

April 26, 2006

Nathan Lakey, CEO
Orion Genomics, LLC
4041 Forest Park Avenue
St. Louis, Missouri 63108

SUBJECT: NRC INSPECTION REPORT NO. 030-35318/06-001(DNMS) AND NOTICE OF VIOLATION; ORION GENOMICS, LLC

Dear Mr. Lakey:

This refers to the routine inspection conducted on March 27, 2006, at the Orion Genomics, LLC facility in St. Louis, Missouri. The inspection results were discussed with John Aktinson and Tracy Rohlfig of your staff at the conclusion of the inspection. This also refers to a followup telephone conversation, conducted on April 24, 2006, between Ken Lambert of my staff and Ms. Rohlfig to discuss your corrective action plan.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with 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 a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Enforcement Policy**. The violation is cited in the enclosed Notice of Violation (Notice) and involves the failure to have a radiation safety officer (RSO) as listed on your NRC license. Specifically, the individual named on the license as the RSO has not been employed at your facility since May 2002 and another qualified individual has not been named as the RSO. While you do not currently possess radioactive material under your NRC license, it is imperative that a qualified individual, in your employment, is named on the license to ensure that when radioactive materials are possessed a knowledgeable person is present to ensure that your radiation safety program is implemented to protect the workers and the public.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the

N. Lakey

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NRC Public Document Room or from the NRC's document 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.

Sincerely,

/RA/

John Madera, Chief
Materials Inspection Branch

Docket No. 030-35318
License No. 24-32213-01

Enclosures:

1. Notice of Violation
2. Excerpt from NRC Information Notice 96-28

cc w/encls: State of Missouri

Distribution:

Docket File w/encl
G. Grant, RIII w/encl
S. Reynolds, RIII w/encl
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NOTICE OF VIOLATION

Orion Genomics, LLC
St. Louis, Missouri

Docket No. 030-35318
License No. 24-32213-01

During an NRC inspection conducted on March 27, 2006, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 11 of License No. 24-32213-01, dated April 6, 2000, states that the Radiation Safety Officer for the license is Robert G. Freese.

Contrary to the above, as of May 2002, Robert G. Freese has not been the Radiation Safety Officer. Specifically, Mr. Freese has not been employed by the licensee since May 2002 and another individual has not been named on the license as the radiation safety officer.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Orion Genomics, LLC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, 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 for the violation: (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 to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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.

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 26th day of April 2006