UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 8, 2015

EA-15-164

Mr. Douglas Dawkins
Site Head of Operations
EMD Millipore
6 Research Park Drive
St. Charles, MO 63304

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03032903/2015001(DNMS) AND NOTICE OF VIOLATION – EMD MILLIPORE

Dear Mr. Dawkins:

On June 23, 2015, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your St. Charles, Missouri facility, with continued in-office review through August 25, 2015. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review and coordination of your license amendment request with our Materials Licensing Branch. Ms. Deborah Piskura of my staff conducted a final exit meeting by telephone with you on August 25, 2015, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the licensee's failure to confine the use of byproduct material to the purposes authorized in the license, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 30.34(c). Specifically, from approximately 2010 to May 2015, the licensee distributed approximately 900 in-vitro kits containing five microcuries of iodine-125 to persons under general licenses, which was not authorized by your NRC license. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because the inspectors identified violation.

The root cause of the violation was your staff's belief that you were authorized to distribute in vitro kits to general licensees under your NRC license because these kits contained the same activity of iodine-125 in kits which you were authorized to distribute to specific licensees as authorized on your license. In addition, your staff misunderstood the terms of Condition 13 of your NRC license, which specifies that your license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31. Based on the NRC Enforcement Policy, the failure to seek required NRC approval before the implementation of a change of licensed activities is normally considered a Severity Level III violation; however, the NRC determined that the health and safety risk from your unauthorized distribution activities to general licensees was minimal, because you were distributing an approved product for which you did have authorization to distribute to specific licenses and you maintained adequate radiation safety and management oversight programs for the safe use of unsealed radioactive materials for manufacturing and distribution of in vitro kits to specifically licensed customers. As a result, the NRC has categorized the violation at Severity Level IV. Please be aware that future violations of a similar nature may result in escalated enforcement action by the NRC.

As corrective actions to restore compliance and to prevent recurrence, you: (1) halted all distributions of in vitro kits to generally licensed customers until the license was amended to authorize those activities; (2) instructed the customer service staff on the types of licensees with direction not to fill any orders for generally licensed customers; (3) submitted an amendment request to authorize the distribution of generally licensed kits; and (4) received an amended license on August 4, 2015, authorizing the distribution of kits to general licensees.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in attached inspection report. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Ms. Deborah Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-32903
License No. 24-26445-01

Enclosures:
1. Notice of Violation
2. IR 03032903/2015001(DNMS)

cc w/encls: James Hatten, Radiation Safety Officer
State of Missouri

Please feel free to contact Ms. Deborah Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

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cc w/encls: James Hatten, Radiation Safety Officer
State of Missouri

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NOTICE OF VIOLATION

EMD Millipore
St. Charles, Missouri

License No. 24-26445-01
Docket No. 030-32903
EA-15-164

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 23, 2015, with continued in-office review through August 25, 2015, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) section 30.34(c) states, in part, that each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.
>
> Condition 13 of License Number 24-26445-01 specifies, in part, that the license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31.
>
> Contrary to the above, between 2010 and May 2015, the licensee failed to confine the use of byproduct material to the purposes authorized in the license. Specifically, between 2010 and May 2015, the licensee distributed approximately 900 in-vitro kits containing licensed material to four clinical laboratories that were generally licensed pursuant to 10 CFR Part 31 or equivalent Agreement State regulations and the licensee was not authorized to commercially distribute licensed material to persons generally licensed.

This is a Severity Level IV Violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in this letter and the subject inspection report. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03032903/2015001(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 8th day of September 2015.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-32903
License No.	24-26445-01
Report No.	03032903/2015001(DNMS)
EA No.	EA-15-164
Licensee:	EMD Millipore
Facility:	6 Research Park Drive St. Charles, Missouri 63304
Inspection Dates:	June 23, 2015 - August 25, 2015
Exit Meeting Date:	August 25, 2015
Inspectors:	Deborah A. Piskura, Senior Health Physicist Materials Inspection Branch Edward F. Harvey, Health Physicist Materials Inspection Branch
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

EMD Millipore
NRC Inspection Report 03032903/2015001(DNMS)

This was a special inspection conducted to review the licensee's activities involving the distribution of diagnostic *in vitro* kits byproduct material (iodine-125) to generally licensed clinical laboratories.

The inspectors identified an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR). The violation concerned the licensee's failure to confine the use of byproduct material to the purposes authorized in the license, as required by Title 10 CFR Section 30.34(c). Specifically, between 2010 and May 2015, the licensee distributed approximately 900 in-vitro kits containing licensed material to four clinical laboratories that were generally licensed pursuant to 10 CFR Part 31 or equivalent Agreement State regulations and the licensee was not authorized to commercially distribute licensed material to persons generally licensed. The root cause of the violation was the licensee's belief that it was authorized to distribute *in vitro* kits to general licensees under its NRC license because these kits contained the same activity of iodine-125 in kits which were authorized to distribute to specific licensees as authorized on the license. In addition, the licensee staff misunderstand the terms of Condition 13 of the NRC license, which specifies that the license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31.

As corrective actions to restore compliance and to prevent recurrence, the licensee: (1) halted all distributions of *in vitro* kits to generally licensed customers until the license was amended to authorize those activities; (2) instructed the customer service staff on the types of licensees with direction not to fill any orders for generally licensed customers; (3) submitted an amendment request to authorize the distribution of generally licensed kits; and (4) received an amended license on August 4, 2015, authorizing the distribution of kits to general licensees.

REPORT DETAILS

1 Program Overview and Inspection History

License No. 24-26445-01 authorized EMD Millipore (the licensee) to use iodine-125 for the purpose of preparation and distribution of *in vitro* diagnostic kits used by the medical and veterinary industries for diagnostic testing. The licensee distributed approximately 8000-9000 *in vitro* kits of 20 different models to its customers annually. The licensee received stock iodine-125 solution, performed iodinations of proteins specific to the diagnostic testing kit, and assembled the kits. One individual performed the protein iodinations within a dedicated fume hood. The licensee held all radioactive waste for decay-in-storage. All manufactured kits were shipped as excepted packages, limited quantity.

The licensee retained the services of a consulting physicist who served as the Radiation Safety Officer and audited the radiation safety program.

The previous inspections conducted on August 19, 2014, and September 29, 2009, identified no violations of NRC requirements.

2 Distribution activities involving licensed material

2.1 Inspection Scope

The inspectors reviewed the licensee's distribution activities of its licensed material to specific and general licensees. The inspectors interviewed select licensee staff, reviewed select records and toured the licensee's facility.

2.2 Observations and Findings

The licensee was authorized to manufacture and distribute in-vitro diagnostic kits containing iodine-125 to specifically licensed customers. In May 2015, the Massachusetts Department of Public Health's Bureau of Environmental Health's Radiation Control Program noted during an inquiry for a customer who was licensed under the Commonwealth's equivalent provisions of Title 10 of the *Code of Federal Regulations* (CFR) Part 31. The Commonwealth inquired if the licensee distributing in-vitro kits to generally licensed customers. The Commonwealth prompted the licensee to review the conditions of its licensee and its distribution activities. The Radiation Safety Officer recognized that the licensee had been distributing in-vitro kits to generally licensed customers, reviewed the NRC license, and noted the specifications in Condition 13. Condition 13 specified, in part, that "this license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31." On May 23, 2015, the licensee submitted an amendment request to include authorization to distribute in-vitro kits to general licensees.

The inspectors and the licensee reviewed the customer license files and identified four laboratories that had general license registrations forms on file. The licensee reviewed its customer database and determined that between 2010 and May 2015, and determined that it shipped approximately 900 diagnostic kits to the same four customers that were generally licensed under the provisions of Section 31.11.

Title 10 CFR 30.34(c) states, in part, that each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Condition 13 of License Number 24-26445-01 specifies, in part, that the license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31. The licensee's failure to confine the use of byproduct material to the purposes authorized in its NRC license is a violation of 10 CFR 30.34(c) and License Condition 13. Specifically, between 2010, and May 2015, the licensee distributed approximately 900 *in vitro* kits containing licensed material to four clinical laboratories that were generally licensed pursuant to 10 CFR Part 31 and the licensee was not authorized to commercially distribute licensed material to persons generally licensed pursuant to 10 CFR Part 31.

The root cause of the violation was attributed to a misunderstanding by the licensee staff of the terms of License Condition 13. The staff believed it was authorized to distribute *in vitro* kits to general licensees under the NRC license because these kits contained the same activity of iodine-125 in other kits which the licensee was authorized to distribute to its specifically licensed customers.

Once the licensee became aware of its unauthorized distribution activities, it halted all distributions of *in vitro* kits to its generally licensed customers. The licensee's RSO provided instruction to the customer service staff who fill orders for kits. The RSO showed the examples of the types of licenses (general registration verses specific licenses) to the staff and instructed the staff not to fill any orders for generally licensed customers until the receipt of the license amendment. The licensee submitted an amendment request to authorize distribution of *in vitro* kits to general licensees. The licensee received an amended license authorizing those activities on August 4, 2015.

2.3 Conclusions

The inspectors identified one violation of 10 CFR 30.34(c) and License Condition 13 involving the licensee's unauthorized distribution activities *in vitro* kits to general licensees. The root cause of the violation was licensee's misunderstanding of the terms of its license. The licensee implemented corrective actions including requesting an amendment to its license to authorize distribution of *in vitro* kits to general licensees.

3 Other Areas Inspected

3.1 Inspection Scope

The inspectors reviewed other aspects of the licensee's radiation protection program, which included security of licensed material, labeling of containers, and postings. The inspectors interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers and reviewed selected records. The inspectors performed independent surveys around the licensee's use and storage areas.

3.2 Observations and Findings

The inspectors determined that the licensee's facilities observed during the onsite inspection were the same as those described in the NRC license application and supporting material. Licensed material was secured within the licensee's laboratory and

shipping areas. Iodinations were performed within a designated fume hood in the hot lab.

The inspectors performed independent surveys of the licensee's material, waste and product areas using a Canberra UltraRadiac survey meter, NRC Tag No. 33564G, calibration date January 6, 2015. All surveys were indistinguishable from background.

The inspectors reviewed other radiation safety program areas including: postings, radiation surveys, survey instrument calibration, packaging and labeling of product, and customer instructions/product insert. The licensee maintained copies of its customer's NRC/Agreement State licenses as well as the general license registrations for its four generally licensed customers.

The inspectors noted that the laboratory personnel followed the following radiation safety practices during this inspection:

1. All laboratory personnel wore their assigned dosimetry
2. Staff performed personal surveys prior to leaving the restricted area
3. Staff wore gloves and used tongs while handing radioactive material
4. Waste was stored in designated areas
5. No evidence of eating or drinking in the restricted area

3.3 Conclusions

The inspectors identified no violations of NRC requirements.

4 Exit Meeting Summary

The inspectors discussed the preliminary inspection findings, as described in this report, with licensee management during the exit meeting conducted on June 23, 2015. The inspectors also discussed the violation with the RSO during a final telephone exit conference on August 25, 2015. The inspectors discussed the activities reviewed, the inspection findings, and the violation. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

+Douglas Dawkins, Site Head of Operations
#James Hatten, Radiation Safety Officer
#John Nichols, Operations Biochemist II
#Cheryl Prichard, Site Head of Quality

Attended on-site exit meeting on June 23, 2015
+Individual contacted by telephone on August 25, 2015 for final exit meeting

INSPECTION PROCEDURES USED

IP 87125, Materials Processor/Manufacturer Programs"