



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

March 29, 2013

Docket No. 030-38622
Control No. 580121

License No. 06-35047-01

Lance Rozear, DVM, DACVR
Radiation Safety Officer
New Haven Central Hospital for Veterinary Medicine, Inc.
843 State Street
New Haven, CT 06511

SUBJECT: NEW HAVEN CENTRAL HOSPITAL FOR VETERINARY MEDICINE, INC.,
REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION
FOR AMENDMENT TO LICENSE, CONTROL NO. 580121

Dear Dr. Rozear:

This is in reference to your application dated February 22, 2013 requesting to amend Nuclear Regulatory Commission License No. 06-35047-01. In order to continue our review, we need the following additional information:

1. The NRC does not find your proposed release criteria of 1 millirem per hour at a distance of 1 meter from an animal treated with iodine-131 (I-131) to be acceptable. Current NRC guidance recommends holding cats treated with I-131 for a minimum of 96 hours (4 entire days) and a maximum dose rate of 0.25 millirem per hour (mrem/h) at 1 foot, in order to ensure that no individual member of the public receives more than 2 millirem in any one hour AND 100 millirem total radiation exposure. Confirm that animals will be held for a minimum of 96 hours (4 entire days) and will not be released unless the maximum dose rate is 0.25 mrem/h or less at a distance of 1 foot from the animal.
2. If you wish to propose alternate radiation level measurement criteria for release of the animal, the following limitations are acceptable to the NRC providing appropriate human interaction/isolation instructions are provided to animal caretakers, and you have high confidence that the caretakers will follow the instructions. Animals would still be required to be held a minimum of 96 hours.
 - a. If release is at a radiation level of 0.25 mrem/h measured at 1 foot from the animal, close contact with the animal should be restricted. NRC calculations estimate that a cat measuring 0.25 mrem/h at 1 foot retains about 100 microcuries of I-131 in its thyroid and body. This would expose its caretaker to about 4 mrem/h at the time of release if held by the caretaker.
 - b. If release is at a radiation level of 0.5 mrem/h measured at 1 foot from the animal, human interaction will be restricted, isolation of the animal will be

required for 1-2 days, and close contact with the animal should be limited for several days following isolation. NRC calculations estimate that a cat measuring 0.5 millirem per hour (mrem/h) at 1 foot retains about 200 microcuries total of I-131 in its thyroid and body. This would expose its caretaker to 8 mrem/h at the time of release if held by the caretaker, and a person sleeping within 3 inches of the cat could approach the 100 millirem limit in about 12 hours.

- c. If release is at a radiation level of 0.5 mrem/h measured at 1 meter from the animal, the animal and its owner will be pre-screened to determine if release of the animal can be accomplished under the limitations required at this release level. Release criteria include that the animal should be isolated for several days to a few weeks, that human interaction should be very limited for several weeks; and that you will perform post-administration evaluations of the animal to ensure that instructions are followed, and if instructions need to be amended (more restrictive or less restrictive), based on dose rates from the animal and/or the ability of the animal to be isolated as required.) NRC calculations estimate that a cat measuring 0.5 mrem/h at 1 meter retains about 2.4 millicuries of I-131 in its thyroid and body. This would expose its caretaker to approximately 86 mrem/h at time of release if held by the caretaker; a person could exceed the 100 millirem limit from holding the animal in less than 1.5 hours.

Specify any alternate criteria for release of animals treated with I-131, and confirm the limitations you plan to use.

3. Alternate release criteria which specifies a holding time of less than 96 hours, or radiation levels greater than 0.5 mrem/h at a distance of more than 1 meter from the animal, may be proposed. However, such criteria requires that you provide dose calculations and limitations which demonstrate that members of the public, including the animal caretakers, will not exceed the NRC limit of 2 millirem in any one hour and 100 millirem in a year. Any additional information to justify more lenient release criteria should be included in your request.
4. Confirm that written instructions will be provided to animal caretakers, with each animal that is released after treatment under your license, and that these instructions will address (1) waste handling, (2) contamination, and (3) appropriate human interaction/isolation instructions. The instructions should clearly state the regulatory limits and the need to keep doses as low as reasonably achievable (ALARA), indicate the potential radiation fields surrounding the animal and potential dose with time at various distances, describe the permitted extent and duration of contact by individuals with the animal, and indicate how to handle contaminated litter, bedding and other objects with which the animal comes in contact.
5. Provide a copy of the written instructions that will be given to owners/handlers when animals are released after treatment with I-131. A sample of instructions to animal caretakers may be found in Appendix H of NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope." This may be found at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/>.

6. Confirm that your procedures for safe use and emergencies will consider the conditions under which use of ring dosimetry and syringe shields when administering I-131, and bioassay of personnel in the event of a spill, needle-stick or other such emergency, will be required.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 580121. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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