NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
EMD Millipore 3050 Spruce Street St. Louis, MO 63103 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-32903	24-26445-01	02/08/19, with in-office review through 02/22/19

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 violations(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	Ryan Craffey	Ryan Craffey	03/08/2019
BRANCH CHIEF	Aaron McCraw	Robert D. Hattone, Jr. for AJM	3/15/19

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
EMD Millipore 3050 Spruce Street St. Louis, MO 63103 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-32903	24-26445-01	02/08/19, with in-office review through 02/22/19

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87125	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03214	5	Robert E. Lee McVay - RSO	(314) 267-2010

☑ Main Office Inspection Next Inspection Date: 02/08/2024

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a life science services corporation authorized to use byproduct material for the production and distribution of in-vitro radioimmunoassay (RIA) kits containing microcurie quantities of I-125, and for in-house bioanalytical testing using microcurie quantities of P-32 at its facility in downtown St. Louis, Missouri. The licensee sold RIA kits primarily to specifically-licensed customers, but also sold around a dozen kits per quarter to generally-licensed customers as well. One authorized user was primarily responsible for protein iodinations and radiochemical preparation using stock I-125 solution, and several others were involved in the occasional use of P-32. The licensee retained the services of a health physics consultant to audit the program annually.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in St. Louis to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys throughout this facility, and found no evidence of residual contamination nor exposures in excess of regulatory limits. The inspector observed and discussed various aspects of ongoing kit production processes, including iodinations and other radiochemical preparation, kit assembly, preparation for shipment, and waste handling. The inspector also observed the receipt of a package containing P-32 radiochemicals, and discussed the use of this material for bioanalytical testing. Through these observations and discussions the inspector found that the licensee's staff were knowledgeable of radiation protection principles, and implemented adequate ALARA practices. The inspector also reviewed a selection of records, including consultant audits, radiation safety training records, material receipt and accountability documents, bioassay results for all personnel who frequent the hot lab, and an exposure evaluation demonstrating that extremity monitoring was not required for P-32 users, based on current utilization of the radionuclide.

The inspector also reviewed the licensee's corrective actions for a violation of 10 CFR 30.34(c) identified in IR 03032903/2015001(DNMS) for the distribution of RIA kits to generally-licensed customers without prior authorization by the NRC. The inspector reviewed the licensee's corrective actions, which appeared to be adequate, and found that the violation had not occurred again since. The violation is therefore closed.

BG.