Triad Isotopes®
patient focused. community driven.

3 November 2016

Kevin Null
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.- Detroit
2252 East 14 Mile Road
Warren, MI 48092

Dear Mr. Null:

This letter is to provide additional information requested with Conversation Record dated 11/2/2016 pertinent to the Amendment Request for Radioactive Materials License 09-32781-02MD, Docket No. 030-38278.

1. Describe the safety-related facilities and equipment that will be used for handling and compounding iodine-123 capsules. For Example, will you be doing compounding in an enclosed, filtered system, e.g. glove box?

   Triad Isotopes will be compounding the I-123 capsules in an enclosed glove box as detailed in item 9 of our RAML renewal application dated 2/12/2013.

2. Describe the monitoring and filtration of iodine-123 air effluent that will be created as a result of the compounding. Describe your processes/procedures for checking filters for saturation and periodic change-out.

   Triad Isotopes is expanding the air monitoring program detailed in item 9 of the RAML renewal application dated 2/12/2013 to include I-123 air monitoring for I-123 compounding activities. The program will be expanded to include the use of a Co-57 standard and using a region of interest for I-123 when counting air monitoring samples. Samples will be counted no later than 24 hours after compounding activities.

3. Describe/submit a bioassay program for iodine-123.

   Triad Isotopes will continue the bioassay program that is detailed in item 9 of the RAML renewal application dated 2/12/2013 and expand to include monitoring of I-123 after compounding activities. The program will be expanded to include the use of a Co-57 standard and using a region of interest for I-123 when performing bioassay counting. Bioassays of the authorized nuclear pharmacist will be measured no later than 24 hours after any compounding activities.

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4. Describe the expected frequency of compounding iodine-123, and maximum quantities that you expect will be processed at any one time.

   Triad Isotopes is currently not requesting an increase in the already approved possession limit of 250 mCi of the current RAM license (Amendment 9). If an increase in customer demand requires an increase in the authorized posse4ssion limit, a separate request will be made at that time.

5. Identify the authorized users who will compound iodine-123.

   All compounding of iodine will only be performed by authorized nuclear pharmacists authorized by the current amendment 9.

Please contact Neil Stubbs, Pharmacy Safety Specialist, if you have any questions at 419-705-1359. A completed copy of the amendment request can be sent to the Triad Corporate offices ATTN: Legal at 4205 Vineland Road, Suite L1, Orlando, FL. 32811 and/or to the Warren pharmacy address to the RSO's attention.

Thanks,

Neil Stubbs, CNMT, RT(N)
Pharmacy Safety Specialist
Triad Isotopes, Inc.
(419) 705-1359: office/cell
(407) 455-6732: fax
Cc: file, Debra Rogers, Erica Sztangret, Craig Kinne

Taylor, Tiresha

From: Tomczak, Tammy
Sent: Thursday, November 03, 2016 4:38 PM
To: Taylor, Tiresha
Subject: FW: RE: RE: additional info for compounding iodine-123
Attachments: Detroit.Amendment Request.add I-123 compounding authorization.response additional information conversation record.11-2-2016.pdf

Can you please let Kevin know the accession number when this is completed?

Thank you,
Tammy

From: Null, Kevin
Sent: Thursday, November 03, 2016 4:36 PM
To: Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
Subject: FW: RE: RE: additional info for compounding iodine-123

Hi Tammy, the attached document needs to get into ADAMS. Please let me know what the ADAMS number is.

Thanks,

Kevin

From: Neil P. Stubbs [mailto:NStubbs@triadisotopes.com]
Sent: Thursday, November 03, 2016 2:42 PM
To: Null, Kevin <Kevin.Null@nrc.gov>
Cc: Erica G. Sztangret <ESztangret@triadisotopes.com>
Subject: [External_Sender] RE: RE: additional info for compounding iodine-123

Kevin,

Attached is the response for additional information from Conversation Record dated 11/2/2016. If you require any additional information, please do not hesitate to contact me.

Neil Stubbs CNMT, RT(N)
Pharmacy Safety Specialist
Triad Isotopes, Inc.
Pottstown, PA
(419) 705-1359 (office/cell)

From: Null, Kevin [mailto:Kevin.Null@nrc.gov]
Sent: Thursday, November 3, 2016 10:12 AM
To: Neil P. Stubbs <NStubbs@triadisotopes.com>
Subject: RE: RE: additional info for compounding iodine-123

thanks

From: Neil P. Stubbs [mailto:NStubbs@triadisotopes.com]
Sent: Thursday, November 03, 2016 8:52 AM
To: Null, Kevin <Kevin.Null@nrc.gov>
Subject: [External_Sender] RE: additional info for compounding iodine-123

Kevin,

I will work on this today and try and get to you before COB. Thanks.

Neil Stubbs CNMT, RT(N)
Pharmacy Safety Specialist
Triad Isotopes, Inc.
Pottstown, PA
(419) 705-1359 (office/cell)

From: Null, Kevin [mailto:Kevin.Null@nrc.gov]
Sent: Wednesday, November 2, 2016 11:24 AM
To: Neil P. Stubbs <NStubbs@triadisotopes.com>
Subject: additional info for compounding iodine-123

Hi Neil,

Attached is the additional information that I need.

If you could possibly provide a response by COB tomorrow, that would be great.

Please prepare a letter response, with original signature.

Scan in the letter response and e-mail to me at kevin.null@nrc.gov.

Call or e-mail me if you have any questions.

Please confirm receipt of this e-mail.

Thanks,

Kevin Null
USNRC, Region III
630-829-9854