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September 2, 2005

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

**Re: Radioactive Material License No. 07-16529-01, Docket # 03011379,
Reply to a Notice of Violation**

Dear Sir/Madam,

This letter is written in response to your letter of August 19, 2005, which details the Notice of Violation identified during your inspection of our facilities on July 20 and 21, 2005.

As Ms. Tara Weidner identified during the Commission's inspections of our Papastavros' Associates Medical Imaging sites, Dr. Satyajit Sarangi was not authorized for 10 CFR Part 35.300 administrations. He, however, wrote written directives for the administration of NaI-131 in activities greater than 30 microCuries at our Lewes, DE facility. Ms. Weidner's findings initiated an immediate Papastavros' Associates Medical Imaging fact-finding investigation to determine the conditions surrounding the omission of Dr. Sarangi as an authorized user for Part 35.300 administrations. The results of this immediate investigation were shared with Ms. Weidner on the July 21, 2005.

Papastavros' Associates determined that the following apparent actions led to this violation:

1. Dr. Sarangi did have the formal education and experience required to be authorized as a Part 35.300 authorized user. This documentation was/is on file in the Nuclear Medicine Department at Papastavros' Polly Drummond Hill facility.
2. Additionally, a letter dated February 6, 2003 and addressed to the U.S. Nuclear Regulatory Commission's Region I office requested that Dr. Sarangi be added as an authorized user for 10 CFR Part 35.300 uses. His appropriate fellowship training documentation was referenced (and attached) in this letter. This letter, although addressed to the USNRC, was apparently never received by Region I office. Hence, the license amendment was never granted.

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3. During the time of the creation of this letter, Papastavros' Associates Medical Imaging Nuclear Medicine Department was in the midst of the departure of the Chief Technologist who drafted the letter and was responsible to mail this amendment request letter to the USNRC. Most likely, the departing Chief Nuclear Medicine Technologist inadvertently forgot to mail the amendment request letter, or, she mailed the amendment request letter and it never reached the King of Prussia office. (During the evaluation, Papastavros' Associates noted that the complete street address for the King of Prussia office was not included.)

Since Ms. Weidner's visit, Papastavros' Associates has provided all supporting documentation regarding Dr. Sarangi's credentials and experience to USNRC Region I. Ms. Weidner took a copy of the February 6, 2003 amendment request letter with her on July 21, 2005. On July 29, 2005 Papastavros' Associates faxed a Form 313A detailing Dr. Sarangi's training and experience at the University of Alabama to Ms. Weidner's attention at Region I. Although he was not authorized to use radioactive materials for part 35.300 uses, Dr. Sarangi did have the appropriate experience and training to use these radioactive materials. Although he was not appropriately authorized, Dr. Sarangi never clinically compromised patient safety.

Since July 20, 2005 Dr. Sarangi has not created written directives for or administered NaI-131 in activities greater than 30 microCuries. We are awaiting a license amendment, which will authorize him for 10 CFR Part 35.300 uses. We believe that we have taken appropriate steps to correct these deficiencies. We look forward to receiving the license amendment the license amendment which will authorize Dr. Sarangi to administer therapeutic amounts of radioactive material to appropriate patients.

Thank you for your attention to this matter. Please contact me if I can provide additional information.

Sincerely,


Garth A. Koniver, M.D.
Radiation Safety Officer

Cc:
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