

Regional Internal Medicine Associates
390 Middletown Blvd, Suite 604
Langhorne, Pennsylvania 19047
(215)750-6777

March 1, 2005

Michelle Beardsley, Health Physicist
U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pa. 19406

LL 31025
030 36887

62201

05
MAR 16 10:57

RECEIVED
REGION I

Dear Ms. Beardsley,

(37-31025-01)

We wish to apply for an NRC license to conduct nuclear cardiology procedures under 10 CFR 35.200. We have enclosed our application as well as the application fee of \$1900.00 payable to the U.S. Nuclear Regulatory Commission.

We would like to get our lab up and running as soon as possible and if this application can be expedited in any way it would be greatly appreciated.

If you have any questions with regard to our license request, please contact our consultant physicist, Sam Payne at: (570) 477-3925.

Sincerely,



Andrew Friedman, D.O.
Regional Internal Medicine Associates.

136593
NMSS/RGNI MATERIALS-002

Item 5: Radioactive Material

Byproduct Material Requested

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material included in 10 CFR 35.200	Any	As needed

Financial Assurance and Recordkeeping for Decommissioning

Not applicable

Sealed Sources and Devices

Not applicable

Item 6: Purpose(s) for which Licensed Material will be used

Any imaging and localization procedure approved in 10 CFR 35.200 – Cardiovascular clinical procedures

Item 7: Individual(s) Responsible for Radiation Safety Program and their Training and Experience

RSO: Tracy M. Berry, B.S., CNMT (see attached NRC form 313A attached)

Delegation of Authority – refer to attachment 1, page 4

AU: John V. Calce, M.D. 10 CFR 35.200 (see NRC license No. 37-04185-01)

This individual was specifically named as an AU for the uses requested on the following NRC license:

Williamsport Hospital; Williamsport, PA. License No.: PA-0092

Item 9: Facilities and Equipment

Facility Diagram

A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use.

Refer to attachment 3, page 5

Radiation Monitoring Instruments

Description of instruments used to perform required radiation surveys:

Geiger Mueller, range 1-1000 mR/hr

Nal well counter – sensitivity 22 dpm/100cm²

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

Dose Calibrator and Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions.

(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8084

Handwritten: LL 31025, 030 36887, 02201

Handwritten: (37-31025-01)

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE (checked)
B. AMENDMENT TO LICENSE NUMBER
C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Regional Internal Medicine Associates
390 Middletown Blvd., Suite 604
Langhorne, PA 19047

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

390 Middletown Blvd., Suite 604
Langhorne, PA 19047

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Samuel L. Payne, M.S.
(570) 477-3925

TELEPHONE NUMBER
(215) 750-6777

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY 7C AMOUNT ENCLOSED \$ 1900.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE
Andrew Friedman, D.O.

SIGNATURE
[Handwritten Signature]

DATE
3/11/02

FOR NRC USE ONLY

Table with columns: TYPE OF FEE, FEE LOG, FEE CATEGORY, AMOUNT RECEIVED, CHECK NUMBER, COMMENTS. Includes 'APPROVED BY' and 'DATE' fields.

Item 5: Radioactive Material**Byproduct Material Requested**

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material included in 10 CFR 35.200	Any	As needed

Financial Assurance and Recordkeeping for Decommissioning

Not applicable

Sealed Sources and Devices

Not applicable

Item 6: Purpose(s) for which Licensed Material will be used

Any imaging and localization procedure approved in 10 CFR 35.200 – Cardiovascular clinical procedures

Item 7: Individual(s) Responsible for Radiation Safety Program and their Training and Experience

RSO: Tracy M. Berry, B.S., CNMT (see attached NRC form 313A attached)

Delegation of Authority – refer to attachment 1, page 4

AU: Lakshmi D.J. Mizin, M.D., 10 CFR 35.200 (see NRC license No. 37-30789-01)

This individual was specifically named as an AU for the uses requested on the following NRC license:

Kevin Olsen, M.D., Clarks Summit, PA. License No.: 37-30789-01

Item 9: Facilities and Equipment**Facility Diagram**

A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use.

Refer to attachment 3, page 5

Radiation Monitoring Instruments

Description of instruments used to perform required radiation surveys:

Geiger Mueller, range 1-1000 mR/hr

Nal well counter – sensitivity 22 dpm/100cm²

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

Dose Calibrator and Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Therapy Unit -Calibration and Use

Not applicable

Other Equipment and Facilities

Not applicable

Item 10: Safety Procedures and Instructions**Safety procedures required by 10 CFR 35.610**

Not applicable

Occupational Dose

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG- 1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002.

Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet requirements of 10 CFR 20.1501 and 10 CFR 20.1301.

Safe Use of Unsealed Licensed Material

We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Spill Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

Installation, Maintenance, Adjustment, and Repair, and Inspection of Therapy Devices Containing Sealed Sources

Not Applicable

Minimization of Contamination

Not Applicable

Item 11: Waste Management

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

Attachment 1 of 3 - Delegation of Authority

November 3, 2002

Memo To: Radiation Safety Officer
From: Regional Internal Medicine Associates
Subject: Delegation of Authority

You, Tracy M. Berry, B.S., CNMT, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.

I accept the above responsibilities,

Tracy Berry BS CNMT 3/2/05
Tracy Berry, B.S., CNMT Date
Signature of Radiation Safety Officer

Andrew Friedman D.O. 3/1/05
Andrew Friedman, D.O. Date
Signature of Management Representative

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3180-0100 EXPIRES: 10/31/2005	
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT					
PART I - TRAINING AND EXPERIENCE					
<p>Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.</p>					
<p>1. Name of individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)</p> <p style="text-align: center;">Tracy M. Berry B.S., C.N.M.T.</p>					
<p>2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed</p>					
3. CERTIFICATION					
Specialty Board		Category		Month and Year Certified	
<i>Step here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.</i>					
4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)					
Description of Training	Location	Clock Hours	Dates of Training		
Radiation Physics and Instrumentation	Cedar Crest College Allentown, PA.	Approx. 400	8/97 to 5/98		
Radiation Protection	Cedar Crest College	Approx. 400	8/97 to 5/98		
Mathematics Pertaining to the Use and Measurement of Radioactivity	Cedar Crest College	Approx. 200	8/97 to 5/98		
Radiation Biology	Cedar Crest College	Approx. 400	8/97 to 5/98		
Chemistry of Byproduct Material for Medical Use	Cedar Crest College	Approx. 200	8/97 to 5/98		
OTHER					

NRC FORM 312A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

8a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Date and Clock Hours of Experience
STAFF technologist - 1054	NPNA HUBAL Chief technologist	Mercy Health Care 37-01374-03	6/98 - 1/01
STAFF technologist - 1054	John Hreh A Director of imaging	Moses Taylor Hospital 37-15456-01	1/01 - 1/03
Solo technologist responsible for cardiac spect imaging, All QC-QA & radioactive handling & SAFETY & other Ancillary job duties	LAKSHMI MIZIN M.D.	CLARKSUMMIT, PA 37-30789-01	1/03 - present

8b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Date and Clock Hours of Experience

NRC FORM 313A
(7-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicists)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Date	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.400)

7. RADIATION SAFETY OFFICER - ONE-YEAR FULL-TIME WORK EXPERIENCE

YES Completed 1-year of full-time radiation safety experience (in areas identified in Item 5a) under supervision of Lakshmi Mizin, MD the RSO for License No. 37-30789-01

N/A

8. MEDICAL PHYSICIST - ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of _____ who meets requirements for Authorized Medical Physicists; and

N/A

YES Completed 1-year of full-time work experience (for areas identified in Item 5a) for _____ who meets

N/A modality(ies) under the supervision of _____ requirements of Authorized Medical Physicists for _____ modality(ies).

9. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

A. Name of Supervisor: Lakshmi Mizin, MD

B. Supervisor is:

Authorized User Authorized Medical Physicist

Radiation Safety Officer Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.200

for medical uses in Part 35, Section(s) 35.200

D. Address: Dr Olsen's Office

200 Abington Executive Park Suite 208

CLARKS Summit, PA 18411

E. Materials License Number: 37-30789-01

NRC FORM 31SA (10-2003) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II - PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete Items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

10. The individual named in Item 1 has satisfactorily completed the training requirements in 10 CFR 35.590 and is competent to independently operate a nuclear pharmacy.

11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.900.

11b. The individual named in Item 1 is competent to independently function as an authorized Radiation Safety Officer for medical uses (or units).

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of Item 10 and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of Items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

OR

I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of Pennsylvania or equivalent Agreement State requirements to be a preceptor authorized Radiation Safety Officer for the following uses (or units) of byproduct material: medical 35.200

A. Address

Kevin Olsen, MD
200 Abington Executive Park, Suite 208
Clarks Summit, PA 18411

B. Materials License Number

37-30789-01

C. NAME OF PRECEPTOR (print clearly)

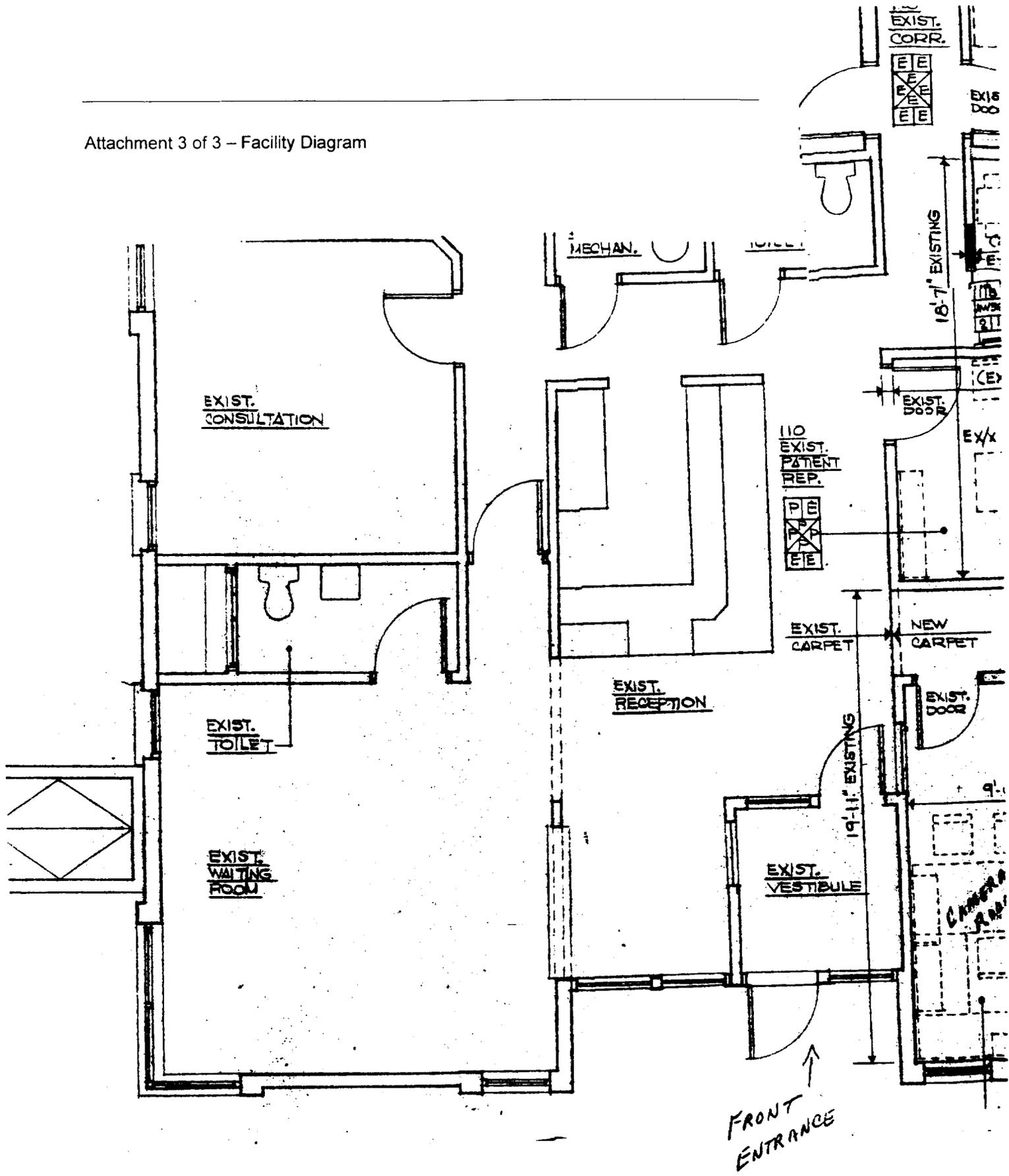
Lakshmi Mizin

D. SIGNATURE - PRECEPTOR

[Handwritten Signature]

E. DATE

2/13/05



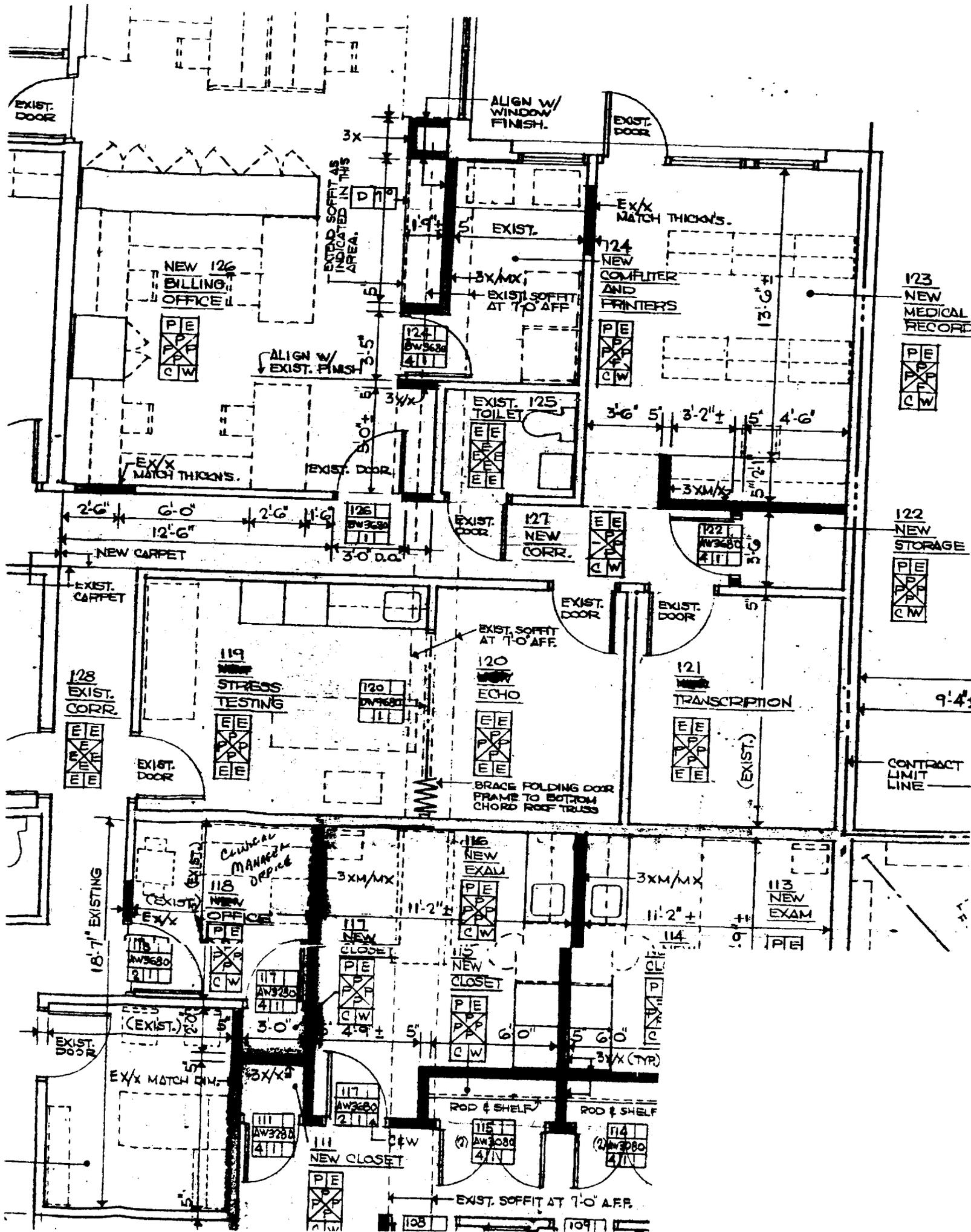
FLOOR PLAN

1/4"=1'-0"

CAMERA ROOM 16' x 9'

HOT LAB

16' x 7'4"



This is to acknowledge the receipt of your letter/application dated

3/11/2005, and to inform you that the initial processing which includes an administrative review has been performed.

New License Application (03036887)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136593.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

: (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 BETWEEN: :
 :
 License Fee Management Branch, ARM : Program Code: 02201
 and : Status Code: 3
 Regional Licensing Sections : Fee Category: _____
 : Exp. Date: 0
 : Fee Comments: _____
 : Decom Fin Assur Reqd: _
 : ::

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: REGIONAL INTERNAL MEDICINE ASSOC.
 Received Date: 20050316
 Docket No: 3036887
 Control No.: 136593
 License No.: 27-31625-01
 Action Type: New Licensee

2. FEE ATTACHED

Amount: 21,400.00
 Check No.: 859856

3. COMMENTS

Signed *Rebecca Jones*
 Date 3/16/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
 Renewal _____
 License _____

3. OTHER _____

Signed _____
 Date _____