



Northwest Indiana

Cardiovascular Physicians, P.C.

Keith Atassi, M.D.
John A. Forchetti, M.D.
Fred J. Harris, M.D.
Akram Kholoki, M.D.
Daniel P. Linert, M.D.
Hector J. Marchand, M.D.
M. Satya Rao, M.D.
Sandeep Sehgal, M.D.
Michael L. Wheat, M.D.

March 14, 2011

Nancy George, B.S., M.P.A.
Chief Executive Officer

Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
Radioactive Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: NW Indiana Cardiovascular Physicians, P.C.
License Number 13-26691-01
Request for Amendment of Authorized User

Dear Sir/Madam,

Please amend the above-referenced license in the appropriate section to add the following authorized user:

Add:	<u>Authorized User</u>	<u>Authorized Use</u>
	Michael Wheat, M.D.	35.200

I am enclosing a preceptorship letter and coursework completion certificates for this physician to document his experience and competency. All other license commitments and conditions will remain unchanged.

Should you have any questions, I can be contacted at (219) 531-9419.

Sincerely,

John A. Forchetti, M.D., F.A.C.C., F.C.C.P., F.S.C.A. & I.
President
Northwest Indiana Cardiovascular Physicians, P.C.
2000 Roosevelt Road
Valparaiso, IN 46383

JAF/ltn

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To Whom It May Concern:

Nancy George, B.S., M.P.A.
Chief Executive Officer

This letter is to affirm that Michael Wheat, M.D. has obtained supervised nuclear medicine nuclear cardiology, clinical and work experience in our institution. This experience, preceptorship, began March 22, 2010 and continued through March 11, 2011.

The clinical experience includes active participation in the following procedures:

702 Gated (SPECT)
780 Cardiolite stress imaging/function procedures
780 Cardiolite resting imaging/function procedures
702 Ejection fraction calculation procedures
702 Wall motion evaluation studies

During this clinical experience, the physician examined patients and reviewed histories to determine the suitability for these procedures; select the suitable radiopharmaceutical and dose; administered radiopharmaceuticals using a syringe shield; collaborated with an authorized user in the interpretation of the procedure and used the interpretation in the management of patients. Affidavits of didactic radiation safety training totaling 80 hours are enclosed.

Concurrent with clinical experience was supervised work experience. This included but was not limited to the procedures for ordering, receiving and unpacking radioactive materials. Calibrating the dose calibrator and other instruments, as well as checks for proper operation; calculating and preparing patient dosages; using administrative controls to prevent misadministration; using procedures to contain spills and decontamination procedures.

Dr. Wheat supervised clinical and work experience during this period totaling 750 hours.

Sincerely,

Sandeep Sehgal, M.D., F.A.C.C.
Northwest Indiana Cardiovascular Physicians, P.C.
Authorized User – License Number: 13-26691-01

SS/ltn

**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

State or Territory Where Licensed

Michael L. Wheat, M. D.

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	Classroom and laboratory training is documented on the attached letter and certificate of Completion from Consultants in Nuclear Medicine, 2910 W. Estes Ave., Chicago, IL 60645		March 14 to March 21, 2010
Radiation protection	Same as above		Same as above
Mathematics pertaining to the use and measurement of radioactivity	Same as above		Same as above
Chemistry of byproduct material for medical use (not required for 35.590)	Same as above		Same as above
Radiation biology	Same as above		Same as above
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: 750	
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	Northwest Indiana Cardiovascular Physicians, P. C. License Number 13-26691-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	March 22, 2010 to March 11, 2011
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above

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

Supervising Individual
Sandeep Sehgal, M. D.

License/Permit Number listing supervising individual as an authorized user
13-26691-01

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 **Michael L. Wheat, M. D.** has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

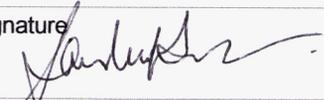
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Sandeep Sehgal, M. D.	Signature 	Telephone Number (219) 531-9419	Date 03/14/2011
License/Permit Number/Facility Name 13-26691-01 Northwest Indiana Cardiovascular Physicians, P. C.			

Consultants in Nuclear Medicine
2910 W. Estes Avenue
Chicago, IL 60645

March 21, 2010

To Whom It May Concern:

In accordance with the regulations set forth in the NRC Regulations, Title 10 of the Code of Federal Regulations, Part 35, Section 290, one who wishes to become an authorized user on a license must complete the 80 hour BRIH Course (see attached certificate verifying attendance). The Basic Radioisotope Handling Course sponsored by Consultants in Nuclear Medicine took place on March 14-21, 2010.

In addition, there are specific items mentioned in Section 290 that one must have performed to qualify as an authorized user. This letter certifies that **Dr. Michael Wheat** has been specifically trained at our course to perform the items on the list below which are highlighted in yellow. In particular, I would like to certify that the above named physician had actual experience in eluting a generator and is able to perform the requisite quality control tests

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for 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.

Please feel free to contact me at 708/216-6353 or -9421 if you need additional information.

Sincerely,


Stephen M. Karesh, PhD
Course Director

Consultants in Nuclear Medicine

2910 W. Estes Avenue

Chicago, IL 60645

This certificate verifies that on March 21, 2010

Dr. Michael Wheat

*Completed 80 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. 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 as outlined in the
Code of Federal Regulations.*

Stephen M. Karesh Ph.D.

Stephen M. Karesh, PhD, Course Director

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. NW Indiana Cardiovascular Physicians, P.C.</p> <p>2. 2000 Roosevelt Road Valparaiso, IN 46383</p>	<p>In accordance with the application dated December 21, 2010,</p> <p>3. License number 13-26691-01 is renewed in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2021</p> <hr/> <p>5. Docket No. 030-34025 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p>
<p>9. Authorized Use:</p> <p>A. Medical use permitted by 10 CFR 35.100.</p> <p>B. Medical use permitted by 10 CFR 35.200.</p>		

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2000 Roosevelt Road, Valparaiso, Indiana.
11. The Radiation Safety Officer for this license is Hector J. Marchand, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|--------------------------|-------------------------|
| John A. Forchetti, M.D. | 10 CFR 35.200. |
| Hector J. Marchand, M.D. | 10 CFR 35.200. |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-26691-01Docket or Reference Number
030-34025

Amendment No. 11

Akram Kholoki, M.D. 10 CFR 35.100 and 35.200.

Sandeep Sehgal, M.D. 10 CFR 35.200.

Keith Atassi, M.D. 10 CFR 35.200.

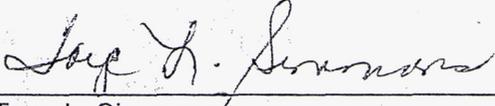
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated December 21, 2010.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

FEB 29 2011

Date _____

By _____


Toye L. Simmons
Materials Licensing Branch
Region III

NICP
2000 Roosevelt Rd
Valparaiso, IN 46383



Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
Radioactive Materials Licensing Section
2443 Warrenville Road, suite 210
Lisle, ILLINOIS ~ 60532-4352

