From:

Abogunde, Maryann

To:

Subject:

NRC request for additional information - License amendment for Connecticut Heart & Vascular Center, PC

Tuesday, July 09, 2013 4:38:00 PM Date:

Licensee(s): Connecticut Heart & Vascular Center, PC (request involving change of licensee name to

PriMed, LLC)

License No.: 06-30537-01 Docket No.: 030-35233 Control No.: 581102

Dear Dr. Sackstein.

In order to continue our review of your amendment request dated May 31, 2013, we need the following additional information:

1. Your request states that Connecticut Heart & Vascular Center, PC merged with the practice of PriMed, LLC. Please clarify if there has been a change or transfer of control.

With regards to changes of control (transferor and/or transferee, as appropriate):

- a. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.
- b. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
- c. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
- d. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
- e. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
- f. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Submit the above requested information signed by senior management from both Connecticut Heart & Vascular Center, PC and PriMed, LLC.

- 2. The letter you submitted was signed by you, with your title as Radiation Safety Officer. In order to complete review of this license action, please confirm that you are also a senior management representative of this facility. Otherwise, please have a senior management representative review and confirm that they are in agreement with the information provided in this response and your amendment request letter dated May 31, 2013.
- 3. Please confirm that PriMed, LLC does not perform any activities that fall under any other active NRC licenses.

- 4. Please confirm that you want to keep the mailing address that is currently listed on your license as 2979 Main Street, Bridgeport, Connecticut 06606. Otherwise, provide a current mailing address that you would like listed on your license.
- 5. With regards to adding a new facility, please provide the following additional information. Please be aware that information (including diagrams) that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information withhold under 2.390":
 - a. Please confirm that the proposed location of use is not a location of use for any other active NRC license.
 - b. Please indicate room numbers (if any) for all areas of byproduct material use or preparation for use (e.g. hot lab).
 - c. The diagram you provided titled <u>Rooms specific to our nuclear cardiac service</u> is not legible. Please re-submit a facility diagram that is legible.
 - d. A scaled diagram and detailed description of your hot-lab room and indicate the position of each of the areas described below:
 - i. Storage of radiopharmaceuticals;
 - ii. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste; and
 - iii. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).
 - e. In addition, please provide a detailed description of:
 - i. Any radioactive waste storage areas outside of the hot lab room; and
 - ii. Shielding for the dose storage, dose preparation, waste storage, and radiopharmaceutical administration areas.
- 6. In order to facilitate future communications, please provide a current contact e-mail address, telephone, and fax number for you and your senior management representative that can be made public.

You may fax your reply to my attention to 610-337-5269. Please reference Mail Control No. 581102 in your response.

Please send a return e-mail to confirm that you received this message.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your assistance,

Maryann Abogunde Medical / Health Physicist U.S. NRC Region 1 610-337-5090 (voice) 610-337-5269 (fax)