

8 July 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 requests to license #09-32781-03MD are submitted below:

1. Please, add Robert Masa as an Authorized Nuclear Pharmacist. Mr. Masa's ANP training and experience is attached for your reference, as is the verification of his Michigan pharmacist's license #5302040548. Mr. Masa completed experiential training hours in the Triad Isotopes, Inc. nuclear pharmacy in Elk Grove Village, IL and a preceptor attestation is attached.
2. Please, remove as Authorized Nuclear Pharmacists James Burzynski, Eric Lester, and Selina Mirjavadi.

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

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200 S. Orange Avenue • Suite 2100 • Orlando, FL 32801-3439
phone 407.455.6700
www.triadisotopes.com

NRC FORM 313A (ANP) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]		

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed
Robert Masa	Michigan

PART I -- TRAINING AND EXPERIENCE
(Select one of the two 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 nuclear pharmacy uses.

- 1. **Board Certification**
 - a. Provide a copy of the board certification.
 - b. Skip to and complete Part II Preceptor Attestation.
- 2. **Structured Educational Program for Proposed Authorized Nuclear Pharmacist**
 - a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Purdue University	85	2/11 - 5/11
Radiation protection	Purdue University	46	2/11 - 5/11
Mathematics pertaining to the use and measurement of radioactivity	Purdue University	23	2/11 - 5/11
Chemistry of byproduct material for medical use	Purdue University	40	2/11 - 5/11
Radiation biology	Purdue University	21	2/11 - 5/11

Total Hours of Training: 215

NRC FORM 313A (ANP)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	Triad Isotopes 601-F Busse Rd Elk Grove Village, IL 60007 054.017338	40	2/11 - 5/11
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	Triad Isotopes 601-F Busse Rd Elk Grove Village, IL 60007 054.017338	40	2/11 - 5/11
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Triad Isotopes 601-F Busse Rd Elk Grove Village, IL 60007 054.017338	300	2/11 - 5/11
Using administrative controls to avoid medical events in administration of byproduct material	Triad Isotopes 601-F Busse Rd Elk Grove Village, IL 60007 054.017338	100	2/11 - 5/11
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Triad Isotopes 601-F Busse Rd Elk Grove Village, IL 60007 054.017338	100	2/11 - 5/11

Total Hours of Experience: 580

Supervising Individual
Darren Prusha, Pharm.D.

c. Go to and complete Part II Preceptor Attestation.

NRC FORM 313A (ANP)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

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:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Nuclear Pharmacist
10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

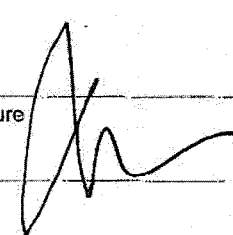
I attest that Robert Masa has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist
educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Triad Isotopes, Elk Grove Village, Illinois
Nuclear Pharmacy or Medical Facility

054.017338 IL-0117-01
License/Permit Number

Name of Preceptor Darren Prusha	Signature 	Telephone Number (847) 593-5206	Date 06/30/2011
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VERIFY A LICENSE/REGISTRATION

Name and Address			
Name : ROBERT MICHAEL MASA			
Address : South Elgin, IL 60177			
Profession and License/Registration Information			
Profession : Pharmacy		Type : Pharmacist	
Permanent ID #	Status	Issue Date	Expiration Date
5302040548	Active	06/24/2011	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/registant 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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PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

Robert Masa

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

May 27, 2011

Yara D. Weatherman

Director of Nuclear Pharmacy Training Programs

May 27, 2011


Robert Masa
Triad Isotopes
601-F Busse Road
Elk Grove, IL 60007

Dear Robert,

We are pleased to provide the enclosed certificate to recognize formally your completion of the Purdue University Nuclear Pharmacy Certificate Program. You have successfully completed all requirements of both the distance and on-campus components of the program as set forth by the Nuclear Regulatory Commission and Purdue University. We enjoyed the brief opportunity to share our knowledge from the world of academia. We wish you the very best for a gratifying and successful professional career.

As you continue on in your career, please do not hesitate to let us know if we can be of any assistance to you – we consider you part of the “Purdue family” and we look forward to hearing from you in the future!

Sincerely,



Kara Duncan Weatherman, PharmD, BCNP, FAPhA
Clinical Assistant Professor of Pharmacy Practice
Nuclear Pharmacy Programs
Purdue University



Nuclear Pharmacy Programs, Department of Pharmacy Practice

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

*Robert Masa
Certificate Program #73
Campus session: May, 2011*

College of Pharmacy
Department of Pharmacy Practice
Nuclear Pharmacy Programs
Purdue University
West Lafayette, Indiana 47907

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Nuclear Pharmacy Certificate Program Outline:

Contents:

1. Program Concept
2. Synopsis of Clock Hours of Training
3. DVD and Workbook (Self-Study Portion) Clock Hours
4. Campus Portion Laboratory and Lecture Clock Hours
5. Instructional Staff

Abbreviations Used:

RPI:	Radiation Physics / Instrumentation
RP:	Radiation Physics
MA:	Math
RB:	Radiation Biology
RC:	Radiochemistry

Nuclear Pharmacy Certificate Program Concept

The School of Pharmacy and Pharmacal Sciences at Purdue University offers a Certificate Program in Nuclear Pharmacy. The goal of the certificate program is to provide fundamental information to post-graduate pharmacists that will serve as a foundation for attaining competency as practitioners in nuclear pharmacy. The program follows the guidelines for nuclear pharmacy training prepared by nuclear pharmacists in the American Pharmaceutical Association, Section on Nuclear Pharmacy Practice.

This student completed the videotaped distance learning portion of the certificate program. This training module utilizes self-study concepts, including lectures on videotape and correlated reading assignments. The nuclear pharmacy manager, or other qualified nuclear pharmacist at the practice site, serves as the clinical instructor and mentor for the pharmacist in training. This portion is self-paced by the trainee with regular examinations returned to Purdue to assist in monitoring the learning process.

Form Updated 08/10

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: **ROBERT MASA**
 Date issued: **MAY 27, 2011**

				Breakdown of Course Content in Clock Hours				
Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radio-pharmaceutical Chemistry
Purdue University	February, 2011 Thru May, 2011	DVD-Workbook	150	51	33	13	21	32
	May, 2011	On-Site	65	34	13	10	0	8
Total Hours Received			215					
Hourly breakdown by topic				85	46	23	21	40

* This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Director of Nuclear Pharmacy Training Programs:

Kara D. Weatherman

Kara Duncan Weatherman, PharmD, BCNP, FAPhA
 Clinical Assistant Professor of Pharmacy Practice
 Purdue University
 Nuclear Pharmacy Programs

**Nuclear Pharmacy Certificate Program
DVD and Workbook (Self-Study Portion) Clock Hours**

DVD	Instructor	Hours
Physics and Overview Disc 1-4	Dr. Stanley M. Shaw	RP/I: 11 RP: 4 MA: 1
Radiation Protection Disc 1-2	Dr. Paul Ziemer	RP: 8
Instrumentation Disc 1	Dr. Kara Weatherman	RP/I: 4
Radiopharmaceuticals Disc 1-3	Dr. Kara Weatherman	RP: 3 RB: 3 RC: 6
Math Review Disc 1	Dr. Kara Weatherman	MA: 4
Radionuclide Generators Disc 1	Ms. C. Anne Smith	RP/I: 2 MA: 2
Kit Preparation Disc 1	Dr. Kara Weatherman	MA: 4
Quality Control Disc 1	Ms. C. Anne Smith	RP/I: 2 MA: 1 RC: 1
Radiopharmaceutical Formulations (Disc 1)	Mr. James Ponto	RP/I: 1 MA: 1 RC: 2
Health Physics and Recordkeeping (Disc 1)	Dr. Brigitte McGhee	RP/I: 2 RP: 2
Radiation Biology Disc 1-3	Dr. Stanley M. Shaw	RP/I: 3 RB: 9
Late Effects of Ionizing Radiation (Disc 1)	Dr. William R. Widmer	RP/I: 1 RB: 3
Radiation Safety in Pregnant and Breastfeeding Patients (Disc 1)	Mr. James Ponto	RP/I: 1 RP: 3
Adverse Drug Reactions (Disc 1)	Mr. James Ponto	RP/I: 1 RP: 2 RB: 1
Radiopharmaceutical Updates (Disc 1-3)	Dr. Richard Kowalsky	RP/I: 9 RB: 3
Blood Pool Imaging (Disc 1)	Dr. Ronald Calahan	RP/I: 1 MA: 1 RC: 2
Clinical PET	Dr. Laura Boles Ponto	RP/I: 1 RP: 1 RC: 2
Nuclear Pharmacy Regulations (Disc 1-2)	Dr. Stanley M. Shaw	RP: 8
Radiopharmaceutical Chemistry (Disc 1-4)	Dr. Mark A. Green	RC: 16

**Nuclear Pharmacy Certificate Program
On-Campus Portion Clock Hours**

Session	Instructor	
On-Campus portion:	Dr. Kara Weatherman	RP/I: 34 RP: 13 MA: 10 RB: 0 RC: 8

**Nuclear Pharmacy Certificate Program
Instructional Staff**

Dr. Stanley M. Shaw, Ph.D.
Professor of Nuclear Pharmacy
Purdue University
West Lafayette, Indiana 47097

Brigette McGhee
Staff Pharmacist
Central Pharmacy Services, Inc
Jacksonville, FL

Dr. Paul Ziemer, Ph.D.
Professor Emeritus of Health Physics
Purdue University
West Lafayette, Indiana 47097

Dr. William R. Widmer, D.V.M.
Associate Professor of Diagnostic Imaging
Department of Veterinary Clinical Sciences
School of Veterinary Medicine
Purdue University
West Lafayette, Indiana 47907

Dr. Kara Weatherman, PharmD, BCNP, FAPhA
Assistant Professor of Nuclear Pharmacy
Purdue University
West Lafayette, Indiana 47907

Dr. Richard J. Kowalsky, PharmD, BCNP, FAPhA
Associate Professor Pharmacy and Radiology
University of North Carolina
Chapel Hill, North Carolina 27599

Ms. C. Anne Smith, M.S., B.C.N.P.
Nuclear Pharmacy Program Director
Purdue University
West Lafayette, IN 47907

Dr. Ronald Callahan, PhD
Harvard Medical School
- Associate Professor of Radiology
Massachusetts General Hospital
- Director of Nuclear Pharmacy
Boston, Massachusetts 02114

Mr. James A. Ponto, M.S., B.C.N.P.
Division of Nuclear Medicine
University of Iowa Hospitals and Clinics
Iowa City, Iowa 52242

Dr. Laura Boles Ponto, PhD
Division of Nuclear Medicine
University of Iowa Hospitals and Clinics
Iowa City, Iowa 52242

Dr. Mark A Green, PhD
Professor of Industrial and Physical Pharmacy
Division of Nuclear Pharmacy
Purdue University
West Lafayette, Indiana 47907

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

Jacksonville, FL 32225

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LISLE, IL 60532

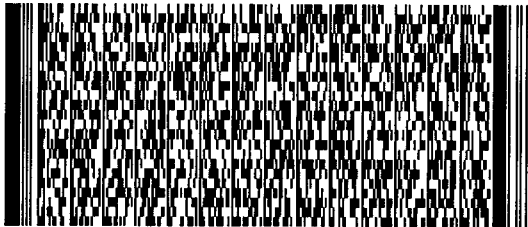
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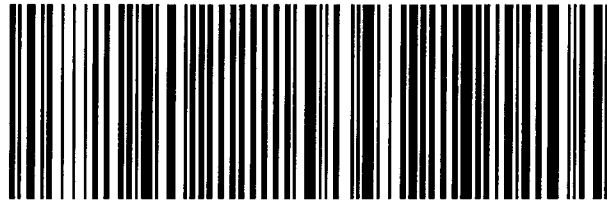
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