

NRC FORM 313

(6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 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. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNRB-7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE WITH

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

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:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
61 Forsyth Street, NW, SUITE 23 T 85
ATLANTA, GA 30303-3415

(47-31060-01)

IF YOU ARE LOCATED IN:

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

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

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, 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

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

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

LL 31060
03036965
02201RECEIVED
REGION I
JUN 15 PM 1:16

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)

Raleigh Heart Clinic, Inc.
304 Carriage Drive
Beckley, WV 25801

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

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Sharon L. Long
National Physics Consultants

TELEPHONE NUMBER 330-878-8057

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. INDIVIDUALS 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. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C
	AMOUNT ENCLOSED \$ 2100.00

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

* THAIR BARGHOUTHI, MD President *

SIGNATURE

* [Signature] *

DATE

* 06/13/05 *

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	137182

NMSS/RGNI MATERIALS-002

Raleigh Heart Clinic, Inc

Item #5 and #6, RADIOACTIVE MATERIAL, AMOUNT AND PURPOSE: Refer to Attachment 5.

Item #7 RADIATION SAFETY OFFICER: Refer to Attachment #7.1

Item #7 AUTHORIZED USERS: Refer to Attachment 7.1.

Item #8.1, TRAINING PROGRAM: We will establish and implement the training program that is enclosed as Attachment 8.1.

Item #9.1 THERAPY UNIT CALIBRATION AND USE : NA

Item #9 FACILITIES AND EQUIPMENT:

- a. Our facilities and equipment diagram is enclosed as Attachment 9.2
- b. Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.
- c. A list of equipment is attached as item 9.2 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.
- d. Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Item #9.2 OTHER EQUIPMENT AND FACILITIES: NA

Item # 10 RADIATION PROTECTION PROGRAM:

- a. Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in any 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 Licenses" dated October 2002.
- b. 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.
- c. We have developed and will implement and maintain procedures for the safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 20.1301.

- d. We have developed and will implement and maintain procedures for the safe responses to spills of licensed materials in accordance with 10 CFR 20.1101

Item # 10.1 SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADING UNITS: NA

Item #10.2 INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES: NA

Item #11.1, WASTE MANAGEMENT: We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Support K to 10 CFR Part 20 and 10 CFR 35.92

Attachment 5

Name of Corporation/Individual Applying for License: Raleigh Heart Clinic, Inc

BYPRODUCT MATERIAL	AMOUNT	PURPOSE
Material in 10 CFR 35.200	As needed	Medical use

Attachment 7.1

AUTHORIZED USERS FOR MEDICAL USE

Name of Corporation/Individual Applying for License: **Raleigh Heart Clinic, Inc.**

AUTHORIZED USER

AUTHORIZATION

Thair A. Bargouthi, MD

10 CFR 35.200

The Radiation Safety Officer for this license is: Thair A. Bargouthi, MD

Please refer the West Virginia Appalachian Regional Healthcare, Inc NRC license #47-17725-02 for verification of training and experience for the above noted physician. A copy of this document is attached for reference.

Attachment 8.1

Training Program

Name of Corporation/Individual Applying for License: Raleigh Heart Clinic, Inc.

The following identifies the groups of workers who will receive training and the method and frequency of training. Records of training will include a list of attendees, dates, and topics and will be retained for three years.

<u>INDIVIDUALS</u>	<u>FREQUENCY</u>	<u>METHOD</u>
Chief Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user and/or as provided by our visiting consultants.
Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or as provided by our visiting consultants.
Other staff as appropriate	At orientation and annually thereafter	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or participation in health physics consultations or review of the consulting reports as provided by our visiting consultants.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training will be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training will be tailored to meet the needs of the individuals in attendance.

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues (10 CFR 19.12)
- Basic radiation protection to include concepts of time, distance, and shielding (10 CFR 19.12)
- Concept of maintaining exposure ALARA (10 CFR 20.1101)
- Risk estimates, including comparison with other health risks (10 CFR 19.12)
- Posting requirements (10 CFR 20.1902)
- Proper use of personnel dosimetry (when applicable) (10 CFR 20.1201)
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802)
- Proper use of radiation shielding, if used (10 CFR 19.12)
- Patient release procedures (10 CFR 35.75)
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care. (10 CFR 19.12)
- Occupational dose limits and their significance (10 CFR 20.1201)
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208)

- Workers right to be informed of occupational radiation exposure (10 CFR 19.13)
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12)
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12)
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11)
- Proper recordkeeping required by NRC regulations (10 CFR 19.12, 10 CFR 35.27)
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas (10 CFR 20.1501)
- Proper use of required survey instruments (10 CFR 20.1501)
- Emergency procedures (10 CFR 19.12)
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36)
- Dose to individual members of the public (10 CFR 20.1301)
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (10 CFR 35.27)

A Question and answer period will be provided.

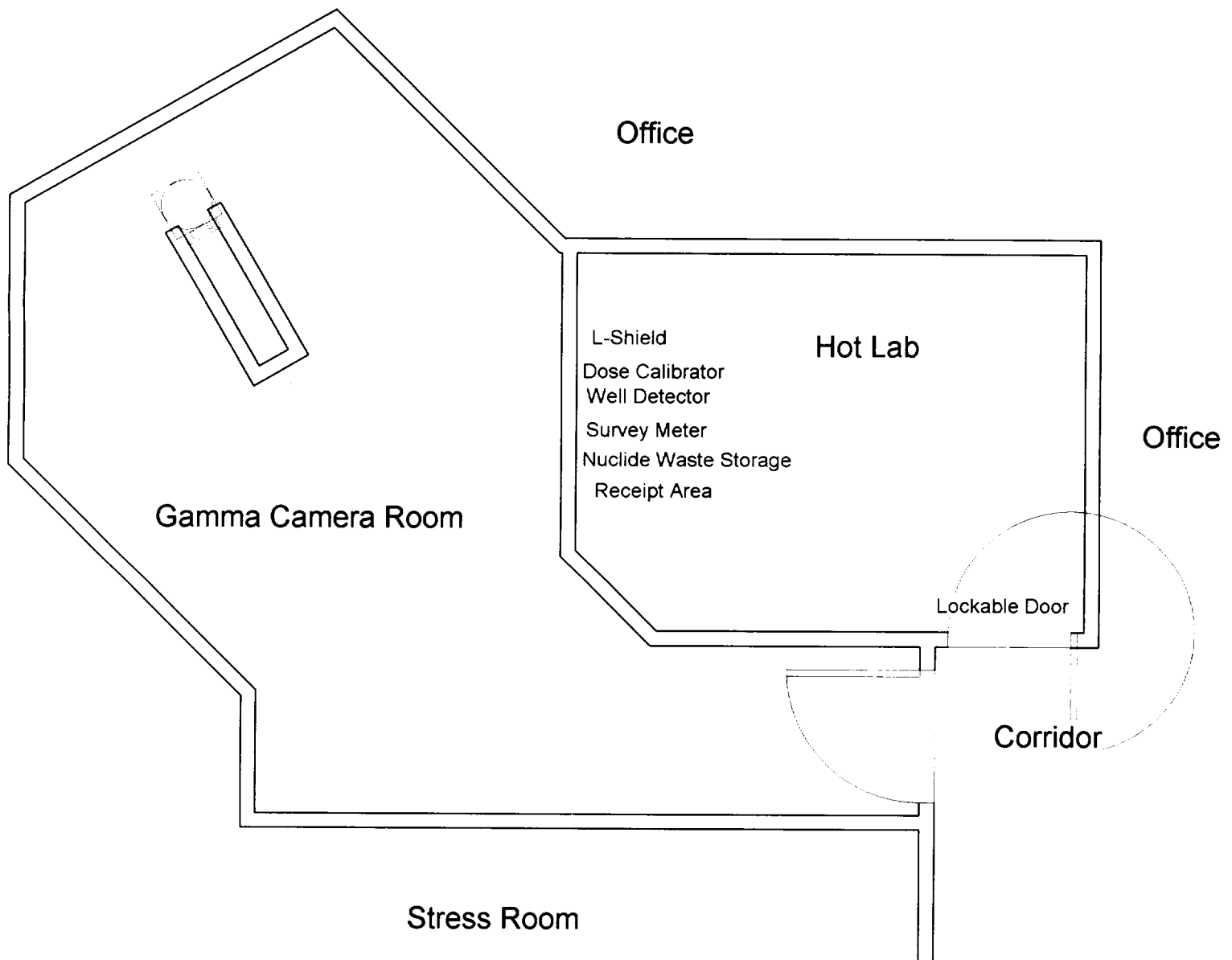
Attachment 9.2

Equipment

Name of Corporation/Individual Applying for License: **Raleigh Heart Clinic, Inc.**

Survey Meter	Ludlum 14 C or equivalent
Wipe Test Counter	CRC 15W or Equivalent
Dose Calibrator	CRC 15W or Equivalent

Raleigh Heart Clinic, Inc.
Attachment 9.2
2005



NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 3 PAGES
Amendment No. 14**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.

<p align="center">Licensee</p> <p>1. West Virginia Appalachian Regional Healthcare, Inc. d/b/a Beckley Appalachian Regional Hospital</p> <p>2. 306 Stanaford Road</p> <p>Beckley, West Virginia 25801</p>	<p align="center">In accordance with the application dated March 21, 2001</p> <p>3. License No. 47-17725-02</p> <p>is amended in its entirety to read as follows:</p> <p>4. Expiration date: June 30, 2011</p> <p>5. Docket No. 030-29017</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p>
<p>9. Authorized Use:</p> <p>A. Medical use identified in 10 CFR 35.400.</p> <p>B. Medical use identified in 10 CFR 35.200.</p>		

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 306 Stanaford Road, Beckley, West Virginia.
11. The Radiation Safety Officer for this license is Bharat G. Patel, M.D.

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No. 47-17725-02

Docket No.
030-29017

Amendment No. 14

12. Licensed material listed in Item 6 above shall be used by, or under the supervision of, the following individuals for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
A. Mohammad Ebrahim Dehgen, M.D.	Medical uses in 10 CFR 35.100 and §35.200
B. Alex A. Favelukes, M.D.	Medical uses in 10 CFR 35.100 and §35.200
C. Jebran G. Karam, M.D.	Medical uses in 10 CFR 35.100 and §35.200
D. Bharat G. Patel, M.D.	Medical uses in 10 CFR 35.100 and §35.200
E. Manu N. Patel, M.D.	Medical uses in 10 CFR 35.100 and §35.200
F. Lingadahalli H. Subbaraya, M.D.	Medical uses in 10 CFR 35.100 and §35.200
G. Thair A. Bargouthi, M.D.	Medical uses in 10 CFR 35.200
H. Halberto G. Cruz, M.D.	Medical uses in 10 CFR 35.100 and §35.200

13. Sealed sources containing licensed material shall not be opened by the licensee.

14. In addition to the possession limits in item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35 for establishing decommissioning financial assurance.

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No. 47-17725-02

Docket No.
030-29017

Amendment No. 14

15. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The 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 March 21, 2001 ~~[complete application]~~

B. Letters dated:

1. May 29, 1991 [exclude all iodine radioisotopes]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

DATE

6/21/01

BY

Region II, Division of Nuclear Materials Safety
61 Forsyth Street, S.W., Suite 23T85
Atlanta, GA 30303-8931

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

6/13/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ New License Application (03036965)
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** 137182.
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 Req'd: _
 : ::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
Applicant/Licensee: RALEIGH HEART CLINIC, INCORPORATED
Received Date: 20050615
Docket No: 3036965
Control No.: 137182
License No.: 47-31060-01
Action Type: New Licensee

2. FEE ATTACHED
Amount: \$210.00
Check No.: 2403

3. COMMENTS

Signed *Rebecca J. Jurek*
Date *6/15/05*

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 _____