Triad Isotopes
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10 May 2011

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

RE: Amendment RAM license #09-32781-03-MD
Triad Isotopes, Inc.- Saginaw
2795 Universal Drive
Saginaw, MI 48603

Dear License Reviewer:

The following amendment request to license #09-32781-03MD is submitted below:

1. Please, add as authorized nuclear pharmacist to this RAM license Joseph Gatton. Mr. Gatton will be providing relief pharmacist coverage in this location. Mr. Gatton is listed on Ohio RAM license # 02500490000. A copy of Mr. Gatton's Michigan RPh license #5302033763 is attached. You will find a copy of the referenced RAM license attached, as well.

We appreciate an expedited review of this request. Please contact Brigette Nelson, Senior Director, Quality and Safety, if you have any questions at 904-220-7210. A completed copy of the amendment request can be sent to the Triad Corporate offices at 200 S. Orange Ave., Ste. 2100, Orlando, FL 32801 and/or to the Saginaw pharmacy address to the RSO's attention.

Thanks,

Brigette Nelson, MS, PharmD, BCNP
Sr. Director, Quality & Safety
1554 Nottingham Knoll Drive
Jacksonville, FL 32225
(904)-220-7210 (office)
(904)-220-6980 (fax)
(904)-562-8260 (cell)
bnelson@triadisotopes.com
Cc: Shannon Julian, file, Neil Stubbs

RECEIVED MAY 12 2011

OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

Ted Strickland/Governor

Alvin D. Jackson, M.D./Director of Health

OCT 29 2010

Attn: Radiation Safety Officer
Triad Isotopes
3222 Hill Avenue
Toledo, OH 43607

Re.: License No. 02500490000

Dear Radiation Safety Officer:

Enclosed is Amendment #33 to your State of Ohio Radioactive Materials License No. 02500490000 in accordance with your amendment request.

Please review the license to ensure that you understand all of the conditions. If you have any questions or detect any errors, do not hesitate to contact the Bureau of Radiation Protection at (614) 644-2727.

Your license will expire on 10/01/2015. You must conduct your radioactive material program in accordance with your license, representations made in your license application and the Ohio Administrative Code. In particular, you must:

1. Notify the Bureau of Radiation Protection in writing, within thirty days:
   a. When an authorized user or Radiation Safety Officer discontinues duties under the license or has a name change.
   b. When the licensee's mailing address changes.
2. Notify the Bureau of Radiation Protection promptly, in writing, to request termination of license.
   a. When you decide to terminate all activities involving radioactive materials authorized under your license.
   b. If you decide not to possess or use the authorized radioactive material.
3. Request to obtain a license amendment before you:
   a. Receive or use radioactive material not authorized on your license.
   b. Change Radiation Safety Officers.
   c. Order radioactive material of different form of radionuclide or in excess of the authorized amount.
   d. Add or change the areas of use, which involve the use of radioactive materials requiring a written directive.
   e. Add or change areas or addresses of use identified in the license application or on the license.
   f. Change ownership of the organization.
   g. Permit anyone to work as an authorized user who is not listed on your license.
4. Submit a complete license Renewal Application or Termination Request at least 90 days before the expiration date of your license.

The Bureau of Radiation Protection will periodically inspect you. Failure to conduct your radioactive material program in accordance with State of Ohio regulations, license conditions and representations made in your license application may result in enforcement actions against you.

Sincerely,

Mark Light
Licensing and Inspection Supervisor
Bureau of Radiation Protection

Amendment No. 33

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1. Triad Isotopes, Inc.	3. 02500490000
	EXPIRATION DATE
2. 200 South Orange Avenue Suite 2100 Orlando, Fl 32801	4. October 1, 2015
	BUREAU FILE / ID NUMBER
	5. 500606 / 4181

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material, atomic nos. 3 to 83, limited to isotopes with half-lives of less than 120 days, excluding Iodine-131, Yttrium-90, Molybdenum-99, Technetium-99m.	A. Any radiopharmaceutical form	A. 185 GBq (5 Ci)
B. Yttrium-90	B. Any form	B. 37 GBq (1.0 Curie)
C. Iodine-131	C. Any radiopharmaceutical form	C. 92.5 GBq (2.5 Curies)
D. Technetium-99m	D. Any radiopharmaceutical form	D. 7.4 TBq (200 Curies)
E. Molybdenum-99	E. Solid	E. 7.4 TBq (200 Curies)
F. Any radioactive material permitted by rule 3701:1-46-11 of the Ohio Administrative Code	F. Prepackaged units for in vitro diagnostic tests	F. 740 MBq (20 mCi)
G. Any radioactive material permitted by rule 3701:1-58-26 of the Ohio Administrative Code	G. Sealed Sources	G. 3.7 GBq (100 mCi)
H. Uranium (depleted in the isotope uranium-235)	H. Metal encased in stainless steel	H. 600 kilograms
I. Any radioactive material, atomic nos. 3 to 83, inclusively	I. Analytical samples	I. 3.7 GBq (100 mCi)

9. Authorized Use

A. – E. Radioactive material that will be used for preparation, dispensing, and/or distributing prepared radioactive drugs to authorized recipients.

Unused generators may be redistributed to persons licensed pursuant to rule 3701:1-58-34 of the Ohio Administrative Code. Generators redistributed for human use will not be redistributed beyond the generator's expiration date.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 3 License Number: 02500490000 BUREAU FILE / ID NUMBER: 500606 / 4181 Amendment No. 33

9. Authorized Use

F. **Redistribution to specific licensees or general licensees pursuant to rule 3701:1-46-11 of the Ohio Administrative Code provided the packaging and labeling remain unchanged.**

G. **Check, calibration and reference sources for licensee use and for redistribution to authorized recipients.**

H. **Shielding for Mo-99/Tc-99m generators.**

I. **Leak test samples from clients.**

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

3222 Hill Avenue Suite A
Toledo, Ohio 43607

11. The Radiation Safety Officer for this license is: **Darlene Rubin, R.Ph.**

12. Licensed material shall be limited by the procedures outlined in Sections 6, 7, and 8 of this license. Materials may only be used by, or under the supervision of, the below listed individual(s) designated in writing:

Authorized Nuclear Pharmacists

A. **Alexander, Donnia R.Ph.**
B. **Ancona, Peter R.Ph.**
C. **Armstrong, Robert R.Ph.**
D. ***Barr, Erin D. R.Ph.***
E. **Burzynski, James R.Ph.**
F. **Coats, Lisa R.Ph.**
G. **Debelak, Kenneth J. R.Ph.**
H. **Eberly, Kerry R.Ph.**
I. **Gavin, Jason R.Ph.**
J. ***Gatton, Joseph M. R.Ph.***
K. **Goetting, Christine L. R.Ph.**
L. **Herrmann, David R.Ph.**
M. **Kliche, Todd A. R.Ph.**
N. **Klug, Michael R.Ph.**
O. **Koss, Lisa L. R.Ph.**
P. **Lutes, David R. R.Ph.**
Q. **McLeland, David R.Ph.**
R. **Ng, Valerie R.Ph.**
S. **Olsen, Shanna R.Ph.**
T. **Price, Kirk R.Ph.**
U. **Prusha, Daren R.Ph.**
V. **Remesz-Guerrette, Joseph R.Ph.**
W. **Ross, Debra A. R.Ph.**
X. **Rubin, Darlene R.Ph.**
Y. **Schnur, Crystal Pharm.D.**
Z. **Schork, Robert R.Ph.**
AA. ***Schroeder, Michael L. R.Ph.***
BB. **Skripac, David R.Ph.**
CC. **Treolo, Christine R.Ph.**
DD. **Vaught, Deirdre J. R.Ph.**
EE. **Vaught, Jonathan R.Ph.**

13. **The licensee is authorized to transport licensed material in accordance with Chapter 3701:1-50 of the Ohio Administrative Code.**

14. Sealed Sources

A. **Sealed sources shall be tested in accordance with rule 3701:1-38-24 of the Ohio Administrative Code.**

B. ***The licensee is authorized to collect leak test samples for analysis. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Director, the NRC or an Agreement state to perform such services.***

15. **In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in rule 3701:1-40-17 of the Ohio Administrative Code, for establishing decommissioning financial assurance.**

16. **Notwithstanding the requirements of rule 3701:1-46-43 (C) of the Ohio Administrative Code, the licensee may re-distribute alpha, beta, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to rule 3701:1-46-43 of the Ohio Administrative Code, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and the label.**

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 3 of 3
	License Number: 02500490000
	BUREAU FILE / ID NUMBER: 500606 / 4181
	Amendment No. 33

17. **Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.**

A. **Renewed in its entirety; application dated: July 9, 2010 (Amendment #32)**

B. ***Letter dated October 8, 2010 (Amendment #33)***

For the Ohio Department of Health

DATE: 10/27/10 **BY:**

Robert E. Owen, Chief
Bureau of Radiation Protection
on behalf of the Director of Health



VERIFY A LICENSE/REGISTRATION

Name and Address

Name : JOSEPH MICHAEL GATTON
Address : Steamboat Springs, CO 80487

Profession and License/Registration Information

Profession : Pharmacy **Type :** Pharmacist

Permanent ID #	Status	Issue Date	Expiration Date
5302033763	Active	11/09/2001	06/30/2012

Complaint(s)

Open Formal Complaints
None

Disciplinary Action

Disciplinary Action
None

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DISCLAIMER

The **Issue Date** is the date the license/registration was first issued. Please note this information is not always available in the database. The **Expiration Date** given above is the date the license/registration expired or will expire. The license/registration may not have been active from the **Issue Date** to the **Expiration Date.** There may have been periods of non-licensure or registration.

For those licensees/registrants who have actions listed in the **Disciplinary Action** section above, the date the licensee/registrant complied with their board order is listed for all disciplinary actions subsequent to January 1, 2005. The date of compliance is not listed for disciplinary actions that began prior to that date. You should check with our office to confirm the status of the cases if the date of compliance is not listed.

You may fax a request for additional information under the Freedom of Information Act (FOIA) at 517-241-1212 or contact Mary E. Hess, Asst. FOIA Coordinator at BHP-FOIAINFO@michigan.gov for directions on how to obtain more information regarding the license/registration history or disciplinary actions.

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From: (904) 220-7210
Brigette Nelson
Triad Isotopes
1554 Nottingham Knoll

Jacksonville, FL 32225

Origin ID: USTA

FedEx Express

J111511022502225

Ship Date: 10MAY11
ActWgt: 1.0 LB
CAD: 2600876/INET3130

Delivery Address Bar Code

SHIP TO: (904) 562-8260 BILL SENDER

Region III Licensing
U.S NRC Materials Licensing Section
2443 WARRENVILLE RD

LISLE, IL 60532

Ref #
Invoice #
PO #
Dept #

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