



NEW HAVEN CENTRAL HOSPITAL FOR VETERINARY MEDICINE

24 HOUR CARE • *We're always here*

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August 9, 2013

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Ms. Betsy Ullrich
Senior Health Physicist
Licensing Assistance Team
United States Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

License No: 06-35047-01

Docket No: 030-38622

Dear Ms. Ullrich,

The New Haven Central Hospital for Veterinary Medicine, Inc., is requesting an amendment to our license #06-35047-01, as described below.

We request an alteration of our current release criteria. The approved current release criteria in our license are based on correspondence from Betsy Ulrich on 3/29/13. We based our home care instructions on Ms. Ulrich's guidelines presented in part C. of section 2. In an effort to be conservative, however, we based our release criteria on part B. of section 2, specifically a release of the patient at 0.5mR/h at 1 foot. We are finding that our patient hospitalization times are significantly longer than anticipated, patients being held for up to 10 days. This places undue stress on owners, isolates patients for excessive periods of time, and places additional economic, waste management, and personnel exposure pressures on our company. It also puts us at a competitive disadvantage due to reduced throughput and decreased owner willingness to participate in our program (this is more than twice as long as our colleagues in the state, who release at 0.5mR/h at 3 feet, typically in 3 days). We request that our release criteria be amended to 0.5mR/h at 1 meter. The minimum hospitalization of 4 days and the conservative home care instructions will remain the same to minimize exposure to owners. We hope that this will satisfy the conditions of option C of part 2 of Betsy's letter and will be approved. We

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NMSS/RGNI MATERIALS-002



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have included copies of our home care instructions and Ms. Ulrich's correspondence with this letter.

Please do not hesitate to contact us if you have any questions or require additional information. Since there is an urgency associated with this request, any consideration and priority you may be able to provide will be greatly appreciated.

Thank you,

Dr. Lance Rozear, DVM, RSO

Mr. Kenneth Aldrich, Management
Representative, Chief Operating Officer,

The New Haven Central Hospital
for Veterinary Medicine
843 State Street
New Haven, CT 06511
Phone (203) 865-0878

I-131 Patient discharge and home care instructions

New Haven Central Hospital for Veterinary Medicine

Your cat was treated with _____ mCi of radioactive iodine (I-131) at New Haven Central Hospital for Veterinary Medicine (NHCHVM) on _____ for the treatment of hyperthyroidism. He/she has been housed at NHCHVM in a safe and secure environment while the radioactivity level has been high. Now the levels are low enough that he/she can go home to continue his/her recovery in your care.

Because your cat still has a small amount of radioactive material in his/her body, they continue to emit a low level of radiation. The level is low enough that no member of the public should be exposed to unhealthy levels of radiation (less than 100 mrem/year and less than 2 mrem per hour as defined by the Nuclear Regulatory Commission) as long as you follow the guidelines below. This radioactivity will gradually decline and will be gone about 3 weeks after you take him/her home. During this time you must follow the safety procedures listed below to minimize any risk of exposure to you or your family or others.

If you have any questions or concerns, please do not hesitate to call us here at NHCHVM.

Household safety procedures

- Keep your cat in his/her carrier until you get home.
- Your cat must be kept strictly indoors for 3 weeks to minimize exposure to other people, pets and wildlife and so you can closely monitor his/her treatment response.
- Your cat must be isolated to one quiet room in your house for the first week. This should not be an occupied bedroom, a frequented bathroom or other high-traffic room. After the first week, your cat may be given access to the remainder of the home.
- Keep your cat off the counters to prevent the contamination of food-preparation surfaces for 3 weeks. If this is not possible, make sure you clean any surfaces thoroughly before food preparation.
- Please **do not kiss your cat and avoid contact with your face for 3 weeks**. Radioactive material is excreted in the cat's saliva, which is then deposited onto its fur when they groom. This material is easily absorbed orally, and we do not want you or anyone else becoming contaminated.
- Wash your hands thoroughly after any contact with your cat, its food/water dishes and toys.
- No one under the age of 12 should be allowed to have access to your cat or the room in which it is isolated for the first week, and should avoid close contact (within 3 feet) for the subsequent 2 weeks.
- Pregnant women or women who are breastfeeding should not be allowed near the cat or the contaminated litter or bedding (within 3 feet) for 3 weeks.
- Personal contact should be restricted at first, but can be gradually increased over time based on the following
 - Week 1
 - Close contact (within one foot) such as petting must be avoided completely
 - **Do not** hold the cat or allow it to sit in your lap.
 - The cat **may not** sleep in a bed with a person

- Maintain a distance of more than 3 feet from your pet
 - Week 2
 - Petting is allowed, but should be limited to 20 minutes per day
 - Wash hands after any direct contact
 - **Do not** hold the cat or allow it to sit in your lap
 - The cat **may not** sleep in a bed with a person
 - At all other times maintain a distance of more than 3 feet
 - Week 3
 - Petting is unrestricted
 - Wash hands after any direct contact
 - Laptime/holding should be limited to 30 minutes per day
 - The cat **may not** sleep in a bed with a person
- For 3 weeks, you should use plastic litter pan liners and flushable litter, and you should flush all waste. You should wear protective gloves while cleaning the litter and wash your hands thoroughly afterwards. After this 3 weeks, take any residual litter and double bag it. Leave it in an isolated corner of the garage or basement for another 2 weeks, then discard into the trash. Most landfills do not allow the disposal of low-level radioactive materials, and have sensitive equipment to detect its presence. To avoid being fined, please be sure to follow the above guidelines.
- All cleaning rags, rubber gloves and other discarded material used to clean the animal's litter box or contaminated surroundings (for example if they vomit or eliminate outside the litter box) should be treated as if they are contaminated as well, and kept with the bagged contaminated litter and held for the additional 2 weeks.
- After 3 weeks, you may return to your normal household routine.

Medical issues

- If you have any concerns about your pet's response to the therapy or any other issues that develop during this period, please contact us at NHCHVM or your regular veterinarian as soon as possible.
- If your pet requires medical attention, we recommend that you bring him/her back to NHCHVM during their radioactive period. Our facilities are designed to safely house/hospitalized radioactive patients and our staff is trained to handle their special needs. If you return, please call ahead of time so that we may prepare for your arrival.
- If your cat requires medical attention and you wish to take him/her back to your regular vet during this time, call them first and explain the situation. Make sure you bring these instructions to give to your veterinarian. They can contact Dr. Harley or Dr. Rozear at NHCHVM for more information and safety instructions.
- Remember to keep your cat in his/her carrier at all times during transport.

I understand that my pet is being discharged from the hospital with residual amounts of radioactive materials, and that there is the potential for radiation exposure to me, my family and members of the public. I further understand that these instructions/restrictions are designed to minimize exposure and to keep any potential exposure within the safe limits as defined by the Nuclear Regulatory Commission. I understand these instructions, and all questions I have regarding these instructions have been explained to me in a satisfactory manner. I agree to follow the instructions in this document fully.

_____ Date:
Owner/primary caretaker

_____ Date:
Radiation safety officer or Authorized user



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,



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

This is to acknowledge the receipt of your letter application dated

08/09/2013, and to inform you that the initial processing which includes an administrative review has been performed.

06-35047-01 (Amendment)
 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 581561
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.