



January 23, 2013

RECRG1 01 24 *13 AM 10:40

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

Q-5
MS-16

SUBJECT: Amendment NRC Lic: 47-25375-01MD
Mail Control No. 579543

03034289

Dear Ms. Ullrich:

This letter is in reference to your letter dated January 11, 2013, requesting additional information for our amendment to the NRC license for our facility at:

PharmaLogic WV Ltd
#9 W Benedum Industrial Park Dr.
Bridgeport, WV 26330

1. We confirm as stated in our license we comply with condition 13. Our possession of Radioactive Materials with half-lives in excess of 120 days will not exceed the limits set forth in 10CFR35.35(d) that would require financial assurances for decommissioning.
2. We do confirm and will revise our inventory. The 48mCi Cobalt-57 source listed in ATT 5.2 does not qualify for classification under 36.65(a). We have removed it from ATT 5.2 (revision attached). It will be, from this point forward, inventoried under license condition 6.A. "Byproduct Materials with Atomic Number 1-83".
3. We would like to remove James Honce from consideration; he is no longer employed by PharmaLogic.
4. At this time we ask and have no objection to this amendment being issued authorizing the new location to be licensed to possess RAM for calibration purposes only. At this point we have not received our Pharmacy registration we are waiting on the final inspection. Upon receipt of our registration it will be forwarded to you and at that time we will ask to amend to practice pharmacy.
5. a) The use of the leakage assumptions:
0.1% for I-131
0.5% for Xe-133
Although no specific reference can be cited for these values, they have both been accepted historically as industry standards. In the past the values have been cited, accepted, used for calculation purposes and approved on all of the PharmaLogic NRC licenses.
- b) The location in Bridgeport, WV we are moving to is being built out for us. We are the only tenant in the building so in this case the need for the stack to be 2.5 times the building height does not exist however the distance to the nearest receptor has been measured again and has been reduced to 40m from 290m which was the distance to the nearest residence. The corrected COMPLY calculation, with a 5% correction for trapping efficiency, is attached.
- c) The trapping efficiency for the inline sampling filters is reported from HI-Q. At the flow rates we use for sampling the current efficiency is 97% to 99%. For our calculations using comply we will assume 95% trapping efficiency and correct our values prior to running COMPLY.

PharmaLogic Holdings
1 S. Ocean Blvd ♦ Suite 206 ♦ Boca Raton ♦ Florida 33432
561-416-0085 ♦ 561-416-0083 FAX

579543

NMSS/RGN1 MATERIALS-012

6. All employees, irrespective to job classification, will be required to wear whole body badges supplied by Landauer, these badges will be exchanged and monitored on a monthly basis

Handlers – 2 rings, 1 on each hand, monitored monthly. These employees are likely to exceed 10% of the regulatory limits to their extremities. This would include any employee who is in direct contact with an unshielded source at any time, ie. eluting, kit preparation, dose drawing and quality control testing.

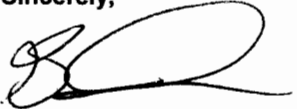
Non-Handlers – 1 ring, worn on the dominant hand, monitored monthly. This ring will be worn by any person employed who is not in direct contact with open sources, job duties would include packing delivery cans in the pharmacy and driving the delivery cars.

7. We do confirm that our labels will be affixed to all “transport radiation shields” and each container used to hold radiopharmaceuticals.

8. We will not be performing calibration services. We will pick-up instruments from our customers and send them out to a “third party”, there the instruments will be calibrated, returned to the pharmacy and the returned to the PharmaLogic customer.

Thank you in advance for your further consideration of this request. Upon review, if there are any questions, please contact me directly.

Sincerely,



**Glen Palmer, RPh,
Vice President, Operations
304-669-1992
gp@citynet.net**

WVNNEWFA

♀

COMPLY: V1.6.

1/22/2013 12:01

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH
THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS
FROM THE COMPLY CODE - V1.6.

Prepared by:

PharmaLogic, WV
PharmaLogic, WV
9 W. Benedum Industrial Park, Bridgeport, WV 263

Glen Palmer
304-842-0935

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

♀

COMPLY: V1.6.

1/22/2013 12:01

PharmaLogic

SCREENING LEVEL 4

DATA ENTERED:

Nuclide		Release Rate (curies/YEAR)
I-131	D	3.343E-04

Release height 11 meters.

Building height 8 meters.

The source and receptor are not on the same building.

Distance from the source to the receptor is 40 meters.

Building width 20 meters.

Default mean wind speed used (2.0 m/sec).

Distance from the SOURCE to the FARM producing
VEGETABLES is 2500 meters.

Distance from the SOURCE to the FARM producing
MILK is 2500 meters.

Distance from the SOURCE to the FARM producing
MEAT is 2500 meters.

NOTES:

Input parameters outside the "normal" range:

None.

COMPLY: V1.6.

1/22/2013 12:01

RESULTS:

Effective dose equivalent: 6.3E-03 mrem/yr.

Effective dose equivalent: 6.3E-03 mrem/yr due to Iodine.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

***** END OF COMPLIANCE REPORT *****

Items 5 & 6 on NRC Form 313: Radioactive Material and Use				
	Radioisotope	Form or Mfg / Model No.	Maximum Qty	Purpose of Use
1	Byproduct Materials with Atomic Number 1-83	Any, except sealed sources	200 milliCuries per nuclide, 2 Curies total possession, except as noted	10 CFR 32.72 and 10 CFR 30.41
2	Fluorine-18	Any, except sealed sources	1 Curie	10 CFR 32.72 and 10 CFR 30.41
3	Gallium-67	Any, except sealed sources	500 mCi	10 CFR 32.72 and 10 CFR 30.41
4	Strontium-89	Any, except sealed sources	80 mCi	10 CFR 32.72 and 10 CFR 30.41
5	Yttrium-90	Any, except sealed sources	1 Curie	10 CFR 32.72 and 10 CFR 30.41
6	Molybdenum-99	Any, except sealed sources	200 Curies	10 CFR 32.72 and 10 CFR 30.41
7	Technetium-99m	Any, except sealed sources	200 Curies	10 CFR 32.72 and 10 CFR 30.41
8	Indium-111	Any, except sealed sources	300 mCi	10 CFR 32.72 and 10 CFR 30.41
9	Iodine-123	Any, except sealed sources	50 mCi	10 CFR 32.72 and 10 CFR 30.41
10	Iodine-131	Any, except sealed sources	5 Curies	10 CFR 32.72 and 10 CFR 30.41
11	Xenon-133	Any, except sealed sources	3 Curies	10 CFR 32.72 and 10 CFR 30.41
12	Samarium-153	Any, except sealed sources	1.5 Curies	10 CFR 32.72 and 10 CFR 30.41
13	Thallium-201	Any, except sealed sources	1 Curie	10 CFR 32.72 and 10 CFR 30.41
14	Any Byproduct Material listed in 10 CFR 31.11(a)	Prepackaged units for in-vitro diagnostic tests	100 milliCuries	10 CFR 31.11

ATT 5.1 (con't)

Items 5 & 6 on NRC Form 313: Radioactive Material and Use				
	Radioisotope	Form or Mfg / Model No.	Maximum Qty	Purpose of Use
15	Any Byproduct Material in a Brachytherapy Source, as listed in 10 CFR 35.400	Brachytherapy Inc. Model STM 1251; IsoAid LLC Model IAI-125A; North American Scientific Model MED 3631, or MED 3633; Theragenics Model 200; Best Medical Models 2301-2308, 2309-2316 or 2331-2335)	500 mCi	10 CFR 32.74 and 10 CFR 30.41
16	Any Byproduct Material authorized under 10 CFR 35.65	Sealed Sources (International Isotopes Idaho Inc. Model BM06E series, BM06S series, BM03-XXA & BM03-XXL series; North American Scientific Inc. Model MED3503, MED3550, MED3400 or MED3402; Isotopes Product Laboratories Model RV-XXX series, EG-XXX series)	100 milliCuries	Calibration and checking of the licensees instruments and 10 CFR 32.74 and 10 CFR 30.41
17	Depleted Uranium	Metal	400 kilograms	Shielding for Molybdenum-

Radioisotope	Mfg / Model No.	Maximum Amount	Description	Authorized under	Sealed Sources & Devices Registry #
Barium-133	International Isotopes Idaho / Model BM06E & BM06S Series	2 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
Barium-133	North American Scientific / Model MED3550	1 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
Barium-133	North American Scientific / Model MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Barium-133	Isotope Products Laboratories Model RV-133-250U	1 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
Barium-133	Isotope Products Laboratories Model EG-133-MX6-5U Series LVM	20 uCi	charcoal cartridge standard	10 CFR 35.65	CA-0406-S-148-S
Cesium-137	International Isotopes Idaho / Model BM06E & BM06S Series	2 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
Cesium-137	North American Scientific / Model MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Cesium-137	North American Scientific / Model MED3550	1 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
Cesium-137	Isotope Products Laboratories Model RV-137-200U & RV-137-250U	1 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
Cobalt-57	North American Scientific / MED3550	30 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
Cobalt-57	International Isotopes Idaho / Model BM06E & BM06S Series	30 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
Cobalt-57	North American Scientific / MED3503	0.4 mCi	medical reference source	10 CFR 35.65	CA-0510-S-116-S

ATT 5.2 (con't)

Radioisotope	Mfg / Model No.	Maximum Amount	Description	Authorized under	Sealed Sources & Devices
					Registry #
Cobalt-57	North American Scientific / MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Cobalt-60	International Isotopes Idaho / Model BM06E & BM06S Series	0.4 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
Cobalt-60	North American Scientific / Model MED3550	0.4 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
Cobalt-60	Isotope Products Laboratories Model RV-060-50U	0.4 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
Cobalt-60	North American Scientific / MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Europium-152	North American Scientific / Model MED3400 & MED3402	0.4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Europium-152	Isotope Products Laboratories Model GF-152-R2 & GF-152-R3	0.4 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-107-S
Iodine-125	Bard Brachytherapy / Model STM 1251	250 mCi	therapeutic sealed source	10 CFR 35.400	IL-1074-S-101-S
Iodine-125	IsoAid / Model IAI-125A	20 mCi	therapeutic brachytherapy seed	10 CFR 35.400	FL-1146-S-101-S
Iodine-125	North American Scientific / Model MED3631	100 mCi	brachytherapy source	10 CFR 35.400	CA-0510-S-126-S
Iodine-125	North American Scientific / Model MED3400 & MED3402	1 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
Palladium-103	Theragenics / TheraSeed Model 200	200 mCi	brachytherapy source	10 CFR 35.400	GA-0645-S-101-S
Palladium-103	North American Scientific / Model MED3633	100 mCi	brachytherapy source	10 CFR 35.400	CA-0510-S-126-S
Radium-226	North American Scientific / Model MED3400 / MED3402	1 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S