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U.S. Nuclear Regulatory Commission
 Region I
 Division of Nuclear Materials Safety
 475 Allendale Road
 King of Prussia, PA 19406-1415

4/20/2007

RE: Reply to a Notice of Violation; EA 07-009

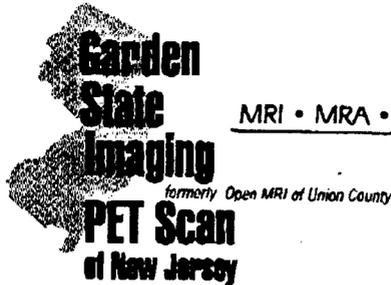
Subject: Inspection 030-36417/2006-001, PET Scan of New Jersey,
 Elizabeth, New Jersey Site and Notice of Violation
 License Number: 29-30840-01
 Docket Number: 030-36417

To Whom it May Concern:

Please accept the following as this facilities response to the above referenced Notice of Violation.

Violation A: During the period of July 28, 2006 through October 27, 2006 this facility utilized Tc-99m for medical imaging and localization studies on 52 patients, pursuant to 10 CFR 35.200, a use not authorized by the license.

- (1) Reason for violation: The licensee did not understand that their current authorization for Tc-99m under 35.56 did not include authorization to perform medical imaging and localization studies.
- (2) Corrective steps: Immediately upon notification of this over-sight by the facilities commercial pharmacy all prohibited activities were stopped and representatives of Region 1 of the Nuclear Regulatory Commission were notified by both this facility and the commercial pharmacy. Immediate action was taken to prepare a License Application for authorization to use materials under 10 CFR 35.200. Nuclear Medicine scanning activities did not resume at this facility until this license amendment was received.



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- (3) **Corrective steps to avoid further violations:** All future licensing actions will be undertaken with full participation of the Radiation Safety Officer, Authorized User and Consulting Health Physicists. During the quarterly Radiation Safety Audit by the Consulting Health Physicists a review of all current activities will be performed and documented to insure only procedures authorized by the facilities licensure are performed. This review will be submitted to the Radiation Safety Officer for his review and signature.
- (4) **Date of full compliance:** We consider this facility in full compliance as of the date of this response.

Violation B: As of November 14, 2006, the licensee permitted the use of byproduct material by an individual under the supervision of an authorized user and licensee did not instruct this individual in the regulations of this chapter and the license conditions with respect to licensee's use of byproduct material and did not instruct personnel during annual refresher training or when there was a significant change in the duties, regulations or terms of the license, including training on the applicable regulations and license conditions.

- (1) **Reason for violation:** The Authorized User and the Consulting Health Physicists failed to provide adequate training to the technical staff in a timely fashion after the amendment of the facility license to insure full compliance with all current regulations and license commitments pertaining to the changes in the facilities scope of operation.
- (2) **Corrective steps:** Training was delivered by the Consulting Health Physicists to the current technical staff with special attention to the activities required to achieve full compliance with all current license conditions and corresponding regulations. The results of this training are signed, dated and on file in the department.
- (3) **Corrective steps to avoid further violations:** During the quarterly Radiation Safety Audit by the Consulting Health Physicists a review of all current activities will be performed and documented to insure only procedures authorized by the facilities licensure are performed and that the current technical staffed is fully training in all compliance measures. This review will be submitted to the Radiation Safety Officer for his review and signature.
- (4) **Date of full compliance:** We consider this facility in full compliance as of the date of this response.



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Should you have any questions regarding this response, please feel free to contact me.

Sincerely,

Ralph DeBellonia
Administrator
PET Scan of New Jersey

DR. D'AMICO
RSD