

Hazardous Waste Section
File Room Document Transmittal Sheet

Your Name: Phil Orozco
EPA ID: N C D 9 8 2 1 5 7 1 2 5
Facility Name: bioMérieux, Inc.
Document Group: Inspection/Investigation (I)
Document Type: Compliance Evaluation Inspection (CEI)
Description: Standard NOV Docket 2014-072 issued for CEI conducted on 6/20/14.
Date of Doc: 6/20/1014
Author of Doc: Phil Orozco

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Date Recieved by File Room:
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Month	Day	Year

NCD982157125
Scanner's Initials:

Hazardous Waste Compliance Data Entry Form

EPA ID Number: NCD982157125

Facility Name: dioMerieux Inc.

Address: 100 Rodolphe St.
Durham, NC 27712

County: Durham

Contact Name: Nick Barr

Phone#: Office 919-620-2109
Cell 919-618-9278

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EVALUATION DATA: New: **XX** Change: ____ Delete: ____

Date: 6/20/14

Evaluation Type: CEI

Inspector ID #: 018

Evaluation Comments:

SQG – Standard NOV 2014-072 issued

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SNC DETERMINATION: If this evaluation resulted in a SNC determination, fill in this block. (NOTE: SNC determinations are SNY/SNN evaluations. The SNY/SNN evaluation can also be submitted later on a separate form.)

Facility is (check one):

_____ a SNC (SNY evaluation)

Docket # 2014-072

or

_____ no longer a SNC (SNN evaluation)

=====

YES / NO CSE ONLY

Waste Involved	Volume	Exposure Media (a, gw, sw, s)	Distance to Residences	Number of People involved	Distance to On-site wells	Distance to Off-site wells

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Date Determined: 6/20/14

Branch: 07

Person: 018

Return to Compliance:

8/25/14
Scheduled

____/____/____
Actual

Regulation Description: **15A NCAC 13A .0107(d)**

Comment: Failed to maintain a written record of the required weekly inspections during 2012 and 2013.

**STATE OF NORTH CAROLINA
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
DIVISION OF WASTE MANAGEMENT
HAZARDOUS WASTE SECTION**

COMPLIANCE EVALUATION INSPECTION (CEI) REPORT

1. FACILITY INFORMATION:

Name: **bioMérieux, Inc.**
EPA ID Number: **NCD982157125**
Type of Facility: Small Quantity Generator (SQG)
Facility Location: 100 Rodolphe St., Durham, NC 27712

2. FACILITY CONTACT(S): Nicholas (Nick) Barr, Manager, HSE Affairs, bioMérieux, Inc.
Nicholas.barr@BioMérieux, Inc. .com
Office 919-620-2109; Cell 919-618-9278

3. SURVEY PARTICIPANTS: Nick Barr, bioMérieux, Inc.
Phil Orozco, Environmental Senior Specialist, NCDENR (inspector)
Shreya Nimmagadda, Intern, DWM - NCDENR

4. DATE OF INSPECTION: **June 20, 2014** On-site: 10:15 hrs.
Off-site: 15:40 hrs.

5. PURPOSE OF INSPECTION:

To conduct a Compliance Evaluation Inspection (CEI) to determine compliance with the North Carolina Hazardous Waste Management Rules (Rules), including the regulations described at 40 CFR 261, 262, 264, 265, 268 and 273.

6. FACILITY DESCRIPTION:

bioMérieux, Inc. manufactures a product that serves as a standard blood culture test. The company has been in the field of in vitro diagnostics for 50 years and is present in more than 150 countries. The Durham facility serves to increase production of products critical to fighting sepsis/infections found in the blood of individuals. The product is an automated microbial detection system that integrates blood and mycobacteria culturing.

bioMérieux, Inc. has contracted with Veolia Technical Solutions, LLC (NCD986166338) to manage the hazardous waste generated on site. Typically, one Veolia employee comes to the facility twice a week. A Compliance Assistance Visit was conducted on 1/28/09.

General Information:

- Legal owner of business: bioMérieux, Inc. Inc.
- Legal owner of property: bioMérieux, Inc. Inc.
- Square Footage: 250,000
- Acreage: 147
- Operating shifts: Three, Monday – Friday and occasionally on weekends
- Number of employees: 630
- Water supply (municipal or well): Municipal (City of Durham)
- Municipal sewer/septic/on-site treatment facility: Municipal (City of Durham)
- Number of on-site water wells : None
- Distance to closest off-site well: Unknown
- Closest private residence : ~ 0.6 miles North

7. HAZARDOUS WASTE (HW) STREAMS INCLUDE:

The largest quantity of hazardous waste generated at the facility appears to be the Adhesion Promoter waste (AP-Waste). As much as 1,600 lbs. may be generated in one month. According to the manufacturer, it is a D003 reactive waste while in a liquid state. Once the waste has hardened, the characteristic of reactivity drops out and the waste may no longer be a hazardous waste. The waste is generated in the manufacturing lines at the bottle assembly process.

Hazardous waste that is also commonly generated include: F002, F003, F005; D001, D002, D003 and D022. Other, less common wastes include: D007, D009, D011 and 30 or more U-listed wastes that may occur when off-spec. material is declared as waste for disposal. U-listed waste may include: U008, U052, U117, U133, U147, U149, U160, U190, U196, U210, U223 and U228. In addition, a few P-listed (acute hazardous waste) may be generated when such chemicals expire. These may include P014, P030, P105 and P106.

Universal Waste and Used Oil are managed by the facilities group.

8. AREAS OF REVIEW AND INSPECTION:

- **Emergency Preparedness and arrangements with local agencies** – *Refer to Deficiencies.* The typical inspections are made by the local Fire Marshal. However, arrangements in accordance with 40 CFR 265.37 with the local, County Sheriff and police departments, and medical centers have not been made.
- **Emergency Information** - *Refer to Deficiencies.* The emergency response phone number is found on a sticker placed on the handle to every phone.
- **Inspection Records** (storage) - *Refer to Deficiencies.* Weekly inspections for all of 2012 and 2013 were not maintained. An inspection log was initiated on 1/11/14.
- **Manifests** – The records appeared to be in compliance. In the past 12 months, shipments of hazardous waste have occurred on a monthly basis. *These manifests have ranged from ~ 1,500 lbs. to ~2,199 lbs. per month.
- **Training** – *Refer to Deficiencies.* Employees have completed safety training for all the appropriate personnel. Based on the number of violations discovered during the inspection, it appears evident that the appropriate employees had not been sufficiently trained in hazardous waste management.
- **Transporters:**
 - Veolia Technical Solutions NJD 080 631 369
- **TSD's:**
 - Veolia Technical Solutions, LLC NCD 986 166 338
- **Satellite Accumulation Areas (SAAs):** *Refer to Deficiencies.*
Various labs and clean rooms maintain satellite containers. The following areas were inspected: Rooms 704, 736B, 736H, 517, 533, Manufacturing Area – Line 3 and the warehouse (no hazardous waste was observed).
- **Hazardous Waste (HW) < 180-Day Storage Area(s):** *Refer to Deficiencies.*
The primary HW storage is located at the waste dock.
A 24” aisle space was not being maintained between containers holding HW located on secondary containment pallets in the primary HW storage area.
A secondary HW storage area is maintained in an individual room near the QA lab.

External Condition of Facility: No adverse conditions observed.

- 9. WASTE MINIMIZATION:** At the Durham facility, recycling practices in the offices and compliance with waste segregation are audited on a regular basis. The management takes part in these audits.

10. SITE DEFICIENCIES:

- A. 15A NCAC 13A .0107(d).** A generator shall keep a written record of inspections required by 40 CFR 262.34 for at least three years from the date of inspection.

bioMérieux, Inc. is in violation of this regulation in that the generator did not maintain a written record of the required weekly inspections of the hazardous waste storage area during 2012 and 2013. Records of inspections were initiated in January, 2014.

- B. 15A NCAC 13A .0110(c).** The owner or operator must maintain an aisle space of at least two feet to allow for the unobstructed movement of personnel, fire prevention equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency.

bioMérieux, Inc. is in violation of this regulation in that the facility failed to maintain two feet (24 inches) of aisle space between containers holding hazardous waste in the main hazardous waste storage area located at the waste dock. Pictures 5 & 6.

- C. 40 CFR 262.34(c)(1)(i), adopted by reference at 15A NCAC 13A .0107.** A generator may accumulate as much as 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in § 261.31 or § 261.33(e) in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste, without a permit or interim status and without complying with paragraph (a) or (d) of this section provided he complies with §§ 265.171, 265.172, and 265.173(a) of this chapter.

- 1. 40 CFR 265.173(a), adopted by reference at 15A NCAC 13A .0110.** A container holding hazardous waste must always be closed during storage, except when it is necessary to add or remove waste.

bioMérieux, Inc. is in violation of this regulation in that one 5-gallon container accumulating OS-20 waste (D001 Methyl Siloxane liquid waste) at Line 3 in the manufacturing area was not properly closed. The container had a custom fitted funnel attached to it and an oversized lid on the funnel. The lid was not and could not be properly secured to the funnel. Therefore, the container is considered open by the fact that liquid waste would spill out if the container were to be knocked on its side. Picture 1.

- D. 40 CFR 262.34(d)(2), adopted by reference at 15A NCAC 13A .0107.** Pursuant to this section, a generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status, provided that the generator complies with the requirements of Subpart I of part 265 of this chapter, except for Sections 265.176 and 265.178.

- 1. 40 CFR 265.173(a), adopted by reference at 15A NCAC 13A .0110.** A container holding hazardous waste must always be closed during storage, except when it is necessary to add or remove waste.

bioMérieux, Inc. is in violation of this regulation in that one 55-gallon steel container holding an adhesion promoter waste (AP-Waste) was observed with a wide-diameter drum funnel placed in the bung hole. The funnel had no lid on it and is designed to sit on top of the drum without threading it into the bung hole. Therefore, the container was considered open. AP-waste is a D003-reactive hazardous waste. In addition, the inside surface of the funnel and one 1-gallon container used to pour the AP-waste into the 55-gallon container had a significant amount of the adhesive waste adhered to the

surface. The pour off container had approximately one cup of AP-waste that had solidified at the bottom of it. Therefore, it was also considered an open container. Pictures 2 & 3.

E. 40 CFR 262.34(d)(4), adopted by reference at 15A NCAC 13A .0107. Pursuant to this section, a generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status, provided that the generator complies with the requirements of paragraphs (a)(2) and (a)(3) of this section, the requirements of subpart C of part 265, and the requirements of 40 CFR 268.

- 1. 40 CFR 262.34(a)(2), adopted by reference at 15A NCAC 13A .0107.** The date upon which each period of accumulation begins is clearly marked and visible for inspection on each container.

bioMérieux, Inc. is in violation of this regulation in that the facility did not mark two containers in the hazardous waste storage area with an accumulation start date. The containers held a combined total of 7kg (~1.75 gallons) of RBS 35 Detergent, a D002 corrosive and D003 reactive waste. The two containers not marked with an accumulation start date were sitting in a secondary containment bin with 12 other small containers. The other containers in the bin were determined not to be hazardous waste. A hazardous waste label with a start date of accumulation marked on it was placed on the side of the open bin, but not on the subject hazardous waste containers. In addition, one 55-gallon container holding AP-waste located in the hazardous waste storage area was not marked with an accumulation start date. Picture 4.

- 2. 40 CFR 262.34(a)(3), adopted by reference at 15A NCAC 13A .0107.** While being accumulated on-site, each container and tank is labeled or marked clearly with the words, "Hazardous Waste".

bioMérieux, Inc. is in violation of this regulation in that the facility did not mark two containers in the hazardous waste storage area with the words "Hazardous Waste". The containers held a combined total of 7kg (~1.75 gallons) of RBS 35 Detergent, a D002 corrosive and D003 reactive waste. In addition, one 55-gallon container holding AP-waste located in the hazardous waste storage area was not marked or labeled with the words "Hazardous Waste". Picture 4.

- 3. 40 CFR 265.37(a), adopted by reference at 15A NCAC 13A .0110.** The owner or operator must attempt to make arrangements with local authorities, as appropriate for the type of waste handled at his facility and the potential need for the services of these organizations:

- (1) Arrangements to familiarize police, fire department, and emergency response teams with the layout of the facility, properties of hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes;
- (2) Where more than one police and fire department might respond to an emergency, agreements designating primary emergency authority to a specific police and a specific fire department, and agreements with any others to provide support to the primary emergency authority;
- (3) Agreements with State emergency response teams, emergency response contractors, and equipment suppliers; and
- (4) Arrangements to familiarize local hospitals with the properties of hazardous waste handled at the facility and the types of illnesses and injuries which could result from fires, explosions, or releases at the facility.

bioMérieux, Inc. is in violation of this regulation in that attempts to make arrangements with the hospital, police and other authorities that provide emergency services have not been made.

- F. 40 CFR 262.34(d)(5)(ii)(B), adopted by reference at 15A NCAC 13A .0107.** Pursuant to this section, a generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status, provided that the generator must post the following information next to the telephone:
(B) Location of fire extinguishers and spill control material, and, if present, fire alarm.

bioMérieux, Inc. is in violation of this regulation in that the location of fire extinguishers and spill control material, and, fire alarms were not posted by any phone.

- G. 40 CFR 262.34(d)(5)(iii), adopted by reference at 15A NCAC 13A .0107.** A generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status, provided that the generator ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies.

bioMérieux, Inc. is in violation of this regulation in that employees were not sufficiently trained in hazardous waste management requirements. This was evident by the number of violations discovered.

- H. 40 CFR 273.13(d)(1), adopted by reference at 15A NCAC 13A .0119.** A small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions.

bioMérieux, Inc. is in violation of this regulation in that it failed to close one box holding six used UV lamps. Picture 7.

- I. 40 CFR 273.14(e), adopted by reference at 15A NCAC 13A .0119.** Each lamp or container or package in which such lamps are contained must be labeled or marked clearly with one of the following phrases: “Universal Waste –Lamp(s)” or “Waste Lamp(s)” or “Used Lamp(s).”

bioMérieux, Inc. is in violation of this regulation in that it failed to mark one box holding six used UV lamps with the words “Universal Waste—Lamps” or “Waste Lamps” or “Used Lamps.” A “Chemical Waste Disposal Form” taped to the box identified the contents as “UV-lamps”. It was dated 6/8/14. Picture 8.



Phillip G. Orozco
Senior Environmental Specialist, NCDENR

Date: July 15, 2014

BioMerieux - NCD982157125
100 Rodolphe St., Durham, NC
Compliance Evaluation Inspection – 6/20/14



Picture 1. - One 5-gallon container accumulating OS-20 waste (D001) at Line 3 in the manufacturing area was not properly closed. The container had a custom fitted funnel attached to it and an oversized lid on the funnel. The lid was not and could not be properly secured to the funnel.



Picture 2. - One 55-gallon steel drum (blue) holding AP- Adhesion Promoter waste (a D003-reactive hazardous waste) was observed with a wide-diameter drum funnel placed in the bung hole. The funnel had no lid on it and is designed to sit on top of the drum without threading it into the bung hole. Therefore, the drum was considered open.



Picture 3. – One pour off container had approximately one cup of AP-waste that had solidified at the bottom of it. Therefore, it was also considered to be an open container holding hazardous waste. It was not properly marked with the words “Hazardous Waste” or an accumulation start date.



Picture 4. – Two containers in the bin (shown on the right) located in the primary hazardous waste storage area were not marked with the words “Hazardous Waste” or the accumulation start date. The subject containers held 7 kg of RBS 35 Detergent, a D003 Reactive waste. It was determined that all other containers shown held non-RCRA regulated waste.



Picture 5. – An aisle space of 24” was not maintained between four containers holding hazardous waste located on the secondary containment pallets shown in the picture. Some of the containers shown above held non-RCRA regulated waste.



Picture 6. – An aisle space of 24” was not maintained between the two drums on the right of the picture. These are the same containers shown in Picture 5.



Picture 7. – A box holding six used UV lamps in the primary HW storage area was observed open.

CHEMICAL WASTE DISPOSAL FORM
This form must be completed for all chemicals being disposed of by the HSE Department.

Page 1 of 1

DEPARTMENT NAME _____

DATE	CHEMICAL DESCRIPTION	AMOUNT ml/lb./gal.	RESPONSIBLE PERSON	DISPOSAL CODE
6/8/14	UV-Lamps	6	Robert Cochran	7

DISPOSAL GUIDELINES

- All chemicals must be properly identified.
- Do not use abbreviations or formulas.
- Containers must be tightly closed.
- Open lid containers will not be accepted.

DISPOSAL CODE	REASON
1	Product Testing
2	Product Failure
3	Product Expiration
4	Development of new products
5	Unused Lab Reagents

Picture 8. – The same box holding six used UV lamps was not properly marked with the words “Universal Waste—Lamps” or “Waste Lamps” or “Used Lamps.” A “Chemical Waste Disposal Form” taped to the box identified the contents as “UV-lamps”. It was dated 6/8/14.