

Top Ten Violations in the Biotech/R&D Industry

Presented By Kathryn Paras

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OBJECTIVES

01

To make you aware
of the most
common violations

02

To give you a
refresher on the
requirements

03

To help you achieve
compliance

ACRONYMS

ACRONYM/INITIALS

MEANING

EPIC +

Education, Process Improvements, Compliance for Environmental Risk Reduction

CUPA

Certified Unified Program Agency

CERS

California Environmental Reporting System

HMBP

Hazardous Materials Business Plan

EPA

Environmental Protection Agency

HSC

Health and Safety Code (CA)

CCR

California Code of Regulations

MWMA

Medical Waste Management Act (CA)

DTSC

California Department of Toxic Substances Control

RCRA

Resource Conservation and Recovery Act

820



Inspections conducted
for Biotech/R&D facilities

364



Biotech/R&D facilities

59



EPIC+ Participants

WITHIN THE LAST THREE YEARS...

A worker in a yellow hard hat and blue shirt is shown in profile, holding a clipboard and pen. The background is a dimly lit industrial facility with various equipment and structures. The text "VIOLATION #10:" is overlaid in a large, white, outlined font.

VIOLATION #10:

**Unified Program
Facility Permit not
obtained &/or
maintained.**

SDCC 68.905, 68.906, 68.907

UNIFIED PROGRAM FACILITY PERMIT



COMMON ISSUES

- A UPFP is needed for facilities who participate in any of the following categories:
 - Handle or store reportable thresholds of Hazardous Materials
 - Are part of the California Accidental Release Prevention Program (CalARP)
 - Generate or treat Hazardous Waste
 - Generate or treat Medical Waste
 - Store at least 1,320 gallons of Aboveground Petroleum (APSA)
 - Own or operate Underground Storage Tanks (UST)
- Facility must apply for a UPFP within 30 days of being subject to any of the categories listed above
- Operating and/or managing any of the mentioned categories for longer than 30 days without a UPFP
- Expired permit



VIOLATION #9:

**Accumulated
waste too long
(>180 or 270 days)
or (>90 days).**

*HSC 25201(a), 25123.3(h)(1); 22 CCR
66262.34(d); 40 CFR 262.34(e) and/or (f)*

HAZARDOUS WASTE ACCUMULATION TIMES



COMMON ISSUES

- Small Quantity Generators
 - > 100 kgs per month
 - < 1,000 kgs per month
 - 180 days or 270 days if shipping a distance greater than 200 miles
- Large Quantity Generators
 - $\geq 1,000$ kg per month
 - ≥ 1 kg per month of acutely HW
 - 90 days
- Exceeding storage time limit for generator status
- Improper accumulation start date

A photograph of a laboratory bench. On the top shelf, there are numerous white plastic bottles of various sizes, some with blue caps and others with red caps. Below the shelf, there are electrical outlets and some equipment. A green label with the text "EAU DE VILLE" and a downward arrow is visible. The text "VIOLATION #8:" is overlaid in large, white, outlined letters.

VIOLATION #8:

**Failed to report &/or
update the required
inventory information
for hazardous
waste(s) generated at
the facility in CERS.**

SDCC 68.904(a)(2)



INVENTORY

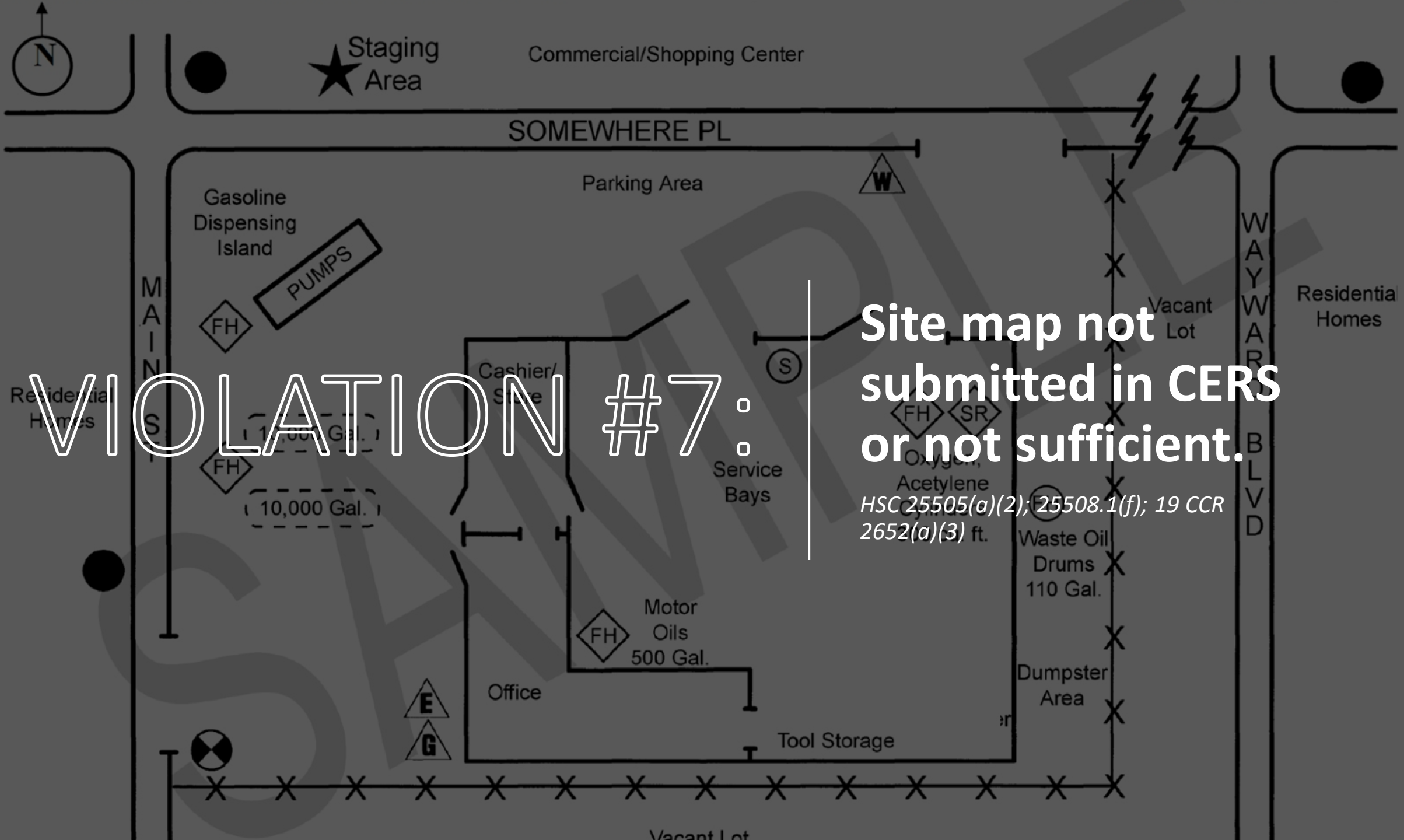
- Significant changes in inventory must be made within 30 days of change



COMMON ISSUES

- Not reporting change within 30 day time frame

NOT FOR PUBLIC DISCLOSURE



Site map not submitted in CERS or not sufficient.

HSC 25505(a)(2); 25508.1(f); 19 CCR 2652(a)(3)

SITE MAPS

- North orientation
- Loading areas
- Internal roads
- Adjacent streets
- Storm and sewer drains
- Access and exit points
- Emergency shutoffs
- Evacuation staging areas
- HM handling and storage areas
- Emergency response equipment



COMMON ISSUES

- Not submitted
- Not updated
- Not enough information
- Too much or unnecessary information
- Multiple-page site map as multiple files in CERS
- Obsolete site maps not deleted

Save

Cancel

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Edit

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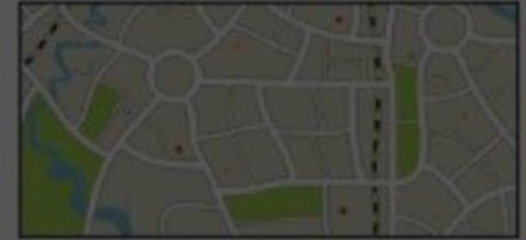
Edit

CA 92123
n Diego

CERSID
10144127

EPA ID Number
CA1234567890

Edit



Edit Mapping

s Materials

Facility have on site (for any purpose) at any one time, hazardous materials at or above 55 gallons for liquids, 500 pounds for solids, or 200
or compressed gases (include liquids in A.B.'s and U.S.'s) or is regulated under restrictive local inventory control requirements (now
sent); or the applicable Federal threshold quantity for an extremely hazardous substance specified in 40 CFR Part 355, Appendix A or B; or
biological materials in quantities for which an emergency plan is required pursuant to 10 CFR Parts 30, 40 or 50.

☐ Yes ☒ No

Failed to obtain &/or
maintain an active
EPA ID Number.

22 CCR 66262.12(a)

und Petroleum Storage (UST)

Facility own or operate underground storage tanks?

☐ Yes ☒ No

s Waste

Facility generate Hazardous Waste?

☐ Yes ☒ No

Provide an EPA Identification Number (EPA ID).

Facility treat hazardous waste on-site?

☐ Yes ☒ No

EPA ID NUMBERS

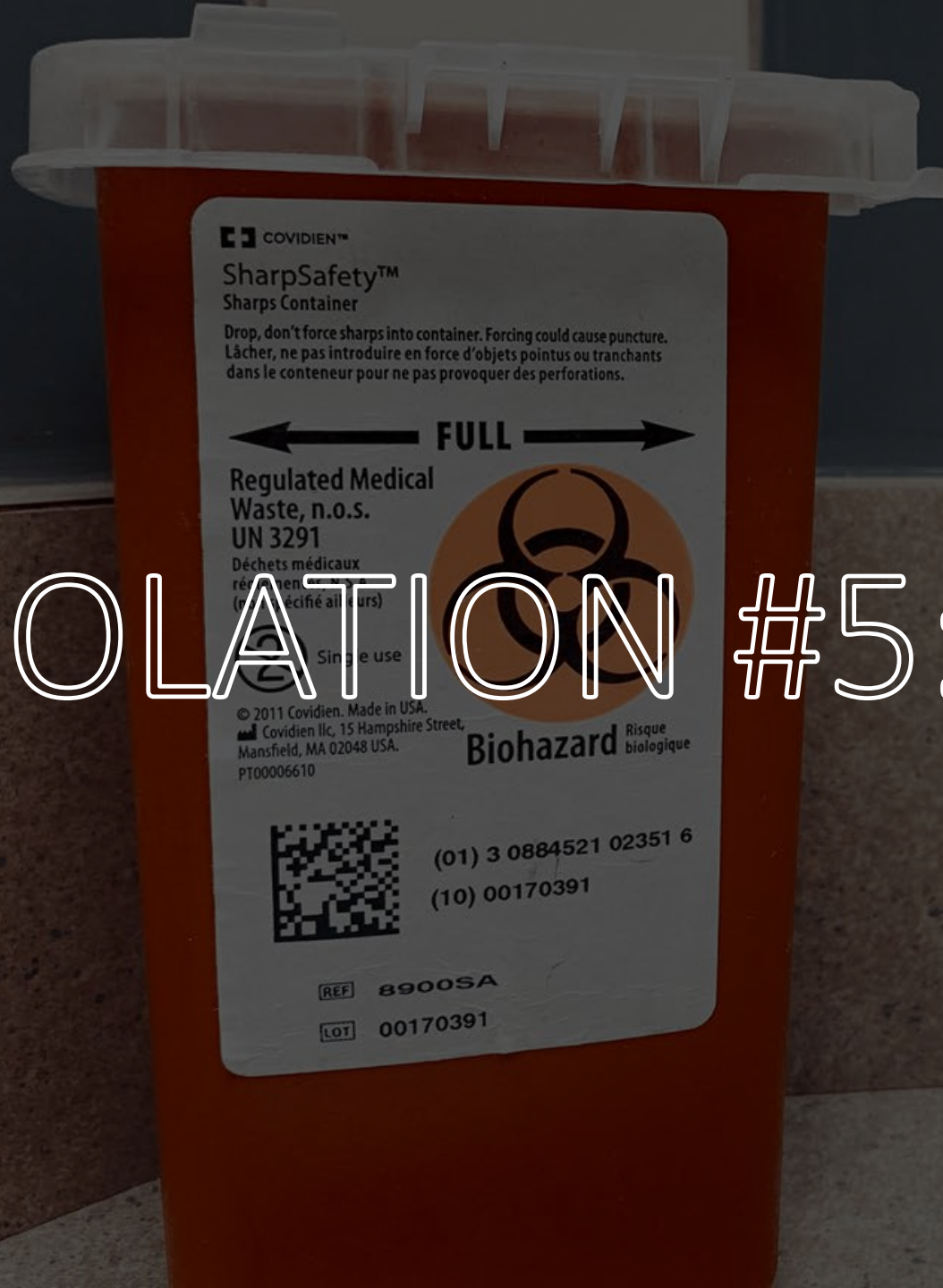
- Federal ID Number
 - ≥ 100 Kg of RCRA HW/month
 - > 1 Kg of RCRA Acutely HW/month
 - CAR, CAP, CA, CAD, CAT
- State ID Number
 - < 100 Kg of RCRA HW/month
 - ≤ 1 Kg of Acutely RCRA HW/month
 - Non-RCRA HW
 - CAL, CAC
- Annual electronic verification questionnaire required through eVQ



COMMON ISSUES

- EPA ID or State ID inactive
- EPA ID or State ID not obtained
- Incorrect ID obtained
 - Federal v. State

VIOLATION #5:



Primary containers accumulating MW not labeled with an electronic tracking system label or a label with generator's name, address and phone number.

SDCC 68.1205

MEDICAL WASTE LABELING



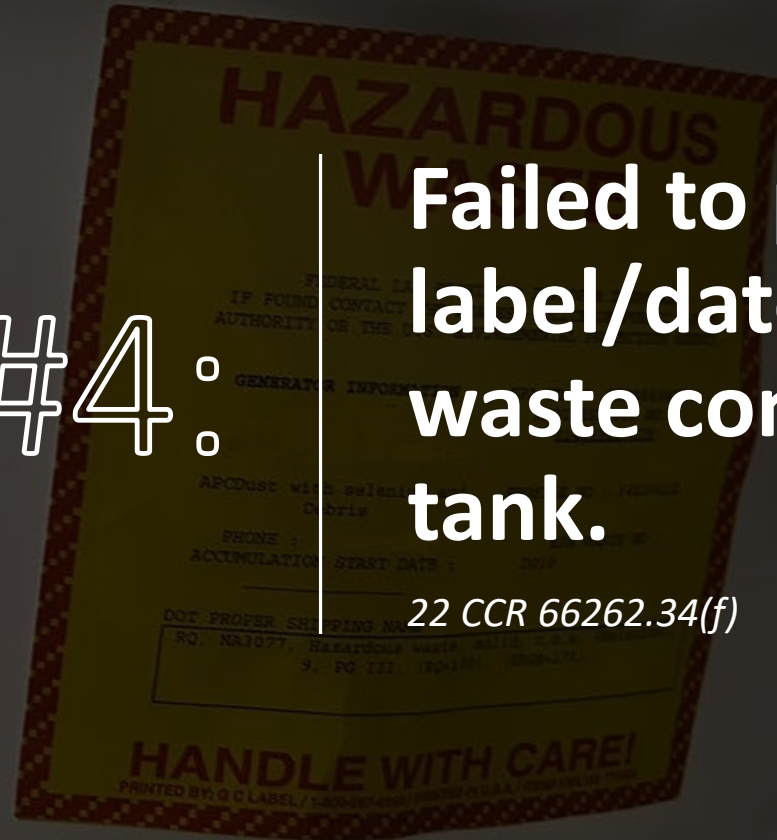
COMMON ISSUES

- Primary container's labels (i.e. red bags, sharps containers, Non-RCRA pharmaceutical containers)
 - Electronic tracking system or label that includes:
 - Generator's name
 - Generator's address
 - Generator's phone number
 - Must be visible on the outside of the container
 - Attached to container when it is first used to accumulate MW
- MW label missing
 - Label on primary and/or secondary container
 - Incomplete information

VIOLETION #4:

Failed to properly
label/date hazardous
waste container &/or
tank.

22 CCR 66262.34(f)



HAZARDOUS WASTE LABELING

- Information required to be clearly marked and visible on each container:
 1. The words “HAZARDOUS WASTE”
 2. Accumulation start date
 3. Composition and physical state
 4. Hazardous Properties
 5. Generator name and address



COMMON ISSUES

- Incomplete information
- Faded information
- Incorrect information
- No HW label or markings

Submittal Finished: Medical Facility

[Home](#) >> [Draft Submittal](#) >> Submittal Finished (10172672)

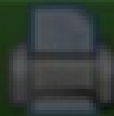


VIOLATION #3:

**HMBP not
submitted to the
CUPA in CERS.**

*HSC 25508(a)(1)(A);
27 CCR 15188(a),(b),(d)*

Print Submittal



HMBP SUBMITTALS

- Comprised of three elements:
 - Facility Information
 - Business Activities
 - Business Owner/Operator Identification
 - Hazardous Materials Inventory
 - Inventory
 - Site Map
 - Emergency Response and Training Plans
 - Emergency Response Plan
 - Employee Training Plan
- Annual certification required



COMMON ISSUES

- All three elements not submitted
- Annual re-certification not met



VIOLATION #2:

Initial &/or annual employee training not conducted &/or employee training records not available or not maintained for 3 years.

HSC 25505(a)(4); 19 CCR 2659(b)

EMPLOYEE TRAINING

- Must include at minimum:
 - Methods of safe-handling of HM
 - Procedures for coordination with local emergency response organizations
 - Use of emergency response equipment
 - Address safety procedures in the event of a release or a threatened release of a HM or HW for all employees



COMMON ISSUES

- Initial training not provided
- Annual training not provided
- 3 years worth of records not available
- No HMBP training provided



VIOLATION #1:

**Chemical inventory
incomplete or not
submitted in CERS.**

*HSC 25505(a)(1); 25507(a); 25508.1(a-b);
19 CCR 2654 (a) or (d)*

CHEMICAL INVENTORY INCOMPLETE

- Hazardous Materials (HM)
 - ≥ 55 gallons of liquids
 - ≥ 500 pounds of solids
 - ≥ 200 cubic feet of gas
- Hazardous Waste (HW)
 - Any amount
- Medical Waste (MW)
 - Any amount



COMMON ISSUES

- Not submitted
- Incomplete
- Not updated
- Type of inventory
- Incorrect physical characteristics
- Incorrect units
- Information missing
 - Mixture components, Extremely Hazardous Substances, Waste Codes, etc.

1. Inventory incomplete
2. Initial &/or annual employee training not conducted &/or employee training records not available or not maintained for 3 years
3. HMBP not certified
4. Hazardous Waste labeling
5. Medical Waste labeling
6. Inactive EPA/State ID
7. Site map not sufficient
8. Report/Update inventory after substantial change
9. Accumulated waste too long
10. Unified Program Facility Permit not obtained &/or maintained

Top 10 Violations in Biotech/R&D Facilities

Contact

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