



Top Ten Violations in the Biotech/R&D Industry

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EPIC+ Seminar 6/18/2024



Objectives

- Awareness of the most common violations
- Provide a refresher on the requirements
- Help you maintain compliance

Remember: Achieving compliance is different for every facility.



Top Ten Violations

1. Chemical inventory incomplete or not submitted in CERS. HSC 25505(a)(1); 25507(a); 25508.1(a-b); 19 CCR 26
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)
3. Failed to Obtain &/Or Maintain an Active EPA ID Number. 22 CCR 66262.12(a)
4. Failed to submit or report in CERS chemical inventory information for hazardous waste and/or medical waste, and keep up to date. SDCC 68.904(a)(2)
5. HMBP not certified as complete and accurate in CERS by the required due date. HSC 25508.2, 19 CCR 2654(b)
6. Failed to report &/or update the required inventory information for hazardous waste(s) generated at the facility in CERS. SDCC 68.904(a)(2)
7. Biohazard bag waste stored more than 7 days at $>0^{\circ}\text{C}$ (for generators of 20 or more pounds a month). HSC 118280(e)(1)(A)
8. Site map not submitted in CERS or not sufficient. HSC 25505(a)(2); 25508.1(f); 19 CCR 2652(a)(3)
9. 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
10. Manifest signed by the TSDF not available for inspection. 22 CCR 66262.40(a); HSC 25185(a)(4)



Violations 1, 4, & 6: Incomplete inventory

Hazardous Materials (HMBP):

- Most reportable at 55 gal, 500 lbs, 200 cu ft
- Must update Hazardous Materials Inventory in CERS within 30 days of substantial change
- Substantial Change (HSC 25508.1):
 - A 100 percent or more increase in the quantity of a previously disclosed material
 - Handling of a previously undisclosed hazardous material



Hazardous & Medical Wastes:

- Reportable in any amount
- Must report all commonly generated waste streams in CERS



Violations 1, 4, & 6: Incomplete inventory

Common issues observed:

- Hazardous materials/wastes on site not reported in CERS
- Hazardous material previously on border of reporting threshold
- Hazardous waste stream new or periodically generated

Tips to maintain compliance:

- Routinely check hazardous materials inventory on site
- Review past three years of manifests for waste streams
 - Lab packs must be reported



Violation 2: HMBP Employee training

Must perform initial and annual employee training

- Maintain training records for three years

Employee training must include:

- Methods for safely handling hazardous materials
- Procedures for coordination with local emergency response organizations
- Use of emergency response equipment
- Address safety procedures in the event of a release or threatened release of a hazardous material or hazardous waste for ALL employees.



Violation 2: HMBP Employee training

Common issues observed:

- Initial or annual training not provided
- 3 years of records unavailable
- No training plan/schedule is in place, required by HMBP

Tips for compliance:

- Train all employees in release/threatened release procedures
- Properly train staff interacting with hazardous materials
- Ensure employees are confident in their role if a release occurs
 - Do employees know how to access/review the HMBP?
 - Will a competent individual always be present?
- Ensure training records are accessible



Violation 3: Inactive or no EPA ID

Federal EPA ID Numbers (CAR, CAP, CA, CAD, CAT) are required for facilities that generate:

- ≥ 100 Kg of RCRA HW per month; or
- ≥ 1 Kg of RCRA acutely HW per month

State (CA) EPA ID Numbers (CAL, CAC, etc.) are required for facilities that generate:

- < 100 Kg of RCRA HW per month;
- < 1 Kg of RCRA acutely HW per month
- ANY Non-RCRA HW



Violation 3: Inactive or no EPA ID

Common issues observed:

- Inactive EPA ID Number
- Incorrect EPA ID Number type (Federal vs. State)

Tips for maintaining compliance:

- Conduct the Electronic Verification Questionnaire (eVQ) *annually*
 - Reporting Cycle – July
 - Guides found on DTSC Website
(https://evq.dtsc.ca.gov/Documents/user_guide.pdf)
- Review HW manifests to confirm if you meet threshold for Federal EPA ID



Violation 5: HMBP not certified on time

HMBP shall be submitted/certified annually in CERS, includes:

- Business Information
- Chemical Inventory with site map
- Emergency Response/Contingency Plan

Submit/certify annually

- Can certify when no changes have occurred
- Must submit at least every three years



Violation 5: HMBP not certified on time

Common issues observed:

- CERS submittal is overdue
- Missing or incomplete element
 - Confusion about due date (one year from of previous full submittal)
 - “Not Accepted” submittal elements not corrected by the facility (due 30 days after review by EHS)
- CERS Submittal has been “Certified” instead of “Submitted”

Tips for maintaining compliance:

- Set a reminder to complete HMBP submittal one year from past submittal date
- Certify annually and submit every three years
- Or just submit every year



Violation 5: HMBP not certified on time



Submitted	Facility	Inventory	Plans
12/22/2021 8:44AM	Accepted 12/27/2021		
8/31/2021 12:42PM	Accepted 9/3/2021	Accepted 9/3/2021	
6/17/2021 3:19PM	Accepted 7/29/2021	Not Accepted 7/29/2021	Accepted 7/29/2021
8/17/2020 4:53PM	Accepted 8/28/2020	Not Accepted 2/22/2021	Accepted 8/28/2020

Submitted	Facility	Inventory	Plans
6/7/2023 8:48AM	Accepted 6/28/2023		
2/17/2023 12:47PM	Certified 2/17/2023	Certified 2/17/2023	Certified 2/17/2023
6/30/2022 7:36AM	Accepted 8/31/2022		
3/1/2022 9:49AM	Certified 3/1/2022	Certified 3/1/2022	Certified 3/1/2022
12/22/2021 8:44AM	Accepted 12/27/2021		
8/31/2021 12:42PM	Accepted 9/3/2021	Accepted 9/3/2021	
6/17/2021 3:19PM	Accepted 7/29/2021	Not Accepted 7/29/2021	Accepted 7/29/2021

Certified – 2/17/2023

Certified – 3/1/2022

Submittal – 6/17/2021

6-17-21 is the most recent *complete* HMBP Submittal (Facility, Inventory, Plans); next submittal due date based on the date the oldest HMBP submittal element was accepted.

Submittal is required in 2024.

Violation 7: Biohazardous waste stored too long

Maximum storage time limits for biohazardous waste:

- Generators of 20 lbs/month or more: seven days
- Generators of less than 20 lbs/month: 30 days
- Generators who freeze their biohazardous waste: 90 days



Violation 7: Biohazardous waste stored too long

Common issues observed:

- Waste on site for too long
- Missing weekly pick ups

Tips for compliance:

- Schedule weekly pickups
- Maintain medical waste disposal receipts for two years (LQG) or three years (SQG)
- Be able to explain missing weeks



Violation 8: Site map not submitted or insufficient

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

Must submit site map in CERS with HMBP submission



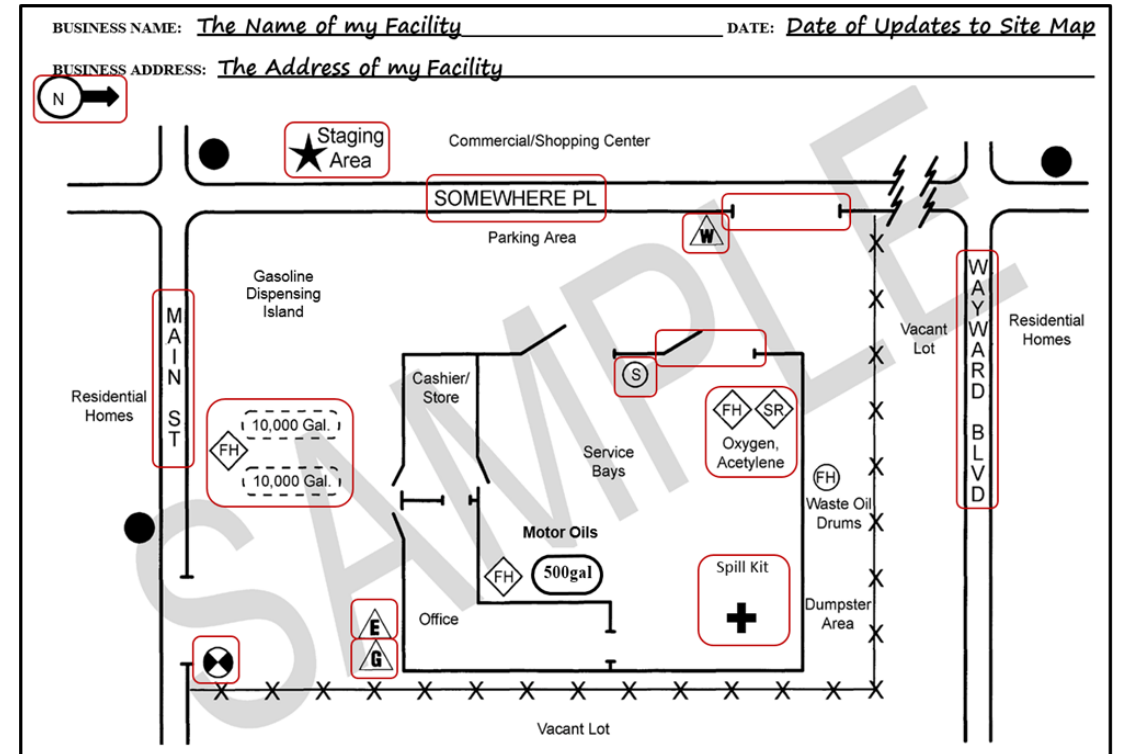
Violation 8: Site map not submitted or insufficient

Common issues observed:

- Missing or misplaced elements
- Site map not updated with substantial change

Tips for compliance:

- Review site map with HMBP submissions or changes on site



Violation 9: Unlabeled MW containers

- Primary containers accumulating medical waste (MW) must be labeled with electronic tracking system or generator's name, address, and phone number
- Required when container begins accumulating MW
- Can be label/sticker or pre-printed on bags



Violation 9: Unlabeled MW containers

Common issues observed:

- Facilities add label when moving container/bag to MW storage area
 - Or expect hauler to add label
- Labels have wrong/old information
- Labeling not part of standard procedures
- Label on inside of bag

Tips for compliance:

- Keep labels near bags, label bags/containers immediately
- Incorporate into procedures
- Walkthrough and check for labels



Violation 10: Completed manifests unavailable

- Treatment, Storage, and Disposal Facilities (TSDFs) sign the bottom of the manifest and mail it to generator
- Three years of TSDF signed copies required on site
 - Only the signed copy required

Please print or type. (Form designed for use on 8 1/2" x 11" paper)

Form Approved OMB No. 2000-0089

UNIFORM HAZARDOUS WASTE MANIFEST

1. Generator's Name and Address (21001) (Optional) 2. Generator's Phone Number 3. Page 1 of 2 (Emergency Response/Phone) 4. Manifest Tracking Number

5. Material's Name and Hazard Characteristics (See Section 304 for Hazardous Waste Definitions) 6. Material's Quantity (Specify Unit Measure) (3000)

7. Generator's (Facility) Name 8. EPA ID Number 9. EPA Region

10. Generator's Company Name 11. U.S. State Number

12. Designated Facility Name and Address 13. EPA ID Number

Facility's Phone

14. U.S. DOT Classification (including Proper Shipping Name, Hazard Class, ID Number and Packing Group (if any))	15. Containers		17. Total Quantity	18. Total Weight	19. Waste Codes		
	No.	Type			11	12	13
1							
2							
3							
4							

14. Additional/Restricting Information and/or Special Instructions

15. GENERATOR'S OFFICER'S CERTIFICATION: I hereby declare that the content of this manifest is fully and accurately described above by accurate description, amount described, packaged, manifested, identified, and correct, except as noted in proper condition for transport according to applicable international and national government regulations. I request shipment under the following: (Specify I certify facilities systems of this manifest comply in full with the standards of the National Fire Protection Association of California.) I certify that this waste destination is as described in 14. (If I am not a party generator) or as follows:

Destination/Officer's Facility/Type Name Signature Month Day Year

16. Manifestation (Remarks) (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information)

17. Generator's Acknowledgment of Receipt of Material Signature Month Day Year

18. Generator's Representative Name Signature Month Day Year

19. Emergency (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information) (Emergency Response/Contact Information)

20. Acceptance by Generator (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone)

Facility's Phone

21. Generator's Representative Name/Address/Phone (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone)

22. Manifestor/Receiver Representative Name/Address/Phone (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone)

23. Designated Facility Owner or Operator (Designated Facility Name/Address/Phone) (Designated Facility Name/Address/Phone) (Designated Facility Name/Address/Phone) (Designated Facility Name/Address/Phone) (Designated Facility Name/Address/Phone)

Signature Month Day Year

24. Manifestor/Receiver Representative Name/Address/Phone (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone) (Generator's Name/Address/Phone)

Signature Month Day Year

DESIGNATED FACILITY TO DESTINATION STATE (IF REQUIRED)



Violation 10: Completed manifests unavailable

Common issues observed:

- Missing manifests
 - Only have initial copy
 - Copy sent to DTSC and not kept on site

Tips for compliance:

- Keep manifests on site
- Review manifests to ensure none are missing
- Request missing copies from HW hauler



Honorable mention: HW labeling

Hazardous waste (HW) labels shall contain:

- The Words “HAZARDOUS WASTE”
- Name and address of generator
- HW accumulation start date
- Physical state of the HW
- Composition of the HW
- Hazard classification/properties

HAZARDOUS WASTE

STATE AND FEDERAL LAWS PROHIBIT IMPROPER DISPOSAL
IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY
AUTHORITY, THE U.S. ENVIRONMENTAL PROTECTION AGENCY OR
THE CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL

GENERATOR INFORMATION:
NAME _____
ADDRESS _____ PHONE _____
CITY _____ STATE _____ ZIP _____

EPA ID NO. / MANIFEST DOCUMENT NO. _____
EPA WASTE NO. _____ CA WASTE NO. _____ ACCUMULATION START DATE _____

CONTENTS, COMPOSITION: _____

PHYSICAL STATE: SOLID LIQUID HAZARDOUS PROPERTIES: FLAMMABLE TOXIC
 CORROSIVE REACTIVITY OTHER _____

D.O.T. PROPER SHIPPING NAME AND UN OR NA NO. WITH PREFIX

HANDLE WITH CARE!



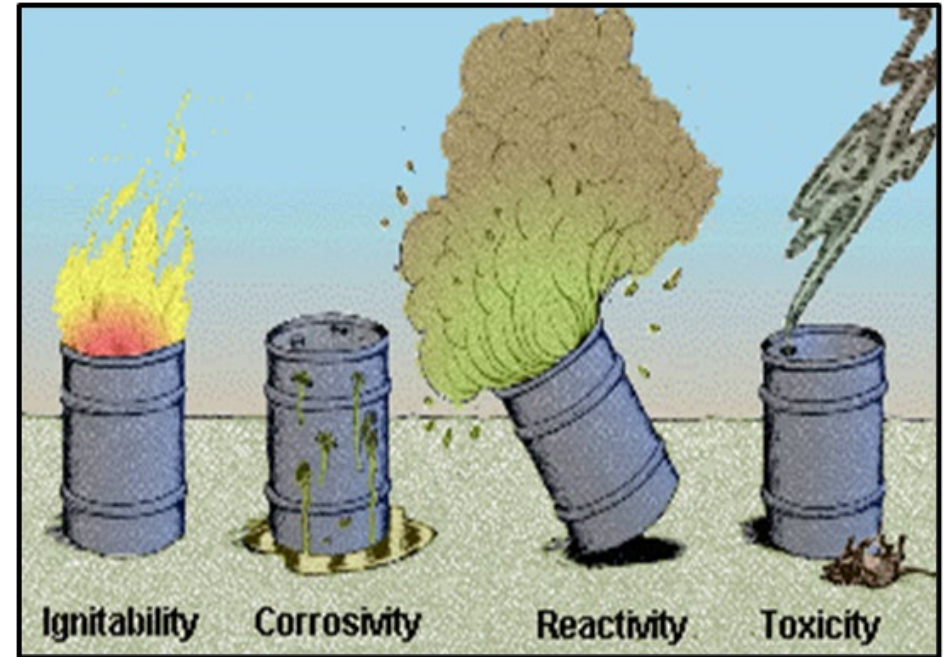
Honorable mention: HW labeling

Common issues observed:

- Incomplete or incorrect information
- Label faded or missing

Tips for maintaining compliance:

- Proper waste determination
- Check your labels periodically



Honorable mention: No permit

Unified Program Facility Permit required if subject to any CUPA program


- Hazardous Waste
- Hazardous Materials Business Plan
- Underground Storage Tank
- Aboveground Petroleum Storage Act
- CA Accidental Release Prevention
- Medical Waste

Common issues observed:

- Operating without permit for more than 30 days
- Allowing permit to expire

SEP **County of San Diego** **2023**
DEPARTMENT OF ENVIRONMENTAL HEALTH AND QUALITY
UNIFIED PROGRAM FACILITY PERMIT
P.O. BOX 129261, SAN DIEGO, CA 92112-9261 / (858) 505-6661 / (800) 253-9933 / FAX (858) 999-8920
www.sddehq.org

Owner/Operator Name: [REDACTED]
Facility Name: [REDACTED]
Facility Located at: [REDACTED]
Mailing Address: [REDACTED]


Amy Harbert
Director

Record Number: [REDACTED]

UNIFIED PROGRAM FACILITY PERMIT
Permit valid: 10/1/2022 to 9/30/2023
RENEWAL IS REQUIRED BEFORE EXPIRATION DATE

The Unified Program Facility Permit is required due to the following Program elements:

- Facility stores/handles Hazardous Materials in reportable quantities and is subject to Hazardous Materials Business Plan requirements.
- Facility generates Hazardous Waste.

This information is taken from the California Environmental Reporting System (CERS), unless discrepancies were observed during an inspection.



Honorable mention: No permit

Tips to maintain compliance:

- If you become subject to a CUPA program:
 - Update business activities in CERS
 - Update hazardous materials inventory
- Must renew permit annually
 - Check date on permit
 - Ensure permit fees are paid

Site Identification

Hazardous Materials

Does your 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 cubic feet for compressed gases (include liquids in ASTs and USTs); or is regulated under more restrictive local inventory reporting requirements (shown below if present); or the applicable Federal threshold quantity for an extremely hazardous substance specified in 40 CFR Part 355, Appendix A or B; or handle radiological materials in quantities for which an emergency plan is required pursuant to 10 CFR Parts 30, 40 or 70? [*](#)

Unified Program Local Reporting Requirements for San Diego County Department of Environmental Health and Quality

- **Hazardous Waste Reporting:** Regulated facilities in this jurisdiction are required by local ordinance to report all hazardous waste(s), including wastes that are less than 55 gallons, 500 pounds, and for waste compressed gases less than 200 cubic feet. To comply with the law report all hazardous waste generated in the Hazardous Materials Inventory Submittal Element (San Diego County Code §68.904(a)(2) and §68.905).
- **Medical Waste Reporting:** Regulated facilities in this jurisdiction are required by local ordinance to report all medical waste(s), including wastes that are less than 55 gallons and 500 pounds. To comply with the law report all medical waste generated in the Hazardous Materials Inventory Submittal element (San Diego County Code §68.904(a)(2), §68.905, and §65.1202).
- **Toxic Gas Reporting:** Regulated facilities in this jurisdiction are required to report, as a hazardous material inventory any quantity of toxic gas with a TLV value of less than or equal to 10 ppm in the Hazardous Materials Inventory Submittal Element (San Diego County Code §68.1113).
- **Photographic Silver Waste:** Regulated facilities in this jurisdiction are required to report onsite photographic waste treatment/silver recovery annually (San Diego County Code §65.107(k)(14) and §68.909.5).

Yes

Underground Storage Tank(s) (UST)

Does your facility own or operate underground storage tanks? [*](#)

No

Hazardous Waste

Does your Facility...

Does your facility generate Hazardous Waste? [*](#)

No

If yes, an EPA Identification Number (EPA ID) is required.



Honorable mention: Bilingual biohazardous waste warning sign

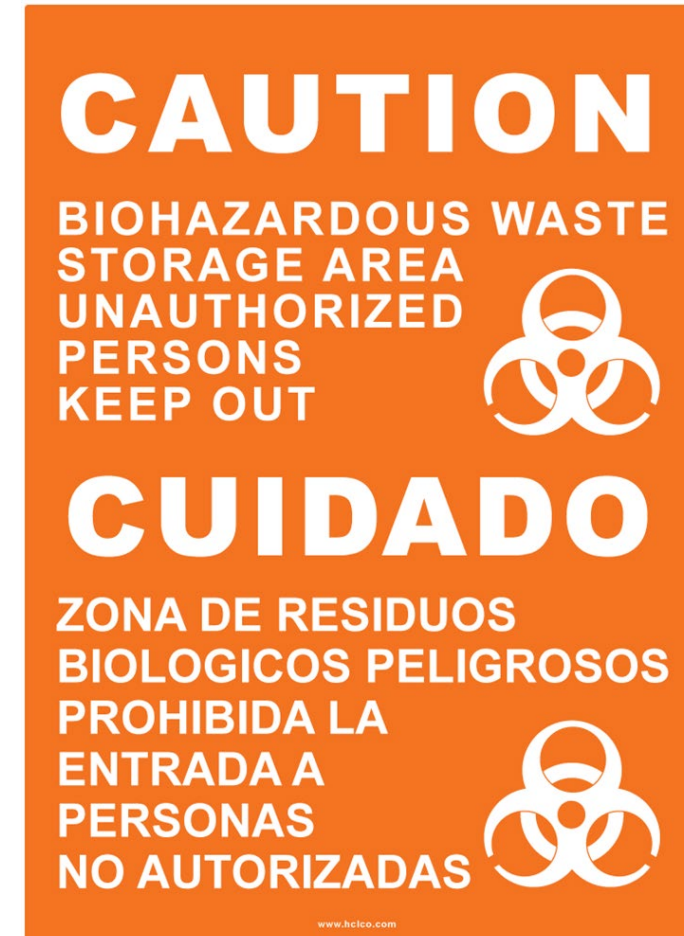
- Must label designated MW accumulation area with a bilingual biohazardous warning sign
- Must read “CAUTION--BIOHAZARDOUS WASTE STORAGE AREA--UNAUTHORIZED PERSONS KEEP OUT,”
- Two languages, English and another
- Legible from 25 feet

Common issues observed:

- Sign missing or does not meet requirements

Tip for compliance:

- Walk through facility to ensure requirements met



Questions?

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