



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

October 26, 2010

Docket No. 03011379

License No. 07-16529-01

Kenneth E. Ames
Vice President of Operations, RadNet, Inc.
c/o Papastavros' Associates Medical Imaging, LLC
Professional Building IV
1701 Augustine Cut-Off, Suite 100
Wilmington, DE 19803

**SUBJECT: NRC INSPECTION REPORT NO. 03011379/2010001, PAPASTAVROS'
ASSOCIATES MEDICAL IMAGING, LLC, WILMINGTON, DELAWARE SITE**

Dear Mr. Ames:

During a review of your license amendment request received on July 9, 2010 (dated June 14, 2010), Penny Lanzisera of this office identified a violation of NRC requirements. In our letter to your Radiation Safety Officer, Dr. Garth Koniver, dated October 4, 2010, the NRC authorized the release of your Mobile Positron Emission Tomography (PET) unit for unrestricted use; and we noted the following:

1. In Amendment No. 27, dated November 7, 2003, NRC authorized the use of cesium-137 sources only on the Mobile PET unit. The use of PET radionuclides was authorized by the State of Delaware at that time.
2. In accordance with Section 651(e) of the Energy Policy Act of 2005 which expanded the definition of byproduct material to include accelerator-produced radioactive material (NARM), the PET radioisotopes came under the NRC's regulatory authority in the State of Delaware on November 30, 2007. Licensees using NARM radioisotopes had until May 30, 2008, to amend their current NRC licenses to add any new areas of use, new radioisotopes (e.g., PET radioisotopes), or new authorized users affected by this change in regulatory authority.
3. An amendment to use PET radioisotopes on the Mobile PET unit was not submitted to the NRC, until a request to remove the use was submitted on July 9, 2010.

The findings of the inspection were discussed with Dr. Koniver on October 8, 2010. Specifically, as a result of an in-office review, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. This violation is being treated as a Non-Cited Violation (NCV), because it was non-repetitive, licensee-identified, and has been corrected. The NCV involved the failure to apply for and receive an amendment in order to continue NARM activities under your NRC license upon expiration of the NARM waiver on May 30, 2008, and in accordance with 10 CFR 30.3. During the inspection exit meeting on October 8, 2010, Dr. Koniver indicated that the failure to apply for an amendment was an oversight on the part of Papastavros' Associates Medical Imaging, which was identified and corrected by submission of the amendment request on July 9, 2010.

Papastavros' Associates Medical Imaging, LLC

You are not required to respond to this letter unless the description of your corrective actions in this letter does not accurately reflect your corrective actions or your position. In addition, if you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region I; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement**; then **Enforcement Policy**. 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).

Please contact Penny Lanzisera at (610) 337-5169 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc S. Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

cc:

Garth A. Koniver, M.D., Radiation Safety Officer
Donna Grace, Office Manager
State of Delaware

Papastavros' Associates Medical Imaging, LLC

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cc:
Garth A. Koniver, M.D., Radiation Safety Officer
Donna Grace, Office Manager
State of Delaware

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