EPA United States Environmental Protection Agency

RCRA Compliance Branch

INSPECTION REPORT

Inspection Date(s):	6/23/2023	**Inspection Announced:** No
Facility or Site Name:	Celgene Corporation	
Facility/Site Physical Location:	7 Powder Horn Drive	
(City, state, zip code)	Warren, NJ 07059	
Mailing address (if different from above):		
Facility/Site Contact:	Michael J. Vala	Environmental Health and Safety Lead
	Michael.vala@bms.com	
	(848) 297-2264	
RCRA ID Number:	NJD981874779	
Inspector:		
Areeba Khan	AREEBA KHAN Digitally signed by AREEBA KHAN Date: 2023.08.21 15:18:26 -04'00'	
Supervisor:		
Derval Thomas	DERVAL THOMAS Digitally signed by DERVAL THOMAS Date: 2023.08.21 15:53:07 -04'00'	

SECTION I – INTRODUCTION

Purpose of the Inspection Objective

The purpose of the inspection was to perform a Resource Conservation and Recovery Act (RCRA) comprehensive evaluation inspection (CEI) at this facility. The inspection was conducted by EPA RCRA inspector Areeba Khan.

Opening Conference

EPA Region 2 RCRA inspector Areeba Khan arrived at Celgene Corporation on June 23, 2023, for an unannounced inspection. I was greeted by the receptionist in the front lobby. The receptionist called Michael J. Vala the Environmental Health and Safety Lead to the lobby. I presented my credentials to Mr. Vala and informed him that this was an EPA inspection to determine the facility's compliance with RCRA regulations. The scope of the inspection was to conduct a compliance evaluation inspection (CEI).

Facility/Site Description

Celgene Corporation is a global pharmaceutical manufacturing company based in Summit, New Jersey. Celgene was bought by Brystol Meyers in 2019 and became one of their subsidiaries. The facility specializes in cell therapy products and development. The facility has thirty labs on site, twenty labs are used for research and development and ten labs are medical labs. The facility generates both hazardous waste and medical waste. The hazardous waste is generated from the following: lab reagents, expired products, IPA alcohols, sodium azide, cleaning, and sanitization of the products. The facility generates red bag medical waste from their medical labs and from their operations on the modification of the t-cells. The hazardous waste generated are from cleaning equipment and was stored in 55-gallon drum to be picked up by Clean Harbors. Due to the acquisition by Brystol Meyers, the facility changed its hazard waste management team from Cycle Clean to Clean Harbors.

After review of the manifest information and statements made by Mr. Vala, the facility was determined to be a Small Quantity Generator (SQG) of hazardous waste at the time of the inspection. The facility also generates universal waste from normal upkeep. The hours of operation are Monday through Friday 8 am to 5 pm. At this location, there are 300 employees.

SECTION II – OBSERVATIONS

Mr. Vala stated that the facility is now recognized as Brystol Myers Squibb. I asked if they are going to change the name on the EPA ID number. The facility representative stated that they will keep the Celgene Corporation name and will notify if they make any changes in the future.

Universal Waste Cylinder

Located on the first floor of the main building by the office space, there was a three-foot-tall clear cylinder container with an opening on top to put batteries inside. Mr. Vala stated that this cylinder container is used to collect alkaline batteries. There was signage near the cylinder stating that this was universal waste. At the time of the inspection the cylinder was in the process of being filled. The cylinder itself was dated, labeled, and open from the top. Mr. Vala stated that clean harbors pick up the cylinder once a month.

Central Storage Area

Mr. Vala stated that the facility has one central storage area that holds all their waste (hazardous, non-hazardous, medical, and universal waste). The central storage area is divided into different sections for each of the different waste streams. In the central storage area, there was a sign on the door labeled with the words hazardous waste. There was a fire extinguisher present, a list of phone numbers in case of an emergency and the weekly inspections log is kept up to date.

Universal Waste Section

In the universal waste section there were the following:

- One 10-gallon container of mixed batteries labeled, closed, and dated.
- One 10-gallon container of lead acid batteries labeled, closed, and dated.
- One 10-gallon container of nickel batteries labeled, closed, and dated.
- One 10-gallon container of electronic ballast labeled, closed, and dated.
- One 6- foot container that was empty.
- One 4 ft container that was empty.
- One 4 ft container of fluorescent bulbs that was being filled it was labeled, closed, and dated.
- One box that was empty.
- One box containing lead acid battery that was labeled, closed but, no date.
- One 30-gallon drum that was empty.
- One 30-gallon drum that was ¾ fill containing fluorescent tubes that was labeled and closed but not dated.

Non- Hazardous Waste Section

Mr. Vala stated that the facility generates non-hazardous waste from phosphate buffers. The facility refers to it as muck water. At the time of the inspection, there was the following:

- One 30-gallon drum of nonhazardous waste that was closed, labeled, dated.
- One 30-gallon drum of nonhazardous waste that was empty.
- One 55-gallon drum of nonhazardous waste that was empty.

Hazardous Waste Section

The hazardous waste was seperated into different categories. Mr. Vala stated the facility generates four to five drums a month. At the time of the inspection there were the following:

- Two 30-gallon drum that was empty and in secondary containment.
- Four 55- gallon drum of hazardous waste in secondary containment containing IPA bottles that was closed, dated, placard, and labeled.
- One 55- gallon drum of hazardous waste in secondary containment containing Spor Klenz bottle that was closed, dated, placard, and labeled.

Hazardous Waste Cabinet

Mr. Vala stated that this three-foot tall cabinet is used to store small amounts of hazardous waste that can not be stored inside the drum. The facility representative stated the waste inside the

cabinet comes from their labs and are either medical waste or D001 waste. At the time of the inspection, inside the cabinet there were the following:

- Two 1 liter of expired reagents that was non-hazardous closed, labeled and dated.
- One 1-gram bottle of methanol labeled, closed, and dated.
- One tray containing four small bottles of: methanol, ethanol, biohazard, and water, HCL (refer to figure 1)
- Three boxes of ethanol tissue wipes
- One small bottle of sodium chloride
- One bottle of expired aspirin, lidocaine, glaucine
- Two boxes of EpiPen that was expired.
- One NaCl bottle

Corrosive Waste Cabinet

Mr. Vala stated that this six-foot tall cabinet is used to store corrosive waste. At the time of the inspection the cabinet was empty.

Labs

After the Central Storage Area Mr. Vala showed me the labs.

Medical Manufacturing Labs

Mr. Vala stated there were ten manufacturing labs that all deal with medical waste. The facility representative stated for anyone to enter the lab they had to put on personal protective equipment and follow their procedure to enter. I did not have the level of proper personal protective equipment clearance, so I did not enter.

Research and Development Labs

Mr. Vala took me around twenty research and development labs. Seven research and development labs were under construction as the facility was creating and expanding the labs. Three research and development labs were empty.

There was one lab for test products that contained no hazardous waste, just medical waste. There were four labs for quality control that contained no hazardous waste, just medical waste. There was one lab for analytical investigation for their cell-therapy process that contained no hazardous waste, just medical waste. There was one lab used for training personnel on how to decontaminate before and after use of their medical manufacturing labs. There was one process lab that contained no hazardous waste just, medical waste. Mr. Vala stated there was one clinical quality control lab that generates hazardous waste from its water bath quality that uses reagents.

Mr. Vala stated that it generates a couple of liters and is taken into a drum by clean harbors. At the time of the inspection, there was no hazardous waste observed in any of the labs.

Maintenance Shop

Mr. Vala stated the maintenance shop generates non-hazardous waste, used oil and universal waste. At the time of the inspection there was one drum being filled with used oil. There was a closed container that contained paint cleaners and spray oils used for maintenance. There was a fire extinguisher present and weekly inspections are conducted in the maintained shop.

Records Review

- Basic Plan

After review of the emergency response plan, there were no discrepancies.

- Manifests and Land Disposal Restrictions

After review of the manifest and land disposal restriction documentation, there were no discrepancies.

- Personnel Training

After reviewing the training records, I determined that there was sufficient personnel training.

- Arrangement with Local Authority

The facility showed a return receipt showing that they notified the local authority, so there were no discrepancies.

SECTION III – AREAS OF CONCERN

Regulatory Concerns

1. 40 CFR 262.15.A.3.iii states "A container holding a hazardous waste that is incompatible with any waste or other materials accumulated nearby in other containers must be separated from the other materials or protected from them by any practical means.
    a. At the time of the inspection there was one tray containing four small bottles of: methanol, ethanol, biohazard, and water, HCL (refer to figure 1)

(Figure 1 shows one tray containing four small bottles of: methanol, ethanol, biohazard, and water, HCL)

2. 40 CFR 273.15(c) requires that a small quantity handler of universal waste, "demonstrate the length of time that the universal waste has been accumulated from the date it becomes a waste or is received".
    a. At the time of the inspection there was one box containing lead acid battery that was labeled, closed, but no date.

General Concerns

There were no regulatory concerns at the time of the inspection.

Closing Conference

The closing conference was conducted by EPA inspector Areeba Khan and the facility representative Michael J. Vala. Inspector Khan explained to the facility representative the area of concern. Mrs. Vala stated that he will follow up and tend to the areas of concern immediately.