Top Five Violations in the Biotech/R&D Industry

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Objectives

➢ Awareness of the most common violations

- Easily overlooked
- Misunderstood
- Difficult to track

➢ Provide a refresher on the requirements

- Summary and generalization

➢ Assist you in maintaining compliance

- Explanations
- Tips

Remember: Achieving compliance is different for every facility.

Definitions

Acronym	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
UPFP	Unified Program Facility Permit

Top Violations: #5 (A and B)

A. Chemical inventory incomplete or not submitted in CERS.
[HSC 25505(a)(1); 25507(a); 25508.1(a-b); 19 CCR 26]

B. Failed to report &/or update the required inventory information for hazardous waste(s) generated at the facility in CERS [SDCC 68.904(a)(2)]

Reportable Hazardous Materials (HMBP)

- Ensure that Hazardous Materials are updated in CERS, <u>WITHIN 30 DAYS</u> of a <u>SUBSTANTIAL CHANGE</u> to your facility inventory.

Reportable Hazardous Wastes

- Ensure all commonly generated Hazardous Waste streams are reported in CERS.

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Common Issues Observed:

- Hazardous materials/hazardous wastes stored on site not reported in CERS

- Hazardous materials previously on the border of being non-reportable (Example: Compressed gases with different reporting requirements, such as CO_2, Nitrogen, Argon, etc.)

- Periodically/rarely generated hazardous waste streams not reported in CERS

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Helpful tips to Maintain Compliance – HMBP

- Substantial Change is defined in HSC 25508.1

  →A 100 percent or more increase in the quantity of a previously disclosed material.

  →Any handling of a previously undisclosed hazardous material subject to the inventory requirements of this article.

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B. Failed to report &/or update the required inventory information for hazardous waste(s) generated at the facility in CERS [SDCC 68.904(a)(2)]

Helpful Tips to Maintain Compliance – HW Reporting

- All **routinely generated** hazardous waste shall be reported in CERS.

  – Even if the waste is generated every 2-3 years (Example: HW generated from periodic maintenance)

  – Check past three years of HW manifests

  – Lab packs have special exceptions, but are required to be reported
    https://www.sandiegocounty.gov/content/dam/sdc/deh/hmd/pdf/HMG-4020%20(02-2020)%20Lab%20Pack%20CERS%20Reporting%20Guidance.pdf

Top Violations: #4

Failed to Obtain &/Or Maintain an Active EPA ID Number.
[22 CCR 66262.12(a)]

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

EPA ID prefix definition guide found on DTSC Website

Top Violations: #4

Failed to Obtain &/Or Maintain an Active EPA ID Number.

[22 CCR 66262.12(a)]

Common Issues observed:

- Failing to keep EPA ID Number active

- Incorrect EPA ID Number type (Federal vs. State) used by the facility

Top Violations: #4

Failed to Obtain &/Or Maintain an Active EPA ID Number.
[22 CCR 66262.12(a)]

Tips for Maintaining Compliance:

- Conduct the Electronic Verification Questionnaire (eVQ) <u>ANNUALLY</u>

  – Reporting Cycle – July

  – Guides found on DTSC Website
    (https://evq.dtsc.ca.gov/Documents/user_guide.pdf)

- If you are a Non-RCRA HW generator and manage any RCRA HW streams:

  – Review HW manifests each month, to ensure you are below the threshold for a Federal EPA ID

Top Violations: #3

Failed to properly label/date hazardous waste container &/or tank [22 CCR 66262.34(f)]
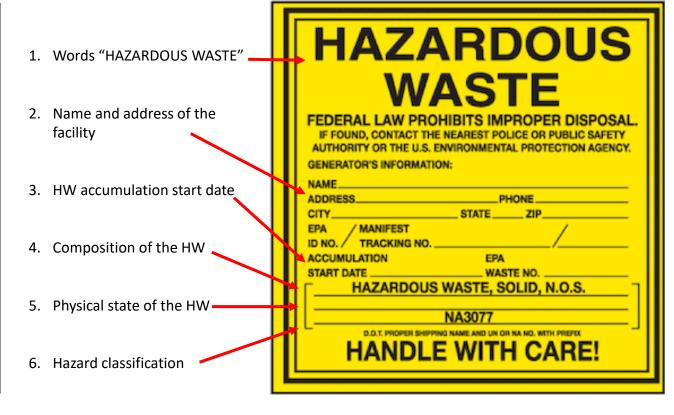
Hazardous waste labels shall contain:

- The Words "HAZARDOUS WASTE"

- Name and address of the facility generating the HW

- HW accumulation start date (first drop of waste)

- Physical state of the HW (solid vs. liquid)

- Composition of the HW (What is the waste?)

- Hazard classification/properties (flammable, toxic, corrosive, reactive, etc.)

Top Violations: #3

Failed to properly label/date hazardous waste container &/or tank [22 CCR 66262.34(f)]

Ensure your labels have all information required by 22 CCR 66262.34(f). Keep in mind different label formats.

1. Words "HAZARDOUS WASTE"

2. Name and address of the facility

3. HW accumulation start date

4. Composition of the HW

5. Physical state of the HW

6. Hazard classification

Top Violations: #3

Failed to properly label/date hazardous waste container &/or tank [22 CCR 66262.34(f)]

Common Issues Observed:

- Incomplete information

- Information faded from sunlight exposure

- Incorrect information

- Missing labels

Top Violations: #3

Failed to properly label/date hazardous waste container &/or tank [22 CCR 66262.34(f)]

Tips for Maintaining Compliance:

- Does the container have HW?

  - Proper waste determination

- Check your labels periodically

  - Is the HW label completely filled out?

  - You should be checking your HW containers weekly, at minimum

Top Violations: #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 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.

  ✓ Training program may take employee positions and/or job responsibilities into consideration.

Top Violations: #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)]

Common Issues Observed:

- Initial training not provided to new employees

- Annual training not provided to current employees

  – Or training missed for the year

- 3 years of records are unavailable

- No training plan/schedule is in place, required by HMBP

Top Violations: #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)]

Tips for Maintaining Compliance:

- ALL employees are trained in release/threatened release procedures.
- Are staff commonly interacting with hazardous materials properly trained?
- Are employees confident about their role if a release occurs? (i.e. evacuation route, staging area, contact agencies, etc).
  - Do employees know how to access/review the HMBP?
    - Is the HMBP accessible?
  - Will a competent individual be present at all times (work/after hours)?
- Do YOU have access to training records?
  - LMS records typically maintained by HR
- Is there a colleague/backup with access to training records?

Top Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

HMBP shall be submitted/certified <u>ANNUALLY</u> in CERS, which includes:

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

Top Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

HMBP shall be submitted/certified <u>ANNUALLY</u> in CERS:

- 19 CCR 2654(b) – Submitted/certified annually (using CERS "Recertify" function).
  - Applicable when NO changes have occurred.

- 27 CCR 15188(a),(b),(d), HSC 25508(a)(1) – Submitted every three years

Top Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

Common Issues Observed:

- CERS submittal is overdue

- Missing or incomplete element

  - Confusion about due date (one year from date of previous COMPLETE submittal)

  - "Not Accepted" submittal elements are not corrected by the facility (this is due 30 days after being reviewed by EHS)

- CERS Submittal has been "Certified," instead of "Submitted" (three-year mark)

Top Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

Tips for Maintaining Compliance:

- Set a reminder to complete HMBP submittal one year from your submittal date

- Certify annually, AND

- Submit every three years

Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

When is the next HMBP Due?

A. 12-22-22
B. 8-31-22
C. 6-17-22
D. None of the Above

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

Violations: #1

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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

6-17-21 is the most recent <u>COMPLETE</u> HMBP Submittal (Facility, Inventory, Plans); Based on the date the oldest HMBP submittal element was accepted.

Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

Should the Facility Submit or Certify in 2024?

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

Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

Answer – Make a Submittal on or before 2/17/ 2024

Certified – 2/17/2023

Certified – 3/1/2022

Submittal – 6/17/2021

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

Violations: #1

HMBP not certified as complete and accurate in CERS by the required due date. [HSC 25508.2, 19 CCR 2654(b)]

Tip for Avoiding a headache:

- Re-submit every year even if no changes occur…

*Note: Submittals can count as your recertification but not the other way around

Violations: Honorable Mention

Unified Program Facility Permit Not Obtained &/Or Maintained
(SDCC 68.905, 68.906, 68.907)

Common Issues Observed

- Operating within <u>ANY</u> CUPA programs (and MW program) for more than 30 days, without a UPFP

  - HW
  - HMBP
  - UST
  - APSA
  - CalARP
  - MW (Non-CUPA)

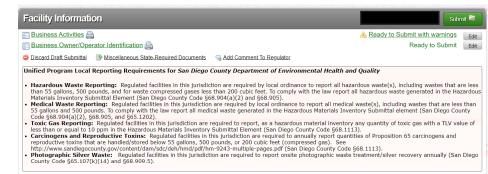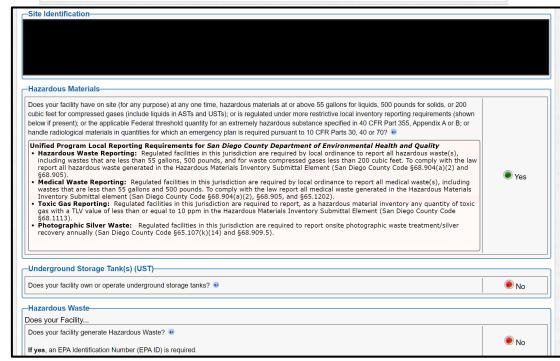- Allowing UPFP to expire

Violations: Honorable Mention

Unified Program Facility Permit Not Obtained &/Or Maintained

(SDCC 68.905, 68.906, 68.907)

Tips for Maintaining Compliance

- If you find you are or will be subject to a CUPA Program, update:

  - Business information element in CERS. Change program from "No" to "Yes"

  - Chemical Inventory (to include applicable Hazardous Material/Waste)

- UPFP is required to be renewed annually

  - Check the due date listed ON YOUR PERMIT

  - Ensure the permit balance is PAID IN FULL (Fees are subject to change annually)

    - https://www.sandiegocounty.gov/content/sdc/deh/hazmat/hmd_permits.html

    - FY23-24 Approved Fees.pdf (sandiegocounty.gov)

Questions?