

MATERIALS LICENSE

Amendment No. 18

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

302252

<p>Licensee</p> <p>1. St. Lawrence Hospital Sisters of Mercy</p> <p>2. 1210 W. Saginaw Street Lansing, MI 48915</p>	<p>In accordance with the letter dated January 20, 1997</p> <p>3. License Number 21-15462-01 is amended in its entirety to read as follows:</p> <p>4. Expiration Date February 28, 2004</p> <p>5. Docket or Reference No. 030-09151</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Any byproduct material identified in 10 CFR 35.300</p> <p>D. Any byproduct material identified in 10 CFR 31.11</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200</p> <p>C. Any radiopharmaceutical identified in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma therapy)</p> <p>D. Prepackaged Kits</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (not to exceed one curie of iodine-131)</p> <p>D. As needed</p>

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.

260038

COPY

9702260127 970213
PDR ADOCK 03009151
C PDR

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

21-15462-01

Docket or Reference Number

030-09151

Amendment No. 18

9. Authorized Use (Continued)

C. Medical use described in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma therapy)

D. In vitro studies.

CONDITIONS

10. Location of Use: 1210 W. Saginaw, Lansing, Michigan.
11. Radiation Safety Officer: John Chalmers Crockett, M.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

Stephen P. Wilensky, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

Gerald R. Aben, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

John Chalmers Crockett, M.D.

10 CFR 35.100, 35.200 and 31.11.

Gordon L. Bartek, M.D.

10 CFR 35.100, 35.200 and 31.11.

E. Tryciecky, D.O.

10 CFR 35.100, 35.200 and 31.11.

Teresa G. Kelly, M.D.

10 CFR 35.100, 35.200 and 31.11.

Kent W. Graham, D.O.

10 CFR 35.100, 35.200 and 31.11.

Joseph R. Pernicone, D.O.

10 CFR 35.100, 35.200 and 31.11.

Alexander Gottschalk, M.D.

10 CFR 35.100, 35.200 and 31.11.

E. James Potchen, M.D.

10 CFR 35.100, 35.200 and 31.11.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

21-15462-01

Docket or Reference Number

030-09151

Amendment No. 18

12. (Continued)

Authorized UsersMaterial and Use

K. P. Gunaga, Ph.D.

10 CFR 31.11.

Michael J. Potchen, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

Michael P. Buetow, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

Mark A. Bisesi, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

Mark C. Delano, M.D.

10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and 31.11.

Ruggero Battan, M.D.

10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma therapy).

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 11, 1993; and

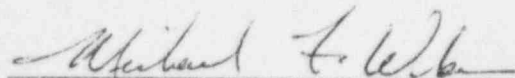
B. Letter dated January 20, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

2/13/97

By



Nuclear Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20040228
Fee Comments: CODE 21
Decom Fin Assur Req'd: N

52

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. LAWRENCE HOSPITAL
Received Date: 970128
Docket No: 3009151
Control No.: 302252
License No.: 21-15462-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 319739

3. COMMENTS

Signed
Date

S. Hersey
1-27-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

1. Fee Category and Amount: 7C 2B \$440

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC
2/4/97

FEB 10 1997

Log	<i>Feb 1 III</i>
Remitter	
Check No.	<i>319739</i>
Amount	<i>\$440</i>
Fee Category	<i>7C 2B</i>
Type of Fee	<i>AMD</i>
Date Check Rec'd	<i>2/3/97</i>
Date Completed	<i>2/4/97</i>
By:	<i>SC</i>

1997 FEB -97 AM 1:24



ST. LAWRENCE HOSPITAL & HEALTHCARE SERVICES

A member of Mercy Health Services

1210 West Saginaw
Lansing, Michigan 48915-1999
517/372-3610

United States Nuclear Regulatory Commission
Region III Medical Licensing Division
801 Warrenville Road
Lisle, IL 60532

Re: License # 21-15462-01

January 20, 1997

Please add the following physicians to our license for section 35.3000. We have enclosed preceptor forms for the physicians.

Michael J. Potchen, M.D.
Michael P. Buetow, M.D.
Mark Delano, M.D.
Mark A. Bisesi, M.D.
Ruggero Battan, M.D.

The \$440.00 amendment fee is enclosed. If you have any questions regarding this request, please contact our physicist Tracy I. King (810) 662-3197

Jean Miller
Senior Vice President

RECEIVED

JAN 28 1997

REGION III

302252

JAN 28 1997

pm: 1-24-97

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER
Mark A. Bisesi, M.D.

2. FOR PHYSICIANS, STATE OR
TERRITORY WHERE LICENSED
Michigan

3. CERTIFICATION

SPECIALTY BOARD
A

CATEGORY
B

MONTH AND YEAR CERTIFIED
C

American Board of Radiology

Diagnostic Radiology

6/95

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING
A

LOCATION AND DATE(S) OF TRAINING
B

TYPE AND LENGTH OF TRAINING

CLOCK HOURS IN
LECTURE OR
LABORATORY

CLOCK HOURS OF
SUPERVISED
ON-THE-JOB
EXPERIENCE

a. RADIATION PHYSICS AND
INSTRUMENTATION

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

mCi USED AT ONE TIME

LOCATION

CLOCK HOURS

TYPE OF USE

I 131

200 mCi

St. Mary's Hospital
200 Jefferson
Grand Rapids MI 49504

100

theapeutic

**EXHIBIT 3
SUPPLEMENT B**

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<i>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.</i>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF:	
FULL NAME Mark A. Bisesi, M.D.		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.	
STREET ADDRESS Dept. of Radiology B 220 Clinical Center - MSU			
CITY East Lansing MI	STATE	ZIP CODE 48824	
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN			
ISOTOPE <small>A</small>	CONDITIONS DIAGNOSED OR TREATED <small>B</small>	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION <small>C</small>	COMMENTS <small>(Additional information or comments may be submitted in duplicate on separate sheets.) D</small>
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER

Mark Bisesi, M.D.

PRECEPTOR STATEMENT (Continued)

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

ISOTOPE	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.)
A	B	C	D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	4	
	TREATMENT OF HYPERTHYROIDISM	17	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
	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

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
GRAMEC - Michigan State University	7/91 - 6/95	100

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

a. NAME OF SUPERVISOR

Dr. F. Verde

b. NAME OF INSTITUTION

Grand Rapids Medical Education Center

c. MAILING ADDRESS

St. Mary's Hospital-200 Jefferson SE

d. CITY

Grand Rapids MI 49503

5. MATERIALS LICENSE NUMBER(S)

21-01078-01

6. PRECEPTOR'S SIGNATURE

Francis Verde M.D.

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

FRANCIS VERDE, M.D.

8. DATE

1-9-97

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Michael J. Potchen, M.D.		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED Michigan		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
American Board of Radiology	1. Diagnostic Radiology 2. CAQ - Neuroradiology	6/93 11/96		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION				
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	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I 131	140 mCi	St. Mary's Hospital 200 Jefferson Grand Rapids MI 49504	100 hours	therapeutic

EXHIBIT 3
SUPPLEMENT B

[illegible]

PROPOSED PHYSICIAN USER.

Michael J. Potchen, M.D.

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	4	
	TREATMENT OF HYPERTHYROIDISM	34	
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		
Sr-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
GRAMEC - Michigan State University	7/89 - 6/93	100

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

A. NAME OF SUPERVISOR

Dr. F. Verde

B. NAME OF INSTITUTION

Grand Rapids Medical Education Center

C. MAILING ADDRESS

St. Mary's Hospital - 200 Jefferson S.E.

D. CITY

Grand Rapids MI 49503

E. MATERIALS LICENSE NUMBER(S)

21-01098-01

F. PRECEPTOR'S SIGNATURE

Francis Verde MD

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

FRANCIS VERDE, MD

8. DATE

7-9-97

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Michael Patrick Buetow, MD		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED PA / MI / VA		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
Diagnostic Radiology		June 1992		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-TIME-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	Hershey Medical Center June 1989 Jan 1990 June 91 Aug 1989 Jul 1990 May 92	100	120	
b. RADIATION PROTECTION	Same	30	120	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same	20	120	
d. RADIATION BIOLOGY	Same	20	120	
e. RADIOPHARMACEUTICAL CHEMISTRY	Same	30	120	
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I 131	300 mCi	Hershey Med. Center	1200 hours	Diagnostic and Therapeutic
99mTc	1.4 Ci			
201 Thal	100 mCi			
Ind 111	100 mCi			
Ga 67	100 mCi			
I 123	100 mCi	Naval Hospital Guam (practice)	900 hours	Diagnostic
I 131	30 mCi			
99mTc	25 mCi			
Ga 67	100 mCi			
Ind III	100 mCi			

EXHIBIT 3 SUPPLEMENT B

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p>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.</p>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C	
<p>FULL NAME</p> <p>Michael P. Buetow, MD</p> <p>STREET ADDRESS</p> <p>MSU Radiology B 220 Clinical Ctr</p> <p>CITY STATE ZIP CODE</p> <p>East Lansing MI 48824</p>		<p>PERSONAL PARTICIPATION SHOULD CONSIST OF:</p> <p>1 Supervised examination of patients to determine the suitability for radiobiologic diagnosis and/or treatment and recommendation for prescribed dosage.</p> <p>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.</p> <p>3 Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.</p>	
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 sheet.) D
	Thyroid scan	85	This details experience in training at Hershey Medical Center.
	Thyroid uptake	87	
	Lung perfusion scan	75	
	Xenon ventilation study	-	
	Aerosol ventilation scan	75	
	Renal flow scan	95	
	Brain scan	8	
	Liver/spleen scan	45	
	Bone scan	450	
	Gastroesophageal study	70	
	LeVeen shunt study	-	
	Cystogram	35	
	Dacryocystogram	2	
	Cardiac perfusion scan.	390	
	Cardiac stress ventriculogram	-	
	Cardiac rest ventriculogram	45	
	Gallium scan	30	
	Renal DMSA	25	
	Bone Density	150	
	Cisternogram	8	
Ind 111 Scan	25		
Hepatobiliary	45		
Testicular	6		

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

Michael P. Buetow, MD

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 sheet.) D
P-32 (Calcitriol)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Calcitriol)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	4	
	TREATMENT OF HYPERTHYROIDISM	13	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Co-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192 Co-60 or Co-137	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	5	
Sr-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	5	
Other	Radiopharmaceutical administration	5	

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

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
Hershey Medical Center	June 89 Jan 90 June 91 Aug 89 Jul 90 May 92	1200 hours

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

A. NAME OF SUPERVISOR

Douglas Eggli, MD

B. NAME OF INSTITUTION

Hershey Medical Center

C. MAILING ADDRESS

Box 850

D. CITY

Hershey, PA

E. MATERIALS LICENSE NUMBER(S)

37-13831-01

6. PRECEPTOR'S SIGNATURE

Douglas F. Eggli, MD

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

Douglas Eggli, MD

8. DATE

30 June 1992

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <div style="font-size: 1.2em;">Mark De Lano</div>		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
3. CERTIFICATION				
SPECIALTY BOARD <small>A</small>	CATEGORY <small>B</small>	MONTH AND YEAR CERTIFIED <small>C</small>		
ABR	① Diagnostic Radiology ② CAQ - Neuroradiology	6/94 11/96 (anticipated)		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING <small>A</small>	LOCATION AND DATE(S) OF TRAINING <small>B</small>	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION				
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	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I-131	29.9mCi	Duke University Medical Center Box 3808 Erwin Road Durham, NC 27710	100 hours	Therapeutic

EXHIBIT 3
SUPPLEMENT B

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<i>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.</i>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS <div style="border: 1px solid black; padding: 2px;"> FULL NAME Mark Delano </div> <div style="border: 1px solid black; padding: 2px;"> STREET ADDRESS B-220 Clinical Center Dept. of Radiology, Mich. State Univ. </div> <div style="border: 1px solid black; padding: 2px;"> CITY STATE ZIP CODE 2. Lansing MI 48824 </div>		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 <small>A</small>	CONDITIONS DIAGNOSED OR TREATED <small>B</small>	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION <small>C</small>	COMMENTS <small>(Additional information or comments may be submitted in duplicate on separate sheets.) D</small>
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
Gallium scan			

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER <i>Mark DeLano</i>			
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	12	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT INTRACAVITARY TREATMENT		
I-125 or Ir-192 Co-60 or Cs-137	INTERSTITIAL TREATMENT 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		
LOCATION <i>Duke University Med. Ctr. Dept Radiology Box 3808 Durham NC, 27710</i>	DATES <i>7-90 to 6-94</i>	CLOCK HOURS OF EXPERIENCE <i>100</i>

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR'S SIGNATURE <i>R. Edward Coleman</i>	
a. NAME OF SUPERVISOR <i>R. Edward Coleman, M.D.</i>		7. PRECEPTOR'S NAME (Please type or print) <i>R. Edward Coleman, M.D.</i>	
b. NAME OF INSTITUTION <i>Duke University Medical Ctr.</i>			
c. MAILING ADDRESS <i>Dept of Radiology Box 3808</i>			
d. CITY <i>Durham, NC 27710</i>		8. DATE <i>10/19/96</i>	
e. MATERIALS LICENSE NUMBER(S) <i>NC 032-0247-4</i>			

(9-31)

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Ruggero Battan, M.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE Massachusetts		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
Internal Medicine	Diplomate	September 1990		
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	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	40	5	
b. RADIATION PROTECTION	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	25	5	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	10		
d. RADIATION BIOLOGY	UMass Medical Center Dept. of Nuclear Medicine Worcester, MA (7/90 - 1/93)	20		
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
I - 131	150 mCi	UMass Medical Center	7/90 - 1/93	Therapy & Diagnosis
I - 123	300 micro Ci	UMass Medical Center	7/90 - 1/93	Diagnosis
Tc - 99m	10 mCi	UMass Medical Center	7/90 - 1/93	Diagnosis

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

Ruggero Battan, M.D.

STREET ADDRESS

38 Elm Street Apt. 4

CITY

Worcester

STATE

MA

ZIP CODE

01655

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	20	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	I-123 Thyroid Imaging	500	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	20	
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	10	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER	I-131 Adrenal Imaging	2	

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
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	12	
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
Between 7/90 and 1/93 250 hours of Clinical Radioisotope Training

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

a. NAME OF SUPERVISOR

Lewis E. Braverman, M.D.

b. NAME OF INSTITUTION

UMass Medical Center

c. MAILING ADDRESS

55 Lake Ave North

d. CITY

Worcester

5. MATERIALS LICENSE NUMBER(S)

20-13758-01

6. PRECEPTOR'S SIGNATURE

Lewis E. Braverman

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

Lewis E. Braverman, M.D.
Professor and Chairman
Dept. of Nuclear Medicine

8. DATE

11/4/93

JOHN ENGLER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF CONSUMER & INDUSTRY SERVICES

I 358348

BOARD OF MEDICINE

PHYSICIAN
LICENSE

RUGGERO BATTAN MD
ENDOCRINE ASSOC OF W MICH
243 CHERRY ST SE
GRAND RAPIDS MI 49503

PERMANENT L.D. NO.

EXPIRATION DATE

4301061291

01/31/00

3726176

THIS DOCUMENT IS DULY
ISSUED UNDER THE LAWS OF
THE STATE OF MICHIGAN.

FEB 13 1997

Jean E. Miller
Senior Vice President
St. Lawrence Hospital
1210 West Saginaw St.
Lansing, MI 48915

Dear Ms. Miller:

This refers to your January 20, 1997 amendment request, and to our telephone conversation with your physicist, Ms. Tracy King, on February 6, 1997.

Enclosed is Amendment No. 18 to your NRC Material License No. 21-15462-01 in accordance with your request. Please review the document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

As discussed with Ms. King, please be advised that your license was also updated in accordance with your September 27, 1996 letter, and in accordance with current NRC policy. Specifically: (1) Drs. DeLano and Bisesi were added as authorized users, (2) Drs. DeLaFe and Krecke were deleted as authorized users, (3) License Condition Nos. 7.C. and 9.C. now exclude the use of iodine-131 for thyroid carcinoma therapy (this restriction had been included in License Condition No. 12, but had been inadvertently omitted from License Condition Nos. 7.C. and 9.C.), and (4) License Condition No. 8.C. now includes a possession limit of one curie for iodine-131.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
or

- b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or 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. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

J. Miller

-3-

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No.: 21-15462-01
Docket No.: 030-09151

Enclosure: Amendment No. 18

DOCUMENT NAME: M:\03009151.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="checked" type="checkbox"/>							
NAME	MWEBER:jaw								
DATE	02/3/97								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME

8:00 am

DATE

2/6/97

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Tracy King, consultant physicist

St. Lawrence Hospital

313-662-3197

SUBJECT

Amendment request (Control No. 302252)

SUMMARY

We discussed the following updates/corrections to the license:

- 1) LCs 7C and 9C now exclude I-131 for thyroid cancer therapy (this agrees w/ LC 12)
- 2) LC 8C limits I-131 to 1 Ci.

ACTION REQUIRED

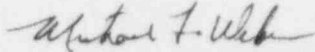
Approve request.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Michael F. Weber

|  |

2/6/97

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME

3:30 pm

DATE

1/97

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Ken Miller, RSO

Hershey Med. Ctr.

717-531-8521

SUBJECT

Amendment request for St. Lawrence Hospital (Control No. 302252)

SUMMARY

Q: Is Dr. Douglas Eggli an Authorized User for 35,300 uses and materials?

A: Yes.

ACTION REQUIRED

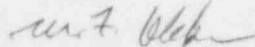
Approve request.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Michael F. Weber

|  |

1/31/97



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 29, 1997

John Chalmers Crockett
Radiation Safety Officer
St. Lawrence Hospital
Sisters of Mercy
1210 West Saginaw Street
Lansing, MI 48915

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 01/20/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302252
License No. 21-15462-01