

MERCY HOSPITAL

West Central Park at Marquette • Davenport, Iowa 52804 • 319-383-1000

May 7, 1984

RECEIVED BY LFMB	
Date	5/18/84
Log	May 14
By	[Signature]
Orig. To	[Signature]
Action Compl.	[Signature]

Medical Licensing
Materials Branch
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Amendment Request
License No. 14-14621-01

Applicant	...
Check No.	21833
Amount	\$40.00
Type of Fee	amendment
Date Check	5/18/84
Received By	[Signature]

230 - 11496

Dear Sirs:

This is a request to amend our license to include the use of 137-cesium sealed sources for brachytherapy use, and to add Dr. Farida B. Rajput, M.D. as an authorized user for this material. A check for \$40.00 for the amendment fee is enclosed.

Note that this amendment will only become effective following the approval of a license application to store and own the 137 cesium sealed sources by Dr. Rajput. Also, please note that we are eager to begin brachytherapy procedures and would appreciate your prompt attention to these requests.

In support of this request we offer the following responses to your questions in Regulatory Guide 10.8 of October, 1980. The first items are the enumeration of Item 20, Page 10.8-11.

20a. The sources will not be stored in the hospital. They will be brought from Dr. Rajput's facility immediately before use and will be returned promptly following use.

20b. Sources will be used in Fletcher-Suit or similar afterloading applicators. Long-handled forceps and/or long handled hemostats will be available during source implantation and removal. Specialized leaded source carriers will be used when sources are moved within the hospital.

20c. Dr. Rajput or other source handler (such as her physicist) will use both whole body film badges and TLD ring badges. These will be read monthly.

20d. Special leaded carriers will be used to move the sources from Dr. Rajput's facility into and through the hospital.

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Affiliated with Misericordia Health REGION III

20e. Source loading into the applicator inserts and of the inserts into the carriers will occur in Dr. Rajput's facility. Reference should be made to her application; however, sources will be counted and logged both in loading and unloading.

20f. As soon as is practical after implant the patient and environs will be surveyed. Survey points will include bedside, 3 ft. visitor's chair, and adjacent areas in other rooms, halls, etc. The survey will be conducted by or under the supervision of Dr. Rajput or her physicist. Dr. Rajput will survey the patient immediately after the sources have been removed to assure full removal of the sources. The patient will not be discharged until this survey is completed and noted in the patient's chart. The patients' bedding or other items retained will be surveyed at this time before release to the laundry, disposal or other normal channels.

20g. The instructions under "8" in Appendix L of the Guide (10.8) will be supplied to the nurses with each case as well as a completed copy of page 10.8-49.

Appendix L items will be followed in exact detail as indicated below.

1. Brachytherapy patients will have sole occupancy of their room during treatment. Patients who are able to use toilet facilities during treatment will have a room with private toilet facilities.
2. The patient's room will be posted with a large placard with a magenta radiation symbol as specified in Part 20. The placard will also have the words "CAUTION -- RADIOACTIVE MATERIAL" as well as two smaller statements: "visitors must check with the nursing station for instructions before entering", and "In an emergency contact Dr. F. Rajput at 383-2563".
3. As indicated above for item 20f, these surveys will be carried out with notations in the chart and the nursing instruction form.
4. Will be followed.
5. Radiation levels in adjacent unrestricted areas will be maintained below 2 mR/hr or 100 mR/case. Not more than one case per week in a particular room is anticipated. If levels greater than this are encountered on survey, the patient may be repositioned within the room or to another room to reduce the exposure to the mandated levels, the unrestricted area may be made a restricted area with appropriate postings, barricades, etc.; however, such area shall not contain an adjacent non-radioactive patient. If all else fails to reduce the levels to the above values some or all of the sources will be removed.

6. Film badges will be assigned to the nurses. If extended personal care is needed this will either be supplied by the physician or the sources will be temporarily removed and shielded by the physician. If after at least half a dozen cases the nurses' film badges indicate values of exposure well below those requiring badging, the Radiation Safety Committee may approve their termination.

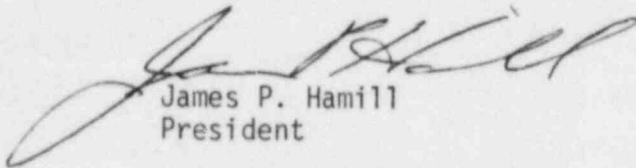
7. Will be followed.

8. Will be supplied to the nurses with section 8.0.3 being completed. In cases which state Radiation Safety Officer, also include Radiation Therapist or Radiation Therapy Physicist.

In addition to the above responses this amendment application contains a copy of Dr. Rajput's preceptor statement and other supporting data.

While we realize your review will take some time, we are eager to start offering our patients this new service. As such, we will be prompt in supplying you with additional material if you will indicate what you need.

Sincerely,



James P. Hamill
President

JPH/pc

Encls.

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Rajput, Farida B., M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE Iowa & Illinois
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3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiology	Board Eligible (passed written boards)

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	University of Iowa Hosp.&Clinics 1. Residency July 1978-June 1982 2. Junior Faculty Oct. 1982-Dec. 1983	100HRS.	
b. RADIATION PROTECTION	"	36 HRS	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	22 HRS	
d. RADIATION BIOLOGY	"	80 HRS	
e. RADIOPHARMACEUTICAL CHEMISTRY	"	27 HRS	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Ra-226 Cs-137	1 GM	University of Iowa Hsp.&Clinic	4 years	Intracavitary Application for Gynecological Malignancies
P32	80 mci	" " " " "	4 years	Intraperitoneal Applic for Cancers of ovary
Au198	3-400 mci	" " " " "	4 years	Interstitial application for head neck cancers

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			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.
FULL NAME			
Farida B. Rajput, M.D.			
STREET ADDRESS			
1351 W. Central Park Ave.			
Central Park Medcial Pavilion			
CITY	STATE	ZIP CODE	
Davenport	IA	52804	

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	20	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT	10	
	INTRACAVITARY TREATMENT	160	
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT	550	
Sr-90	TREATMENT OF EYE DISEASE	3	
	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

07/01/78 to 06/30/82 Resident, Division of Radiation Therapy, University
of Iowa Hospitals and Clinics
Clinical Training in Group VI Procedures: a. Training in basic Radioisotope
handling (400 hours) b. Experience with radioactive material 700 hours

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

a. NAME OF SUPERVISOR

Hamed H. Tewfik, M.D.
Howard B. Latourette, M.D.

b. NAME OF INSTITUTION

University of Iowa Hospitals and Clinics

c. MAILING ADDRESS

Iowa City, Iowa 52242

d. CITY

5. MATERIALS LICENSE NUMBER(S)

14-02938-07

6. PRECEPTOR'S SIGNATURE

Howard B. Latourette M.D.

7. PRECEPTOR'S NAME (Please type or print)

Howard B. Latourette, M.D.

8. DATE

April 12, 1984

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	20	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT	10	
	INTRACAVITARY TREATMENT	160	
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELE THERAPY TREATMENT	550	
Sr-90	TREATMENT OF EYE DISEASE	3	
	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

July 1st / 1978 → June 31 / 1982 :- as a Resident in Radiation Therapy Residency Program
 Clinical Training in Group VI Procedures :- { (a) Training in basic Radioisotope handling : 400 hours
 (b) Experience with Radioactive material : 700 hours.

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

a. NAME OF SUPERVISOR
 7/78 to 6/80 Howard Latourette, M.D.
 7/80 to 6/82 Hamed H. Tewfik, M.D.
 b. NAME OF INSTITUTION
 University of Iowa Hospitals and Clinics
 c. MAILING ADDRESS
 Division of Radiation Therapy
 d. CITY
 Iowa City, Iowa 52242
 5. MATERIALS LICENSE NUMBER(S)
 14-02938-07

6. PRECEPTOR'S SIGNATURE



7. PRECEPTOR'S NAME (Please type or print)

Hamed H. Tewfik, M.D.

8. DATE

April 9, 1984

The University of Iowa

UNIVERSITY HOSPITALS AND CLINICS

THIS IS TO CERTIFY THAT

Farida B. Rajput, M.B.B.S.

HAS COMPLETED THE SERVICE OF

Resident Physician

*in the Department of
Radiology*

Therapeutic Radiology

July 1, 1978 to July 1, 1982

TO THE SATISFACTION OF THE

OFFICERS AND STAFF OF THE UNIVERSITY HOSPITALS AND CLINICS

IN WITNESS WHEREOF, THIS CERTIFICATE IS AWARDED AT IOWA CITY, IOWA.

JULY 1, 1982

James O. Freedman
.....
PRESIDENT OF THE UNIVERSITY

[Signature]
.....
HEAD OF THE DEPARTMENT



John W. Callahan
.....
DIRECTOR, UNIVERSITY HOSPITALS AND CLINICS AND ASSISTANT
TO THE PRESIDENT FOR STATEWIDE HEALTH SERVICES

John W. Eckstein
.....
DEAN OF THE COLLEGE OF MEDICINE