

Essential Isotopes
1513 Research Park Dr
Columbia, MO 65211

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III Office
2443 Warrensville Rd, Suite 210
Lisle, IL 60532-4352

September 26, 2011

Dear Sir,

Please amend our NRC Material License No. 24-32762 to reflect the following changes. From section 12 please remove William Brent McHugh, RPh as an authorized user and add Andrew Borrok, RPh. Included with this letter is documentation to confirm that Mr. Borrok has the training and experience to handle cyclotron related materials in accordance with NUREG -1556, Vol. 21, section 8.7.2.

Sincerely,

Marc D. Weichelt RPh, BCNP
Essential Isotopes, LLC.
1513 Research Park Dr.
Columbia, MO 65211
573-882-0245

RECEIVED SEP 30 2011

Certificate of Completion

The University of Arkansas for Medical Sciences
and the
University of New Mexico Health Science Center
certify that

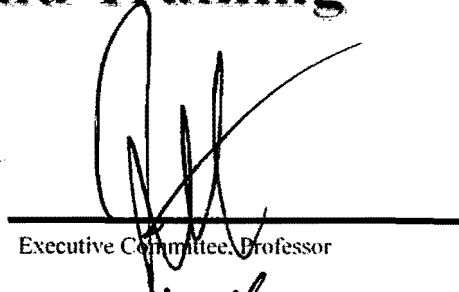
Andrew Borrock

has completed the didactic education requirements for
Authorized Nuclear Pharmacist education
as specified by the Nuclear Regulatory Commission.

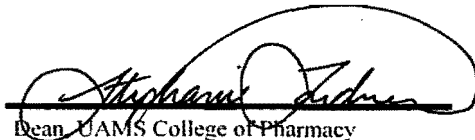
Nuclear Pharmacist Education and Training



Dean, UNM College of Pharmacy



Executive Committee, Professor



Dean, UAMS College of Pharmacy



Executive Committee, Professor

November 4, 2010



**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.55]**APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012Name of Proposed Authorized Nuclear Pharmacist
Andrew N Borrok, Pharm.D.State or Territory Where Licensed
Missouri**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**

- Provide a copy of the board certification.
- Skip to and complete Part II Preceptor Attestation.

☒ **2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

- Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Arkansas for Medical Sciences Nuclear Education On-Line (NEO) Columbia, Missouri	100	08-16-2010 To 11-04-2010
Radiation protection	University of Arkansas for Medical Sciences Nuclear Education On-Line (NEO) Columbia, Missouri	30	08-16-2010 To 11-04-2010
Mathematics pertaining to the use and measurement of radioactivity	University of Arkansas for Medical Sciences Nuclear Education On-Line (NEO) Columbia, Missouri	20	08-16-2010 To 11-04-2010
Chemistry of byproduct material for medical use	University of Arkansas for Medical Sciences Nuclear Education On-Line (NEO) Columbia, Missouri	30	08-16-2010 To 11-04-2010
Radiation biology	University of Arkansas for Medical Sciences Nuclear Education On-Line (NEO) Columbia, Missouri	20	08-16-2010 To 11-04-2010
Total Hours of Training: 200			

**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	Mid-America Isotopes, Inc. 706 East Liberty Lane Ashland, MO 65010 License number 24-26241-01MD	350	06-26-07 To 11-10-10
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	Mid-America Isotopes, Inc. 706 East Liberty Lane Ashland, MO 65010 License number 24-26241-01MD	200	06-26-07 To 11-10-10
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Mid-America Isotopes, Inc. 706 East Liberty Lane Ashland, MO 65010 License number 24-26241-01MD	200	06-26-07 To 11-10-10
Using administrative controls to avoid medical events in administration of byproduct material	Mid-America Isotopes, Inc. 706 East Liberty Lane Ashland, MO 65010 License number 24-26241-01MD	100	06-26-07 To 11-10-10
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Mid-America Isotopes, Inc. 706 East Liberty Lane Ashland, MO 65010 License number 24-26241-01MD	200	06-26-07 To 11-10-10

Total Hours of Experience: 1050

Supervising Individual

William Brent McHugh, Pharm.D, Authorized Nuclear Pharmacist

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 Andrew N. Borrok, Pharm.D. has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

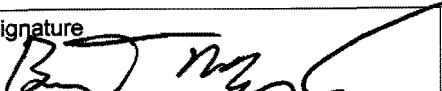
educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Mid-America Isotopes, Inc ,
Nuclear Pharmacy or Medical Facility

24-26241-01MD 
License/Permit Number

Name of Preceptor William Brent McHugh, Pharm.D.	Signature 	Telephone Number (573) 657-1776	Date 11/10/2011
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STANDARD OPERATING PROCEDURE	
Radiation Protection Training	RC-3 Attachment 1
Originator: Marc Weichelt	Revision: A
Management Approval: Scott Brower	
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New Employee: OrientationEmployee Name (Print) Andrew BorrokEmployment Start Date 8/2/10Training Date(s) 8/2/10**Required Training Topics****Trained (✓)**

1. RPP/Policies Manual-Orientation
2. RP/SOPs Manual-Orientation
3. Exposure Controls- Orientation
4. Contamination Controls-Orientation
5. Dosimetry and ALARA Programs
6. Survey Meters and Instrumentation
7. Radiological Emergencies and Reporting

✓
✓
✓
✓
✓
✓
✓

Employee's Signature Andrew Borrok Date 8/2/10Instructor's Signature Marc Weichelt Date 8/2/10

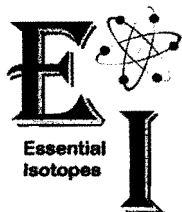
STANDARD OPERATING PROCEDURE	
Radiation Protection Training	RC-3 Attachment 2
Originator: Marc Weichelt	Revision: A
Management Approval: Radiation Safety Officer	
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New Employee: Formal TrainingEmployee Name (Print): Andrew BorrokEmployment Start Date: 8/2/2010Training Dates: 8/2/10 - 8/13/10Required Training TopicsTrained (✓)

1. Radiological Compliance Program
2. RPP/Policies Manual
3. RPP/SOPs Manual
4. Radiation Protection Principles & Controls
 - Radiological Characteristics & Units
 - Exposure Controls
 - Contamination Controls
5. Dosimetry Program
6. ALARA Program
7. Biological Effects of Radiation and Radiation Risks
8. Radiological Instrumentation
9. Radiological Emergencies & Incident Response
10. Cyclotron Radiation Protection
11. Nuclear Regulations & Licensing
12. Radiation Protection: Practices & Precautions

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Employee's Signature Cathy BkDate 8/13/10Instructor's Signature Marc WeicheltDate 8/13/10



Essential Isotopes
1513 Research Park Dr
Columbia, MO 65211

September 9, 2011

To whom it may concern,

I hereby attest that Andrew Borrok, RPh has been employed by Essential Isotopes since August 2, 2010. During that time he has received training and supervision by myself and other qualified staff to safely operate a PETtrace cyclotron to produce Curie amounts of F-18 and F-18 labeled products. He has received a minimum of 40 hours of radiation safety training specific to safe handling of positron emitting radionuclides.

Sincerely,

Marc D. Weichelt RPh, BCNP
Essential Isotopes, LLC.
1513 Research Park Dr.
Columbia, MO 65211
573-882-0245

From:

Essential Isotopes

1513 Research Park Dr

Columbia MO 65211



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60532

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Nuclear Regulatory Commission

Region III Office

2443 Warrensville Rd, Suite 210

Lisle, IL 60532-4352