

March 14, 2013 Amended April 26, 2013

Elizabeth Ullrich Senior Health Physicist U.S. Nuclear Regulatory Commission Region I Licensing Assistance Team Division of Nuclear Materials Safety 475 Allendale Road King of Prussia, PA 19406-1415

SUBJECT: Amendment NRC Lic: 44-30124-01MD

Mr. Dennis Lawyer:

PharmaLogic respectfully submits a request to amend the existing commercial nuclear pharmacy US NRC Radioactive Materials License # 44-30124-01MD to include the following change:

1. Remove the following commercial nuclear pharmacy location from the existing U.S. Nuclear Regulatory Commission Radioactive Materials License.

PharmaLogic Ltd 9 Krupp Dr. Williston, VT 05495

The original nuclear pharmacy radioactive materials have been transferred to the new commercial nuclear pharmacy location.

PharmaLogic Ltd 1191 S. Brownell Road, Suite 30 Williston, VT 05495

PharmaLogic followed guidance in NUREG-1757 to decommission the Krupp Dr. location. Our RSO and Manager followed a 100% survey scan of the areas in the facility to identify existing and residual radiation levels. Surveys were also taken around areas in which radioactive material would have been kept or drawn to confirm activity levels were negligible.

The lodine Exhaust System has been dismantled under the guidance of the Radiation Safety Officer. The exhaust duct work was surveyed for radiation exposure and removable contamination. Surveys revealed an exposure that did not exceed background at surface and 0 dpm and 0 dpm at the proximal and distal ends of the ductwork respectively. This ventilation shaft was not connected to a wall so no wipe test was completed of the surrounding area, but the duct was surveyed and revealed exposure mentioned above.

PharmaLogic did conduct a survey for all areas as described in the following wipe reports of this packet and included the survey device and detectible levels found. This included waste barrels, sinks and flow hoods including ventilation ducts

Radiation surveys were performed thereafter at the Krupp Dr. pharmacy that confirms the absence of radioactive materials at the Krupp Dr. location. The survey results and survey diagrams and a completed NRC Form 314 are attached. Also attached are transfer reports of materials moved to a new location and their activity readings.

I wish to thank you for your consideration of this request. Upon review, if there are any questions, please contact me directly.

Sincerely,

Rich Sucese, RPh Radiation Safety Officer

rsucese@pharmalogic.info

Brian D. Davis, RPh Regulatory Affairs bdavis@pharmalogic.info

561-405-0349

ATT: Radiation Survey Reports and Diagrams

NRC FORM 314

Iodine Room Survey and Wipes

Prior to our schedule pharmacy move into the new site, Iodine room glove box and fume hood will be surveyed and wiped daily (both inside and outside of each), excluding weekend. Values will be documented below. No I-131 doses for treatments or whole body scans will be compounding between 2/18 and the anticipated move date of 2/27.

Instruments: GM Meter: 110522; Ludlum SCA

Date	BKG	Glove	Fume	BKG	Glove box wipe	Fume Hood	Initials
		Box	Hood		(inside/outside)	wipe	
	mR/hr	Survey	Survey	CPM		(inside/out)	
Mon.	0.01-	0.1	0.4	58	62/64	64/59	rs
2/18	0.04						
Tues.	0.01-	0.08	0.4	70	74/73	69/67	rs
2/19	0.04						
Wed.	0.02-	0.08	0.3	61	68/66	63/64	rs
2/20	0.06						
Thru.	0.01-	0.08	0.3	65	66/69	62/64	rs
2/21	0.04						
Fri.	0.01-	0.06	0.2	64	72/70	68/70	rs
2/22	0.04						
Mon.	0.01-	0.04	0.2	61	62/66	61/65	rs
2/25	0.04						
Tues.	0.01-	0.04	0.2	60	64/61	68/70	rs
2/26	0.04						
Wed.	0.01-	0.04	0.04	69	57/60	62/60	rs
2/27	0.04						

2/27/2013 Iodine Room Dismantle and Move

0630: Final I-131 Air Monitoring/Charcoal Filter Test/Bioassay Done

0700: All remaining I-131 Liquid placed in sealed zip lock bags and moved to generator box.

Any unit dose pig or old lead container still contaminated with radioactivity, sealed in zip lock bag and moved to generator hood. NB: All pigs and remaining lead not contaminated where boxed up and moved out of the I-131 room yesterday 2/26/13

0715: Fume hood/glove box air flow system shut off

Charcoal filters and charcoal sampling disks removed, sealed in zip lock bags and placed in gen box

Survey of exhaust tube: GM Meter: 110522; BKG: 0.01-0.04; Survey: 0.01-0.04

0745: Two workers from Omega (See visitor log) began dismantling fume hood, glove box and sampling tubes

0850: 10 feet of exhaust tube removed. Survey & Wipe done on the inside of tube, just after disconnection. Results below:

GM Meter: 110522; Ludlum SCA

Survey Bkg: 0.01-0.04; Inside tubing Survey 0.01-0.04

Wipe Bkg: 63 cpm; Inside surface wipe: 68

0930: All items removed; workers checked out (see visitors log) prior to leaving building

3/1/13

Laminar Flow Hoods/Biological Safety Cabinet Survey and Wipes

Prior to our scheduled move 3/1/13, beginning at 0900, all hoods will be surveyed and wiped (results shown below) before any movers begin to dismantle and transfer the hoods to the new pharmacy.

Instruments: GM Meter: 110522; Ludlum SCA

<u>Item</u>	<u>Time</u>	Bkg (mR/hr)	Survey (mR/hr)	Wipe Bkg (dpm)	Wipe (dpm)	RPh
Waste	0713	0.01-0.04	0.04	160	161	rs
Barrels						
CRC-7	0714	0.01-0.04	0.04	151	160	rs
Horz.	0715	0.01-0.04	0.04	149	148	rs
Flow						
Hood						
Small L	0718	0.01-0.04	0.04	140	145	rs
Block in						
BSC						
BSC	0719	0.01-0.04	0.04	144	146	rs
Hood #2	0835	0.02-0.05	0.05	167	173	ZW
Hood #1	0937	0.02-0.05	0.04	155	154	ZW
I-131 cans	0941	0.01-0.04	0.03	155	147	ZW
Pigs	0957	0.01-0.04	0.03	157	125	ZW

SCA Set up

• Range: x100

• Window: 450; was switched to off. This was done to include counts for all energies above 50keV

• Threshold: 50

Isotopes transferred over to the new location that had decayed less than ten half-lives (or had higher than background exposure readings) included:

- I-131 liquid
- 3 Mo99/Tc99m generators
- Mo99 Cores waste
- Sm-153 waste
- Tc99m waste

Note: Metastron was dispensed on 10/17/12. A unit dose was drawn from the manufacturer vial and dispensed to a customer. Remaining in the vial was only residual activity and once place in its waste barrel no detectable exposure was found. The barrel was transferred as a UN 2910 package.

3/2/12

Krupp Drive Facility Wipe Test Results

Instrument: Ludlum SCA

Background (average): 45 dpm

Area/Section	DPM
1 – Restricted Area (RA) unit dose counter	52
2 – RA DOT table	49
3 – RA DOT table	44
4 – RA Gen table	39
5 – RA Gen Box	56
6 – RA Iodine room counter	57
7 – RA Shipping counter	44
8 – RA Shipping counter	48
9 – RA breakdown room counter	50
10 – RA breakdown room counter	54
11 – RA breakdown room counter	60
12 – RA QC table	65
13 – RA sink	56
14 – RA processing counter	51
15 – RA prescription table	52
16 – RA prescription table	53
17 – RA compounding area floor	51
18 – RA compounding area floor	44
19 – RA gen room floor	46
20 – RA iodine room floor	52
21 – RA breakdown room floor	42
22 – RA ship area floor	46

23 – RA DOT area floor	49
24 – Non restricted area(NRA) desk	37
25 – NRA breakroom table	43
26 – NRA front office desk	37
27 – RA backroom floor	51
28 – NRA bathroom sink	49
29 – NRA floor	46
30 – NRA floor	56
A – Fume hood exhaust (FHE) lower	54
section	
B – FHE middle section	51
C – FHE upper section	51

Additional Information requested

This is in reference to your letter dated March 14, 2013 and amended April 11, 2013, requesting for amendment to Nuclear Regulatory Commission License No. 44-30124-01MD. In order to continue our review, we need the following additional information:

1. Please provide the probe type, model number, and scan sensitivity of your instruments for the different radionuclides used at your facility. NUREG- 1757 Volume 1, "Consolidated Decommissioning Guidance, Decommissioning Process for Materials Licensees "simplified survey plan states to use an appropriate radiation instrument including scan sensitivity. With the given information, it is difficult to determine if appropriate scan sensitivity was used.

1. PharmaLogic Response:

Based on the meter that PharmaLogic uses, we have identified the information needed. Our scan speed is 3cm/second, Window Diameter is 1.75 inches or 4cm, Meter face is 2.43in l x 1.43in w, Efficiency (4pi): 5% for C-14, 22% for Sr-90/Y-90, 19% for Tc-99, 32% for P-32, 15% for Pu-239. Background levels for our device are between 0.01 to 0.05mR/hr.

All surveys were done with Biodex Model 14c Survey Meter Serial #110522; Probe Type: Pancake GM probe model # 44-9, serial # pr111227; Scan sensitivity: x0.1 All DOTs were done with Biodex Model 3 Survey Meter Serial #102137; Probe Type: Pancake GM probe model #44-9, serial #pr185130; Scan sensitivity: x0.1

- 2. Please provide the instrument calibration dates and due dates for the two instruments used in the survey.
 - 1. PharmaLogic Response:

Survey Meter #110522 Calibrated 12/5/2012; Due 12/5/2013 Survey Meter #102137 Calibrated 9/21/2012; Due 9/21/2013

Ludlum SCA #101373 Calibrated 09/30/2008; Efficiency 3/13/2013; Constancy done daily; next calibration will be done if machine falls out of range of efficiency or daily constancy

3. You noted that you had disbursed a unit dose of Metastron, which has ⁸⁹Sr isotope decaying by beta only. None of the wipes were counted utilizing a beta counter. Please perform wipes in the area where the Metastron dose was drawn and stored and submit beta measurement results.

1. PharmaLogic Response:

No direct wipes measurements done to determine beta contamination.

The hood was surveyed with survey meter 110522 before compounding and after compounding. Both readings were background level, indicating no beta contamination occurred. The unit dose was dispensed and the source container was placed in waste container. The waste container was surveyed with meter 110522 prior to moving. The hood we compounded in was moved to new location.