TOP 10 VIOLATIONS CITED DURING BIOTECH /R&D INSPECTIONS

EPIC + Program

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PURPOSE OF TODAY'S PRESENTATION

- **Goals of EPIC+ Program**
- **Top 10 Commonly Cited Violations for 2015-2016**
- **Reminders about inspection process**

GOAL & OBJECTIVES OF THE EPIC+ PROGRAM

Goal: Reduce non-compliance of Unified Program Agency violations through **education and outreach**

(1) reflect improved compliance by the regulated community

(2) Motivate regulated parties to reduce their negative impacts on the environment

(3) Establish a risk based inspection process that can direct resources to areas of high risk and non-compliance

INCENTIVES FOR COMPLIANCE WITH EPIC +

- Reduce inspection frequency for R&D Laboratories and Biotechnology businesses from 24 to 36 months
- Institute a flat fee to reflect 36-month inspection frequencies
- UST & Medical Waste LQGs retain 12-month statutory inspection interval.

Significant Non-Compliance status would trigger return to the 24-month inspection interval and a comparable fee schedule.

THE TOP 10 VIOLATIONS

Focus on a narrow set of hazardous waste, hazardous materials, and medical waste violations and show trends in commonly cited violations

The following are the top ten most common violations found at local biotech facilities during 2015-2016

VIOLATION #1: HAZARDOUS MATERIALS BUSINESS PLAN NOT UPDATED

HAZARDOUS MATERIALS VIOLATIONS:

- *Failure to submit a revised business plan upon a substantial change in the handler's operations. HSC 6.95 25508.1(f)*
- *Chemical inventory incomplete or not submitted in CERS. HSC 25505(a)(1); 25506; 25507; and 25508(a)(1)(A).*
- *HMBP not updated to reflect inventory changes or facility information. HSC 25508.1(a-e)*
- *Site map not submitted in CERS or not sufficient. HSC 25505(a)(2) and 25508(a)(1)(A).*

MOST COMMON VIOLATION

Most commonly cited for updates needed to the chemical inventory and facility site map

Certain inventory items are frequently overlooked or the total quantities not reported accurately in the inventory and/or represented on the site map

REPORTABLE CHEMICAL INVENTORY NOT UPDATED IN CERS

Compressed Gases: Remember the changes in threshold quantities of certain compressed gases :

- Compressed Carbon Dioxide- 1000 cubic feet
- Cryogenic (liquefied) gas still reportable at 200 CF but are reported in CERS in gallons
- Compressed gas at STP that are Inert gases (simple asphyxiation or pressure release), the reporting threshold is 1000 CF
  - **Nitrogen**
  - **Helium**
  - **Argon**
  - **Compressed Air**

REPORTABLE CHEMICAL INVENTORY NOT UPDATED IN CERS

Also don't forget to inventory changes to:

- **Diesel fuel for generators**
- **New waste streams generated** (in any amount)- Check your manifests to ensure that all reportable waste streams being generated are also reported in CERS
- **Chemicals in the facilities or engineering department**
  - Boiler and Water Treatment chemicals frequently change

SITE MAP NOT UPDATED

Emergency Response /Spill Response Equipment

- On January 1, 2015, Senate Bill 1261 became effective resulting in changes to the California Health & Safety Code (HSC), Chapter 6.95, Article 1, which governs requirements for the Hazardous Material Business Plan (HMBP).
- Site maps are now required to contain locations of emergency response/spill response equipment.
- For detailed information and guidance see this link on our HMD webpage: http://www.sandiegocounty.gov/content/dam/sdc/deh/hmd/pdf/hmbp/hm-952%20(02-16)%20HMBP.pdf

SITE MAP NOT UPDATED

Standard information missing

- North orientation, adjacent streets, storm and sewer drains, access and exit points, emergency shutoffs, evacuation staging areas, and hazardous material handling/storage areas.

Map not legible/symbols not clear

VIOLATION #2: HAZARDOUS WASTE SATELLITE STORAGE

Hazardous Waste Violation: *Failed to comply with hazardous waste satellite container regulations. 22CCR 66262.34(e)*

WHAT IS SATELLITE ACCUMULATION?

What is required to meet the hazardous waste satellite container regulations?

- The containers holding the waste must be managed in accordance with the requirements of Title 22, Cal. Code Regs., sections 66265.171 (Condition of Containers), 66265.172 (Compatibility of Waste with Containers) and 66265.173(a) (Management of Containers).
- Each container must be labeled with a complete Hazardous Waste Label
- No treatment of hazardous waste is allowed while being accumulated under the satellite accumulation exemption.
- Defined in Title 22 Cal. Code Regs., section 66262.34(e): Allows accumulation of hazardous waste at a generation point for up to one year subject to certain limitations:

SATELLITE ACCUMULATION

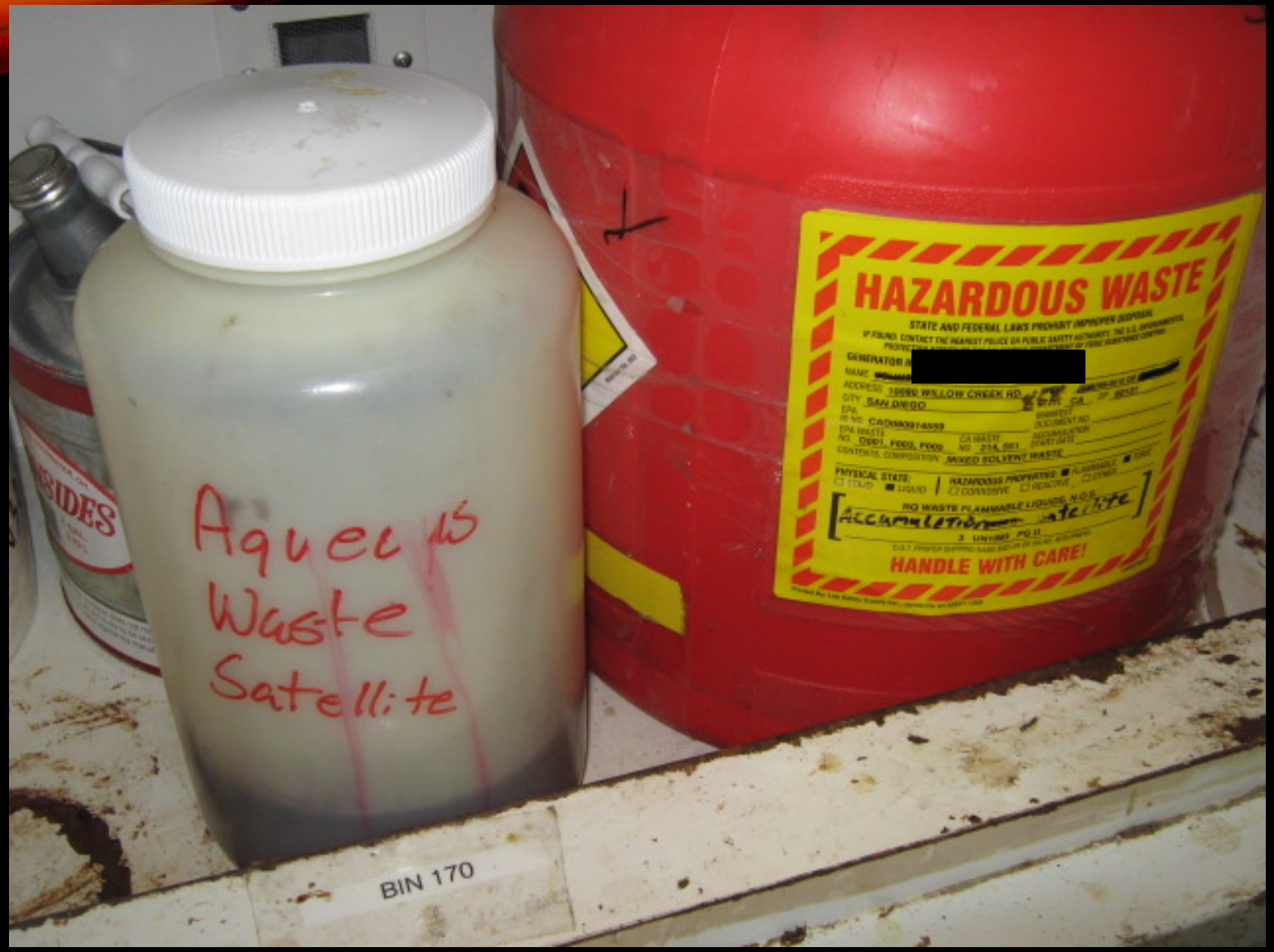
A generator may accumulate as much as 55 gallons of one type of hazardous waste, or one quart of acutely or extremely hazardous waste, provided they meet the following:

1. The waste is accumulated in containers (not tanks) at the initial accumulation point, near or at the generation point, and is under the control of the operator of the process generating it.
2. The generator does not hold the hazardous waste onsite for more than one year from the initial date of accumulation.
3. The initial date of accumulation is clearly marked and visible on each container
4. 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 discussed above.

EXAMPLES OF SATELLITE ACCUMULATION

A satellite hazardous waste container must be labeled with:

- "Hazardous Waste"
- The name and address of generator
- Physical state and waste composition
- Hazardous properties, and
- Accumulation start date.



Hazardous waste container not labeled properly. Missing information. Wrong generator name on the mixed solvent waste.

VIOLATION #3: HAZARDOUS WASTE LABELING

HAZARDOUS WASTE VIOLATION: *22 CCR 12 66262.34(f); 66262.34(a)(2), 66262.34(a)(3)*

Failure to properly label Hazardous Waste accumulation containers with the following requirements:

- *words "Hazardous Waste",*
- *Name and address of the generator,*
- *Physical and chemical characteristics of the Hazardous Waste,*
- *Starting accumulation date*

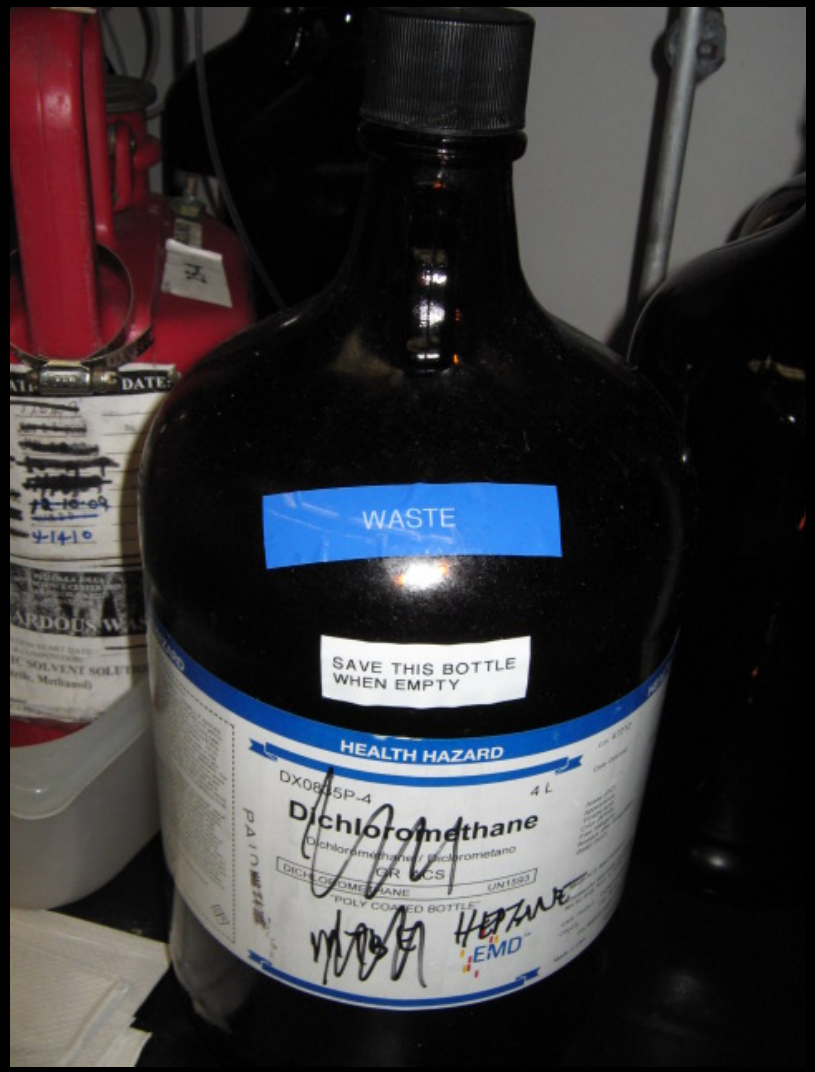
HAZARDOUS WASTES IN THE TRAY WERE IDENTIFIED AS TOXIC SOLIDS. THESE WASTES WERE NOT LABELED WITH A WASTE LABEL.

ETHIDIUM BROMIDE WASTE MISSING HAZARDOUS WASTE LABEL

UNREADABLE LABEL. MAKE SURE ALL INFORMATION IS LEGIBLE

DON’T FORGET TO LABEL NON-LABORATORY WASTE STREAMS

HEXANE WASTE: MISSING A LABEL



WASTE VACUUM PUMP OIL: LABEL NOT COMPLETE

VIOLATION # 4: MEDICAL WASTE CONTAINER LABELING

MEDICAL WASTE VIOLATION:

Primary containers accumulating Medical Waste not labeled with generator's name, address, and phone number. SDCC 68.1205

Applies to all medical waste containers

Sharps container-No identifying waste generator information (e.g., name, address, & phone number)

Medical waste accumulation storage – 7 red bags observed not labeled with generators name, address, and phone number.

VIOLATION #5: AUTOCLAVE THERMOMETER NOT ANNUALLY CALIBRATED

MEDICAL WASTE VIOLATION: *Recording thermometer not calibrated annually. HSC 118215 (a)(2)(B)*

- Applies to facilities that treat medical waste using steam sterilization
- Confirms steam sterilization reached 121 C/250 F for 30 minutes

REQUIREMENTS FOR TREATING MEDICAL WASTE ONSITE (AUTOCLAVE)

Remember …..

Other required MW Treatment records:

- Standardized written operating procedures for steam sterilization
- Monthly spore test (biological indicator) records maintained to confirm proper disinfection
- Treatment records/logs of dates, time, and temperature onsite for the past 2 years
- Current MW Treatment Permit with HMD (LQG'S)

VIOLATION #6: HAZARDOUS WASTE ACCUMULATION TIME

Violation: Accumulated waste too long

- >90 days for **Large Quantity Generators.** HSC 25201(a); 22 CCR 66262.34 (a) and (c)

- >180 days for **Small Quantity Generators** (or 270 if waste is transported over 200 miles) or (>90 days for acutely hazardous waste)

40 CFR 262.34 (e) and (f); HSC 25201 (a); 22 CCR 66262.34(d)

ACUTELY OR EXTREMELY HAZARDOUS WASTE

- If you accumulate more than one (1) kilogram of acutely hazardous waste (P-listed) or extremely hazardous waste, you must comply with the hazardous waste large quantity generator standards for that period.
- Detailed training plans, contingency plans and records
- 90 day accumulation.

Remember: P listed waste must be managed as a RCRA HW if:

(1) It contains a sole active ingredient that appears on the P list, AND

(2) It has <u>not</u> been used for its intended purpose

P-listed Chemicals Common to Biotechs and Research Labs

- **Sodium Cyanide- P106**
- **Osmium textroxide- P087**
- **Potassium Cyanide- P098**
- **Sodium Azide- P105**
- **Nitric Oxide- P076**

VIOLATION #7: OPEN HAZARDOUS WASTE CONTAINERS

Hazardous Waste Violation: *Failed to keep container closed.*

66265.173(a); 40 CFR 262.34 (d)(2); 265.173; 22 CCR 66262.34(d)(2) SQG and LQG

- Containers must be kept closed except while adding or removing waste
- Funnels count!!

Container of ethidium bromide waste was missing a lid and missing the hazardous waste label

Organic solvent hazardous waste can not closed.

IN THE FUME HOOD A CONTAINER HOLDING A WASTE SOLVENT MIXTURE (TFA, ACETONITRILE, METHANOL, ETHANOL, ISOPROPYL

VIOLATION #8: FAILED TO MAKE A PROPER WASTE DETERMINATION

HAZARDOUS WASTE VIOLATION:

Failed to make a proper waste determination. 22 CCR 66262.11, 66262.40(c)

- Generator's responsibility
  - Generator knowledge
  - Laboratory testing
  - Classification as a waste

- Violation can apply to several different situations.....

PAINT CANS DAMAGED AND RUSTED-HAZARDOUS WASTE ?

Flammable cabinets– All of these containers were identified as hazardous waste and nearly all were not labeled at the time of the inspection

Check fume hoods for containers that look like this!!

Chemical fume hood -multiple unknown unclassified wastes accumulating for an unknown length of time.

Lab hood: Several containers identified as hazardous waste by onsite staff. Other violations that can apply: Hazardous waste not accumulated in containers, not kept closed, or not properly labeled, etc

Don't forget to check chemical storage lockers and flammable cabinets!

Chemical Storage Locker – Hazardous waste containers not labeled properly. Declared hazardous waste upon discovery of compromised container.

VIOLATION #9: DAMAGED/DETERIORATED CONTAINERS

HAZARDOUS WASTE VIOLATION:

Failure to repackage damaged/deteriorated hazardous material container with in 96 hours. HSC 25124(b)(3)(B) & CCR 66262.34(f)

- Deteriorated material not repackaged with 96-hours is then deemed waste by the State law
- Most commonly damaged or leaking containers are found in flammable storage cabinets, under fume hoods, and in chemical storage areas
- Check for containers leaking, crystallizing, damaged, rusted…etc

Check Corrosive and Acid storage cabinets!

70% Nitric Acid bottle found in the Corrosive cabinet, observed in poor condition and the cap was damaged/deteriorated.
This was identified as hazardous waste during the inspection and transferred into a labeled hazardous waste container

The rusted container labeled as Phosphorous oxychloride

Close up of a material container rusted and leaking

Chemical storage room cabinet: this 500mg bottle of sodium tert butoxide was observed damaged and the contents spilling out

Bottle of Cyanogen Bromide was observed to be open and the contents spilling out onto the lab bench and covering the opening of the bottle.

open bottle of Cyanogen Bromide, an extremely toxic and poisonous chemical

Rust

Corrosive storage locker- Potassium tert-butoxide leaked and corroded the bottom of the container holding it.

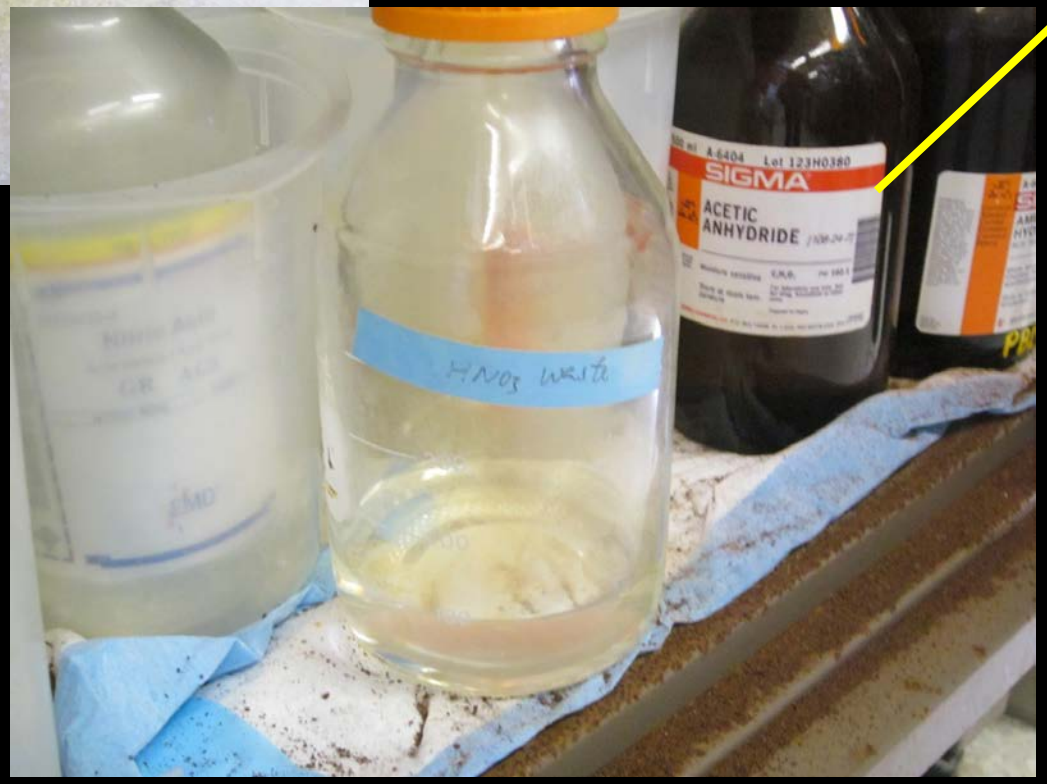
VIOLATION #10: INCOMPATIBLE WASTE NOT SEPARATED

HAZARDOUS WASTE VIOLATION: *Failed to properly separate incompatible waste (SQG and LQG). 40 CFR 262.34 (d)(2); 265.177; 22 CCR 262.34(d)(2); 22 CCR 66265.17(b), 66265.177*

Steps must be taken to ensure that:

- Incompatible wastes are not placed in the same container
- Hazardous waste is not placed in an unwashed container that previously held an incompatible waste.
- The purpose of this is to prevent fires, explosions, reactions, gaseous emissions, leaching, or other discharge of hazardous waste or hazardous waste constituents which could result from the mixing of incompatibles

Bottle labeled “Nitric acid waste” under a lab hood, missing a hazardous waste label

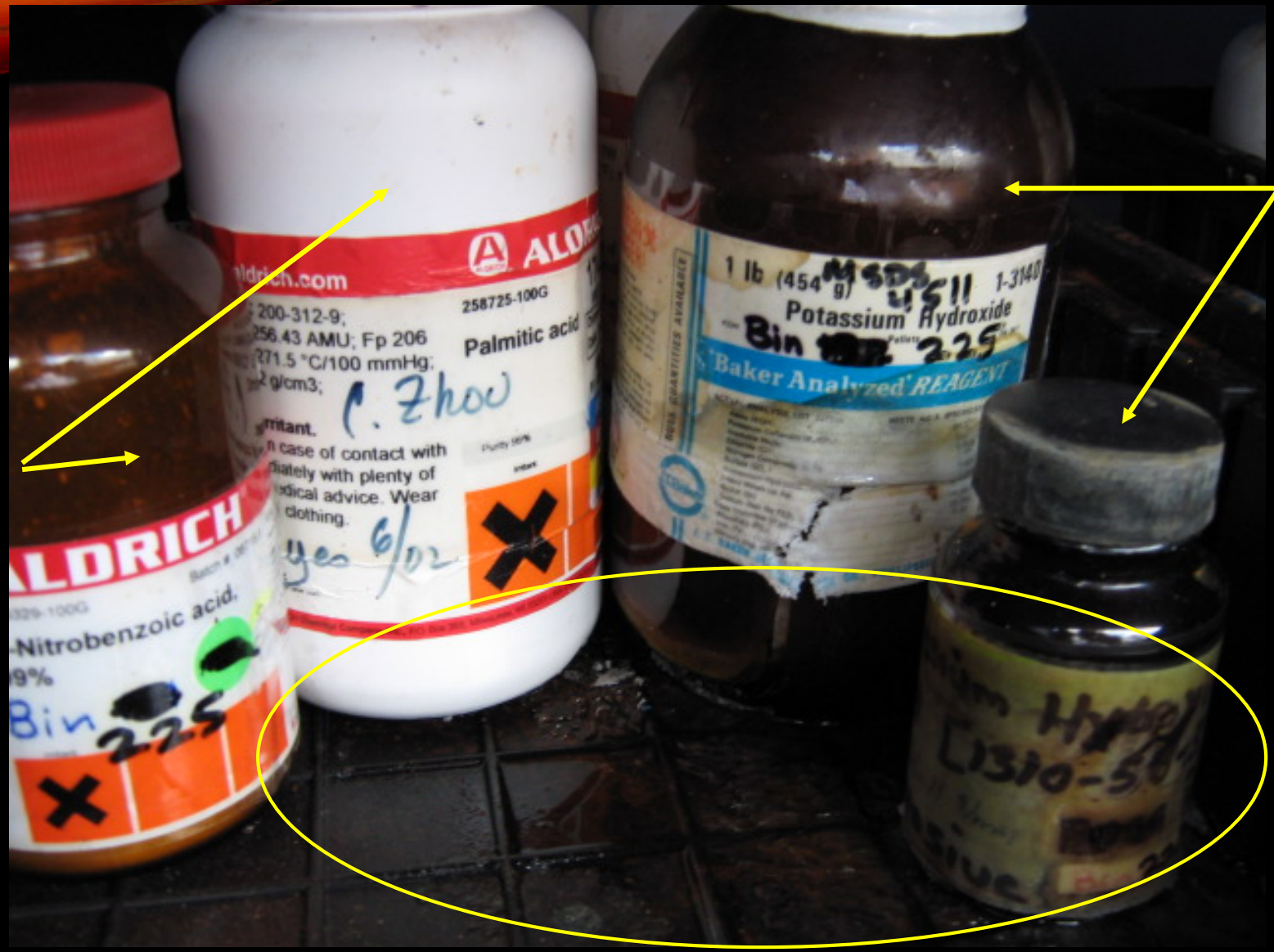


Stored among bottles of incompatible chemicals such as acetic anhydride, and ammonium hydroxide

Leaked material

Corrosive storage locker. Incompatible acid and bases shown leaking next to each other. Damaged hazardous materials that are not repackaged within 96 hours are considered a hazardous waste

Close up…



Close up- Incompatible acid and bases shown leaking next to each other.

A bulging HW drum observed, see next slide. Generator was combining <u>incompatible waste</u> in drum.

Laboratory chemical waste stored in the hazardous waste storage area of a local college

- Bulging container of <u>incompatible mixed inorganic waste</u>
- Top and bottom of container rounded to indicate pressurized
- All waste from non-organic chemistry class dumped into same container, no segregation of acids and bases
- Poorly labeled hazardous waste label, missing hazard properties and only states “Inorganic waste”

- HMD's Emergency Response Team response to this incident of the pressurized container
- Container released reddish-brown gas tested as chromic acid (pH<2)

Reaction within the container from incompatible waste mixing

REMEMBER, YOU ARE REQUIRED TO INSPECT HAZARDOUS WASTE **STORAGE** AREAS **EACH WEEK**

Check for completed labels, damaged containers, open containers, etc during weekly storage area inspections

HOW CAN YOU PREPARE FOR YOUR INSPECTION?

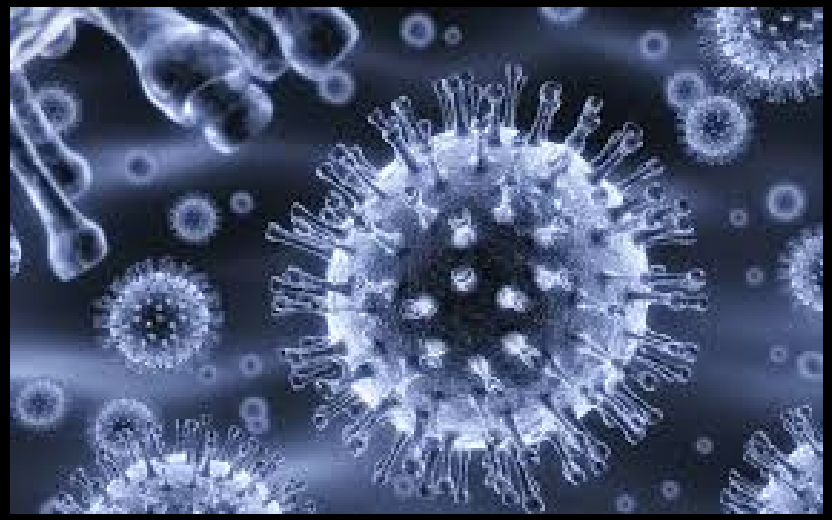
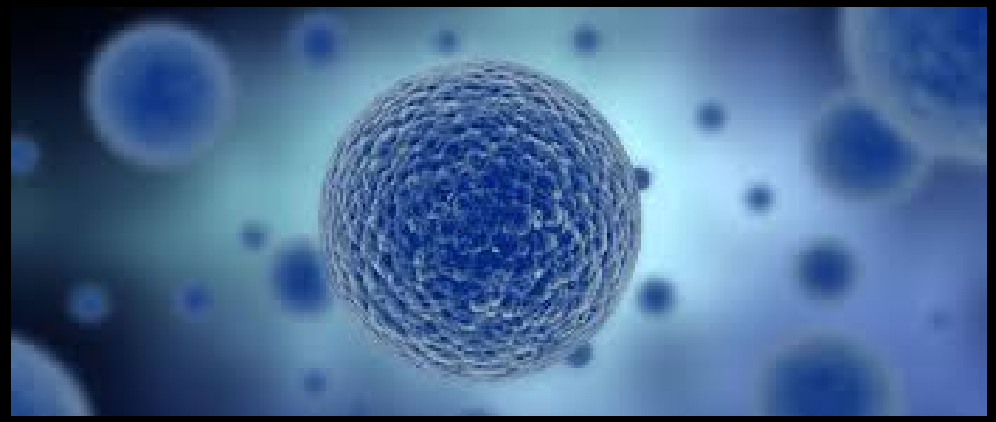
Some Quick Reminders .....

1. Weekly walk through of HW areas- don't forget under sinks, lab hoods, and chemical storage cabinets!
2. Scheduling of inspections-remember your inspection frequency
3. Know your Hazardous Waste generator status -SQG or LQG
4. Training! effective, quality employee training
5. Remember your annual EPIC+ online training
6. Take repeat violations seriously- repeats, even minor violations, add up and can affect your status in EPIC
7. Recertify your HMBP annually based upon your last submittal date and include Inventory and Site Map updates

AREAS OF INTEREST DURING AN INSPECTION INCLUDE:

- Facility perimeter (waste dumpsters, power generators, water treatment system, waste accumulation/storage areas)
- Custodial areas (cleaning chemicals, paints, oils)
- Labs, hazmat storage, facility maintenance areas, manufacturing/mixing areas
- Points of waste generation for medical and hazardous wastes, sinks, chemical storage & satellite waste accumulation areas
- Universal wastes accumulation areas

INSPECTOR: ITEMS CHECKED BEFORE AN INSPECTION MAY INCLUDE

- Site's EPA ID number current?
- Hazardous Waste generator status per tracking system/data collected during previous inspections, SQG or LQG?
- Previous violations observed?
- Hazardous Materials Business Plan (HMBP), annual Carcinogen List, last HMBP submittal in CERS, site maps on file?
- Medical Waste Management Plan (MWMP) on file, if required?

QUESTIONS?