From: Weidner, Tara
Sent: Tuesday, February 07, 2012 3:00 PM
To: 'donnamarie.grace@radnet.com'
Cc: 'garth.koniver@radnet.com'
Subject: Papastavros' Associates NRC License Renewal

License No. 07-16529-01
Docket No. 03011379
Control No. 576092

SUBJECT: PAPASTAVROS' ASSOCIATES MEDICAL IMAGING, LLC, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 576092

Dear Ms. Grace:

This is in reference to your application dated September 23, 2011 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 May 24, 2011 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. To facilitate future communications, please provide e-mail addresses and the fax number for yourself and Dr. Koniver, M.D., Radiation Safety Officer.

2. Please indicate whether 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.

3. Please confirm that Iodine-131 therapy treatments are performed on an outpatient basis only.

4. Item 6.D. of your current license lists the use of 10 CFR 35.500 materials. Item 7.D lists a specific sealed source (IPL Model HEG-137) which is not listed on the renewal application. If you wish to have the use of 10 CFR 35.500 materials removed from your license, we will need documentation of the transfer of the IPL Model HEG-137 sealed source to a licensed recipient.

If you intend to keep the use of 10 CFR 35.500 materials on your license, provide the manufacturer and model number for all sealed sources that do not meet the criteria in 10 CFR 35.65 (e.g. greater than 30 millicuries).

5. The facility diagrams that you submitted were difficult to read and 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.

6. Please provide a description of the radiation monitoring instruments (e.g gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys.

7. 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 found 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 with 10 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. 576092. 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.

Tara L. Weidner
Health Physicist
US Nuclear Regulatory Commission