NRC FORM 591M PART 1
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Millipore Corporation 15 Research Park Drive St. Charles, Missouri 63304 REPORT NUMBER(S) 2009-001	**Region III** **U.S. Nuclear Regulatory Commission** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-32903	24-26445-01	Sept. 25, 2009

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, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

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	Geoffrey M. Warren		9/25/09

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

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1. LICENSEE	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87125, 87126	03.01 – 03.07; 03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03214	5	John Nichols, ARSO; Nann Green, Ph.D.	636-441-8400; 636-442-6000

[X] Main Office Inspection — Next Inspection Date: Sept. 2014

[X] Field Office 6 and 14 Research Park Drive, St. Charles, MO

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

John Nichols was the ARSO for the manufacturing/distribution activities, and Nann Green was the authorized user for the laboratory activities. The RSO for this license was a consultant who visited the licensed facilities monthly. Since the previous inspection, this license was merged with NRC License No. 24-32505-01 (Docket No. 030-36554), which had authorized the activities at 15 Research Park Drive.

The licensee produced and distributed approximately 1200-1500 radioimmunoassay (RIA) kits, including approximately 20 different products, monthly to customers worldwide from the facility in St. Charles, Missouri. Each kit contained up to 5 µCi of iodine-125. The licensee verified that recipients of the kits were authorized to receive the kits before shipping. The licensee shipped materials as excepted packages – limited quantity. All iodinations were made under fume hoods by two personnel, including the ARSO for manufacturing. Twelve additional personnel were involved in assembling and shipping the RIA kits. One individual performed research into new RIA kits in support of the manufacturing group, using materials prepared under this license.

The licensee also performed contract pharmaceutical research services using RIA kits manufactured by the licensee or ordered from outside companies, analyzing samples provided by clients. Approximately 30-40 personnel were involved in performing these analyses under the supervision of the authorized user for the laboratory activities. The licensee had added some research laboratories as use areas since the previous inspection; the facilities were consistent with maps provided to NRC. All iodine-125 waste was stored for decay in storage or disposed through sewerage disposal; the licensee had determined that such disposals remained below release limits.

Performance Observations

The inspector toured all manufacturing areas and representative storage, laboratory, and waste storage areas. The inspector observed packaging and shipment of licensed materials and waste disposal, and attended an annual training session. Licensee personnel demonstrated iodinations, survey meter QC, package receipt surveys, disposal surveys, and RIA kit assembly and use, and described quality assurance and bioassay procedures and contamination surveys. The inspector found no issues with the activities. All licensed materials were secured when unattended. Interviews with licensee personnel indicated adequate knowledge of radiation safety procedures and concepts. Surveys indicated radiation levels consistent with licensee postings and records.