30 May 2021

Lizette Roldan-Otero, Ph.D., Chief
U.S. Nuclear Regulatory Commission
Region IV
Materials Licensing & Inspection Branch
Division of Nuclear Materials Safety
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
030-38401/2021-001 AND NOTICE OF VIOLATION

PHARMALOGIC MONTANA - NOTICE OF VIOLATION RESPONSE

Dear Dr. Roldan-Otero:

This correspondence is respectfully submitted in response to the recent Nuclear Regulatory Commission Inspection Report License # 030-38401/2021-001 and Notice of Violation. Each violation has been included in this correspondence with root cause identification and resultant actions implemented and future scheduled actions.

PharmaLogic Montana is not contesting any of these apparent violations. Our response for each apparent violation includes:

1. Reasons for the apparent violation;
2. Corrective steps that have been taken and the results achieved;
3. Corrective steps that will be taken; and
4. Date when full compliance will be achieved.

A. 10 CFR 20.1302(b)(2)(ii) requires, in part, that a licensee shall show compliance with the annual dose limit in 10 CFR 20.1301 by demonstrating that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour.

Contrary to the above, since January 5, 2011, the licensee failed to show compliance with the annual dose limit in 10 CFR 20.1301 by demonstrating that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour.

Specifically, the licensee failed to demonstrate that doses from external radioactive material released into an unrestricted area at the opening of a fume hood exhaust vent on the roof did not exceed 2 mrem in an hour.

Correct Action Process

Interviews of site and company management and site authorized users has been completed. A virtual tour of the Facility was conducted in compliance with PharmaLogic COVID restrictions. Review of Iodine-131 policies and procedures has been completed.

The following Root Causes have been identified:

1. Lack of PharmaLogic follow-up with the NRC regarding open request for information on public dose assessment from I-131 air effluent. Last PharmaLogic email, dated 26 June 2018, was emailed and no response received from the NRC. PharmaLogic assumed open action item was addressed and closed.

2. Inadequate level of management oversight and follow-up of regulatory incidents. PharmaLogic management was not present for post-inspection exit meetings with relevant regulatory agencies and not copied on post email requests for information.

Prompt & Comprehensive Corrective Actions

1. In order to address the primary request for information regarding public dose assessment during manipulation of I-131 solutions and capsules. PharmaLogic Montana conducted a 4-week exposure survey at the terminal I-131 air effluent release point with an immediate read-out dosimeter. Each I-131 manipulation was monitored during the 4-week period. Exposure survey was initiated prior to dose preparation and concluded after the dose was prepared and I-131 returned to storage. The result summary is provided. Resultant radiation exposures at the terminal release point during I-131 manipulations are below regulatory limits for public dose in accordance with 10 CFR Part 20.1302. **Completed.**

PharmaLogic Montana
Radioiodine (I-131) Exhaust Radiation Exposure Survey
APRIL 2021

Date	Start Time	Reading (mR/hr) @ Exhaust Stack Terminal Point	End Time	Reading (mR/hr) @ Exhaust Stack Terminal Point	Total Time	Total Reading (mR/hr) @ Exhaust Stack Terminal Point	I-131 Capsules Compounded	Total I-131 Quantity Compounded (mCi)	I-131 Manufacturer	Pharmacist
4/6/21	11:11	16.3	13:29	16.4	2:18	0.1	1 X 15 mCi 7 x 15 uCi 3 x 8 uCi	15.129	DraxImage	Wetzel
4/8/21	11:03	16.9	13:20	16.9	2:17	0.0	1 x 20 mCi	20	DraxImage	Wetzel
4/12/21	9:00	17.8	11:35	17.9	2:35	0.1	1 x 200 mCi	200	DraxImage	Stellpfhug
4/13/21	12:00	18.2	13:40	18.3	1:40	0.1	1 x 75 mCi 1 x 30 mCi 1 x 15 mCi	120	DraxImage	Stellpfhug
4/19/21	10:47	19.7	13:00	19.8	2:13	0.1	1 x 30 mCi 1 x 10 uCi	30.01	DraxImage	Stellpfhug
4/20/21	11:28	20.0	14:58	21.1	3:30	1.1	1 x 3 mCi 1 x 20 mCi 1 x 30 mCi 5 x 15 uCi 5 x 8 uCi	53.115	International Isotopes	Wetzel
4/21/21	10:10	21.3	13:40	21.6	3:30	0.3	1 x 20 mCi 2 x 15 uCi	20.03	International Isotopes	Wetzel
4/27/21	10:45	23.2	13:15	23.8	2:30	0.6	1 x 50 mCi 1 x 30 mCi 1 x 20 mCi 1 x 15 mCi	115	International Isotopes	Stellpfhug
4/29/21	9:55	24.2	13:22	24.4	3:27	0.2	1 x 50 mCi	50	International Isotopes	Stellpfhug
5/4/21	9:33	25.8	14:22	26.3	4:49	0.5	1 x 180 mCi 1 x 50 mCi 1 x 15 mCi 1 x 18 mCi	263	International Isotopes	Wetzel

Instrumentation: RADOS 60, Serial # 311125, Calibration Date 25 January 2021

2. PharmaLogic Montana initiated a 6-month exposure survey study, utilizing Landauer environmental badges, with badges placed at rooftop perimeter and air intake equipment. Study is in progress and will be completed in October 2021. Data will be reviewed and summarized at which time a final report will be sent to the NRC. **Suspense Date: November 2021**

3. PharmaLogic Montana has provided annual release summaries for 2020 and 2021 which are below regulatory limits established in 10 CFR Part 20 Appendix B Table 2.

I-131 Radioconcentration (2020) = 3.6 E-12 uCi/mL

I-131 Radioconcentration (2021) = trending lower than 2020 due to improved procedures using resealable plastic bags for I-131 radioactive waste and active I-131 storage containers.

4. Updated Audit Program –The Radiation Safety audits, currently being conducted under the PharmaLogic Pharmacy <825> audit program, will be updated and transitioned to a stand-alone Radiation Safety Program-dedicated audit. **Suspense date 4th Quarter 2021.**

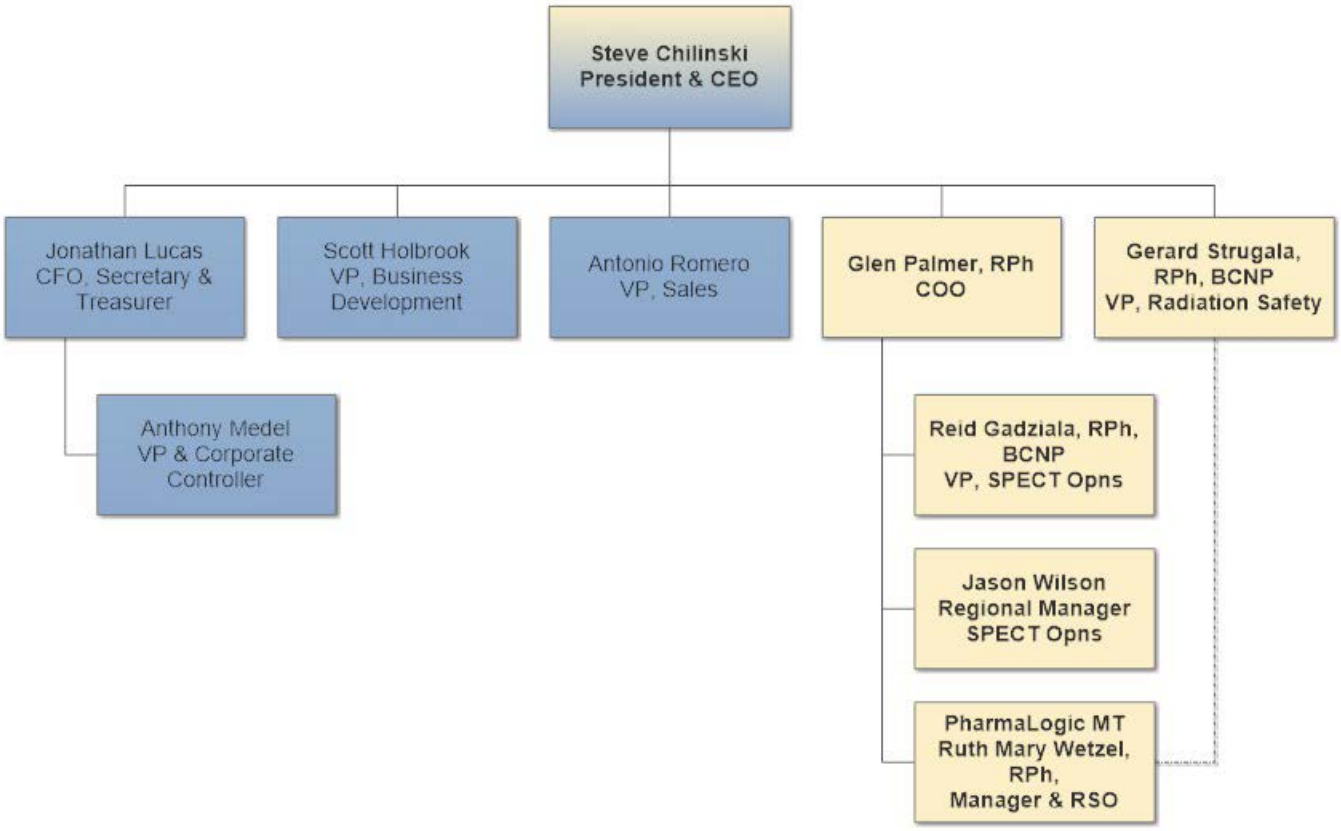
4.a. Institute a gap analysis program between policies & procedures and regulations – harmonization of all policies into a unified company program that includes an ongoing continuous quality improvement cycle.

5. Organizational Changes – **Completed**

5.a. New Management structure was created with the establishment of Vice President, Radiation Safety and placing an individual in this position effective 24 April 2021. The responsibilities include improved management and communication between the local RSO, Operations Management and the Radiation Safety Department and the PharmaLogic President. Another responsible area of this individual is keeping abreast of new or modified NRC requirements. Adoption and application of these changes. Dose Monitoring for radiation workers and the general public in unrestricted areas.

5.b. Improved communication and oversight through new regional and national management structure.

PharmaLogic Montana
Organizational Chart
May 2021



PharmaLogic Montana believes that full compliance was achieved after the immediate exposure study was completed when PharmaLogic Montana became aware of the issue.

B. License Condition 21 A. of NRC License No. 09-29398-01MD, Amendment 18, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures in the license application.

The License Application dated July 1, 2010, Attachment 9.3, "Description of the radioactive exhaust system," requires a minimum flow rate of 450 SCFM (standard cubic feet per minute) be maintained through the emissions point.

Contrary to the above, from October 15, 2019 - December 9, 2019, the licensee failed to maintain a minimum flow rate of 450 SCFM (standard cubic feet per minute) through the emissions point.

Specifically, the blower motor for the exhaust system became inoperable but iodine-131 was still handled and compounded while the exhaust system was under repair.

Correct Action Process

Interviews of site and company management and site authorized users has been completed. A virtual tour of the Facility was conducted in compliance with COVID restrictions. Review of Iodine-131 policies and procedures, I-131 air effluent data, and bioassay program has been completed.

Identify Root Cause

1. Non-compliance of license commitments with regard to I-131 exhaust and air sampling functionality when manipulating I-131 radiopharmaceuticals.

2. Authorized User lack of attention to detail in assuring public and radiation worker safety

3. Requires updating of unspecific I-131 related radiation safety SOPS, training, individual proficiency-testing and improved documentation of training

Prompt & Comprehensive Corrective Actions

1. PharmaLogic Management issued a company directive to all RSO & Facility Managers requiring verification of operation of I-131 radioactive exhaust system and air sampling system prior to I-131 manipulations. In the event that either the I-131 radioactive exhaust system or air sampling system is inoperable, no I-131 manipulations will be conducted until the systems are fully operational. **Completed.**

2. Training Authorized Users – adequacy, documentation, retrain and document updated training on I-131 supporting infrastructure, functionality and data gathering and interpretation. **Suspense date is 3rd Quarter.**

3. New SOP and log for functionality of I-131 exhaust system and air monitoring system under development. Suspense date for final draft is **30 June 2021** with training and implementation scheduled with a **Suspense Date 3rd Quarter 2021.**

4. Update and development of a Radiation Safety-dedicated Audit program. **Suspense date: 4th Quarter 2021.**

    4.a. Institute a gap analysis program between policies & procedures and regulations – harmonization of all policies into a unified company program that includes an ongoing continuous quality improvement cycle.

5. Focus PharmaLogic Management oversight / communication in the event of exhaust system and sampling systems non-compliance. Improved and immediate management communication already recognized. Severity and duration of non-compliance / out of specification will be reported immediately to the Operational Management Team and the Vice President, Radiation Safety. **Initiated & Continuous Process**

5.a. Improved communication between on-site RSO and management as to issues of compliance, in this case, out of specification of I-131 exhaust system, severity and duration of non-compliance required.

6. New Management structure was created with the establishment of Vice President, Radiation Safety and placing an individual in this position effective 24 April 2021. The responsibilities include development of a Radiation Safety Program with the following characteristics: **Initiated & Continuous Process**

6.a. Continual assessment of company-wide compliance to the current NRC and Agreement State regulations and NRC Radioactive Materials Licenses in the normal operations of diagnostic and therapeutic SPECT radiopharmaceutical manufacturing / quality control / distribution, PET cyclotron operations, PET cyclotron servicing and PET radiopharmaceutical manufacturing / quality control / distribution activities.

6.b. Coordination of on-site audits and evaluation of the adequacy of facilities, personnel and equipment in order to maintain compliance with regulatory statutes / guidelines

6.c. Development, review and evaluation of written procedures with the Radiation Safety Officers (RSO) for the Radiation Safety Program

6.d. Harmonization and implementation of radiation safety program training content at each company facility. Management and evaluation of training effectiveness, scheduling and personnel readiness

6.e. Management of the NRC inspections and corrective actions as necessary. In tandem with the local RSO will identify and implement corrective courses of action in deficient areas

6.f. Maintain oversight of the internal audits conducted by the RSO. Together corporate and local RSO will identify and implement corrective courses of action in deficient areas

6.g. Implementation of corrective actions, improvements and evolution of the Radiation Safety Program across all company facilities

6.h. Establishment of trending oversight to maintain control over equipment and Radiation Worker performance and exposure data. In the event of an unusual occurrence, reviews investigation and develops corrective courses of action with the local RSO

7. Establishment of regional and national management individuals to assist in the observation and management of local RSO and Facility Manager. **Completed**

PharmaLogic Montana believes that full compliance was achieved after the issuance of company policy requiring functionality checks which was taken when PharmaLogic Montana became aware of the issue. In support of this policy statement, SOP development and training will be completed by 30 June 2021.

PharmaLogic views these apparent violations as serious and requiring both management and local RSO scope of work improvement. Actions has been implemented and will be assessed for quality impact on operations and radiation safety. Restructuring of management and improved training cycles have been initiated and will be monitored for effectiveness. Establishment of a Vice President of Radiation Safety and Regional Pharmacy Manager will help to increase radiation safety awareness, auditing programs and communication to enable increased focus on radiation safety program initiatives and a more responsive and more informed decision-making process.

After consideration of our planned actions to the recent inspection report and notice of violations, please contact me to address any further information required.

Sincerely,

Gerard Strugala

Digitally signed by Gerard Strugala
DN: cn=Gerard Strugala, o=PharmaLogic Inc, ou, email=gstrugala@radiopharmacy.com, c=US
Date: 2021.06.03 16:25:42 -04'00'

Gerard A. Strugala, RPh, BCNP
Vice President, Radiation Safety
gstrugala@radiopharmacy.com
732-539-9395

PharmaLogic
Take The Lead

28 May 2020

Facility Managers & Radiation Safety Officers

RE: Iodine-131 Exhaust System & Air Monitoring System Functionality Tests

In regards to new regulatory requirements and our commitment to the ALARA philosophy, PharmaLogic radiopharmacies who manipulate and dispense Iodine-131 (I-131) radiopharmaceuticals will institute the following standard of practice immediately.

Effective immediately all Authorized Users, ***PRIOR*** to handling, manipulation and dispensing of I-131 radiopharmaceuticals will ensure the I-131 air exhaust system AND the restricted and unrestricted areas air sampling system is operational.

- Employing the use of a portable velometer, air flow rates will be monitored at the openings of the glove box and fume hood. These flow rates will be converted from FPM (feet per minute) to SCFM (standard cubic feet per minute). The calculated SCFM will be equal to or greater than applicable RAM License commitments.

- Concerning the air sampling system for restricted and unrestricted areas, permanent flow meters will be viewed and flow rates will be verified to be greater than or equal to 0.5 CFM.

Both the I-131 exhaust system and the I-131 air sampling system must meet the minimum established air flow parameters in order to initiate I-131 manipulation and dispensing activities. In the event of one or both systems are below established air flow limits, the Radiation Safety Officer will be notified. ***NO I-131 MANIPULATIONS OR DISPENSING WILL BE CONDUCTED UNTIL THE AIR EXHAUST OR SAMPLING SYSTEM IS RESTORED TO PROPER OPERATION.***

All existing license conditions and radiation safety policies & procedures will apply to the use of these radionuclides. Existing equipment, described in the initial license application, will be used to provide a safe radiation environment in accordance with ALARA initiatives.

A procedure and spreadsheet for the review and documentation of air exhaust and air sampling system data is under development and will be approved for use by 30 June 2021.

Sincerely,

Gerard Strugala, RPh, BCNP
Vice President, Radiation Safety
gstrugala@radiopharmacy.com
732-539-9395