



U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section, Suite 210  
2443 Warrenville Road  
Lisle, Illinois 60532  
Attention: Colleen Casey

**Control # 313298 Additional information**

Dear Ms. Casey,

In response to your fax communication dated July 13, 2004 we respectfully submit additional information to support our request to add Dr. Garry Malnar, D.O. as an authorized user on license 13-01787-01 for 35.100 and 35.200. Attached is a preceptor statement detailing recent clinical experience and a supporting letter from Timothy Whiteman, M.D., an Authorized User and Radiation Safety Officer for Good Samaritan Hospital. Please contact Perry Snyder by phone (812)885-3441 or fax (812)885-3662 should you need further information. Thank you for your assistance.

Sincerely,

Gerald E. Waldroup, Senior Vice President  
Title

October 6, 2004  
Date

Attachments:

- Preceptor Statement
- Dr. Whiteman support letter

*Improving the healthcare of your community one patient at a time!*

September 9, 2004

I have supervised Gary Malnar, D.O. in his performance and interpretation of Nuclear Medicine procedures at Good Samaritan Hospital in Vincennes, Indiana for the past nine months and have determined that he should qualify as an authorized user under parts 35.100 and 35.200.

A handwritten signature in black ink that reads "Timothy R. Whiteman, M.D., R.S.O." The signature is written in a cursive style with a large initial 'T' and 'W'.

Timothy R. Whiteman, M.D., R.S.O.

**TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT**

**PART I -- TRAINING AND EXPERIENCE**

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Garry Malnar, D.O., Proposed Authorized User 35.100 and 35.200  
Training requirements 35.190 (a) and 35.290 (a)

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Indiana

**3. CERTIFICATION**

Specialty Board	Category	Month and Year Certified
American Osteopathic Board of Radiology	Diagnostic Radiology	7/88

*Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.*

**4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			





TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME WORK EXPERIENCE

YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision  
 N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

8. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of  
 N/A \_\_\_\_\_ who meets requirements for Authorized Medical Physicists; and

YES Completed 1-year of full-time work experience (for areas identified in item 5a) for \_\_\_\_\_  
 N/A modality(ies) under the supervision of \_\_\_\_\_ who meets requirements of Authorized Medical Physicists for \_\_\_\_\_ modality(ies).

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

A. Name of Supervisor

B. Supervisor is:

TIMOTHY R. WHITEHEAD, MD

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) \_\_\_\_\_

for medical uses in Part 35, Section(s) 100, 200, 300

D. Address

DEPT. OF RADIOLOGY  
 GOOD SAMARITAN HOSPITAL  
 VINCENTES, IN 47591

E. Materials License Number

13-01707-01

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in  
 N/A 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s) 190  
 N/A and Paragraph(s) 35.190(a), 35.290(a)

YES 11b. The individual named in Item 1. is competent to independently function as an authorized  
 N/A User for 35.100, 35.200 uses (or units).

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of 35.190, 35.290, 35.50  
or equivalent Agreement State requirements to be a preceptor authorized User and RSO  
for the following uses (or units) of byproduct material: 35.100, 35.200, 35.300

A. Address  
Good Samaritan Hospital  
520 S. 7th St  
Vincennes, IN 47591

B. Materials License Number

13-01787-01

C. NAME OF PRECEPTOR (print clearly)  
Timothy Whiteman, M.D.

D. SIGNATURE -- PRECEPTOR  
Timothy Whiteman

E. DATE  
8/31/04

**§ 35.290 Training for imaging and localization studies.**

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the use authorized under § 35.200 to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include at a minimum,--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving--

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

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of scintillation detectors;

(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; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

✓AOA

Lifetime - per AOA  
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# American Osteopathic Board of Radiology



certifies that

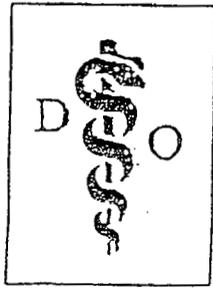
**Garry R. Malnar, D.O.**

having met the prescribed qualifications and standards and  
passed the required examinations of this Board,  
is qualified as a specialist in

**Diagnostic Radiology**

and is hereby awarded this certificate as of

July 28, 1988



American Osteopathic Association

*Robert Ruben*  
Executive Director

American Osteopathic Board of Radiology

*George D. Fausch*  
Chairman

*Michael K. Willman, D.O. FAOCR*  
Secretary

Certificate No. 641

Duplicate

**Table 5 - Certification Requirements  
Authorized User in Imaging and Localization Studies (35.290)**

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs of Training and Experience		(B) Certification	
	<u>35.290(c)(1)(i)</u> Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	<u>35.290(c)(1)(ii)</u> Supervised work under AU (who meets 35.290 or 35.390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrating dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages 7. Eluting generator systems & preparing radioactive drugs	<u>35.290(c)(2)</u> Signed by a preceptor AU who meets 35.290 or 35.390 that the candidate satisfies (A) + can function independently	<u>35.290(a)</u> (A) + (B) + Additional Board Requirements (e.g. examination)
Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine in nuclear medicine	1. Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

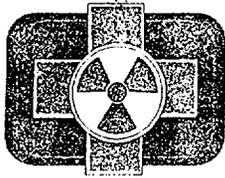
**Table 4 - Certification Requirements for  
Authorized User in Uptake, Dilution, and Excretion Studies (35.190)**

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 60 hrs of Training and Experience		(B) Certification	
	<u>35.190(c)(1)(i)</u> Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	<u>35.190(c)(1)(ii)</u> Work experience under AU (who meets 35.190, 290, or 390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrate dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages	<u>35.190(c)(2)</u> Signed by a preceptor AU (who meets 35.190, 290, or 390) that the candidate satisfies (A) + can function independently	<u>35.190(a)</u> (A) + (B) + Additional Board Requirements (e.g. examination)
<b>Example of Boards Listed in Subpart J</b>	<b>Training/ Education</b>	<b>Experience</b>	<b>Certification</b>	<b>Additional Board Requirements</b>
Am B of Nuclear Medicine in nuclear medicine	1. Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

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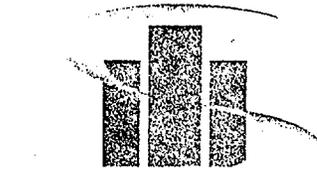
**MEMO**

**GOOD SAMARITAN HOSPITAL**



**Nuclear Medicine Department**

**Vincennes, IN**



**GOOD SAMARITAN  
HOSPITAL**

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**To:** Dr. Whiteman  
**From:** Perry Snyder (B)  
**Date:** May 24, 2004  
**Re:** Questions

1. It has been our practice for many years to tape the left breast up during myocardial perfusion exams. Dr. King had instituted this after seminars he attended in the past. During the past year I have raised the question of taping during several meetings I have attended with the speakers and with other technologists in the area. All say they are having the women remove their bra and let the breast lay naturally. I have not been able to find literature to support either way. Anecdotally, some of the speakers say they have found more artifacts with taping or leaving bras on due to compression. My inclination is to discontinue taping if you agree.
2. Myocardial perfusion studies done with the Profile attenuation correction currently have only the corrected slices sent to PACs. The uncorrected slices are available on the review program when you read the studies but do not get sent to Synapse. Should we also send the uncorrected slices to Synapse for reference?
3. I received a call from the NRC regarding the recentness of experience for Dr. Malnar. They have asked us to submit a preceptor statement to document recent experience. I have prepared this form and attached it. If you have reviewed Dr. Malnar's work and feel he has appropriate experience to perform Nuclear Medicine studies, we can complete section 5b and include a letter from yourself stating you have supervised him and reviewed his cases and feel he is competent to perform these procedures. The NRC is very vague on this issue. I spoke with Patty Pelky of the NRC who states it is left to the supervising authorized user to determine competency and there are no specific guidelines to refer to. Please advise how to proceed.



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GOOD SAMARITAN  
HOSPITAL

[www.gshvin.org](http://www.gshvin.org)

*Nuclear Medicine Dept.*

520 S. 7th Street  
Vincennes, Indiana 47591

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Lisle, Illinois 60532  
Attention: Colleen Casey

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