



**Charleston Area
Medical Center**

NUCLEAR PHARMACY
3200 MacCorkle Ave. SE
Charleston, WV 25304
(304) 388-9295
Pharmacy (304) 388-9701
Fax: (304) 388-8922

Br. 1

11/10/2015

**U.S. NRC Region I DNMS
2100 Renaissance Blvd.
King of Prussia, PA 19406**

Re: Amendment Request NRC License #47-15473-01 03009164

Tara Weidner, Senior Health Physicist

Please amend the above referenced license as follows:

1. Please remove the mobile PET coach as a location of use at CAMC Memorial Hospital as added per amendment request dated May 29, 2015 and request for additional information dated June 8, 2015.
 - a. Please see attached decommissioning wipes and surveys performed on June 26, 2015 at the end of the day and prior to release of the mobile coach for transportation.
 - b. Copies of calibration information for instruments used for decommissioning wipes and surveys.
2. Please remove Jaime K. Salvatore, D.O. from the above license as an authorized user.
3. Please reference calibration documentation dated July 15, 2015 for the dose calibrator located at CAMC General Hospital Nuclear Medicine used in administration of Ra-223 radium dichloride. Calibration was performed prior to the administration of a patient dose as requested at our last inspection.

If there are any questions regarding this amendment please feel free to contact me at the telephone numbers provided below or you may e-mail your questions to me at kim.lowe@camc.org.

Sincerely,

Kim Lowe, Pharm.D, BCNP, Assistant RSO
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-9295 office
(304) 549-0147 mobile

Christine Oskin, MBA, RT
Corporate Director
Medical Imaging Services
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304

REC'D 11/20/15 10:07:43

589438

Decommissioning Wipes

Area Wiped	1	2	3	4	5	6	7	8	9	10	11
BKG	138	138	138	138	138	138	138	138	138	138	138
Wipe (Net DPM)	0	0	0	0	0	0	0	0	0	0	0
DPM after Clean											

1. Dose Calibrator
2. Hot Lab Countertop
3. L-Block
4. Waste Bins
5. Hot Lab Floor
6. Patient Chairs
7. Control Room and Floor
8. Patient Gantry
9. Scanner Room Floor
10. Rear of Scanner Floor
11. Control Room Counter

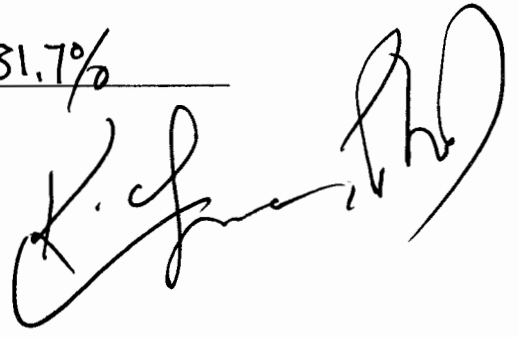
Performed by Ben Barido
 Date June 26 2015

**Wipes not to exceed 200 dpm over background (dpm=cpm/efficiency)

Survey Instrument Used: AccuSync Spectro Wipe #51060117
see attached efficiency
Ludlum 14-C #227706

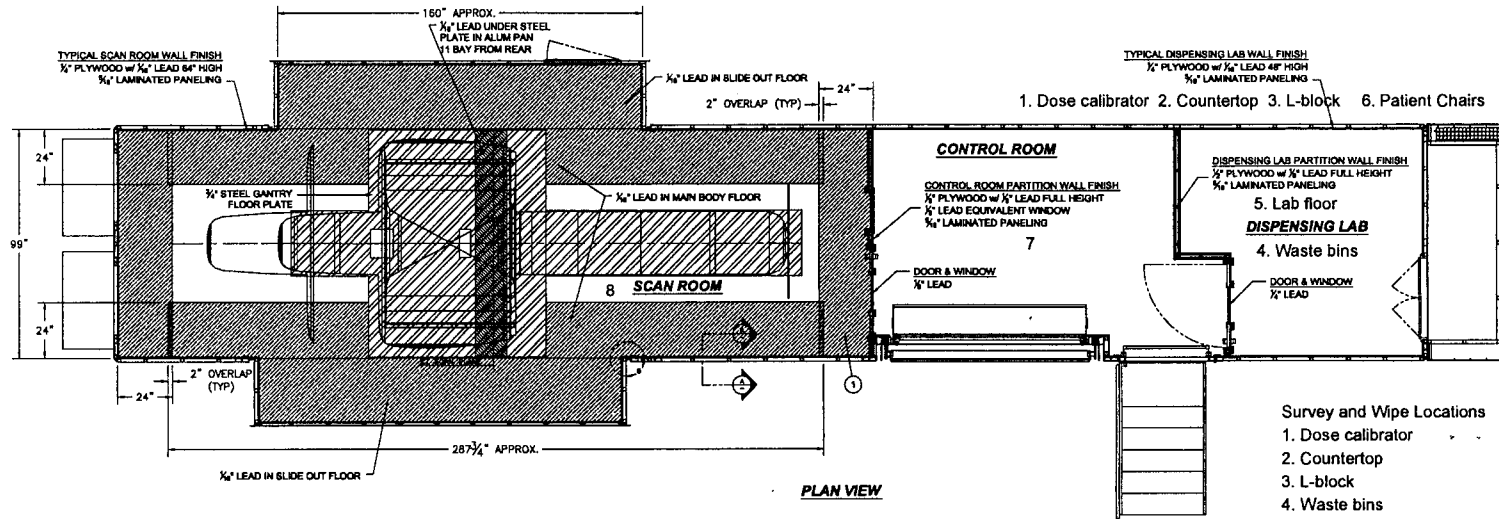
Current Efficiency: 81.7%

All surveys background

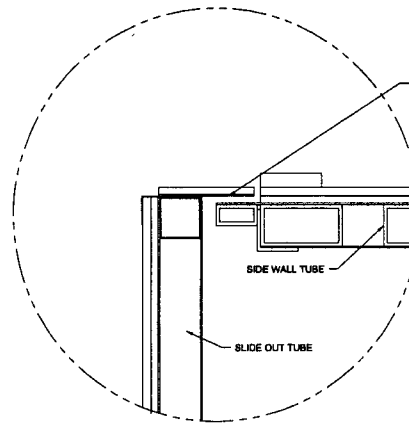
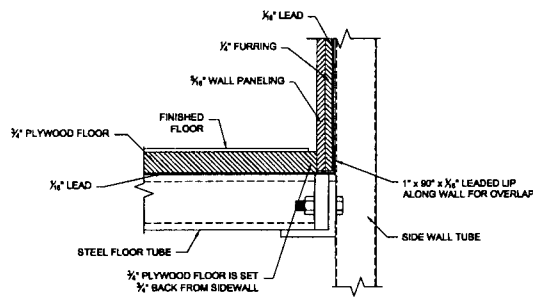
REVISIONS					DESCRIPTION
REV.	REV. DATE	CHK. BY	CHK. DATE	ENG.	
1	12/01/06	W.L.	12/02/06	P. REZACK	UPDATED PLAN VIEW

Survey and Wipe Map



IMPORTANT NOTE:
ALL WALLS IN SCAN ROOM INCLUDING EXPANDING WALL SECTIONS TO BE 1/16" LEAD LINED.
LEAD IN SCAN ROOM WALL TO BE A MINIMUM OF 84" ABOVE FINISHED FLOOR
ALL FLOOR, WALL AND CORNER SEAMS TO HAVE OVERLAPPING LEAD

- Survey and Wipe Locations**
1. Dose calibrator
 2. Countertop
 3. L-block
 4. Waste bins
 5. Lab floor
 6. Patient chairs
 7. Control room and floor
 8. Patient gantry



IMPORTANT NOTE:
LEAD MATERIAL TO BE INSTALLED UNDERNEATH FINISH BAR STOCK FOR LEAD OVERLAPPING.

ITEM	QTY	PART NUMBER	DESCRIPTION
1		60090077	LEAD ROLL 1/16 X 24-1/2 X 8'

BILL OF MATERIALS

CUSTOMER AUTHORIZATION

COMPANY NAME: _____

NAME (PRINT): _____ TITLE: _____

SIGNATURE: _____ DATE: _____

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SHEET NUMBER: SHEET 1 OF 1 REFERENCE DRAWING: 10227-A18-08 TITLE: PLAN VIEW OF LEAD REQUIREMENTS GE MEDICAL SYSTEMS DISCOVERY ST PETCT 8'-0" x 13'-0" x 48'-0" TRAILER. DATE: 08/28/01 SCALE: 1/2"=1'-0"

JOB# _____

OSHKOSH SPECIALTY VEHICLES 18748 S. LATHROP AVENUE HARVEY, IL 60426 PHONE: (708) 886-6286 FAX: (708) 886-3460

CREATED BY: _____ DRAWING NUMBER: 12193-A18

Wipe Meter Efficiency Test

Charleston Area Medical Center

3200 MacCorkle Ave SE

Charleston, WV 25304

47-15473-02MD exp: 11/16

FACILITY NAME/ADDRESS:

CAMC Nuclear Pharmacy
3200 MacCorkle Avenue SE
Chaleston, WV 25304

DATE PERFORMED: 06/16/2015 08:30

NEXT DUE DATE: 09/16/2015

INSTRUMENT INFORMATION:

Model Number: SW1000-ID

Manufacturer: AccuSync Medical

Serial Number: S1060117

AccuSync Medical

S1060117

HV Setting: 706.00 volts

Window: 50.0 keV to 750.0 keV

Count Time: 0.17 mins

SOURCE INFORMATION:

Nuclide: Co57

Source Type: Co-57 Source

Manufacturer: RadQual, LLC3

Serial Number: BM0805713304102

Calibration Amt: 1.401 uCi

Calibration D/T: 10/31/2013 12:00

Current Activity: 0.30742195 uCi / 682476 DPM

WIPE METER EFFICIENCY TEST DATA:

Measurement	Wipe (COUNTS)	Background (COUNTS)	NET (CPM)	Efficiency
1	92986	3	556785	81.583 %
2	93279	3	558539	81.84 %
3	93226	3	558222	81.794 %
Average	557865	17	557848	81.739 %

NOTES:

$NET_CPM = (Wipe_CPM - Background_CPM) / Count_Time$

$Efficiency_Of_Meter = (NET_CPM / Current_DPM_Of_Known_Source) * 100$

$DPM_Per_uCi = 2.22 * 10^6$

$LLD = 4.65 * Sqrt(Background_Counts) + 3$

$MDA = LLD / (Efficiency_Of_Meter * DPM_Per_uCi)$

If MDA is greater than 0.005 uCi, a longer count time is required

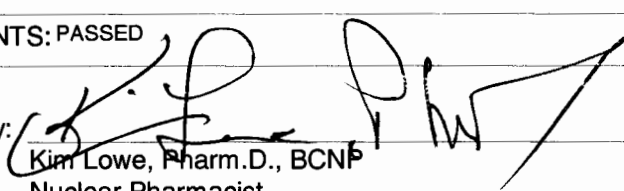
Minimum Detectable Activity (MDA)

Value	Results
LLD	22.172 CPM
MDA	0.000012 uCi

TEST COMMENTS: PASSED

TEST DATA:

Performed by:


Kim Lowe, Pharm.D., BCNP
Nuclear Pharmacist

Licensee: Charleston Area Medical Center

Registration: 47-15473-02MD exp: 11/16

Prepared by: Kim Lowe, Pharm.D., BCNP

Printed: 11/13/2015 8:27:32 AM Wipe Meter Efficiency Test ID: 212

Page: 1

Certificate of Calibration

A.M. Calibration Services

9620 Medical Center Drive
 Rockville Md 20850
 Phone: 301-610-6001

amcalibration@aol.com

Meter Owner:	CAMC-Memorial Division	Manufacturer:	Ludlum
Calibration Date:	11/11/2014	Model Number:	14-C
Calibration Due Date:	11/11/2015	Serial Number:	227788



AM Calibration Radioactive Material License: MD-31-206-01

Inspection Item	
Batteries Changed	no
Internal Adjustment	no

Instrument Calibration Information

Probe: 44-9 237678 w/cap

Instrument Scale	mR/hr		CF	Scale
	Meter Exposure	True Reading		CF
x 1000.0	1150	1428	1.240	1.087
x "	380	355	0.934	"
x 100.0	145	158	1.090	1.032
x "	40	39	0.975	"
x 10.0	14	14	1.000	1.000
x "	3.6	3.6	1.000	"
x 1.0	1.6	1.6	1.000	1.000
x "	0.4	0.4	1.000	"
x 0.1	0.14	0.14	1.000	1.000
x "	0.075	0.075	1.000	"

Check Source Reading = 5.20mR/hr Cap Off

This certifies that the instrument above was calibrated with a Cs-137 source, Shepherd Model 28-6 #10258-300mCi. Exposure rate for this source has been verified with instrumentation whose calibration is traceable to NIST standards. And in accordance with ANSI-N323 and as recommended by manufacturer.

Calibrated By: Andrew J McAleer

FORM FOR ESTABLISHING A RA 223 DOSE CALIBRATOR DIAL SETTING

Section 1: Decay correction of Ra 223 sample and dose calibrator dial setting

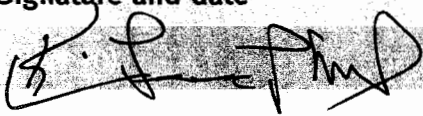
Activity at reference date [μCi]	Reference date/time; mm/dd/yy; hh:mm	Date/time of dial setting determination of dose calibrator mm/dd/yy; hh:mm	Decay factor (from decay correction table)	Decay-corrected activity of Ra 223 reference sample [μCi]
121.28 μCi	07/15/15 09:00 ^{07:00 AM} ET	07/15/15 08:00 ^{07:00 AM} ET	0.997	121.7 μCi
Dose calibrator: manufacturer, model, serial number			Reference sample ID number	Dial setting (calibration number) for Ra 223
Capintec CRC-12 #13325			131224	280

Section 2: Measurements (Note: first and second repeat measurements should be essentially the same [i.e., within 5% of the decay-corrected reference standard activity as obtained in Step 8])

Activity measurement at calibrated dial setting [μCi]	Activity measurement at calibrated dial setting [μCi]	Second repeat activity measurement [μCi]
122 μCi	122 μCi	122 μCi

Facility name
 CAMC General Hospital

Performed by (print name) Email address
 Kim Lowe, Pharm.D., BCNP kim.lowe@camc.org

Signature and date
 7/15/15



For further information, please visit www.xofigo-us.com



Radium Ra 223 dichloride (Ra 223) is primarily an alpha emitter; however, beta particles and photons (gamma and x-rays) are also emitted during decay. The gamma radiation associated with the decay of Ra 223 and its daughters allows for the radioactivity measurement of Xofigo with standard instruments.

The methodology used for measurement of Xofigo dosages to patients as given in this procedure may be used as a standard operating procedure (SOP) for determining the appropriate dial setting for use with Ra 223. An example form is provided with this procedure for recordkeeping.

PROCEDURE FOR RA 223 DOSE CALIBRATOR DIAL SETTING:

STEP 1

A reference standard containing a secondary NIST traceable amount of Ra 223 dichloride solution will be provided in a syringe or vial to the facility from Cardinal Health central radiopharmacy. The reference standard will include paperwork containing the source activity and a decay correction factor table.

STEP 2

Conduct standard quality control and background correction of the dose calibrator according to the manufacturer's instructions and facility SOPs.

STEP 3

Using the paperwork that accompanies the Ra 223 reference standard, enter the following into the form provided:

- Activity at reference date (to 1 decimal place)
- Reference date and time
- Date and time of calibration for this dose calibrator

STEP 4

Using the decay factor correction table included with the Ra 223 reference standard, determine the decay correction factor based on the number of days between the reference date and date/time that this dial setting is being established and record it on the form.

STEP 5

Calculate the decay-corrected activity by multiplying the reference activity by the decay factor and record on the form.

STEP 6

Record the manufacturer, model, and serial number of the dose calibrator on the form.

STEP 7

Record the ID number of the Ra 223 reference standard.

STEP 8

Place the Ra 223 reference standard in the dose calibrator, making sure the sample is centered in the measuring chamber. Adjust the dose calibrator dial setting according to the instrument's operating manual until the dose calibrator reading matches the calculated decay-corrected activity of the reference sample, as determined in Step 5, and record this activity and dial setting on the form. Once the dial setting is determined, it should be used for all subsequent radioactivity measurements of Ra 223.

STEP 9

A total of 3 measurements of the Ra 223 reference standard utilizing the dose calibrator dial setting for Ra 223 should be performed. Record the results on the form. Make sure to allow the dose calibrator time to return to background level between the measurements. All repeat measurements should be essentially the same as determined in Step 8, but must each be within $\pm 5\%$ of the decay-corrected reference standard activity; if not, repeat the measurement.

STEP 10

Record the facility name, name of individual performing calibration, email address, signature, and date completed.

Note: The licensee will not need to perform any geometrical testing.¹

Dose calibrator requirements may vary by Agreement State regulation.

1. Bergeron D, Zimmerman B, Cessna J, 2010. Development of secondary standards for ²²³Ra. *Appl. Radiat. Isot.* (68):1367-1370.

This is to acknowledge the receipt of your letter application dated

11/10/2015, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-15473-01) 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** 509438.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.