From: Gallaghar, Robert
Sent: Friday, September 04, 2015 1:10 PM
To: Gregory Hisel (Gregory.Hisel@ibamolecular.com)
(Gregory.Hisel@ibamolecular.com)
Cc: Lanzisera, Penny; Gallaghar, Robert
Subject: Request for Additional Information - Control Number 586709

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Mr. Hisel,

This refers to your request dated April 15, 2015 to renew License No. 06-00854-03. In order to continue our review the following additional information is requested:

1. Please provide the manufacturer and the model number for the C-14 plated source for instrument calibration. Also provide information on how the source was obtained (obtained from a person licensed to manufacture and distribute under 10 CFR 32.74 or equivalent agreement state regulations; or from a person licensed to manufacture and distribute to persons for use under a general license.

2. Please describe the areas above and below the Main Radiopharmacy and indicate whether they are restricted or unrestricted areas. In addition regarding the PET Suite, describe any changes or modifications made to the area since 2007 that could have affected the shielding design and construction (the shielding plan is dated May 31, 2007).

3. Your response to our question regarding rooms used for in-patient therapies addressed patients receiving I-131 therapy but not those patients receiving therapy under 10 CFR 35.400. Please provide information on rooms used for in-patient treatments involving manual brachytherapy, or, alternatively, you may state that no such patients will require in-patient treatment (i.e. all such treatments are performed on an out-patient basis). Additionally, please describe shielding in the walls, ceiling, and floors of these rooms and indicate how public dose limits will be met.

4. Please note that your response included procedures that were not required to be submitted, were not reviewed in detail, and will not be included as a commitment in your license. A cursory review, however, identified the following concerns:

    a. The attachment to your response titled “Attachment 10” references HDR full calibration procedures that appear to be incomplete. Please note that 10 CFR 35.633(b) requires that full calibration measurements must include, as applicable, determination of:

        i. The output within ±5 percent;

        ii. Source positioning accuracy to within ±1 millimeter;

        iii. Source retraction with backup battery upon power failure;

        iv. Length of the source transfer tubes;

v. Timer accuracy and linearity over the typical range of use;

vi. Length of the applicators; and

vii. Function of the source transfer tubes, applicators, and transfer tube applicator interfaces.

b. The last page of Attachment 10 states that the authorized user (AU) or a physician under the supervision of an AU must be physically present during treatments. Please confirm that an AU will be physically present during treatment initiation in accordance with 10 CFR 35.615.

5. Your responses in Item 11.c and 11.e in regards to the location of the room radiation monitors and audiovisual system indicates that they are located “just outside” the treatment room. Please clarify since these are typically installed within the treatment room.

6. As required by 10 CFR 35.610, please submit detailed step-by-step spot check procedures, with acceptance criteria for:

    a. Electrical interlocks at each remote afterloader unit room entrance;
    b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
    c. Viewing and intercom systems in each remote afterloader facility;
    d. Emergency response equipment;
    e. Timer accuracy;
    f. Clock (date and time) in the unit’s computer; and
    g. Decayed source(s) activity in the unit’s computer.

7. Item 12 provides documentation of annual training for HDR personnel, however all authorized users are not listed. Please confirm training of all authorized users for the remote afterloader.

8. Please describe the warning systems and controls (signs, lights, alarms, interlock system) for the remote afterloader facility.

We will continue our review of your request to renew License No. 06-00854-03 upon receipt of the requested information. Please contact Robert Gallaghar at (610) 337-5182 if you have any questions.

Regards,

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