



Dennis C. Besley, M.D.
John D. Call, Jr., M.D.
Harish R. Chandra, M.D.
Lynn J. Cronin, M.D.
Robert C. Davidson, M.D.
Michael G. Dickinson, M.D.
Dennis W. Dunning, M.D.
Darryl A. Elmouchi, M.D.
Bohuslav Finta, M.D.
William A. Frauenheim, M.D.
Timothy D. Fritz, M.D.

Andre J. Gauri, M.D.
J. Robert Grove, M.D.
David B. Johnson, M.D.
John A. Key, D.O.
Paul J. Kovack, D.O.
David E. Langholz, M.D.
William F. LaPenna, M.D.
Michael A. Lojek, M.D.
Richard F. McNamara, M.D.
Roger D. Miller, M.D.
J. Craig Mulligan, D.O.

Iihad A. Mustapha, M.D.
Maurice J. Norman, M.D.
Raymond A. Roden, M.D.
Andrew M. Rosenblum, M.D.
Matthew W. Sevensma, D.O.
Helayne L. Sherman, M.D., Ph.D.
Michael C. Vredenburg, D.O.
Eric T. Walchak, D.O.
Alan K. Woelfel, M.D.
David Wohns, M.D.
Kevin G. Wolschleger, M.D.

April 23, 2007

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Amendment to License No. 21-26543-01, West Michigan Heart, P.C.

Please amend our license as follows:

1. Add Michael G. Dickinson, M.D. and Dennis Besley, M.D. as authorized users of 10 CFR 35.200, limited to cardiovascular clinical studies. Form 313A is enclosed for each physician.
2. Add 5900 Byron Center Avenue, Wyoming, MI 49519 as an additional address of use of radioactive materials.


This new location will be connected to the new Metro Health Hospital that will be opening this fall. At this time we are unsure if we will also have a suite number for our office. The building we will be located in is a one story building with nothing above or below.


Once construction at the new site is complete, we will move from our current Metro Health location at 1945 Boston SE, Suite G-1, Grand Rapids, MI. At that time we will perform a close out survey of the Boston SE address and submit it for your review.

There are twelve rooms at the new address that will be areas of use of radioactive materials. The hot lab will be the only room in which radioactive materials are stored. All other areas are for injection only. The rooms will not have numbers but will be labeled according to their use. Diagrams of the use areas are enclosed.


The hot lab will have lead lined cabinets for the storage of radioactive sources and waste. The ceiling will be plaster and the door will have a key pad entrance. The room will be labeled Hot Lab and will have a Caution Radioactive Materials sign on the door.


We do not use generators at any of our offices and will not be using them at the new address of use.

 **BRADFORD**
2900 Bradford St. NE
Grand Rapids, MI 49525
Phone (616) 885-5000
Fax (616) 885-5020

 **BUSINESS OFFICE**
P.O. Box 152057
Grand Rapids, MI 49515-2057
Phone (616) 752-5000
Fax (616) 913-9025
Toll Free Phone (866) 752-5002

 **METRO**
1945 Boston SE, Suite 201
Grand Rapids, MI 49506
Phone (616) 241-2333
Fax (616) 452-6767

 **HOLLAND**
904 S. Washington, Suite 120
Holland, MI 49423
Phone (616) 392-3824
Fax (616) 392-3570

 **GREENVILLE**
709 S. Greenville West Drive
Greenville, MI 48838
Phone (616) 754-3880
Fax (616) 754-8941

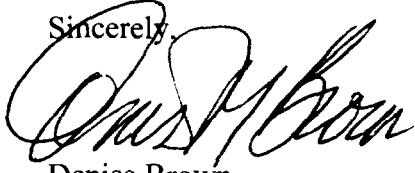
OTHER LOCATIONS
Big Rapids, Canadian Lakes, Edmore, Fremont, Hastings, Ionia, Reed City, Sheridan, Zeeland

www.wmheart.com

RECEIVED MAY 02 2007

Thank you for your cooperation in this matter. If you have any questions, please contact our consulting physicist, Dawn Edwards at 734-662-3197.

Sincerely,

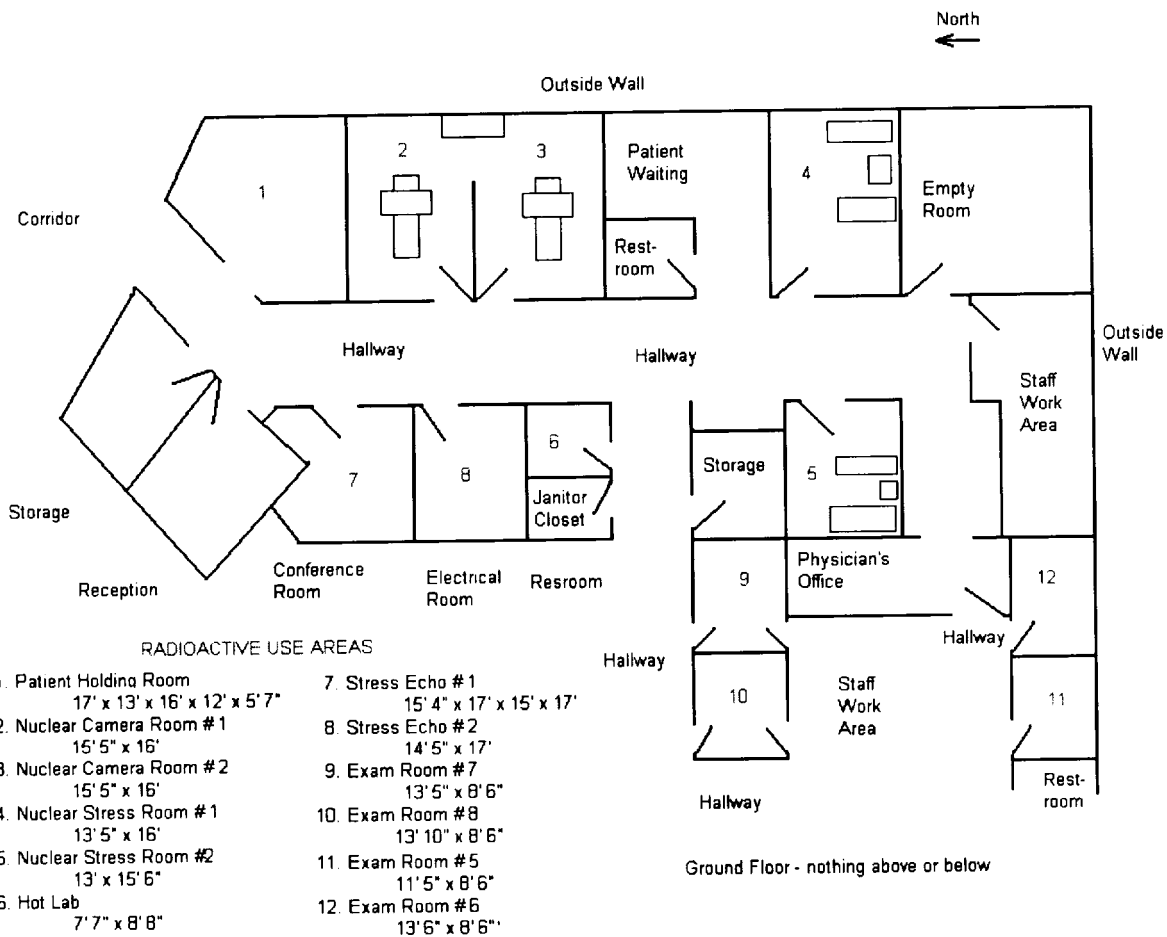
A handwritten signature in black ink, appearing to read "Denise Brown". The signature is written in a cursive, flowing style with large loops and a prominent initial "D".

Denise Brown
Chief Operations Officer

West Michigan Heart – April 2007
 License No. 21-26543-01

New Facility Diagram – Metro Health site
 5900 Byron Center Avenue
 Wyoming, MI 49519

Diagram 1 of 2

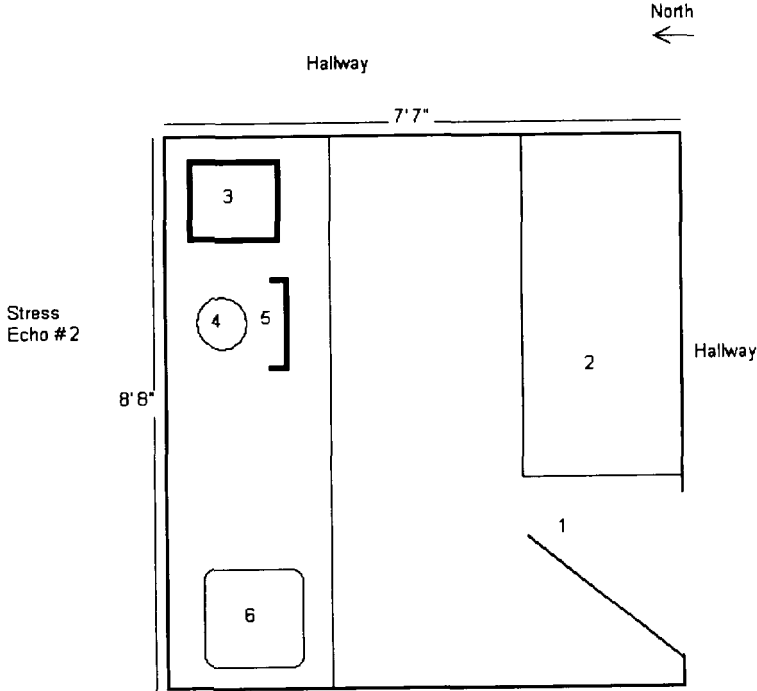


West Michigan Heart – April 2007
License No. 21-26543-01

New Facility Diagram – Metro Health site
5900 Byron Center Avenue
Wyoming, MI 49519

Diagram 2 of 2

Hot Lab



- 1. Locked Door
 - 2. Package Receipt Area
 - 3. Leaded Waste / Radiopharmaceutical Storage
 - 4. Dose Calibrator
 - 5. Lead Glass Face Shield
 - 6. Hand Sink
- Janitor Closet

**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

Dennis Besley MD

Michigan

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	CONSULTANTS in Nuclear Medicine 2910 W. ESTER AVE Chicago, IL 60645	27.5	Nov 6, 2006 Oct 30, 2005
Radiation protection	"	26.5	Nov 6, 2006 Oct 30, 2005
Mathematics pertaining to the use and measurement of radioactivity	"	35.0	"
Chemistry of byproduct material for medical use (not required for 35.590)	"	5.0	"
Radiation biology	"	6.0	"
Total Hours of Training:		100	

**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.)**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	West Michigan Heart PC License # 21-26543-01	24	Oct 2005 Nov 2006
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	23	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	54	"

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	West Michigan Heart License # 21-26543-01	5	Oct 2005 to Nov 2006
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	10	"
Administering dosages of radioactive drugs to patients or human research subjects (observed)	"	1.0	"
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	Do Not Use Generators AT OUR FACILITY	—	
* Review Case Histories + Interpreting Nuclear Cardiology Scans		Total Hours of Experience:	526 (Oct 2005 Nov 2006) 643
Supervising Individual	License/Permit Number listing supervising individual as an authorized user		
DAVID E. Langholz	21-26543-01		

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 Dennis Besley 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
David Langholz	<i>[Signature]</i>	(616) 885-5000	4/27/07
License/Permit Number/Facility Name	21-26543-01 West Michigan Heart, P.C.		

Consultants in Nuclear Medicine

2910 W. Estes Avenue

Chicago, IL 60645

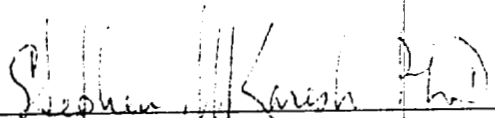
This certificate verifies that on November 6, 2006

Dr. Dennis Besley

*Completed Part 2 (100 hours) of the
Basic Radioisotope Handling Course
Covering the Topics of*

*Radiopharmacy, Radiation Biology,
Radiation Protection, Instrumentation and Physics,
and the Mathematics Associated with Radioactivity*

*and received a passing grade for Part 2. This course is designed to
qualify a physician as an authorized user of radiopharmaceuticals,
generators, and reagent kits and meets all requirements set forth by
the US Nuclear Regulatory Commission and all agreement states as
outlined in the Code of Federal Regulations.*


Stephen M. Karesli, PhD, 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

Michael G. Dickinson, M.D. *Michigan*

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

- Provide a copy of the board certification.
- 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

- Authorized user on Materials License meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- 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 Co"	22.0	May 29, 2006 Jan 21, 2007
Radiation protection	"	21.0	"
Mathematics pertaining to the use and measurement of radioactivity	"	29.0	"
Chemistry of byproduct material for medical use (not required for 35.590)	"	2.0	"
Radiation biology	"	6.0	"
Total Hours of Training:		80.0	

**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.)**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	West Michigan Health, PC License #21-26543-01	27	May 2006 + Jan 2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	24	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	45	"

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	West Michigan Heart License # 21-26543-01	5	May 2008 to Jan 2009
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	10	"
Administering dosages of radioactive drugs to patients or human research subjects (observed)	"	1.0	"
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	Do Not Use Generators AT our facility	-	
* Review Case Histories + interpreting Nuclear Cardiology Scans		544 656	May 2008 to Jan 2009
Supervising Individual <u>Michael C. Vredenburg</u>		Total Hours of Experience: License/Permit Number listing supervising individual as an authorized user <u>21-26543-01</u>	

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 Michael G. Dickins 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

Michael Vredenburg

Michael Vredenburg

(616) 885-5000

4/27/07

License/Permit Number/Facility Name

21-26543-01

West Michigan Health, P.C.

Certificate of Completion
Authorized User Classroom and Laboratory
Training Program

Michael G Dickinson, 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(i)(G) and

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

January 21, 2007

Date

TRK# 8416 5668 2350 FORM 0200

Deliver By:
01MAY07
A2

60532 -IL-US

ORD
NY BDFA



FedEx USA Airbill
Express

841656682350

1 From
Date: 4/30/07
Sender's Name: Chris Bopp
Company: [Redacted]
Address: [Redacted]
City: [Redacted] State: [Redacted] ZIP: [Redacted]

2 Your Internal Billing Reference

3 To
Recipient's Name: United States Nuclear Regulatory Commission
Company: Reg. of Nuclear Materials Licensing
Address: 2443 Warrenville Rd, Suite 210
City: Lisle State: IL ZIP: 60532-4352

Recipient's Copy

4a Express Package Service
 FedEx Priority Overnight
 FedEx Standard Overnight
 FedEx 2Day
 FedEx Express Saver

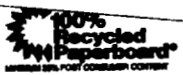
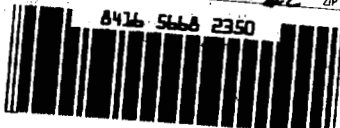
4b Express Freight Service
 FedEx 1Day Freight
 FedEx 2Day Freight
 FedEx 3Day Freight

5 Packaging
 FedEx Envelope
 FedEx Pak

6 Special Handling
 SECURITY Sensitive
 Fragile
 Dry Ice
 Hazardous

7 Payment Method
 Recipient
 Third Party
 Credit Card
 Cash/Check

8 Release Signature



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