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

Parma Podiatry, Inc.
5275 Pearl Road
Parma, OH 44129

TELEPHONE NO.: AREA CODE (216) 661 6300

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

5275 Pearl Road
Parma, OH 44129

1134 N. Abbe Road
Elyria, OH 44035

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mark Hayes, DPM

TELEPHONE NO.: AREA CODE (216) 661 6300

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

a. XXX ☒ 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.)*

Mark Hayes, DPM

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.)*

Mark Hayes, DPM

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
Iodine 125	Absorbed on solid sealed source AECL-C-324 or Amersham IMC P2 Lixiscope Mod LSM82-209	500mCi per source (1 curie, 2 sources not to exceed 500mCi each)	As a source of ionizing radiation for the purpose of diagnostic x-ray of extremities of sick or injured patients.

CONTROL NO. 7 8 7 1 3

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**
	☐ Detailed Information Attached
☐ 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

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24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

Applicant apd 24 III
Check No. 2396 $580
Amount Fee Category 7C
Type of Fee apd
Date Check Rec'd 4/11/85
Received By

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)*

RECEIVED
APR 11 1985
REGION III

(1) LICENSE FEE CATEGORY

(2) LICENSE FEE ENCLOSED $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)* Mark Hayes, DPM

(2) TITLE R.P.O.

c. DATE March 31, 1985

FORM NRC-313M (8-78)

CONTROL NO. 78716

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
Mark Hayes, DPM	Ohio

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	Case Western Reserve Univ Ohio College of Pod Medicine '82	'76 3 credit hours	
b. RADIATION PROTECTION	Lixi Training Course Course outline attached	2hrs	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	Case Western Reserve Univ Ohio College of Pod Medicine '82	'76 3 credit hours	
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

SUPPLEMENTAL INFORMATION

PARMA PODIATRY, INC.

11. Sketch of facility attached.

12. Qualified personnel will be trained by licensee using the S.A. Huber training course and Lixiscope instruction manual. Outline of course attached (Supplement A, 4b). Such persons may only use the device under the direct supervision and presence of licensee.

13. Orders for material will be placed using Lixi, Inc., catalog
14. numbers and specifications. When received, packages will be inspected for damage. Contents will be inspected and operational checks performed. Receiving records will be maintained and material will be logged into accountability system. Device will be placed in secured storage until utilized.

15. Licensee will observe the following general rules:
    1. Device will be kept in secure storage when not in use. Locks will be kept in place.
    2. Licensee will not permit anyone to place fingers, hands or feet into beam to test device for operation.
    3. The device will not be used to experiment on patients. Use will be limited to diagnostic examination of patients with specific applicable medical problems.
    4. Source holder will be left attached to device except for leak testing and source exchange.
    5. Device will be returned to secure storage after use.

16. Lost of stolen material will be reported immediately to the NRC.

18. Disposal of material will be by return of source holders to Lixi, Inc.

23. All precautions and procedures as described in item 15 plus the following:
    1. Licensee will not remove the sealed source from the source holder.
    2. Leak test will be performed at six month intervals.
    3. Transport of materials will be in accordance with D.O.T. regulations.
    4. Source exchange will be through the manufacturer.
    5. All procedures covered by the Lixiscope instruction manual will be followed.
    6. During transport and at temporary job sites, the licensee will insure that the device is attended and secured at all times by the licensee, or locked in secure storage.
    7. In the event of an accident wherein damage to the Lixiscope occurs, NRC will be notified immediately.

8. Leak test will be performed every six months using the Stan A. Huber Consultants leak test kit, LT-2.

* [signature]
Applicant's signature

CONTROL NO. 78716

MARK W. HAYES, D.P.M.

CURRICULUM VITAE
AUGUST, 1982

HIGH SCHOOL

Cathedral Latin High School
East 107th Street
Cleveland, Ohio 44106

Records on file:

St. Joseph High School
18491 Lake Shore Boulevard
Euclid, Ohio 44119

DATES IN ATTENDANCE: September 1963 - June 1967
AREA OF CONCENTRATION: College Preparatory
DEGREE RECEIVED: Diploma

COLLEGE - UNDERGRADUATE

Case Western Reserve University
2040 Adelbert Road
University Circle
Cleveland, Ohio 44106

DATES IN ATTENDANCE: June 1973 - June 1976
AREA OF CONCENTRATION: Pre-medical Study/Anesthesia
DEGREE RECEIVED: B.S. Health Science/Associate Anesthesia
AWARDS RECEIVED: Dean's List, WRU Scholar end of Freshman year

CURRICULUM:

Pre-Med Requirements	Hours
Biology	8
Physics	8
Calculus	8
Inorganic Chemistry	8
Organic Chemistry	8

Major Requirements - Anesthesia

Cardio Respiratory Physiology I	3
Cardio Respiratory Physiology II	3
Clinical Practice Lab I	3
Clinical Practice Lab II	3
Cardio Respiratory Pharmacology	3
Pharmacology of the Nervous System	3
Clinical Practice Lab III	3
Clinical Practice Lab IV	12
	12

Minor Requirements - Psychology	Hours
General Psychology	3
History of Psychology	3
Abnormal Psychology	3
Child Psychology	3

The Practical Laboratory courses noted above required that I complete three quarterly rotations at three different hospitals for a period of approximately three and one-half months.

During this time I was exposed to all phases of surgical anesthesia from Pediatrics to Thoracic Surgery. In addition, I participated in anesthesia induction for Electro-Convulsive Therapy and Cardioversion. It was further required that I learn to intubate patients both awake and asleep and administer Cardio-Pulmonary Resuscitation.

Traditionally, Anesthesia personnel have been recognized as experts in life support and emergency resuscitation. As a result, the field has tended to span all facets and sub specialties of medicine, uniquely preparing me for the study of Podiatry.

COLLEGE - GRADUATE

Ohio College of Podiatric Medicine
10515 Carnegie Avenue
Cleveland, Ohio 44106

DATES IN ATTENDANCE: September 1978 - May 1982
AREA OF CONCENTRATION: Podiatric Medicine
DEGREE RECEIVED: Doctorate of Podiatric Medicine

CURRICULUM:

		Hours (Clock)
Year I	Anatomy	394
	Basic Podiatry	18
	Biochemistry	78
	Histology	20
	Podiatric Medicinel	52
	Profession of Podiatry	20
	Medicine	10
	Biomechanics I	12
	Community Podiatry	11
	Neuroanatomy	22
	Physiology	160
	Introduction to Pharmacology	20
Year II	Biomechanics II	93
	Clinical Podiatry	58
	General Pathology	44
	Medical Emergencies	102
	Microbiology	150

Year II- Continued	Neurology	32
	Pharmacology	64
	Physical Diagnosis	64
	Podiatric Medicine II	44
	Podopediatrics	32
	Principles of Surgery	44
	Radiology	24
	Clinical Pathology	46
	Physical Medicine Rehabilitation	24
	Radiology	24
	Biomechanical Surgery	20
	Peripheral Vascular Disease	20
Year III	Anesthesia	20
	Medical Specialties	104
	Orthopedics	28
	Podiatric Medicine II	64
	Podiatric Surgery	54
	Surgical Anatomy	20
	Surgical Specialties	44
	Ambulatory Foot Surgery	12
	Dermatology	32
	Podiatric Radiology	32
	Orthotics and Prosthetics	20
Year IV	Epidemiology & Biostatistics	14
	Forensic Medicine	14
	Nitrous Oxide Analgesia	10
	Human Behaviors	14
	Shoe Therapy	7
	Practice Administration	14

Clinical Rotations

Extension Clinics	172
Radiology	86
Biomechanics	86
Surgery	150
Sports Medicine	75
Physical Therapy	75
Podopediatrics	130
Primary Suite	288

The Clinical Rotations provided the opportunity for the podiatry student to treat patients under the supervision of experienced clinicians in an ongoing clinical setting. Intensive training in the various sub-specialties initiate the student to treating patients in an office environment.

Lixiscope - Training Course Outline

(Registration of Attendees and Introduction to Course)

1. Overview of federal NRC and Agreement State Regulations for Radiation Protection. (Special emphasis on 10CFR Parts 19 & 20)

2. General Radiation Safety Instructions to Workers.
   NRC Regulation Guide
   NRC Prenatal Exposure Instructions for any female worker

3. Need for Specific Radiation Safety Program for each Lixiscope Licensee (Regulations and License conditions)

(Question - Answer Session and Break)

4. Elements of an Effective Radiation Management Program

   a) Restricted Users (only trained personnel can use Lixiscope).
   b) Security against theft or loss of radioactive material (includes receiving procedures, key controls and return or disposal procedures).
   c) Thorough familiarity of licensed users with individual facility application to NRC for licensure, as well as the license itself.
   d) Accountability and specific secure storage area for the Lixiscope(s).
   e) Quarterly inventory and source exchange or transfer or disposal records.
   f) Semi-annual leak test records and how to use leak test kits.
   g) Discussion of radiation surveys - if required by NRC.
   h) Personnel exposure monitoring systems - film and TLD badges.
   i) Maximum permissible doses (MPD) and how to read film badge reports.
   j) "ALARA" philosophy - to keep radiation exposures as low as reasonably achievable.
   k) NRC posting and labeling requirements and DOT requirements in any transportation.
   l) Reason for R.S.O. and duties of this individual.
   m) Advantages of centralized record system (recommended type).
   n) Review of required reports and sample forms and "year at a glance" management chart.
   o) Audits, annual safety reviews and preparation for inspections.
   p) New users personnel orientation and license amendments.

(Question - Answer Session and Break)

5. Elements of an NRC license application.

   a) Discuss licensing checklist resumes and individual or special needs.

   b) Review licensing services or consultation available.

6. Review of the Lixiscope Instruction Manual and specific safety instructions.

   a) Characteristics of I-125 source and discussion of half-life.

   b) Inverse square law and basic radiation safety principles of time, distance and shielding.

   d) Demonstrate Lixiscope operation.

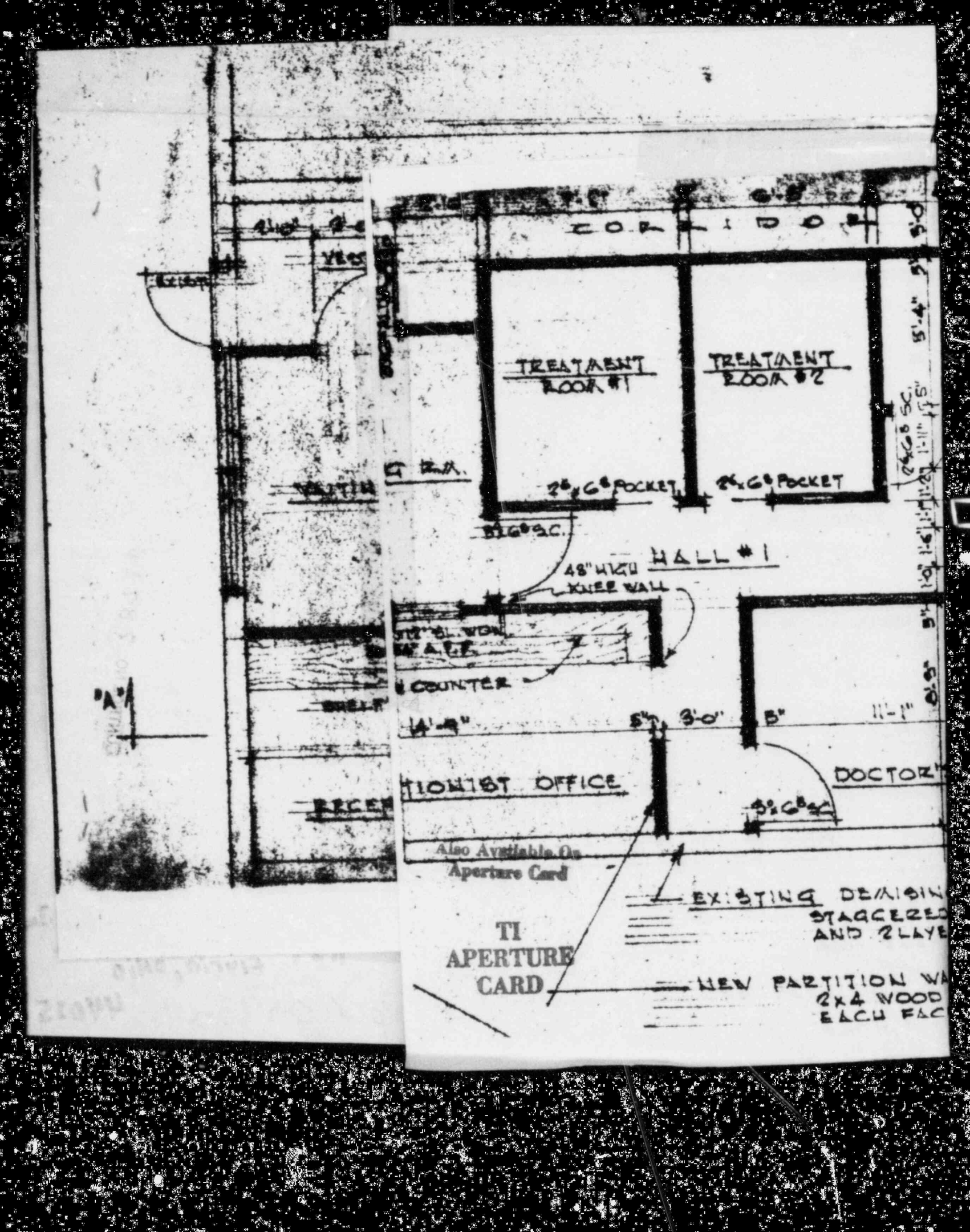
   e) Final Question and Answer Session.

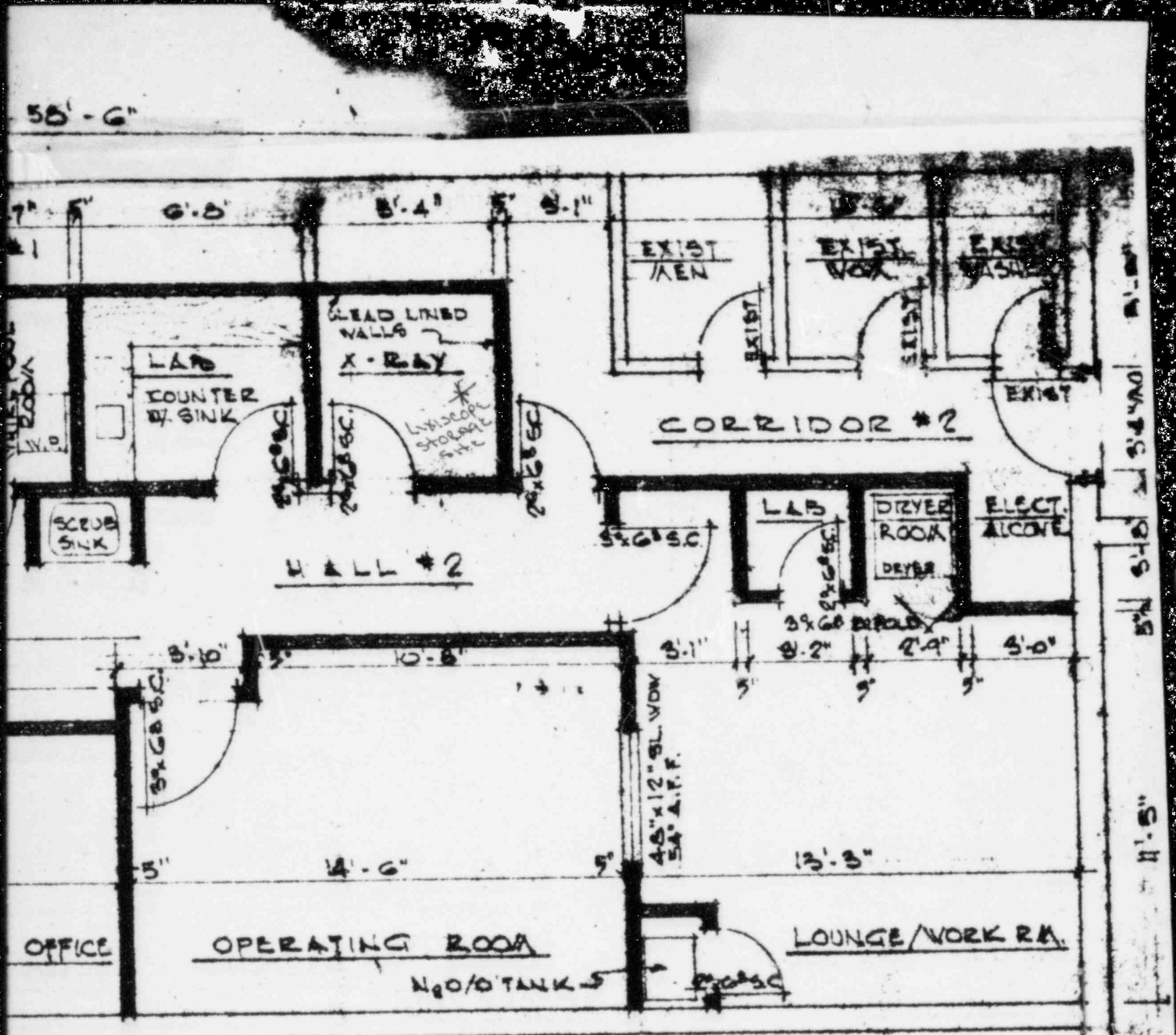
   f) Test.

   g) Certification of Attendance or Completion.

Total Course Time = Approximately 4½ to 5½ hours with 3 ten minute breaks = 5 to 6 hours total time (not counting 15 minute test).

NOTE: These are very rough time estimates. With smaller classes it may be possible to complete the course in 2 or 3 hours total time.


TREATMENT ROOM #1
TREATMENT ROOM #2
HALL #1
48" HIGH KNEE WALL
COUNTER
DOCTOR'S
Also Available On Aperture Card
TI APERTURE CARD
EXISTING
NEW PARTITION

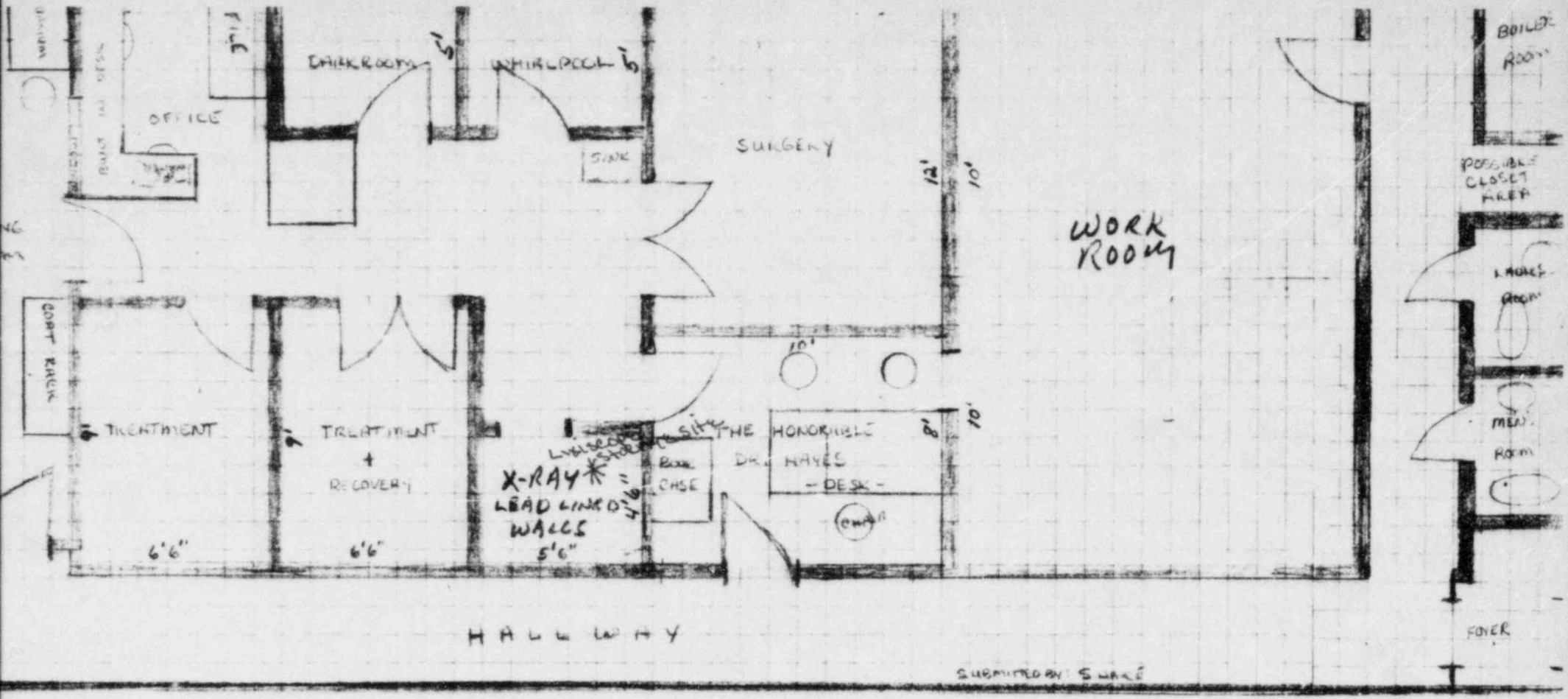


PARTITION WALL CONSISTS OF:
2x6 METAL STUDS W/ INSULATION
2@ OF 5/8" F.C. DRYWALL EACH FACE. TYPICAL

LS:
STUDS @ 16" O.C. W/ 1/2" F.C. DRYWALL

North Abbe Podiatry Inc.
1134 North Abbe Road
Elyria, Ohio

8506060593-01 44035



Parma Podiatry Clinic, Inc.
5275 Pearl Road
Parma, OH 44129

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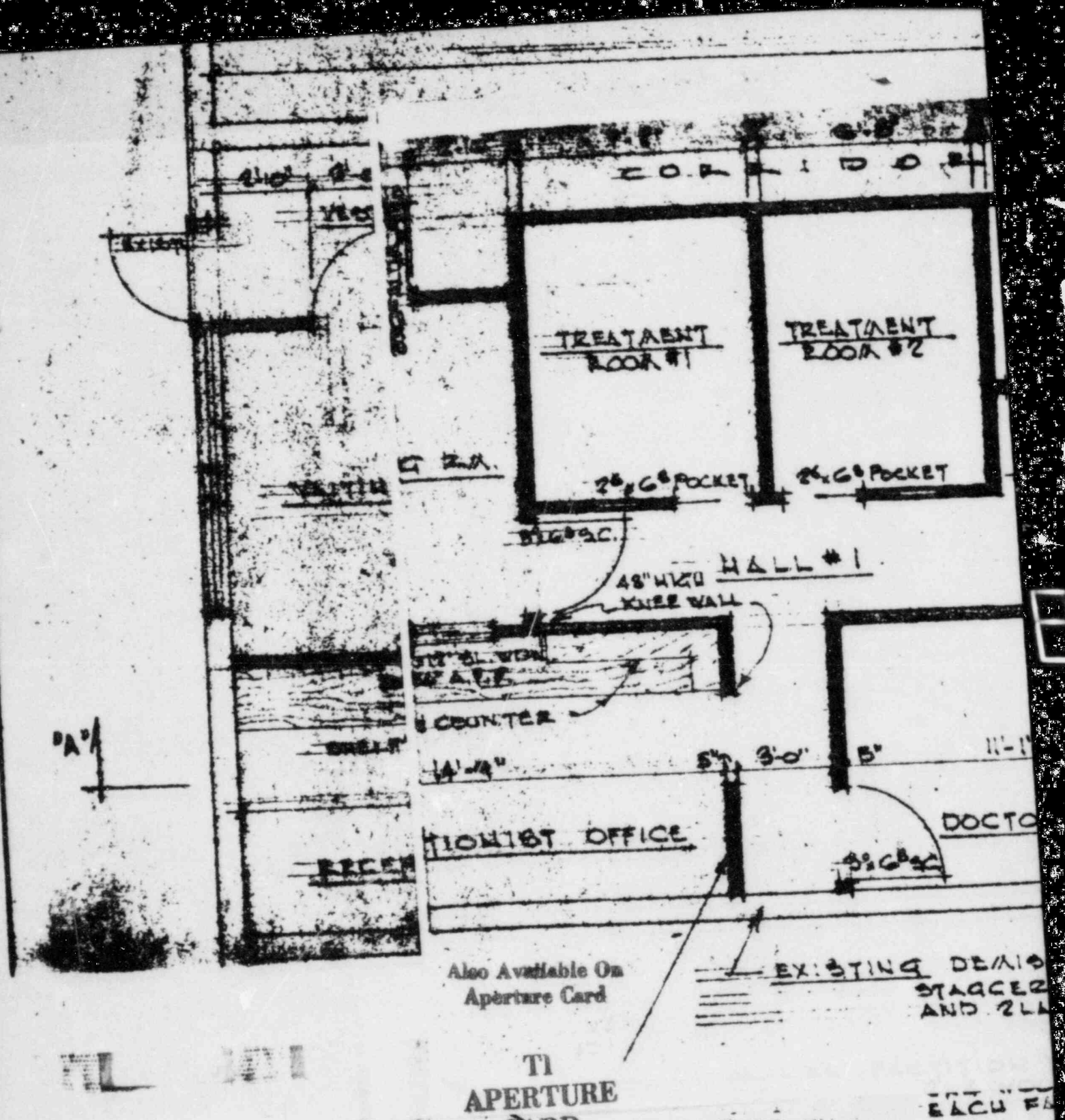

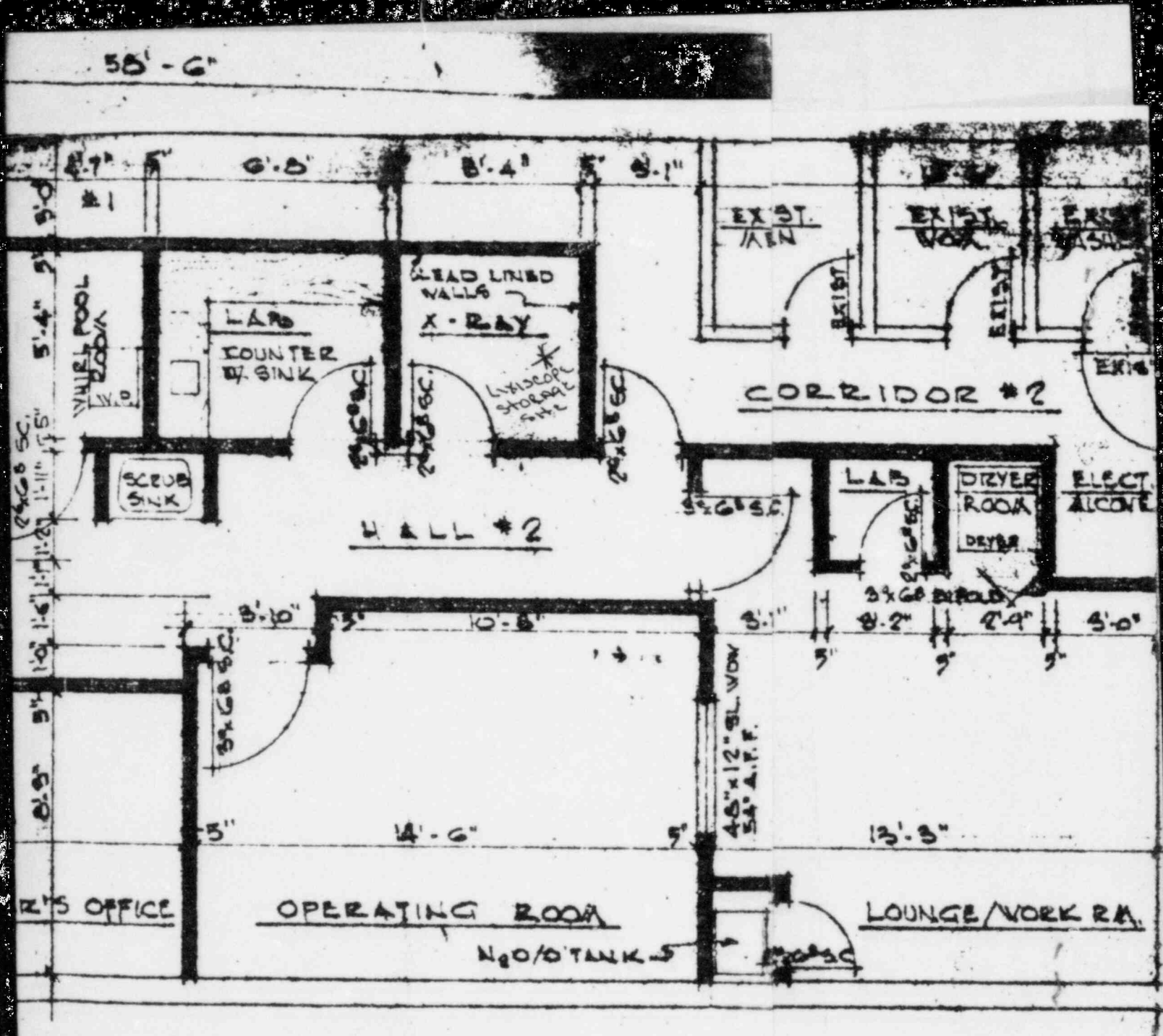

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YERS OF 5/8" F.C. DRYWALL EACH FACE. TYPICAL

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