HEARTLAND
HOSPITAL EAST

January 26, 1988

U.S. Nuclear Regulatory Commission
Regional Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: License #24-18287-01

Gentlemen:

We wish to have the Radioactive Materials License referenced above, issued to Heartland Hospital East, 5325 Faraon, St. Joseph, Missouri, amended as requested below. A $120 amendment fee check is enclosed.

1. We wish to have Edward Stevens, M.D. listed as the Radiation Safety Officer at our facility. Dr. Stevens is currently listed on our license as an authorized user.

2. We wish to have Randall J. Moeller, M.D. listed as an authorized user on our license for I-125 seeds. Supplement A & B for Dr. Moeller is attached.

If you have any questions concerning the above request, please do not hesitate to call.

Sincerely,

Robert J. LaDue, Director
Radiology Services

RJL/jd

Enc.

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Randall J. Moeller, M.D.	Missouri

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board Of Urology		February 1984

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	(SEE ATTACHED SHEET)		
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		(SEE ATTACHED SHEET)		

CONTROL NO. 8485 7

TRAINING

A. B.S. Chemical Engineering, Michigan Technological University, 1969-1973

1) Calculus 1½ years

2) Physics - for physics major 1 year

3) Chemistry - Inorganic 1 year

Organic 1 year

Physical 1 year

4) Biochemistry 1 year

B. Medical School, University Of Michigan, 1973-1977

1) Radiation Physics in Basic Science

2) Rotation in Radiology

a) 1 hour/day for 1 month on Radiation Biology and Protection

C. Residency Urology, Henry Ford Hospital, 1979-1982

1) Direct supervision of implantation and source accounting by Dr. Bae

IMPLANTATION OF I-125

Patient Selection:

1. Radioactive I-125 interstitial therapy for prostatic carcinoma is used for patients who have:

    a) Biopsy proven adenocarcinoma of the prostate.

    b) No evidence of metastatic disease with a normal acid phosphatase, bone scan and computerized axial tomography. Generally the options of radical prostatectomy versus external beam radiotherapy versus radioactive Iodine implantation along with the risks and complications of each option are given to the patient. The patient selecting radioactive I-125 implantation is generally a healthy patient over the age of 70 with localized prostatic carcinoma. It's principal advantage over external beam radiotherapy is the ability to sample the pelvic lymph nodes by doing a concomitant pelvic lymphadenectomy.

2. Implantation technique. The sources are ordered, loaded into the cassettes and then placed into the holding block of the MIC applicator by representatives of the Nuclear Medicine Department. Intraoperatively this block, with the cassettes, filled with radioactive material, are placed in the corner of the operating room.

    A pelvic lymphadenectomy is performed on the patient through a midline incision and the prostate gland is partially exposed. With a finger through a sterile rectoshield into the rectum, insertion of needles is accomplished. The needles are counted, length, depth and width of the prostate are obtained and a representative from the Nuclear Medicine Department then uses these measurements along with a nomogram to calculate the proper number of sources to be implanted. The wheeled cart with the I-125 sources in the holding block is then placed close to the operating room personnel and a cassette with 10 sources is then unscrewed, visually inspected for damage and if no visable damage is seen, implanted with a MIC applicator. The total time for handling the radioactive sources generally runs 8 to 10 minutes. During that time I have surgical radiation protection gloves with an equivalent of .05 millimeters of lead on and I wear a radiation finger badge for radiation exposure determination.

    After the implantation is accomplished the patient has drains left in place. A copious amount of irrigation fluid is used and there is the representative from the Nuclear Medicine Department with radiation detection equipment capable of detecting 30 key x-ray equivalents. All of the sponges used during the operation, the irrigating fluids, surgical drapes and the operating room are checked for any lost sources. During the implantation of the radioactive material a very accurate count of the number of needles and the number of sources per needle is accomplished. Then, at the end of the case, the number of sources, if any, remaining in the cassettes, are also counted so that we have an accurate count of the sources.

Postoperatively, the patient is placed in a special room in recovery. On the floor, he is placed in a private room with a radiation sign placed on his door. We do not allow pregnant women to care for the patient. During recovery all of his bedsheets, linens, dressings and drainage along with urine is monitored on a daily basis by the Nuclear Medicine Department representatives, again with the radiation detection equipment. In approximately four to five days postoperatively the patient is taken to the Radiology Department where the Foley catheter is removed, x-rayed and checked with the radiation detection equipment for any sources within the Foley catheter. The patient then has AP films of the pelvis taken and a source count is obtained to make sure that we accurately account for all of the sources that were implanted in the patient.

When the patient goes home he is instructed to watch his urine for any lost sources. This has not been a problem for us as it seems that if the patient is going to pass any sources he generally passes them while he is in the hospital.

There have been a few patients who have eventually required a TURP after the implantation of radioactive Iodine. We delayed the TURP at least six months after the implantation. During the TURP representatives from the Nuclear Medicine Department with radiation detection equipment were present in the operating room and all sources removed were accounted for and disposed of in accordance with recommendations from the Nuclear Regulatory Commission.

Complications:

We have currently done 42 radioactive Iodine implantations with concomitant pelvic lymph node dissections since I started practice in the St. Joseph area in August of 1982. During that time we have had one patient who had transient frequency which cleared after three months and a second patient who had transient diarrhea, again which cleared in six weeks. There was only one patient that needed reoperating and this was for a lymphocele formation which was unrelated to the implantation of the I-125 but rather due to the pelvic lymph node dissection. Finally, there has been no major complication such as colostomy, cystectomy or fistula formation as a result of the I-125 implantation.

In conclusion, we try to pay particular attention to:

1) Proper patient selection for radioactive Iodine implantation.

2) Minimizing radiation exposure to our operating room personnel during the implantation.

3) Careful followup to make sure that no sources are lost and that they are all accounted for.

4) Instructing the patient on followup care for lost sources and radiation exposure at hospital discharge.

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Randall J. Moeller, M.D.

STREET ADDRESS

1322 North 36th Street

CITY	STATE	ZIP CODE
St. Joseph	Mo.	64506

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT - prostate	20	
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Y. C. Bae, M.D.

b. NAME OF INSTITUTION
Henry Ford Hospital

c. MAILING ADDRESS
2799 W. Grand Blvd.

d. CITY
Detroit, Michigan 48202

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
Young C. Bae

7. PRECEPTOR'S NAME *(Please type or print)*
Young C. Bae

8. DATE
12/14/87

FORM NRC-313M-SUPPLEMENT B
(8-78)