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June 24, 2005

Licensing Assistance Section
Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: License Amendment Application – 29-30967-01 03036685
Expiration Date: October 31, 2014

Dear Sir/Madam:

We are herein requesting that our license 29-30967-01, Item Number 11B, be amended as follows:

Radioactive materials listed in items 6 A shall be used by in accordance with 10 CFR 35.13 and 10 CFR 35.14:

Authorized Users	Material and Use
Feraydoon Kohan, M.D.,	35.200
Merwin Richard, M.D.	35.200

Please include Merwin Richard, M.D., as an authorized user in Item Number 11B.

Following are attached to expedite the review of this amendment for Dr. Richard:

1. A copy the certificate from The American Board of Internal Medicine
2. A copy of the certificate from State Board of Medical Examiners concerning New Jersey Medical License
3. A copy of the certificates from Institute for Nuclear Medical Education
4. Resume
5. Copy of the letter from Nuclear Cardiology

Please make appropriate changes to our license 29-30967-01

137132
NMSS/RGN1 MATERIALS-002

License Amendment- 29-30967-01
Dr. Merwin Richard

We request that you execute an expedited review of this amendment. Should you have any questions please contact me at (973) 972-6019 for any additional information.

Sincerely,

Feraydoon Kohan, M.D.
Radiation Safety Officer and
Administrator
550 Newark Avenue, Suite 201 A
Jersey City, NJ 07306

C: File

ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR:

Type of Action	License No.
☐ A. New License	Not Applicable
☒ B. Amendment to License No.	29-30967-01
☐ C. Renewal of License No.	Not applicable

ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Merwin Richard, M.D.
550 Newark Avenue, Suite 301 A
Jersey City, NJ 07306

Telephone: 201-418-9111
Fax: 201-418-9118

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

550 Newark Avenue, Suite 301 A
Jersey City, NJ 07306

Telephone: 201-418-9111
Fax: 201-418-9118

ITEM 4: PERSON TO BE CONTACTED ABOUT THISAPPLICATION

Feraydoon Kohan, M.D.
550 Newark Avenue, Suite 301 A
Jersey City, NJ 07306

Telephone: 201-418-9111
Fax: 201-418-9118

or

Venkata K. Lanka
Telephone: 973-972-5305 or
908-788-4931

ITEM 5: RADIOACTIVE MATERIAL

Byproduct, Source, Special Nuclear Material	Chemical and/or Physical Form	Maximum Amount Licensee Possesses
A. Any byproduct material permitted by 10 CFR 35.200	A. Any (no generators)	A. As needed

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

Radioactive Material specified in Item 5 will be used as follows:

A.	Any Imaging and localization studies permitted by 10 CFR 35.200

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

Responsible Individual for Radiation Safety Program:	Feraydoon Kohan, M.D. Radiation Safety Officer
Training and Experience for Merwin Richard, M.D.	See attached.

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

The following individuals may be working in/frequenting restricted areas:

1. The Nuclear Medicine Technologist
2. Nurse
3. Housekeeping

We provide both initial training on annual training for Nuclear Medicine Technologist and Nurse with reference to their specific tasks and film badges, ALARA program, patient handling, personal protection, ambient surveys, general safety rules. The records of training will be maintained as required.

The House keeping individual will be trained on what the radiation symbol represents and which waste can to empty and which waste can was held for decay, etc.

ITEM 9: FACILITY DIAGRAM

See Attached

Stress/Hot Lab:

i. Walls – The walls have a low flame spread characteristic.

ii. Floors – The floor covering is sealed with wax so that spills are contained and they are easily decontaminated.

iii. Surfaces – Surfaces on benches are non-porous and smooth to facilitate cleanup should a spill occur.

a. Stress/Hot Lab Equipment for Radiation Safety

i. The storage cabinet is lockable. Entrances to lab and storage areas are posted with radioactive signs.

ii. Protective Clothing – We insure that there are lab coats and an adequate supply of disposable rubber or plastic gloves available for individuals under my supervision.

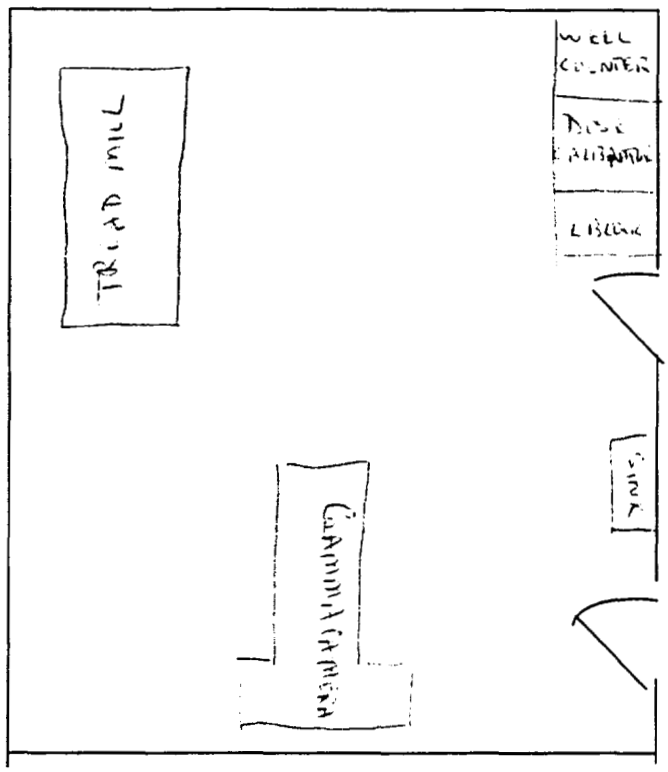
iii. Bench Top Covering – we will have adequate supplies of absorbent plastic backed paper to cover bench tops where radioactive materials are handled.

iv. Radiation detection and counting equipment are used in evaluating contamination levels.

RADIATION SAFETY SURVEY (WIPE TEST) REPORT

Licensee: Dr. Kohan **Location:** Suite 301 A

Date Performed: _____ **By:** _____.



Efficiency= 0.90

Background (Wipe Test) = _____ **CPM**

Location	Net CPM	DPM
1. L- Block Area		
2. Sink		
3. Well Counter Area		
4. Dose Calibrator Area		
5. Rad Waste Area		
6. Gamma Camera Area		
7. Patient Injection Area		
8. Treadmill Area		
9.		

ITEM 9: RADIATION MONITORING INSTRUMENTS

Survey Meter:

Radiation Monitoring Instrument (Survey Instruments): Radiation detecting instrument (GM Counter) which will be capable of detecting gamma radiation will be purchased as soon as possible. This will be used to conduct daily contamination surveys, and personal monitoring surveys, etc.

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

Survey Instruments are calibrated annually, before first use and after servicing and repairs which effect calibration. Battery changes are not considered "servicing."

Before use, perform daily check (with a dedicated check source) and battery checks.

Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 20% are acceptable if a calibration chart or graph is prepared and made available with the instrument.

A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061)

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.

Well/Gamma Counter:

Well counter is used to conduct wipe test surveys.

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

☐ Calculate efficiency of the instrument.

$$\text{Eff} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

where:

Eff = efficiency, in cpm / microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

☐ The date of the next efficiency due and

☐ Results of efficiency calculation(s).

ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. We use attenuators for the linearity test.

ITEM 10: RADIATION PROTECTION PROGRAM

As stated in the original application, we commit to the ALARA program. See original application.

ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

Model Spill Procedures

We will establish and implement the following model procedures published in Appendix N of NUREG-1556, Vol.9, Consolidated Guidance About Materials Licenses.

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be restricted

access pending complete decay.

Note: A report to NRC may be required pursuant to 10 CFR 30.50.

Use Table P.1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

Table N.1 Relative Hazards of Common Radionuclides

Radionuclide	Millicurie	Radionuclide	Millicurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- ☐ Disposable gloves and housekeeping gloves;
- ☐ Disposable lab coats;
- ☐ Disposable head coverings;
- ☐ Disposable shoe covers;
- ☐ Roll of absorbent paper with plastic backing;
- ☐ Masking tape;
- ☐ Plastic trash bags with twist ties;
- ☐ "Radioactive Material" labeling tape;
- ☐ Marking pen;
- ☐ Pre-strung "Radioactive Material" labeling tags;
- ☐ Contamination wipes;

- ☐ Instructions for "Emergency Procedures";
- ☐ Clipboard with copy of Radioactive Spill Report Form;
- ☐ Pencil; and
- ☐ Appropriate survey instruments, including batteries.

ITEM 10: OCCUPATIONAL DOSE

Either we will perform 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 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials License: Program-Specific Guidance About Medical Use Licensees," dated October 2002.

We will establish and implement the Model Procedures for an Occupational Dose Program published in NUREG-1556, Vol.9 (attached for your reference).

Model Procedures for an Occupational Dose Program

The As Low As Reasonably Achievable "ALARA" Program

10 CFR 20.1101 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities" and, "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally, 10 CFR 20.1101 requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

10 CFR 20.1502(a) requires the use of individual monitoring devices for the following:

☐ Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 10 CFR 20.1201(a). Monitoring devices are accordingly required for adults with an annual dose in excess of

- 0.5 rem (0.005 Sv) DDE
- 1.5 rem (0.015 Sv) eye dose equivalent
- 5 rem (0.05 Sv) shallow-dose equivalent to the skin
- 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.

☐ Minors who are likely to receive an annual dose in excess of

- 0.1 rem (1.0 mSv) DDE
- 0.15 rem (1.5 mSv) eye dose equivalent
- 0.5 rem (5 mSv) shallow-dose equivalent to the skin
- 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.

☐ Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.

☐ Individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, NRC does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

☐ Prior Experience: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;

☐ Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable 'accident' scenarios should also be evaluated);

☐ The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by 10 CFR 20.1501.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (10 CFR 20.1201(c)). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

In order to demonstrate compliance with occupational dose limits of 10 CFR 20.1201, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table M.1 (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table M.1 (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table M.1 Investigational Levels

Part of Body	**Investigational Level I (mrem per year)**	**Investigational Level II (mrem per year)**
whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on NRC Form 5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table M.1 are reached:

□ Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than Table M.1 values for the Investigational Level I.

□ Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements additional safety measures are needed to reduce exposures. Evaluate in the context of ALARA program quality and record the results of investigations and evaluations.

☐ Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

☐ Re-establishment of Investigational Level II to a level above that listed in Table M.1.

Declared Pregnancy and Dose to Embryo/Fetus

10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

☐ The deep-dose equivalent to the declared pregnant woman; and

☐ The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year (10 CFR 20.1502). 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in □Ci/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in 10 CFR Part 20, Appendix B.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR Part 20 ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

i. adequate equipment to perform bioassay measurements,

ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,

iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),

iv. the interval between bioassays,

v. action levels, and

vi. the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993, Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, dated July 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.2106. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, the external and internal doses shall be summed if required to monitor both under 10 CFR 20.1502.

ITEM 10: AREA SURVEYS

We are implementing and maintaining written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

We implement and maintain procedures for safe use of unsealed byproduct material in accordance with 10 CFR 20.1101, that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Posting Requirements

(a) All signs and labels used to caution individuals of the presence of radiation or radioactive materials shall have a standard three-bladed radiation symbol in black or purple on a yellow background.

(b) The Nuclear Medicine suite/room shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

(c) If there is a location in our nuclear medicine suite where an individual may receive a whole body dose equivalent of 5 millirem in one hour at a distance of 30 centimeters from a source or a surface through which the radiation penetrates shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radiation Area".

(d) Each cabinet or other device or appliance that contains radioactive material shall have a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

(e) Each container of radioactive material shall have a durable label bearing a radiation symbol and the words "Caution, Radioactive Material." In addition, the label will also specify the radionuclide present, the date, and the activity present on that date.

(f) Each container used for temporary storage of radioactive waste shall be conspicuously posted with a label bearing a radiation symbol.

(g) The bench area routinely used for handling radioactive material shall be posted with a conspicuous sign having a label bearing a radiation symbol and which reads "Caution Radiation Work Area." Each sink used for decontamination shall be posted with a sign bearing a radiation symbol and the words "Caution, Radioactive Material."

(h) In addition to posting signs and labels to caution individuals of the presence of radiation and/or radioactive materials, we will post the following documents and ensure that each individual under my supervision knows of their presence.

i Copies of forms NRC-3 "Notice to Employees", and NJDEP (8/89) "Notice to Employees: Standards for Protection Against Radiation."

ii Copies of the emergency procedures and a list of individuals, with telephone number, who should be contacted in the event of a radiation incident.

(l) We will, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the

container no longer contains radioactive material.

Labeling Syringes:

Each syringe that contains unsealed radioactive material, we will ensure that we label to identify that radioactive drug.

Each syringe shield will be labeled when the label on the syringe is not visible or shielded.

Radiation Safety Surveys

(a) All areas where unsealed radioactive material is used will be surveyed with radiation detection survey instrument at the end of each day of use.

(b) We will retain the records of each survey in accordance with 10 CFR 35.2070

(c) Wipe tests shall be made of all surfaces where radioactive materials are handled, and in other locations which have a risk of becoming contaminated.

(d) Each wipe test shall cover an area no greater than 100 square centimeters, and the number of wipe tests taken per survey shall be sufficient to ensure that any contamination within the work area is detected.

(e) Wipe tests for contamination shall be counted using a well type sodium iodide scintillation counting system for which the counting efficiency is known for radionuclide being sampled and the counting source geometry used.

(f) The results of wipe test surveys will be recorded and maintained as required.

(g) Wipe test samples, which give a count rate in excess of three times the background level, shall indicate the presence of contamination and will be decontaminated.

(h) Spot checks for personal and area contamination should be performed between routine contamination surveys. Spot checks may be performed using a GM survey meter having a probe with a window sufficiently thin to allow detection of the radionuclide(s) being surveyed.

(i) Decontamination procedures shall be initiated immediately whenever a contamination survey or spot check yields positive results. The trigger levels for removable contamination surveys in research laboratories are 200 dpm per 100 cm^2.

General Rules of Safety

(a) Each individual under the supervision of the licensee, who handles radioactive material is responsible for minimizing the radiation exposure to themselves and other individuals within the work area, and to take appropriate steps to prevent personal contamination and contamination of the environment. To satisfy this requirement, we will ensure that, as a minimum, the following rules are observed, where unsealed sources of radioactive material are handled:

i Eating and drinking, or the presence of food or beverages, is be forbidden.
ii The presence of reusable cups or eating implements in the suite is forbidden.
iii Smoking, or the presence of tobacco products and smoking paraphernalia, shall be forbidden.
iv Pipetting by mouth shall be forbidden.
v Radioactive materials shall not be handled by individuals with exposed cuts or abrasions.
vi No individual shall handle unsealed radioactivity unless he/she is wearing protective gloves and a lab coat. Protective gloves and lab coats shall be removed immediately when contamination is suspected.
vii Handling of radioactive material shall be limited to the smallest area possible. To the extent practical, radioactive work areas shall be delineated using warning tape or warning signs. Each worker is responsible for informing others in the laboratory of the locations where he/she is using radioactive material.
viii All items used during procedures involving unsealed radioactivity shall be labeled with radioactive material warning tape.
ix All surfaces on which work with unsealed radioactivity is conducted shall be covered with waterproof backed absorbent paper. This covering shall be changed when contaminated.
x Sources of penetrating radiation shall be maintained in a suitable shield to the extent practical.
xi Unshielded sources of radioactivity shall only be handled using forceps or other device to maintain an adequate distance from the fingers.
xii When personal or area contamination is suspected, work with unsealed radioactivity shall be stopped as soon as possible so that decontamination procedures may be undertaken.

(b) Immediate notification to the licensee shall be required in the event of any of the following incidents:

i A known or suspected whole body radiation exposure which may result in an absorbed dose equivalent of 25 millirem in one hour;
ii Any known or suspected internalization of radioactive material by an individual;
iii Any known or suspected presence of airborne radioactivity;
iv Any known or suspected unauthorized release of radioactive material to an unrestricted area, or exposure of a member of the general public; and
v Any theft or otherwise unauthorized removal of radioactive material.

Also, we will implement the following Model Procedure published in the NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses":

Model Procedures for Safe Use of Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure. (Some of the health physics practices listed below may also apply to sealed sources.)

- ☐ Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

- ☐ Wear disposable gloves at all times while handling radioactive materials.

- ☐ Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.

- ☐ Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)

- ☐ Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.

- ☐ Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.

- ☐ Wear extremity dosimeters, if required, when handling radioactive material.

- ☐ Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

- ☐ Never pipette by mouth.

- ☐ Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.

- ☐ Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70 (except when administering therapy dosages in patients' rooms when patients are confined).

- ☐ Store radioactive solutions in shielded containers that are clearly labeled.

- ☐ Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904.

- ☐ Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the

container is holding less than the quantities listed in Appendix C to Part 20, the syringe or vial need only be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

- ☐ For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).

- ☐ Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.

- ☐ When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.

- ☐ Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).

- ☐ Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

- ☐ Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the NRC license (or such individual's designee).

ITEM 10: 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.

Emergency Procedures for Radioactive Contamination:

I Small Spills of non-volatile radioactive liquids

1. Obtain protective shoe covers. Don two pairs of protective gloves.

2. Avoid personal contamination and spreading of the spill. Use a Geiger counter or make wipe tests to determine the extent of the effected area. Mark the perimeter of the spill and cover with absorbent paper.

3. Place saturated paper in double plastic trash bags. Continue covering the spill with absorbent paper until all free liquid has been absorbed.

4. Remove residual radioactivity with detergent and water (use commercial decontaminant when available). Clean a small area at a time using a minimum amount of liquid. Work your way toward the center of the spill. Use Geiger counter or liquid scintillation counter to check paper towels used. Place contaminated towels directly into the plastic waste bags.

5. The spill is considered clean when radioactivity can no longer be detected in the effected area and when the measurements made of the paper towels reveal that there is no longer any removable activity.

6. When decontamination is finished, place shoe covers and gloves into the plastic waste bag, seal it, and label with a radioactive material warning sticker.

7. The Radiation Safety Officer shall confirm that decontamination is complete, monitor individuals for personal contamination.

II Large spills of non-volatile radioactive liquids

1. Alert the nearest person (s) that spill has occurred.

2. Don two pairs of protective gloves. While avoiding personal contamination, prolonged exposure, or spreading of the spill, cover the effective area and a two foot perimeter with absorbent paper.

3. Follow the procedure above as in I

III Skin Contamination

1. Alert the nearest person(s).

2. Immediately begin decontamination. Use mild soap and water - wash the effected area two or three times, but no more. Be careful not to spread localized contamination. Strenuous scrubbing will defat and abrade the skin, leading to increased penetration of the contaminant. Do not use strong alkaline detergents or organic solvents. Simple washing should be adequate to remove most of the contamination. If residual radioactivity remains on the hands, donning protective gloves to induce sweating will help flush out skin pores; however, the gloves must be removed and the hands washed immediately after profuse sweating begins or else contamination will penetrate the dilated pores.

3. If hair becomes contaminated, immediately begin washing with soap and water. Avoid spreading contamination to other parts of the head.

4. If contamination of the eyes occurs, flush with copious amounts of isotonic solution (if available), otherwise, use water. Be sure to roll back the eyelid as far as possible. If residual contamination remains, further decontamination shall require medical supervision.

5. If contamination of nose or mouth occurs, immediately flush with copious amounts of water: be careful not to ingest the rinse.

6. If contamination of a small wound occurs, stimulate bleeding and flush with sterile water, then follow standard first aid procedures. If contamination of a large wound occurs, control the bleeding and seek medical attention. Decontamination may be undertaken when the situation is medically under control.

IV Contamination of Clothing

1. Obtain disposable paper surgical scrubs. Change out of effected clothing being careful not to contaminate your skin. Place effected clothing in plastic bag, label with a radioactive material warning sticker, and hold for decay.

2. If the soles of the shoes become contaminated, remove shoes and wear surgical booties. Do not cause the spread of contamination by moving around in contaminated shoes. Shoe soles are typically decontaminated easily using soap and water. Perform this procedure over a sink normally used for radioactive materials. Use a Geiger counter or make wipe tests to determine when decontamination is complete. Initiate a survey of your work area to determine the source of the contamination. If not possible to decontaminate, we hold for decay.

ITEM 11: WASTE MANAGEMENT

We have developed and implementing and maintaining 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.

We hold by product material with physical half-life less than 120 days for decay-in-storage prior to disposal with out regard to radioactivity. We will perform the following prior to disposal:

(1) Monitors material at surface with an appropriate radiation detection survey meter set on its sensitive scale with no interposed shielding before disposal and determines that its radioactivity cannot be distinguished from the background radiation levels; and
(2) Removes or obliterates all radiation labels, except for radiation labels on material that are within the containers and that will be managed as biomedical waste after they have been released from the license.

We maintain and retain a record of each permitted disposal in accordance with 35.2092.

ITEM 12: FEES

None Required

ITEM 13: CERTIFICATION

We certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, and that all information contained herein is true and correct to the best of their knowledge and belief.

COLUMBIA UNIVERSITY
COLLEGE OF PHYSICIANS & SURGEONS
HARLEM HOSPITAL CENTER
DEPARTMENT OF MEDICINE

June 1, 2005

Certification Board of Nuclear Cardiology

Re: Merwin Richard, M.D

Dr. Merwin Richard 's training was equivalent to Level 2 training in nuclear cardiology as outlined in the ACC/ASNC COCATS Guidelines (revised 2000).

Dr. Richard is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses. Dr. Richard trained under Dr. Major Geer (deceased) Physician-in-Charge Cardiovascular Exercise Laboratory, Nuclear Cardiology HHC License #91-29-04-01

If additional information is required, please contact me at (212) 939-4701.

Sincerely yours,

Eric J. Vanderhush, M.D.
Chief, Division of Cardiology
Harlem Hospital Center

EJV:meh

506 Lenox Avenue New York, NY 10037

NRC FORM 313A (10-2001) U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2004

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT

PART I – TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Merwin Richard, M.D.

2. For Physicians, Podiatrists, Dentists, Pharmacists – State or Territory Where Licensed

New Jersey

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
Cardiology	Cardiology	2001

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Institute for Nuclear Medicine Secaucus, N.J	40+50 = 90	11-2004
Radiation Protection	" "	25	5-14-22, 2005
Mathematics Pertaining to the Use and Measurement of Radioactivity	" "	10	5-14 through 5-22-2005
Radiation Biology	" "	25	5-14 through 5-22-05
Chemistry of Byproduct Material for Medical Use	" "	50	5-14 through 5-22-05
OTHER			

NRC FORM 313A (10-2001)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
All aspects of technical work in medicine lab	Dr. Geer	Harlem Hospital Columbia University	6-1999 7-2000 200 hrs
Including: Stress, Administration of radiopharm			200 Hours
gamma camera imaging camera QC, hot lab			
elution + preperation of radiopharmic central lab			

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
TL 201	Resting Cardiac Viabity	500 25		University Hosp.	7/03/6/04
Tc 99m	mibi Fosmin Stress Imases	500			300 Hrs.
Tc 99m	RBC	50			

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

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

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
M.D. Cardiology N/A			

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

☐ YES ☒ N/A Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of _____ the RSO for License No. _____.

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

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

☐ YES ☒ N/A Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ modality(ies) under the supervision of _____ who meets 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 [signature]

B. Supervisor is:
☒ Authorized User ☐ Authorized Medical Physicist
☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.390 for medical uses in Part 35, Section(s) 35.390

D. Address

E. Materials License Number

NRC FORM 313A (10 2002) 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.

☐ YES ☒ N/A 10. The individual named in item 1 has satisfactorially completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

☒ YES ☐ N/A 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.290.

☒ YES ☐ N/A 11b. The individual named in item 1. is competent to independently function as an authorized User for imaging/localization 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 35.390 or equivalent Agreement State requirements to be a preceptor authorized for the following uses (or units) of byproduct material: imaging

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR *(print clearly)*	D. SIGNATURE – PRECEPTOR	E. DATE

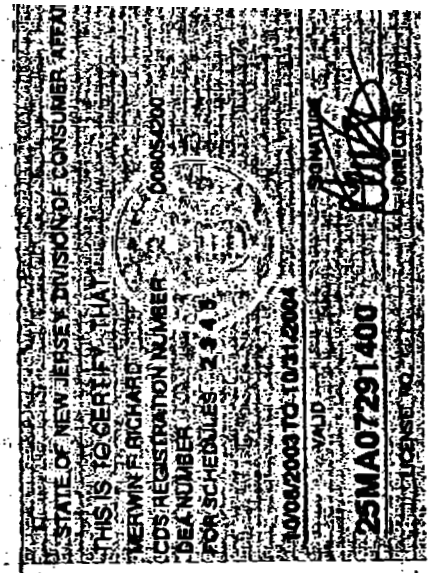
PAGE 4

State Of New Jersey Department Of Health

IN AGREEMENT WITH
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
IN ACCORDANCE WITH N.J.S.A. 24:21-1 ET SEQ.

CONTROLLED DANGEROUS SUBSTANCES
CDS REGISTRATION NUMBER
D08054200

MERWIN F. RICHARD
DEPT OF CARDIOLOGY MSB I-536
185 SO ORANGE AVENUE
NEWARK NJ 07103



IS REGISTERED AS: CDS Physician

FOR SCHEDULES: 2 3 4 5

10/08/2003 TO 10/31/2004
VALID

DEA NO.

25MA07291400
LICENSE/REGISTRATION/CERTIFICATION #

Merwin Richard
SIGNATURE OF REGISTRANT

DIRECTOR

PLEASE DETACH HERE

IF YOUR LICENSE/ID CARD IS LOST PLEASE NOTIFY:

Drug Control Unit
P.O. Box 45022
Newark, NJ 07101

PLEASE DETACH HERE

THE AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

Merwin F. Richard

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY

CERTIFIED FOR THE PERIOD 1995 THROUGH 2005

AS A DIPLOMATE IN

INTERNAL MEDICINE

Jerome P. Kassirer
CHAIRMAN

John A. Stobo
CHAIRMAN-ELECT

Mark A. Kelley
SECRETARY-TREASURER

Henry R. Clemmesbrook
PRESIDENT

William M. Burnett

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Arthur Cassel

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Mark A. Klempner

Phillip P. Toskes

R F G Bond

Arthur Ulmann

Roland W. Moskowitz

Jacob Teitelbaum

James R. Vaughton

Douglas P. Zipes

NUMBER 162557

1995

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion

This document is to attest that

Merwin Richard, M.D.

has successfully completed the didactic program

MEDICAL RADIATION PROTECTION

and has provided evidence of attendance in this program and evidence of achieving the objectives of program hours. This program provides the following levels of accomplishment:

5.0 Continuing Education Units (CEU)
50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
50 Board Accepted Hours NUSPEX, NMTCB III b, ABMRSO, CBNC, MRLB
3.0 Semester Hours American Council on Education (ACE), American Association for Collegiate Registrars

Certifying Official

18 May 2005
Date Completed

203162
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States

NUCLEAR MEDICAL EDUCATION PROGRAM

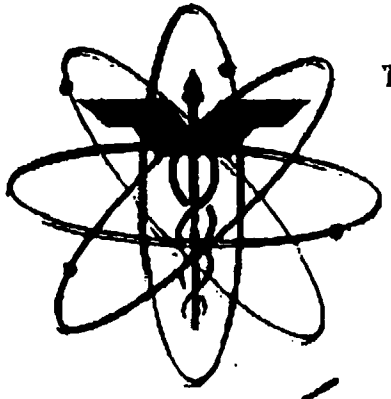
Affidavit of Academic Completion

This document is to attest that

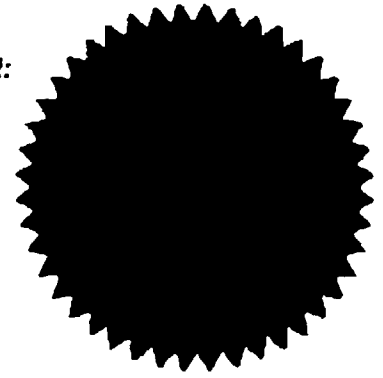
Merwin Richard, M.D.

has successfully completed the didactic program

RADIOPHARMACEUTICALS AND CHEMISTRY



and has provided evidence of attendance in this program and evidence of achieving the objectives of program hours. This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH) In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b, ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on Education (ACE), American Association for Collegiate Registrars

Certifying Official	Date Completed	Certification
	22 May 2005	203226

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States

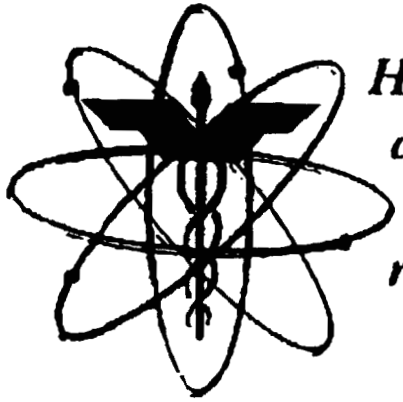
RMEA132-Class IV-Complete 1.07

CERTIFICATE OF COMPLETION

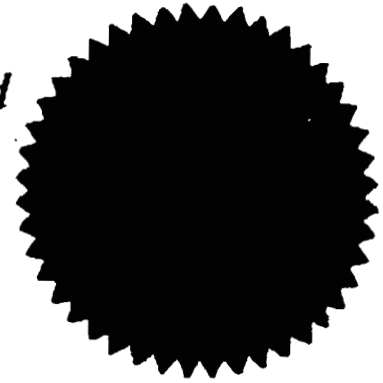
HAZMAT TRAINING - RADIOACTIVE MATERIALS

This document is to certify that

Merwin Richard, M.D.



Has received training and has been tested as required by 49CFR 172.704(d). This training was limited to diagnostic radioactive materials received or offered for shipment in approved Type A Packages, Class 7, UN2915, Yellow II.



Certifying Official

19 May 2005
Date Completed

203276
Certification

Training Materials and Records are located at

INME - Institute for Nuclear Medical Education • 5660 Airport Boulevard, Suite 101 • Boulder, Colorado 80301
(303) 541-0044 • (303) 541-0066 FAX • (800) 548-4020 • inme@nuclearcardiology.com • http://www.nuclearcardiology.com/ines

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion

This document is to attest that

Merwin Richard, MD

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of attendance in this program and evidence of achieving the objectives of program hours. This program provides the following levels of accomplishment:

- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH) In compliance with 10CFR35/AEA 73-669
- 50 Board Accepted Hours NUSPEX, NMTCB III b, ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on Education (ACE), American Association for Collegiate Registrars

Certifying Official

17 October 2004
Date Completed

202761
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class II-Complete 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion

This document is to attest that

Merwin Richard, MD

has successfully completed the didactic program

PRINCIPLES OF RADIATION PHYSICS

and has provided evidence of attendance in this program and evidence of achieving the objectives of program hours. This program provides the following levels of accomplishment:

- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH) In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b, ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on Education (ACE), American Association for Collegiate Registrars

Certifying Official

13 October 2004
Date Completed

202709
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class I-Complete 1/00

Curriculum Vitae

Merwin Richard, M.D., FACC

[redacted]

973-972-5507 (Office)

[redacted](Home)

973-972-2169 (Fax)

[redacted](Cell)

[redacted]

Hospital Appointment:

March 2004 – Present	**Director of the Cardiac Catheterization** Jersey City Medical Center/ Liberty Healthcare Systems Jersey City, NJ
October 2002 – March 2004	**Associate Chief Division of Cardiology** **Director of the Cardiac Catheterization/** **Interventional Procedure Laboratory** Assistant Professor of Medicine New Jersey Medical School/ University of Medicine and Dentistry New Jersey Newark, NJ
July 2001 – October 2002	**Staff Interventionalist** Assistant Professor of Medicine New Jersey Medical School/ University of Medicine and Dentistry New Jersey Newark, NJ

Education:

July 2000 - June 2001	**Interventional Cardiology Fellow/ Interventional Researcher** Mount Sinai School of Medicine New York, NY
July 99 - June 2000	**Interventional Cardiology Research Fellow-** Mount Sinai School of Medicine New York, NY
July 97- June 99	**Cardiology Fellow-**

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

College of Physicians and Surgeons Columbia University/
Harlem Hospital New York, NY

July 92 - June 95 **Internal Medicine Residency**
Albert Einstein College of Medicine
Bronx -Lebanon Hospital
New York, NY

Education:

1982 – 1990 **Medical School**
Stanley Medical College
University of Madras
Madras, India
Bachelor of Medicine and Surgery
July 1988 Graduate

Previous Hospital Appointments:

Aug 1995 - May 1997 Attending Emergency Room
Albert Einstein College of Medicine
Bronx Lebanon Hospital, NY

Research Grants Awarded-

Synergistic effects of Abciximab and enoxaparin with flow mediated cytometry
Principle Investigator-
Award- $850,000

Monitoring of dalteparin in the cardiac catheterization lab using the activated clotting time. Co-Principle investigator-
Award- $270,000

Pre hospital use of Abciximab in ST elevation myocardial infarction-
Principle Investigator
Award- $450,000

Papers / Reports Published

1. Abstract presented at the annual American College of Physicians (ACP) conference Atlanta Georgia, March 1995
In the South Bronx there are more women having and dying of myocardial infarctions than men

Merwin Richard, Jonathan Gold, Steve Blum, N.C. Bhalodkar, Sarah Garrison, Bronx Lebanon Hospital Center

2. Abstract presented at the Albert Einstein College of Medicine- Department of Medicine annual scientific poster session April 1995 - same title as above

3. Abstract presented at the American Heart Association (AHA) Scientific conference on Hormonal Metabolic, and cellular influences on women in San Diego California, Oct 1995
   Risk factors for coronary artery disease in pre and postmenopausal women are higher than in men in the South Bronx resulting in more myocardial infarctions among women
   Narendra C Bhalodkar, **Merwin F Richard**, Steve Blum, Jonathan WM Gold, Edward J. Brown Jr, Ferdinard J Visco. Bronx Lebanon Hospital Center

4. Bilateral complete sensoineural hearing loss after 3 days of gentamycin treatment in a young man Bronx Lebanon Hospital NY
   Merwin Richard, Edward Brown Jr., Imad Alhaddad, Jonathan Gold, Bronx Lebanon Hospital

5. Abstract presented at the Second International Congress on Coronary Artery Disease- From prevention to intervention, Florence, Italy, October 1998.
   Coronary Artery Disease Frequency in Inner city Hispanics compared to African Americans.
   Oscar West, **Merwin F. Richard**, Jothi Shani, Eric Vanderbush Harlem Hospital Center/ Columbia University, NY

6. Abstract presented and winning honorable mention at The Northern Manhattan network poster competition
   Supraventricualar arrhythmias in Atrial Fibrillation
   Merwin Richard, Oladipo Aloa, Steven Winters Morristown Memorial Hospital, NJ

7. Abstract presented at The Cleveland clinic foundation heart failure summit IV Oct 1998 Clinical Characteristics and Length of Stay of 107 patients hospitalized for CBF: Diastolic versus systolic dysfunction
   Merwin Richard, Satish Kenchaiah, Chakra Desaraju, Vasu Rajan, Wayne Longmore, Eric Vanderbush, Thierry Lejemtel Harlem Hospital Center, College of Physicians and Surgeons, Columbia University, New York, NY

8. Abstract presented at the American Heart Association meeting (AHA) 1999
Atrial Fibrillation and the risk of stroke during cardioverter-Defibrillator implantation: a sentinel event and prevention strategy
Jay H Curwin, Robert F Coyne, Giuseppe Limandri, Sherri Raquet, **Merwin Richard**, Nagesh Chopra, John S. Banas Stephen L Winters, Morristown Memorial Hospital, Morristown NJ

9. Oral presentation at the American Heart Association meeting (AHA) 2000
Assessing Safety and Efficacy of FFR-FVIIa in Percutaneous Transluminal Coronary Angioplasty (ASIS) Trial- Perfusion chamber Substudy
Eli Lev, Jonathan Marmur, Jonathan Robbins, **Merwin Richard**, Juan Badimon
Mount Sinai School of Medicine NY, NY

10. Oral presentation at the American Heart Association meeting (AHA) 2000
Tirofiban, Eptifibatide and Abciximab in Minimizing CK-MB Release during Coronary Intervention (TEAM Trial)
Samin Sharma, **Merwin Richard**, Kini Annapoorna, Javed Suleman, Steve Fisher, Jonathan Marmur
Mount Sinai School of Medicine NY, NY

11. Oral presentation at the American Heart Association meeting (AHA) 2000
Tirofiban, Eptifibatide and Abciximab in Minimizing CK-MB Release during Coronary Intervention (TEAM Trial)
Samin Sharma, **Merwin Richard**, Kini Annapoorna, Javed Suleman, Steve Fisher, Jonathan Marmur
Mount Sinai School of Medicine NY, NY

12. The Activated Clotting Time (ACT) Can Be Used to Monitor the Anticoagulant Effect of Intravenous Dalteparin During Percutaneous Coronary Intervention
Jonathan D. Marmur, MD, Sunil Anand, BA, Ramanjit S. Bagga, MD, Jawed Fareed, PhD, Samin K. Sharma, MD, **Merwin F. Richard, MD**
Mount Sinai School of Medicine NY, NY

13. Administration of Abciximab in patient's receiving Tirofiban or Eptifibatide: Effects on platelet function
Eli I Lev, Julio I Osende, **Merwin F. Richard**, Tim Jayasundera, Oswaldo Rodriguez, Jenny A Delphin, Jonathan A Robbins, Samin Sharma, Juan J Badimon, Jonathan D Marmur
Journal of the American College of Cardiology Vol. 37, No 3 2001

14. Testing platelet activation with a shear-dependent platelet function test versus aggregation-based tests. Relevance for monitoring long term glycoprotein IIb/IIIa inhibition.
Julio I. Osende MD, Valentin Fuster MD PhD, Eli Lev MD, Daichi Shimbo MD, Ursula Rauch MD, Jonathan Marmur, MD, **Merwin Richard MD**, David Veron MD, Juan Badimon PhD
Circulation Vol 96, No. 5, 2001

15. Tirofiban, Eptifibatide and Abciximab in Minimizing CK-MB Release during Coronary Intervention (TEAM Trial)
Samin Sharma, Kini Annapoorna, Javed Suleman, Steve Fisher, Jonathan Marmur, **Merwin Richard**
American Journal of Cardiology Vol. 9, No 5 2002

16. The activated clotting time can be used to monitor the low molecular weight heparin dalteparin after intravenous administration
Jonathan D. Marmur, MD, Sunil Anand, BA, Ramanjit S. Bagga, MD, Jawed Fareed, PhD, Samin K. Sharma, MD, **Merwin F. Richard, MD**
Journal of the American College of Cardiology Vol. 41, No. 3 2003

Multi center studies

1. Losartan Intervention For End-point reduction in hypertension (LIFE) and Echo Substudy -Secondary investigator
College of Physicians and Surgeons Columbia University/ Harlem Hospital New York, NY
2. PREvention of recurrent VENous Thromboembolism (PREVENT)-
Study coordinator
College of Physicians and Surgeons Columbia University/ Harlem Hospital New York, NY
3. Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines: The Crusade study- Co-Investigator
New Jersey Medical School/ University of Medicine and Dentistry of New Jersey

Educational Activity-

Course Director Update on Acute Coronary Syndromes 2003 May 1st and 2nd 2003 New Jersey Statewide Symposium

Course Director Update on Acute Coronary Syndromes and Heart Failure 2004 June 4th and 5th 2004 New Jersey Statewide Symposium

Board Certifications-

Internal Medicine Board Certified 1995

Cardiology Board Certified 2001

Interventional Cardiology Board Certified 2002

Society Membership

American College of Physicians

American College of Cardiology

American Heart Association

Society of Coronary Angiography and Interventions

Invited Lectures

Eastern united states Leading Edge program moderator, June 2001, New York City, NY
Antithrombotics in cardiology

Cardiology grand rounds June 2001 Georgia Medical Center at Augusta
Augusta Georgia, Use of Low molecular weight heparin in ACS

Cardiology Grand Rounds, January 2002, Parkway Regional Hospital, Miami, FL
Anticoagulants in the cath lab

Cardiology Grand Rounds, February, 2002, Allegheny General Hospital, Pittsburgh, PA
Treatment of ACS

Cardiology Grand Rounds, March, 2002, Regional Hospital, St. Paul, MN,
Anticoagulants in the cath lab

Cardiology Grand Rounds, April, 2002, Marshfield Hospital, WI, Anticoagulants in ACS

Cardiology Grand Rounds, April, 2002, Wausau Hospital, WI Low molecular weight heparin in the cath lab

Cardiology Grand Rounds, April, 2002, Green Bay Hospital, WI, Anticoagulants in ACS

Cardiology Grand Rounds, April, 2002, Kennedy Hospital, Stratford, NJ Low molecular weight heparin in the cath lab

Cardiology Grand Rounds, April, 2002, Santa Rosa Memorial Hospital, Santa Rosa, CA Treatment of ACS

Cardiology Grand Rounds, April, 2002, Cedar Sinai Medical Center, CA, Anticoagulants in ACS

Cardiology Grand Rounds, April 2002, Mayo Clinic, Phoenix, AZ Treatment of ACS

Cardiology Grand Rounds, April 2002, St. Joseph's Hospital, Phoenix, AZ, Anticoagulants in ACS

Cardiology Grand Rounds, May 2002, Trinitas Hospital, Elizabeth, NJ Treatment of ACS

Cardiology Grand Rounds, June 2002, Deborah Heart & Lung Center, Brown Mills, NJ, Anticoagulants in ACS

Cardiology Grand Rounds, July 2002, Sentara Norfolk General Hospital, Norfolk, VA Low molecular weight heparin in the cath lab

Cardiology Grand Rounds, July 2002, Legacy Good Samaritan Hospital, Portland, OR Low molecular weight heparin in the cath lab

Cardiology Grand Rounds, July 2002, St. Alexius Medical Center, Bismarck, ND Treatment of ACS

Cardiology Grand Rounds, November 2002, Mercy Hospital, St. Paul, MN Antithrombotics in cardiology

Cardiology Grand Rounds, November 2002, Allina Health System, Minneapolis, MN Low molecular weight heparin in the cath lab

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

6/24/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 29-30967-01

☒ 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

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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** 137232.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 02201
and	:	Status Code: 0
Regional Licensing Sections	:	Fee Category: 7C
	:	Exp. Date: 20141031
	:	Fee Comments: _____
	:	Decom Fin Assur Reqd: N
	::	

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: KOHAN, FERAYDOON MD
   Received Date: 20050628
   Docket No: 3036685
   Control No.: 137232
   License No.: 29-30967-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Jessed
Date 6/29/2005

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 _____