RCRA COMPLIANCE EVALUATION INSPECTION REPORT

1) Inspector and Author of Report

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Environmental Engineer
RCRA Enforcement Section
EPA Region 4, AFC-10th Floor
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2) Facility Information

CryoLife, Inc.
1655 Roberts Blvd., NW
Kennesaw, Georgia 30144

EPA ID # GAR000015370

Primary NAICS Code: 621511 Medical Laboratories

3) Primary Contact

Gerald G. Klima
Director of Facilities
Telephone: (404) 376-6782
Klima.greg@cryolife.com

4) Inspection Participants

Gerald Klima, CryoLife, Inc.
Lila Nichols, CryoLife, Inc.
Dillon Long, Georgia Environmental Protection Division
Lynn Preston, Georgia Environmental Protection Division
Sara Porter, Georgia Environmental Protection Division
Javier García, EPA Region 4

5) Date of Inspection

September 15, 2021

6) Applicable Regulations

Chapter 391-3-11 of the Georgia Hazardous Waste Management Act, adopts and incorporates by reference 40 CFR Parts 260 - 266, 268, 270, 273 & 279. The Georgia Hazardous Waste Management Act, O.C.G.A. 12-8-60, et seq. as amended (Act), Chapter 391-3-11 of the Georgia

Rules for Hazardous Waste Management (Rules), and those portions of 40 CFR Parts 260-270, 273, and 279 that are adopted into the Rules by reference).

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15], a generator may accumulate up to 55 gallons of hazardous waste at or near the 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 without having interim status, as required by Section 12-8-66 of the GHWMA, Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17], except as required in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F. R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation management requirements listed in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15] (hereinafter referred to as the "SAA Permit Exemption").

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17], a large quantity generator (LQG) of hazardous wastes may accumulate its hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 12-8-66 of the GHWMA, Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17] (hereinafter referred to as the "LQG Permit Exemption").

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.18 [40 C.F.R. § 273.9], a "Small Quantity Handler of Universal Waste" (SQHUW) is a Universal Waste handler who does not accumulate 5,000 kilograms or more of Universal Waste (batteries, pesticides, mercury-containing equipment, or lamps, calculated collectively) at any time.

As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.

7) Purpose of Inspection

This announced compliance evaluation inspection (CEI) was conducted to evaluate the facility's compliance with applicable requirements of RCRA and corresponding the Georgia Environmental Protection Division (GAEPD) regulations.

8) Facility Description

CryoLife Inc. (Cryolife) is a manufacturer of biomedical devices marketed as PerClot® and PhotoFix®. PerClot® is a bioinert blood clotting agent used in surgical procedures. PhotoFix® is a patch tissue used for vascular and heart tissues repairs. In addition, Cryolife provides preserved human tissues for cardiac and vascular surgeries, mechanical heart valves for aortic or mitral valve replacement. The facility is on a 21-acre campus in Kennesaw, Georgia, with 23,700 square feet of controlled-cleaned areas.

Cryolife is registered with the GAEPD as large quantity generator of hazardous wastes (D001, D002, D007, D011, F002, F003, U041, U112, and U154). The facility became an LQG in March

2019, when it begun to manufacture PerClot®. Routine hazardous waste streams generated at the facility are:

- Spent solvent (D001, F002 and F003) from cleaning activities in the PerClot® and PhotoFix® manufacturing laboratories.
- Spent ethanol (D001) from dye removal activities conducted in the PerClot® manufacturing laboratory.
- Non-halogenated spent solvent (D001 and F003) generated in the pathology and analytical laboratories.
- Off spec and shelf-life expired laboratory products (D001, D002, D007, D011, U122, U041, U112, and U154).

9) Previous Inspection History

No prior RCRA inspection conducted at the facility.

10) Findings

Due to the Coronavirus (COVID-19), the EPA preannounced the inspection via an email sent to Mr. Gerald Klima on September 13, 2021. In the email, the EPA explained the purpose of the inspection and included a list of the documents to be reviewed as part of the inspection. Upon arrival to the facility on September 15, 2021, the inspectors met Mr. Klima and presented their credentials.

Mr. Klima led the inspectors to a conference room, where they were met Lila Nichols. After introductions, the EPA inspector explained the purpose of the inspection and indicated the use of a camera to take pictures during the inspection. In addition, the EPA inspector discussed the company's ability, pursuant to 40 C.F.R. § 2.203, to assert a business confidentiality claim for information submitted to the EPA and confirmed the personal protection equipment required for the facility tour. The inspectors explained that due to COVID-19, the record review was going to be virtual. Next, Mr. Klima provided a safety briefing and a description of the facility's operations. After the briefings, Mr. Klima and Ms. Nichols, led the inspectors to a tour of the facility. The following were the observations made during the inspection.

PerClot® Manufacturing Laboratory:

This a certified cleanroom which requires the use of sterile lab coats and other covers. Because the laboratory has a glass wall that provides a clear view of the room, the inspectors opted to stay outside the laboratory. In the laboratory, the facility generates a spent solvent hazardous waste stream (D001/F002/F003) from cleaning a reactor and a dryer; and spent ethanol (D001) from dye removal activities.

The laboratory operator indicated that to minimize fire risk, the spent solvent from cleaning the reactor and dryer is collected in 10-gallon containers (Photograph 1) and transferred to a 55-gallon container also kept in the laboratory. The inspectors observed that the two 10-gallon containers were neither marked nor labeled with the words "Hazardous Waste." The 55-gallon containers were properly labeled, closed, and appeared to be in good condition (Photographs 2

and 3). *Note: Following the site visit, Mr. Klima sent an email to the inspectors with pictures of the containers with the required markings/labels.*

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to do the following: mark or label its containers (i) with the words "Hazardous Waste."

Analytical Laboratory:

This laboratory generates non-halogenated spent solvents (D001/F003) from testing activities, which are collected in 4-liter containers. The laboratory operators keep a log with the composition of the waste in each container. The containers are kept in cabinets. During the inspection, the inspectors observed 19 4-liter containers (Photograph 4). All containers were properly labeled "Non-halogenated waste," closed, and appeared to be in good condition.
Note: Following the site visit, Mr. Klima sent an email to the inspectors with pictures of the containers with the required markings/labels.

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to do the following: mark or label its containers (i) with the words "Hazardous Waste."

Hazardous Waste Central Accumulation Area (CAA):

The hazardous waste CAA is in a room off the unloading/loading dock area, in the back of Building #2. Access to the room is controlled with an electronic lock. In the CAA, the inspectors observed one 55-gallon container with spent solvent (D001/F003), dated 9/14/21 (Photograph 5); and one 55-gallon with non-halogenated spent solvent (D001/F003), dated 8/26/21 (Photograph 6).

Pathology Laboratory:

In the laboratory, the inspectors observed ten 1-gallon containers of spent alcohol (D001/F003) and one 1-gallon container of spent xylene (D001/F003). Both solvents are used for tissue samples preparation. The containers were in good condition, closed, labeled with the hazards of their contents, and marked with the word "Waste" (Photographs 7 and 8).
Note: Following the site visit, Mr. Klima sent an email to the inspectors with pictures of the containers with the required markings/labels.

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to do the following: mark or label its containers (i) with the words "Hazardous Waste."

<u>Records Review</u>

Because of COVID-19 exposure concerns, no records were reviewed onsite. The facility provided hard copies of the following documents to the inspectors:

- Universal waste shipment documents
- Hazardous waste manifests
- Hazardous waste training program records
- Facility contingency plan
- Weekly Inspection logs

All hazardous waste manifests and universal wastes shipping documents from January 2019 to August 2021 were found to be complete.

The facility training records, and inspection logs were found to be complete. Cryolife's inspection form only tracks the inspector's name and the date of the inspection. Although this meets the requirements, the inspectors recommended that the form be revised to track what the inspector is evaluating (e.g., containers conditions, labeling requirements, etc.). Following the inspection, the GAEPD inspector emailed Mr. Klima an inspection form example.

Cryolife's quick reference guide to the contingency plan does not include a map showing the location of the satellite accumulation areas in the Pathology, Analytical, and Manufacturing laboratories.

Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], which incorporates Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.262(b)(4)], and is a condition of the LQG Permit Exemption, a large quantity hazardous waste generator must include in its quick reference guide a map of the facility showing where hazardous wastes are generated, accumulated, and treated and routes for accessing these wastes.

11) Summary

The inspectors conducted an exit meeting with Gerald Klima and Lila Nichols and provided the preliminary results of the inspection.

12) Signed

JAVIER GARCIA Digitally signed by JAVIER GARCIA Date: 2021.10.25 06:37:00 -04'00'

Javier E. García — Date
Inspector and Author of Report

13) Concurrence and Approval

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ Date: 2021.10.26 11:25:23 -04'00'

Araceli B. Chavez — Date
Chief
RCRA Enforcement Section

CryoLife, Inc.
Kennesaw, Georgia

EPA ID No.: GAR000015370

EPA RCRA CEI Photographs

Photos taken by Javier García
September 15, 2021
Camera Type: Samsun WB250F
EPA Serial Number: S75915


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CHEMICAL WASTE
DO NOT USE!
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