From:

Gaskins, Farrah

To:

Sciole, Kelly A. (Kelly, Sciole@nemours.org)

Subject:

Request for additional information, License number 07-16199-02

Date:

Friday, January 27, 2017 9:05:00 AM

## PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Licensee:

Alfred I. DuPont Hospital for Children

License No.: 07-16199-02 Docket No.: 030-19939

Control No.: 592696

Dear Ms. Sciole:

This is in reference to your letter dated December 14, 2016, requesting to amend Nuclear Regulatory Commission License No. 07-16199-02. In order to continue our review, we need the following additional information:

- 1. In accordance with regulations in 10 CFR 35.290. an authorized user (AU) must be a physician. Please note that Dr. Shaohui Zhang may not be added as an authorized user but may use material under the supervision of an AU that has already has 35,200 authorization. You may also request another AU that meets the criteria in 35.290.
- 2. The hot cell that is described in the amendment request has a "optional" built in dose calibrator feature. Please confirm if you intend to use this feature and describe additional shielding that may be required.
- 3. Please describe the areas above and below the PET Chemistry facility. In addition, describe shielding in place in the walls and ceiling.
- 4. Your current authorization of F-18 for medical use is covered under 35.200. This authorization is for possession limit "as needed". Based on the conversation during the visit to the facility, F-18 will be used to label imaging agents and will be acquired in bulk from an area nuclear pharmacy. Please confirm if this is the case. If so, F-18 will need to be listed as a separate line item, therefore, please describe the Physical and/or chemical form, maximum possession limit, and purpose.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 592661. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5143.

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).



## Farrah C. Gaskins

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