

Pharmaceutical Waste Management Practices

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Outline

- Classification & Sorting
- Labeling, Containment & Storage
- Recordkeeping & Documentation
- Process Improvement

Classification & Sorting

Post Instructions

CA Pharmaceutical Waste



Controlled Substances



RCRA P Listed



Unregulated Pharmaceuticals



RCRA U Listed



Chemotherapy



Sorting Pharmaceuticals

- Sorting at the Point of Origin HSC§118275
- Disposal References
- Disposal Bins
 - California (MWMA) Pharmaceutical Waste
 - Federal Regulated (RCRA) Hazardous Waste (40CFR§261.33)
 - Trace Chemotherapy
 - Reverse Distribution
 - Controlled Substances
 - Not RCRA Nor CA Toxic Pharmaceuticals

Reverse Distribution

- Expired, Recalled, Overstocked, Short-term
- Eligible for Credit
- Unopened Packaging
- Not for Spilled or Damaged Pharmaceuticals
- Controlled Substances if CSA Registrant

Empty Container Management

- RCRA P List Requirements
 - Triple Rinse With Effective Solvent
 - Dispose of Rinsate as Hazardous Waste
40CFR§261.7(b)(3)
- RCRA U List Requirements
 - All Wastes Removed by Pouring, Pumping, Aspirating. 40CFR§261.7(b)(1)
- Chemotherapy If Pourable, No Drainage When Inverted. If Not Pourable, No Scrape Residuals
HSC§117635(f)

Containment, Labeling & Storage

California Pharmaceutical Waste Containers



Pharmaceutical Waste Labeling

Incineration Only

And

**Facility Name
Facility Address
Facility Phone**

Commingled Pharmaceutical/Sharps Container Labeling

HSC§118275(h)

**Incineration
Or
High Heat Only**

AND

PLUS

**Facility Name
Facility Address
Facility Phone**



Trace Chemotherapy Waste Containers



Trace Chemotherapy Waste Labeling

**Chemotherapy
Waste**

OR

Chemo

AND

**Facility Name
Facility Address
Facility Phone**

RCRA Waste Containers



HAZARDOUS WASTE

STATE & FEDERAL LAW 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

PROPER D.O.T. SHIPPING NAME:

UN OR NA #:

GENERATOR'S NAME AND ADDRESS:

NAME: _____

ADDRESS: _____

CITY: _____ STATE: CA ZIP: _____

GENERATOR'S EPA ID NUMBER:

MANIFEST TRACKING
NUMBER: _____

ACCUMULATION START DATE:

____ / ____ / ____

CA WASTE NUMBER:

EPA WASTE NUMBER:

CONTENTS, COMPOSITION: _____

PHYSICAL STATE:

☐ SOLID ☐ LIQUID

HAZARDOUS PROPERTIES:

☐ CORROSIVE ☐ REACTIVE ☐ OTHER

☐ FLAMMABLE

☐ TOXIC

COMPLETE
FOR
STORAGE

HANDLE WITH CARE!
CONTAINS HAZARDOUS OR TOXIC WASTES

COMPLETE
FOR
TRANSPORT

Pharmaceutical Waste Storage Time

- 90 days after Pharmaceutical Container is Ready for Disposal.

At least Once Per Year.

- 30 Days After Trace Chemotherapy Sharps Container is Full.
- 30 Days After Commingled Pharmaceutical/Sharps Container is Full.

Designated Accumulation Area

Sign (HSC§118310)

**CAUTION-BIOHAZARDOUS WASTE STORAGE
AREA-UNAUTHORIZED PERSONS KEEP OUT**

**CUIDADO-ZONA DE RESIDUOS-BIOLOGICOS
PELIGROSOS-PROHIBIDA LA ENTRADA A
PERSONAS NO AUTORIZADAS**

Interim Storage Area Signs (HSC§118307)

Text

International Symbol

OR

**CAUTION-BIOHAZARDOUS
WASTE STORAGE AREA-
UNAUTHORIZED PERSONS KEEP
OUT**

**CUIDADO-ZONA DE RESIDUOS-
BIOLOGICOS PELIGROSOS-
PROHIBIDA LA ENTRADA A
PERSONAS NO AUTORIZADAS**



RCRA Hazardous Waste Storage Time

- 90 days > 2,200 lbs./month or > 2.2 lbs.
Acutely Hazardous Waste (LQG)
- 180 days 220 lbs. to 2,200 lbs./month or < 2.2
lbs. Acutely Hazardous Waste (SQG)
- 270 days 220 lbs. to 2,200 lbs./month or < 2.2
lbs. Acutely Hazardous Waste if transported
over 200 miles (SQG)

Documentation & Recordkeeping

BIOMEDICAL WASTE RECEIPT LOG		JFH 103
NAME/ADDRESS THIS FACILITY		
RECEIVED FROM:		
REGISTERED TRANSPORTER		

[illegible]

**UNIFORM HAZARDOUS
WASTE MANIFEST**

1. Generator ID Number

2. Page 1 of

3. Emergency Response Phone

4. Manifest Tracking Number

5. Generator's Name and Mailing Address

Generator's Site Address (if different than mailing address)

Generator's Phone:

6. Transporter 1 Company Name

U.S. EPA ID Number

7. Transporter 2 Company Name

U.S. EPA ID Number

8. Designated Facility Name and Site Address

U.S. EPA ID Number

Facility's Phone:

GENERATOR

9a.
HM9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number,
and Packing Group (if any))

10. Containers

No.

Type

11. Total
Quantity12. Unit
Wt./Vol.

13. Waste Codes

1.

2.

3.

4.

14. Special Handling Instructions and Additional Information

15. **GENERATOR'S/OFFEROR'S CERTIFICATION:** I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. If export shipment and I am the Primary Exporter, I certify that the contents of this consignment conform to the terms of the attached EPA Acknowledgment of Consent.

I certify that the waste minimization statement identified in 40 CFR 262.27(a) (if I am a large quantity generator) or (b) (if I am a small quantity generator) is true.

Generator's/Offeror's Printed/Typed Name

Signature

Month Day Year

Manifest Copy Distribution

- Copy 1 Goes to the Destination Facility
- Copy 2 Goes to DTSC
- Copy 3 Is Returned to the Generator
- Copy 4 Goes to the Destination Facility
- Copy 5 Goes to the Transporter
- Copy 6 Stays with the Generator

DTSC Mailing Address

- On receipt, mail the generator manifest copy to:
- DTSC Generator Manifests
- PO BOX 400
- Sacramento, CA 95812-0400

INT'L
TRANSPORTER

16. International Shipments		☐ Import to U.S.	☐ Export from U.S.	Port of entry/exit _____	
Transporter signature (for exports only)		Date leaving U.S. _____			
17. Transporter Acknowledgment of Receipt of Materials					
Transporter 1 Printed/Typed Name	Signature	Month	Day	Year	
Transporter 2 Printed/Typed Name	Signature	Month	Day	Year	

DESIGNATED FACILITY

18. Discrepancy					
18a. Discrepancy Indication Space ☐ Quantity ☐ Type ☐ Residue ☐ Partial Rejection ☐ Full Rejection					
Manifest Reference Number _____					
18b. Alternate Facility (or Generator)			U.S. EPA ID Number _____		
Facility's Phone _____					
18c. Signature of Alternate Facility (or Generator) _____					
Month Day Year					
19. Hazardous Waste Report Management Method Codes (i.e., codes for hazardous waste treatment, disposal, and recycling systems)					
1.	2.	3.	4.		
20. Designated Facility Owner or Operator: Certification of receipt of hazardous materials covered by the manifest except as noted in Item 18a					
Printed/Typed Name		Signature		Month	Day Year

DESIGNATED FACILITY TO GENERATOR

Destination Copy Not Received

- After 35 Days, Contact the Transporter & Destination Facility
- Exception Report after 60 days to:
- DTCS Report Repository
- Generator Information Services Section
- PO BOX 806
- Sacramento, CA 95812-0806
- (22CCR§66262.42)

Record Keeping

- California Large Quantity Generator Medical Waste Disposal Receipts (≥ 200 lbs./month) in any month of 12 month period – Three Years
- California Small Quantity Generator Medical Waste Disposal Receipts < 200 lbs./month – Two Years
- RCRA Hazardous Waste Disposal Manifests – Three Years

Process Improvement

Continuous Review Inventory Management

- Implement Pull Inventory System
- Coordinate with Responsive Primary & Alternate Vendors
- Track Wasted Inventory for Corrections
- Communicate Internal Inventory Availability Between Departments
- Make Pre-existing Arrangements for Unused Pharmaceuticals

Hierarchy of Conservation



Waste Minimization

- Implement Early Identification of Expiration Dates
- Make Allowances for Adverse Reaction, Refusal, and Expired Usefulness when Dispensing
- Optimize Inventory for Use-Specific Package Sizing
- Samples

Summary

- Classification & Sorting
- Labeling, Containment & Storage
- Recordkeeping & Documentation
- Process Improvement

Contact Information

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