Fax cover NRC Ccontrol # 142988.txt

Associated Specialists, Inc.
Phone Number 304-623-5711
Fax Number 304-624-0461

MS16
P-7

47-31344-01
03037662

Fax Transmittal Form

To: USNRC
Name: Thomas Thompson

From: Jessie Sizemore, RT(N)
Date Sent: January 14, 2009
Number of Pages: including cover 12
Fax: 610-337-5269

Message: Please forward to Mail Control # 142988 as soon as possible.

Thank You

Jessie S. Sizemore, RT(N)

Jessie S. Sizemore, RT(N)

142988

Dear Mr. Thompson,

The following is in response to information requested for our application. I have included an NRC form 313A (RSO) for the proposed Radiation Safety Officer. Continuing education requirements are evident in that in order to maintain ARRT registry requirements, 12 credit hours are needed per year, which compliance has been maintained since 1990. I will forward a copy of the NRC form 313A (AU) as soon as I have received it from Dr. Abdulnabi.

Contiguous areas surrounding the areas of use:

1. North wall, DIGIRAD (camera room), Treadmill room; the back wall is a brick wall adjacent to the outdoors, which being located on the first floor, is partially underground.
2. West wall; this wall borders a pharmacy, and internal medicine physician's office.
3. South wall, or front entry way to office; this wall is a brick wall which faces outside.
4. East wall; this wall is adjacent to a psychiatrist's office.

Radiation Safety:

1. Surveys to be performed; we have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 33.70.
2. Personnel Dosimetry; either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Volume 9, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'"
3. Spills and emergencies; we have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101. In the case of missing licensed materials due to loss, theft, or other means, the RSO will notify the NRC immediately by phone, followed by written report within 24 hours, and reports filed to local authorities as advised by the NRC.
4. Mobile requirements; all licensed materials will be transported meeting state and federal DOT guidelines. Under no circumstances will licensed materials be received from the radiopharmacy at any of the "secondary" sites. All deliveries will be received in the "Primary" office only for proper monitoring and dose verification prior to being administered to patients. "Secondary" sites will be monitored and wipe tested at the end of the days of use in all areas where licensed materials are used. All suspected contaminated waste will be removed and kept in the "Primary" office for proper decay, or returned to the radiopharmacy. A copy of the facility diagram of the "secondary" sites will be maintained and stored at the "Primary" location. A letter signed by management of the "secondary" site location

stating 'knowledge of use of licensed materials' will also be kept on file at the "Primary" site. The vehicle or "van" will be used only for business purposes, and will not be used as a "personal" vehicle. The van will be monitored and wipe tested at the end of all days of use. These readings will be recorded and maintained for review at the "Primary" location.

5. Radiation monitoring equipment; we have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.
6. Dose calibrator; equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Please call with any questions.
301-535-4410

Jessie S. Sizemore, RT(N) Proposed RSO
Associated Specialists, Inc.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

☐ Yes ☐ No	This response includes security-related sensitive information (see Section 5.2) which is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390"			
Yes	**Radionuclide**	**Form or Manufacturer/ Model No.**	**Maximum Quantity**	**Purpose of Use**
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
✓	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	Any byproduct material permitted by 10 CFR 35.300	Any	_____ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ______________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ______________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ______________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ______________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

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NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2009

Name of Proposed Radiation Safety Officer: Jessie S. Sizemore RT(N)

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

☒ 35.100 ☒ 35.200 ☐ 35.300 ☐ 35.400 ☐ 35.500 ☐ 35.600 (remote afterloader)

☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 ( )

PART I – TRAINING AND EXPERIENCE
(Select one of the four 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. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

OR

☐ 2. **Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above**

a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.

b. Skip to and complete Part II Preceptor Attestation.

OR

☒ 3. **Structured Educational Program for Proposed Radiation Safety Officer**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Prince George's Community College Largo Md.	100	1984-1986
Radiation protection	Prince George's Community College Largo, Md.	100	1984-1986
Mathematics pertaining to the use and measurement of radioactivity	Prince George's Community College Largo, Md.	100	1984-1986
Radiation biology	Prince George's Community College Largo Md.	100	1984-1986
Radiation dosimetry	Prince George's Community College Largo Md.	100	1984-1986
	Total Hours of Training:	500 hrs	

NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Structured Educational Program for Proposed Radiation Safety Officer (continued)**

b. Supervised Radiation Safety 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 Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Securing and controlling byproduct material	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Using administrative controls to avoid mistakes in administration of byproduct material	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Using emergency procedures to control byproduct material	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Disposing of byproduct material	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 35.100, 35.200	HPV Heart, P.A. Columbia, Md. # MD-27-036-01	5-2005 thru 4-2007

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Structured Educational Program for Proposed Radiation Safety Officer (continued)**

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
Jack McWatters, MD, RSO	MD-27-036-01

This license authorizes the following medical uses:

- [X] 35.100
- [X] 35.200
- [ ] 35.300
- [ ] 35.400
- [ ] 35.500
- [ ] 35.600 (remote afterloader)
- [ ] 35.600 (teletherapy)
- [ ] 35.600 (gamma stereotactic radiosurgery)
- [ ] 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Jack McWatters, MD, RSO	5-2005 thru 4-2007
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):	N/A	

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NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual
Jack McWatters, MD, RSO	MD-27-036-01

License/Permit lists supervising individual as:

☒ Radiation Safety Officer ☒ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

☒ 35.100 ☒ 35.200 ☐ 35.300 ☐ 35.400

☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)

☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

OR

☐ **4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license**

a. Provide license number.

b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete 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:

☐ **1. Board Certification**

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer

10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☒ **2. Structured Educational Program for Proposed Radiation Safety Officers**

☒ I attest that Jessie S. Sherrow, RT(N) has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

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NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)
Check one of the following:

☐ 3. **Additional Authorization as Radiation Safety Officer**

☐ I attest that _____ is an
Name of Proposed Radiation Safety Officer

☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section
Complete for all ***(check all that apply)***:

☒ I attest that Jessie S. Sizemore, RT(N) has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

☒ 35.100

☒ 35.200

☐ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

☐ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

☐ 35.300 parenteral administration of any beta-emitter, or a 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

☐ 35.400

☐ 35.500

☐ 35.600 remote afterloader units

☐ 35.600 teletherapy units

☐ 35.600 gamma stereotactic radiosurgery units

☐ 35.1000 emerging technologies, including:

_____
_____
_____

NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

Third Section
Complete for ALL

☒ I attest that Jessie S. Sizemore, RT(N) has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer

sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for HPV Heart, P.A.
Name of Facility

License/Permit Number: MD-27-036-01

Name of Preceptor	Signature	Telephone Number	Date
JACK W. MCWHITTERS	Jack W. McWhitters	410-997-9097	1/13/08

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MARYLAND
Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Pursuant to the Maryland Radiation Act, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

1. Name:	HPV Heart	3. License No.:	MD- 27-036-01
2. Address:	11085 Little Patuxent Parkway Suite 002 Columbia, Maryland 21044	4. Amendment No.:	21 (CODE 02201)
		5. Expiration Date:	January 31, 2013

6. Radioactive material element & mass number:	7. Chemical and/or physical form:	8. Maximum amount of radioactivity which licensee may possess at any on time:
A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01	A. Any radioactive material listed in Section G.100 of COMAR 26.12.01.01	A. As needed to perform diagnostic tests
B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01	B. Any radioactive material listed in Section G.200 of COMAR 26.12.01.01	B. As needed to perform diagnostic tests
C. Cobalt-57	C. Sealed Source	C. No source to exceed 15 millicuries
D. Gadolinium-153	D. Sealed Source	D. No source to exceed 500 millicuries

9. Authorized Use(s):
A. Any uptake, dilution, and excretion procedure approved in Section G.100 of COMAR 26.12.01.01.
B. Any imaging and localization procedure approved in Section G.200 of COMAR 26.12.01.01.
C&D. Calibration and/or reference source.

10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address as is required

11A. The radiation protection program shall be under the supervision of Jack McWatters M.D.
11B. Radioactive material shall be used by:

- Jack McWatters M.D.
- Keith Friedman, M.D.
- William Herzog, M.D.
- Adrian Le Preston, M.D.
- Michael E. Silverman, M.D.
- Alexander Chudnovsky, M.D.
- **Monica Aggarwal, M.D.**

West Virginia University
Radiation Safety Department

12/12/2008

U.S. Nuclear Regulatory Commission
Region I
Attn: Licensing Assistance Team
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Authorized User(s) Under WVUH US NRC Broad-Scope License

This letter dated December 12, 2008, hereby confirms that **Gary Marano, MD**, has been an authorized user of radionuclide at the department of nuclear medicine at West Virginia University Hospitals, Inc., under US NRC broad-scope license # 47-23066-02 since September, 2001. And also **Naresh Gupta, MD** was an authorized user at West Virginia University Hospitals, Inc., under the same US NRC broad-scope license # 47-23066-02 from February 1994 to February 2003. Dr. Gupta was previously authorized and Dr. Marano currently is authorized for:

- 10 CFR35.100, ***"Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directives is not required."***
- 10 CFR 35.200, ***"Use of unsealed byproduct material for imaging and localization studies for which a written directives is not required."***
- 10 CFR 35.300, ***"Use of unsealed byproduct materials for which a written directives is required."***

If any additional information is needed, please contact West Virginia University Radiation Safety Department at (304)293-3413.

Sincerely;

Nasser Razmianfar
Director and Radiation Safety Officer

Robert C. Byrd Health Sciences Center
West Virginia University
WVU Hospitals

G-139 Health Sciences North
PO Box 9006
Morgantown, WV 26506-9006

Phone: 304-293-3413
Fax: 304-293-4529