

INSPECTION RECORD

Region: III

Inspection Report No. 2017001

License No. 24-32214-01

Docket No. 030-36107

Licensee: DNA Polymerase Technology, Inc.
11 Princeton Avenue
University City, MO 63130

Locations Inspected: 1508 South Grand Boulevard, St. Louis, Missouri

Licensee Contact: Wayne Barnes, Ph.D., RSO

Telephone No. 314-707-4919

Program Code: 03620 Priority: 5

Type of Inspection: () Initial (X) Routine () Announced
() Special (X) Unannounced

Last Inspection Date: 1/17/2013

Date of This Inspection: 12/11-12/2017, with continued in-office review through 1/17/2018

Next Inspection Date: 5/11/2020

() Normal (X) Reduced

Justification for reducing the routine inspection interval: Inspection frequency reduced based on numerous violations and "management paragraph" indicating a lack of management oversight of the program.

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

Inspectors: Deborah A. Piskura, Senior Health Physicist

/RA/
Signature

Date 02/06/2018

Jason D. Draper, Health Physicist

/RA/
Signature

Date 02/06/2018

Approved: Aaron T. McCraw, Chief, MIB

/RA/
Signature

Date 02/06/2018

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
01	04/26/2013	license renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during prior routine inspections on January 17, 2013, and May 9, 2008.

3. INCIDENT/EVENT HISTORY:

A review of ADAMS and NMED identified no open items. No events had been reported by the licensee since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was a routine inspection of a small, privately-owned bio-research company authorized to possess and use phosphorus(P)-32, P-33, and sulfur-35. The licensee's use was limited to laboratory in-vitro studies. The licensee performed its experiments in 2-3 dedicated areas with the laboratory. All stock material was stored within an unlocked refrigerator/freezer. The laboratory was staffed by the Radiation Safety Officer (RSO)/owner and two authorized users; these individuals were specifically listed on the license as authorized users. The licensee's experiments used low quantities of P-32. Solid wastes were held for decay-in-storage. Liquid waste/washes were disposed of under the provisions of 10 CFR 20.2005(a)(1) via the sanitary sewer system. At the time of this inspection, the licensee possessed no licensed material. The most recent use of licensed material occurred in January 2017; the RSO could not anticipate future use of licensed material. The inspectors reviewed the requirements of 10 CFR 30.36(d), involving decommissioning timeliness notifications, with the RSO.

The licensee's laboratory was located within a multitenant building. During the day, the doors to the licensee's laboratory remained unlocked to allow other building tenants to pass through the laboratory to access to the exit to the parking lot. The licensee stored its solid radioactive wastes, held for decay, in a dedicated corner in the basement of the building; the basement space was shared by other building tenants. No other barriers or security measures (locked doors, locked partitions, etc.) were in place to secure the radioactive wastes in the basement. At the time of the inspection, the licensee possessed approximately one cubic yard of solid wastes (originally placed in storage between October and December 2016 with approximately 10-50 microcuries P-32) stored in the basement. This waste had decayed to levels indistinguishable from background, and would therefore be eligible for disposal with regular trash. Item 9 of the licensee's renewal application stated that radioactive materials within the lab will be kept locked in the freezer and refrigerator. In letter dated April 24, 2013 (third information item), the licensee stated that "all of our operations area, including the basement require a key for access." Because the licensee did not possess any licensable radioactive

material at the time of the inspection, nor could the inspectors ascertain exact instances where licensable radioactive materials were unsecured, the inspectors limited their security findings to performance observations. The inspectors discussed these observations with the RSO and reminded the RSO of the licensee's security commitments in its renewal application dated October 28, 2012, and its letter dated April 24, 2013.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the research laboratory and waste storage area, and independent measurements. As the inspectors arrived into the research laboratory, the inspectors observed a researcher retrieve dishware from the counter next to the sink where radioactive material is disposed via the sanitary sewer system. Radioactive material had not been used in the lab since December 2016 and January 2017; at the time of this inspection, all radioactive material previously used had decayed to levels indistinguishable from background. The inspectors discussed this observation with the RSO explaining that these findings are not in accordance with good laboratory practices.

The licensee maintained its records including area surveys, package receipts, and survey instrument calibrations in a dedicated binder. However, the inspectors noted that these records were last dated 2012-2013 with no additional entries. The inspectors informed the licensee that its NRC license renewal application included commitments to maintain records of surveys, receipt and usage logs, disposal of solid radioactive wastes, and training. The licensee provided no explanation for the lack of current records maintained in its files.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

<u>Survey instrument</u>	<u>Serial No.</u>	<u>Calibration date</u>
Ludlum Model 2403	NRC Tag No. 49505G	06/07/2017

The inspectors performed direct radiation measurements in and around the licensee's research lab, the waste storage area and the freezer where stock solution was previously stored. All radiation levels in the laboratory, storage areas, and the unrestricted areas outside the lab were indistinguishable from background.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspectors identified four violations of NRC requirements as documented below:

- 1) The last receipt of a package containing radioactive material occurred on October 23, 2016. Title 10 CFR 20.1906(b) requires, in part, that each licensee to monitor the external surfaces packages labeled with a Radioactive White 1 label for: (1) radioactive contamination and (2) radiation levels. According to the licensee's records, no surveys were performed on a package containing

250 microcuries of P-32 that the licensee received on October 23, 2016, as required by 10 CFR 20.1906(b). The licensee's failure to perform the required surveys on a package is a violation of 10 CFR 20.1906(b).

- 2) The licensee periodically obtained P-32 from the owner's research lab operated at Washington University in St. Louis. According to the entries in the "radioactivity accountability form," the last interlab transfer of 100 microcuries P-32 (a limited quantity as defined in 49 CFR 173.403) that occurred on January 11, 2017. The material was presumed to be pipetted from the stock vial into a microcentrifuge tube/vial. The RSO stated that this interlab transfer involved transporting the material in a personal vehicle on the local public roads. The inspectors determined that the material was transported approximately six miles. The RSO was unaware of the DOT requirements for transporting radioactive materials and acknowledged that no DOT requirements were followed for transporting this material. The inspectors informed the RSO of references to review the DOT requirements. The inspectors identified one violation of NRC and DOT requirements involving the licensee's failure to provide DOT HAZMAT training to its personnel who transported a limited quantity of radioactive material from its Washington University lab to the DNA Polymerase lab.
- 3) Title CFR 20.1101 requires, in part, that a licensee to periodically (at least annually) review the radiation protection program content and implementation. Interviews with the RSO revealed that he infrequently visited the DNA Polymerase lab. The RSO had not performed a review of the radiation protection program since the previous inspection; the RSO indicated that he was unaware of the requirement. The licensee's failure to review the radiation protection program content and implementation at least annually is a violation of 10 CFR 20.1101.
- 4) License Condition 19 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in application dated October 28, 2012. Item 10.7 "Surveys" in the licensee's application dated October 28, 2012, states that weekly surveys will be done with a Geiger-Muller detector and wipe tests will be performed monthly if there is use of radioactive materials. Based on the licensee's records of use, radioactive material was received on October 23, 2016, and used during the months of October, November and December 2016. The licensee's records at its DNA Polymerase lab did not show the January 11, 2017, interlab transfer of radioactive material or use. In accordance with its commitments, the licensee was required to perform weekly (exposure-rate) surveys and monthly wipe tests (for contamination) during the months of October 2016 through January 2017; however, the licensee failed to perform surveys or wipe tests at the required frequency during this timeframe. The licensee's failure to perform the required surveys and wipe tests is an example of a violation of Condition 19.

In the licensee's application dated October 28, 2012, the Section entitled, "Instrumentation," states that the licensee will calibrate its survey instrument every six months. The licensee possessed an Accoma Instruments Model 4200 GM survey meter. According to the calibration sticker on the meter, a service provider last calibrated the meter on February 14, 2014. The inspectors noted that the survey instrument was inoperable with a dead/corroded battery. A researcher immediately replaced the batteries. The inspectors guided the researcher how to perform an

operability check of the survey meter using the attached check source and comparing the reading to the data listed the calibration sticker. The instrument responded within 10 percent of the count-rate referenced on the calibration sticker. The inspectors discussed these observations with the RSO. The RSO was unaware that the survey instrument was out of calibration. The RSO committed to send the instrument out for re-calibration prior to the next order/use of RAM. The inspectors identified the licensee's out-of-calibration survey instrument as another example of a violation of Condition 19.

Item 8, "Training for individuals working in or frequenting restricted areas," of the licensee's renewal application dated October 28, 2012, states, in part, that an annual review will be provided to all authorized users. The inspectors determined that the authorized users had not received an annual review of the licensee's radiation safety program, as the licensee had committed to in its application. The inspectors identified the licensee's failure to provide an annual review to its authorized users as a third example of a violation of Condition 19.

5. PERSONNEL CONTACTED:

#*Wayne M. Barnes, Ph.D., President and Radiation Safety Officer
John Hartman, Chief Financial Officer
Milko Kermekchiev, Ph.D., authorized user
Zhian Zhang, Ph.D., authorized user

Attended exit meeting on December 12, 2017

* Individual contacted on January 17, 2018, for final telephonic exit meeting

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