



030-33449

9/10/95

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

**License No. 44-30124-01MD**

Dear Sir/Madam,

Please amend PharmaLogic Ltd. radioactive material license #44-30124-01MD to include the following:

1. Authorization to provide sealed source leak testing services to our customers.
2. Add Howard Stoops R.Ph.,BCNP, Sandra Geysler R.Ph.,BCNP, Walter Adichie R.Ph.,BCNP, and Todd Landry R.Ph. to PharmaLogic PENN Ltd. Radioactive Material License as authorized users.

Enclosed please find the appropriate ammendment explanations. If their are any questions or comments please call 1-802-862-9944. Your cooperation in this matter is greatly appreciated.

Sincerely,

William Chatoff R.Ph.,BCNP

**OFFICIAL RECORD COPY**

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## 2. Authorization for Sealed Source Leak Testing

PharmaLogic of PENN Ltd. is requesting authorization to provide leak testing service to PharmaLogic PENN Ltd. customers. The following includes PharmaLogic PENN Ltd. procedures, Customer procedures, and a complete listing of the items that will be provided to the customer in the leak testing kit.

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.

**CUSTOMER SEALED SOURCE WIPE TEST KIT:**

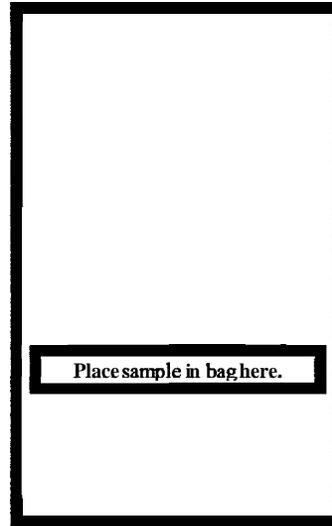
1. Procedure page
2. Filter paper sealed source wipe applicator
3. Bag or plastic tube far sealed source wipe

## PROCEDURES

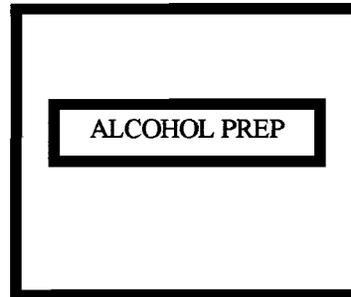
1. Fill out the criteria page. Be sure to include all available information on the source being tested.
2. Wear disposable gloves when wiping the source. Change gloves when wiping multiple sources.
3. Moisten the applicator with the alcohol prep.
4. Wipe the outside of the source. Include the top, bottom, and sides as well as any seals or edges. Also, wipe the container that the source is stored in, if applicable.
5. Place the applicator in the bag and staple to the sample sheet.
6. Survey the sample with a survey meter to ensure that the sample does not exceed background levels. If any reading above the background is noted please **notify PharmaLogic Ltd.** :

**1-802-862-9944**

## SAMPLE SHEET



A large rectangular box representing a sample bag. At the bottom center, there is a smaller rectangular box containing the text "Place sample in bag here."



A large rectangular box representing an alcohol prep container. At the bottom center, there is a smaller rectangular box containing the text "ALCOHOL PREP"

*Authorized for Leak-Testing:*  
xxxxxxxxxxxxxxxxxxxx

## CRITERIA PAGE

Hospital: \_\_\_\_\_

Address: \_\_\_\_\_

Wipe Date: \_\_\_\_\_

### SEALED SOURCE INFORMATION

Radionuclide: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Model Number: \_\_\_\_\_

Serial Number: \_\_\_\_\_

Original Cal. Date: \_\_\_\_\_

Original Activity: \_\_\_\_\_

Source Wiped By: \_\_\_\_\_

Next Wipe Date: \_\_\_\_\_

Item 4 ·

Please add **Howard Stoops R.Ph.,BCNP, Sandra Geysler R.Ph.,BCNP, Walter Adichie R.Ph.,BCNP, and Todd Landry R.Ph. to PharmaLogic Ltd. Material License No. 44-30124-01MD.**

All these individuals have been previously listed on **Syncor International** master license No. **34-16654-01MD.**

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