

MAY 30 1986

License No. 20-05696-02
Docket No. 030-01876
Control No. 105177

St. Anne's Hospital Corporation
ATTN: Alan D. Knight
President
795 Middle Street
Fall River, Massachusetts 02721-1798

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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OFFICIAL RECORD COPY

ML 20-05696-02/LTR - 0001.0.0
05/28/86

ML10

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Edwin A. Wurtz

Edwin A. Wurtz, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 27
2. Requirements for Materials Licensees
3. NRC Forms 3 and 313M

EAW
DRSS:RI
Wurtz/k1

5/30/86

OFFICIAL RECORD COPY

ML 20-05696-02/LTR - 0002.0.0
05/28/86

ref Lic ~~Am.~~ #20-05696-02

Re: Conv of 3/26/82

1) Dr Simon Y. Kim has documented four (4) active participation in four (4) cases of Thyroid carcinoma treated with I-131. Two cases under the preceptorship of Dr Merrill J. Feldman, and two under the preceptorship of Dr ~~Robert Lee~~ Jerome Shapiro as evinced by the enclosed copies of NRC Form 313M suppl. B.

2) A copy of Dr Genacovi's preceptor statement is enclosed.

3) As Colloidal ~~I-131~~ P-32 is not employed at this institution, we would request a qualified group IV status for Dr Kim and Dr Genacovi, excluding Colloidal P-32 if this is appropriate.

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105177

"OFFICIAL RECORD COPY" ML10

APR 01 1986

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
FULL NAME FARES A. GENNAOUI, M.D. STREET ADDRESS 795 Middle St. CITY STATE ZIP CODE Fall River, Ma. 02722	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			

APR 01 1986

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	6	
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM	10	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
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

MERRILL I. FELDMAN, M.D., F.A.C.R.

b. NAME OF INSTITUTION

St. Anne's Hospital

c. MAILING ADDRESS

795 Middle St.

d. CITY

Fall River, Ma. 02722

5. MATERIALS LICENSE NUMBER(S)

20-05696-02

6. PRECEPTOR'S SIGNATURE

Merrill I. Feldman

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

Merrill I. Feldman, M.D. F.A.C.R.
University Hospital
Boston, Ma.

8. DATE

2/6/86

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
FULL NAME SIMON Y. KIM, M.D. STREET ADDRESS 795 Middle St. CITY STATE ZIP CODE Fall River, Ma. 02722	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.

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PRECEPTOR STATEMENT (Continued)

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a. NAME OF SUPERVISOR
MERRILL I. FELDMAN, M.D. F.A.C.R.

b. NAME OF INSTITUTION
St. Anne's Hospital

c. MAILING ADDRESS
795 Middle St.

d. CITY
Fall River Ma. 02722

5. MATERIALS LICENSE NUMBER(S)
20-05696-02

5. PRECEPTOR'S SIGNATURE

Merrill I. Feldman

7. PRECEPTOR'S NAME (Please type or print)
Merrill I. Feldman M.D., F.A.C.R.
University Hospital
Boston, Ma

8. DATE

2/6/82

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 SIMON Y. KIM, M.D. STREET ADDRESS 795 Middle St. <table style="width: 100%;"> <tr> <td style="width: 33%;">CITY</td> <td style="width: 33%;">STATE</td> <td style="width: 33%;">ZIP CODE</td> </tr> <tr> <td style="text-align: center;">Fall River,</td> <td style="text-align: center;">Ma.</td> <td style="text-align: center;">02722</td> </tr> </table>	CITY	STATE	ZIP CODE	Fall River,	Ma.	02722	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.
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PRECEPTOR STATEMENT (Continued)

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Tc-99m	REAGENT KITS		
Other			

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

Resident in Radiation Medicine, 1975-1977

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

a. NAME OF SUPERVISOR

Jerome Shapiro, M.D.

b. NAME OF INSTITUTION

Boston City Hospital

c. MAILING ADDRESS

Harrison Avenue

d. CITY

Boston, Ma.

6. PRECEPTOR'S SIGNATURE

Victor Lee

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

Victor Lee, M.D.

Jerome Shapiro, M.D.

Jerome H. Shapiro

8. DATE

February 7, 1986

5. MATERIALS LICENSE NUMBER(S)

20-0027508

License No. 20-05696-02
Docket No. 030-01876
Control No. 105177

(ADDRESS)

St. Anne's Hospital Corp.
Department of Nuclear Medicine
ATTN: Alan D. Knight
President
795 Middle Street
Fall River, Massachusetts 02721

SUBJECT: TELEPHONE CONVERSATION ON

3/27/86

This is in reference to your (letter)(application) dated 2/24/86, (~~for a license~~)(to amend your license)(~~to renew your license~~). As discussed in the telephone conversation between J. Kelly (of your staff)(yourself) and E. Wurtz (of this office), we need the following additional information to complete our review:

1. Your submission did not include the first page of Dr. Gennaoui's preceptor statement. Please submit the complete preceptor statement.
2. ~~The experience~~ Dr. Kim's clinical experience did not include the use of colloidal ³²P or the use of ¹³¹I for the requisite 3 cases of the use of ¹³¹I for the treatment of thyroid carcinoma to allow us to authorize him for all of Groups IV and Group V. If Dr. Kim has additional training, submit it on a preceptor statement.

We will continue our review upon receipt of this information.
Please reply in duplicate and refer to the Control Number listed
above.

If we do not receive a reply from you within 30 calendar days from
the date of this letter, we shall assume that you do not wish to
pursue your application.

Sincerely,

Nuclear Materials Safety Section B
Region I

Wurtz Glenn
(concurrences)