MERCY

Mercy Hospital

2200 Jefferson Avenue Toledo, Ohio 43624 (419) 259-1500

June 17, 1985

United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Il 60137

Re: License renewal application Control #78367

Dear Mr. Mullauer:

In reply to the conversation we had on 5-28-85 concerning our application for renewal of License #34-00305-03 I will attempt to answer your questions Item by Item.

Item 6 A

Delete Group VI from our license
Delete the Americium source from our license as we have never owned one of these and do not intend to purchase one in the near future.

Item 6 B

Add ^{131}I as Iodocholesterol for Adrenal imaging we will never have more than 50mCi at any given time our IND # is 21818.

Item 10

Regarding survey meter calibration they will be calibrated according to procedures outlined in Appendix D regulatory guide 10.8. A Raduim sealed source will be used. Calibrations are stagered so a calibration of survey meters is 2-4 days.

Item 12

All personnel working in or frequenting Nuclear Medicine Department or RIA lab. will be reoriented at least yearly especially concerning Radiatin safety procedures.

Item 15

Syringe shields will be used at all times when handling and administering Radioactive materials. Shield used is Pro-Tec II. We have 3 cc, 5 cc, and 10 cc sizes.

All doses will be assayed before administration, if there is a greater than $\pm$ 10 % variance between our assay and the manufacturers assay the radioactive material will not be used.

Thyroid uptakes will not be performed on physicians and personnel involved in the treatment and care of patients receiving thera peutic

amounts of ^{131}Iodine as this is administered via an essentially closed system as described on the enclosed documents.

Item 17

RIA area survey procedures should be ammended to read:

Room surveys will be performed monthly using our Ludlum Model 3 survey meter. Readings below 0.1 mR/hr. have been designated as acceptable and will not be recorded.
Wipe tests will be performed monthly by R/A personnel.

Item 21

The Xenalert will be calibrated yearly or after repairs according to Manufactures instructions. It is also checked each day of use for constancy using a sealed source of Eesium if there is a greater than $\pm$ 10% deviation it will be repaired.

Thank You,

Mary K. Raglow

Mary K. Raglow,
R.T., R-NM), CNMT

I^{131} DOSE ADMINISTRATION PROCEDURE

The prescribed dose being received from Syncor, and after being checked for the proper dosage via dose calibrator, is prepared as follows for administration to the patient:

Syncor supplies a special needle-straw type device (see attached) called an oral administration set-- Manufacturer PARA Medical, Part #32-27.

This device is used to administer the I^{131} to the patient, as outlined in the attached memo, dated April 24, 1981, from Pharmatopes, Inc. (now called Syncor).

After the administration is complete, all contaminated material is returned to Syncor for proper disposal.

Kenneth A. Pikor, BS, NM (ASCP) CNMT

MERCY RIA

Pharmatopes, Inc.

April 24, 1981

TO: All Nuclear Medicine Customers using Oral I-131 NaI Solution

RE: New Oral I-131 Patient Delivery System

We have adopted a new system for administering I-131 NaI solution orally. It is hoped that this new system will make it easier for you to administer the dose and for the patient to take it. This new system is also designed to decrease the possibility of contamination of your environment.

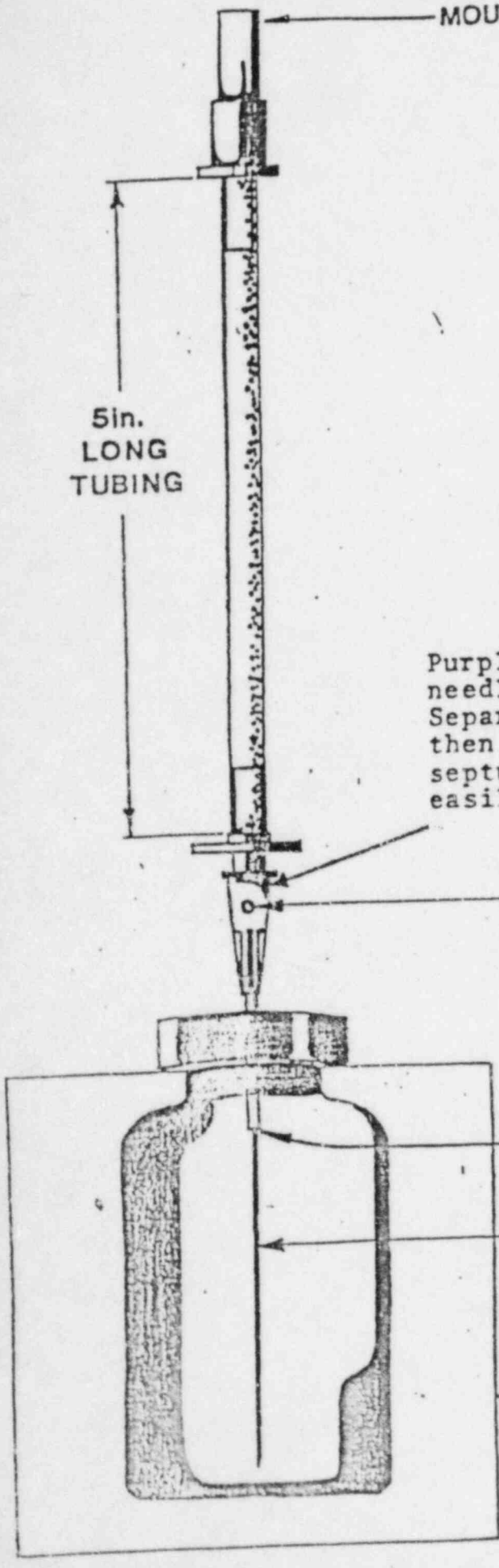
In the future, I-131 NaI therapy solutions will be dispensed in 10 ml vials. The pressure in these vials will be slightly negative so there will be less hazard of isotope leakage.

There will be an administration set dispensed with each dose. Inside a plastic straw there is a long large gauge needle which is attached to a drinking tube. Around this needle is a sheath with a purple venting hub to allow air into the vial while the solution is being sucked out. First, you should loosen the purple venting hub so it moves freely from the needle--this will allow easy passage of air into the vial while the patient drinks. Second, insert needle and hub through the center of the rubber septum. The long needle can be maneuvered the same as a drinking straw to withdraw all the solution. You will probably wish to rinse the solution out of the vial, so you may use one of these procedures: You may put the rinsing solution into the vial before the patient drinks, but BE SURE THAT YOU WITHDRAW AN EQUAL VOLUME OF AIR TO EQUALIZE THE PRESSURE INSIDE THE VIAL. This is very important to prevent possible contamination of your environment. If you wish, you may rinse the vial as the patient is drinking by putting a syringe needle through the rubber septum and injecting rinsing solution into the vial as the patient drinks.

If you have any problems with this, please let me know.

2208 W. CENTRAL AVENUE • TOLEDO, OHIO 43606 • 419-473-1215

ORAL RADIOISOTOPE ADMINISTRATION



USED FOR ADMINISTRATION OF ORAL RADIOISOTOPE SOLUTIONS WHERE MAXIMUM SHIELDING IS DESIRED.

Purple Venting Hub must be separated from long needle hub so air will pass freely into the vial. Separate purple venting hub from long needle hub, then insert BOTH needle and sheath through rubber septum. Long needle should move up and down easily inside sheath

MANUFACTURER:
PARAMEDICAL
PART NUMBER:
32-27