From: Gaskins, Farrah
To: pbenetti@hsc-pr.com
Cc: Nguyen, Janice
Subject: Request for additional information for License No. 52-35511-01
Date: Wednesday, November 07, 2018 5:04:00 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 the application dated October 29, 2018 requesting a new Nuclear Regulatory Commission License No. 52-35511-01. In order to continue our review, we need the following additional information:

1. Our records indicate that there is a $300 balance required for your application fee. An NRC Form 577 has been sent requesting this balance. Please confirm that you have received it and that it has been paid. Please note, we will not be able to issue the license until the fee is paid in full.

2. It appears that you are requesting to use the Varian Gammamed Plus 1X. Please confirm the manufacturer and model number of the High Dose Rate Remote Afterloader (HDR) unit you are requesting to use. In addition, on page 13, your license application 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. Please confirm that you do not have licensed material at this time.

3. Your proposed Authorized User (AU) and Authorized Medical Physicist (AMP) for HDR are currently on licenses which authorize the Nucletron Microselectron Model HDR unit. It appears that you are requesting the Varian Gammamed Plus 1X. Please confirm that the AU and AMP will receive training on this specific manufacturer and model number prior to first clinical use of the device.

4. You have requested Carmelo Perez, M.S. be named as the Radiation Safety Officer (RSO) for your license. It appears that Mr. Perez is an outside contractor/or consultant and is currently named on other NRC licenses. Please provide the following information to support this request:

    a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

    b. Describe the relationship that will exist between the consultant-RSO and your

Recd. in LAT- 11/08/2018

institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

5. You have requested therapy uses, including 10 CFR 35.400. Please provide facility diagrams of in-patient rooms that will be used for this authorization, including areas above, below, and adjacent, and indicate any installed shielding if applicable. For therapy in-patients who are administered materials permitted by 10 CFR 35.400, and are not releasable pursuant to 10 CFR 35.75, please confirm that these patients will be quartered in private rooms with private bathroom facilities. Please also confirm that surveys will be performed to ensure compliance with 10 CFR 20.1301(a). Alternatively, you may confirm that all patients administered 35.400 materials will be released in accordance with 10 CFR 35.75, and you will treat manual brachytherapy patients on an outpatient basis.

6. Please confirm that you will develop, implement and maintain *written* procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.

7. You have requested the use of 10 CFR 35.100 and 35.200. PET materials are authorized under 10 CFR 35.200. Please confirm if you will perform any other studies other than PET/CT scans under 10 CFR 35.100 and 35.200. In addition, please submit facility diagrams which describe the areas of use for 10 CFR 35.100 and 35.200 (not associated with PET/CT). The facility diagrams should include areas above, below, and adjacent, and indicate any installed shielding if applicable. Please also indicate what areas are restricted or unrestricted as defined in 10 CFR 20.1003.

8. Please resubmit your PET facility diagrams and include PET "quiet rooms" (areas where patients wait after the PET radioactive drug is administered) and any dedicated PET bathrooms. Please also indicate installed shielding.

9. Please describe other equipment and facilities for safe use and storage of PET radioactive materials (i.e. describe remote handling devices, special delivery systems, hot cells, etc.). Additionally, please include a detailed diagram of the hot lab, indicating if there is any shielding in the walls and what specialized equipment (specific to 511 keV) is present. If your well counter is located in your hot lab, describe any additional shielding of the detector.

10. With regard to your HDR unit and in accordance with the regulations set forth in 10 CFR 35.610, please confirm that you will:

    a. Secure the unit, the console, and the console keys, and the treatment room when not in use or unattended;
    b. provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties; and
    c. ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually;

11. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an unretracted or stuck HDR source.

12. You requested to use sealed source AEA Technology QSA Incorporate (formerly Amersham Corporation) Model CDC-T1 for 10 CFR 35.400. A Sealed Source and Device Registry (SSDR) certificate could not be located for this source model number. Please confirm that this is the correct model number and provide a copy of its SSDR certificate.

13. With regard to your daily HDR spot check procedures required by 10 CFR 35.643, please confirm that the source exposure indicator lights will be checked on the remote afterloader unit, on the control console, and in the facility.

14. Please describe the emergency response equipment available for your HDR unit. For remote afterloaders, emergency equipment should include at a minimum, shielded storage containers, remote handling tools, and supplies for removal of applicators or sources from patients, such as scissors and cable cutters.

15. With regard to your HDR facility, please confirm the steps that will be taken to ensure that no two radiation producing units can be operated simultaneously (i.e. two way switch), if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room.

16. Please confirm what dosimetry system will be used in calibrating the HDR (e.g., electrometer with chamber).

17. 10 CFR 35.610 requires that licensees develop written safety procedures for

emergency response for HDR units. The actions specified for emergency response should give primary consideration to minimizing exposure to patient and healthcare personnel while maximizing patient safety. Please submit a single document with written safety procedures that you will implement for emergency response to include:

a. Step-by-step instructions/actions for responding to single and/or multiple equipment failures and the individual(s) responsible for implementing each action. Clearly specify which steps are to be taken under different scenarios (i.e., exposed source versus detached source);

b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

c. The names and telephone numbers of authorized users, authorized medical physicists, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

Please confirm that a copy of these procedures will be posted at the HDR unit console.

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 Thursday November 8, at 1pm. As explained in an email between you and Janice Nguyen of our office, if you are able to respond to the questions regarding the use of materials authorized by 10 CFR 35.100 and 35.200 (specifically, questions 1, 4, 6, 7, 8, and 9), we may be able to grant your license for those uses only. If additional time is needed to respond to the questions regarding 10 CFR 35.400 and 35.600. You will be able to amend at a later date to add materials authorized by 35.400 and 35.600. 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!

Farrah 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