

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041
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INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE St. John's Hospital 800 E. Carpenter Springfield, IL 62769 TELEPHONE NO.: AREA CODE (217) <u>544</u> <u>6464</u>	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE
2. PERSON TO CONTACT REGARDING THIS APPLICATION Ray Capestrain TELEPHONE NO.: AREA CODE (217) <u>544</u> <u>6464</u> x4787	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. <u>12-00026-02</u> c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) Refer to NRC313M:A&B Forms	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.) Ray Capestrain, M.S. with consultation from Nuclear Medicine Assoc. Inc., Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE					
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP III			PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP VI			XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)			
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
The purpose of this amendment is to: 1) Amend our users list, see attachment 1A. 2) Move our RIA Laboratory, see attachment 2A. 3) Add a new in-vitro laboratory, see attachment 3A. 3a) Add Cr-51 for in-vitro testing in the new in-vitro lab, see attachment 3A.			

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8, Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
Names and Specialties Attached; and		Appendix G Rules Followed; or	
Duties as in Appendix B; or _____ (Check One)		Equivalent Rules Attached	
Equivalent Duties Attached		16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		Appendix H Procedures Followed; or	
Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached	
Supplement A Attached for RSO.		17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		Appendix I Procedures Followed; or	
Appendix C Form Attached; or		Equivalent Procedures Attached	
List by Name and Model Number		18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		Appendix J Form Attached; or	
Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)		Equivalent Information Attached	
Equivalent Procedures Attached; and		19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)		Appendix K Procedures Followed; or	
Equivalent Procedures Attached		Equivalent Procedures Attached	
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
Description and Diagram Attached		Detailed Information Attached; and	
12. PERSONNEL TRAINING PROGRAM		Appendix L Procedures Followed; or _____ (Check One)	
Description of Training Attached		Equivalent Procedures Attached	
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
Detailed Information Attached		Detailed Information Attached	
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
Appendix F Procedures Followed; or		Detailed Information Attached	
Equivalent Procedures Attached		23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
		Detailed Information Attached	

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
b. FINGER	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
c. WRIST	FILM		
	TLD		
	OTHER <i>(Specify)</i>		

d. OTHER *(Specify)*

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY

STATE

ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:
7C

(2) LICENSE FEE ENCLOSED: \$ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME (Type of Print)

Sr. Ann Pitsenberger

(2) TITLE

Executive Vice President

c. DATE

8/29/85

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Amendment to NRC 12-00026-02

8-27-85

Amend Users List

- I) Delete the following users from our license.
 - a) R. Bruce Hoskins, M.D.
 - b) Erwin M. Janzen, M.D.

- II) Add Gregory A. Gregg, M.D. for Groups I, II, III and Xe-133. See enclosed NRC 313M A & B for training and experience.

- III) Add Thomas D. Miale, M.D. and Michael T. Gallagher, Ph.D. for in-vitro assay using Chromium-51 and Iodine-125. For training and experience refer to NRC 313M supplement A.

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Gregory A. Gregg, M.D.

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

Illinois

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Diagnostic	June 1984

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	SIU School of Medicine & Affiliated Hospitals June 1980 - June 1984	160	
b. RADIATION PROTECTION	"	40	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	40	
d. RADIATION BIOLOGY	"	30	
e. RADIOPHARMACEUTICAL CHEMISTRY	"	30	

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	Same as above	1980 - 1984	Therapy
I-123	3 mCi	"	"	Diagnosis
Xe-133	20 mCi	"	"	"
Tc-99m	1.5 mCi	"	"	"
P-32	5 mCi	"	"	"
In-111	1.5 mCi	"	"	"
Tl-201	5 mCi	"	"	"
Ga-67	10 mCi	"	"	"

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

Gregory A. Gregg

STREET ADDRESS

St. John's Hospital
800 E. Carpenter

CITY

STATE

ZIP CODE

Springfield

IL

62769

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		Includes Mugas
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	20	
	IN VITRO STUDIES		
OTHER	I-123 Thyroid Uptake	100	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	5	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	150	
OTHER			
Tc-99m	BRAIN IMAGING	15	
	CARDIAC IMAGING	200	
	THYROID IMAGING	5	
	SALIVARY GLAND IMAGING	2	
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	225	
	LUNG IMAGING	150	
	BONE IMAGING	450	
OTHER			

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Thomas D. Miale, M.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE Illinois		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
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	University of Florida 1971-1973	24 hrs	24 hrs	
b. RADIATION PROTECTION	University of Florida 1971-1973	24 hrs	24 hrs	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Florida 1971-1973	10 hrs	--	
d. RADIATION BIOLOGY	University of Florida 1971-1973	10 hrs	10 hrs	
e. RADIOPHARMACEUTICAL CHEMISTRY	University of Florida 1971-1973	10 hrs	10 hrs	
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
³ H-Thymidine	2mCi	University of Florida	2 yrs	Course & Autoradiography
⁵¹ Cr	100mCi	University of Florida	2 yrs	NK Assay
¹²⁵ I	5mCi	Cook Childrens Hosp. Univ of Ill. at Chicago	4 yrs 2½ yrs	NK Assay & Beta-2-microglobulin assay

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Michael T. Gallagher, Ph. D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	Northwestern University 1967-1969 M.S. Radiation Health Physics	5 courses 15 semester hours credit	Numerous labs in each course
b. RADIATION PROTECTION	Northwestern University 1967 - 1969 M.S. Radiation Health Physics	2 courses 6 semester hours credit	Numerous labs in each course
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Houston 1963-66 B.S. Northwestern University 1967-69 M.S. Radiation Heath Phy.	Many courses	N.A.
d. RADIATION BIOLOGY	Northwestern University 1967-69 M.S. Baylor College of Medicine 1970-74, Ph.D.	2 courses 6 semester hours credit	Labs in each course.
e. RADIOPHARMACEUTICAL CHEMISTRY	None	--	--

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{137}Cs	1300 Ci Source	Baylor college of medicine	1970-80	Animal irradiation
^3H	5mCi	Baylor college of medicine	1970-80	Cell Proliferation
^{51}Cr	5mCi	Baylor college of medicine	1976-80	studies
^3H	5mCi	City of Hope Medical Ctr.	1980-85	NK Cell Assay
^{51}Cr	5mCi	City of Hope Medical Ctr.	1980-85	Cell Proliferation
				studies
				NK Cell Assay

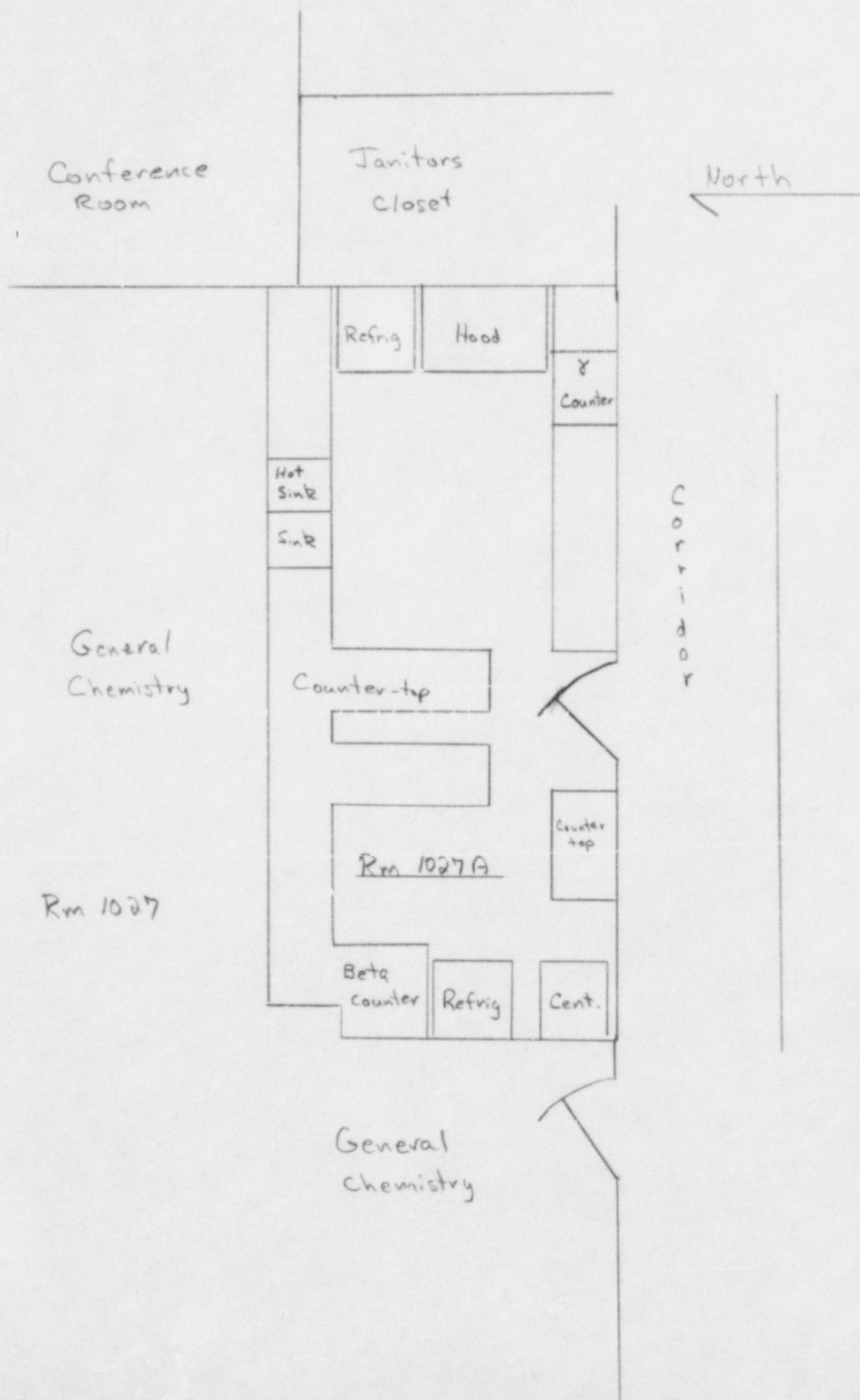
Amendment to NRC 12-00026-02

8-27-85

Moving RIA Laboratory

The RIA Laboratory will be moved to a new location in Laboratory. (Room 1027A) (See attached drawings). After RIA has vacated their present location, the laboratory will be wipe tested for any residual contamination. Any areas found to be above background will be de-contaminated prior to releasing the laboratory for general use. Records of this close-out survey will be kept on file for a period of 5 years.

8-27-85

New RIA Laboratory Room 1027A

Amendment to NRC 12-00026-02

8-27-85

Add New In-vitro Lab

Attached you will find a drawing of the new in-vitro lab (Room 1052). Note that this was the previous location of the RIA laboratory. This lab will be primarily used for in-vitro assay using Chromium-51. This lab will be wiped tested monthly.

Add Chromium-51 for In-vitro Testing

We wish to add Chromium-51 in the chemical form of sodium chromate and physical form of liquid, to be used in the new in-vitro lab (room 1052). Maximum possession limit will be 3.0 millicuries. All applicable rules & regulations as specified in our license application dated Nov. 25, 1983, and letter dated April 30, 1984, will be followed.

CONTROL NO. 79686

CONTROL NO. 79687

8-27-85

New In-vitro Lab Rm 1052