

From: [VonEhr, Jason](#)
To: ["Gregory.Hisel@TrinityHealthofNE.org"](mailto:Gregory.Hisel@TrinityHealthofNE.org)
Bcc: [Lanzisera, Penny](#)
Subject: Saint Francis Hospital and Medical Center - Request for Additional Information
Date: Tuesday, June 15, 2021 8:22:00 AM

Licensee: Saint Francis Hospital and Medical Center
License Number: 06-00854-01
Docket Number: 030-01246
Mail Control Number: 625512

Dear Mr. Gregory S. Hisel,

This refers to your request to amend the above license to add two authorized users and an authorized medical physicist, dated April 5 and 16, 2021. In order to continue our review of your request, the following additional information is needed:

1. Regarding the addition of David James Grew, M.D. as an Authorized User on the NRC license, please provide:
 - a. A copy of Dr. Grew's original ABR certificate;
 - b. A copy of the NYU License demonstrating that the supervised uses and supervising users were therein listed. If the license is a broad scope license, please include the permit issued for the uses and supervising users;
 - c. Please confirm that the vendor operational and safety instructions and training on your operating and emergency procedures will be provided to Dr. Grew prior to his use of the therapy device.

2. Regarding the addition of Miguel Ramirez, M.D., as an Authorized User on the NRC license, please provide:
 - a. A copy of Dr. Ramirez's original ABR certificate. In addition, please note that ABR in Diagnostic Radiology is only recognized for uses under 10 CFR 35.100, 35.200, 35.392, and 35.394. Full 35.390 use is not recognized for this board certification pathway.
 - b. Casework for I-131 uses, including dates, activities, and supervising user;
 - c. NRC or Agreement State license listing supervising user.

3. Regarding the addition of Xin Xie, Ph.D., as an Authorized Medical Physicist, please provide:
 - a. Confirmation that documented training on your operating and emergency procedures was completed at Saint Francis Hospital and Medical Center;
 - b. Documentation to support that the supervising Authorized Medical Physicist is authorized by Nucletron to provide the vendor operational and safety instructions for use your unit. If not, please provide documentation of vendor training for Dr. Xie;

Please note that your submission dated April 5, 2021, included a document which had specific patient identifying information. In the future, please review your submissions for sensitive information that is not otherwise necessary for the associated action or report. If the sensitive information is so required, please ensure that the document is marked in

accordance with 10 CFR 2.390.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Thank you for your assistance. Please contact me with any questions,

--

Jason vonEhr
Health Physicist
Commercial, Industrial, Research & Development, and Academic Branch,
Division of Radiological Safety and Security,
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Office: (610) 337-5256

Email: jason.vonehr@nrc.gov

-

