



11155 E. Dunn Road, Ste. 304E
St. Louis, Missouri, 63136

Phone: 314-741-0911
Fax: 314-741-0501

June 9.2011

Ref. License # 24-32384-01

U.S. N.R.C. Region III
Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

To Whom it May Concern:

This is to request an amendment to the radioactive material license for
St. Louis Heart and Vascular, P.C., St. Louis, MO.

Please add Saulius Kalvaitis, MD as an authorized user for Nuclear Cardiology procedures. Dr. Kalvaitis has done 700 hours of preceptorship under the guidance of Toniya Singh MD (an Authorized User on our existing NRC license).

Enclosed is form 313 with the signature of the certifying officer for the facility. Also enclosed is a copy of Dr. Kalvaitis' COR training certificate and the Preceptor Attestation (form 313A).

This information is submitted on behalf of the management at St. Louis Heart and Vascular, P.C. If you have any questions concerning this matter, please contact me at 314-741-0911 ext. 4020 or my e-mail is ccandela@slhv.com.

Sincerely,


Candace Candela, CNMT, ARRT (R)(N)
Technical Director Nuclear Cardiology

Enclosures: NRC form 313
NRC form 313A Page One
Corscan Certificate
Certificate of Radiation Safety Training

RECEIVED JUN 14 2011

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
☒ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

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

St. Louis Heart & Vascular, PC
11155 E. Dunn Road, Ste 304E
St. Louis, Missouri 63136

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

SEE ABOVE
and also
12277 DePaul Drive, Suite 503
Bridgeton, Mo 63044

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Candace Candela, CNMT, ART (R)(N)

TELEPHONE NUMBER

314-741-0911 ext. 4020

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. 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 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

Sundee Das, MD (Rso)

SIGNATURE

SDA

DATE

6/9/11

FOR NRC USE ONLY

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

APPROVED BY

DATE

**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: 3/31/2012

Name of Proposed Authorized User

Saulius Kalvaitis

State or Territory Where Licensed

Missouri

Requested Authorization(s) (check all that apply)

☐ 35.100 Uptake, dilution, and excretion studies☒ 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.

☐ **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	Corscan	80	7-12-05
Radiation protection	Corscan	80	7-12-05
Mathematics pertaining to the use and measurement of radioactivity	Corscan	80	7-12-05
Chemistry of byproduct material for medical use (not required for 35.590)	Corscan	80	7-12-05
Radiation biology	Corscan	80	7-12-05
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	St. Louis Heart & Vascular, PC NRC# 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	St. Louis Heart & Vascular, PC NRC# 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11

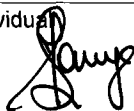
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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	St. Louis Heart & Vascular, PC NRC # 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	St. Louis Heart & Vascular, PC NRC # 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	St. Louis Heart & Vascular, PC NRC # 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11
Administering dosages of radioactive drugs to patients or human research subjects	St. Louis Heart & Vascular, PC NRC # 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11
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	St. Louis Heart & Vascular, PC NRC # 24-32384-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1/3/11 thru 5/20/11

Supervising Individual

 TSINATHMSLicense/Permit Number listing supervising individual as an
authorized user

24-32384-01

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.

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 _____ 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 Saulius Kalvaitis, MD 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 <u>T. SINGH MD</u>	Signature <u>[Signature]</u>	Telephone Number <u>314-741-0911</u>	Date <u>6/9/11</u>
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License/Permit Number/Facility Name
St. Louis Heart & Vascular, P.C NRC # 24-32384-01

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

Saul Kalvatis, M.D.

has successfully completed 80 hours of classroom and laboratory training that included:

Corscan™
The Nuclear Imaging Company
www.corscanplus.com

Radiation physics and instrumentation; Radiation protection; Mathematics pertaining to the use and measurement of radioactivity; Chemistry of byproduct material for medical use; Radiation biology; Generator elution; Review of regulations regarding the medical use of radioisotopes and performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

Steven W. Walter, MD

Steven W. Walter, MD
Program Director
General Manager and CEO
CorScan Plus
910-246-0434
Authorized User NRC License No. 32-31038-01

July 12, 2005

Date

Certificate of Completion

This certifies that on

September 25, 2009

SAULIUS KALVAITIS

Successfully completed the web-based and hands-on training
and passed the written examination on

Radiation Safety Training for Radioisotope Users

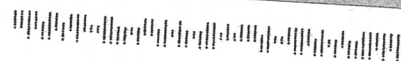
The six hour course received from the Radiological Health Department at the University of Utah addressed aspects of radiation sources, biological effects and risks, safe handling techniques, dosimetry and proper use of safety and monitoring devices, conditions of licenses and regulations and responsibilities and rights of individual radiation users.



Karen S. Langley M.S.

Radiation Safety Officer

St. Louis Heart & Vascular, P.C.
11155 E. Dunn Road, Ste 304E
St. Louis, Mo. 63136



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Material Licensing Section
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