

VOID SHEET

TO: License Fee Management Branch

FROM: Region IV

SUBJECT: VOIDED APPLICATION

Control Number: 466245

Applicant: Sacred Heart Hospital (40-01683-01)

Date Voiced: 1/24/97

Reason for Void: \_\_\_\_\_

License withdrawn amendment request see  
letter dated 1/15/97. Review accomplished.

Jacqueline Buck 1/24/97  
Signature Date

Attachment:  
Official Record Copy of  
Voided Action

FOR LFMB USE ONLY

200086

Final Review of VOID Completed:

☐ Refund Authorized and processed

☐ No Refund Due

☒ Fee Exempt or Fee Not Required

9702200232 970124  
PDR ADDCK 03003235  
C PDR

Comments: \_\_\_\_\_

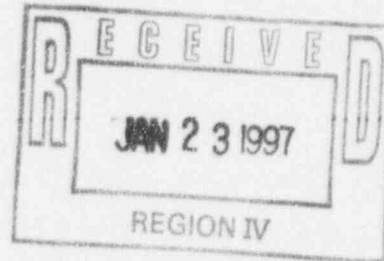
Log completed ☒

Processed by: lem

ML40

15 January 1997

Jacqueline D. Burks  
Health Physicist  
Nuclear Materials Licensing Branch  
Nuclear Regulatory Commission  
Region IV  
611 Ryan Plaza Drive  
Suite 400  
Arlington, Texas 76011-8064



Re: License # 40-01683-01

Dear Ms. Burks:

In response to your latest communication to us regarding our license amendment request originally submitted on July 25, 1996 to include Dr. Fred Van Dis on our NRC license to use material identified in 10 CFR 35.200 for nuclear cardiology procedures, we have decided to not proceed any further with this particular amendment request. We have communicated to Dr. Van Dis the additional steps he would need to complete to be in compliance with NRC guidelines regarding nuclear cardiology procedures. When Dr. Van Dis has completed the additional education required for someone to be authorized to use material identified in 10 CFR 35.200 we will file a new amendment request.

Thank you very much for your assistance during the past few months concerning this particular amendment request.

Yours truly,

A handwritten signature in cursive script, appearing to read "Franklin E. Pope".

Franklin E. Pope M.A., R.T. (R)  
Director of Radiology

cc: Dennis Sokol



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

December 2, 1996

Sacred Heart Hospital  
Department of Radiology  
ATTN: Franklin Pope  
Director of Radiology  
501 Summit  
Yankton, SD 57078-9967

SUBJECT: LICENSE AMENDMENT

We have reviewed your letter dated November 1, 1996, requesting an amendment to your byproduct material license for use in nuclear medicine. Before further action can be taken, we will need the following additional information.

1. Dr. Frederic J. Van Dis has satisfied the 200 hours of classroom and laboratory training requirements specified in 10 CFR 35.920(b)(1).

However, documentation has not been provided to demonstrate that Dr. Van Dis has satisfied the required 500 hours of supervised work experience described in 10 CFR 35.920(b)(2) or the required 500 hours of supervised clinical experience specified in 10 CFR 35.920(b)(3). Clear documentation should be provided regarding successful completion of the training and experience obtained in both the supervised clinical and supervised work experience categories. Dr. Van Dis appears to have less than the 1000 hours for the sum of both categories. If it is your intent to demonstrate that the required 1000 hours of supervised work experience has been satisfied along with the supervised clinical experience, you should ensure that all subject matters and tasks in 10 CFR 35.920(b)(2) and 35.920(b)(3) have been addressed. Authorized users of 10 CFR 35.200 material must have completed both **supervised work** and **clinical experience** as follows:

- 500 hours of **supervised work experience** under the supervision of an authorized user that includes the items outlined in §35.920(b)(2) [see the following];
  - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys.
  - Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters.
  - Calculating and safely preparing patient dosages.
  - Using administrative controls to prevent the misadministration of byproduct material.

- Using procedures to contain spilled byproduct material safely and using proper decontamination procedures.
- 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
- 500 hours of **supervised clinical experience** under the supervision of an authorized user that includes the items outlined in §35.920(b)(3) [see the following]
  - Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications.
  - Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages
  - Administering dosages to patients and using syringe radiation shields.
  - Collaborating with the authorized user in the interpretation of radioisotope test results.
  - Patient followup.

It is important that the licensee document that all required experience elements as identified (as outlined above) in the applicable section of Subpart J have been met. Until such documentation is provided to demonstrate how Dr. Van Dis satisfies 10 CFR 35.920(b)(2) and 10 CFR 35.920(b)(3), Dr. Van Dis can not be approved as an authorized user for 10 CFR 35.200 materials.

Demonstrate how Dr. Van Dis's qualifications satisfy these requirements using Supplement B (Exhibit 3 of Regulatory Guide 10.8, Revision 2).

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. Please reply in duplicate and refer to the license, docket, and control number specified below. If you have questions or require clarification on any of the information stated above, we encourage you to contact us at (817) 860-8132.

Sincerely,

Original Signed By  
Jacqueline D. Burks

Jacqueline D. Burks  
Health Physicist  
Nuclear Materials Licensing Branch

License: 40-01683-01  
Docket: 030-03235  
Control: 466245

Enclosure:

1. 10 CFR Part 35
2. Supplement B

DEC 2 1996

Sacred Heart Hospital

-4-

DOCUMENT NAME: P:\DEFICIEN\SACREDHRT.DEF

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

RIV:NMLB	N						
JDBurks	<i>JDBurks</i>						
12/2/96							

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

Program Code: 02120  
Status Code: 0  
Fee Category: 7C  
Exp. Date: 20041231  
Fee Comments: CODE 21  
Decom Fin Assur Regd: N

1996 NOV -8 PM 1:44

LICENSE FEE TRANSMITTAL

A. REGION IV

1. APPLICATION ATTACHED

Applicant/Licensee: SACRED HEART HOSPITAL  
Received Date: 9/11/96  
Docket No.: 3003235  
Control No.: 466245  
License No.: 40-01683-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 11  
Check No.: 11

3. COMMENTS

\* See below

Signed  
Date

Billie Gussowski  
11/7/96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered 11)

1. Fee Category and Amount: 7C

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

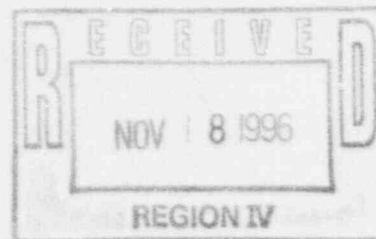
Amendment 11  
Renewal 11  
License 11

**FEE NOT REQUIRED**  
Cont # 466158

3. OTHER

Signed  
Date

Rita Messier  
11/14/96



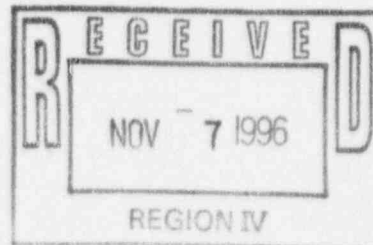
\* Continuation of m/c # 466158. by

RECEIVED BY LFMS	
Date	<u>11/8/96</u>
Log	<u>Rev 1-IV</u>
By	<u>rem</u>
Date Completed	<u>11/14/96</u>



1 November, 1996

Jacqueline D. Burks  
Health Physicist  
U.S. Nuclear Regulatory Commission  
Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400  
Region IV  
Arlington, Texas 76011



Re: Resubmission of documents needed for amendment  
License # 40-01683-01  
Docket # 030-03235  
Control # 466158  
Sacred Heart Hospital, Yankton, SD

Dear Ms. Burks:

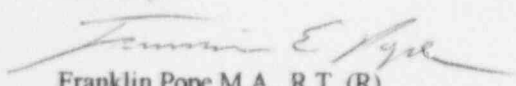
On July 24, 1996 Sacred Heart Hospital submitted a request to amend our NRC license. As part of this amendment the following was requested:

"Include Frederic J. Van Dis M.D. as an authorized user to perform studies listed under 10 CFR Part 35.100 and 35.200. Dr. Van Dis is eligible to take the American College of Cardiology Board Examination. Enclosed are supplements A & B of Preceptor Statement made in support of Dr. Van Dis by Dr. Jonathan White M.D., Ph. D."

In your reply of August 7, 1996 you indicated that the documentation supplied in support of our request to authorize Dr. Van Dis to use material identified in 10 CFR 35.200 was insufficient to grant our request at that time. Subsequent to receiving your correspondence we informed Dr. Van Dis of the additional documentation needed. The RSO who submitted the preceptor statement for Dr. Van Dis was contacted. He has supplied us with a corrected preceptor statement. A copy of this statement is attached to this correspondence.

Please accept this corrected preceptor statement in support of our original request of July 24, 1996 for authorization for Dr. Van Dis to use material identified in 10 CFR 35.200. If you have any additional questions, or if additional materials are needed for submission, please do not hesitate to contact me. I can be reached at 605-668-8000.

Sincerely,

  
Franklin Pope M.A., R.T. (R)  
Director of Radiology  
Sacred Heart Hospital

enc: Preceptor Statement for Dr. Van Dis

cc: Dennis Sokol - President, Sacred Heart Health Services  
John Wells M.D., Ph.D. - RSO, Sacred Heart Health Services



EXHIBIT 2  
SUPPLEMENT A

SUPPLEMENT	U.S. NUCLEAR REGULATORY COMMISSION
<b>TRAINING AND EXPERIENCE</b> <b>AUTHORIZED USER OR RADIATION SAFETY OFFICER</b>	

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <b>Frederic J. Van Dis MD</b>	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED <b>South Dakota</b>
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American College of Cardiology American Board of Int. Medicine	Board Eligible	cert. exam 11/97 September 1980

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	Maine Medical Center 1/94 - 6/96	160	80
b. RADIATION PROTECTION		20	200
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		60	20
d. RADIATION BIOLOGY		40	20
e. RADIOPHARMACEUTICAL CHEMISTRY		20	20

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Thallium <sup>201</sup>	3	Maine Medical Center Nuclear Medicine Department	350	Diagnostic myocardial Perfusion scanning
Sestamibi - Tc <sup>99m</sup>	3 # 24	"	350	Diagnostic myocardial perfusion scanning and cardiac ventriculography scanning

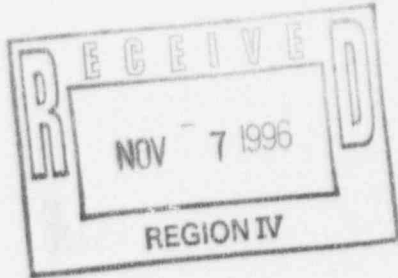
## EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

Frederic J. Van Dis 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 sheets.) D
P-32 (Samarium)	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 Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	30	
Sr-90/ Y-90	GENERATOR		
Tc-99m	REAGENT KITS	30	
Other			

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

LOCATION

DATES

CLOCK HOURS OF EXPERIENCE

Maine Medical Center  
Portland, Maine

1/94 - 6/96

700

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

a. NAME OF SUPERVISOR

Jonathon White MD, PhD; Joe Blinnick PhD

b. NAME OF INSTITUTION

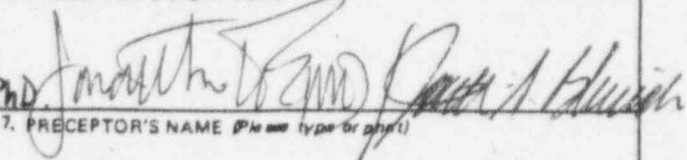
Maine Medical Center

c. MAILING ADDRESS

Portland, ME 04102

d. CITY

## 5. PRECEPTOR'S SIGNATURE



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

JONATHAN C. WHITE MD, PhD

8. DATE

9-23-96

## 6. MATERIALS LICENSE NUMBER(S)

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>			
<b>1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS</b> <hr/> <b>FULL NAME</b> <div style="font-size: 1.2em; font-family: cursive;">Frederic J. Van Dis MD</div> <hr/> <b>STREET ADDRESS</b> <div style="font-size: 1.2em; font-family: cursive;">1104 W. 8<sup>th</sup> St.</div> <hr/> <div style="display: flex; justify-content: space-between;"> <div><b>CITY</b> <div style="font-size: 1.2em; font-family: cursive;">Yankton</div></div> <div><b>STATE</b> <div style="font-size: 1.2em; font-family: cursive;">SD</div></div> <div><b>ZIP CODE</b> <div style="font-size: 1.2em; font-family: cursive;">57078</div></div> </div>		<b>KEY TO COLUMN C</b> <b>PERSONAL PARTICIPATION SHOULD CONSIST OF:</b> 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.	
<b>2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN</b>			
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>
<div style="font-size: 2em; font-family: cursive;">X</div>	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.	352	
	Cardiac stress ventriculogram	3	
Cardiac rest ventriculogram	210		
Gallium scan			