chest X-rays: 15 mrem
- b. CT of head: 3 mrem
- c. CT of pelvis: 1 mrem
- d. Mammogram: 150 mrem
- e. KUB series: 350 mrem
- f. Radiation Therapy: 5,000 cGy (rad) or 5,000,000 mrem

VII. Exposure Limits for Radiation Workers (that you!)

- a. Whole Body:5 rem (5,000 mrem) per yearb. Lens of the eye:15 rem (15,000 mrem) per year
- c. Skin 50 rem (50,000 mrem) per year
- d. Extremities: 50 rem (50,000 mrem) per year

VIII. Monitoring and the ALARA Concept

- a. The TLD badge (mistakenly referred to a film badge) records the amount of radiation we are exposed to on quarterly bases. It can not record the radiation exposure if it is not worn daily.
- b. <u>As Low As Reasonably Achievable</u>: A concept that states that we will do those things that are reasonable to keep our dose from radiation as low as we can.
- c. **Time, Distance, Shielding:** The three golden rules for radiation safety and ALARA are:
 - i. Time: Reduce the amount of time around radiation to a reasonable level.
 - ii. Distance: Exposure to radiation falls off by the square of the distance. By doubling your distance from a radioactive source, (i.e., the patient) your exposure drops by ¼ however by getting twice as close to a source of radiation your exposure increases by 4 times.
 - iii. Shielding: By introducing material between you and the source of radiation you reduce your exposure.

IX. Your Rights as a Pregnant Radiation Worker

- a. Radiation Safety Consult with the RSO or Medical Physicist
- b. Monthly TLD Monitoring for Baby

Procedure	Risk of Death from (a) leukemia or (b) thyroid cancer	Equivalent to Number of Cigarettes Smoked	Equivalent to Number of Miles Driven
Chest X-ray	2×10^{-7} (a)	1.5	3.6
Chest X-ray	12×10^{-7} (b)	8.7	21
Skull examination	1.6 x 10 ⁻⁶ (a)	11.4	28
Skull examination	20 x 10 ⁻⁶ (b)	144	352
Barium enema	17.5 x 10 ⁻⁶ (a)	128	313

X. Relative Risk

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Accidents: Number of fatalities per year among 15 million people living within 20 miles of 100 nuclear reactors

Accident type	Fatalities	Injuries
Motorcar	4,200	375,000
Falls	1,500	75,000
Fire	560	22,000
Lighting	8	-
Reactor	0.3	6

Source: Taken from the Rasmussen Report on Reactor Safety

Major Disasters: Probability of major disasters – man-made and natural.

Type of Event	Probability of 100 or more fatalities			
Natural:				
Tornado	1 in 5 years			
Hurricane	1 in 5 years			
Earthquake	1 in 20 years			
Man-made:				
Airplane crash	1 in 2 years			
Fire	1 in 7 years			
Explosion	1 in 16 years			
Toxic gas	1 in 100 years			
Reactor (100 plants)	1 in 10,000 years			

Source: Taken from the Rasmussen Report on Reactor Safety



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Retreat Hospital Seed Assay I-125 Source Tech Model STM1251

Patient:			Date:			
MR Number:			Certificate Number:			
			Lot Number:			
Well Ch	amber:		Electrometer:			
Model ##	###, Serial #: ##	#####	Model ######,	Serial #:	###	
Manufac	turer: #####		Manufacturer: #	4#####		
Calibrate	:d: #/#/####		Calibrated: #/#/	/####		
Today Da	ate:		Activity on Day of Implant: mCi			
Date of I	mplant:		Corrected Activity for Today: mCi			
Number	of Days:		Tolerance: CA7	Г х 0.05:	mCi	
Adjustme	ent Factor:		Upper Limit: C	AT + Tol	mCi	
5		······································	Lower Limit: CAT – Tol: mCi			
Total Number of Seeds:			Number to be assayed: 2			
Seed #	Electrometer	Correction	Activity	Withi	Comments	
	Reading	Factor	mCi	n		
	-			±5%		
1 0.02048						
2		0.02048				

Assayed By: _____ Date: _____

Reviewed By: _____ Date: _____

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I-125 Radioactive Material Inventory

Date	Time	Isotope	Control Number	Activity mCi	In Storage	Taken	Disposition/Initials
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Retreat Hospital Third Floor Endoscopy / Recovery Rooms

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Third Floor Endoscopy. Shows the two procedure rooms and the Recovery Room.

Retreat Hospital

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Post Implant With Radioactive Iodine-125 Seed

Radioisotope: I-125 Amount:____mCi Date:_____

	SURVEY DATA				
Date/Time Implanted:	Background:	mR/hr			
	Patient Contact:	mR/hr			
Patient Location:	1 M from Patient:	mR/hr			

OR Room Diagram		Survey Instrument
Head		Make/ Model: Inovision 451B
		Serial #:
Ð	+	Calibration Date: #####, 2006
Foot		Survey By:

Note: No special precautions are necessary with this patient with regards to the radioactive materials.

Patient ID	IN CASE OF EMERGENCY CONTACT:
Name:	Radiation Safety Officer at 804- or
Hospital ID#:	Medical Physicist at 757-876-0734

Retreat Hospital

I-125 or Pd-103 Radioactive Material Waste Log

Date	Time	Isotope	Control Number	Activity (mCi)	Decay in Storage	Exposure Check Date	Disposition/ Initials
				<u> </u>			
<u> </u>							

Comments: _____

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This is to acknowledge the receipt of your letter/application dated

2/(4/2006), and to inform you that the initial processing which includes an administrative review has been performed.

 \checkmark As 240 - 45 - 15643 - 01There ware no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

138445 Your action has been assigned Mail Control Number ____ When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI) (6-96)

Sincerely, Licensing Assistance Team Leader