**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 9, 2014

Docket No. 03036176 License No. 07-30790-01
EA-14-084

Frank DiGregorio
President and Chief Executive Officer
Molecular Imaging Services, Inc.
10 Whitaker Court
Bear, DE 19701

SUBJECT: NRC INSPECTION REPORT NO. 03036176/2014001, MOLECULAR IMAGING SERVICES, INC., NEWARK AND SEAFORD, DELAWARE SITES; EXERCISE OF ENFORCEMENT DISCRETION

Dear Mr. DiGregorio:

On March 6 & 11, and April 17, 2014, Janice Nguyen of this office conducted a safety inspection at 200 Federal Street, Seaford, Delaware and G-36 Omega Drive, Newark, Delaware, of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and an examination of records. The findings of the inspection were discussed with you at the conclusion of the inspection on May 22, 2014.

Based on the results of this inspection, the NRC has determined that two violations of NRC requirements occurred. The first violation involved 10 CFR 35.60 which requires, in part, that licensees calibrate the instrument used to measure the activity of the dosage before it is administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. Contrary to the above, Molecular Imaging Services, Inc. (MIS) was unable to calibrate a Rubidium-82 (Rb-82) generator unit in accordance with the regulations because there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (*i.e.*, while liquids are flowing past the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible. The second violation involved 10 CFR 35.63 which requires, in part, that a licensee determine the activity of each dosage administered before medical use. Due to the 76 second half-life of Rb-82 and direct infusion of the Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration.

Although violations of 10 CFR 35.60 and 10 CFR 35.63 were identified, and the issue was discussed during the exit meeting, MIS met all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, “Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses,” dated April 18, 2013. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations. The NRC’s decision is based on the criteria listed in EGM 13-003.

Specifically, (1) MIS has written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications; (2) MIS has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, on June 6, 2013, and February 26, 2014, and has maintained records documenting the performance and results of these tests; (3) all authorized users for medical uses under 10 CFR Part 35.200 who are using the Rb-82 generator and infusion cart, as well as the Radiation Safety Officer, have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) MIS has recorded the activity of each dosage administered, as provided by the infusion cart.

On May 22, 2014, Ms. Nguyen informed your staff of this conclusion by telephone and stated that a letter documenting the conclusion would be issued. No further action or response is required on your part. 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 and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** 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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please contact Ms. Nguyen at (610) 337-5006 if you have any questions regarding this matter.

Your cooperation is appreciated.

Sincerely,

***/RA/***

James W. Clifford, Director
Division of Nuclear Materials Safety

cc:
State of Delaware

Please contact Ms. Nguyen at (610) 337-5006 if you have any questions regarding this matter.

Your cooperation is appreciated.

Sincerely,

***/RA/***

James W. Clifford, Director
Division of Nuclear Materials Safety

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State of Delaware

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