

**HAZARDOUS WASTE SECTION - COMPLIANCE BRANCH
FILE TRANSMITTAL & DATA ENTRY FORM**

Your Name: Phil Orozco

Facility ID Number: NCR000143826

Facility Name: Merck Sharpe & Dohme Corp.

Document Group: Inspection/Investigation (I)

Document Type: I - Compliance Evaluation Inspection (CEI)

Description for File (for CARA): SQG - No violations cited.

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Author(s) of Document: Phil Orozco

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Suborganization: Eastern Region

Comments for RCRAInfo: SQG - No violations cited.

County (if not on report): DURHAM

**STATE OF NORTH CAROLINA
DEPARTMENT OF ENVIRONMENTAL QUALITY
DIVISION OF WASTE MANAGEMENT
HAZARDOUS WASTE SECTION**

**COMPLIANCE EVALUATION VISIT (CEI) REPORT
Small Quantity Generator**

1. FACILITY INFORMATION:

Name: **Merck Sharpe & Dohme Corp.**
EPA ID Number: **NCR000143826**
Type of Facility: Small Quantity Generator (SQG)
Facility Location: 5325 Old Oxford Highway
Durham, NC 27712
County: Durham
Telephone Number: 919-884-4267 (Jim Kenny)

2. FACILITY CONTACT(s): Jim Kenny, EHS Specialist (On-site) james_kenny@merck.com
Jimmy Stewart EHS Specialist (On-site) james.stewart@merck.com

3. SURVEY PARTICIPANTS: Jim Kenny, EHS Specialist
Phillip G. Orozco – Environmental Senior Specialist, NCDEQ

4. DATE OF INSPECTION: January 29, 2016

5. PURPOSE OF INSPECTION:

An unannounced audit to determine compliance with the regulations described at Chapter 40 of the Code of Federal Regulations (40 CFR) Parts 261, 262, 265, 268, 273, 279; and, the North Carolina Hazardous Waste Management Rules (Rules). Previous Compliance Assistance Visits (CAVs) were conducted on 6/6/12 and 9/9/08. A previous CEI was conducted on July 18, 2014.

6. FACILITY DESCRIPTION:

Merck Sharpe & Dohme Corp. (Merck) in Durham manufactures specific vaccines including the Measles, Mumps, Rubella (MMR) vaccine - ProQuad®; the Zoster Vaccine - ZOSTAVAX®; and the Varicella Virus (chicken pox) vaccine - VARIVAX®.

ZOSTAVAX® is a vaccine that is used for adults 50 years of age or older to prevent shingles (also known as zoster).

VARIVAX® is also known as Varicella Virus Vaccine Live. It is a live virus vaccine that is given as a shot. It is meant to help prevent chickenpox. Chickenpox is sometimes called varicella

General Information:

- Legal owner of business: Merck Sharp & Dohme
- Legal owner of property: Merck Sharp & Dohme
- Square footage of occupied space: ~928,000
- Acreage: 75 developed, 272 overall
- Operating shifts: 3
- Number of employees: 1,000
- List of non-haz waste streams (other than common garbage):
 - Recyclable (cardboard, glass, metals, paper)
 - Vaccine waste (BSL 1 materials)
 - Raw materials (expired)
 - Sugar

- Protein
- Anti-bacterial agents
- Disinfectant/Detergents
- Ethanol for reclaim (not processed prior to sale)
- Water supply (municipal or well): City of Durham
- Municipal sewer/septic/ or on-site treatment on site: Each building in which manufacturing takes place has its own wastewater treatment unit. Once treated, wastewater is sent to the City of Durham (North Durham Facility) POTW.
- Number of on-site water wells : 2 – both inactive (both are sealed)
- Groundwater monitoring wells on-site: None
- Distance to closest off-site water well : Unknown
- Closest private residence : 4,000 ft. (from entrance of the facility to the nearest house)

Names & Job Titles of those who are involved in HW management (records, HW manifests, moving HW from SAA to storage, managing Used Lamps &/or Used oil):

| Name | Job Title | Responsibility |
|----------------|-----------------------------------|---|
| Jeremy Hoadley | EHS Contractor | Hazardous Waste handling and labeling, Used Lamps, Used Oil |
| Lee Daughtry | Southern Industrial Contractor | Used Lamps |
| Mark Hoadley | Facilities Maintenance Technician | Used Lamps |
| Steve Gay | Facilities Maintenance Technician | Used Lamps |
| William Powers | Electrician | Used Lamps |
| Jimmy Stewart | EHS Specialist | Records, HW Manifests, Hazardous Waste Handling, Used Lamps, Used Oil |
| Jim Kenny | EHS Specialist | Records, HW Manifests, Hazardous Waste Handling, Used Lamps, Used Oil |

7. HAZARDOUS WASTE (HW) STREAMS INCLUDE:
D001, D002, P105

8. AREAS OF REVIEW AND INSPECTION:

➤ **Waste Determinations:**

The facility must ensure that waste determinations are performed in a timely manner and that the material is managed properly during the waste determination process. *As a reminder*, Hazardous Waste determinations must be made within a period of a few days; or, when analytical analysis is necessary, within 30 days. Until a proper waste determination is made, the container holding an unknown material should be marked with the date of discovery and with words to identify the material as unknown and pending a waste determination.

➤ **Emergency Preparedness** – The facility appeared to be in compliance. Notifications to confirm arrangements with the local authorities (as described at 40 CFR 265.37) were sent out in July 2012.

- **Emergency Information at Phone (40 CFR 262.34(d)(5)(ii):**
A SQG must post the following information by a phone at the facility:
 1. Name and phone number of emergency coordinator.
 2. Location of fire extinguishers, spill control equipment, and fire alarms.
 3. Number to the fire department (or to facility security when applicable), unless there is a direct alarm.

Please refer to the Comments.
- **Inspection Records (HW storage)** – The inspection records appeared to be complete.
- **Training** – Employees are thoroughly trained in a wide variety of safety concerns and related responsibilities. Overall, the staff is well-trained in a manner that will help to maintain compliance with the RCRA rules.
- **Manifests / Land Disposal Restriction (LDR) Notifications** – Manifests and LDR notifications appeared to be in compliance with the rules.
- **Hazardous Waste Transporters:**
Clean Harbors Environmental Svcs. MAD 039 322 250
- **TSD Facilities:**
Clean Harbors El Dorado LLC - ARD 069 748 192
- **Satellite Accumulation Areas (SAAs):** *Refer to Comments.*
The following areas were inspected: Rooms: 2021 and 2013.
(In the previous inspection the EM Lab and Rooms 2060, 2021, 2020, 2011, 2013 and 2019.)
- **Less than (<) 180-Day Hazardous Waste Storage Areas:**
The facility maintains two (2) < 180-day hazardous waste storage areas.

Room 1001, Inside Storage Area – This area is a receiving and staging room inside the main facility. It is connected to a long, wide corridor referred to as the “spine”. The room is located at the closest end of the spine to the visitor entrance. No hazardous waste was observed in storage here.

Alcohol Shed - The shed is located outside the alcohol building. Now that a Hazardous Waste Building has been built, this shed will no longer be used as a 180-day storage area.

Hazardous Waste Building – *Refer to Comments.*

Containers appeared to be properly labeled and dated. Special shelves allow labels/dates to be clearly visible on the numerous small containers that Merck manages as hazardous waste. The entire building was in very good order and is a great improvement from the much small flammable materials shed used in previous years.

9. DEFICIENCIES:

No violations were cited.

10. COMMENTS:

- A. It is noted that the new hazardous waste storage building does not have a phone. At Merck, waste handlers do always carry a communication device that could be used in case of an emergency. Ensure that this practice is continued. In addition, the location of a phone that the emergency information should be posted was discussed. At the time of inspection, it was decided the information could be posted at the phone in the security station to maintain compliance.

- B.** The location of a satellite accumulation area (SAA) within the Potency Lab, Room 2021, was discussed. Merck has the option to locate the SAA within the main room. An alternative would be to carry the waste into the interior room located within the lab. In so doing, the interior room would be managed as a 180-day storage area.
- C.** The connection used to run tubing from an instrument into a 5-gallon red safety can was discussed. The connection is shown below. The container was located in the Potency Lab, Room 2021, on a sliding tray and housed within the instrument. The connection device is held in place by the spring loaded safety can lid. The inspector judged the spring load lid was strong enough to hold the connection device in place. The location of the can also minimized the possibility that the can could be disturbed. As such, the can in the picture is considered a closed container and in compliance with the rule.



Phillip A Orozco
Phillip G. Orozco
Environmental Senior Specialist, NCDEQ 919-212-2501
February 4, 2016