Biorisk Workshop

JORDAN UNIVERSITY OF SCIENCE AND TECHNOLOGY

APRIL 10 – 11, 2011

www.biosecurity.sandia.gov

SAND No. 2010-2121P, 2009-1580P, 2008-0480P
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Biorisk Workshop Overview

- **Day 1: Introduction to Risk Assessment**
- **Day 1: Introduction to Hierarchy of Controls**
  - Engineering Controls

- **Day 2: Hierarchy of Controls**
  - Procedural Controls
  - Administrative Controls
  - Personnel Protective Equipment

Course Structure

- **This course will be made up of discussion and activities**
- **You will be working in groups or pairs**
- **Ask questions and participate!**

Learning Objectives

- **Define biosafety, biosecurity, and biorisk**
- **Define risk and conduct a simple bio-risk assessment**
- **Identify necessary risk mitigation measures based upon the risk assessment**
- **Define a basic structure for standard operating procedures (SOPs)**
- **Define engineering controls, procedural and administrative controls, and personnel protective equipment**
  - What risks these mitigate, when to use them, and how

- **Take two minutes and write down a short definition for:**
  - Laboratory Biosafety
  - Laboratory Biosecurity

- **Now, define:**
  - Biorisk

- **Laboratory Biosafety**
  - A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent

- **Laboratory Biosecurity**
  - A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm

- **Biorisk**
  - The combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological toxin or agent
  - The source may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.

Biorisk Assessment

Why Risk Assessment?

- **Laboratory Biosafety**

  A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent

- **Laboratory Biosecurity**

  A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm

- **Identification of preventive measures is determined by the RISK ASSESSMENT**

What is the risk of being attacked by a tiger?

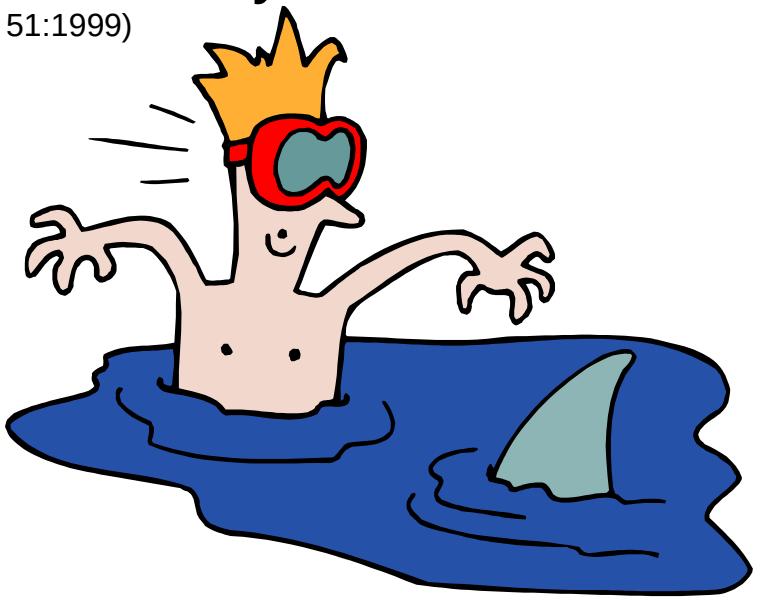
Work in your group to identify factors that would help you determine this risk.

Risk

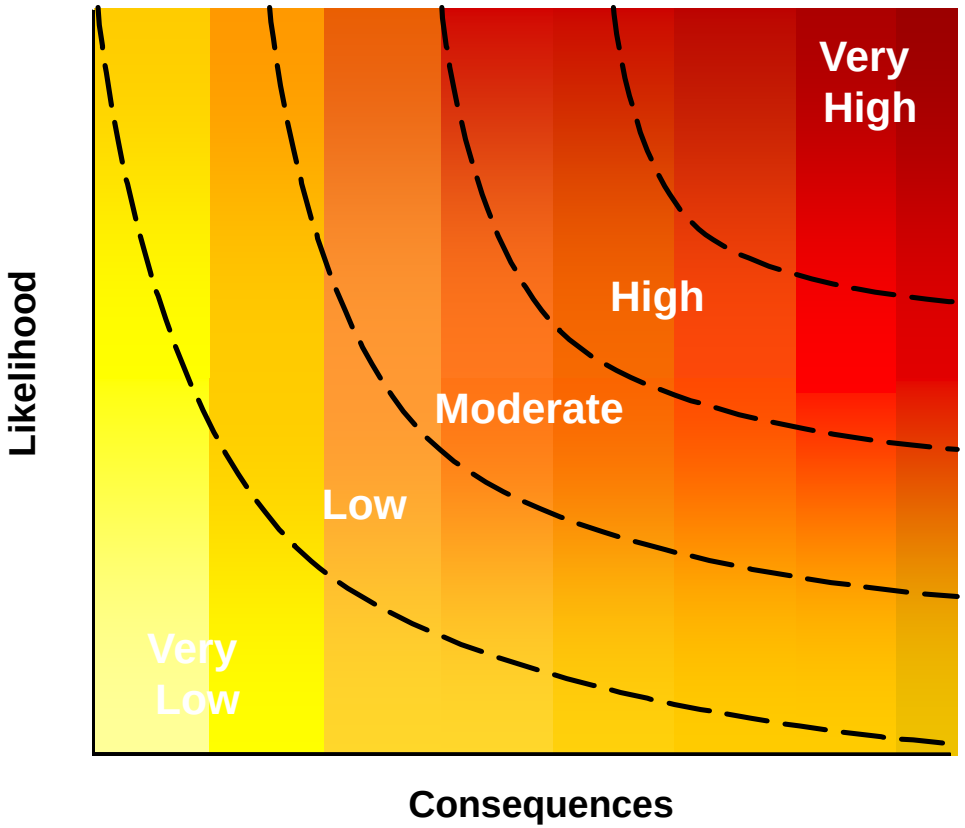
- Risk is the **likelihood** of an undesirable event, involving a specific hazard, that has **consequences**

- **Risk** is a combination of the probability of occurrence of harm and the severity of that harm

(ISO/IEC Guide 51:1999)

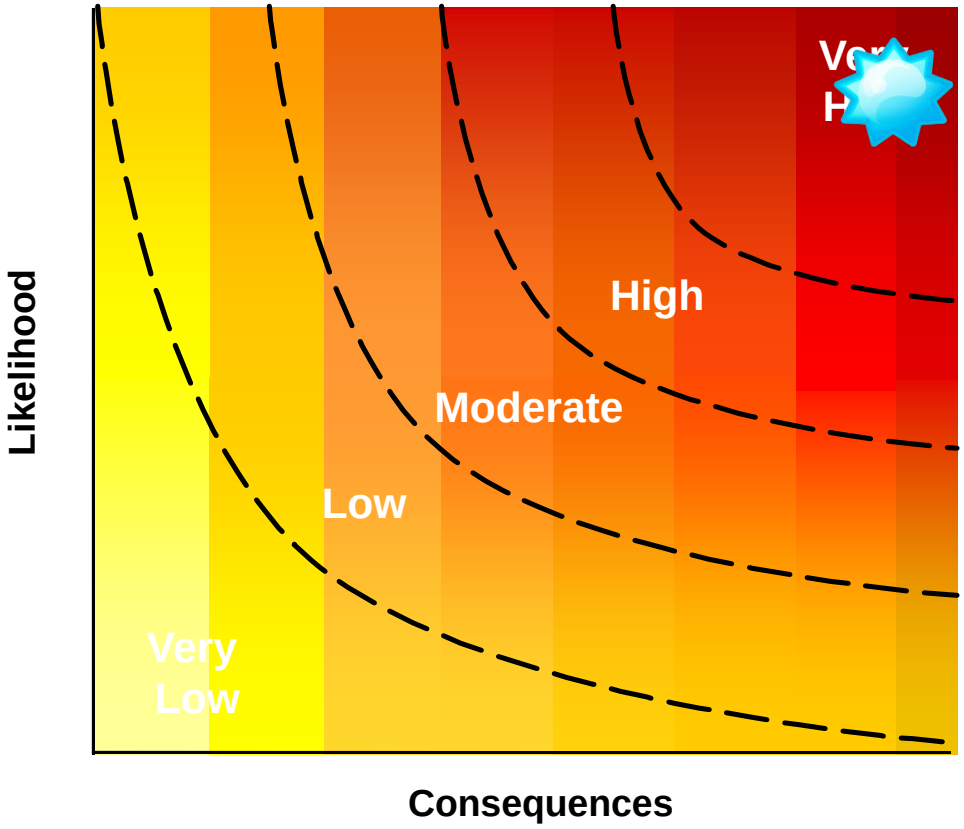


Risk is a function of likelihood and consequences R = f(L,C)



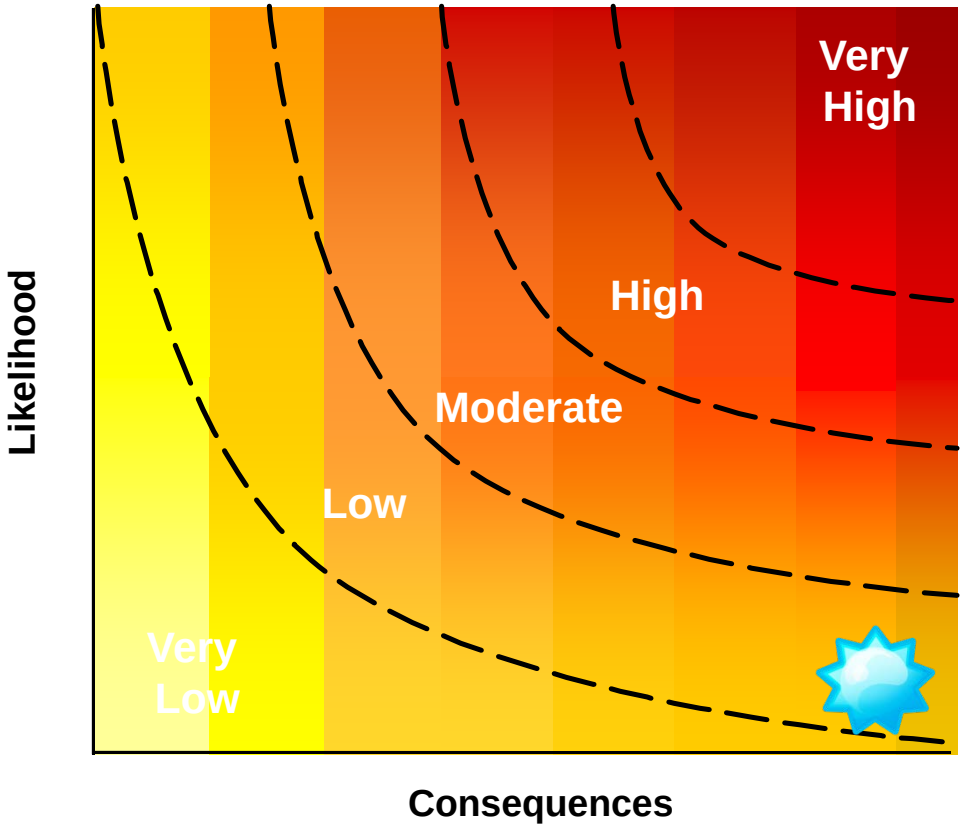
Risk = f(L,C)

You are in an open field next to a very hungry, aggressive, adult tiger that is unrestrained and sees you as a food source.



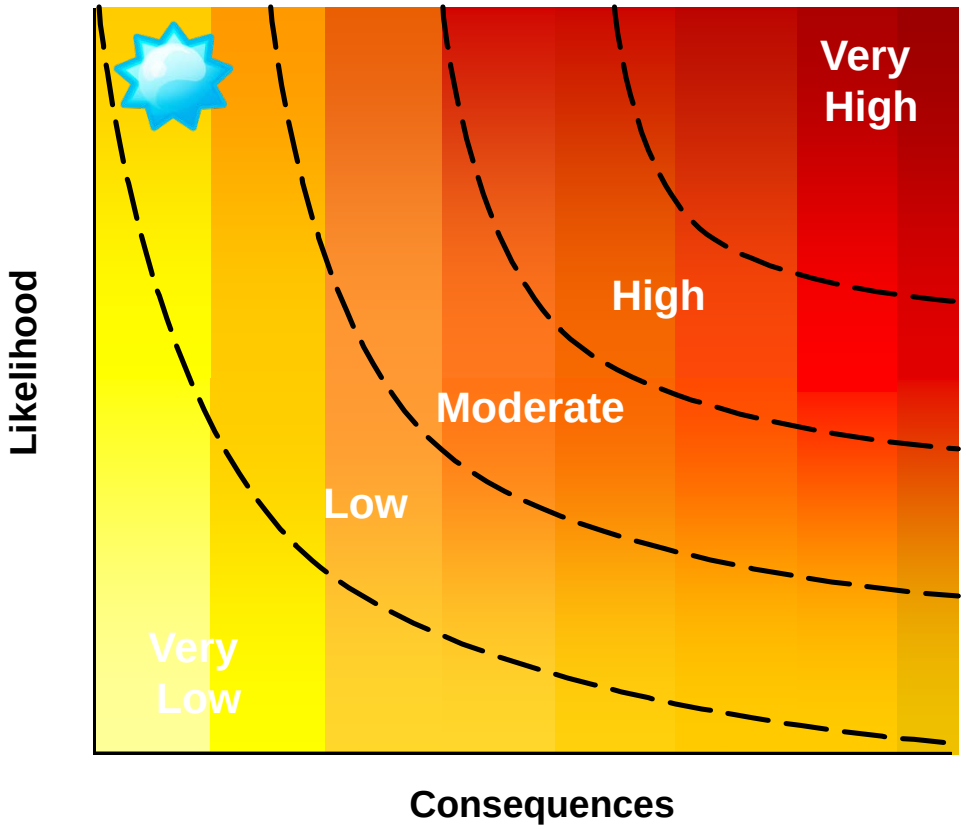
Risk = f(L,C)

You are at the zoo, looking at an adult tiger which is well fed, has a mild temperament and is restrained in a secure tiger enclosure.



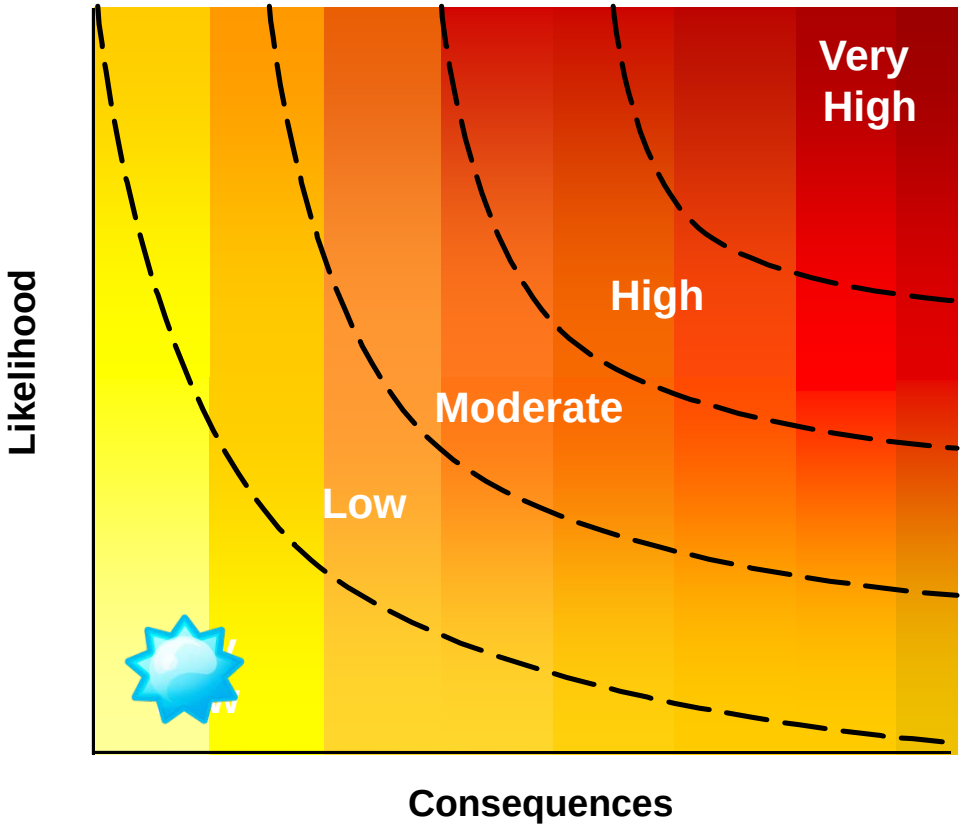
Risk = f(L,C)

You are holding a baby tiger with a playful temperament



Risk = f(L,C)

You are at the zoo looking at a toothless older adult tiger which has been declawed, raised in a zoo, and well fed. It has a mild temperament and is restrained in a secure tiger enclosure.



Risk Assessment Principles

Define the problem

- Think about how the factors would change if you were assessing the risk of someone stealing a tiger?

The risk assessment method should be as simple as possible

- Elaborate when needed

Those conducting risk assessments should be explicit about uncertainties

Risk assessment methods can incorporate one or more approaches

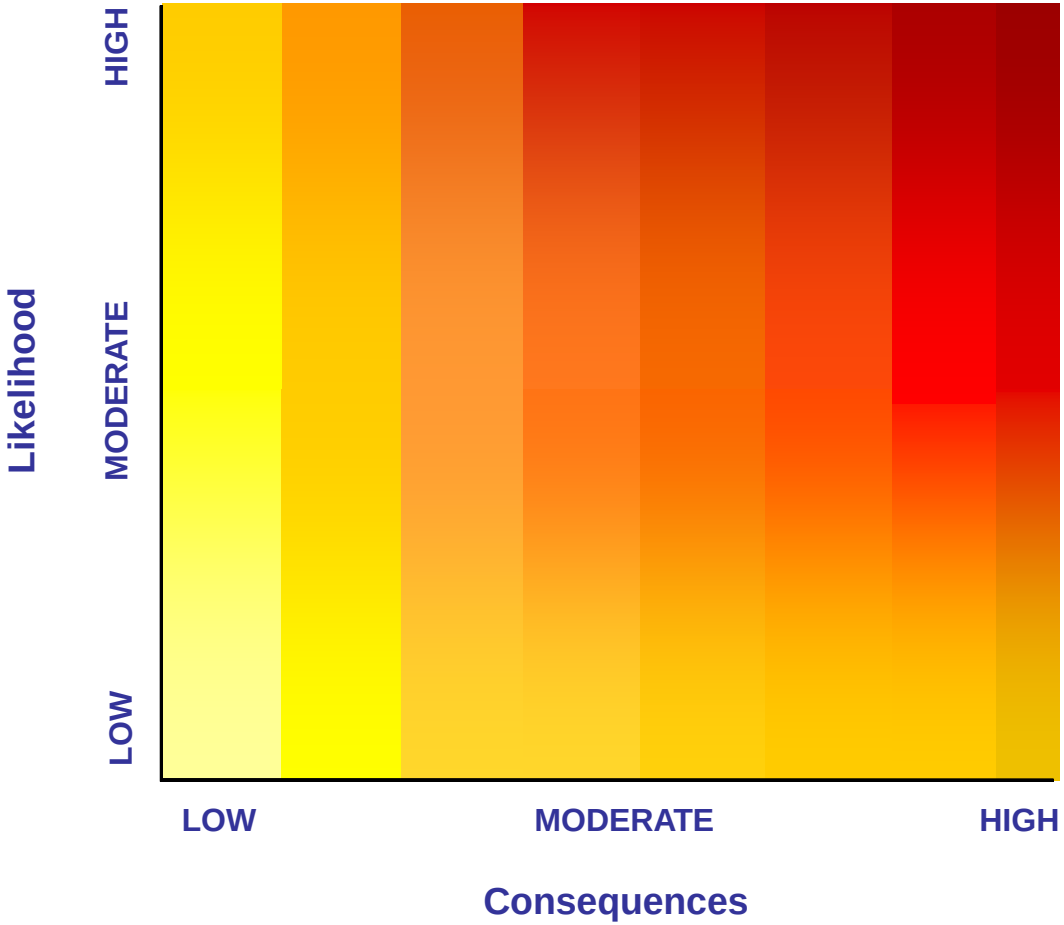
Laboratory Biorisk Assessment

Activity:

Diagnostic testing via culture for a possible case of anthrax

- **As a group, let's define the risks:**
  - What is/are the risk(s) we need to assess?
    - **Write down the risk(s) you are going to assess**
  - What are the key factors needed to conduct a risk assessment?

Risk Characterization



Laboratory Biosafety Risk Assessment Methodology (Biosafety RAM)

Risk = f (Likelihood, Consequence)

- **Likelihood**

  The likelihood of infection by the agent and the likelihood of exposure through an infectious route based on the procedures and work practices

- **Consequences**

  Of disease from accidental exposure

- **Risks**

  To laboratory workers
  - **Researchers**
  - **Animal care workers**
  - **Technicians**
  - **Engineers**

  Risk of accidental exposure to community

  Risk of accidental exposure to animal community

  Risks of secondary exposure to human and animal community

Biosecurity RAM

Risk = f (Likelihood, Consequence)

Likelihood

- The likelihood of theft from a facility and the likelihood an agent can be used as a weapon

Consequences

- Of a bioattack with the agent

Risks

- Persons in area of attack
- Persons in larger community from secondary exposure
- Animals in area of attack
- Animal in larger community from secondary exposure

Biorisk Mitigation

Group Exercise

Thinking about the questions from the risk assessment, take 5 minutes in your groups to discuss and identify eight different biorisk mitigation measures.

- **Four for safety**
- **Four for security**

Use post-it notes for each mitigation measure you identify.

Report on your answers to the class.

Working Definitions for Mitigation Control Measures

Engineering Controls	• *Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards*
Administrative Controls	• *Policies, standards and guidelines used to control risks*
Practices and Procedures	• *Processes and activities that have been shown in practice to be effective in reducing risks*
Personal Protective Equipment	• *Devices worn by the worker to protect against hazards in the laboratory*

Group Exercise

Engineering Controls

Administrative Controls

Practices and Procedures

Personal Protective Equipment

Place your post-it notes in the appropriate rows

Use the working definitions

Group Exercise

Engineering Controls

Administrative Controls

Practices and Procedures

Personal Protective Equipment

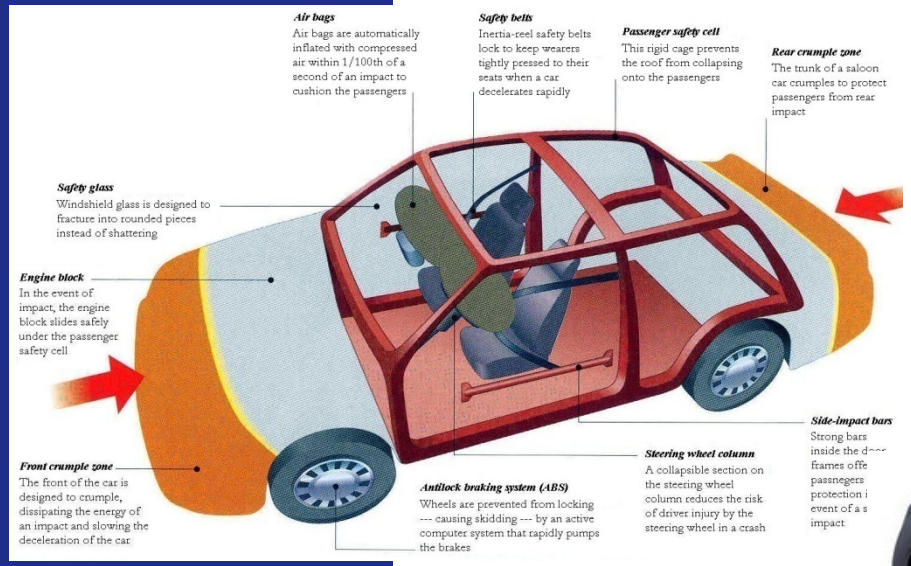
Considering these mitigation control measures take 5 minutes:

- **In your group discuss the advantages and disadvantages of each measure,**
- **Record your findings on post-it notes**
- **Populate the flipchart with your notes**

	Advantages	Disadvantages
Engineering Controls		
Administrative Controls		
Practices and Procedures		
Personal Protective Equipment		

	Advantages	Disadvantages
Engineering Controls	Efficient, eliminates hazard	Cost, complexity
Administrative Controls	Authority approach	Indirect approach, primarily addresses the human factor
Practices and Procedures	SOP based (standardized approach)	Training and supervision requirements
Personal Protective Equipment	Ease of use, relative cost	Does not eliminate hazard, PPE fails exposure happens, uncomfortable, limits ability

Car Safety vs Motorcycle Safety



- Car safety is all about engineering systems
- Motorcycle safety is all about PPE

Hierarchy of Controls (HOC)

- ***Elimination or Substitution***
- **Engineering Controls**
- **Administrative Control**
- **Practices and Procedures**
- **Personal Protective Equipment**

Control methods at the top of the list are in general more effective and protective than those at the bottom.

Standard Operating Procedures

- **Standard Operating Procedures (SOPs)**
  - Written instructions that document a routine or repetitive activity
  - Detail of processes necessary to perform a job safely and properly
  - Describe both technical and administrative practices and operations
  - Specific to an organization or laboratory

Sections

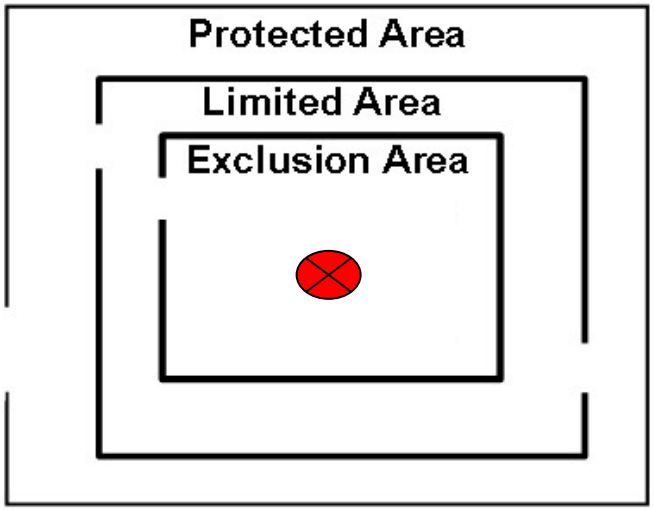
- **Title Page**
- **Table of Contents**
- **Required Controls**
  - Limited Access
  - Containment
- **Required Training**
  - PPE
  - Equipment
- **Body**
  - Brief description of the procedure
  - Risks
  - Definitions
  - Procedures
- **Emergency Response Measures**
- **References**
  - Other relevant SOPs
  - Relevant Guidelines and Regulations
- **Contact Information**
  - PI
  - RO
  - Biosafety Office

Title Page

- **Information that may be included on the title page includes:**
  - Title of Procedure
  - Date of Document Preparation
  - Person Preparing the Document

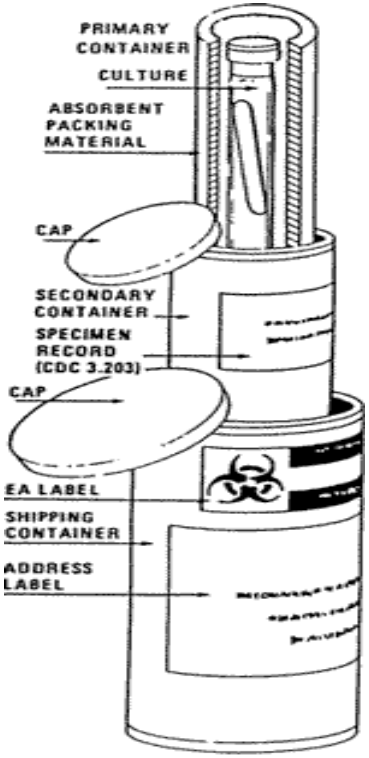
Required Controls

- **Protection Areas**
  - Grounds
  - Public Access
- **Limited Areas**
  - Laboratories
  - Hallways surrounding Exclusion Areas
- **Exclusion Areas**
  - High Containment Areas



Required Training

- **Personal Protective Equipment**
  - Selection of Proper Equipment
  - Don Procedures
  - Doff Procedures
- **Proper Use of Equipment**
  - Biosafety Cabinets
  - Autoclaves
  - Centrifuges
- **Specimen Receipt and Processing**
- **Required Documentation**
  - Autoclave log
  - Training
- **Transport of Infectious Substances**
- **Emergency Response**

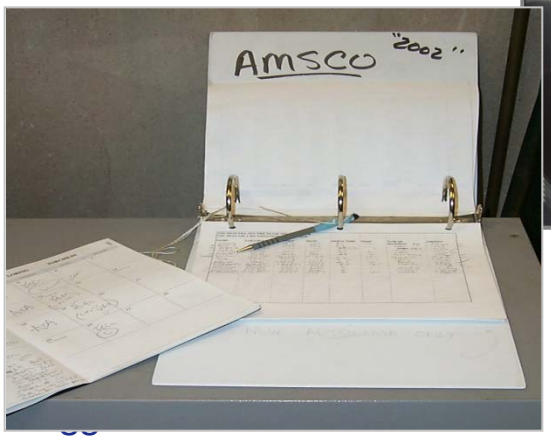


Body of the SOP

- **Format**
  - Easy to read and concise
  - Sufficient detail to enable persons with basic knowledge to successfully reproduce procedure without supervision
- **Title and brief description of the procedure or experiment**
- **Special health and safety precautions**
- **Associated Risks**
  - Burns (Autoclaves; UV lights)
  - Rotor failure
- **Definitions**
- **Experience Requirements**
  - Formal training
  - Supervision
  - Documentation and evaluation of training
- **Procedures**
  - Step-by-step description of the procedure
  - Steps written in the order they occur

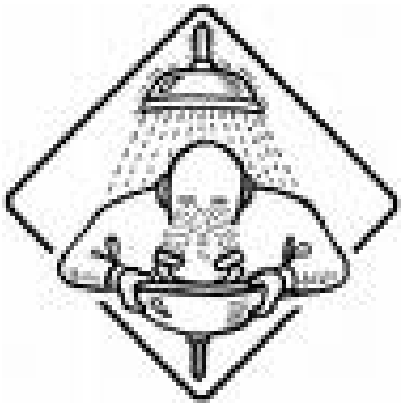
Other Information

- **Specific work areas for specific procedures**
- **Proper decontamination procedures**
- **Emergency decontamination procedures**
- **Proper waste disposal methods**
  - Incineration
  - Autoclaving
- **Required documentation**
  - Laboratory Location
  - Dates of service visits



Emergency Response

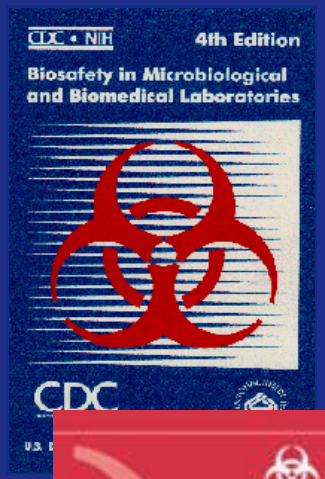
- **Exposure Response**
- **Spill Clean-up**
  - Inside Biosafety Cabinet
  - Outside Biosafety Cabinet
  - Large spills
  - Small spills

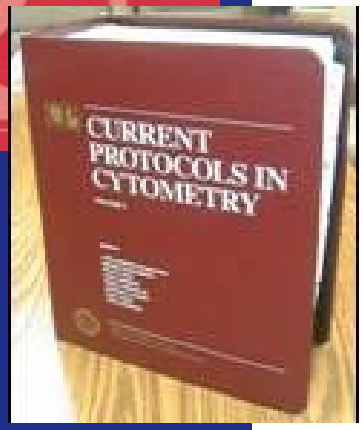


Contact Information

- **Name and Phone Number of Relevant Laboratory Personnel**
  - Principle Investigator
  - Lab Manager
  - Biosafety Officer
  - Security
  - Back-up Personnel
- **Other**
  - Police
  - Fire
  - Emergency Medical Services
  - Hospital Emergency Room
  - Poison Control

References





- **Regulations**
  - Select Agent Rule
- **Guidelines**
  - Biosafety in Microbiological and Biomedical Laboratories
- **Laboratory Manuals**
  - IACUC Guidance
- **Books**
  - *Molecular Cloning*
  - *Current Protocols in Molecular Biology*

Engineering Controls

- *Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards*

Administrative Controls

Practices and Procedures

Personal Protective Equipment

Some Examples of Engineering Controls

Engineering Controls

- **Primary Containment**
  - BSC
  - Sealable Containers including rotor cups
  - Cages
- **Secondary Containment**
  - Facility layout and construction
  - Airflow
  - Doors (with locks and access controls)
  - Sealable rooms
- **Waste**
  - Autoclave/Incinerator
  - Sharps Container

Activity

Engineering Controls

Engineering Controls

Administrative Controls

- *Policies, standards and guidelines used to control risks*

Practices and Procedures

- *Processes and activities that have been shown in practice to be effective in reducing risks*

Personal Protective Equipment

Some Examples of Administrative/Procedural Controls

Administrative Controls

Practices and Procedures

- **Personnel Management**
  - Training
  - Integrity verification
  - Medical clearance
- **Good Lab Practices**
  - No eating or drinking /No mouth pipetting
  - Hand washing
  - Spill cleaning / standard cleaning
  - Sharps handling
  - Aerosol prevention
  - Inventory
  - Documentation
  - Waste handling
  - Entry and Exit procedures

Definitions

Administrative Controls

Practices and Procedures

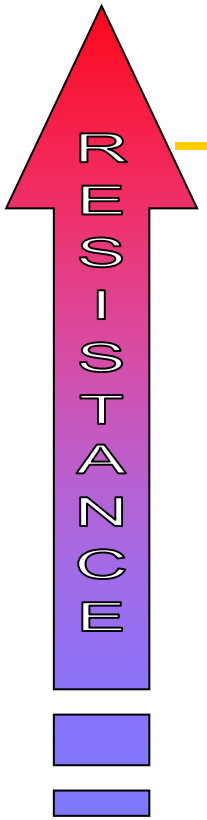
- *Sterilization* **- act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms**
- *Disinfectant* **- an agent, usually chemical, that inactivates viruses or kills vegetative microbes but not necessarily resistant forms such as spores**
- *Antiseptic* **- a substance that prevents or arrests the growth or action of microbes, either by inhibiting their activity or by destroying them (living tissue use)**
- *Decontamination* **- disinfection or sterilization of contaminated articles to make them suitable for use**
- *Sanitizer* **- an agent that reduces the numbers of vegetative bacteria only**

Class Activity: Choosing Disinfectants

- **The disinfectant needs to be appropriate for the biological agent of interest**

Administrative Controls

Practices and Procedures



Prions
Bacterial spores
Coccidia (*Cryptosporidium*)
Mycobacterium
Nonlipid viruses
(*e.g.* hep A, polio)
Fungi
Rickettsiae, chlamydiae
Vegetative bacteria
Lipid-containing viruses
(*e.g.* HIV)

The Basics: Hand washing

Administrative Controls

Practices and Procedures

- **In 1847, Dr. Ignaz Semmelweis, a physician in a Vienna hospital, insisted that students and physicians clean their hands with chlorine prior to patient contact, especially after leaving the autopsy floor.**

- **Childbirth fatalities dropped dramatically due to the new practice.**

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Surface Decontamination

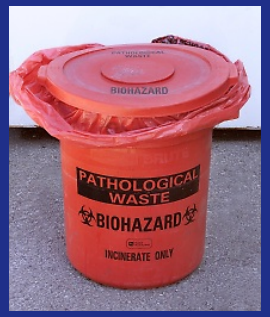
Administrative Controls

Practices and Procedures

- **Typically wipe or spray surface with liquid disinfectant**
- **Factors to consider include**
  - Surface topography (wooden surfaces, cracks, etc)
  - Organic load
  - Concentration
  - Contact time
  - Shelf life

- **Remember, these are hazardous chemicals**
  - Training
  - PPE
  - Ventilation
  - Regulatory issues
  - Hazardous waste disposal

Waste Handling and Decontamination



- **Laboratory wastes that may need decontamination include**
  - Solid, non-sharp waste, such as
    - **<u>Plastic</u> labware (flasks, tubes, plates, bottles, vials)**
    - **Tissue or carcass waste (pathological)**
  - Liquids, such as
    - **Aspirates, culture fluids, rinses, washes, etc.**
    - **Sera, body fluids**
  - Sharps, such as
    - **Anything with a point or edge capable of piercing or cutting human skin**
    - **Glass labware (sometimes also broken plastic)**

Waste Handling and Decontamination

Administrative Controls

Practices and Procedures

- **Autoclaves may be used to sterilize instruments, other media, and biohazard waste**
- **Facility needs:**
  - Waste designation process
  - Waste collection, packaging, and transport procedures
  - Treatment capabilities (intermediate and/or final)
  - Disposal options (backups)
  - Training

Personnel Reliability

Administrative Controls

Practices and Procedures

- **The objectives of a personnel reliability program are to**
  - Help to judge a person's integrity
    - **E.g. reduce the risk of theft or fraud**
    - **E.g. reduce the risk of scientific misconduct**
  - To support the procedural and administrative access control requirements
  - To support the biosafety program

Material Control & Accountability Examples

- **Moderate risk biological agents**

  Seed stocks cataloged and records stored securely

  - **Transfers in and out**
  - **Source**
  - **Strain**
  - **Form**
  - **Responsible individual**

  Working stocks, including infected animal status, tracked through laboratory notebooks

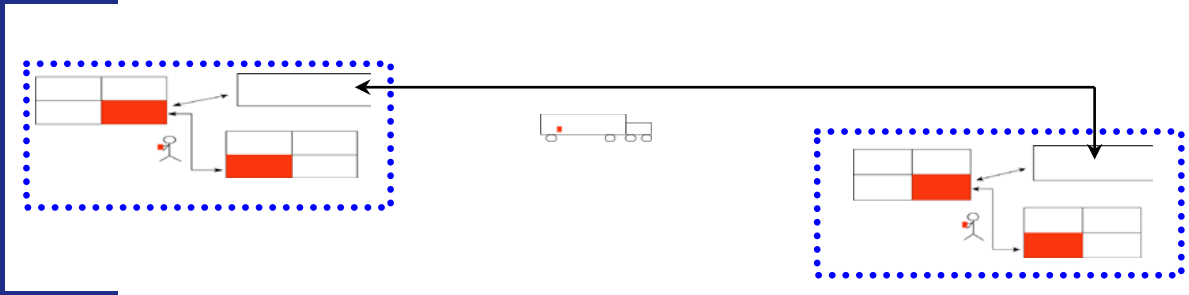
- **High risk biological agents**

  Moderate plus

  - **Increased control over working stocks**

Infectious Substance Transport

- **Transport – movement of biological material outside of a restricted area**
- **Transport can occur**
  - Across international borders
  - Within a country
  - Within a facility
- **Protection while in transport should be comparable that in the restricted area**
  - May require a documented chain of control



Engineering Controls

Administrative Controls

Practices and Procedures

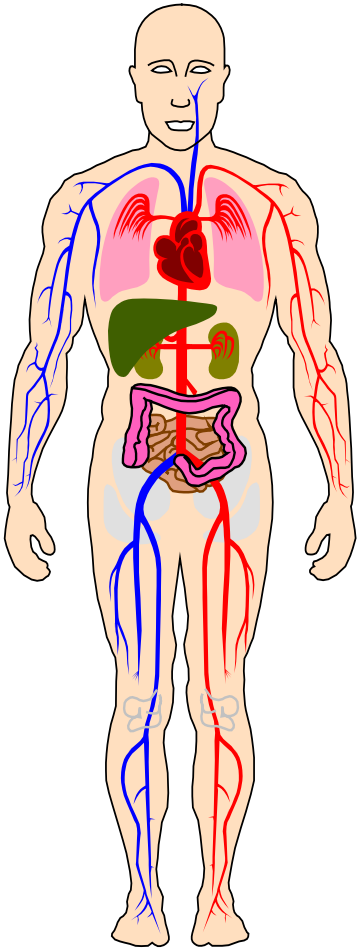
Personal Protective Equipment

- *Devices worn by the worker to protect against hazards in the laboratory*

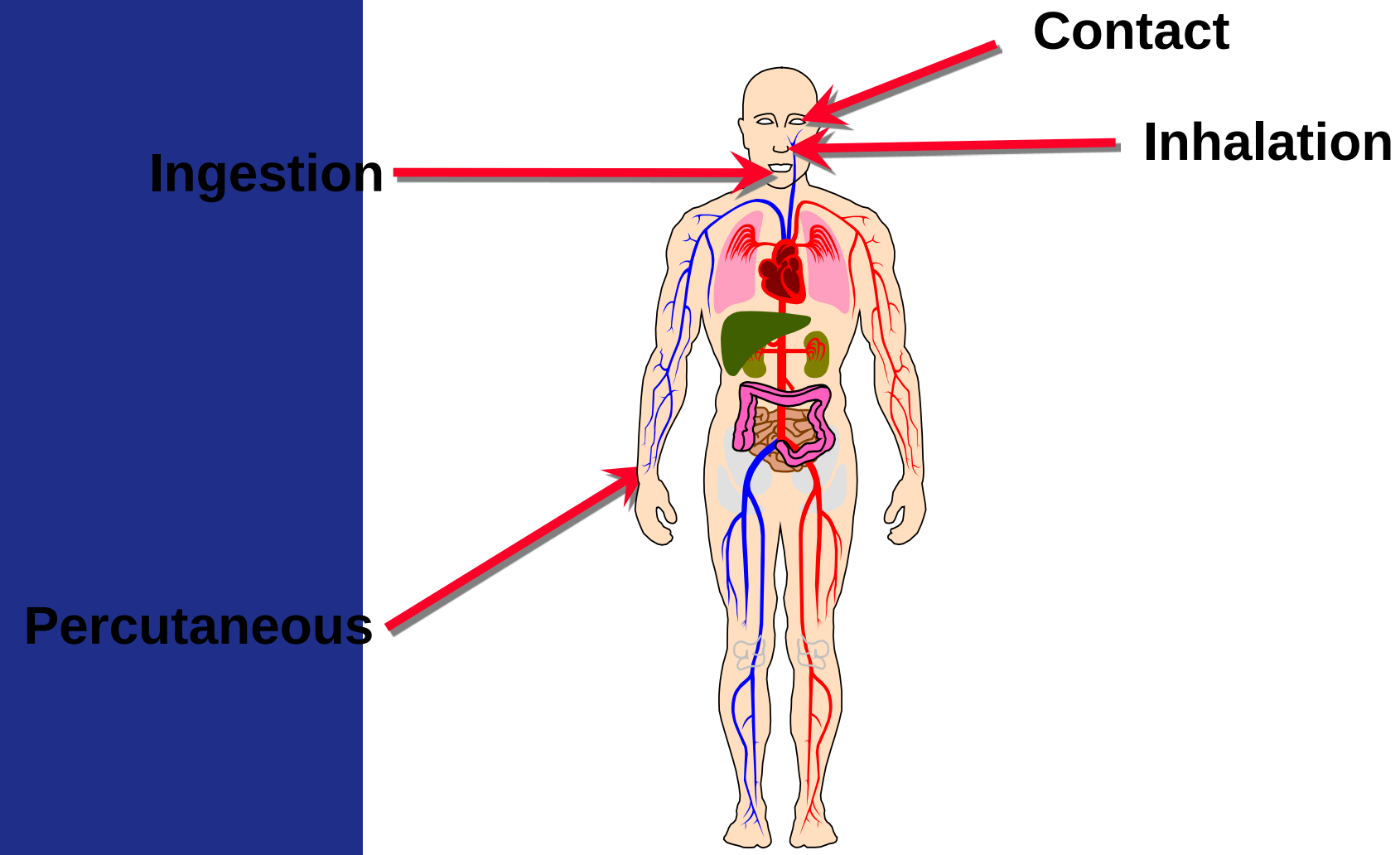
Examples of Personal Protective Equipment (PPE)

- Respiratory Protection and Fit
- Gloves
- Body cover
- Feet cover
- Eyewear
- Face cover

Routes of Exposure



Routes of Exposure



Activity

- **Examine the collection of PPE**
- **What route of exposure do they protect?**

Does Order Matter?

- **What are some key considerations in putting on (or donning) your PPE?**
- **What are some key considerations in removing (or doffing) your PPE?**
- **What are some key considerations for reusing PPE?**

ACTIVITY

- **Donning and Doffing gloves**

- **Review the Voluntary Use of Respirator Form, sign and return**

REVIEW

- **Identify and list the topics covered over the last two days:**

- **Select one topic and outline the body of an SOP for this topic**

- **E.g. *SOP on risk assessment:***

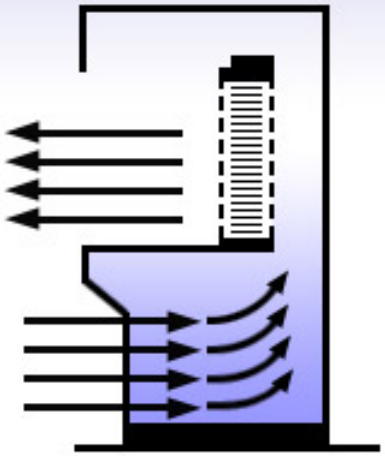
1. ***Describe the work activities***
2. ***Identify the hazards/threats***
3. ***Determine the risks***
    1. *Define the likelihood*
    2. *Define the consequences*
    3. *Characterize the risk*
4. ***Determine if the risk is acceptable or not***

Summary

- **Assessing the risk and determining likelihood and consequence will allow for strategic decisions on control measures**
- **Ideally we will consider first elimination or substitution**
- **A combination of control measures should be used based on their effectiveness and our ability of implementation**

Clean Bench

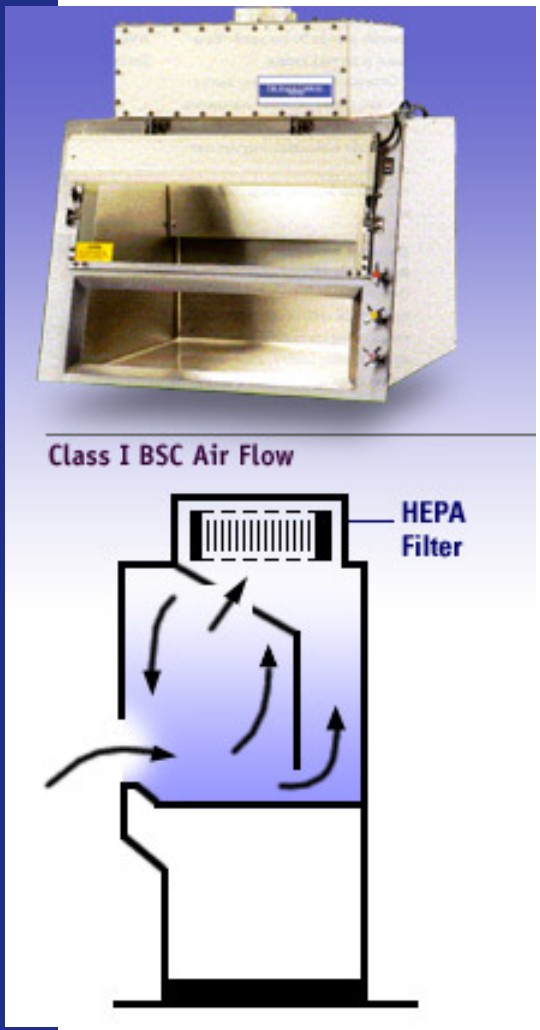
Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- **Provide product protection only**
- **Product protection is provided by creating a unidirectional airflow generated through a HEPA filter**
- **Discharge air goes directly into workroom**
- **Applications**
  - Any application where the product is not hazardous but must be kept contaminant free
  - Preparation of non-hazardous intravenous mixtures and media
  - Particulate free assembly of sterile equipment and

Class I Cabinet

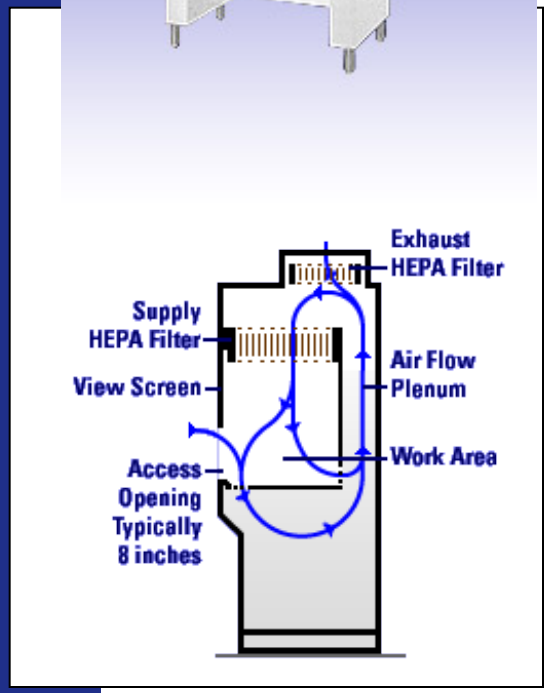
Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- **75 fpm face velocity**
- **Provides personnel and environmental protection**
- **No product protection**
- **Requires an exhaust blower to pull the air through - usually to the outdoors**
- **Applications**
  - Housing centrifuges, fermenters
  - Cage dumping in an animal lab
  - Aerating cultures

Class II Cabinets

Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- **Ventilated cabinet**
- **Provides personnel, product, and environmental protection**
- **Open front with inward airflow for personnel protection**
- **Downward HEPA filtered laminar airflow for product protection**
- **HEPA filtered exhaust air for environmental protection**
- **Also called:**
  - Hood
  - Tissue Culture Hood
  - Vertical Flow Hood

Class II A1 Cabinet

Source:
Biological Safety Cabinets
"A Web-based Training Program"
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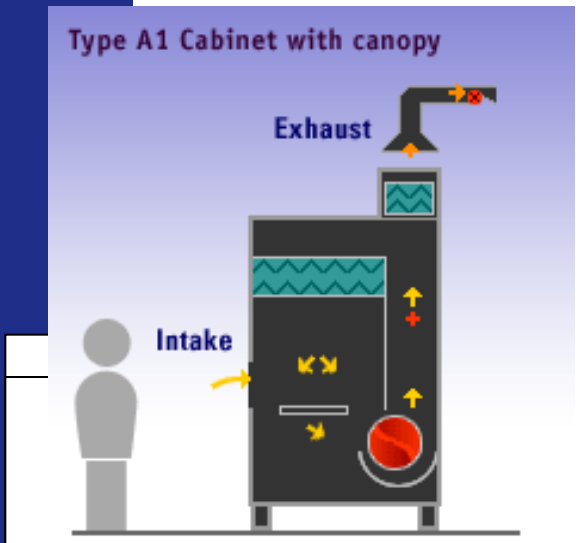
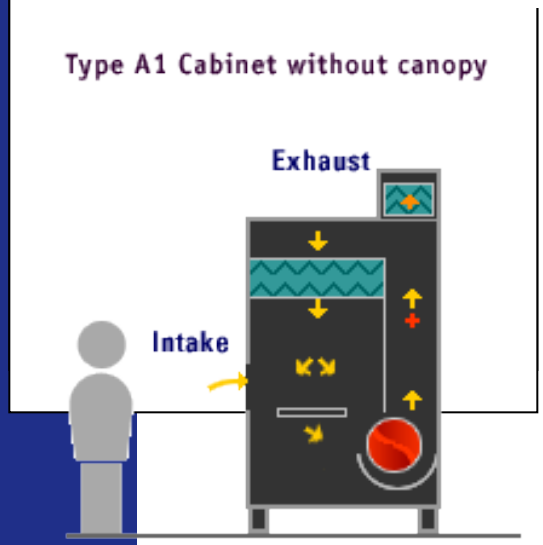
www.eagleson.org

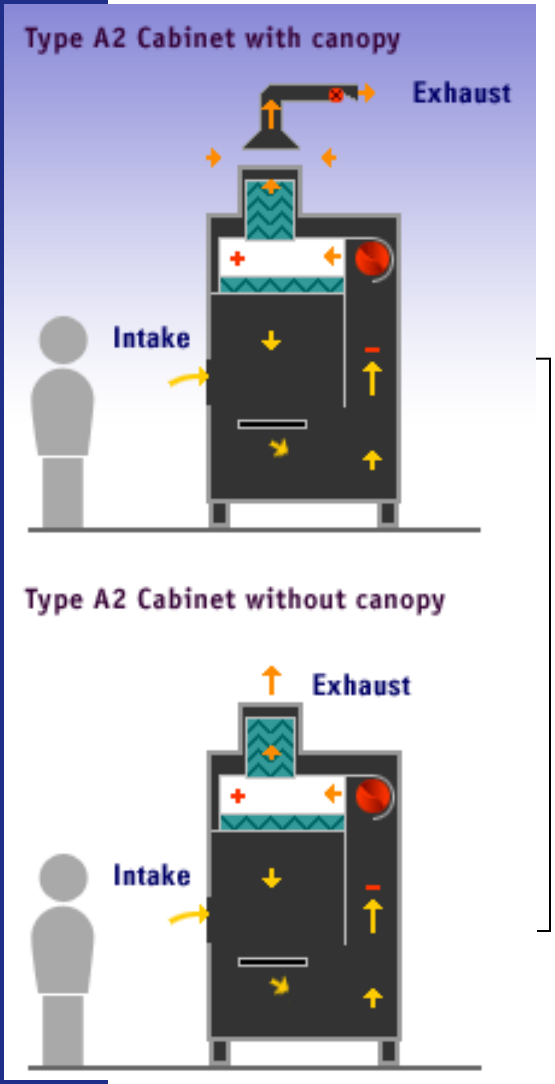




- **75 fpm face velocity**
- **70% recirculated air, 30% exhausted (thru HEPA)**
- **Exhaust to room or thimble connected to external exhaust duct**
- **Potentially contaminated ducts and plenums under positive pressure to the room**
- **Not suitable for work with volatile toxic chemical and volatile radionuclides**

Class II A2 Cabinet

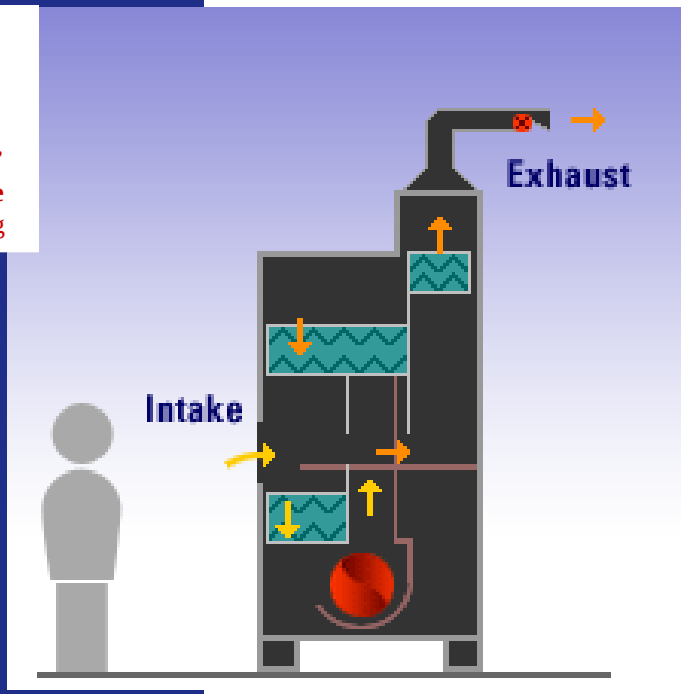
Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- **100 fpm face velocity**
- **70% recirculated air, 30% exhausted (thru HEPA)**
- **Exhaust to room or thimble connected to external exhaust duct**
- **Potentially contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts and plenums**
- **May be used for work with minute quantities of volatile toxic chemicals and tracer amounts of radionuclides if they are exhausted through properly functioning exhaust canopies**

Class II B1 Cabinet

Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org

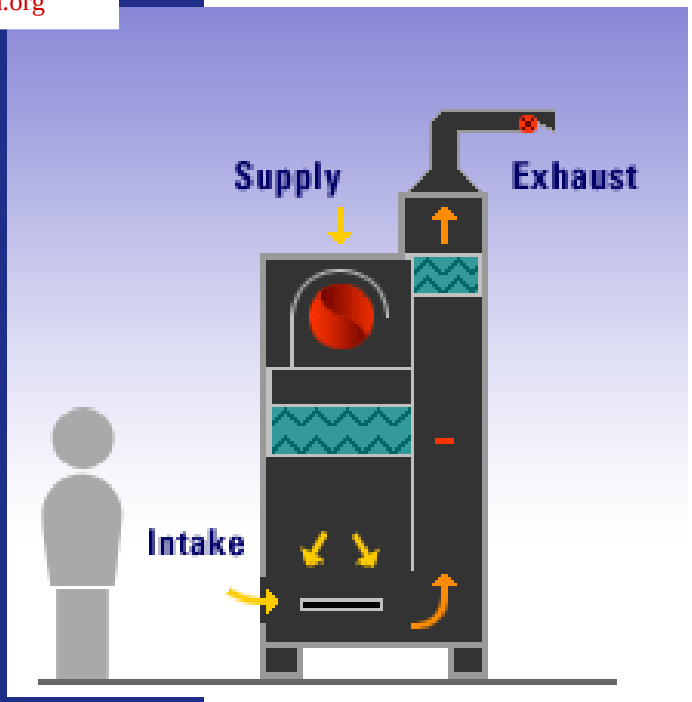


- 100 fpm f
- 30% recir
exhauste

- Air in the back of the cabinet is exhausted to the outdoors through a dedicated exhaust plenum and the air in the front is recirculated
- Must be hard ducted to the outside for the cabinet to function
- All biologically contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts and plenums
- Minute quantities of volatile toxic chemicals and tracer amounts of radionuclide permitted if work is done in the direct exhausted portion of the cabinet

Class II B2 Cabinet

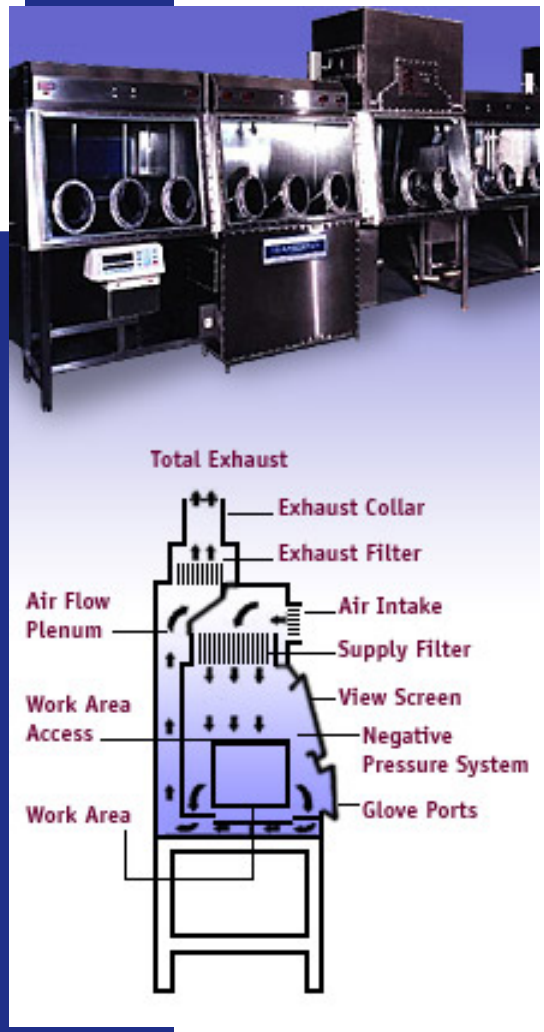
Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- **100 fpm face velocity**
- **Exhaust 100% of the air to the outside after filtration through a HEPA filter**
- **Must be hard ducted to the outside**
- **Sometimes called "Total Exhaust"**
- **All contaminated ducts and plenums under negative pressure, or surrounded by (directly exhausted non-recirculated through the work area) negative pressure ducts and plenums**
- **May be used for work with volatile toxic chemicals and radionuclides**

Class III Cabinet

Source:
Biological Safety Cabinets
"A Web-based Training Program"
Eagleson Institute
www.eagleson.org



- Air-tight absolute containment enclosure
- Product, personnel and environmental protection
- Minimum air intake velocity through a glove port is 100 fpm, if the glove is cut or removed
- Integral equipment allows the safe introduction and removal of materials
- Exhaust air is treated by double HEPA filtration or HEPA filtration and incineration
- Supply air is HEPA filtered
- Operation in cabinet performed through attached rubber gloves
- Operates under negative pressure of at least 0.5" w.g. (124 Pa)