



14 June 2021

**Jason Dykert
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 Mr. Dykert:

This correspondence is respectfully submitted in response to the recent Nuclear Regulatory Commission's questions regarding the analysis of public exposure data obtained during Iodine-131 compounding of diagnostic and therapeutic capsules at the PharmaLogic Montana radiopharmacy.

Analysis of Exposure Survey Results

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 performed was monitored during the 4-week period. An exposure survey was initiated prior to dose preparation and concluded after the dose was prepared and I-131 returned to storage. There were ten (10) days when I-131 capsule compounding was conducted. The exposure summary has been provided as an embedded spreadsheet.

Initial impression is that the exposure at the I-131 exhaust stack terminal release point did not exceed 1.1 mR during any I-131 capsule compounding activity. Each I-131 manipulation required a time period of ≥ 1.7 hours.

Data for each manipulation has been analyzed and incorporated into the spreadsheet provided to include Total Time for each manipulation, Total exposure reading and Resultant Exposure Rate (Total Time/Total Exposure).

PharmaLogic Holdings Corp.

**433 Plaza Real ♦ Ste 275 ♦ Boca Raton, FL 33432
561-416-0085**

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

Date	Start Time	Reading (mR) @ Exhaust Stack Terminal Point	End Time	Reading (mR) @ Exhaust Stack Terminal Point	Total Time	Total Reading (mR) @ Exhaust Stack Terminal Point	Exposure Rate (mR/hr) (Total Reading / Total Time)	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	0.04	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	0.0	1 x 20 mCi	20	DraxImage	Wetzel
4/12/21	9:00	17.8	11:35	17.9	2:35	0.1	0.04	1 x 200 mCi	200	DraxImage	Stellpflug
4/13/21	12:00	18.2	13:40	18.3	1:40	0.1	0.06	1 x 75 mCi 1 x 30 mCi 1 x 15 mCi	120	DraxImage	Stellpflug
4/19/21	10:47	19.7	13:00	19.8	2:13	0.1	0.05	1 x 30 mCi 1 x 10 uCi	30.01	DraxImage	Stellpflug
4/20/21	11:28	20.0	14:58	21.1	3:30	1.1	0.31	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	0.09	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	0.24	1 x 50 mCi 1 x 30 mCi 1 x 20 mCi 1 x 15 mCi	115	International Isotopes	Stellpflug
4/29/21	9:55	24.2	13:22	24.4	3:27	0.2	0.06	1 x 50 mCi	50	International Isotopes	Stellpflug
5/4/21	9:33	25.8	14:22	26.3	4:49	0.5	0.1	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

The total data set reveals:

Total Exposure recorded for all I-131 manipulations = 3.1 mR

Total time period for all manipulations = 28.9 hours

Total Exposure / Total Time = 0.11 mR/hr

In summary, the following characteristics have been identified:

- The highest exposure rate at the terminal exhaust point was 0.31 mR/hr on 20 April 2021 when 13 capsules were compounded.
- The corresponding exposure rate for the largest amount of radioactivity handled (263 mCi) on 4 May 2021 was 0.1 mR/hr.

Based on these results for the period 6 April to 4 May 2021, the public dose possible for an individual positioned next to the I-131 exhaust stack during all I-131 compounding activities would be < 2 mR/hr.

In addition to this exposure survey utilizing an immediate readout dosimeter, PharmaLogic Montana has initiated a 6-month exposure survey study, utilizing Landauer environmental badges, with badges placed at the rooftop perimeter and air intake equipment. Study is in progress and will be completed in October 2021. This will provide data for monitoring of public dose for a continuous and an extended period of time.

Upon review of this additional information, please contact me with any additional questions.

Sincerely,

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