FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved: GAO R0557

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

Community Blood Center of Greater Kansas City
4040 Main
Kansas City, Missouri 64111
TELEPHONE NO.: AREA CODE (816) 753 4040

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1.A.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Dr. Gary Tegtmeier
TELEPHONE NO.: AREA CODE (816) 753 4040

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] 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.)*

Dr. Walter Dukstein
Dr. Gary Tegtmeier

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.)*

N/A

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	5
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
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
Cr-51	Liquid	2.0	Red Blood Cell Survival
H - 3	Liquid/solid	5.0	In-Vitro Studies
C - 14	Liquid/solid	5.0	In-Vitro Studies

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Control No. 02102

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: Jan. 1977

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	Duties as in Appendix B; or _____ *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or _____ *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

TRAINING AND EXPERIENCE

Name:	Previous License Number:
Walter G. Dukstein, M.D.	24-15894-01
Gary Tegtmeier, Ph.D.	See Attached

Item No. 8

Date: 8-8-79

Control No. 02102

community (NONPROFIT) blood center of greater kansas city

TO: U.S. Nuclear Regulatory Commission

FROM: Gary E. Tegtmeier, Ph.D.

DATE: July 23, 1979

RE: Graduate course in radioisotope methodology.

During the winter quarter, 1974, I took a five credit hour graduate course at Southern Illinois University, Carbondale, on the principles of radioisotope methodology which included three hours of lecture and six hours of laboratory each week. The course covered the following broad topic areas: (1) atomic and molecular structure (2) principles of radiation measurement (3) indeterminate and determinate errors in measurement (4) radioactive decay (4) properties of radiation and its interaction with matter (6) radiation detection by ion collection (7) scintillation techniques (8) autoradiographic techniqes (9) use of isotopic tracers in biology and (10) radiation biology.

4040 main street, kansas city, missouri, 64111 · (816) 753-4040

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Eberline Instrument Corporation

Manufacturer's model number: E120

Number of instruments available: _____

Minimum range: 0 mr/hr to 0.5 mr/hr

Maximum range: 0 mr/hr to 50 mr/hr

b. Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

Ranges: _____

Minimum range _____ mr/hr to _____ mr/hr

Maximum range _____ mr/hr to _____ mr/hr

Item No. 9

Date: 8-8-79

2. Dose calibrator

Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

3. Diagnostic instruments

TYPE OF INSTRUMENT	MANUFACTURER'S NAME	MODEL NO.
Well Counter	Abbott	Auto Logic
LSC	Nuclear Chicago	

4. Other

Item No. 9.

Date: 8-8-79

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items:

XX 1. Survey instruments will be calibrated at least annually and following repair.

XX 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

____ 3. Survey instruments will be calibrated.

____ a. By the manufacturer.

____ b. At the licensee's facility.

____ (i) Calibration source
Manufacturer's name_____
Model no._____
Activity in millicuries_____
Accuracy_____
Traceability to primary standard_____

(ii) The calibration procedures in Appendix D, Section I will be used,

or

(iii) The step-by-step procedures including radiation safety procedures are attached.

____ c. By a consultant or outside firm.

(i) Name PHARMACO NUCLEAR INC.

(ii) Location 1734 E. 63rd Street - Kansas City, Mo. 64110

(iii) Procedures and sources

XX have been approved by NRC and are on file in License No. 24-16617-01MD.

____ are attached

FACILITIES and EQUIPMENT

Two rooms plus a cold storage area have been set up for using radioactive material at the Community Blood Center of Greater Kansas City. Diagrams of the two rooms are enclosed. The areas will be used for the receipt, use, storage (including waste), preparation, and measurement of radioactivity.

The following items are provided for handling radioactive material safely:

1. Disposable Gloves
2. Lead Vial Shields
3. Tongs and Forceps
4. Absorbent Paper
5. Fume Hoods
6. Survey Meter

I-125 and Cr-51 waste will be stored in a plastic lined box located in the 2" thick lead brick safe until it decays to background. H - 3 and C - 14 waste will be stored in a commercial radioactive waste disposal drum obtained from an approved radioactive waste disposal company. When the drum is full, it will be picked up by the disposal company.

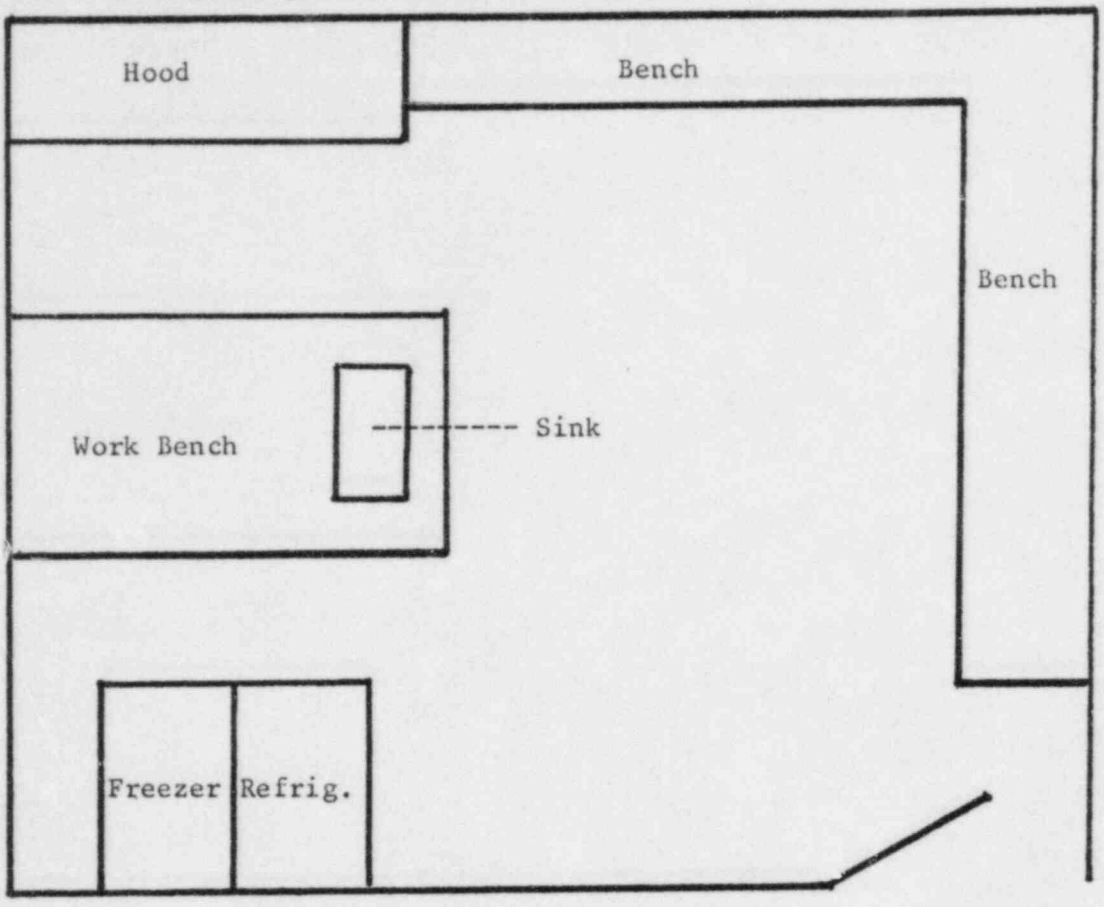
Item No. 11

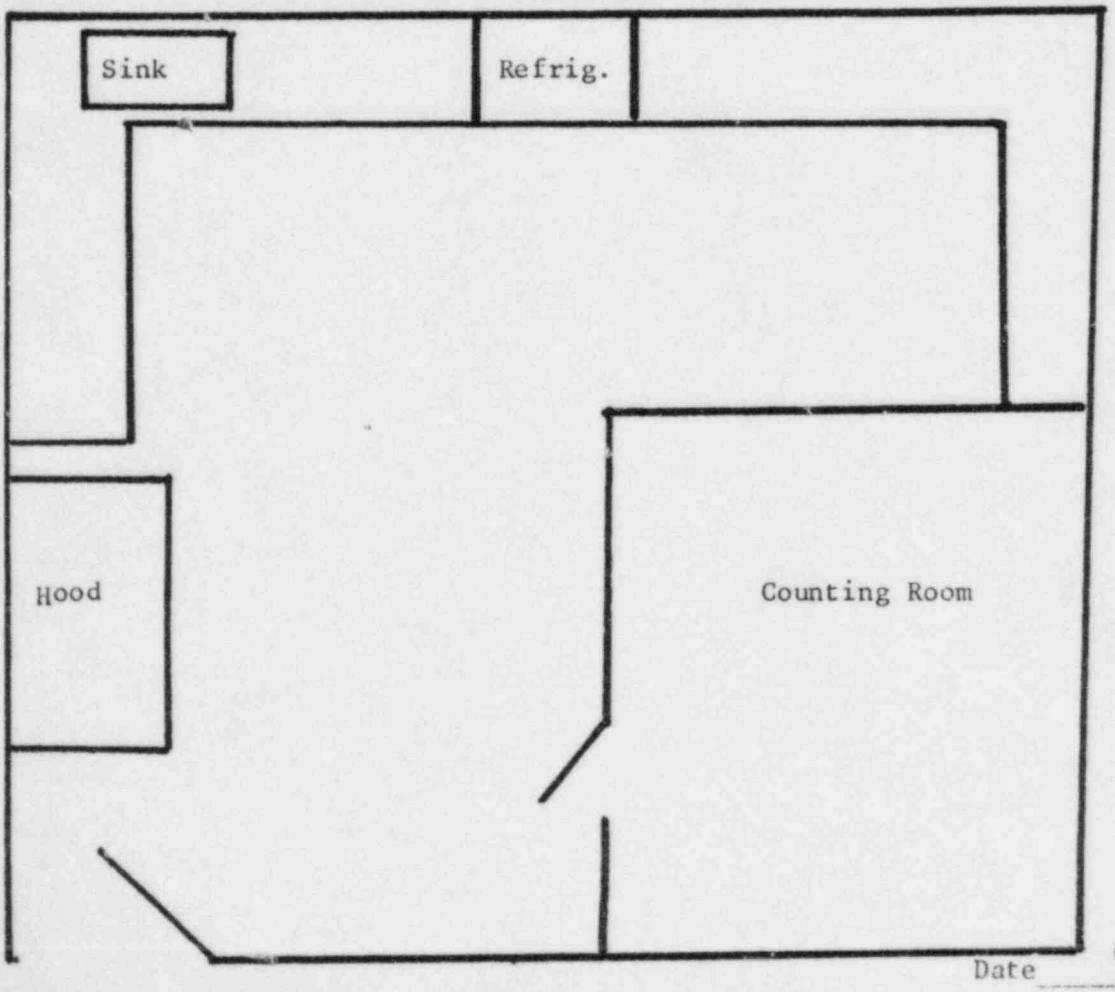
Date 8-8-79

Control No. 02102

ISOTOPE LABS

Community Blood Center of Greater Kansas City





Date 8-8-79

PERSONNEL TRAINING PROGRAM

The individuals who routinely handle radioactive material will be trained laboratory technologists. Personnel who will work around radioactivity infrequently include housekeeping, maintenance, and security.

Personnel who routinely handle radioactive material will be required to hear a lecture before assuming their duties and annually for refresher training. The training lecture will include the following:

1. Parts 19 and 20 of 10 CFR
2. Areas where radioactive material is used
3. Potential hazards associated with the use of radioactive material
4. Radiological Safety Procedures
5. Pertinent NRC Regulations
6. Pertinent terms of the license and license application
7. Their obligation to report unsafe conditions
8. Emergency response
9. Their right to be informed of their radiation exposure

Personnel who work infrequently with or around radioactivity will be given annual in-service lectures based on the items listed above and they will be given specific safety instructions prior to initiating their duties for a particular job.

Lectures will be given by the RSO or a consulting physicist.

Item No. 12

Date 8-8-79

Control No. 02102

PROCEDURES FOR ORDERING AND RECIEVING RADIOACTIVE MATERIALS

1. The chief laboratory technologist or an approved user will place all orders for radioactive materials and will insure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. Cr-51 will be ordered on an as need basis from Pharmaco Nuclear, Inc. in precalibrated, unit dose vials. The vials will be assayed on a dose calibrator just prior to delivery to the Blood Center.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Blood Center.

4. During off-duty hours, Shipping Department, will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed memorandum. (Attached)

Item No. 13

Date 8-8-79

MEMORANDUM FOR

FROM: Gary E. Tegtmeier, Ph.D.

SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:00 p.m. and 7:30 a.m. or on Saturday or Sunday shall be signed for by the Shipping Department personnel on duty and taken immediately to the walk-in refrigerator in the Research Department. Place the package on the work bench in the walk-in refrigerator and leave a note in the Hepatitis Laboratory that a package has been delivered.

If the package is wet or appears to be damaged, IMMEDIATELY contact the Radiation Safety Officer. Ask the carrier to remain at the Community Blood Center until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: Gary E. Tegtmeier, Ph.D.

OFFICE PHONE: 753-4040 extension 143

HOME PHONE: 362-8596

Item No. 13

Date: 8-8-79

Control No. 02103

PROCEDURES FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIALS

Packages will be opened in accordance with 20.205 of 10 CFR, Part 20. Procedures for safely opening packages will be in accordance with Regulatory Guide 10.8, A Guide for Preparation of Applications for Medical Programs, Rev _____, Dated 1/79 .

Item No. 14

Date: 8-8-79

LABORATORY RULES FOR USE OF RADIOACTIVE MATERIAL

We will follow the laboratory rules described in Regulatory Guide 10.8, Rev _____ Dated 1/79 .

Item No. 15

Date: 8-8-79

EMERGENCY PROCEDURES

Emergency Procedures will be posted in all laboratory areas where radioactive materials are used. The Emergency Procedures in Appendix H of Regulatory Guide 10.8, Rev. _____, Dated 1/79, will be used for this purpose.

Item No. 16

Date: 8-8-79

Control No. 02102

AREA SURVEY PROCEDURES

Area surveys will be performed with a low level survey meter to detect any radiation areas and wipe tests to detect any areas of contamination.

The radiation survey will be performed weekly. Wipe tests will be performed monthly. The radiation survey meter will be capable of measuring .1 mR/hr. Wipe tests will be counted on the Abbot Logic Well Counter. The wipe test is sensitive enough to detect 100 DPM/100 cm^2.

A permanent record will be kept of all survey results and any corrective action taken in case of contamination or excessive exposure rates.

Item No. 17

Date 8-8-79

X Disposed of by commerical waste disposal service (See also No. 4 below)

___ Other (Specify): _____

_____

4. The commerical waste disposal service used will be: _____

Rad Services Inc. Laurel Maryland 20810
(Name) (City, State)

NRC/Agreement State License No. M.D.-21-0I2-0I

Item No. 18
Date: 8-8-79

APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

____ By commercial waste disposal service (See also No. 4 below)

x In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be:

(Check as appropriate)

____ Returned to the manufacturer for disposal

____ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants)

____ Disposed of by commercial waste disposal service (See also No. 4 below)

____ Other (specify): _____

3. Other Solid Waste will be:

(Check as appropriate)

X Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed) have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

Item No. 18
Date: 8-8-79

PROCEDURES AND PRECAUTIONS FOR USE OF

RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.B.

See items #14, 15, 15, 17, and 18.

Item No. 23

Date 8-8-79

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Landeaur Jr. & Son	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

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: 7B

(2) LICENSE FEE ENCLOSED: $ 190 ~~00~~

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* William M Coenen

(1) NAME *(Type or Print)* William M. Coenen

(2) TITLE Adminstrator

c. DATE August 8, 1979

FORM NRC-313M (8-78)

Control No. 02103

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 Form NRC-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.