



Tuesday, April 7, 2015

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Via: Fed Ex

RE: Amendment RAM license #09-31406-01MD *1030-38269*
Triad Isotopes, Inc.
180 Pepes Farm Road
Milford, CT 06460

REG 1040915M1017

Dear Mr. Gallagher:

Per your conversation with Craig Kinne, Triad Corporate RSO on 4/2/2015 you requested additional information on our previous RAM license amendment request to name Erica Sztangret as RSO for RAML #09-31406-01MD. In addition you also requested additional information on our decommissioning timeline and a listing of radioisotopes, present at the location, with greater than a 120 day half-life.

Please find below as requested the additional information to amend the above referenced materials license to reflect the following modifications:

1. Please add Erica Sztangret, PharmD as an authorized nuclear pharmacist (ANP) to this RAM license. Dr. Sztangret was initially approved and added as an ANP under RAM license Amendment 4, issued January 3, 2013. Our RAML renewal application, submitted 2/12/2013, also listed Dr. Sztangret as an ANP, however upon issue of RAM license Amendment 6 which renewed our RAM license Dr. Sztangret was inadvertently left-off the list of approved ANPs.
2. Please change the RSO in this location, effective immediately, to Erica Sztangret, PharmD. Dr. Sztangret is currently requested as above to be re-listed as an authorized nuclear pharmacist on this license. Dr. Sztangret will be the temporary radiation safety officer per 10 CFR 35.24(c) while the location is prepared for final decommissioning over the next 2 months. By virtue of past training and experience, Dr. Sztangret satisfies the requirements listed in 10 CFR 35.50 for Radiation Safety Officer. Triad Management agrees to provide Dr. Sztangret with sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the duties as assigned. A signed Radiation Safety Officer Delegation of Authority is attached to certify Dr. Sztangret's ability to function independently as the RSO.

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NUCLEAR MATERIALS-002



Please find below as requested the additional information for (1) known byproduct material, present at the location, with a half-life greater than 120 days and (2) decommissioning timeline for 180 Pepe's Farm Road, Milford Connecticut.

1. Eu-152: This is a known contaminate in the Sm-153 Quadramet product vial waste. Only residual amounts remain in each dispensed vial. Total estimated activity is less than 50 microcuries.
2. Sealed sources – Total activity less than 300 microcuries

Timeline for decommissioning activities at 180 Pepe's Farm Road, Milford Connecticut is the following:

1. Return Mo-99 / Tc-99m generators to manufacturer (i.e. Covidien). **Completed** 1/22/2015.
2. Survey "decay in storage" biomedical waste to ensure radiation levels are at or below background levels. Projected completion date 04/24/2015.
3. Dispose of biomedical waste through licensed waste vendor (i.e. Stericycle). Projected completion date 05/29/2015.
4. Disposal of sealed sources and Quadramet dispensing vial waste through licensed waste vendor (e.g. Bionomics). Projected completion date 06/20/2015.
5. Perform final contamination and dose rate surveys of facility to include all restricted areas, equipment in restricted areas and unrestricted areas. Projected completion date 04/24/2015.
6. Submit final decommissioning surveys and request for RAML termination. Projected completion date 06/30/2015.

Please contact me at 407-455-6704 or via e-mail at wmccormick@triadisotopes.com if there are any questions regarding this amendment and response to additional information.

You can also contact Dr. Fred Gattas, Triads Senior Director of Quality and Safety at 901-652-3733 (email fgattas@triadisotopes.com) or Craig Kinne, Triads Corporate Radiation Safety Officer at 407-257-8998 (email ckinne@triadisotopes.com).

Sincerely

William P. McCormick
SVP/General Counsel
Triad Isotopes, Inc.



Triad Isotopes®

patient focused. | community driven.

Attachment

cc: S. Julian, Debra Rogers, Erica Sztangret, Quality and Safety



Attachment I
Sztangret Radiation Safety Officer Delegation of Authority

RSO Delegation of Authority

29 January 2015

To: Erica Sztangret

From: William P. McCormick, SVP and General Counsel, Triad Isotopes, Inc.

Effective as of January 29, 2015, You, Erica Sztangret, have been appointed the Radiation Safety Officer ("RSO") and are responsible for ensuring the safe storage, use, handling, packaging, shipping and transportation of radioactive materials for the Triad Isotopes, Inc. pharmacy located at

**Triad Isotopes, Inc.
180 Pepes Farm Road
Milford, CT 06460**

You are responsible for managing the radiation protection program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with Triad's radiation protection program rules. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements to do so and shutting down operations when justified by radiation safety issues. You are required to notify management if employees do not cooperate and do not properly address radiation safety issues. In addition, you are free to raise issues with the United States Nuclear Regulatory Commission at any time. It is estimated that you will spend eight (8) hours per week conducting radiation protection activities.

The RSO is responsible for establishing, implementing, managing, and auditing the radiation protection program, including employee training and ALARA program implementation, identifying and investigating radiation safety problems, initiating recommendations and ensuring implementation of corrective actions, ensuring compliance with all regulatory requirements, termination of unsafe practices and conditions, timely reporting of safety or employee incidents involving radiation exposure and timely reporting of all quality related incidents to the Triad Quality and Safety management team. The RSO must always report incidents to Triad Isotopes incident reporting system and if required by regulation or license commitment, to the United States Nuclear Regulatory Commission.

Triad Management agrees to provide you, as the RSO of the above pharmacy, with sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the following duties:

- a) Identification of radiation safety problems, and,
- b) Initiation of recommendations, or provide corrective actions, and,
- c) Stopping unsafe operations, and,
- d) Verification of timely implementation of corrective actions, and,
- e) Assumption of the full responsibilities for radiation protection and safety programs.

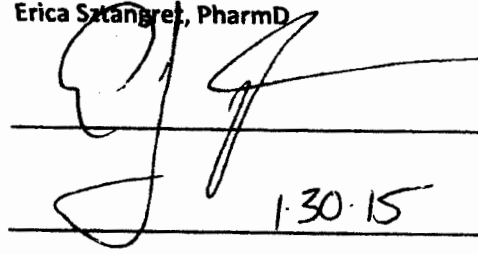


You agree, by your signature below as RSO, to accept responsibility for implementing the radiation protection program and shall ensure that radiation safety activities are being performed in accordance with Triad's Policies and Procedures and the United States Nuclear Regulatory Commission, regulatory requirements.

I accept these RSO responsibilities;

Pharmacy RSO Name (printed): Erica Stangret, PharmD

Pharmacy RSO (Signature):



Date:

1-30-15

SVP/ General Counsel: William P. McCormick

SVP / General Counsel Signature:



Date:

1/30/15
