Branch 1

NRC FORM 313 (3-2009) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES: 3/31/2012

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 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 and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@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, the 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:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, 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 BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

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 — 03029521
- [ ] B. AMENDMENT TO LICENSE NUMBER — 07-27897-01
- [x] C. RENEWAL OF LICENSE NUMBER — ~~07-27891-01~~

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

Cardiovascular Consultants of Southern DE, LLC
16704 Kings Highway Lewes DE 19958

RECEIVED
REGION 1
2012 FEB -3 AM 10: 58

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

1.Kings Highway Lewes DE 19958

2. 35141 Atlantic Ave #3 Millville DE 19967

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Kimberly Robles

TELEPHONE NUMBER

(302) 645-1233

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. maiximum 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. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	AMOUNT ENCLOSED $

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 CONTANED 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	SIGNATURE	DATE
Kimberly Robles Cardiac Testing Manager	Kimberly Robles	2/1/12

FOR NRC USE ONLY

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

NRC FORM 313 (3-2009) PRINTED ON RECYCLED PAPER

576889

NMSS/RGN1 MATERIALS-002

January 17, 2012

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pa 19406-1415

To Whom it May Concern:

We, ***Cardiovascular Consultants of Southern Delaware, LLC*** wish to renew our radioactive materials license (07-27897-01) under the current NRC 10 CFR 35 regulations. Please find attached: our signed application form and this letter answering items 5-11.

Items 5 and 6: Radioactive Material and Use

We wish to be licensed for the following material categories and associated quantities.

- Any byproduct material permitted by 10 CFR 35.200 (use of unsealed byproduct material for imaging and localization studies for which a written directive is not required), in any chemical/physical form, and with quantities as needed.

Item 7: Radiation Safety Officer

- We wish to name Barry S. Denenberg, M.D. as our Radiation Safety Officer (RSO). Dr. Denenberg is currently our RSO.

Regarding the control over the radiation safety program that will be delegated so that the RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

- We have delegated Dr. Denenberg the duties and responsibilities of the Radiation Safety Officer as outlined in NUREG 1556 (final version).

- Dr. Denenberg will have the authority to meet these responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations when justified by radiation safety.

- Dr. Denenberg will have the authority to raise issues with the Nuclear Regulatory Commission at any time.

Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

- Kimberly J. Robles, CNMT will be the point of contact during Dr. Denenberg's absence.
- Adam M. Henry of Keystone Physics LTD. will provide health physics consultant support to licensee.

Describe the overall availability of the RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires this presence.

- Dr. Denenberg will be available 24 hours a day, seven days a week via a pager and/or cellular phone to respond to any questions or to address any operational issues.

- The maximum amount of time it will take Dr. Denenberg to arrive at the facility in the event of a radiation emergency that requires his presence is 2.0 hours.

Our list of authorized users will be the same as they are currently listed.

Item 8: Safety Instructions for Individuals Working in or Frequenting Restricted Areas

- We will provide radiation safety instructions as required by 10 CFR 19.12 and 10 CFR 35.27 to those individuals working in restricted areas.

Item 9: Facilities and Equipment

- A diagram is enclosed that describes the facility and identifies activities conducted in all contiguous areas surrounding the area(s) of use.

Item 9: Radiation Monitoring Instruments

- Radiation monitoring equipment is as follows:
    - Ludlum 14 C radiation survey meters
    - Biodex Medical Systems, ATOMLAB 100 dose calibrator
    - Ludlum Model 2200 well counting system

- Radiation monitoring equipment will be calibrated by a qualified person authorized by the NRC to perform radiation survey meter calibrations. We have developed and will implement and maintain written survey meter calibration procedures in accordance with 10 CFR 20.1501 and 10 CFR35.61. 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.

Item 9: Dose Calibrators and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material

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

Attachment 9.4: Other Equipment and Facilities

Nuclear Medicine:
We have the following additional radiation safety equipment:

1. Lead-L-block
2. Lead-lined radioactive waste containers
3. Leaded syringe shields
4. Leaded syringe transport carrier
5. Leaded sealed source containers

- We will receive packages, prepare doses, store our sealed sources and store radioactive waste in the hot lab.

Item 10: Occupational Dose

- 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, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated May 2005.

Item 10: Area Surveys

- 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.

Item 10: Safe Use of Unsealed Licensed Material

- We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Item 10: Spill Procedures

- We have developed and will implement and maintain written procedures for safe response to spills of radioactive material in accordance with 10 CFR 20.1101.

Item 10: Minimization of Contamination

- We will minimize potential contamination from radiopharmaceuticals with the following disposal and preventative measures. The radiopharmacy will pick up

the majority of spent syringes on the days following use. All other contaminated waste including such items as vials, syringes, wipes, and swabs are kept until surveys are indistinguishable from background measurements and disposed as normal trash, or normal bio-waste. If a room is to be removed from licensed activities, a close-out final survey will be performed.

Item 11: Radioactive Waste Management

- We have developed and will implement and maintain written radioactive 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 of 10 CFR 20 and 10 CFR 35.92.

Regards,

Robert W. Denenberg, M.D.
Radiation Safety Officer

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

02/01/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Renewal (07-27897-01)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

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** 576889.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader