



Hazardous Waste Regulatory Compliance Assistance: Biotechnology, Pharmaceutical and Medical Device Industry

Liliana Mejia, Hazardous Materials Specialist IV
San Mateo County Environmental Health Services

Agenda

- San Mateo County CUPA
- Hazardous Waste Generator Program
- Common Violations
- Regulatory Updates
- Facility Closure Requirements

CUPA Programs

San Mateo County Environmental Health is a Certified Unified Program Agency (CUPA) designated by the state to implement the following programs:

- Hazardous Materials Business Plan
- Hazardous Waste Generator
- Hazardous Waste Treatment
- California Accidental Release Reporting
- Aboveground Petroleum Storage Act
- Underground Storage Tanks

Hazardous Waste Generator Program

Regulatory Requirements

- Health and Safety Code, Division 20, Chapter 6.5
- Code of Federal Regulations, Title 40
- California Code of Regulations, Title 22

Biotechnology, Pharmaceutical and Medical Device Industry

- Characteristics - San Mateo County
 - Research, development and manufacturing
 - Small and large scale
- Requirements for new hazardous waste generators
 - EPA ID number (Cal or Federal)
 - Obtain a CUPA permit
 - HMBP if over reportable threshold
- Types of waste
 - Solvents
 - Lab debris
 - Expired chemicals (unused)

Hazardous Waste Generator Program

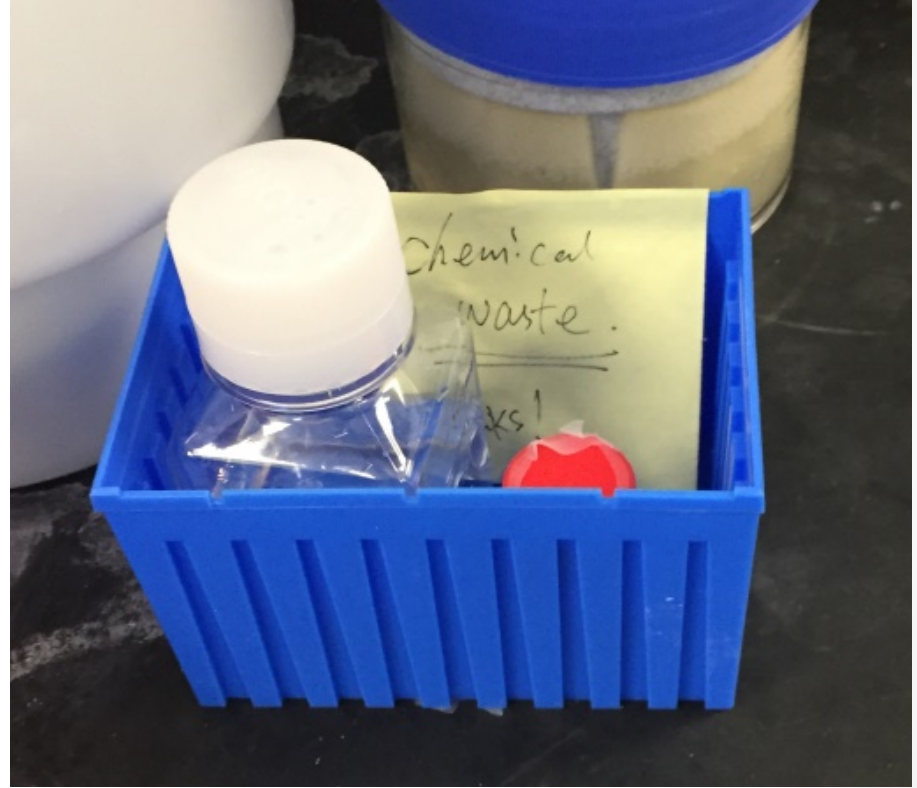
- Types of Generators
 - Small Quantity Generator (SQG)
 - <1,000 kg of hazardous waste of <1 kg of acute hazardous waste
 - Large Quantity Generator (LQG)
 - $\geq 1,000$ kg of hazardous waste of ≥ 1 kg of acute hazardous waste
- Inspection Frequency SMC
 - SQG – Every 2 years
 - LQG – Annually

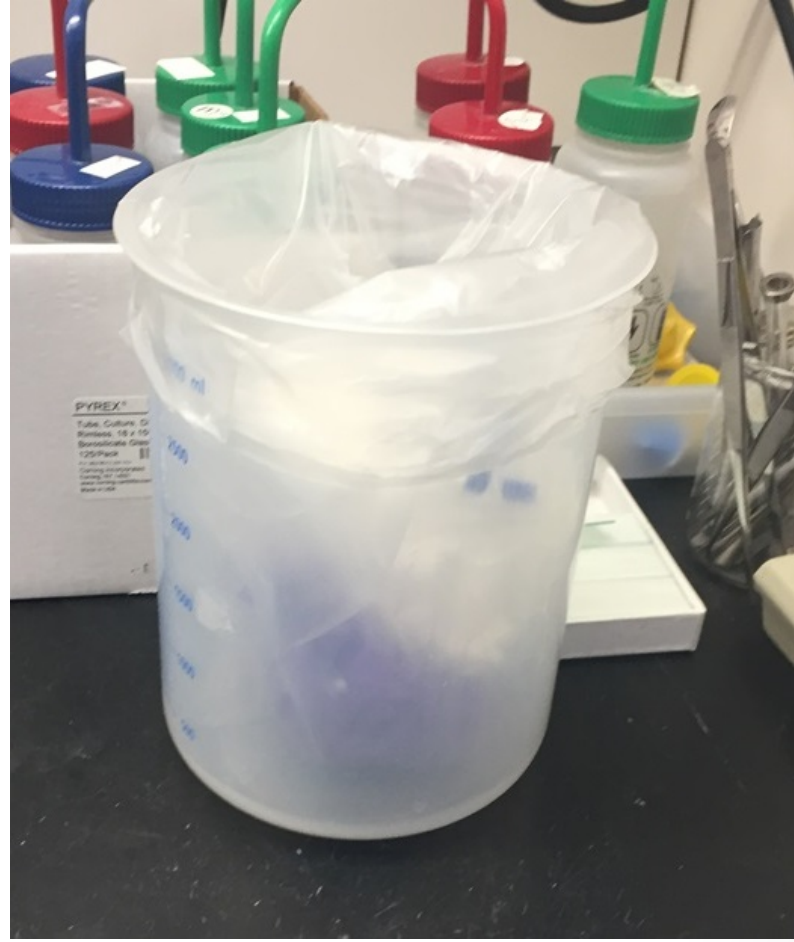
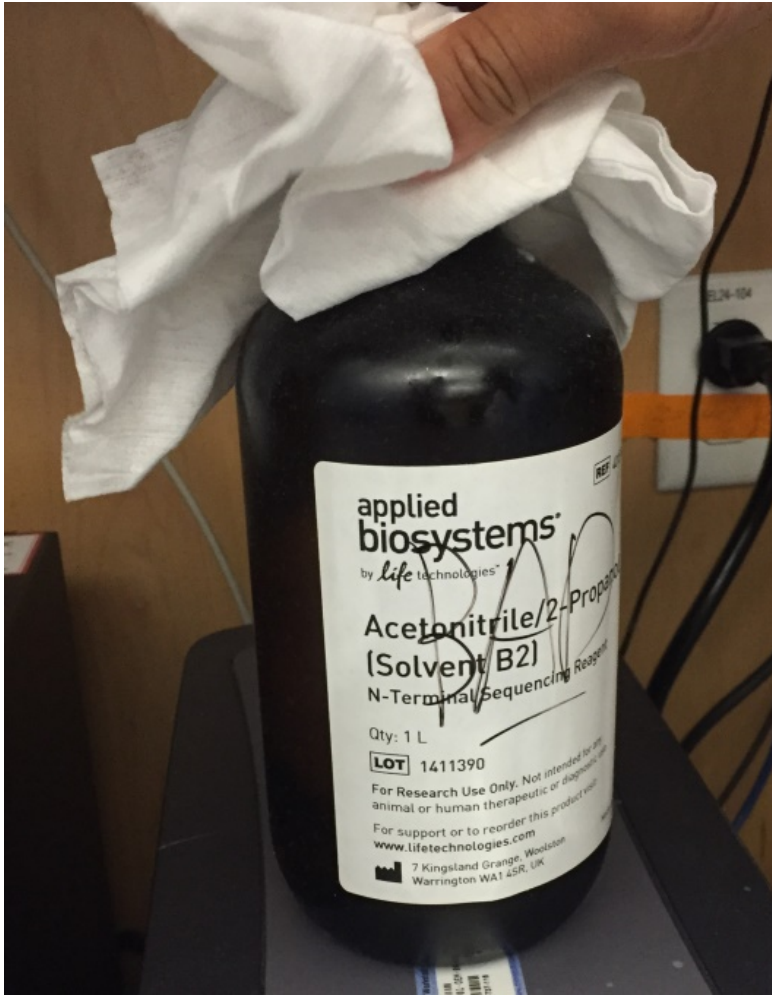
Biotechnology, Pharmaceutical and Medical Device
Industry

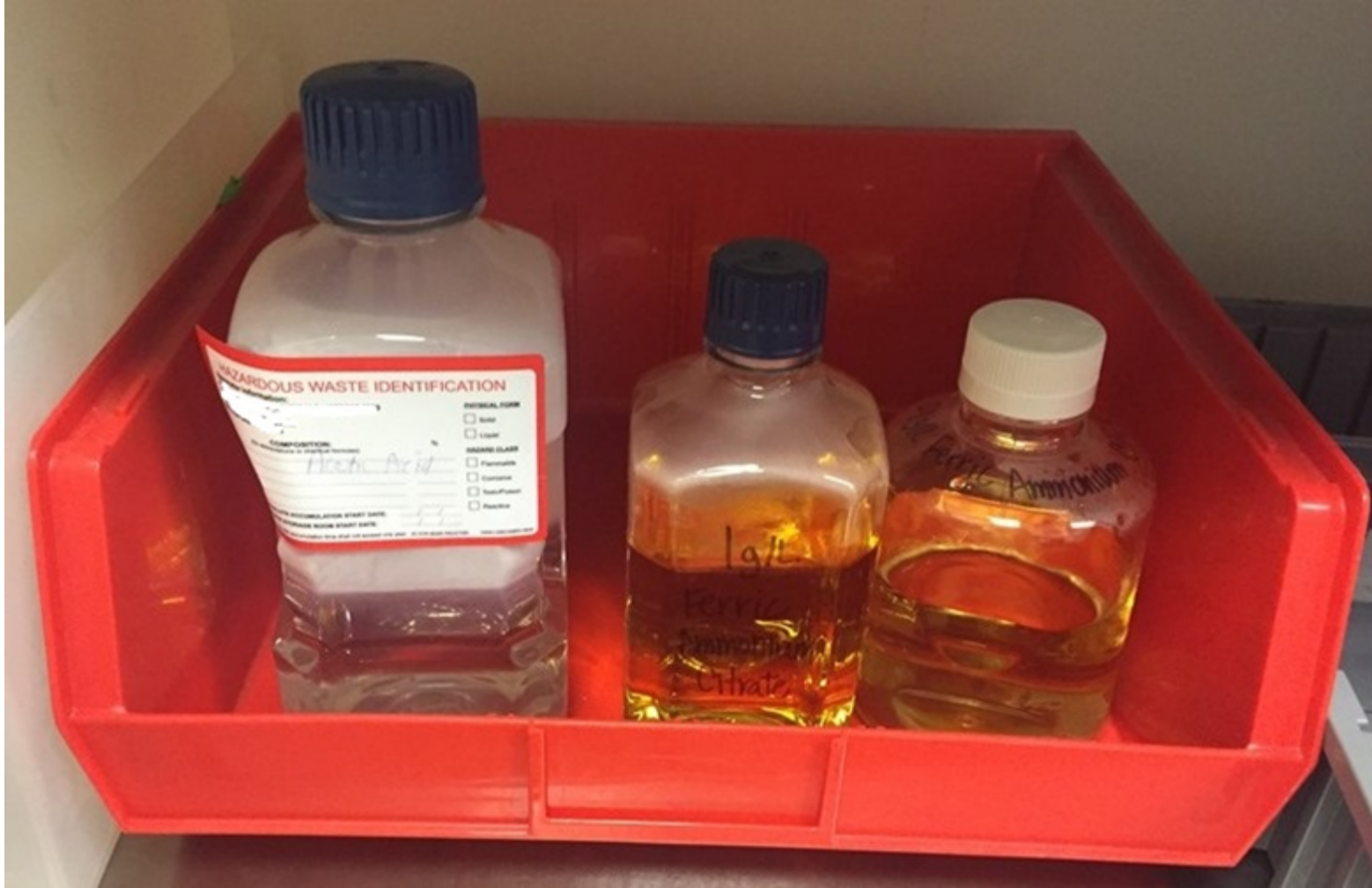
COMMON HAZARDOUS WASTE VIOLATIONS

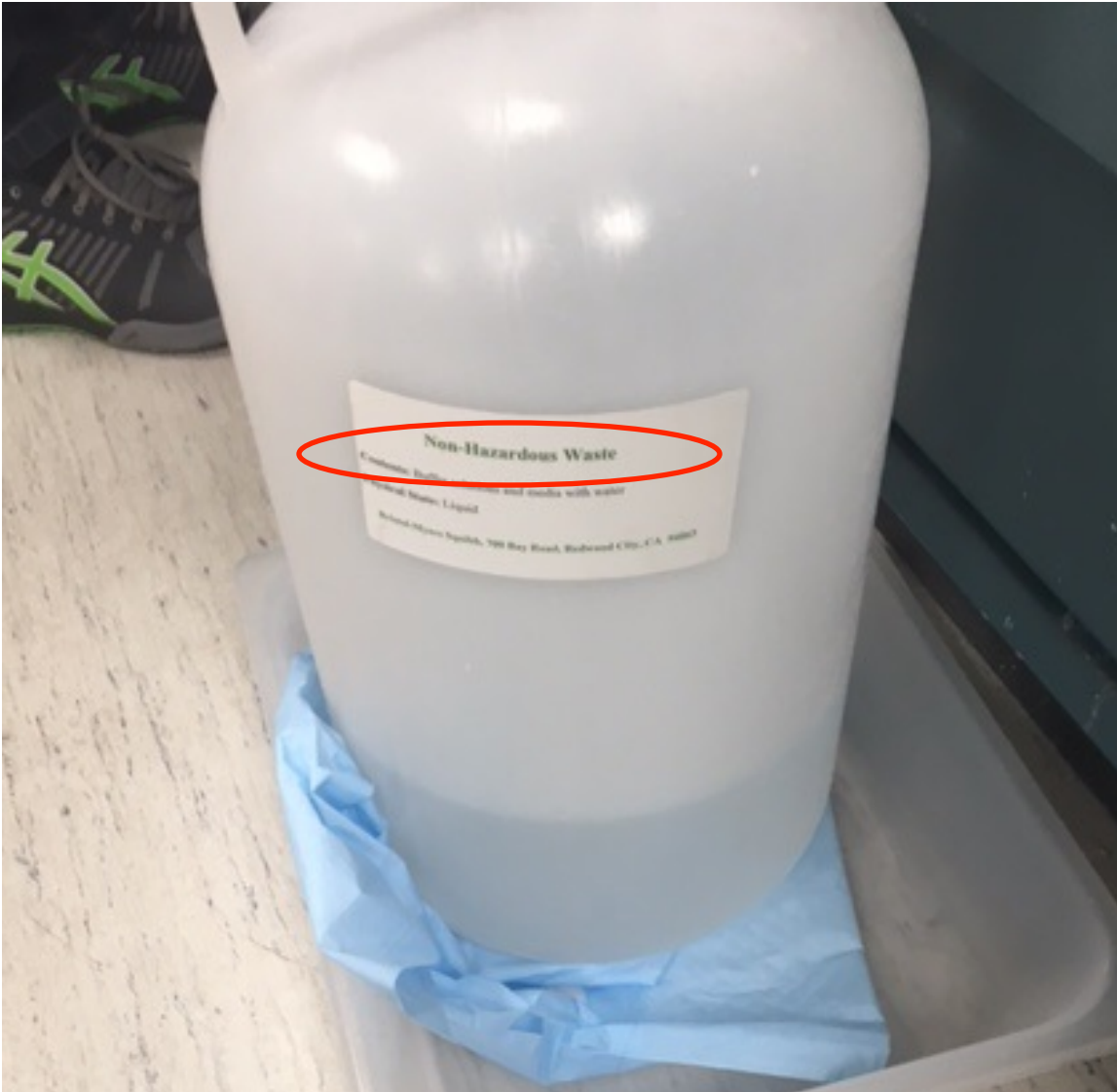
Common Violations

- **Hazardous waste determination:** *Failure to determine if the waste generated is a hazardous waste and to maintain analysis results for three years. 22 CCR 12 66262.11, 66262.40(c)*
 - Is it a waste?
 - It has to be discarded
 - No potential use
 - Expiration date
 - Types of determination
 - Testing the waste
 - Applying knowledge of the hazard characteristic of the waste in light of the materials or the processes used







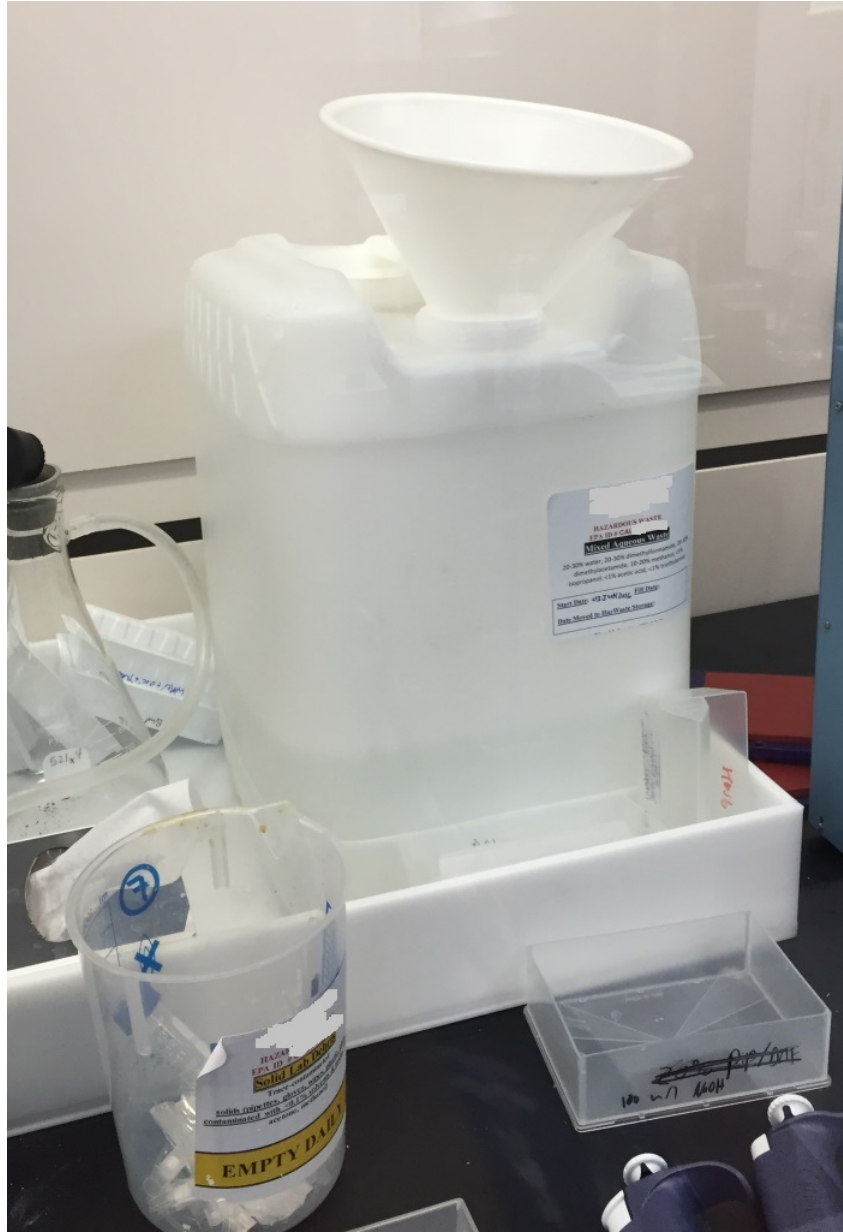


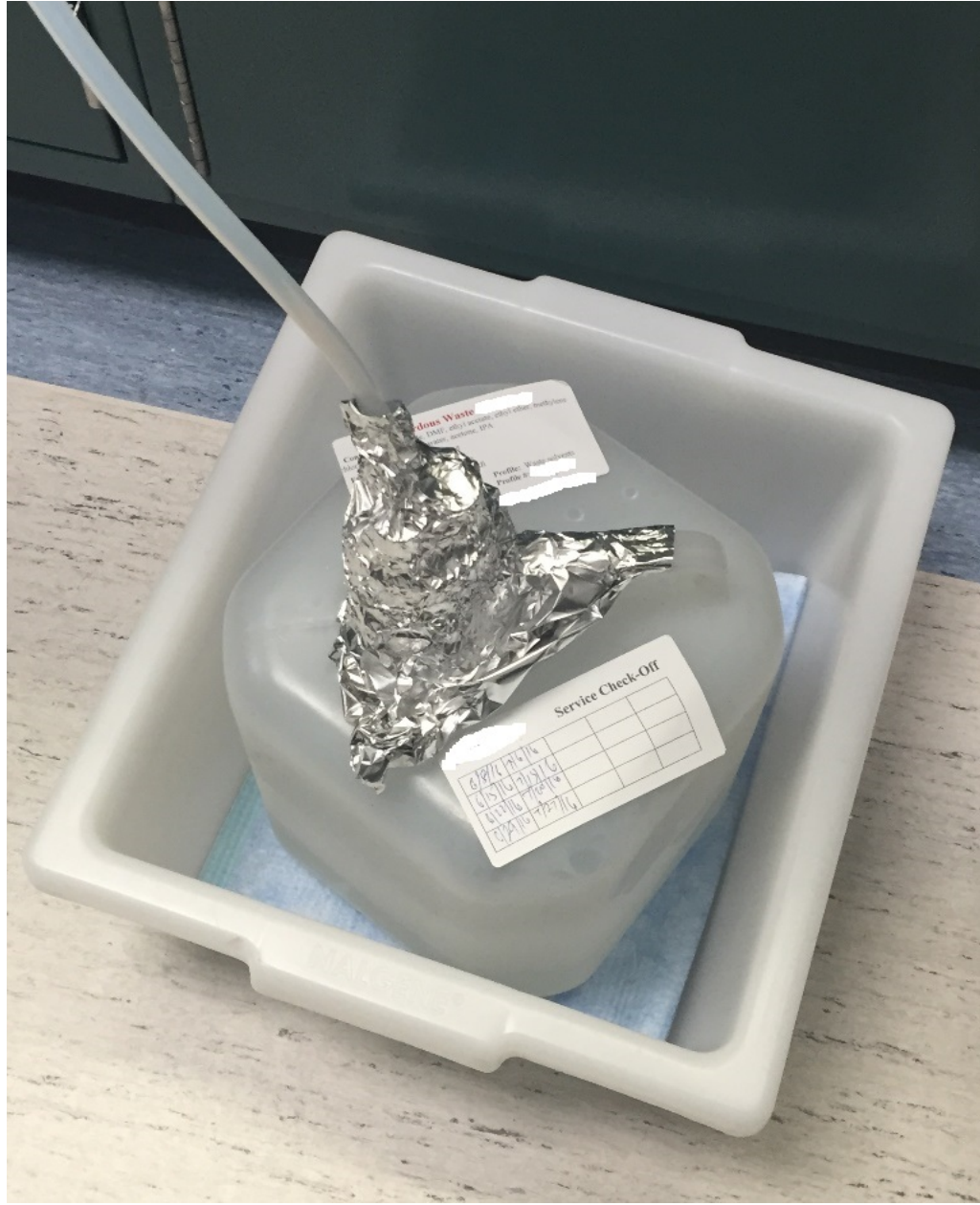
Common Violations Cont.

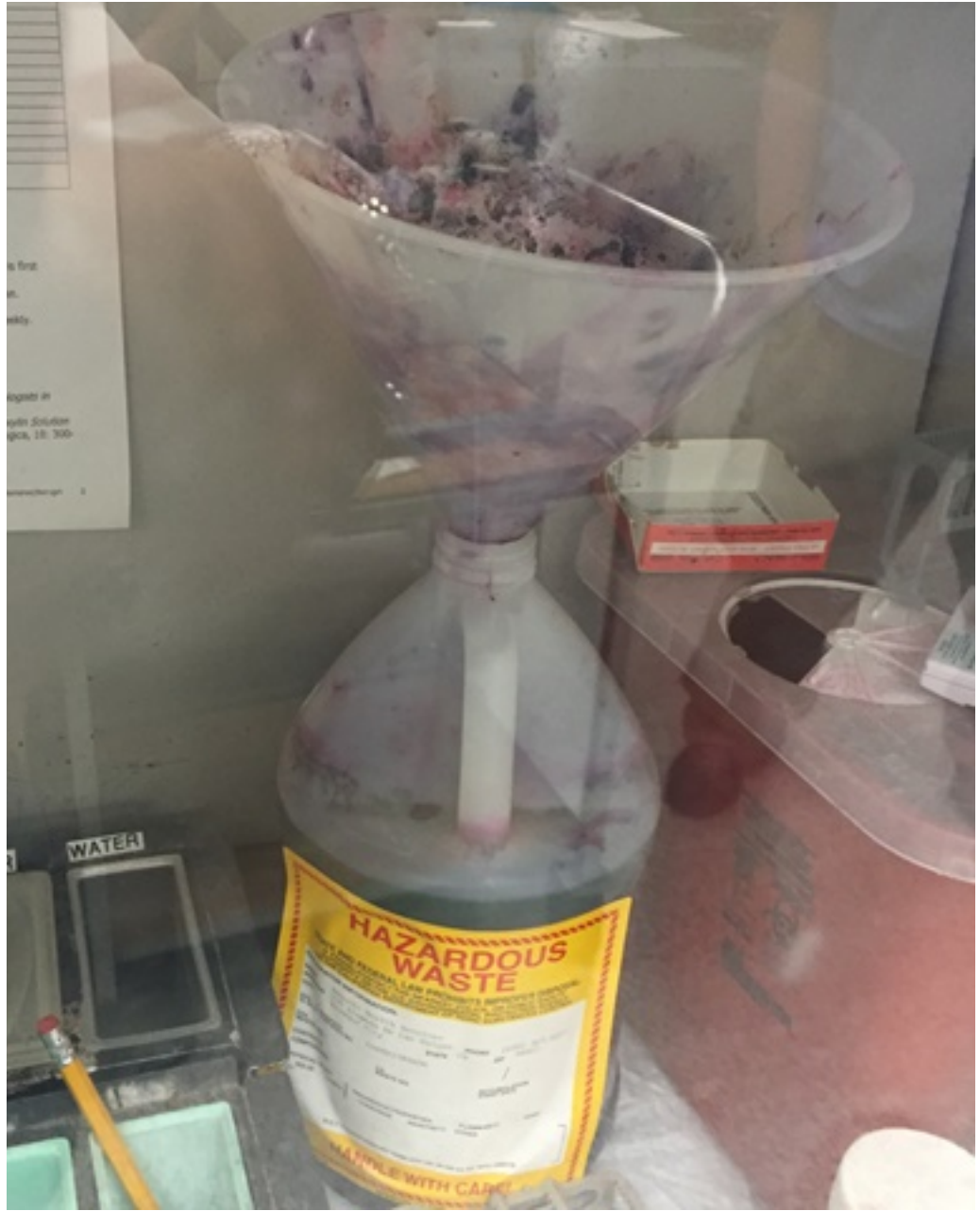
Close containers: *Failure to properly close hazardous waste containers when not in active use (adding or removing hazardous waste). 22 CCR 15 66265.173*

- Container needs to be designed to be closed.
- Applicable to Satellite Accumulation Containers.
- EPA RO14826 (2009)
 - A container "closed" when they are sealed to the extent necessary to keep the hazardous waste and associated air emissions inside the container.
 - Liquid hazardous waste: all openings or lids are properly and securely affixed to the container.
 - Solids and semi-solids hazardous waste: complete contact between the lid and the rim all around the top of the container. Containers opened by a foot pedal or with a self-closing swing door are acceptable.

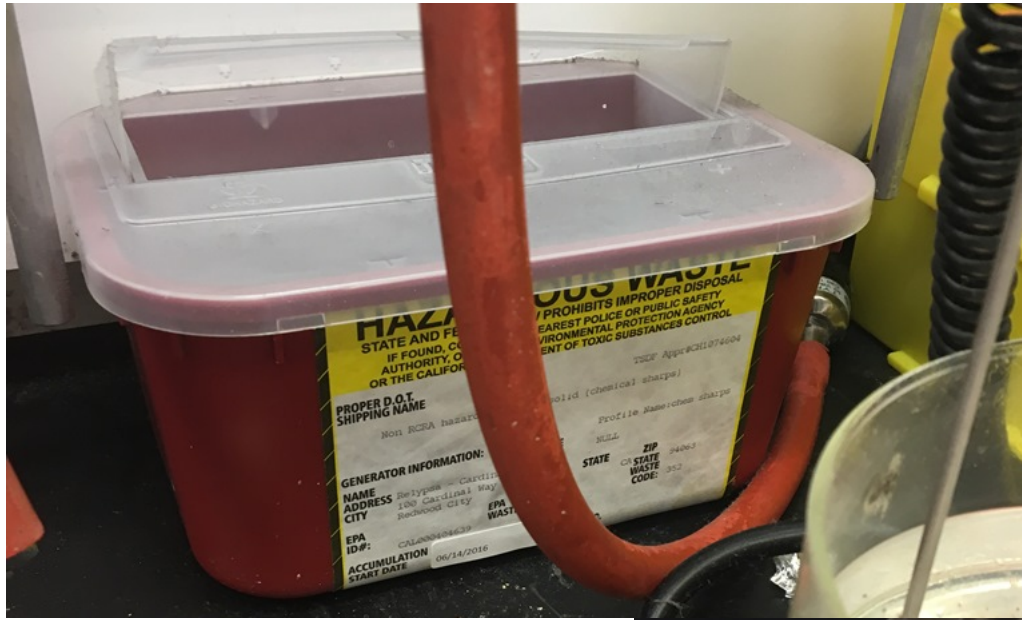












Common Violations Cont.

Training requirements:

- **SQG:** *Failure to ensure employees are familiar with the handling and compliance of hazardous waste regulations and emergency response. 22 CCR 12 66262.34(d)(2); 40 CFR 1 262.34(d)(5)(iii)*
- **LQG:** *Failure to provide employees within the first six months after the date of their employment, or assignment to the facility, or to work unsupervised, or to a new position at a facility with hazardous waste training to ensure employees are competent in the following areas: hazardous waste management procedures relevant to the positions in which they are employed, emergency response and emergency equipment, and procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment. Facility personnel must take part in an annual review of the initial training and maintain adequate records. 22 CCR 15 66265.16*

Common Violations Cont.

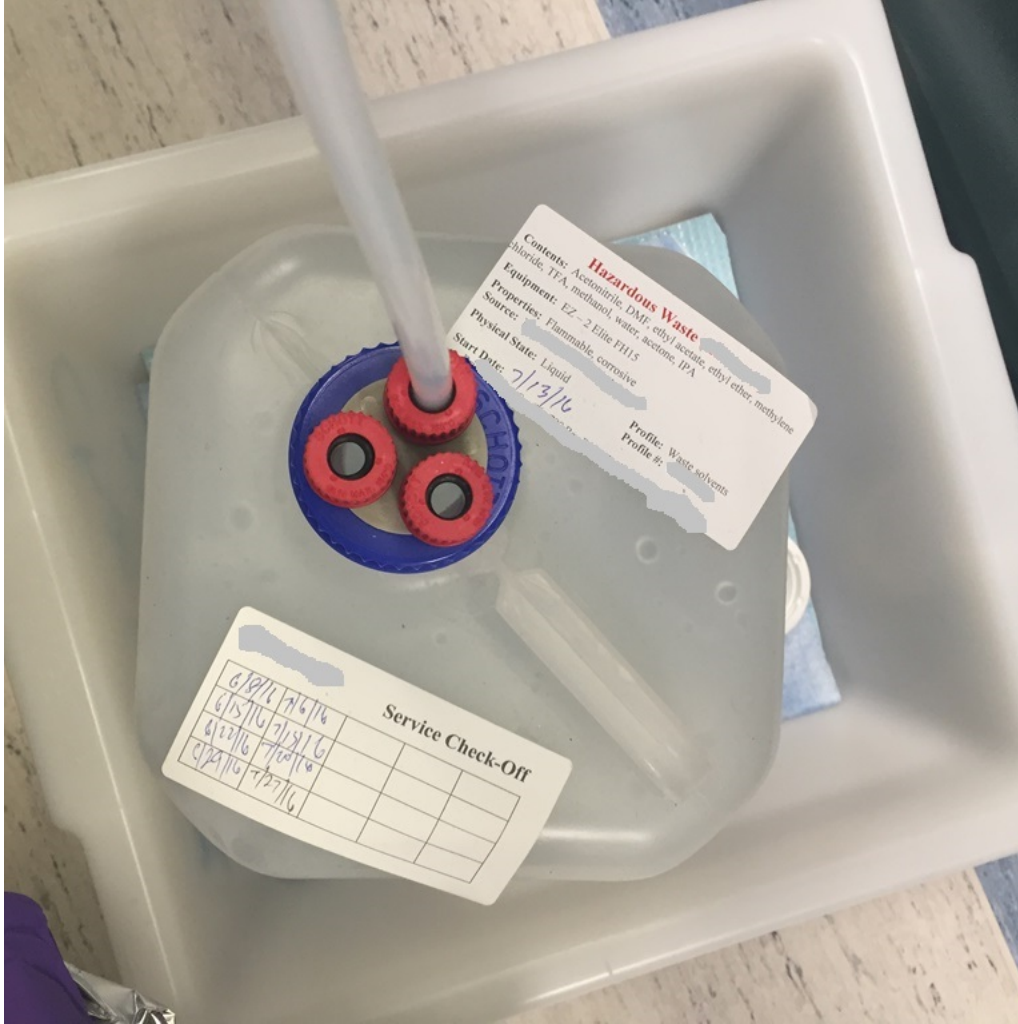
Satellite accumulation: *Failure to comply with 22 CCR § 66262.34 and HSC § 25123.3(d)*

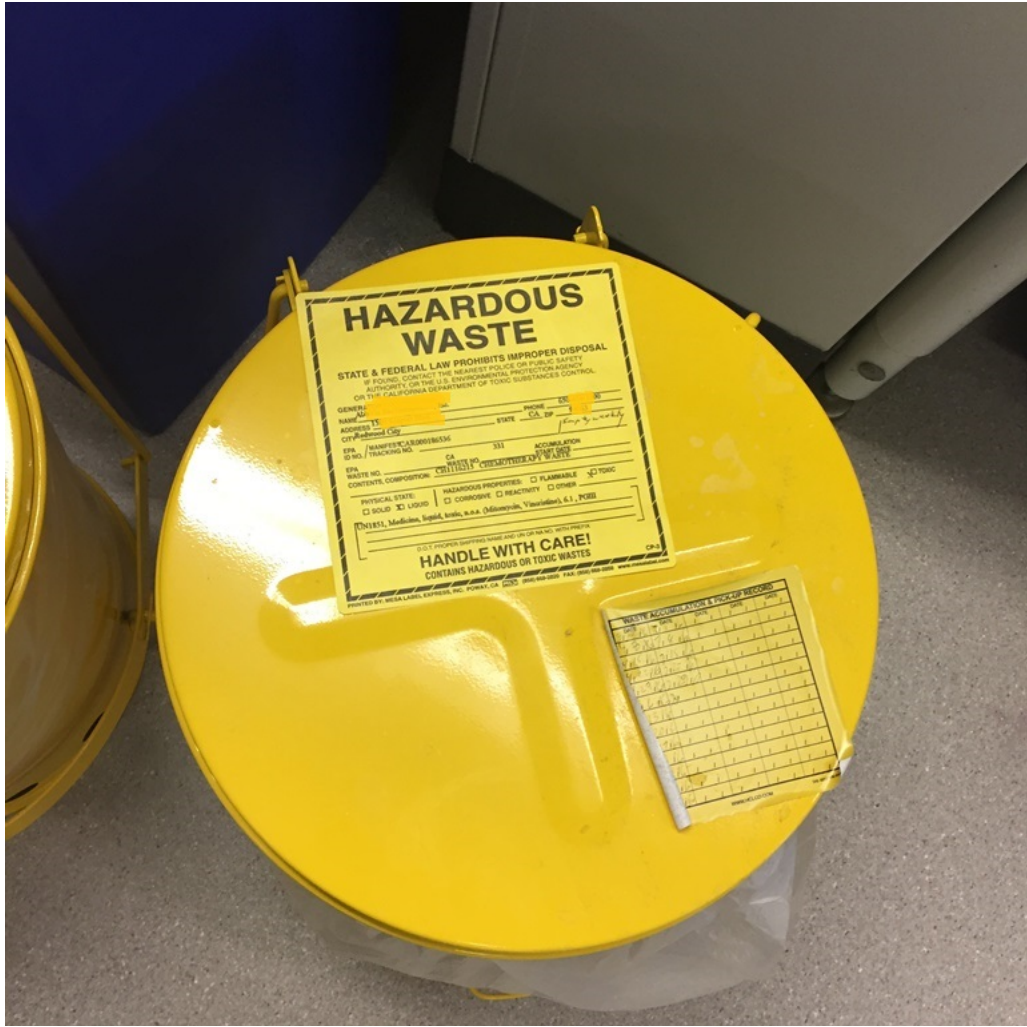
- The waste is accumulated in **containers** at the initial accumulation point, which is at or near the area where the waste is generated and which is under the control of the operator of the process generating the waste.
- The generator accumulates a maximum of 55 gal. of hazardous waste, one quart of acutely hazardous waste, or one quart of extremely hazardous waste.
- The generator **does not hold the waste onsite for more than one year** from the initial date of accumulation, or for longer than the applicable accumulation period for SQG or LQG.
- The initial date of accumulation is clearly marked and visible on each container, and the containers are managed according to regulation.
- Within three days of reaching the quantity limits, the generator must mark the container with the date that limit was reached, and comply with the other applicable regulations.

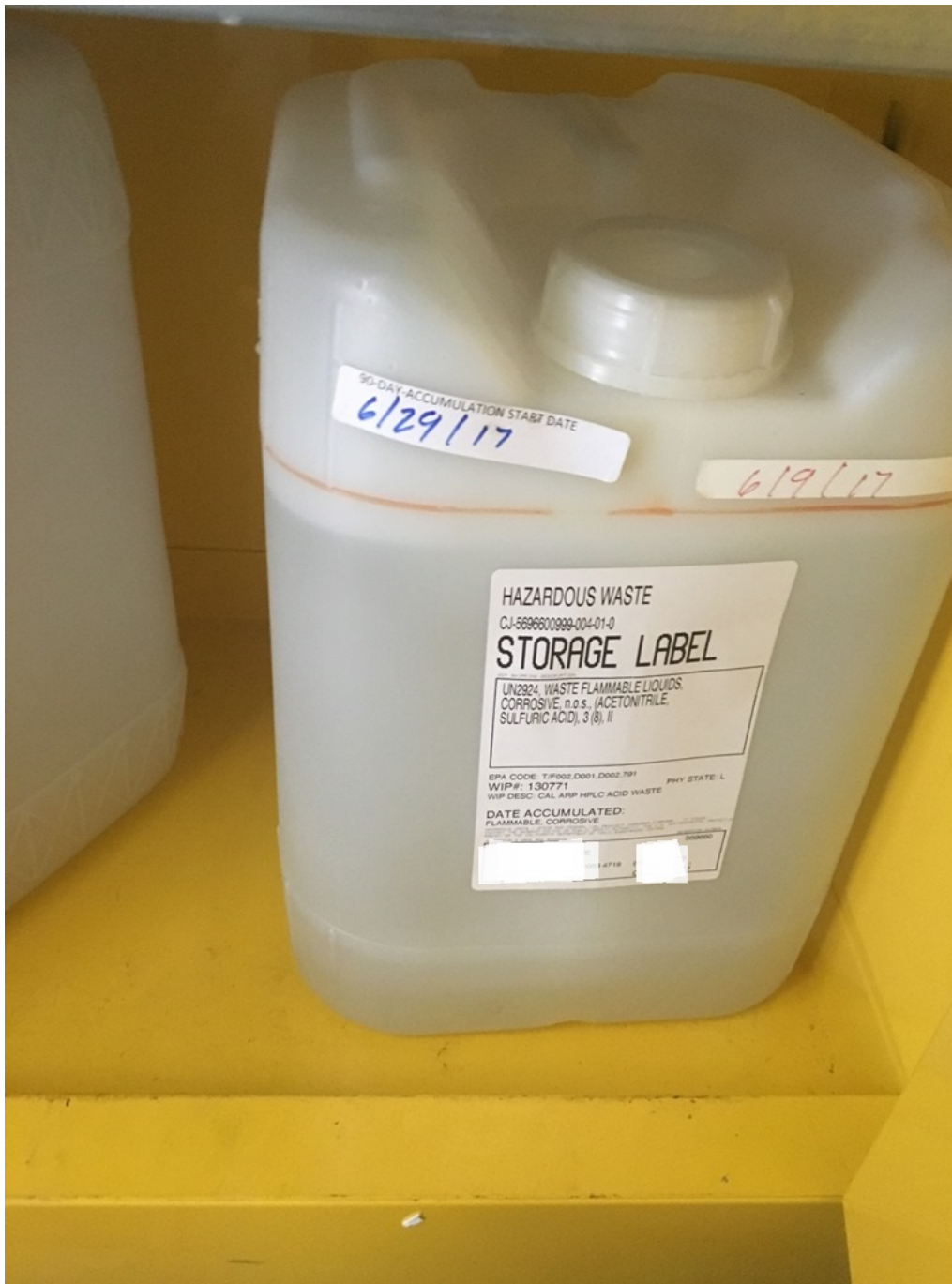
Common Violations Cont.

Satellite Accumulation: Violations

- Initial accumulation start date is not clearly marked.
- Hazardous waste is consolidated and earliest initial accumulation start date is not recorded.
- No operator = no longer Satellite Accumulation.
- Operator of the process that generates the waste is not responsible for the satellite accumulation container (SAC).
- No inspections after the container is in the 90/180 day accumulation area.







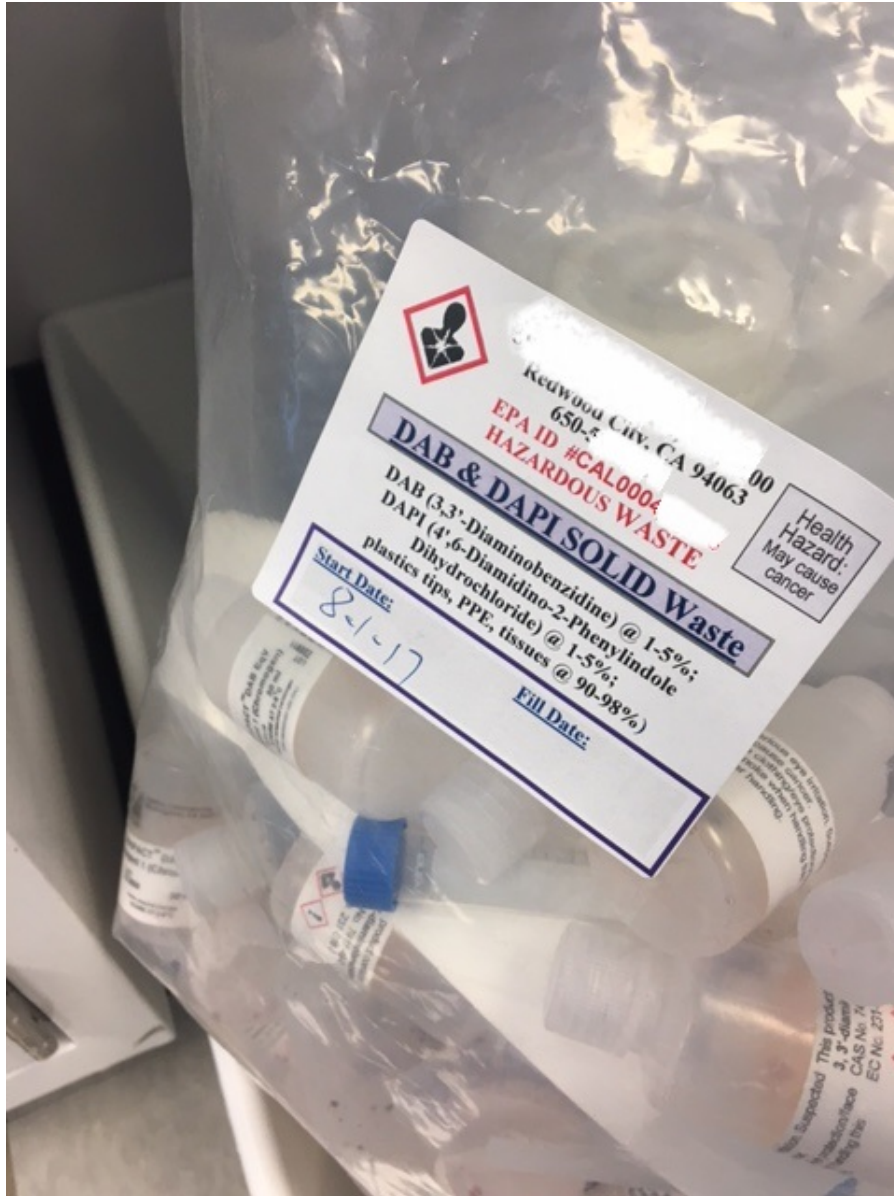
90-DAY ACCUMULATION START DATE
6/29/17

6/19/17

HAZARDOUS WASTE
CJ-5696600999-004-01-0
STORAGE LABEL

UN2924: WASTE FLAMMABLE LIQUIDS,
CORROSIVE, n.o.s. (ACETONITRILE,
SULFURIC ACID), 3 (8), II

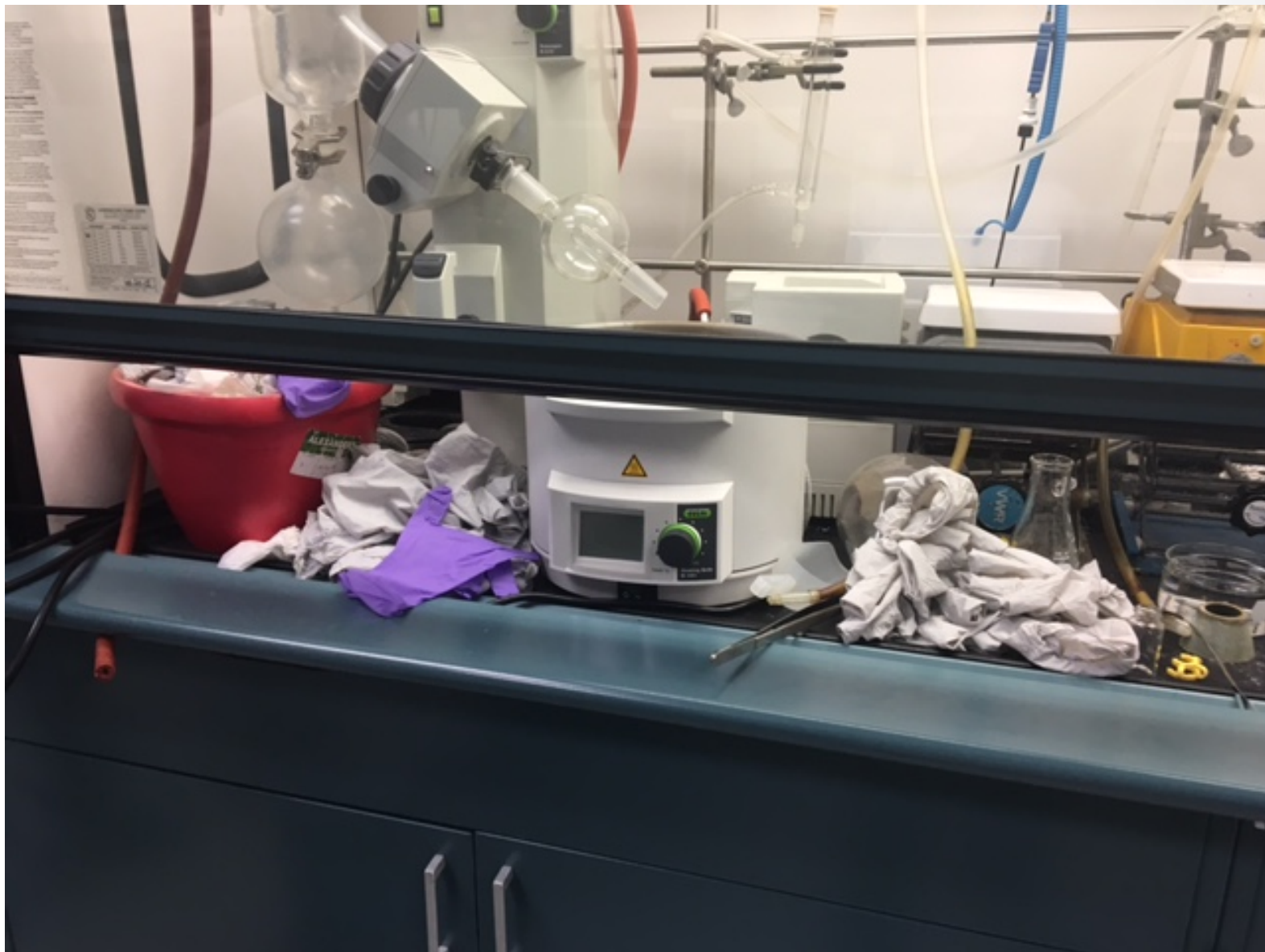
EPA CODE: T1002.D001.D002.701 PHY STATE: L
WIP#: 130771
WIP DESC: CAL ARP HRLC ACID WASTE
DATE ACCUMULATED:
FLAMMABLE CORROSIVE



Other violations:

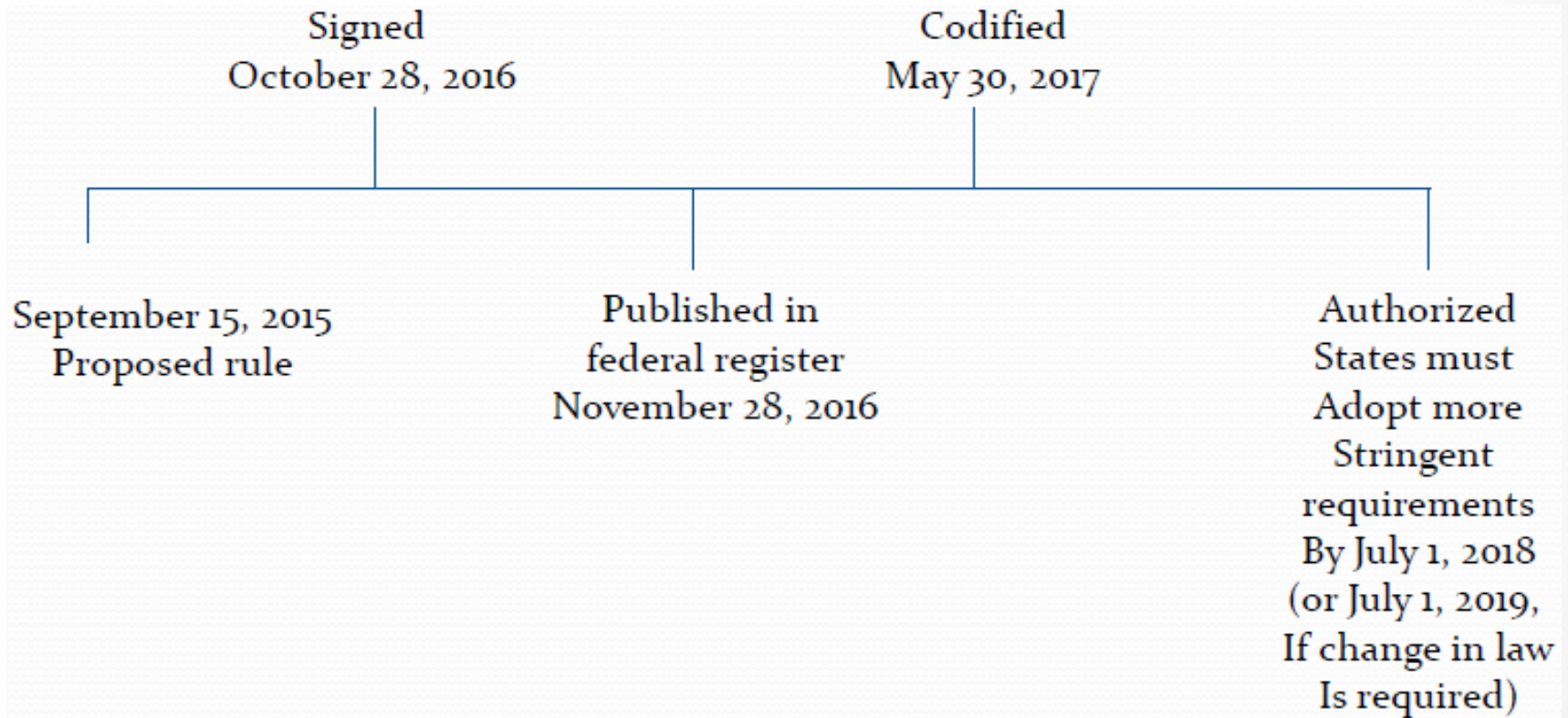
- Incomplete label
- No weekly inspections
- Failure to maintain and operate the facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to the air, soil, or surface water which could threaten human health or the environment
- SQG – No emergency posting



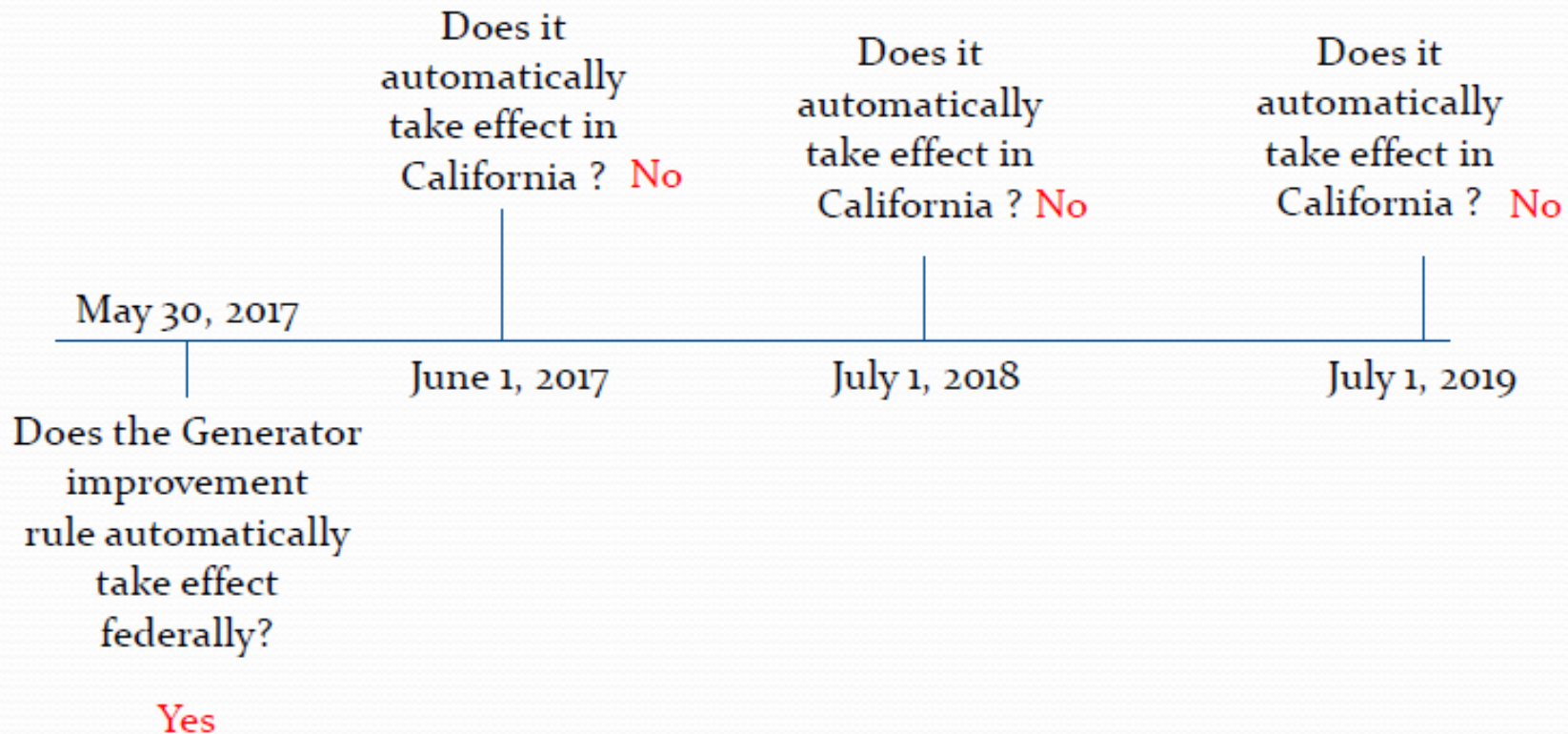


REGULATORY UPDATES

RCRA Generator Improvement Rule



RCRA Generator Improvement Rule Cont.



RCRA Generator Improvement Rule Cont.

- The hazardous waste generator improvement rule does not take effect in California until DTSC adopts it.
- To retain state authorization, DTSC is required to adopt those provisions within the rule that are more stringent.
- DTSC may adopt provisions that are less stringent or neither less nor more stringent, but is not required to.

FACILITY CLOSURE REQUIREMENTS

Regulatory Requirements for LQGs

22 CCR § 66265.111 Closure Performance Standard

- Minimizes the need for further maintenance
- Controls, minimizes or eliminates, to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated rainfall or run-off, or waste decomposition products to the ground or surface waters or to the atmosphere.

Regulatory Requirements for LQGs Cont.

22 CCR § 66265.114 Disposal or Decontamination of Equipment, Structures and Soils

- Contaminated equipment, structures and soil shall be properly disposed of, or decontaminated
- Remove all hazardous waste and residues

Regulatory Requirements for LQGs

Cont.

References cited in section 22 CCR § 66265.111 relating to closure:

- **66265.197 Closure and Post Closure Care of Tank Systems**
- 66265.228 Closure and Post Closure Care of Surface Impoundments
- 66265.258 Closure and Post Closure Care of Waste Piles
- 66265.280 Closure and Post Closure Care of Land Treatment
- 66265.310 Closure and Post Closure Care of Landfills
- 66265.351 Closure of Incinerators
- 6265.381 Closure of Thermal Treatment facilities
- 66265.404 Closure of Chemical, Physical and Biological Treatment facilities
- 66265.1102 Closure of Containment Buildings

Regulatory Requirements for SQGs

66262.34 (d)(2)

262.34(d)(4)

40 CFR 265.31

Maintenance and Operations of Facility

Facility must be maintained and operated to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

Other Violations to Consider

HSC 6.5 § 25189

- (c) A person who **intentionally** disposes or causes the disposal of a hazardous or extremely hazardous waste at a point that is not authorized according to the provisions of this chapter shall be subject to a civil penalty ...
- (d) A person who **negligently** disposes or causes the disposal of a hazardous or extremely hazardous waste at a point which is not authorized according to the provisions of this chapter shall be subject to a civil penalty

Other Violations to Consider Cont.

HSC 6.5 § 25189.2 (c)

A person who disposes, or causes the disposal of, a hazardous or extremely hazardous waste at a point that is not authorized according to the provisions of this chapter is liable for a civil penalty ...

Other Violations to Consider Cont.

HSC 6.5 § 25189.5 (a)

The disposal of any hazardous waste, or the causing thereof, is prohibited when the disposal is at a facility which **does not have a permit ... or at any point which is not authorized ...**

Other Violations to Consider Cont.

HSC 6.5 § 25189.5 (b)

Any person who is convicted of **knowingly** disposing or causing the disposal of any hazardous waste, or who **reasonably should have known** that he or she was disposing or causing the disposal of any hazardous waste, at a facility which does not have a permit ... or at any point which is not authorized according to this chapter shall, upon conviction... shall go to jail...

San Mateo County Hazardous Waste Generator Closure Policy

- **Objective:** Provide guidance to comply with closure standards.
- **Goals:** Facility needs to demonstrate the proper removal and disposal of hazardous wastes and chemicals, the absence of visible contamination, and that there has been no release to the environment.
- **Applicability:** Full and partial closures, and ownership changes
- **Notification requirement:** 30 days before beginning closure activities.
- Closure plan may be required depending on the complexity of the closure activities.
- San Mateo County will close the permit once all the requirements have been satisfied.

Work Plan/Closure Plan

- History and background
- Chemical inventory (current and previous)
- Proposed schedule
- Decontamination procedures
 - All surfaces and equipment where hazardous waste or chemicals were stored or used **need to be cleaned** to remove any liquid or solid residues.
 - Surfaces and equipment where hazardous waste or direct chemical contact occurred **need to be decontaminated** using a solution to effectively remove any chemical residue.

Work Plan/Closure Plan – Cont.

- Sampling and analysis plan
 - Sampling could be required to **validate the effectiveness of any required decontamination** on equipment or structures, and to **demonstrate that there has been no release to the environment.**
 - It must identify the sample locations, analytical parameters, applicable standards, sampling methods, handling procedures, management and tracking, and the state-certified laboratory that will be used for sample analysis.
- Project management team, and Health and Safety Plan
- Management of closure derived hazardous waste
 - Identify characterization procedures for waste that will be generated during closure activities.
 - Waste containerization, storage locations, labeling, transportation and disposal, inspections, etc. All chemical products must to be removed from the building, and their disposition must be documented.

CUPA Oversight

- Inspections
 - Pre-inspection
 - Sampling locations verification
 - Sampling observation
 - Final inspection - REQUIRED
- Closure documentation
 - Final manifests
 - Sampling report and analysis of the results
 - Summary of closure activities
- Closure Certification
 - San Mateo County will provide confirmation that the closure was conducted in compliance with applicable requirements.

Compliance Assistance

San Mateo County Health Department, CUPA Program
2000 Alameda de las Pulgas, San Mateo CA 94403
(650) 372-6200

<http://www.smchealth.org/hazardous-materials-cupa>

Liliana Mejia
Hazardous Waste Program Specialist
(650) 339-9791
lmejia@smcgov.org

Thank you!

...QUESTIONS