

October 21, 1987 101-2

United States Regulatory Commission Region III 700 Roosevelt Road Glen Ellyn, Illinois 60137 Licensing Section

RE: NRC License Number 48-24566-01

Mobile Cardiovascular Testing is requesting an amendment to the above noted license. The purpose of the amendment is to initiate the provision of imaging procedures utilizing byproduct material at several sites. These sites will not need to invest in expensive, delicate equipment. In addition, the studies will be performed under the supervision of individuals with extensive clinical training and history of successful safe use of byproduct material. Our goal is to run a business which addresses an economic problem while assuring adequate radiation protection to minimize exposure in providing sophisticated diagnostic procedures.

Specifically, information topics relating to mobile nuclear services have been attached to this request to detail the procedures under consideration. An attempt was made to address receipt, assay, transport, quality control of equipment, contamination survey and training in the hopes of making a complete amendment request.

Sincerely,

John Carpenter Technical Director

8902280179 880121 RE93 LIC30 48-24566-01 PNU

> 1218 W. Kilbourn Avenue Suite 307 Milwaukee, WI 53233 (414) 289-8164

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Information to be submitted for a licensing amendment to operate a mobile nuclear medicine service

1. Description of Services

Services will include imaging procedures as listed in Groups II and III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulation. These services will include, but not be restricted to, thallium myocardial perfusion imaging, equilibrium myocardial blood pool imaging utilizing technetium-99m in vivo labeled pyrophosphate, and first transit radionuclide angiography utilizing technetium-99m DTPA.

2. Site Approval

See attachments A, B, C, D.

3. Physician Control of Byproduct Material

A physician listed on the Materials License will be available by phone in case of an emergency relating to byproduct material administration or exposure. A nuclear medicine technologist under the direction of the Radiation Safety Officer will administer each dose.

4. Confirmation of Dose Calibration

All doses will be assayed prior to transport.

5. Transport Procedures

See Attachment I

6. Van Security

Byproduct materials will be secured during transit. The vehicle will be locked when unattended.

7. Training of Drivers

See Attachment J

8. Site Description

See attachments E, F, G, H.

9. Calibration of Equipment

Mobile Cardiovascular Testing will establish and implement the model procedure for insuring imaging equipment performance that was published in Appendix E to Regulatory Guide 10-8, Revision 2.

10. Contamination Survey

A contamination survey will be performed at each site using the survey meter assuring that areas of byproduct use are at levels indistinguishable from background. Contamination will be removed as necessary.

11. Storage

Byproduct material will not be stored in the vehicle overnight. The vehicle will be checked for contamination after each day of use to assure levels indistinguishable from background.

12. Receipt

Byproduct material will be received at Mobile Cardiovascular festing under the terms and condition of its license.

13. Gases

The use of radioactive gases is not currently under consideration.



This letter is to confirm that I authorize the use of byproduct material at:

Homestead Family Health Center 4922 Columbia Road Cedarburg, Wisconsin 53012

The office does not have an active NRC license.

Cham & Henzigh was

Thomas J. Shewczyk, M.D.



This letter is to confirm that I authorize the use of byproduct material at:

210 N.W. Barstow Street Suite 110 Waukesha, Wisconsin 53188

The office does not have an active NRC license.

Kraig Lorenzen, M.D. Ph.D.

1218 W. Kilbourn Avenu∈ Suite 307 Milwaukee, WI 53233 (414) 289-8164

Attachment B



This letter is to confirm that I authorize the use of byproduct material at:

Cardiology Associates 515 Washburn Suite 104 Oshkosh, Wisconsin 54904

The office does not have an active NRC license.

Mamoun B. Al-Nouri, M.D.

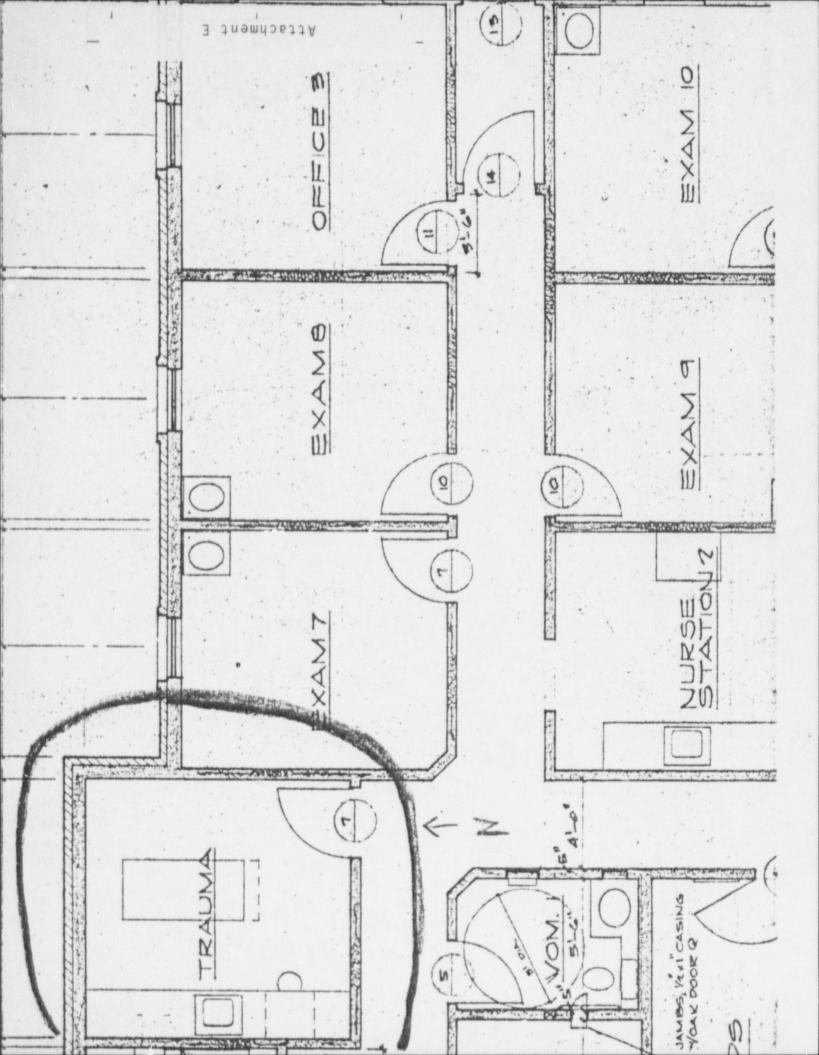


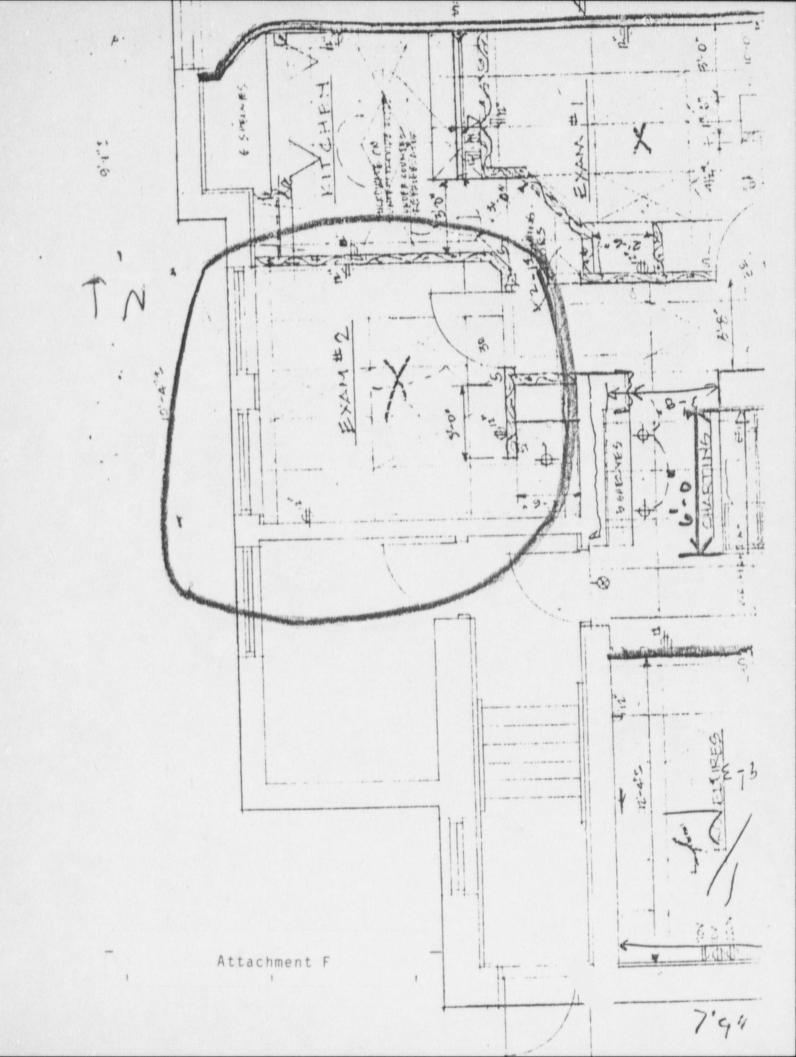
This letter is to confirm that I authorize the use of byproduct material at:

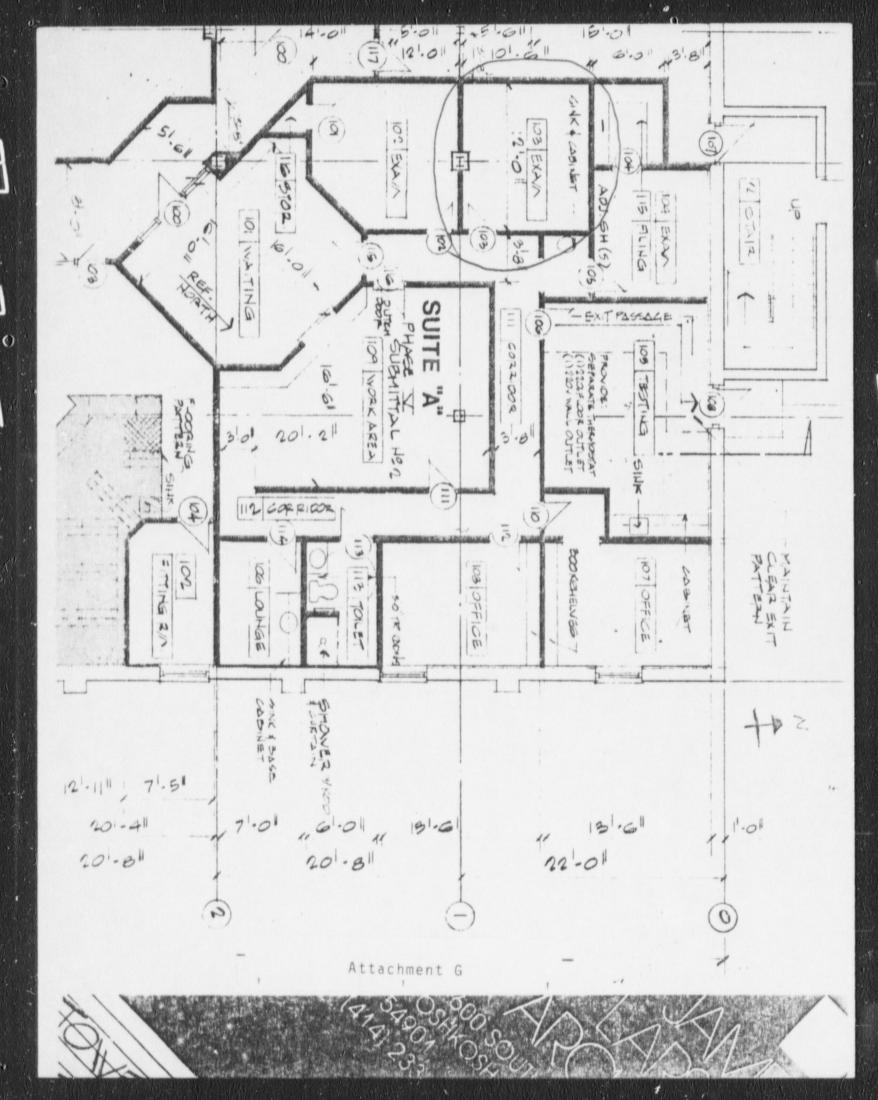
Park Crest Medical Clinic, S.C. 2665 S. Moorland Road New Berlin, WI 53151

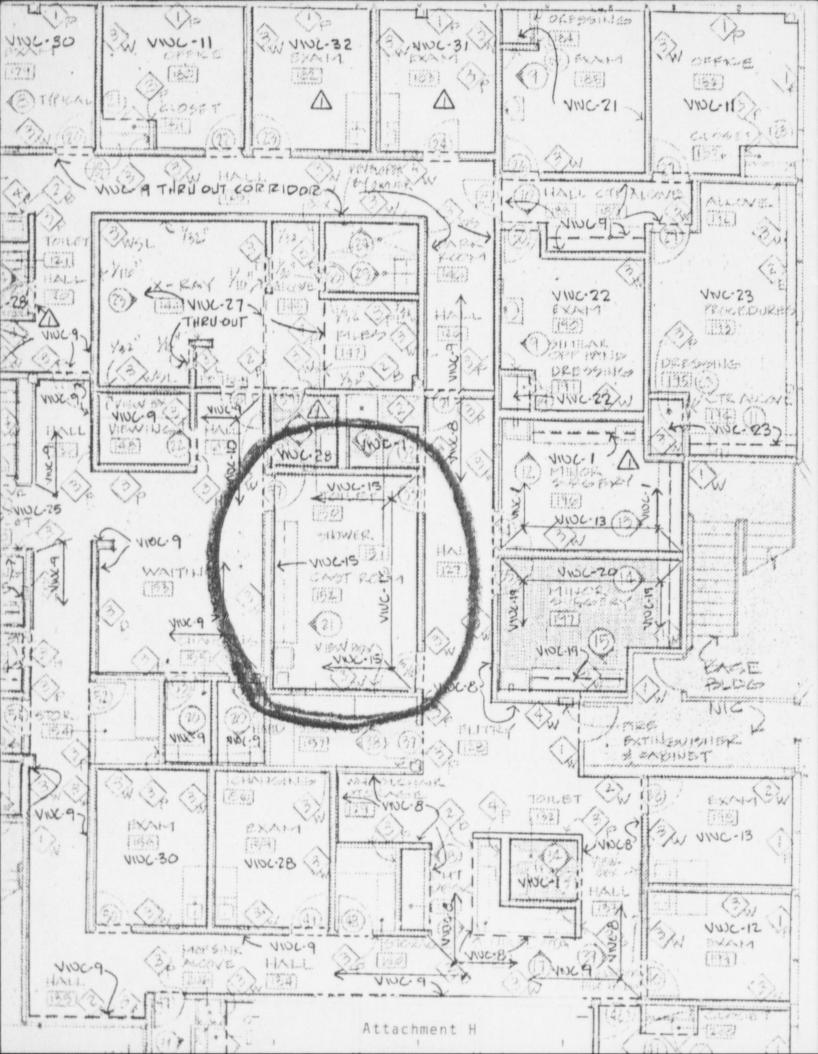
The office does not have an active NRC license.

Herbert A. Oxman, M.D.









#### TRANSPORTING RADIOACTIVE MATERIALS

Notwithstanding Section 35.14 (b)(1)(i) of 10 CFR 35, the licensee may transport radioactive materials to temporary job sites listed in Item 2 of this application. There will be no storage of radioactive materials at any of the satellite sites. Any used radioactive sources or syringes containing residual radioactivity will be returned to this licensee's storage area.

# TRANSPORT PROCESS:

All radioactive material will be transported by van or car by the licensed physician users or Nuclear Medicine technologist employed by this license applicant. This carrier will be responsible for pick-up, packaging, and transporting radioactive materials between the base and satellite sites. Radioactive materials will at all times be in the possession of this individual during the entire transporting process.

# PACKAGE DESCRIPTION:

All radioactive materials will be placed within lead shipping containers sufficient to reduce external exposure to background levels or as low as reasonably achievable. These lead shipping containers will be sealed with tape and placed in a DOT approved container which is locked to restrict access by unauthorized personnel and secured to the vehicle. Through layering of absorbent material in the package, the lead shipping container(s) will be placed in the geometrical center of the package.

Any applicable Department of Transportation regulations with reference to vehicle placarding will be followed.

### LABELING:

Package: The package described above will be labeled on opposite sides with, "Radioactive Materials Package" labels as specified in § 172.438. Appropriate "Radioactive Materials Package" labels will be determined by exposure rate limits as specified in §172.399. "Caution - Radioactive Materials", labels and the trefoil radiation symbol will be posted on the top of the package.

# VIALS AND/OR SYRINGES:

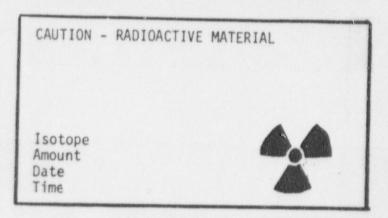
Each vial or syringe containing radioactive material will be labeled to note the following:

- 1. Date and time of assay.
- 2. Radioactive material identity (radionuclide and chemical form).

3. Activity at time of assay.

Each label will contain the trefoil radiation symbol and the words, "Caution - Radioactive Materials".

Sample Label



The above sample is a facsimile of Nuclear Associates, Inc., Model 09-112, pressure sensitive tape with official NRC radiation symbol in magenta on a yellow background. Each label from this roll tape measures about 1" wide by 2" in length.

# ASSAYS

All assays, materal preparations, packaging and labeling will be performed only by a licensed nuclear physician user or his/her designated, trained nuclear technologist.

Each patient dose will be assayed in our Hot Lab dose calibrator prior to transport. A decay chart, or decay calculations, will then be used at each facility to define any applicable corrections in actual patient dosage, at time of dose administration.

### RADIATION SAFETY AND SECURITY

The radioactive material transport container will be secured in a locked car trunk, or compartment in the locked van, as far away as possible from the driver compartment. Transportation of passengers is not anticipated. The transport container will be braced or anchored to prevent shifting of the container during transport. The drivers are instructed to call the licensee's main office if any delays are encountered in service - schedule routes and to check in when they arrive at the service facility, In the event an undue delay occurs and no call-in report is made, the main office would conduct a search along the transport route. In the event an accident occurs which could involve contamination or public concern, the main office (R.S.O. or his/her delegate) would immediately report such an incident to the appropriate nuclear materials licensing and inspection authorities as designated on the, "Notice to Employees" sign, required to be posted in the main office (Hot Lab) facility.

The Radiation Safety program in this application is applicable to the temporary job sites as well as to the base lab.

# NOTICE

"This package conforms to the conditions and limitations specified in § 173.421 for excepted radioactive material, limited quantity, n.o.s., UN2910."

This exception from the Department of Transportation (DOT) specification packaging, shipping paper certification, marking, and labeling requirements applies if the following conditions are met:

- a) The materials are in a package that will not leak any of the radioactive materials during conditions normally incident on transportation.
- b) The radiation level at any point on the external surface of the package does not exceed 0.5 mR per hour. (These surface readings are usually measured with a low level Geiger-Mueller [g.m.] survey meter.)
- The removable radioactive contamination on the external surface of the package does not exceed 22 disintegrations per minute (DPM), per square centimeter (cm²) or 2,200 DPM/ 100 cm². (these surface "wipe tests" are often taken with a moist 2" x 2" or alcohol swab used to wipe a total of 300 square centimeters of package surface, or about 50 cm² on each of the 6 sides of a typical square package.) To be exact, the counting efficiency of the instrument used to count the wipe test sample(s) needs to be known to convert displayed counts per minute (CPM) to DPM.
- d) The outside of the <u>inner</u> package bears the marking, "Facioactive". <u>Or</u>, if there is no inner package, the outside of the packaging itself bears the marking, "Radioactive".
- e) The shipment must be certified as being acceptable for transportation by having a <u>notice</u> enclosed <u>in</u> or <u>on</u> the package, included with the packaging list, <u>or</u> otherwise forward with the package. This notice must include the name of the consignor (shipper) or consignee (receiver) and the statement as quoted in the first paragraph of this notice. Completion of this notice by the shipper and taking the notice with the shippement will meet these requirements.

CONSIGNE Name:	E (Receiver)	
Address:		
ading:	_mR/hr	
ce:	DPM/100 cm <sup>2</sup>	
	Name:	Address:mR/hr

Date:

PERSONNEL TRAINING PROGRAM [REF: NRC 313M - ITEM 12] Individuals who work in or frequent restricted areas will be instructed at in the items specified in 10 CFR 19.12 at the time of initial employment and at lease annually thereafter. This instruction will include: a) All terms of the license pertinent to radiation safety; Areas where radioactive material is used or stored; Potential hazards associated with radioactive material; Radiological safety procedures appropriate to their d) respective duties; e) Pertinent NRC regulations; Rules and regulations of the license; f) Obligation to report unsafe conditions to the Radiation q) Safety Officer; Appropriate response to emergencies or unsafe conditions; Right to be informed of their radiation exposure and bio-assay results; j) Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19. 2. Individuals whose duties may require them to work in the vicinity of license material will be informed about radiation hazards and appropritae precautions at the time of initial employment, and at lease annually thereafter. This information will be provided initially at employee orientation sessions and annually thereafter at in-service meetings. CONTROL NO. 8 4 3 6 2 Attachment J