From: Sandra Gabriel
To: jmdubois@optonline.net
Date: Fri, Apr 23, 2004 4:30 PM
Subject: NRC license application for Veterinary Surgical and Diagnostic Specialists, mail control 134654

To: Joan Dubois, Veterinary Surgical and Diagnostic Specialists
From: Sandy Gabriel, Senior Health Physicist, NRC Region I, Nuclear Materials Safety Branch 1

As we discussed, additional information is required to evaluate your application for an NRC license. The questions are summarized in the list below. We can discuss the questions next Friday, then Dr. Stobie may provide a written response within 30 days. You may fax the response to 610-337-5269, referencing mail control 134654.

1. Item 5 of your application requests authorization to use iodine-131 in liquid form, with a typical dose of 3-5 millicuries. Please confirm that the chemical state of the iodine-131 will be sodium iodide in solution, that only pre-calibrated unit doses will be used, and that you will not adjust the iodine-131 activity within the unit dose syringe. Specify the maximum amount of iodine-131 contained in a single unit dose and the maximum amount of iodine-131 you will have on-site at one time, including waste.

2. The description of Dr. Stobie's training, attached to Item 7 of your application, indicates that he has been trained in radiation safety and nuclear medicine, and that he assisted in iodine-131 treatment of hyperthyroid cats during his internship. Please confirm that Dr. Stobie has received training in radiation protection, biological hazards of exposure to radiation, radiation instrumentation/survey techniques, contamination control techniques, and disposal of radioactive material. Describe Dr. Stobie's hands-on training and experience handling and administering iodine-131, including the number of cats treated. It is not necessary to provide any additional information about Karen Wheeler's training, as this has been submitted to NRC in the past by another licensee.

3. Item 8 of your application includes a listing of topics that will be included in training for individuals working in or entering restricted areas. Please specify the group(s) of workers who will receive training, the method of training, the qualifications of the instructor(s), and the method used to assess the success of the training. In addition, please confirm that your training program for individuals who handle animals injected with licensed material (and/or their cages) will include hands-on training on routine decontamination techniques, proper use of safety devices and equipment, contamination control, and handling of loose radioactive materials. Confirm that this training will be given both initially before beginning work and annually thereafter on a refresher basis, and confirm that you will keep records of the individuals receiving this training.

4. The facility description in Item 9 of your application does not contain sufficient detail. Please resubmit the drawing, indicating the locations of radioactive materials storage, treatment, and decay-in-storage, including the location of lead shielding. Describe the type of animal housing

that will be used (e.g., cages separate from other animals in order to minimize the spread of contamination). Confirm that radioactive materials storage and animal housing facilities will be secured to prevent unauthorized access.

5. Your application includes a letter from you to Karen Wheeler dated February 18, 2004 that refers to a long term waste storage area on your premises, but outside of your building. This storage area was not mentioned in any other part of your application and was not shown in your facility diagram. It is preferable to store waste in a secured area within your building. If you are requesting to use a waste storage area outside of your building, please provide the following information:

a. Justify the need to use a waste storage area outside of your building

b. Provide a diagram of your facility that includes both your building and the waste storage area

c. Describe in detail the proposed waste storage container, including information about shielding, labeling, and security. Do you propose to use a labeled, locked, shielded container inside a locked, fenced area? Who will have access to this area?

d. Describe how you will assure compliance with 10 CFR 20.1301 in the area surrounding the waste storage container. 10 CFR 20.1301 requires you to limit the dose in unrestricted areas to no more than 2 mrem in any one hour and to limit the dose to individual members of the public to 100 mrem in a year.

6. Item 10 of your application addresses area surveys, however it does not provide any information about your procedures. Appendix Q of NUREG-1556, Vol. 7 may be helpful to you in developing your survey program. (I believe I mailed you a copy of this NUREG earlier this year. Please let me know if you need another copy.) In your response to this e-mail, please provide either a statement that "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Vol. 7, 'Consolidated Guidance About Materials Licensees, Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,' dated December 1999" or a description of an alternate method for demonstrating compliance with 10 CFR 30.53, 20.1501, and 20.2103, including contamination limits.

7. Item 10 of your application also includes a section titled "Procedures for Device Calibration, Safety Checks, Operation, and Inspection" which is not applicable to your program. You may withdraw this section from your application.

8. Item 10 of your application also addresses waste management, although it does not provide a description of your procedures. Your letter to Karen Wheeler dated February 18, 2004 states that you will store waste for no less than ten half-lives. We will consider this statement to be a license commitment.

9. Your application includes two sets of discharge instructions. It appears that you intend to use two sets of release criteria in different situations. One applies to cats released a minimum of 96 hours post-treatment at 0.5 mR/hr at a meter, and the second applies to cats hospitalized for a longer period of time and released at 0.5 mR/hr at a foot. Your program must assure that the dose to individual members of the public (including family members) from a cat treated with iodine-131 does not exceed the 100 mrem annual public dose limit in 10 CFR 20.1301. Please address the following:

a. Your proposed discharge instructions for cats released at 0.5 mR/hr at a meter include the statement: "Do not sleep, sit or hold your cat for any length of time." Please note that current NRC guidance suggests that a cat released at a radiation level of 0.5 mR/hr at a meter could expose its owner to approximately 86 mR/hr at release when hugged or held in the lap. This type of close contact could easily result in a dose in excess of 100 mrem. In addition, current NRC guidance suggests that a release criterion of 0.5 mR/hr at a meter is acceptable only for cats that do not seek human companionship. Please consider revising your instructions to owners to be more specific, for example: "Maintain a distance of at least 3 feet from the cat at all times, except when administering medication."

b. Describe the method you will use to determine which owners and cats are candidates for the earlier release at 0.5 mR/hr at a meter (i.e., owner's ability to comply with the instructions and cat's need for human companionship).

c. Confirm that you will maintain records to document that the release criterion used for each individual cat will ensure compliance with 10 CFR 20.1301.