MOUNT SINAI MEDICAL CENTER

DANIEL A. KANE
President

RECEIVED BY LFMB
Date 7/9/81
Log July PGS III
By Brown
Orig. To ....
Action Compl. 7/13/81

June 9, 1981

Director
Medical Licensing
U.S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

030-03439

Dear Sir:

We request our byproduct materials license number 48-03280-01 dated January 30, 1979 be amended as follows:

A. Item 12, addition of Uri Vaisman, M.D. for use of all, except Group VI. See attachment for credentials.

B. Item 5 (Radiation Protection Officer), change from Robert Yoss to Charles Wilson, Ph.D. Dr. Wilson's credentials are on file with the NRC as Radiation Protection Officer for Milwaukee County Medical Complex; NRC license number 48-04193-01.

C. Item 11 (Facilities and Equipment) to reflect the addition of:

Applicant 42715
Check No. ...
Amt. of Fee $40.—
Type of Fee Amendment
Date Check Rec'd 7/9/81
Received By Brown

1. | | |
|---|---|
| Name | Single Plane Cardiac Catheterization Laboratory |
| Number | R352.7 |
| North | Outside wall |
| South | X-ray dark room - lead lined wall |
| East | Monitoring room - lead lined wall |
| West | Outside wall |
| Above | Research facilities |
| Below | Hemodialysis Service |
| Comments | Radionuclide use including Xenon-133. All access doors are lead lined. |

2. | | |
|---|---|
| Name | Bi Plane Cardiac Catheterization Laboratory |
| Number | R360.1 |
| North | Outside wall |
| South | Corridor - lead lined wall |
| East | Storage room/data center - lead lined wall |
| West | Monitoring room/corridor/storage room - lead lined walls |
| Above | Research facilities |
| Below | Hemodialysis Service |
| Comments | Radionuclide use including Xenon-133. All access doors are lead lined. |

950 North Twelfth Street, P.O. Box 342 • Milwaukee, Wisconsin 53201 • 414/289-8001

8603070218 860122
REG3 LIC30
48-03280-01 PDR

Control No. 05061 JUL 1 1981

3. Name — Nuclear Cardiology Imaging Room
   Number — R360.?
   North — Outside wall
   South — Corridor - controlled access
   East — Monitoring room
   West — Monitoring room
   Above — Research facilities
   Below — Hemodialysis Service
   Comments — Routine Imaging Procedures

4. Name — Nuclear Cardiology Imaging Room
   Number — R466
   North — Corridor
   South — Outside wall
   East — Offices
   West — Hot Lab/Bathroom/Equipment Room
   Above — Outside Space - Controlled Access
   Below — Offices
   Comments — Routine Imaging Procedures

5. Name — Nuclear Cardiology Hot Lab
   Number — R466.1
   North — Corridor
   South — Equipment room
   East — Imaging room
   West — Office
   Above — Outside space - controlled access
   Below — Offices
   Comments — Radionuclide nuclide storage and preparation area, including Xenon-133. All radionuclides will be stored in lead lined cabinets. Preparation of radiopharmaceuticals will be in lead lined hood. All walls are lead lined.

6. Name — Research Laboratory
   Number — W417/422
   North — Offices/Corridor - Controlled Access
   South — Outside wall
   East — Storage room
   West — Animal Post Operative Recovery Room
   Above — Outside Space - Controlled Access
   Below — Research Laboratory
   Comments — Radionuclide use in animals including Xenon-133.

In support of our request for the use and storage of Xenon-133 as stated above in items C 1, 2 and 6, we submit the following for your consideration:

Quantities to be used:

The maximum use in any one area above will be 12 procedures per week with a maximum of 40 millicuries per procedures.

Use and Storage Areas:

The areas where Xenon-133 will be used and stored are as described above. Diagrams of the rooms are attached indicating airflow supply and exhaust locations. Airflow rates are described in step 5 of this section. There is no recirculation of air. The exhaust is released on the roof of the building where the rooms are located. The exhausts are at least 30 feet from any supply ducts. The roofs are controlled access areas. We confirm that we will semiannually measure airflow rates with a calibrated velometer.

Procedures for Routine Use:

During Xenon-133 procedures, a RADX system will be used to trap expired Xenon-133. During human use, the patient's nose will be clamped, and the patient will breath through a mouthpiece connected to the Xenon trap. During animal use, the animal will be prepared by placement of a cuffed endotracheal tube that will be connected to the Xenon trap. The room will be monitored with a XenAlert monitor. The equipment described above is the same equipment as described in our application dated December 1, 1978. All doors and windows will be closed during the procedure.

Emergency Procedures:

In the event of the accidental release of Xenon-133, we will close air supply vents and evacuate all nonessential persons until such time the room monitor indicates normal background levels are achieved. The persons required to stay in the room will be monitored upon leaving the room.

Air Concentrations of Xe-133 in Restricted Areas:

The following calculations are based on maximum use for above mentioned areas of Xenon-133 use.

$$12 \frac{\text{procedures}}{\text{week}} \times 40 \frac{\text{mCi}}{\text{procedure}} \times 10^3 \frac{\text{uCi}}{\text{mCi}} \times .25 = 1.2 \times 10^5 \frac{\text{uCi}}{\text{wk}} \text{ released}$$

assuming a loss of 25%

$$\text{therefore } \frac{1.2 \times 10^5 \text{ uCi/wk}}{1 \times 10^{-5} \text{ uCi/ml}} = 1.2 \times 10^{10} \frac{\text{ml}}{\text{wk}}$$

or

$$\frac{1.2 \times 10^{10} \text{ ml/wk}}{40 \text{ hr/wk}} \times \frac{1 \text{ cfm}}{1.7 \times 10^6 \text{ ml/hr}} = 176 \text{ cfm ventilation}$$

necessary to be in compliance.

We will provide a negative airflow in each cardiac catheterization laboratory and the hot lab of at least 500 cfm.

We will provide a negative airflow in the Research Laboratory of at least 250 cfm.

Air Concentrations of Xe-133 in Unrestricted Areas:

$$A = 12 \frac{\text{procedures}}{\text{wk}} \times 40 \frac{\text{mCi}}{\text{procedure}} \times 10^{3} \frac{\text{uCi}}{\text{mCi}} \times .02 \times 52 \frac{\text{wks}}{\text{yr.}} = 4.99 \times 10^{5} \frac{\text{uCi}}{\text{yr.}}$$

assuming the charcoal trap is absorbing 98% of the activity

$$V = 500 \text{ cfm} \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{cfm}} = 7.45 \times 10^{12} \frac{\text{ml}}{\text{yr}}$$

$$C = \frac{A}{V} = \frac{4.99 \times 10^{5} \text{ uCi/yr}}{7.45 \times 10^{12} \text{ ml/yr}} = 6.7 \times 10^{-8} \frac{\text{uCi}}{\text{ml}}$$

which is in compliance with paragraph 20.1(c) and 20.106 of 10CFR Part 20.

Enclosed is our check, payable to the U.S. Nuclear Regulatory Commission, in the amount of $40.00 for the amendment.

If you have any questions regarding this amendment, please contact Marshall Seiden, Senior Assistant Vice President, (414) 289-8005.

Sincerely,

Daniel A. Kane

DAK:ns

Enclosures

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Uri Vaisman, M.D.	Wisconsin

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Diagnostic Radiology		June, 1978

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	Downstate Medical Center and General Electric, Oconomowoc	SEE ATTACHED DOCUMENTS	
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	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		SEE FORM NRC-313M, Supp. B		

FORM NRC-313M-SUPPLEMENT B
(8-78)

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Uri Vaisman, M.D.

STREET ADDRESS

Mount Sinai Medical Center
950 North 12 Street

CITY | STATE | ZIP CODE

Milwaukee | WI | 53233

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 or I-123	DIAGNOSIS OF THYROID FUNCTION	100+	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	^{99m}Tc-DTPA Renogram	50+	
I-125	DETECTION OF THROMBOSIS	30+	
I-131	THYROID IMAGING	100+	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	10	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	150+	
OTHER			
Tc-99m	BRAIN IMAGING	200+	
	CARDIAC IMAGING		
	THYROID IMAGING	5	
	SALIVARY GLAND IMAGING	10	
	BLOOD POOL IMAGING	20	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	200+	
	LUNG IMAGING	150+	
	BONE IMAGING	200+	
OTHER	Hepatobiliary	50+	

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	3	
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	15	
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

July, 1978 - Present, 1,000+ hours

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

a. NAME OF SUPERVISOR
Richard H. Christenson, M.D.

b. NAME OF INSTITUTION
Mount Sinai Medical Center

c. MAILING ADDRESS
950 North 12 Street

d. CITY
Milwaukee, WI 53233

5. MATERIALS LICENSE NUMBER(S)
48-03280-01

6. PRECEPTOR'S SIGNATURE
Richard H. Christenson

7. PRECEPTOR'S NAME *(Please type or print)*
Richard H. Christenson, M.D.

8. DATE
March 31, 1981

FORM NRC-313M-SUPPLEMENT B
(8-78)

FORM NRC-313M-SUPPLEMENT B
(7-77)
10 CFR 30

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
Uri Vaisman, M.D.

STREET ADDRESS
Mount Sinai Medical Center
950 N. 12th Street

CITY | STATE | ZIP CODE
Milwaukee | Wi. | 53233

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	50 +	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	4	
	LIVER FUNCTION STUDIES	10	
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	10	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	50 +	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING	5	
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	10	
OTHER			
Tc-99m	BRAIN IMAGING	50 +	
	CARDIAC IMAGING		
	THYROID IMAGING	10	
	SALIVARY GLAND IMAGING	3	
	BLOOD POOL IMAGING	5	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	50 +	
	LUNG IMAGING	50 +	
	BONE IMAGING	50 +	
OTHER			

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 AND CARDIAC CONDITION	2	
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 May 1975 and June 1978 - 960 hours

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

a. NAME OF SUPERVISOR
Nathan Solomon, M.D.

b. NAME OF INSTITUTION
Downstate Medical Center

c. MAILING ADDRESS
450 Clarkson Av.

d. CITY
Brooklyn, N.Y. 11203

5. MATERIALS LICENSE NUMBER(S)
82-73

6. PRECEPTOR'S SIGNATURE
Nathan A. Solomon, MD

7. PRECEPTOR'S NAME *(Please type or print)*
NATHAN A. SOLOMON

8. DATE
3/16/79

FORM NRC-313M SUPPLEMENT B
(7-77)

MEDICAL EDUCATION

AFFIDAVIT OF COMPLETION

TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

THIS DOCUMENT IS TO ATTEST THAT

URI VAISMAN, MD

HAS SUCCESSFULLY COMPLETED THE FORMAL COURSE

RADIOISOTOPE HANDLERS

WHICH PROVIDED THE FOLLOWING LEVELS OF DIDACTIC, DEMONSTRATIVE AND LABORATORY TRAINING:

FIELD OF TRAINING	TYPE AND LENGTH OF TRAINING	
	LECTURE/ LABORATORY COURSES (HOURS)	SUPERVISED LABORATORY EXPERIENCE (HOURS)
RADIATION PHYSICS AND INSTRUMENTATION	7	
RADIATION PROTECTION	15	
MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	4	
RADIOBIOLOGY	2	
RADIOPHARMACEUTICAL CHEMISTRY	2	

FROM 12/3/80 TO 12/5/80
PROGRAM DATES

Monica Randall
INSTRUCTOR

OCONOMOWOC, WISCONSIN
PROGRAM LOCATION

DIRECTOR, MEDICAL EDUCATION

GENERAL ELECTRIC Control No. 0506

Addendum to FORM NRC-313M Supplement A

MEDICAL EDUCATION

AFFIDAVIT OF COMPLETION

TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

THIS DOCUMENT IS TO ATTEST THAT

URI VAISMAN, MD

HAS SUCCESSFULLY COMPLETED THE FORMAL COURSE

RADIOPHARMACEUTICAL TECHNIQUES

WHICH PROVIDED THE FOLLOWING LEVELS OF DIDACTIC, DEMONSTRATIVE AND LABORATORY TRAINING:

FIELD OF TRAINING	TYPE AND LENGTH OF TRAINING	
	LECTURE/ LABORATORY COURSES (HOURS)	SUPERVISED LABORATORY EXPERIENCE (HOURS)
RADIATION PHYSICS AND INSTRUMENTATION	8	
RADIATION PROTECTION	4	
MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	4	
RADIATION BIOLOGY	3	
RADIOPHARMACEUTICAL CHEMISTRY	11	

FROM 12/4/80 TO 12/6/80

PROGRAM DATES

Monica D. Randall

INSTRUCTOR

OCONOMOWOC, WISCONSIN

PROGRAM LOCATION

DIRECTOR, MEDICAL EDUCATION

GENERAL ELECTRIC

Addendum to FORM NRC-313M Supplement A

MEDICAL EDUCATION

AFFIDAVIT OF COMPLETION

TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES.

THIS DOCUMENT IS TO ATTEST THAT

URI VAISHAN, MD

HAS SUCCESSFULLY COMPLETED THE FORMAL COURSE

QUALITY CONTROL & COMPLIANCE IN NUCLEAR MEDICINE

WHICH PROVIDED THE FOLLOWING LEVELS OF DIDACTIC, DEMONSTRATIVE AND LABORATORY TRAINING:

FIELD OF TRAINING	TYPE AND LENGTH OF TRAINING	
	LECTURE/ LABORATORY COURSES (HOURS)	SUPERVISED LABORATORY EXPERIENCE (HOURS)
RADIATION PHYSICS AND INSTRUMENTATION	18.5	
RADIATION PROTECTION	4	
MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	2	
RADIATION BIOLOGY	2	
RADIOPHARMACEUTICAL CHEMISTRY	3.5	

FROM 12/1/80 TO 12/3/80

PROGRAM DATES

Monica N Randall

INSTRUCTOR

OCONOMOWOC, WISCONSIN

PROGRAM LOCATION

DIRECTOR, MEDICAL EDUCATION

GENERAL ELECTRIC

Addendum to: FORM NRC-313M Supplement A

MEDICAL EDUCATION

AFFIDAVIT OF COMPLETION

TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

THIS DOCUMENT IS TO ATTEST THAT

URI VAISMAN, MD

HAS SUCCESSFULLY COMPLETED THE FORMAL COURSE

BASICS OF NUCLEAR MEDICINE

WHICH PROVIDED THE FOLLOWING LEVELS OF DIDACTIC, DEMONSTRATIVE AND LABORATORY TRAINING:

FIELD OF TRAINING	TYPE AND LENGTH OF TRAINING	
	LECTURE/ LABORATORY COURSES (HOURS)	SUPERVISED LABORATORY EXPERIENCE (HOURS)
RADIATION PHYSICS AND INSTRUMENTATION	66.5	
RADIATION PROTECTION	7	
MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	10	
RADIATION BIOLOGY	13	
RADIOPHARMACEUTICAL CHEMISTRY	14	

FROM 7/7/80 TO 7/18/80
PROGRAM DATES

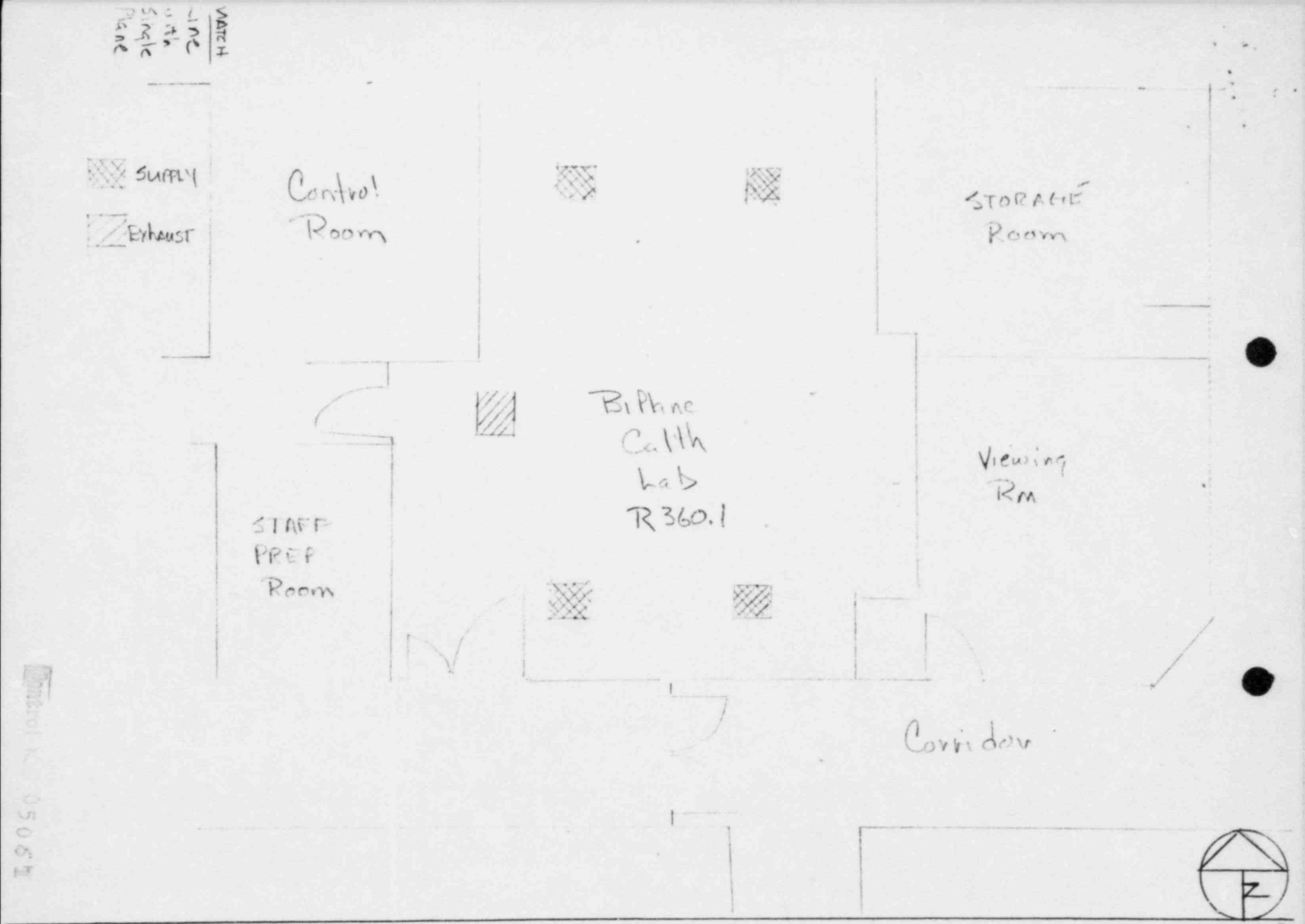
Monica N. Randall
INSTRUCTOR

OCONOMOWOC, WISCONSIN
PROGRAM LOCATION

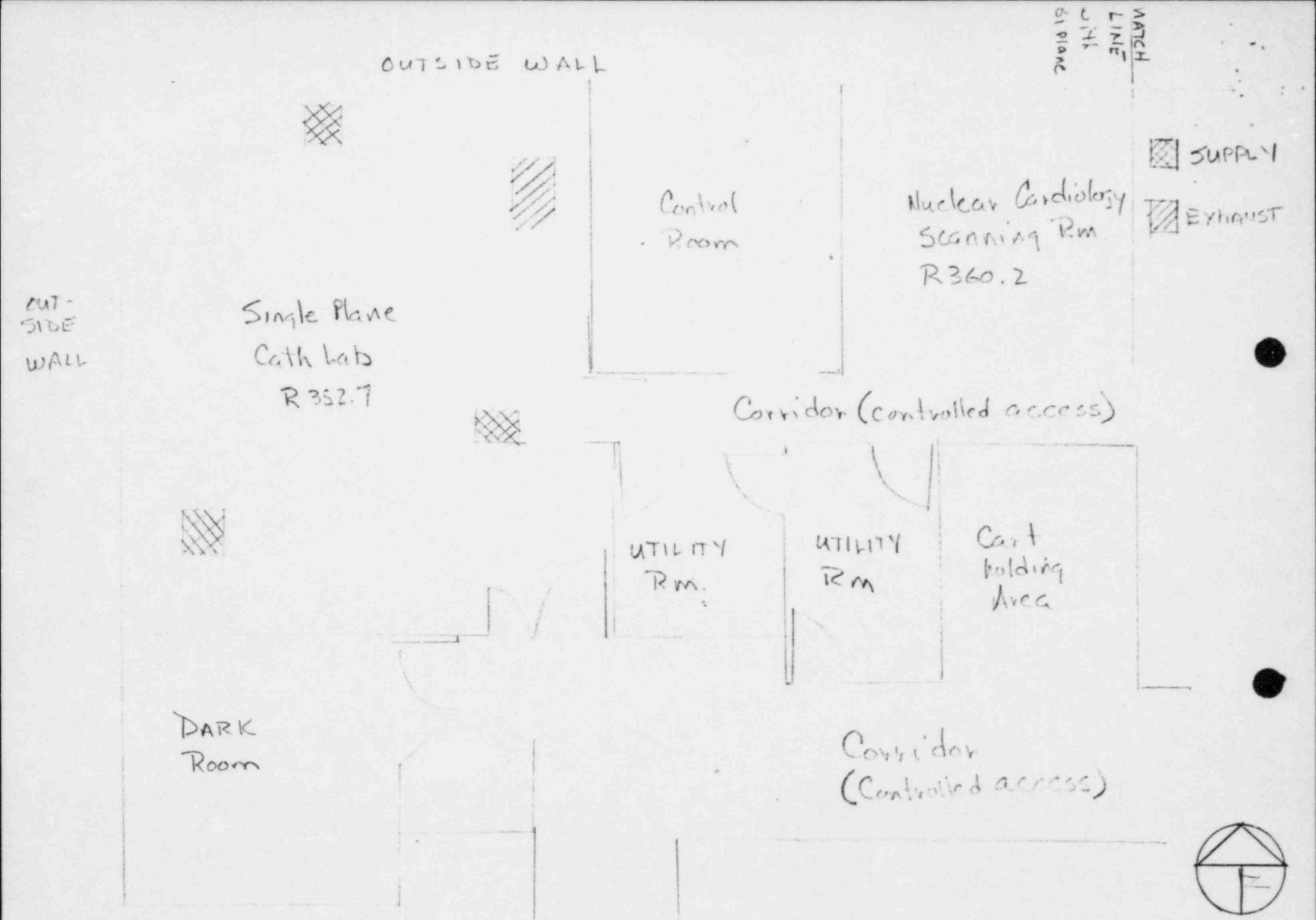
DIRECTOR, MEDICAL EDUCATION

GENERAL ELECTRIC

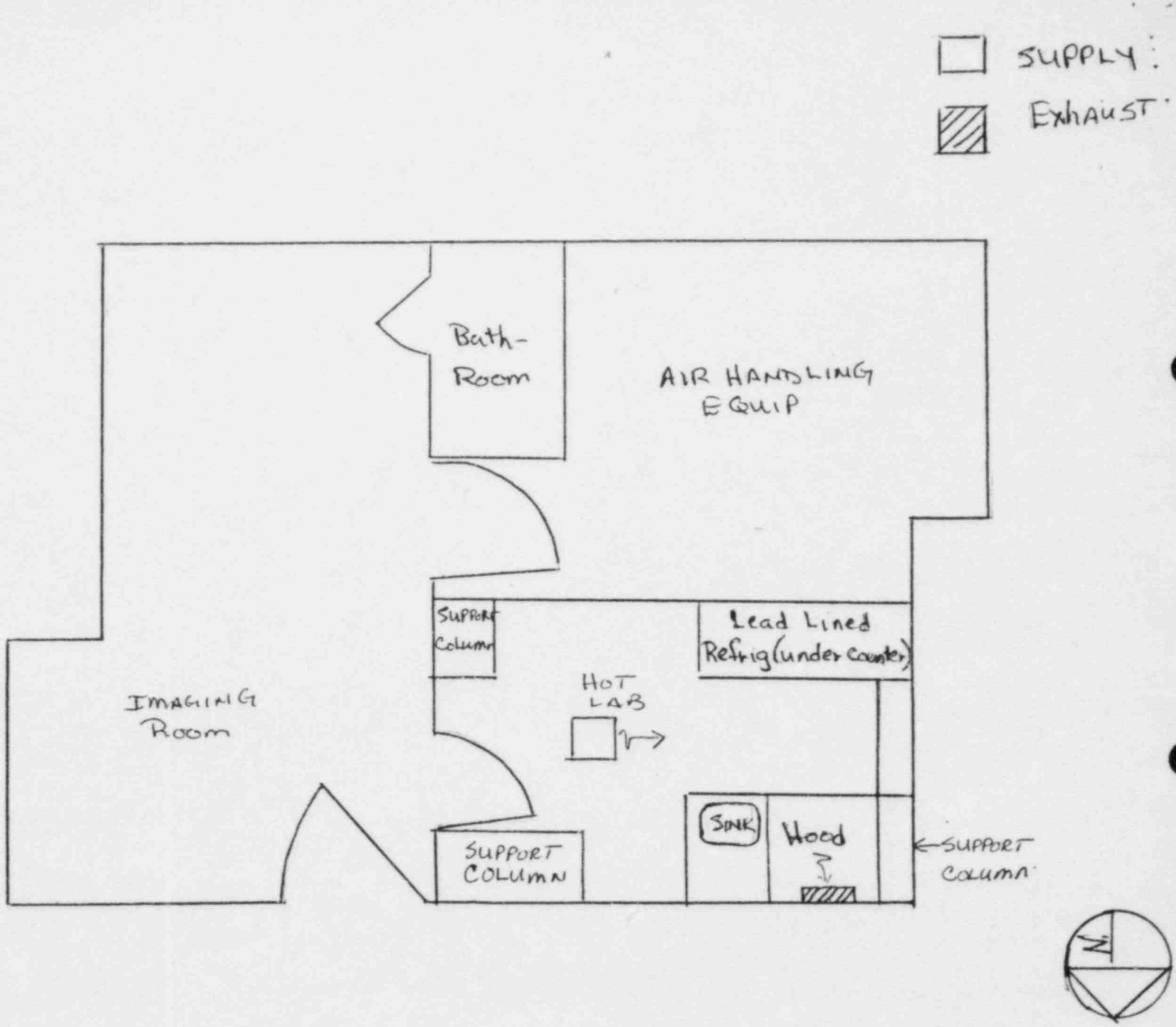
Addendum to FORM NRC-313M Supplement A



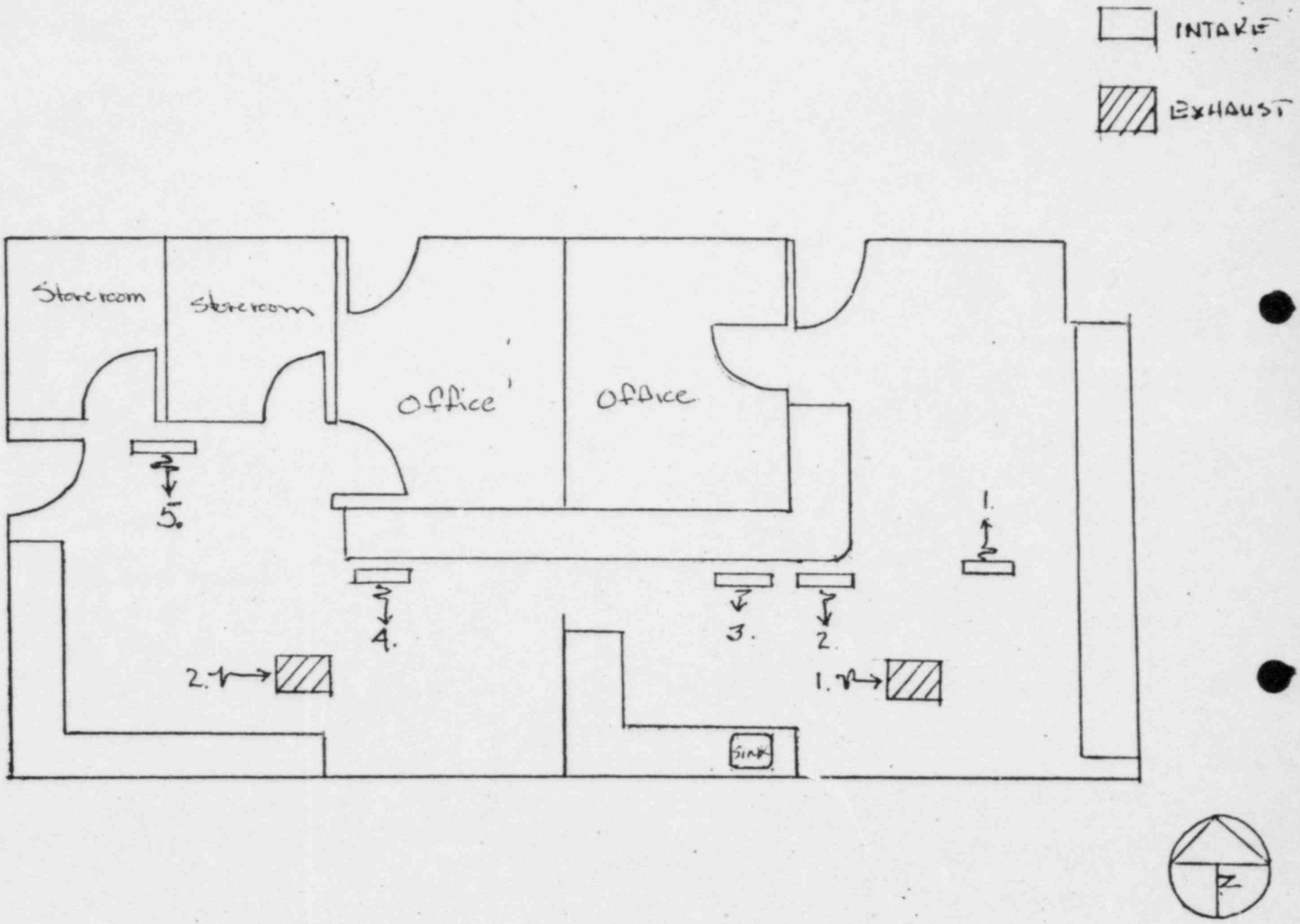
Biplane Cardiac Catherization Lab - R360.1



SINGLE Plane Cardiac Catherization Lab - R352.7



Nuclear Cardiology Imaging Room / HOTLAB R466/R466.1



C-V Research - Winter Building - W 417/422