

From: Ullrich, Elizabeth
Sent: Tuesday, March 23, 2010 7:48 AM
To: douglas.vizard@carestreamhealth.com
Cc: Gaskins, Farrah; Dwyer, James
Subject: Carestream amendment request dated March 2, 2010 - additional information needed

License No. 06-21254-01
Docket No. 030-20106
Control No. 144491
Carestream Molecular Imaging

Dr. Vizard,

In order to continue the review of your amendment request, please provide the following additional information:

1. You requested F-18, Tc-99m, In-111, and Tl-201. Will you be receiving these radionuclides as unit doses, or will you be receiving these as bulk doses? Will you be doing your own radiochemical-labeling or receiving prepared radiochemicals? If you are doing your own radio-labeling, provide the name(s) of persons who have experience doing this, and describe the radionuclides, amounts used, and years of experience performing radio-labeling.
2. In addition to the facility description you provided, describe the equipment that you will have available for the safe handling of the new materials, especially if you receive bulk doses. Such equipment would include syringe shields, shielded syringe carriers, lead shields (L-blocks), lead shielding/containers for bulk doses, dose calibrators for assessing doses to be injected, shielded waste containers for decay-in-storage of animal wastes and/or animal carcasses, etc.
3. Provide the following information to support your request to use radiochemicals in animal studies:
 - a. Describe your facilities in which animals injected with radionuclides will be used and housed. Describe any special radiation safety equipment related to animal housing and/or handling.
 - b. Describe your procedures for disposal of contaminated animal carcasses, bedding etc.
 - c. If you will be releasing live animals for unrestricted use, provide your procedures that ensure that members of the public will not receive more than 2 millirem in any one hour, and not more than 100 millirem in any one year, from animals released for unrestricted use.
 - d. Provide your animal handling instructions to researchers and animal caretakers. Confirm that animal caretakers will be provided radiation safety training prior to working with, or in the vicinity of, radioactive animals or contaminated animal facilities. Confirm that animal caretakers will be provided with radiation monitoring if they will be working with, or in the vicinity of, radioactive animals or contaminated animal facilities.

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You should refer to NUREG 1556, Volume 7, Appendix H "Considerations for Laboratory Animal and Veterinary Medicine Uses" for procedures that are acceptable to the NRC.

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/>

4. You requested to be authorized to possess two 1-microcuries Cs137 sources. In order to authorize such sources on the license, you must provide the manufacturer's name and model number(s) so that we can verify that these sources are listed in the NRC's Sealed Source and Device Registry. It is possible that these sources may be items that have been approved to be exempt from licensing; you should check with the manufacturer about this. If these sources are exempt from licensing, they will not be listed on your license. However, you should be sure to retain any documentation that the manufacturer provides to you about the exempt sources for future reference.

5. Based on your letter, it appears that you are requesting to add Rao Papineni, Mary Catherine Muenker, and Warren Matthew Levy as additional authorized users to be listed on your license.

a. Rao Papineni appears to have experience with low-energy beta-emitters and I-125, a low-energy gamma emitter. Describe any experience he has in handling for the types of positron emitters (with higher-energy gammas) that you are proposing to add to your license (types of radionuclides, quantities handled, number of years of experience).

b. Mary Catherine Muenker appears to have limited handling experience with radionuclides. Please provide additional information about her experience handling radionuclides (types, quantities, years of experience) and her experience as an RSO at Albert Einstein College of Medicine (types and quantities of radionuclides authorized and used at this facility, and duties and years of experience performing those RSO duties).

c. Warren Leevy appears to have experience only with F18. If he has other experience with handling radionuclides, please provide a description of the radionuclides, amounts handled, and years of experience. If he has no other experience, we will authorize him to use, or supervise the use of, only the F18 until he has gained additional experience with other radionuclides.

6. Confirm that your radiation safety training will include ancillary personnel who may work in areas where radioactive materials are used or stored, such as animal caretakers, animal handlers, custodial workers, security staff, etcetera.

7. In order to release the 4 Science Park, New Haven, Connecticut site for unrestricted use and remove it from your license, we need additional information regarding the surveys that were done. This also refers to information received during the recent inspection by Farrah Gaskins of our office.

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a. According to you March 10 decommissioning notes, it appears that you removed the americium-241 and radium-226 sealed sources from your liquid scintillation counter in February 2003 and stored them until their recent disposal. Most likely, these sources were possessed under a general license, and therefore subject to the regulations of 10 CFR 31.5, which prohibits removal of the sources by anyone except those who are authorized. You are not authorized to remove such sources from the liquid scintillation counter. However, it appears that the surveys

you performed detected no leakage of the sources. I understand from your notes that these sources were disposed of as radioactive waste by the Chase Environmental Group in November 2009; if my understanding is not correct, please inform me in writing.

b. It appears that you performed only radiation-level surveys of the "storage room (118, ground floor, laboratory)" in October 2009. Considering that tritium and carbon-14 were stored in this area, and that tritium cannot be detected with most radiation survey instruments and carbon-14 is difficult to detect with radiation survey instruments, state if any wipe tests for removable contamination were performed in this area, or any other areas where tritium and carbon-14 were used in the past.

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c. Please provide the final status surveys that were done of all areas where radioactive materials were used and stored while you were at your former location at 4 Science Park in New Haven. If no final status surveys were performed, confirm if you still have access to this facility in order to perform such surveys. If you do not have access to the facility, provide us with information regarding the types of surveys that were done in that facility, the frequency of those surveys, and the results of the most recent surveys. The minimum survey that the NRC finds acceptable for final status surveys of facilities such as yours is described in NUREG 1757, Volume 2, Appendix B, "Simple Approaches for Conducting Final Radiological Surveys".
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v2/>

d. Based on the information you provided in your decommissioning notes and during the recent inspection, you also disposed of the tritium and carbon-14 remaining waste into normal trash during October 2009. This is not an allowed disposal method for this material, as Farrah Gaskins discussed with you. Confirm that only waste contaminated with short-lived radioactive materials (those with half-lives less than or equal to 120 days) will be disposed of by decay-in-storage, as stated in condition 14 of your license.

e. Please note that, because long-lived materials were used at your 4 Science Park facility, we must develop an environmental assessment and have it published in the Federal Register prior to our being able to release the facility for unrestricted use. Please provide a brief description of the facility at 4 Science Park, including the overall building size; the number of rooms and their sizes in which you used or stored radioactive materials; the type of area this facility is located in (commercial, residential, industrial, mixed commercial/residential, and if urban, suburban or rural), a short history of the types, quantities, and frequency of use of licensed materials at this facility.

Please submit your additional information by hard-copy letter, signed by your general manager, within 30 days. We cannot accept e-mail responses. If you have any questions about this request, please contact me by telephone or email; contact information is below.

Sincerely,
Betsy Ullrich