INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 21-24683-01
Docket No. 030-29143

Licensee: Cayman Chemical Company, Inc.
1180 East Ellsworth Road
Ann Arbor, MI 48108

Locations Inspected: 5025 Venture Drive
Ann Arbor, MI

Licensee Contact: Elizabeth Hurst, RSO **Telephone No**. 734-635-3858

Program Code: 03620 **Priority**: 5

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

Last Inspection Date: 02/24/2011 **Date of This Inspection**: 04/14/2016

Next Inspection Date: 04/14/2021 (X) Normal ( ) Reduced

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: Ryan Craffey, Health Physicist

/RA/ Date 5/5/2016
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 5/5/2016
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
14	11/24/15	Permanently ceased activities at Ellsworth Road facility
13	01/29/14	Revised AU list, added Venture Drive facility
12	12/19/11	License renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

REPORT	DATE	RESULTS
2011001	02/24/11	No violations identified
2005001	09/15/05	No violations identified

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Cayman Chemical Company, Inc. was authorized by its NRC license to use byproduct material for research and development, and for redistribution of prepackaged kits to specifically licensed persons, at its facilities on Ellsworth Road and Venture Drive in Ann Arbor, Michigan. At the time of the inspection, the Radiation Safety Officer (based at the Venture Road facility) and one other authorized individual occasionally used hydrogen-3, carbon-14, and phosphorous-32 for testing the function of proteins used in immunoassay kits at the Venture Road facility. The licensee no longer used any radioactive material at the Ellsworth Road facility, and was in the process of decommissioning those restricted areas. The licensee had not redistributed any kits since prior to the last inspection.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: All

The inspector toured the Venture Road facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector was unable to observe the conduct of any licensed activities, as the use of byproduct material was very infrequent (the last was in March 2015) and none was anticipated for the day of the inspection. Instead, the licensee's staff demonstrated the implementation of procedures for receipt of packages containing licensed material, material accountability, use of byproduct material, implementation of ALARA concepts, area surveys, spill

response, and waste handling. The inspector also reviewed a selection of relevant records, including receiving logs, utilization logs, and area survey records.

Because of the infrequent conduct of licensed activities, the inspector also discussed with the RSO the NRC's decommissioning timeliness requirement contained in 10 CFR 30.36(d).

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector calibrated on August 8, 2015, the inspector conducted independent surveys at each of the locations inspected. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Survey Instrument Calibrations

During a discussion of area surveys, the inspector identified a violation of Condition 20.B of Cayman Chemical's license for the failure to calibrate a survey instrument at committed intervals.

Condition 20.B requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in its renewal application dated November 18, 2011. Section 10.2 of that application states in part that: (1) Cayman Chemical has a Ludlum Model 3 portable survey meter with a Model 44-9 pancake probe for measurement of phosphorous-32 and iodine-125, and that this instrument will be used for ambient radiation surveys for high energy beta emitters; and (2) that survey instruments which are used for health protection purposes will be calibrated annually.

Contrary to those statements, on nine occasions between July 21, 2014 and November 3, 2014, Cayman Chemical Company conducted research with phosphorous-32, and used, for ambient radiation surveys following each experiment, a Ludlum Model 3 portable survey meter with Model 44-9 pancake probe that was last calibrated on November 8, 2003.

The inspector evaluated the operability of the licensee's survey meter, its battery level was acceptable for use, and still appeared to return comparable measurements to the inspector's meter (also a pancake probe) when measuring exposure from the same vial of licensed material in a similar configuration.

The inspector determined that the root cause of this violation appeared to be an oversight. As a contributing factor, the licensee did not perform required reviews of the content and implementation of the radiation protection program, which may have provided an opportunity to identify the out-of-calibration instrument (see Section B). As corrective action, the licensee committed to send this survey instrument in for calibration within the next two weeks, and to ensure that the instrument is calibrated on an annual basis.

B. Radiation Safety Program Review

During a review of the radiation safety program, the inspector identified a violation of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.1101(c) for the failure to periodically (at least annually) review the radiation protection program content and implementation. The licensee's staff stated that they did not routinely perform these reviews, and could not recall when the last review, if any, was performed.

The inspector determined that the root cause of this violation appeared to be a lack of understanding of regulatory requirements. As corrective action, the licensee committed to perform an audit of the program within the next two weeks, and to ensure that the program is reviewed on an annual basis.

5. PERSONNEL CONTACTED:

Elizabeth Hurst, PhD - RSO

Attended exit meeting on April 20, 2016