

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Sigma Aldrich MFG LLC 3050 Spruce Street St. Louis, MO 63103 REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-39156	4. LICENSE NUMBER(S) 24-35528-01E	5. DATE(S) OF INSPECTION October 18, 2019	

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:

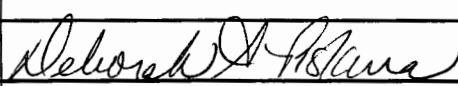

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Deborah A. Piskura, Senior Health Physicist		10/23/19
BRANCH CHIEF	Robert Ruiz, Acting Chief, MIB		10/24/19

Docket File Information
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6. INSPECTION PROCEDURES USED 87128	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03253	2. PRIORITY 5	3. LICENSEE CONTACT Robert E. Lee McVay -X7889	4. TELEPHONE NUMBER (314) 286-6600
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Main Office Inspection Next Inspection Date: October 18, 2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an initial, announced inspection of a large biomedical R&D company authorized to possess and distribute various models of exempt analytical laboratory instruments containing carbon-14. The possession license (License No. 24-26445-01) was previously inspected on February 8-22, 2019; no violations of NRC requirements were identified. The exempt distribution license was issued on April 19, 2019. All licensed material distributed under this license was to be obtained from an authorized source manufacturer and intended to be transferred to customers within the US. At the time of this inspection, the licensee was utilizing the services of the device manufacturer (authorized under its Agreement State distribution license) to directly distribute exempt sources to the licensee's customers on its behalf. As of the date of this inspection, the licensee reported that it distributed zero sources (no principal activities have been conduct to date). In accordance with MC 2800, the next inspection date is scheduled for one year.

This inspection consisted of interviews with licensee personnel; a review of select records and a tour of the laboratory and storage areas. The inspector reminded the licensee of the annual transfer reporting requirements in 10 CFR 32.20.

No violations of NRC requirements were identified during this inspection.