

Michael W. Lairmore Associates
P.O. Box 296
Midland Park, New Jersey 07432
(201) 693-2277

July 12, 2008

Br. 2

Change of Heart Cardiology, ILC
2130 Route 35, Building C, Suite 321
Sea Girt, New Jersey 08570

LL 31323
03037804
02201

2008 JUL 21 AM 11:04

RECEIVED

RE: New NRC License Applications

(29-31323-01)

Dear Pat:

Please find attached to this cover page, a new license applications for the Nuclear Regulatory Commission (NRC). To conclude the application process, please complete the following:

1. Please review the NRC application for accuracy and completeness. Have Dr. Eisenberg, sign, date and identify his title at Item #13. Make two copies of the signed application. Send the original and one copy to the address listed below:

License Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Retain the final copy for your files.

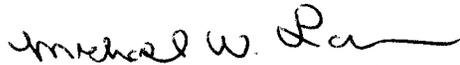
In addition, a check for processing of the new application, must accompany the application and copy. Please prepare a check for \$2,300.00 made payable to: Nuclear Regulatory Commission. Processing of the new application will take between 30 - 90 days. I suggest you send the application certified mail to confirm receipt.

142638
NMSS/RGNI MATER. ALS-002

Finally, an amendment letter has been attached for Mr. Moore at MIS to review and sign. Please forward to Bill for signature. Subsequently, have Bill return the signed letter to you. The signed amendment letter will be sent with the new license application for processing.

If you have additional questions, please contact me at (201) 693-2277.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael W. Lairmore". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Michael W. Lairmore, M.S.
Medical Physics Consultant

REVISED APPLICATION FOR MATERIAL LICENSE

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 APPLICATION WITH:

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

ALL OTHER PERSONS FILE APPLICATION 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:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

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
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

LL 31323
030 37804
02201

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
- B. AMENDMENT TO LICENSE NUMBER _____
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Includes Zip Code)

Change of Heart Cardiology, LLC
2130 Route 35, Building C, Suite 321
Sea Girt, New Jersey 08570
(732) 774-3440

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

Change of Heart Cardiology, LLC
2130 Route 35, Building C, Suite 321
Sea Girt, New Jersey 08570
(732) 774-3440

(29-31323-01)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Michael W. Lairmore, M.S., Medical Physics Consultation

TELEPHONE NUMBER

(201) 693-2277

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 AND 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 **\$2,300.00**

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, 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.

SIGNATURE - CERTIFYING OFFICIAL

TYPED/PRINTED NAME

TITLE

DATE

SCOTT R. EISENBERG

PRESIDENT 7/15/08

FOR NRC USE ONLY

TYPE OF FEE FEE LOG FEE CATEGORY COMMENTS

AMOUNT RECEIVED CHECK NUMBER

APPROVED BY

DATE

142638

<u>BYPRODUCT MATERIAL</u>	<u>ITEM #5</u> <u>AMOUNT</u>	<u>ITEM #6</u> <u>PURPOSE</u>
Any byproduct materials identified in 35.200 (except generators and gases)	As needed	Medical Use

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM - THEIR TRAINING & EXPERIENCE

Item 7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER

Robert Granville Kayser, Jr., M.D.

Any cardiovascular procedures and materials approved in 35.200 (except gases and generators).

The above mentioned physician is board certified by the Certification Board of Nuclear Cardiology and has completed the training requirements outlined in 35.290. Documentation attesting to his training and experience are enclosed in Attachment A. Please refer to this section for details.

Item 7.2

RADIATION SAFETY OFFICER

Michael W. Lairmore, M.S.

Mr. Lairmore is currently listed as the radiation safety officer on the byproduct material license approved for Garden State Cardiology (License Number: 29-28049-01). Please refer to this license for RSO confirmation.

Item 8.1

TRAINING PROGRAM:

We will establish and implement the model training program outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix J entitled; "Model Training Program"**.

Item 9.1

FACILITIES AND EQUIPMENT DIAGRAM

Refer to Attachment 9.1

Item 9.2

INSTRUMENT CALIBRATIONS:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix K entitled; "Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program"**.

Records of survey meter calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration. If needed, a loaner survey meter will be made available at the time of annual calibration.

Survey meter calibrations will be performed by MPM Products or an equivalent service vendor. MPM Products operates under, Texas Radioactive Material License Number: LO0967.

Item 9.3

DOSE CALIBRATOR CALIBRATION

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

Item 9.4

PERSONNEL MONITORING PROGRAM:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix M** entitled; **"Model Procedures For an Occupational Dose Program"**.

Attachment 9.6

NUCLEAR MEDICINE EQUIPMENT

1. Survey Meters:

- a. Manufacturer's name: Ludlum 14C or comparable meter
- Manufacturer's model number: 14C with 44-9 pancake probe
- Number of instruments available: 2
- Instrument range: 0.01 - 2000 mrem/hr

2. Dose Calibrator:

- a. Manufacturer's name: Capintec 25 or equivalent
- Manufacture's model number: 25 or equivalent
- Number of instruments available: 1

3. Well Detector:

- a. Manufacturer's name: Ludlum SCA 2200 & Well Counter or equivalent
- Manufacturer's model: 2200
- Number of instruments available: 1

4. Gamma Camera:

- a. Manufacturer's name: DiGiRad or equivalent
- Manufacturer's model number: ----
- Number of instruments available: 1

Item 10.1

RADIATION SAFETY OFFICER: DELEGATION OF AUTHORITY:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix I** entitled; **"Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority"**.

Item 10.3

PROCEDURE FOR LEAK TESTING SEALED SOURCES:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix Q** entitled; **"Model Leak Test Program"**.

Item 10.4

RULES FOR SAFE USE OF RADIOPHARMACEUTICAL:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix T** entitled; **"Model Procedure for Safe Use of Unsealed Licensed Material"**.

Item 10.5

EMERGENCY PROCEDURES:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix N** entitled; **"Model Emergency Procedures"**.

Item 10.6

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix O** entitled; **"Model Procedures for Ordering and Receiving Packages"**.

Item 10.7

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix P** entitled; **"Model Procedures for Safely Opening Packages Containing Radioactive Material"**

Item 10.8

RECORDS OF UNIT DOSE USE:

We will establish and implement the model procedure outlined in Regulatory Guide 10.8, Revision 2, Appendix M. for Unit Dosage Record System.

Item 10.9

RECORDS OF MULTIDOSE VIAL USE:

We will establish and implement the model procedure outlined within Regulatory Guide 10.8, Revision 2, Appendix M for a Multi Dose Vial Record System

Item 10.12

PROCEDURE FOR AREA SURVEY:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix R entitled; "Model Procedures for Area Surveys"**

Action trigger limits for ambient exposure and removable contamination will be as follows:

Restricted Areas:

Ambient exposure = 5.0 mR/hr

Removable Contamination:

2,000 dpm/100 cm² (gamma emitters)

Unrestricted Areas:

Ambient exposure = 0.05 mR/hr

Removable Contamination:

200 dpm/100 cm²

Item 11

PROCEDURE FOR WASTE DISPOSAL:

We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision I, **Appendix W entitled; "Model Procedures for Waste Disposal by Decay-In-Storage"**

Additional Confirmation:

1. We do not intend to use I-131 at this facility. Therefore, a Written Directive Program will not be implemented at this institution. Please allow this statement to serve as our "Negative Declaration".
2. In conjunction with the new licensing guide, we will continue to follow regulations addressed in 10 CFR Parts 19, 20, 21, 30, and 35.

3. **Molecular Imaging Services** currently list this imaging center as a “location of use” on their byproduct material license”. In an attached amendment letter, they request the deletion of this “location of use”, Their amendment will allow Change of Heart Cardiology, LLC to operate as a new licensee. Please refer to the attached amendment letter for details.

Attachment A

Certification Board of Nuclear Cardiology

Incorporated 1996

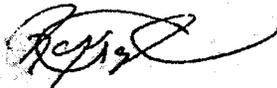
Certifies That

Robert Granville Kayser Jr., MD, MBA

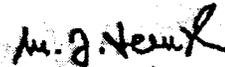
HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2006 - 2016



President



Secretary



CERTIFICATE NUMBER: 4616

NRC FORM 313A (AUD)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Robert Kayser, Jr. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor <u>MELVIN J FRANKIN, MD</u>	Signature <u>[Signature]</u>	Telephone Number <u>804 828 6828</u>	Date <u>6/27/08</u>
--	---------------------------------	---	------------------------

License/Permit Number/Facility Name
NRC# 45-00048-17

NRC FORM 313A (AUD)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AUD)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			

**b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)**

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

NRC FORM 313A (AUD) (10-2007)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]		

Name of Proposed Authorized User <i>Robert Kayser, Jr</i>	State or Territory Where Licensed <i>NS</i>
--	--

Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device _____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
 - b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
 - b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

35.290 35.390 + generator experience in 32.290(c)(1)(ii)(G)



V I R G I N I A C O M M O N W E A L T H U N I V E R S I T Y

Health System

MCV Hospitals and Physicians

MCV Campus

**Department of
Radiology**
Division of Nuclear Medicine

1300 East Marshall Street
P.O. Box 980001
Richmond, Virginia 23298-0001

804 828-6828
Fax: 804 628-0275 Scheduling
Fax: 804 828-4181
TDD: 1-800-828-1120

May 18, 2006

Certification Board of Nuclear Cardiology
19562 Clubhouse Rd
Montgomery Village, MD 20886

Re: **Robert G. Kayser, M.D.**
2408 Penniman Ct
Richmond, VA 23228

Dear Sirs:

I am writing to verify that Robert G. Kayser, M.D. is qualified to sit for the CBNC exam. During his cardiology fellowship at Virginia Commonwealth University Medical Center, Dr. Kayser achieved Level 2 Training in Nuclear Cardiology. This training included pertinent instruction in radiopharmacy, radiation biology, instrumentation, and radiation safety as required by the NRC, as well as the requisite hands-on experience. His training also included Nuclear Cardiology services for over 300 studies, with angiographic correlation in at least 30 of them.

In summary, Dr. Kayser's training/experience meets the requirements as outlined in the ACC/ASNC COCATS Guidelines. Dr. Kayser is competent to independently function as an authorized user under 10 CFR 35.290 uses.

Sincerely,

A handwritten signature in black ink, appearing to read "Melvin J. Fratkin".

Melvin J. Fratkin, MD
Professor of Radiology & Medicine
Chairman, Division of Nuclear Medicine
Vice Chairman, Department of Radiology
NRC# 45-00048-17

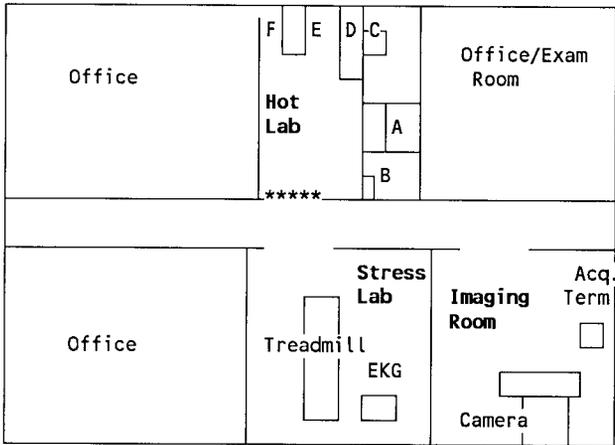
MJF/tlb

Attachment 9.1

**Change of Heart Cardiology
2130 Route 35, Suite 321
Sea Grit, New Jersey 08750**

**Department of Nuclear Cardiology
Updated Diagram**

North



Legend:

- A. L-Shield & Preparation Area (1/4" lead shielding)
- B. Dose Calibrator
- C. Well Counter
- D. Sealed Source & Waste Storage (Under Counter - 1/8" lead lining)
- E. Package Receipt/Return Area
- F. Injection Area
- ** Locked Door

**Molecular Imaging Services, Inc.
200 Biddle Avenue, Suite 103
Newark, DE 19702**

July 11, 2008

License Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment Request - Molecular Imaging Services
License Number: 07-30790-01

Dear License Reviewer:

Please amend our byproduct material license to delete the following imaging center as a "location of use" on our byproduct material license. Administrative personnel at "Change of Heart Cardiology" have submitted a new license application to operate this imaging center. We confirm our approval of this licensing change.

**Change of Heart Cardiology, LLC
2130 Route 35, Building C, Suite 321
Sea Grit, New Jersey 08570**

All sealed sources and nuclear medicine equipment approved by this license will be transferred to the Change of Heart Cardiology, when their request for a new license is approved by the Nuclear Regulatory Commission.. They will retain responsibility for all radioactive materials and nuclear cardiology operations.

The only unsealed byproduct material used at this site is Tc-99m. Therefore, a Close-Out Survey" will not be performed at this site location. The administrative and radiation safety staff of "Change of Heart Cardiology" will take full responsibility of all radioactive waste and areas requiring decontamination.

If you have additional questions, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 693-2277.

We thank you in advance for your assistance with this licensing action.

Sincerely,

William Moore
Administrative Representative

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

7/15/08, and to inform you that the initial processing which includes an administrative review has been performed.

New License Application (03037804)
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** 142638.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.