

From: [Gaskins, Farrah](#)
To: [Makrides, Demetrios](#)
Subject: Request for additional information for LN 06-06941-01
Date: Wednesday, February 12, 2020 10:02:00 AM

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION.

Licensee: Norwalk Hospital
License No.: 06-06941-01
Docket No.: 030-01267
Control No.: 617440

Dear Mr. Makrides:

This is in reference to the application dated December 23, 2019, requesting to amend Nuclear Regulatory Commission License No. 06-06941-01. In order to continue our review, we need the following additional information:

1. You requested to add Dr. Philip Gilbo to your license as an Authorized User (AU). Please provide the appropriate professional suffix for Dr. Gilbo (i.e. D.O., M.D., etc.)
2. Please note the Form 313A (AUS) that you submitted has an issue date of 06-2016. The form has been superseded by the form issued 01-2020, which can be located here <https://www.nrc.gov/reading-rm/doc-collections/forms/>.
3. You requested to add Dr. Gilbo as an AU for materials authorized by 10 CFR 35.600, specifically, gamma stereotactic radiosurgery (GSR). Please note that your license does not authorize GSR use, therefore, the authorization for GSR for Dr. Gilbo cannot be granted.
4. In accordance with 10 CFR 35.490 and 35.690, an applicant must demonstrate that they have completed a structural educational program with 200 hours of classroom and laboratory experience. You indicated that Dr. Gilbo satisfied this requirement at Northwell Health Department of Radiation Medicine. This appears to be a hospital or medical facility and also the same institution the supervised work and clinical experience (i.e. residency program) was completed. Please confirm if this requirement was fulfilled in an educational setting and provide a diploma or certificate of completion.
5. Dr. Rajiv Sharma signed as the supervising individual for the supervised work and clinical experience under 10 CFR 35.490. Please submit the license (if agreement state) or license number (if NRC) on which Dr. Sharma is authorized under 10 CFR 35.490.
6. In accordance with 10 CFR 35.490 (b)(1)(ii), an applicant must demonstrate 500 hours of supervised clinical work experience under the supervision of an AU involving (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology.

The form submitted demonstrates 52.5 hours. Please submit documentation demonstrating 447.5 hours of work experience in the above referenced topics. In addition, the dates appear to be simultaneous with the classroom and laboratory training. Please confirm that they were not acquired concurrently.

7. Regarding the supervised work and clinical experience submitted in accordance with 10 CR 35.690:
 - a. Please provide the name of the supervising individual for supervised work and clinical experience and submit a copy of the license, permit or license number that the individual is named as an authorized user in accordance with 10 CFR 35.690.
 - b. Please provide documentation that Dr. Gilbo has received training in device operation, safety procedures, and clinical use for the high dose rate remote afterloader (HDR) unit authorized on your license. (Varian Medical Systems UK, Ltd, Varisource iX). This requirement may be satisfied by satisfactory completion of a training program provided by the vendor or by receiving training supervised by an AU or authorized medical Physicist (AMP) who is authorized for the specific HDR unit. The section was not signed by a supervising individual.
8. You submitted Page 6 of NRC Form 313A (AUS) twice signed by two different preceptors. Please confirm if you intended to submit both individuals to provide preceptor attestation for Dr. Gilbo. If so, please provide telephone number or both individuals and license/permit/facility name for the individuals.

We will continue our review upon receipt of the requested information. Please reply within 30 days of the date of this email. If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your application. 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 617440. 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,

Farah C. Gaskins

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