

MSI'o
K7



07/08/94

License No. 44-30124-01MD
Docket No. 030-33449
Control No. 119902

Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Sir,

In reference to your letter dated June 28, 1994, please find the following additional information in order to continue your review of NRC license No. **44-30124-01MD**:

1. **PharmaLogic** Ltd. requests that I-131 possession limit be increased to 900 millicuries **from** 400 millicuries. Since **PharmaLogic** Ltd. will now be compounding I-131 therapy capsules, their will be increased utilization of I-131 in **PharmaLogic's** market.
2. Regarding item 9.4, "Special Equipment for Handling **Millicurie** Quantities of Liquid **Radioiodine**":
 - a. The fume hood and glove box that was purchased is **from** Mid-America Isotopes **Inc** is a system that provides a wider range of airflow velocity due to a larger **motor/blower**. The maximum air flow capacity for this system is in excess of 80 CFM.
 - b. **PharmaLogic** Ltd. will operate its air sampling equipment continually. As **stated** in **Item 9.4**, **two(2)** charcoal filters will be used in the Iodine **fume** hood. Each filter is one foot square and one inch thick. One filter will be stacked on top of the other so that the Iodine will be exhausted through two inches of charcoal. This ensures a trapping efficiency of 98%. Measurements with an anemometer of air flow at the arm ports for this Iodine-131 fume hood show a **minimum** linear air flow of 50-70 **feet/min**. with a total exhaust of 25 CFM.

OFFICIAL RECORD COPY **ML 10**

119902
JUL 15 1994

The efficiency of this trapping system is checked weekly using a survey meter. The filters are removed and the radiation levels at their surfaces is measured with a pancake probe type survey meter. Air sampling for volatile **131-Iodine** will be performed in conjunction with the use of the radioiodine **fume** hood. Please note that the air sampling equipment will be running 24 hours a day **giving** the charcoal filters ample residence time for adsorption to the charcoal filter bed.

c. On this system, the air speed **control** is now inside the upper unit. A start-stop **switch** is located in the outside of the upper unit with a indicator light. This allows the "Radiation Safety **Officer**" to maintain a constant airflow velocity with every individual who uses the glove box. At a minimum, the linear air flow will be 50-70 **feet/min.** with a minimum total exhaust, in the glove box, of 25 CFM. Measurements with an anemometer will be taken daily to assure that the minimum air **flow** rate is being maintained.

3. **Regarding "Procedures for Installation"**, filter holder #1 will be positioned on the outside of the glove box fume hood, just above where the individual compounding the material will be. By positioning this filter in this manner, the **air** being sampled, just above the individuals head, is an accurate sample of the **air** the individual is breathing.

4. **PharmaLogic** Ltd. will operate its air **sampling** equipment continually in the evaluation of the effluent concentrations. The vacuum pump **will** be pulling a **minimum** of 25 **liters per minute** from the exhaust stack and from the restricted area through the charcoal impregnated **filters**. These filters will be checked in 24 hour increments from the **time** that liquid **Iodine-131** is handled for liquid doses or therapy capsules. Each filter will be counted separately in a counting vial or in the same geometrical configuration as the standard source. The analyzer window will be set for 131-Iodine and a efficiency factor (F_e **131-Iodine**) for this analyzer setting will have been calculated.

5.

a. Every employee of **PharmaLogic** Ltd. that works in the restricted area or works sufficiently close to the **handling** process will have a bioassay done one day per week.

b. **PharmaLogic** Ltd. confirms that every employee that works in the restricted area or works sufficiently close to the handling process will have a bioassay done once per week.

c. PharmaLogic Ltd. **confirms** that new workers will be **bioassayed** within 72 hours of each use of **Iodine-131** for a specified initial "training" period to ensure that these workers have followed procedures for safe handling.

d. **PharmaLogic** Ltd. will make appropriate changes to "corrective action taken" with regard to prevention of **further** uptake.

6. Monitoring of the air flow in the Iodine hood **will** be obtained daily or prior to use of the hood system for handling **Iodine-131**. A flow meter device will be placed at all locations for evaluating linear flow through the arm ports of the glove box. A base line linear flow will be measured, which shall be consistent with the value used to calculate standard cubic feet per minute semi-annually. This linear flow measurement will be obtained at the same position to ensure consistency.

Individuals who will perform the measurements **will** have been trained in proper monitoring techniques by

William Chatoff R.Ph., BCNP
Radiation Safety Officer

Whatever corrective actions are necessary to return exhaust flow to the required level will be taken in the event that linear flow falls below that quantity necessary for compliance with the commitments stated in the license application. Example of corrective actions: Replacement of clogged or saturated charcoal filter; replacement of inoperable or **fatigued fan** motor; repair of crimped or defective duct work, etc.

7. PharmaLogic Ltd. confirms that the **geometry** evaluation of the dose calibrators **will** include the Iodine-131 stock vial, the low volume syringe, and the capsule.

8. Every lead container, before leaving PharmaLogic Ltd., will be wipe tested with an alcohol saturation pad and counted in the appropriate manner to assure that there is no removable contamination. Upon arrival to **PharmaLogic** Ltd. of used lead containers, each container will also be wipe tested with an alcohol saturation pad and counted in the appropriate **manner** to assure that there is no removable contamination.

9.

a. PharmaLogic Ltd. notes that 10 CFR 20.1901 and 20.1904 now apply.

b. The labels required by 10 CFR **20.1904** and 10 CFR **32.73(a)(4)** and (5)(ii) are attached by the manufacturer directly on the generator itself. These labels that the manufacturer puts on the generators **identify** the radionuclide, **chemical/physical** form, quantity, assay **date/time**, and licensing statement: "This generator is approved for distribution to persons

licensed by the U.S. Nuclear Regulatory Commission to use **byproduct** material identified in 10 CFR 35.200 or under equivalent licenses of Agreement States." Please find enclosed a label **from** an **actual** generator that is used by **PharmaLogic** when logging in the generator. This information is identical to the **permanent** label that is on the generator. **Please note that PharmaLogic Ltd. does not tamper with or mark the manufacturer's label on the generator which is required by 10 CFR 20.1904 and 10 CFR 32.73(a)(4) and (5)(ii).**

Item 1
Sample Generator Label



124206D20431

Total Activity

100.0 GBq
(2700 mCi)

Calib. Noon ET

24 May 94

Exp. Date

4 Jun 94

Lot No

9420-6D-204

Molybdenum Mo 99-Technetium Tc 99m Generator

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, Massachusetts, U.S.A. 01862

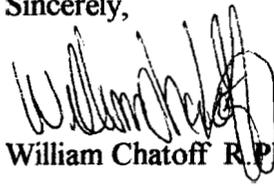
DU PONT
PHARMA

PULL

c. PharmaLogic Ltd. is in the process of getting a hard copy correspondence from the Emily Florio, Ph.D. of the Food and Drug Administration.

If you have any question, please feel free to call me at 1-802-862-9944.

Sincerely,



William Chatoff R.Ph., BCNP

OFFICIAL RECORD COPY ML 10