

Sara A.B. Forster, M.S.

TO: Yuenian (Neal) Zhang, Ph.D.



Company: Parkview Health

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
(630) 829-9892 FAX: (630) 515-1078

Number of Pages: 3

Email: Neal.zhang@parkview.com

CONVERSATION RECORD

|TIME |DATE
11:00 am 12/27/2012

NAME OF PERSON(S) CONTACTED |TELEPHONE NO. |ORGANIZATION
Yuenian (Neal) Zhang, Ph.D. (260) 266-9145 Parkview Health

REPRESENTED PERSON or PERSONS |ORGANIZATION
Yuenian (Neal) Zhang, Ph.D., RSO., and
Ray Gonterman, Sr. VP, Cancer Service Line Parkview Health
Parkview Comprehensive Care Center

SUBJECT
|License No.: 13-01284-02 |Control No.: 578051

SUMMARY

We have conducted a preliminary review your license renewal application dated July 31, 2012, and find that we are unable to continue this action until we have received information regarding the following:

1. AUTHORIZED USER CLARIFICATIONS:

The initial request to add Nathan D. Comsia, M.D., as an Authorized User did not include complete documentation as to his total training and experience hours. However, another reviewer pursued confirmation of training and experience hours directly with Dr. Comsia's residency program office. Therefore, Dr. Comsia may be added as an AU on the basis of his being listed on two other NRC licenses. Dr. Comsia's 10 CFR 35.600 authorization is currently limited to HDR Ir-192 in a GammaMed 232 device. The licensee's license authorizes only HDR Ir-192 in a Nucletron microselectron 105.999. **The October 17, 2012 letter qualifies as the notification required under 10 CFR 35.14, and Dr. Comsia may work as an AU even prior to being listed on the license. Please provide documentation confirming Dr. Comsia's completion of Nucletron-specific device orientation, training, and/or other experience.**

Next, as discussed in our phone conversation of December 27, 2012, **please submit written confirmation of that existing AUs John Borman, M.D., Randall J. Phillips, M.D., Timothy J. Grissom, M.D., and/or James Arata, M.D., should be deleted from the license.**

In addition, also discussed in our phone conversation of December 27, 2012, **please submit written confirmation of whether the spelling for existing AUs Michael A. Kinzer, M.D., and Frederich N. Vandeman, M.D., have changed to Kinser and Vanderman, respectively.**

2. The occupational dose commitment referenced NUREG 1556, Volume 9, Revision 2, Section 8.22, instead of Section 8.23 . **Please revise as necessary.**

3. The license renewal application does not adequately provide Item 9 high dose rate (HDR) remote afterloader information. Additional Guidance for Item 9 (Therapy Unit – Calibration and Use), may be found in NUREG 1556, Volume 9, Revision 2. As discussed in our phone conversation of December 27, 2012, **please submit required HDR emergency and other safety procedures and information, as outlined in the guidance and required under 10 CFR 35.610 and 35.643. The emergency procedure should be a copy of the document normally affixed to the HDR console. Please also submit a copy of your daily calibration spot check procedure.**
4. Facility diagrams for each address to be listed on the license should include any room numbers on the diagram, note whether any PET isotopes are used at the facility, and what the uses are above and below the facility. **As indicated in our December 27, 2012, phone conversation, please include a description of any activities being conducted in the areas contiguous to the proposed radioactive materials use area(s) and note whether PET isotopes are being used at those facilities. Please note the address associated with the diagram entitled, “Parkview Heart Institute.”**
5. In accordance with current NRC licensing policy, the NRC now lists an overall 10 CFR 35.300 material possession limit for, rather than a limit specific to iodine-131. **Please indicate whether a 5 Ci overall limit is sufficient to meet your needs.** If additional capacity is needed, please consider that a limit of 10 Ci or greater would also require the submission of an emergency plan, under 10 CFR 30.72.
6. In accordance with current NRC licensing policy, the NRC is now listing out the authorizations for 10 CFR 35.400 sources by isotope. **As discussed, please indicate whether each of Cs-137, I-125, Pd-103, and Ir-192 have ever been or may be, in the future, used or stored at at any or all of the 2200 Randallia Drive, 11109 Parkview Plaza Drive, and 11141 Parkview Plaza Drive locations.**
7. The license lists the Nucletron MicroSelectron 105.999 but the application requests Nucletron Microselectron HDR. From our December 27, 2012, phone conversation, we understand that the removal of the identified model was due to a software upgrade, which has been completed. Accordingly, **please submit documentation confirming the date on which the software upgrade was completed.**
8. The license renewal application does not adequately provide Item 9 facility information, with regard to the use of PET materials. Additional Guidance for Item 9 (Facility Diagrams) may be found in NUREG 1556, Volume 9, Revision 2. As discussed in our December 27, 2012, phone conversation, **please submit a more recent survey of the areas adjacent to each PET use area. For any PET use area, please indicate the actual specifications of shielding in the facility.**
9. The license renewal application does not adequately provide Item 9 facility information, with regard to the use 10 CFR 35.600 (HDR) materials. As discussed in December 27, 2012, phone conversation, **please confirm that the HDR room specifications meet or exceed those listed on the page indicated as “page 7,” included in the license application.**

Please submit the following items to my attention via either facsimile (630-515-1078), or as a pdf file attached to an email addressed to sara.forster@nrc.gov:

- Authorized User clarifications
- Occupational Dose commitment, corrected
- HDR emergency & daily spot check procedures
- Revised facility information including room numbers and PET activities, as noted
- Confirmation that 10 CFR 35.300 possession limit is sufficient
- 10 CFR 35.400 use and storage addresses of use, by isotope
- Nucletron upgrade details
- Actual PET shielding specifications and area survey data confirming shielding adequacy
- Actual HDR shielding specifications

Reference Control No. 578051, listed at the top of this memo, when submitting your responses. Include a dated cover letter with your response, signed and dated. As discussed in our December 27, 2012, phone conversation, a response is expected on or before January 24, 2013. Do not hesitate to call me at (630) 829-9892 with any questions you may have.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Sara A.B. Forster

Sara A.B. Forster 01/07/2013

Forster, Sara

From: Forster, Sara
Sent: Monday, January 07, 2013 2:30 PM
To: Neal.zhang@parkview.com
Subject: FW: Lic. No. 13-01284-02, Parkview Health, Control No. 578051; attachment included
Attachments: 02240.578051.13-01284-02 telecon signed.PDF

Hi Dr. Zhang-

Please see attached and confirm receipt of this message. Do not hesitate to call me if you have any questions. Thank you.

Sara A. B. Forster, Health Physicist Licensing Reviewer
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Division of Nuclear Materials Safety
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