



5 June 2014

U.S. Nuclear Regulatory Commission  
Nuclear Materials Licensing Section  
Region III  
2443 Warrenville Road  
Lisle, IL 60532-4351

RE: Amendment RAM license #09-32781-02MD  
Triad Isotopes, Inc.- Warren  
2252 East 14 Mile Road  
Warren, MI 48092

Dear License Reviewer:

Please amend the above referenced material license to reflect the following modification:

1. Please change the RSO in this location, effective immediately, to Erica Sztangret, PharmD. Ms. Sztangret is currently listed as an authorized nuclear pharmacist on this license. By virtue of past training and experience, Ms. Sztangret satisfies the requirements listed in 10 CFR 35.50 for Radiation Safety Officer. Triad Management agrees to provide the RSO with sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the duties as assigned. A signed preceptor attestation, NRC Form 313a (RSO), is attached to certify Ms. Sztangret's ability to function independently as the RSO.
2. Please remove as Authorized Nuclear Pharmacist Joseph Remesz-Guerrette and C. Dewayne Boyd

We appreciate an expedited review of this request. Please contact Brigette Nelson, Senior Director, Quality and Safety, if you have any questions at 904-647-5161. A completed copy of the amendment request can be sent to the Triad Corporate offices at 4205 Vineland Rd, Suite L1, Orlando, FL 32811 and/or to the Warren pharmacy address to the RSO's attention.

Thanks,

A handwritten signature in black ink, appearing to read "Brigette", is written over a large, faint, circular watermark that is partially visible in the background of the page.

Brigette Nelson, PharmD, BCNP, FAPhA  
Sr. Director, Quality & Safety  
Triad Isotopes, Inc.  
(904) 647-5161 (office)  
(407) 455-6732 (fax)  
Cc: file, Shannon Julian, Neil Stubbs, Erica Sztangret

RECEIVED JUN 05 2014

4205 Vineland • Suite L1 • Orlando, FL 32811  
www.triadisotopes.com

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

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (05/31/2015)

Name of Proposed Radiation Safety Officer

Erica Sztangret, PharmD

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

**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		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>		

+ 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).

**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
This license authorizes the following medical uses:	
<input type="checkbox"/> 35.100	<input type="checkbox"/> 35.200
<input type="checkbox"/> 35.500	<input type="checkbox"/> 35.300
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.400
	<input type="checkbox"/> 35.600 (remote afterloader)
	<input type="checkbox"/> 35.600 (teletherapy)
	<input type="checkbox"/> 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	Michael Klug, R.Ph, RSO	11/2013-6/2014
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Michael Klug, R.Ph., RSO	11/2013-6/2014
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Michael Klug, R.Ph., RSO	11/2013-6/2014
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

**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 <i>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.)</i>	License/Permit Number listing supervising individual
Michael Klug, R.Ph., RSO	09-32781-02MD

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 \_\_\_\_\_ 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**

**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 Erica Sztangret, PharmD 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 Erica Sztangret, PharmD 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:

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

**AND**


**Third Section  
Complete for ALL**

I attest that Erica Sztangret, PharmD 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 Triad Isotopes, Inc. - Detroit  
Name of Facility

License/Permit Number: 09-32781-02MD

Name of Preceptor	Signature	Telephone Number	Date
Michael Klug		(586) 268-5300	6/4/2014

From: (904) 562-8260  
Brigette Nelson  
Triad Isotopes  
1554 Nottingham Knoll  
  
JACKSONVILLE, FL 32225

Origin ID: USTA



Ship Date: 05JUN14  
ActWgt: 1.0 LB  
CAD: 2600876/INET3490

Delivery Address Bar Code



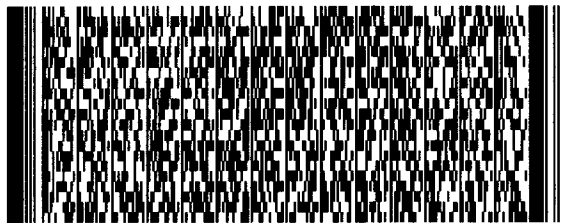
SHIP TO: (904) 562-8260  
**License Review**  
**US NRC Region III**  
**2443 WARRENVILLE RD**  
  
**LISLE, IL 60532**

**BILL SENDER**

Ref #  
Invoice #  
PO #  
Dept #

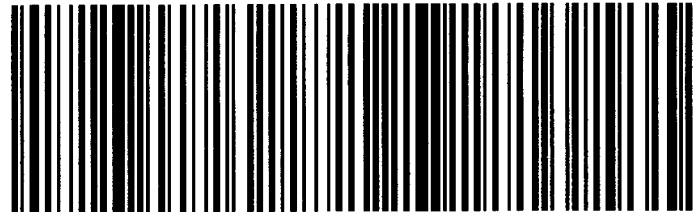
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