

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Sigma-Aldrich Manufacturing LLC 3300 South Second Street St. Louis, MO 63118 REPORT NUMBER(S) 2016001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-28992	4. LICENSE NUMBER(S) 24-16607-03	5. DATE(S) OF INSPECTION September 2, 2016	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

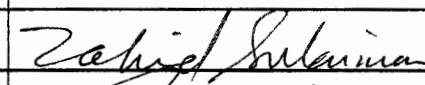
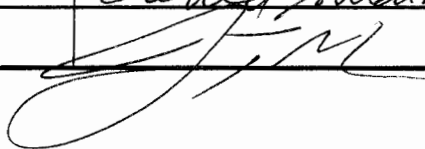
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
 (Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist		9/2/2016
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		9/26/16

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01-03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03620	2. PRIORITY 3	3. LICENSEE CONTACT Thomas Spencer, RSO	4. TELEPHONE NUMBER (314) 771-5765
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Main Office Inspection Next Inspection Date: 09/02/2019

Field Office Inspection 2909 Laclede Ave, St. Louis, MO

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a research and development licensee authorized to use a variety of radionuclides for analytical testing of biochemical products. The licensee had four authorized users (AU) who were authorized to use millicurie quantities of byproduct materials for non-human research studies. The licensee was authorized to use the licensed material at two locations: 3300 South Second Street, St. Louis, Missouri, and 2909 Leclde Avenue, St. Louis, Missouri.

The licensee got purchased by Millipore on November 17, 2015 and now the company's official name is Millipore Sigma. The licensee will submit the license amendment request to reflect the company name change. The licensee is planning to close the location of use at 3300 South Second Street and move all the operations to the 2909 Laclede Ave facility.

Performance Observations

The inspection consisted of interviews with select licensee personnel; review of select records; tours of the research and development facility and research laboratories; and independent measurements to verify compliance with public dose limits. The inspector interviewed the RSO, an AU who uses byproduct materials, and the technician; all demonstrated adequate knowledge of radiological principles and practices. The inspector: (1) had the AU demonstrate the survey instrument battery check and the use of instrument; (2) observed the AU conduct a physical inventory of licensed material, and all licensed materials were accounted for. The inspector reviewed following records: radiation safety committee minutes, annual program audits, spill procedures, package check-in procedures, licensed materials inventory tracking database, records of licensed material usage, and waste disposal records, with no issues noted. The inspector reviewed dosimetry records for 2014 and 2015, which indicated minimum detectable doses for monitored individuals.

No violations of NRC requirements were identified during this inspection.