VOID SHEET

TO: License Fee Management Branch

FROM: Region IV

SUBJECT: VOIDED APPLICATION

Control Number: 46323

Applicant: St. Peter's Community Hospital

Date Voided: 10/24/90

Reason for Void: Licensee unable to provide requested information at this time. They will provide later in fee-exempt request for amendment.

Billie Gruszynski 10/24/90
Signature Date

9012140046 901024
REG4 LIC30
MATLSLICENSING PDR

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☐ No Refund Due

☑ Fee Exempt or Fee Not Required

Comments: _____

Log completed ☑

Processed by: M. Russell 10/30/90

# CONVERSATION RECORD

TIME 4:15p DATE 10/23/90

TYPE ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

| NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU | ORGANIZATION (Office, dept., bureau, etc.) | TELEPHONE NO. |
|---|---|---|
| John Guy, Administrator | St. Peter's Comm. Hosp | (406) 444-2100 |

ROUTING

| NAME/SYMBOL | INT |
|---|---|
| | |
| | |
| | |
| | |
| | |

SUBJECT Shelbi Carden - secretary

William Austin, M.D. - training & experience w/ I-131

SUMMARY

I informed Mr. Guy that we would be unable to authorize Dr. Austin to use I-131 for hyperthyroid tx with the experience provided in his prayer for relief. Mr. Guy said that he believed he Dr. Austin would need additional training.

We agreed to said this action. Mr. Guy would use the fee exempt request after Dr. Austin completed the training

ACTION REQUIRED

LA void action

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE Vivian A. Campbell | DATE 10/23/90

ACTION TAKEN

SIGNATURE | TITLE | DATE

50271-101 CONVERSATION RECORD OPTIONAL FORM 271 (12-76) DEPARTMENT OF DEFENSE

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 19920831
FEE COMMENTS: CODE 23

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

LICENSE FEE TRANSMITTAL

A. REGION IV

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. PETER'S COMMUNITY HOSPITAL
RECEIVED DATE: 901002
DOCKET NO: 3010917
CONTROL NO.: 463303
LICENSE NO.: 25-12453-02
ACTION TYPE: AMENDMENT

OCT 15 1990

2. FEE ATTACHED
AMOUNT: /
CHECK NO.: /

3. COMMENTS
* See below

SIGNED Billie Gruszynski
DATE 10/2/90

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 08 IS ENTERED /✓/)

1. FEE CATEGORY AND AMOUNT: _____

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓ 463102
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED M. Mercy
DATE 10/9/90

* Continuation of Mail Control # 463102

ST. PETER'S
COMMUNITY HOSPITAL

(406) 442-2480 • 2475 Broadway, Helena, Montana 59601

RE: Mail Control # 463102

September 28, 1990

OCT 2 1990

William L. Fisher, Chief
Nuclear Materials Licensing Section
Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Fisher:

Pursuant to your letter of June 28, 1990 (copy attached), I am hereby requesting that St. Peter's NRC Materials License No. 25-12453-02 be amended to include the use of Iodine-131 by William Austin, M.D. Enclosed is the preceptor statement you requested for this fee-exempt amendment.

If you have any questions or need anything further, please contact me at (406) 444-2100. Thank you for your attention to this matter.

Sincerely,

John A. Guy
President

JAG/swg
Enclosures

cc: Joe Rizza, M.D., Radiation Safety Officer
Joe Marcello, Manager, Diagnostic Imaging Dept.
William Austin, M.D., Radiology
Diane Runnestrand, Vice President

RECEIVED
90 OCT 29 P3:30 OFC-9 A8:31
U.S. NRC FEE MGMT BRANCH

FEE NOT REQUIRED
Con't 463102

10/5/90
Oct-2-E
Rennie
10/5/90

463303

cc: Joe Rizza, M.D.
Joe Marcello
Diane Runnestrand
Dr. Austin

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

JUN 28 1990

RECEIVED
JUL - 2 1990
ST. PETER'S COMMUNITY HOSPITAL
ADMINISTRATION

St. Peter's Community Hospital
ATTN: John A. Guy, President
2475 Broadway
Helena, Montana 59601

Gentlemen:

Please find enclosed Amendment No. 12 to your NRC material license. You should review this amendment carefully and be sure that you understand all conditions. If you have any questions, you may contact the reviewer who signed your license amendment at 817/860-8100.

We were unable to include the use of Iodine-131 for Dr. Austin since proper documentation of his training and experience were not included with your request. For a fee exempt amendment to include the use of Iodine-131, please send a copy of his preceptor statement and refer to Mail Control No. 463102.

Please be advised that you must conduct your program involving radioactive 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. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).

5. Request and obtain appropriate amendments if you plan to change ownership of your sole proprietorship or partnership, change the corporate status of your company, change locations of radioactive material within NRC jurisdiction, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. A license fee may be charged for the amendments if you are not in a fee-exempt category.

6. Submit a complete renewal application with proper fee, or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

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 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; 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 Action, 10 CFR Part 2, Appendix C. 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 the NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

William L. Fisher

William L. Fisher, Chief
Nuclear Materials Licensing Section

Enclosure:
As stated

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the doseges;

(iii) Administering doseges to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

**§ 35.920 Training for imaging and localization studies.**

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

**§ 35.930 Training for therapeutic use of radiopharmaceuticals.**

Except as provided in § 35.970, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who:

(a) Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology or therapeutic radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

**§ 35.932 Training for treatment of hyperthyroidism.**

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

**§ 35.934 Training for treatment of thyroid carcinoma.**

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

**§ 35.940 Training for use of brachytherapy sources.**

Except as provided in § 35.970, the licensee shall require the authorized

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 |
|---|---|
| WILLIAM ROBERT AUSTIN, M.D. | |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| AMERICAN BOARD OF RADIOLOGY | Diagnostic Radiology Service | June 1982 |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>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 | Veterans Affairs Medical Ctr. and University of Minnesota 7/1/79 - 6/30/82 | 80 | 20 |
| b. RADIATION PROTECTION | " " " | 20 | 10 |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " " " | 20 | 0 |
| d. RADIATION BIOLOGY | " " " | 20 | 0 |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " " " | 20 | 10 |

**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 | 50 mCi | V.A.M.C. | 2 months | thyroid therapy |
| In-111 | 0.5 mCi | V.A.M.C. | 2 months | diagnostic |
| Xe-133 | 10 mCi | V.A.M.C. | 2 months | diagnostic |
| Tc-99m | 20 mCi | V.A.M.C. | 2 months | diagnostic |
| Mo-99 | 2.5 Ci | V.A.M.C. | 2 months | diagnostic |
| Tl-201 | 2 mCi | V.A.M.C. | 2 months | diagnostic |

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT | 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. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME: WILLIAM ROBERT AUSTIN, M.D.

STREET ADDRESS: 2106 Grizzley Gulch

CITY: Helena | STATE: Montana | ZIP CODE: 59601

**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 |
|---|---|---|---|
| | Thyroid scan | 10 | |
| | Thyroid uptake | 10 | |
| | Lung perfusion scan | 30 | |
| | Xe 3n ventilation study | 15 | |
| | Aerosol ventilation scan | 15 | |
| | Renal flow scan | 100 | |
| | Brain scan | 6 | |
| | Liver/spleen scan | 100 | |
| | Bone scan | 100 | |
| | Gastroesophageal study | 10 | |
| | LeVeen shunt study | 5 | |
| | Cystogram | 10 | |
| | Dacryocystogram | 0 | |
| | Cardiac perfusion scan. | 100 | |
| | Cardiac stress ventriculogram | 50 | |
| | Cardiac rest ventriculogram | 100 | |
| | Gallium scan | 10 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

WILLIAM ROBERT AUSTIN, M.D.

**PRECEPTOR STATEMENT** *(Continued)*

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

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | 0 | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | 0 | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 1 | |
| | TREATMENT OF HYPERTHYROIDISM | 2 | |
| Au-198 | INTRACAVITARY TREATMENT | 0 | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | 0 | |
| | INTRACAVITARY TREATMENT | 0 | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | 0 | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | 0 | |
| Sr-90 | TREATMENT OF EYE DISEASE | 0 | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | 10 | |
| Sn-113/ In-113m | GENERATOR | 0 | |
| Tc-99m | REAGENT KITS | 5 | |
| Other | HSA-99mTc cisternography | 2 | |
| | 111 in WBC's | 10 | |

OCT 2 1990

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

| LOCATION | DATES | CLOCK HOURS OF EXPERIENCE |
|---|---|---|
| V.A.M.C. and Univ. of Minnesota | 7/1/79 - 6/30/82 | 3 months |

approximate hours of training: 480 hrs.

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

a. NAME OF SUPERVISOR
DONOVAN B. REINKE, M.D.

b. NAME OF INSTITUTION
VETERANS AFFAIRS MEDICAL CENTER

c. MAILING ADDRESS
One Veterans Drive

d. CITY
Minneapolis, MN 55417

5. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME (Type or print)
REX B. SHAFER, M.D.

8. DATE
August 29, 1990

6. MATERIALS LICENSE NUMBER(S)
22-01859-01