

RCRA Inspection Report

1) Inspector and Author of Report

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U.S. Environmental Protection Agency, Region 4
Enforcement and Compliance Assurance Division
Chemical Safety and Land Enforcement Branch
RCRA Enforcement Section
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2) Facility Information

Vanderbilt Center for Neuroscience
Drug Discovery
393 Nichol Mill Lane
Franklin, Tennessee 37067

EPA ID#: TNR000038760
NAICS #: 54171 – Research and Development
in the Physical, Engineering, and Life Sciences

3) Responsible Officials

Kevin Warren
Director, Environmental Health & Safety
Kevin.Warren@vumc.org

4) Inspection Participants

Bruce Melancon, Vanderbilt Center for
Neuroscience Drug Discovery
(VCNDD)
Paul Spearing, VCNDD
Daniel Haymer, VCNDD
Alison Gregro, VCNDD

Al Majors, Tennessee Department of
Environment and Conservation (TDEC)
Michael Horsley, TDEC
Lucas McKinney, TDEC
Kayla Acosta, U.S. Environmental Protection
Agency (USEPA)

5) Date of Inspection

July 13, 2023 at 9:00 am.

6) Applicable Regulations¹

Resource Conservation and Recovery Act (RCRA) Sections 3002 (42 U.S. Code – Annotated U.S.C.A. 6925 and 6927), and 40 Code of Federal Regulation (C.F.R.) Parts 260 - 270, 273, 278, & 279; Tennessee Hazardous Waste Management Act of 1977, Tennessee Code Annotated (Tenn. Code Ann.) § 68-212-101 *et seq.*, and Chapter 0400-12-01 of the Rules and Regulations of the State of Tennessee (Tenn. Comp. R. & Regs.)

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10], a large quantity generator of hazardous waste (LQG) is a generator who generates greater than or equal to 1,000 kilograms (2,200 pounds) of non-acute hazardous waste in a calendar month.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)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 any

¹ As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions will be to the authorized State program. However, for ease of reference, the federal citations will follow in brackets.

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 Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1. [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(g)2. or 0400-12-01-.03(1)(h)1. [40 C.F.R. § 262.16(b) or § 262.17(a)], except as required in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1.(vii and viii) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in Ten Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1. [40 C.F.R. § 262.15(a)] (hereinafter referred to as the “SAA Permit Exemption”).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h) [40 C.F.R. § 262.17], an LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h) [40 C.F.R. § 262.17] (hereinafter referred to as the “LQG Permit Exemption”).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(1)(i) [40 C.F.R. § 273.9], a small quantity handler of universal waste (SQHUW) is a universal waste handler who does not accumulate 5,000 kilograms or more of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or aerosol cans, calculated collectively) at any time.

7) Purpose of Inspection

The purpose of this inspection was to conduct an unannounced compliance evaluation inspection to determine Vanderbilt Center for Neuroscience Drug Discovery’s compliance with the applicable requirements of RCRA and the corresponding Tennessee regulations. This was an EPA lead inspection.

8) Facility Description

Vanderbilt Center for Neuroscience Drug Discovery (known herein after as “VCNDD” or “facility”) is a research and drug discovery facility. VCNDD is associated with Vanderbilt University but is now operating independently of the university. VCNDD specializes in developing therapeutics for serious brain disorders. The laboratory conducts drug discovery activities, medicinal chemistry, and pharmacology. The research areas of focus include Alzheimer’s Disease, Parkinson’s Disease, and Schizophrenia. Research scientists are divided into four discovery team categories which include medicinal chemistry, molecular pharmacology and biology, drug metabolism and pharmacokinetics, and behavioral pharmacology.

VCNDD has been operating at this location since 2014. The facility operates one shift, Monday-Friday with limited activity occurring on Saturday and Sunday, from 9:00 am to 5:00 pm. In total, there are 65 employees and 42 employees specifically working in the chemistry laboratory. The front entrance to the facility is a controlled access door.

The facility has been operating as a Large Quantity Generator (LQG) of hazardous waste since October 17, 2014, and most recently submitted its notification of regulated waste activity to TDEC on February 24, 2023. Hazardous waste generated at the facility include ignitable waste (D001), corrosive waste (D002), mercury waste (D009), chloroform waste (D022), dichloroethylene waste (D028), pyridine waste (D038), halogenated solvents (F002), non-

halogenated solvents (F003 & F005), cyanide waste (P030), and potassium cyanide waste (P098). Since the facility leases space in the building, lighting is managed by the building owner. Most of the facility uses LED lighting. The facility also occasionally generates a small amount of spent alkaline batteries that are recycled.

9) **Previous Inspection History**

TDEC has conducted one RCRA CEI at the subject facility between 2018 and 2023. On January 16, 2020, TDEC conducted the most recent RCRA CEI at the subject facility and found one apparent violation of RCRA's requirements for not marking hazardous waste containers stored in the 90-day central accumulation area (CAA) with an accumulation start date. The apparent violation was corrected onsite.

10) **Opening Conference**

On July 13, 2023, EPA inspector Kayla Acosta, accompanied by Tennessee inspectors Al Majors, Michael Horsley, and Lucas McKinney, arrived at VCNDD at approximately 8:50 am. Bruce Melancon, Senior Director for Medicinal Chemistry, immediately received the inspectors. Bruce and the inspectors were joined by Paul Spearing, Associate Director of Safety and Daniel Haymer, Junior Safety Officer for the opening conference. The inspectors introduced themselves, showed their credentials to the facility representatives, and explained the purpose of the visit.

The inspectors described the anticipated use of equipment (digital camera) during the inspection and provided a request for records. The EPA inspector explained that the Small Business Regulatory Enforcement Fairness Act's classification of a "small business" is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. A copy of the EPA's information sheet for small businesses can be found at <https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf>. The EPA inspector also discussed the company's ability, pursuant to 40 C.F.R. § 2.203, to assert a business confidentiality claim for information submitted to EPA. The company did not assert a business confidentiality claim.

Bruce Melancon provided an overview of the facility's history and current operations during the opening conference. The inspection participants also discussed health and safety protocols and required personal protective equipment before Facility representative led the inspectors on a tour of the Facility operations.

11) **Inspection Observations**

Purification Bay with Satellite Accumulation Areas (SAA):

The facility manages a SAA in the Purification Bay for ignitable and toxic liquids and used vials that are generated by the 18 chromatography instruments in this area. The chromatography instruments are used to purify components in the chemistry laboratory. Each instrument has its own SAA. The inspectors observed 27 5-gallon containers of hazardous waste (Photos 1-7). All of the containers were closed, labeled with the words "hazardous waste", and were labeled with the word "flammable" or both "flammable and toxic" to indicate the hazard of the contents.

Chemistry Laboratory with SAAs:

The chemistry laboratory consists of approximately six (6) bays that contain 2-4 workstations with fume hoods. Each bay contains an SAA for non-halogenated solvent waste (stored in containers with red colored lids) and halogenated solvent waste (stored in containers with yellow-colored lids). Each bay also has a 20-gallon red container for flammable, toxic solids (Photos 8 and 9). Each workstation contains an SAA in the fume hood for additional flammable wastes varying in size from 1 quart to 1-gallon containers. At this time the inspectors were joined by Alison Grego, Senior Safety Officer. The inspectors observed the following hazardous wastes:

- Five (5) 5-gallon containers of halogenated waste. The containers were closed, labeled "Hazardous Waste", and labeled "flammable liquid toxic" to indicate the hazard of the content.
- Five (5) 5-gallon containers of non-halogenated waste. The containers were closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- One (1) 5-gallon container of selenium dioxide waste. The container was closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- One (1) 5-gallon container of palladium waste. The container was closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- (16) 20-gallon red containers of flammable solid waste. The containers were closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- Two (2) quart-sized containers of solvent waste. The containers were closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- Five (5) one-gallon containers of filter paper waste. The containers were closed, labeled "Hazardous Waste", and labeled "flammable" to indicate the hazard of the content.
- (29) one-gallon red containers of syringes and needles waste. The containers were closed, labeled "Hazardous Waste", and labeled "DOT Hazard Class:09". The DOT Hazard Class 09 label indicates a miscellaneous material and does not indicate the hazards of the content such as ignitable, corrosive, toxic, or reactive (Photo 10).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)(1)(v)(ii) [40 C.F.R. § 262.15(a)(5)(ii)], a generator must mark or label its container 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 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).

In workstation B316, the inspectors observed one gallon-sized closed container with material inside but no label (Photo 11). The facility representatives stated the contents of the container was a paper towel contaminated with phenylhydrazine resulting from a small spill at the workstation.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)(1)(v)(i & ii) [40 C.F.R. § 262.15(a)(5)(ii)], a generator must mark or label its container with the following: (i) The

words “Hazardous Waste” and (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 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).

The facility representatives immediately had the employee working at this workstation label the container and mark it with an indication of the hazard contents (Photo 12).

SFC Chromatography with SAAs:

This area stores superfluid chromatography instruments for laboratory analysis. Each instrument has its own SAA (Photos 13 and 14). The inspectors observed seven (7) 5-gallon containers of hazardous waste. Each container was closed, labeled with the words “hazardous waste”, and labeled with flammable, or flammable toxic to indicate the hazard of the contents.

90-Day Central Accumulation Area (CAA):

The facility manages a hazardous waste CAA in an enclosed room outside of the Chemistry Laboratory and next to the Recycling Center where the facility collects paper, cardboard, plastics, and aluminum to be recycled. The CAA was identified with a sign which read “Chemical Waste”. The facility manages ignitable waste in this CAA, and the inspectors observed a “No Smoking” sign on the wall at the entrance of the Chemical Waste room. The CAA is equipped with an alarm system capable of providing immediate emergency instruction to facility personnel and is equipped with fire control equipment. The room also has spill control equipment, decontamination equipment, and equipped with a water spray system. Inspectors observed the following hazardous waste (Photos 15-20):

- 16 5-gallon containers of hazardous waste, labeled “Hazardous Waste”, dated, closed, and marked with indication of the hazard of the contents.
- Four (4) 55-gallon containers of hazardous waste, labeled “Hazardous Waste”, dated, closed, and marked with indication of the hazard of the contents.
- Three (3) one-gallon containers of hazardous waste, labeled “Hazardous Waste”, dated, closed, and labeled "DOT Hazard Class:09". The DOT Hazard Class 09 label indicates a miscellaneous material and does not indicate the hazards of the content such as ignitable, corrosive, toxic, or reactive.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)(1)(v)(I)(II) [40 C.F.R. § 262.17(a)(5)(i)(B)], a generator must mark or label its container 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 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).

The oldest hazardous waste container was dated 6/12/23. The facility appears to be compliant with the 90-day storage limit.

12) **Records Review**

Contingency Plan and Quick Reference Guide (QRG):

The actions that facility personnel should take in response to an emergency are described in the facility's Hazardous Waste Emergency Preparedness and Response Plan, which was last updated on October 24, 2019. The plan describes actions facility personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility. The plan describes arrangements agreed to with the fire department. The plan lists the names and emergency telephone numbers for persons identified as emergency coordinators. Craig Lindsley is listed as the primary emergency coordinator, and Alison Gregro and Nathan Kett as alternates.

The plan includes a list of all emergency equipment at the facility. The list includes fire extinguishing systems, spill control equipment, communications and alarm systems, and decontamination equipment. The list appears to be up to date. The plan includes the location and a physical description of each item on the list, and a brief outline of its capabilities. The plan does not include an evacuation plan for personnel. This plan should include signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(12)(i)(6) [40 C.F.R. § 262.261(f)], the plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

A copy of the Hazardous Waste Emergency Preparedness and Response Plan was most recently submitted electronically to the fire department on February 19, 2023. The plan did not include a quick reference guide.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(12)(j)(2) [40 C.F.R. § 262.262(b)] a large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee. The required contents of the quick reference guide are specified in Tenn. Comp. R. & Regs. 0400-12-01-.03(12)(j)(2) [40 C.F.R. § 262.262(b)].

Training Records:

The inspectors reviewed facility job descriptions and employee names that were provided for laboratory scientists and the senior safety officer. Each description included the requisite skill, education, or other qualifications, and duties of facility personnel assigned to that position. The facility uses an online training and tracking system through Vanderbilt University which demonstrates the type and amount of both introductory and continuing training to be given to

each person filling the positions listed above. The inspectors reviewed records of employee hazardous waste training completed in January 2023 for Alison Gregro, Darren Engers, and Patrick McKinney.

Waste Manifest and Land Disposal Restriction (LDR) Records:

The inspectors reviewed available hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent since between 2020-2023. Hazardous waste manifest records show that hazardous waste is routinely shipped to Safety-Kleen Systems, Inc. (EPA ID KYD053348108) and Clean Harbors El Dorado, LLC (EPA ID ARD069748192), and the most recent shipment was made on July 10, 2023.

Weekly Inspection Records:

The inspectors reviewed the facility's available records of inspections of the hazardous waste central accumulation area (CAA) since 2020. There were six (6) instances where inspections were conducted over a week (seven days) apart:

01/10/2023—01/18/2023	05/15/2023-05/23/2023
02/07/2023—02/15/2023	05/23/2023—05/23/2023
03/22/2023-03/30/2023	05/31/2023—06/06/2023

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)(1)(i)(v)[40 C.F.R. § 262.17(a)(1)(v)] at least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(1)(ii) of this section for remedial action required if deterioration or leaks are detected.

Annual Reports:

The facilities annual reports were available for review.

Hazardous Waste Reduction Plan:

The facility has not been updating their plan on an annual basis as required by the state.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(6)(a)(1), except for very small quantity generators who remain very small quantity generators for all 12 months of the calendar year, all generators shall complete a hazardous waste reduction plan in accordance with the requirements of subparagraph (b) of this paragraph. After completion of a plan, the generator shall maintain a current copy of the plan at the generating facility. The plan and the annual progress reports under subparagraph (c) of this paragraph shall be made available, upon request, to a representative of the department at any reasonable time. The department may make use of the information as it deems necessary to carry out its duties under this rule.

13) **Closing Conference**

The inspectors conducted the exit meeting with Alison Gregro. During this meeting, the inspectors stated their preliminary conclusions of the inspection.

14) **List of Appendices**

Appendix 1 – Photo Log:

15) **Signed**

KAYLA ACOSTA

Digitally signed by KAYLA

ACOSTA

Date: 2023.08.21 08:49:43 -04'00'

Kayla Acosta
Physical Scientist

16) **Concurrence**

ARACELI CHAVEZ

Digitally signed by ARACELI

CHAVEZ

Date: 2023.08.21 09:23:14 -04'00'

Araceli B. Chavez
Chief
RCRA Enforcement Section

Appendix 1 – Photo Log

[20] Photos taken on: July 13, 2023

Photos taken by: Kayla Acosta

Photos taken with: Canon PowerShot Elph 180

EPA Property Tag: S/N 902063018726



Photo 1: 5-gallon SAA containers in the Purification Bay for each chromatography instrument.



Photo 2: 5-gallon SAA containers in the Purification Bay for each chromatography instrument.



Photo 3: 5-gallon SAA container in the Purification Bay for each chromatography instrument.



Photo 4: 5-gallon SAA containers in the Purification Bay for each chromatography instrument.

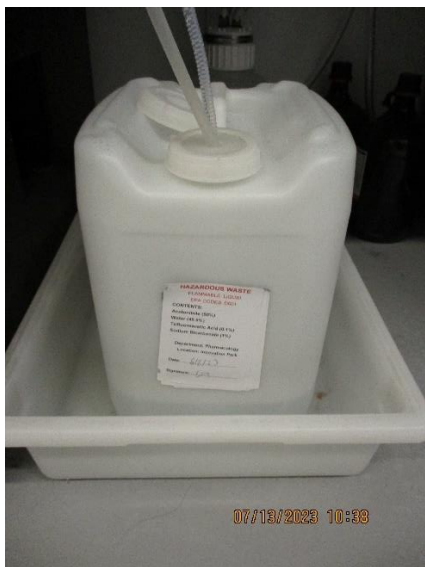


Photo 5: 5-gallon SAA container in the Purification Bay for each chromatography instrument.



Photo 6: 5-gallon SAA container in the Purification Bay for contaminated vials.



Photo 7: 5-gallon SAA containers in the Purification Bay for each chromatography instrument.



Photo 8: Chemistry Laboratory: Each bay contains a 5-gallon SAA for non-halogenated solvent waste (containers with red colored lids) and halogenated solvent waste (containers with yellow-colored lids). Each bay also has a 20-gallon red container for flammable, toxic solids.



Photo 9: In the Chemistry Lab, each bay also has a 20-gallon red container for flammable, toxic solids.



Photo 10: In the Chemistry Lab, each hood has a one-gallon container of waste syringes and needles. The containers were labeled "DOT Hazard Class:09".



Photo 11: In the Chemistry Lab, in workstation B316, the inspectors observed one gallon-sized closed container with material inside but no label (Photo 11).

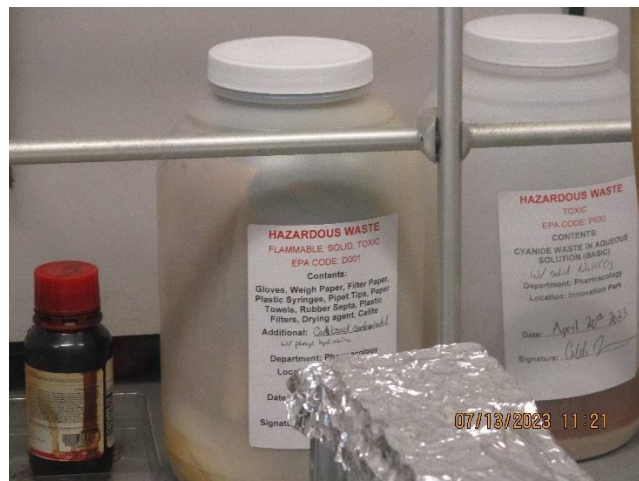


Photo 12: Unlabeled container in workstation B16 labeled and marked with an indication of the hazard contents (Photo 12).

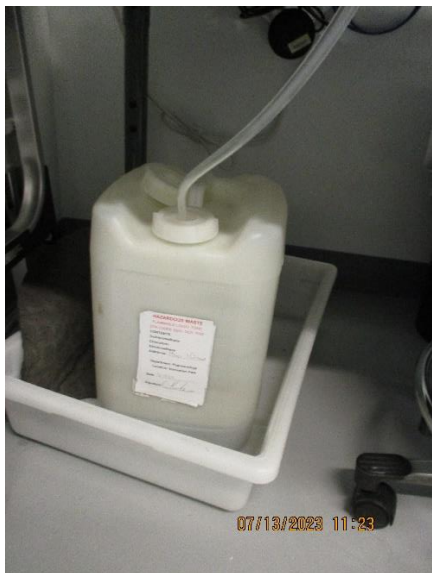


Photo 13: In the SFC Chromatography area, a 5-gallon SAA for each instrument. Each container was closed, labeled with the words “hazardous waste” and labeled toxic to indicate the hazard of the contents.



Photo 14: In the SFC Chromatography area, a 5-gallon SAA for each instrument. Each container was closed, labeled with the words “hazardous waste” and labeled toxic to indicate the hazard of the contents.

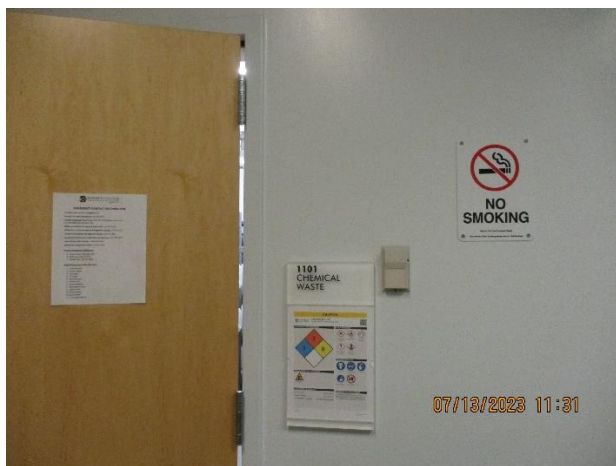


Photo 15: Entrance to 90-Day CAA

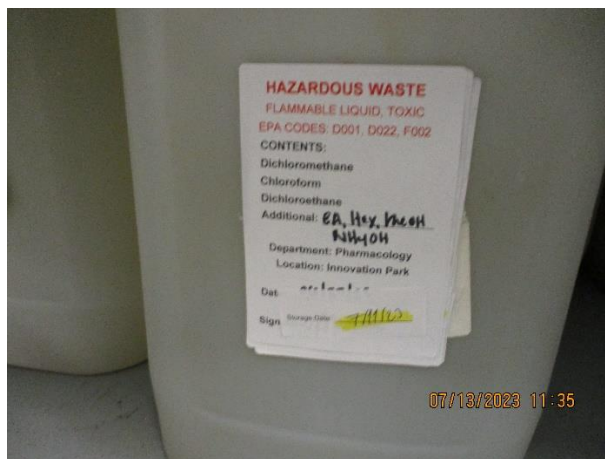


Photo 16: Labeled, closed, and dated hazardous waste container in CAA.



Photo 17: 5-gallon hazardous waste containers in the CAA closed, labeled, dated, marked with the indication of the hazard of the contents.



Photo 18: 55-gallon hazardous waste containers in the CAA. Containers are labeled, dated, closed, and marked with the indication of the hazard of the contents.



Photo 19: 55-gallon hazardous waste containers in the CAA. Containers are labeled, dated, closed, and marked with the indication of the hazard of the contents.

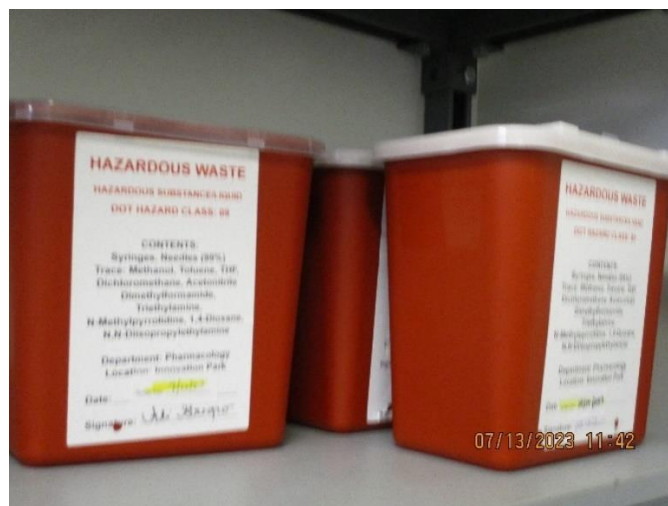


Photo 20: Three (3) one-gallon containers of hazardous waste, labeled, dated, closed, and missing indication of the hazard of the contents.