

INSPECTION RECORD

Region III
License No. 21-32816-01

Inspection Report No. 03038386/11-001(DNMS)
Docket No. 030-38386

Licensee (Name and Address):

Charles River Discovery and Imaging Services – Ann Arbor
800 Technology Drive
Ann Arbor, Michigan 48108

Licensee Contact: Carol Lentz, RSO

Telephone No. (734) 260-7431

Priority: 5 Program Code: 03620

Date of Last Inspection: N/A

Date of This Inspection: November 8, 2011

Type of Inspection: ☒ Initial ☒ Announced ☐ Unannounced
 ☐ Routine ☐ Special

Next Inspection Date: 11/2016 (X) Normal () Reduced
Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- (X) Violation(s), regional letter issued
- () Follow-up on previous violations

Inspector Lizette Roldán-Otero

Date _____

1/18/12

Laura Bloomer for
(Signature)

Approved **Tamara E. Bloomer, Chief, MIB**

Date _____

1/18/12

Lanana Bloomer for
(Signature)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
1	11/10/2011	Removing and adding authorized users

2. INSPECTION AND ENFORCEMENT HISTORY:

None. This was an initial inspection.

3. INCIDENT/EVENT HISTORY:

No incidents or events were identified in the Nuclear Materials Events Database since the issuance of the license in January 29, 2011.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The radiation safety officer (RSO) reports directly to the President/CEO. The CEO stated during interviews that he was very willing to follow the recommendations of the RSO, including but not limited to, stopping a procedure.

This research facility is open from 7:00 am to 5:00 pm. The licensee is authorized to perform research and development (R & D) on rodents as defined in Title 10 of the Code of Federal Regulations (CFR) 30.4. The licensee is a contract research organization whose focus is on cancer drug development. They have two authorized users. They receive 20 to 30 millicuries of fluorine-18 (F-18) and use microcurie quantities per experiment. The F-18 is injected into the anesthetized rodent. The rodent is then imaged using a positron emission tomography (PET) scanner to determine the uptake of the drug.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: IP 87126

The facility to the laboratory is control accessed and is adequate to prevent loss of licensed material. The research laboratory has two different security levels and is accessible by key card only. The licensee has comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The licensee maintains shielding of licensed materials in the laboratory in a manner consistent with operating procedures. The rodents that have not been injected are stored in locked cages outside of the restricted area (laboratory). The rodents that will be imaged are anesthetized and injected with the F-18 in the laboratory. After an allotted time, the rodent is imaged using a PET scanner. At the conclusion of the PET scan the rodent is placed in a led lined cage located inside the laboratory for 24 hours. The rodent is surveyed to ensure the injected radioactive material has decayed to background levels before it is returned to the cage outside of the restricted area.

The licensee implements a radiation dosimetry program to accurately measure and record radiation doses received by workers. The staff is badged and they have dosimeters around the laboratory to monitor the radiation levels. The records were reviewed and were adequate.

The licensee had sufficient number of radiation instrumentation to accurately monitor radiation levels in areas where licensed material is used and stored.

Through interviews, the inspector was able to determine that workers are 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 records pertaining to inventory (performed quarterly), daily surveys (after an experiment is performed and/or a package is received), instrument calibrations, and dosimetry records. All records were found to be adequate. The licensee had not performed an annual audit at the time of the inspection.

All the records were up to date and determined to be adequate.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

A Ludlum Model 2401-P Survey Meter (calibration due 12/6/11) was used to perform area surveys in both restricted and unrestricted areas. All area surveys reflected background radiation levels.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Two SL IV violations were identified during the November 8, 2011, inspection and are discussed below:

- A. Title 10 CFR 30.34(b) states, no license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Atomic Energy Act (the Act) and shall give its consent in writing.

Contrary to the above, on April 29, 2011, the licensee failed to receive consent in writing from the NRC Commission prior to transferring control of the license in accordance with 10 CFR Part 30.34(b). Specifically, the licensee transferred their NRC radioactive materials license to MIR Acquisition without the Commission's consent in writing determining that the transfer was in accordance with the provision of the Act.

The root cause of this violation was that the licensee submitted an amendment request dated May 10, 2011 to inform the NRC of the change of ownership but failed to follow up to ensure the request was received by the staff after not receiving any

documentation acknowledging receipt of the request within six months. The regional office did not receive the aforementioned correspondence.

As corrective actions, on November 8, 2011, the licensee submitted the documents necessary to request the change of ownership. The Region III Licensing Branch has requested, that the licensee resubmit the amendment request.

- B. NRC License No 21-32816-01, Condition 11, states licensed material shall only be used by, or under the supervision of William Elliott, Ph.D. and Vinod Kaimal Ph.D.

Contrary to the above, as of April 29, 2011, the licensee failed to limit licensed material use to, or supervision under William Elliott, Ph.D. and Vinod Kaimal Ph.D. Specifically, as of April 29, 2011, William Elliott, Ph.D. and Vinod Kaimal Ph.D. were no longer employed by Charles River Discovery and Imaging Services-Ann Arbor and two individuals not named on the license continued to perform experiments using licensed material at Charles River Discovery without being authorized by license or under the supervision of the authorized individuals.

The root cause of this violation was that the licensee submitted an amendment request dated May 10, 2011, to change the authorized users to the license but failed to follow up to ensure the request was received by the staff after not receiving any documentation acknowledging receipt of the request within six months. The regional office did not receive the aforementioned correspondence.

As corrective actions, on November 8, 2011, the licensee submitted an amendment request to remove the authorized users on the license and add the individuals that were currently performing the experiments. The amendment was issued on November 10, 2011. In addition, to prevent recurrence of this violation, on November 8, 2011, during the inspection, your staff discussed their understanding of the need to follow up with NRC staff, to ensure that any future amendment requests sent are approved prior to implementing the requested actions.

5. PERSONNEL CONTACTED:

- * Carol Lentz, Radiation Safety Officer
- * Tom Ludlam, Jr, President/CEO
- * Patrick McConville, Director of Imaging Services
- * Deanne Lister, authorized user
- * Jennie Baranski, research scientist

- * Individual(s) present at the exit meeting.

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