CARDIOLOGY ASSOCIATES OF CENTRAL CONNECTICUT, LLC

WILLIAM J. FARRELL, MD, FACC
ROBERT J. GOLUB, MD, FACC
GEORGE SPIVACK, MD, FACC
HAROLD S. WILKES, MD, FACC
JOHN M. DINKLER, MD
RICHARD A. BUGLIARI, MD, FACC (RETIRED)
NICK CALABRESE, ACNP-BC
MICHAEL V. McMAHON, PA-C

Br. 1
03036420

May 2, 2016

USNRC Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713



To NRC Inspector,

Please amend our byproduct materials license number 06-30842-01 as follows:

We need to remove Richard Bugliari, MD from Cardiology Associates of Central CT NRC license # 06-30842-01 as an authorized user. He has retired as of December 31, 2015.

We need to add John M. Dinkler, MD to the Cardiology Associates of Central CT NRC license #06-30842-01 as an authorized user permitted by 10 CFR 35.100 and 10 CFR 35.200. Enclosed you will find form 313a. In addition are a copy of our current NRC license and a copy of Dr. Dinkler's certification of his nuclear cardiology boards.

Thank you for you consideration.

Sincerely yours,

Robert J. Golub, MD
Radiation Safety Officer

590948



LANDMARK BUILDING • SUITE 300 • 1062 BARNES ROAD • WALLINGFORD, CT 06492
TEL: 203-265-9831 • FAX 203-265-2977

NRC FORM 313A (AUD)
(04-2016)

U.S. NUCLEAR REGULATORY COMMISSION

# AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
## (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 04/30/2016

| Name of Proposed Authorized User | State or Territory Where Licensed |
|---|---|
| JOHN M. DINKLER, M.D. | CONNECTICUT |

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 35.200 Imaging and localization studies
- [ ] 35.500 Sealed sources for diagnosis (specify device) _____

## PART I -- TRAINING AND EXPERIENCE
***(Select one of the three methods below)***

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- [x] **1. Board Certification**

  a. Provide a copy of the board certification.

  b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

- [ ] **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

  a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

  b. Supervised Work Experience.
  *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

| Description of Experience | Location of Experience/License or Permit Number of Facility | Clock Hours | Dates of Experience* |
|---|---|---|---|
| Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs | | | |
| **Total Hours of Experience:** | | | |

| Supervising Individual | License/Permit Number listing supervising individual as an authorized user |
|---|---|
| | |

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply).*

- [ ] 35.290
- [ ] 35.390 + generator experience in 32.290(c)(1)(ii)(G)

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

| Description of Training | Location of Training | Clock Hours | Dates of Training* |
|---|---|---|---|
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Chemistry of byproduct material for medical use *(not required for 35.590)* | | | |
| Radiation biology | | | |
| **Total Hours of Training:** | | | |

b. Supervised Work Experience (completion of this table is not required for 35.590).
*(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

**Supervised Work Experience** — **Total Hours of Experience:**

| Description of Experience Must Include: | Location of Experience/License or Permit Number of Facility | Confirm | Dates of Experience* |
|---|---|---|---|
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys | | ☐ Yes ☐ No | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | ☐ Yes ☐ No | |

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

### PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**
**Check one of the following for each use requested:**

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

**OR**

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☑ I attest that JOHN M. DINKLER, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**OR**

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**
**Complete the following for preceptor attestation and signature:**

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience

| Name of Preceptor | Signature | Telephone Number | Date |
|---|---|---|---|
| ROBERT J. GOLUB | | (203) 265-9831 | 05/02/2016 |

License/Permit Number/Facility Name

NRC LICENSE #06-30842-01 CARDIOLOGY ASSOCIATES OF CENTRAL, CT, LLC

**3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience. (continued)

| Description of Experience Must Include: | Location of Experience/License or Permit Number of Facility | Confirm | Dates of Experience* |
|---|---|---|---|
| Calculating, measuring, and safely preparing patient or human research subject dosages | | ☐ Yes ☐ No | |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | | ☐ Yes ☐ No | |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | | ☐ Yes ☐ No | |
| Administering dosages of radioactive drugs to patients or human research subjects | | ☐ Yes ☐ No | |
| Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs | | ☐ Yes ☐ No | |

| Supervising Individual | License/Permit Number listing supervising individual as an authorized user |
|---|---|
| | |

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

| Device | Type of Training | Location and Dates |
|---|---|---|
| | | |
| | | |

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

# Certification Board of Nuclear Cardiology

Incorporated 1996

A Division of the Council for Certification in Cardiovascular Imaging

## Certifies That

# John Michael Dinkler, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS TRAINED IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

## NUCLEAR CARDIOLOGY

VALID: JANUARY 1, 2016 – MARCH 1, 2026

Thomas Holly

President

CBNC

Mary Lee Zaret

Secretary

CERTIFICATE NUMBER: 10372

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 7

# 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 September 20, 2013, |
|---|---|
| 1. Cardiology Associates of Central Connecticut, LLC | 3. License number 06-30842-01 is amended in its entirety to read as follows: |
| 2. 1062 Barnes Road, Suite 300<br>Wallingford, CT 06492 | 4. Expiration date January 31, 2024 |
| | 5. Docket No. 030-36420<br>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. Gadolinium-153 permitted by 10 CFR 35.500 | C. Sealed Sources (Isotope Products Laboratories Model NES8497) | C. 288 millicuries per source and 1 curie total |

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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

## CONDITIONS

10. Licensed material may be used or stored only at the licensee=s facilities located at 1062 Barnes Road, Suite 300, Wallingford, Connecticut.

11. The Radiation Safety Officer for this license is Robert J. Golub, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE SUPPLEMENTARY SHEET**

License Number
06-30842-01

Docket or Reference Number
030-36420

Amendment No. 7

B. The following individuals are authorized users for medical use as indicated:

| Authorized Users | Material and Use |
|---|---|
| Richard A. Bugliari, M.D. | 35.100; 35.200 |
| Robert J. Golub, M.D. | 35.100; 35.200; 35.500 |
| George Spivack, M.D. | 35.100; 35.200 |
| Harold S. Wilkes, M.D. | 35.100; 35.200 |

13. 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(d) for establishing decommissioning financial assurance.

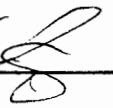
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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. 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. Letter (with attachments) dated September 20, 2013 [ML13295A511]

For the U.S. Nuclear Regulatory Commission

Date January 23, 2014

By 

Héctor Bermúdez
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Thursday, January 23, 2014 10:07:39

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

# ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

**Name and Address of Applicant and/or Licensee**

Cardiology Associates of Central Connecticut, LLC
Landmark Building
Suite 300
1062 Barnes Road
Wallingford, CT 06492

**Date**
05/25/2016

**License Number(s)**
06-30842-01

**Mail Control Number(s)**
590948

**Licensing and/or Technical Reviewer or Branch**
Medical Branch

**This is to acknowledge receipt of your:** ☑ **Letter and/or** ☐ **Application** **Dated:** 05/02/2016

**The initial processing, which included an administrative review, has been performed.**

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

**Follow the instructions on the form for submission.**

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

**Region I**
**U. S. Nuclear Regulatory Commission**
**Division of Nuclear Materials Safety**
**2100 Renaissance Boulevard, Suite 100**
**King of Prussia, PA 19406-2713**
**(610) 337-5260, (610) 337-5313,**
**(610) 337-5398, or (610) 337-5239**