From: Elliott, Robin
To: Howard.J.DiPiazza@kp.org
Cc: mike.x.ofori-darkwa@kp.org; michele.c.davis@kp.org
Subject: Request for Additional Information regarding License Amendment for License No. 19-31420-01, CN592701
Date: Thursday, February 02, 2017 3:16:00 PM

License No.: 19-31420-01
Docket No: 030-38361
Control No: 592701

Licensee Name: Kaiser Permanente

Dear Dr. DiPiazza,

This refers to your request dated December 16, 2016, to amend your license. In order to continue our review of your request, the following additional information is needed:

1. Your letter dated December 16, 2016, should have been signed by a senior management representative. Please submit the additional information requested, signed by a senior management representative, and confirm that management has reviewed the letter dated December 16, 2016, and concurs with the statements and representations contained therein.
2. It is my understanding from my phone conversation with Mike Ofori-Darkwa on February 1, 2017, that you intend to only use I-131 at this time. Please confirm that you are requesting use of I-131 as permitted by 10 CFR 35.300 and not all materials and uses permitted under 10 CFR 35.300. Please note that, Vincent Dam, M.D., will be restricted on your license at this time to authorizations limited to the use of I-131.
3. Please provide facility diagrams for rooms that will be used for the storage and the administration of the I-131, if they are different from those currently being used for licensed materials. In addition, please provide the location, room number, and principal use of each adjacent room (e.g., office, file, closet, hall way), including areas above, beside, below and indicate whether the room is a restricted area as defined in 10 CFR 20.1003.
4. Please confirm that iodine will be obtained and administered in capsule form only, or if liquid will be used, confirm that a properly operating fume hood is available for storage and use of the licensed material.
5. Provide a facility diagram for rooms used to house any therapy patients that will be admitted prior to release. Include a description of shielding, if applicable. Provide documentation that adjacent unrestricted areas will not exceed the public dose limits in 10 CFR 20.1301. Alternatively, you may limit administrations to those that will allow patients to be released under the provisions of 10 CFR 35.75.
6. Please submit documentation to demonstrate that you, as Radiation Safety Officer (RSO), have obtained the training required by 10 CFR 35.50(e) for I-131 procedures. Mr. Ofori-Darkwa indicated that you are listed on a State of Maryland license for these activities. If so, please provide the licensee name and license number and if possible, provide a copy of the license listing you as RSO.

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; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. 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.

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

Regards,

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