

From: Sandra Gabriel
To: Pcgoah@aol.com
Date: Tue, May 18, 2004 5:53 PM
Subject: Application for NRC license for Oradell Animal Hospital; mail control 134679

Dr. Gambardella:

As we discussed, additional information is required to evaluate your application for an NRC license. The questions are summarized in the list below. Please provide a written response within 15 days. You may fax the response to 610-337-5269, referencing mail control 134679.

1. Item 5 of your application requests authorization to use iodine-131 in liquid form, with a dose of 3-6 millicuries. Your license will be written in a format that specifies the maximum amount of iodine-131 contained in a single unit dose. Please confirm that you intend to treat both feline hyperthyroidism and feline thyroid carcinoma using a maximum dose of 6 millicuries. 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.
2. Items 7.2 and 8.1 of your application include a description of Dr. Sartor's training. Please confirm that Dr. Sartor will receive the training by George Zacharopoulos prior to the start of licensed activities. Describe Dr. Sartor's hands-on experience in handling and administering iodine-131, including the number of cats treated.
3. Item 8.2 of your application includes a description of worker training. Please describe the method of training, the qualifications of the instructor(s), and the method used to assess the success of training. Confirm that your program will include hands-on training. Confirm that each worker will receive training both initially before beginning work and annually thereafter on a refresher basis. Confirm that you will keep records of the individuals receiving this training.
4. Item 9 of your application includes a drawing of your facility. The text of your application refers to "the hot lab" and the drawing shows a room labelled "I-131". Please indicate whether the room labelled I-131 serves as the hot lab alone, or if this room is also used for patient dosing, animal housing, and radioactive waste storage. Please resubmit this drawing, showing the details of the locations of patient dosing, animal housing, and radioactive waste storage. In addition, 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 the animal housing facility will be secured to prevent unauthorized access.
5. Item 9.2 of your application states that you will obtain a Ludlum Model 14C survey instrument. The description of your radiation safety program in Item 10.2d refers to both a pancake GM probe and a scintillation probe. Please confirm that you will obtain both a pancake GM probe and a scintillation probe.
6. Item 9.2 of your application also states that you will use the model procedure for survey

instrument calibration from Appendix B to Regulatory Guide 10.8. Please note that Regulatory Guide 10.8 has been superseded. If your instruments will be calibrated by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State for instrument calibration, you only need to specify the name of the firm, the license number that authorizes the firm to perform calibrations, and the calibration frequency. As an alternative you may choose to implement the model survey meter calibration program published in Appendix M to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

7. Item 10.1 of your application addresses your personnel monitoring program. Please confirm that you will monitor individuals in accordance with the criteria in the section entitled "Radiation Safety Program - Occupational Dose" on pages 8-31 to 8-34 of the NUREG referenced above.

8. Item 10 of your application lists some of your procedures for safe use of radioactive materials. Please confirm that you will also develop and maintain procedures for management of emergencies, such as spills of radioactive material. You may find it helpful to review the section titled "Model Procedures for Handling Emergencies" in Appendix P of the NUREG.

9. Your license application does not include information about your facility survey program. Appendix Q of the NUREG may be helpful to you in developing your survey program. 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, dated December 1999" or provide a detailed description of an alternative survey program, including survey frequencies and trigger levels.

10. Item 10.2 of your application states that animals treated with iodine-131 will be released to their owners as per NRC Regulatory Guide 8.39., and that you will not release a cat until the exposure rate at a foot from the cat does not exceed 0.5 millirem per hour. Please note that NRC Regulatory Guide 8.39 applies only to human patients and not to cats. However, your release criterion of 0.5 millirem per hour at one foot is acceptable if you provide the owner with written instructions addressing as a minimum: waste handling, contamination, and appropriate human interaction/isolation instructions. It is also recommended that no cat be released prior to 96 hours following iodine-131 administration. Please provide a copy of the safety instructions that you will provide to cat owners at the time the cat is released from your facility. State the minimum time that you will retain a cat in your facility prior to release. Confirm that you will maintain records to document that the release criterion used for each cat will ensure compliance with 10 CFR 20.1301.

11. Item 11 of your application addresses waste management, describing a decay-in-storage procedure. Item 8.2 of your application also refers to training of workers who will be involved in "safe disposal of animal carcasses." Please confirm that any carcasses will be held for decay-in-storage in a freezer dedicated for radioactive material. Item 10.2b refers to designation of a sink for sanitary disposal. If you intend to dispose of liquids into sanitary sewerage, please provide your detailed procedures, or confirm that you will follow the "Model Procedure for Disposal of Liquids into Sanitary Sewerage" in Appendix T of NUREG-1556, Vol. 7, dated

1999.

If you have any questions, please feel free to call me at 610-337-5182 or to send an e-mail. Please note that I will be away on an inspection trip from May 24-28, however I will check my voicemail and e-mail periodically.

Thank you.

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NRC Region I
Nuclear Materials Safety Branch 1
610-337-5182