



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 6, 2018

Wayne M. Barnes, Ph.D., President
Radiation Safety Officer
DNA Polymerase Technology, Inc.
11 Princeton Avenue
University City, MO 63130

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036107/2017001(DNMS) AND
NOTICE OF VIOLATION – DNA POLYMERASE TECHNOLOGY, INC.

Dear Dr. Barnes:

On December 11 and 12, 2017, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri facility, with continued in-office review through January 17, 2018. 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 an evaluation the applicable requirements involving your transportation activities of a limited quantity of radioactive material. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with you on January 17, 2018, to discuss the inspection findings.

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 four 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the licensee's failure to: (1) review the radiation protection program content and implementation at least annually, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1101(c); (2) monitor the external surfaces of packages labeled as Radioactive White I, as required by 10 CFR 20.1906(b); (3) provide an annual review to all authorized users, calibrate survey instrumentation every six months, and perform surveys after the use of radioactive materials, as required by Condition 19 of your NRC radioactive materials license; and (4) provide training to its hazmat employees, as required by 49 CFR 172.702. The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the enclosed Notice because the inspectors identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the IN on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Collectively, the violations are of concern to the NRC because these violations indicate a lack of management oversight of your radiation safety program. Individually, the safety significance of the violations is low based on the small quantity of radioactive material that was used and the fact that you are not currently using radioactive material. The NRC recognizes that only small quantities of unsealed licensed material are used on a few occasions during a calendar year at your facility; however, you are expected to comply with all pertinent NRC requirements, including commitments made in your application for the renewal of your license, at all times during possession and use of licensed material. Effective management oversight of the radiation safety program is vital to the licensee's achieving safe and compliant operations. Because these violations indicate a lack of management oversight of your radiation safety program, you are requested in your response to describe: (1) how you plan to improve the management oversight of your radiation safety program; (2) how you plan to monitor the effectiveness of your actions to improve the management oversight of your radiation safety program; and (3) why you believe your corrective actions for these violations will be successful in preventing similar violations in the future.

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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's 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 publicly available without redaction.

Please feel free to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA Christine Lipa Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-36107
License No. 24-32214-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

Letter to Wayne M. Barnes, Ph.D. from John B. Giessner dated February 6, 2018

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036107/2017001(DNMS) AND
NOTICE OF VIOLATION – DNA POLYMERASE TECHNOLOGY, INC.

DISTRIBUTION w/encl:

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NOTICE OF VIOLATION

DNA Polymerase Technology, Inc.
University City, Missouri

License No. 24-32214-01
Docket No. 030-36107

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 11 and 12, 2017, with continued in-office review through January 17, 2018, four 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* (CFR) 20.1101(c), requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, between January 17, 2013, and December 11, 2017, the licensee failed to review its radiation protection program content and implementation periodically (at least annually).

This is a Severity Level IV violation (Section 6.7).

- B. Title 10 CFR 20.1906(b) requires each licensee to monitor the external surfaces packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Title 10 CFR 20.1907(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, on October 23, 2016, the licensee received a package labeled with a Radioactive White I label during working hours, the package was not exempt from the monitoring requirement for radioactive contamination and radiation levels, and the licensee did not perform the required monitoring. Specifically, the package received by the licensee contained 250 microcuries of phosphorus-32 in liquid form.

This is a Severity Level IV violation (Section 6.7).

- C. Condition 19 of NRC Radioactive Materials License No. 24-32214-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated October 28, 2012.

1. Item 8, Training for individuals working in or frequenting restricted areas, of application dated October 28, 2012, states, in part that an annual review will be provided to all authorized users.

Contrary to the above, between January 17, 2013, and December 12, 2017, the licensee failed to provide an annual review to all authorized users.

Enclosure

2. Item 10.6, Attachment 4, Safe Use of Radionuclides and Emergency Procedures, of application dated October 28, 2012, entitled, "Instrumentation," states, in part, that radiation protection instruments shall be calibrated at least every six months.

Contrary to the above, between February 14, 2014, and December 12, 2017, the licensee failed to calibrate its radiation protection instrument every six months. Specifically, the licensee's survey instrument was last calibrated on February 14, 2014, a period greater than six months.

3. Item 10.7, of application dated October 28, 2012, entitled, "Surveys" requires, in part, that weekly surveys will be done with a Geiger-Muller Detector. Wipe tests will be performed monthly if there is use of radioactive materials.

Contrary to the above, during the months of October through December 2016 and January 2017, the licensee did not perform weekly surveys with a Geiger-Muller Detector and wipe tests monthly during these times when there was use of radioactive materials.

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

- D. Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

Title 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

Contrary to the above, as of December 12, 2017, the licensee did not provide training for its hazmat employees as required by Subpart H to 49 CFR Part 172, and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8.

This is a Severity Level IV violation (Section 6.8).

Pursuant to the provisions of 10 CFR 2.201, DNA Polymerase Technology, Inc. is hereby required to submit a written statement or explanation 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; NRC IR No. 03036107/2017001(DNMS)" and should include: (1) the reason for the violations, or, if contested, the basis for disputing the violations or its 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 was or will be achieved. Your response may reference or include previously 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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's 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 publicly available without redaction.

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

Dated this 6th day of February 2018.