UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

November 22, 2011

Docket No. 03035779 License No. 06-30657-01
Control No. 575973

Anthony W. D'Souza, M.D.
President and Radiation Safety Officer
Heart Specialists, PC of Southern Connecticut
Four Corporate Drive, Suite 100
Shelton, CT 06484

SUBJECT: HEART SPECIALISTS, PC OF SOUTHERN CONNECTICUT, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 575973

Dear Dr. D'Souza:

This is in reference to your application dated September 8, 2011 requesting to renew Nuclear Regulatory Commission License No. 06-30657-01. In order to continue our review, we need the following additional information:

1. Item 2 and 3 of this application lists:

    a. The name of the applicant as Heart Specialist, L.L.C. Your current license lists the licensee name as Heart Specialists, PC of Southern Connecticut. Please clarify if there has been a change of ownership. Please see Appendix F for information needed for transfer of control in NUREG-1556, Volume 15.

    b. The mailing address and address where license material will be used or possessed as Four Corporate Drive, Suite 100, Shelton, CT 06484. Please confirm that you wish to include Suite 100 to both addresses and that this is the same suite previously used as part of your facilities.

2. Item 5 and 6 of this application listed the purpose of use of byproduct material permitted by 10 CFR 35.200 as cardiac imaging and localization procedures. Please note that 10 CFR 35.200 authorizes use of byproduct material for imaging and localization studies, and does not limit the use to cardiac only. This current authorization will be retained on your license.

3. Your application and facility diagram did not indicate any use of PET materials, which are now regulated by the NRC. Please indicate if there is or will be any use of PET isotopes (e.g., C-11, N-13, O-15, F-18, Rb-82), and if so, provide a detailed description of PET facilities, including shielding calculations. In addition, please list the manufacturer and model number for any sealed sources that do not fall under 10 CFR 35.65.

4. Dr. Kenneth S. Spector was not listed in the application. Please confirm that he is to be removed as an authorized user (AU) from the license.

5. Regarding your facilities:

    a. Please provide a scaled diagram that includes room numbers (if any) for areas of byproduct material use or preparation for use (e.g. hot lab). Please be aware that information (including diagrams) that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 2.390."

    b. The diagram you provided does not indicate a door for the hot lab. Please confirm that a lockable door exists or provide a description of how you will maintain security and control access to that area.

    c. The diagram you provided includes areas outside the hot lab that house a "long held storage waste" and "stress lab hot trash". Please describe how both areas will be secured and confirm that waste will be labeled in accordance with 10 CFR 20.1904(a).

    d. Please provide a description of the areas and rooms above and below Suite 100.

6. The statement you provided in Item 10 of your application regarding occupational dose appears to have a typographical error, and your statement addressing safe use of unsealed licensed material did not indicate that they will be written in accordance with 10 CFR 20.1101 (See Appendix C in NUREG-1556, Volume 9, Rev. 2, dated January 2008: "Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Medical Licenses"). Please revise the commitments below by stating:

    a. Occupational dose: "We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide Dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 2, dated January 2008."

    b. Safe use of unsealed licensed material: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

7. In order to facilitate future communications, please provide a current contact e-mail address, telephone and fax number for your RSO and Senior Management.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, & Academic Uses of Nuclear Materials;** then **Licensee Toolkits, See our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 575973. If you have any technical questions regarding this deficiency letter, please call Ms. Maryann Abogunde at (610) 337-5090.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

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SUNSI Review Complete: MAbogunde

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