



MS-16  
-6

Control No. 119277

05/10/94

Nuclear Regulatory Commission  
ATTN.: Neelam Bhalla  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

Dear Ms. Bhalla,

As per our phone discussion on Tuesday May 10th at 4:00 pm, enclosed please find the responses. If there are additional questions, please call me at 1-802-862-9944.

Sincerely,



William Chatoff R.Ph., BCNP

119277  
MAY 11 1994

*Item 1 PharmaLogic Ltd. will follow the procedures, which follow, for leak testing of sealed sources.*

### **Procedure for Leak-Testing Sealed Sources**

1. Make a list of all sources to be tested. These should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sampled for each source. A cotton swap, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
  - c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and **mirror** nor crosshairs. Also wipe the primary and secondary collimators and trimmers.
  - d. If you are testing radium sources at the same time you are testing **NRC-licensed** sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
4. The samples will be analyzed as follows:
  - a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

- b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
- c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
- d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under and NRC or Agreement State License, the NRC must be notified.
- g. Sign and date the list of sources, data, and calculations.

**Item 2**

Every item dispensed by PharmaLogic Ltd. **will** be accompanied by the prescription attached. This includes unit doses, multidoses, and any item that is ordered by a physician and that PharmaLogic Ltd. dispenses. Therefore, every item that leaves PharmaLogic Ltd. will be accompanied by the following prescription with the appropriate statement.

DU PONT PHARMA		STUDY
HOSPITAL		DATE
PROCEDURE		DOCTOR
DRUG		PT:
LOT NO.	ASSAY	PT#:
EXP. TIME	CAL. TIME	DOSE REQUESTED
EXP. DATE	VOL.	ACT. DISP. ±10%
SPECIAL		
INSTRUCTIONS		
CAUTION: To be used under the direct supervision of physician. WARNING: The U.S. Nuclear Regulatory Commission has approved this radio-pharmaceutical for distribution pursuant to		BY
of 10 CFR Part 35, or under equivalent licenses of Agreement States.		
		CAUTION RADIOACTIVE MATERIAL
		CAUTION RADIOACTIVE MATERIAL

***Item 3***

**Enclosed please find PharmaLogic's Vermont Board of Pharmacy Temporary License # 38-0003193.**

Office of the Vermont Secretary of State  
Redstone Building, 26 Terrace Street

Mail: 109 Slate Street  
Montpelier, VT 05609-1101



Donald M. Hooper  
Secretary of State

Claudia Horack Bristow  
Deputy Secretary of State

Office of the Secretary of State  
VERMONT BOARD OF PHARMACY

TEMPORARY LICENSE  
# 38-0003193

I hereby certify that the following pharmacy is granted a Temporary License to operate as a **Nuclear** pharmacy:

PHARMALOGIC LIMITED

d/b/a **PharmaLogic**

9 Krupp Drive

Williston, Vermont

**This Temporary License will expire on July 31, 1994.**

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the **BOARD OF PHARMACY**, at Montpelier, in the County of Washington, State of Vermont, this 27th day of April, 1994.

A handwritten signature in cursive script that reads "Carla Preston".

Carla Preston, Staff Assistant

seal

Toll Free:  
1-800-439-VOTE

Main Office:  
Tel.: (802) 828-2363  
Fax: (802) 828-2496

Corporations Division:  
Tel.: (802) 828-2386  
Fax: (802) 828-2853

119:77