

MATERIALS LICENSE

Amendment No. 61

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.

301820

Licensee

1. Theda Clark Regional
Medical Center
Department of Nuclear Medicine
2. 130 Second Street
Neenah, WI 54956

In accordance with letter dated
September 9, 1996

3. License Number 48-09494-01 is amended
in its entirety as follows:

4. Expiration Date May 31, 2003

5. Docket or
Reference No. 030-03463

6. Byproduct, Source, and/or
Special Nuclear Material

7. Chemical and/or Physical
Form

8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

- A. Any byproduct material
identified in 10 CFR
35.100

- A. Any
radiopharmaceu-
tical identified
in 10 CFR 35.100

- A. As needed

- B. Any byproduct material
identified in 10 CFR
35.200

- B. Any
radiopharmaceu-
tical identified
in 10 CFR 35.200

- B. As needed

- C. Any byproduct material
identified in 10 CFR
35.300

- C. Any
radiopharmaceu-
tical identified
in 10 CFR 35.300

- C. As needed
(not to exceed two
curies of iodine-131)

- D. Any byproduct material
identified in 10 CFR
31.11

- D. Prepackaged Kits

- D. As needed

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
 - B. Medical use described in 10 CFR 35.200.
 - C. Medical use described in 10 CFR 35.300.

230086

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oh
mc
230
SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-09494-01

Docket or Reference Number

030-03463

Amendment No. 61

9. Authorized Use:

D. In vitro studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 130 Second Street, Neenah, WI.
11. Radiation Safety Officer: Edward Marlewski, C.N.M.T.
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

- | | |
|------------------------------|--|
| A. R. F. Douglas, M.D. | 10 CFR 35.100, 35.200, 35.300 and 31.11. |
| B. Katrina Rosculet, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| C. Timothy T. Flaherty, M.D. | 10 CFR 35.100, 35.200, 35.300 and 31.11. |
| D. John R. McKenzie, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodine for treatment of thyroid carcinoma) and 31.11. |
| E. Donald C. Turner, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodine for treatment of thyroid carcinoma) and 31.11. |
| F. P. N. Gohdes, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| G. Eric Wilson, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodine for treatment of thyroid carcinoma) and 31.11. |

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-09494-01

Docket or Reference Number

030-03463

Amendment No. 61

12. (Continued)

Authorized UsersMaterial and Use

H. Jerry C. Doss, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
I. Forrest T. Bates, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
J. Robert H. Spencer, M.D.	10 CFR 35.100, 35.200 and 31.11.
K. Robert A. Vincent, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodide for treatment of thyroid carcinoma) and 31.11.
L. Sue A. Hausserman, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
M. John F. AufDerHiede, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
N. Lawrence L. Bauer, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodide for treatment of thyroid carcinoma) and 31.11.
O. Michael A. SanDretto, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
P. Fred Emil Klein, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
Q. Paul A. Larson, M.D.	10 CFR 35.100, 35.200, iodine-131 as iodide for treatment of hyperthyroidism and 31.11.
R. Frank E. Barber, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
S. William Fletcher, M.D.	10 CFR 35.100, 35.200, limited to cardiovascular clinical procedures and 31.11.
T. Issam Al-Bittar, M.D.	10 CFR 35.100, 35.200 and 31.11.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-09494-01

Docket or Reference Number

030-03463

Amendment No. 61

12. (Continued)

- U. Thomas L. Tolly, M.D. 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as iodide for treatment of thyroid carcinoma) and 31.11.
- V. Patrick O'Brien, M.D. 10 CFR 35.100 and 35.200 (limited to cardiovascular clinical studies).
- W. Ramamohan Turlapati, M.D. 10 CFR 35.100 and 35.200 (limited to cardiovascular clinical studies).

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 U.S. 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 March 24, 1993; and
- B. Letter dated September 1, 1995 (with attachments, excluding request to add Dr. Ramamohan Turlapati).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

December 13, 1996

By

Colleen C. Casey
Nuclear Materials Licensing Branch, Region III

COPY

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: 20030531
Fee Comments: CODE 23
Decom Fin Assur Req'd: N
.....

56

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: THEDA CLARK REGIONAL MEMORIAL HOSP.
Received Date: 960912
Docket No: 3003463
Control No.: 301820
License No.: 48-09494-01
Action Type: Amendment

2. FEE ATTACHED

Amount: ~~-----~~
Check No.: ~~-----~~

* ADDL INFO
399,21-56

3. COMMENTS

Signed D. Hersley
Date 9-22-96

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

1. Fee Category and Amount: 7C 2B

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

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed SC
Date 9/24/96

1996 SEP 20 PM 3:08

SEP 30 1996

RECEIVED BY LFDCB	
Date	<u>Sept. 20, 1996</u>
Log	<u>Sept 6 III</u>
By	<u>SC</u>
Date Completed	<u>9/24/96</u>

Thecla Clark
Medical Center
United Health Partner

Thecla Clark Medical Center
130 Second St.
P.O. Box 2021
Neenah, WI 54957-2021
Phone 414-729-3100

September 9, 1996

Ms. Colleen C. Casey,
Materials Licensing Section,
U.S. Nuclear Regulatory Commission,
801 Warrenville Road,
Lisle, IL 60532

Reference: Byproduct Material License # 48-09494-01
Control # 99121

Dear Ms. Casey:

Please accept the enclosed completed documents in duplicate in reference to the above control number to add Dr. Ramamohan Turlapati to our license as an authorized user.

I hope this information submitted is satisfactory.

Sincerely,

Edward Marlewski

Edward Marlewski, CNMT, RT
Radiation Safety Officer

Continuation of 399121
FEE NOT REQUIRED

Pm: 9-9-96

RECEIVED
SEP 12 1996
REGION III
301820
SEP 12 1996

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		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
RAMAMOJAN TURLAPATI		WISCONSIN		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
AMERICAN BOARD OF INTERNAL MEDICINE	INTERNAL MEDICINE	9/88		
AMERICAN BOARD OF CARDIOLOGY	CARDIOVASCULAR DISEASE	11/93		
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	CHICAGO, ILL 11/5/94 - 11/9/94	100 Hr.		
b. RADIATION PROTECTION	CHICAGO, ILL 10/17/94 - 10/22/94	30 Hr.		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	CHICAGO, ILL 10/17/94 - 10/22/94	20 Hr.		
d. RADIATION BIOLOGY	NEW ORLEANS, LA 10/23/94 - 10/26/94	20 Hr.		
e. RADIOPHARMACEUTICAL CHEMISTRY	NEW ORLEANS, LA 10/23/94 - 10/26/94 SEE ATTACHED CERTIFICATES FOR ALL OF THE ABOVE.	30 Hr.		
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
²⁰¹ Tl	1.0 - 4.0 mCi	St. ELIZABETH HOSPITAL 1506 S ONEIDA STREET APPLETON WI 54915	600+	DIAGNOSTIC NUCLEAR CARDIOLOGY
^{99m} Tc	8.0 - 25.0 mCi	AS ABOVE	320	

**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 <hr/> FULL NAME <u>RAMAOGHAN V. TURLAPATI, M.D.</u> <hr/> STREET ADDRESS <u>900 E. GRANT ST, APPLETON, WI 54911</u> <hr/> CITY _____ STATE _____ ZIP CODE _____		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 or 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		
	Decryocystogram		
	Cardiac perfusion scan.	1000	
	Cardiac stress ventriculogram	50	
Cardiac rest ventriculogram	100		
Gallium scan	20		

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

RAMAMOCHAN V. "TURLAPATI, 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 (Sodium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloid)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Co-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Co-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sr-113/ In-113m	GENERATOR		
Ti-99m	REAGENT KITS		
Other			

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

LOCATION
ST. ELIZABETH HOSPITAL
1506 S. ONEIDA STREET
APPLETON, WI. 54915

DATES
1. 1. 92
THROUGH
5. 31. 96.
CLOCK HOURS OF EXPERIENCE
600+ Thallium
470+ Technetium
20+ Gallium

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

a. NAME OF SUPERVISOR
Robert H. Spencer MD
b. NAME OF INSTITUTION
St. Elizabeth Hospital
c. MAILING ADDRESS
1506 S. Oneida Street
d. CITY
Appleton, WI 54915

e. PRECEPTOR'S SIGNATURE

[Signature]

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

Robert H. Spencer

g. DATE

6/1/96

h. MATERIALS LICENSE NUMBER(S)

48-10219-01

Cardiology Care Specialists™



3340 Hamilton Boulevard
Allentown, PA 18103
Telephone (610) 433-6442
Facsimile (610) 776-6645

Hours by appointment

Luis Constantin, M.D.
Bruce A. Feldman, D.O.
David B. Goldner, M.D.
J. Patrick Kleaveland, M.D.
D. Lynn Morris, M.D.
Michael A. Rossi, M.D.
Melvin H. Schwartz, M.D.
Bruce J. Silverberg, M.D.
Steven L. Zelenkofske, D.O.

December 13, 1994

RE: Ram V. Turlapati, M.D.

Dear Sir:

This letter is to affirm that Dr. Ram V. Turlapati gained clinical experience at Albert Einstein Medical Center in Philadelphia in nuclear cardiology. During his clinical cardiology fellowship from 7/1/88 to 6/30/90 he actively participated in exercise testing, patient evaluation, and scan interpretation for patients passing through the nuclear medicine lab for a four month period. During this period he interpreted approximately 325 stress-redistribution thallium studies and 230 gated blood pool studies. Interpretation of stress redistribution thallium studies involved both planar and SPECT imaging. He also gained experience in quantitative analysis of thallium imaging, analysis of gated blood pool studies involved ejection fraction calculation, analysis of chamber size and left ventricular wall motion, as well as phase analysis and amplitude image analysis.

Dr. Turlapati also participated in monthly nuclear cardiology conferences during the years of his cardiology training.

If you have any further questions, please do not hesitate to ask.

Sincerely,

Melvin H. Schwartz, M.D.

MHS/jy

dd: 12/13/94

dt: 12/14/94

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

RAMAMOHAN TURELAPATI

2. FOR PHYSICIANS, STATE OR
TERRITORY WHERE LICENSED

WISCONSIN

3. CERTIFICATION

SPECIALTY BOARD
A

CATEGORY
B

MONTH AND YEAR CERTIFIED
C

AMERICAN BOARD OF
INTERNAL MEDICINE

INTERNAL MEDICINE

9/88

AMERICAN BOARD OF
CARDIOLOGY

CARDIOVASCULAR DISEASE

11/93

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

CHICAGO, ILL

11/5/94 - 11/9/94

100 Hr.

b. RADIATION PROTECTION

CHICAGO, ILL

10/17/94 - 10/22/94

30 Hr.

c. MATHEMATICS PERTAINING TO
THE USE AND MEASUREMENT
OF RADIOACTIVITY

CHICAGO, ILL

10/17/94 - 10/22/94

20 Hr.

d. RADIATION BIOLOGY

NEW ORLEANS, LA

10/23/94 - 10/26/94

20 Hr.

e. RADIOPHARMACEUTICAL
CHEMISTRY

NEW ORLEANS, LA

10/23/94 - 10/26/94
SEE ATTACHED CERTIFICATES
FOR ALL OF THE ABOVE.

30 hr.

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
²⁰¹ Tl	10-40 mCi	ALBERT EINSTEIN MED. CENTER YORK & TAPSCOTT ROADS PHILADELPHIA, PA 19141	Four months	DIAGNOSTIC NUCLEAR CARDIOLOGY

**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; margin-bottom: 5px;"> FULL NAME RAMAOKHAN V. TURLAPATI, M.D. </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> STREET ADDRESS 900 E. GRANT ST, APPLETON, WI 54911 </div> <div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px; flex: 1;"> CITY </div> <div style="border: 1px solid black; padding: 2px; flex: 1;"> STATE </div> <div style="border: 1px solid black; padding: 2px; flex: 1;"> ZIP CODE </div> </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 or separate sheets.) <small>D</small></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.	325	
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram	230	
Gallium scan			

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

RAMAMOCHAN V. TURLAPATI, 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 (Sodium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloid)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Co-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Co-137	TELE THERAPY 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
ALBERT EINSTEIN MEDICAL
CENTER
YORK & TADDO RD
PHILADELPHIA, PA. 19141

DATES
7-1-88
to
6-30-90

CLOCK HOURS OF EXPERIENCE
FOUR MONTHS

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

a. NAME OF SUPERVISOR

MELVIN H. SCHWARTZ, M.D.

b. NAME OF INSTITUTION

ALBERT EINSTEIN MED CENTER

c. MAILING ADDRESS

d. CITY

Philadelphia PA 19151

e. MATERIALS LICENSE NUMBER(S)

37-00448-19

5. PRECEPTOR'S SIGNATURE

Mel H Schwartz MD

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

Melvin H Schwartz MD

6. DATE

6/26/95

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

RAMAMOCHAN V. TURLAPATI, 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 (Colloid)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Co-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Co-137	TELE THERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	4	
Sr-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	17	
Other			

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

LOCATION

DATES

CLOCK HOURS OF EXPERIENCE

Synco International
420 E Northland
Appleton, WI 54915

7-11-96

2 hrs

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

a. NAME OF SUPERVISOR

Lois Jo Kiewel

b. NAME OF INSTITUTION

Synco International

c. MAILING ADDRESS

420 E Northland

d. CITY

Appleton WI 54915

e. MAYNARD'S LICENSE NUMBER(S)

04-26307-0100

5. PRECEPTOR'S SIGNATURE

Lois Jo Kiewel

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

Lois Jo Kiewel

8. DATE

7-11-96

DEC 16 1996

Edward Marlewski, CNMT, RT
Radiation Safety Officer
Theda Clark Regional
Medical Center
Department of Nuclear Medicine
130 Second Street
Neenah, WI 54956

Dear Mr. Marlewski:

Enclosed is Amendment No. 61 to your NRC Material License No. 48-09494-01 in accordance with your request.

Please review the enclosed 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.

- A. In preparing this amendment, we took the opportunity to update and reformat your license as discussed below. These changes were essentially administrative modifications only that should have no effect on your licensed program.

Subitems A.1., A.2. and A.3. of this letter were discussed in a telephone conversation between Colleen Casey and Edward Marlewski on December 6, 1996.

1. Please note that, at this time, we changed the expiration date in Item No. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.
2. We deleted Condition No. 13., as it appeared on Amendment No. 60, because the regulations in 10 CFR 30.35(g) contain the same provision. Therefore, this Condition is no longer necessary.
3. At this time, we limited your authorization for iodine-131, as listed in 10 CFR 35.300 and Item 8.C., in order to preclude your having to file an emergency plan, per 10 CFR 30.32(i) and 30.72, enclosed. Your total possession limit for iodine-131 is two curies and includes waste activity also. Mr. Marlewski advised us of the possession limit you wish to have for iodine-131 in the telecon on December 6, 1996.

301820

4. If your understanding differs from ours in any of these matters, or if you have questions concerning this amendment, please contact Colleen C. Casey at (630) 829-9841.
- B. 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, 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
Colleen C. Casey
Nuclear Materials Licensing Branch

License No. 48-09494-01
Docket No. 030-03463

Enclosures:

1. Amendment No. 61
2. 10 CFR Part 30

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 12, 1996

Edward Marlewski, CNMT
Radiation Safety Officer
Theda Clark Regional Memorial Hospital
Department of Nuclear Medicine
130 Second Street
Neenah, WI 54956

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 09/09/96)

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. 301820
License No. 48-09494-01