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Cc: ["john_desiderio@bayhealth.org"](mailto:john_desiderio@bayhealth.org)
Subject: NRC Request for Information for Bayhealth Medical Center (Mail Control Number 582455)
Date: Friday, January 03, 2014 10:48:00 AM

Licensee: Bayhealth Medical Center
License No.: 07-14850-01
Docket No.: 030-07565
Mail Control No.: 582455

Dear Mr. Henry,

Can you please reply to this email to confirm receipt?

This letter is in reference to Bayhealth's letter dated October 3, 2013, requesting an amendment to NRC License No. 07-14850-01, to add a mobile PET trailer as an additional location of use at your Dover and Milford facilities. Based on our conversations on December 12, 2013 and January 2, 2014, it is our understanding that you currently utilize PMS Health Technologies to provide mobile PET services. Specifically, you are requesting that a mobile PET unit provided by PMS Health Technologies (PMS HT) be added to your license as an additional location of use of PET radiopharmaceuticals, and will be located on Bayhealth Medical Center property. In order to process your request, please provide the following additional information:

1. Please describe the equipment that you will have for use on the PMS HT trailer (e.g. dose calibrator, survey meters, and well counter). If your well counter will be located in proximity to PET radiopharmaceuticals, please describe additional shielding that will be used.
2. If the PMS HT trailer will be transported back to PMS HT periodically, please describe closeout surveys that will be performed by Bayhealth Medical Center prior to release and return of the trailer to control of PMS HT.
3. Please confirm that secured off-street parking owned or under control of Bayhealth Medical Center will be provided for the PMS HT trailer. Please note that public rights-of-way are not considered part of the address of Bayhealth Medical Center.
4. Please describe how secured access will be maintained to the mobile PET trailer and confirm that there will be secured storage facilities available for storage of byproduct material and radioactive waste.
5. Please confirm that byproduct material will be delivered directly to the PMS HT trailer only if the trailer is occupied by Bayhealth Medical Center personnel at the time of delivery.
6. Please confirm that you will require the supervised Bayhealth Medical Center personnel associated with PET radiopharmaceutical use to follow the instructions of the supervising authorized user and the Radiation Safety Officer for medical uses of byproduct material, written radiation protection procedures established by the

Bayhealth Medical Center, regulations in 10 CFR Parts 19, 20, 30, 35, and 71, and license conditions of your license.

7. Please confirm that technologists will be trained in emergency procedures that you have developed and implemented in accordance with the Radiation Protection Program required by 10 CFR 20.1101, for activities associated with the PMS HT trailer.
8. Describe who (PMS HT or Bayhealth Medical Center) will be responsible for radioactive waste generated as a result of possession and use of PET radiopharmaceuticals on the PMS HT trailer. For instance, will radioactive waste stay on the PMS HT trailer and transferred to PMS HT, or will radioactive waste be controlled under the Bayhealth Medical Center radioactive waste program? If radioactive waste will be transferred to PMS HT, please note that PMS HT must be licensed by NRC as a waste broker. Therefore, an amendment to their NRC license would be required.
9. Describe the method of storage and final disposal of radioactive waste. If radioactive waste will be stored in the PMS HT trailer, the trailer must be properly secured and posted as a byproduct material storage location.
10. Please confirm that transportation requirements specified in 49 CFR as they relate to radioactive waste generated while the PMS HT trailer is onsite at Bayhealth Medical Center, the return of unused PET radiopharmaceuticals and the transport back to PMS HT of any sealed sources used for equipment QA, will be followed.
11. Confirm whether the “quiet room”, bathroom, etc. are located on the PMS HT trailer or whether these facilities are located in Bayhealth Medical Center. If patients who receive PET radiopharmaceuticals are not releasable pursuant to 10 CFR 35.75, and are being transported to these areas in the hospital, then the “quiet room”, and bathroom, etc. are additional locations of use of PET radiopharmaceuticals in the Bayhealth Medical Center facility. If this is the case, please provide a description of following:
 - a. Patient “quiet rooms” for patients waiting to be scanned. Please describe shielding, (e.g., $\frac{1}{4}$ to $\frac{1}{2}$ inch lead shielding in walls, floor, and ceiling).
 - b. Dedicated patient bathrooms. Please describe shielding, (e.g., $\frac{1}{4}$ to $\frac{1}{2}$ inch lead shielding in walls, floor, and ceiling).
12. On a detailed version of your facility and PET trailer diagrams, please indicate the position of the PET areas described below and describe the type, dimensions, and thickness of installed shielding.
 - a. Storage of PET radiopharmaceuticals (e.g., stored in transport shielding from radiopharmacy).
 - b. Preparation and dispensing of PET radiopharmaceuticals (e.g., 2 inch lead glass L-block, 511 keV syringe shields, flush counter mount for dose calibrator, shielded well counter, etc.).

- c. Scan rooms (e.g., ¼ to ½ lead shielding in walls, floor and ceiling).
- d. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe how you will secure the material.
- e. Storage of sealed sources.

In addition, identify areas adjacent to the trailer and, for locations within the hospital, identify areas across the walls from use and storage/use locations, and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

- 13. Identify any additional authorized users involved in the administration of PET radiopharmaceuticals, and provide their training and experience as describe in 10 CFR 35.290. NRC Form 313A (AUD) may be used to document this information.
- 14. Please provide a description of the sealed sources that are maintained on board the mobile PET trailer. In addition, describe the process of: 1) transferring the sources from PMS HT to Bayhealth Medical Center; 2) performing sealed source inventories and leak tests required by 10 CFR 35.67; and 3) transferring sources back to PMS HT.
- 15. Please provide a copy of the signed contract between PMS HT and Bayhealth Medical Center that shows that Bayhealth will have full control of the PET trailer while in use on Bayhealth Medical Center property. In addition, the contract should address many of the items described above.

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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is 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.

You may respond to my attention in writing by letter, email (if letter is signed and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 582455. If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your amendment.

Thank you for your cooperation. Please feel free to contact me by telephone or e-mail if you have any questions.

Sincerely,

Jan Nguyen

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