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

March 2, 2012

Docket No. 03028939 License No. 06-23559-01
Control No. 576931

Joseph Corning, M.D.
Radiation Safety Officer
Middlesex Cardiology Associates, P.C.
520 Saybrook Road, Suite 100N
Middletown, CT 06457

SUBJECT: MIDDLESEX CARDIOLOGY ASSOCIATES, P.C., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 576931

Dear Dr. Corning:

This is in reference to your application dated February 8, 2012 requesting to renew Nuclear Regulatory Commission License No. 07-16529-01. On April 24, 2002, NRC published new medical regulations in 10 CFR Part 35. These regulations became effective on October 24, 2002. Concurrent with the issuance of the new medical regulations, NRC published NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses", Volume 9, Revision 2 (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/). The intent was that licensee's would use NUREG 1556, Volume 9, Revision 2 to prepare the license renewal. You will note that the NUREG generally does not require the submission of detailed procedures during the licensing process. As described in the NUREG, in many cases a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures. Appendix C of the NUREG 2 should be helpful in identifying the information required by NRC to process your request for license renewal. Therefore, the procedures submitted in your application dated February 8, 2012 were not reviewed in detail and will not become a condition of your NRC license. Procedures that you commit to develop, implement, and maintain will be reviewed during future inspections.

In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative. Please confirm that you are the management representative for your organization. Otherwise, submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license. Also, to facilitate future communications, please provide e-mail addresses and fax numbers for yourself and any other management representatives.

2. The mailing address of your current license is 14 Jones Hollow Road, Suite 9, Marlborough, Connecticut. The application dated February 8, 2012 indicates that the mailing address is 520 Saybrook Road, Suite 100N, Middletown, Connecticut. Please verify which address should be listed as the mailing address for your license. Also, confirm that the locations of use are as follows: (1) 520 Saybrook Road, **Suite 100N**, Middletown, (2) Jones Hollow Road, **Suite 9**, Marlborough, and (3) 51 Main Street, Old Saybrook. Finally, is there a suite number for the Old Saybrook location?

3. In your application you did not specify the byproduct material you intend to use. Please confirm that it is your intention to continue using byproduct material that is permitted by 10 CFR 35.200 and indicate whether or not PET radionuclides will be used. If PET materials are used, provide shielding evaluations for areas of use. The evaluation should include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations.

4. The facility diagrams that you submitted did not contain all of the information that we require. Please provide diagrams that are legible and contain the following:

   a. location, room numbers, and principal use of each room or area where byproduct material, including PET materials, are prepared, used, or stored.

   b. location, room numbers, and principal use of each adjacent room (e.g. office, toilet, closet, hallway, etc.), including areas above and below the treatment rooms.

   c. indicate whether the identified rooms are considered a restricted or unrestricted area, as defined in 10 CFR 20.1003.

   Drawings should be marked as “Security-Related Sensitive Information”. See Section 8.16 Figure 8.1 and Appendix E Figure E.1 of NUREG-1556, Vol. 9, Rev. 2 for examples of acceptable diagrams.

5. In accordance with the guidance provided in NUREG-1556, Vol. 9, please confirm the following commitments found in Table C.3 of the NUREG to develop, document, and maintain written procedures. These commitments replaced the procedures in the superceded Regulatory Guide 10.8:

   a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.”

   b. "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

   c. "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 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, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

d. "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20. 1101 that meet the Requirements of 10 CFR 20.1501 and 10 CFR 35.70."

e. "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."

f. "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

g. "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** 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 8:00 a.m. to 5:30 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. 576931. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

DOCUMENT NAME: G:\WordDocs\Current\Lic Def Letter\L06-23559-01.576931a.doc

SUNSI Review Complete: TWeidner

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	TWeidner/TW							
DATE	3/2/2012							

OFFICIAL RECORD COPY