

MIDWEST CARDIOVASCULAR SPECIALISTS

WILLIAM S. SARNAT, M.D., F.A.C.C.
AJAZUDDIN SHAIKH, M.D., F.A.C.C.
MARK L. SMUCKER, M.D., F.A.C.C.
ASHFAQ TURK, M.D., F.A.C.C.
CHARLES A. MATHIS, M.D., F.A.C.C.

MIDWEST MEDICAL GROUP, LLC



DONALD WESTERHAUSEN, JR., M.D., F.A.C.C.
FARID JALINOUS, M.D., F.A.C.C., F.S.C.A.I.
SACHIN R. PATEL, M.D.
GURUDUTT B. KULKARNI, M.D.
DJAVID HADIAN, M.D.

July 6, 2007

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

Dear Sir or Madam:

Cardiology Division, Midwest Medical Group, LLC would like to resubmit its' request to amend its NRC Byproduct Materials License, Number 13-26679-01 to add Charles A. Mathis, M.D. and also Vijay A. Mehta, M.D. as Authorized Users of materials licensed under 10 C.F.R.35.200. The resubmission includes additional information that was requested for Voided Control 316127 by Mr. William Reichhold.

Please note that the original request was submitted to add Charles A. Mathis, M.D. Since that time we have had another physician join our practice and have included NRC form 313A (AUD) to amend our license to add Vijay A. Mehta, M.D. as well. A copy of his Nuclear Cardiology Board Certification is enclosed as well.

If there are any questions concerning this notification, please contact our Nuclear Medicine Physicist, Mr. Patrick Byrne, D.A.B.R., C.H.P. at (877) 317-5811 from Medical Physics Consultants, Inc. (MPC)

Sincerely,



William Sarnat, M.D.
Radiation Safety Officer and Authorized User
Partner, Midwest Medical Group, LLC

837 East Cedar Street, Suite 420 • South Bend, IN 46617
(574) 232-5928 • FAX (574) 232-4888 • 800-439-4468

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**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

Vijay Arvindkumar Mehta, M.D.

State or Territory Where Licensed

Indiana

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 (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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> 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		<input type="checkbox"/> Yes <input type="checkbox"/> 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.

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 (<i>not required for 35.590</i>)			
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> 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)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

☒ I attest that Vijay A. Mehta, M.D. 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 Vijay A. Mehta, 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
William Sarnat, M.D., RSO, AU

Signature


Telephone Number
(574) 232-5928

Date
07-06-2007

License/Permit Number/Facility Name
13-26679-01 Cardiology Division, Midwest Medical Group, LLC

Certification Board of Nuclear Cardiology

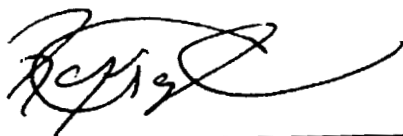
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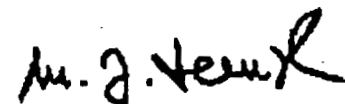
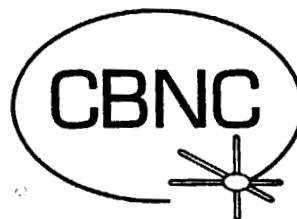
Vijay Arvindkumar Mehta, MD

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

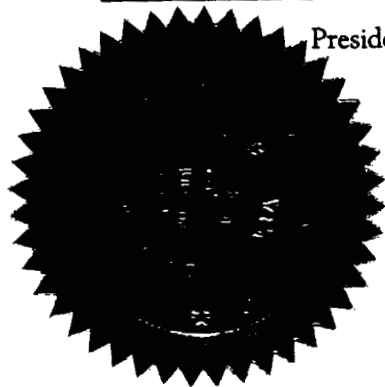
FOR THE PERIOD 2006 - 2016



President



Secretary



CERTIFICATE NUMBER: 4477

**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: 10/31/2008Name of Proposed Authorized User
CHARLES AUGUSTINE MATHIS, M.D.State or Territory Where Licensed
INDIANA

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 The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois (See attached certificate)	18	Jan 18, 2005 to Feb 14, 2007
Radiation protection	CORSCAN The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois (See attached certificate)	16	Jan 18, 2005 to Feb 14, 2007
Mathematics pertaining to the use and measurement of radioactivity	CORSCAN The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois (See attached certificate)	20	Jan 18, 2005 to Feb 14, 2007
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	CORSCAN The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois (See attached certificate)	10	Jan 18, 2005 to Feb 14, 2007
Radiation biology	CORSCAN The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois (See attached certificate)	16	Jan 18, 2005 to Feb 14, 2007

Total Hours of Training: 80 Hours

- 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: 624 Hours

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	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present

(3-2007)

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	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present
Administering dosages of radioactive drugs to patients or human research subjects	Cardiology Div., Midwest Medical Group, LLC 500 Arcade Avenue Elkhart, IN 46561 License Number 13-26679-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	January 2005 to the present
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 The Nuclear Imaging Company Steven Walter, M.D. Chicago, Illinois	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Jan. 29, 2005

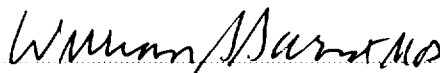
Supervising Individual

License/Permit Number listing supervising individual as an authorized user

William Sarnat, M.D.

13-26679-01

RSO & Auth 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.

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 CHARLES A. MATHIS, M.D. 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 CHARLES A. MATHIS, 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.

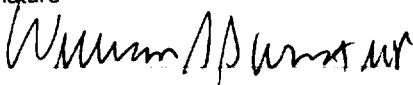
Second Section

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
William Sarnat, M.D., RSO, AU

Signature


Telephone Number
(574) 232-5928

Date
07-06-2007

License/Permit Number/Facility Name
13-26679-01 Cardiology Division, Midwest Medical Group, LLC

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

Charles Mathis, 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 material for medical use;

Radiation biology; Generator elution for 10CFR35.290(ii)(G) and

Review of regulations regarding the medical use of radioisotopes.

Corscan

The Nuclear Imaging Company
www.corscanplus.com

Steven W. Walter, MD

February 14, 2007

Steven W. Walter, MD

Program Director

General Manager and CEO

Corscan

910 528 6251

Authorized User and RSO NRC No. 47-25351-01

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