

January 18, 2012

Mr. Patrick McConville
Director of Imaging Services
Charles River Discovery and
Imaging Services-Ann Arbor
800 Technology Drive
Ann Arbor, Michigan 48108

SUBJECT: NRC ROUTINE INSPECTION REPORT 03038386/11-001 (DNMS) AND
NOTICE OF VIOLATION – CHARLES RIVER DISCOVERY AND IMAGING
SERVICES – ANN ARBOR

Dear Mr. McConville:

On November 8, 2011, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your Ann Arbor, Michigan facility, with continuing in-office review through December 20, 2011. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of the amendment request for the change of ownership and authorized users. Mr. Bill Lin of my staff and Lizette Roldan-Otero, Ph.D, of NRC Region IV, held a final exit meeting with your Radiation Safety Officer (RSO) Ms. Carol Lentz by telephone on December 21, 2011.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the failure to: (1) receive the consent of the NRC in writing before transferring controlled of your NRC license, as required by Title 10 of the Code of Federal Regulations (CFR) Part 30.34(b); and (2) have the individuals specifically named on your license as authorized users. The individuals who were named on the license were no longer employed by Charles River Discovery and Imaging as of April 2011. The root cause of these violations was the licensee failed to follow up with the NRC to ensure the amendment request was received by the NRC prior to making the changes. The NRC did not receive the aforementioned correspondence.

The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations because the inspector identified the violations.

You are required to respond to Violation A in the enclosed Notice (failure to receive written consent from the NRC prior to transferring control of Charles River Discovery and Imaging Services NRC materials license) and should follow the instructions specified in the Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Your corrective action for Violation B in the enclosed Notice (failure to have authorized users listed on your NRC materials license, your staff submitted an amendment request on November 8, 2011) included submitting an amendment request, which was approved and 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. As such, you are now in compliance with NRC requirements regarding specifically naming authorized users on your license.

The NRC has concluded that information regarding the reason for Violation B, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to provide a response to Violation B in the enclosed Notice unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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.

P. McConville

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Please feel free to contact Bill Lin of my staff if you have any questions regarding this inspection. Mr. Lin can be reached at (630) 829-9829.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-38386
License No. 21-32816-01

Enclosure:
Notice of Violation

cc (w/encl): Ms. Carol Lentz, RSO
State of Michigan

P. McConville

-3-

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Docket No. 030-38386
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Enclosure:
Notice of Violation

cc (w/encl): Ms. Carol Lentz, RSO
State of Michigan

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NOTICE OF VIOLATION

Charles River Discovery and
Imaging Services-Ann Arbor
Ann Arbor, Michigan

Docket No. 030-38386
License No. 21-32816-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 8, 2011, with continuing in-office review through December 20, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the Code of Federal Regulations (10 CFR) Part 30.34(b) requires that no license issued or granted pursuant to the regulations in this Part and Part 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.

This is a Severity Level IV violation (Section 6.3).

- 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.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of CFR 2.201, Charles River Discovery and Imaging Services-Ann Arbor is hereby required to submit a written statement or explanation regarding Violation A, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response.

Enclosure

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

For Violation B (above), the NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03038386/11-001 (DNMS)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 18th day of January 2012.