

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Michael Lala, M.D., P.C., South Allen Radiology 26699 W. 12 Mile Road Southfield, MI REPORT NUMBER(S) 2009-001		2. NRC/REGIONAL OFFICE REGION III US NUCLEAR REGULATORY COMMISSION 2443 WARRENVILLE ROAD STE 210 LISLE IL 60532-4352	
3. DOCKET NUMBER(S) 03018558	4. LICENSE NUMBER(S) 21-24380-01	5. DATE(S) OF INSPECTION 5/6/09	

LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

1. Based on the inspection findings, no violations were identified.

2. Previous violation(s) closed.

3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ non-cited violation(s) were discussed involving the following requirement(s):

4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE			
NRC INSPECTOR	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	7/13/09

J. S. Sloan

Docket File Information
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6. INSPECTION PROCEDURES USED 87131		7. INSPECTION FOCUS AREAS 03.01-03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02200	2. PRIORITY 3	3. LICENSEE CONTACT Michael Lala, M.D.	4. TELEPHONE NUMBER 248-225-6909
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Main Office Inspection Next Inspection Date: 05/06/2012

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

Licensed activities were limited to about two technetium-99 Myoview cardiac imaging studies on Tuesdays from about 7:30 a.m. to about 3:00 p.m. Only unit dosages were used. One nuclear medicine technologist (NMT) conducted the studies under the supervision of the RSO/authorized user. Radiopharmaceutical therapy was not done. Licensed activities were not conducted during the inspection.

The licensee provided nuclear medicine services to Dr. Mendiratta's medical practice. Dr. Mendiratta filed for bankruptcy without notifying the NRC. However, the inspector, in collaboration with the Regional Counsel determined that no violation of 10 CFR 30.34(h)(1) occurred because, in part: (1) the bankruptcy did not increase the risk of unauthorized transfer since licensed material was not listed as property of the estate; (2) there was no increased risk of safety or security of licensed material as a result of the bankruptcy; and (3) Dr. Mendiratta owned the licensee's facility in his personal capacity and not under the auspices of the entity that filed bankruptcy. NRC in-office review continued until July 13, 2009, in order to obtain and review bankruptcy information that was unavailable during the site inspection.

Performance Observations

The inspector observed: (1) that the facility was as authorized; (2) that licensed material was secured from unauthorized access; (3) the NMT demonstrate how he had used licensed material; (4) dosimetry records indicating that licensee staff received radiation doses that were less than 10% of the regulatory dose limits; (5) a maximum of 1.5 milliroentgens per hour at selected surfaces behind an L-block based on his independent survey with a calibrated NRC survey instrument; (5) a maximum of 0.4 milliroentgen per hour at selected surfaces of the hot lab and imaging rooms based on his independent survey with a calibrated NRC survey instrument; (6) less than 0.5 milliroentgen per hour at selected surfaces of a properly marked Limited Quantity package based on his independent survey with a calibrated NRC survey instrument; (7) that the licensee used a calibrated Bicon Surveyor 2000 to conduct ambient exposure rate surveys; (8) the NMT demonstrate how he had conducted operability checks on a survey instrument; (9) the NMT demonstrate how he had prepared unit dosages for administration; (10) the NMT demonstrate how he had conducted dose calibrator constancy checks; (11) the NMT demonstrate how he would respond to a radioactive spill, based on a scenario posed by the inspector; (12) a maximum of 9 microroentgens per hour at selected surfaces of a treadmill based on his independent survey with a calibrated NRC survey instrument; and (13) selected records indicating that sealed source leak tests and physical inventories were done as required.