



18 August 2011

United States Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Triad Isotopes, Inc.-Milford RAM License #09-31406-01MD
180 Pepes Farm Road
Milford, CT 06460

Dear License Reviewer:

03038269

RECEIVED
REGION 1
2011 AUG 19 AM 10:46

The following amendment requests to license #09-31406-01MD are submitted below:

1. Please, add as authorized nuclear pharmacist to this radioactive materials license Ian McColl, R.Ph. Mr. McColl has recently completed the training and experience requirements in 10 CFR 35.55 to be named as an Authorized Nuclear Pharmacist. Attached are signed forms 313a (ANP) attesting to Mr. McColl's training and experience as Attachment A.
2. Please add as Authorized Nuclear Pharmacists to this license Nicholas Plumeri, Christopher Stanton, and Jeffrey Cone.

Mr. Plumeri and Mr. Stanton are currently recognized as Authorized Nuclear Pharmacists by the New York Board of Pharmacy and are included on the attached list, Attachment B, of Certified Nuclear Pharmacists.

Mr. Cone is currently listed as ANP on our Canton, MA license#41-0148, attached as Attachment C.

Verification of Connecticut pharmacist licenses for all individuals is attached as Attachment D.

3. Please remove as Authorized Nuclear Pharmacists Kerry Eberly, Thu Dang, Richard Hylinski, John Keenan, and Hussam Abbassi.

575823
NMSS/RGN1 MATERIALS-002



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 4205 Vineland Rd., Ste. L1, Orlando, FL 32811 and/or to the Milford pharmacy address to the RSO's attention.

Thanks,

A handwritten signature in black ink, appearing to read "Brigette Nelson", with a stylized flourish at the end.

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



Attachment A
Ian McColl ANP Training Documentation

**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

Ian T. McColl

State or Territory Where Licensed

State of 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. Nuclear Pharmacy Certificate Program	85	6/20/2011- 8/12/2011
Radiation protection	Purdue University, West Lafayette, IN. Nuclear Pharmacy Certificate Program	46	6/20/2011- 8/12/2011
Mathematics pertaining to the use and measurement of radioactivity	Purdue University, West Lafayette, IN. Nuclear Pharmacy Certificate Program	23	6/20/2011- 8/12/2011
Chemistry of byproduct material for medical use	Purdue University, West Lafayette, IN. Nuclear Pharmacy Certificate Program	40	6/20/2011- 8/12/2011
Radiation biology	Purdue University, West Lafayette, IN. Nuclear Pharmacy Certificate Program	21	6/20/2011- 8/12/2011
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	Cardinal Health Nuclear Pharmacy East Hartford, CT 06108 34-29200-01MD	100	5/1/2008-12/31/2010
	Triad Isotopes, Inc. Nuclear Pharmacy Milford, CT 06460 09-31406-01MD	50	6/20/2011-8/12/2011
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	Cardinal Health Nuclear Pharmacy East Hartford, CT 06108 34-29200-01MD	50	5/1/2008-12/31/2010
	Triad Isotopes, Inc. Nuclear Pharmacy Milford, CT 06460 09-31406-01MD	50	6/20/2011-8/12/2011
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Cardinal Health Nuclear Pharmacy East Hartford, CT 06108 34-29200-01MD	200	5/1/2008-12/31/2010
	Triad Isotopes, Inc. Nuclear Pharmacy Milford, CT 06460 09-31406-01MD	100	6/20/2011-8/12/2011
Using administrative controls to avoid medical events in administration of byproduct material	Cardinal Health Nuclear Pharmacy East Hartford, CT 06108 34-29200-01MD	75	5/1/2008-12/31/2010
	Triad Isotopes, Inc. Nuclear Pharmacy Milford, CT 06460 09-31406-01MD	40	6/20/2011-8/12/2011
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Cardinal Health Nuclear Pharmacy East Hartford, CT 06108 34-29200-01MD	75	5/1/2008-12/31/2010
	Triad Isotopes, Inc. Nuclear Pharmacy Milford, CT 06460 09-31406-01MD	40	6/20/2011-8/12/2011

Total Hours of Experience: 780

Supervising Individual

Peter Sposato (Cardinal Health) and Joseph Remesz-Guerrette (Triad Isotopes)

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

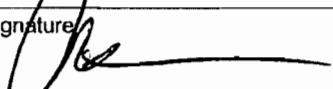
Structured Educational Program

☒ I attest that Ian T. McColl 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 Cardinal Health, East Hartford, CT 
Nuclear Pharmacy or Medical Facility
34-29200-01MD 
License/Permit Number

Name of Preceptor Peter Sposato, RPh.	Signature 	Telephone Number (860) 291-9027	Date 8/16/11
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**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 Ian T. McColl has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

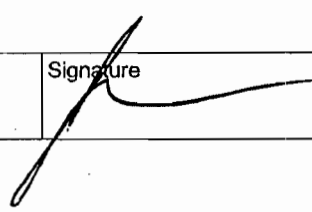
educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

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 Remesz-Guerrette, PhramD.	Signature 	Telephone Number (203) 882-9903	Date 8/16/2011
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PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

Ian McColl

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

August 12, 2011

Kara D. Weatherman

Director of Nuclear Pharmacy Training Programs

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

***Ian McColl
Certificate Program #74
Campus session: August 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: IAN McCOLL

Date issued: AUGUST 12, 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	June 2011 – August 2011	DVD-Workbook	150	51	33	13	21	32
	August 2011	On-Site	65	34	13	10	0	8
Total Hours Received			215	85	46	23	21	40
Hourly breakdown by topic								

* 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

STATE OF CONNECTICUT ♦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

IAN T MCCOLL
339 WEST LANE
KENSINGTON, CT 06037

has been certified by the Department of Consumer Protection as a licensed

PHARMACIST

License # PCT-0011990

Effective: 06/14/2011

Expiration: 01/31/2012


William M. Rubenstein, Commissioner



**PRECEPTOR CERTIFICATION OF TRAINING
FOR**

NAME OF NUCLEAR PHARMACIST TRAINEE IAN MCCOLL

The individual named above has completed 780 hours (must be > 500) of supervised experience at: Triad Isotopes, Inc. Milford, CT location and Cardinal health, East Hartford, 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	6/20/11-8/15/11	1,6
Tc-99m	13 Ci	Milford, CT	6/20/11-8/15/11	3,4,5,6
I-131	150 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
Xe-133	40 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
Sr-89				1,3,4,5
I-123	2 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
Cr-51				1,3,4,5
IN-111	6.3 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
P-32				1,3,4,5
Ga-67	26 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
Tl-201	200 mCi	Milford, CT	6/20/11-8/15/11	1,3,4,5
Co-57	2 mCi	Milford, CT	6/20/11-8/15/11	2
Cs-137	170 uCi	Milford, CT	6/20/11-8/15/11	2
Ba-133	59 uCi	Milford, CT	6/20/11-8/15/11	2
			Total: 780 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.

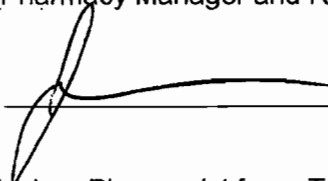
Elution of Technetium 99m generator systems, assay and testing of the eluate for Molybdenum 99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceutical.

I attest that Ian McColl (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 Remesz-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: 8/15/2011



Attachment B
New York Board of Pharmacy Certified Nuclear Pharmacists

Certified Nuclear Pharmacists

Approved by the New York State Board of Pharmacy

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
Afari Tawiah	George	052315	1/28/2008
AFARI-TAWIH	GEORGE	052315	1/28/2008
Agnelio	Michael	050886	12/5/2006
Aladesanmi	Ayoola	052462	2/19/2009
ALBERTO	Norberto	041628	11/16/1993
ALDI	Christopher A.	031452	5/11/1993
ALLEGRA	Thomas	030673	12/13/1989
Altaye	Dawit	045860	11/3/2009
Arwin	Sara	037342	3/19/2009
AVLONITIS	Vasilidis	042452	11/19/1993
AWADALLAH	Robert	046732	9/9/2001
Bartoszek	Julia	04685	11/18/2004
BELL	Heather	047631	12/26/2002
BIBER	Marshall Z.	030090	11/21/1988
BILHORN	Teresa	041135	3/24/1993
BIVENS	Kelly	048420	2/6/2002
BLANCHARD	David	045984	11/4/1998
BLAUM	Curtis	034604	2/4/1986
BLIZINSKI	Mark J.	040638	6/18/1992
BOESCHEN	Laurel	033208	2/3/2004
BOLAND	Thomas	036482	11/16/1993
BORTZ	Christine	048032	7/9/2001
BOWE	HOWARD	033727	3/23/2006
BRODERICK	Patrick	034451	10/28/2002
Brown	Christine	047861	1/10/2001
CALLENDER	DENISE	049772	1/31/2007
CALLENDER	Robert	034617	9/5/1986
CARLO	John A.	032303	3/2/1993

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
CARR	John Christopher	040021	7/3/1997
CHACKO	Rinsl	046274	9/9/2001
CHOI	Kevin	042141	7/27/1994
CHUN	Byung S.	030451	2/5/1996
Chung	Johnny	054057	10/7/2009
CLARY	Michael	042669	2/10/2000
COLANGELO	Anthony V.	043599	6/3/1996
CONWAY	Michael J.	030457	10/8/1992
CORALLO	John	038870	2/9/1995
CRAIG	Corey	048206	10/18/2001
CRUZ	ANNETTE	050594	9/19/2005
CUTRO	William A.	026604	11/2/1993
CZAPCZYNSKI	Joseph J.	032174	10/29/1993
DANSEREAU	Raymond N.	031209	12/20/1995
D'ARDUINI	Rosanna	048782	3/3/2005
D'ARDUINO	Rosanna	048782	3/3/2005
DELANEY	James J.	022801	7/5/1994
DELISO	Vito	029469	11/25/1988
DICAIRANO	Emile Nicholas	044116	4/22/1999
DINGMAN	VICTORIA	048973	4/25/2006
DIVITA	George	028214	2/19/1991
DRESCHER	Darrell Mark	034717	5/26/1983
DUVIGNEAUD	Rose-Anne Bettino	043463	11/25/1996
ENGLISH	DIAN	044464	12/9/2004
EYBS	Edward J.	037758	10/21/1991
FANG	Chungshen	043116	9/8/1996
FERY	Joseph A.	034731	11/22/1985
Fisk	John	041894	2/20/2003
FISKE	John C.	037269	12/7/1988
Fry	William	042156	10/19/2005

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
GALLAGHER	Patrick	047411	9/29/2000
GAMEZ	SABINA D.	050775	4/16/2007
GHANI	Rashid E.	033312	8/3/1999
Gillespie	John	048871	7/6/2007
Giovanniello	Dominick	051189	1/16/2007
GLENNON	Margaret E.	030802	10/26/1992
GOMEZ	SABINA	040103	10/8/1992
GONZALEZ	Jose	044804	11/14/2001
GUARASCI	Daniel	044656	3/20/2002
HANSEN	Craig Edward	043447	4/11/1995
Hellman	Matthew James	047083	4/23/2002
Hellman	Matthew James	047083	4/23/2002
HEUVEL	Joseph Michael	035162	5/6/1997
HO	Chinghan Joyce	034417	1/13/2004
HOST	Brian H.	048014	6/8/2001
Hua	Rebecca	047123	11/19/2002
HUNTER	Bruce	048904	2/16/2005
JOHNSON	Ross A.	043715	10/6/1999
JOHNSON	THOMAS	043427	6/17/2003
JULIANO	Louis	036102	5/15/1987
KASSEL	Richard J.	042192	10/28/1993
KEENAN	John J.	036110	2/16/1993
Kelly	Brian	047032	11/26/2002
Khan	Saman	052017	1/16/2008
Kim	Hijin	053151	1/27/2009
KIM	Joseph	031254	11/16/1993
KOHEN	Randy R.	032574	11/9/1993
KOZAK	Lora R.	042410	1/19/1996
KRAEMER	Beth	037351	8/7/1988
KUMAR	SUNITA	040536	5/17/2006

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
Kusiowski	Kim	038771	8/5/2002
LARDNER	Sue	036126	5/25/1987
LEON	Christopher	047736	11/28/2000
LEONARD	George	037434	1/8/2001
LEVY	NEAL ZACHARY	052345	2/20/2008
LEWIS	Thomas	038052	12/1/1998
LOFARO	Joseph A.	030902	7/27/1993
Loiseau	Michael	049838	6/13/2007
LONG	Jon	047842	1/21/2001
Lyashchenko	Serge	053302	3/9/2009
MANONI	Cleto J.	042287	8/23/2000
MANTZ	Gary	038648	10/11/2000
MARZOCCA	John	042506	7/26/1996
McLeland	David	0491061	10/1/2007
MIANO	John A.	036949	10/19/1994
MILETTA	Joseph F.	024193	7/31/1989
Missal	Barbara	050656	11/22/2005
MONK	Daniel P.	043063	4/21/1995
MORRILL	Richard	038293	1/25/1988
MUNROE	Gizelle Natasha	046463	8/31/1998
NASSIRI	Val Vahid	044256	6/18/1997
NICKEL	Richard A.	040343	4/11/1994
NIZZA	Vincent	034862	11/2/1992
NYBO	Mark R.	043301	3/24/1995
OKUNEWITCH	Thomas	037586	8/7/1988
OSNARD	Richard	040392	10/21/1991
PALMER	Glen	041402	10/28/1993
PALMQUIST	Dan	048120	8/2/2001
PECORARO	Anthony J.	035539	6/16/2000
PERRYMAN	DOUGLAS	036199	1/7/2005

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
PFEIFFER	Jay Justin	045673	10/15/1997
PHELPS	Kristin Rice	040763	11/8/1996
Pietronigro	Elisabeth	052350	4/23/2008
Plattner	Wayne	028324	8/18/2005
PLUMERI	Nicholas	037550	12/7/1998
POLEON	Gregory P.	034519	2/19/2003
POWERS	Wesley	037555	8/24/1988
Price	Alan	038234	1/29/2008
Rahman	Zubaida	047806	4/23/2002
RANDALL		026553	12/31/1999
RANDALL	Angela	048157	3/18/2002
RANDALL	ANGELA	048157	3/18/2002
RATHOD	MAHIPAL	050682	4/24/2006
RATTIGAN	John G.	027952	6/18/1992
REDMORE	Gary R.	036376	11/21/1988
REDZIKOWSKI	Robert	043393	9/24/1998
Repecki	Steven	039635	7/2/2002
ROBINSON	FRANKLYN	047997	6/4/2002
ROSENTHAL	Mark	025042	3/20/1990
RUDDY	Frances	034423	12/7/1988
RUNCO	Ernest J.	036973	1/12/1998
Russell	Albert	048747	4/28/2003
SALE	Paul D.	035061	11/21/1988
SAMUEL	Ernesto	046481	8/31/1998
SANFILIPPO	Michael	042425	11/16/1993
SHAW	Richard John	048080	9/9/2001
SHEIKH	Afzal	031044	11/16/1993
SHENG	Zury-Lin	046609	10/12/2001
SHEPARD	Kelly	046887	1/22/2001
SIMON	Garcia	036383	8/3/1994

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
SIVU	Peter G.	036237	10/27/1988
SOFFIFNG	Mark	034280	1/3/2001
SOSA	Louis P.	037919	3/8/1988
SPOSATO II	Peter	038609	8/16/1988
Stanton	Christopher Warren	054336	4/26/2010
STEINIG	Kevin	038210	6/16/1993
STRAUSS	Ross	040084	7/26/1996
STRUGALA	Gerald A.	041881	2/16/1993
TAKAMI	Sandra	047908	11/9/2001
TAN-CHEUNG	Ying	047340	9/9/2001
TASCIONE	Anthony	035610	10/21/1991
TIRADO	WILMER	051844	9/3/2007
Tremblay	Andrea	051519	3/19/2007
Tumino	Joseph	051023	10/20/2006
UHM	THOMAS	045897	10/16/2003
Unger	Howard	033104	7/26/2002
VAN COTT	SUSAN	051556	4/4/2007
VARGHESE	BLESSEN	049157	3/16/2004
VELEZ	James W.	034987	3/21/1989
Victoria	Cynthia	047319	3/8/2006
VUONCINO	Lois	041197	3/7/2001
WALKER	Jill	040876	9/22/1993
WELCH	Brian M.	040574	11/9/1993
WELLINS	Robert Mark	035228	1/8/1986
Whitehead	Robert	049778	10/26/2004
WHITING	Jacqueline	045350	8/4/1997
WIGGINS	Michael	047823	11/15/2000
WILLIAMS	Bryan	046070	1/10/2001
Wilson	David	050662	11/22/2005
WONG	Alison	000033	5/10/2001

<i>Last Name</i>	<i>First Name</i>	<i>License #</i>	<i>Date Approved</i>
WONG	K. Wayne	037841	8/3/1994
YEE	Archie	040562	11/5/1995
YOON	Michael C.	032077	4/12/1990
YOUNKIN	Timothy O	043169	9/8/1995



Attachment C
Massachusetts License#41-0148



THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
MATERIALS LICENSE

Pursuant to Massachusetts General Laws Chapter 111, Sections 3, 5M, 5N, 5O and 5P and Massachusetts Regulations for the Control of Radiation, Section 120.100, Licensing of Radioactive Material, and in reliance on statements and representation heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials 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 regulations 105 CMR 120.000. This license shall be deemed to contain the conditions specified in 105 CMR 120.000 and is subjected to all applicable rules, regulations of the Department of Public Health, Commonwealth of Massachusetts, now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Triad Isotopes, Inc.</p> <p>2. 200 South Orange Avenue Suite 2100 Orlando, Florida 32801</p>	<p>3. License Number: 41-0148 is amended in its entirety, in accordance with the letter dated January 7, 2010, to read as follows:</p> <p style="text-align: center;">Amendment No: <u>25</u></p> <hr/> <p>4. Expiration Date: February 28, 2014</p> <hr/> <p>5. Docket No: 03-0338</p>
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6. Radioactive Material	7. Chemical / Physical Form	8. Maximum Possession Limit
A. Any radioactive material with atomic number 1 through 83, except molybdenum-99, technetium-99m, iodine-131 and xenon-133	A. Any, except sealed sources	A. 500 millicuries per radionuclide; 1 curie total, except as noted below
B. Molybdenum-99	B. Any	B. 200 curies
C. Technetium-99m	C. Any	C. 200 curies
D. Iodine-131	D. Any	D. 5 curies
E. Xenon-133	E. Any	E. 6 curies
F. Thallium-201	F. Any	F. 3 curies
G. Gallium-67	G. Any	G. 1 curie
H. Yttrium-90	H. Any	H. 1 curie

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0148
	DOCKET NUMBER: 03-0338
	AMENDMENT NUMBER: <u>25</u>

6. Radioactive Material	7. Chemical / Physical Form	8. Maximum Possession Limit
I. Cobalt-57	I. Any, prepackaged units for <i>in vivo</i> diagnostic tests	I. 20 millicuries
J. Cobalt-58	J. Any, prepackaged units for <i>in vivo</i> diagnostic tests	J. 20 millicuries
K. Any radioactive material listed in 105 CMR 120.128(H)	K. Prepackaged units for <i>in vitro</i> diagnostic tests.	K. 20 millicuries
L. Any radioactive material authorized under 105 CMR 120.535	L. Sealed sources	L. 300 millicuries
M. Depleted Uranium	M. Metal	N. 1000 kilograms

9. Authorized use:

A. through H. For possession, use, and processing incident to manufacture, preparation and distribution of radiochemicals and radiopharmaceuticals; compounding of iodine-131; production of technetium-99m pertechnetate; and distribution of unused molybdenum-99/technetium-99m generators to authorized recipients in accordance with 105 CMR 120.128(J) for medical use or to authorized recipients in accordance with 105 CMR 120.140 for non-medical use.

I. and J. Redistribution to specific licensees in accordance with 105 CMR 120.128(J) provided the packaging and labeling remain unchanged.

K. Redistribution to specific licensees or general licensees pursuant to 105 CMR 120.122(I)(1) provided the packaging and labeling remain unchanged.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0148
	DOCKET NUMBER: 03-0338
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- L. Redistribution of sealed sources, initially distributed by a manufacturer licensed pursuant to 105 CMR 120.128(L), to authorized recipients for medical use; or by a manufacturer licensed pursuant to 105 CMR 128(N) to authorized recipients for non-medical use. Calibration and checking of the instruments of the licensee.
- M. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

10. Radioactive materials shall only be used or stored at the licensee's facilities located at 65 Shawmut Road, Unit 8, Canton, Massachusetts.
11. This license is subject to an annual fee as determined by the Executive Office for Administration and Finance.
12. The Radiation Safety Officer for this license is James Flynn, R.Ph.
13. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
 - A. In accordance with 105 CMR 120.128(J)(2)(a) or (d), pharmacists working as authorized nuclear pharmacists.
 - B. Authorized nuclear pharmacists: James Flynn, R.Ph.; Jeffrey S. Cone, R.Ph.; Collin O'Neill, R.Ph.; and Dean Wahlstrom, PharmD.
 - C. At least one individual authorized by Paragraph A or B of this Condition shall be physically present at the authorized place of use whenever licensed material is being used.
14. The licensee shall not acquire licensed material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State. The licensee may possess and use sealed sources which were in the licensee's possession as of the date of this license.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0148
	DOCKET NUMBER: 03-0338
	AMENDMENT NUMBER: <u>25</u>

15. A. The sources specified in Item 7 shall be tested for leakage and/or contamination at intervals not to exceed six months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within six months before the transfer, shall not be put into use until tested.
- B. Any source in storage, and not being used, need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.
- C. Tests for leakage and/or contamination shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on the test sample. If the test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the source shall be removed from service and decontaminated, repaired or disposed of. A report of this shall be filed with the Director of the Radiation Control Program within 5 days of the date the leak test result is known. The report shall specify the source involved, the test results and the corrective action(s) taken. Records of leak test results shall be kept in units of becquerel or microcurie and shall be maintained for inspection by the Agency.
- D. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Agency, or the NRC, an Agreement State, or Licensing State to perform such services.
16. Sealed sources containing licensed material shall not be opened or sources removed from the device by the licensee.
17. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of inventories shall be maintained until inspection by the Radiation Control Program and shall include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.
18. Reagent kits may be redistributed to persons licensed pursuant to 105 CMR 120.547 or equivalent licenses of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State.
19. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0148
	DOCKET NUMBER: 03-0338
	AMENDMENT NUMBER: <u>25</u>

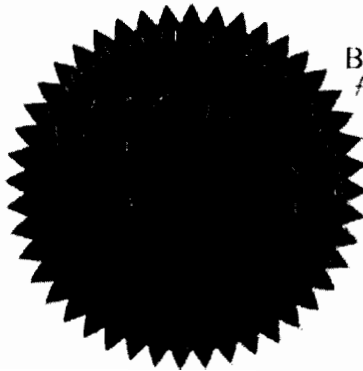
- A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. Except for syringe labels, all radiation labels shall be removed or obliterated.
 - B. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. 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 105 CMR 120.125(C) for establishing financial assurance for decommissioning.
 21. Radioactive waste may be picked up from the customers of the licensee and disposed of in accordance with the statements, representations and procedures in the application dated May 31st, 2007 and the letters dated August 5th and December 11th, 2008
 22. The licensee shall only transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of 49 CFR Parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770, "Transportation of Radioactive Material".
 23. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including any enclosures, listed below. The Massachusetts Regulations for the Control of Radiation (105 CMR 120.000) shall govern, unless statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated May 31, 2007
 - B. Letter dated August 5, 2008
 - C. Letter dated November 10, 2008
 - D. Letter dated December 11, 2008
 - E. Letter dated February 10, 2009

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 41-0148
	DOCKET NUMBER: 03-0338
	AMENDMENT NUMBER: <u>25</u>

- F. Letter dated April 22, 2009
- G. Letter dated May 26, 2009
- H. Letter dated June 2, 2009
- I. Letter dated January 7, 2010

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date 5-28-2010



By MPL Whelan DR
for Robert L. Gallagher, Acting Director



DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
Radiation Control Program
Schrafft Center - Suite 1M2A
529 Main Street, Boston, Massachusetts 02129
(617) 242-3035 (617) 242-3457 - Fax

May 28, 2010

William P. McCormick
Senior Vice-President, General Counsel
Triad Isotopes, Inc.
200 South Orange Avenue, Suite 2100
Orlando, Florida 32801

RE: Amendment Number: 25
License Number: 41-0148
Docket Number: 01-8858

Dear Mr. McCormick:

Enclosed is the above referenced license amended as requested in your letter dated January 7, 2010.

Please review the enclosed document carefully. If there are any errors or questions please do not hesitate to contact this office at the number above.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Whelan" followed by a stylized "R" or "G".

for Robert L. Gallagher, Acting Director
Radiation Control Program

RLG/sf

Enclosure:(1)

Attachment D
Connecticut Pharmacist Licenses



State of Connecticut

Lookup Detail View**Contact Name****Name**

CHRISTOPHER W STANTON

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
PCT.0011919	PHARMACIST	06/29/2011	01/31/2012	ACTIVE

Generated on: 8/17/2011 2:47:30 PM



State of Connecticut

Lookup Detail View**Contact Name****Name**

IAN T MCCOLL

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
PCT.0011990	PHARMACIST	06/14/2011	01/31/2012	ACTIVE

Generated on: 8/17/2011 2:33:46 PM



State of Connecticut

Lookup Detail View**Contact Name****Name**

JEFFREY S CONE

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
PCT.0011233	PHARMACIST	02/01/2011	01/31/2012	ACTIVE

Generated on: 8/18/2011 10:24:09 AM



State of Connecticut

Lookup Detail View**Contact Name****Name**

NICHOLAS J PLUMERI

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
PCT.0011761	PHARMACIST	01/26/2011	01/31/2012	ACTIVE

Generated on: 8/17/2011 2:45:46 PM

This is to acknowledge the receipt of your letter/application dated

8/18/2011, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment (09-31406-01MD)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 515823.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.