

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p><i>EMD Millipore</i> <i>6 Research Park Drive</i> <i>St. Charles, MO 63304</i></p> <p>REPORT NUMBER(S)</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p><i>030-32903</i></p>	<p>4. LICENSE NUMBER(S)</p> <p><i>24-26445-01</i></p>	<p>5. DATE(S) OF INSPECTION</p> <p><i>8/19/14</i></p>
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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	Bill C. Lin	<i>[Signature]</i>	<i>8/19/14</i>
BRANCH CHIEF	Aaron McCraw	<i>[Signature]</i>	<i>9/2/14</i>

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: EMD Millipore 6 Research Park Drive ST. Charles, Missouri, 63304 REPORT NUMBER(S) 2014-001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-32903	4. LICENSE NUMBER(S) 24-26445-01	5. DATE(S) OF INSPECTION 08/19/2014
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6. INSPECTION PROCEDURES USED 87125, 87126	7. INSPECTION FOCUS AREAS 3.01-3.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 3214	2. PRIORITY 5	3. LICENSEE CONTACT John Nichols, ARSO	4. TELEPHONE NUMBER (636) 441-8400
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Main Office Inspection Next Inspection Date: 08/19/2019

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an routine inspection of a manufacturing/distribution radioimmunoassay (RIA) kit licensee located in St. Charles, Missouri. Mr. John Nichols was the Assistant Radiation Safety Officer (ARSO) for the manufacturing/distribution activities. The RSO for this license was a consultant who visited the licensed facilities monthly. The licensee produced and distributed approximately 700-800 RIA kits, including approximately 20 different products monthly to customers worldwide from the facility in St. Charles, Missouri. The licensee verified that recipients of the kits were authorized to received the kits before shipping. The licensee shipped materials as excepted packages-limited quantity.

Performance Observations

The inspection consisted of tour of the facility, independent measurements, and interviews with selected licensee personnel. The inspector observed packaging and shipment of licensed materials and waste disposal. Licensee personnel demonstrated iodinations, survey meter QC, and package receipt surveys. Interviews with licensee personnel indicated adequate knowledge of radiation safety procedures and concepts. Surveys indicated radiation levels consistent with licensee postings and records.