

From: [Gaskins, Farrah](#)
To: [Barreca, Leandro J.](#)
Subject: Request for Additional Information for License No. 09-31177-01
Date: Tuesday, November 21, 2017 11:30:00 AM

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION.

Licensee: 21st Century Oncology
License No.: 09-31177-01
Docket No.: 030-37316
Control No.: 601493

Dear Mr. Barreca:

This is in reference to the letter signed by Eric Lee dated October 18, 2017, requesting to amend Nuclear Regulatory Commission License No. 09-31177-01. In order to continue our review, we need the following additional information:

1. Although you submitted a diagram to show the areas of use to support the request to add Xofigo to the license, the diagram submitted was not clear. Please submit a diagram that clearly describes the facilities and equipment (e.g., remote handling equipment, storage containers, shielding,) to be made available at each location where licensed material will be used. The diagram should include a description of the areas assigned for the receipt, storage, preparation, and measurement of licensed materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Diagrams should be drawn to a specified scale, or dimensions should be indicated.
2. You submitted NRC form 313A(AUT) to demonstrates training and experience for Dr. Kiggundu. Part I, item 2 of the form discusses individuals that meet requirements in 35.391, 35.392, 35.394, 35.490, and 35.690. On the form submitted, 35.392 and 35.394 are checked as authorizations Dr. Kiggundu already has under this license, however 35.300 is not currently authorized on this license. In addition Item 3.b. describes supervised work experience but does not provide total hours of experience. Please resubmit Form 313A(AUT) with the correct information and include the total number of hours of supervised work experience.
3. Dr. Keith Miller is named as the preceptor that meets the requirements under 35.396 and is named on a State of Florida radioactive materials license as an authorized user. Please provide a copy of the license in which Dr. Miller is named as an authorized user.

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 601493. If you have any 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).

Sincerely,

Farrah C. Gaskins

Health Physicist, Medical and Licensing Assistants Branch
U.S. NRC, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406
(610) 337-5143 office
(610) 337-5269 fax