



Mid-Atlantic Permanente Medical Group, P.C.
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

U.S. Nuclear Regulatory Commission, Region II
Materials Licensing
Division of Nuclear Materials Safety
Atlanta Federal Center
61 Forsyth Street, SW, Suite 23T85
Atlanta, GA 30303

LL 30980

03036776

02201

(45-30980 - 01)

RE: Application for New License

Dear Sirs:

Please find the enclosed application (two copies) for our radioactive materials license. All provided information has been updated and includes modifications as per NUREG 1556, Vol. 9.

Please contact me should you have any questions or need additional information. We wish to have the process of the application review expedited in order to provide diagnostic services to our patients. Your assistance with this request is much appreciated.

Sincerely,

Carol P. Cardinale, MD

Carol P. Cardinale, M.D.
Radiation Safety Officer

Enclosures

Professional Services Building
1400 Forest Glen Road, Suite 300
Silver Spring, Maryland 20910

136113

NMSS/RGNI MATERIALS-002
REC'D IN LAT DEC 13 2004

NRC FORM 313

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/10/2003

(8-1999)
10 CFR 30, 32, 33
34, 35, 38, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-8 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

LL 30980
036 36776
02201

(45-30980-01)

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

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

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

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

Kaiser Permanente
12011 Lee-Jackson Highway
Fairfax, VA 22033

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

Kaiser Permanente
12011 Lee-Jackson Highway
Fairfax, VA 22033

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Alan W. Goldey

TELEPHONE NUMBER
(301) 345-6803

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY 7C | AMOUNT ENCLOSED \$2200.00

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

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

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

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Carol P. Cardinale, MD, RSO

SIGNATURE

Carol P. Cardinale

DATE

11/25/94

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		

APPROVED BY

DATE

136113

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the "yes" column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
X	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
X	Any byproduct permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	Any byproduct material permitted by 10 CFR 35.300	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.

Table C.3 is a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: _____ Carol P. Cardinale, M.D.	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.900(b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual <u>Carol P. Cardinale, M.D.</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p style="text-align: center;">OR</p> <p>A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists Names: <u>NA</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency</p> <ul style="list-style-type: none"> • sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or • sufficient to independently operate a nuclear pharmacy (10 CFR 35.980). <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Medical Physicists</p> <p>Names: <u>NA</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the units requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Facility Diagram</p>	<p>A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:</p> <ul style="list-style-type: none"> • Drawings should be to scale, and indicate the scale used. • Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion"; • Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and • Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.). <p>In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.</p>	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9: Radiation Monitoring Instruments	<p>A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."</p> <p style="text-align: center;">AND/OR</p> <p>A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."</p> <p style="text-align: center;">AND</p> <p>A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.</p> <p style="text-align: center;">AND</p> <p>A statement that: "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."</p>	<p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p>
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	<input checked="" type="checkbox"/>
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	<input type="checkbox"/>
Item 9: Other Equipment and Facilities	<p>Attached is a description identified as Attachment 9.4, of additional facilities and equipment.</p> <p>For manual brachytherapy facilities, we are providing a description of the emergency response equipment.</p> <p>For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:</p> <ul style="list-style-type: none"> • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; <input type="checkbox"/> • Area radiation monitoring equipment; <input type="checkbox"/> • Viewing and intercom systems (except for LDR units); <input type="checkbox"/> • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; <input type="checkbox"/> • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and <input type="checkbox"/> • Emergency response equipment. <input type="checkbox"/> 	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
Item 10. Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	<input type="checkbox"/>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Occupational Dose	<p>A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002."</p> <p style="text-align: center;">OR</p> <p>A description of an alternative method for demonstrating compliance with the referenced regulations.</p>	<p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p>
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain 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."	<input checked="" type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	<input checked="" type="checkbox"/>
Item 10: Spill Procedures	A statement that: "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."	<input checked="" type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	<p>Name of the proposed employee and types of activities requested:</p> <hr/> <p style="text-align: center;">AND</p> <p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p style="text-align: center;">AND</p> <p>Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92."	<input checked="" type="checkbox"/>

Radioactive Material

5.	<u>Radioactive Material</u>	<u>Chemical/ Physical Form</u>	<u>Maximum Amount</u>	6.	<u>Purpose</u>
5.a	Material in 35.100	Any except I-125 and I-131	As needed	6.a	Medical use
5.b	Material in 35.200	Any except I-125 and I-131	As needed	6.b	Medical use

- 6.a. Medical use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
- 6.b. Medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Individuals Responsible for Radiation Safety Program

7.1 User – Materials/Documentation

- 7.1.1 Carol P. Cardinale, M.D.
Any material from Sections 35.100, and 35.200

Training and experience documentation for Dr. Cardinale is enclosed.

The radiation safety officer for the activities authorized by this license will Carol P. Cardinale, M.D.

Training for Individuals Working In or Frequenting Restricted Areas

8.1 Personnel Training

The personnel training will be given on an annual basis to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures or videotape presentations and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all ancillary personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instructions in items A and B below, and that radiation workers (i.e., technologists), receive instruction in all items below.

- A. Areas where radioactive materials are used or stored.
- B. Potential hazards associated with radioactive material.
- C. Radiological safety procedures appropriate to their respective duties.
- D. Pertinent NRC regulations.
- E. Pertinent terms of the license including licensee's in-house work rules.
- F. Their obligation to report unsafe conditions.
- G. Appropriate response to emergencies or unsafe conditions.
- H. Their right to be informed of their radiation exposure and bioassay results.
- I. Locations where the licensee has posted or made available notices, copies of pertinent licenses, and license conditions (including applications and applicable correspondence), as required by NRC regulations.

Personnel will be properly instructed as follows:

- A. Before assuming duties with or in the vicinity of radioactive materials.
- B. During annual refresher training.
- C. Whenever there is a significant change in duties, regulations, or terms of the license.

Facilities and Equipment

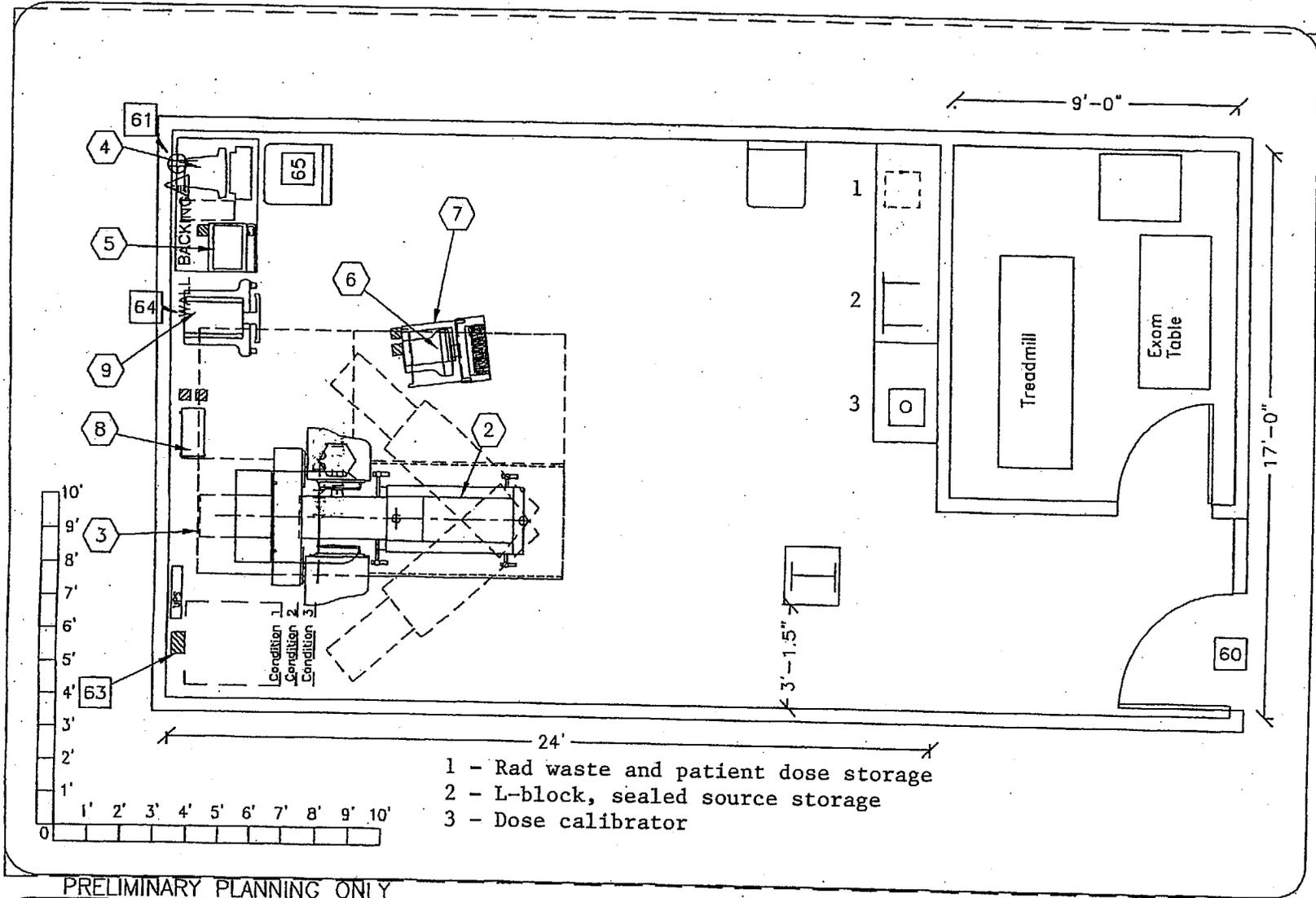
- 9.1 See enclosed submitted floor plan for layout of the Nuclear Cardiology department depicting details of the hot lab and scan room.
- 9.2 Equipment available:
- a. Lead syringe shields
 - b. Lead syringe holders
 - c. Lead containers and pigs
 - d. Lead bricks
 - e. Lead L-block
 - f. Lead-lined waste containers
 - g. Plastic-backed absorbent pads
 - h. Rubber gloves
 - i. Remote handling equipment (i.e., tongs)
 - j. Laboratory coats/smocks
 - k. Portable survey instrumentation (see Item 9.4)
- 9.3 Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.

Facilities and Equipment (continued)

9.4	<u>Instrument</u>	<u>No.</u>	<u>Range</u>	<u>Use</u>
	Ludlum 14C GM meter with 44-9 pancake probe	1	0.01 - 2000 mR/hr	Monitoring
	Ludlum 2200 Rate Meter with 44-3 NaI Detector	1	0 - 999,999 cpm	Measuring
	Atom Lab Dose Calibrator Model 100 (or equivalent)	1	0 - 20 Ci	Measuring
	G.E. Millennium MyoSIGHT Gamma Camera	1	----	Imaging

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

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



PRELIMINARY PLANNING ONLY

PROJECT TITLE:

Millennium Myosight
Fairfax, VA

SCHEME NO.: 04bef026a DRAWN BY: swg DATE: 8/20/04

THIS LAYOUT MUST BE APPROVED BEFORE
FINAL DRAWINGS CAN BE STARTED. THANK YOU

CUSTOMER _____ DATE: _____



GE Medical Systems

Modality Installation Planning
Milwaukee, Wisconsin

Wisconsin

Radiation Safety Program

- 10.1 Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements under "Criteria" in NUREG - 1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002.
- 10.2 We have developed and will implement and maintain 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.
- 10.3 We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.
- 10.4 We have developed and will maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101

Waste Management

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

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)

Carol Cardinale, M.D.

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

New York, Virginia, Maryland

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified

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	Health + Radiological Seminars 3 Hillcrest Dr. Suite 200A Frederick, MD 21703	100 hrs	11/03
Radiation Protection	"	30 hrs	11/03
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	20 hrs	11/03
Radiation Biology	"	20 hrs	11/03
Chemistry of Byproduct Material for Medical Use	"	30 hrs	11/03
OTHER			

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

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	Cardiac Imaging	500	Steven Bergmann, MD	Columbia Presbyterian NY	7/98 - 7/2001 500hrs
Tc ^{99m}	Cardiac Imaging	200	"	"	200hrs
Tc ^{99m}	Muga / PYP	100	"	"	100hrs

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)

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

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

N/A

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

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

N/A

YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ who meets requirements of Authorized Medical Physicists for _____ modality(ies) under the supervision of _____ modality(ies).

N/A

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

Steven R. Bergmann

B. Supervisor is:

- Authorized User Authorized Medical Physicist
- Radiation Safety Officer Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.410 & 35.420

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

D. Address

630 W 168th St
New York, NY
10032

E. Materials License Number

75-2878-01

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

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

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

A. Address

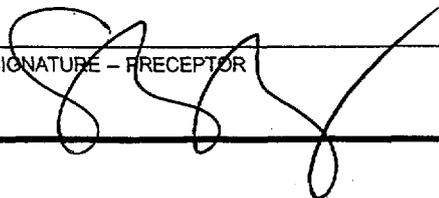
B. Materials License Number

75-2878-01

C. NAME OF PRECEPTOR (print clearly)

Steven R. Bergmann

D. SIGNATURE - PRECEPTOR



E. DATE

11/3/04



University Hospital and
Manhattan Campus for
the Albert Einstein College
of Medicine

**Continuum Heart Institute
Beth Israel Medical Center**

Milton and Carroll Petrie Division
First Avenue at 16th Street
New York, NY 10003
Tel: 212 420 4681
Fax: 212 420 4222
E-mail: sbergmann@bethisraelny.org

Steven R. Bergmann, M.D., Ph.D.
Chief, Division of Cardiology
Professor of Medicine
Albert Einstein College of Medicine

January 15, 2004

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Carol Cardinale, M.D.

Dear Sir or Madam:

This is to certify that Carol Cardinale, M.D. has been under my supervision and training in performance of imaging and localizing techniques as related to the field of nuclear cardiology. Dr. Cardinale was a Fellow in Clinical Cardiology at the Columbia Presbyterian Medical Center/New York Presbyterian Hospital from July 1998 to July 2001 and had 4 months of dedicated nuclear cardiology training (>800 hours). Dr. Cardinale used thallium and technetium and performed more than five hundred thallium studies and upwards of two hundred technetium studies. Dr. Cardinale also gained in-depth knowledge of gated pool studies and myocardial uptake and localization studies and their proper evaluation and interpretation.

Dr. Cardinale has had actual hands on experience in terms of properly handling the isotopes with careful selection of patient's with their clinical conditions, appropriate dose calculation and administration of the radionuclide and thereafter scanning the patients using Single Photon Emission Computerized Tomography (SPECT) and planar imaging equipment.

I also note that she has obtained 200 hours of didactic training in nuclear cardiology from the Health and Radiological Seminars Inc.

In my judgment, Dr. Cardinale has the appropriate knowledge and experience to perform these studies independently. I have no hesitation whatsoever in recommending her to be licensed in the use of these isotopes.

If you have any questions or need additional information, please feel free to contact me at (212) 420 4681.

Sincerely,

Steven R. Bergmann, M.D., Ph.D.
Chief, Division of Cardiology
NYC Licenses: # 75-2878-01
91-3154-01



Health & Radiological Seminars, Inc.

Hereby certifies that

Carol Cardinale, M.D.

has successfully completed the 200 Hour Physician Training
Program in Basic Radioisotope Handling conducted
in accordance with the requirements of the
U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

Radiation Physics and Instrumentation - 100 hours
Mathematics pertaining to the use and measurement of radioactivity - 20 hours
Radiopharmaceutical Chemistry - 30 hours
Radiation Biology - 20 hours
Radiation Protection - 30 hours



Shannon R. Saville
Course Coordinator

November 9, 2003



David J. Goodenough, Ph.D.
Scientific Advisor

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

11/23/2014, and to inform you that the initial processing which includes an administrative review has been performed.

NEW LICENSE APPLICATION (03036776)
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** 136113.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

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

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 Applicant/Licensee: KAISER PERMANENTE
 Received Date: 20041213
 Docket No: 3036776
 Control No.: 136113
 License No.: 45-30980-01
 Action Type: New Licensee

2. FEE ATTACHED
 Amount: \$2,200.00
 Check No.: 2164

3. COMMENTS

Signed M. A. Perkins
 Date 12/13/04

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 _____