

FAIRFAX HEART ASSOCIATES, P.C.

3299 Woodburn Road, Suite 470

Annandale, Virginia 22003

Telephone: (703) 204-9301

PAUL E. DiLORENZO, M.D., F.A.C.C., TESTAMUR NASPE_xAM

RAYMOND VERGNE, M.D., F.A.C.P., F.A.C.C.

FELIX D. CASTRO, M.D., F.A.C.C.

[November 11, 2004]

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

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NOV 11 2004 11:51

RE: Application for New License

(45-30978-01)

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,

Brigid Anne Carlos, M.D.
Radiation Safety Officer

Enclosures

136084

NMSS/RGNI MATERIALS-002

NRC FORM 313
(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 38 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/10/31/2005

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 23785
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 30978
030 36772
02201
(45-30978-01)

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)

Fairfax Heart Associates, P.C.
3299 Woodburn Road, Suite 470
Annandale, VA 22003

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

Fairfax Heart Associates, P.C.
3299 Woodburn Road, Suite 470
Annandale, VA 22003

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

DAVID A. JONES (2/15/04)

SIGNATURE

Alan W. Goldey (2/29/04)

DATE

FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|-------------|---------|--------------|-----------------|--------------|----------|
| | | | \$ | | |
| APPROVED BY | | | | DATE | |

136084

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 (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>Brigid Anne Carlos, 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 checked="" 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> |
| <p>Item 7: Authorized Nuclear Pharmacists</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 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><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 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 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 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 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 align="center"><input checked="" type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input checked="" type="checkbox"/></p> <p align="center"><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." | <p align="center"><input checked="" type="checkbox"/></p> |
| 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. | <p align="center"><input type="checkbox"/></p> |
| 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; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • 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; • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and • Emergency response equipment. | <p align="center"><input type="checkbox"/></p> |
| Item 10. Safety Procedures and Instructions | Attached procedures required by 10 CFR 35.610 | <p align="center"><input type="checkbox"/></p> |

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 style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> |
| Item 10: Area Surveys | <p>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."</p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> |
| Item 10: Safe Use of Unsealed Licensed Material | <p>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."</p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> |
| Item 10: Spill Procedures | <p>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."</p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> |
| 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 style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> |
| Item 10: Minimization of Contamination | <p>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.</p> | <p style="text-align: center;">N/A</p> |
| Item 11: Waste Management | <p>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."</p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> |

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 Brigid Anne Carlos, M.D.
Any material from Sections 35.100, and 35.200

Dr. Carlos is listed as an authorized user on NRC license number 45-17128-01. This documentation is enclosed.

The radiation safety officer for the activities authorized by this license will Brigid Anne Carlos, 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

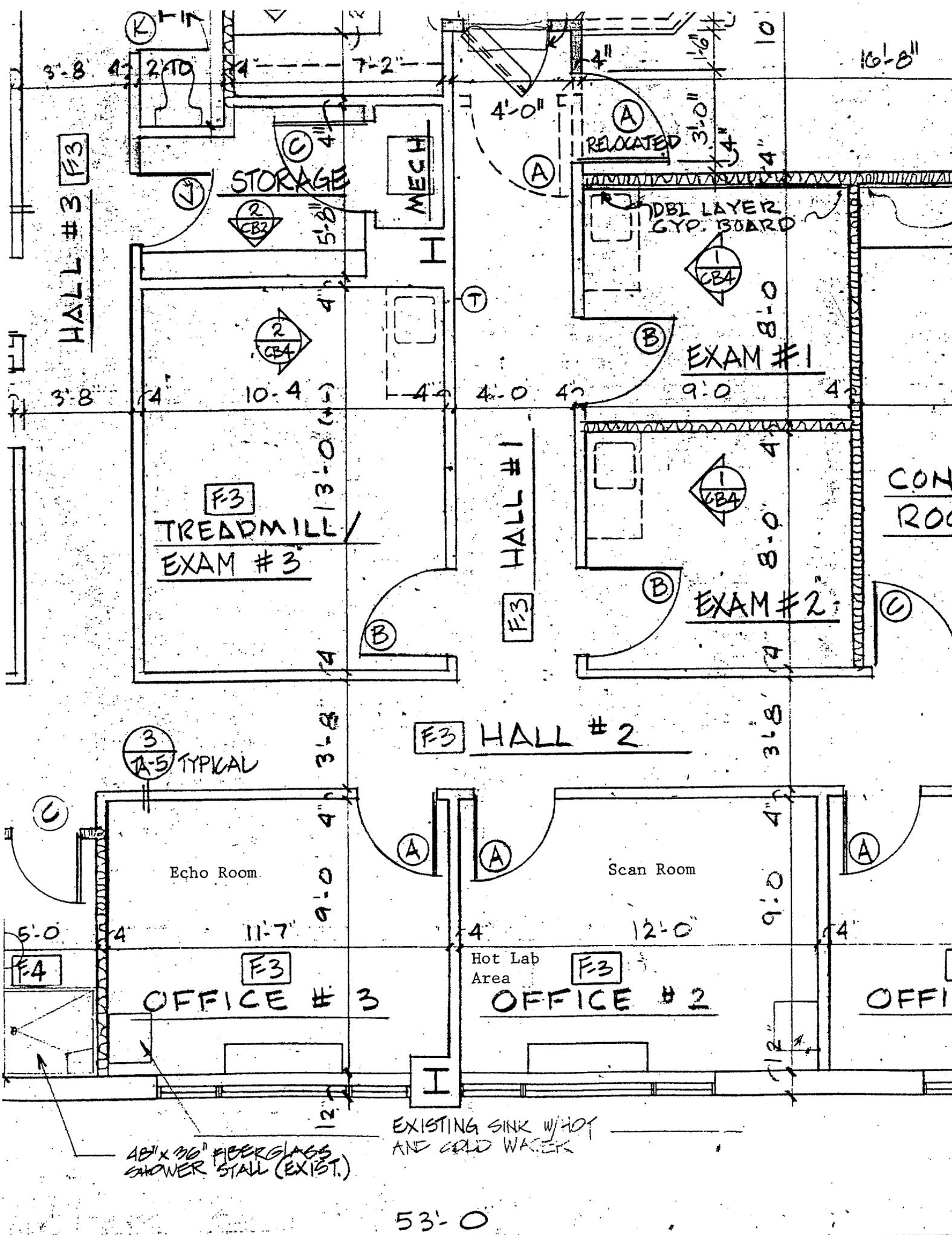
- 9.1 See enclosed submitted floor plan for layout of the Nuclear Cardiology department depicting details of the hot lab and scan room.
- 9.2 Equipment available:
- a. Lead syringe shields
 - b. Lead syringe holders
 - c. Lead containers and pigs
 - d. Lead bricks
 - e. Lead L-block
 - f. Lead-lined 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)

| <u>9.4</u> | <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 |
| | IS 2 Pulse 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.

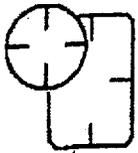
9.6 Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.



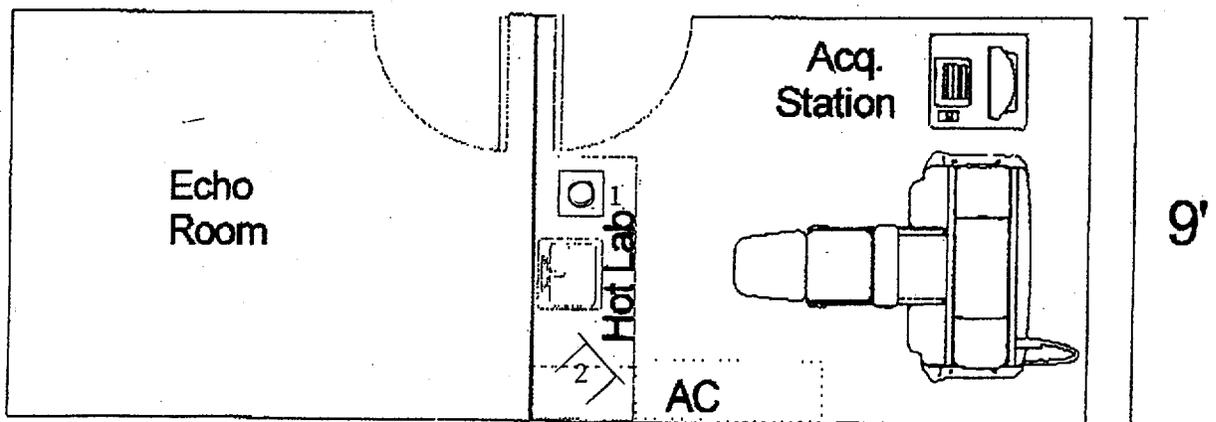
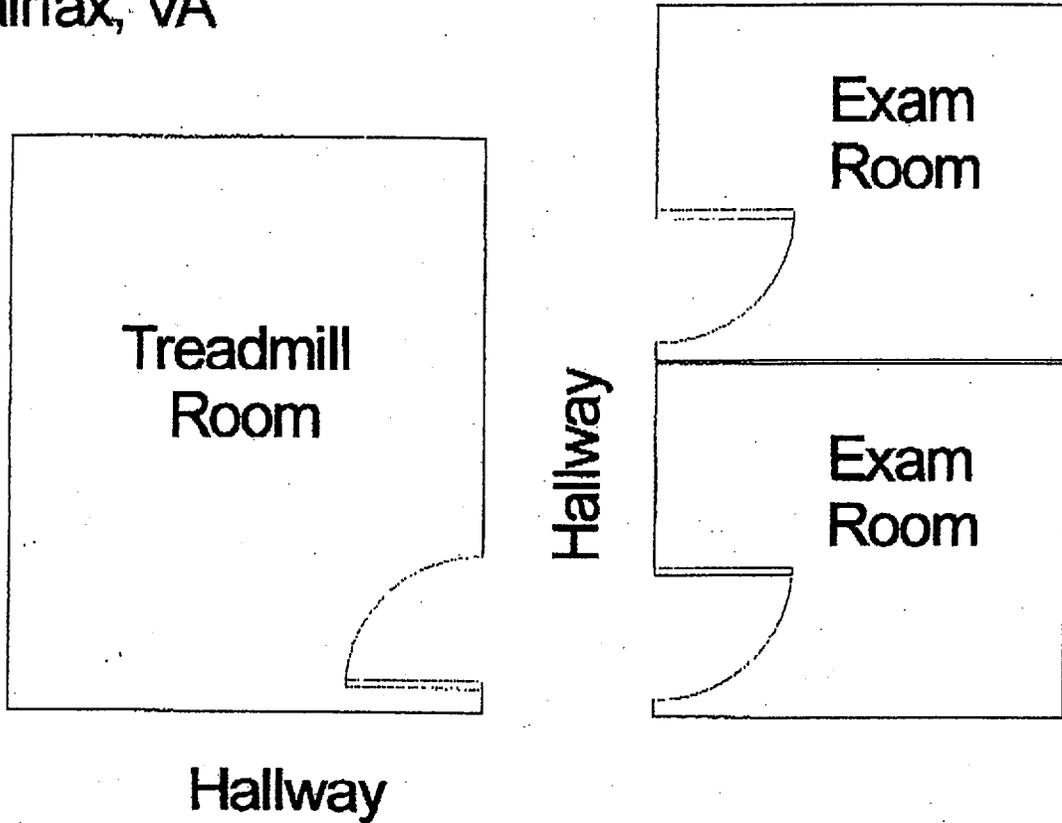
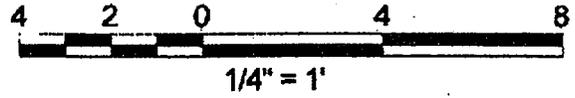
EXISTING SINK W/ HOT AND COLD WATER

48" x 36" FIBERGLASS SHOWER STALL (EXIST.)

53'-0"



3299 Woodburn Road
Suite 470
Fairfax, VA



Fourth Floor - Outside Wall

- 1 - Dose calibrator
- 2 - L-block and sealed source storage

12'

9'

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

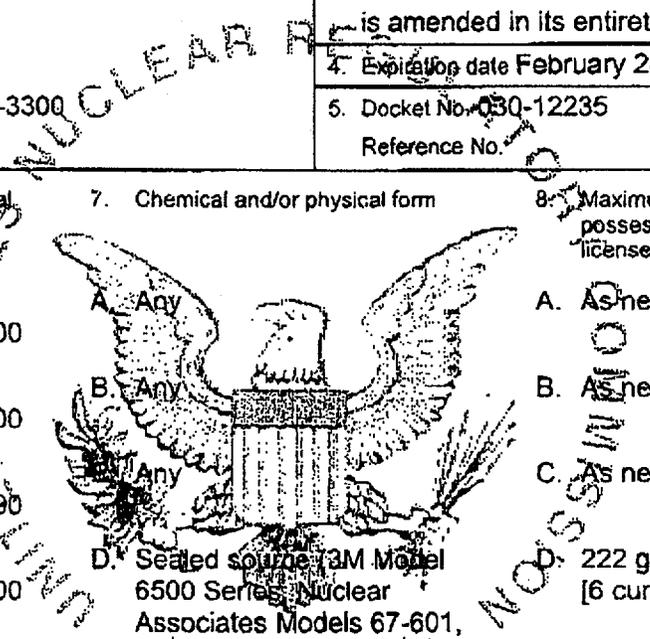
- 11.1 We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

| | |
|---|---|
| Licensee | In accordance with the letter dated May 12, 2004 |
| 1. Inova Fairfax Hospital | 3. License number 45-17128-01 |
| 2. 3300 Gallows Road Falls Church, Virginia 22042-3300 | is amended in its entirety to read as follows: |
| | 4. Expiration date February 28, 2013 |
| | 5. Docket No. 030-12235 Reference No. |

| | | |
|---|--|---|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Any byproduct material permitted by 10 CFR 35.100 | A. Any | A. As needed |
| B. Any byproduct material permitted by 10 CFR 35.200 | B. Any | B. As needed |
| C. Any byproduct material permitted by 10 CFR 35.300 | C. Any | C. As needed |
| D. Any byproduct material permitted by 10 CFR 35.400 | D. Sealed source (3M Model 6500 Series; Nuclear Associates Models 67-601, 67-802, 67-803, 67-804 and 67-805; Medix Physics, Inc. Model CDC-T1; Best Medical Models 81-01 and 2301; NEN Model NB-1; Isotope Products Labs Model 67-6500 Series) | D. 222 gigabecquerels (GBq) [6 curies (Ci)] |
| E. Any byproduct material permitted by 10 CFR 31.11 | E. Prepackaged Kits | E. As needed |
| F. Phosphorus 32 | F. Sealed source (Guidant Corp. Models GDT-P32-1 and GDT-P32-2) | F. 22.2 GBq [600 millicuries (mCi)] per source assembly and 66.6 GBq (1.8 Ci) total |
| G. Cesium 137 | G. Sealed source (Nordian, Inc. Model ISO-1000) | G. One source not to exceed 103.6 terabecquerels (TBq) (2,800 Ci) total |



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- | | | |
|---|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| H. Cesium 137 | H. Sealed source (Isomedix RAMCO-50, ISO-1000; Nordian C-1000, C-1001, C-3000, C-3001) | H. Two sources not to exceed 120.77 TBq (3,264 Ci) total |
| I. Strontium 90 | I. Sealed source (BEBIG Model Sr0.S03 and AEA Technology/QSA Model SICW Series) | I. Not to exceed 185 MBq (5 mCi) per source; 29.6 GBq (800 mCi) total |
| J. Iridium 192 | J. Sealed source (Nucletron Product Code 105.002) | J. Not to exceed 518 GBq (14 Ci) per source; 888 GBq (24 Ci) total |
| K. Iridium 192 | K. Sealed source (Best Industries 17003, 31-01) | K. No single seed to exceed 13 GBq (35 mCi); 77.7 GBq (21 Ci) total in two ribbon sets consisting of three ribbons each containing 6, 10, or 14 seeds per ribbon |
| L. Iodine 125 | L. Liquid as follows | L. As needed |

9. Authorized use:

- ★ ★ ★ ★ ★
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
 - B. Any imaging and localization study permitted by 10 CFR 35.200.
 - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
 - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
 - E. In vitro studies.
 - F. One source assembly for medical use in a Guidant Galileo Radiotherapy System intravascular brachytherapy remote afterloader unit. Two source assemblies in shipping containers as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.
 - G. For use in Nordion, Inc. Model Gamma Cell 1000(D) for irradiation of human blood samples for use in treatment of patients.
 - H. For use in Nordion International, Inc. GAMMACELL 3000 Elan Model II for the irradiation of human blood samples for use in the treatment of patients.
 - I. One source assembly for medical use in a Novoste Beta-Cath System A1000 Series intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary.

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- J. 1) One source for medical use permitted by 10 CFR 35.600, in a Nucletron Engineering B.V. Model 105.999 Remote Afterloading Brachytherapy Unit not to exceed 370 GBq (10 Ci). One source in its shipping container as necessary for replacement of the source in the remote afterloader unit; and
- 2) For non-human use in radiation physics for those purposes as described in licensee letter dated February 7, 2003.
- K. One source assembly for medical use in a Cordis-Checkmate Catheter System intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.
- L. For use in the form of Iotrex™ liquid brachytherapy source in the Proxima Therapeutics' GliaSite® Radiotherapy system balloon catheter for brachytherapy.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities at 3300 Gallows Road, Falls Church, Virginia.
- B. Licensed material listed in items 6, 7, 8, and 9 H shall be used only at the licensee's facilities at 3289 Woodburn Road, Suite 40, Annandale, Virginia (Inova Blood Donor Services).
- C. Licensed material shall be used only at Inova Heart and Intravascular Institute, 3300 Gallows Road, Falls Church, Virginia.
11. The Radiation Safety Officer for this license is Gary F. Talkington.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Gary A. Krasicky, M.D.

Michael G. Velchik, M.D.

Material and Use

35.100; 35.200; 35.300

35.100; 35.200; 35.300; 31.11

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Authorized UsersMaterial and Use

Sang Nam Lee, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Glenn L. Tonnesen, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Susan Boylan, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Susan M. Pierce, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Paul Y. Song, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Stella Hetelekidis, M.D.

35.300; 35.400; phosphorus-32, strontium-90 and iridium-192 in Intravascular Brachytherapy Afterloader Devices; iodine-125 for GliSite® brachytherapy; and iridium-192 for use in a High Dose Remote Afterloader Unit

Brigid Anne Carlos, M.D.

35.100; 35.200; 35.300

Daniel Robert Swerdlow, M.D.

35.100; 35.200

Nakul Jerath, M.D.

35.100; 35.200

Ho Song Lee, M.D.

35.100; 35.200

Jonathan Alfert, M.D.

35.100; 35.200; 35.300

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15. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
16. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
 - Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
18. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.
19. Except for labeling as required by 10 CFR Parts 20 or 71, the licensee shall obtain authorization from the U. S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificate issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
20. The procedures contained in the irradiator distribution instruction manual for the Gamma Cell 1000 and GAMMACELL 3000 Elan Model shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.
21. This license does not authorize the irradiation of explosives, highly flammable materials or any other materials which might result in damage to the sealed sources or the containment (shielding of the irradiator). In addition, the licensee may not irradiate food or food products for human consumption.
22. After installation or relocation of each irradiator and sealed source (cesium 137) and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine radiation levels in accessible locations about the irradiator with the source in the irradiate and shielded positions. A detailed report of the results of the survey shall be sent to the U. S. Nuclear Regulatory Commission, Region I, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415, not more than 30 days after each installation of the irradiator sources.
23. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
24. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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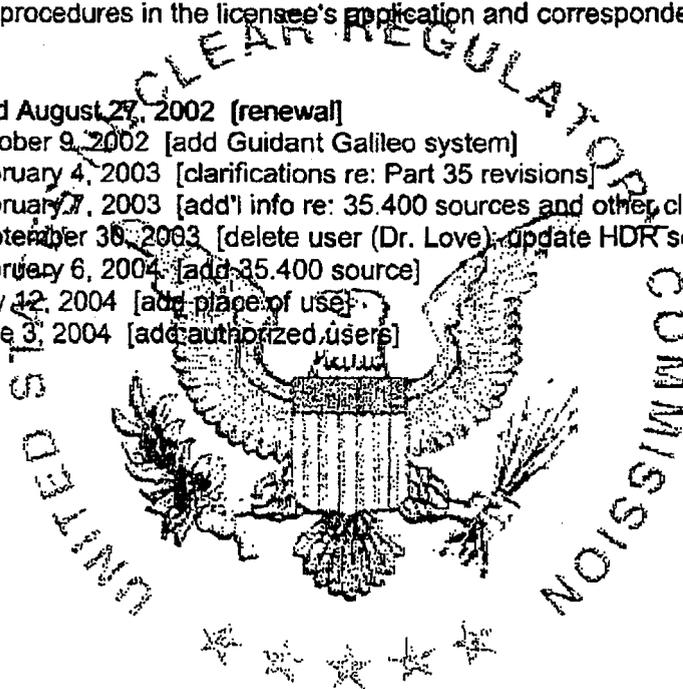
Docket or Reference Number

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25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated August 27, 2002 [renewal]
- B. Letter dated October 9, 2002 [add Guidant Galileo system]
- C. Letter dated February 4, 2003 [clarifications re: Part 35 revisions]
- D. Letter dated February 7, 2003 [add'l info re: 35.400 sources and other clarifications]
- E. Letter dated September 30, 2003 [delete user (Dr. Love); update HDR source for new vendor]
- F. Letter dated February 6, 2004 [add 35.400 source]
- G. Letter dated May 12, 2004 [add place of use]
- H. Letter dated June 3, 2004 [add authorized users]



For the U.S. Nuclear Regulatory Commission

Date

JUL 13 2004

By

Orysia Masnyk Bailey
 Orysia Masnyk Bailey
 Nuclear Materials Safety Branch 3
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406

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

11/28/2004, and to inform you that the initial processing which includes an administrative review has been performed.

NEW LICENSE APPLICATION (03036772)
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 136084.
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:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 02201
: Status Code: 3
: Fee Category: _____
: Exp. Date: 0
: Fee Comments: _____
: Decom Fin Assur Req'd: _
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: FAIRFAX HEART ASSOCIATES, PC
Received Date: 20041209
Docket No: 3036772
Control No.: 136084
License No.:
Action Type: New Licensee

2. FEE ATTACHED \$2,200.00
Amount:
Check No.: 9936

3. COMMENTS

Signed M. A. Perkins
Date 12/10/04

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 _____