From: Lanzisera, Penny
To: Mohapatra, Shashadhar M (Shashadhar.M.Mohapatra@Medstar.net)
Cc: Gaskins, Farrah; Gallaghar, Robert
Subject: Request for Additional Information
Date: Friday, April 21, 2017 2:05:00 PM

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

MedStar Washington Hospital Center
License No. 08-03604-03
Docket No. 03001325
Control No. 592388

Dear Dr. Mohapatra, as we discussed yesterday:

In order to continue our review of your renewal request, please submit the following additional information:

1. In your response, you stated that Gayle Thompson Smillie, Senior Director of Imaging, Radiation Safety and Patient Transport is currently acting as the licensee's management representative. You submitted a letter dated July 22, 2014 to support that statement; however, the letter states that Ms. Smillie will receive correspondence and be the management representative on the Radiation Safety Committee (RSC), but does not state that Ms. Smillie may make commitments on behalf of the licensee. Submit a letter signed by senior management clearly designating Ms. Smillie the authority to make commitments on behalf of the licensee. In addition, please also submit a letter signed by either Catherine Monge, Senior Vice President, or John Sullivan, President, agreeing to the statements in the renewal application documents.

2. Please confirm that you wish to change the mailing address on your license from:
   Administration, Room 2A2
   110 Irving Street, NW
   Washington, D.C. 20010-2975
   To:
   110 Irving Street, NW
   Room BA94
   Washington, DC 20010-2975

   In addition, please confirm that the post office address for the Hyman Research Building is now 100 Irving Street in place of 106 Irving Street.

3. To support your request for a broad scope license:

   a. The organizational chart submitted in your response to our request for additional information (RAI) does not include the RSC. In accordance with Section 8.7.1 of NUREG-1556, Volume 11, provide a description or an

organizational chart describing the management structure, reporting paths, and flow of authority between executive management and RSC.

b. Your response to questions on the RSC included quorum criteria. However, the current membership and criteria for selecting future members was not specified. Please provide a list of your current members, including functional areas covered, and provide criteria for selecting future members. Please note that, in accordance with 10 CFR 35.24(f), your RSC must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer (RSO), a representative of the nursing service, a representative of management who is neither an authorized user nor the RSO, and other members as appropriate.

c. The form you submitted in Attachment 4C in your original application does not document training and experience for non-medical authorized users. Please confirm that training and experience for non-medical authorized users is documented and provided to the RSC for approval. In addition, please confirm that NRC Form 313, which documents training and experience for medical authorized users (AU) is provided to the RSC for review.

d. Submit a description of the RSC program for review of protocols/permits issued to AUs. For example, the types and quantities of licensed material, a description of the experimental protocol and maximum quantities used at one time, a description of the clinical trial, the facilities and equipment proposed, the operating or handling procedures, the types of surveys and frequency required, the training of supervised individuals who will work under the protocol, potential exposure pathways, and appropriate shielding should be addressed during protocol review. You may confirm that the above topics are documented in the permit request and provided to the RSC for their approval.

e. Describe the criteria your RSC will use to approve new uses in medical areas, including Nuclear Medicine and Radiation Oncology. For instance, will the criteria used for approval of your current facilities and as described in NUREG-1556, Volume 9 be used (e.g. Section 8)?

f. In item 10.b. of your response, you stated that the audit will be performed in house and that a report will be available. Describe how the audit will be performed to determine user compliance with NRC regulations, the license, the requirements of the Radiation Safety Committee, and good health physics practices. Appendix L “Sample Audit Program” in NUREG 1556, Volume 7 and Appendix L, “ Model Medical Licensee Audit” in NUREG 1556, Volume 9 contains guidance that may helpful in developing your response and may be adopted for your use.

4. In item 10.2 of your original application, you describe the use of contractor staff in medical areas and in Item 8 of your response received April 7, 2017 you discuss

nursing contracting staff and indicate that “adequate mechanisms for oversight will be in place.” Describe the mechanisms for oversight (e.g., supervisor and radiation safety office) and confirm that the licensee accepts responsibility for all activities conducted by contractor staff.

5. In our email dated March 17, 2017, we asked you to provide additional information for the items listed below. While some items only required a confirmation, others asked for specific detail. Although you state that you do not conduct research involving byproduct material at this time, because you are requesting authorization for research and development, please describe:

    a. the method of classifying laboratories based on types, quantities, and toxicity of the byproduct material requested to be used.

    b. the criteria the RSC will use to determine if special use facilities are required, such as: use of fume hood, glove box, etcetera when working with volatile radioactive materials; use of remote handling equipment when working with high-activity sources; the types of storage containers and/or shielding for high-energy beta-emitting or gamma-emitting radionuclides.

    c. sample diagrams for each classification scheme that considers radiation safety of workers and proximity to unrestricted areas, and ventilation if radioactive materials may become airborne. You may submit diagrams of facilities that have been used in the past to demonstrate your criteria used.

    d. locations of currently approved facilities designed or established for special uses (such as laboratories using greater than 10 millicuries per experiment, nuclear pharmacies, iodination/tritiation laboratories, unsealed alpha laboratories, animal facilities, incinerators, compactors, large quantity/high activity processing facilities, instrument calibration facilities, waste handling or processing facilities, long-term waste storage facilities).

    The criteria in NCRP Report No. 127, and NUREG-1556, Volume 11, Appendix E “Facilities and Equipment Considerations” and Appendix H “Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument and Air Sampler Calibration Program” may be adopted in reviewing your routine and special use facilities.

6. Your response did not include performance of area surveys or criteria for evaluating. Please submit criteria for performing area surveys and evaluating them. Alternatively, you may commit to procedures in Appendix J “Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program” in NUREG 1556 Volume 7.

7. In item #6, you stated that Dr. Ron Waksman , cardiologist, is “very actively involved in research on animals and humans and serves as a member of the RSC”. Earlier in that paragraph, you stated that the only research on animals and humans involves x-

ray. Please confirm that the research Dr. Waksman performs is limited to X-ray and does not involve the use of byproduct material.

8. In accordance with Section 8.10.3 of NUREG-1556, Volume 11, describe your administrative procedures and other provisions to assure (1) control of procurement and use of licensed material; and (2) inventory, control and accounting of licensed material.

9. In your response to waste disposal, procedures for decay-in-storage (DIS) only were provided. Model waste procedures provided in Appendix T of NUREG-1556, Volume 7, include other disposal options. Confirm if you want to be authorized to approve other disposal options and whether procedures in Appendix T will be adopted.

10. We understand that you do not intend to re-start conventional manual brachytherapy at this time. However, in the event that these procedures are re-started, confirm that an Authorized User will complete and sign the 2nd part of the Written Directive in accordance with 10 CFR 35.40(b)(6)(ii).

11. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an un-retracted stuck HDR source.

12. In you patient release calculations summarized in response to Question 24.f, the formula you provided did not appear to include the I-131 gamma constant (e.g., 2.2) or an activity. Please confirm that your calculations performed to support release of patients following I-131 administrations will include the gamma constant and activity.

13. Please describe your HDR door interlock and confirm that the interlock retracts the source upon opening the treatment room door.

14. The values listed in your Post Treatment Surgical Considerations for microspheres indicate that no special handling (e.g., shielded gloves or ring badge) is needed by the surgeon if the skin surface dose rate is less than 20 mSv and that container labeling is not needed for an explanted liver with a dose rate of less than 50 uSv/hour. These values appear high. Please confirm that extremity monitoring and container labeling will be conducted in accordance with the applicable requirements in 10 CFR Part 20.

Please reply within 10 days of the date of this email. Please contact Farrah Gaskins or Robert Gallaghar with any questions. Thank you for your assistance,

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