

From: [Gaskins, Farrah](#)
To: pbenetti@hsc-pr.com
Cc: [Nguyen, Janice](#)
Subject: Addition
Date: Thursday, November 08, 2018 3:59:00 PM

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION.

Licensee: San Cristobal Oncology Services, Inc.
License No.: 52-35511-01
Docket No.: 030-39138
Control No.: 610361

Dear Mr. Benetti:

This is in reference to your letter dated November 8, 2018, responding to our email dated November 7, 2018 requesting additional information for a new Nuclear Regulatory Commission License No. 52-35511-01. In order to continue our review, we need the following additional information:

1. Please confirm that you do not have licensed material at this time. On page 13 of your license application, it states, "We **have** the HDR Gammamed Plus 1X with source CA-1080D-103-S." Please note that you are not authorized to possess any licensed material.
2. Although you have submitted additional information to support Mr. Carmelo Perez being named as your Radiation Safety Officer (RSO), please confirm the number of facilities that Mr. Perez currently serves as RSO. In addition, please confirm the number of hours Mr. Perez will be on-site at your facility (i.e., you indicated two days per month, but how many hours each day).
3. Confirm that the in-house representative who will serve as the point of contact during the RSO's absence will be the PET/CT Technologist.
4. You have indicated that the PET "quiet room" is located in the HDR Room although you stated in your original application that the HDR unit will be controlled from unauthorized access. Please describe where and how the HDR unit will be secured when not in use. In addition, please indicate on the facility diagram where the HDR patient treatment will occur. Please also confirm there is only one PET "quiet room".
5. Please indicate on your facility diagram where your alarming radiation monitor (i.e. Primalert system) will be installed in the treatment room (e.g., will these be visible to someone who enters the room during source exposure). Please also indicate the trigger levels for the Primalert (e.g., will it go off when PET radiopharmaceuticals are being administered). In addition, please confirm that back-up battery testing will be performed on HDR treatment days before patient treatments.
6. Please confirm what type of shielding is installed between the PET/CT camera and

Rec'd. in LAT - 11/08/2018

NMSS/RGNI MATERIALS-001

PET/CT control room (i.e. lead glass and thickness).

7. Please confirm that the additional shielding for the location labeled "Wall E" was installed in accordance with the shielding calculations recommended by Miguel Rios on September 12, 2018.

We will continue our review upon receipt of the requested information. Because you requested to have this action completed by Friday November 9, we ask that you reply no later than Friday morning. 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 610361. 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).

Thank you for your assistance!

Farrak C. Gaskins

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