PUBLIC

MAY 2 4 1994

Pyramid Diagnostics Services, Inc.
Attn: Melissa Christopher
5909 Shelby Oaks, Suite 226
Memphis, TN 38134

License No. 41-26525-01MD
Docket No. 030-30262

Dear Ms. Christopher:

This refers to our letter dated April 26, 1994, and your request dated January 7, 1994, to increase your possession limit of iodine-131 and compound iodine-131 capsules. During our review we found we were unable to grant your request due tc lack of sufficient information. We discussed the deficiencies of your amendment request with your consultant, Diane Boisvert, on April 25, 1994. In order to authorize your request, we need additional information on the following:

1. Bioassay Program

Describe, in greater detail, the criteria used to determine the type of bioassay and the frequencies at which bioassay will be performed to evaluate intakes. The criteria must also describe how you will derive tables of investigation levels and the actions you will take if an employee approaches or exceeds these limits. Your response should also describe the methodology used by your office to evaluate internal dose assessments (the empirical models used to interpret the raw bioassay data).

a. Monitoring frequency:

We note that in Item 10.10 B of your application, you stated that bioassay will be performed monthly for individuals who dispense iodine from open containers. Based on the half-life of iodine-131 and lack of information on the sensitivity of your bioassay equipment, we feel that a more appropriate monitoring frequency should be at intervals not to exceed 72 hours following each manipulation. After you have demonstrated that your engineering controls, air sampling program and bioassay data show you have not exceeded 10 % of the ALI, your may amend your license for less frequent bioassay.

We also note that in Item 10.10 B. you stated that in addition to routine bioassay you will also perform "special bioassay" in the event of loss of glove box or container integrity ... . Please augment your bioassay program to include baseline measurements, prior to performing work; termination measurements, upon leaving your company; and measurements as requested by an employee.

1/0

ML
3P DH

b. Volatility Study of Iodine-131

In Item 10.10 A. of your application, you submitted data from a volatilization study on sodium iodine (I-131) solution that was performed by Mallinckrodt Medical, Inc. This data was used in your calculations for expected iodine-131 concentrations in restricted and unrestricted areas. In order for us to properly evaluate your calculations we need a more detailed description of the study performed by Mallinckrodt Medical, Inc. Please state if this study was published. If so, please supply reference to the journal, author, date of publication and submit a copy of the article. If this data is not published, please submit a copy of Mallinckrodt's experimental write up for our review.

2. Procedures for Compounding Capsules

Please state the linear flow rate across each arm port of the glove box. This should be measured prior to performing the first I-131 capsule compounding procedure, across each arm port of the glove box with an anemometer under conditions of normal operations (negative air flow, speed adjusted to maximum, and the charcoal filters in place). Our calculations indicated that the minimum flow rate should be about 120 linear feet per minute based on your minimum flow rate of 80 cfm and size of the arm ports. Confirm that quarterly measurements will be obtained to insure that the unit continues to operate at this baseline level. If the flow decreases below a specified level of the baseline measurement (80 %), commit that maintenance will be performed (filter or fan motor replacement) to insure proper operation.

3. Facilities and Equipment

During our telephone conference, it was noted that you will store xenon-133 vials and iodine-131 liquid within the same glove box. NRC discourages this practice because there is a potential of cross contamination. Typically, nuclear pharmacies store their xenon-133 vials in a separate fume hood, with the exhausts for each exiting through a combined vent and blower. In our telephone conference, it was indicated that a special container, kept inside the glove box, may be used to store xenon-133 vials. Please describe, in detail, including diagrams, the system you will use to store xenon-133 vials. If you wish to use this glove box addition your consultant described in our telephone conference, you need to justify its use by demonstrating how it will prevent cross contamination.

4. Air Sampling Program

Confirm that the restricted area sample is collected in the breathing zone of workers processing iodine-131. This should be outside the glove box above the area where an individual would be working.

Confirm that samples for iodine-131 will be collected on a continuous basis in both the restricted area (to demonstrate compliance with

allowable air concentration in workers breathing zone) and the unrestricted area (as collected from exhaust vent to demonstrate compliance with effluent concentrations).

Specify the frequency that you intend to change/analyze these filters. A daily frequency is ideal. If, however, you wish to extend the frequency (weekly is considered maximum due to the relatively short half life of iodine-131), confirm that you will use a decay correction factor in calculating the air concentration. Also confirm that you will change and analyze the filter promptly when a known spill or incident occurs that has the potential to significantly increase air concentrations in either the restricted or unrestricted areas.

In your amendment application, you stated that the charcoal filter, which filters the glove box effluent, will be replaced when the filter becomes "saturated." Describe in detail your method and procedure for determining filter saturation, your acceptance/rejection criteria, and the frequency that filter saturation for determining filter saturation.

5. Calibration of Instrumentation

Provide your calibration procedures for each instrument used in the determination of effluent and bioassay measurements. Regarding bioassay measurements, include a description of the phantom, instrumentation, and a commitment to calibrate instrumentation using standards traceable an NITS standard. Commit to maintaining records of all calibrations for two years. Demonstrate by calculation that the sensitivity of the system is adequate to measure I-131 accurately at 10% of the 0.02 ALI action level.

If you wish to pursue your request, please resubmit your request to compound I-131 capsules in its entirety, incorporating the information above. You may submit the above as additional information to Control Number 96281, within one year, and we will continue our review.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,
Original Signed by
Deborah A. Piskura
Health Physicist
Nuclear Materials Licensing Section

Enclosures:
1. Regulatory Guide 8.9
2. Draft Guidance for Nuclear Pharmacy

RIII
Piskura/dp
05/20/94