

RCRA Compliance Branch INSPECTION REPORT

Inspection Date(s):	11/29/2023	Inspection Announced: No
Facility or Site Name:	Himed, Inc.	
Facility/Site Physical Location:	148 Sweet Hollow Road	
(City, state, zip code)	Old Bethpage, NY 11804	
Mailing address (if different from above):		
Facility/Site Contact:	Frank Vitale	Vice President, Quality Assurance & Regulatory Affair
	Frank.vitale@himed.com	
	(631) 603-9896	
RCRA ID Number:	NYD089399489	
Facility/Site Personnel Participating in Inspection:		
Frank Vitale	See above	See above
Arthur Mucciolo	Director of Operations	Arthur.Mucciolo@himed.com (516) 586 5700 x151
Rodel Bencio	Maintenance Worker	Rodel.Bencio@himed.com (732) 499- 9700
Alexandra Ferraiuolo Rodriguez	Quality Assurance Manager	Alexandra.Ferraiuolo@himed.com (347) 860- 0525
Inspector:		
Areeba Khan	AREEBA KHAN  Digitally signed by AREEBA KHAN Date: 2024.02.06 18:39:31 -05'00'	
Supervisor:		
Derval Thomas	DERVAL THOMAS  Digitally signed by DERVAL THOMAS Date: 2024.02.06 16:01:48 -05'00'	

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 Himed, Inc. on November 29, 2023, for an unannounced inspection. I met with Rodol Bencio the Maintenance Worker and Arthur Mucciolo the Director of Operations in person and spoke with Frank Vitale the Vice President of Quality Assurance & Regulatory Affairs over the phone at the opening conference of the inspection. I presented my credentials to the facility representatives and informed them 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

Himed is a manufacturing company located in Old Bethpage, NY. Himed manufactures calcium phosphate biomaterial powders and does surface treatment on dental and orthopedic implants. The facility generates hazardous (corrosive, flammable, and toxic) and nonhazardous waste from the development of the products. The facility determines hazardous waste based on their classifications. Corrosive waste (D002) is determined through laboratory tests. Flammability/Ignitable waste (D001) is determined through scientific computations for percentage alcohol. Toxic waste is determined through the safety data sheets (SDS) for each chemical used. The facility has one central storage area and two satellite accumulation areas. Himed uses Republic Environmental as its transporter. The facility also generates universal waste (batteries) from general upkeep. After review of manifest information and statements made by the facility representatives, the facility was determined to be a Small Quantity Generator (SQG) of hazardous waste at the time of the inspection. The hours of operation are Monday through Friday 6 am to 5 pm. At this location, there are 35 employees.

SECTION II – OBSERVATIONS

Research and Development Lab

The following was observed in the lab:

- One 55 gallon satellite accumulation drum of nonhazardous waste (Acrylamide rinse water) that was closed, labeled, and dated.
- One 55 gallon satellite accumulation drum of hazardous waste (Acrylamide) that was closed, labeled, and dated.

Anodizing Area

In the anodizing area there was one 55 gallon satellite accumulation drum of hazardous waste that was closed but there was no hazardous waste label.

Central Storage Area:

The facility representatives stated that the facility has one central storage area that holds all their waste (hazardous waste, and non-hazardous waste). In the central storage area, there was a sign labeled central storage area near a phone with the phone numbers of the emergency contacts. There was a fire extinguisher present and spill kit present. At the time of the inspection the following was observed:

- One 55 gallon drum of hazardous waste (D002) that was labeled, dated, and closed.
- One 55 gallon drum of hazardous waste (D001) that was labeled, dated, and closed.
- One 30 gallon drum of propanal that was labeled, dated, and open.
- One 5 gallon drum of universal (batteries) waste that was labeled, dated, and closed.

Records Review

The facility representatives stated that Mr. Vitale has all the records in his computer. At the time of the inspection, Mr. Vitale was not at the facility. The facility representatives stated they would notify Mr. Vitale about the records. On December 18, 2023, Mrs. Alexandra Ferraiuolo Rodriguez, Quality Assurance Manager, sent me an email regarding the following records:

- Basic Plan

At the time of the inspection there was no emergency response plan.

- Manifests and Land Disposal Restrictions

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

- Personnel Training

After reviewing the statement from the facility representative there was sufficient personnel training determined.

- Arrangement with Local Authority

After reviewing the statement from the facility representative, the facility has made arrangements with the local authorities.

SECTION III – AREAS OF CONCERN

Regulatory Concerns

1. Pursuant to 6 NYCRR § 372.2(a)(8)(i)(a)(2), Containers are marked with the words “Hazardous Waste” and with other words that identify the contents of the containers.

At the time of the inspection, there was one 55 gallon drum that contained hazardous waste located in the anodizing area, that had no label on it. On December 18, 2023, Mrs. Rodriguez followed up in an email regarding the area of concerns. Mrs. Rodriguez stated “Yes. Drum was labeled and picked up by transporter on 12/7. See attached (Figure I)”



(Figure 1: Hazardous waste label on 55 gallon drum)

2. Pursuant to 6 NYCRR § 372.2(a)(8)(ii), The date upon which each period of accumulation begins is clearly marked and visible for inspection on each container.

At the time of the inspection, there was one 55 gallon drum that contained hazardous waste located in the anodizing area, that had no date on it.

On December 18, 2023, Mrs. Rodriguez followed up in an email regarding the area of concerns. Mrs. Rodriguez stated “Yes. Drum was labeled and picked up by transporter on 12/7. See attached (Figure I)”

3. Pursuant to 6 NYCRR § 373-3.9(d)(1), management of containers. (1) A container holding hazardous waste must always be closed during storage, except when it is necessary to add or remove waste.

At the time of the inspection, there was one 30 gallon drum containing hazardous waste (proponal) located in the central storage area that had an open funnel in the opening of the drum. During the inspection Mr. Bencio closed the funnel and later in an email from Mrs. Rodriguez, the facility provided a picture which shows that a gasket was added to the funnel as shown below.



(Figure 2: Funnel with gasket on)

General Concerns

Recommended that you should have an emergency response plan, in case of an emergency.

Closing Conference

The closing conference was conducted by EPA inspector Areeba Khan and the facility representatives Rodel Bencio, Arthur Mucciolo and Frank Vitale (via phone call). Inspector Khan explained the areas of concerns to the facility representatives. The facility representatives stated they would follow up and tend to the areas of concern immediately.