



100 Executive Drive, Sterling, VA 20166 • phone: (703) 787-7900, fax: (703) 787-4079 • www.easternisotopes.com

Mr. Brian Parker, Health Physicist
Nuclear Regulatory Commission, Region II
61 Forsyth St. SW, Suite # 23T85
Atlanta, GA 30303

03032974

January 6, 2008

Subject: Amendment Request To License # 45-25221-01MD

Dear Mr. Parker,

Eastern Isotopes would like to clarify and amend the aforementioned license.

1. Clarification of Ownership: This license is owned and managed by Eastern Isotopes, Inc. a Virginia Corporation. Eastern Isotopes, Inc. is owned by IBA Radioisotopes, Inc. a Delaware Corporation. IBA Radioisotopes, Inc. is owned by IBA (Ion Beam Applications) SA, a Belgium company.
2. The contact address for all correspondence for this license should be:
Joe Harless
Eastern Isotopes, Inc.
100 Executive Drive, Suite #100
Sterling, VA 20166
3. Retain Joe Harless as Authorized Signatures. Remove Mark A. Smith, CHP, as Authorized Signature.
4. Remove the Little Ferry address from Item 10 – Facility Locations. That site is no longer used as a radiopharmacy and no isotopes have been stored on site for some time. Final Decommissioning Wipes and Surveys have been conducted and the facility has been declared free of all radioactivity. Wipes and Surveys enclosed.
5. Correct the title for Mr. Ali A. Abassi, (currently listed in Item 11B) from RPh to PharmD.
6. Item 12 - Remove John Zehner from the list of RSOs. Add to Item 12 as Alternate RSO – James Alan Kostka. Credentials enclosed.
7. Add to Item 11B - list of Authorized Nuclear Pharmacists:
John C. Chen, R.Ph.
Kim C. Hosen, R.Ph.

Thank you for your attention to this matter. If you have any questions, please contact me at (704) 226-8100.

Sincerely,

C. Joseph Harless, CNMT, President, General Operations & Corporate RSO, Eastern Isotopes, Inc.
Cell [REDACTED] Phone (704) 399-0673 Fax (704) 391-9382

Enclosure: Credentials for Assistant RSO, 2 x ANPs and Decommissioning Surveys

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

Delivering Solutions for PET™

NMSS/RGNI MATERIALS-032

Decommission Report

On 06/29/2004 the Eastern Isotopes site in Little Ferry, NJ was inspected and tested for radioactive material. Meter surveys and wipe tests were done of the entire location. There was previous radioactive materials on site, which included F-18, I-131, Ga-67, and I-123. There were also sealed sources (Ba-133, Co-57, and Cs-137) that were transferred to Eastern Isotopes in Somerset, NJ. The last date which any of these material was used or received on site, was 02/02/2004. This site was found to be free of radioactive contamination. Data is included below.

Location:

Eastern Isotopes, Inc
212 Gates Road
Little Ferry, NJ 07643

Date

06/29/2004

Brian Host
RSO

Single Channel Analyzer

Ludlum Model 2200
Serial Number 17451
Last Calibration: 11/26/2003
Window: 80 - 880
Voltage setting: 236
Cs-137 Efficiency: 0.3136
LLD: 105 cpm
MDA: 335 dpm or 1.50×10^{-4} uCi

Survey Meter

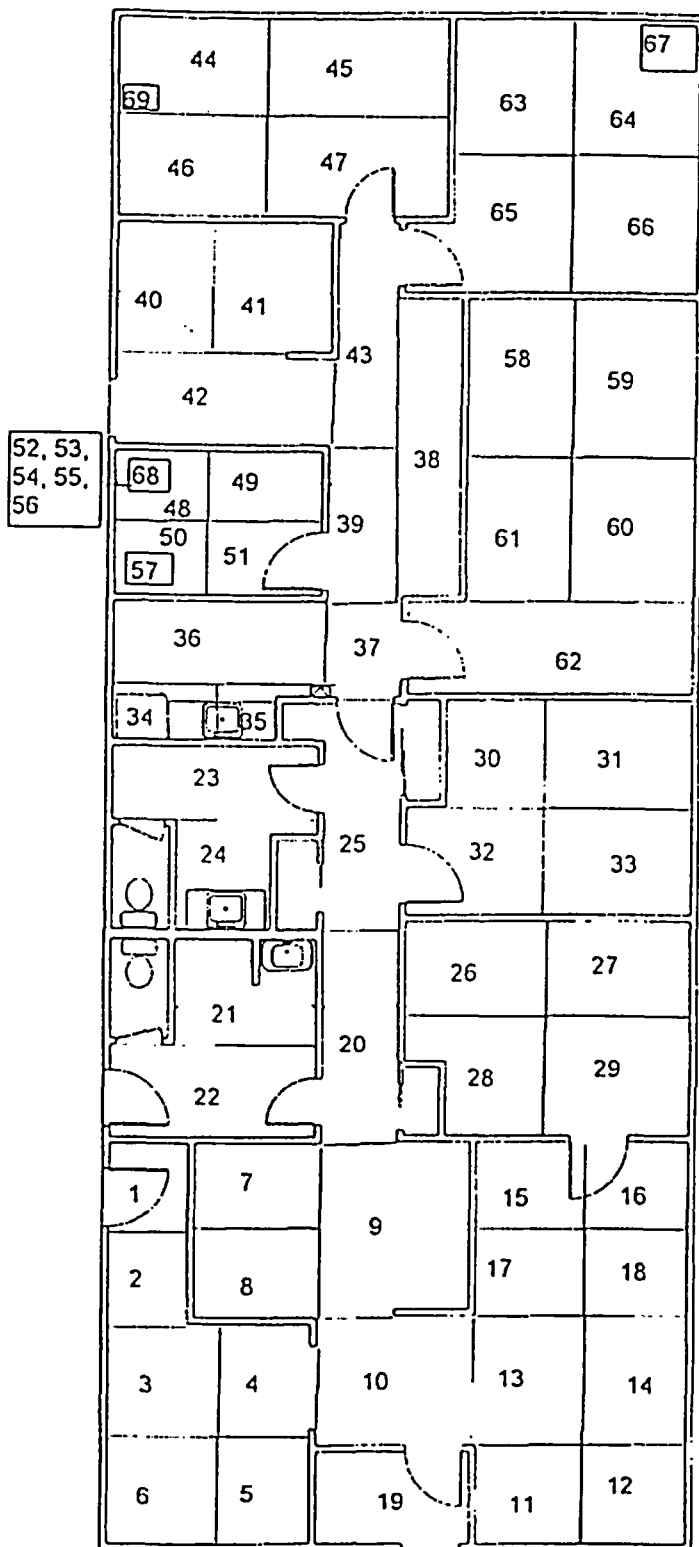
Ludlum Model 3
Serial Number 74949
Last Calibration: 10/27/2003

Jim Keston
Conference
Assistant

Joe Haul
CORPORATE RSO

pg 1 of 4

Map of Wipe and Surveys



col
JK
pg 2 of 4

Location on Map	Wipe - <i>cpm</i>	Wipe - <i>dpm</i>	Survey - mR/hr	Notes
Background	228		0.1 mR/hr	
1	214	682	0.09	
2	202	644	0.09	
3	221	705	0.08	
4	216	689	0.09	
5	203	647	0.08	
6	198	631	0.09	
7	215	686	0.09	
8	209	666	0.07	
9	201	641	0.08	
10	200	638	0.08	
11	210	670	0.09	
12	196	625	0.09	
13	222	708	0.09	
14	209	666	0.07	
15	211	673	0.09	
16	204	651	0.09	
17	220	702	0.09	
18	217	692	0.09	
19	203	647	0.08	
20	196	625	0.09	
21	213	679	0.07	
22	219	698	0.08	
23	204	651	0.07	
24	221	705	0.08	
25	201	641	0.09	
26	196	625	0.09	
27	199	635	0.09	
28	208	663	0.08	
29	217	692	0.08	
30	204	651	0.08	
31	199	635	0.08	
32	209	666	0.09	
33	203	647	0.08	
34	206	657	0.09	
35	218	695	0.09	
36	200	638	0.09	
37	220	702	0.08	
38	218	695	0.09	
39	209	666	0.09	
40	205	654	0.05	
41	215	686	0.06	
42	202	644	0.05	
43	222	708	0.08	

col

q/c

1.2.2.2

44	224	714	0.06	
45	216	689	0.05	
46	211	673	0.07	
47	227	724	0.07	
48	203	647	0.06	
49	215	686	0.06	
50	208	663	0.07	
51	215	686	0.09	
52	201	641	0.06	Iodine Glove Box
53	213	679	0.05	Iodine Storage
54	194	619	0.07	Iodine Storage
55	199	635	0.07	Stainless Steel Storage
56	212	676	0.07	Stainless Steel Storage
57	193	615	0.08	Stainless Steel Hood
58	200	638	0.09	
59	195	622	0.08	
60	219	698	0.09	
61	202	644	0.07	
62	208	663	0.08	
63	211	673	0.08	
64	198	631	0.09	
65	201	641	0.07	
66	221	705	0.08	
67	214	682	0.08	Traditional Hood
68	225	717	0.07	Iodine Exhaust
69	211	673	0.07	Iodine Exhaust

cost
OK

NRC License
#45-25221-01MD
Item #12

FIGURE G - NUREG 1556, Vol. 13, Appendix G

Eastern Isotopes, Inc.
Corporate Headquarters
100 Executive Drive, Suite 100
Sterling, VA 20166
Phone (703) 787-7900
Fax (703) 787-4078

RADIATION SAFETY OFFICER
TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name (Last, First, Initial) **Kostka, James, Alan**

10 Years Experience with Eastern Isotopes to include 6 years as Lab Tech and 4 years as Compliance Manager & Assistant to Corporate Radiation Safety Officer

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RP& I	RP	MATH	RB	DOT/NRC
Livermore CA	June 02	RRI's Advance RAM transport by Air	32 DOT					32
Houston TX	June 02	DGAC Transport by Ground	24 DOT					24
Newport MN	May 02	UN Package Testing	40 DOT					40
Gaithersburg, MD	May 01	CSI Rad-Train RSO Training & DOT	40 RSO	16	6	6	6	6
Las Vegas NV	Feb 02	Englehardt RSO Training	40 RSO	16	6	6	6	6
Sterling VA	Dec 03	EII Annual Radiation Safety Retraining *	8	2	3	1	1	1
Sterling VA	Dec 02	EII Annual Radiation Safety Retraining *	8	2	3	1	1	1
Sterling VA	Dec 01	EII Annual Radiation Safety Retraining *	8	2	3	1	1	1
Sterling VA	Dec 00	EII Annual Radiation Safety Retraining *	8	2	3	1	1	1
Sterling VA	Sept 94	Initial New Hire Radiation Training *	16	4	6	2	2	2
* Author and Administrator of program at EII			TOTALS	44	30	18	18	114

Signature of Preceptor Radiation Safety Officer:

"I certify that the above described training/experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to work independently as a Radiation Safety officer."

Signature:


Print: Joe Harless

Title: EII
Corporate RSO and
Operations Mgr.

Date:

1/6/05

RP&I – Radiation Protection Principles

RP – Biological Hazards

RB – Ionizing Radiation Units & Characteristics

MATH – Radiation Detection Instrumentation

NRC Regulations and Standards to include Department of Transportation DOT – Shipping Hazmat and RAM

CHEM – 'radiochemistry' column eliminated.

NRC License
#45-25221-01MD
Item #12

FIGURE G - NUREG 1556, Vol. 13, Appendix G
RADIATION SAFETY OFFICER
EXPERIENCE IN HANDLING RADIOISOTOPE

Eastern Isotopes, Inc.
Corporate Headquarters
100 Executive Drive, Suite 100
Sterling, VA 20166
Phone (703) 787-7900
Fax (703) 787-4078

(Actual use of radioisotopes under the supervision of an Authorized User or Radiation Safety Officer, respectively)

Name (Last, First, Initial) **Kostka, James, Alan**

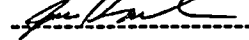
10 Years Experience with Eastern Isotopes to include 6 years as Lab Tech and 4 years as Compliance Manager & Assistant to Corporate Radiation Safety Officer

Isotope(s) Used	Maximum amount used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience
Tc-99m Mo99	3 Ci	Sterling Virginia	7, 4, 6, 1, 2, 3	3000
Tl-201	1 Ci	Sterling Virginia	7, 4, 6, 1	1000
In-111	100 mCi	Sterling Virginia	7, 4, 6, 1	80
Ga-67	100 mCi	Sterling Virginia	7, 4, 6, 1	500
Rb-82	300 mCi	Sterling Virginia	7, 4, 6, 1	10
F-18	6 Ci	Sterling, Virginia	7, 4, 6, 1, 2, 3	3000
I-131	3 Ci	Sterling, Virginia	7, 4, 6, 1	1000
Xe-133	1 Ci	Sterling, Virginia	4, 6, 1	300
I-123	10 mCi	Sterling, Virginia	4, 6, 1	500
Co-57, Cs-137, Ba-133	5 mCi as sealed sources	Sterling Virginia	2, 3, 1	300
Ge-68, Sr-82, Sr-85	800 mCi as SS & Gen.	Sterling Virginia	1	10

Signature of Preceptor Radiation Safety Officer:

"I certify that the above described training/experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to act independently as Radiation Safety Officer."

Signature:



Print: Joe Harless

Title: EII

Corporate RSO and
Operations Mgr

Date:

1/6/05

* Purpose of Use

1. Shipping, receiving, and performing related radiation surveys.
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon-and high energy beta- emitting radionuclides.
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides.
4. Calculating, assaying, and safely preparing dosages for patients or human research subjects.
5. Use of administrative controls to avoid mistakes in the administration of byproduct material.
6. Use of procedures to prevent or minimize contamination/or use of proper decontamination procedures.
7. Compounding radiopharmaceuticals for distribution to authorized recipients.

Certificate of Completion

awarded to

Jim Kostka

for participation in

Radiation Safety Seminar

February 4-6, 2002 - Las Vegas

presented by Engelhardt & Associates, Inc.

Susan Engelhardt
Susan J. Engelhardt, M.S.

Ralph Grunewald
Ralph Grunewald, Ph.D.

Joshua Walkowicz
Joshua Walkowicz, M.S.

Judith Grunewald
Judith Grunewald, R.N., M.S.

Dee Ann Kaiser
Dee Ann Kaiser, M.S.

Radiation Safety Officer Certificate

Awarded to

James A. Kostka

recognizing completion of 40 hours of specialized instruction

April 30-May 4, 2001

Presented By

CSI-Radiation Safety Academy
481 North Frederick Avenue, Suite 302
Gaithersburg, Maryland 20877

AAHP has awarded this course 32 Continuing Education Credits, 99-00-011
ABIH has awarded this course 4.5 CM Points, CM Approval #13421

Ray Johnson

Raymond Johnson, CHP, PE, RSO
Training Director



Certificate of Training

This Certifies That

Jim Kostka

has successfully completed the 1-day course of instruction for

DOT Requirements for Transportation of Radioactive Material

March 17, 2000

Presented By

CSI-Radiation Safety
481 North Frederick Avenue, Suite 302
Gaithersburg, Maryland 20877

For

Eastern Isotopes
Sterling, Virginia

Ray Johnson
Raymond Johnson, C.H.P., P.E.
Training Director



Advanced Radioactive Materials Packaging and Transportation Workshop

James Kostka

a Hazmat Employee of

*Eastern Isotopes, Inc.
Sterling, Virginia*

has been trained and tested in RRI's
Advanced Radioactive Materials Packaging and Transportation
Workshop conducted June 10-13, 2002, in Livermore, California

Instruction provided by:

 Regulatory Resources, Inc.
Kennewick, Washington 

Material Revision No.: 0602



Dangerous Goods Advisory Council

Certifies that

James Kostka
Eastern Isotopes

has been awarded 2 CEU for successful completion of

HMT-601

Transportation of Radioactive Materials

Initial Training

Houston, TX June 19-21, 2002

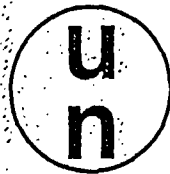
conducted by

DANGEROUS GOODS ADVISORY COUNCIL


DIRECTOR, EDUCATION AND TRAINING



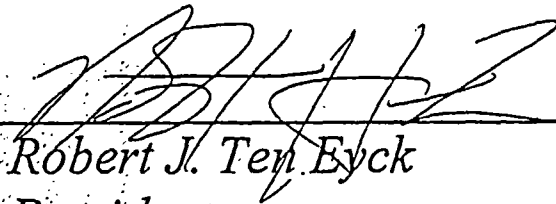
DANGEROUS GOODS CERTIFICATION



This is to certify
James Kostka

has successfully completed the UN performance oriented packaging standards program in accordance with DOT requirements for function-specific and general awareness/familiarization training.


Presented for
Eastern Isotopes Inc
May 17, 2002
by TEN-E Packaging Services, Inc.


Robert J. Ten Eyck
President

TEN-E
SETTING THE STANDARD
1666 County Road 74
Newport, Minnesota 55055
Phone: (651) 459-0712
Fax: (651) 459-1430

RADIATION ANNUAL REFRESHER TRAINING				(X) HAZMAT EMPLOYEE TRAINING REQUIRED	
HAZMAT EMPLOYEE TRAINING RECORD AND CERTIFICATION				X General Awareness	X Safety Training
				X Function Specific	X Driver Training
				X Recurrent Training Date	next Dec 13, 04
EMPLOYEE NAME (LAST, FIRST, MIDDLE) Kostka James A.			EMPLOYER NAME EASTERN ISOTOPES, INC.		
EMPLOYEE IDENTIFICATION NUMBER FOR EXPOSURE PURPOSES Landauer Participant Number # 54			EMPLOYER STREET ADDRESS 100 Executive Drive		
JOB POSITION Compliance Assist.	SITE LOCATION Sterling, Virginia	CITY Sterling	STATE VA	ZIP CODE 20166	
<p align="center">REGULATIONS and TRAINING INSTRUCTIONS quoted from 49 CFR 172 Subpart H</p> <p>172.704(d) Record keeping. A record of current training, inclusive of the preceding two years, in accordance with this subpart shall be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record shall include: (1) The hazmat employee's name; (2) The most recent training completion date of the hazmat employee's training; (3) A description copy, or the location of the training materials used to meet the requirements in paragraph (a) of this section; (4) The name and address of the person providing the training; and (5) Certification that the hazmat employee has been trained and tested as required by this subpart.</p> <p>The training requirements in 172.704 and 177.816 cover four areas of training for hazmat employees. Based on the training required for the above named hazmat employee, provide the training and testing for compliance. Satisfy the record keeping requirements in 172.704(d) by completing the information on this form.</p>					
<p align="center">RADIATION AND DOT ANNUAL REFRESHER TRAINING</p> <p align="center">This Employee has been trained and tested in accordance with 49 CFR 172 Subpart H.</p>					
COMPLETION DATE	DESCRIPTION OF TRAINING/ LOCATION OF MATERIALS USED	TRAINER/ ADDRESS	TRAINING AND TESTING CERTIFIED BY	CERTIFICATION DATE	
12/11/03 Item #1	Requirements of the License for Annual Training	Michael Ball Sterling, Virginia	Reading - one page	13-Dec-03	
11/18 Item #2	Test for 'Basics of Radiation' knowledge to test out of videos.	<p align="center">TAKE QUIZ WITHOUT HELP OR REFERENCE</p> <p>Present quiz to manager for correction PASS >80% go to step 3 / FAIL <80% go to step 2a</p>		13-Dec-03 to be filed	
Item #2a	Tape #1 Fundamentals of Radiation	If <80% then watch complete video while taking quiz		to be filed	
Item #2b	Tape #2 Radiation Risks Revised	If <80% then watch complete video while taking quiz		to be filed	
Item #2c	Tape #3 Radiation Safety and Common Sense	If <80% then watch complete video while taking quiz		to be filed	
12/11/03 Item #3	Yearly Exposure Limits, your 'Right to Know' Where are Exposure Reports?	Michael Ball Sterling, Virginia	Reading - part of one page	13-Dec-03	
12/11/03 Item #4	NRC - 10 CFR 19 - Instructions to Workers Where are the regulations kept?	Michael Ball Sterling, Virginia	NRC Notice to Employees & VA State Notice to Employees	13-Dec-03	
12/11/03 Item #5	NRC - 10 CFR 20 - Standard for Protection Where are the regulations kept?	Michael Ball Sterling, Virginia	NRC Notice to Employees & VA State Notice to Employees	13-Dec-03	
12/11/03 Item #6	Obligation to Report Unsafe Conditions to the RSO	Michael Ball Sterling, Virginia	Reading - part of one page	13-Dec-03	
12/11/03 Item #7	Lab Emergency Procedures	Michael Ball Sterling, Virginia	Reading - 1 pages	13-Dec-03	
12/11/03 Item #8	Personnel and Area Decontamination Procedures	Michael Ball Sterling, Virginia	Reading 4 pages	13-Dec-03	
12/11/03 Item #9	Survey Meter Reading	Michael Ball Sterling, Virginia	Quiz - 4 pages	13-Dec-03 to be filed	
12/11/03 Item #10	Fire Safety Booklet	Michael Ball Sterling, Virginia	Read Coastal Training Booklet Quiz - 1 page	13-Dec-03 to be filed	
Distribution Staff: Couriers, Dispatchers and Courier Supervisors					
12/11/03 Item #11	EII RAM Delivery Driver Training & SOP for Courier on a run	Michael Ball Sterling, Virginia	Reading - 4 pages	13-Dec-03	
12/11/03 Item #12	Glovebox Emergency Procedures	Michael Ball Sterling, Virginia	Reading 2 pages	13-Dec-03	
All Job positions Except Couriers/Drivers					
12/11/03 Item #13	NEW - Radiation Safety Manual (RSM) Orientation to this Reference Material	Michael Ball Sterling, Virginia	Page through RSM Binder and get familiar with the materials	13-Dec-03	


 I have read these documents and understand the materials.
EMPLOYEE'S SIGNATURE


 I certify this employee as complete Annual Training
CERTIFICATION & TRAINERS SIGNATURE

11/18/03 jk

ATTACH NECESSARY TRAINING DOCUMENTATION AND COMPLETED QUIZZES
 Finished quizzes and this signed off grid should be filled under each employee's name.
 Other training materials used will be filed in the front of the 'Record of Training "A" binder on site

RADIATION ANNUAL REFRESHER TRAINING		(X) HAZMAT EMPLOYEE TRAINING REQUIRED	
HAZMAT EMPLOYEE TRAINING RECORD AND CERTIFICATION		<input checked="" type="checkbox"/> General Awareness	<input checked="" type="checkbox"/> Safety Training
Without Meeting Attendance		<input checked="" type="checkbox"/> Function Specific	<input checked="" type="checkbox"/> Driver Training
		<input checked="" type="checkbox"/> Recurrent Training Date	next DEC 2003

EMPLOYEE NAME (LAST, FIRST, MIDDLE) KOSTKA JAMES		EMPLOYER NAME EASTERN ISOTOPES, INC.	
EMPLOYEE IDENTIFICATION NUM 19950301		EMPLOYER STREET ADDRESS	
Landauer Participant Number # 054		100 Executive Drive	
JOB POSITION Compliance	SITE LOCATION STERLING Virginia	CITY Sterling	STATE VA
			ZIP CODE 20166

REGULATIONS and TRAINING INSTRUCTIONS quoted from 49 CFR 172 Subpart H

172.704(d) Record keeping. A record of current training, inclusive of the preceding two years, in accordance with this subpart shall be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record shall include: (1) The hazmat employee's name; (2) The most recent training completion date of the hazmat employee's training; (3) A description copy, or the location of the training materials used to meet the requirements in paragraph (a) of this section; (4) The name and address of the person providing the training; and (5) Certification that the hazmat employee has been trained and tested as required by this subpart.

The training requirements in 172.704 and 177.816 cover four areas of training for hazmat employees. Based on the training required for the above named hazmat employee, provide the training and testing for compliance. Satisfy the record keeping requirements in 172.704(d) by completing the information on this form.

SECTION 1 RADIATION ANNUAL REFRESHER TRAINING

This Employee has been trained and tested in accordance with 49 CFR 172 Subpart H.

COMPLETION DATE	DESCRIPTION OF TRAINING/ LOCATION OF MATERIALS USED	TRAINER/ ADDRESS	TRAINING AND TESTING CERTIFIED BY	CERTIFICATION DATE
Item #1	Requirements of the License for Annual Training	Mike Ball Sterling, Virginia	Reading - one page	
Item #2	Basics of Radiation, Types of Radiation Terms and Definitions, Units of Measure	Mike Ball Sterling, Virginia	Reading and Review - 7 pages Take Quiz - 2 pages	
Item #3	ALARA Terms of the License Pertinent to Rad Safety	Mike Ball Sterling, Virginia	Reading - one page Give Examples of ALARA	
Item #4	General Rules for Safe Use of Radioactive Materials	Mike Ball Sterling, Virginia	Reading - one page	
Item #5	Visitor Procedure	Mike Ball Sterling, Virginia	Reading - one page	
Item #6	Personnel Monitoring with Assigned Badges	Mike Ball Sterling, Virginia	Reading and Review - 3 pages	
Item #7	Personnel Monitoring with Pocket Dosimeters	Mike Ball Sterling, Virginia	Reading and Review - 3 pages	
Item #8	Federal Yearly Limits, 'Right to Know'	Mike Ball Sterling, Virginia		
Item #9	10 CFR 19 - Instructions to Workers	Mike Ball Sterling, Virginia	NRC-Notice to Employees NRC Form 3	
Item #10	10 CFR 20 - Standard for Protection	Mike Ball Sterling, Virginia	NRC - Notice to Employees NRC Form 3	
Item #11	Obligation to Report Unsafe Conditions to the RSO RSO is Mike Ball	Mike Ball Sterling, Virginia	NRC-Notice to Employees	
Item #12	Lab Emergency Procedures	Mike Ball Sterling, Virginia	Reading - 1 pages	
Item #13	Glovebox Emergency Procedures	Mike Ball Sterling, Virginia	Reading 2 pages	
Item #14	Personnel and Area Decontamination Procedures	Mike Ball Sterling, Virginia	Reading 4 pages	
Item #15	EII RAM Delivery Driver Training & SOP for Courier on a run	Mike Ball Sterling, Virginia	Reading - 3 pages	
Item #16	Survey Meter Reading	Mike Ball Sterling, Virginia	Quiz - 4 pages	

This Employee has been trained and tested in accordance with 49 CFR 172 Subpart H

I have read these documents and understand the materials.
EMPLOYEES SIGNATURE

I certify this employee as complete Annual training
CERTIFICATION & TRAINERS SIGNATURE

11/25/02 jk

ATTACH NECESSARY TRAINING DOCUMENTATION AND COMPLETED QUIZZES

Training materials used will be filed in the front of the 'Record of Training' book on site

RADIATION ANNUAL REFRESHER TRAINING		(X) HAZMAT EMPLOYEE TRAINING REQUIRED	
HAZMAT EMPLOYEE TRAINING RECORD AND CERTIFICATION		X General Awareness	X Safety Training
		X Function Specific	X Driver Training
		X Recurrent Training Date	next 12/01/2002

EMPLOYEE NAME (LAST, FIRST, MIDDLE) Kostka, James A		EMPLOYER NAME EASTERN ISOTOPES, INC.	
EMPLOYEE IDENTIFICATION NUMBER Landauer Participant Number #		EMPLOYER STREET ADDRESS 100 EXECUTIVE DRIVE	
JOB POSITION Compliance Asst	SITE LOCATION (Sterling)	CITY STERLING	STATE VA
		ZIP CODE 20166	

REGULATIONS and TRAINING INSTRUCTIONS quoted from 49 CFR 172 Subpart H

172.704(d) Record keeping. A record of current training, inclusive of the preceding two years, in accordance with this subpart shall be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record shall include: (1) The hazmat employee's name; (2) The most recent training completion date of the hazmat employee's training; (3) A description copy, or the location of the training materials used to meet the requirements in paragraph (a) of this section; (4) The name and address of the person providing the training; and (5) Certification that the hazmat employee has been trained and tested as required by this subpart.

The training requirements in 172.704 and 177.816 cover four areas of training for hazmat employees. Based on the training required for the above named hazmat employee, provide the training and testing for compliance. Satisfy the record keeping requirements in 172.704(d) by completing the information on this form.

SECTION 1: RADIATION ANNUAL REFRESHER TRAINING

This Employee has been trained and tested in accordance with 49 CFR 172 Subpart H.

COMPLETION DATE	DESCRIPTION OF TRAINING/ LOCATION OF MATERIALS USED	TRAINER/ ADDRESS	TRAINING AND TESTING CERTIFIED BY	CERTIFICATION DATE
12/1/2001	Basics of Radiation, Types of Radiation Terms and Definitions, Units of Measure	Jim Kostka Sterling, Virginia	Class Lecture and Review Take Quiz, Review Quiz	12/1/2001
12/1/2001	ALARA Terms of the License Pertinent to Rad Safety	Jim Kostka Sterling, Virginia	Class lecture and Review Overhead	12/1/2001
12/1/2001	General Rules for Safe Use of Radioactive Materials	Jim Kostka Sterling, Virginia	Class lecture and Review Overhead	12/1/2001
12/1/2001	Personnel Monitoring with Assigned Badged and Pocket Dosimeters	Jim Kostka Sterling, Virginia	Class lecture and Review	12/1/2001
12/1/2001	Fed Yearly Limits, Right to Know Landauer Report	Jim Kostka Sterling, Virginia	Class lecture and Review	12/1/2001
12/1/2001	10 CFR 19 - Instructions to Workers 10 CFR 20 - Standards for Protection	Jim Kostka Sterling, Virginia	NRC Form 3	12/1/2001
12/1/2001	Obligation to Report Unsafe Conditions to the RSO RSO is John Thomas	Jim Kostka Sterling, Virginia	NRC Form 3	12/1/2001
12/1/2001	Rules and Regulations of the License Location & Review of NRC License Book	Jim Kostka Sterling, Virginia	Class Lecture and Review	12/1/2001
12/1/2001	Visitor Procedure	Jim Kostka Sterling, Virginia	Class lecture and Review	12/1/2001
12/1/2001	Glovebox - Emergency Instructions	Jim Kostka Sterling, Virginia	Reading	12/1/2001
12/1/2001	Lab Emergency Procedures and Decontamination Kit	Jim Kostka Sterling, Virginia	Location of Lab Emergency Procedures and Decon Kit / use	12/1/2001
12/1/2001	IBA HAZCOM Review	Jim Kostka Sterling, Virginia	Overheads and Discussion	12/1/2001
12/1/2001	HAZCOM Hazard Communication	Jim Kostka Sterling, Virginia	Video and Booklet Quiz	12/1/2001
12/1/2001	MSDS for Healthcare Read it Before You Need It	Jim Kostka Sterling, Virginia	Video and Booklet Quiz	12/1/2001
12/1/2001	MSDS Review MSDS for FDG	Jim Kostka Sterling, Virginia	Class lecture and Review	12/1/2001
12/1/2001	Survey Meter Reading	Jim Kostka Sterling, Virginia	Quiz	12/1/2001
12/1/2001	EII RAM Delivery Driver Training & SOP for Courier on a run	Jim Kostka Sterling, Virginia	Class Lecture and Overheads Handout	12/1/2001

[Signature]

EMPLOYEE'S SIGNATURE

TRAINER

[Signature]

CERTIFICATION & TRAINERS SIGNATURE

1/27/2001 JK

ATTACH NECESSARY TRAINING DOCUMENTATION AND COMPLETED QUIZZES
Meeting materials used will be filed in the front of the 'Record of Training' book on site

**ANNUAL REFRESHER TRAINING
HAZMAT EMPLOYEE TRAINING
RECORD AND CERTIFICATION**

(X) ☒ General Awareness ☒ Safety Training
☒ Function Specific ☒ Driver Training
☒ Recurrent Training Date next 12/04/2001

EMPLOYEE NAME (LAST, FIRST, MIDDLE) <i>Kostka James</i>		EMPLOYER NAME EASTERN ISOTOPES, INC.	
EMPLOYEE IDENTIFICATION NUMBER [REDACTED]		EMPLOYER STREET ADDRESS 100 EXECUTIVE DRIVE, SUITE #3	
JOB POSITION <i>Cyclotron</i>	SITE LOCATION <i>Sta 1g</i>	CITY STERLING	STATE VA ZIP CODE 20166

REGULATIONS and TRAINING INSTRUCTIONS quoted from 49 CFR 172 Subpart H

172.70-4(c) Record keeping. A record of current training, inclusive of the preceding two years, in accordance with this subpart shall be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record shall include: (1) The hazmat employee's name; (2) The most recent training completion date of the hazmat employee's training; (3) A description copy, or the location of the training materials used to meet the requirements in paragraph (a) of this section; (4) The name and address of the person providing the training; and (5) Certification that the hazmat employee has been trained and tested as required by this subpart.

The training requirements in 172.70-4 and 177.8-6 cover four areas of training for hazmat employees. Based on the training required for the above named hazmat employee, provide the training and testing for compliance. Satisfy the record keeping requirements in 172.70-4(c) by completing the information on this form.

COMPLETION DATE	DESCRIPTION OF TRAINING/ LOCATION OF MATERIALS USED	TRAINER/ ADDRESS	TRAINING AND TESTING CERTIFIED BY	CERTIFICATION DATE
12-04-2000	Eastern Isotopes Vehicle policy	Jim Kostka Sterling, Virginia	Handout and review	12-04-2000
12-04-2000	Booklet "Vehicle Safety on the Job"	Jim Kostka Sterling, Virginia	Handout booklet and review Quiz	12-04-2000
12-04-2000	DOT HAZMAT Regulations	Jim Kostka Sterling, Virginia	Class Lecture and Overheads Handout 49 CFR 172	12-04-2000
12-04-2000	Eastern Isotopes license and license application review	Jim Kostka Sterling, Virginia	Class Lecture and Overheads lecture	12-04-2000
12-04-2000	Lab and packaging procedures to meet compliance issues	Jim Kostka Sterling, Virginia	Class Lecture and Overheads Handout	12-04-2000
12-04-2000	Hazmat packaging for shipment: Case package examples.	Jim Kostka Sterling, Virginia	Class Lecture and Overheads lecture and examples	12-04-2000
12-04-2000	EII RAM Delivery Driver Training & SOP for Courier on a run	Jim Kostka Sterling, Virginia	Class Lecture and Overheads Handout	12-04-2000
12-04-2000	DOT HAZMAT Regulations & how EII employees comply	Jim Kostka Sterling, Virginia	Quiz	12-04-2000
12-04-2000	Lab Emergency Procedures and Decontamination Kit	Jim Kostka Sterling, Virginia	Location of Lab Emergency Procedures and Decon Kit, use	12-04-2000
12-04-2000	Booklet "How to Lift Move & Carry Things Safely"	Jim Kostka Sterling, Virginia	Handout booklet and review Quiz	12-04-2000
12/30	TAPE #1 - Fundamentals of Radiation Safety - on site	Jim Kostka Sterling, Virginia	Video, Quiz & Review	12/4
12/30	TAPE #2 - Radiation Risks Revisited - on site	Jim Kostka Sterling, Virginia	Video, Quiz & Review	12/4
12/30	TAPE #3 - Radiation Safety and Common Sense - on site	Jim Kostka Sterling, Virginia	Video, Quiz & Review	12/7
12/30	Glovebox - Emergency Instructions	Jim Kostka Sterling, Virginia	Reading	12/7
12/30	Audit for completion of training for this employee's training records	Jim Kostka Sterling, Virginia	Completed audit of all prior training records on file at job site location and/or Sterling	12/7

EMPLOYEE'S SIGNATURE

CERTIFICATION & TRAINERS SIGNATURE

ATTACH NECESSARY TRAINING DOCUMENTATION AND COMPLETED QUIZZES
 Meeting materials used will be filed in the front of the 'Record of Training' book on site

*Instructor
Self Certified*

PERSONAL INFORMATION WAS REMOVED
 BY NRC. NO COPY OF THIS INFORMATION
 WAS RETAINED BY THE NRC.

Hand 1

12/4/00
D. J. Carr
not

10/30/2000JK

Jim is certified by CSI Radiation Training as DOT Trainer

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

December 29, 2004

To Whom It May Concern:

As of December 29, 2004 I have completed the requirements for nuclear certification. The didactic training was done at Ohio State University, in Columbus OH, where 214 hours of classes were completed on October 1, 2004. The certificate is enclosed with this letter.

A total of 500 hours of work experience has been completed, 460 hours were done at the Eastern Isotopes site in Somerset, NJ under the direction of Jamie Perry, 40 hours were done at the Ohio State University in Columbus, OH under the direction of George Hinkle.

John Chen has achieved a level of competency to sufficiently function individually as an authorized nuclear pharmacist.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Chen RPh', with a stylized flourish at the end.

John Chen, RPh

A handwritten signature in black ink, appearing to read 'Jamie Perry RPh', with a stylized flourish at the end.

Jamie Perry, RPh
Radiation Safety Officer

RADIOISOTOPE HANDLING EXPERIENCE

Name: John Chen, RPh

Date: December 29, 2004

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	MAXIMUM HANDLED ACTIVITY	USE See key below:	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
I-131	1 Ci	1,2,3,4,5,6	10/11/04 to 12/29/04 460 hours 460 Total Hours	Eastern Isotopes Somerset, NJ
I-123	7 mCi	1,2,3,4,5,6		
Ga-67	50 mCi	1,2,3,4,5,6		
In-111	5 mCi	1,2,3,4,5,6		
Ba-133	5 mCi	1,2,5		
Co-57	5 mCi	1,2,5		
F-18	4 Ci	1,2,3,4,5,6		
Cs- 137	250 uCi	1,2,5		

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:

Jamie Perry RPh
Jamie Perry, RPh,

Date: December 29, 2004



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: John C. Chen, R.Ph.

Date: October 1, 2004

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

RADIONUCLIDE	RADIOACTIVITY	USE see below	EXPERIENCE Actual clock hours (Include date range of experience)	LOCATION
Mo-99	10 Curies	1,2,3,4,5,6,7	9/6/04	The Ohio State University Medical Center, Columbus, OH
Tc-99m	8 Curies	1,2,3,4,5,6,7	through	
I-131	200 mCi	1,2,3,4,5,6	10/1/04	
I-123	1 mCi	1,2,3,4,5,6		
Ga-67	25 mCi	1,2,3,4,5		
Tl-201	50 mCi	1,2,3,4,5		
In-111	7.5 mCi	1,2,3,4		
Sr-89	5 mCi	1,2,3,4,5,6		
Sm-153	100 mCi	1,2,3,4,5,6		
F-18	200 mCi	1,2,3,4,5,6		
Cs-137	0.2 mCi	1,2,5		
			TOTAL HOURS: 40 hours	

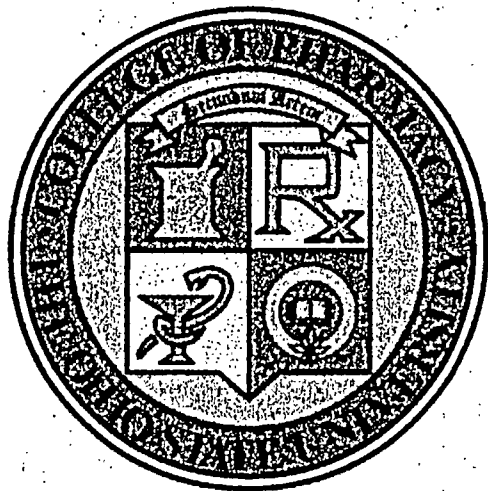
Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:

George H. Hinkle
George H. Hinkle, RPh, MS, BCNP

Date: October 1, 2004



**The Ohio State University
College of Pharmacy
and
University Medical Center
Department of Pharmacy**



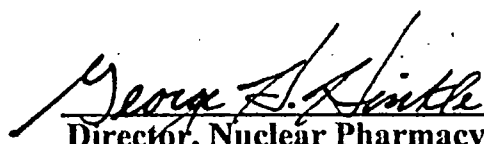
By this certificate warrants that


John C. Chen, R. Ph.

has satisfactorily fulfilled all requirements
and completed the prescribed course

Nuclear Pharmacy Certificate Program

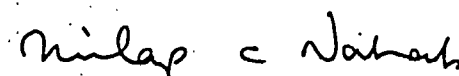
October 1, 2004


Director, Nuclear Pharmacy
Associate Professor of Pharmacy


Executive Director
Council of Ohio Colleges of Pharmacy




Dean, College of Pharmacy


Chair, Pharmacy Practice
and Administration



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: John C. Chen, R.Ph.

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	September 6, 2004 through October 1, 2004	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User:

George H. Hinkle
George H. Hinkle, RPh,MS,BCNP,FASHP,FAPhA

DATE: October 1, 2004

December 15, 2004

Wade Loo
Region II
Materials Licensing
Suite 2900
101 Marietta St.
Atlanta, Ga. 30323


License No. 45-25221-01MD

Dear Sir:

I am requesting a License Amendment to add Kim Hosen to our radioactive materials license (Item 11A on license). Kim has completed her didactic training with *The Ohio State University College Of Pharmacy* on October 1, 2002. Her 500 hours of lab work experience was completed at Eastern Isotopes, Inc. Sterling facility.

As Preceptor, I certify that Kim C. Hosen has completed her 500 hours of hands on training and is competence to perform her duties independently.

Sincerely,



Nasrin Pourkiani PharmD, B.S. ANP
Preceptor / Site Training Manager

Item 11A on
NRC License
#45-25221-01-MD

**AUTHORIZED NUCLEAR PHARMACIST
EXPERIENCE IN HANDLING RADIOISOTOPE**

Eastern Isotopes, Inc.
Corporate Headquarters
100 Executive Drive, Suite 100
Sterling, VA 20166
Phone (703) 787-7900
Fax (703) 787-4078

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)	Hosen	Kim	Carter	Dates: 8/23/04 to 9/3/04 and 10/2/04 to 12/17/04
-----------------------------	-------	-----	--------	--

Isotope(s) Used	Maximum amount used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience
Molybdenum 99	15 Ci	Sterling, VA	5,6,7	60
Technetium 99m	15 Ci	Sterling, VA	4,7	200
Xenon 133	200 mCi	Sterling, VA	1	40
Iodine 131	350 mCi	Sterling, VA	4,7	30
Iodine 123	4 mCi	Sterling, VA	4,7	25
Thallium 201	120 mCi	Sterling, VA	4,7	100
Gallium 67	30 mCi	Sterling, VA	4,7	25
Cs 137, Ba 133, Co 57	300 µCi	Sterling, VA	1,2,5	20
F 18	4.5 Ci	Sterling, VA	4,7	10
Total =				510

Signature of Preceptor Authorized Nuclear Pharmacist:

"I certify that the above described training/experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."

Signature:

Print: Nasrin Pourkiani PharmD, B.S, ANP

Title:

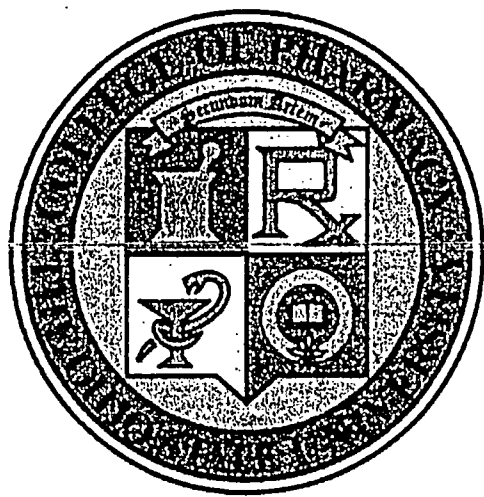
Pharmacist
Training Manager

Date:

12/17/2004

* Purpose of Use

1. Shipping, receiving, and performing related radiation surveys.
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta- emitting radionuclides.
3. Using and performing checks for proper operation of instruments to measure alpha and low energy beta- emitting radionuclides.
4. Calculating, assaying, and safely preparing dosages for patients or human research subjects.
5. Use of administrative controls to avoid mistakes in the administration of byproduct material.
6. Use of procedures to prevent or minimize contamination/or use of proper decontamination procedures.
7. Compounding radiopharmaceuticals for distribution to authorized recipients.



**The Ohio State University
College of Pharmacy
and
University Medical Center
Department of Pharmacy**



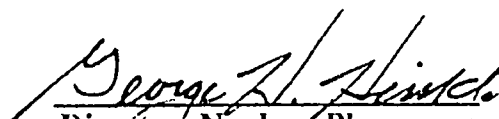
By this certificate warrants that

Kim C. Hosen, R. Ph.

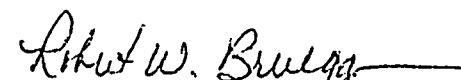
has satisfactorily fulfilled all requirements
and completed the prescribed course


Nuclear Pharmacy Certificate Program

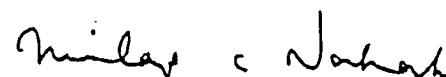
October 1, 2004


Director, Nuclear Pharmacy
Associate Professor of Pharmacy




Dean, College of Pharmacy


Executive Director
Council of Ohio Colleges of Pharmacy


Chair, Pharmacy Practice
and Administration



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Kim C. Hosen, R.Ph.

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	September 6, 2004 through October 1, 2004	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User:

George H. Hinkle
George H. Hinkle, RPh, MS, BCNP, FASHP, FAPhA

DATE: October 1, 2004



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM
RADIONUCLIDE HANDLING EXPERIENCE

Name: Kim C. Hosen, R.Ph.

Date: October 1, 2004

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

RADIONUCLIDE	RADIOACTIVITY	USE see below	EXPERIENCE	LOCATION
			Actual clock hours (Include date range of experience)	
Mo-99	10 Curies	1,2,3,4,5,6,7	9/6/04	The Ohio State University Medical Center, Columbus, OH
Tc-99m	8 Curies	1,2,3,4,5,6,7	through	
I-131	200 mCi	1,2,3,4,5,6	10/1/04	
I-123	1 mCi	1,2,3,4,5,6		
Ga-67	25 mCi	1,2,3,4,5		
Tl-201	50 mCi	1,2,3,4,5		
In-111	7.5 mCi	1,2,3,4		
Sr-89	5 mCi	1,2,3,4,5,6		
Sm-153	100 mCi	1,2,3,4,5,6		
F-18	200 mCi	1,2,3,4,5,6		
Cs-137	0.2 mCi	1,2,5		
			TOTAL HOURS: 40 hours	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:

George H. Hinkle
George H. Hinkle, RPh, MS, BCNP

Date: October 1, 2004

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

1/6/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND 45-25221-01MD
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 136276.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader

BETWEEN: : (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 License Fee Management Branch, ARM : Program Code: 02500
 and : Status Code: 0
 Regional Licensing Sections : Fee Category: 3C 2B
 : Exp. Date: 20130731
 : Fee Comments: _____
 : Decom Fin Assur Req'd: N
 : ::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: EASTERN ISOTOPES, INC.
Received Date: 20050112
Docket No: 3032974
Control No.: 136276
License No.: 45-25221-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: /

3. COMMENTS

Signed M.A. Berlin
Date 1/27/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____