Training of Trainers (TOT) Workshop on Biosafety and Biosecurity Best Practices and Outbreak Response

Hosted by: Centre for Wildlife Health, Odisha University of Agriculture & Technology (OUAT), Bhubaneswar, India

Biosafety, Biosecurity and Biorisk Management

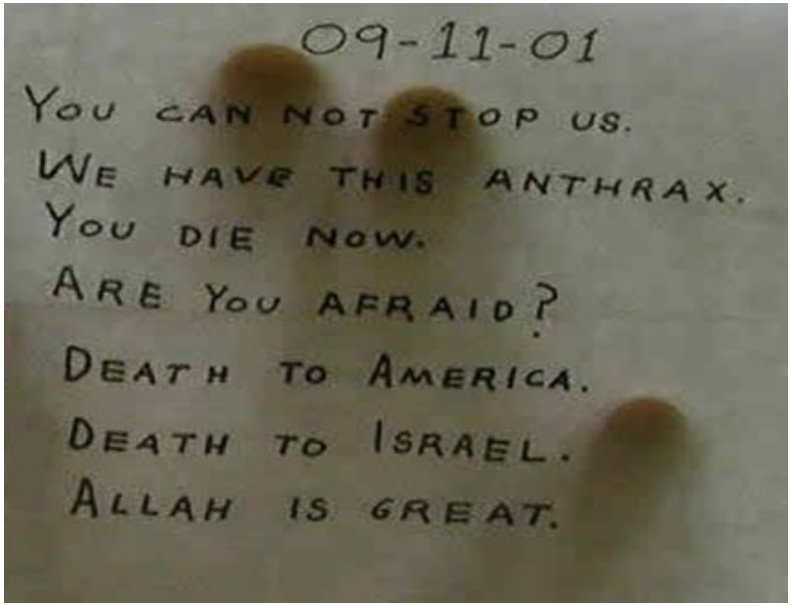
Biosafety and Biosecurity

Biosafety

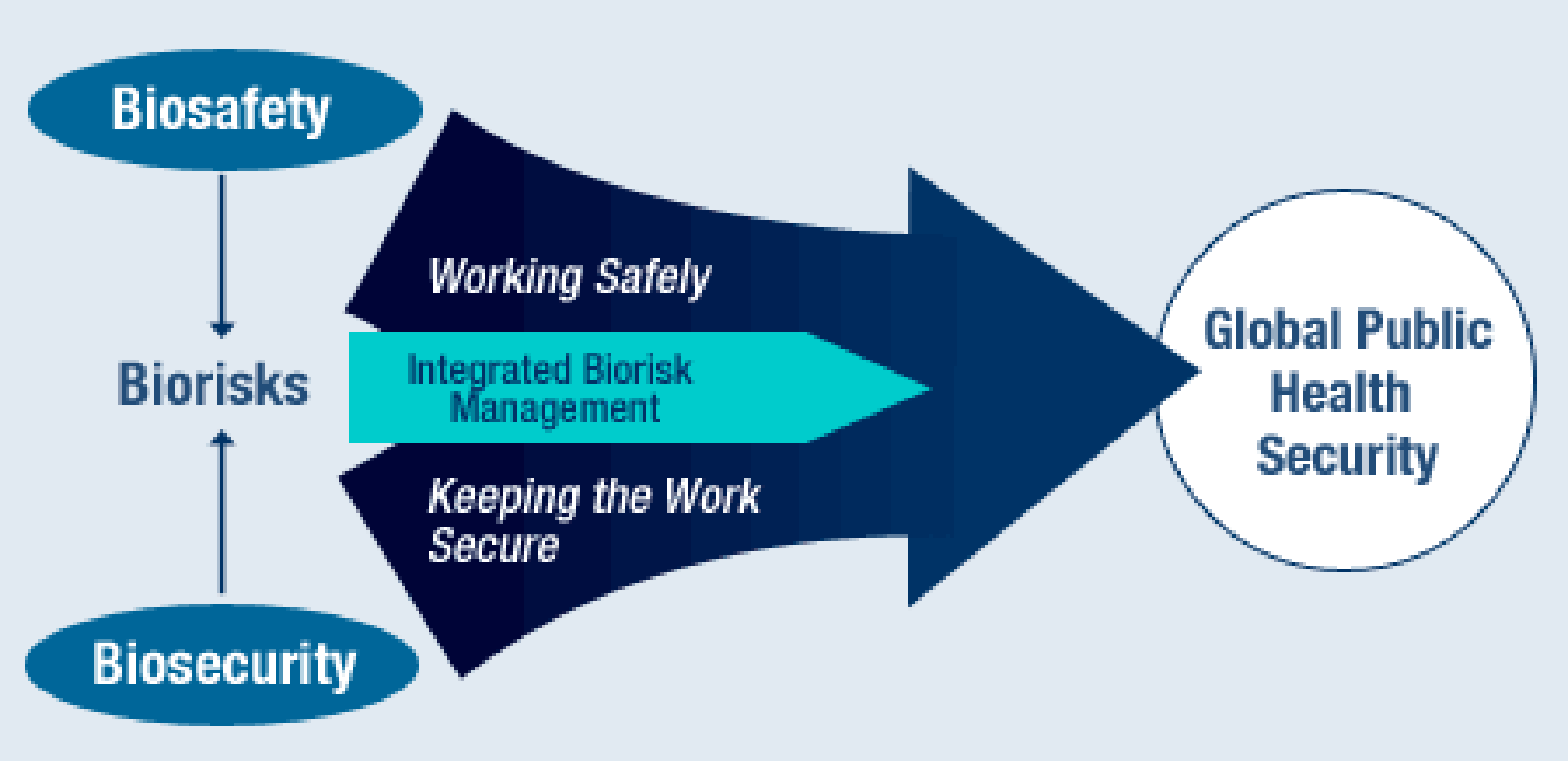
Control unintentional release of biohazards

Biosecurity

Secure the biohazard from intentional release

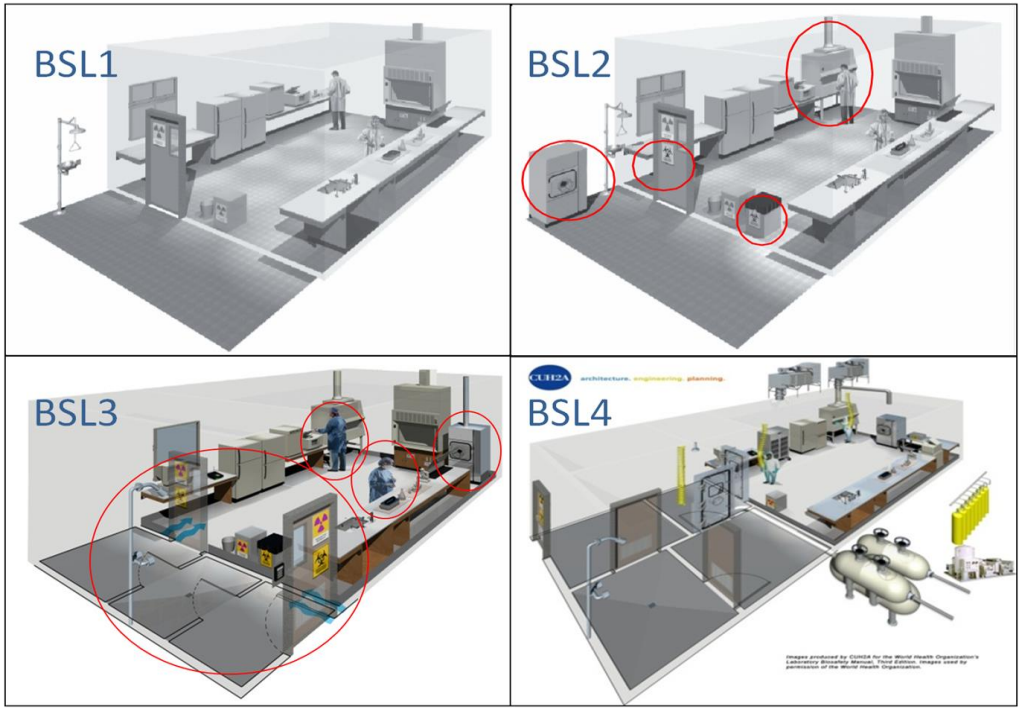


Biorisk Management



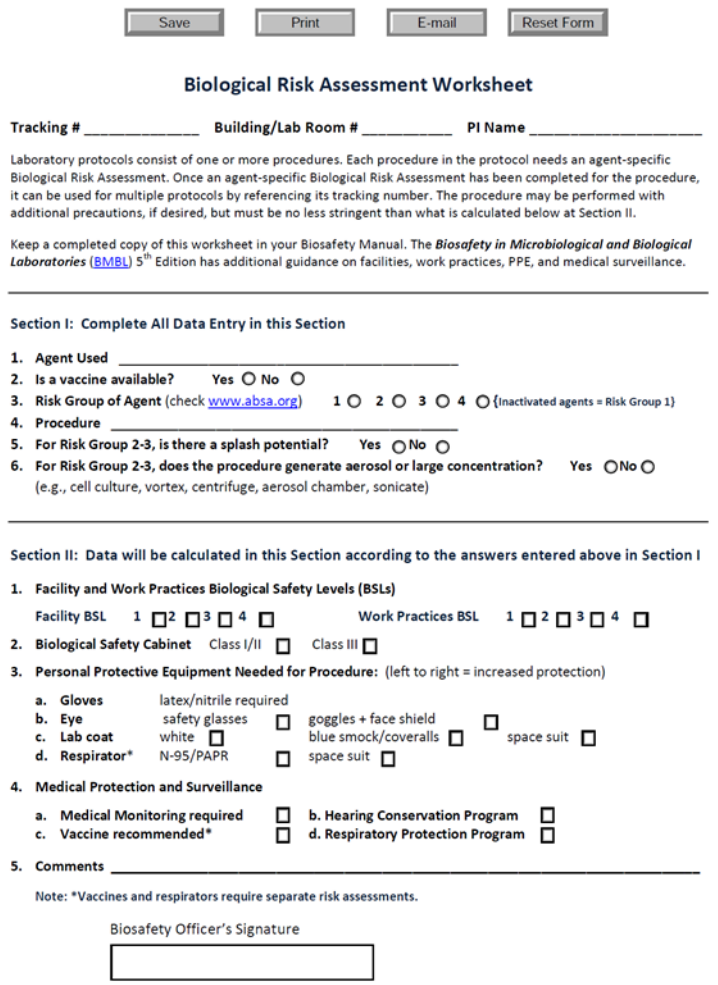
Biorisk Management

- Biosafety
  - Risk Assessment
  - Containment
- Biosecurity
  - Limiting access to-
    - ✓ facilities,
    - ✓ biohazardous materials and
    - ✓ information



Biological Risk Assessment for Laboratories

- All the laboratory staff members should understand how to conduct Biological Risk Assessment focusing on the individuals' job responsibility.
- PIs should complete this Worksheet on Risk Assessment for each ongoing projects.



Save | Print | E-mail | Reset Form

Biological Risk Assessment Worksheet

Tracking # _____ **Building/Lab Room #** _____ **PI Name** _____

Laboratory protocols consist of one or more procedures. Each procedure in the protocol needs an agent-specific Biological Risk Assessment. Once an agent-specific Biological Risk Assessment has been completed for the procedure, it can be used for multiple protocols by referencing its tracking number. The procedure may be performed with additional precautions, if desired, but must be no less stringent than what is calculated below at Section II.

Keep a completed copy of this worksheet in your Biosafety Manual. The ***Biosafety in Microbiological and Biological Laboratories*** (BMBL) 5th Edition has additional guidance on facilities, work practices, PPE, and medical surveillance.

Section I: Complete All Data Entry in this Section

1. **Agent Used** _____
2. **Is a vaccine available?** Yes ○ No ○
3. **Risk Group of Agent** (check www.absa.org) 1 ○ 2 ○ 3 ○ 4 ○ (Inactivated agents = Risk Group 1)
4. **Procedure** _____
5. **For Risk Group 2-3, is there a splash potential?** Yes ○ No ○
6. **For Risk Group 2-3, does the procedure generate aerosol or large concentration?** Yes ○ No ○
   (e.g., cell culture, vortex, centrifuge, aerosol chamber, sonicate)

Section II: Data will be calculated in this Section according to the answers entered above in Section I

1. **Facility and Work Practices Biological Safety Levels (BSLs)**
   Facility BSL 1 ☐ 2 ☐ 3 ☐ 4 ☐ **Work Practices BSL** 1 ☐ 2 ☐ 3 ☐ 4 ☐
2. **Biological Safety Cabinet** Class I/II ☐ Class III ☐
3. **Personal Protective Equipment Needed for Procedure:** (left to right = increased protection)
   a. **Gloves** latex/nitrile required
   b. **Eye** safety glasses ☐ goggles + face shield ☐
   c. **Lab coat** white ☐ blue smock/coveralls ☐ space suit ☐
   d. **Respirator*** N-95/PAPR ☐ space suit ☐
4. **Medical Protection and Surveillance**
   a. **Medical Monitoring required** ☐ b. **Hearing Conservation Program** ☐
   c. **Vaccine recommended*** ☐ d. **Respiratory Protection Program** ☐
5. **Comments** _____

Note: *Vaccines and respirators require separate risk assessments.

Biosafety Officer's Signature

Biosafety & Biosecurity Program

These past scientific developments have all helped initiate the need for Biosafety Program -

1. Institutional Biosafety Committee (IBC)
2. Biosafety Officer/Personal
3. Biosafety Manual
4. Safety Audit
5. Biological Waste Management
6. Orientation, full training and refresher training

Biosafety and Biosecurity in Laboratory Diagnostics and Research

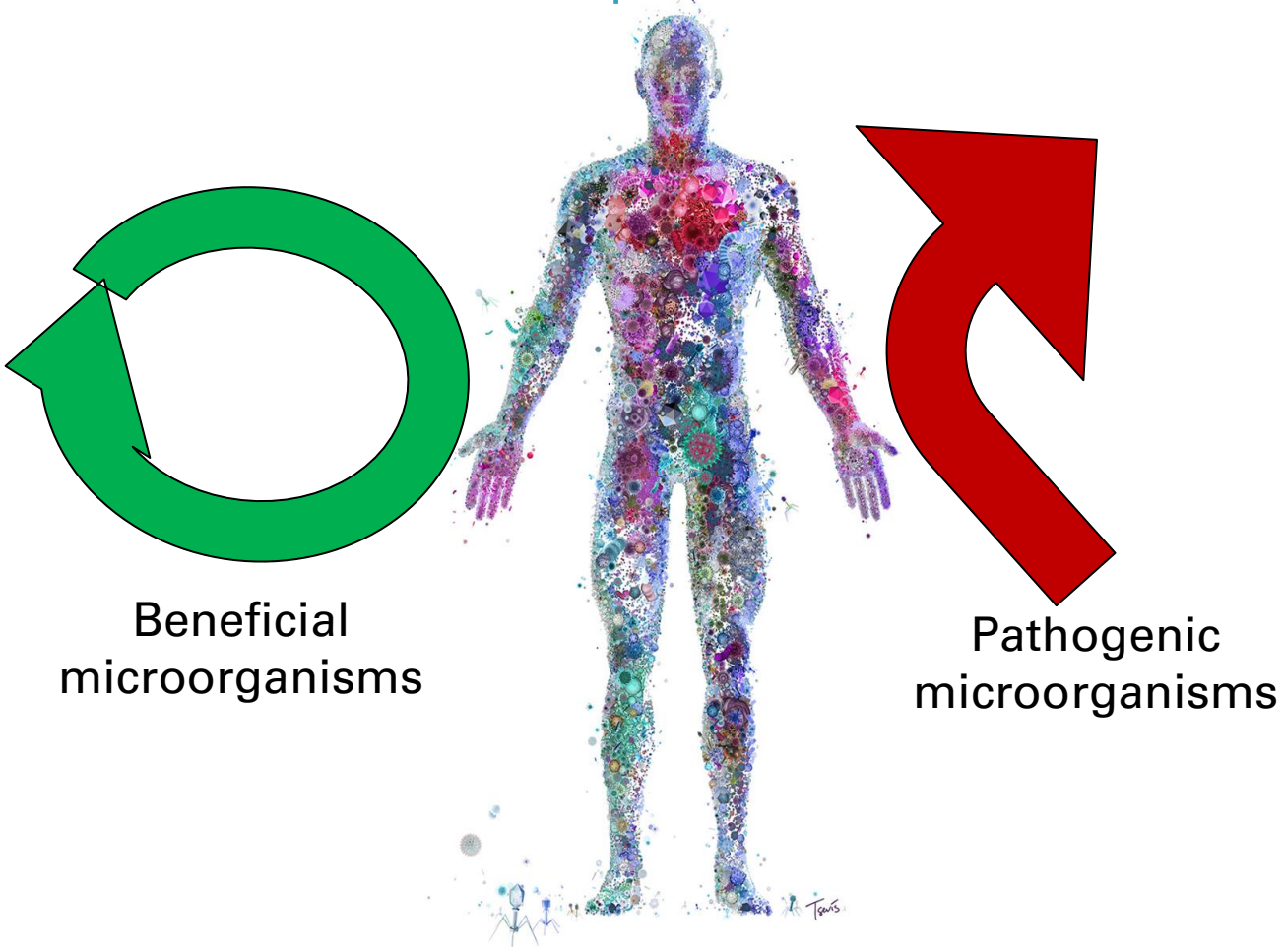
Dr Asadulghani

[MSc, MPhil, PhD]

Head, Biosafety and BSL3 Laboratory, icddr,b

Microorganisms and humans

A mosaic of the diverse and pervasive microbiomes of the human!



Beneficial microorganisms

Pathogenic microorganisms

Objectives

Part 1: Biosafety

- Biohazard
- Biorisk assessment
- Containment

Part 2: Biosecurity

- Physical Security
- Personal Reliability
- Material Control and accountability
- Transportation security
- Information Security
- Program management

Part 3: Biorisk Management Program

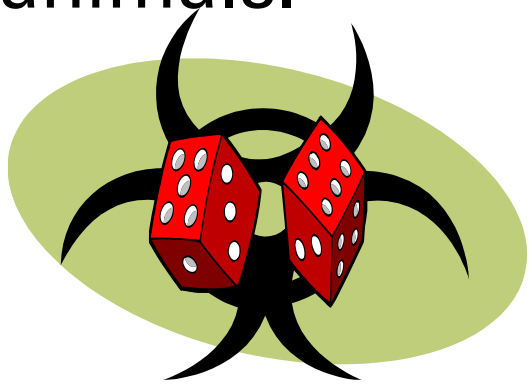
PART 1: Biosafety

Biohazard

An agent of biological origin having the capacity to produce deleterious effects to humans.

Non-infectious: toxins and allergens derived from organisms and allergens and toxins derived from higher plants and animals.

Infectious: microorganisms



What is Biosafety?

Control of biohazard to prevent the transmission to workers, other persons or the environment.

Two principles are-

- Biological risk assessment
- Containment

Its principles were first introduced in 1984 in the first edition of *Biosafety in Microbiological and Biomedical Laboratories (BMBL).*

Biological Risks

- Risk of infection of the laboratory workers while handling or manipulating biological specimens or materials in the laboratory, i.e. risk of laboratory acquired infection (LAI)

- Spread of disease causing agent to the external environment

1.1 Risk Assessment

How to Assess Biological Risk

- First, identify agent risks and perform an initial assessment of risk.
- Second, identify laboratory procedure risks.
- Third, make a final determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment.
- Fourth, review the risk assessment and selected safeguards with a biosafety professional, subject matter expert, and the IBC or equivalent resource.
- Fifth, evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.
- Sixth, revisit regularly and verify risk management strategies and determine if changes are necessary.

Class of the microbes

A Starting Point of the Risk Assessment is the class of the microorganism to be handled

Factors to consider in classification:

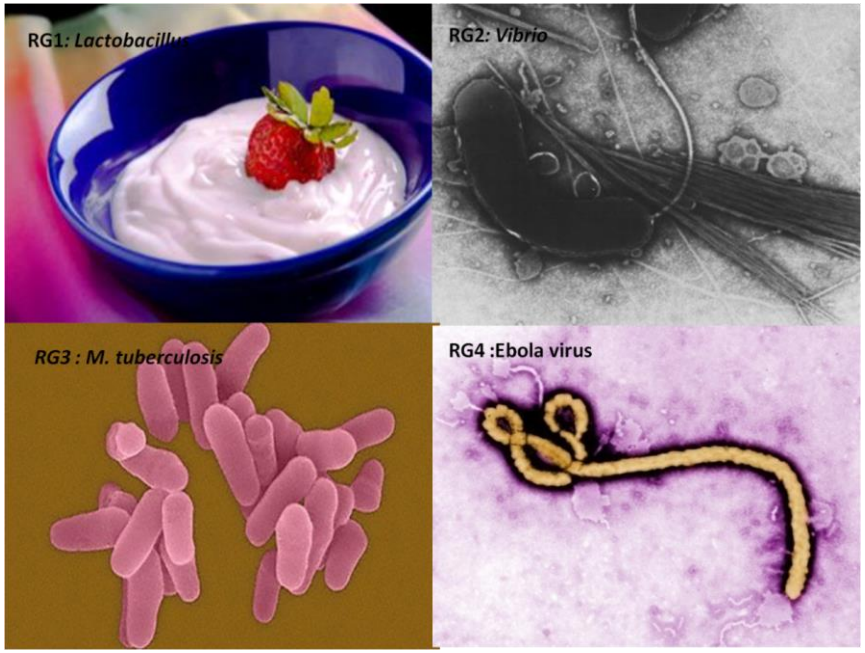
- Pathogenicity of the agent
- Mode of transmission
- Host range of the organism
- Availability of preventive measures
- Availability of treatment

Risk groups of microorganisms

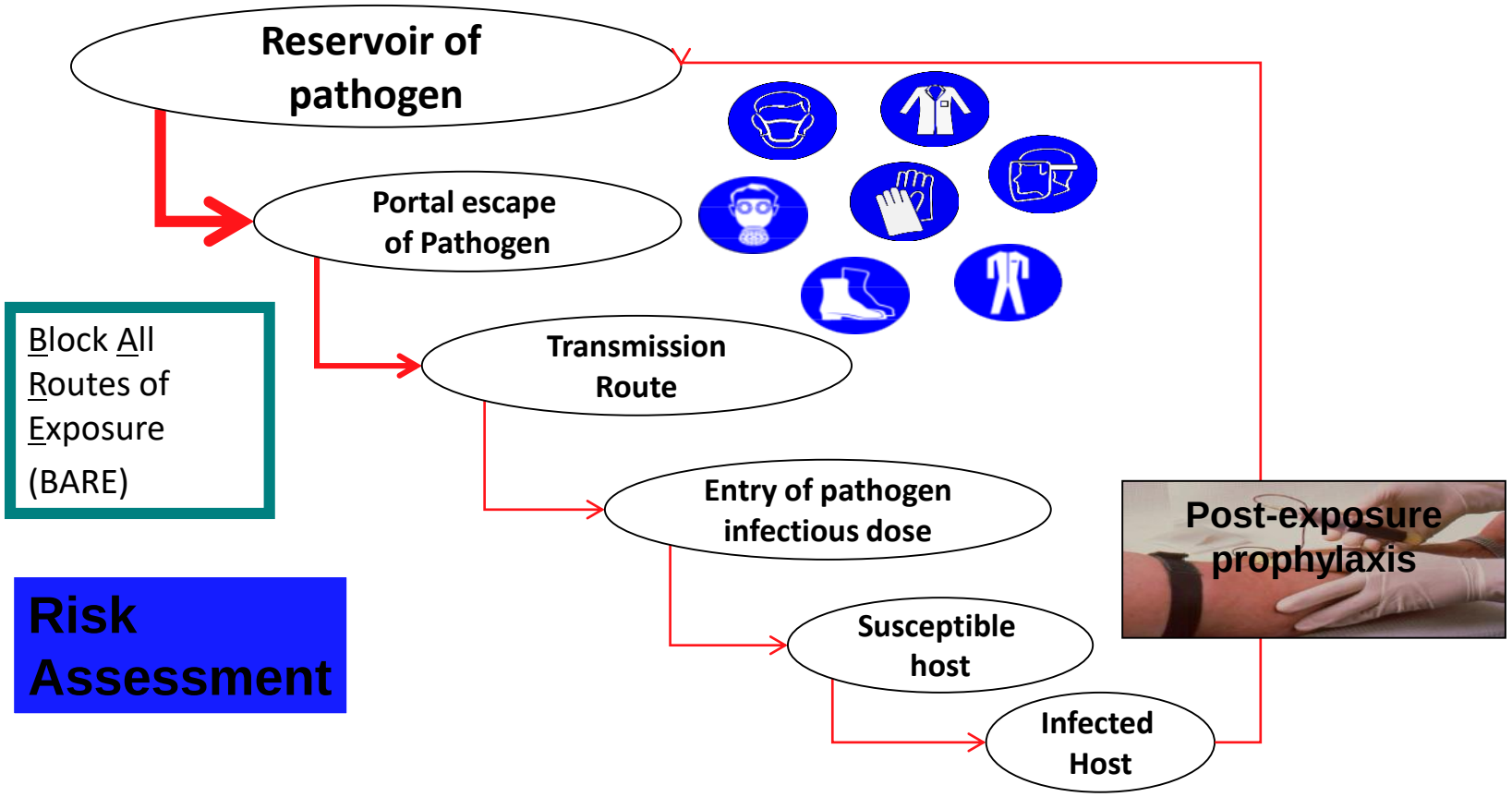
Risk Group (RG)	RG1	RG2	RG3	RG4
Pathogenicity	No	Disease rarely serious	Serious or lethal	Lethal
Transmission	X	Food, water or blood borne	Inhalation	Known or unknown
Host range	X	Human, animal, or both	Human, animal, or both	Human, animal, or both
Prevention	X	*often* available	*May be* available	*Not usually* available
Treatment	X	*often* available	*May be* available	*Not usually* available
Risk Level	X	moderate individual risk and low community risk	High individual risk and low community risk	High individual risk and high community risk

With an Increase in Risk Group Microbes Cause more Severe Diseases

- RG1: Non pathogenic
- RG2: Moderate individual risk and low community risk
- RG3: High individual risk and low community risk
- RG4: High individual risk and high community risk



Understanding the Chain of Infection



Safety equipment

Safety equipment : Primary Barrier

- Primary barriers contain the agent at the source
- Equipment/Engineering Control
  - Biological safety cabinet, fumehood, glove box, animal housing, centrifuge, fermenter

Primary Barriers - Equipment

Personnel Protection

Any aerosol generated within the cabinet is contained and kept away from the researcher

Product Protection

Air within the work space of the cabinet has been filtered so that is virtually free of airborne particles and organisms; thus protecting the work from outside contamination

Environmental Protection

Aerosols generated within the unit are removed from the air before the air is discharged

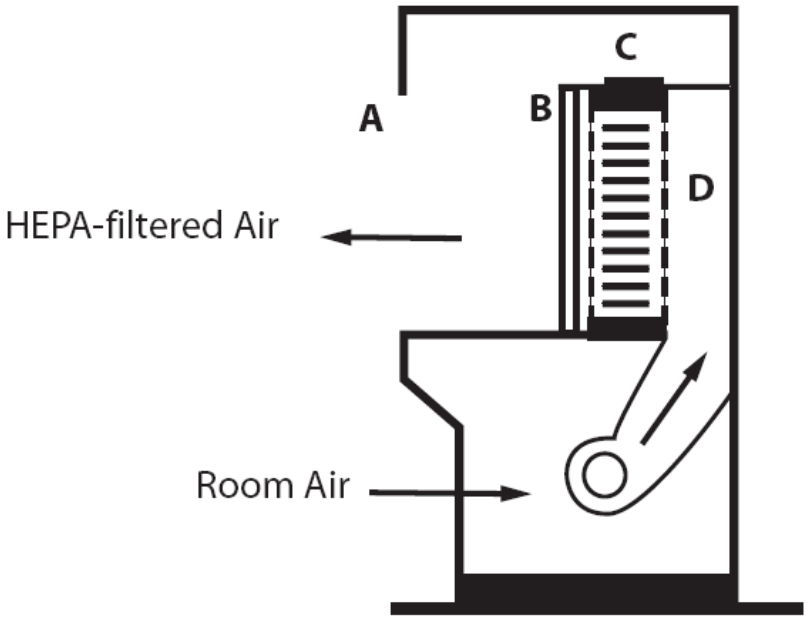
Chemical Fume Hood

- 100 fpm face velocity
- Offer only personnel protection
- Always exhaust air to the outside
- Do not offer protection to the product or the environment, as there is no filtration of intake and exhaust air (Sometimes air cleaning treatment [activated carbon filters] is added to the exhaust.)
- Do draw contaminants in the laboratory air directly over the product being worked on
- Used for work with chemical hazards

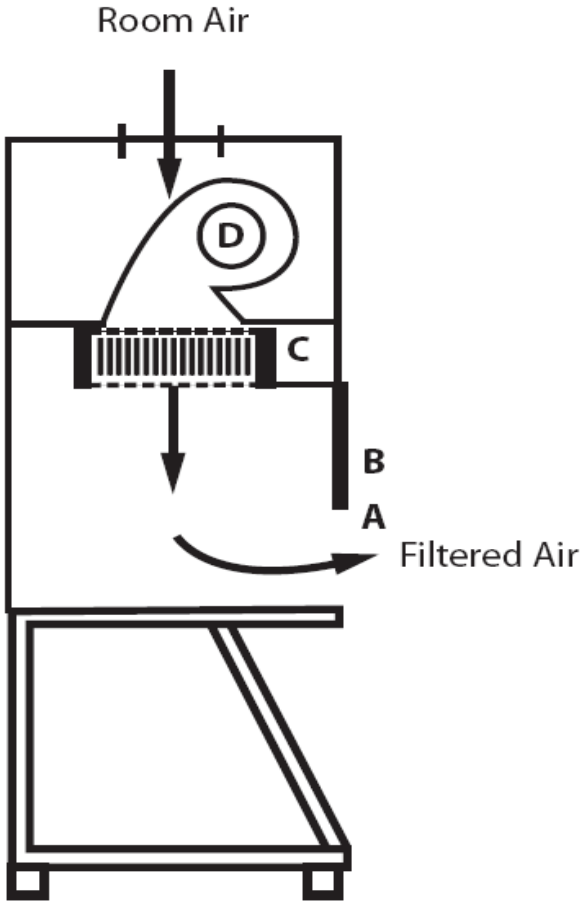
Keep hood clean, sash should be closed when hood is not in use, equipment should be 9” away from sash

Clean Bench / Laminar Flow Hoods

- The horizontal laminar flow “clean bench”.
  - A. front opening,
  - B. supply grille,
  - C. supply HEPA filter,
  - D. supply plenum,
  - E. blower.



Clean Bench / Laminar Flow Hoods



- The vertical laminar flow “clean bench”.
  - A. Front opening,
  - B. Sash,
  - C. Supply HEPA filter,
  - D. Blower.

Biological Safety Cabinets

Designed to contain biological hazards

Inward airflow for personnel protection

HEPA filtered exhaust air for environmental protection

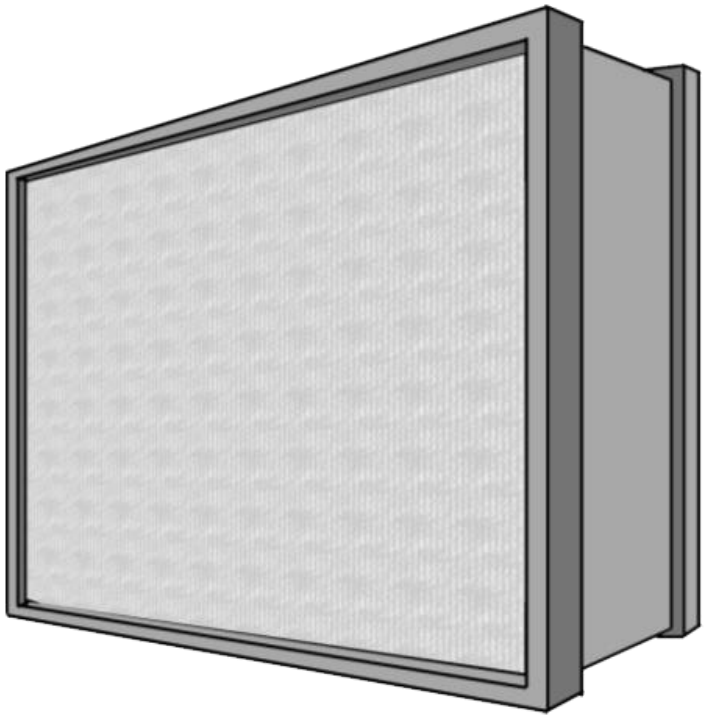
Supply air HEPA filter for product protection (except Class I)

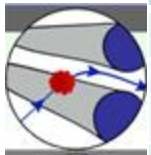
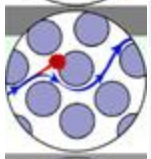
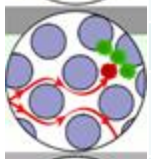
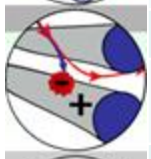
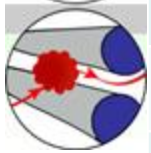
Separated into Classes and Types

- Class I
- Class II
  - Type A1, A2
  - Type B1, B2
- Class III

Microbiological studies, cell cultures, pharmaceutical research and procedures…

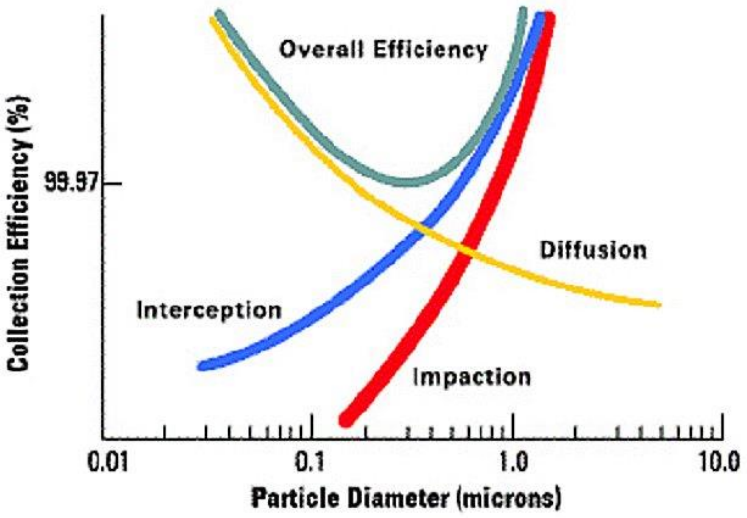
High Efficiency Particulate Air filter



Method of particle collection	
	**Interception** Particles are collected whenever they touch a fiber as they traverse the media.
	**Inertial Impaction** Particles are collected as they travel in a straight path and collide with a fiber. Air continues to flow around the fiber.
	**Diffusion** Particles are collected as they travel from areas of high air flow to areas of low airflow.
	**Electrostatics** Charged particles are attracted to the opposite charges causing the particle to attach to the fiber.
	**Sieving** Particles are too large to pass between fibers and become trapped against them.
	Gravity Particles naturally fall onto fibers and become trapped as a result.

HEPA Filtration Principles

- Filter particles at 99.97% efficiency at 0.3 microns
- Larger and smaller particles are filtered at higher efficiency!!!
- Gases and vapors are not removed from the air stream by HEPA filtration

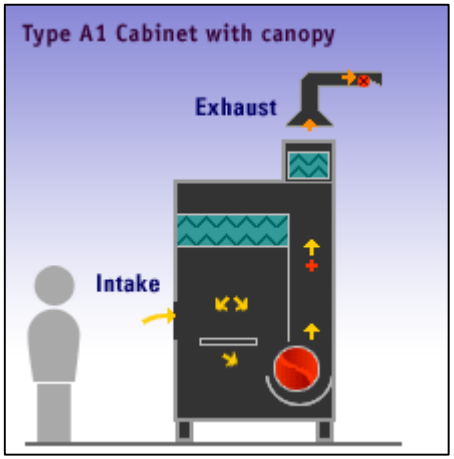


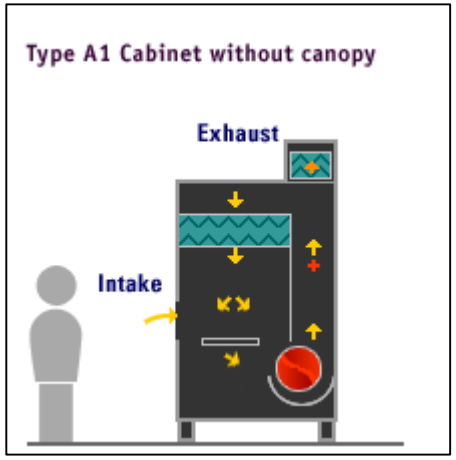
More significant effect for smaller particles

Class I Cabinet

- 75 fpm face velocity
- Provides personnel and environmental protection
- This type of cabinet does not provide protection for the work materials or product.

Class II Cabinets A1

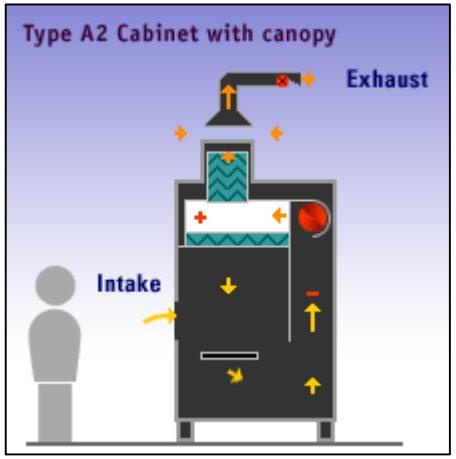


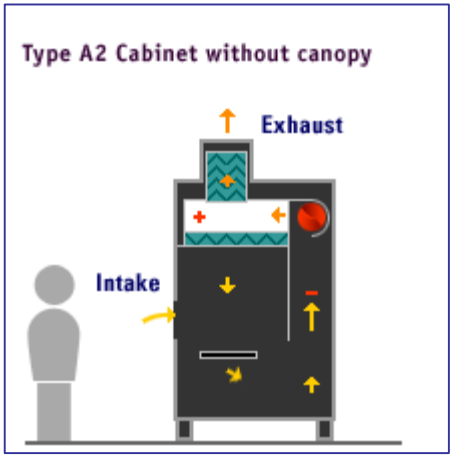


- 75 fpm face velocity
- 70% recirculated air, 30% exhausted (thru HEPA)
- Exhaust to room or thimble connected to external exhaust duct
- Potentially contaminated ducts and plenums under positive pressure to the room
- Not suitable for work with volatile toxic chemical and volatile radionuclides

Class II Cabinets A2

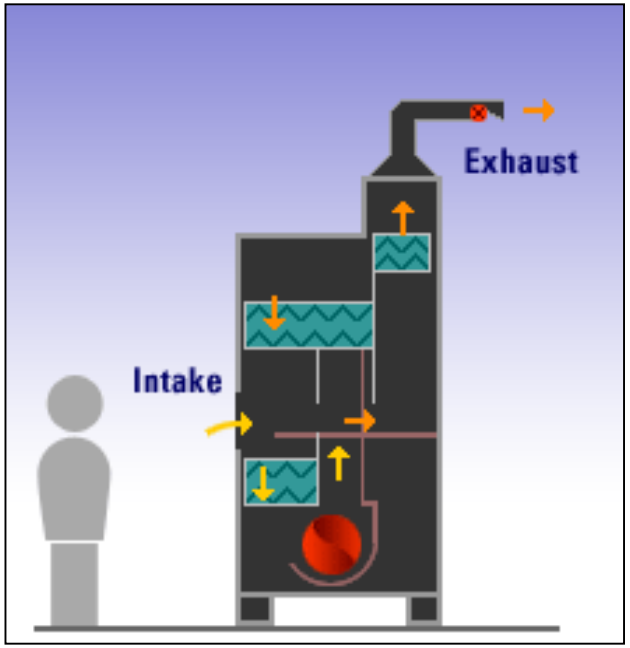
- 100 fpm face velocity
- 70% recirculated air, 30% exhausted (thru HEPA)
- Exhaust to room or thimble connected to external exhaust duct
- Potentially contaminated ducts and plenums under negative pressure or surrounded by negative pressure ducts and plenums
- May be used for work with minute quantities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





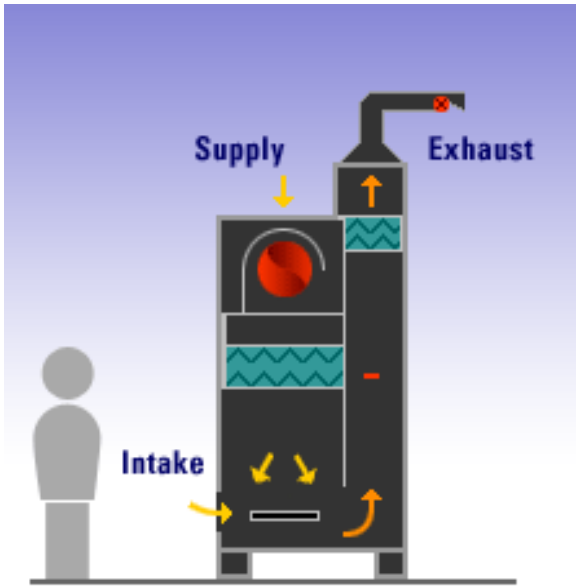
Class II Cabinets B1

- 100 fpm face velocity
- 30% recirculated air, 70% exhausted (thru HEPA)
- 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



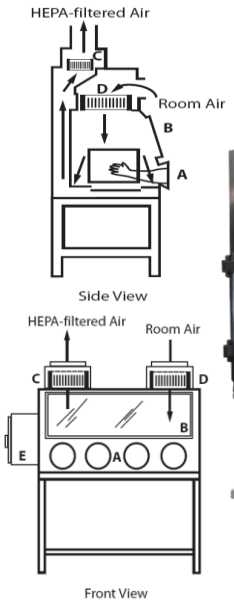
Class II Cabinets B2

- 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 required as an adjunct to microbiological studies



Class III Cabinet

- The Class III BSC.
  - glove ports with O-ring for attaching arm-length gloves to cabinet,
  - sash,
  - exhaust HEPA filter,
  - supply HEPA filter,
  - double-ended autoclave or pass-through box.



BSCs

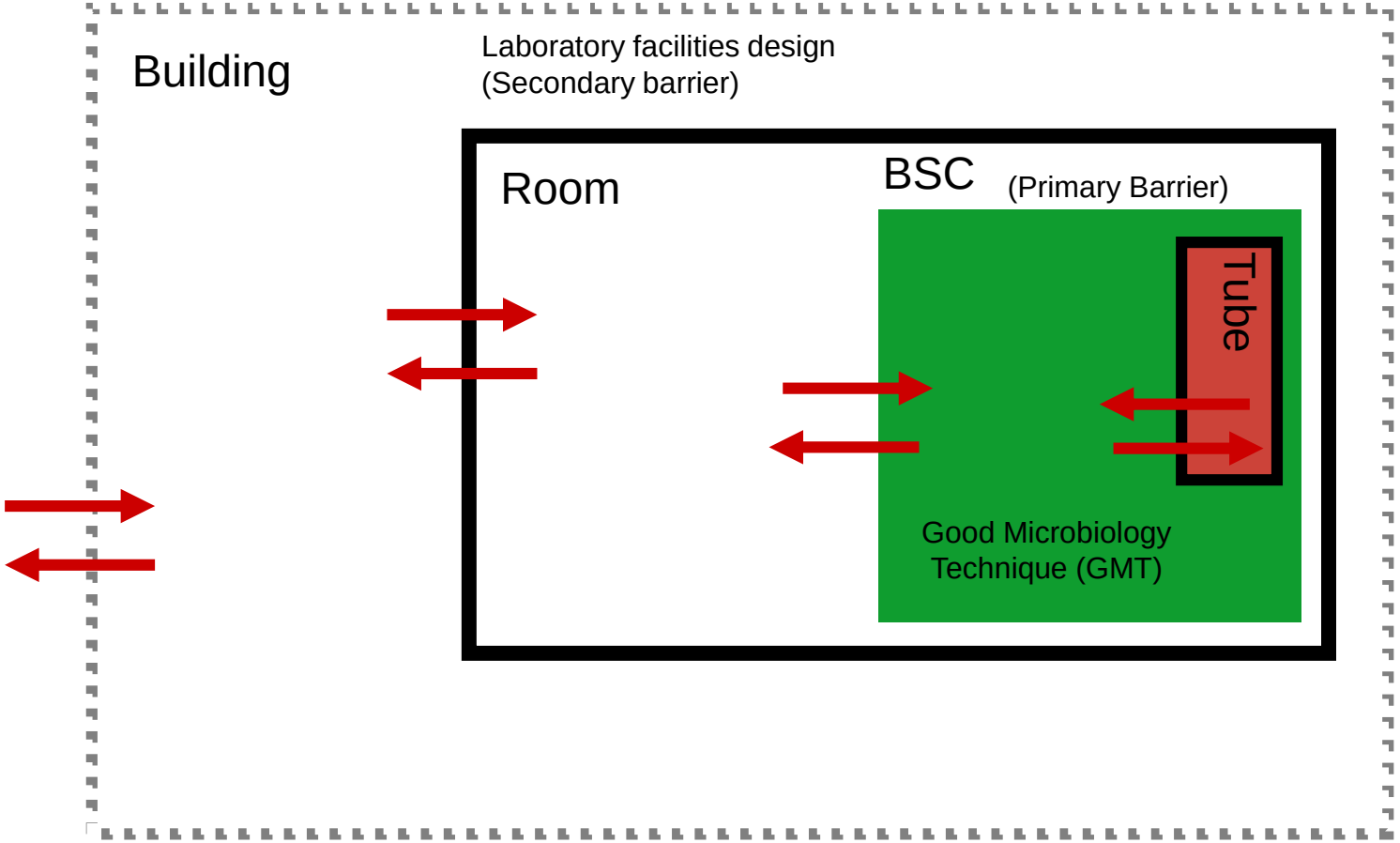
BSC Class	Face velocity (lfpm)	Airflow Pattern	Non-volatil Radionuclides/ Toxic Chemicals	Volatile Radionuclides/ Toxic Chemicals
I	75	In at front through HEPA to the outside or into the room through HEPA	Yes	No
II A1	75	70% recirculated to the cabinet work area through HEPA; 30% balance can be exhausted through HEPA back into the room or to outside through a canopy unit	Yes	No
II A2	100	Similar to II, A1, but has 100 fpm intake air velocity and plenums are under negative pressure to room; exhaust air can be ducted to the outside through a canopy unit	Yes	When exhausted outdoors
II B1	100	30% recirculated, 70% exhausted. Exhaust cabinet air must pass through a dedicated duct to the outside through a HEPA filter	Yes	Yes
II B2	100	No recirculation; total exhaust to the outside through a HEPA filter	Yes	Yes
III	N/A	Supply air is HEPA filtered. Exhaust air passes through two HEPA filters in series and is exhausted to the outside via a hard connection	Yes	Yes

Ventilation equipment application

Ventilation Equipment	Personnel	Product	Environment
Chemical Fumehood	√		
Laminar Flowhood		√	
Class I Biosafety Cabinet	√		√
Class II Biosafety Cabinet	√	√	√
Class III Biosafety Cabinet	√	√	√

1.2 Containment

Containment



- Layers of open and closed systems
- Rely on operational practices + design features
- Incorporates both biosafety and biosecurity

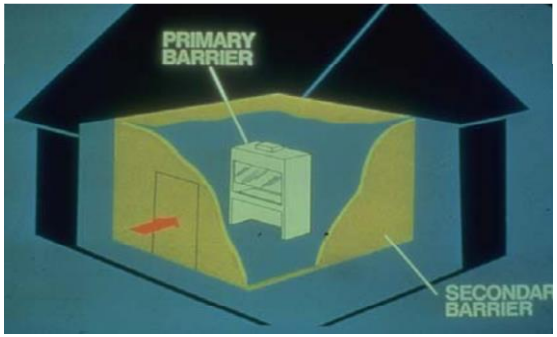
Containment

The principle of holding or being capable of holding or including within a fixed limit or area.

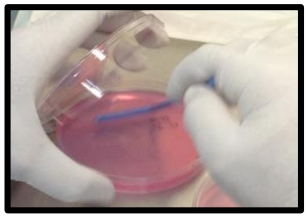
Preventing the unintentional release of biological agents through a combination of laboratory practices, containment equipment (primary barrier) and laboratory facility design (secondary barrier).

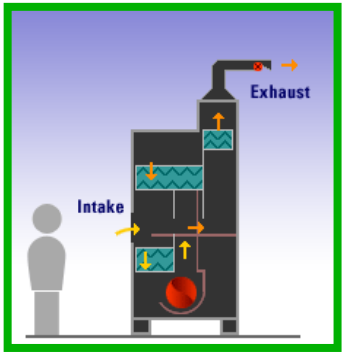
Three elements of containment

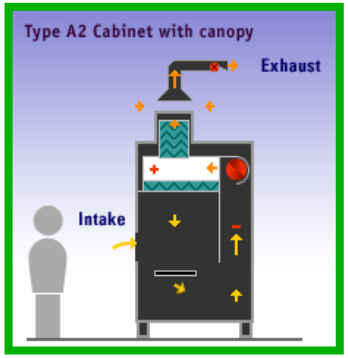
- Laboratory Practice and Techniques
  - Standard Practices
  - Special Practices & Considerations
- Safety Equipment
- Facility Design and Construction
  - Increasing levels of protection

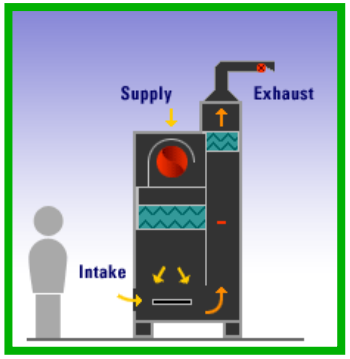


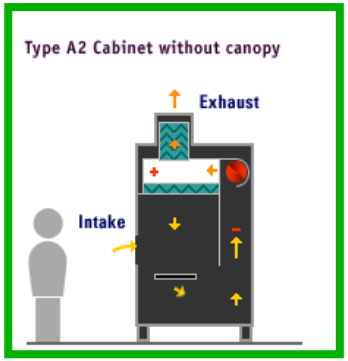
Safety Equipment & Practices











Basic and Containment Laboratories Design Overview

BSL1 - BSL4 Laboratories

BSL1 - basic lab

BSL2 - basic lab + aerosol confinement

Biosafety cabinet

BSL3 - containment laboratory

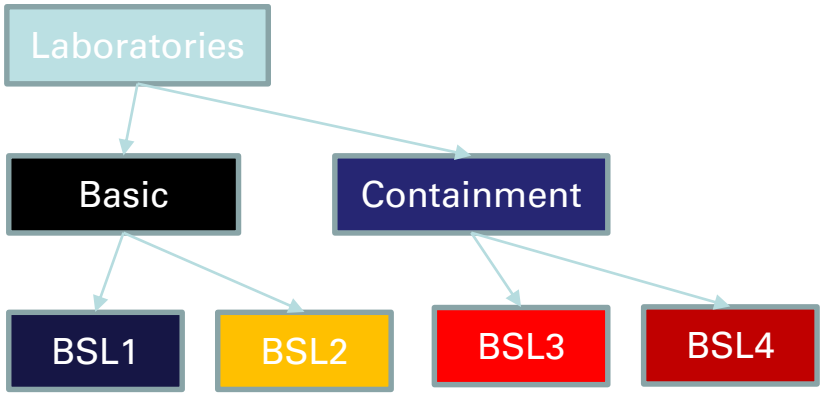
2 door separation from building occupants

Biosafety cabinet

HEPA filtered exhaust

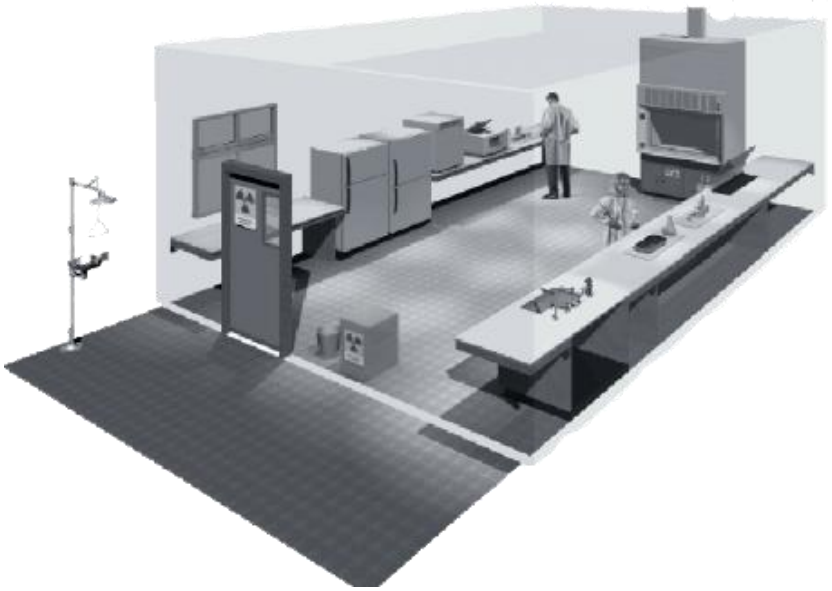
BSL4 - maximum containment laboratory

Separate building from general research population



BSL1 Facility Design & Practices

Laboratory has doors to limit traffic Hand washing sink is available Work surfaces are easy to disinfect



Limit access when working

- No eating, drinking, applying cosmetics or handling contact lenses
- No mouth pipetting
- Gloves must be worn and lab coats and protective eyewear are recommended
- Minimize splashes and creation of aerosols
- Disinfect waste and work surfaces
- Biological waste should be placed in a biohazard disposal box, labeled, and placed outside for pickup when 2⁄3 full

BSL1: Safety Equipment

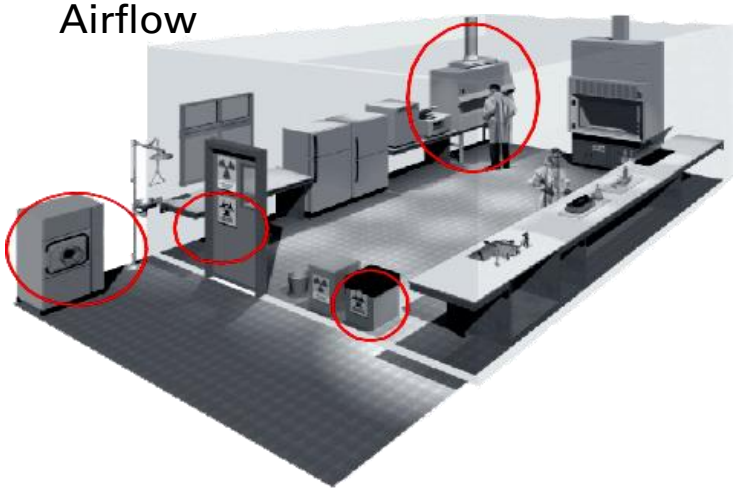
Personal protective equipment

- Lab coat
- Gloves
- Face protection
- Eye protection

BSL2 Facility Design & Practices

All BSL-1 requirements, plus:

- Autoclave is available and Eyewash is present and Signage is posted
- Biological waste stream is separate
- Biological safety cabinets
- Vacuum lines and Directional Airflow



All BSL-1 practices, plus:

- A supervisor must limit access to those who are trained and approved
- Policy for handling sharps must be implemented
- Laboratory equipment must be routinely decontaminated
- Protective lab coats or disposable gowns *must* be worn
- Laboratory-specific Biosafety manual must be available in the lab

BSL2: Safety Equipment

In addition to BSL1:

- Use biosafety cabinets for work with infectious agents involving-
  - Aerosols and splashes
  - Large volumes
  - High concentrations

BSL2: Work Practices and Procedures

- Aerosol generating procedures performed in a biosafety cabinet:
  - Homogenizing
  - Vortexing
  - Vigorous mixing
  - Pipetting infectious liquids
  - Sonication
  - Pouring
- If breach occurs:
  - Evacuate lab, post spill sign
  - With appropriate PPE and disinfectant, decontaminate centrifuge, buckets, other items or areas

BSL2: Correct Use of Biosafety Cabinets

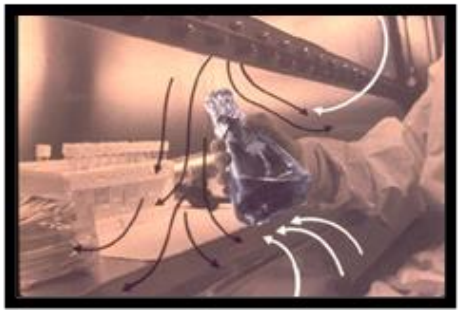
Start Up

- Turn on all blowers and BSC illumination lights.
- Allow five minutes of operation to purge system; check flow alarm system audio and visual alarm function (if so equipped).
- Decontaminate readily accessible interior surfaces and items with a disinfectant (appropriate for the agents or suspected agents present) before loading and wait at least 10 minutes prior to start of work.

BSL2: Correct Use of Biosafety Cabinets

During Use

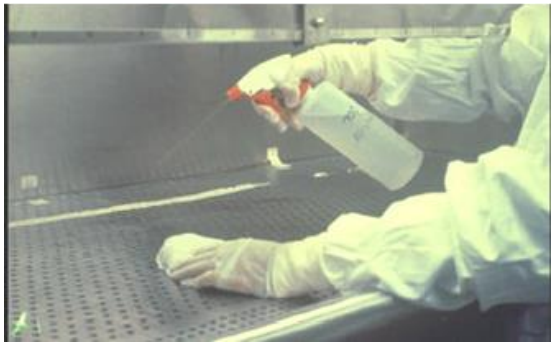
- Load supplies prior to work.
- Do not overload cabinet.
- Separate clean and dirty side.
- Work in center of work area.
- Do not block front or rear grills.
- Minimize disruption of airflow(turbulence).
- Clean up spill promptly.
- Discard waste within the cabinet.



BSL2: Correct Use of Biosafety Cabinets

Shut Down

- Decontaminate and remove all items from interior work area.
- Decontaminate readily accessible interior surfaces with a disinfectant appropriate for the agents or suspected agents present.
- Turn on ultraviolet light (if so equipped).
- Allow five minutes of operation to purge system. Then wait at least 10 minutes.
- Turn off BSC blower.



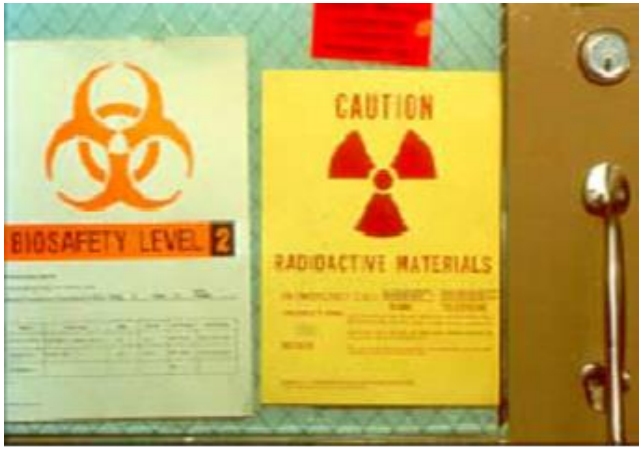
BSL2: Correct Use of Biosafety Cabinets

DO NOT use Bunsen burners or open flames considering:

- Fire hazard
- Can damage HEPA filter
- Interferes with proper air flow
- Microincinerator preferred
- Burner with pilot light not a good alternative
- Open flames react with disinfectants (flammables)

BSL2 : Special Practices

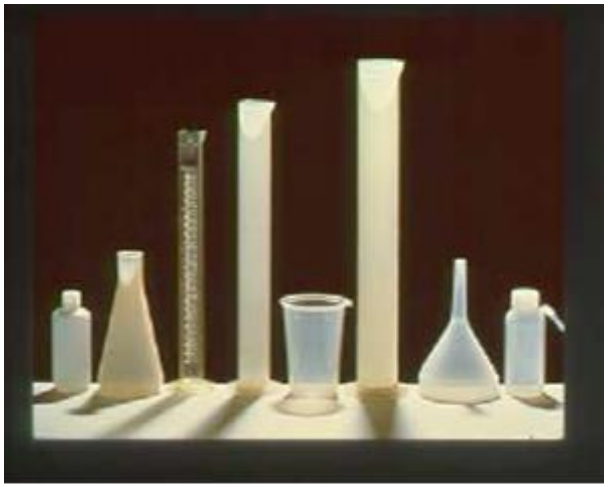
- Laboratory entrance
- Medical surveillance
- Laboratory specific biosafety manual
- Training
- Containers for potentially infectious materials
- Decontamination of laboratory equipment
- Exposure incidents
- Non-research related animals and plants in the laboratory
- Aerosol generating procedures



Biosafety Level 2

Special Practices

- It is recommended to use plasticware
- Policies and procedures for entry
- Biohazard warning signs
- Biosafety manual specific to lab
- Training with annual updates
- Immunizations
- Baseline serum samples
- Use leak-proof transport containers



BSL2: Training Requirements

Supervision

Supervisor is a competent scientist with increased responsibilities

Lab Personnel

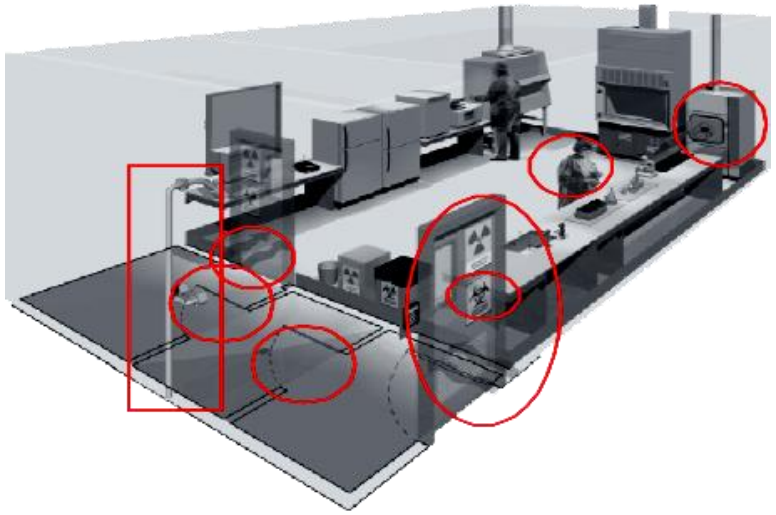
Aware of potential hazards

Proficient in practices/techniques

BSL3 Facility Design & Practices

All BSL-2 requirements, plus:

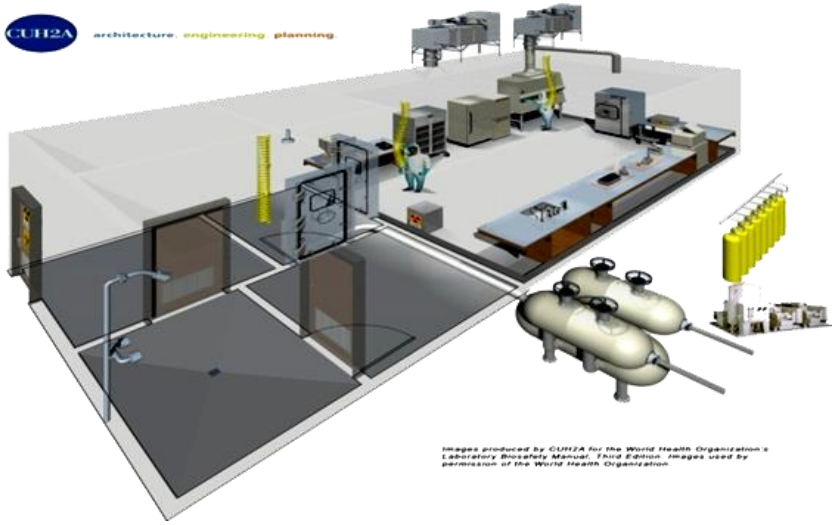
- Lab is separated from general traffic
- Negative air flow must be maintained, Autoclave inside laboratory
- Enclosures for aerosol-generating equipment
- Sealed room penetrations
- Hands-free sink
- Enter and exit through ante-room
- All infectious materials *must* be placed in durable, leak-proof containers
- All surfaces and equipment should be regularly disinfected
- All work with infectious agents *must* be done inside the BSC
- Users *must* complete training and demonstrate proficiency with laboratory manager before being granted access
- It is recommended that personnel work in pairs



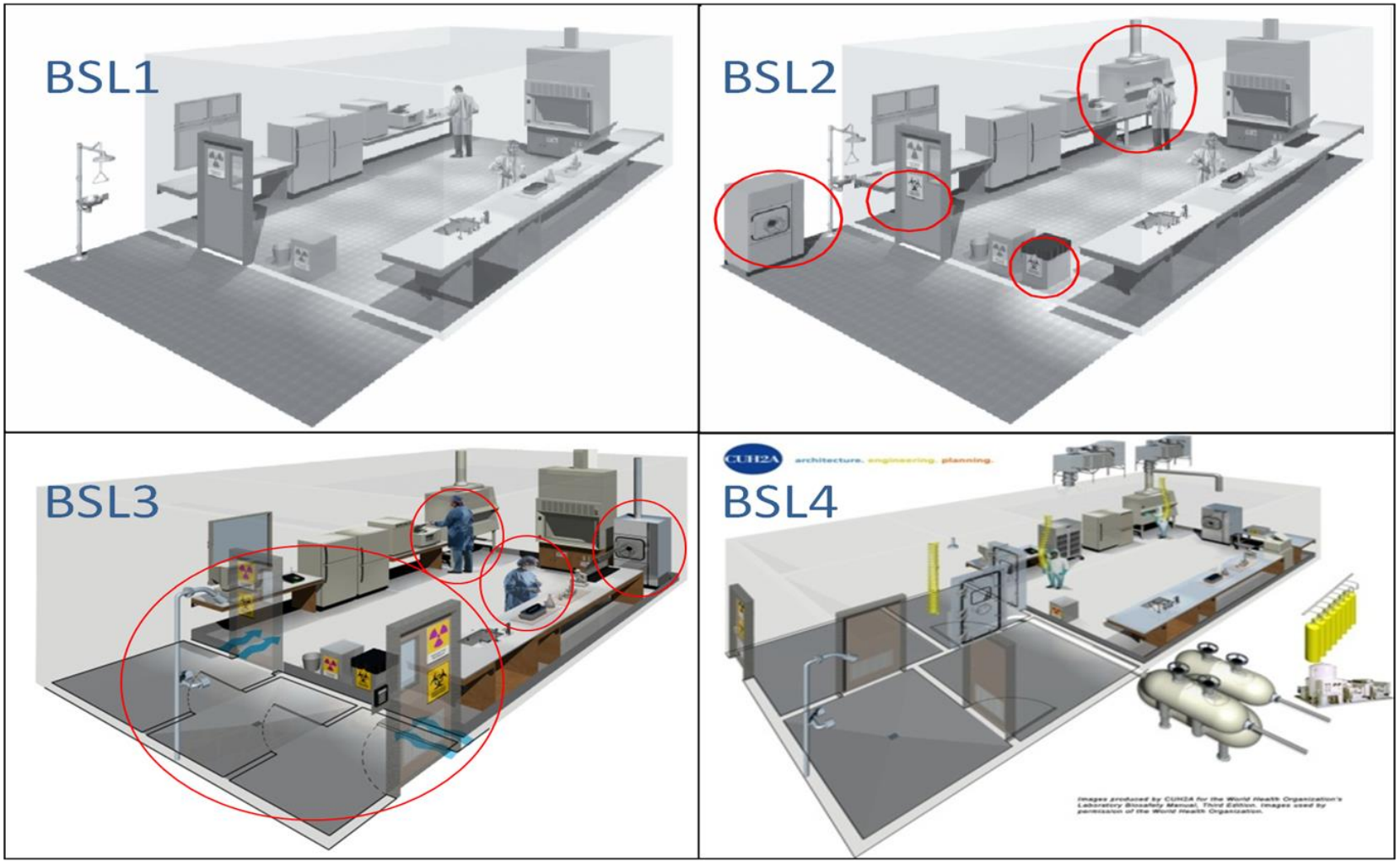
BSL4 Facility Design & Practices

BSL3 facility plus

- Separate building or isolated zone
- Dedicated supply and exhaust, vacuum, and decontamination systems
- All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit
- Clothing change before entering
- Shower on exit
- All material decontaminated on exit from facility



Biosafety Level 1, 2, 3, and 4



ABSL1 through ABSL4

- For the use of experimentally infected animals housed in vivarium research facilities.
- For the maintenance of laboratory animals that may naturally harbor zoonotic infectious agents.
- Designed to provide differential levels of biosafety for animals and the environment.

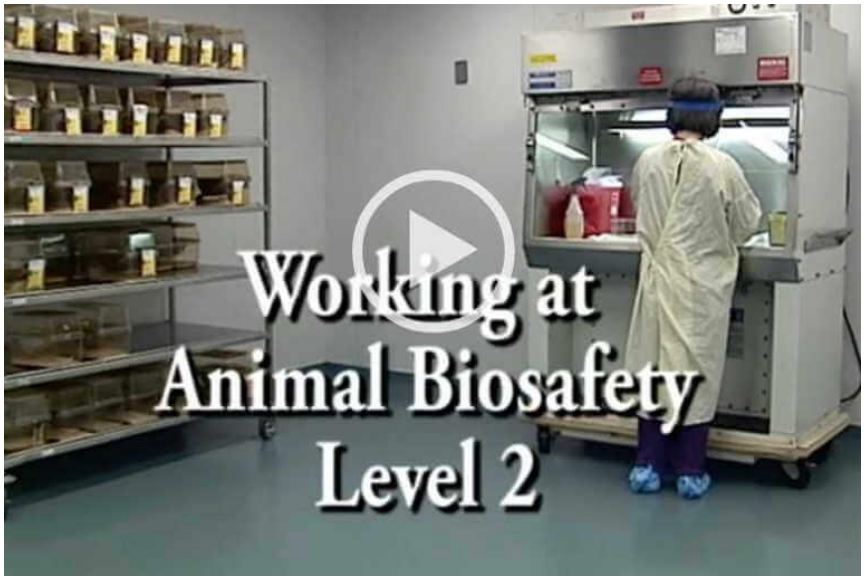
ABSL1

- Facility and practices appropriate for work with well-characterized, low-risk agents not known to cause disease in healthy animals that represent no potential economic loss to agricultural industries.
- No specialized practices other than good microbiological technique are utilized. Facilities should be easily cleanable, have a sink for hand washing, and conform to the facility requirements described in the BMBL for BSL-1.
- These laboratories are typical of undergraduate, or secondary education teaching laboratories.

https://absa.org/absl1vid/

ABSL2

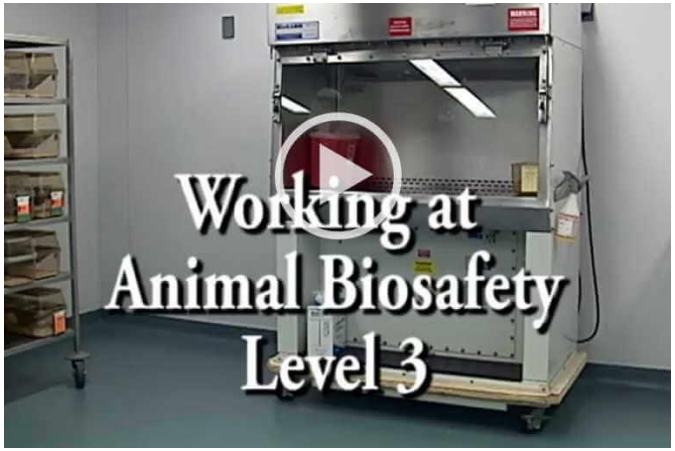
- Facility, safety equipment and practices appropriate for agents of moderate potential hazard to animals or agriculture that are generally endemic, cause illness of varying degree, and are typically treatable or preventable.
- Most research and diagnostic laboratories that work with food-borne pathogens and domestic diseases are designed to perform work at this level.



https://absa.org/absl2vid/

ABSL3

- Work is done with indigenous or exotic agents with a potential for transmission, and which may cause serious and potentially lethal infections in animals, or grave economic consequences to agriculture if released.
- Vivarium facility and practices include inward directional airflow, separation from uninfected animal areas, special laboratory protective clothing, and decontamination of laboratory waste.



https://absa.org/absl3vid/

- For *in vivo work with some highly infectious* agriculture agents, ABSL-3 may be modified further with enhancements specifically designed to protect the environment such as placing animals in isolation containers (isolets or flexible film isolators) with HEPA filtration of supply and exhaust air, sewage decontamination, personnel exit showers, and facility integrity testing (pressure decay test).

BSL3-Ag

- **The USDA Agricultural Research Service** (ARS) has defined enhanced ABSL-3 facilities, safety equipment and practices particular to agriculture research where the facility barriers, usually considered secondary barriers, now act as primary barriers.
- This standard is used when large animals such as cows, pigs, bison and deer, are infected with high consequence agricultural pathogens and cannot be placed inside any other animal isolation device.

BSL-3-Ag facilities utilize the containment features of the standard ABSL-3 facility (as defined in the BMBL) as a starting point, with a number of enhancements specifically designed to protect the environment such as HEPA filtration of supply and exhaust air, sewage decontamination, personnel exit showers, and facility integrity testing (pressure decay test). FMD, CSF, and HPAI are representative of agricultural agents may be assigned to this biosafety level.

ABSL4

- Facility, safety equipment and practices appropriate for research on dangerous and exotic agents that pose a high individual risk of human life-threatening disease which may be transmitted via the aerosol route and for which there is no available vaccine or treatment.
- RG4 agents can only be manipulated at laboratories having BSL-4 capability.
- Currently, fewer than 20 viruses are designated for use at A/BSL-4.

i) Cabinet Lab
ii) Suit Lab

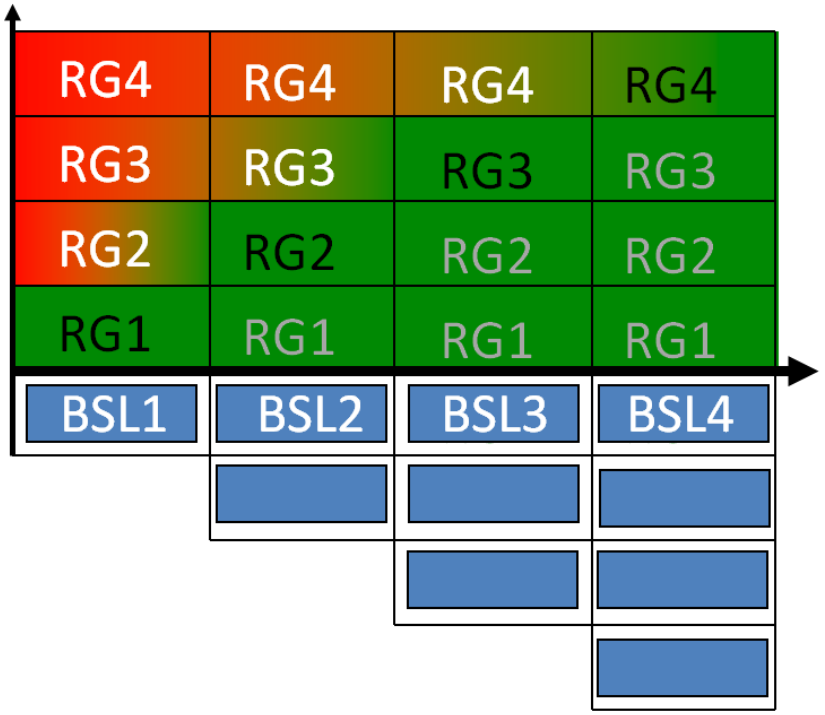
Animal Facility BSC

Working in Animal Facility BSC

- BSC for safe handling and manipulating research animals
- Cleaning and maintain BSCs in animal facility after handling animals for research

Risk Group and Biosafety Levels

Different biosafety levels are designed increasing level of protection against increasing level of risk the worker may face while working with different microorganisms



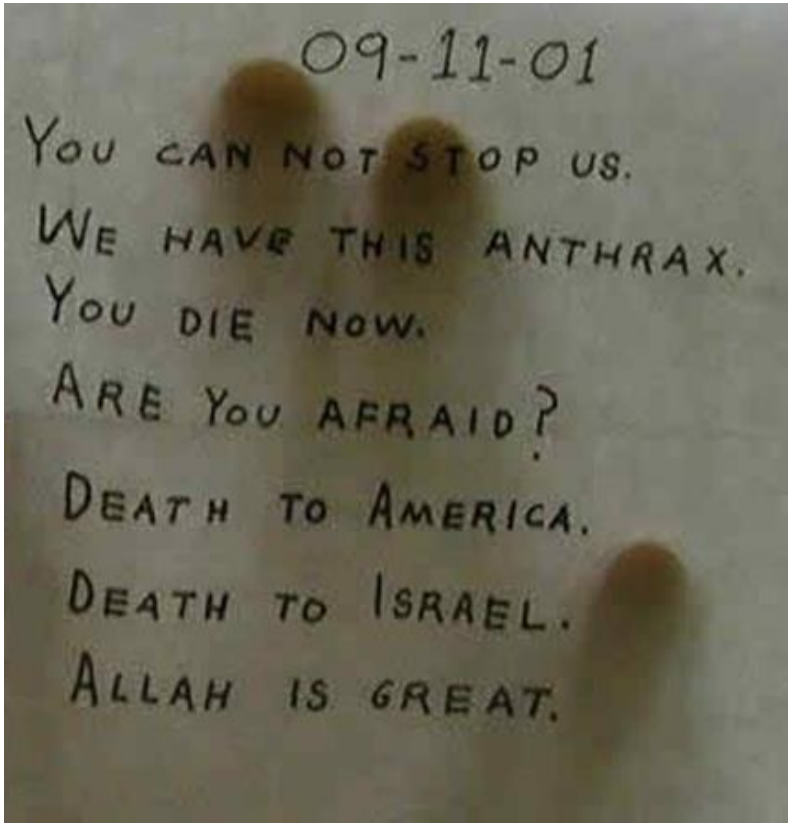
PPE Recommendation and Guidance for each BSL

BSL	A/BSL1	A/BSL2	A/BSL3	A/BSL4
PPE	Lab coats, gowns, etc. Eye protection Latex or nitrile gloves	Lab coats, gowns, etc. •Eye protection •Latex or nitrile gloves •Change when contaminated •Double glove when necessary •Remove gloves and wash hands after working •Do not re-use gloves	All manipulations performed inside a BSC with full protective clothing that must not leave the lab. •Eye protection •Latex or nitrile gloves •BSL-3 work practices •Appropriate respiratory protection	All PPE indicated up to and including BSL-3 •Positive-pressure suit •Special facility engineering features

Part 2: Biosecurity

Biosecurity

- The term biosecurity is a newer term and was first defined in 2007—
- Application of knowledge, techniques and equipment to prevent community and environmental from intentional exposure to potentially infectious agents or biohazards resulting from loss, theft or misuse .
- The principles are limiting access to-
  - facilities,
  - research materials, and
  - information.



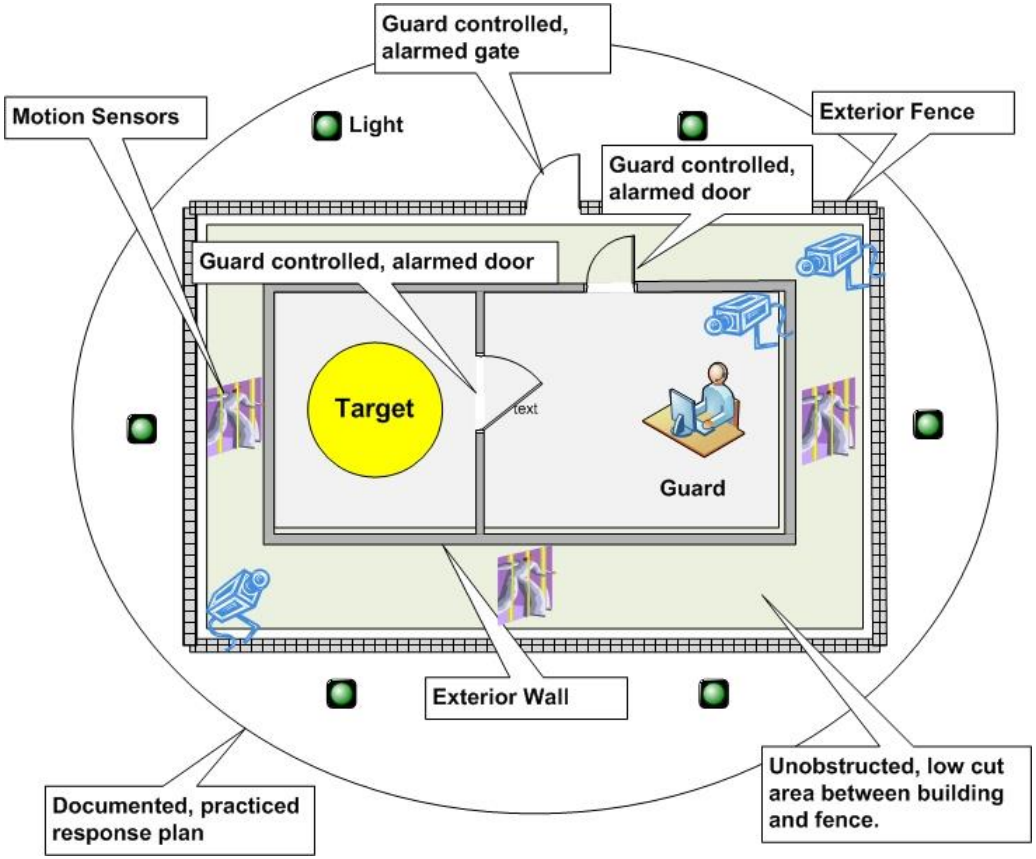
What is Biosecurity?

Security measures to protect the release of high consequence microbial agents, biological pathogens, toxins, critical information, pests or diseases as a result of theft or misuse. Components of a laboratory biosecurity program include:

- Physical security
- Personnel reliability
- Material control & accountability
- Transport security
- Information security
- Program management

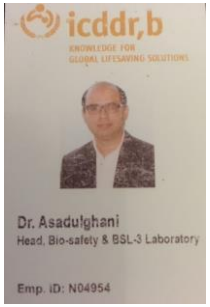
Physical Security

- Access control
- Security guard
- CCTV
- Motion sensor
- Intrusion alarm
- Boundary



Personal Security

- Personal Reliability
  - Comprehensive background investigation
  - Medical screening
  - Constant behavior surveillance
  - Random alcohol/drug screening
  - Periodic re-investigation
- Personal Identification
  - Authorized individuals
  - Qualified Individuals
  - Visitors



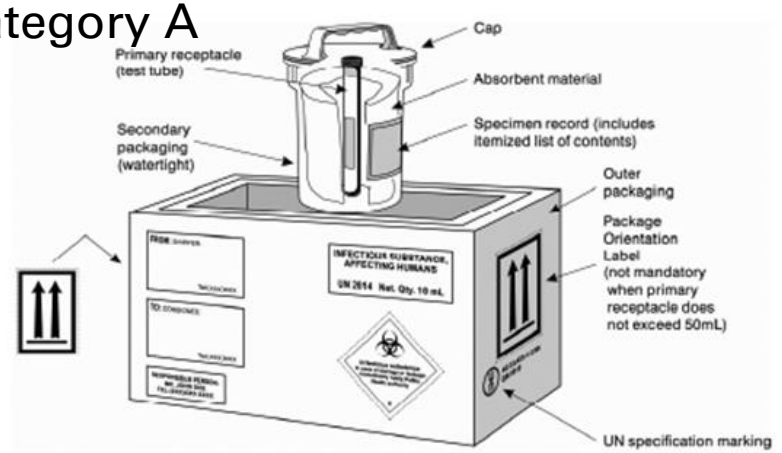
Material control & accountability

- It is the responsibility of each laboratory to establish material accountability procedures.
- These should be designed to track the inventory, storage, use, transfer and destruction of biological materials.
- The purpose is to know what agents are housed in a lab, where they are located and if they are all accounted for.

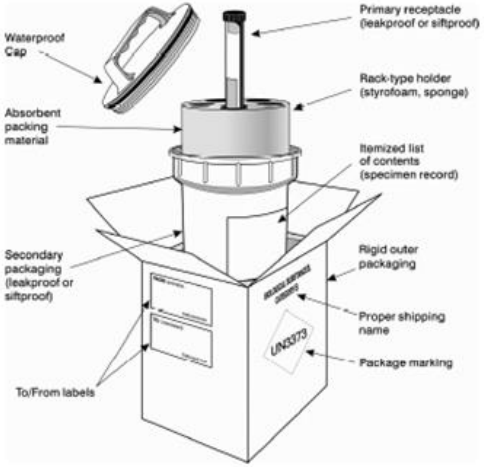
Transport security

- Material transport policies are in place that outline requirements for transporting locally or outside of the country
- Chain of custody during the transport of infectious substances is well defined

Category A

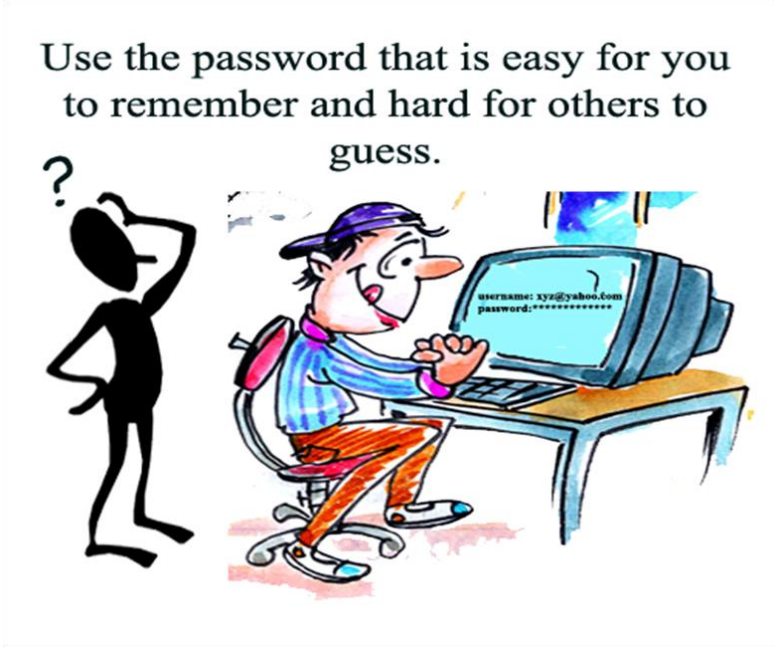


Category B



Information security

- Practices of protecting sensitive information or information of hazardous biological materials by mitigating information risks that typically involves preventing or at least reducing the probability of unauthorized or inappropriate access to data, or the unlawful use, discloser, disruption, deletion, corruption, modification, inspection, recording or devaluation of information, is denoted as information security.
- Sensitive info includes but is not limited to-
  - Pathogen and toxin inventories,
  - Facility blueprints,
  - Security plan information,
  - Personally identifiable information (PII),
  - Protected health information (PHI), and
  - Other criteria established by an entity.



Program management

Reporting and communication:

- Departmental reporting of a security breach occur
- The laboratory must also notify the Biological Officer.
- Investigation into the breach will occur as appropriate.

Training:

- Laboratory security awareness training is required for anyone who has access to a laboratory. This training must be completed as soon as possible after hire.
- Full training on biosecurity is required for all new comers.
- Annual refresher training is offered to all staff members who participated in the full training previously.

Packing and shipping biological specimens

Shipment by Commercial Carrier

Shipment by Commercial Carrier

Laboratories must follow general regulations regarding -

1. Classification,
2. Packaging,
3. Labeling,
4. Documentation, and
5. Training

Planning

Call Recipient:

- Verify shipping address
- Obtain contact name & phone
- Verify when to ship
- Chain of custody form be filled out by shipping entity prior to transport

Note: Chain of custody form should remain with responsible individual throughout the entire transportation process and provided to the receiving entity upon arrival.

Guidance on Regulations

- You cannot transport infectious substances or diagnostic specimens on passenger aircraft as carry-on baggage
- Infectious substances cannot be shipped in diplomatic bags
- Transport of specimens within national borders must comply with national regulations.

WHO/CDS/EPR/2007.2

Guidance on regulations for the
Transport of Infectious Substances
2007– 2008

Applicable as from 1 January 2007

EPIDEMIC AND PANDEMIC ALERT AND RESPONSE

World Health Organization

Classification of Dangerous Goods

- Class 1 Explosives
- Class 2 Substances Gasses
- Class 3 Substances Flammable Liquids
- Class 4 Substances Flammable Solids
- Class 5 Substances Oxidizing Substances
- **Class 6 substances Poisonous and Infectious Substances**
- Class 7 Substances Radioactive Substances
- Class 8 Substances Corrosives
- Class 9 Substances Miscellaneous Dangerous Goods

Class 6.1 Toxic Substances

- Substances which pose a serious threat to human health or life if absorbed through the skin, swallowed, or inhaled
- Toxins from plant, animal or bacterial sources which do not contain any infectious substances, or toxins that are not contained in substances which are infectious substances should be considered for classification in Class 6.1 and assigned to UN 3172 and packaged according to the appropriate packaging regulation.

Class 6.2 Infectious Substances

- Organisms (e.g. bacteria, viruses, fungi) or substances that contain organisms that are infectious or that are reasonably believed to be infectious to humans or to animals.
  - Infectious Substance, Category A
  - Infectious Substance, Category B

Classification: Category A

- An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.
- A good rule of thumb is that if the material must be cultured using containment level 3 or higher containment then it must be shipped as Category A.
- Some organisms if present in any form, even in diagnostic samples must be shipped as Category A (e g Ebola virus) , e.g. virus), whereas many other organisms are Category A only if shipped as cultures (e.g. Hepatitis B virus, HIV).

Classification: Category B

- An infectious substance which does not meet the criteria for inclusion in Category A.

Cultures

- Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined below. Cultures may be classified as Category A or Category B, depending on the microorganism concerned.

Patient specimens

- These are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Biological products

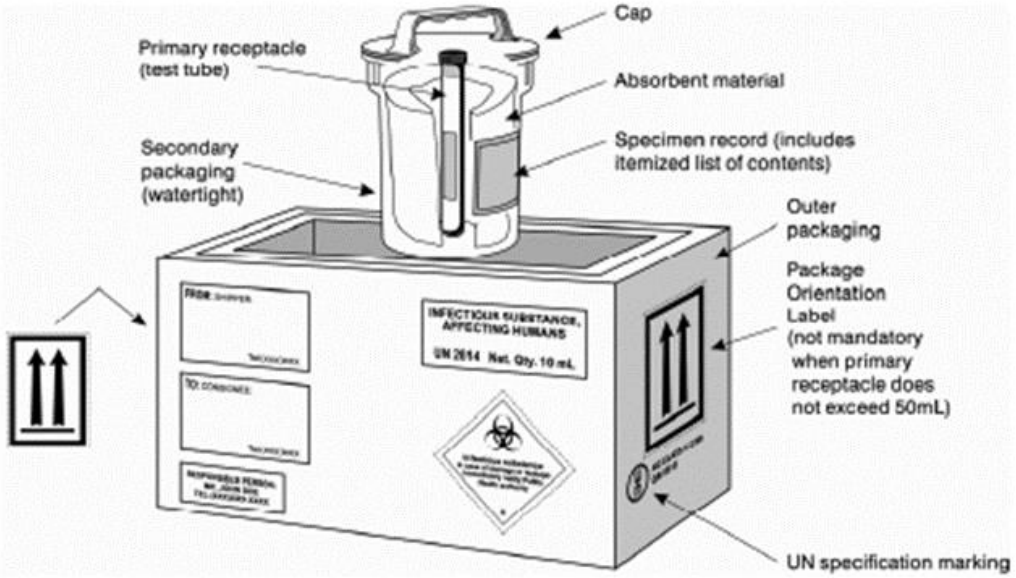
- These are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

Packaging, labelling and documentation requirements

Category A

All personnel involved in shipping pathogens must undergo appropriate training for the transport of Category A infectious substances, in accordance with the modal requirements..

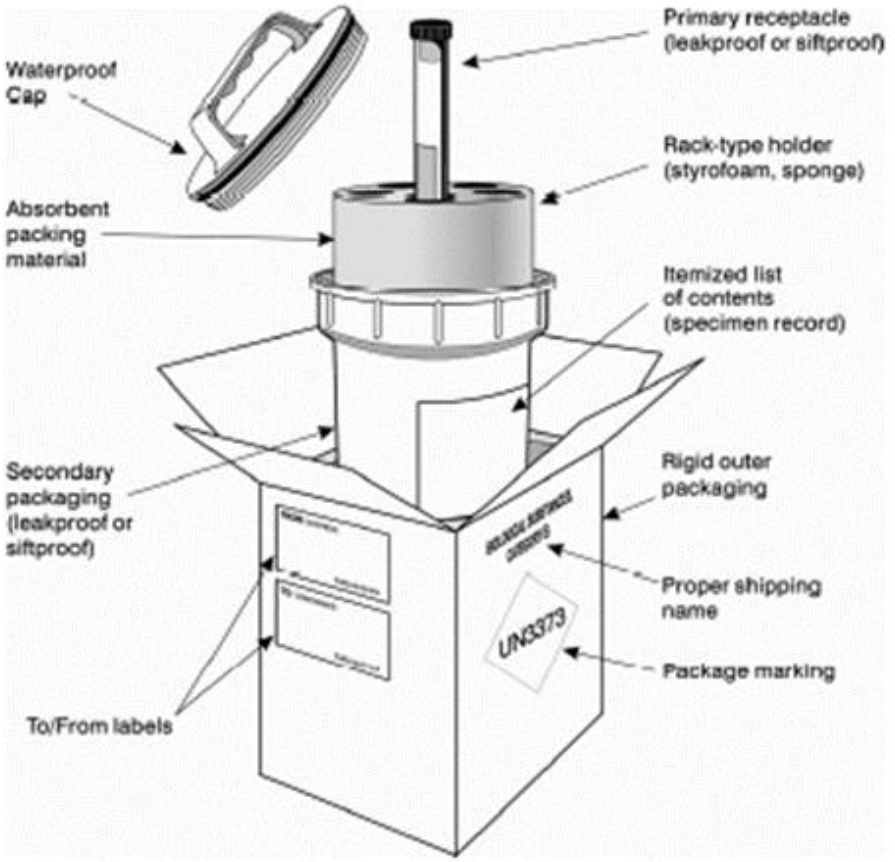
- Category A
  - Special training - attendance at approved courses and passing examinations



Category B

Category B

- Read the instructions! There is a requirement that clear instructions on the use of the packaging are supplied to the user. This is regarded as sufficient training for the shipping of these substances.
  - If specimens are sent with other dangerous goods (e.g. flammable liquids, radioactive materials, liquefied gases etc.), personnel must be trained in the procedures for their transport.



http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html

Part 3: Implementation of Biorisk Management Program

Biosafety & Biosecurity Program

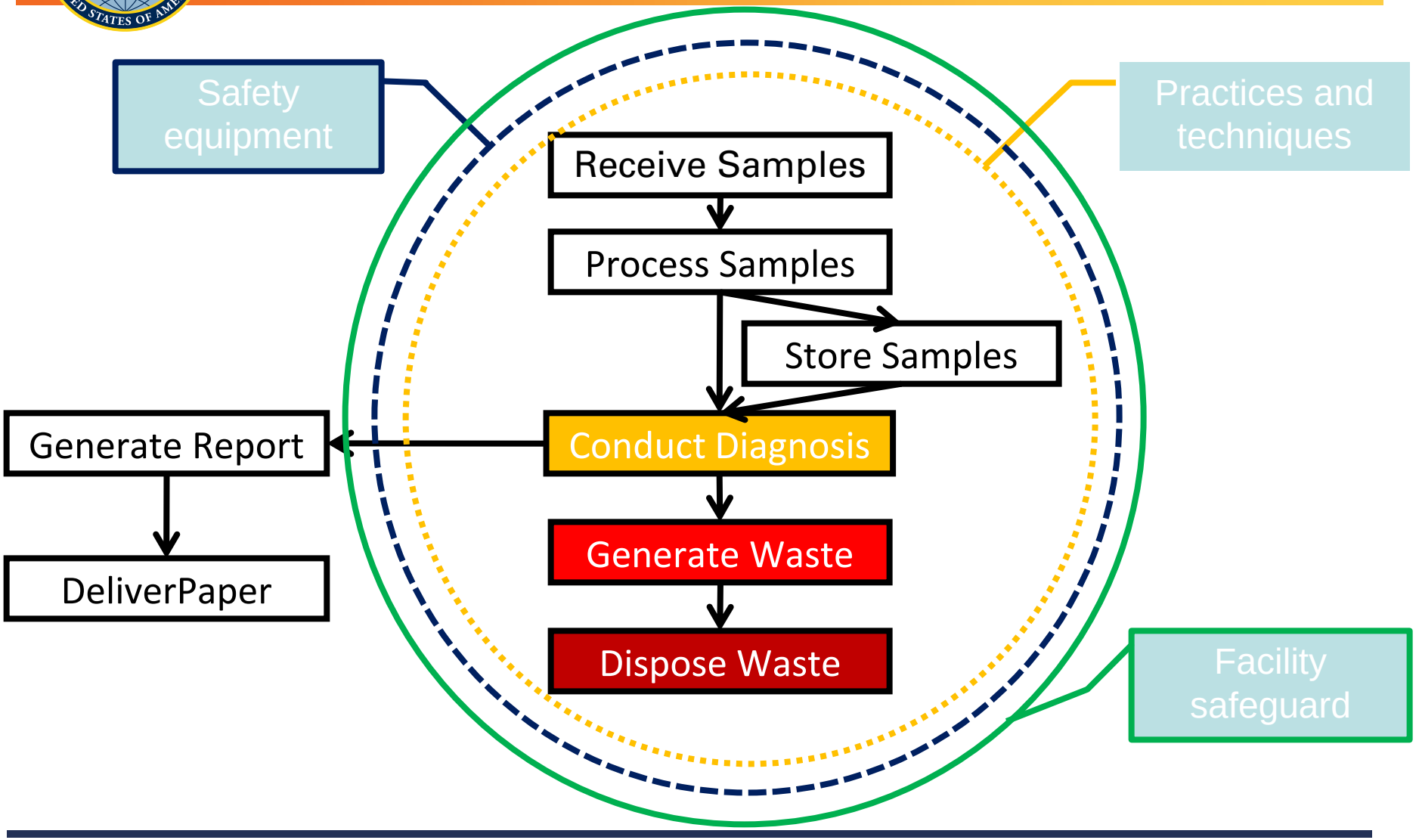
These past scientific developments have all helped initiate the need for Biosafety Program -

1. Institutional Biosafety Committee (IBC)
2. Biosafety Officer/Personal
3. Biosafety Manual
4. Safety Audit
5. Biological Waste Management
6. Orientation, full training and refresher training

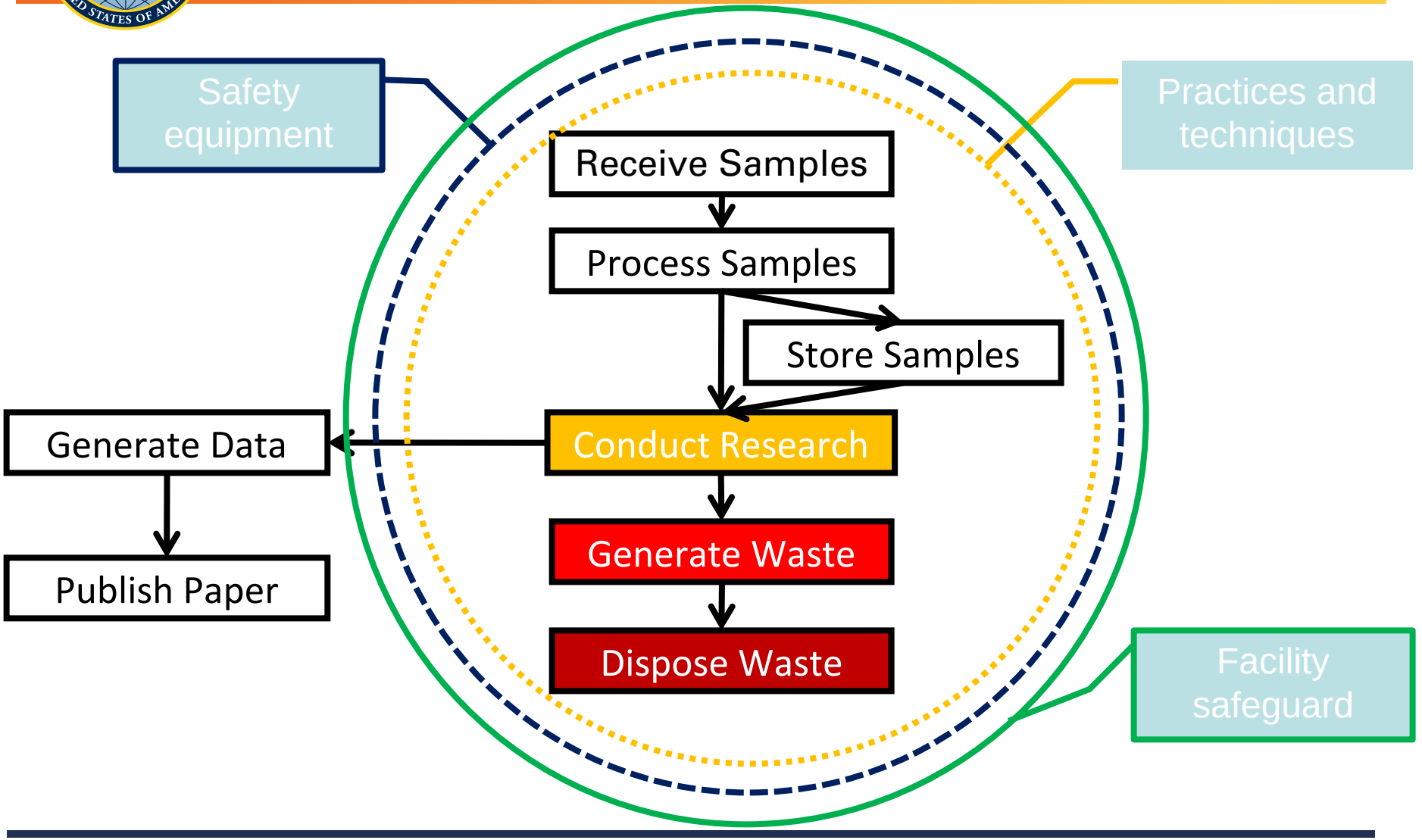
Biosecurity

- No formal Biosecurity committee requirements as yet.
- Movement of infectious agents or Microorganisms are tracked.
- Bioterrorism - real threat to the modern world.
- Biosecurity protocols should be included in the development of any new procedures.
- Awareness of practices in the laboratory are crucial.
- Keeping records of employee/visitor entry/exit; security britches/near misses; biological materials entry, storage, exit and disposal; local and international transportation; information security britches/near misses; and employee training and retraining.

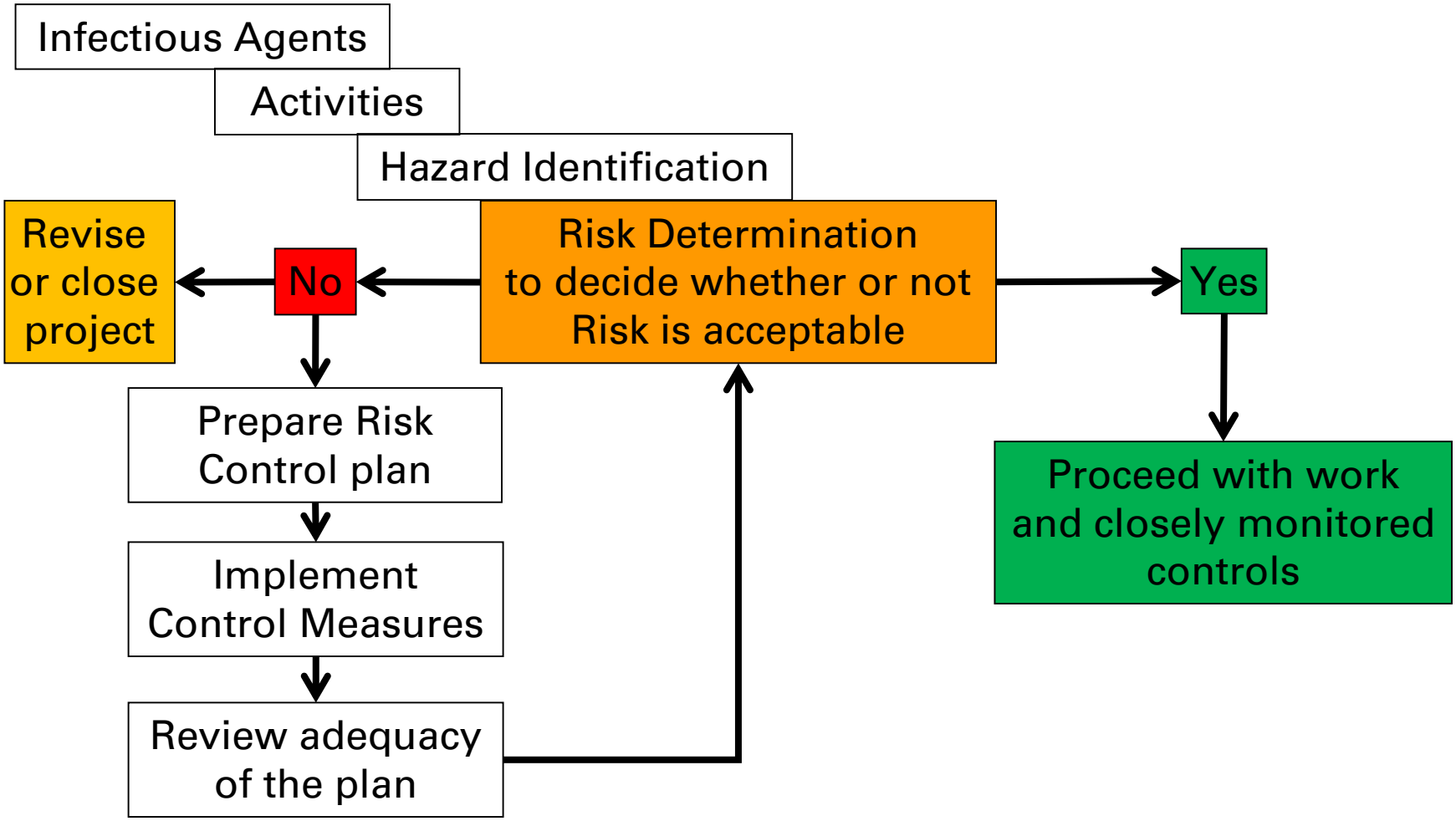
Diagnostic Laboratory



Research Laboratory



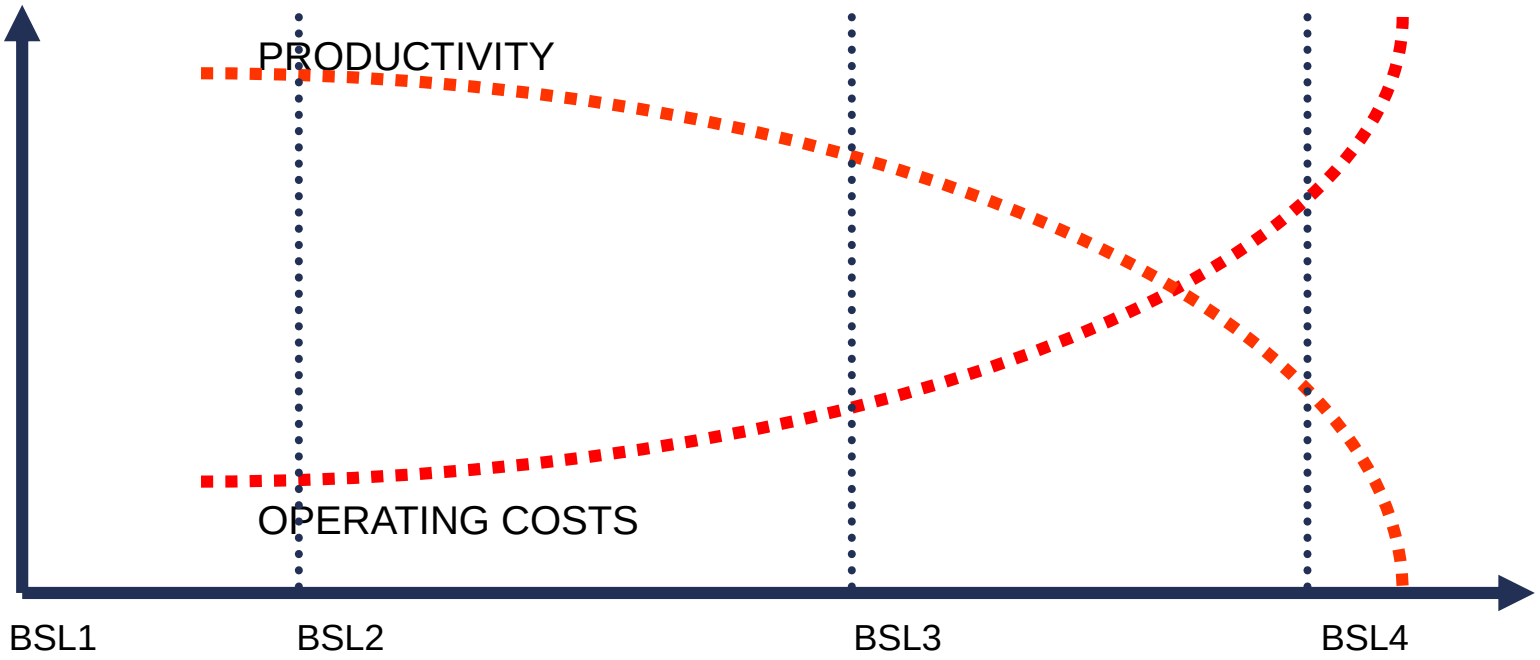
Biorisk assessment and management



Standard Operating Procedure (SOP)

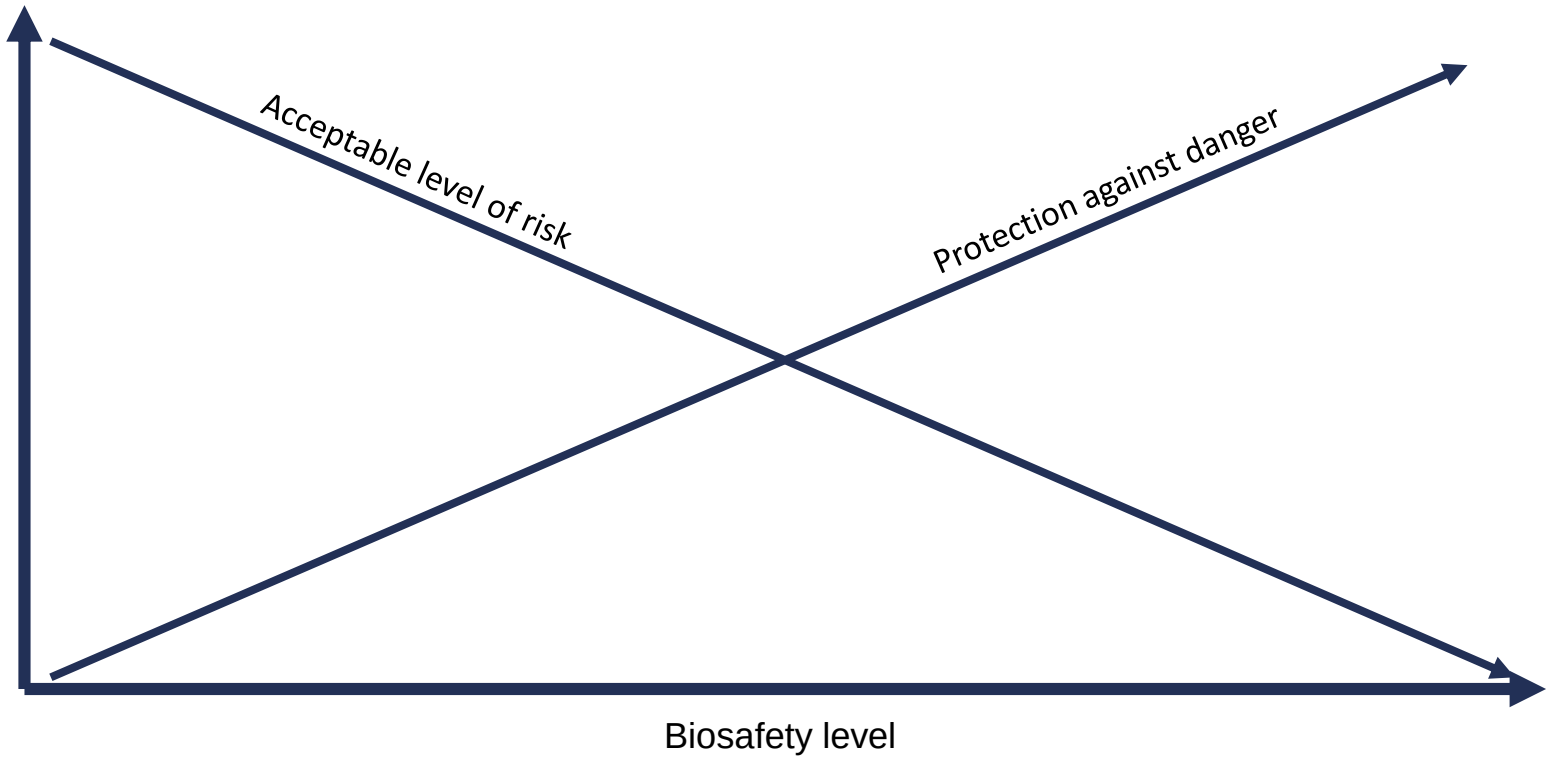
1. Purpose
2. Scope
3. Responsibility
4. Definition
5. Safety
6. Specimen
7. Materials/Equipment used
8. Principle
9. Procedures
10. Spill Cleanup
11. Waste Management
12. Incident Report
13. Record Keeping

Practice of Biosafety & Biosecurity



Impact of Biosafety Levels on productivity

Practice of Biosafety & Biosecurity



Smallpox

- The last cases of smallpox in the world occurred in an outbreak of two cases (one of which was fatal) in Birmingham, UK in 1978. A medical photographer, Janet Parker, contracted the disease at the University of Birmingham Medical School and died on September 11, 1978, after which the scientist responsible for smallpox research at the university, Professor Henry Bedson, committed suicide.
- In light of this incident, all known stocks of smallpox were destroyed or transferred to one of two WHO reference laboratories which had BSL-4 facilities; the Centers for Disease Control and Prevention (CDC) in the United States and the State Research Center of Virology and Biotechnology VECTOR in Koltsovo, Russia.

Training

- At all biosafety levels, personnel must be apprised of potential hazards upon assignment of a task, or when a procedural change occurs
- All staff must be trained for the tasks to which they are assigned and demonstrate proficiency
- Training must be *refreshed annually* and documented
- Personnel should be given information regarding how personal health status can affect susceptibility

Conclusions

- Principles of biosafety are biological risk assessment and containment, and on the other hand, principles of biosecurity are limiting access to facilities, research materials, and information
- First concentrate on strengthening that basis and beware not to neglect it
- Concerted effort to implement biosafety and biosecurity standards is the utmost need for research and diagnosis with biological hazards

Acknowledgements

- Dr Hubert P Endtz, Professor of Tropical Bacteriology, Department of Medical Microbiology & Infectious Diseases, Erasmus MC
- Dr Barbara Johnson, Biosafety and Biosecurity International
- Dr Natasha K. Griffith, Associate Director of Operations, High Containment Core at Georgia State University
- Biosecurity Engagement Program (BEP) of The US Department of State
- CDC, Atlanta, USA

Thank you