GOSHEN HEALTH SYSTEM
CENTER FOR CANCER CARE

April 7, 2008

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

Re: License No. 13-18845-01

To Whom It May Concern:

Please amend our license to add LeRoy Weaver, M.D. as an authorized user for the uses specified in 35.100, 35.200 and 35.392. Copies of his training and experience are enclosed.

We also need to define changes to the PET/CT suite. See the enclosed diagram. The suite consists of the scan room, control room, two prep/injection rooms and a hot lab. The current Hot Lab is being converted to a storage room as indicated on the diagram. A clerical area is to become the new Hot Lab as identified on the diagram. The Hot Lab will contain the receipt area, waste storage, preparation and source storage areas. Shielding is available to comply with exposure limits. All indicated doors are lockable.

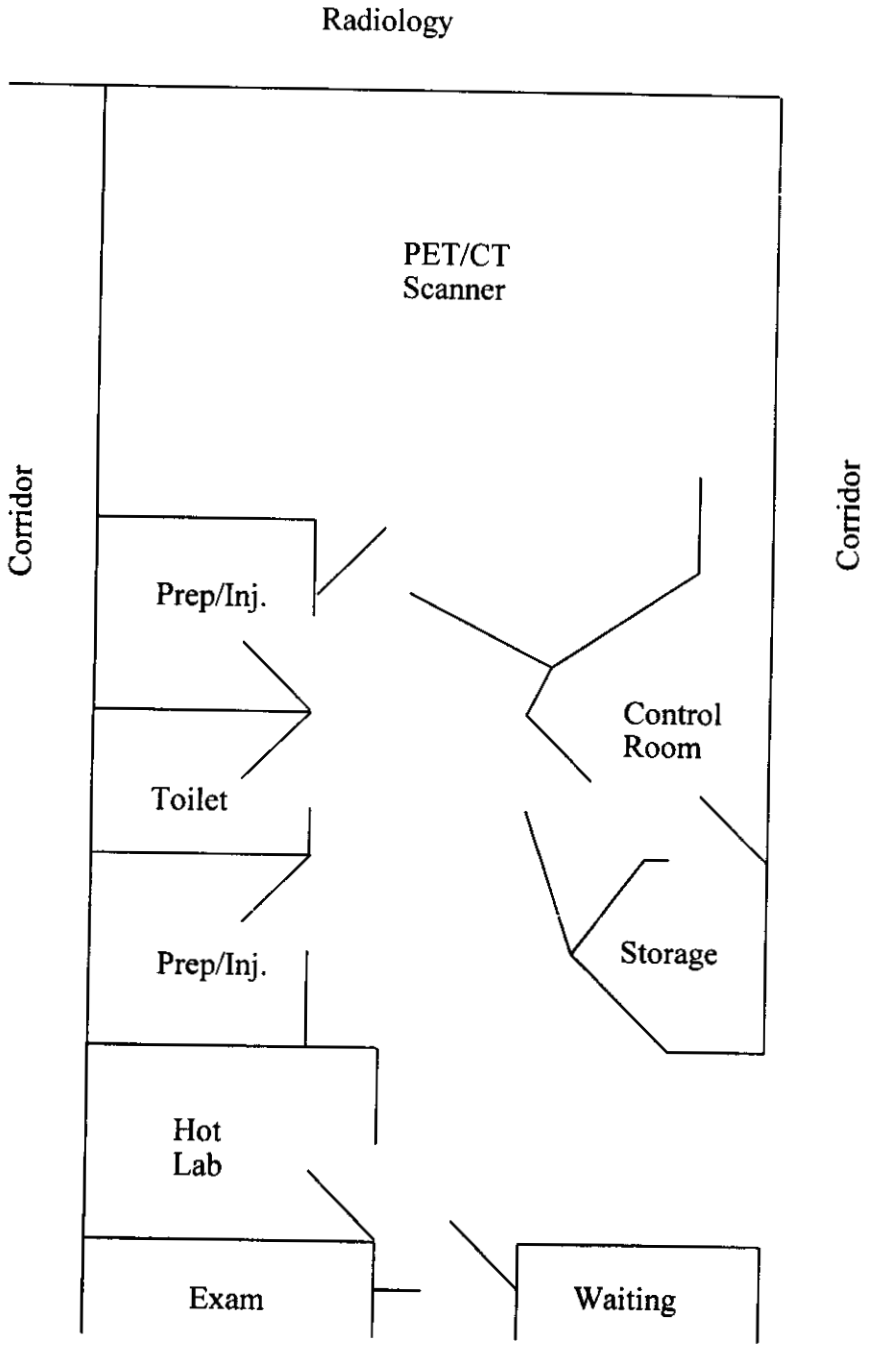
If you have any questions, please feel free to contact us or our consultant, David Close at 440-350-1242.

Sincerely,

Brent Murphy, M.S.
RSO

Goshen General Hospital
200 High Park
Goshen, IN 46526

PET/CT Suite



NRC FORM 313A (AUD) (3-2007) | U.S. NUCLEAR REGULATORY COMMISSION

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
LeRoy Weaver Jr MD	Indiana

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	30	July 2001 - June 2005
Radiation protection	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	20	July 2001 - June 2005
Mathematics pertaining to the use and measurement of radioactivity	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	15	July 2001 - June 2005
Chemistry of byproduct material for medical use *(not required for 35.590)*	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	10	July 2001 - June 2005
Radiation biology	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	20	July 2001 - June 2005
Total Hours of Training: 95			

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	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005

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	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Administering dosages of radioactive drugs to patients or human research subjects	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
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	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005

Supervising Individual: A.R. Muramele

License/Permit Number listing supervising individual as an authorized user: 2100338-02

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.

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(3-2007)

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 _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 LeRoy Weaver Jr (Name of Proposed Authorized User) has satisfactorily completed the 60 hours of training and 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 LeRoy Weaver Jr (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training 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
Appa Rao Muckamala	A.R. Muckamala	810-232-2000	2-15-08

License/Permit Number/Facility Name
2100338-02 Hurley Medical Center

NRC FORM 313A (AUT) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
LeRoy Weaver Jr MD	Indiana

Requested Authorization(s) *(check all that apply)*:

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☑ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 *gigabecquerels (33 millicuries)*

☐ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed 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 ☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	30	July 2001 - June 2005
Radiation protection	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	20	July 2001 - June 2005
Mathematics pertaining to the use and measurement of radioactivity	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	15	July 2001 - June 2005
Chemistry of byproduct material for medical use	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	10	July 2001 - June 2005
Radiation biology	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	20	July 2001 - June 2005
Total Hours of Training: 95			

b. Supervised Work Experience ☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

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	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Calculating, measuring, and safely preparing patient or human research subject dosages	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	☑ Yes ☐ No	July 2001 - June 2005

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Dr Vemblaserry Jayabalan MD	

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390
☑ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	8	Michigan State University/Flint Area Medical Education Diagnositic Radiology Residency	July 2001 - June 2005
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral adminstration of any other radionuclide for which a written directive is required _____ (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
A.R. Mucciarelli	2100338-02

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390	With experience administering dosages of:
☑ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ 35.394	☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ 35.396	☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☑ I attest that LeRoy Weaver Jr MD has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☑ I attest that LeRoy Weaver Jr MD has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☑ I attest that LeRoy Weaver Jr MD has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

Fifth Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.390 ☑ 35.392 ☐ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Appa Rao Mukkamala	A.R. Mukkamala	810-232-2000	2-15-08

License/Permit Number/Facility Name: 400338-02 Hurley Medical Center

GOSHEN HEALTH SYSTEM
CENTER FOR CANCER CARE

200 High Park Ave., Goshen, IN 46526

$1.14
APR 20 2006
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First-Class Mail
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048J0085003709

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

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