

US Environmental Protection Agency – Region 2  
 Caribbean Environmental Protection Division  
 Response and Remediation Branch



*Resource Conservation and Recovery Act (RCRA)*  
 Compliance Evaluation Inspection

|                                                             |                                                                                                                                                                                                        |                                 |                                            |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|
| Facility Name:                                              | Gov. Juan F. Luis Hospital & Medical Center                                                                                                                                                            |                                 |                                            |
| EPA ID Number:                                              | VIN008015919                                                                                                                                                                                           |                                 |                                            |
| Date of Inspection:                                         | September 6, 2023                                                                                                                                                                                      |                                 |                                            |
| Generator Status in Record:                                 | VSQG (Non-Notifier)                                                                                                                                                                                    |                                 |                                            |
| Generator Status at the time of inspection:                 | VSQG                                                                                                                                                                                                   |                                 |                                            |
| RCRA Permitted:                                             | No                                                                                                                                                                                                     |                                 |                                            |
| Basis for Inspection:                                       | Core Program                                                                                                                                                                                           |                                 |                                            |
| Corrective Action:                                          | No                                                                                                                                                                                                     |                                 |                                            |
| Project ID                                                  | CEPD-RCRA-08-0101                                                                                                                                                                                      |                                 |                                            |
| Facility Physical Location:<br>(Municipality, VI, zip code) | 4007 Estate Diamond Ruby, Christiansted,<br>St. Croix U.S.V.I. 00821                                                                                                                                   |                                 |                                            |
| Geographical Coordinates:                                   | 17.733637, - 64.751376                                                                                                                                                                                 |                                 |                                            |
| Facility Owner:                                             | Mr. Douglas E. Koch, Chief Executive Officer<br>dkoch@jflusvi.org                                                                                                                                      | (340) 772-7418 / (340) 474-1812 |                                            |
|                                                             | Mailing address: 4007 Estate Diamond Ruby, Christiansted,<br>St. Croix U.S.V.I. 00821                                                                                                                  |                                 |                                            |
| Facility Operator:                                          | Ms. Hazel Philbert, Chief Operating Officer<br>hphilbert@jflusvi.org                                                                                                                                   | (340) 778-6311 ext. 3302        |                                            |
|                                                             | Mailing address: 4007 Estate Diamond Ruby, Christiansted,<br>St. Croix U.S.V.I. 00821                                                                                                                  |                                 |                                            |
| NAICS:                                                      | 622110 General Medical and Surgical Hospitals                                                                                                                                                          |                                 |                                            |
| SIC:                                                        | 8062 - General Medical and Surgical Hospitals                                                                                                                                                          |                                 |                                            |
| Area:                                                       | 10.1548 acres (Old JFL) / 3.6552 acres (New JFL North) of land property                                                                                                                                |                                 |                                            |
| Number Employees:                                           | Approximately 517                                                                                                                                                                                      |                                 |                                            |
| Personnel participating in inspection:                      |                                                                                                                                                                                                        |                                 |                                            |
| Eduardo R. Gonzalez, P.E.                                   | EPA Region 2-CEPD                                                                                                                                                                                      | Enforcement Officer             | (787) 977-5839<br>gonzalez.eduardo@epa.gov |
| Laura Encarnacion-Pascal                                    | Gov. JFL Hospital                                                                                                                                                                                      | Hospital Safety Officer         | (340) 778-6311 ext. 2217                   |
| Status:                                                     | Final                                                                                                                                                                                                  |                                 |                                            |
| Record Schedule:                                            | 1044(c)                                                                                                                                                                                                |                                 |                                            |
| Multi-media Checklist: ATTACHMENT # N/A                     |                                                                                                                                                                                                        | Referral: No                    |                                            |
| EPA Lead Inspector<br>Signature/Date                        |  12/13/2023                                                                                                         |                                 |                                            |
| Supervisor<br>Signature/Date                                | <br>Digitally signed by DAVID CUEVAS-MIRANDA<br>Date: 2023.12.14 12:22:04 -04'00'<br>David N. Cuevas Miranda, Ph.D. |                                 |                                            |

## 1 INTRODUCTION

On September 6, 2023, and September 8, 2023<sup>1</sup>, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (the “Inspection”) was conducted at Gov. Juan F. Luis Hospital & Medical Center (“JFL Hospital,” or the “Facility”), pursuant to Section 3007 of RCRA. The Facility is located on 4007 Estate Diamond Ruby, Christiansted, St. Croix U.S.V.I. 00821.

As part of the Inspection, an opening meeting, walkthrough, documents review and closing meeting were conducted to evaluate Facility’s compliance with the requirements that govern hazardous waste generators, pharmaceutical wastes, universal waste handlers and used oil generators as per RCRA. Gov. Juan F Luis Hospital is designated in the RCRAInfo<sup>2</sup> database as a Very Small Quantity Generator (VSQG). The Facility was inspected as part of the core program.

According to EPA records, only one RCRA inspection (one-EPA) has been conducted at the Facility during the last 5-years. The Facility was last inspected by EPA on August 21, 2008, in the areas of general generator requirements, and no RCRA violations were found at the time of the EPA compliance evaluation inspection.

## 2 OPENING MEETING

An opening meeting was held between Mr. Douglas E. Koch, Chief Executive Officer, Ms. Hazel Philbert, Chief Operating Officer, and Ms. Laura Encarnacion-Pascal all from Gov. Juan F Luis Hospital and I. I identified myself as EPA RCRA Enforcement Officer and told the Facility representatives that the purpose of my visit was to conduct a RCRA Inspection at the Facility to evaluate its hazardous waste management practices and compliance. I discussed the objectives of my inspection, and the requirements under RCRA for a Very Small Quantity Generator (VSQG). I asked Ms. Encarnacion-Pascal to provide me for review Gov. Juan F Luis Hospital’s manifests (last three years), and land disposal records regarding the handling, transportation, and final disposal of hazardous waste generated, and stored at the Facility. I also asked for review the personnel training requirements, and contingency and emergency preparedness plan.

Ms. Encarnacion-Pascal stated that she maintains manifest records for the management and storage of biomedical wastes, since no hazardous waste is generated at the Gov. Juan F Luis Hospital. I stated that that potentially hazardous wastes could be generated at the Hospital if it is not properly characterized nor manifested as required by RCRA regulations. Therefore, I emphasized that a visual inspection of the Facility areas would help us clarify if no hazardous wastes are generated at the Hospital.

Based on a review of manifests, it was estimated that approximately over 6800 pounds of Medical Waste (i.e., 216 boxes) and untreated sharp needles were generated at the Facility, and disposed of with Virgin

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<sup>1</sup> On September 8, 2023, a second day Inspection was performed to include the new Hospital location known as JFL North. A Closing Meeting was also held to discuss EPA’s observations on complex RCRA compliance requirements related to potentially creditable or non-creditable hazardous waste pharmaceuticals and reverse distributor, and Universal Waste management. Additionally due to the size of the Facility and all areas inspected, it was required to continue and complete the CEI Closing Meeting on September 8, 2023.

<sup>2</sup> RCRA Info and ECHO, EPA’s Enforcement Compliance and History Online system

Islands Regulated Waste Management, Inc. Based on medical waste disposal, I asked if the Facility is covered under 40 Code of Federal Regulations (CFR) Part 266 Subpart P which states that a healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor and hazardous waste pharmaceuticals to another generator pursuant to 40 CFR § 266.504. I stated that I will be asking the Pharmacy about chemotherapy drugs disposition.

## **2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION**

The Governor Juan F Luis Hospital & Medical Center (“the Gov. Juan F Luis Hospital”) is a large, highly affiliated primary care center which since 1982 has been providing a broad spectrum of healthcare programs and services to residences in U.S. Virgin Islands, including surgery, physical and rehabilitation medicine, spinal cord injury, psychiatry, nuclear medicine, dental & their subspecialties, CT scanning, and Magnetic Resonance Imaging (MRI). In 1982, the Government of the U.S. Virgin Islands received federal funds to support the construction and commissioning of the St. Croix Hospital, a 240,000 square foot facility with 250-bed capacity. At the time, management of the institution fell under the purview of the Department of Health, headed by the Commissioner. On May 14, 1999, Governor Charles W. Turnbull and the 23<sup>rd</sup> Legislature of the Virgin Islands passed Bill No. 23-0030 to amend Title 19, Chapter 16 of the Virgin Islands Code to provide for the semiautonomous administration of the Hospital.

On March 7, 2023, the Governor Juan F. Luis Hospital and Medical Center (JFL) held its Ribbon Cutting ceremony to celebrate the opening of the new interim facility referred to as JFL North at a cost in excess of \$120,000,000.00<sup>3</sup>. JFL North is a state-of-the-art, 54-bed facility designed to replace JFL-Main. This 55,000 sq. ft. facility houses 54 inpatient beds, 14 medical/surgical beds, 13 emergency room beds, 4 fast track beds, 4 behavioral health beds, and 4 operating rooms. While the space is smaller than the current state, JFL-North is also equipped with new and improved technology to include a 128-slice CT machine. However, JFL North is a interim facility to maintain Hospital operations until the Old JFL is demolished and reconstructed. The timeline for the completion of the new permanent structure is 6-7 years once demolition begins.

The Gov. Juan F Luis Hospital also offer a Cardiac Center with a wide range of Acute Care, Ambulatory Care, After Care and Preventative Cardiovascular Services such as:

- Diagnostic Imaging (Endoscopy, Infertility Study, Nuclear Medicine, Open Magnetic Resonance Imaging (MRI), Radiography X-Ray, Ultrasonography, and Women’s Imaging Suite);
- Diagnostic Testing (Electrocardiogram (EKG), Echo, Transesophageal Echo, Dobutamine Echo);
- Cardiac Rehabilitation Services (Exercise Testing, Preventative & Post Myocardial Event Care, Smoking Cessation Assistance, Risk Factor Analysis/Stratification and Reduction, Nutritional Counseling, Exercise Management, Telemetry Monitoring, Weight Loss Assistance Program);

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<sup>3</sup> [www.jflusvi.org](http://www.jflusvi.org)

- Pharmacy (dispensing of prescription medications);
- Emergency Services & Acute Inpatient Care;
- Breast Care, Digestive Diseases, Labor and Delivery, Orthopedics, Cardiac Education, and Vascular Access Program;
- Laboratory and Pathology (Blood Gases, Chemistry/Special Chemistry, Coagulation, Hematology, Microbiology, Therapeutic Drug Monitoring, Transfusion Services, and Urinalysis/Clinical Microscopy): and,
- Anatomic Pathology (Surgical tissues, biopsies, frozen sections, Cytology, bone marrow studies, body fluids and Autopsies.

## 2.2 PHYSICAL SETTING

The site is located at approximately 154 feet above mean sea level. **Figure 1** presents the site location on a portion of the US Geological Service (USGS) Topographical Map. **Figure 2** presents an aerial photograph of the site. The closest superficial water body is the Atlantic Ocean located approximately 2.32 miles to the south of the site (see **ATTACHMENT I**).

## 2.3 SOLID AND HAZARDOUS WASTE GENERATION

From a RCRA perspective, typical hazardous waste which is potentially generated from numerous sources throughout the Gov. Juan F Luis Hospital, could include the following areas:

- Medical Technology Unit
- Nursing Unit
- Hospital Laboratory
- Radioactive/X-rays Unit
- Pharmacy Area
- Laboratory Health Clinic
- Printing Shop (Computer Management)
- Painting Room
- Carpentry
- Microbiology/Biology Research Science Laboratories
- Physical Therapy
- Pathology Unit
- Physical and Maintenance Unit
- Morgue Unit

Potential primarily waste generated and stored at Gov. Juan F Luis Hospital could include corrosives, oxidizers, flammable, poisons, acute hazardous wastes, reactive, waste solvents, compressed gas cylinders, waste paint, and other laboratory chemical wastes. Wastes generated from the building

maintenance unit include waste thinner, waste paint, used oil, spent degreaser, spent fluorescent lamps, and used batteries.

Additionally, the Gov. Juan F Luis Hospital generates large quantities of biomedical (i.e., “Medical Wastes”) regulated waste from its Health Clinic, the Medical Technology, Pharmacy, Nursing Unit, and Laboratories where medical analyses are conducted as part of the medical diagnosis examinations. Accordingly, there is a biomedical waste program in place in which biomedical waste is collected in red plastic canisters properly labeled and stored for final disposition. According to Ms. Encarnacion-Pascal, all wastes including Biomedical, Universal Wastes and Used Oil are disposed of through a contract with VI Regulated Waste.

### 3 FACILITY WALKTHROUGH

Ms. Encarnacion-Pascal and Mr. Denis Lynch II, Facility Manager, accompanied me during the Facility walkthrough. During the Facility walkthrough various medical areas, laboratories and supporting units were inspected as described below. The observations for each area are described below. Refer to **Appendix 1** for pictures taken during the inspection.

#### RCRA INSPECTION DAY 1- SEPTEMBER 6, 2023 (MAIN BUILDING)

##### 3.1 INCINERATOR BUILDING AREA

The first area inspected was the Incinerator Building area which houses two former biomedical waste steel chamber incinerators and two auto sterilization-disinfection units. At the time of the inspection, both steel incinerators were out of service and had been dismantled since they were decommissioned. The two auto sterilization units were out of service and provide a service for collecting, storing, inspecting, packing, and before delivering biomedical waste (see **Picture 1**). Each biomedical waste in red plastic bags is transferred into DOT boxes which requires that boxes are arrowed up, no packed on the side, and placed containers on a poly sheet to avoid contact with warehouse floor. Biomedical wastes are packed every two weeks before they are picked up by VI Regulated Waste (see **Picture 2**).

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

##### 3.2 HOSPITAL BACKYARD AREA

I proceeded to inspect the Backyard Area of the Hospital since most of the domestic waste are accumulated and stored in this area. As observed, there was one (1) 20-cubic yard dumpster containing domestic Hospital wastes (see **Picture 3**). Nearby the dumpster, there was one (1) 330-gallon tote containing hand sanitizer that was donated to the JFL Hospital during the COVID-19 pandemic (see **Picture 4**). According to Ms. Encarnacion-Pascal, the hand sanitizer was in use until three (3) months ago that was decommissioned and moved to this location for disposal. As observed, the tote seemed like being abandoned and identified with its hazard communication pictogram as, “Flammable Liquids.” I explained to Ms. Encarnacion-Pascal, if a VSQG accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste limits, all quantities of that hazardous waste are subject to additional conditions for exemption and independent requirements such labeling with the words,

“Hazardous Waste,” and dated with its accumulation start date, and be held on site for no more than 180 days. Nearby the hand sanitizer tote, there was another 275-gallon tote containing discarded cooking oil and grease from JFL Hospital kitchen. I was told that it will be disposed of as non-hazardous waste with VI Regulated Waste (see **Picture 5**).

### **3.3 UNIVERSAL WASTE STORAGE AREA (FACILITY MANAGEMENT ROOM)**

I proceeded to inspect the Universal Waste Storage area located at the Facility Management Room where all new and spent bulbs and fluorescent lamps are stored. In this area I observed the following:

- Forty (40) loose 4-foot spent fluorescent lamps inside a white plastic bin and placed on top of some cardboard boxes, not labeled as “Universal Waste,” or dated (see **Picture 6**).
- One (1) cardboard box with twenty-one (21) 4-foot spent fluorescent lamps, open, not labeled as “Universal Waste,” or dated (see **Picture 7**).

At the time of the Inspection, I observed a white plastic bin (approximate 2 gal) with some spent 4-foot fluorescent lamps, and other lamps placed on top of other cardboard boxes without any kind of protection from breakage (see **Picture 8**). In addition, individually packed and loose spent lamps were observed placed over the floor and on top of other boxes. I expressed the following concerns on the situation, many of these waste lamps could break when moved inside the bin, and the loose ones that were placed over the cardboard boxes, could fit between the gaps of the boxes, fall and break. Ms. Encarnacion-Pascal inquired about EPA recommended/approved method(s) to accumulate “Waste Lamps.” As a result, I indicated, that EPA requires universal waste generators to accumulate waste lamps in a way that prevents breakage and releases of hazardous constituents. Then, she asked if cardboard boxes were more appropriate, and indicated that it is the widely used method. She indicated that spent fluorescent lamps will be packed in appropriate cardboard boxes, labeled with the words, “Waste Lamps” and dated with its accumulation date.

According to Ms. Encarnacion-Pascal, all Universal Wastes are disposed of through a contract with VI Regulated Waste.

### **3.4 PAINTING ROOM AREA**

I proceeded to inspect the Painting Room area which is in the central area of the Facility, where maintenance personnel store parts, tools, and equipment. In this area I observed, around five (5) 5-gallon paint pails and four (4) 1-gallon paint containers. According to Ms. Encarnacion-Pascal, all paints stored in this room are used by the maintenance personnel.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.5 RADIOLOGY DIAGNOSTIC IMAGING AREA (MAIN BUILDING)**

I proceeded to inspect the Radiology Diagnostic Imaging area where X-rays negative and silver recovery process were performed in the past. In this area, the X-ray silver film used to be developed by means of a solvent, a fixer, and a washing and drying process in a closed loop system was decommissioned and

dismantled. In addition, film developing wastewaters that used to be treated on-site using an electrolytic silver recovery unit was removed. Treated wastewater that used to go directly to a sink pipeline which discharges directly to the sewage system was disconnected. According to Ms. Encarnacion-Pascal, the old X-rays developing system was discontinued a long time ago, and all chemical regents were returned to the supplier in Puerto Rico. There was not any recovery system for the silver, and no information on how much and for how long the silver waste was generated and disposed of. At the time of the Inspection, this area was updated and used computer aided X-ray imaging, but based on the upcoming main building demolition project, this area is discontinued and moved to JFL North Building (see **Picture 9**).

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.6 LABORATORY HEALTH CLINIC AREA (MAIN BUILDING)**

I proceeded to inspect the Laboratory Health Clinic area located in the JFL Hospital Main Building which used to conduct chemistry analytical tests including chemical, spectrophotometric, immunochemical and immunoassay analysis. In addition, the laboratory conducted microbiology analysis to identify organisms causing disease, and determine appropriate antibiotics for treatment, and therapeutic drugs. Other biological analysis included bacteria culture, pathology, chemical clinic, biochemistry, coagulation, and ortho-clinical diagnosis. At the time of the Inspection, the Laboratory Health Clinic has been closed and moved to JFL North Building due to the upcoming main building demolition project.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.7 MORGUE AREA (MAIN BUILDING)**

I proceeded to inspect the Morgue area located in the JFL Hospital Main Building. At the time of the Inspection, the Morgue has been closed and moved to JFL North Building due to the upcoming main building demolition project.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.8 LABORATORY STORAGE ROOM (MAIN BUILDING)**

I proceeded to inspect the Laboratory Storage Room where all chemical reactants and clinical test are stored in shelves and cabinets. At the time of the Inspection, the Laboratory Storage Room has been closed and moved to JFL North Building due to the upcoming main building demolition project.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### 3.9 PHARMACY AREA (MAIN BUILDING)

I proceeded to inspect the inpatient Pharmacy Area located in the Main Building of Gov. Juan F Luis Hospital. I was informed by the Ms. Encarnacion-Pascal that a large inventory of medicines is stored and delivery to outpatients or patients hospitalized at the JFL Hospital. As explained by Ms. Laura Forbes, Chief Pharmacist, the pharmacy generates off-specification and outdated medicines and are managed under a creditable medicine and/or pharmaceutical waste program to receive manufacturer credit and a reverse distributor provider that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered under the program (see **Picture 10**). These off-specification medicines are generated in large amounts (e.g., depending on the need and usage), and are “lab packed” for final reverse credit as non-hazardous pharmaceutical waste. Ms. Forbes said that Hospital reverse distributor is Pharm Link, Inc. located at 8285 Bryan Dairy Road, #160, Largo, Florida 33777 (see **Picture 11**).

The only concerns raised by the Inspector was that many of the off-specifications medicines (i.e., chemotherapy solutions) should be managed as hazardous waste since they contained hazardous chemicals as principal active ingredients. Ms. Forbes stated that the JFL Hospital does not managed much chemotherapy drugs and any expired or outdated medicines are returned to the vendor for medicine credits in Florida on a monthly basis. Among the chemotherapy drugs managed by the program included:

- Mitomycin (CAS# 50-07-7) - is a cytotoxic agent that belongs to the group of medicines known as antineoplastics. It is used to treat some kinds of cancer. The material and its container must be disposed of as hazardous waste (RCRA Hazardous Waste Code U010) (see **Picture 12**).
- Cyclophosphamide (CAS# 50-18-0) - is used to treat cancer of the ovaries, breast, blood and lymph system, and nerves (mainly in children). Cyclophosphamide is also used for retinoblastoma (a type of eye cancer mainly in children), multiple myeloma (cancer in the bone marrow), and mycosis fungoides (tumors on the skin). The material and its container must be disposed of as hazardous waste (RCRA Hazardous Waste Code U058) (see **Picture 13**).
- Methotrexate (CAS# 59-05-2) - known as amethopterin, is a chemotherapy agent and immune-system suppressant. It is used to treat cancer, autoimmune diseases, and ectopic pregnancies. (RCRA Hazardous Waste as “Toxic Solid Organic”).
- Chemotherapy Sharp Yellow Container – Used syringes, needles, and chemotherapy agent vials must be thrown away in a “sharps” one (1) 1-gallon yellow container. All syringes, needles, vials, alcohol swabs, and bandages that have come in contact with chemotherapy agents or with blood or body fluid are “Hazardous Pharmaceutical Waste,” Hazardous Wastes,” and/or “Chemotherapy Waste,” (see **Picture 14**).

I explained to Ms. Forbes and Ms. Encarnacion-Pascal that Healthcare facilities that are VSQGs when factoring in both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to opt into 40 CFR Subpart P for the management of their hazardous pharmaceutical waste

pursuant to 40 CFR Part §266.504. These facilities may also choose to manage all their hazardous waste (pharmaceutical and non-pharmaceutical) in accordance with 40 CFR Part §262.14.

In addition, a healthcare facility does not have to count its hazardous waste pharmaceuticals (that are subject to or managed in accordance with Subpart P) when determining its generator category as per 40 CFR Part §262.13(c)(9). As a result, a healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste.

Ms. Forbes replied that JFL Hospital does not manage much chemotherapy drugs as pharmaceutical wastes, instead expired or outdated medicines are returned to the vendor for medicine credits with Pharm Link, Inc. Other pharmaceutical wastes (e.g., sharp containers) are managed as “Medical Wastes.” She added that chemotherapy drugs are collected by Adcon Environmental, LLC. located at 9K Estate Cottage, Christiansted, USVI.

As observed, there was an extractor hood area where medicines are prepared and mixed that collected all chemical fumes in its internal filters. Ms. Forbes was asked about the procedures to dispose of spent filters. She replied that this job is contracted out, and that the contractor replaces that spent filters every six months. It was unknown if the spent filters were disposed of as biomedical waste.

## **RCRA INSPECTION DAY 1- SEPTEMBER 6, 2023 (JFL NORTH BUILDING)**

### **3.10 LABORATORY HEALTH CLINIC AREA (JFL NORTH)**

I proceeded to inspect the Laboratory Health Clinic area located in the JFL North Main Building which conducts chemistry analytical tests including chemical, spectrophotometric, immunochemical and immunoassay analysis. In addition, the laboratory conducts microbiology analysis to identify organisms causing disease, and determine appropriate antibiotics for treatment, and therapeutic drugs. Other biological analysis included bacteria culture, pathology, chemical clinic, biochemistry, coagulation, and ortho-clinical diagnosis.

Biology Clinic Laboratory - As part of the laboratory activities, culture and blood samples are processed and tested. Solid waste generation include alcohol/acetone swabs, needles, and syringes.

Chemical Clinic Laboratory - Chemical clinic laboratory performs chemical analysis for blood test, dermatology test, pathology test, steroid, and hormones specialty tests.

Ortho-Clinical Diagnosis - Ortho-Clinical Diagnosis laboratory performs chemical analysis for serology are run to scientifically study the antibodies in the serum and other bodily fluids.

At the time of the Inspection, I observed that following:

- Chemotherapy Sharp Yellow Container – Used syringes, needles, and chemotherapy agent vials are thrown away in a “sharps” one (1) 1-gallon yellow container. All syringes, needles, vials, alcohol swabs, and bandages that have come in contact with laboratory tests or with blood or body fluid are disposed of as, “Medical Wastes.”

- Biomedical Red Containers - According to Ms. Encarnacion-Pascal, solid wastes are disposed of as Medical Wastes using biohazard plastic bags and red containers for sharp discarded objects (i.e., needles) (see **Picture 15**).

At the time of the Inspection Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.11 LABORATORY STORAGE ROOM (JFL NORTH)**

I proceeded to inspect the Laboratory Storage Room located at JFL North Building where all chemical reactants and clinical test are stored in shelves and cabinets. All chemical reactants were clearly identified, and stored, and seemed in good conditions (see **Picture 16**).

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

### **3.12 MORGUE AREA (JFL NORTH)**

I proceeded to inspect the morgue area located at JFL North Building. As the Inspector explained to Ms. Encarnacion-Pascal, formaldehyde (RCRA Hazardous Waste Code U122) solutions are essential for the proper preservation and fixation of tissue specimens, however, the daily disposal of formaldehyde has become a problem because of the toxic effects and potential cancer risk associated with prolonged exposure to formaldehyde. It was learned that formaldehyde (i.e., RCRA U122) solution is dumped through the sink by the clinic analyst at the Morgue.

According to Ms. Encarnacion-Pascal, tissues and other human organs are disposed of as Medical Wastes using biohazard plastic bags and red containers for sharp discarded objects (i.e., needles).

## **RCRA INSPECTION DAY 2- SEPTEMBER 8, 2023 (MAIN BUILDING)**

### **3.13 UNIVERSAL WASTE STORAGE AREA (FACILITY MANAGEMENT ROOM)**

I proceeded to inspect the Universal Waste Storage area located at the Facility Management Room located at the Main Building where all new and spent bulbs and fluorescent lamps were observed without means of protection or properly labeled. At the time of the Inspection, I observed the following:

- Three (3) cardboard boxes with 4-foot spent fluorescent lamps clearly labeled as “Universal Waste,” and all dated on May 1, 2023 (see **Picture 17**).
- All spent 4-foot florescent lamps placed on top of other cardboard boxes without any kind of protection from breakage were packed in 4-foot cardboard boxes (see **Picture 18**).

According to Ms. Encarnacion-Pascal, all “Universal Wastes” are disposed of through a contract with VI Regulated Waste.

### **3.14 HOSPITAL BACKYARD AREA**

I proceeded to inspect the Backyard Area of the Hospital since most of the domestic waste are accumulated and stored in this area. At the time of the Inspection, I observed the following:

- One (1) 330-gallon tote containing “Discarded Hand Sanitizer” clearly labeled with the words, “Hazardous Waste,” coded as D001, identified with its hazard communication pictogram as, “Flammable Liquids,” and dated with its accumulation start date of May 30, 2023 (see **Pictures 19 and 20**).

According to Ms. Encarnacion-Pascal, all “Hazardous Wastes” are disposed of through a contract with VI Regulated Waste.

## **4 DOCUMENTS REVIEW**

The following documents were reviewed as required by the RCRA Program after the walkthrough Inspection and on a follow-up Inspection on September 8, 2023:

### **4.1 MANIFEST RECORDS AND LAND DISPOSAL RESTRICTION FORMS (LDR)**

Manifests and associated LDRs for all incoming and outgoing shipments for the last three years were reviewed in hard copies. Most of the manifest were associated with the biomedical wastes, sharp needles medical wastes, universal wastes, and twice a year used oil disposals. According to Ms. Encarnacion-Pascal, all wastes including Biomedical Wastes, Universal Wastes and Used Oil are disposed of through a contract with VI Regulated Waste.

### **4.2 PERSONNEL TRAINING RECORDS**

The Facility provided a Record of Training for the personnel associated with the management of hazardous waste. The training record indicated that most of the personnel associated with the management of hazardous wastes have taken “8-Hrs. Hazardous Annual Refresher Training” on a yearly basis, and some OSHA 30-Hrs. “General Industry Standards Training.” I strongly recommended to take some additional training directly related to “RCRA Hazardous Waste Management Course.” After a thorough review of training requirements for a VSQG, it appeared to be properly maintained and in compliance.

### **4.3 CONTINGENCY AND EMERGENCY PLAN**

There was a Contingency Plan, dated 2023, which outlines the procedures and activities required for the prevention of, and respond to an emergency incident at the JFL Hospital. The plan also provided a list of names and telephones in case of an emergency and proper procedures in a case of an emergency. Additionally, the Facility was equipped with alarm systems, sprinkler systems, telephones, certified extinguishers in most areas of the JFL Hospital. All appeared to be properly maintained and in compliance.

## 5 CLOSING MEETING

After completion of the walkthrough and document review, I met with Mr. Douglas E. Koch, Chief Executive Officer, Ms. Hazel Philbert, Chief Operating Officer, Ms. Laura Encarnacion-Pascal, and Mr. Denis Lynch II, Facility Manager, all from Gov. Juan F Luis Hospital. I indicated that the purpose of the closing meeting is to inform the Facility's representatives about the RCRA observations. I indicated based on the RCRA requirements for a Very Small Quantity Generator there were concerns that needed to be addressed in order to reach a full compliance determination of the RCRA program. On September 6 and 8, 2023, I discuss the following EPA's observation:

**EPA's Observation No. 1: As required for all Very Small Quantity Generators (VSQG) and be exempted from other RCRA requirements, VSQG must clearly label with the words, "Hazardous Waste," code and identified with its hazard communication pictogram all drums and containers holding hazardous wastes pursuant to 40 CFR §262.14.**

At the time of the Inspection, I observed one (1) 330-gallon tote containing hand sanitizer that was donated to the JFL Hospital during the COVID-19 pandemic and abandoned at the Backyard of the JFL Hospital. As explained, if a VSQG accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste limits, all quantities of that hazardous waste are subject to additional conditions for exemption and independent requirements such labeling with the words, "Hazardous Waste," and dated with its accumulation start date, posting hazard communication pictogram and be held on site for no more than 180 days.

**Gov. Juan F Luis Hospital's Response:** On September 8, 2023, the 330-gallon tote containing "Discarded Hand Sanitizer" was clearly labeled with the words, "Hazardous Waste," coded as D001, identified with its hazard communication pictogram as, "Flammable Liquids," and dated with its accumulation start date of May 30, 2023, as required by RCRA program.

**EPA's Observation No. 2: According to 40 CFR §273.13(d), a small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions. Also, pursuant to 40 CFR § 40 CFR 273.14(e) each lamp or a container or package in which such lamps are contained must be labeled or marked clearly with one of the following phrases: "Universal Waste—Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)".**

At the time of the Inspection, I observed approximately forty (40) loose 4-foot spent fluorescent lamps inside a white plastic bin and placed on top of some cardboard boxes, not labeled as "Universal Waste," or dated, and one (1) cardboard box with twenty-one (21) 4-foot spent fluorescent lamps, open, not labeled as "Universal Waste," or dated.

**Gov. Juan F Luis Hospital's Response:** On September 8, 2023, all spent 4-foot fluorescent lamps placed on top of other cardboard boxes without any kind of protection from breakage were packed in three (3) 4-foot cardboard boxes clearly labeled as "Universal Waste," and all dated on May 1, 2023.

**EPA’s Observation No. 3: Management of Chemotherapy Drugs as required under 40 CFR §266.504 for healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.**

I explained that healthcare facilities that are VSQGs when factoring in both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to opt into 40 CFR Subpart P for the management of their hazardous pharmaceutical waste pursuant to 40 CFR Part §266.504. These facilities may also choose to manage all their hazardous waste (pharmaceutical and non-pharmaceutical) in accordance with 40 CFR Part §262.14.

In addition, a healthcare facility does not have to count its hazardous waste pharmaceuticals (that are subject to or managed in accordance with Subpart P) when determining its generator category as per 40 CFR Part §262.13(c)(9). As a result, a healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste.

**Gov. Juan F Luis Hospital’s Response:** JFL Hospital does not managed much chemotherapy drugs as hazardous pharmaceutical wastes, instead expired or outdated medicines are returned to the vendor for medicine credits, however this program should be reevaluated.

**EPA’s Observation No. 4: Formaldehyde solutions a RCRA Hazardous Waste Code U122 management and disposal at the Morgue Area.**

I stated that formaldehyde solution a RCRA Hazardous Waste Code U122 is essential for the proper preservation and fixation of tissue specimens, however, the daily disposal of formaldehyde has become a problem because of the toxic effects and potential cancer risk associated with prolonged exposure to formaldehyde. It was learned that formaldehyde (i.e., RCRA U122) solution is dumped through the sink by the clinic analyst at the Morgue.

**Gov. Juan F Luis Hospital’s (BSC) Response:** According JFL Hospital, tissues and other human organs are disposed of as Medical Wastes using biohazard plastic bags and red containers for sharp discarded objects (i.e., needles), therefore this disposal practice should be evaluated at the Morgue area.

## **6 COMPLIANCE ASSISTANCE**

The EPA inspector discussed with Gov. Juan F Luis Hospital’s representatives the specific RCRA program regulations pursuant 40 CFR §262.14, “Conditions for Exemption for a Very Small Quantity Generator, (<https://www.ecfr.gov/current/title-40/section-262.14>) that apply to the Facility, and how to stay in compliance in case they decide to minimize or recover waste streams and implement waste minimization/pollution prevention procedures as required by RCRA.

## **7 CONCLUSION & FOLLOW-UP ACTIONS**

After responding to EPA’s observations, inspection of regulated areas and completion of a document session, EPA determined that the hazardous waste management program at Gov. Juan F Luis Hospital Dorado (Guidant) was not satisfactory since they did not comply with this requirement of several “waste

lamps” (i.e., universal waste lamps) that were placed over a boxes and plastic bins unpacked. In addition, cardboard boxes and lose spent lamps were not labeled as “Waste Lamps.” In addition, JFL Hospital failed to properly label with the words, “Hazardous Waste,” and date with its accumulation start date a container holding hazardous waste at Facility’s Backyard.

## **8 ENFORCEMENT ACTIONS**

Based on the information presented above, it is recommended the following enforcement action:

1. A RCRA §§3007, 3008 Information Request and Notice of Violation Letter, would be issued to the Facility to inquiry about the management of hazardous and/or pharmaceutical waste programs and comply with universal waste rule and exemption condition requirements for very small quantity generator hazardous waste.

## **9 ATTACHMENTS**

- I. Figure 1- Facility Location Map and Figure -2 Aerial Photograph
- II. Photolog and Camera Roll (include all pictures taken during the inspection)