

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

|   |   |  |
|---|---|--|
| 1. LICENSEE/LOCATION INSPECTED:<br><br>Molecular Imaging, Inc.<br>dba MI Bioresearch<br>800 Technology Drive<br>Ann Arbor, MI 48108<br><br>REPORT NUMBER(S) 2017001 | 2. NRC/REGIONAL OFFICE<br><br>Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |  |
| 3. DOCKET NUMBER(S)<br><br>030-38386  | 4. LICENSE NUMBER(S)<br><br>21-32816-01   | 5. DATE(S) OF INSPECTION<br><br>January 12, 2017 |

**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:


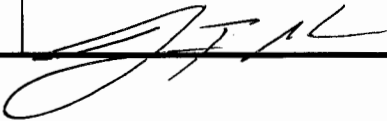
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, 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 in accordance with NRC Enforcement Policy. 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'S REPRESENTATIVE |                  |  |         |
| NRC INSPECTOR             | Edward F. Harvey |  | 1/12/17 |
| BRANCH CHIEF              | Aaron T. McCraw  |  | 1/26/17 |

**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

|   |   |
|---|---|
| 1. LICENSEE/LOCATION INSPECTED:<br><br>Molecular Imaging, Inc.<br>dba MI Bioresearch<br>800 Technology Drive<br>Ann Arbor, MI 48108<br><br>REPORT NUMBER(S) 2017001 | 2. NRC/REGIONAL OFFICE<br><br>Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |
|---|---|

|                                      |   |  |
|--------------------------------------|---|--|
| 3. DOCKET NUMBER(S)<br><br>030-38386 | 4. LICENSE NUMBER(S)<br><br>21-32816-01 | 5. DATE(S) OF INSPECTION<br><br>January 12, 2017 |
|--------------------------------------|---|--|

|  |                                      |
|--|--------------------------------------|
| 6. INSPECTION PROCEDURES USED<br><br>87126 | 7. INSPECTION FOCUS AREAS<br><br>All |
|--|--------------------------------------|

**SUPPLEMENTAL INSPECTION INFORMATION**

|                                 |                      |  |   |
|---------------------------------|----------------------|--|---|
| 1. PROGRAM CODE(S)<br><br>03620 | 2. PRIORITY<br><br>5 | 3. LICENSEE CONTACT<br><br>John Harvey, PhD, RSO | 4. TELEPHONE NUMBER<br><br>(734) 821-1063 |
|---------------------------------|----------------------|--|---|

Main Office Inspection                      Next Inspection Date:    January 12, 2022

Field Office Inspection \_\_\_\_\_

Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was a routine, unannounced inspection of a contract research organization authorized to use byproduct materials for research and development under 10 CFR 30.4. The licensee's primary principal activity was the injection of microcurie quantities of F-18 into anesthetized rodents for cancer drug development. These activities were performed by, or under the supervision of, two authorized users.

The inspector toured the facility and determined that licensed material was adequately secured from public access. Through interviews, the inspector was able to determine that workers were knowledgeable of radiation uses and safety practices, skilled in radiation safety practices under normal and accident conditions, and aware of the radiation protection program. The inspector observed the technologist check incoming packages, verify survey meter operability, and perform required surveys.

The inspector reviewed a selection of licensee records, including program audits, source inventories, survey meter calibration records, package receipt logs, and dosimetry with no issues noted. In addition, the inspector performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

The inspector verified that corrective actions were implemented for two violations that were identified during the previous inspection regarding the licensee's failure to apply for a transfer of control and failure to amend their license to accurately reflect the authorized users.

No violations were identified during this inspection and two previous violations were closed.