UCLA
Biosafety Manual

Table of Contents

Laboratory-Specific Biosafety Manual Checklist

Each laboratory is required to have a lab-specific biosafety manual and cannot be borrowed or copied from another lab. At the time of inspection, applicable documents listed below will be reviewed for completion. For questions please contact the Biosafety Program at biosafety@ehs.ucla.edu or 310-206-3929.

Emergency Contact	X
Emergency contact information sheet (Template Issued by Biosafety) – Principal Investigator, Lab Supervisor, Biosafety Office	☐
Administrative	**X**
Copy of your most current IBC application and approval letter – Include copies of amendment approval letters	☐
Copy of your lab's most recent inspection checklist (Issued by Biosafety)	☐
Hazards of Agents (Biohazard Specific) – Technical Data Sheet or information sheet from the vendor (if available) – A brief description of any possible hazards to lab people if exposed. You can use a MSDS or fact sheet print-out from: – Health Canada website: http://www.phac-aspc.gc.ca/msds-ftss/index.html#menu – CDC Diseases & Conditions A-Z index website: http://www.cdc.gov/DiseasesConditions/az/A.html – Lentivirus Guidance Document from the NIH (cut & paste the link into your web browser to open the webpage): http://oba.od.nih.gov/rdna_rac/rac_guidance_lentivirus.html	☐ ☐ ☐ ☐
Training	**X**
Certificates from Biosafety Training (if missing, email Biosafety Program)	☐
Handouts from Biosafety Training (most current copy)	☐
Lab-specific Safety Training Roster (including occupational health surveillance records) – Lab-specific biosafety training must be given by someone who is experienced in manipulation of the biohazard agent being used. All employees must sign and date a training log showing that they were trained in the manipulation of biohazard materials.	☐
Lab-Specific Procedures	**X**
Standard Operating Procedures: must describe, but not limited to the following, (can use Biosafety template) – Personal protective equipment (e.g., lab coat, gloves, etc) – Manipulation, culturing, handling of biohazard materials (lab and/or animal research) – Transport of biohazard materials (lab and/or animal research) – Decontamination (agent, equipment) and disposal procedure including spill clean-up – Procedure to follow if injury or exposure occurs including reporting	☐
Agent Summary Sheet (animal research, if applicable) – Required for each agent listed in the Biohazardous Agents section of your ARC protocol	☐
Procedure for the Disposal of Biohazardous Animals (Issued by Biosafety, if applicable)	☐
Occupational Health and Resources	**X**
Exposure Control Plan (Template Issued by Biosafety)	☐
OSHA Bloodborne Pathogen fact sheets – Download at http://www.osha.gov/OshDoc/data_BloodborneFacts/	☐
HIV/BBP Exposure Card 2008 (Issued by Biosafety)	☐
CDC/NIH Regulations – Printout relevant sections of CDC/NIH regulations from the BMBL – Download at http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm	☐

Emergency Procedures & Contact Information

Principal Investigator

Name: _____
Phone #: _____
Emergency Phone #: _____

Alternate Contact Person

Name: _____
Phone #: _____
Emergency Phone #: _____

EH&S

310-825-5689 (Main Office)
310-206-3929 (Biosafety Main Line)
310-825-3323 (Biosafety Officer)

UCLA Police Dispatch

911 from a campus landline
310-825-1491 from a cell phone

Where to go for Emergency Care

Staff & Graduate Students
Occupational Health Facility, 67-120 CHS, x56771
Mon – Fri 7:30 am – 4:30 pm

Undergraduate Students
Arthur Ashe Wellness Center (next to the John Wooden Center)
Mon – Fri 7:30 am – 4:30 pm

After hours, holidays, weekends, or for major emergencies
UCLA Emergency Room in the Ronald Reagan Medical Center

In-lab Biosafety Training Record

In-lab Biosafety training is required before the start of experiments and at least annually thereafter. Training must be conducted by the PI, lab manager or someone else proficient in biosafety procedures and techniques that will be used in the lab. For questions contact the Biosafety Program at x63929 or biosafety@ehs.ucla.edu.

Principal Investigator: _____

Training Conducted by: _____

The laboratory research personnel listed below have received training in the following topics:
Example: Read the Biosafety Manual

1. _____
2. _____
3. _____
4. _____
5. _____

Example topics include: Biosafety Manual, emergency procedures, signs and symptoms of exposure, clean-up/decontamination procedures, exposure control plan, etc.

Print Name	Signature	Date	Date Hepatitis B Vaccination Offered

Biosafety Cabinet Certification, Maintenance & Repair

Biosafety Cabinets must be certified:

- Newly purchased
- Annually
- Repaired
- Relocated

Technical Safety Services, Inc (TSS)

Los Angeles Office

562-694-3626

Corporate Office

800-877-7742

Email Contact

Gerry Ruiz

gruiz@techsafety.com

Tim Hassler

thassler@techsafety.com

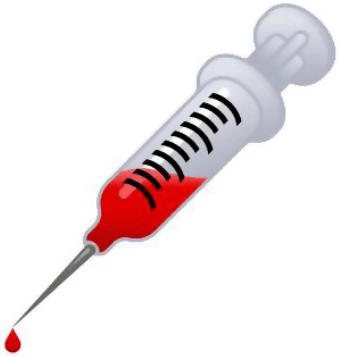
According to the UC system contract, Technical Safety Services (TSS) is the only vendor authorized to service biosafety cabinets at UCLA.

The UCLA EH&S Biosafety Program offers training on the safe use of biosafety cabinets. The training is required for personnel using, purchasing, working with infectious materials under Biosafety Level 2 or higher (including materials under the Bloodborne Pathogens Standard), working with animals requiring biocontainment housing, or other research related projects involving the use of BSC's (also known as tissue culture hoods). Please visit the EH&S website at www.ehs.ucla.edu and click on "Training" for more information.

For more information, please contact the UCLA Biosafety Program at 310-206-3929 or biosafety@ehs.ucla.edu

UCLA ENVIRONMENT, HEALTH & SAFETY

Bloodborne Pathogen Standard Training



UCLA Environment, Health and Safety
Biosafety Program

UCLA ENVIRONMENT, HEALTH & SAFETY

Training Objectives

Identify the hazards associated with Bloodborne Pathogens

Understand local, state and federal regulations

Ensure proper handling and disposal

Review spill response procedures

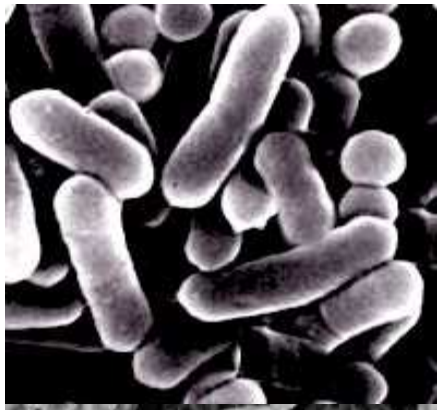
Quiz

Identify the Hazards

Biohazard: An agent of biological origin that has the capacity to produce harmful effects on humans; i.e. microorganisms, toxins and allergens derived from those organisms, and allergens and toxins derived from plants or animals.

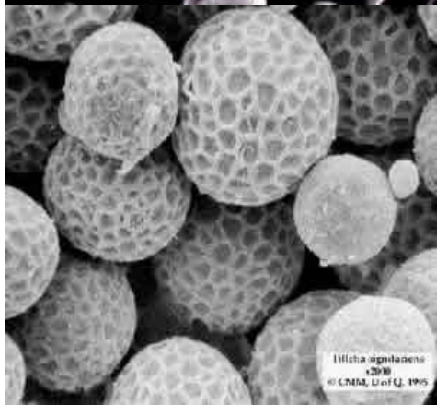
Overview of Disease

- Caused by Pathogens
- Microorganisms are classified into 4 main



Bacteria

Viruses



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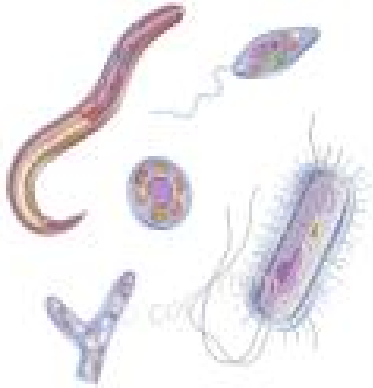


Parasites

Modes of Transmission

Air – drops of mucus, colds, flu (e.g. tuberculosis)

Fecal oral route: enteric usually hand to mouth transmission, contaminated water or food (e.g. salmonella, Hepatitis A)

Bloodborne

What are Bloodborne Pathogens?

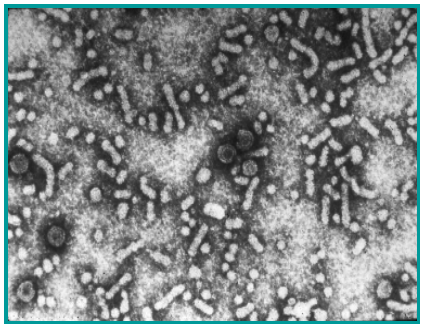
- **Pathogenic microorganisms that are present in in human blood, blood products, and blood components and can cause disease in humans.**

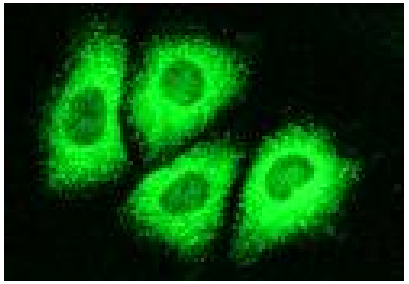
HIV (Human Immunodeficiency Virus)
Hepatitis Viruses (Hepatitis B, C)
Agents that cause…

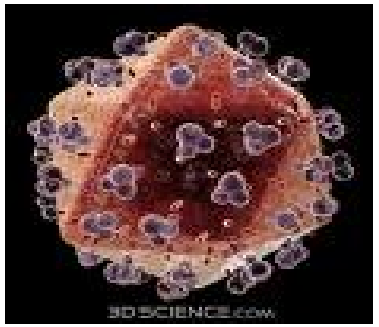
- Babesiosis
- Brucellosis
- Leptospirosis
- Creutzfeldt-Jakob Disease
- HTLV-1 Infections
- Arboviral Infections
- Malaria
- Relapsing Fever
- Viral Hemorrhagic Fever
- Syphilis

Agents which pose the greatest risk for Occupational Exposure:

- Hepatitis B
- Hepatitis C
- HIV







Hepatitis B Virus

Very infectious!

Can live in a dry environment for at least 7 days

Symptoms

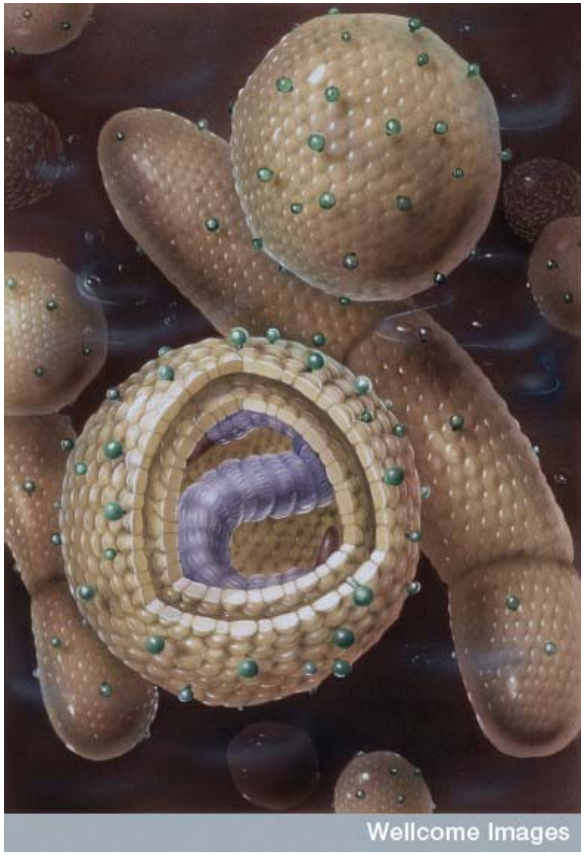
•No Signs
  - After exposure, it can take 1 – 9 months before noticeable symptoms arise
  - Very much like a mild “flu”
  - Fatigue, possible stomach pain, loss of appetite, and even nausea

•1/3 cases no symptoms, 1/3 flu-like, 1/3 severe

•Cause inflammation of the liver

•Liver damage can be mild to fatal

•**Safe and effective vaccine is now available!**



Hepatitis C Virus (HCV)

Very infectious!

Can live outside the body for up to 4 days

Only 25% of those infected have been diagnosed

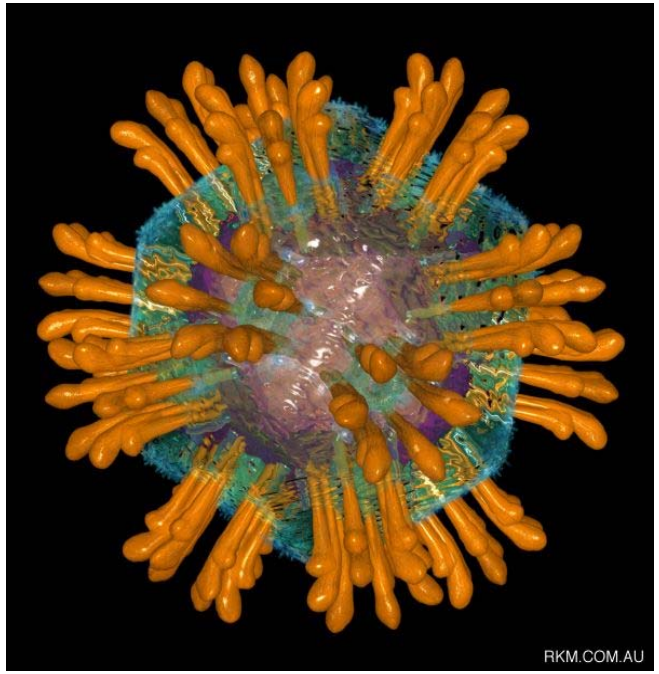
Symptoms

Usually asymptomatic or have mild symptoms

(30 - 90 days)

- Fever
- Fatigue
- Nausea
- Vomiting
- Joint Pain
- Carrier state can develop with or without symptoms
- Causes cirrhosis and liver cancer

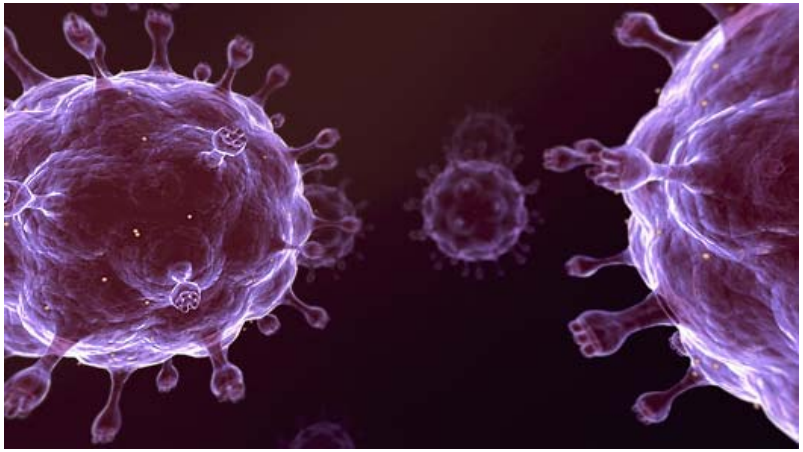
Can get some drug therapy but no vaccine



Human Immunodeficiency Virus (HIV)

- Can live in a dry environment for a few hours

Symptoms



- Some have no symptoms, or less severe symptoms
- Leads to AIDS
- Results from destruction of the human immune system from infection with HIV
- **No vaccine available, some drug therapy**

Risk Factors for HBV, HCV, or HIV Infection

- Sexual Contact
- Sharing of hypodermic needles
- From mothers to their babies at/before birth
- Accidental puncture from contaminated needles, broken glass, or other sharps
- Contact between broken or damaged skin and infected body fluids
- Contact between mucous membranes and infected body fluids

Major sources of Infectious Pathogens

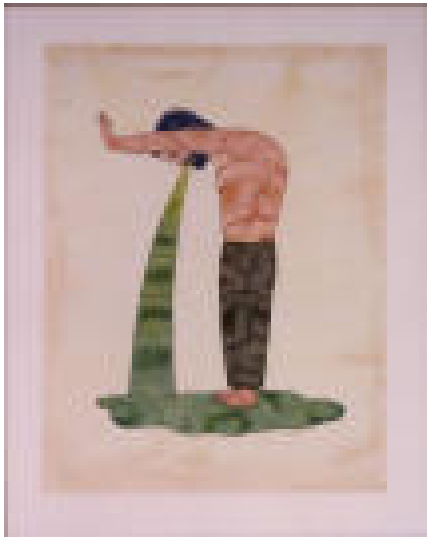
- Blood

Other Potentially Infectious Materials (OPIM)

- Human Body Fluids:
  - Semen
  - Vaginal secretions
  - CSF, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, and amniotic fluid
  - saliva in dental procedures
  - any other body fluid that is visibly contaminated with blood
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead)
- Human cells (primary cell lines and purchased cell lines)
- Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:
  - Cell, tissue or organ cultures from human or experimental animals.
  - Blood, organs, or other tissues from experimental animals.
  - Culture medium or other solutions.

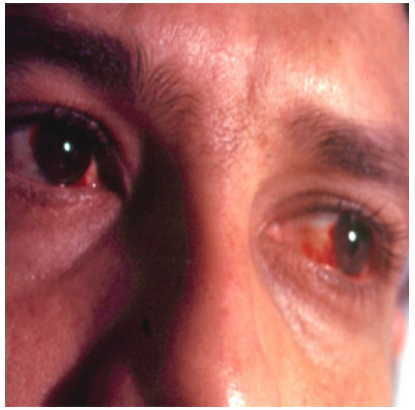
Other Bodily Fluids

- Not expected to contain Bloodborne Pathogens unless contaminated with visible blood:
  - Urine
  - Feces
  - Vomit
  - Sweat
  - Tears



Bloodborne Pathogen Transmission

- Parenteral Exposure
  - Non-intact skin
  - Cutting/Piercing skin with contaminated sharps



- Mucous Membrane Exposure
  - Eyes, mouth, nose

- Transfusion
  - infected body fluids into another person's bloodstream

EXPOSURES TO BLOOD-BORNE PATHOGENS

	<----------RISK OF TRANSMISSION---------->			<------INFECTIOUS MATERIALS---->		
Virus	**Percutaneous Injury**	**Mucosal Contact or Contact with Injured Skin**	**Bite Wound**	**Documented**	**Possible**	**Unlikely**
HBV	2-40%	Not quantified (transmission by this route has been documented; the magnitude of risk is probably high to that for HCV and HIV)	Not quantified (Transmission by this route has been documented)	Blood, blood products	Semen, vaginal fluid, bloody fluids, saliva	Urine, feces
HCV	3-10%	Not quantified (transmission by this route has not been documented but is plausible)	Not quantified (transmission by this route has not been documented	Blood	Blood products, bloody fluids, semen, vaginal fluid	Saliva, urine, feces
HIV	0.2-0.5%	Not quantified (transmission by this route has been documented; pooled risk estimate, 0.1%)	Not quantified (possible route of transmission in 2 cases of non-occupational exposure)	Blood, blood products, bloody fluids	Semen, vaginal fluid, cerebral spinal fluid, breast milk, exudates, serosal fluids, amniotic fluid, saliva (during dental procedures	Saliva, urine, feces

from: Management of Occupational Exposures to

- What the government decided to do about it

History of BBP Regulations

1970 the Occupational Safety and Health Act, regulated by the Occupational Safety and Health Administration (OSHA), was signed into law.
“An act to assure safe and healthful working conditions for working men and women.”

On December 6, 1991, the final regulation on occupational exposure to BBP was issued:
“To protect employees from diseases spread by blood in the workplace.”

Bloodborne Pathogens Standard

- Regulations:
  - Federal: 29 CFR 1910.1030
  - California: Title 8 General Industry Safety Orders, Section 5193
- Purpose:
  - Prevent exposure (reduce or eliminate the hazards of occupational exposure)
  - Prevent disease if exposure occurs
- Regulations apply to:
  - All employees who could have contact with blood or Other Potentially Infectious Materials

Complying with the regulations

1. Exposure Response, Prevention & Control
   - Exposure Control Plan
   - Exposure Determination
   - Sharps Injury Log

2. Methods of Compliance

3. Regulated Waste

4. Research Laboratories (eg. BSL2 not covered in this training)

5. Hepatitis B Vaccination, post-exposure evaluation and follow-up

6. Communicating hazards to employees

7. Record keeping

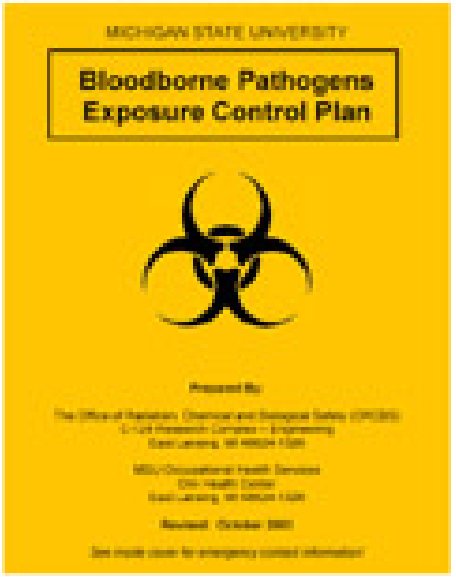
1.Exposure Control Plan

Develop and implement controls that will eliminate and minimize employee exposure

Must be unique to procedures and locations

Must be reviewed and updated annually

This is the responsibility of the Principal Investigator (PI)



The following must be included:

a. Exposure Determination
b. Controls
    c. Standard Precautions
    d. General Engineering
    e. Specific Engineering
    f. Personal Protective Equipment (PPE)
    g. Housekeeping (decontamination)
h. Hepatitis B vaccination, Post exposure evaluation & follow-up
i. Communication and training
j. Recordkeeping

1a.Exposure Determination

- Do we have job classifications where:
  - All employees are occupationally exposed?
    - List classifications
  - Some employees are occupationally exposed?
    - List classifications
    - List tasks with potential for exposure
- Determine the exposure risk without regard for personal protective equipment the worker uses

1.b Work Place Practice Controls

No food or drink should be kept in refrigerators, freezers, cabinets, or on shelves or countertops where blood or other potentially infectious materials are present.

1b. Work Place Practice Controls

Hand washing is the single most important thing that you can do to prevent the spread of infection

When?

- Dirty
- Contaminated with blood or body fluids
- Before eating
- After using the restroom
- After removing your gloves

How?

- Use tepid water (avoid hot water)
- Apply soap
- Rub hands together for at least 15 -30 seconds
- Cover all surfaces of the hands and fingers
- Rinse hands with water
- Dry hands thoroughly

1b. Work Place Practice Controls

Sharps

- Recapping of needles is prohibited
- Do not bend, break, or remove needles
- Dispose of sharp objects into a sharps container
- If no immediate access to a sharps container, use the one-handed recap method

1c. Standard or Universal Precautions

Treat all human blood, other potentially infectious body materials, and unidentifiable body fluids as if they were known to be infectious

1d.Engineering Controls

Isolate or remove the bloodborne pathogen hazard from the workplace

1d. General Engineering

Ventilations hoods, Biosafety Cabinets

1d. General Engineering

- Secondary Transport Container

- Sharps disposal containers
  - Closable
  - Puncture resistant
  - Leakproof
  - Labeled

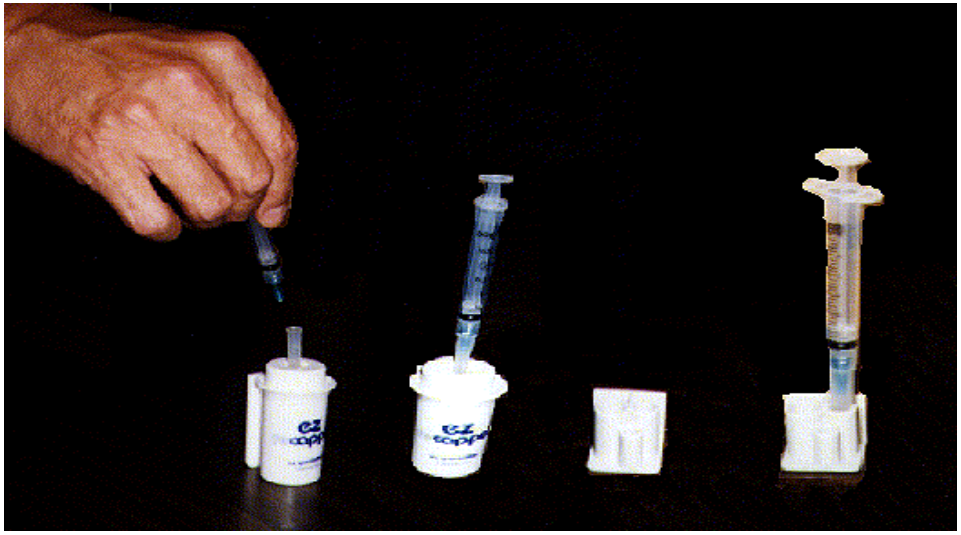
1d. Specific Engineering

Biohazard Plastic Shield

Sealed rotor heads or centrifuge safety cups

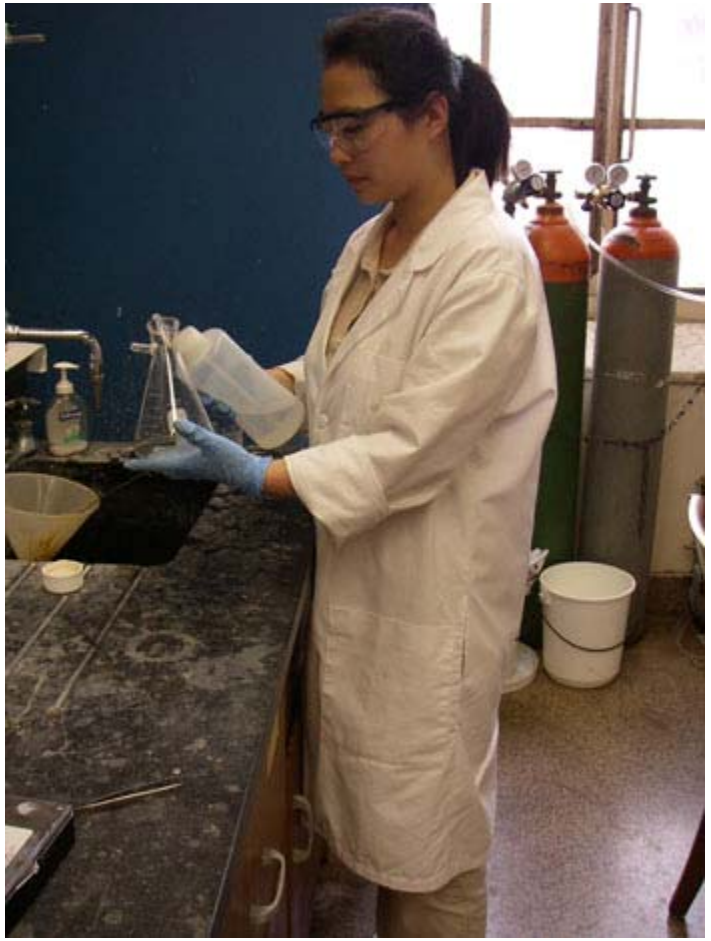
1d. Specific Engineering

- Use safer sharp devices
  - Needleless IV system
  - Retractable syringes and lancets
  - Puncture-resistant capillary tubes



1e. Personal Protective Equipment (PPE)

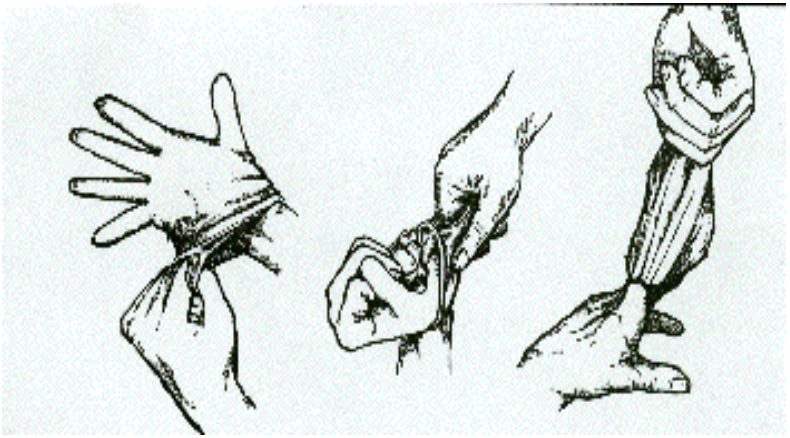
- Must be provided at no cost to the employee
- Based on risk assessment (procedure, locations, hazard, etc)
- Wear a minimum of a lab coat and gloves
- When splashing is anticipated or when handling highly concentrated materials wear eye protection, face protection, disposable gowns, and double gloves



1e. Personal Protective Equipment (PPE)

Know how to use PPE Properly

- Change gloves when compromised, damaged, or contaminated
- Wash hands between glove use
- Remove PPE before leaving the work area (no gloves in the hallways!)



1f. Housekeeping

- Maintain a clean & sanitary workplace
- Written cleaning & decontamination schedule
- Laundry – employer shall clean, launder, and dispose of PPE at no cost to the employee
- Clean and decontaminate all equipment & work surfaces with an appropriate disinfectant
- Follow the regulated waste regulations for the disposal of contaminated waste materials

1f. Housekeeping

What is considered Biohazardous Waste?

- Blood or OPIM (Other Potentially Infectious Materials)
  - Liquid
  - Semi-liquid
  - Contaminated sharps
  - Lab or medical waste
- Other items caked with dried blood or OPIM
- Human cell lines or tissues

Biohazard Bags

- Must be red in color only!!!
- At least 1.5 mil in thickness.
- Labeled with the word “BIOHAZARD” & the biohazard symbol
- Bag must be big enough for the container
- Only fill up to ¾ full
- Tie in a square knot or goose-neck tie

Biohazard Waste Containers (Sharps or Bin)

- Can be any color
- Must be rigid, puncture proof, & leak proof with a tight-fitting lid
- Must be labeled with the word “BIOHAZARD” & the biohazard symbol on all lateral sides.
- Must be clean
- Never overfill - watch the fill-line!

Know the Rules for Biohazard Waste Disposal

Don’t carry a biohazard bag filled with contaminated waste – always use a transport container with a tight-fitting lid!

Don’t mix biohazard waste with household waste, radioactive waste, or hazardous chemical waste!

Biohazard waste cannot be removed from a red biohazard bag unless authorized by a safety officer or unless the waste has been pre-treated

Biohazard Waste Violations

- Unsanitary waste containers
- Use of orange biohazard bag
- Waste containers without visible biohazard labels
- Non-rigid and no lid waste containers
- Overfilled biohazard waste containers
- Sharp items above the fill line of sharps containers

Items that cannot be placed in a Biohazard Bag:

Liquid biohazard waste
- Treat with disinfectant & pour down the drain with lots of running water
- Do not to pour hazardous chemical disinfectants down the drain!

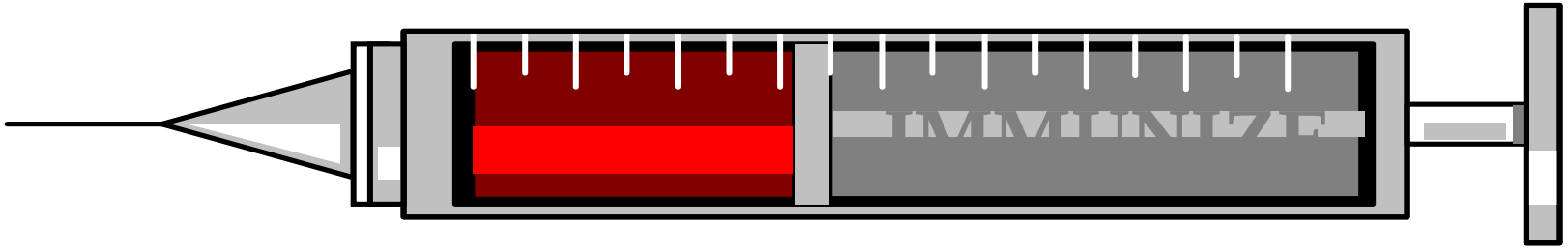
Urine and feces from animals and humans – dispose of via a local sewer or as solid waste

PREVENTION

1g. Hepatitis B Vaccination

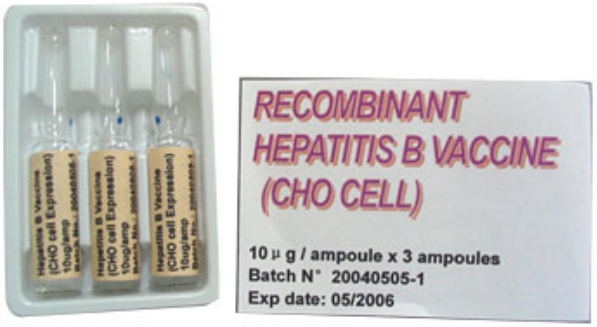
The best protection against HBV is vaccination.

BE WISE!!!



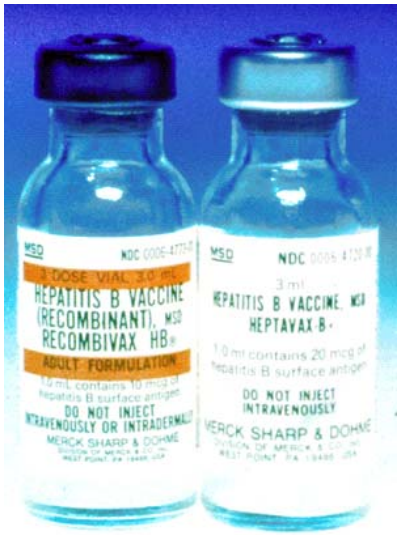
1g. Hepatitis B Vaccination

- Employer must make the Hepatitis B vaccination available
  - Declination statement required
  - Available at later date if desired
- No cost to employees
- Reasonable time and place
- If series is interrupted, continue at any time rather than restart series



1g. Hepatitis B Vaccination

- 3 shot series
- Effective for 95% of adults
- Post-vaccination titers for high risk health care workers

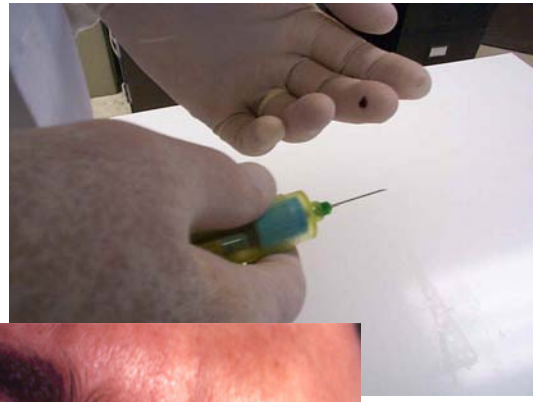


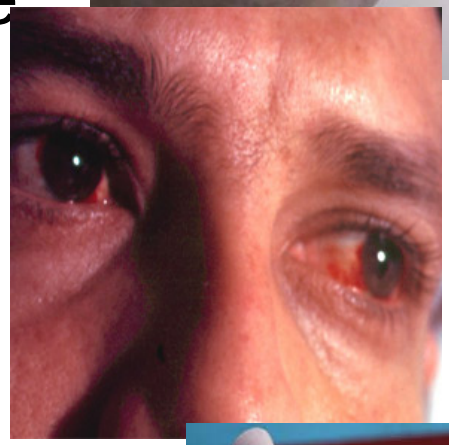
- Exposure without vaccination
  - Immune globulin ASAP after exposure
  - Begin Vaccination series

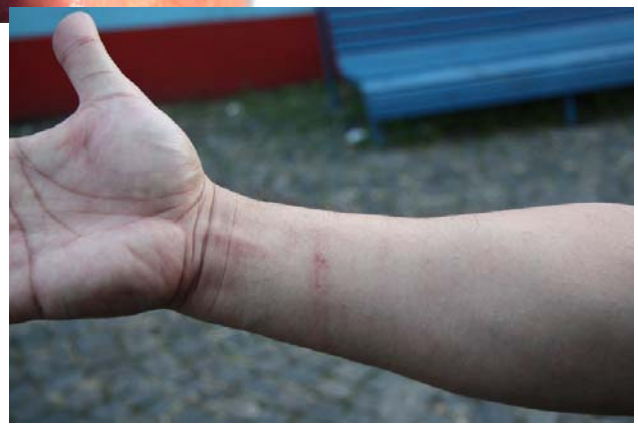
EXPOSURE

1h. Bloodborne Pathogens Exposure Incident

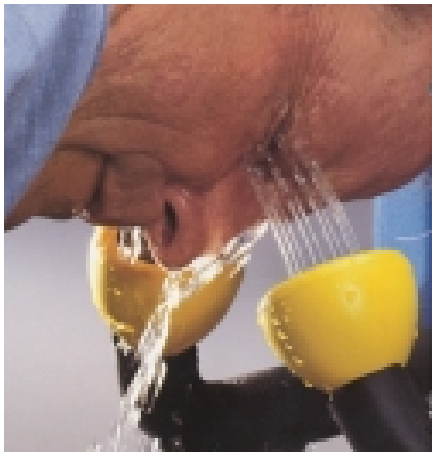
- Contact with blood or OPIM via:
  - Cuts, puncture, needle sticks
  - Exposed Mucous Membrane
  - Splash in the Eye
  - Non-intact skin (eg. dermatitis, abrasions)







1h. Emergency Procedures if Exposed



1. Wash the exposed area thoroughly with soap and running water. Use non-abrasive, antibacterial soap if possible.

2. If blood is splashed in the eye or mucous membrane, flush the affected area with running water for at least 15 minutes.

3. Report the exposure to your supervisor as soon as possible.

Where to go in case of an exposure incident

- Staff & Graduate Students:
  Occupational Health Facility
  Open 7:30 am- 4:30 pm Mon - Fri
  located in 67-120 CHS, extension 56771

- Undergraduate Students:
  Arthur Ashe Student Health & Wellness Center
  located next to the John Wooden Center, extension 54073

- After hours, weekends, holidays, or for immediate treatment:
  UCLA Emergency Room, located in the UCLA Ronald Reagan Medical Center, call 911

Post Exposure Evaluation

Employer's Responsibilities:

- Provide medical evaluation ASAP
  - Testing for HBV, HCV, HIV
  - HIV/HBV PEP when indicated
- Identify source individual, if possible
  - Obtain consent for blood test
- Provide information to healthcare provider
  - Routes of entry
  - Employee's job duties
  - Copy of the regulation
- Ensure that the healthcare provider provides to exposed employee:
  - Results of the source individuals test (if legal)
  - Results of exposed employee's test
  - Post exposure treatment as needed

Provided at no cost to employee

Medical Evaluation and Follow-up

Healthcare Provider's Responsibility

- Provide in writing to employer:
  - Employee has been informed of the results
  - Employee has been informed of any medical conditions resulting from exposure
- All specific findings or diagnoses are confidential to employee

1i. Biohazard Communication

- Door card
- Labels
- Warning Signs

1j. Training

Identify the hazards associated with Bloodborne Pathogens

Understand local, state and federal regulations

Ensure proper handling and disposal

Review spill response procedures

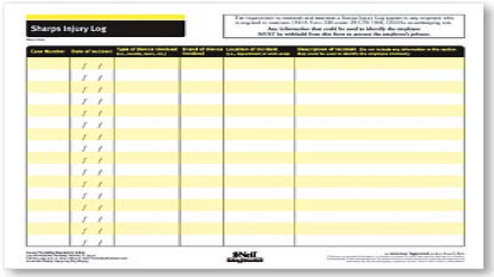
Quiz

Lk. Recordkeeping

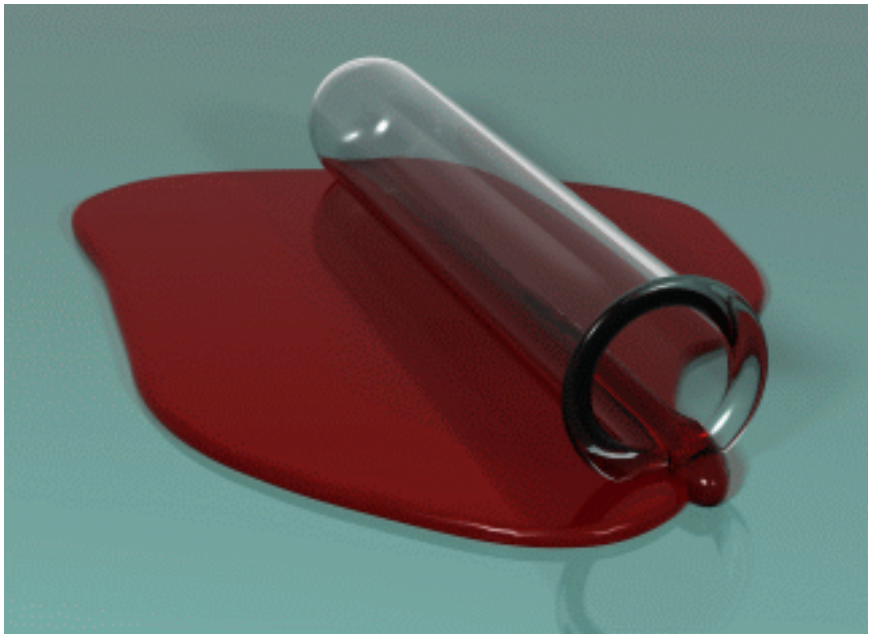
- Medical Records
  - HBV vaccination status
  - Written medical opinion of exposure incidents
  - Exposure incident details
  - Maintained for the length of employment + 30 years
- Training Records
  - Dates
  - Content summary
  - Trainer Name & qualifications
  - Attendee's names & job titles
  - Maintain for 3 years

1k. Sharps Injury Log

- Kept at the Occupational Health Facility (OHF)
- Maintain a separate sharps injury log
- Document sharps injuries
- Recorded as confidentiality case
- Must contain:
  - Type and brand of device involved
  - Department or work area where exposure occurred
  - An explanation of how the incident occurred



SPILLS!



Biohazard Spill Kit

For safe removal of spilled body fluids:

- Contain the spill
- Remove and dispose of spilled body fluids
- Quickly clean and disinfect the spill site

- EPA approved disinfectant
- Vinyl gloves
- Absorbent towels
- Tongs, spatulas
- Biohazard waste bag

Spill Procedures

Wear proper PPE
Use tools (dustpan, tongs, etc.) to pick up sharp objects
Contain the spill by placing absorbent paper towels on top of it
Pour disinfectant on top of the spill all allow it to sit for the required contact time
    Bleach – 10% solution for 10 minutes
Clean and rinse the spill area
Dispose of all solid waste used for clean up as biohazardous waste
Wash hands
Report the spill incident to the supervisor

Emergency

- Dial 911 (from a landline)
- UCLA Dispatch (cell phone)
  - 310-825-1491
- UCLA Trouble Desk
  - On campus: x59236
  - Off campus: 310-825-9236
- EH&S Main Line
  - On campus: x55689
  - Off campus: 310-825-5689

UCLA Biosafety Program Contact Info:

Email: biosafety@ehs.ucla.edu

Website: www.biosafety.ucla.edu

Phone Number: Main Office:x55689

Safe Use of Biological Safety Cabinets

Presented by:
UCLA EH&S
Biosafety Program

Objectives

- Cover how Biological Safety Cabinets function
- Review guidelines for work preparations, cabinet procedures, and cleanup operations
- Video on improvement of work habits
- Review Quiz

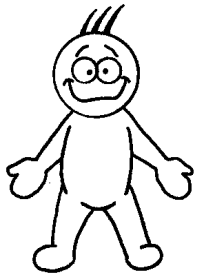
Types of Containment & How They Work

Utilizing Air Flow

All Engineering solutions to air contamination
Utilize Air

3 Types of Protection

Personal

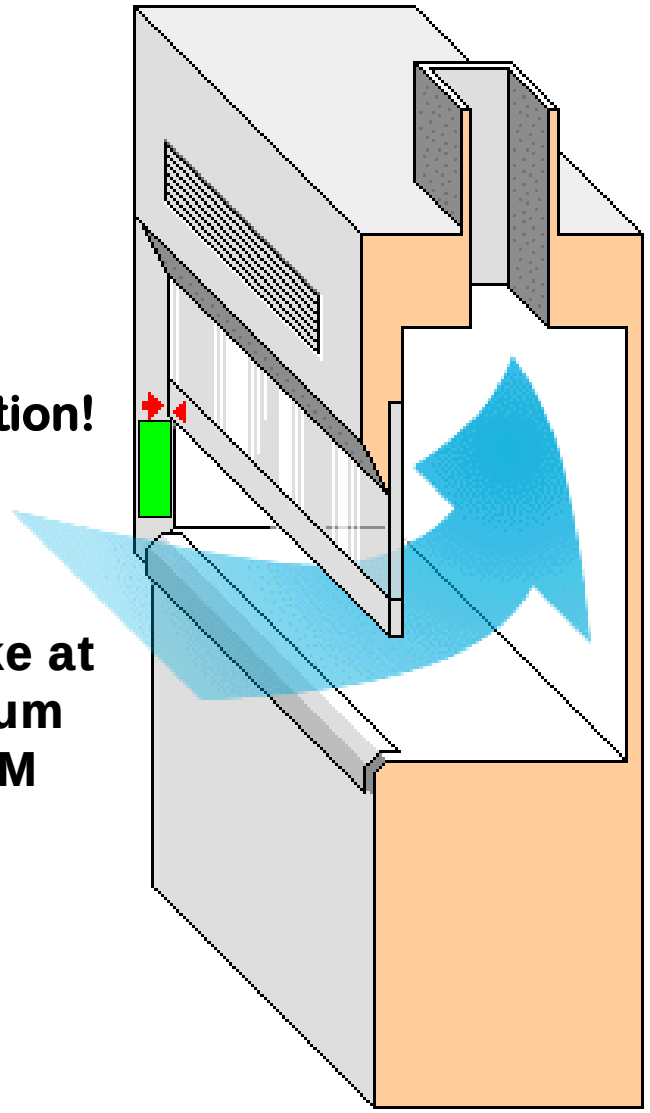


Product

Environmental

Engineering Solutions to Air Contamination

Chemical Fume Hood



Certification!

Air Intake at
A minimum
Of 75 FPM

- Air from inside of the fume hood is expelled outside of the building
- Air is not filtered

What types of protection do you think the Chemical Fume Hood Offers?

Personal?	YES
Product?	NO
Environment?	MAYBE – depends on filters

Chemical Fume Hoods

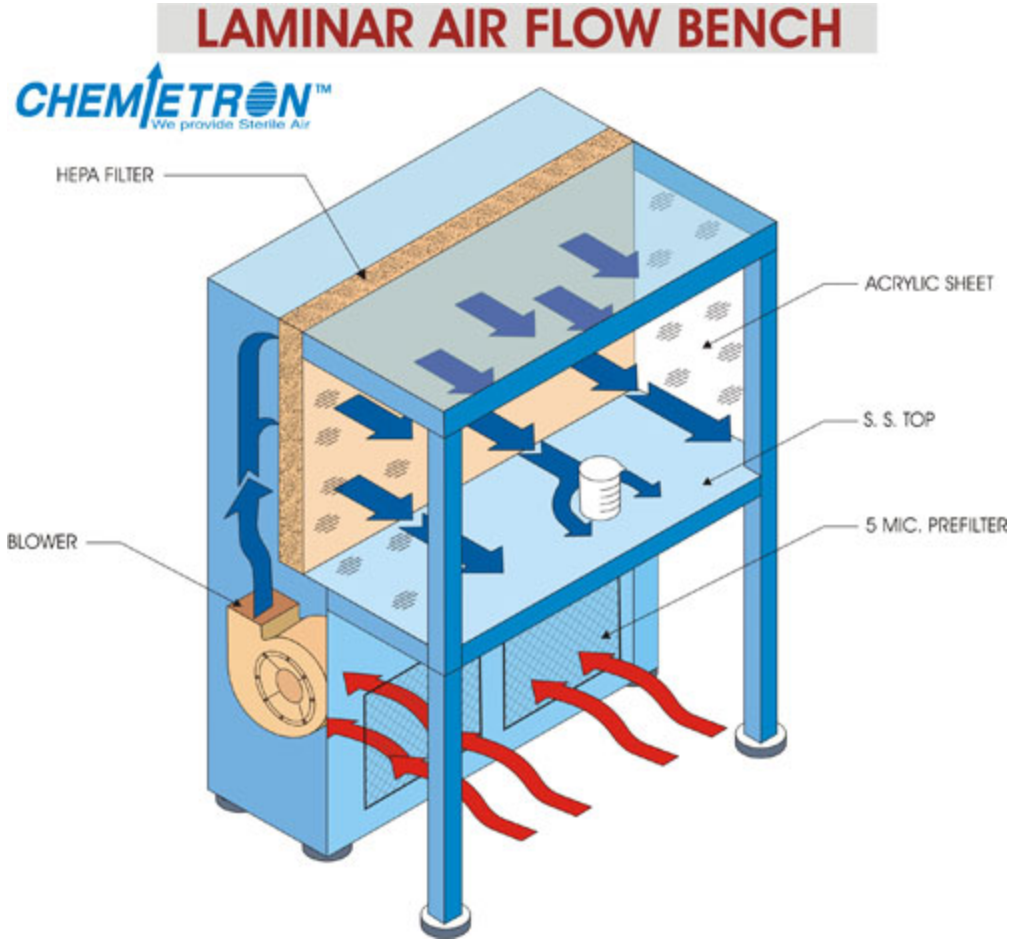
- How it works

- Designed to capture chemical vapors/fumes and sweep them away from the worker
- Offers personal protection from vapors/fumes
- Does not protect the product
- May or may not protect the environment from chemical hazards

- What can I use it for?

- Working with chemicals
- Trace amounts of radiation
- Nothing pathogenic

Horizontal Laminar Flow Cabinet Airflow



What types of protection do you think the Horizontal Laminar Flow Cabinet Offers?

Personal?	NO
Product?	YES
Environment?	NO

Horizontal Laminar Flow Bench

– How it works

- Not a Biological Safety Cabinet
- Do not use with infectious and hazardous agents!!!
- Offers product protection only
- Clean air is directed across the workspace toward the user

– What can I use it for?

- Preparation of intravenous mixtures
- Plant tissue culture
- Electronic and mechanical assembly
- Pharmaceutical procedures
- Media preparation
- Some animal surgeries

Biosafety Cabinets

Three categories

- Class I
- Class II
- Class III

Components of Most BSC's

Biosafety Cabinets

- Continuous inward airflow protects you from aerosols
- Exhaust air is HEPA filtered to protect the environment from becoming contaminated with aerosols
- HEPA-filtered downward laminar airflow over the workspace protects the product from contamination

Biosafety Cabinets have HEPA Filters

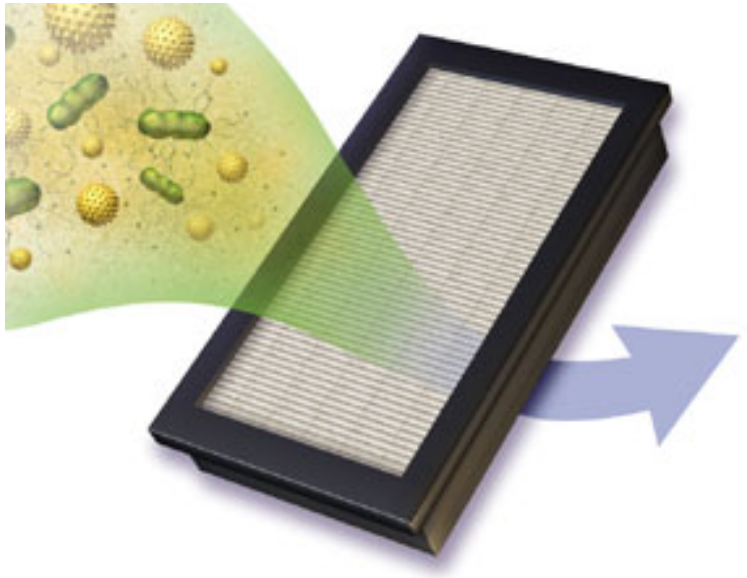
HIGH

EFFICIENCY

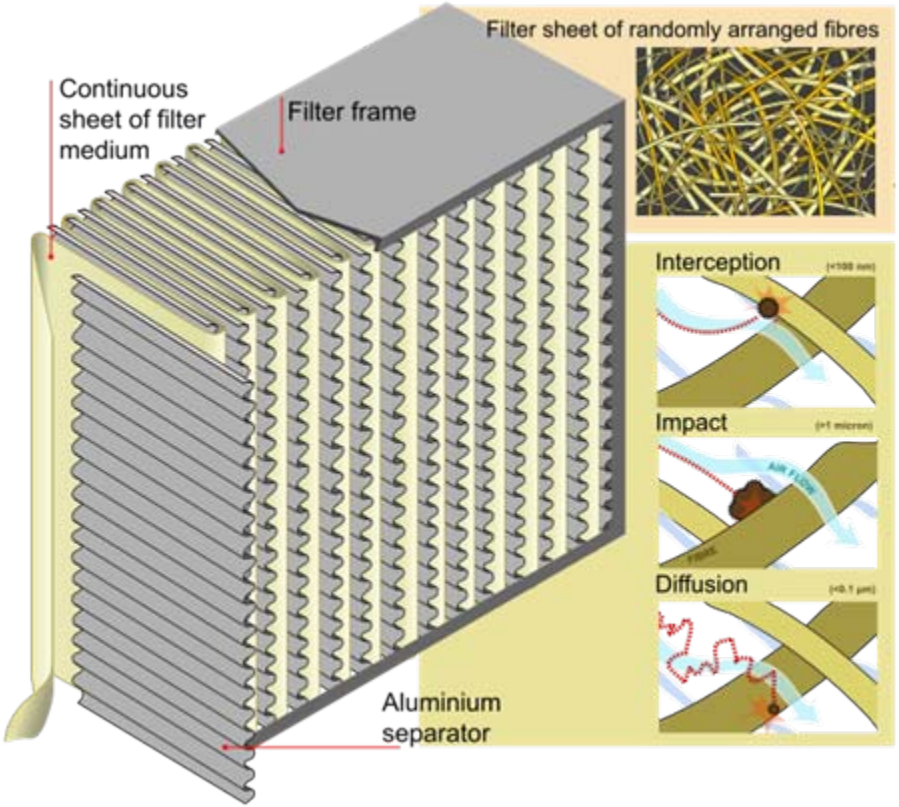
PARTICULATE

AIR

FILTER



Theoretical HEPA Filter Collection Efficiency



- If particle size = 0.3 micron then the filter efficiency is 99.97%.
- At both **smaller than 0.3 microns** and **larger than 0.3 microns** filter **efficiency increases.**
- **<u>Does not</u> filter vapor or gas**

UV Light in BSC

- We **DO NOT recommend** the use of UV light to sterilize biosafety cabinets!

- Can cause skin cancer and burn the cornea!

- Without proper maintenance the CDC
- does not recommend using UV light
  - Must be cleaned weekly to clear of dust
  - Must be monitored to ensure that the appropriate intensity of UV light is emitted (254 nm)
  - Shadows? Don't get touched by the UV rays!

- No one is allowed in the room while the UV light is on.

Location of Class II BSC

- Keep away from all other sources of airflow
  - Open doors & windows
  - Personnel traffic
  - Supply air diffuser
  - Other lab equipment
- Personal & Product protection are compromised as cross drafts approach air intake!
- Must be seismically stabilized (i.e. bolted to the floor)

BSC must be certified when:

1. New
2. Every year
3. If repaired
4. If relocated

University of California has a contract with TSS for certification

Biosafety Cabinet Ducting:

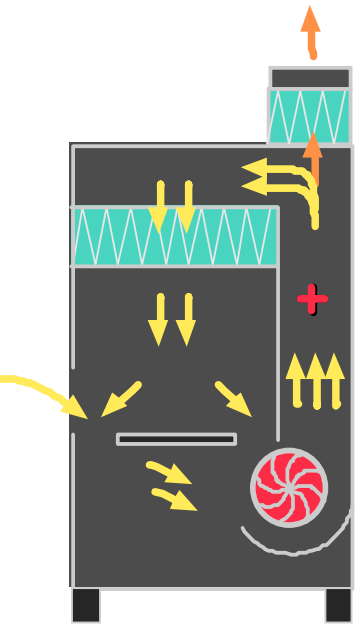
- Can be connected to building exhaust system
- May use hard or thimble connection

Class III

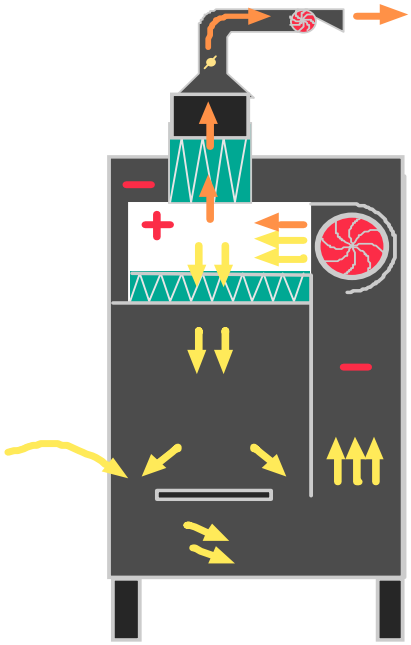
- Personal & Environmental Protection only!
- Personal, Product, & Environmental Protection!
- Gas tight work surface

Class II

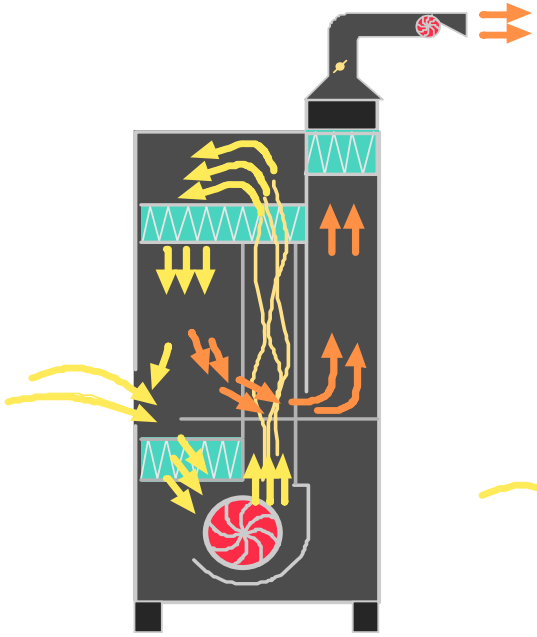
Class II A



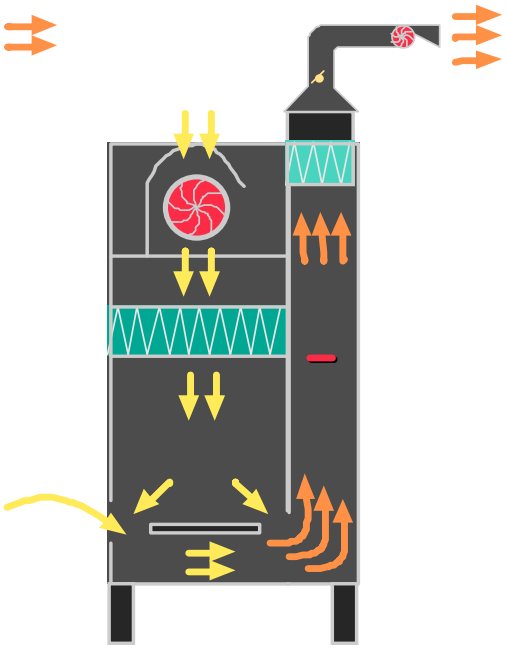
Class II A2



Class II Type B1



Class II Type B2



Class II

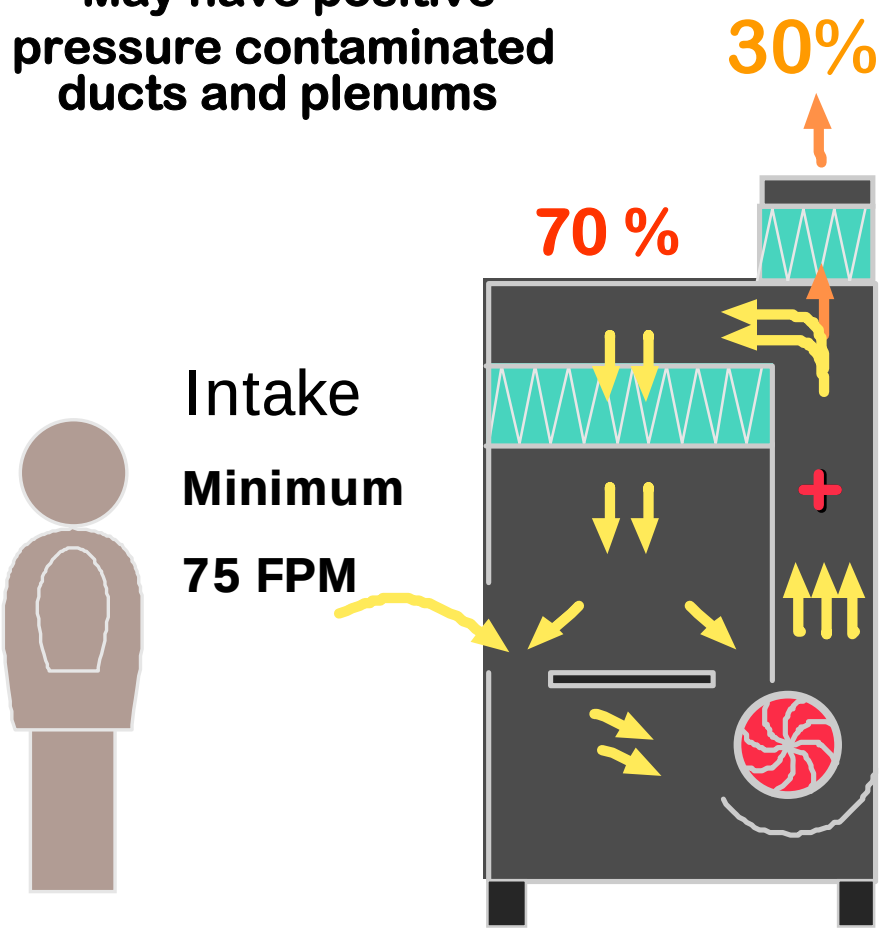
What to consider

1. **Where are the Hepa filters?**
2. **How much air is coming out into the lab?**
3. **What is the pressure in the cabinet (+/-)**
4. **Is the cabinet hard ducted or thimble connection?**

Class II Type A1

- Exhaust HEPA filtered air may be recirculated into room or exhausted outdoors
- Have HEPA filtered recirculated air mixed with HEPA filtered inflow air - 70% of air is recirculated
- May have positive pressure contaminated ducts and plenums
- NO Volatile, Toxics or Radio radionuclides

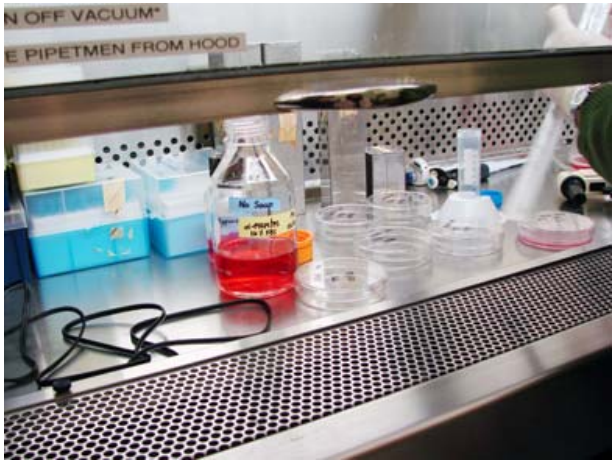
- May have positive pressure contaminated ducts and plenums



National Sanitation Foundation Standard 49

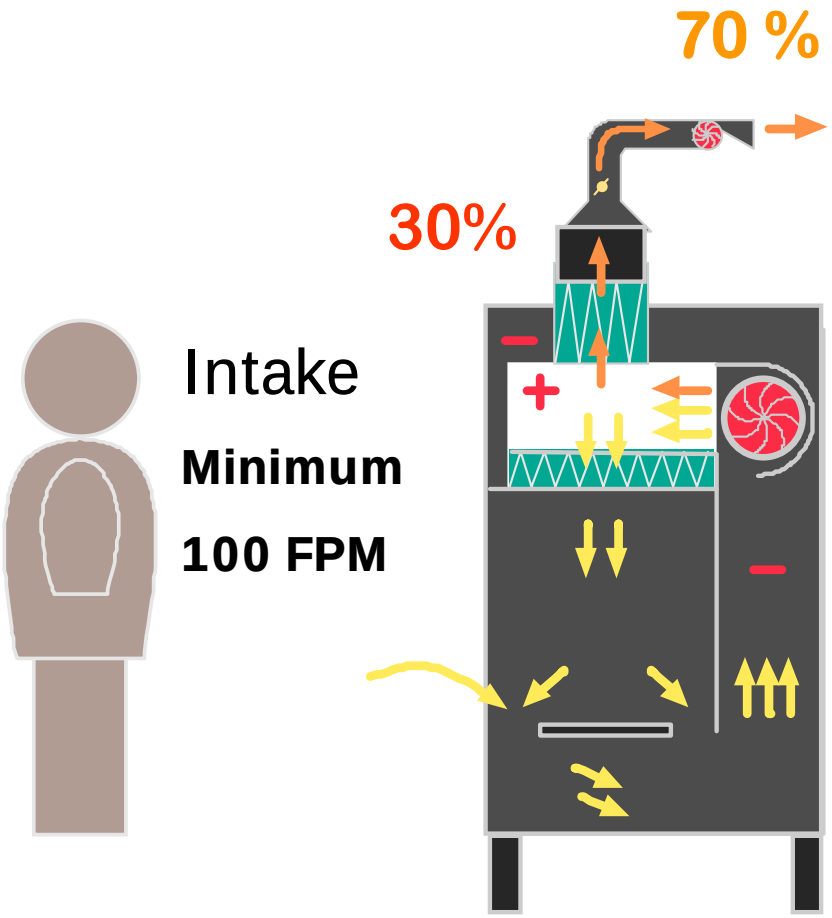
Class II, Type A

Suitable for work with agents assigned to biosafety levels 1, 2, 3 in the absence of volatile toxic chemicals and volatile radionuclides



Class II Type A2

- **Have HEPA filtered recirculated air mixed with HEPA filtered inflow air – 30% of air is recirculated**
- **All biologically contaminated ducts and plenums under negative pressure**
- **All HEPA filtered exhaust can be discarded outside**
- **Minute quantities of volatile toxic chemicals and trace amounts of radionuclides ok**



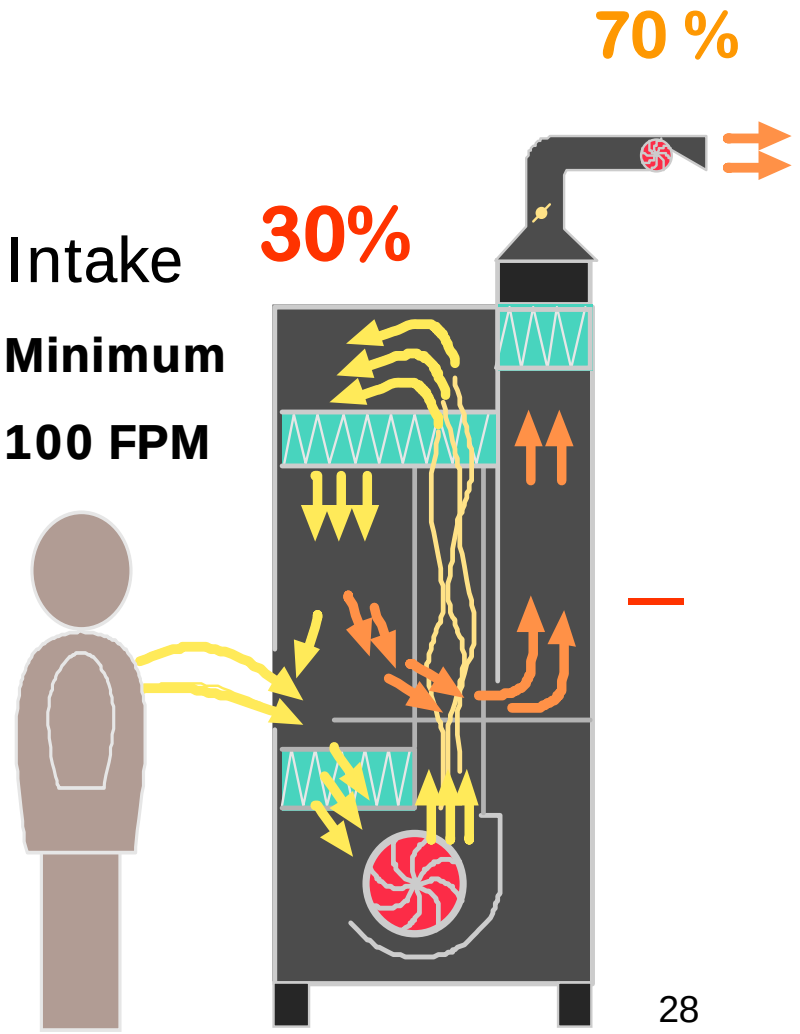
National Sanitation Foundation Standard 49

Class II, Type A2

May be used with agents assigned to biosafety levels 1, 2, 3 treated with minute quantities of volatile toxic chemicals and trace amounts of radionuclides required as an adjunct to microbiological studies that will not interfere with the work when recirculated in the down flow air.

Class II Type B1

- HEPA filtered down flow air composed largely of uncontaminated recirculated inflow – 30% of air is recirculated
- Exhaust most of the contaminated down flow air through a dedicated duct exhausted to the outside after passing through a HEPA filter
- Building exhaust system must pull air out of the BSC
- Cannot use Thimble, **must** use Hard Connection
- Have all biologically contaminated ducts and plenums under negative pressure
- Can use with minute quantities of volatile toxic chemicals and trace amounts of radionuclides



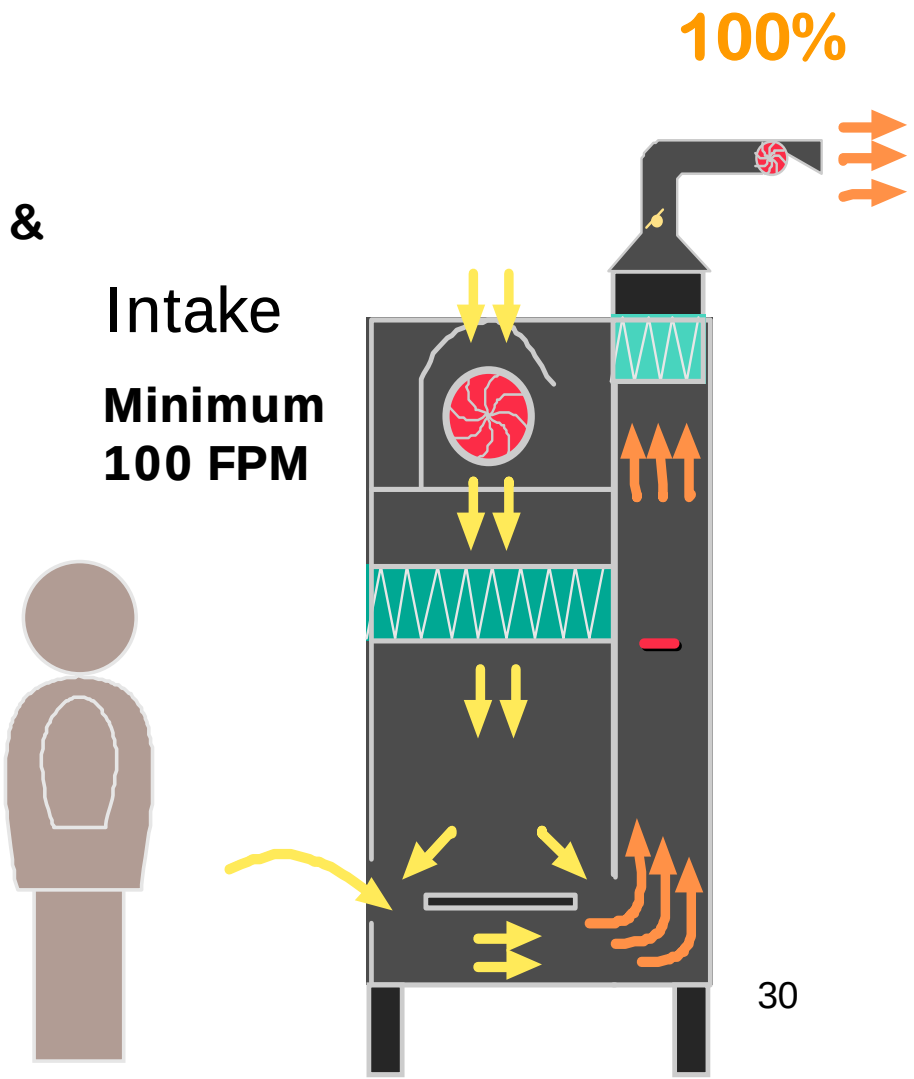
National Sanitation Foundation Standard 49

Class II, Type B1

May be used with agents assigned to biosafety levels 1, 2, 3 treated with minute quantities of volatile toxic chemicals and trace amounts of radionuclides required as an adjunct to microbiological studies if work is done in the direct exhaust portion of the cabinet, or if the chemicals and radionuclides will not interfere with the work recirculated in the down flow air.

Class II Type B2

- Have HEPA filtered down flow air drawn from the laboratory or the outside – No recirculation
- Have all contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts & plenums
- Exhaust circulating air to the outside after HEPA filtration Building exhaust system must pull air out of BSC. Dedicated Exhaust
- Must use hard connection
- Can use volatile toxic chemicals and radionuclides



National Sanitation Foundation Standard 49

Class II, Type B2

May be used with agents assigned to biosafety level 1, 2, 3 treated with volatile toxic chemicals and radionuclides required as an adjunct to microbiological studies.

Working Practices

Guidelines for working in the BSC

Never eat, drink, chew gum, store food, or smoke nearby

Guidelines for Working in the BSC

1. Store papers or pencils outside of the BSC
2. Schedule uninterrupted work times
3. One person at a time
4. Have arm pits level with bottom of the window
5. Use slow movements in BSC
6. Minimize entering and exiting the BSC
7. Do not block any of the grills

Guidelines for Work Preparations

1. Check certification
2. Let BSC run for 2 to 3 min.
   after turning on
3. Disinfect all surfaces of the BSC
4. Properly position the window
5. Close drain valve
6. Make sure that all materials needed are inside the BSC
7. Segregate clean items from ones that will get contaminated

Guidelines for Working in the BSC

No open flames in the BSC!

- → Disrupts airflow
- → Excessive heat build up
- → Possible gas build up
- → Damages Hepa Filter

Don’t let this be your Biosafety Cabinet!

BSC Cleanup

Before and after every procedure!

- Alcohol
- Bleach
- Disinfectant Agent

Guidelines for BSC Cleanup

1. Equipment that has been in contact with the research agent are enclosed
2. Surfaces of all equipment are disinfected
3. Everything is removed from BSC
4. All interior surfaces of the BSC are disinfected
5. Do not store equipment or supplies in or on the BSC
6. If possible leave the BSC running

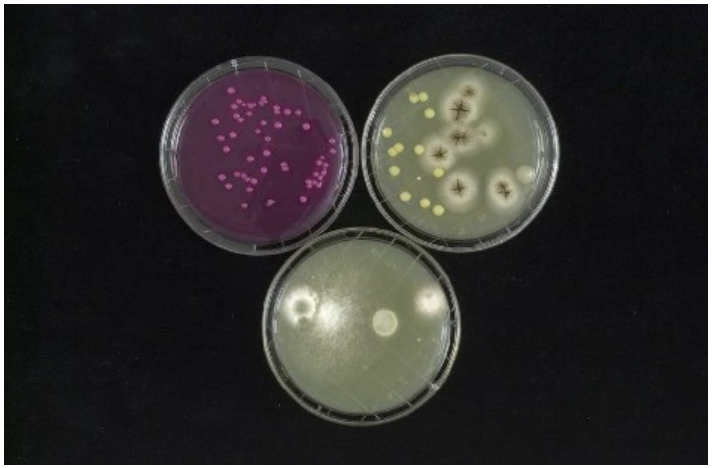
BSC Cleanup

If the BSC must be turned off:

1. Do so after a final purge of two to three minutes

2. Close the cabinet window completely

Validation of Decontamination



- Use RODAC plates to detect presence of microorganisms on surfaces
- Fill with media appropriate for agents you are using
- Incubate for 24 hours and check for growth

Technical Safety Services (TSS)

- To schedule service with TSS call

  1-800-877-7742

- Los Angeles Office

  1-562-694-3626

- TSS should schedule service in 1 to 5 days
  - Usually within 48 hours

biosafety@ehs.ucla.edu

www.biosafety.ucla.edu

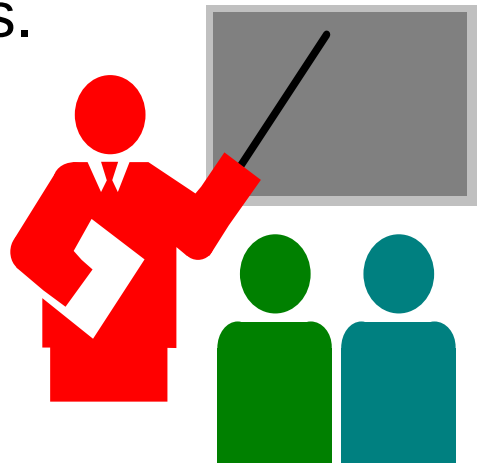
EH&S main line x55689

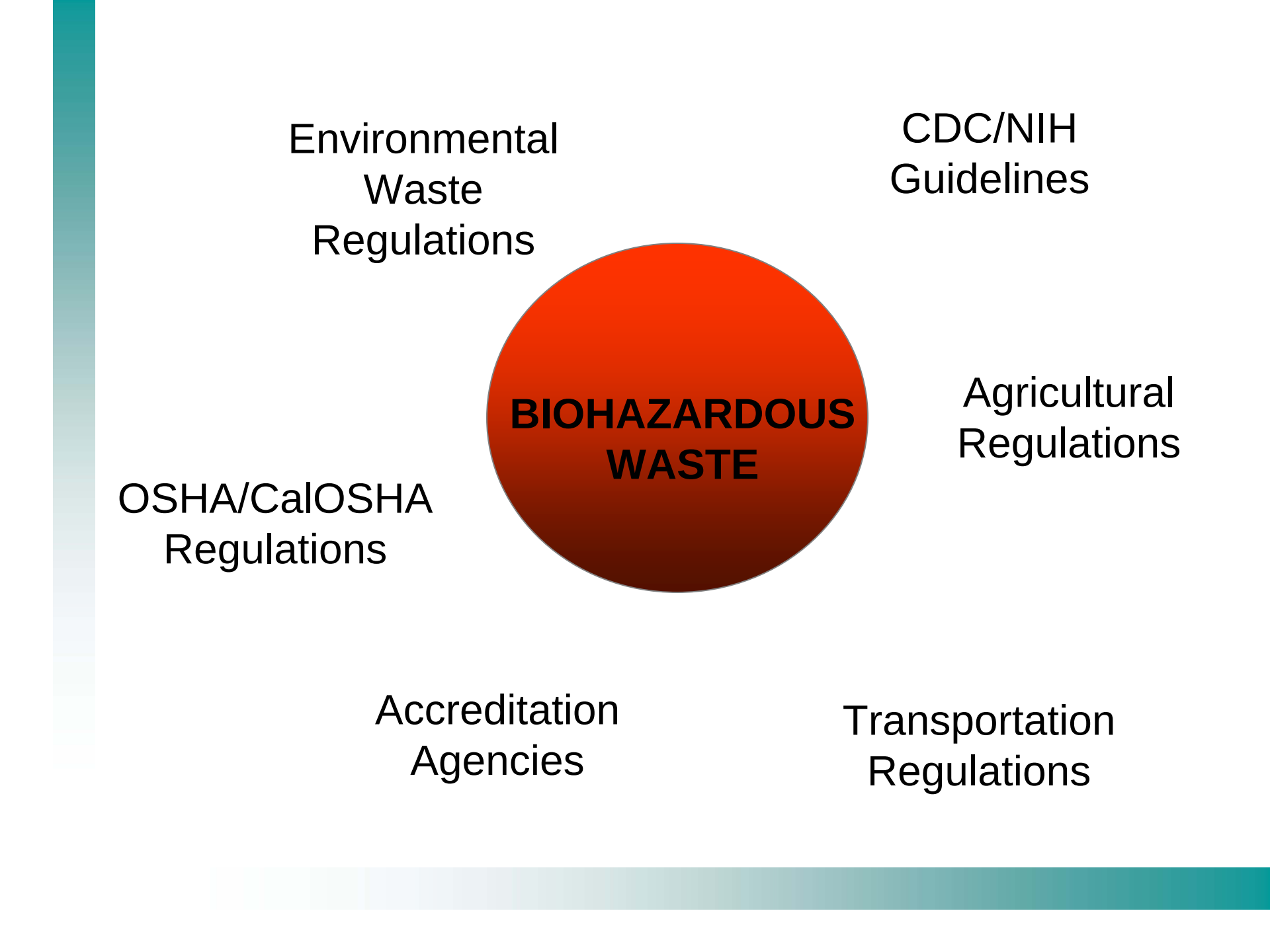
MEDICAL WASTE MANAGEMENT

UCLA Environment, Health and Safety
BiosafetyProgram

Purpose of the Training

- To comply with the local, state and federal regulations.
- To ensure proper handling and disposal.
- To define roles and responsibilities.




Environmental Waste Regulations
CDC/NIH Guidelines
BIOHAZARDOUS WASTE
Agricultural Regulations
OSHA/CalOSHA Regulations
Accreditation Agencies
Transportation Regulations

Department of Transportation (DOT)

- **Responsible for protection of public safety in all areas of transportation in the United States.**
- **In 1999, medical waste was defined by the DOT as hazardous material.**

Hazardous material means any substance or material that can burn, explode, react violently or cause injury or harm to people, property or the environment during transport.

9 Hazardous Classes (1 – 9)

1. Explosives
2. Gases
3. Flammable and combustible materials
4. Materials that can spontaneously combust or are dangerous when wet
5. Oxidizers and organic peroxide
6. Poisonous materials or infectious substances*
7. Radioactive materials
8. Corrosives
9. Miscellaneous hazardous materials

* Classification for Regulated Medical Waste - Hazard class 6.2 because it poses a risk of disease transmission to humans or animals.

Hazmat Employee

- **All employees who dispose of regulated medical waste and infectious substances inside red biohazard bags or sharps container.**
  - **Handling, packaging, storage, transportation, and treatment of medical waste must be done in accordance to ***
- **Required to receive training within 90 days after starting a job involving medical waste and at least every 3 years.**

***California Code of Regulations Section 5193 California Health and Safety Code Chapter 6.1 of Division 20CFR Title 49**

Responsibilities

General

- **Participate in the training.**
- **Use and wear appropriate PPE when handling biowaste.**
- **Package biowaste in designated containers.**
- **Label all containers.**
- **Transport biowaste to accumulation area.**

EH&S

- **Develop and implement MWM program.**
- **Documentation.**

Definition of Medical Waste

CALIFORNIA DEFINITIONS OF "REGULATED WASTE"

Cal/OSHA Bloodborne Pathogens Standard

California Code of Regulations

Section 5193

CALIFORNIA DEFINITIONS OF "MEDICAL WASTE"

Medical Waste Management Act

California Health and Safety Code

Chapter 6.1 of Division 20

California Definitions of "Regulated Medical Waste"
According to Cal/OSHA Bloodborne Pathogens

1. **Liquid or semi-liquid blood or other potentially infectious materials (OPIM)**
2. **Contaminated items that contain liquid or semi-liquid blood, or are caked with dried blood or OPIM and are capable of releasing these materials when handled or compressed.**
3. **Sharps**
4. **Pathological and microbiological wastes containing blood or OPIM.**
5. **Established human or other animal cell lines which are known to be or likely infected/ contaminated with human microbes or agents that are bloodborne pathogens such as HBV, HCV, HIV or EBV**

   All primary human cell explants from tissues and subsequent *in vitro* passages of human tissue explant cultures which are not characterized to be free of microbes and viruses.
6. **Any human tissues or animal tissues that have been injected with an infectious agent, bacteria, virus, prions, protozoa.**
7. **Any specimens obtained from a human even if they have been fixed in formaldehyde**
8. **Any cultured infectious organism such as bacteria and viruses**

California Definitions of "Regulated Medical Waste"

California Medical Waste Management Act

MEDICAL WASTE MEANS:

To be considered MEDICAL WASTE both I. and II. must be met:

I. MEDICAL WASTE is composed of waste which is generated or produced as a result of any of the following actions:

   A. Diagnosis, treatment or immunization of human beings or animals.

   B. Research pertaining to the activities specified in (A).

   C. The production or testing of biologicals.

   D. The accumulation of properly contained home-generated sharps waste that is brought by a patient, a member of his or her family , or by a person authorized by the enforcement agency to a point of consolidation approved by the enforcement agency.

   E. Removal of a regulated waste from a trauma scene by a trauma scene waste management practitioner.

II. Either waste is BIOHAZARD or SHARPS waste

Waste that is hazardous only because it is comprised of pharmaceuticals.

Pharmaceutical means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined by the Federal Food, Drug and Cosmetic Act. Pharmaceutical does not include any pharmaceutical that is regulated following the Federal Resource Conservation and Recovery Act of 1976 or the Radiation Control Law.

What is NOT medical waste?

- Food processing or biotechnology waste that does not contain an infectious agent.
- Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.
- Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless they contain fluid blood.
- Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.
- **Hazardous waste, radioactive waste**, or household waste.
- Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

Medical Waste Disposal Requirements at UCLA (Handling, Disposal, and Storage)

STANDARD LAB PRACTICES WHEN HANDLING MEDICAL WASTE

- Minimum Personal Protective Equipment:
  - lab coat
  - gloves
  - goggles/ safety glasses
    (if splashing is anticipated)
  - shoes (no open-toed shoes)

- Wash hands after removing your gloves, before leaving the lab, etc.

BIOHAZARD CONTAINER IN THE LABORATORY

- ✓ Must be rigid
- ✓ Leak-resistant
- ✓ A lid that fits.
- ✓ Can be in any color.
- ✓ Labeled with word, "BIOHAZARD" and the biohazard symbol on the to and sides.
- ✓ Sanitized when soiled.
- ✓ Lined with a red Biohazard bag that fits!!!

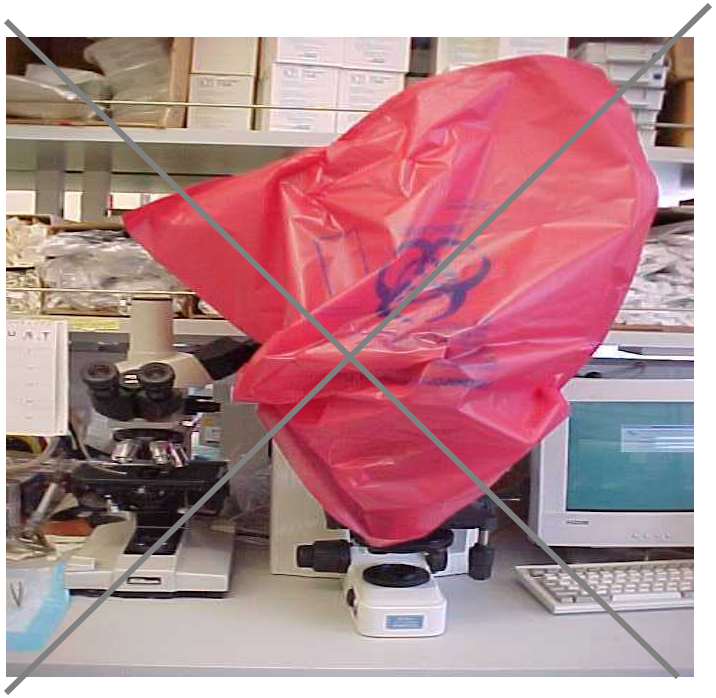
BIOHAZARD BAG

Biohazard bags must be RED in color and at least 1.5 mil in thickness. They must be labeled with the word “BIOHAZARD” and the biohazard symbol.

Managing your biohazard waste:

- ✓ Cannot be over-filled.
- ✓ Lids must be kept on containers when there is waste inside the bag unless the container is in use or it is empty.
- ✓ Biohazard bags must be kept inside a container at all times.
- ✓ Do not store on the floor, in an autoclave pan, on a cart, or on top of containers.
- ✓ Transport the bags inside a biohazard container with the lid on the container.
- ✓ Do not carry by hand.

- ✓ Red biohazard bags can only be used to dispose of medical waste.
- ✓ Do not use red biohazard bags to cover laboratory equipment.
- ✓ Do not store things like packing peanuts inside red biohazard bags.
- ✓ Do not remove items from red biohazard bags.
- ✓ Do not store or transport specimens inside them that will be used or tested later. Use a specimen transport bag (clear in color with a biohazard label).



Specimen transport bag

DOT PACKAGING REQUIREMENT

TRANSPORT:

- ✓ Use the correct biohazard bag.
- ✓ Closed by twisting and tying a square knot or by twisting and folding the twist over itself and taping the bag closed.
- ✓ Use a transport container with a lid.

ACCUMULATION WASTE AREA:

- Vendor's tub is snapped closed prior to pick-up. The lid is required to be in the container once there is medical waste.
- Vendor tubs have a maximum weight limit requirements.

- ✓ **Store containers of medical waste in a secure area such as an autoclave room or laboratory. Do not set them in a hallway.**
- ✓ **Red biohazard bags containing waste can be kept in your work area for up to 7 days from the day you began to fill the bag.**
- ✓ **Full sharps containers can be stored in your work area for up to 7 days.**

Do Not Let This Happen to the Biohazard Accumulation Area!!!

BIOHAZARD LIQUID

- Liquids containing infectious agents, suspected of containing infectious agents, or human cells can be chemically disinfected followed by drain disposal with copious amount of running water.
  - Use a disinfectant appropriate for the infectious agent and let sit for the necessary contact time.
  - Consult laboratory biosafety manual or contact EH&S.

Disposal Procedure for Sharps Contaminated with Biohazardous Materials

What?

- ✓ glass items
- ✓ needles
- ✓ wires
- ✓ razor blades
- ✓ scalpels
- ✓ pasteur pipet
- ✓ capillary tubes

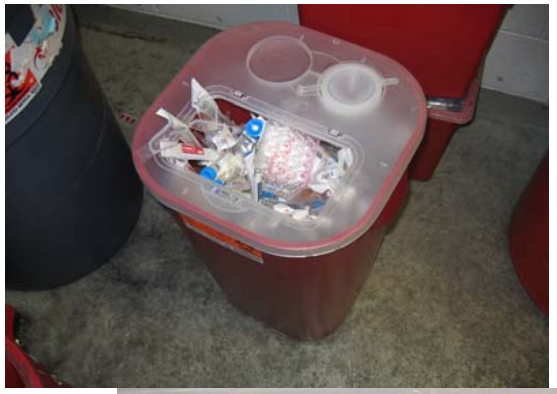
Procedures:

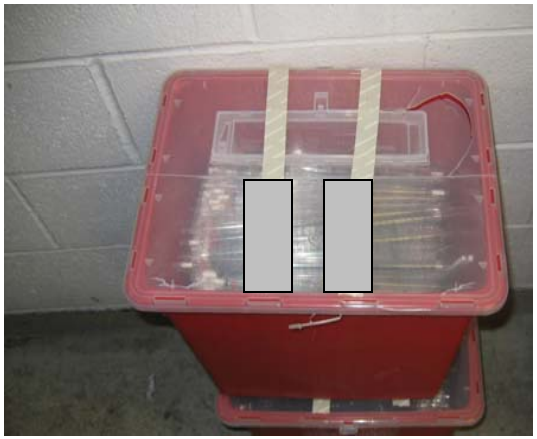
- **Do not use your hands to pick up broken glass.**
- **Push any glass into a dust pan using a handful of disinfectant soaked paper towels or use forceps to pick up the glass.**
- **Immediately after use dispose of sharps into a red biohazard sharps container labeled with biohazard markings.**
- **Dispose of full sharps container into the biohazard waste stream.**

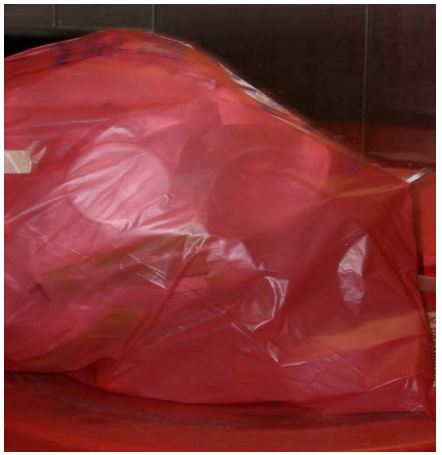
Sharps Container

- ✓ Sharps containers must be rigid, puncture resistant, and leak resistant.
- ✓ They can be any color.
- ✓ They must be labeled with the word “BIOHAZARD” and the biohazard symbol.
- ✓ Anything that is sharp or glass must be placed inside the sharps container.
- ✓ Never allow sharps to stick out of the opening or above the “fill line”.

Sharps Violations!!!







Sharps Disposal Procedures - Summary

Sharps not contaminated with regulated waste

1. Needles, wires, razor blades, scalpels, etc	Non-red sharps container; No biohazard markings; Label container; “Non-hazardous sharps waste”; Dispose to broken glass container.
2. Glass items	Container labeled “Broken Glass” or “Glass Disposal”

Sharps contaminated with hazardous chemicals or drugs

1. Needles, wires, razor blades, scalpels, pasteur pipets, capillary tubes, etc.	Non-red sharps container; No biohazard markings; Label with Hazardous Waste ID tag; Dispose to chemical waste.
2. Empty chemical containers	Rinse and place in container labeled, “Broken Glass” or “Glass Disposal”. You may need to collect rinse water.

Sharps contaminated with biohazardous materials

All glass items and needles, wires, razours, blades, scapels, etc.	Red or other colored sharps container; Labeled with biohazard markings; Dispose in biohazard (medical) waste.

Sharps contaminated with animal blood or tissues

All sharp items contaminated with visible blood	A. Red or other colored biohazard sharps container; Labeled with biohazard markings; Dispose in biohazard (medical) waste; or B. No pourable liquids or “pieces” of tissues allowed – place in Non-red sharps container; No biohazard markings; Label container, “Non-hazardous sharps waste”; Dispose in broken glass container.

Autoclaving

- If using your own autoclave…Must be registered with Public Health Department
- Documentation includes
  - Daily logs of waste processed
  - Monthly logs showing biological inactivation of waste
  - Yearly logs of facilities testing to ensure pressure and temperature are maintained for the full time
- If autoclaving biohazardous and sharps waste, follow the EH&S procedure for autoclave handling and disposal.
- Autoclaving recyclable labware or liquids contaminated with biohazardous materials and disposal in regular trash requires a permit from CA Dept of Health Services thru EH&S.
- Do not autoclave human or animal tissues.

PROCEDURE FOR DECONTAMINATION OF MEDICAL WASTE VIA AUTOCLAVE

A. Preparation and Loading

B. Cycle Selection and Settings

C. Cooling and Disposal

PREPARATION AND LOADING

1. Place heat sensitive tape on each red medical waste bags, sharps container or other container.
2. Place bags and/or containers in a leak-proof, heat-resistant autoclave pan or tub.

- Distribute the load as evenly as possible in the pan or tub.
- Do not over load the autoclave.
- The waste should not touch the interior walls of the autoclave.
- Leave an opening in the bag or loosen tops on the containers to allow steam to penetrate the waste.

3. Place pan or tub of items to be autoclaved inside the autoclave.

4. Close the door and secure it by tightening the handle firmly.

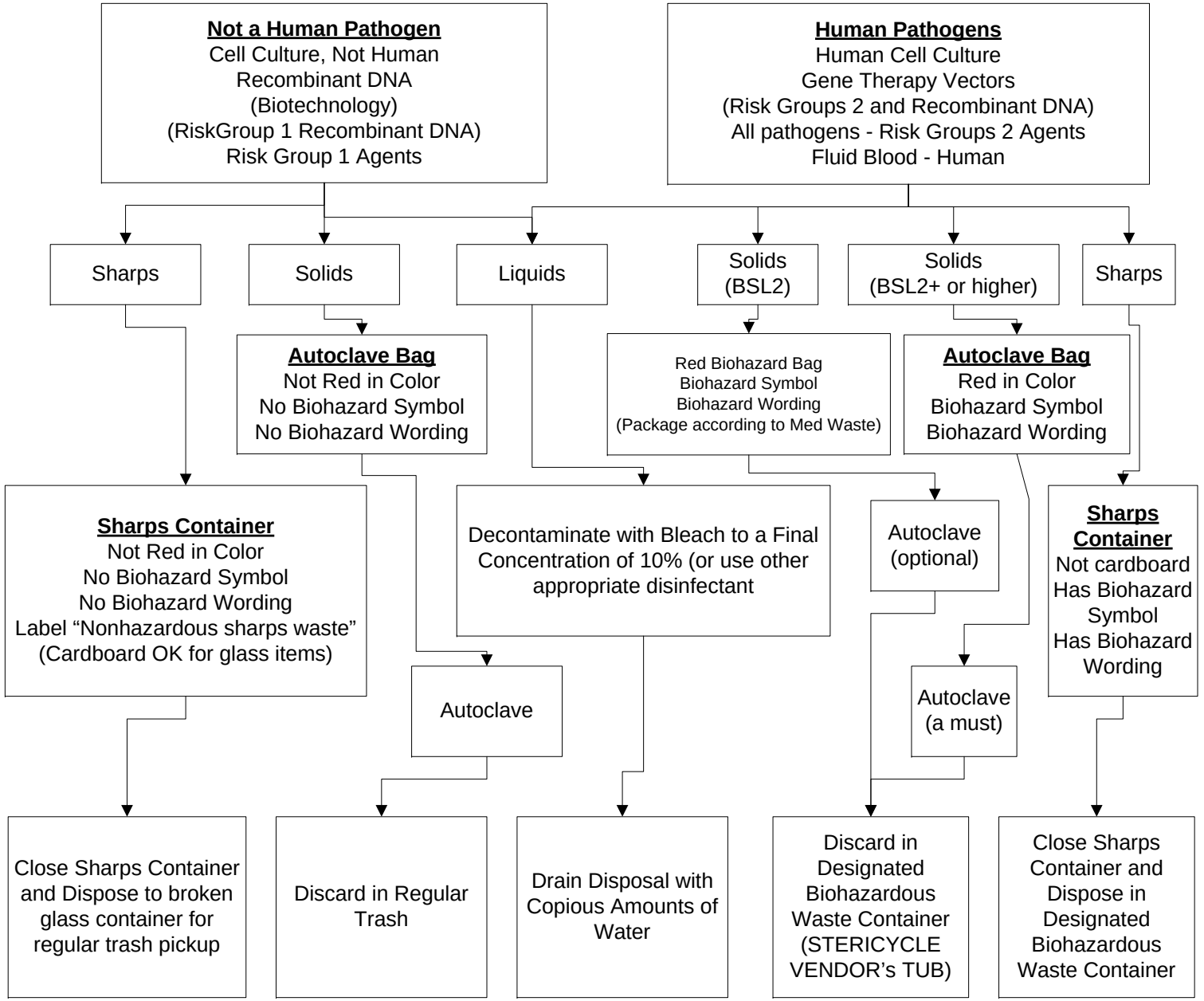
Cycle Selection and Setting

1. Run on the appropriate cycle, liquid or dry (depends on the items being autoclaved).
   - Run the dry cycle for items with a moisture content of less than 10% (paper, plastics, labware, sharps, etc.)
   - Run the liquid cycle for items that may boil and need a slow exhaust.
2. Autoclave the medical waste at 121^{O}C, 15 p.s.i., for a minimum of 45 minutes. Increase autoclave time by a minimum of 15 minutes for more dense loads or loads with a high liquid content.
3. Wait until the pressure has fallen to zero before opening the autoclave.
4. When opening the autoclave door, take precautions to avoid exposure to steam and hot surfaces or liquids.
5. Stand behind the autoclave door as you open it.
6. Allow liquids to cool for several minutes before removing them from the autoclave.
7. Use heat resistant gloves to remove items from the autoclave.
8. Close the autoclave door.
9. Check to make sure that the autoclave tape has changed. If the tape has not changed, re-autoclave the load. You may need to call Facilities Management to repair the autoclave.

VENDOR BARRELS

8. Dispose of autoclaved/ decontaminated medical waste into the medical waste stream (i.e., in the treatment companies 44-gal medical waste tubs).

   DO NOT PLACE IN THE SOLID WASTE STREAM/ REGULAR TRASH!!!


Not a Human Pathogen
Cell Culture, Not Human
Recombinant DNA
(Biotechnology)
(RiskGroup 1 Recombinant DNA)
Risk Group 1 Agents
Human Pathogens
Human Cell Culture
Gene Therapy Vectors
(Risk Groups 2 and Recombinant DNA)
All pathogens - Risk Groups 2 Agents
Fluid Blood - Human
Sharps
Solids
Liquids
Solids (BSL2)
Solids (BSL2+ or higher)
Sharps
Autoclave Bag
Not Red in Color
No Biohazard Symbol
No Biohazard Wording
Red Biohazard Bag
Biohazard Symbol
Biohazard Wording
(Package according to Med Waste)
Autoclave Bag
Red in Color
Biohazard Symbol
Biohazard Wording
Sharps Container
Not Red in Color
No Biohazard Symbol
No Biohazard Wording
Label "Nonhazardous sharps waste"
(Cardboard OK for glass items)
Decontaminate with Bleach to a Final Concentration of 10% (or use other appropriate disinfectant
Autoclave (optional)
Sharps Container
Not cardboard
Has Biohazard Symbol
Has Biohazard Wording
Autoclave
Autoclave (a must)
Close Sharps Container and Dispose to broken glass container for regular trash pickup
Discard in Regular Trash
Drain Disposal with Copious Amounts of Water
Discard in Designated Biohazardous Waste Container (STERICYCLE VENDOR's TUB)
Close Sharps Container and Dispose in Designated Biohazardous Waste Container

4 Types of Medical Waste

1. BIOHAZARD-Biohazard symbol and the word Biohazard Waste. Dispose in Red, Stericyle Tubs.

2. PATHOLOGY-“Path” label for incineration.

- For animals, return to vivarium source, and put in the freezer with Medical Waste tags.
- For human body parts and tissue, return to Dept of Path, Autopsy.

3. CHEMOTHERAPUTIC-Use Carcinogen label. Dispose in Yellow Chemo Waste container.

4. PHARMECETUICAL – Contact the pharmacy

Disposal of Other Types of Medical Waste

- Animal carcasses/Tissues for Medical Waste Disposal
  - Follow UCLA's Procedure for the Disposal of Biohazardous Animals
    - Use secondary containers
    - Use PATH labels
    - Provide Emergency Contact Info (PI's name, lab ext)
    - Return to the vivarium the animal was from

Samples of secondary transport containers:

Disposal of Other Types of Medical Waste

- **Pathology Waste (Human specimens)**
  - Pathology waste containers are medical waste for INCINERATION ONLY! These are red barrels but are 20-gallons in size (about ½ the size of the regular vendor's tub). These containers are labeled with the words "**Pathology Waste".**
  - Contact UCLA Pathology Waste Division x57846.

- **Pharmaceutical Waste**
  - Contact the Pharmacy at x78513 or take to the Pharmacy Vault at B1-504J Ronald Reagan Medical Center

Disposal of Other Types of Medical Waste

- Trace Chemotherapy Waste

  – Dispose of into the yellow barrels marked CHEMO WASTE that are provided by our vendor

  – Chemotherapy Waste Containers are disposed of as trace chemo waste if the material from the container or inner liner…

    - is not pourable when held in any orientation, including, but not limited to, when tilted or inverted

    - cannot be removed from the container by scraping

TRANSPORT CONTAINERS & LABELS FOR REGULATED WASTE

• Biohazardous Waste	• Biohazard symbol and the word Biohazard Waste. Dispose in Red, Stericyle Tubs.
• Chemo Waste	• Use Carcinogen label. Dispose in Yellow Chemo Waste container.
• Path Waste	• "Path" label for incineration. For animals, return to vivarium source, and put in the freezer with Medical Waste tags. For human body parts and tissue, return to Dept of Path, Autopsy.
• Pharm Waste	• Pharm Waste label for "INCINERATION ONLY".

ACCUMULATION WASTE STORAGE

A. Do not store biohazardous waste at a temperature above freezing for more than 7 days. Do not compact biohazardous bags in storage container.

B. Do not store full sharps containers for more than 7 days at a temperature above freezing. Dispose as soon as possible.

C. Do not store red biohazardous waste containing human tissues or animals in a freezer for more than 90 days.

Medical Waste Disposal as Required by the Department of Transportation (Transport)

DOT MARKING REQUIREMENT

A. Universal biohazard symbol.
B. The word “BIOHAZARD”
C. Proper Shipping Name “REGULATED MEDICAL WASTE”
D. UN Number, UN3291
E. Maximum weight allowed in the container
F. UN specification markings for shipping infectious substances
G. Shipper’s address

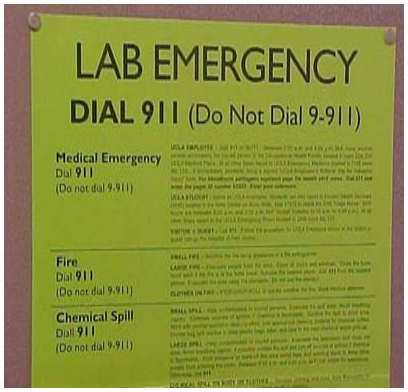
Vendor provides UCLA with labels to affix to each filled container/tub they transport.

DOT DOCUMENTATION REQUIREMENT (Tracking Document)

- Completed by the Vendor
- Type of waste
- Quantity of waste
- Serves as shipping papers
- Signed by an authorized person at UCLA (Custodians, loading dock managers, supervisors)
- Certification (description, packaging, marking, label according to DOT)
- Emergency response phone number (UCLA uses Police Dispatch)

Emergency Response

- Follow the spill clean-up procedures on the emergency poster.
- Facilities Management Trouble Call Center for custodial services x59326.
  - Need more medical waste barrels.
  - Disposal of medical waste barrels.
- Environmental Services for the Hospital x55001



UCLA, EH&S Biosafety Contact Information:

EH&S Training Line
x45328 or training@ehs.ucla.edu

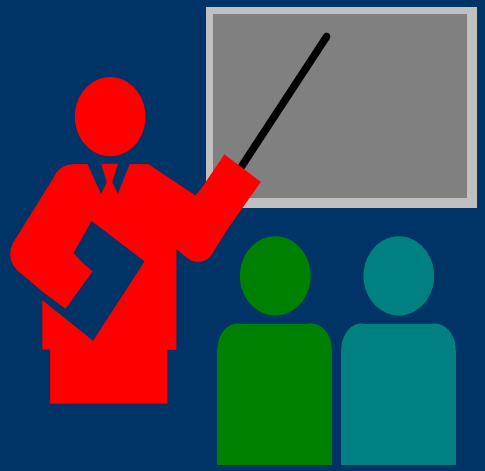
Main Office
x55689 or www.ehs.ucla.edu or
biosafety@ehs.ucla.edu

Biosafety A, B, C's
Biosafety Level 2

UCLA Environment, Health & Safety
Biosafety Program

Training Objectives

- Risk Assessment
  - –Risky Procedures
  - –Risk Groups
- Biosafety Level 2 Containment Requirements
- Emergency Procedures
  - –Medical Emergency
  - –Spill Clean Up Procedures
- Quiz

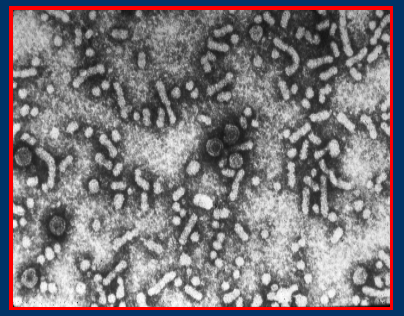


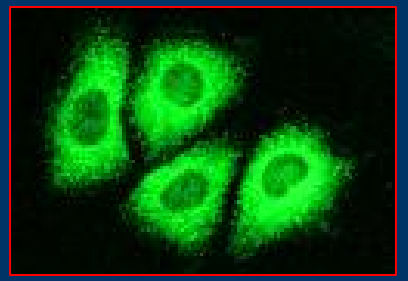
Risk Assessment in Your Lab

- Focuses on the prevention of:
  - Exposures
  - Lab acquired infections
  - Environmental contamination

Background Information on Lab Acquired Infections

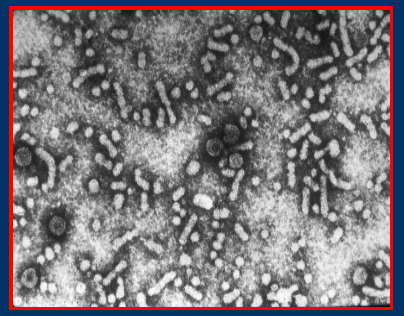
- Lab surveys in the US showed:
  - Between 1930 &1978:
    - 4,079 infections &168 deaths
  - Next 20 years:
    - 1,267 infections & 22 deaths
- In 80% of these cases, no accident or exposure was reported

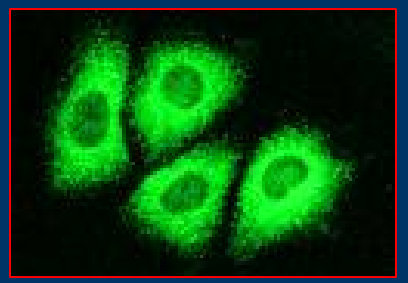




What these studies teach us

- Aerosols assumed to be the cause of these “mystery exposures”
- Number of accidents is decreasing
- Decrease most likely due to improvements in:
  - Containment equipment
  - Engineering controls
  - Training





Conducting a Risk Assessment

- Responsibility of the PI & UCLA's Institutional Biosafety Committee (IBC)

- Tools for Risk Assessment:
    1. Agent Hazards (Risk Group)
    2. Procedure Hazards

Risk Assessment in Your Laboratory

- Risk assessment in Biosafety labs is usually qualitative, not quantitative

- Biosafety risk assessment is based upon what you're working with, not how much of it you have

Biohazardous Agents by Risk Group

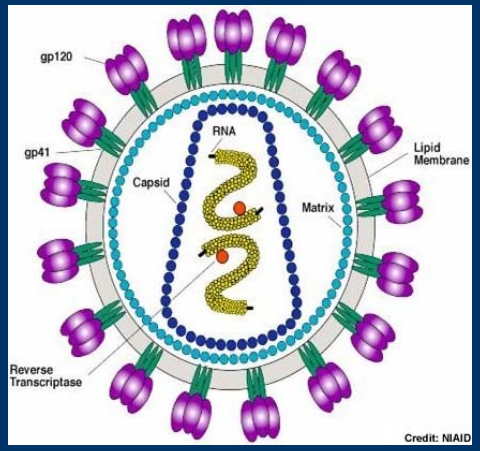
- All agents are assigned to a Risk Group (RG)
- Risk groups vary based on the agent hazards
- Risk groups are not the same as Biosafety Levels

Risk Groups

RG	Agents that are. . .	Examples
1	Not associated with disease in healthy adult humans	E. coli K12, Adeno-Associated Virus
2	Associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available	Adenovirus, Hepatitis, HSV, Salmonella
3	Associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)	Tuberculosis, HIV, HTLV, Yellow Fever Virus
4	Likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk & high community risk)	Ebola virus, Hemorrhagic Fever Agents

Agent Hazards

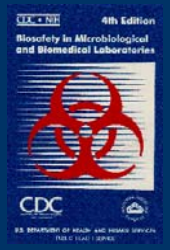
1. Infective dose
2. Environmental stability
3. Host range
4. Endemic nature
5. Routes of transmission



Routes of Transmission

- 20% of lab acquired infections:
  - Direct skin, eye or mucosal membrane contact
  - Inoculation from contaminated sharps or animal bites/scratches
  - Ingestion (hand-to-mouth transmission)
- 80% of lab acquired infections:
  - Inhalation of aerosol

Resources



- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
  http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm

- *NIH GUIDELINES* for Research Involving rDNA
  http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

- American Biological Safety Association
  http://www.absa.org/

- Canada's Biosafety Guidelines & Infectious Agent information:
  http://www.phac-aspc.gc.ca/msds-ftss/

- World Health Organization:
  http://www.who.int/topics/biosafety/en/

Biosafety Levels

- After a risk assessment has been conducted your lab will be assigned a Biosafety Level (BSL)

- There are 4 Biosafety Levels (see chart at end of handout for more info)

Biosafety Containment Levels

Purpose:

- Confine biohazardous material
- Enhance worker safety & environmental protection

Biosafety Lab Requirements:

- Standard & special lab practices
- Containment equipment
- Facility construction

BSL2 Exposure Evaluation

- Incidents that may result in exposure to infectious materials:
  - must be immediately evaluated & treated
  - procedures must described in biosafety manual
  - Must be reported to the lab supervisor
- Spills & accidents resulting in exposures to organisms containing rDNA molecules:
  - Immediately report to Biosafety and NIH/OBA
- Medical evaluation, surveillance, & treatment are provided as appropriate & written records are maintained

BSL2 Biosafety Manual

- Each lab must make their own
- Needs to include lab specific information
- Includes:
  - Standard operating procedures
  - Experimental design
  - Handling of cultures/samples
  - Hazards of agents
  - Training records
  - Emergency procedures
  - Biosafety practices and equipment
  - Biohazard waste disposal procedures

BSL2 Training

- EH&S Biosafety trainings

- Lab specific training:
  - Conducted by the PI or Lab Supervisor
  - Must be documented
  - Required annually
  - Additional training necessary for procedural or policy changes

BSL2 Lab Access

- Limited or restricted
- Everyone entering must:
  - Be advised of potential hazards
  - Be trained
  - Meet entry requirements (immunization, etc.)
- People may not enter if:
  - They are at increased risk of infection
  - Infection may have serious consequences
- For some labs a baseline serum sample may be stored

BSL2 Door Card

- Biosafety Level
- Agents used
- Personal Protective Equipment (PPE)
- Required immunizations
- Personnel groups at risk
- Exit procedures
- PI & Alternate person's contact information
- Non-transferable

Personal Protective Equipment (PPE)

- Lab coats, gowns, or smocks must be worn
- Long pants are recommended and closed toed shoes are required
- Eye & face protection when:
  - splashes or sprays are anticipated
  - biohazards must be handled outside of containment device
  - Wearing contact lenses

Personal Protective Equipment (PPE)

- Respiratory protection when:
  - in rooms with infected animals
  - as determined by a risk assessment
- PPE must be:
  - Removed before leaving the lab
  - Disposed of properly
  - Laundered by the institution

Gloves

- Must be worn
- Selected based on risk assessment
- Double-glove when appropriate
- Should be changed when:
  - Contaminated
  - Compromised
  - Otherwise necessary
- Do not wash or reuse gloves
- Remove before leaving lab
- Dispose of gloves as biohazard waste
- Wash hands after removal

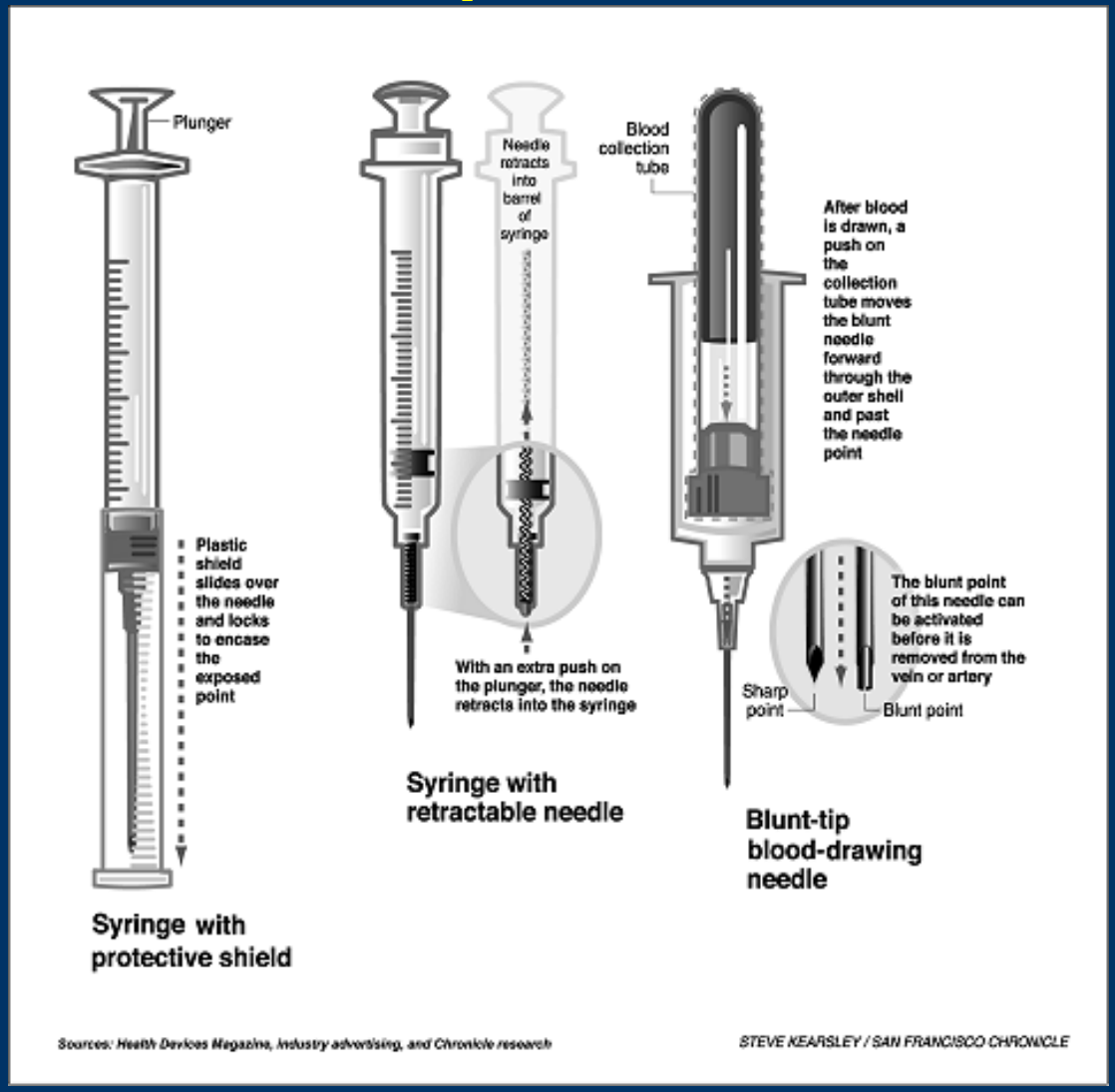
BSL2 Safety Practices

- No eating, drinking or smoking
- No applying contact lenses or cosmetics
- No mouth pipetting
- Pest management
  - If you have a pest problem (rats, bugs, etc.) Call the Trouble Desk at 310-825-9236

BSL2 Sharps Precautions

- Use extreme caution to avoid autoinoculation or aerosol generation
- Avoid sharps if alternatives exist
- Use only integral needle/syringe or needle-locking syringes
- Put used sharps directly into the sharps container
- Needles should not be bent, sheared, recapped or removed from syringe before disposal

BSL2 Sharps Precautions



BSL2 Sharps Containers & Broken Glass

- Sharps containers:
  - Puncture-resistant
  - Conveniently located
  - Should be inside of the Biosafety Cabinet

- Cleaning up broken glass:
  - Do not handle directly
  - Use broom & dustpan, tongs or forceps

- Use plastic instead of glass whenever possible

BSL2 Transport of Agents

Potentially infectious material must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport.

Plants & Animals in the Lab

Animals and plants not research-associated are not permitted in the laboratory

BSL2 Aerosol Generating Procedures

All procedures that involve:

- possible aerosol creation
- high concentrations
- large volumes

must be conducted inside of a biosafety cabinet

Potential Aerosol Generating Procedures

- Inoculating-loop manipulation:
  - Sub-culturing and streaking cultures
  - Flaming a loop
  - Cooling a loop in culture media

- Pipetting:
  - Mixing microbial suspensions
  - Spills on hard surfaces

- Needle and syringe manipulation:
  - Expelling air
  - Withdrawing needle from stopper
  - Injecting animals

Centrifuging of Infectious Materials

May be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups

BSL2 Lab Facilities

- Doors:
  - Self-closing
  - Have a lock
  - Open inwards

- Sink:
  - Near the exit
  - Soap & paper towels

- Eyewash station:
  - Less than 10 seconds away
  - Only 1 doorway away
  - Near exit

BSL2 Lab Facilities

- Lab can be easily cleaned & decontaminated
- No carpets, rugs, drapes, fabric, cardboard, or styrofoam
- Windows that open must have screens
- Negative pressure airflow recommended

BSL2 Lab Furniture

- Must be capable of supporting equipment
- Spaces between furniture must be accessible for cleaning
- Bench tops must be impervious to water and resistant to heat, solvents, acids, alkalis and other chemicals
- No cloth-covered chairs

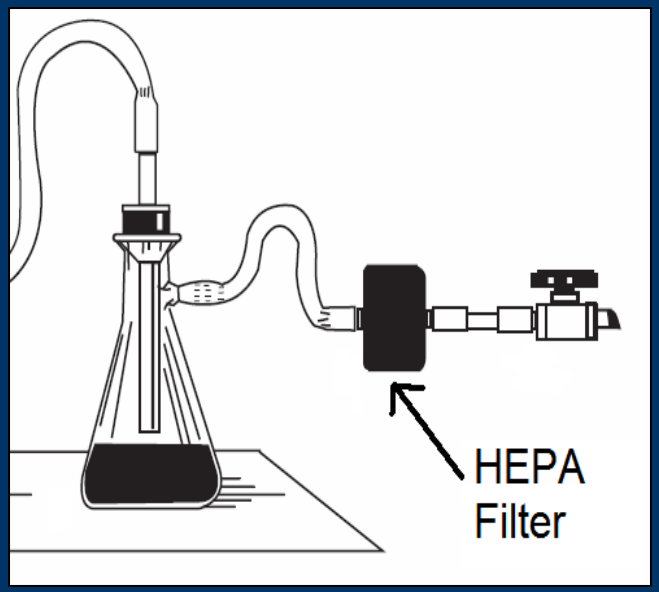
BSL2 Biosafety Cabinet Installation

- Make sure that room air supply & exhaust do not interfere with operation

- Locate away from:
  - Doors
  - Windows that open
  - Heavily trafficked areas
  - Other possible airflow disruptions

BSL2 Aspiration Flasks

- Need to be inside of the biosafety cabinet
- Vacuum lines must be protected with a HEPA filter (replace as needed)



BSL2 Decontamination

- Lab equipment & surfaces must be routinely decontaminated
- Decontaminate surfaces following a spill or splash
- Must be done staff trained to work with biohazards
- Equipment must be decontaminated before repair, maintenance, or removal from lab

BSL2 Waste Disposal

- Dispose of all waste as biohazard waste
- Decontaminate all potentially infectious cultures/stocks before disposal
- Package & transport waste properly
- Do not need to autoclave waste before disposing of it into the 44 gallon red Stericycle biohazard waste barrels

Are these ok?

Cleaning Up a Biohazardous Spill

Only clean up what you are comfortable cleaning up!

Your response depends on:

- Risk of infection
- Location of spill

Goals for Cleanup:

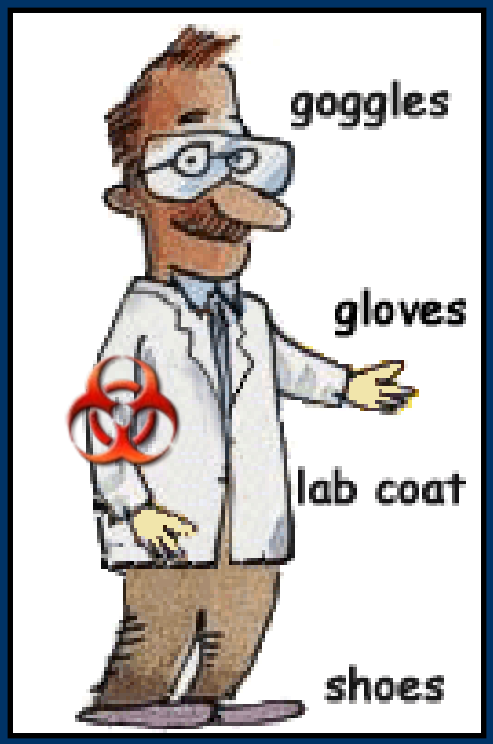
- Minimize potential for infection to yourself, others & the environment
- Minimize splashing & aerosolization

General Biohazard Spill Cleanup Procedure

1. Personal protective equipment: Lab coat, gloves, mask & goggles
2. Place paper towels over & beyond the spill area
3. Pour disinfectant on paper towels around & into the spill area
4. Let sit for the contact time required to inactivate biohazardous agent:
    - 10% Bleach dilution - 10 minutes
    - 70% Ethanol - 20 minutes
5. Dispose paper towels as biohazard waste
6. Clean area again with disinfectant & paper towels
7. Dispose of gloves as biohazard waste
8. Wash hands with soap and water
9. Report the spill

Cleaning up a Biohazard Spill on Yourself

1. Stay where you are
2. Immediately remove contaminated clothing
3. Dispose of contaminated material as biohazard waste
4. Rinse exposed skin with water or wash with a disinfecting soap
5. Receive medical treatment if necessary



Cleaning up a Biohazard Spill Inside of a Biosafety Cabinet

- Keep the Biosafety cabinet running
- For small spills you can finish working before cleanup
- Avoid running your sleeve through the spill or contaminating other items

Cleaning up a splash, spill or aerosolization outside of the biosafety cabinet

- Everyone needs to leave the room
- Hold your breath while exiting
- Shut the door
- Wash exposed skin with soap and water
- Allow aerosols to settle or vent
- Wait at least 30 minutes before re-entering

Report the Biohazard Spill

- All spills or exposures involving biohazardous material must be reported immediately!
- Report To:
  - PI and Lab Supervisor
  - EH&S Biosafety Office x63929 or x55689

Where To Go For Emergency Care

- Staff & Graduate Students:
  Occupational Health Facility
  Open 7:30 am- 4:30 pm Mon - Fri
  located in 67-120 CHS, x56771

- Undergraduate Students:
  Arthur Ashe Student Health & Wellness Center
  next to the John Wooden Center, x54073

- After hours, weekends, holidays, or for immediate treatment:
  UCLA Emergency Room, call 911

- Tell staff that the injury is work related and covered by medical coverage under UCLA Worker's Compensation

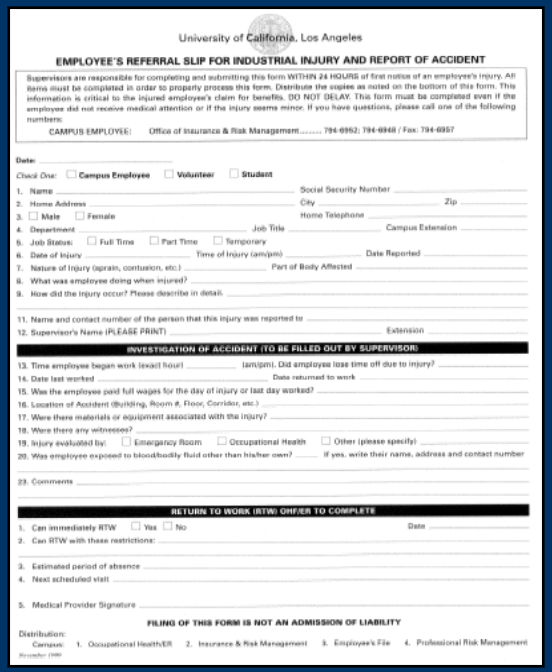
Worker's Compensation Medical Coverage

- Paid employees, guests, & students are covered by worker's compensation
- Visitors & guests:
  - Register with the volunteer's office to get coverage
    - (310) 825-6002
  - Have arrangements made by your department's business office for coverage.

Worker's Compensation

- Fill out:
  - UCLA Employee's Referral Slip for Industrial Injury and Report of Accident form
  - http://www.oirm.ucla.edu/wcoir1.pdf

- Questions:
  - 310-794-6948
  - http://www.oirm.ucla.edu/workers-comp.htm



University of California, Los Angeles

EMPLOYEE'S REFERRAL SLIP FOR INDUSTRIAL INJURY AND REPORT OF ACCIDENT

Supervisors are responsible for completing and submitting this form WITHIN 24 HOURS of first notice of an employee's injury. All items must be completed in order to properly process this form. Distribute the copies as noted on the bottom of this form. This information is critical to the injured employee's claim for benefits. DO NOT DELAY. This form must be completed even if the employee did not receive medical attention or if the injury seems minor. If you have questions, please call one of the following numbers:

CAMPUS EMPLOYEE: Office of Insurance & Risk Management ..... 794-6962; 794-6948 / Fax: 794-6957

Date: _____

Check One: ☐ Campus Employee ☐ Volunteer ☐ Student

1. Name _____ Social Security Number _____
2. Home Address _____ City _____ Zip _____
3. ☐ Male ☐ Female Home Telephone _____
4. Department _____ Job Title _____ Campus Extension _____
5. Job Status: ☐ Full Time ☐ Part Time ☐ Temporary
6. Date of Injury _____ Time of Injury (am/pm) _____ Date Reported _____
7. Nature of Injury (sprain, contusion, etc.) _____ Part of Body Affected _____
8. What was employee doing when injured? _____
9. How did the injury occur? Please describe in detail: _____

11. Name and contact number of the person that this injury was reported to _____
12. Supervisor's Name (PLEASE PRINT) _____ Extension _____

INVESTIGATION OF ACCIDENT (TO BE FILLED OUT BY SUPERVISOR)

13. Time employee began work (exact hour) _____ (am/pm). Did employee lose time off due to injury? _____
14. Date last worked _____ Date returned to work _____
15. Was the employee paid full wages for the day of injury or last day worked? _____
16. Location of Accident (Building, Room #, Floor, Corridor, etc.) _____
17. Were there materials or equipment associated with the injury? _____
18. Were there any witnesses? _____
19. Injury evaluated by: ☐ Emergency Room ☐ Occupational Health ☐ Other (please specify) _____
20. Was employee exposed to blood/bodily fluid other than his/her own? _____ If yes, write their name, address and contact number _____
23. Comments _____

RETURN TO WORK (RTW) OMFER TO COMPLETE

1. Can immediately RTW ☐ Yes ☐ No Date _____
2. Can RTW with these restrictions: _____
3. Estimated period of absence _____
4. Next scheduled visit _____
5. Medical Provider Signature _____

FILING OF THIS FORM IS NOT AN ADMISSION OF LIABILITY

Distribution:
Campus: 1. Occupational Health/ER 2. Insurance & Risk Management 3. Employee's File 4. Professional Risk Management

November 1999

In Case of Emergency

- Dial 911 from any landline on campus
- Dial 310-825-1491 from a cell phone to reach UCLA Police Dispatch
- UCLA Trouble Desk
  - On campus: x 59236
  - Off campus: 310-825-9236
- EH&S Main Office
  - On campus: x 55689
  - Off campus: 310-825-5689

EH&S Biosafety Contact Information

biosafety@ehs.ucla.edu

www.biosafety.ucla.edu

EH&S main line x55689

Quiz Answers

1. Occupational Health Facility
   or UCLA Emergency Room

2. 67-120 CHS
   Monday – Friday 7:30 am – 4:30 pm

Quiz Answers

Question # 3

1 – Put on proper personal protective equipment

2 – Place paper towels on top of spill

3 – Pour disinfectant on top of spill

4 – Let disinfectant sit for required contact time

5 – Clean area again with paper towels

6 – Remove gloves & wash hands

Quiz Answers

4. Inoculating-loop manipulation, Pipetting, Needle & syringe manipulation

5. True – The risk group of an infectious agent never changes

True – The Biosafety level containment can change

Quiz Answers

6. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (**BMBL**) **5th** Edition

7. ***NIH GUIDELINES*** for Research Involving rDNA

8. E – All of the above!

Quiz Answers

9. B – In a Tupperware container (with a lid) labeled with a biohazard sticker

10. All answers are correct except for Rugs and Carpets

Quiz Answers

Question # 11

Required:
Gloves
Goggles
Lab coat
Closed toed shoes
Face protection

Not Required:
Respirator
Sandals & Shorts

STANDARD OPERATING PROCEDURE

Indicate the location, agent name, etc

PURPOSE

The purpose of this document is to specify the procedures used to handle ….

SCOPE

This SOP applies to ….

RESPONSIBILITIES

The Principal Investigator is responsible for reviewing this SOP annually and updating this document as needed — as well as any and all other applicable documents.

All research personnel are responsible for reading and complying with the provisions herein.

SAFETY TRAINING REQUIREMENTS

In addition to receiving laboratory specific training for handling _____, all research personnel handling ____ must take the following EH&S safety training requirements. *Please note that the Animal Research Committee or DLAM may require additional training.*

A. Biosafety Cabinet (once)
B. Biosafety A,B,C's – Biosafety Level 2 (at least every 3 years)
C. Bloodborne Pathogens (annually, through online refresher)
D. Medical Waste Management (at least every 3 years)
E. Hazardous Chemical Waste Training (once), if this study involves hazardous chemicals

DEFINITIONS:

Explain any terms, acronyms, or abbreviations used that might not be commonly understood by a person new to procedure.

REFERENCES:

List any previously published procedures and/or documents used for guidance or reference material to assist in performing the SOP.

MATERIALS and/or EQUIPMENT:

List any material/equipment that is required for the procedure. Examples include equipment, reagents, compounds, chemicals, disposables, etc. Pay particular attention to safety equipment needs.

PROCEDURES:

Describe the procedure in a step-by-step, chronological manner using active verbs and direct statements. List all necessary steps, locations, and conditions in the procedures, for example:

- Setup/shutdown (Personal Protective Equipment);
- Flow Chart of Method;

- Procedure for Sample Preparation,Transfection/Transduction (cell culture experiments), Transport, Storage;
- Cleanup (decontamination);

Any deviations from SOPs should be significant enough to warrant nonconformance.

PRECAUTIONS:

Hazards of the agent, handling instructions/warnings, general safety precautions, protective equipment, etc.

Commonly encountered difficulties or errors.

EMERGENCIES (SPILL and/or EXPOSURE):

Procedures to spill and exposure.

List any anticipated problems that may arise and course of action to be taken, including person (by job title) to consult when each contingency arises.

REPORTING AND DOCUMENTATION:

List information for reporting of accidents, exposure, spills, etc. Information of supervisor, safety offices, emergency rooms, etc. (IMPORTANT CONTACT INFORMATION)

PLEASE READ BEFORE COMPLETING
THE BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN!!

If you have any questions regarding the completing of this document contact the Environment, Health and Safety, Biosafety Division at extension 63929 or biosafety@ehs.ucla.edu.

*The **Exposure Control Plan** on this file is an incomplete document. It must be modified to the characteristics of your lab. The PI is the responsible party, unless designated otherwise.*

1. *To complete the document, fill in the appropriate information in all highlighted areas.*
2. *Modify lists of Engineering Controls, Work Practice Controls, and Personal Protective Equipment to reflect what are utilized in your lab*
3. *Section VII. HIV AND HBV RESEARCH LABORATORIES must only be completed by labs that are engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. Clinical or diagnostic labs engaged solely in the analysis of blood, tissues, or organs are exempted from completing this section. To complete this section add any additional practices, containment equipment, facility and training requirements as applies. **No information in this section can be subtracted. All must be followed.***
4. *Remember that the **Exposure Control Plan** must be updated yearly.*
5. *Remember that upon completion, the **Exposure Control Plan** must be made accessible to all employees in the laboratory.*

BLOODBORNE PATHOGENS STANDARD

EXPOSURE CONTROL PLAN

I. POLICY STATEMENT

Facility (***name of lab or department***)
Principal Investigator or Supervisor (***name of professor or supervisor***)
Location (Building/Room): _____(***location of lab(s))***
Date of preparation: _____

It is the policy of UCLA to ensure the safety of all its employees. The following exposure control plan has been developed for the purpose of:

1) Protecting employees by eliminating or minimizing their occupational exposure to human blood, other body fluids, tissues or organs; HIV, HBV or HCV containing cell or tissue cultures, culture medium or other solutions containing HIV, HBV or HCV; or blood, organs or other tissues from experimental animals infected with HIV,HBV or HCV;
2) Complying with the CAL/OSHA "Bloodborne Pathogens Standard" (Title 8, Code of California Regulations, Section 5193); and
3) Providing an exposure control plan that is consistent with the requirements of the Cal/OSHA "Injury and Illness Prevention Plan" (Title 8, Code or California Regulations, Section 3203).

Evaluation and Review

_____ (***insert name of person and their position title***) has overall responsibility for the Plan, including reviewing and updating the plan annually , when procedures change or when a risk assessment of procedures is conducted. Copies of the Plan may be obtained from _____ (***insert name of person and their position title***) in _____ (***insert location of person's office***).

II. EXPOSURE DETERMINATION:

The exposure determination is made without regard to the use of personal protective equipment.

Category I: All personnel in these job classifications may reasonably be expected to be exposed to blood or OPIM in the course of the performance of their job duties:

(List all job titles that apply --such as examples below. Delete job titles listed below that do not apply to your area.)

Principal Investigator
Graduate Student
Postdoctoral Fellow
Staff Research Associate
Lab Assistant/Helper
Visiting Scholar
Professor
Lifeguard
Nurse
Physician
Custodian

Category II: Some personnel in these job classifications might perform duties which would put them at risk.

(List job classifications and associated tasks and procedures or groups of closely related tasks and procedures for this category as follows. See example below. Delete what does not apply.)

Job Classification

Laboratory Helper

Tasks/Procedures in which occupational exposure occurs:
1. Arranging samples in test tube racks.
2. Loading tubes and retrieving them from the centrifuge.
3. Opening tubes of blood.
4. Lymphocyte separation procedures by Ficoll-Hypaque.
5. Disposing of blood tubes and tissue after lymphocyte isolation is completed.
6. Cleaning out freezer inventories of old sera.
7. Aliquoting blood into tubes before centrifugation.
8. Cleaning up spilled blood, sera or tissue fragments on bench tops, in centrifuges or from the floor.
9. Handling contaminated garments: lab coats, masks, aprons, etc.

III. METHODS OF COMPLIANCE

General: As a mandate by the Standard, **Universal Precautions** shall be followed at UCLA at all times to prevent contact with blood or OPIM by those persons designated to be “at-risk”. Universal Precautions is an infection control mechanism which considers that all human blood and OPIM to be at risk for containing potentially infectious bloodborne pathogens.

Engineering Controls and work Practice Controls – General Requirements:

Engineering and work practice controls will be used at UCLA to eliminate or minimize exposure to bloodborne pathogens. Supervisors will evaluate all tasks with exposure potential and will institute the use of engineering controls and work practices whenever possible to eliminate or minimize exposure to their employees. If occupational exposure remains after institution of these controls, then the facility will provide and assure its employees use personal protective equipment as supplemental protection.

Specific engineering controls and work practices used will be evaluated and updated on a regular schedule to ensure their effectiveness. Engineering controls used will be examined and maintained or replaced on a regular schedule to ensure their effectiveness. All procedures involving blood or OPIM will be performed in such a manner as to minimize splashing, spraying, spattering and generation of droplets of these substances.

Engineering and Work Practice Controls – Specific Requirements

A. Needleless Systems, Needle Devices and Non-Needle Sharps

1. Needleless systems will be used at UCLA for:
   a. Withdrawal of body fluids after initial venous or arterial access is established;
   b. Administration of medications or fluids; and
   c. Any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices.
2. If needleless systems are not used, needles with engineered sharps injury protection shall be used for:
   a. Withdrawal of body fluids;
   b. Accessing a vein or artery;
   c. Administration of medications or fluids; and
   d. Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.
3. If sharps other than needle devices are used, these items will include engineered sharps injury protection.

Exceptions:

1. The engineering control is not required if it is not available in the marketplace.
2. The engineering control is not required if a licensed healthcare professional directly involved in the patient's care determines, in the reasonable exercise of clinical judgment, that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient. The determination will be documented.
3. The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.
4. The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria

whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's work place.

In this facility the following engineering controls used are:

(List controls that apply to your facility; delete examples that do not apply.)

- Sharps containers are used for disposal of all needles and other sharp tools.
- Class II biological safety cabinets
- Contained centrifuge units
- Mechanical pipetting devices
- Capped centrifuge tubes
- Needleless systems
- Needles with engineered sharps protection

B. Prohibited Work Practices**:**

1. Shearing or breaking of contaminated needles and other contaminated sharps is prohibited.
2. Contaminated sharps will not be bent, recapped, or removed from devices. Contaminated sharps may be bent, recapped or removed from devices if the procedure is performed using a mechanical device or a one-handed technique, and the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.
3. Sharps that are contaminated with blood or OPIM will not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.
4. Disposable sharps shall not be reused.
5. Broken glassware which may be contaminated will not be picked up directly with the hands. It will be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.
6. The contents of sharps containers will not be accessed unless properly reprocessed or decontaminated.
7. Sharps containers will not be opened, emptied, or cleaned manually or in any other manner which would exposure employees to the risk of a sharps injury.
8. Mouth pipetting/suctioning of blood or OPIM is prohibited.
9. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.
10. Food and drink will not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or OPIM are present.

C. Requirements for Handling Contaminated Sharps

1. All procedures involving the use of sharps in connection with patient care, such as withdrawing body fluids, accessing a vein or artery, or administering vaccines, medicaltions or fluids, will be performed using effective patient-handling techniques and other methods designed to minimize the risk of a sharps injury.

2. Immediately or as soon as possible after use, contaminated sharps will be placed in a sharps containers.
3. At all time during the use of sharps, containers for contaminated sharps will be:
    a. Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found.
    b. Maintained upright throughout use, where feasible; and
    c. Replaced as necessary to avoid overfilling.

D. Sharps Containers for Contaminated Sharps:

All sharps containers for contaminated sharps will be rigid, puncture resistant, leakproof on the sides and bottom, portable, if portability is necessary to ensure easy access, and labeled as biohazard waste.

If discarded sharps are not to be reused, the sharps container shall be closable and sealable so that when sealed, the container is leak resistant and incapable of being reopened without great difficulty.

E. Regulated Waste

1. Handling, storage, treatment and disposal of all regulated waste will be in accordance with the California Medical Waste Management Act (California Health & Safety Code Chapter 6.1 sections 117600 through 118360) and other applicable regulations of the United States, the State, and political subdivision of the State.
2. When any container of contaminated sharps is moved from the area of use for the purpose of disposal, the container will be:
3. Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; and
4. Placed in a secondary container if leakage is possible. The second container will be closable; constructed to contain all contents and prevent leakage during handling, storage, transport or shipping; labeled as biohazardous waste.
5. Regulated waste not consisting of sharps will be disposed of in containers which are closable, labeled as biohazardous waste, closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
6. If outside contamination of a container of regulated waste occurs, it will be placed in a second container. The second container will be closable, constructed to contain all contents and prevent leakage of fluids during handling, storag, transport or shipping.
7.

F. Handling Specimens of Blood or OPIM

Specimens of blood or OPIM will be place in a container which prevents leakage during collection, handling, porcessing, storage, transport or shipping.

1. The container for storage, transport or shipping will be labeled or color-coded and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such

specimens/containers remain within the facility. Labeling or color-coding is required when such specimens/containers leave the facility.

2. If outside contamination of the primary container occurs, the primary container will be placed within a second container which prevents leakage during collection, handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of the facility.
3. If the specimen could puncture the primary container, the primary container will be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

G. Servicing or Shipping Contaminated Equipment

Work practice controls in place to reduce the likelihood of exposure include:

(List controls that apply to your facility; delete examples that do not apply. The examples are required by the law. Do not delete them unless they really do not apply to your facility.)

- ☐ Handwashing facilities are available in all lab areas.

- ☐ Gloves are removed when answering the telephone or use a Kleenex or Kimwipe when picking up the receiver.

- ☐ Employees wash their hands after removal of gloves and to not wear gloves outside of the work area.

- ☐ Employees thoroughly wash their hands or skin with hot water and soap after exposure to blood or blood products and to flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with potentially infectious material.

- ☐ Contaminated needles are disposed of in appropriately labeled containers. Needles and adapters are thrown out without removing or bending or breaking the needles. The sharps containers are puncture resistant, leak-proof, and labeled to indicate biohazardous material.

- ☐ Eating, drinking, applying lip balm or lipstick or handling contact lenses in the laboratory is prohibited in those areas where there is a reasonable likelihood of occupational exposure.

- ☐ Food and drinks are prohibited from refrigerators, freezers, shelves, and bench tops where blood or other potentially infectious material is present.

- ☐ All procedures involving blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, spattering or otherwise creating droplets or aerosols.

- ☐ Mouth pipetting of potentially infectious material is prohibited.

- ☐ Specimen drawn for shipment are placed in foam and encased in absorbents material that can soak up entire contents then sealed in plastic. The package is placed in an outer box that is again sealed in plastic before being placed in the final shipping container. The container is labeled as containing diagnostic specimens.

- ☐ Equipment needing servicing or repair is decontaminated before the service representative is allowed to work on it. If portions cannot be readily decontaminated, a highly visible label will be affixed to the equipment to warn the service representative or manufacturer of the potential hazard and stating which parts may be contaminated before the equipment is sent for repair or service.

The above engineering and work practice controls will be inspected, maintained and if necessary, replaced on a regular schedule. The schedule for reviewing the effectiveness of the controls is as follows: ***(List schedule, such as daily, once/week, etc., list the name/position of the person(s) responsible for reviewing the effectiveness of these controls.)***

_____
_____

Personal Protective Equipment:

1. Provision:

_____***(insert name of person/position)*** is responsible for ensuring that employees are provided, without cost to them, with appropriate PPE as determined by their anticipated exposure to blood or OPIM.

2. Use:

_____ ***(insert name of person/position)*** will ensure that employees use appropriate PPE as needed by their assigned tasks and will be responsible for investigating and documenting those unusual instances in which PPE is not worn when required.

3. Accessibility:

_____***(insert name of person/position)*** will ensure that appropriate PPE in the appropriate sizes is readily available at this work site and is issued without cost to employees.

4. Cleaning, Laundering and Disposal

The facility is required to clean/launder, repair, replace or dispose of any PPE when necessary without cost to the employee.

All garments including PPE penetrated by blood or OPIM shall be removed immediately or as soon as possible.

PPE is worn only when needed for protection and is removed prior to leaving the work area. When PPE is removed, it is placed in a designated area or container for storage, washing, decontamination or disposal.

5. Gloves

Gloves will be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and other non-intact skin; when performing vascular access procedures, and when handling or touching contaminated items or surfaces.

Disposable gloves will not be washed or decontaminated for re-use and will be replaced when they become contaminated, or if they are damaged in any way that compromises their ability to function as a barrier.

Utility gloves may be decontaminated for re-use unless they show any signs of deterioration or when their ability to function as a barrier has been compromised, in which case they must be discarded.

Gloves will not be worn in public areas but will be removed prior to leaving the work area.

6. Masks, Eye Protection and Face Shields

Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, will be worn whenever splashes, spray, splatter or droplets of blood or OPIM may be generated and eye, nose or mouth contamination can be reasonably anticipated.
The following procedures in this facility would require such protection: ***(List/describe the procedures that require mask, eye protection or face shields.)***
_____
_____

7. Gowns, Aprons and Other Body Protection

Appropriate protection will be worn in situations where gross contamination can be reasonably anticipated.

The following procedures require that protective clothing is worn: ***(List/describe the procedure)***

_____

_____

Housekeeping:

_____ ***(insert name/position)*** is responsible for writing, implementing and maintaining spill cleanup procedures that are site-specific and for training all employees in such procedures.

All receptacles (reusable cans, sharps containers) which may be contaminated will be inspected and decontaminated on a regularly scheduled basis: ***(List frequency and person responsible by name and position.)***

Frequency	*Responsible Person*

The work area will be cleaned and decontaminated according to the following schedule: ***(List areas, schedules, and disinfectants used.)***

Area	*Schedule*	*Procedure and disinfectant*

_____ ***(insert name/position)*** is responsible for ensuring that written guidelines are available for work site clean up and that employees are properly trained in clean up procedures.

All equipment, environmental and working surfaces are cleaned and decontaminated after contact with blood or OPIM as soon as feasible using appropriate disinfectant; wherever there is overt contamination; after any spill of blood or OPIM; and at the end of the work shift.

Any protective coverings used to cover equipment, environmental or working surfaces are removed and replaced as soon as feasible once contaminated.

All bins, receptacles, or cans intended for reuse are lined with red plastic biohazard bags.

Glassware that is broken and may be contaminated is picked up using mechanical means (brush, dust pan, tongs, forceps) and not by hand.

Contaminated sharps are never retrieved by hand from receptacles.

Laundry:

Laundry will be cleaned at _____ ***(Identify facility where soiled laundry is cleaned/laundered.)***

Contaminated laundry will be handled as little as possible and with a minimum of agitation.

Contaminated laundry will be bagged or containerized at the location where it was used; do not sort or rinse it in the location of use.

Contaminated laundry must be place and transported in labeled or color-coded bags or containers.

Supervisors will ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate PPE.

Regulated Waste:

1. Sharps waste

Contaminated sharps will be disposed of as soon as possible into sharps containers which are properly labeled, puncture resistant, leak-proof and closeable to assure containment.

Sharps containers will be easily accessible to personnel and will be located as close as possible to the immediate area where sharps are being used.

Sharps container will be kept upright when used and will not be overfilled and will be replaced routinely.

Sharps container will be closed immediately prior to their removal from the area of use and during handling, storage, transport or shipping.

A secondary container will be used if leakage of the primary container is possible. The secondary container will be properly labeled, closeable, leak-proof and constructed to contain all contents.

2. Other Regulated Waste

Other regulated waste will be placed in containers/bags which the requirements of the California Medical Waste Management Act.

IV. HEPATITIS B VACCINATION AND POSTEXPOSURE EVALUATION AND FOLLOW-UP.

Hepatitis B Vaccination

All employees determined to be at risk will be offered the Hepatitis B vaccine series and tested for antibodies to the hepatitis B antigen (HBsAg) free of charge to the employee after they have received required training and within 10 days of initial job assignment. Employees who do not respond to the primary vaccine series will complete a second vaccine series and re-testing for development antibodies to the hepatitis B surface antigen (HbsAg).

Employees who decline to take the vaccination will be required to sign the Cal/OSHA waiver indicating their refusal. However, employees who initially refuse the vaccine may change their decision and receive the vaccine at any time as long as they are still considered to be at risk.

Exception: Designated first aid providers who have occupational exposure are not required to be offered pre-exposure hepatitis B vaccine if the primary job assignment of the designated first aid provider is not the rendering of first aid.

At UCLA Occupational Health Facility will make available the Hepatitis B vaccine and antibody testing for hepatitis B surface antigen (HBsAg) to all employees who have occupational exposure, and post-exposure follow-up to employees who have had an exposure incident.

_____ ***(insert name of person/position from your area)*** is in charge of the Hepatitis B vaccination program and will ensure that all medical evaluations and procedures including the Hepatitis B vaccination and post-exposure follow-up, including prophlyaxis are:

- made available at not cost to the employees,
- made available to the employee at a reasonable time and place,
- performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional;
- provided according to the recommendation of the US Public Health Service.

HBV VACCINATION DECLINATION FORM

I understand that due to my occupational exposure to blood or other potentially infectious materials, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline to have the hepatitis B vaccination at this time. I understand that by declining to have this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

_____ _____

Date Signature

_____

Print Name

Post-Exposure Evaluation and Follow-up

Any exposure incident will be reported immediately to the supervisor and the employee will report immediately to either Occupational Health Facility or the UCLA Emergency Room. Page them at pager ID number 93333 (On campus dial 231 and enter the ID number when prompted.). Go to Occupational Health Facility (67-120 CHS) between 7:30 a.m. and 12 noon or 1:00 p.m. and 4:00 p.m.; otherwise report to the emergency room (Ronald Reagan UCLA Medical Center).

All exposure incidents on campus will be reported, investigated and documented by UCLA Office of Risk Management, the Office of Environment, Health & Safety and/or the supervisor of the facility. The form titled, "Employee's Referral Slip For Industrial Injury and Report of an Accident" is required to be completed within 24 hour of the incident.

Medical Record Keeping

Records will be maintained by the UCLA Occupational Health Center. Such records would include the employee's name, Social Security number, hepatitis B vaccination status, copy of all results from examinations, testing and follow-up, and the Health-care Professional's (Occupational Health Center's physician) evaluation.

These records are governed by the University of California's policies regarding the Information Practices Act.

V. HAZARD COMMUNICATION

Suitable red or orange/red biohazard signs will be affixed to all containers of possible biohazardous material or contamination including refrigerators, freezers, incubators and containers used to transport samples and regulated waste. Red biohazard bags will be used to dispose of non liquid biohazardous wastes.

VI. TRAINING

Copies of the OSHA Standard and the Exposure Control Plan are kept with the safety manual. Training is given within 12 months of previous training and at the time of initial assignment to task which may result in exposure to potentially infectious materials. Training is given during normal work hours in person by a knowledgable individual. Employees are given the opportunity for interactive questions and answers with the trainer.
Explanations of or information on the following were included in the training:

- an explanation of contents of Exposure Control Plan;
- a general discussion on bloodborne diseases and their transmission;
- an explanation of facility's exposure control plan and its availability;

- a discussion of use and limitations of engineering and work practices controls and personal protective equipment;
- information on types, selection, use, handling and disposal of personal protective equipment
- Hepatitis B vaccine information;
- emergency response procedures involving blood or OPIM;
- information on how to handle exposure incidents;
- an explanation of the post-exposure evaluation and follow-up program;
- an explanation of signs, labels and/or color coding.

Records of the training session will be maintained for 3 years by _____ ***(insert name/position)*** and will include the date of the session, speaker, list of attendees and their job titles. Training records will be maintained in _____***(indicate location)*** .

_____ ***(insert name/position)*** will be held responsible for training the staff.

Date: _____

VII. HIV AND HBV RESEARCH LABORATORIES

All UCLA laboratories engaged in the culture, production, concentration, experimentation , and manipulation of HIV or/and HBV are required to comply with the following special provisions in addition to the other requirements contained in this Plan and guidelines established by the National Institutes for Health and the Centers for Disease Control. These special provisions do not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissue or organs.

Special Practices

Supervisory personnel shall be responsible for preparing, implementing, reviewing and updating written biosafety procedures for their worksite (i.e., biosafety manual). This manual is required reading for all personnel and will be adopted into the Exposure Control Plan.

Personnel are advised of the potential hazards, must read instructions on practices and procedures and must follow them.

All regulated waste is incinerated or decontaminated by a method known to effectively destroy bloodborne pathogens.

Before disposal all waste from work areas and from animal rooms is incinerated or decontaminated.

Laboratory doors are kept closed when work with HIV or HBV is in progress.

Contaminated materials are placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area for decontamination.

Access to the work area is limited.

Written policies and procedures are established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (vaccination, PPE, etc.) and comply with all entry and exit procedures will be allowed to enter the work areas and animal rooms.

When OPIM or infected animals are present in the work place, hazard warning signs are posted on all access doors, and all doors are kept closed while work is in progress.

No work with OPIM is conducted on the open bench. Biological safety cabinets or other physical containment devices are used for manipulations with OPIM.

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing is used in the work areas and animal areas.

PPE is not worn outside the work area and is decontaminated before being laundered.

Skin contact with OPIM is avoided. Gloves are worn when handling infected animals and making hand contact with OPIM materials.

Vacuum lines are protected with liquid disinfectant traps and HEPA filters or similar quality filters. Traps and filters are routinely checked.

Only needle-locking syringes or disposable syringe-needle units(i.e., needle is integral to syringe) is used for infecting or aspirating potentially infectious materials. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles.

Needles are not bent, sheared, replaced in sheath or guard, or removed from syringes after use.

After use needles and syringes are promptly placed in a sharps container.

All spills are contained and cleaned-up immediately by trained personnel.

A spill or accident that results in exposure is reported immediately to the Principal Investigator or other responsible supervisor.

Containment Equipment

Certified biological safety cabinets or other appropriate combinations of personal protection or physical containment devices (e.g., special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for activities with OPIM that pose a threat of exposure to droplets, splashes, spills or aerosols.

Biological safety cabinets are certified when installed, whenever they are moved or undergo major servicing and at least annually.

Facility Requirements

Each laboratory is equipped with handwashing and eye wash facilities which are readily available within the work area.

An autoclave for decontamination of regulated waste is available.

Additional Training Requirements

Principle investigators/laboratory supervisors ensure that prior to working with HBV or HIV, employees:

Demonstrate proficiency in standard microbiological practices and techniques, and in those specific to their work site.

Be experienced in handling human pathogens or tissue culture.

Demonstrate proficiency in techniques in a progression of work activities but without handling pathogens, if there is no prior experience in pathogen handling. Employees are allowed to participate in work activities involving infectious agents only after proficiency has been demonstrated.

_____ ***(insert name/position)*** is responsible for ensuring that laboratory employees use the appropriate containment equipment and adhere to the proper laboratory procedures while carrying out their work tasks.

_____***(insert name/position)*** is responsible for writing and maintaining written biosafety procedures for this facility and ensures that all laboratory personnel who are required to do so have read these procedures.

Training and documentation is the responsibility of _____***(insert name/position)***.

OSHA FACT Sheet

Bloodborne Pathogens

What are bloodborne pathogens?

Bloodborne pathogens are infectious materials in blood that can cause disease in humans, including hepatitis B and C and human immunodeficiency virus, or HIV. Workers exposed to these pathogens risk serious illness or death.

What protections does OSHA's Bloodborne Pathogen standard provide?

The full text of OSHA's Bloodborne Pathogens standard, published in *Title 29 of the Code of Federal Regulations* 1910.1030, details what employers must do to protect workers whose jobs put them at a reasonable risk of coming into contact with blood and other potentially infectious materials. The standard requires employers to do the following:

- Establish an exposure control plan. This is a written plan to eliminate or minimize employee exposures. Employers must update the plan annually to reflect technological changes that will help eliminate or reduce exposure to bloodborne pathogens. In the plan, employers must document annually that they have considered and implemented safer medical devices, if feasible, and that they have solicited input from frontline workers in identifying, evaluating, and selecting engineering controls.
- Use engineering controls. These are devices that isolate or remove the bloodborne pathogen hazard from the workplace. They include sharps disposal containers, self-sheathing needles, and safer medical devices such as sharps with engineered sharps-injury protection and needleless systems.
- Enforce work practice controls. These are practices that reduce the likelihood of exposure by changing the way a task is performed. They include appropriate procedures for hand washing, sharps disposing, lab specimen packaging, laundry handling, and contaminated material cleaning.
- Provide personal protective equipment such as gloves, gowns, and masks. Employers must clean, repair, and replace this equipment as needed.
- Make available Hepatitis B vaccinations to all employees with occupational exposure to bloodborne pathogens within 10 days of assignment.
- Provide post-exposure followup to any worker who experiences an exposure incident, at no cost to the worker. This includes conducting laboratory tests; providing confidential medical evaluation, identifying, and testing the source individual, if feasible; testing the exposed employee's blood, if the worker consents; performing post-exposure prophylaxis; offering counseling; and evaluating reported illnesses. All diagnoses must remain confidential.
- Use labels and signs to communicate hazards. The standard requires warning labels affixed to containers of regulated waste, refrigerators and freezers, and other containers used to store or transplant blood or other potentially infectious materials. Facilities may use red bags or containers instead of labels. Employers also must post signs to identify restricted areas.
- Provide information and training to employees. Employers must ensure that their workers receive regular training that covers the dangers of bloodborne pathogens, preventive practices, and post-exposure procedures. Employers must offer this training on initial assignment, then at least annually. In addition, laboratory and production facility workers must receive specialized initial training.
- Maintain employee medical and training records. The employer also must maintain a Sharps Injury Log unless classified as an exempt industry under OSHA's standard on Recording and Reporting Occupational Injuries and Illnesses.

How can I get more information?

OSHA's website provides more indepth information about bloodborne pathogens on the Bloodborne Pathogens webpage at www.osha.gov/SLTC/bloodbornepathogens and

on the Needlesticks webpages at www.osha.gov/needlesticks and www.osha.gov/SLTC/needlestick.

In addition, OSHA has various publications, standards, technical assistance, and compliance tools to help you, and offers extensive assistance through its many safety and health programs: workplace consultation, voluntary protection programs, grants, strategic partnerships, state plans, training, and education. Documents such as OSHA's ***Safety and Health Management Guidelines*** provide information about elements that are critical to the development of a successful safety and health management system. This and other information are available on OSHA's website.

- For one free copy of OSHA publications, send a self-addressed mailing label to this address: OSHA Publications Office, PO Box 37535, Washington, DC 20013-7535; or send a request to our fax at (202) 693-2498, or call (202) 693-1888.
- Order OSHA publications online at www.osha.gov. Go to **Publications** and follow the instructions for ordering.
- To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call us toll-free at **(800) 321-OSHA (6742)**. The teletypewriter (TTY) number is (877) 889-5627.
- To file a complaint online or obtain more information on OSHA federal and state programs, visit OSHA's website.

U.S. Department of Labor
Occupational Safety and Health Administration
2002

Bloodborne facts

Holding the Line on Contamination

U.S. Department of Labor
Occupational Safety and Health Administration

Keeping work areas in a clean and sanitary condition reduces employees' risk of exposure to bloodborne pathogens. Each year about 8,700 health care workers are infected with hepatitis B virus, and 200 die from contracting hepatitis B through their work. The chance of contracting human immunodeficiency virus (HIV), the bloodborne pathogen which causes AIDS, from occupational exposure is small, yet a good housekeeping program can minimize this risk as well.

DECONTAMINATION

Every employer whose employees are exposed to blood or other potentially infectious materials must develop a written schedule for cleaning each area where exposures occur. The methods of decontaminating different surfaces must be specified, determined by the type of surface to be cleaned, the soil present and the tasks or procedures that occur in that area.

For example, different cleaning and decontamination measures would be used for a surgical operatory and a patient room. Similarly, hard surfaced flooring and carpeting require separate cleaning methods. More extensive efforts will be necessary for gross contamination than for minor spattering. Likewise, such varied tasks as laboratory analyses and normal patient care would require different techniques for clean-up.

Employees must decontaminate working surfaces and equipment with an appropriate disinfectant after completing procedures involving exposure to blood. Many laboratory procedures are performed on a continual basis throughout a shift. Except as discussed below, it is not necessary to clean and decontaminate between procedures. However, if the employee leaves the area for a period of time, for a break or lunch, then contaminated work surfaces must be cleaned.

Employees also must clean (1) when surfaces become obviously contaminated; (2) after any spill of blood or other potentially infectious materials; and (3) at the end of the work shift if contamination might have occurred. Thus, employees need not decontaminate the work area after each patient care procedure, but only after those that actually result in contamination.

If surfaces or equipment are draped with protective coverings such as plastic wrap or aluminum foil, these coverings should be removed or replaced if they become obviously contaminated. Reusable receptacles such as bins, pails and cans that are likely to become contaminated must be inspected and decontaminated on a regular basis. If contamination is visible, workers must clean and decontaminate the item immediately, or as soon as feasible.

Should glassware that may be potentially contaminated break, workers need to use mechanical means such as a brush and dustpan or tongs or forceps to pick up the broken glass--never by hand, even when wearing gloves.

Before any equipment is serviced or shipped for repairing or cleaning, it must be decontaminated to the extent possible. The equipment must be labeled, indicating which portions are still contaminated. This enables employees and those who service the equipment to take appropriate precautions to prevent exposure.

REGULATED WASTE

In addition to effective decontamination of work areas, proper handling c regulated waste is essential to prevent unnecessary exposure to blood anc other potentially infectious materials. Regulated waste must be handled with great care --i.e., liquid or semi liquid blood and other potentially infectious materials, items caked with these materials, items that would release blood or other potentially infected materials if compressed, pathological or microbiological wastes containing them and contaminate sharps.

Containers used to store regulated waste must be closable and suitable tc contain the contents and prevent leakage of fluids. Containers designed for sharps also must be puncture resistant. They must be labeled or colo coded to ensure that employees are aware of the potential hazards. Such containers must be closed before removal to prevent the contents from spilling. If the outside of a container becomes contaminated, it must be placed within a second suitable container.

Regulated waste must be disposed of in accordance with applicable state and local laws.

LAUNDRY

Laundry workers must wear gloves and handle contaminated laundry as little as possible, with a minimum of agitation. Contaminated laundry should be bagged or placed in containers at the location where it is used, but not sorted or rinsed there.

Laundry must be transported within the establishment or to outside laundries in labeled or red color-coded bags. If the facility uses Universa Precautions for handling all soiled laundry, then alternate labeling or color coding that can be recognized by the employees may be used. If laundry is wet and it might soak through **laundry** bags, then workers must use bags that prevent leakage to transport it.

RESEARCH FACILITIES

More stringent decontamination requirements apply to research laboratories and production facilities that work with concentrated strains of HIV and HBV.

This is one of a series of fact sheets that discusses various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3101, 20O Constitution Avenue,N.W., Washington, DC 20210 and

Bloodborne facts

Hepatitis B Vaccination--Protection For You

U.S. Department of Labor
Occupational Safety and Health Administration

WHAT IS HBV?

Hepatitis B virus (HBV) is a potentially life-threatening bloodborne pathogen. Centers for Disease Control estimates there are approximately 280,000 HBV infections each year in the U.S.

Approximately 8,700 health care workers each year contract hepatitis B, and about 200 will die as a result. In addition, some who contract HBV will become carriers, passing the disease on to others. Carriers also face a significantly higher risk for other liver ailments which can be fatal, including cirrhosis of the liver and primary liver cancer.

HBV infection is transmitted through exposure to blood and other infectious body fluids and tissues. Anyone with occupational exposure to blood is at risk of contracting the infection.

Employers must provide engineering controls; workers must use work practices and protective clothing and equipment to prevent exposure to potentially infectious materials. However, the best defense against hepatitis B is vaccination.

WHO NEEDS VACCINATION?

The new OSHA standard covering bloodborne pathogens requires employers to offer the three-injection vaccination series free to all employees who are exposed to blood or other potentially infectious materials as part of their job duties. This includes health care workers, emergency responders, morticians, first-aid personnel, law enforcement officers, correctional facilities staff, launderers, as well as others.

The vaccination must be offered within 10 days of initial assignment to a job where exposure to blood or other potentially infectious materials can be "reasonably anticipated." The requirements for vaccinations of those already on the job take effect July 6, 1992.

WHAT DOES VACCINATION INVOLVE?

The hepatitis B vaccination is a noninfectious, yeast-based vaccine given in three injections in the arm. It is prepared from recombinant yeast cultures, rather than human blood or plasma. T'hus, there is no risk of contamination from other bloodborne pathogens nor is there any chance of developing HBV from the vaccine

The second injection should be given one month after the first, and the third injection six months after the initial dose. More than 90 percent of those vaccinated will develop immunity to the hepatitis B virus. To ensure immunity, it is important for individuals to receive all three injections. At this point it is unclear how long the immunity lasts, so booster shots may be required at some point in the future.

The vaccine causes no harm to those who are already immune or to those who may be HBV carriers. Although employees may opt to have their blood tested for antibodies to determine need for the vaccine, employers may not make such screening a condition of receiving vaccination nor are employers required to provide prescreening.

Each employee should receive counseling from a health care professional when vaccination is offered. This discussion will help an employee determine whether inoculation is necessary.

WHAT IF I DECLINE VACCINATION?

Workers who decide to decline vaccination must complete a declination form. Employers must keep these forms on file so that they know the vaccination status of everyone who is exposed to blood. At any time after a worker initially declines to receive the vaccine, he or she may opt to take it.

WHAT IF I AM EXPOSED BUT HAVE NOT YET BEEN VACCINATED?

If a worker experiences an exposure incident. such as a needlestick or a blood splash in the eye, he or she must receive confidential medical evaluation from a licensed health care professional with appropriate follow-up. To the extent possible by law, the employer is to determine the source individual for HBV as well as human immunodeficiency virus (HIV) infectivity. The worker's blood will also be screened if he or she agrees.

The health care professional is to follow the guidelines of the U.S. Public Health Service in providing treatment. This would include hepatitis B vaccination. The health care professional must give a written opinion on whether or not vaccination is recommended and whether the employee received it. Only this information is reported to the employer. Employee medical records must remain confidential. HIV or HBV status must NOT be reported to the employer.

Bloodborne facts

Personal Protective Equipment Cuts Risk

U.S. Department of Labor
Occupational Safety and Health Administration

Wearing gloves, gowns, masks, and eye protection can significantly reduce health risks for workers exposed to blood and other potentially infectious materials. The new OSHA standard covering bloodborne disease requires employers to provide appropriate personal protective equipment (PPE) and clothing free of charge to employees.

Workers who have direct exposure to blood and other potentially infectious materials on their jobs run the risk of contracting bloodborne infections from hepatitis B virus (HBV), human immunodeficiency virus (HIV) which causes AIDS, and other pathogens. About 8,700 health care workers each year are infected with HBV, and 200 die from the infection. Although the risk of contracting AIDS through occupational exposure is much lower, wearing proper personal protective equipment can greatly reduce potential exposure to all bloodborne infections.

SELECTING PPE

Personal protective clothing and equipment must be suitable. This means the level of protection must fit the expected exposure. For example, gloves would be sufficient for a laboratory technician who is drawing blood, whereas a pathologist conducting an autopsy would need considerably more protective clothing.

PPE may include gloves, gowns, laboratory coats, face shields or masks, eye protection, pocket masks, and other protective gear. The gear must be readily accessible to employees and available in appropriate sizes.

If an employee is expected to have hand contact with blood or other potentially infectious materials or contaminated surfaces, he or she must wear gloves. Single use gloves cannot be washed or decontaminated for reuse. Utility gloves may be decontaminated if they are not compromised. They should be replaced when they show signs of cracking, peeling, tearing, puncturing, or deteriorating. If employees are allergic to standard gloves, the employer must provide hypoallergenic gloves or similar alternatives.

Routine gloving is not required for phlebotomy in voluntary blood donation centers, though it is necessary for all other phlebotomies. In any case, gloves must be available in voluntary blood donation centers for employees who want to use them. Workers in voluntary blood donation centers must use gloves (1) when they have cuts, scratches or other breaks in their skin, (2) while they are in training; and (3) when they believe contamination might occur.

Employees should wear eye and mouth protection such as goggles and masks, glasses with solid side shields, and masks or chin-length face shields when splashes, sprays, splatters, or droplets of potentially infectious materials pose a hazard through the eyes, nose or mouth. More extensive coverings such as gowns, aprons, surgical caps and hoods, and shoe covers or boots are needed when gross contamination is expected. This often occurs, for example, during orthopedic surgery or autopsies.

Employers must provide the PPE and ensure that their workers wear it. This means that if a lab coat is considered PPE, it must be supplied by the employer rather than the employee. The employer also must clean or launder clothing and equipment and repair or replace it as necessary.

Additional protective measures such as using PPE in animal rooms and decontaminating PPE before laundering are essential in facilities that conduct research on HIV or HBV.

EXCEPTION

There is one exception to the requirement for **protective gear.** An employee may choose, temporarily and briefly, **under rare and extraordinary circumstances,** to forego the equipment. It must be the employee's professional judgment that using the protective equipment would prevent the delivery of health care or public safety services or would pose an increased hazard to the safety of the worker or co-worker. When one of these excepted situations occurs, employers are to investigate and document the circumstances to determine if there are ways to avoid it in the future. For example, if a firefighter's resuscitation device is damaged, perhaps another type of device should be used or the device should be carried in a different manner. Exceptions must be limited--this is not a blanket exemption.

DECONTAMINATING AND DISPOSING OF PPE

Employees must remove personal protective clothing and equipment before leaving the work area or when the PPE becomes contaminated. If a garment is penetrated, workers must remove it immediately or as soon as feasible. Used protective clothing and equipment must be placed in designated containers for storage, decontamination, or disposal.

OTHER PROTECTIVE PRACTICES

If an employee's skin or mucous membranes come into contact with blood, he or she is to wash with soap and water and flush eyes with water as soon as feasible. In addition, workers must wash their hands immediately or as soon as feasible after removing protective equipment. If soap and water are not immediately available, employers may provide other handwashing measures such as moist **towelettes.** Employees still must wash with soap and water as soon as possible.

Employees must refrain from eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in areas where they may be exposed to blood or other potentially infectious materials.

This is one of a series of fact sheets that discusses various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3101, 200 Constitution Avenue, N. W, Washington DC 20210 and from OSHA regional offices.

Bloodborne facts

Reporting Exposure Incidents

U.S. Department of Labor
Occupational Safety and Health Administration

OSHA's new bloodborne pathogens standard includes provisions for medical follow-up for workers who have an exposure incident. The most obvious exposure incident is a needlestick. But any specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials is considered an exposure incident and should be reported to the employer.

Exposure incidents can lead to infection from hepatitis B virus (HBV) or human immunodeficiency virus (HIV) which causes AIDS. Although few cases of AIDS are directly traceable to workplace exposure, every year about 8,700 health care workers contract hepatitis B from occupational exposures. Approximately 200 will die from this bloodborne infection. Some will become carriers, passing the infection on to others.

WHY REPORT?

Reporting an exposure incident right away permits immediate medical follow-up. Early action is crucial. Immediate intervention can forestall the development of hepatitis B or enable the affected worker to track potential HIV infection. Prompt reporting also can help the worker avoid spreading bloodborne infection to others. Further, it enables the employer to evaluate the circumstances surrounding the exposure incident to try to find ways to prevent such a situation from occurring again.

Reporting is also important because part of the follow-up includes testing the blood of the source individual to determine HBV and HIV infectivity if this is unknown and if permission for testing can be obtained. The exposed employee must be informed of the results of these tests.

Employers must tell the employee what to do if an exposure incident occurs.

MEDICAL EVALUATION AND FOLLOW-UP

Employers must provide free medical evaluation and treatment to employees who experience an exposure incident. They are to refer exposed employees to a licensed health care provider who will counsel the individual about what happened and how to prevent fiuther spread of any potential infection. He or she will prescribe appropriate treatment in line with current U.S. Public Health Service recommendations. The licensed health care provider also will evaluate any reported illness to determine if the symptoms may be related to HIV or HBV development.

The first step is to test the blood of the exposed employee. Any employee who wants to participate in the medical evaluation program must agree to have blood drawn. However, the employee has the option to give the blood sample but refuse permission for HIV testing at that time. The employer must maintain the employee's blood sample for 90 days in case the employee changes his or her mind about testing--should symptoms develop that might relate to HIV or HBV infection.

The health care provider will counsel the employee based on the test results. If the source individual was HBV positive or in a high risk category, the exposed employee may be given hepatitis B immune globulin and vaccination, as necessary. If there is no information on the source individual or the test is negative, and the employee has not been vaccinated or does not have immunity based on his or her test, he or she may receive the vaccine. Further, the health care provider will discuss any other findings from the tests.

The standard requires that the employer make the hepatitis B vaccine available, at no cost to the employee, to all employees who have occupational exposure to blood and other potentially infectious materials. This requirement is in addition to post exposure testing and treatment responsibilities.

WRITTEN OPINION

In addition to counseling the employee, the health care provider will provide a written report to the employer. This report simply identifies whether hepatitis B vaccination was recommended for the exposed employee and whether or not the employee received vaccination. The health care provider also must note that the employee has been informed of the results of the evaluation and told of any medical conditions resulting from exposure to blood which require further evaluation or treatment. Any added findings must be kept confidential.

CONFIDENTIALITY

Medical records must remain confidential. They are not available to the employer. The employee must give specific written consent for anyone to see the records. Records must be maintained for the duration of employment plus 30 years in accordance with OSHA's standard on access to employee exposure and medical records.

Bloodborne facts

Protect Yourself When Handling Sharps

U.S. Department of Labor
Occupational Safety and Health Administration

A needlestick or a cut from a contaminated scapel can lead to infection from hepatitis B virus (HBV) or human immunodeficiency virus (HIV) which causes AIDS. Although few cases of AIDS have been documented from occupational exposure, approximately 8,700 health care workers each year contract hepatitis B. About 200 will die as a result. The new OSHA standard covering bloodborne pathogens specifies measures to reduce these risks of infection.

PROMPT DISPOSAL

The best way to prevent cuts and sticks is to minimize contact with sharps. That means disposing of them immediately after use. Puncture-resistant containers must be available nearby to hold contaminated sharps--either for disposal or, for reusable sharps, later decontamination for re-use. When reprocessing contaminated reusable sharps, employees must not reach by hand into the holding container. Contaminated sharps must never be sheared or broken.

Recapping, bending, or removing needles is permissible only if there is no feasible alternative or if required for a specific medical procedure such as blood gas analysis. If recapping, bending, or removal is necessary, workers must use either a mechanical device or a one-handed technique. If recapping is essential--for example, between multiple injections for the same patient--employees must avoid using both hands to recap. Employees might recap with a one-handed "scoop" technique, using the needle itself to pick up the cap, pushing cap and sharp together against a hard surface to ensure a tight fit. Or they might hold the cap with tongs or forceps to place it on the needle.

SHARPS CONTAINERS

Containers for used sharps must be puncture resistant. The sides and the bottom must be leakproof. They must be labeled or color coded red to ensure that everyone knows the contents are hazardous. Containers for disposable sharps must have a lid, and they must be maintained upright to keep liquids and the sharps inside.

Employees must never reach by hand into containers of contaminated sharps. Containers for reusable sharps could be equipped with wire basket liners for easy removal during reprocessing, or employees could use tongs or forceps to withdraw the contents. Reusable sharps disposal containers may not be opened, emptied, or cleaned manually.

Containers need to be located as near to as feasible the area of use. In some cases, they may be placed on carts to prevent access to mentally disturbed or pediatric patients. Containers also should be available wherever sharps may be found, such as in laundries. The containers must be replaced routinely and not be overfilled, which can increase the risk of needlesticks or cuts.

HANDLING CONTAINERS

When employees are ready to discard containers' they should first close the lids. If there is a chance of leakage from the primary container, the employees should use a secondary container that is closable, labeled, or color coded and leak resistant.

Careful handling of sharps can prevent injury and reduce the risk of infection. By following these work practices, employees can decrease their chances of contracting bloodborne illness.

This a one of a series of fact sheets that discusses various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. *Single copies of fact sheets are available from OSHA Publications, Room N-3101, 200 Constitution Avenue, N.W., Washington DC 20210 and from OSHA regional offices.*

Biosafety Considerations for Research with Lentiviral Vectors

Recombinant DNA Advisory Committee (RAC) Guidance Document

Background: The use of lentiviral vectors has been increasing because the vector system has attractive features; however, such research also raises biosafety issues. The NIH Office of Biotechnology Activities has received frequent questions regarding the appropriate containment for lentiviral vectors, particularly those derived from HIV-1. Because the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) do not explicitly address containment for research with lentiviral vectors, the RAC was asked to provide additional guidance for institutional biosafety committees (IBCs) and investigators on how to conduct a risk assessment for lentiviral vector research. At the March RAC 2006 meeting (webcast), the RAC offered the following findings and recommendations.

Risks of lentivirus vectors: The major risks to be considered for research with HIV-1 based lentivirus vectors are

- potential for generation of replication-competent lentivirus (RCL), and
- potential for oncogenesis.

These risks can be mitigated by the nature of the vector system (and its safety features) or exacerbated by the nature of the transgene insert encoded by the vector.

General criteria for risk assessment of lentivirus vectors: Decisions about containment should take into account a range of parameters/considerations including:

- the nature of the vector system and the potential for regeneration of replication competent virus from the vector components,
- the nature of the transgene insert (e.g., known oncogenes or genes with high oncogenic potential may merit special care)
- the vector titer and the total amount of vector,
- the inherent biological containment of the animal host, if relevant,
- negative RCL testing (*see section below*)

General containment considerations: Either BL2 containment or enhanced BL2 containment is often appropriate in the laboratory setting for research involving the use of advanced lentivirus vector systems that have multiple safety features and that segregate vector and packaging functions onto four or more plasmids. Enhanced BL2 containment may include in addition to attention to sharps (and use of safety needles where feasible), the use of personal protective equipment intended to reduce the potential for mucosal exposure to the vector. In most such research, these levels of containment are also expected to be appropriate even when producing large volumes of HIV-1 vectors (>10 L).

The appropriate containment level for specific lentivirus vector research is, of course, determined following a complete risk assessment and local IBC review. The following sections discuss some considerations which should form an important part of the biosafety assessment for research involving lentivirus vectors.

Potential for generation of replication competent lentivirus (RCL) from HIV-1 based lentivirus vectors: The potential for generation of RCL from HIV-1 based lentivirus vectors depends upon several parameters, the most important of which are

- the number of recombination events necessary to reassemble a replication competent virus genome and
- the number of essential genes that have been deleted from the vector/packaging system.

On this basis, later generation lentivirus vector systems are likely to provide for a greater margin of personal and public safety than earlier vectors, because

- they use a heterologous coat protein (e.g., VSV-G) in place of the native HIV-1 envelope protein (However, the use of the certain coat proteins, such as VSV-G, may broaden the host cell and tissue tropism of lentivirus vectors, which should also be considered in the overall safety assessment by the IBC),
- they separate vector and packaging functions onto four or more plasmids and
- they include additional safety features (e.g., they do not encode Tat, which is essential for replication of wild-type HIV-1).

In contrast, earlier vector systems (such as two-plasmid vector systems) may have a higher potential for generation of RCL.

RCL testing: The National Gene Vector Laboratory (NGVL) has produced over 60 liters of HIV-1 vector and has screened supernatant and cells from different vector systems, using different assays, without detecting RCL (K. Cornetta, personal communication of unpublished data). This suggests that the frequency of RCL generation using lentivirus vectors is very low. It may not, however, be zero. There is a need for continued investigation of RCL generation using lentivirus vectors, in order to inform and advance the field of lentivirus vector technology.

The FDA requires that lentiviral vector stocks used in human clinical trials be tested for RCL. Individual research laboratories conducting preclinical research often use only small volumes (e.g., a few milliliters) of lentivirus vectors expressing lower risk transgenes such as GFP. While these laboratories are not mandated to characterize vector stocks, such testing should be encouraged. However, RCL testing requires expertise with the appropriate assays and such expertise may not be available in laboratories that do not work regularly with infectious lentiviruses. In such laboratories, the use of a positive control may increase risk to the investigator as compared to use of the test material. IBCs may make containment assignments without requiring such testing by undertaking a risk assessment that considers the nature of the specific vector system being used and overall past experience with the system.

Animal studies: Some animals, such as wild-type mice, cannot support replication of infectious HIV-1. As a result, the potential for shedding of RCL from such animals is very low (even if RCL were present in the original vector inoculum). IBCs may consider the biosafety issues associated with animal husbandry and housing *after* the initial injection separately from the initial inoculation itself. In general, the initial delivery of vector should be performed under Biosafety Level 2 for Animals (BL2-N) or under enhanced BL2-N containment (see "*General containment considerations*"), so as to minimize the risk of autoinoculation by the investigator. However, it may be permissible to reduce the containment level at some point following vector delivery. For example, if there is no expectation of infection (see below), the site of inoculation has been thoroughly cleansed, and the bedding changed, it may be acceptable to consider reducing containment from BL2-N to BL1-N within a few days (the specific time period can be specified by the local IBC, and may vary anywhere from 1-7 days depending on local and experimental considerations). Animals engrafted with human cells or animal hosts that are permissive for HIV-1 replication constitute a special case, in light of their potential to support replication of infectious HIV-1. Use of lentivirus vectors in these animals requires a higher level of containment.

Other lentivirus vectors: Some non-human lentivirus vectors (e.g., FIV, SIV, EIAV, etc.) are also in use. Of these, the most frequently encountered are feline immunodeficiency virus (FIV) vectors. In the Appendix B-V of the *NIH Guidelines*, a containment level appropriate for Risk Group 1 agents is recommended for use of certain animal viral etiologic agents not associated with disease in healthy human adults. However, replication-defective vectors in which a heterologous envelope (such as VSV-G) is used for vector packaging may require BL2 containment in the laboratory setting, since

these vectors have the potential to transduce human cells, and thus have the potential to cause insertional mutagenesis. Under circumstances in which mice are not permissive hosts for FIV replication, BLN-1 containment may be acceptable for mouse housing and husbandry when dealing with mice that have received FIV vectors (subject to the considerations noted above).

Summary: A comprehensive risk assessment and determination of containment for research with lentiviral vectors should consider the nature of the vector system, transgene insert, and type of manipulations involved. For many experiments, either BL-2 or enhanced BL-2 will be appropriate. Examples of biosafety considerations and risk assessments for three different scenarios are included below.

Examples of Biosafety Considerations

Vector Considerations

- Potential for generation of RCL
    - Vector and packaging functions separated onto multiple plasmids
    - Deletion of viral genes
- Viral Env used in packaging system
    - Non-native Env (decrease potential for generation of RCL)
    - Coat protein that increases species or cell type tropism of parent virus (e.g., VSV-G)
- Safety modifications (e.g., no expression of Tat)

Transgene Considerations

- Oncogene
- Non-oncogene

Vector Generation Considerations

- Laboratory scale
- Large scale

Animal Research Considerations

- Permissive host
- Non-permissive host
- Animal engrafted with permissive cells
- Vector Administration (e.g., injection)
- Housing and husbandry

Practices, Containment Equipment and Training Considerations

- Training in use of PPE
- Availability of safety equipment (e.g., sealed centrifuge rotor cups)
- Laboratory-specific safety and spill cleanup protocols
- Availability of on-site occupational health support in the event of accident

Biosafety Considerations and Risk Levels

Biosafety Considerations	**Higher Risk**	**Lower Risk**
		
Vector Design	• Vector packaging functions on two plasmids • Expression of viral genes	• Vector and packaging functions separated onto multiple plasmids • Deletion of viral genes
Transgene	• Oncogene	• Non-oncogene
Vector Generation	• Large scale	• Laboratory scale
Animal Hosts	• Permissive host • Animals engrafted with human cells	• Non-permissive host
Animal Manipulation	• Vector administration (e.g., use of sharps during injection	• Housing and husbandry (no use of sharps)

EXAMPLE SCENARIOS

EXAMPLE ONE: *In vitro* study A:
Use of a 4-plasmid derived lentivirus vector encoding siRNA against Lck in primary human T cells.

Considerations
1. *What is the amount of vector to be produced?* A = LOW (100 ml)
2. *What is the nature of the vector?* A = 4-Plasmid System
3. *What is the nature of the insert?* A = Non-Oncogenic

Tentative Safety Assessment = BL2
(Note that the use of primary human cells would require BSL2 containment, independent of the vector, as well as use of Universal Precautions and compliance with the OHSA standard for Bloodborn Pathogens)

EXAMPLE TWO: *In vitro* study B:
Use of a 2-plasmid derived lentivirus vector encoding luciferase in a human cell line (A549 cells).

Considerations
1. *What is the amount of vector to be produced?* A = LOW (100 ml)
2. *What is the nature of the vector?* A = 2-Plasmid System (non-commercial)
3. *What is the nature of the insert?* A = Non-Oncogenic

Tentative Safety Assessment = BL2 enhanced

BSL2 "enhanced" stipulations might include:
- Avoidance of needles and sharps, where possible
- Use of a containment hood for all work with the vector (including the loading and unloading of centrifuge rotors, which should have an aerosol-tight seal)
- Use of personal protective equipment [PPE] designed to prevent a mucosal exposure/splash to the face and exposure of hands (especially in persons with broken skin or open cuts)
- A requirement for an in-person consultation between biosafety staff and lab personnel prior to initiation of experiments

EXAMPLE THREE: *In vivo* study A
Use of a 4-plasmid derived lentivirus vector encoding brain-derived neurotrophic factor (BDNF) in mouse brain

Considerations
1. *What is the amount of vector to be produced?* A = LOW (100 ml)
2. *What is the nature of the vector?* A = 4-Plasmid System
3. *What is the nature of the insert?* A = Non-Oncogenic (*: see below)
4. *What is the nature of the animal host?* A = Non-permissive for HIV-1

Tentative Safety Assessment = BL2-N for lab work and initial injection of mice (which would probably be done using a stereotactic frame); after 1-7 days, animals could be moved to BL1-N containment.

Added explanation:

- Even though BDNF is a growth factor for neurons, it has no known oncogenic activity for skin or blood cells that might be the target of a potential needle stick. Hence, this insert would not automatically trigger a requirement for increased biocontainment.
- Stereotactic injection frames cannot easily be placed into a laminar flow hood, and may use a syringe or pulled glass pipette for inoculation; they may also use a pump to ensure a slow rate of delivery of the agent. BL-2 containment does NOT require the use of a biosafety cabinet, and is therefore compatible with the use of a stereotactic frame, even if that frame is not contained within a laminar flow cabinet.

Additional points to consider:

- An in-person consultation between biosafety staff and lab personnel prior to initiation of experiments may be a useful stipulation
- One might also impose additional biosafety enhancements during the injection process, perhaps by requiring use of additional PPE above and beyond the stipulated requirements associated with BL2/BL2-N. See Example 2 for examples of such stipulations.

APPENDIX

Sections from the *NIH Guidelines*

General Considerations

Section II-A. Risk Assessment
Section II-A-3. Comprehensive Risk Assessment. BL2 containment is recommended for activities involving all blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV – or HBV-infected or inoculated laboratory animals. Activities such as the production of research-laboratory scale quantities of HIV or other bloodborne pathogens, manipulating concentrated virus preparations, or conducting procedures that may produce droplets or aerosols, are performed in a BL2 facility using the additional practices and containment equipment recommended for BL3. Activities involving industrial scale volumes or preparations of concentrated HIV are conducted in a BL3 facility, or BL3 Large Scale if appropriate, using BL3 practices and containment equipment. Appendix

Section III-D. Experiments That Require Institutional Biosafety Committee Approval Before Initiation
Section III-D-3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems. Recombinant DNA or RNA molecules derived therefrom, which contain less than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V-J, *Footnotes and References of Sections I-IV*) being considered identical (see Section V-K, *Footnotes and References of Sections I-IV*), are considered defective and may be used in the absence of helper under the conditions specified in Section III-E-1, *Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus*.

Section III-E. Experiments That Require Institutional Biosafety Committee Notice Simultaneous with Initiation
Section III-E-1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus. Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical [see Section V-J, *Footnotes and References of Sections I-IV]*) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-D-3, *Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems*, should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Animal Studies

Section III-D-4-a. Recombinant DNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment

comparable to BL1 or BL1-N and appropriate to the organism under study (see Section V-B, *Footnotes and References of Sections I-IV*). Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b, *Experiments Involving Whole Animals*. For experiments involving recombinant DNA-modified Risk Groups 2, 3, 4, or restricted organisms, see Sections V-A, V-G, and V-L, *Footnotes and References of Sections I-IV*. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G, *Footnotes and References of Sections I-IV*).

APPENDIX B. CLASSIFICATION OF HUMAN ETIOLOGIC AGENTS ON THE BASIS OF HAZARD

Appendix B-III-D. Risk Group 3 (RG3) - Viruses and Prions

Retroviruses
--Human immunodeficiency virus (HIV) types 1 and 2

BL2 Facilities

Appendix G-II-B-3. Containment Equipment (BL2)
Appendix G-II-B-3-a. Biological safety cabinets (Class I or II) (see Appendix G-III-L, *Footnotes and References of Appendix G*) or other appropriate personal protective or physical containment devices are used whenever:

Appendix G-II-B-3-a-(1). Procedures with a high potential for creating aerosols are conducted (see Appendix G-III-O, *Footnotes and References of Appendix G*). These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.
Appendix G-II-B-3-a-(2). High concentrations or large volumes of organisms containing recombinant DNA molecules are used. Such materials may be centrifuged in the open laboratory if sealed beads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

Appendix G-II-B-4. Laboratory Facilities (BL2)
Appendix G-II-B-4-a. The laboratory is designed so that it can be easily cleaned.
Appendix G-II-B-4-b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
Appendix G-II-B-4-c. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.
Appendix G-II-B-4-d. Each laboratory contains a sink for hand washing.
Appendix G-II-B-4-e. If the laboratory has windows that open, they are fitted with fly screens.
Appendix G-II-B-4-f. An autoclave for decontaminating laboratory wastes is available.

UCLA *LABWORKER* HIV/BBP Exposure Info 2008

INSTRUCTIONS TO BE FOLLOWED BY THE LAB WORKER (LW) – **following an exposure to blood or other body fluid.**	
INITIAL RESPONSE	**1. Wounds and skin sites that have been in contact with blood or body fluids should be washed immediately with soap and water; mucous membranes should be flushed thoroughly with water. There is no evidence that the use of antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk for bloodborne virus transmission.** **2. IMPORTANT: Every effort must be made to evaluate high-risk exposures and administer post-exposure prophylaxis within 1 hour of the exposure incident.**
IMMEDIATE REPORTING AND MEDICAL EVALUATION	**3. Immediately report the incident to the supervisor.** **4. Supervisor: Signs the Industrial Injury Referral form and either pages OHF (Occupational Health Facility) on pager 93333 or has the LW report directly to OHF (CHS 67-120) during clinic hours (7:30am - 4:30pm Monday-Friday). If the exposure incident occurs after hours or on weekends or holidays, the LW should go directly to the EMC (Emergency Medical Center).**
DOCUMENTATION AND FOLLOW-UP	**5. LWs: Must bring the Industrial Injury Referral form and applicable information such as blood or body fluid source, if known, with them to OHF (or EMC after hours, weekends, and holidays). If specific HIV strain is known, provide this information to OHF or EMC.** **6. LWs: When the initial post-exposure management is performed in the EMC, must complete a follow-up evaluation on the next weekday to review blood tests and provide continuity of care. Call (56771) or page (93333) to arrange an appointment with OHF. If possible, to facilitate appropriate follow-up, the LW should bring applicable source information to his/her appointment at OHF.** **7. BRING THIS INFO WITH YOU TO OHF OR EMC.**

MANAGEMENT OF EXPOSURE EVENT TO HIV/BBP

The following information has been adopted from the UCLA Medical Center's Infection Control Policy:
(http://www.mednet.ucla.edu/policies/pdf/ww/IC-006.pdf)

1. To determine the need for post-exposure prophylaxis, the exposure incident will be evaluated for potential to transmit bloodborne pathogens based on the type of body substance involved and the route and severity of exposure. The exposure evaluation includes review of hepatitis B vaccine status, Hepatitis C Virus (HCV) serological testing, and prophylaxis as indicated.
2. The source will be evaluated for possible risk factors for bloodborne pathogens, including determining the HBsAg status, HCV antibody status, and HIV 1 and 2 antibody status. As required by Medical Center policy, written informed consent must be obtained from the source or the source's legal representative before HIV testing of the source can be performed.
3. Exposed LWs should receive baseline antibody testing for hepatitis C virus (HCV), hepatitis B virus, and HIV (with consent) as indicated. EMC after-hours care does not usually perform baseline testing for the emergency management it provides. LWs shall return to OHF on the next weekday, at which time baselines can be done, along with additional counseling and testing. Removed statement about "In-house confidential coding of LW HIV tests is only offered through OHF". Follow-up care when the source is high risk for HIV infection or HIV positive includes:
    a. The LW is counseled regarding the risk of infection and precautions to observe to prevent possible secondary transmission.
    b. Clinical and serologic evaluation of the LW is provided.
    c. The LW is advised to report any symptoms, such as fever, lymphadenopathy, rash, profound fatigue, or persistent headache, that develop within 12 weeks of the exposure.
    d. LWs found to be HIV seronegative at baseline should be re-tested at 6 weeks, 12 weeks, and 6 months post exposure.
    e. Additional counseling and medical management for the LW will be arranged by OHF personnel as indicated.
4. If the exposed LABWORKER (LW) has not received hepatitis B vaccine, they should receive it. If the source is HBsAg positive and the LW is unvaccinated, the LW should receive hepatitis B immune globulin (HBIG) with their first hepatitis B vaccine dose. If the LW has been vaccinated but has been tested for anti-HBsAb previously: 1.) Testing for anti-HBsAb should be performed, and 2.) A decision regarding administration of one dose of hepatitis B vaccine plus HBIG should be made based on the availability of the source for rapid testing and the ability of the LW to return to OHF in a timely fashion for HBV vaccination, if indicated.
5. If the source is HIV antibody positive or at risk for HIV infection, prophylaxis to decrease the risk of HIV transmission is recommended for both less severe and more severe exposures. Post exposure prophylaxis (PEP) should be started as soon as possible following the exposure.
6. Based upon recommendations in the 2005 "Updated U.S. Public Health Service Guideline for the Management of Occupational Exposure to HIV and Recommendations for Postexposure Prophylaxis" [MMWR 2005; 54 (No.RR-9)1-17], either a **basic 2-drug** or **expanded 3-drug regimen** will be prescribed based upon exposure risk assessment and expert consultation (see Tables 1 and 2 on the reverse side).
7. Basic 2-drug regimen:

    Truvada one tablet daily [= tenofavir DF (Viread) 300 mg once daily + emtricitabine (Emtriva) 200 mg once daily.

    Combivir one tablet twice daily [= zidovudine (Retrovir) 300 mg twice daily + lamivudine (Epivir) 150 mg twice daily), if the LW is pregnant.
8. Expanded 3-drug regimen:
    Basic 2-drug regimen + **Kaletra two capsules twice daily** (= lopinavir/ritonavir 200mg/50mg)**.**
9. PEP should be administered for 4 weeks, if tolerated.

10. If the source HIV antibody status in unknown, a decision regarding HIV prophylaxis should be made on a case-by-case basis, based on the severity of the injury, the likelihood of HIV infection in the source (or possible sources), and discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
11. PEP can be discontinued if the source is determined to be HIV antibody negative, which is often known within <2 hours if the rapid HIV test is used.
12. Follow-up care and counseling for other bloodborne exposures will be managed by OHF. Persons exposed to HCV positive sources shall have hepatic function and antibody testing at least at baseline and 6 months post-exposure.

SEE REVERSE SIDE FOR RECOMMENDED HIV POSTEXPOSURE PROPHYLAXIS (PEP)

UCLA *LABWORKER* HIV Management Exposure Info 2008

TABLE 1. Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries.

	Infection status of source			
Exposure type	**HIV-positive, class 1***	**HIV-positive, class 2***	**HIV source testing pending**	**Source of unknown HIV status† or unknown source§**
Less severe¶	Recommend basic 2-drug PEP	Recommend expanded >3-drug PEP	Recommend basic 2-drug PEP pending HIV result††	Consider basic 2-drug PEP** for source with HIV risk factors or setting in which exposure to HIV-infected persons is likely††
More severe§§	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Recommend expanded 3-drug PEP pending HIV result††	Consider basic 2-drug PEP** for source with HIV risk factors or setting in which exposure to HIV-infected persons is likely††

*HIV-positive — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL).
*HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation.
† For example, deceased source person with no samples available for HIV testing.
§ For example, a needle from a sharps disposal container.
¶ For example, solid needle or superficial injury.
** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.
§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein, or exposure to known positive culture supernatant.

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and nonintact skin* exposures

	Infection status of source			
Exposure type	**HIV-positive, class 1†**	**HIV-positive, class 2†**	**HIV source testing pending**	**Source of unknown HIV status§ or unknown source ¶**
Small volume**	Consider basic 2-drug PEP††	Recommend basic 2-drug PEP	Consider basic 2-drug PEP†† pending HIV result§§	Generally, no PEP warranted§§
Large volume¶¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Recommend basic 2-drug PEP pending HIV result§§	Consider basic 2-drug PEP†† for source with HIV risk factors§§

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).
† HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation.
§ For example, deceased source person with no samples available for HIV testing.
¶ For example, splash from inappropriately disposed blood.
** For example, a few drops.
†† The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
§§ If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.
¶¶ For example, a major blood splash.

CONTACT INFORMATION AND/OR TO REQUEST COPIES
UCLA Office of Environment, Health & Safety, Biosafety Division
501 Westwood Plaza, 4th Floor, MC 160508
310-206-3929 or 310-825-5689 or email: biosafety@ehs.ucla.edu
(EH&S Biosafety Division, Rev 04/08)

LAB EMERGENCY

DIAL 911 (DO NOT DIAL 8-911)

Medical Emergency Dial **52111** or **911**	Dial **911** or contact UCLA Emergency Medicine directly at **52111**, located in **Reagan/UCLA Medical Center 1st Floor**. For **bloodborne pathogens** exposure page the needle stick nurse. Dial **231** and enter the pager ID number **93333**. Enter your extension. This service is available between 8:00 a.m. and 4:00 p.m. M-F. At all other times report to UCLA Emergency Medicine. **Occupational Health Facility** is located in **CHS room 67-120** and can be reached at **56771**. Occupational Health is open Monday to Friday 7:30am to 4:00pm.
Fire Dial **911**	**SMALL FIRE** – If you have been trained, you may smother the fire using a fire extinguisher. **LARGE FIRE** – Evacuate people from the area. Close all doors and windows. Close the fume hood sash if the fire is in the fume hood. Activate the nearest alarm. Call **911** from the nearest phone. Evacuate the area using the stairwells. Do not use the elevator. **CLOTHES ON FIRE** – Use nearest safety shower. If none available, STOP-DROP-ROLL to quickly smother the fire. Seek medical attention.
Chemical Spill Dial **55689** (8 a.m.-5 p.m.) or Dial **911**	**SPILL** – Help contaminated or injured persons. Evacuate the spill area. Avoid breathing vapors. Eliminate sources of ignition if the chemical is flammable. Confine the spill to small area. Post someone or mark-off the area using tape and warning signs to keep other people from entering contaminated area. **SMALL**– If you have had training, you may work with another person in a clean-up effort. Use appropriate personal protective equipment and clean-up material for chemical spilled. Double bag spill residue in clear plastic bags, label, and take to the next chemical waste pick-up. **LARGE** - Between 8:00 a.m. and 5:00 p.m. M-F, call **55689** for assistance. Otherwise, dial **911**. **CHEMICAL SPILL ON BODY OR CLOTHES** – Remove clothing and rinse body thoroughly in emergency shower for at least 15 minutes. Seek medical attention. **CHEMICAL SPLASH INTO EYES** – Immediately rinse eyeball and inner surface of eyelid with water for 15 minutes by forcibly holding the eye open. Seek medical attention.
Biohazardous Spill Dial **55689** (8 a.m.-5 p.m.) or Dial **911**	**BL 1 SPILL** – Wear disposable gloves. Clean-up spill with disinfectant (1:10 dilution of bleach) soaked paper towels. Sweep broken glass into a dustpan using disinfectant-soaked paper towels. Do not pick up broken glass with hands. Dispose of paper towels and other clean-up materials inside a plastic bag. **BL 2 and 3 SPILLS** – Notify room occupants of spill. Hold your breath and immediately leave the room. Post someone or mark-off the area using tape and warning signs to keep other people from entering the room. Everyone should wash their hands and face or shower using a disinfecting soap. Do not reenter the room for at least 30 minutes. Wear protective equipment to clean up spill. Cover the spill with paper towels or other absorbent materials. Without splashing, pour a freshly made 1:10 dilution of bleach around the edges of the spill and then into the spill. Allow 20 minutes of contact time and then clean up the spill with paper towels soaked in disinfectant. Shower or wash with disinfecting soap. Call **55689** for assistance between 8:00 a.m. and 5:00 p.m., M-F. Otherwise, call **911**. **BIOHAZARDOUS SPILL ON BODY OR CLOTHES** – Remove contaminated clothing and place in a plastic bag or sealable pail. Wash exposed area with disinfecting soap for at least one minute.
Radioactive Spill Dial **55689 or 55396** (8 a.m.-5 p.m.) or Dial **911**	**SMALL** – Cover spill with absorbent material. Notify others in the area of the spill. Continue clean-up of the area with absorbent materials. Use disposable gloves and change frequently. Place all contaminated materials in a radioactive waste bag. Monitor spill area and all personnel participating in decontamination efforts with appropriate survey instrument. Record incident in the laboratory survey log and call Radiation Safety, **55396** or **55396**. **LARGE** – Contain spill with absorbent material and shield spill if necessary. Evacuate all personnel from immediate area and prevent entry of others. Personnel that are potentially contaminated should be surveyed with appropriate survey instruments. Call **55396** or **55689** for assistance between 8:00 a.m. and 5:00 p.m., M-F. Otherwise, call **911**. **EXTERNAL CONTAMINATION** – Immediately remove contaminated clothing. Rinse area, especially between fingers and around fingernails with water first, then wash with mild detergent. Call Radiation Safety at **55396** or **55689** for assistance between 8:00 a.m. and 5:00 p.m., M-F. Otherwise, call **911**.
Earthquake	Take cover in the laboratory underneath a table or desk, or move to the hallway and brace yourself against the wall, covering your head with your arms. After the shaking has stopped: 1) Remain in the building if the quake was minor; 2) Evacuate the building if the quake was severe. Do not use the elevators; use the stairwells. After evacuation, report to your designated meeting place (refer to your Laboratory Safety Manual, Appendix A-2).

For more information call EH&S at **55689**.