

Phillip G. Apprill, MD, FACC
Gregory W. Botteron, MD
Charles F. Carey, MD, FACC
Duck Sung Chun, MD, FACC
Dennis L. Disch, MD, FACC
David J. Dobmeyer, MD, FACC
Manoj K. Eapen, MD
Darlene L. Eyster, MD, FACC
Leonard F. Fagan, MD, FACC
M. Carolyn Gamache, MD, FACC
Michael G. Goldmeier, MD, FACC



Rajiv R. Handa, MD
M. Kiran Kancherla, MD, FACC
David J. Kardesch, MD, FACC
John W. Kilgore, MD, FACC
David J. Morton, MD, FACC
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
David J. Sewall, MD, FACC
Michael L. Shapiro, MD, FACC
Robert Snitzer, MD, FACC
Richard B. Whiting, MD, FACC

U. S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

License Number 24-32184-01

Dear Materials Licensing Section:

We are requesting an amendment to our Radioactive Material License to add the following physicians to are license as Authorized Users permitted to use radioactive material in 35.200 for cardiovascular imaging and localization studies:

1. Manoj K. Eapen, M.D.
2. Bassam A. Roukoz, M.D.
3. David J. Sewall, M.D.

Attached are NRC FORM 313A (AUD), letters/certificates of training and experience, and preceptor attestation. The above physicians are licensed to practice medicine in Missouri.

If you have any additional questions, please contact me at (314) 997-6001 or Tiffany Door (RSO) at (636) 939-4820.

Sincerely,


Signature

N. Rock Erickson
Name

Executive Director
Title

1.10.2008
Date

RECEIVED JAN 23 2008

**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: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Manoj K. Eapen, M.D.

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	See attached letter Medical Physics Department of Diagnostic Imaging Rhode Island Hospital		February 5 through May 31, 2001
Radiation protection	See attached letter Medical Physics Department of Diagnostic Imaging Rhode Island Hospital		February 5 through May 31, 2001
Mathematics pertaining to the use and measurement of radioactivity	See attached letter Medical Physics Department of Diagnostic Imaging Rhode Island Hospital		February 5 through May 31, 2001
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	See attached letter Medical Physics Department of Diagnostic Imaging Rhode Island Hospital		February 5 through May 31, 2001
Radiation biology	See attached letter Medical Physics Department of Diagnostic Imaging Rhode Island Hospital		February 5 through May 31, 2001

Total Hours of Training: 200

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

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Total Hours of Experience:	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003

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	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01 (see attached letter)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Administering dosages of radioactive drugs to patients or human research subjects	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual: M. Kiran Kancherla, M.D.
License/Permit Number listing supervising individual as an authorized user: 24-32184-01

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
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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)

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 Manoj K. Eapen, M.D. 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
M. Kiran Kancherla, M.D.	<i>M.K. Kancherla</i>	(314) 645-6450	01-11-08
License/Permit Number/Facility Name			
24-32184-01/Metro Heart Group of St. Louis, Inc.			

Phillip G. Apprill, MD, FACC
Gregory W. Botteron, MD
Charles F. Carey, MD, FACC
Duck Sung Chun, MD, FACC
Dennis L. Disch, MD, FACC
David J. Dobmeyer, MD, FACC
Manoj K. Eapen, MD
Darlene L. Eyster, MD, FACC
Leonard F. Fagan, MD, FACC
M. Carolyn Gamache, MD, FACC
Michael G. Goldmeier, MD, FACC



Rajiv R. Handa, MD
M. Kiran Kancharla, MD, FACC
David J. Kardesch, MD, FACC
John W. Kilgore, MD, FACC
David J. Morton, MD, FACC
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
David J. Sewall, MD, FACC
Michael L. Shapiro, MD, FACC
Robert Snitzer, MD, FACC
Richard B. Whiting, MD, FACC

October 1, 2007

To Whom it Concerns:

This letter attests that Manoj K. Eapen, M.D. has satisfactorily completed the training and experience requirements in Section 35.290 (c)(1)(i) and (ii) for an Authorized User (AU). Dr. Eapen completed his training and experience under my supervision at Metro Heart Group of St. Louis, Inc., under Radioactive Material License No. 24-32184-01.

The dates of his clinical training and work experience under my supervision were July 1st, 2003 until December 30, 2003. Dr. Eapen received more than 500 hours in clinical training under my supervision. Attached is documentation of Dr. Eapen's 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. Dr. Eapen has completed his required 700 hours of training and experience for imaging and localization studies.

Dr. Eapen has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under section 35.200 limited to cardiovascular clinical procedures.

I am specifically listed as an AU approved for material permitted by 10 CFR 35.200, on the license issued to Metro Heart Group of St. Louis, Inc.

If you require any addition information, please contact me at (314) 645-6450.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Kiran Kancharla", written over a horizontal line.

M. Kiran Kancharla, M.D., F.A.C.C.
Authorized User

Certificate of Participation

THIS IS TO CERTIFY THAT

Manoj K. Eapen, M.D.

successfully completed the course for physicians entitled

***Formal Training for Physicians in Physics & Instrumentation
of Nuclear Cardiology and Endocrinology Procedures***

for a total of two hundred hours of lectures, demonstrations, and related assignments

SUBJECTS COVERED INCLUDE

Radiation Physics & Instrumentation
Radiation Protection
Mathematics Pertaining to the Use and
Measurement of Radioactivity

Instrumentation for Radionuclide Imaging
Radiation Biology
Radiopharmaceutical Chemistry

as specified in NRC Part 35

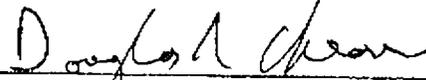
Sponsored by

Medical Physics, Department of Diagnostic Imaging, Rhode Island Hospital



Rhode Island Hospital
A Lifespan Partner

Dates: February 5 - May 31, 2001


Douglas R. Shearer, Ph.D., Course Director

**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: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Bassam A. Roukoz, M.D.

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	See Attached Certificate from MCP Hahnemann University	100	September 2001 through June 2002
Radiation protection	See Attached Certificate from MCP Hahnemann University	30	September 2001 through June 2002
Mathematics pertaining to the use and measurement of radioactivity	See Attached Certificate from MCP Hahnemann University	20	September 2001 through June 2002
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	See Attached Certificate from MCP Hahnemann University	30	September 2001 through June 2002
Radiation biology	See Attached Certificate from MCP Hahnemann University	20	September 2001 through June 2002

Total Hours of Training: 200

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

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Total Hours of Experience:	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003

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	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01 (see attached letter)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
Administering dosages of radioactive drugs to patients or human research subjects	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 2003 through December 30, 2003
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual

M. Kiran Kancherla, M.D.

License/Permit Number listing supervising individual as an authorized user

24-32184-01

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)

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 Bassam A. Roukoz, M.D. 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

M. Kiran Kancherla, M.D.

Signature

M. K. Kancherla MD

Telephone Number

(314) 645-6450

Date

01-11-08

License/Permit Number/Facility Name

24-32184-01/Metro Heart Group of St. Louis, Inc.

Phillip G. Apprill, MD, FACC
Gregory W. Botteron, MD
Charles F. Carey, MD, FACC
Duck Sung Chun, MD, FACC
Dennis L. Disch, MD, FACC
David J. Dobmeyer, MD, FACC
Manoj K. Eapen, MD
Darlene L. Eyster, MD, FACC
Leonard F. Fagan, MD, FACC
M. Carolyn Gamache, MD, FACC
Michael G. Goldmeier, MD, FACC



Rajiv R. Handa, MD
M. Kiran Kancharla, MD, FACC
David J. Kardesch, MD, FACC
John W. Kilgore, MD, FACC
David J. Morton, MD, FACC
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
David J. Sewall, MD, FACC
Michael L. Shapiro, MD, FACC
Robert Snitzer, MD, FACC
Richard B. Whiting, MD, FACC

October 1, 2007

To Whom it Concerns:

This letter attests that Bassam A. Roukoz, M.D. has satisfactorily completed the training and experience requirements in Section 35.290 (c)(1)(i) and (ii) for an Authorized User (AU). Dr. Roukoz completed his training and experience under my supervision at Metro Heart Group of St. Louis, Inc., under Radioactive Material License No. 24-32184-01. The dates of his clinical training and work experience under my supervision were July 1st, 2003 until December 30, 2003. Dr. Roukoz has received more than 500 hours in clinical training under my supervision. Attached is documentation of Dr. Roukoz's 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. Dr. Roukoz has completed his required 700 hours of training and experience for imaging and localization studies.

Dr. Roukoz has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under section 35.200 limited to cardiovascular clinical procedures.

I am specifically listed as an AU approved for material permitted by 10 CFR 35.200, on the license issued to Metro Heart Group of St. Louis, Inc.

If you require any addition information, please contact me at (314) 645-6450

Sincerely,

M. Kiran Kancharla, M.D., F.A.C.C.
Authorized User

MCP HAHNEMANN UNIVERSITY

This is to certify that

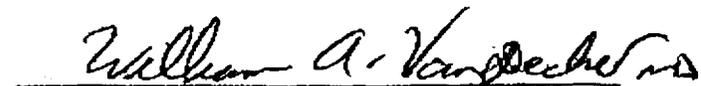
Bassam A. Roukoz, M.D.

has successfully completed a 200-hour course of study and laboratory sessions on the principles and practices of nuclear technology including radiation physics and instrumentation (100 hours), radiation protection (30 hours), mathematics pertaining to use and measurement of radioactivity (20 hours), radiation biology (20 hours), and radiopharmaceutical chemistry (30 hours).

This course of study was conducted at MCP Hahnemann University.

September 2001 to June 2002


Ph.D. Radiation Physicist Educator


MCPHU Nuclear Cardiology Staff

**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: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

David J. Sewall, M.D.

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	See Attached Letter & Certificate from Corscan		March 1, 2007 through August 28, 2007
Radiation protection	See Attached Letter & Certificate from Corscan		March 1, 2007 through August 28, 2007
Mathematics pertaining to the use and measurement of radioactivity	See Attached Letter & Certificate from Corscan		March 1, 2007 through August 28, 2007
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	See Attached Letter & Certificate from Corscan		March 1, 2007 through August 28, 2007
Radiation biology	See Attached Letter & Certificate from Corscan		March 1, 2007 through August 28, 2007

Total Hours of Training: 80

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	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007

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	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01 (see attached letter)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007
Administering dosages of radioactive drugs to patients or human research subjects	Metro Heart Group of St. Louis, Inc St. Louis, MO 24-32184-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through September 27, 2007
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	Corscan 37-31143-01 (See attached letter)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 1, 2007 through August 28, 2007

Supervising Individual: M. Kiran Kancherla, M.D.
License/Permit Number listing supervising individual as an authorized user: 24-32184-01

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)

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 David J. Sewall, M.D. 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

M. Kiran Kancherla, M.D.

Signature

M. K. Kancherla

Telephone Number

(314) 645-6450

Date

01-11-08

License/Permit Number/Facility Name

24-32184-01/Metro Heart Group of St. Louis, Inc.

Phillip G. Apprill, MD, FACC
Gregory W. Botteron, MD
Charles F. Carey, MD, FACC
Duck Sung Chun, MD, FACC
Dennis L. Disch, MD, FACC
David J. Dobmeyer, MD, FACC
Manoj K. Eapen, MD
Darlene L. Eyster, MD, FACC
Leonard F. Fagan, MD, FACC
M. Carolyn Gamache, MD, FACC
Michael G. Goldmeier, MD, FACC



Rajiv R. Handa, MD
M. Kiran Kancherla, MD, FACC
David J. Kardesch, MD, FACC
John W. Kilgore, MD, FACC
David J. Morton, MD, FACC
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
David J. Sewall, MD, FACC
Michael L. Shapiro, MD, FACC
Robert Snitzer, MD, FACC
Richard B. Whiting, MD, FACC

October 1, 2007

To Whom it Concerns:

This letter attests that David J. Sewall, M.D. has satisfactorily completed the training and experience requirements in Section 35.290 (c)(1)(i) and (ii) for an Authorized User (AU). Dr. Sewall completed his training and experience under my supervision at Metro Heart Group of St. Louis, Inc., under Radioactive Material License No. 24-32184-01. The dates of his clinical training and work experience under my supervision were from March 1st, 2007 to September 27, 2007. Dr. Sewall received more than 620 hours of clinical training under my supervision. Attached is documentation of Dr. Sewall's 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This dictactic training was performed in August, 2007. Dr. Sewall has completed his required 700 hours of training and experience for imaging and localization studies.

Dr. Sewall has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under section 35.200 limited to cardiovascular clinical procedures.

I am specifically listed as an AU approved for material permitted by 10 CFR 35.200, on the license issued to Metro Heart Group of St. Louis, Inc.

If you require any addition information, please contact me at (314) 645-6450.

Sincerely,

M. Kiran Kancherla, M.D., F.A.C.C.
Authorized User

Corscan

2318 Highstone Rd.

Cary, NC 27519

910-528-6251

December 3, 2007

To whom it may concern:

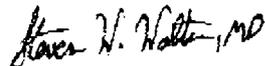
David Sewall, MD successfully completed 80 hours of classroom and laboratory training as required by CFR 35.290 that included:

- radiation physics and instrumentation
- radiation protection
- mathematics pertaining to the use and measurement of radioactivity
- chemistry of byproduct material for medical use
- radiation biology
- instrument quality control and generator elution and kit preparation

The training was completed between March 1, 2007 and August 28, 2007.

If there are additional questions please feel free to contact me.

Sincerely,



Steven W. Walter, MD

General Manager and CEO

Corscan

Authorized User NRC license no: 37-31143-01

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

David Sewall, M.D.

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

Radiation physics and instrumentation.

Radiation protection.

Mathematics pertaining to the use and measurement of radioactivity.

Chemistry of byproduct materials for medical use.

Radiation biology. Generator elution for ^{99m}Tc/²⁰¹Tl and ^{99m}Tc/²⁰¹Tl.

Review of regulations regarding the medical use of radioisotopes.

Corscan

The Nuclear Imaging Company
www.corscanplus.com

Steven W. Walter, MD

Steven W. Walter, MD
Program Director
General Manager and CEO
Corscan
910 528 6251
Authorized User and RSO NRC No. 47-25351-01

August 28, 2007

Date

Metro Heart Group of St. Louis
12855 N. Forty Drive, Suite 300
St. Louis, MO 63141



US Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352



LIC NO: 24-32184-01