



FLORIDA DEPARTMENT OF Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Secretary

November 3, 2023

Sent electronically to: kellji@shands.ufl.edu

Mr. James J. Kelly, Jr., Interim CEO, Sr. Vice President & Chief Financial Officer
Shands Teaching Hospital and Clinics, Inc.
1600 SW Archer Rd.
Gainesville, FL 32610

SUBJECT: Department of Environmental Protection v. Shands Teaching Hospital and Clinics, Inc.
OGC File No.: 23-0141
EPA/DEP ID: FLR000093096

Dear Mr. Kelly:

Enclosed is a copy of the executed Consent Order to resolve Case Number 23-0141.

The effective date of this Order is November 3, 2023, and all time frames will be referenced from this date.

As a reminder, a Consent Order is a binding legal document and was voluntarily entered into by both parties.

Should you have any questions concerning the Consent Order, please contact Bonnie Bradshaw at (904) 256-1638, or Bonnie.Bradshaw@floridadep.gov. Your continued cooperation in the matter is appreciated.

Sincerely,

A handwritten signature in blue ink that reads "TG Kallemeyn".

Thomas G. Kallemeyn
Assistant District Director

Enclosure: Executed Consent Order

cc: Suzanne DeKay (dekays@shands.ufl.edu)
Mark DeLuna (delunm@shands.ufl.edu)
Carly Mitchell (mitccm@shands.ufl.edu)
FDEP-OGC: Lea Crandall, Agency Clerk
FDEP-NED: Cheryl Mitchell, Bonnie Bradshaw, Joni Petry, DEP_NED



FLORIDA DEPARTMENT OF Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
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Secretary

October 20, 2023

Sent electronically to: kelljj@shands.ufl.edu

Mr. James J. Kelly, Jr., Interim CEO, Sr. Vice President & Chief Financial Officer
Shands Teaching Hospital and Clinics, Inc.
1600 SW Archer Rd.
Gainesville, FL 32610

SUBJECT: Department of Environmental Protection v. Shands Teaching Hospital and Clinics, Inc.
OGC File No. 23-0141
EPA/DEP ID: FLR000093096

Dear Mr. Kelly:

The State of Florida Department of Environmental Protection ("Department") finds that Shands Teaching Hospital and Clinics, Inc. ("Respondent") did not complete hazardous waste determinations on three (3) waste streams, did not correctly determine its generator category, did not properly label three (3) hazardous waste satellite containers, did not provide the proper emergency equipment in the hazardous waste accumulation area, did not have an adequate hazardous waste training program, did not attempt to make arrangements with the local emergency authorities, did not have an adequate Contingency Plan, did not submit a copy of the Contingency Plan and its Quick Reference Guide to local emergency authorities, did not submit the required biennial report, and did not notify the Department as a Large Quantity Generator of hazardous waste. This is in violation of the rules and statutes cited in the attached Warning Letter (WL23-044). Before sending this letter, the Department requested that the Respondent undertake certain actions to resolve the violations. These actions have since been completed. However, due to the nature of the violations, the Respondent remains subject to civil penalties. The Respondent is also responsible for costs incurred by the Department during the investigation of this matter.

The Department's Offer

Based on the violations described above, the Department is seeking \$11,090.00 in civil penalties and \$500.00 for costs and expenses the Department has incurred in investigating this matter, which amounts to a total of \$11,590.00. The civil penalty in this matter includes one violation of \$2,000.00 or more.

Respondent's Acceptance

If you wish to accept this offer and fully resolve the enforcement matter pending against the Respondent, please sign this letter and return it to the Department at 8800 Baymeadows Way West, Suite 100, Jacksonville, Florida, 32256, by November 3, 2023. The Department will then countersign it and file it with a designated clerk of the Department.

Once the document is filed with the designated clerk, it will constitute a final order of the Department pursuant to Section 120.52(7), Florida Statutes (F.S.), and will be effective unless a request for an administrative hearing is filed by a third party in accordance with Chapter 120, F.S., and the attached Notice of Rights.

By accepting this offer you, Mr. Kelly:

- (1) certify that you are authorized and empowered to negotiate, enter into, and accept the terms of this offer in the name and on behalf of Respondent;
- (2) acknowledge and waive Respondent's right to an administrative hearing pursuant to Sections 120.569 and 120.57, F.S., on the terms of this offer, once final; and
- (3) acknowledge and waive Respondent's right to an appeal pursuant to Section 120.68, F.S.

The Department acknowledges that the Respondent's acceptance of this offer does not constitute an admission of liability for the violation(s) referenced above.

Respondent's Performance

After signing and returning this document to the Department:

- (1) Respondent must pay \$11,590.00, in full, within 60 days from the execution date of this Order.
- (2) Respondent shall make all payments required by this Order by cashier's check, money order or on-line payment. Cashier's check or money order shall be made payable to the "Department of Environmental Protection" and shall include both the OGC number assigned to this Order and the notation "Water Quality Assurance Trust Fund." Payment shall be sent to the Department of Environmental Protection, 8800 Baymeadows Way West, Suite 100, Jacksonville, Florida, 32256. Online payments by e-check can be made by going to the DEP Business Portal at: <http://www.fldepportal.com/go/pay/>. It will take a number of days after this order is final and effective, by filing with the Clerk of the Department, before ability to make online payment is available.

The Department may enforce the terms of this document, once final, and seek to collect monies owed pursuant to Sections 120.69 and 403.121, F.S.

Until clerked by the Department, this letter is only a settlement offer and not a final agency action. Consequently, neither the Respondent nor any other party may request an administrative hearing to contest this letter pursuant to Chapter 120, F.S. Once this letter is clerked and becomes a final order of the Department, as explained above, the attached Notice of Rights will apply to parties, other than the Respondent, whose interests will be substantially affected.

Electronic signatures or other versions of the parties' signatures, such as .pdf or facsimile, shall be valid and have the same force and effect as originals. No modifications of the terms of this Order will be effective until reduced to writing, executed by both Respondent and the Department, and filed with the clerk of the Department.

Please be aware that if the Respondent declines to respond to the Department's offer, the Department will assume that the Respondent is not interested in resolving the matter and will proceed accordingly.

If you have any questions, contact Bonnie Bradshaw at (904) 256-1638, or via email at Bonnie.Bradshaw@FloridaDEP.gov.

Sincerely,



Thomas G. Kallemeyn
Assistant District Director

FOR THE RESPONDENT:

I, James J. Kelly, Jr. [Type or Print Name], **HEREBY ACCEPT THE TERMS OF THE SETTLEMENT OFFER IDENTIFIED ABOVE.**

By: _____

[Signature]

Title: _____

Interim CEO

Date: _____

11/2/23

FOR DEPARTMENT USE ONLY

DONE AND ORDERED this 3rd day of November 2023, in Duval
County, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION



Gregory J. Strong
District Director

Filed, on this date, pursuant to section 120.52, F.S., with the designated Department Clerk,
receipt of which is hereby acknowledged.



Clerk

November 3, 2023

Date

Attachments: Notice of Rights
 Warning Letter WL23-044

Final clerked copy furnished to:

TGK

Lea Crandall, Agency Clerk (lea.crandall@floridadep.gov)

Sarah Harris, FDEP NED (sarah.b.harris@floridadep.gov)

NOTICE OF RIGHTS

Persons who are not parties to this Order, but whose substantial interests are affected by it, have a right to petition for an administrative hearing under Sections 120.569 and 120.57, Florida Statutes. Because the administrative hearing process is designed to formulate final agency action, the filing of a petition concerning this Order means that the Department's final action may be different from the position it has taken in the Order.

The petition for administrative hearing must contain all of the following information:

- a) The OGC Number assigned to this Order;
- b) The name, address, and telephone number of each petitioner; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding;
- c) An explanation of how the petitioner's substantial interests will be affected by the Order;
- d) A statement of when and how the petitioner received notice of the Order;
- e) Either a statement of all material facts disputed by the petitioner or a statement that the petitioner does not dispute any material facts;
- f) A statement of the specific facts the petitioner contends warrant reversal or modification of the Order;
- g) A statement of the rules or statutes the petitioner contends require reversal or modification of the Order; and
- h) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the Department to take with respect to the Order.

The petition must be filed (received) at the Department's Office of General Counsel, 3900 Commonwealth Boulevard, MS# 35, Tallahassee, Florida 32399-3000 within 21 days of receipt of this notice. A copy of the petition must also be mailed at the time of filing to the District Office at the address indicated above. Failure to file a petition within the 21-day period constitutes a person's waiver of the right to request an administrative hearing and to participate as a party to this proceeding under Sections 120.569 and 120.57, Florida Statutes. Mediation under Section 120.573, Florida Statutes, is not available in this proceeding.



FLORIDA DEPARTMENT OF Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Secretary

February 20, 2023

Sent via email: delunm@shands.ufl.edu

Mr. Mark De Luna, Lab Quality Assurance Coordinator
UF Health Shands Hospital
Post Office Box 100344
Gainesville, Florida 32608

**RE: Warning Letter No. WL23-044 (Significant Non-Complier)
Shands Medical Laboratory at Rocky Point
EPA/DEP ID No. FLR 093096
Alachua County – Hazardous Waste**

Dear Mr. De Luna:

A Hazardous Waste Compliance Inspection was conducted at your facility on November 16, 2022. During this inspection, possible violations of Chapters 376 and 403, Florida Statutes (Fla. Stat.), and Chapter 62-730, Florida Administrative Code (Fla. Admin. Code), were observed.

During this inspection, Department personnel noted the following:

- The facility did not conduct complete and accurate hazardous waste determinations on three (3) waste streams.
- The facility did not correctly determine its generator category.
- The facility did not properly label three (3) hazardous waste satellite containers.
- The facility did not provide the proper emergency equipment in the hazardous waste accumulation area.
- The facility did not have an adequate hazardous waste training program.
- The facility did not attempt to make arrangements with the local emergency responders.
- The facility did not have an adequate Contingency Plan.

- The facility did not submit a copy of the Contingency Plan and its Quick Reference Guide to local emergency responders.
- The facility did not submit the required biennial report.
- The facility did not notify the Department as a Large Quantity Generator of hazardous waste.

Violations of Florida Statutes or administrative rules may result in liability for damages and restoration, and the judicial imposition of civil penalties, pursuant to Sections 376.121 and 403.121, Florida Statutes.

Please contact Bonnie Bradshaw at (904) 256-1638, or via email at Bonnie.Bradshaw@FloridaDEP.gov, within 15 days of receipt of this Warning Letter to arrange a meeting to discuss this matter. The Department is interested in receiving any facts that you may have which might assist in determining whether any violations have occurred. You may bring anyone with you to the meeting that you feel could help resolve this.

Please be advised that this Warning Letter is part of an agency investigation, preliminary to agency action in accordance with Section 120.57(5), Florida Statutes. We look forward to your cooperation in completing our investigation and resolving this as soon as possible.

Sincerely,



Gregory J. Strong
District Director

Attachment: Final Inspection Report

cc: FDEP-NED: Bonnie Bradshaw, Cheryl Mitchell, Joni Petry, Thomas G. Kallemeyn,
DEP_NED, Monique Jordan
Alachua County EPD: Christopher Gilbert, cgilbert@alachuacounty.us
Shands: Mary Reeves, reevml@shands.ufl.edu
Pamela Gillard, pgil0002@shands.ufl.edu
Robert Anthony, anthra@shands.ufl.edu



**Florida Department of
Environmental Protection
Hazardous Waste Inspection Report**

FACILITY INFORMATION:

Facility Name: Shands Medical Laboratory at Rocky Point
On-Site Inspection Start Date: 11/16/2022 **On-Site Inspection End Date:** 11/16/2022
ME ID#: 40476 **EPA ID#:** FLR000093096
Facility Street Address: 4800 SW 35th Dr , Gainesville, Florida 32608-7686
Contact Mailing Address: 4800 SW 35th Dr, Gainesville, Florida 32608-7686
County Name: Alachua **Contact Phone:** (352) 265-9900

NOTIFIED AS:

SQG (100-1000 kg/month)

WASTE ACTIVITIES:

Generator: LQG

INSPECTION TYPE:

Routine Inspection for LQG (>1000 kg/month) Facility

INSPECTION PARTICIPANTS:

Principal Inspector: Bonnie M Bradshaw, Inspector
Other Participants: Troy Auffenburg, Business Manager

LATITUDE / LONGITUDE: Lat 29° 36' 27.6096" / Long 82° 22' 29.4889"

NAIC: 611310 - Colleges, Universities, and Professional Schools

TYPE OF OWNERSHIP: Private

Introduction:

Shands Medical Laboratories at Rocky Point (Rocky Point Lab, the facility) was inspected November 16, 2022, as an unannounced hazardous waste compliance evaluation. The Rocky Point Lab was last inspected by the Department at this location on February 7, 2013, as an unannounced hazardous waste compliance assistance site visit. The facility last notified as a Small Quantity Generator (SQG) of Hazardous waste in 2002. The facility is currently operating as a Large Quantity Generator (LQG) of Hazardous waste. The facility has been issued the EPA/DEP identification number FLR000093096. Please use this number on all correspondence with the Department's Hazardous Waste Section. The Rocky Point Lab is located in the same building as the UF Pathology Laboratories (FLR000099986). The facilities operate under separate ownership. The Rocky Point Lab address includes "Unit 2" to differentiate the addresses. Hazardous waste is accumulated in the same room for both facilities, but the waste is not commingled and it is manifested off-site under each facility's ID number. The UF Pathology Laboratories were inspected on the same day as the Rocky Point Lab and a separate inspection report will be issued for that inspection.

The Rocky Point Lab is a clinical laboratory. The facility has been in operation at this location for approximately twenty years, has 200 employees, and is on city water and sewer. The areas evaluated during this inspection included the HLA Lab (previously identified as the Transplant Lab), the Hematopathology Lab, the Histology Lab, the Cytology Lab and the Hazardous Waste Accumulation Area. There is no longer an area identified as the Pathology Lab.

Process Description:

HLA Lab

This lab performs compatibility testing for solid organ and stem cell transplants. No hazardous waste is generated in this area.

Shands Medical Laboratory at Rocky Point Inspection Report

Inspection Date: 11/16/2022

Hematopathology Lab

The Hematopathology Lab processes blood, tissue and fluids for leukemia and lymphoma immunophenotyping. The lab conducts staining using Wright Giemsa Stain Solution (flashpoint 54°F). The methanol (flashpoint 54°F) used to fix the sample to the slide and spent solution is released to the drain. Although the facility had documentation of a Gainesville Regional Utilities (GRU) Pretreatment Authorization Form dated July 2, 2009, which authorized the "discharge of small quantities of analytical reagents," the form states that "GRU restricts or prohibits the discharge to the wastewater collection system of untreated photographic fixer; solvents and flammable liquids (gasoline, paint thinners, acetone, etc.);....." This is therefore an Area of Concern.

Histology Lab

Tissue samples are prepared for pathology analysis in the Histology Lab. Samples arrive fixed in a buffered 10% formalin solution. Formalin decanted from the samples is taken to the Hazardous Waste Accumulation Area (HWAA), described below, for disposal and managed as D001 Formalin hazardous waste. Tissue samples are processed in an automatic processing machine. The processing machine uses either xylene and a series of different grades of alcohols or ethanol and a series of isopropyl alcohols to dehydrate the samples before the samples are fixed with formalin. The formalin and solvents are reused in the closed-loop system, but must be replaced every 450 specimens. Spent formalin is taken to the HWAA, described below, for disposal and managed as D001 Formalin hazardous waste. The spent solvents are also taken to the HWAA for disposal and managed as D001/F003 Xylene and Alcohol hazardous waste. The processing machine embeds the tissue samples in a paraffin block which is then sliced and put onto a slide.

Slides are stained in one of three types of automatic staining machines that each use a series of unit specific chemicals to conduct the staining. The Roche Ventana HE600 machines uses nine consumable chemicals (Photo 1). Only the Coverslip Activator, which is applied to the slides, generates a D001 hazardous waste if disposed of. Waste generated by the two Roche Ventana HE600 machines is collected in a reservoir behind the machine before being discharged to the city sewer. GRU authorized the discharge of this wastestream on October 30, 2021. Waste from each of the three Roche Ventana Benchmark Special Stainers drains into 5-gallon carboys beneath the machines and is managed as D001/D011 Silver Nitrate – Gold hazardous waste, however, the facility has not conducted and documented a complete hazardous waste determination to support this action [40 CFR 262.11]. The three 5-gallon carboys were not labeled as "Hazardous Waste" [40 CFR 262.15(a)(5)(i)] or with an indication of the hazards of the contents (Photo 2) [40 CFR 262.15(a)(5)(ii)]. Waste DAB from each of the five Roche Ventana Benchmark Ultra System stainers (Photo 3) drains into 5-gallon carboys beneath the machines and is managed as non-hazardous waste, however, the facility has not conducted and documented a complete hazardous waste determination to support this action [40 CFR 262.11]. Stained slides are sent to the hospital pathologists for interpretation.

Cytology Lab

The Cytology Lab processes liquid gynecologic cell samples preserved in a methanol-based fixative in one of three Thin Prep 2000 machines (Photo 4). The machine mixes the sample, collects the cells, transfers the cells onto a slide and deposits the slide into a 95% alcohol fixative solution. A portion of the sample waste used during this process drains into 1-gallon containers connected to the machines and is managed as D001/F003 Xylene and Alcohol hazardous waste. Each of the three containers was properly labeled (Photo 5). The original sample vial, containing methanol-based fixative is retained for 2-3 weeks in the event additional testing needs to be conducted. After the retention period, waste sample vials are collected, taken to the HWAA, described below, and managed as D001/F003 Methanol/Ethanol Loosepack hazardous waste.

Cytolyt (flashpoint 109°F) may be used to thin certain samples. Waste Cytolyt is decanted from the sample and placed into a 1-liter container of Cytolyt Waste. The liquid is managed D001/F003 Xylene and Alcohol hazardous waste. The container was closed and properly labeled.

Fine needle sample aspiration samples fixed in alcohol may be processed manually. The fixative is decanted from the cells into a small satellite container that is managed as D001/F003 Xylene and Alcohol hazardous waste. The facility is reminded that the containers should be labeled as "Hazardous Waste" with an indication of the hazards of the contents. The cells are placed onto slides and then stained in a Leica Autostainer XL machine (Photo 6). One of three programs dips the slide in various baths for the prescribed amount of time. Baths include xylene (flashpoint 82°F), various alcohols (flashpoint<140°F), Orange G6 (flashpoint 68°F), EA65 (flashpoint 68°F), Gill Hematoxylin, Modified Scotts, Quick Dip Solution #1, Quick Dip Solution #2, Quick Dip

Shands Medical Laboratory at Rocky Point Inspection Report

Inspection Date: 11/16/2022

Solution #3 and water. Baths may be filtered with filter paper for reuse. Spent filter paper is disposed of in the trash. The facility has not conducted and documented a hazardous waste determination on spent filter paper used to filter ignitable baths with a flashpoint of less than 140°F [40 CFR 262.11]. Once spent, water-based baths are flushed to the drain and solvent-based baths are managed as D001/F003 Xylene and Alcohol hazardous waste in the HWAA, described below.

Hazardous Waste Accumulation Area

Hazardous waste is accumulated in a room that is shared with the UF Pathology Laboratories. Wastes are maintained segregated.

There was one 55-gallon drum of D001/F003 Xylene and Alcohol hazardous waste, one 55-gallon drum of D001/F003 Methanol/Ethanol Thin Prep hazardous waste, two 55-gallon drums of D001 Formalin hazardous waste and one 55-gallon drum of D001/D011 Silver Nitrate Gold hazardous waste. There were also two 55-gallon drums of non-hazardous DAB accumulating. All drums were closed, properly labeled and had accumulated for less than 90 days. Emergency information and a "No Smoking" sign were posted. There was a spill kit and fire extinguisher in the area. There was no eyewash in close proximity to the HWAA [40 CFR 262.16(b)(8)(ii)(C)].

Record Review

The Rocky Point Lab is currently a Large Quantity Generator of hazardous waste.

Waste generation records were reviewed dating back to December 2020. Hazardous waste is transported one to four times each month by Clean Earth Specialty Solutions (MNS000110924) and Freehold Cartage, Inc. (NJD054126164) to Allworth, LLC (ALD094476793) for disposal. Records indicate that the facility has transported between 756 kilograms and 1,962 kilograms (4-10 drums) of hazardous waste each month during the review period. The facility has consistently operated as an LQG of hazardous waste since March 2021, transporting between 1,040 kilograms and 1,962 kilograms (5-10 drums) of hazardous waste each month, but the facility had not notified DEP as an LQG of hazardous waste [62-730.150(2)(b)] and had not correctly identified its generator category [40 CFR 262.13].

The facility did not have a hazardous waste training program that included the required elements [40 CFR 262.17(a)(7)(i)(A)].

The facility did not have a Contingency Plan [40 CFR 262.260(a)], did not submit a copy of the Contingency Plan to local emergency responders [40 CFR 262.262(a)] and did not submit a Quick Reference Guide of the Contingency Plan to local emergency responders [40 CFR 262.262(b)]. The facility also did not attempt to make arrangements with local emergency responders [40 CFR 262.256(a)].

The facility had not submitted the required biennial report due March 1, 2022 (2021 Biennial Report) [40 CFR 262.41(a)].

Copies of Northeast District's Hazardous Waste Generator Workshop PowerPoint training documents and other workshop files that may be useful can be found here:
<ftp://ftp.dep.state.fl.us/pub/outgoing/NED%20-%20HazWaste/LQG%20WORKSHOP/>

Please note that you cannot access this site using Chrome so you will have to use another browser such as Edge, Firefox, Internet Explorer, etc.

Please note that 40 CFR 262.18 requires re-notification for LQGs as follows:
 LQGs - notify by March 1 of each even-numbered year, or via submittal of a Biennial Report.

For Outstanding Items of Potential Non-Compliance

Please review the following section – New Potential Violations and Areas of Concern. This section includes potential violations observed at your facility during this inspection. For any potential violations below that have

Inspection Date: 11/16/2022

not been corrected, please refer to the Corrective Action for each item that is suggested to bring your facility into compliance. Once the corrective action has been completed, please send documentation to the Principal Inspector listed on page 1 of this Inspection Report. This documentation includes, but is not limited to, photos of corrected items, manifests, SDSs or other documents that will show that each potential violation has been fully addressed.

Area of Concern:

1. Hematopathology Lab: Spent methanol and Wright Giemsa Stain Solution is released to the drain. Although the facility had documentation of a GRU Pretreatment Authorization Form dated July 2, 2009, which authorized the "discharge of small quantities of analytical reagents," the form states that "GRU restricts or prohibits the discharge to the wastewater collection system of untreated photographic fixer; solvents and flammable liquids (gasoline, paint thinners, acetone, etc.);....." The facility should obtain written authorization for the discharge of this specific wastestream to GRU. If authorization is not obtained, the facility should begin collecting and managing this wastestream as a hazardous waste.

New Potential Violations and Areas of Concern:

Violations

Type:	Violation
Rule:	262.11
Explanation:	The facility did not conduct and document a complete hazardous waste determination on the following wastestreams: 1. Histology Lab: Waste generated by the Roche Ventana Benchmark Special Stainers that is managed as D001/D011 Silver Nitrate – Gold hazardous waste 2. Histology Lab: Waste generated by the Roche Ventana Benchmark Ultra System Stainers that is managed as non-hazardous Waste DAB 3. Cytology Lab: Spent filter paper used to filter spent ignitable Leica Autostainer XL baths with a flashpoint of less than 140°F
Corrective Action:	In order to return to compliance, the facility should: 1. Histology Lab: Review and provide copies of the Safety Data Sheets (SDSs) for each product that may be a constituent of the Roche Ventana Benchmark Special Stainers wastestream to verify that all of the applicable hazardous waste codes have been applied. Copies of the SDSs should be maintained with the waste profiles to document the hazardous waste determination. 2. Histology Lab: Review and provide copies of the SDSs for each product that may be a constituent of the Roche Ventana Benchmark Ultra System Stainers wastestream to verify that all of the applicable hazardous waste codes have been applied. Copies of the SDSs should be maintained with the waste profiles to document the hazardous waste determination. 3. Cytology Lab: The facility should use generator knowledge or a combination of generator knowledge and analytical testing to determine if the spent filter paper exhibits the ignitability characteristic. The facility should use generator knowledge to determine if the spent filter paper is capable, under standard temperature and pressure, of causing fire through friction, absorption of moisture or spontaneous chemical changes. The facility may use generator knowledge or EPA Method 1030 to determine if the spent filter paper burns so vigorously and persistently that it creates a hazard.
Type:	Violation
Rule:	262.13
Explanation:	The facility did not correctly determine its status as an LQG of hazardous waste.
Corrective Action:	In order to return to compliance, the facility should correctly determine its generator status as an LQG and notify DEP of its status using the 8700-12FL form. In the future, the facility should correctly determine its generator status on a monthly basis and update DEP of any changes.
Type:	Violation

Shands Medical Laboratory at Rocky Point Inspection Report

Inspection Date: 11/16/2022

Rule:	262.15(a)(5)(i)
Explanation:	Histology Lab: There were three 5-gallon carboys of D001/D011 "Silver Nitrate – Gold" hazardous waste that were not properly labeled as "Hazardous Waste."
Corrective Action:	Histology Lab: No further action is required. The facility returned to compliance via an email dated January 27, 2023.
Type:	Violation
Rule:	262.15(a)(5)(ii)
Explanation:	Histology Lab: There were three 5-gallon carboys of D001/D011 "Silver Nitrate – Gold" hazardous waste that were not properly labeled with an indication of the hazards of the contents.
Corrective Action:	Histology Lab: In order to return to compliance, the facility should label each container with 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 CFR 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 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704.
Type:	Violation
Rule:	262.16(b)(8)(ii)(C)
Explanation:	Hazardous Waste Accumulation Area: The area was not equipped with an eyewash.
Corrective Action:	Hazardous Waste Accumulation Area: In order to return to compliance, the facility should install an eyewash in the area.
Type:	Violation
Rule:	262.17(a)(7)(i)(A)
Explanation:	The facility did not have a hazardous waste training program that included the required elements.
Corrective Action:	<p>In order to return to compliance, the facility should implement a training program in compliance with 40 CFR 262.17(a)(7) and provide the following documentation:</p> <ol style="list-style-type: none"> 1. The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job; 2. A written job description for each position listed under 40 CFR 262.17(a)(7)(iv)(A). This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position; 3. A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under 40 CFR 262.17(a)(7)(iv)(A); 4. Records that document that the training or job experience, required under p40 CFR 262.17(a)(7)(i), (ii), and (iii) , has been given to, and completed by, facility personnel.
Type:	Violation
Rule:	262.256(a)
Explanation:	The facility failed to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers

Inspection Date: 11/16/2022

and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility.

Corrective Action: In order to return to compliance, the facility should attempt to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility. The emergency arrangements coordination described herein is to familiarize them with the layout of the facility, the properties of hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes as well as the types of injuries or illnesses that could result from fires, explosions, or releases at the facility. The facility should maintain records documenting the arrangements for a period of three years. This documentation should either confirm such arrangements actively exist or, in cases where no arrangements exist, confirm that attempts to make such arrangements were made.

The facility should submit documentation to the Department that emergency arrangements have been made with these organizations or that the required information described above has been provided to these organizations and the facility attempted to make such arrangements.

Type: Violation
Rule: 262.260(a)
Explanation: The facility did not have a Contingency Plan.
Corrective Action: In order to return to compliance, the facility should develop a Contingency Plan that contains the required elements under 40 CFR 262.261. A Contingency Plan submitted subsequent to the inspection on January 30, 2023, did not contain the required elements.

Type: Violation
Rule: 262.262(a)
Explanation: The facility did not submit a copy of the Contingency Plan to local emergency responders.
Corrective Action: In order to return to compliance, the facility should prepare and submit a copy of the Contingency Plan to local emergency responders (fire, police, hospital, etc.) and submit documentation that the Contingency Plan has been received (e.g. signed certified return receipt cards, email read receipts, etc.).

Type: Violation
Rule: 262.262(b)
Explanation: The facility did not submit a Quick Reference Guide to the Contingency Plan to local emergency responders.
Corrective Action: In order to return to compliance, the facility should prepare and submit a copy of a Quick Reference Guide to the Contingency Plan to local emergency responders (fire, police, hospital, etc.) and submit documentation that the Quick Reference Guide has been received (e.g. signed certified return receipt cards, email read receipts, etc.).

Type: Violation
Rule: 262.41(a)
Explanation: The facility did not submit the required biennial report due March 1, 2022 (2021 Biennial Report).
Corrective Action: In order to return to compliance, the facility should prepare and submit the required biennial report. The facility should also verify additional reporting periods did not require submittal.

Shands Medical Laboratory at Rocky Point Inspection Report

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Type: Violation

Rule: 62-730.150(2)(b)

Explanation: The facility did not notify DEP as an LQG of hazardous waste.

Corrective Action: In order to return to compliance, the facility should notify DEP of its status as an LQG of hazardous waste by submitting the 8700-12FL form available at the following link in accordance with the form instructions: <https://floridadep.gov/waste/permitting-compliance-assistance/forms/8700-12fl-florida-notification-regulated-waste-activity>

PHOTO ATTACHMENTS:

Photo 1



Photo 2



Photo 3



Photo 4



Shands Medical Laboratory at Rocky Point Inspection Report

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Photo 5

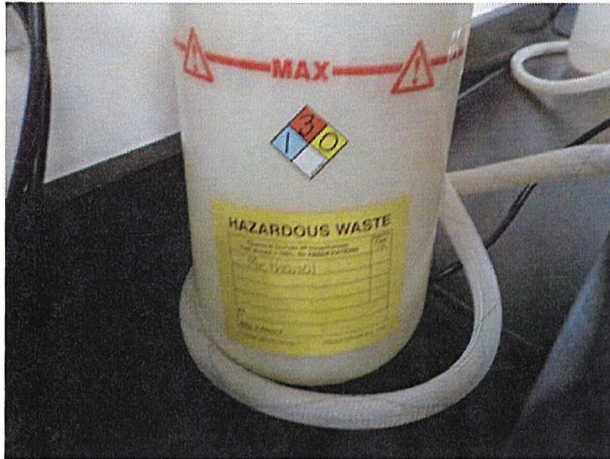


Photo 6



Inspection Date: 11/16/2022

1.0: Pre-Inspection Checklist**Requirements:**

The requirements listed in this section provide an opportunity for the Department's inspector to indicate the conditions found at the time of the inspection. A "Not Ok" response to a requirement indicates either a potential violation of the corresponding rule or an area of concern that requires more attention. Both potential violations and areas of concern are discussed further at the end of this inspection report.

Note: Checklist items with shaded boxes are for informational purposes only.

Item No.	Pre-Inspection Review	Yes	No	N/A
1.1	Has the facility notified with correct status? 262.18(a)			✓
1.2	Has the facility notified of change of status? 62-730.150(2)(b)			✓
1.3	Did the facility conduct a waste determination on all wastes generated? 262.11			✓

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Signed:

A hazardous waste compliance inspection was conducted on this date, to determine your facility's compliance with applicable portions of Chapters 403 & 376, F.S., and Chapters 62-710, 62-730, 62-737 & 62 -740 Florida Administrative Code (F.A.C.). Portions of the United States Environmental Protection Agency's Title 40 Code of Federal Regulations (C.F.R.) 260 - 279 have been adopted by reference in the state rules under Chapters 62-730 and 62-710, F.A.C

Bonnie M Bradshaw

Inspector

Principal Investigator Name

Principal Investigator Title

B. Bradshaw

DEP

01/30/2023

Principal Investigator Signature

Organization

Date

Troy Auffenburg

Business Manager

Representative Name

Representative Title

Shands Medical Laboratory at
Rocky Point

Organization

NOTE: By signing this document, the Site Representative only acknowledges receipt of this Inspection Report and is not admitting to the accuracy of any of the items identified by the Department as "Potential Violations" or areas of concern.

Report Approvers:

Approver: Bonnie M Bradshaw

Inspection Approval Date:

01/30/2023