

Cathryn M. Calia, D.V.M.
CARIOPET VETERINARY ASSOCIATES, PA
48 Notch Road
Little Falls, NJ 07424
April 21, 1997

MS 16
Q-6

Docket No. 030-34385
Control No. 124231

James Bondick, Health Physicist
USNRC Region I
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, Pa. 19406-1415

Dear Mr. Bondick:

This is in reference to our license dated February 6, 1997 and your letter requesting additional information dated February 24, 1997.

1. Maximum therapy amount in doubled assayed syringe.

The empirical therapy dose range for feline hyperthyroidism is 3 to 5 millicuries. The 10 millicuries was only to provide the latitude in ordering and so not to violate a license condition if a maximum limit of 5 millicuries was specified. Can this condition list both a maximum and also typical dose range? Please advise.

Double assayed syringes are at the same time precalibrated unit dosages which have been measured by two individuals and each initials a document confirming both activity and radiopharmaceutical. This method is used in the place of a dose calibrator.

And, the chemical state of the iodine-131 will be sodium iodide in solution.

2. Radiation Safety Officer.

Name and qualifications are attached. Please disregard our request to have Hardi Liauw recognized as RSO.

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3. In service Training.

We confirm that In service training will be given both initially before beginning work and annually thereafter on a refresher basis, and that the training will be documented.

4. Animal Holding Facility and Handling.

The area for materials receiving, storage, animal treatment and waste storage is on the ground floor of our building. Only animals being treated are placed in this area thus separating them from other veterinary patients. The holding area (see attached diagram) is on an outside wall and this is below grade. There is room for six cats.

The outer most door will be locked when radioactive materials to be administered or containers with used syringes are present. This will prevent unauthorized removal. Materials will delivered directly to the treatment area. The driver or delivery person will be escorted by an employee who has previously been trained by our health physicist or radiation safety officer. Materials will be stored in the shipping container. This will supply adequate shielding. These rooms have a dedicated ventilation system. Air is not circulated to any unrestricted area.

Animal waste is double bagged and dated when placed for decay. Bags are stored for decay in a chest type freezer. At this time we do not plan to use any additional shielding.

5. Radiation Monitoring Devices.

The Ludlum Model 3 has a range of detection from less than 0.1 up to 200 mR/hr. The Model 9 measures from less than 1 up to 500 mR/hr.

The Model 2200 is for determining any removable contamination. The physicist has experience with this device. Typical counting efficiency can be thirty percent for Cesium 137 (CPM/DPM) to ninety percent for Cobalt 57. As for Minimum Detectable Activity for I-131 this will have

to be determined once approval has been granted and we obtain a calibrated Barium 133 rod source.

I have not decided what firm will provide calibration services. Bio Med Associates, Inc. or Syncor both provide such a service.

6. Personnel Monitoring.

A monitoring service will be provided by a company that is NVLAP-accredited as required by 10 CFR 20.1501(c). Each person responsible for handling will be issued a whole body monitor such as a film type badge and a ring monitor for evaluating hand exposure. Monthly wear frequency will be followed.

7. ALARA Levels.

Item 10, Appendix G, clearly identifies the two investigational levels for extremity exposure which come directly from the Regulatory Guide 10.8, rev.2. Please clarify your statement.

As for the number of iodine-131 therapy cases to be performed in a year this will have to be determined.

8. Radiation Safety Officer.

The typical duties of a Radiation Safety Officer:

- a. To assess radiological hazards and prescribe, and ensure the implementation of, appropriate radiation safety precautions.
- b. To ensure that the use of licensed material is by or under the direct supervision of individuals specifically listed on your license.
- c. To ensure that all users (where appropriate) wear personnel monitoring equipment when using licensed materials.
- d. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

- e. To perform routine inspections of all laboratories using or storing licensed materials.
- f. To ensure that the terms and conditions of our license are met, and that all required records are maintained.

9. Release Criteria.

The exposure rate specified in our application is an error. The exposure rate must be no more than 0.36 mR/hr at one meter (attached corrected Item 10.1).

Length of confinement can be up to 16 days. However during the time of confinement following therapy each animal shall be monitored at 1 meter from the approximate center of the target organ. This reading is recorded and entered as a permanent part of the patient's record. The maximum exposure rate shall determine the length of time an attending clinician spends near the patient performing any necessary treatments, examinations, etc. When redistribution or significant excretion of the radionuclide is anticipated, the exposure rate should be re-measured and recorded. In doing this we will know approximately when the patient will approach the release rate of 0.36 mR/hr.

One meter is taken from Appendix A Guidelines for Release Criteria for Veterinary Patients from the Handbook of Veterinary Nuclear Medicine page 179.

We confirm animals will be released only after measurements are made by a calibrated, operable survey instrument. The exposure rate measurement will be recorded.

Exposure rate release criteria must be met prior to discharge. This rate is 0.36 mR/hr measured at 1 meter. This will ensure a total integrated dose accumulated by an individual in close association (1 meter or less) with the patient for an infinite period of time is less than 100 mR.

10. Receiving Incoming Packages.

We confirm to use a package receipt and monitor log form similar to Exhibit 12 of Regulatory Guide 10.8, Revision 2. Results of the wipe tests performed on incoming packages will be recorded on this form.

11. Waste Disposal.

We confirm to abide by the Nuclear Pharmacy requirements to return empty therapeutic syringes.

We confirm all other waste will be disposed on in accordance with the "Procedure For Disposal By Decay-In-Storage (DIS) in item 11.1-page 2 of our application.

12. Dosage Log for Unit Doses.

We don't have an official log yet. However, we confirm that the log will be similar to Exhibit 13 as contained in Regulatory Guide 10.8, Rev.2.

13. Death of Animal Treated with Therapeutic I-131.

The untimely death of an animal will necessitate that animal to be placed in a heavy plastic bag. This bag will be labeled as to its contents and dated. This in turn will be placed in the freezer for D-I-S. At ten half lives the carcass will be removed and using an operable calibrated survey meter measurements will be made at the surface. If the measurement is not distinguishable from background arraignments will be made to have the remains incinerated.

If you require additional information please contact me. You may also contact our health physicist, John Ramsey, at 908-788-9440.

Sincerely,



Cathryn M. Calia