

25 January 2011

United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415
Attn: Dennis Lawyer, dennis.lawyer@nrc.gov

RE: Triad Isotopes, Inc.- Milford RAM License #~~24-04206-15MD~~ ^{09-31406-01MD} *Neil*
180 Pepes Farm Road
Milford, CT 06460

Br 2

03038269

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REGION 1
2011 JAN 28 PM 12: 25

Dear Mr. Lawyer:

The purpose of this correspondence is to request an amendment to RAM License #~~24-04206-15MD~~ ^{09-31406-01MD} *Neil*, as outlined below:

1. Please, add authorized nuclear pharmacist Nanci Russo to this radioactive materials license. Ms. Russo has recently completed the training and experience required to be named as an ANP. You will find the training and experience credentials, a signed preceptor attestation and Ms. Russo's CT pharmacist license verification attached in Appendix A.

We appreciate your prompt attention to this request. Please, forward the amended radioactive materials license to Triad Isotopes, Inc., Attn: Shannon Julian, 200 S. Orange Avenue, Ste. 2100, Orlando, FL 32801 or to the Milford pharmacy location to the attention of the pharmacy manager/site RSO, Joseph Remesz-Guerrette, Pharm.D.

Should you have specific questions about this amendment request, you may contact me at (904)-220-7210 or by email at bnelson@triadisotopes.com. Joseph Remesz-Guerrette, Pharm.D., can be reached at the pharmacy at 203-882-9903 to provide additional information, as well.

Sincerely,



Brigitte Nelson, MS, PharmD, BCNP
Sr. Director of Quality and Safety
Triad Isotopes, Inc.
(904)-220-7210 (office)
(904)-562-8260 (cell)
(904)-220-6980 (fax)
bnelson@triadisotopes.com
Cc: file, Neil Stubbs, Joseph Remesz-Guerrette, Pharm.D.

574340

NMSS/RGN1 MATERIALS-002

Appendix A



State of Connecticut

Lookup Detail View

Contact Name

Name

NANCI M RUSSO

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
PCT.0006470	PHARMACIST	02/01/2011	01/31/2012	ACTIVE

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PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

Nanci Russo

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

January 3, 2011

Kara Weatherman
Director of Nuclear Pharmacy Training Programs

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

*Nanci Russo
Certificate Program #72
Campus session: December, 2010*

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: NANJI RUSSO

Date issued: January 3, 2011

Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radio-pharmaceutical Chemistry
Purdue University	October 2010 thru January 2011	DVD-Workbook	150	51	33	13	21	32
	December 2010	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 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

Brigitte 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



PRECEPTOR CERTIFICATION OF TRAINING

FOR

NAME OF NUCLEAR PHARMACIST TRAINEE NANCI M. RUSSO

The individual named above has completed 600 hours (must be > 500) of supervised experience at: Triad Isotopes, Inc. Milford, CT location

NAME OF PHARMACY TRIAD ISOTOPES, INC.

SITE ADDRESS 180 PEPES FARM RD.
MILFORD, CT 06460

RAM LICENSE # 09-31406-01MD ,

as outlined in the attached form, "documenting radioisotope handling experience."

His/her training has included the following (see attached documentation):

- ❖ Shipping, receiving, and performing related radiation surveys;
- ❖ Using and performing checks for proper operation of dose calibrators, survey meters, and counting devices;
- ❖ Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- ❖ Using administrative controls to avoid mistakes in the administration of radiopharmaceuticals; and
- ❖ Using procedures to prevent or minimize contamination and using proper decontamination procedures

This training has been satisfactorily completed. This trainee has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

**DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE
COMPLETED IN PHARMACY UNDER PRECEPTOR SUPERVISION**

NAME Milford, CT

EXPERIENCE WITH RADIOACTIVE MATERIAL (>500 HOURS OF
ACTUAL USE OF RADIOISOTOPES UNDER THE SUPERVISION OF AN
AUTHORIZED USER)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	LOCATION OF USE	TOTAL HOURS OF USE (MAY LIST DATE RANGE)	PURPOSE OF USE 1,2,3,4,5,6 (SEE KEY BELOW)
Mo-99	19 Ci	Milford, CT	9/13/10-1/20/11	1,6
Tc-99m	13 Ci	Milford, CT	9/13/10-1/20/11	3,4,5,6
I-131	150 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
Xe-133	40 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
Sr-89				1,3,4,5
I-123	2 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
Cr-51				1,3,4,5
IN-111	6.3 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
P-32				1,3,4,5
Ga-67	26 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
Tl-201	200 mCi	Milford, CT	9/13/10-1/20/11	1,3,4,5
Co-57	2 mCi	Milford, CT	9/13/10-1/20/11	2
Cs-137	170 uCi	Milford, CT	9/13/10-1/20/11	2
Ba-133	59 uCi	Milford, CT	9/13/10-1/20/11	2
			Total: 600 hours	

Key for "Purpose of Use"

The number or numbers entered under "Purpose of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrator, scintillation detectors, and survey meters.
3. Calculation, dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.

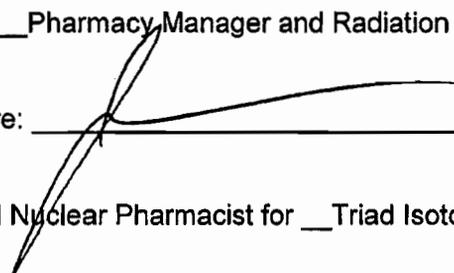
Elution of Technetium 99m generator systems, assay and testing of the eluate for Molybdenum 99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceutical.

I attest that Nanci M. Russo (trainee name) has satisfactorily completed a 700 hour structured 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 (ANP).

Preceptor Information:

Preceptor Printed Name: Joseph Remez-Guerrette

Preceptor Title: Pharmacy Manager and Radiation Safety Officer

Preceptor Signature: 

I am an Authorized Nuclear Pharmacist for Triad Isotopes, Inc., Milford, CT (Name of facility),

RAM license # 09-31406-01MD. Telephone # 203-882-9903.

Date: 1/20/2011

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION**
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Nuclear Pharmacist

Nanci M Russo

State or Territory Where Licensed

Connecticut

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, West Lafayette, IN	85	10/1/2010-1/3/2011
Radiation protection	Purdue University, West Lafayette, IN	46	10/1/2010-1/3/2011
Mathematics pertaining to the use and measurement of radioactivity	Purdue University, West Lafayette, IN	23	10/1/2010-1/3/2011
Chemistry of byproduct material for medical use	Purdue University, West Lafayette, IN	40	10/1/2010-1/3/2011
Radiation biology	Purdue University, West Lafayette, IN	21	10/1/2010-1/3/2011

Total Hours of Training: 215

**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, Inc. Milford, CT	75	9/13/2010-1/20/2011
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, Inc. Milford, CT	75	9/13/2010-1/20/2011
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Triad Isotopes, Inc. Milford, CT	250	9/13/2010-1/20/2011
Using administrative controls to avoid medical events in administration of byproduct material	Triad Isotopes, Inc. Milford, CT	75	9/13/2010-1/20/2011
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Triad Isotopes, Inc. Milford, CT	125	9/13/2010-1/20/2011

Total Hours of Experience: 600

Supervising Individual

Joseph Remez-Guerrette, PharmD., Pharmacy Manager and Radiation Safety Officer

c. Go to and complete Part II Preceptor Attestation.

**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

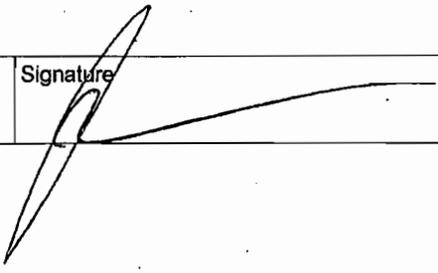
I attest that Nanci M. Russo has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist
educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has 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, Inc. Milford, CT
Nuclear Pharmacy or Medical Facility

09-31406-01MD
License/Permit Number

Name of Preceptor Joseph Remez-Guerrette, PharmD.	Signature 	Telephone Number (203) 882-9903	Date 01/20/2011
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