

From: [Lanzisera, Penny](mailto:Penny.Lanzisera@nrc.gov)
To: [Sciole, Kelly A.](mailto:Kelly.Sciole@nemours.org)
Subject: RE: RE: Request for Additional Information
Date: Thursday, September 15, 2016 4:48:00 PM

07-16199-02
03019939

Hi Kelly. See my comments noted in red below:

From: Sciole, Kelly A. [<mailto:Kelly.Sciole@nemours.org>]
Sent: Monday, September 12, 2016 9:58 AM
To: Lanzisera, Penny <Penny.Lanzisera@nrc.gov>
Subject: [External_Sender] RE: Request for Additional Information

Penny,

Just to keep things straight- I would like to confirm that the letters you have for amendment are:

- to change signing authority from Roy Proujansky to Paul Kempinski. (this you need no more verification for.) - Correct
- the second is for the PET/MR suite and to add FDG clinical doses to my hospital license? - Correct; waiting for answers to Items 3-6 below in a letter signed by management
- The Quality Control lab is going under the 01 research license and that RSO has sent the paperwork over to Betsy on Friday (if not – he will be sending it today). I will sent a separate amendment request to add the quality control lab to my license after the other requests are completed. – in that request I will submit shielding and diagrams and everything that was submitted for the 01 license. – Noted, I will void Mail Control No. 591637 and await a new submittal when you are ready
- The stretcher rooms are the quiet rooms for the patients. They will be injected and uptake will occur in this room. There are 2 as indicated on the paperwork I already sent. – Noted, submit this information in a letter signed by management
- The instrumentation used to measure doses: Atomlab 500 plus ; wipes will be performed on the well counter that accompanies the Atomlab 50 plus. There were 2 GM counters ordered for the new space for daily surveys. – Noted, submit this information in a letter signed by management.

Does this answer the questions you had below? – No, need a signed letter to document the last two bullets and also need Items 4 and 5 below addressed in a written response signed by management.

If we are still able to meet – can we get that on the calendar or is that something you do not typically do? We can review if a visit is still needed after the response.

Again, I cannot thank you enough for your guidance with all this.

Thank you
Kelly Sciole

From: Lanzisera, Penny [<mailto:Penny.Lanzisera@nrc.gov>]
Sent: Thursday, September 01, 2016 4:11 PM
To: Sciole, Kelly A.
Subject: Request for Additional Information

591457/591637

Licensee: Nemours-Alfred I. DuPont Hospital for Children
License No. 07-16199-02
Docket No. 03019939
Mail Control Nos. 591457 and 591637

Ms. Sciole, in order to continue our review of your requests, please provide the following additional information:

1. The request for use of F-18 in water (MCN 591637) to perform radiotracer set up and validation is considered a research use. Please submit an amendment request for your -01 license describing this use, your facilities, and the authorized users and their training and experience. You may contact Ms. Betsy Ullrich at 610-337-5040 with questions on this topic.
2. The use of the QC Lab for future testing of radiopharmaceuticals prepared for use in humans under an Investigational New Drug (IND) protocol approved by the FDA may be authorized under your medical license (in addition to the authorization under the research license noted above) under MCN 591457. To support the addition of this facility, please provide a detailed diagram of this Lab and describe the shielding installed in this room and in the fume hood located in this room where radiopharmaceuticals will be used and stored.
3. Please confirm if the rooms notated as Stretcher Rooms are the same as described Quiet Rooms.
4. Please describe installed shielding for exterior walls (with the exception of the lead shield wall). In addition, please confirm that the material shown on Diagrams L548 and V548 is concrete; and therefore from 6-12 inches of concrete is installed in the ceiling and floor, depending on the area.
5. Please indicate the location of the hot lab and describe any shielding and how it will be secured from unauthorized access.
6. Please describe instrumentation for use in the PET imaging facility for conducting radiation level surveys and radioactive contamination and package wipes.

In addition, please note that the production lab facilities and research use will not be addressed in this amendment. Separate amendment requests for research use (see Item 1) and, once your facilities are nearing completion, for production, should be submitted.

Please submit the additional information within 30 days to my attention, either via signed pdf from management or via fax to 610-337-5269. Please reference Mail Control No. 591457 in your response. If we do not receive a reply from you within 30 days, we will assume that you no longer require the requested amendment and void your request. Thank you for your assistance,

Penny Lanzisera
Senior Health Physicist
US NRC Region I