From: Gabriel, Sandra
Sent: Thursday, March 24, 2011 7:29 PM
To: Chowdhury, Anisuzzaman
Subject: Additional information for license renewal, mail control 573711

Licensee: District Health Partners, L.P., D/B/A The George Washington University Hospital
License Number: 08-30607-01
Docket Number: 03035424
Mail Control: 573711

To: Anis Chowdhury, RSO

This is in reference to your license renewal application and our telephone conversation earlier today. Please provide the following additional information by Monday, April 11.

1) Two locations of use on your current license do not appear to be addressed in the renewal application: the Ambulatory Care Center at 2150 Pennsylvania Avenue and Warwick Building at 2300 K Street. Please provide the current status of use of licensed materials at these locations.

2) Current NRC practice requires use of a more specific possession limit for the broad authorization in Item E of your current license (atomic number 1-101, half-life greater than 120 days, any form). Item 5.1(c) on page 7 of your application said that these materials are not currently in use. One option is to remove this authorization and submit an amendment request in the future if you wish to use these materials. Another option is to request a limit such as "100 millicuries per radionuclide and 200 millicuries total." Please select one of these options.

3) Please clarify your maximum possession limit request for Y-90 SIR-Spheres. Page 3 of your renewal application refers to a 2500 mCi limit and page 119 refers to a 1 Ci limit.

4) The list in Item 5.1(a) of "sources that require leak test and are in use" includes three brachytherapy sources designated as "Medi 3M Model 6503." The Sealed Source and Device Registry includes 3M Series 6500, but nothing similar for Medi-Physics. Today you provided a faxed copy of a source calibration certificate from Medi-Physics, Inc. (MPI) plus a second sheet identifying these as 3M sources distributed by MPI. We will list these sources on your license as manufactured by 3M. No response to this item is required.

5) The list in Item 5.1(b) of "sources that require leak test and are in use" does not appear to include the irradiator source. Please confirm that this source is leak-tested and indicate if any other sources were inadvertently excluded from the lists in Items 5.1(a) or 5.1(b).

6) You requested authorization for research and development including animal studies. Please provide descriptions and locations of animal facilities or the criteria that your Radiation Safety Committee will use to approve them in the future. Describe the training that will be provided to individuals caring for animals containing licensed materials. Also submit a copy of the instructions provided to animal caretakers for handling of animals,

animal waste carcasses, and cleaning/decontamination of animal cages. Alternatively, you may request to remove the authorization for animal studies and state that you will submit an amendment request with this information in the future if you wish to initiate animal studies.

7) Describe the approach your Radiation Safety Committee will use to approve 35.1000 medical uses and users, for example, will you follow the then-current licensing guidance on the NRC website?

8) What is your method to assess effectiveness of the worker training you committed to provide? For example, will this involve quizzes or observation of work practices?

9) On page 88 of your application, item D.3 for calibration and use of self-reading dosimeters is incomplete; please provide the remainder of this item.

10) Please provide further explanation of the PET/CT shielding design to demonstrate compliance with 10 CFR 20.1301 and 1302, and including consideration of as-built shielding. One option could be to do an assessment based on results of surveys or area radiation monitoring rather than design criteria. One possible concern is the use of occupancy assumptions of 1/20 and 1/40, in contrast with the higher occupancy assumptions in the table on page 160 of your application.

11) You requested flexibility to make certain program changes and revise procedures without amendment of the license. Please confirm that your process will include documentation of the specific change including the reason for the change and a summary of the radiation safety matters that were considered prior to approval of the change.

12) In a telephone conversation on January 20, 2011, you discussed relocation of a source storage area. Please provide additional information, including the room number and diagram of the new area and the sources that will be stored there.

13) Is it acceptable to remove references to intravascular brachytherapy from this license?

14) Regarding your personnel dosimetry program, please confirm that you have performed and documented a prospective evaluation demonstrating that unmonitored individuals are not likely to receive 10% more of annual dose limits, and will do this as needed in the future.

15) Regarding your irradiator, please confirm that you will implement and maintain procedures for routine maintenance according to the irradiator manufacturer or distributor's written instructions. Also confirm that non-routine maintenance of your irradiator will be performed only by the manufacturer, distributor, or other person authorized by the NRC or an Agreement State to perform this maintenance.

16) On page 119 of your renewal application, you committed to notify the NRC within 30 days after a provisional authorized user for SIR-Spheres or Therasphere completes a third clinical case supervised by a manufacturer's representative. Please note that it is not necessary for a broad scope licensee to make a notification to the NRC, however you should update the AU's permit from provisional to full authorization at that time.

17) On page 120 of your application, you committed to perform semi-annual inventories of Y-90 microspheres. Please confirm that you will retain each semi-annual inventory record (if applicable) for three years.

18) In a telephone conversation today, you discussed a possible restart of your prostate brachytherapy program. If you plan to use brachytherapy sources that will exceed the possession limit for material in "any form" in Item A of your current license, please provide the manufacturers and model numbers of sources to be used in accordance with the "sealed source" authorization in Item F of your current license.

Please provide a written response to these items by Monday, April 11 under signature of senior management. You may provide this to my attention by letter or fax (610-337-5269), referencing mail control 573711.

You may contact me by telephone or e-mail with any questions. Please note that I will be out of the office periodically, but will check e-mail and voicemail messages daily. Thank you.

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