

RCRA Compliance Evaluation Inspection Report

1) Inspector and Author of Report

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2) Facility Information

Beckman Coulter Hialeah Facility
740 W 83rd Street
Hialeah, Florida 33014

County: Miami Dade
Latitude: 25° 53' 53.8227"
Longitude: 80° 17' 49.0396"
EPA ID Number: FLD042558775

Primary NAICS: 334510 – Electromedical and Electrotherapeutic Apparatus Manufacturing and
325413 – In-vitro Diagnostic Substance
SIC Code: 3845 – Electromedical Equipment and 3842 – Surgical Appliances and Supplies

3) Responsible Official

Tariq Beazer, Environmental Health and Safety, Beckman Coulter Hialeah Facility
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4) Inspection Participants

Parvez Mallick, US EPA Region 4
Jared Haynes, Florida Department of Environmental Protection (FDEP)
Alannah Irwin, FDEP
Justin Stark, FDEP
Patrick Scott, FDEP
Tariq Beazer, Environmental Health and Safety, Beckman Coulter Hialeah Facility

5) **Dates of Inspection**

August 26, 2021, 10:00 a.m.

6) **Applicable Regulations**

Resource Conservation and Recovery Act (RCRA) Sections 3002, 3005 and 3007 (42 U.S.C. §§ 6922, 6925 and 6927), and the regulations promulgated pursuant thereto at 40 Code of Federal Regulations (C.F.R.) Parts 260-270, 273 and 279.

Florida Statutes (F.S.) Chapter 403.702 et seq., and the regulations promulgated pursuant thereto and set forth at the Florida Administrative Code (Fla. Admin. Code Ann. r.), Chapters 62-710, 62-730 and 62-750.

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.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17], a LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 403.722 of the Florida Statutes, Fla. Stat. § 403.722 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17] (hereinafter referred to as the LQG Permit Exemption).

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers 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 403.722 of the Florida Statutes, Fla. Stat. § 403.722 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.16(b) or §262.17(a)], except as required in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)] (hereinafter referred to as the SAA Permit Exemption).

7) **Purpose of Compliance Evaluation Inspection**

On August 26, 2021, Jared Haynes, Alannah Irwin, and Justin Stark, Florida Department of Environmental Protection (FDEP), and Parvez Mallick, EPA, conducted a routine compliance evaluation inspection of Beckman Coulter Hialeah Facility (Beckman or the facility) to determine the facility's compliance with state and federal hazardous waste regulations. This was an EPA lead inspection. Beckman was represented by Mr. Tariq Beazer, Environmental Health and Safety, Beckman Coulter Hialeah Facility. Upon entering the facility, the inspectors introduced themselves, showed their credentials and explained the purpose of the visit and a description of the facility's process was discussed. The inspectors described the anticipated use of digital camera during the inspection. The inspectors briefly 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. The company did not assert a business confidentiality claim. The

inspection participants also discussed health and safety protocols and required personal protective equipment before Mr. Beazer led the inspectors on a tour of the facility operations.

8) **Facility Description**

Beckman Coulter Hialeah Facility develops, manufactures, and markets products that simplify, automate, and innovate complex biomedical testing. Beckman's diagnostic systems are found in hospitals and other critical care settings around the world and produce information used by physicians to diagnose disease, make treatment decisions, and monitor patients. Some of Beckman's products are Hemocult Sensa Patient Kits, DxH 500 Series Lyse, AQUIOS Cleaning Agent, FlowClean Cleaning Agent, Vi-Cell Blue Reagent, Vi-Cell XR Reagent. In addition, the Hialeah facility manufactures materials to be used in equipment manufactured in their Beckman Coulter Kendall Facility, South Miami plant.

The Hialeah facility is situated on approximately 50 acres and located at the northwest corner of the intersection of SW 147th Avenue and SW 120th Street. The facility campus incorporates three buildings: Building 700, Building 740, and Building 780, totaling 96,633 square feet. The three buildings serve as a multi-utilization facility for development, production, and distribution of Beckman Coulter reagents and specialty products.

The facility originally notified FDEP as a large quantity generator (LQG) of hazardous waste on June 14, 1992, under the name Coulter Corporation and was issued EPA identification number FLD042558775. In April 1998, Beckman Instruments, Inc. changed its name to Beckman Coulter, Inc., to reflect the October 1997 acquisition of Coulter Corporation. Beckman Coulter, Inc. was acquired by Danaher Corporation in 2011. The Hialeah facility notified FDEP of the name change to Beckman Coulter Hialeah Facility on March 14, 2014. The facility most recently notified FDEP as a large quantity generator (LQG) of hazardous waste on February 13, 2020. Hazardous wastes generated at the facility include, but are not limited to, flammable materials, solvent, solvent filters, lab pack materials, isopropyl alcohol, isopropanol, methanol, potassium cyanide, dichloromethane, sodium hydroxide, cyanides, mercury, discarded chemicals, and acute empty waste containers.

9) **Inspection Findings**

Building 740 (Blood Products Reagents and Calibration Reagents)

Building 740 is the main entrance of the facility. Building 740 is located at 740 West 83rd Street and comprised of a 1.44-acre lot with a 29,051 sq. ft. building forming the center portion of the campus. The facility inspection started at the Building 740. A variety of reagents that are designed for cell counters and analyzers that optimize instrument setup, sample preparation and quality control are manufactured in Building 740. The labs in Building 740 primarily generate biohazardous waste regulated by Florida Department of Health (FDOH). The biological materials are used to calibrate the equipment, ensuring the sampled analytes are captured. The biological materials are centrifuged (i.e., separated) to process the analytes and allow them to mimic human behavior. No hazardous wastes are generated from this process. Each laboratory in this area is broken up into four segments: Gowning, Materials, Labeling, and Capping. There was one flammable cabinet in each laboratory used to hold alcohol and cleaning products.

Building 780

Building 780 is located at 780 West 83rd Street and comprised of a 1.35-acre lot with a 40,041

sq. ft. building forming west side of the campus. The building is comprised of a 90-day Central Accumulation Area (CAA), known as the “Waste Bunker,” the Plant Engineering Workshop, and the Receiving Area. The CAA is located on the southern side of Building 780 and has “No Smoking” and “Hazardous Waste” signage outside the door. Eye wash and safety showers were located directly outside of the CAA and were confirmed to be operable during the inspection. Spill kits and fire extinguishers were also located within the CAA. The following containers were stored in the Waste Bunker during the inspection (Photo #1):

- One closed 55-gallon container of “Hazardous Waste Flammable” hemocult developer dated 5/26/21 (Photo #2). *The 55-gallon container has been in storage at the facility for greater than 90 days without a permit;*
- One closed 55-gallon container of “Hazardous Waste Flammable” developer dated 7/25/21;
- One closed 30-gallon poly container of rejected laboratory filling. The container was marked “Hazardous Waste” and “Flammable” but missing an accumulation start date. The container was marked with an accumulation start date during the inspection;
- One closed 8-liter corrosive sodium hydroxide solution. The container was not marked with the words “Hazardous Waste,” an indication of hazards of the contents, or an accumulation start date;
- One closed 55-gallon overpack container of non-hazardous reagents;
- One closed 30-gallon hazardous waste container of “Polymer/xylene/DCM/ethanol & chloroform” dated 7/30/21. The container was not marked with the words “Hazardous Waste,” an indication of hazards of the contents, or an accumulation start date;
- Eight boxes of rejected dichloromethane (DCM), methylene chloride. These boxes were identified as non-hazardous; however, during the record review, it was determined that the wastes are considered discarded commercial chemical products with a U080 waste code, listed for toxicity. The boxes were not marked with the words “Hazardous Waste,” an indication of hazards of the contents, or an accumulation start date (Photo #3);
- One closed 80-liter container of non-hazardous sodium sulfate solution;
- One 55-gallon container marked “Used Oil;”
- Nineteen boxes of used universal waste lamp. The boxes were not marked “Universal Waste-Lamp(s),” or “Waste Lamp(s),” or “Used Lamps” and were not dated to demonstrate the length of time that the universal waste boxes have been accumulated from the date it became wastes or were received (Photo #4);
- One closed 1-gallon container of “Universal Waste” lithium batteries dated 10/6/20;
- One closed 1-gallon container of “Universal Waste” alkaline batteries dated 10/6/20;
- One closed 1-gallon container of “Universal Waste” nickel cadmium batteries dated 10/6/20;
- Three boxes of spent sealed lead acid batteries. The boxes were not marked “Universal Waste - Battery(ies),” or “Waste Battery(ies),” or “Used Battery(ies)” and were not dated to demonstrate the length of time that the universal waste boxes have been accumulated from the date it became wastes or were received (Photo #5);
- One closed 55-gallon container of non-hazardous oil contaminated materials;
- Two closed 55-gallon blue containers of non-hazardous buffer solution;
- One open 55-gallon gray container of “Hazardous Waste” solvent contaminated rags. The container was dated 1/18/17. *The 55-gallon container has been in storage at the facility for greater than 90 days without a permit;*

- One push-cart contained twenty 1-gallon containers of used paint and coating materials (Photo #6). The cart itself was labeled with the words “Hazardous Waste” however the contents on the label were “ink cartridge”. The inspectors instructed the facility to conduct a waste determination and ensure that the wastes are disposed of accordingly. In an email dated September 3, 2021, Mr. Beazer stated that the items were reviewed and determined not to be waste at this time. The paint and coating materials will be re-used, the area will be organized further, and additional appropriate labels will be added.
- One 10-gallon container with a corrosive placard of unknown content and an expiration date of 6/8/21. The inspectors instructed the facility to conduct a waste determination on the corrosive solutions;
- Three 1-gallon containers of Photo-Flo 600 solution with an expiration date of 11/20/20 (Photo #7). The inspectors instructed the facility to conduct a waste determination on the Photo-Flo 600 solutions;
- One bin of waste chemicals marked “Hazardous Waste” lab pack dated with an accumulation date of 7/6/2021. The lab pack had an indication of hazards of the contents.
- Two 30-gallon poly containers holding “non-RCRA regulated” cyanates solution. The facility’s waste information profile indicated that cyanates solution is non-hazardous waste;
- One 55-gallon overpack containing non-hazardous laboratory reagents;
- One 80-liter containing non-hazardous sodium sulfate waste;
- Eight containers contained non-hazardous waste;
- Seven empty 10-gallon containers; and
- Adequate aisle space was not observed in the CAA. The area was congested with containers and the inspector’s movement was obstructed to inspect all containers due to no aisle space.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17], a LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 403.722 of the Florida Statutes, Fla. Stat. § 403.722 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17]. *The hemocult developer and the solvent contaminated rags containers have been in storage greater than 90 days without a permit.*

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17(a)(5)(i)(A-C)], which is a condition of the LQG Permit Exemption, a generator must mark or label its containers with the following: (A) the words “Hazardous Waste;” (B) an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 C.F.R. part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 C.F.R. 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and (C) the date upon which each period of accumulation begins clearly visible for inspection on each container. *The corrosive sodium hydroxide solution, polymer/xylene/DCM/ethanol & chloroform, and DCM containers were not marked “Hazardous Waste” and an indication of the hazards of the contents. The rejected*

laboratory filling, corrosive sodium hydroxide solution, polymer/xylene/DCM/ethanol & chloroform, and DCM containers were not marked with and an accumulation start date.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Fla. Admin. Code Ann. r. 62-730.030(1) [40 C.F.R. § 261.2], must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable RCRA regulations articulated in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.11]. *The facility did not conduct waste determination on the 10-gallon container of corrosive solution and three 1-gallon container of Photo-Flo 600 solution.*

Pursuant to Fla. Admin. Code Ann. r. 62-730.185(1) [40 C.F.R. § 273.14(e)], a SQHUW must label or mark each lamp or container of lamps clearly with one of the following phrases: “Universal Waste-Lamp(s),” or “Waste Lamp(s),” or “Used Lamp(s).” *The facility failed to label nineteen boxes of universal waste lamps.*

Pursuant to Fla. Admin. Code Ann. r. 62-730.185(1) [40 C.F.R. § 273.14(a)], a small quantity handler of universal waste (SQHUW) must label or mark each battery or container of batteries clearly with one of the following phrases: “Universal Waste—Battery(ies),” or “Waste Battery(ies),” or “Used Battery(ies).” *The facility failed to label three boxes of universal waste batteries.*

Pursuant to Fla. Admin. Code Ann. r. 62-730.185(1) [40 C.F.R. § 273.15(a) and (c)], a SQHUW may accumulate universal waste no longer than one year and must be able to demonstrate the length of time that the universal waste has accumulated from the date that it became a waste or was received. *The facility failed to mark the containers of universal waste with a date when universal waste became a waste.*

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17(a)(6)], which incorporates Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.255], and is a condition of the LQG Permit Exemption, a generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

On September 3, 2021, the facility informed the EPA and FDEP that all the waste stored in the Waste Bunker were shipped off to Veolia ES Technical Solutions, LLC in Beaumont, TX (TXD000838894) and Veolia ES Technical Solutions, LLC in Tallahassee, FL (FL0000207449). It appears that 2,310 lbs. of hazardous and 1,685 lbs. of non-hazardous wastes were shipped to Beaumont, Texas, designated facility (manifest number 001963040VES, shipping date 9/2/21) and 1,015 lbs. of universal wastes to Tallahassee, Florida, designated facility (manifest number ZZ00160261, shipping date 9/2/21).

Engineering Workshop

The Engineering Workshop is located in the western side of Building 780 and is primarily used to retrofit equipment. The facility has three machines used for milling, sawing, and grinding of parts to assist with the retrofitting process. The inspectors observed one 55-gallon container of non-hazardous oily rags in the engineering workshop. Eye wash stations, fire extinguishers, and one flammable cabinet were observed in this area. No hazardous wastes were observed in the

engineering workshop during the inspection.

Receiving and Finishing

The Receiving Area is located on the northern side of the facility and is used to receive and ship out finished products. Hazardous wastes are not generated in this area. During the inspection, the inspectors observed a box of universal waste lamps in the receiving area. The box was closed, marked “Universal Waste Lamps,” and dated 9/23/20. The inspectors informed the facility that per 40 C.F.R. § 273.15(a), a small quantity handler of universal waste may accumulate waste on-site for one year and should ensure that the container is properly disposed of before 9/23/21.

The Finishing Area contained CNC machines that are used to cut containers, shredding, and packaging. During the inspection the inspectors observed the following containers in the satellite accumulation area:

- One closed 55-gallon container of “Hazardous Waste Flammable” flushing solution;
- One 55-gallon drum of oily rags;
- One 20-gallon of waste solution. This container was not marked and the facility representative did not know the contents of the container. On October 28, 2021, the facility informed the EPA that the container contained hydrochloric acid waste solution; and
- The area had a spill kit, an eye wash, and a safety shower.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Fla. Admin. Code Ann. r. 62-730.030(1) [40 C.F.R. § 261.2], must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable RCRA regulations articulated in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.11]. The facility failed to conduct a waste determination on the 20-gallon waste container.

Building 700 (Bulk Reagents and Specialty Products)

Building 700 is located at 700 West 83rd Street and comprised of a 1.24-acre lot with a 27,541 sq. ft building forming east side of the campus. Bulk size reagents and specialty products are manufactured in this building. During the inspection, the inspectors observed the following containers in the satellite accumulation area:

- One 55-gallon blue container of reticulon stain reagent waste in the Pooling Room. The container was closed, marked “Hazardous Waste,” but did not have an indication of hazards of the contents.
- One 55-gallon container of filters, tubing (DCM Contact). The drum was labeled with the words “Hazardous Waste” and had an indication of hazards of the contents.
- One 55-gallon container of polymer, xylene, DCM, ethanol, and chloroform. The drum was labeled with the words “hazardous waste” and had an indication of hazards of the contents.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator must mark or label its containers with the following: (ii) an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of

Transportation requirements at 49 C.F.R. part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 C.F.R. 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

The stain reagent waste container was not marked with an indication of the hazards of the contents.

Record Review

Hazardous waste manifest records were reviewed for 2019, 2020, and 2021 during the inspection. Waste profiles and Land Disposal Restriction (LDR) notification forms were available on-site for review and were up to date. At the time of inspection, the most recent waste pickup had occurred on 8/12/21. The waste transporter was Veolia ES Technical (NJD080631369) and the designated facility was Veolia ES Technical Solutions (TXD000838896). The following wastes were transported on 8/12/21:

- One drum containing 300 pounds of Waste Flammable Liquid (EPA Waste Codes: D001, D002, and F003);
- One drum containing 400 pounds of Waste Flammable Liquid (EPA Waste Code: D001); and
- One drum containing 400 pounds of Waste Flammable Liquid (EPA Waste Code: D001).

The facility maintains a contingency plan that includes emergency contact information, an evacuation map, emergency response and preparedness procedures, and emergency equipment descriptions and locations. The facility demonstrated that the appropriate arrangement with the local police, fire department, hospital, and local emergency response agencies have been made. Spill kits, eye wash and shower stations, fire alarms, and fire extinguishers are available on-site. The facility conducts routine inspections, testing, and maintenance of all communications systems, fire protection equipment, spill control equipment, and decontamination equipment. The facility utilizes a two-way radio system for internal communications. Landlines were observed throughout the facility for external communication.

The most recent container inspection was conducted on 8/24/21. The container inspection log included the date and time of inspection, the name of the staff member conducting the inspection, any corrective actions taken, and the total number of bins in the CAA.

The facility conducts annual hazardous waste training to all staff in contact with hazardous materials and hazardous wastes. This training includes the management of hazardous wastes for LQGs and DOT fundamentals of hazardous materials. The training is proctored by Knowledge Connection; the most recent training was completed in 3/22/21. The individual signing the manifest is DOT/HazMat certified. Documentation of job titles and position descriptions for personnel involved with hazardous waste management are managed on-site.

Biennial reports for 2018 and 2020 were available on-site. The Biennial report for reporting year 2019 was submitted to FDEP on February 13, 2020. A review of Biennial report indicated the following waste quantities were reported:

- Flammable methylene chloride; D001 waste-156 lbs;
- Flammable solvent filters; D001 waste-200 lbs;
- Lab pack materials; D001 waste-295 lbs;

- Acute lab pack materials; D001 and P030 waste-61 lbs;
- Acute empty containers; D001, P098 and P105 waste-87 lbs;
- Flammable Epics solvents; D001 waste-806 lbs;
- Loose pack flammable materials; D001, D035, F003, U002, U003, U112, U159, U220, and U239 waste-2,130 lbs;
- Flex solution flushing; D001 waste-757 lbs;
- Hemmocult printing solutions; D001 waste-389 lbs;
- Solvents with chloroform; D001, D022, and F003 waste-117 lbs;
- Methanol solutions CD 1904; D001 and F003 waste-281 lbs;
- Flammable Arquad 2C-75; D001 waste-411 lbs;
- Sodium hydroxide solutions; D002 waste-21 lbs; and
- Dichloromethane spill clean-up; U080 waste-285 lbs.

10) Closing Conference

A closing conference was conducted at the conclusion of the inspection. Mr. Tariq Beazer participated in the closing conference. The observations made during the inspection were discussed and the inspection was concluded. Beckman was inspected as a large quantity generator of hazardous waste.

11) Signed

Parvez Mallick
Inspector and Author of Report

Date

12) Concurrence and Approval

Araceli B. Chavez
Chief
RCRA Enforcement Section

Date

Compliance Evaluation Inspection photos taken by Justin Stark, FDEP



Photo #1 – Central Accumulation Area (Waste Bunker).



Photo #2 – 55-gallon drum of hazardous waste dated 5/26/21.



Photo #3 – Eight boxes of rejected DCM.



Photo #4 – Boxes of universal waste lamps.



Photo # 5 - Boxes of spent lead acid batteries.



Photo #6 – Push-cart containing paint and coating containers.

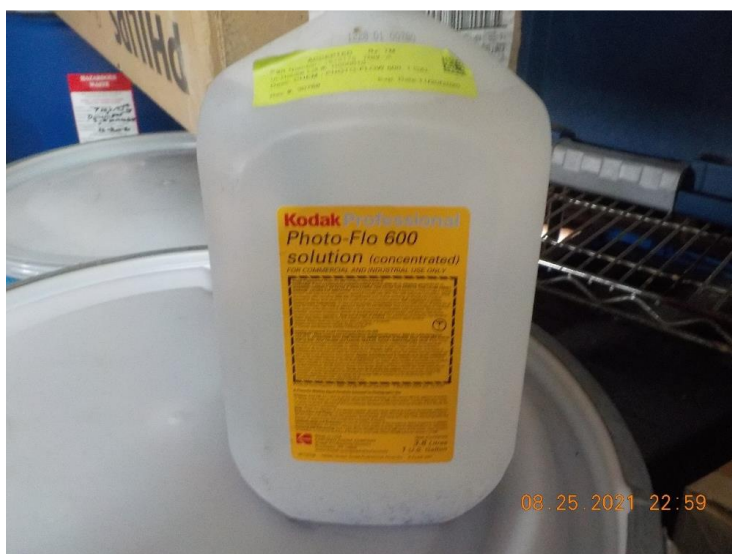


Photo #7 – Expired Photo-Flo solution.