

**GENESYS
HURLEY
CANCER
INSTITUTE**
Radiation Oncology

December 19, 2019

**United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352**

**Re: Control # 616241, Amendment NRC License No. 21-32322-01
Genesys-Hurley Cancer Institute**

ATTN: Colleen Casey:

Please find the additional information you requested to expedite our request by January 1, 2020 for the additional use of Xofigo (35.300).

Dr. Paul G. Kocheril, M.D. is currently an authorized user for 35.300 (limited to the oral administration of Na-I-131 greater than or equal to 33 mCi). According to the 313 (AUT) form, that is no longer in use, as Dr. Kocheril is already authorized for a subset of 35.300, he need only provide the three preceptored cases (3.c), since he has already provided training and experience (3.a) and supervised work experience (3.b) for 35.300.

As of 12/30/19 Dong Whan Oh, M.D. will be locum tenens physician only. We are leaving him as authorized user on our NRC license so he will be able to sign written directives that may be required during any future time we may use his service. Therefore, Dr. Kocheril will be the only working physician to complete the Xofigo studies that are currently in progress. As previously stated, we would like to remove Ahmed Akl, M.D. and Haesook S. Kim, M.D. as authorized users from our NRC license as they are not currently employed at Genesys Hurley Cancer Institute.

Since we are unable to use the 313(AUT) forms I will list Dr. Kocheril's 3 cases performed on site at Genesys Hurley Cancer Institute, #21-32322-01, under the supervision of Dr. Dong Whan Oh, M.D. We mistakenly sent patient dosage information, however you can see that each case documented Dr. Oh and Dr. Kocheril's signature. We have also provided a preceptor statement from Dr. Oh.

**Case #1 7/19/17 and 8/17/17
Case #2 2/15/18, 3/15/18 and 4/12/18
Case #3 9/25/19**

As a preceptor for Dr. Kocheril, Dr. Dong Whan Oh, M.D. meets the requirements for 35.390, 35.394 and 35.396 on license # 21-32322-01, Genesys Hurley Cancer Institute.

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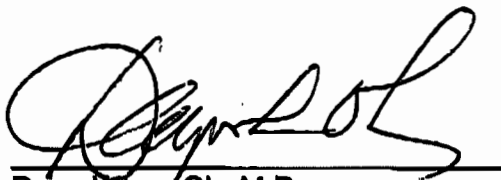
Genesys Hurley Cancer Institute

Additional Information CN# 616241

December 2019

I attest that Dr. Paul G. Kocheril, M.D. has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G for parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV for which a written directive is required.

I attest that Dr. Paul G. Kocheril, M.D. is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV for which a written directive is required.

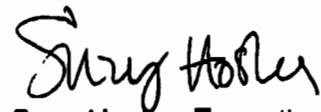


Dong Whan Oh, M.D.
Preceptor
810-762-8062

12/19/2019
Date

We appreciate your help with this matter. If you have any questions or require additional information please contact our physicist Dr. Ibrahim Abdulhay, Ph.D. at 810-762-8490, email labdulhay@ghci.org or fax 810-7623735.

Sincerely,



Suzy Hosler, Executive Director
Genesys-Hurley Cancer Institute