MS 18
P2

Cardiovascular Associates, P.C.
WALLACE B. LEBOWITZ, M. D.
Theodore F. RITZER, M.D.

2660 MAIN STREET
BRIDGEPORT, CONNECTICUT 06606
TELEPHONE 334-1755

2068 BRIDGEPORT AVENUE
MILFORD, CONNECTICUT 06460
TELEPHONE 874-1799

DocKet # 030-28674
Control # 18953

7/23/85

Dear DR. Glenn,

Pursuant to your letter of 5/29/85 (xerox copy enclosed) refering to my application for a medical byproduct materials license, please find enclosed:

a) supplement A form including the suffix to my name with medical degree. and the states and territories I'm licensed to practice.

b) answers to questions 2 + 3 submitted on separate sheets.

c) The mailing address to be shown on The license is 2660 Main ST, Bpt, Conn 06606.

I hope The information enclosed answers all your questions. If you require any other information please notify me.

Thank you for your prompt attention to This matter.

Sincerely,
Theodore F. Ritzer

18953

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

MAY 29 1985

DOCKET NO. 030-28674
CONTROL NO. 18953

Theodore F. Ritzer
45 Bluebird Drive
Colchester, VT 05446

Dear Dr. Ritzer:

This is in reference to your application received May 10,1985, for a medical byproduct materials license. In order to continue our review, we need the following additional information:

1. The submitted NRC-313M, Supplement A form does not document a physician's name. Please submit your Supplement A form (or on an equivalent form), specifying the state or territory of the United States of America where you are authorized to dispense drugs in the practice of medicine. Also include the suffix to your name specifying your medical degree.

2. The training and experience documented on your Supplement B form indicates Groups II and III experience with Tc-99m and Mo-99/Tc-99m generators, but no experience with uptake and dilution studies (Group I) using I-125, I-131, Cr-51, Co-58, Co-60 and Fe-59 in the forms specified under Group I in Section 35.100 of 10 CFR 35 (enclosed). Accordingly, Please clarify what authorization(s) or Groups for which you wish to be licensed.

3. You failed to submit the information required under Items 9, 10, 11, 13, 14, 15, 16, 17 and 18 of your application. Please submit this information. Refer to the enclosed Regulatory Guide 10.8 for the minimum procedures and criteria needed in a nuclear medicine/imaging program that we find acceptable.

4. Please confirm that the mailing address to be shown on the license is your Connecticut address.

We will continue our review of your application upon receipt of the above information. Please reply in duplicate, referencing Control No. 18953.

Sincerely,

John E. Glenn

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

NRC FORM 313M SUPPLEMENT A
(9-81)

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
THEODORE F. RITZER M.D., Ph.D.	CONN, VT, Pa, MAINE

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			
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

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Pursuant to item 2 of your letter referring to supplement B, I wish to be licensed only for use of Tc-99m for cardiac imaging.

T. Ruffer.

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	[X] 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	[X] Appendix H Procedures Followed; or
[X] 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)*	[X] Appendix I Procedures Followed; or
[X] 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
[X] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	[X] Equivalent Information Attached
[ ] Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
[X] 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**
[X] 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)**
[X] 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**
	[ ] Detailed Information Attached
[X] Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
[ ] Equivalent Procedures Attached	[ ] Detailed Information Attached

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041

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 TELEPHONE NO.: AREA CODE( ) _____ _____	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 TELEPHONE NO.: AREA CODE( ) _____ _____	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ 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.)*	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.)*

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		
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

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: ATOMIC Products CORP

   Manufacturer's model number: 052-496 Probe — 052-170

   Number of instruments available: _____

   Minimum range: 0 mR/hr to 500 ~~mR/hr~~ cts/min

   Maximum range: 0 mR/hr to 500,000 ~~mR/hr~~ cts/min

   b. Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

   Minimum range: _____ mR/hr to _____ mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

2. ✓ Dose calibrator

   Manufacturer's name: ATOMIC Products CORP.

   Manufacturer's model number: CAL/RAD II Isotope CalibratoR - 086-061

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
MEDX HS-10/S High Speed Gamma Camera	MEDX	HS-10/S

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

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11- Facilities + Equipment

Initially we plan to house our equipment in a room 7½' x 23'
Please see drawing attached.

Facilities

1- Table top (metal) for opening and preparation of radionuclide materials and immediate storage of radionuclide syringes in lead lined caddy. also storage of waste syringes + associated materials before pickup by Mallinckrodt. Table will be used for storage of absorbant chucks, syringes, needles, alcohol + providine wipes, butterfly venipuncture + CMP bolus injection sets.
2- lead lined storage containers - 1/8" lead shielding 6¾" x 5"
3- Metal container for disposal of nonradioactive materials.
4- Mini table top shield - ½" lead wall, ¼" lead glass
5- Lead lined syringe carrier (caddy)
6- Chucks, alcohol wipes, idophour wipes, 5", 10 cc syringes, 18G needles, 0.9% NaCl, sterile vials.
7 Radiation area monitor (05-2-496) & Probe (05-2-170)
8- 100, 250 cc bags of DSW and 0.9% NaCl.
9- Dose Calibrator - CaL/Rad II. Isotope Calibrator.
10- High handle foot stool.
11 Scanning COT } double duty
12 Cardiac stress table }
13. Flood phantom, Bar phantom.
14. 3 channel ECG, Disc Electrodes.
15. Treadmill
16. MEDX 750/3 Nuclear Medicine Gamma Camera computer System.

(cont)

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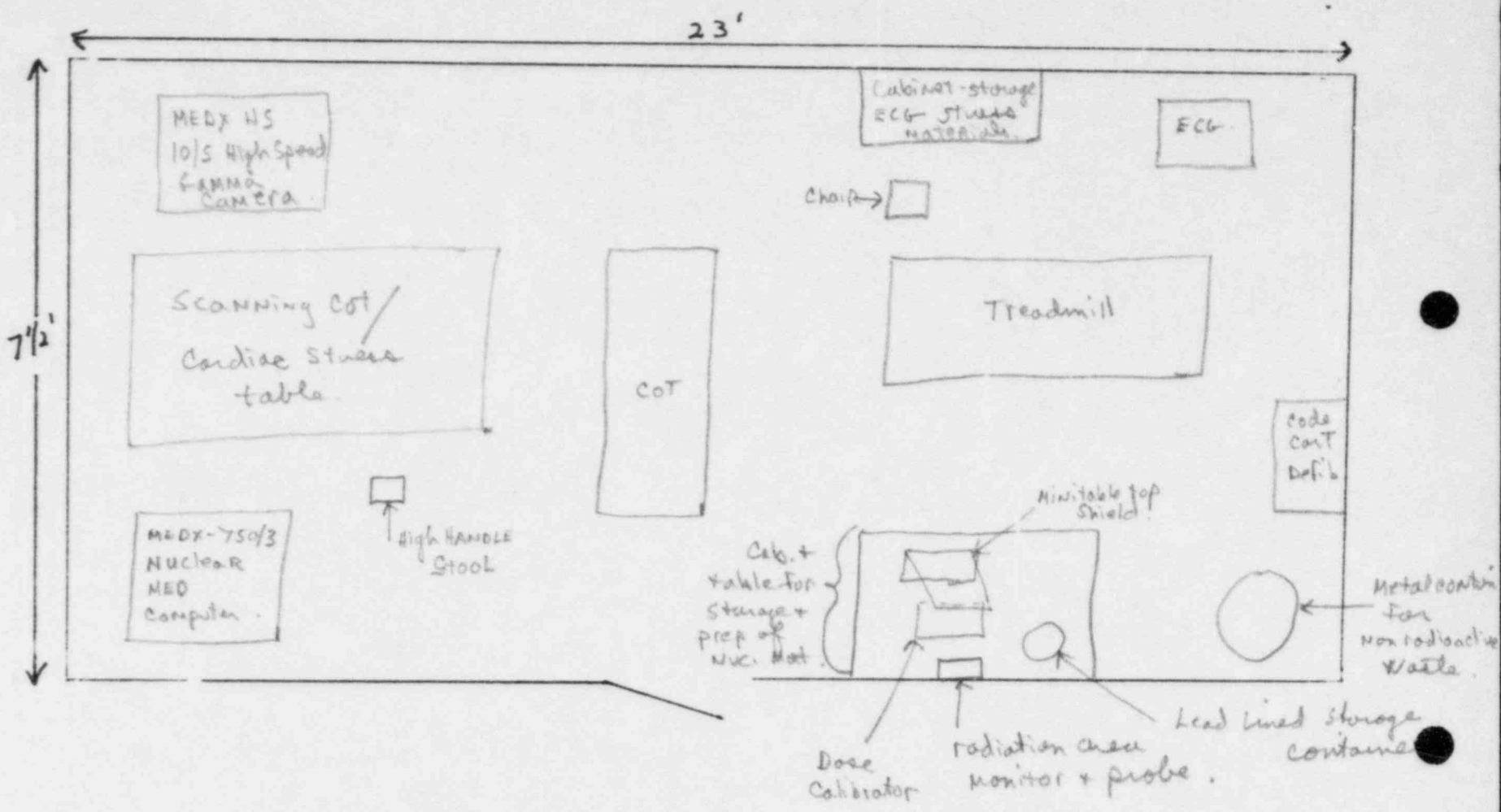
(Cont)

17 - Brattle 212 ECG gate + R wave trigger & PVC rejection.
18 - Video imager.
19 - MEDX HS-10/5 High Speed Gamma Camera System.
20 - Defibrillator, Code Cart.

T. Phelps


23'
7½'
MEDX HS
10/5 High Speed
GAMMA
Camera
Cabinet - storage
ECG Stress
material
ECG
Chair
Scanning Cot/
Cardiac Stress
table
COT
Treadmill
Code
Cart
Defib
MEDX-750/3
NUCLEAR
MED
Computer
High HANDLE
Stool
Mini table top
Shield
Cab. +
table for
storage +
prep of
Nuc. Med
Metal contain
for
Non radioactive
Waste
Lead lined storage
container
Dose
Calibrator
radiation meter
monitor + probe.

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13- Procedures for ordering and receiving radioactive material.

ALL of our radionuclide material (Tc-99m and Thallium 201) will be delivered by Mallinckrodt Co. (College Point Bld, Flushing, N.Y.) in individual doses delivered in sterile syringes ready for injection. There will be no mixing or drawing up of radionuclide materials. The syringes will be placed in syringe shields or stored in a lead lined syringe carrier (caddy) until time of injection. The package will be opened in a corner of the room on a table covered ~~c~~ absorbent chucks monitored by a survey meter behind a table top lead barrier shield behind which a dose calibrator will be located.

T. Thuyen

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18. WASTE Disposal

As previously stated in section 13 all our radionuclide material (Tc 99m and Thallium 201) will be delivered by Mallinckrodt Co. (College Point Blvd., Flushing N.Y.) in individual doses in sterile syringes ready for injection. As part of the company's service they will take back all used syringes and associated materials - i.e. alcohol wipes, heparin locks, saline flushes, tubing etc. Therefore, we do not anticipate having any low level radioactive material to dispose of unless there is a spill. If there is a spill we will follow procedures as outlined in section 16. All the materials used to clean the spill would be stored in an appropriate receptacle for 4-5 half lives or until the activity was less than 2x background before disposal as non radioactive material.

T. Thaler