Biosafety&Biosecurity
Biology 2022-2023
First stage
Morning&Eveninig

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Occupational Safety and Health

Occupational safety and health is defined as the science concerned with preserving human safety and health, by providing safe working environments free from the causes of accidents, injuries or occupational diseases, or in other words it is a set of procedures, rules and regulations within a legislative framework aimed at preserving the human being from the risk of injury and preservation on the property from the risk of damage and loss.

Occupational safety and health are involved in all areas of life. When we deal with electricity or household electrical appliances, it is essential to follow safety rules and their principles, and when driving cars or even walking on the streets, we need to follow safety rules and principles. To safety rules, but we can say that when taking medicines for treatment or food for the growth of our bodies, we need to follow safety rules.

General objectives of the Occupational Safety and Health

1. Protecting the human from injuries resulting from the hazards of the work environment by preventing them from being exposed to accidents, injuries and occupational diseases.
2. Preserving the components which represented in the installations and the devices and equipment they contain from damage and loss as a result of accidents.
3. Providing and implementing all occupational safety and health requirements that ensure the provision of a safe environment that achieves protection from risks for the human and physical components.
4. Occupational safety and health as a scientific approach aims to establish safety and assurance in the hearts of workers while they carry out their work and to reduce the worry and fear attacks that trouble them as they coexist by virtue of the necessities of life with tools, materials and machines in whose folds there is a danger that threatens their lives and under insecure conditions that expose their lives from time to time to dangers Fatal.

In order to achieve the above-mentioned goals, the following elements must be available: -

1. Proper and targeted technical planning of the foundations of prevention in facilities.
2. Legislation stemming from the need to implement this technical planning
3. Implementation based on sound scientific foundations for construction operations, with the provision of specialized technical devices to ensure the continued implementation of occupational safety and health services.

Biosafety

Biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. The maintenance of safe conditions in biological research to prevent harm to workers, non-laboratory organisms, or the environment.

A fundamental objective of any biosafety program is the containment of potentially harmful biological agents.

The term “containment” is used in describing safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained.

Technical Definitions

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

- **Biosafety:** The containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.
- **Biosecurity:** Control of accidental and deliberate release of biohazardous material.
- **Hazardous waste** is defined by the US Environmental Protection Agency (EPA) as a waste or a mixture of several wastes that pose a threat to human health or other living organisms, whether in the short or long time as: -
- A- Non-degradable and durable in nature.
- B- Or it may cause harmful cumulative effects.

There is another definition of hazardous waste by the British government, which is; "Hazardous waste is toxic or harmful to public health, or it is pollutant material that leads to environmental damage, which poses a threat to human health and living organisms as a result of pollution of environmental elements with these materials, especially surface and groundwater sources."

To control hazardous waste and reduce its damage to the environment and public health, many countries have put in place legislation to control hazardous waste and dispose of it in safe ways to reduce its potential risks to humans, animals and plants, but these controls were recently introduced and their application is relatively due to the presence of many The abuses that are carried out outside the scope of control, as there are many cases in which dangerous levels of toxic substances are discovered in them, and for the ease of classifying these wastes, they have been placed into five main groups :

1. Radioactive materials
2. Chemicals
3. Biological waste
4. Flammable waste
5. Explosives

Biological waste. This group includes medical waste and waste resulting from biological research, and includes medical wraps resulting from emergency departments and operating rooms in hospitals and medical clinics, in addition to syringes and human tissues, damaged blood units, dead animal corpses, as well as expired medical drugs. Some of these wastes may be toxic, and others pose a risk to health as a result of bacterial contamination, so it must be handled with sufficient care to ensure that it does not affect public health, especially for the people who deal with it, whether in collecting or transporting and disposing it, and it can be collected in paper bags lined with material Wax, or plastic bags, and placed inside lined metal containers.

Treatment and drainage methods

The choice of appropriate treatment and disposal methods depends on the type of waste, its degree of risk and its quantity, and the following are some of the options available for this purpose:

A. Recycling and recovery.

B. Alter the chemical or physical properties using one or some of the following methods:

1. Incineration and pyrolysis
2. Biological treatment
3. Chemotherapy
4. Physical treatment

Mitigation and drainage

Storage by using permanent underground stores; Mines, silos, or warehouses in the form of tanks built underground to be insulated to prevent leakage into the groundwater.

The governmental authority concerned with the health and safety of the environment must have approved systems for controlling hazardous wastes before disposal, using a special form in which data related to hazardous wastes. The type of waste, quantity, and other specific information related to the waste. In light of this information, the appropriate method for its final disposal shall be determined.

Decontamination in the laboratories of Microbiology

There are other ways to remove contamination such as use of dry heat, as well as the microwave, ultraviolet and ionizing rays may not be suitable in microbiology laboratories.

There are new techniques such as alkaline analysis or alkaline digestion that may be an alternative to incinerators in some cases.

Some contaminated materials or tools that have microbial contamination are removed with an autoclave can then be washed, reused or recycled.

Sodium hypochlorite and phenolic compounds are the materials most used in disinfection in laboratories as a general use, but there are other materials that are used according to the purpose for which they are used, such as some substances with surface activity or degreasers, and this includes alcohol, iodine and other oxidizing materials, as well as lowering the pH level it is effective in some cases.

Procedures and methods of trading and dealing with laboratory waste

The laboratory must adopt a system for identifying and separating infectious substances and their packages, and that system includes certain directions, for example:

Non-infectious waste can be recycled or reused like normal household waste.

Contaminated materials with sharp ends such as syringes, scalpels, knives, and shattered glass. All these items must be collected in non-perforating containers that are well sealed and treated as dangerous infectious substances.

The use of autoclaves is the preferred method for all decontamination operations, and there are materials that are intended to be decontaminated or disposed of that must be placed in packages.

The responsibility of management in achieving safety at work sites: -

1. Spreading awareness among workers.
2. Training individuals before starting their work, informing them of the risks of work, and ways to prevent them.
3. Direct control and supervision of the work environment.
4. Providing the work site with the required devices, such as devices for measuring temperature and humidity, devices for measuring work environment pollutants ... etc.
5. Taking appropriate measures when violating these regulations.
6. Form a special committee for occupational safety
7. Supporting safety programs.
8. Ensure that the right individual is appointed in the appropriate location.
9. Determining the responsibility of each individual.
10. Follow up on accidents, and take appropriate measures to prevent them from recurring.
11. Determining working and rest times.

Why we need Biosafety?

Some unfortunate examples of disease outbreaks in research labs:

1950-1976:

•A survey of 5000 labs showed 3921 cases of disease outbreaks

•Most commonly reported were: Hepatitis, tuberculosis, typhoid, brucellosis, rabbit fever

2003-2014:

•SARS infects researchers in a lab in Singapore

•AUS. and a Russian scientist are infected by Ebola. One survives, one dies.

•Polio virus escapes from two Indian labs.

•Scientists from Boston University contract rabbit fever (a serious bacterial disease).

•Anthrax exposure in a Huston lab due to aerosols leaked inside an unshielded Centrifuge.

- Dengue
- Ebola

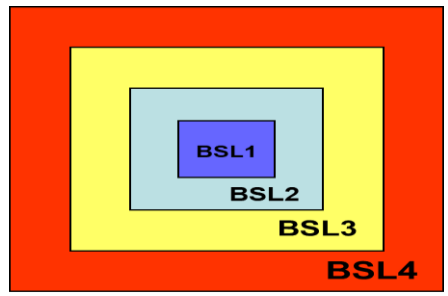
- Support medical and scientific research on microbes and the human immune response to them.
- Apply such research to the discovery and development of vaccines, drugs, and diagnostic tests designed to protect the general population
- Ensure that the ever has sufficient research facilities to carry out these activities.

Biosafety is related to several fields

- ECOLOGY
- AGRICULTURE
- MEDICINE
- CHEMISTRY
- EXOBIOLOGY

Biosafety is related to several fields

- **ECOLOGY:** referring to imported life forms not indigenous to the region.
- **AGRICULTURE:** reducing the risk of alien viral or transgenic genes, or prions such as BSE/"Mad Cow "; reducing the risk of food bacterial contamination
- **MEDICINE:** referring to organs or tissues from biological origin, or genetic therapy products, virus; levels of lab containment protocols BSL-1, 2, 3, 4 in rising order of danger



- **CHEMISTRY:** i.e., nitrates in water, PCB levels affecting fertility
- **EXOBIOLOGY:** i.e., NASA's policy for containing alien microbes that may exist on space samples - sometimes called "biosafety level 5"

Biosafety containment levels

- **Biosafety levels**
  - Level 1& 2: basic laboratories.
  - Level 3: containment laboratories.
  - Level 4: high containment laboratories.
  - Level 5: NASA's policy for containing alien microbes.
- Each level associated with appropriate equipment, practices, work procedures. Diagnostic and health-care laboratories must be biosafety level 2 or above.
- **Risk group classification**

Risk Group	Individual risk	Community risk
1	no, low	no, low
2	moderate	low
3	high	low
4	high	high

5	high	high

- **Risk Group 1**: Unlikely to cause animal or human disease, non-pathogenic agent
- **Risk Group 2**: Pathogenic for humans, Unlikely a serious hazard, Treatment and preventive measures available, limited risk of spread of infection.
- **Risk Group 3:** Pathogenic, cause serious disease, Effective treatment and preventive measures usually available, little person-to-person spread.
- **Risk Group 4:** Lethal, pathogenic agent, Readily transmittable
  Direct or indirect, effective treatment and preventive measures not usually available

This table shows risk groups, biosafety levels, practices and equipment

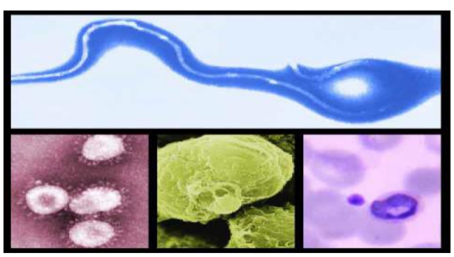
BSL	Laboratory type	Laboratory practices	Safety equipment
1	Basic teaching, research	Good microbiological techniques	None Open bench work
2	Primary health services; diagnostic services, research	Good microbiological techniques, protective clothing, biohazard sign	Open bench PLUS biological safety cabinet for potential aerosols
3	Special diagnostic services, research	As BSL 2 PLUS special clothing, controlled access, directional airflow	Biological safety cabinet and/or other primary devices for all activities
4	Dangerous pathogen units	As BSL 3 PLUS airlock entry, shower exit, special waste	Class III biological safety cabinet, positive pressure suits, double ended autoclave (through the wall), filtered air

Biohazard Symbol

- In 1966, Charles Baldwin at National Cancer Institute at NIH (National Institute of Health).
- Symbol to be memorable but meaningless" so it could be learned.
  (الرمز الذي لا ينسى ولكنه لا معنى له "حتى يمكن تعلمه)
- Blaze orange – most visible under harsh conditions
  (اللون البرتقالي - أكثر وضوحا تحت الظروف القاسية)

Biosafety Issues

- Laboratory Safety
- Blood borne pathogens (BBP)
- Recombinant DNA (rDNA)
- Biological waste disposal
- Infectious substance and diagnostic specimen shipping



- Respiratory Protection
- Bioterrorism and Select agents
- Outdoor and indoor air quality
- Occupational safety and health in the use of research animals
- Biohazards used in animal models

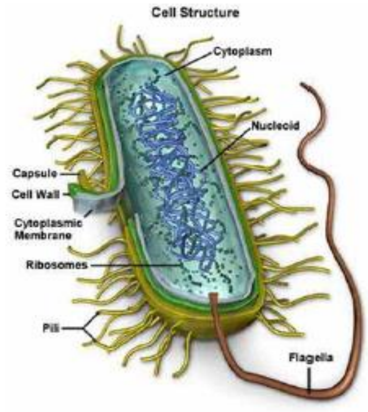
What are biological hazards?
Biological hazards - bacteria, viruses, mold and parasites have the ability to multiply quickly if given the right conditions or it is the negative effect of some microorganisms on the human body) The biological hazards have a strong and dangerous effect when exposed to them, they lead to death or infection with serious and infectious diseases, and the biological risks lie in occupational exposure to infectious microorganisms, their toxic secretions and parasites

Biohazards Materials

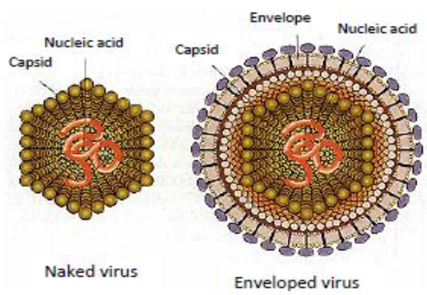
- Viruses
- Bacteria
- Fungi
- Chlamydia/Rickettsia
- Prions
- Recombinant DNA

Types of pathogens
Bacteria
– Size: 0.3 to 2 µm
– Single-celled organisms
– Various morphologies
– Examples: *Salmonella spp., E. coli, Vibrio spp.* (Cholera), *Mycobacterium* (Tuberculosis)

Lung infected by tuberculosis



- **Virus**



Girl with polio

– Size: 18-200 nm
– Basic structure: capsid (protein) + nucleic acid
– Obligate parasites
– Enveloped vs. non-enveloped
– Examples: Hepatitis, polio, HIV

Protozoa

Size: 5-10 µm
– Single-celled eukaryotes
– Numerous morphologies
– Examples: *Cryptosporidium* spp., *Plasmodium* spp. (Malaria), *Giardia* spp.

Giardia

Malaria patient

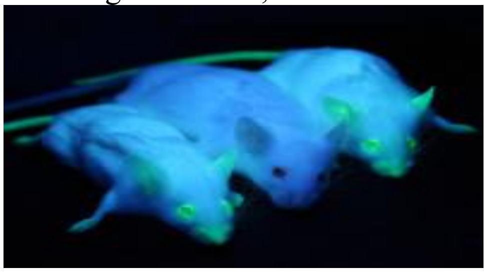
Helminthes

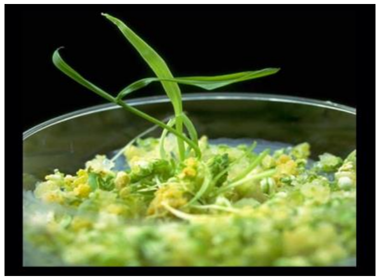
- – Size: 20-100 µm
- – Multi-cellular eukaryotes
- – For transmission mainly concerned with eggs

Ascaris lumbricoides egg
- Causes human roundworm
- 70 µm length

Biohazardous Materials

- Transgenic Plants, Animals and Insects



- Human and Primate Cells, Tissues, and Body Fluids

Pathogen risk assessment

To analyze the biological risk, we must take into account:

- Pathogenicity/infectivity
- Virulence/lethality
- Infective dose
- Therapy/Prophylaxes
- Epidemic potential
- Resistance
- Survival in the environment
- Geographic spread (endemic)
- Mode of transmission

Control of biological hazards

The best way to prevent disease is to reduce or eliminate exposure to biological agents. Here are some tips to protect yourself from injury:

1. Practice good personal hygiene (such as regular hand washing) it is one of the best ways to prevent cross infection.
2. Keep your vaccinations up-to-date.
3. Ensure that any equipment that may harbor biological hazards (such as fans, ventilation systems) is regularly maintained, cleaned and sterilized.
4. Cleaning and disinfecting work surfaces often.Clean up stains instantly.
5. Treat and dispose of all hazardous biological waste safely. Wear personal protective equipment (such as gloves, masks), where appropriate

Methods of control biological hazards

A. Construction design and furnishing of the laboratory

When preparing and equipping science laboratories, the following requirements and rules have been taken into consideration, which will help in reducing and controlling risks:

1. The area of the laboratory must be proportional to the numbers of students, in order to allow them freedom of movement during the conduct of experiments without crowding.
2. There must be two doors in the laboratory hall for entry and exit, and the direction of opening the doors should be to the outside (in the direction of people rushing).
3. Windows shall be provided with fire-resistant curtains and movable protection bars.
4. Equipping laboratories with natural and industrial lighting and ventilation in accordance with the permissible limits tables in this field, and following up on the periodic maintenance process for lighting and industrial ventilation equipment.
5. Floors for laboratories, sinks and tables must be of types that are not affected by chemicals.
6. A gas cabinet (the room for hazardous reactions) must be provided for use when preparing harmful or unpleasant-smelling gases such as hydrogen sulfide gas, carbon monoxide, chlorine gas, nitrogen peroxide and others.
7. The necessity to equip laboratories with comfortable and easy-to-move seats inside the laboratory, whose height can be controlled according to the student's height.
8. The laboratories must be equipped with a sufficient number of electrical points with covers (socket protectors) on both the laboratory walls and the student and teacher tables.
9. The gas pipelines must be made of copper pipes so as not to rust and be carried out in accordance with the technical principles recognized in this field to ensure that gas does not leak in the laboratories.
10. A special cabinet for gas cylinders must be allocated to the laboratory in one of the corners of the school far from the laboratory, and it must be safe and closed continuously to prevent tampering with gas cylinders and it is strictly forbidden to place gas cylinders inside the laboratory.The laboratory gas system should be equipped with a control switch and placed in a visible location that can be easily and quickly accessed in emergency situations.
11. Laboratories must be equipped with the necessary water and sewage installations.The necessity of equipping the laboratory record room with water, gas and electricity installations, a desk and a table or a shelf for conducting experiments.
12. The necessity to equip laboratories with storage rooms for tools, devices and chemical materials and separate from the laboratory record office and are equipped with cabinets, drawers, and a refrigerator to preserve chemicals, and these stores must be well ventilated.
13. It is recommended that the chemistry laboratory be equipped with mobile transport vehicles to transport devices, tools and materials from the preparation room to the laboratory and back, in order to save time and effort and prevent injuries that may occur as a result of dropping chemicals or tools as a result of collision while transporting materials and tools manually.
14. Laboratories must be equipped with primary firefighting means (fire extinguishers and dry sand buckets) and keep them in a visible place in the laboratory and carry out regular

maintenance for them on an ongoing basis and ensure their suitability for use in emergency situations.

15. A cabinet should be provided for first aid and first aid supplies, and chemistry laboratories should be equipped with an emergency shower in order to quickly carry out the first aid operation in the event of injuries to anyone in the laboratory.
16. It is recommended to provide a means of communication to the administration and an alarm device to alert those present in the laboratory in the event of a fire, provided that it be connected to the main fire alarm panel located in the guard's room.

Note: - The laboratory must not be used for anything other than the purpose that it was established for, and in the event of an urgent need for that, a modification must be made in the laboratory that is compatible with the nature of the new work.

2. Training and qualification of laboratory personnel

Training and qualification is of particular importance in reducing work risks. There are many definitions of the concept of training, but in its general entirety, it aims to define training as the process of improving the performance of an individual, building his capabilities and developing his skills and behaviors, in a way that directly affects the performance of his tasks in the best way and according to what is required.

Based on these basic concepts of training, the importance of training appears for the new employee and the old employee alike. A new employee who has recently joined the organization may not have the skills and experience necessary to perform the job duties with the required efficiency.

3. The right choice for those working in laboratories

There is a famous saying (the right person in the right place)

None of the workers in the field of microbiology or biomedical laboratories is allowed to work before verifying his background in dealing with this type of laboratory that includes microorganisms.

In many cases, some people are assigned tasks that they do not have sufficient experience to do. Or do not possess the scientific and physical qualifications for that.

4. Work Permits

A. Hot work permits:

These permits are issued for the completion of work that takes place in a dangerous area, as this hot work may pose great risks.

B. Cold work permits:

This type of permit is issued for the performance of actions that are not likely to have significant risks when carrying out them.

General precautions that must be followed when issuing work permits

Each type of work permit has the necessary precautions for it, but in general there are some general precautions that must be taken into account in all types of permits, including:

1. The correct choice of the type of work permit.

2. The described process should be specific and clear.

3. Determine the equipment on which the operation is performed.

4. The time allotted for the validity of the permits must be specified.

5. The workplace must be examined by the authority issuing the permits and permit executors before the permit issuance begins.

6. The necessary procedures for the mechanical isolation operations must be specified.

7. The necessity or not to implement the electrical separation operations must be determined.

8. The necessity of conducting gas detection operations must be determined.

9. The necessary safety tasks and equipment must be specified.

10. In cases of emergency, all work permits are suspended and canceled immediately.

5. Human relationships

Human relations are highlighted in their goals through the following: -

1-. Achieving the principle of cooperation between workers in the work environment on the one hand, and in aspects of society on the other hand, to enhance friendly ties, close understanding, and mutual trust.

2-. Achieving increased production, which would be an expected result of increased cooperation.

3- Achieving the fulfillment of the diverse needs of individuals, and achieving the objectives of the organization in which they work.

4-. Achieving high morale among working individuals in order to create a general psychological atmosphere in favor of work and production.

The most important behaviors of human relations

Humility, Encouragement, Cooperate, Justice

Good example, the responsibility, mercy.

6. Psychological state and mental of safety

Excessive workloads. Conflicting demands and lack of clarity of the role. Not being involved in making decisions that affect workers and having no influence over the way the job is done.

Poorly managed organizational change, job insecurity. Ineffective communication, lack of support from management or colleagues. Psychological and sexual harassment, and third-party violence.

7. The division of labor system

1- Increasing the skill in performing the work, in order to simplify the required work.

2- Organize work in an efficient manner in terms of timing, sequence and supervision.

3- Save time and reduce waste during worker transition from one process to another.

4- Facilitating the use of the machine as a result of dividing the production process into several partial operations.

5- All of the above leads to an increase in production efficiency and an increase in production.

6- And most importantly, division of work and specialization contribute effectively to reducing work accidents

8.Follow-up and continuous inspection

In all scientific institutions there are occupational safety units or safety committees. It is professional in proportion to the size of the facility and one of the duties of these departments is to control and inspect all works that take place inside it.

Inspection includes the following:

The extent to which workers apply safety and security instructions.

Inspection of devices and equipment.

Conditions for material transfer

Proper storage methods .... etc.

9. Issuing instructions and legislation laws when needed

There are general instructions in the occupational safety literature that can be used in controlling work risks, but each institution maintains the privacy of its work, so it is the responsibility of a department, unit or occupational safety committee to issue instructions for work as well as to legislate laws that would reduce work accidents.

10.The media role

The media side has a special importance in reducing accidents and controlling work risks by raising awareness among workers and clarifying the danger of work and how to prevent risks. Among the most important methods adopted for this are: -

1- Signs and stickers.

2- Holding seminars.

3- Establishing workshops.

4- Issuing awareness brochures.

5- Audio and video means.

11.Proper storage

Many accidents happen as a result of poor storage in the laboratories so it's a duty attention to providing suitable storage conditions:

1- The materials shall be stored in places prepared for storage.

2- All appropriate conditions are taken into consideration for each article.

3- Not to store the dangerous materials with regular and traded materials.

4- Not to store dangerous materials with food .... etc.

12.The last line of defense (PPE)

After applying all the previous procedures, it became necessary to wear personal protective equipment**(PPE)** and according to the type of work, and here comes a responsible role biosafety and laboratory supervisors and do not forget the important role of the administration in providing these requirements.

Biological Agent:

- The number of microorganisms required to initiate infection

Q fever	**10 organisms by inhalation**
E. coli	**10^8 organisms by ingestion**
Malaria	**10 organisms by IV injection**
Poliovirus 1	**2 pfu (plaque- forming unit) by ingestion**

Biosafety Levels of Containment

Containment involves a combination of laboratory issues to include:

- Standard microbiological practices (Personal protective equipment).
- Safety equipment (Primary barrier).
- Laboratory facilities (Secondary barrier).

Standard Microbiological Practices

1. Needles & sharps precautions
   - Use sharps containers
   - DON'T break, bend, re-sheath or reuse syringes or needles
   - Use alternatives to needles when available
2. Use mechanical pipetting devices
3. Wash hands

Safety Equipment (Primary Barrier)

- Biological Safety Cabinet

1. To protect product, personnel and the environment.
2. Equipment is laid out to not restrict airflow in the cabinet.

Facility Design (Secondary Barrier)

- Facilities PLUS:

—Decontamination method

•Autoclave may be available

•Off-site program

—Eyewash station present

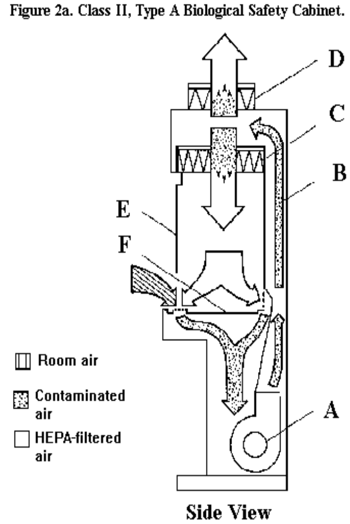
- **Biological Safety Cabinets (BSCs)**

– Protection of

—Product

—Personal

Figure 2a. Class II, Type A Biological Safety Cabinet.



– Environment

- Biological Safety Cabinet Airflow
  A. Blower
  B. Rear plenum
  C. Supply HEPA filter
  D. Exhaust
  E. Sash
  F. Work surface
- Biological Safety Cabinet Operation
  1. Not designed for chemical use
  2. May be used for non-volatile toxic chemicals or low-level radioactive materials
  3. May be used for "minute" amounts of volatile chemicals <u>if canopy connected</u>

Ensure annual certification
Place all work materials into cabinet before starting

- **Biological Safety Cabinet Operation**

CAUTIONS

– Chemicals may damage HEPA filter
– Volatile chemicals NOT retained by HEPA filter
– Exposes personnel if not exhausted
– Fans NOT spark proof
– Chemical use may result in fire and/or explosion
– Never use flammable
– Open fire can damage HEPA filter

Elements of Biosafety

Preventing lab-acquired infections

1. Bacteria
2. Viruses
3. Fungi
4. Human blood, unfixed tissue
5. Human cell lines
6. Recombinant DNA

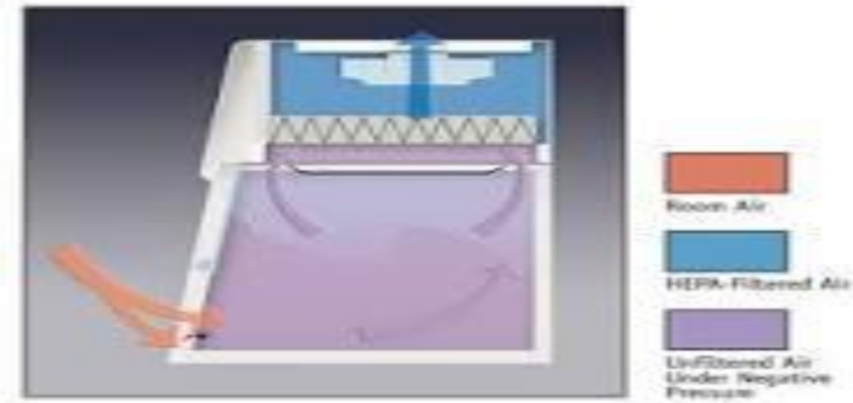
Biosafety in Microbiological and Biomedical Laboratories.
Biosafety/Cabinets

Use of Biosafety Cabinet

1. Turn on fan 15 min before starting
2. Don't block grille
3. Disinfect work surface 70% alcohol
4. Discard pipets inside cabinet
5. Minimize movement of hands
6. Avoid use of flame unless necessary
7. Have cabinet certified annually

What are the different types of biological safety cabinets?

There are three classes of biosafety cabinets designated in the United States: **Class I, Class II, and Class III**. Class I biosafety cabinets are infrequently used and provide personnel and environmental protection but no product protection.



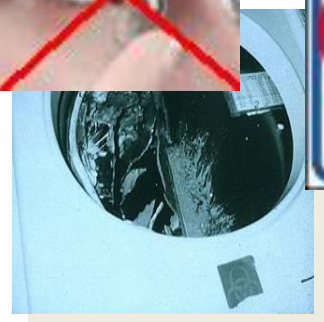
Class II BSCs are designed with an open front with **inward airflow (personnel protection)**, downward HEPA-filtered laminar airflow (product protection) and HEPA-filtered exhaust air (environmental protection).

The Class III biological safety cabinet was designed for work with biosafety level 4 (BSL-4) microbiological agents, and **provides maximum protection to the environment and the worker**. It is a gas-tight enclosure with a non-opening, completely sealed, viewing window.

Biosafety Cabinets (BSCs) are **enclosed workspaces with** a ventilated hood that is designed to contain pathogenic microorganisms during microbiological processes. ... BSCs are an essential part of biosafety as they minimize the formation of aerosol, protecting the environment, the pathogen, and the laboratory personnel.

Centrifuge - Hazards

- Mechanical failure
- Lab equipment failure
- Aerosol generation
- Operator error

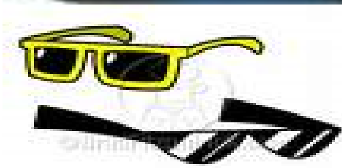


Ultraviolet Lamps in BSCs

UV lamps are not required or recommended in BSCs. If operated properly, BSCs do not need UV lights.

If installed UV lamps must be:

- Cleaned weekly to remove dirt and dust (they block germicidal effectiveness of UV light)
- Checked periodically to ensure the appropriate intensity of UV light is being emitted
- Turned off when the room is occupied to protect eyes and skin from UV exposure
  **can burn the cornea and cause skin cancer



Biohazard work area

Mark the work area with the Warning sign and contact information

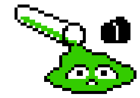
OSHA Standard requires:

1. Annual training
2. Web-based program/DES homepage
3. Free HBV vaccine
4. Use of Universal Precautions

Standard Microbiological Practices

- NOT permitted in laboratories:
- Eating .

- Drinking.
- Smoking.
- Handling contact lenses.
- Pipetting by mouth.
- Storing food and drink.



- ALWAYS wash hands:
- After handling microorganisms and animals.
- After removing gloves.
- Before leaving laboratory.

- Discard needles, razor blades, and scalpel blades into red, puncture resistant sharps containers.
- Dispose of broken glass into "broken glass" containers, never regular trash.

- NEVER
  1. recap, bend, or break needles.
  2. discard needles or sharps into biological waste bags.
  3. discard needles into regular trash.
- Decontaminate all biological waste (including BL1) before disposal Solid waste (Petri dishes, cultures): autoclave and put in dumpster.
  Liquid waste: add disinfectant (bleach to 10%) and pour down drain.

Autoclaves

Autoclaves use pressurized steam to sterilize materials.
There is usually steam remaining in the chamber at the end of a liquid cycle.

Autoclave Safety

1. Opening door at end of liquid cycle:
   - **i)** Wear eye and face protection.
   - **ii)** Stand behind door when opening it.
   - **iii)** Slowly open door only a crack to allow residual steam to escape.
   - **iv)** Keep face away from door as it opens.

2. Removing liquids at end of cycle:
   - **i)** Wait 5 min. before removing liquids.
   - **ii)** Liquids removed too soon may be super-heated and boil up and out of container.
   - **iii)** Aim mouth of flask away from face.
   - **iv)** Don't knock flask against bench.

Standard Microbiological Practices

1. Decontaminate work surfaces daily and after any spill of viable material.
2. Report accidents.
3. Tell Health Care Provider that you work with infectious agents or chemicals.

Think Again
You've carefully thought out all the angles.
You've done it a thousand times.
Nothing could possibly go wrong, right?

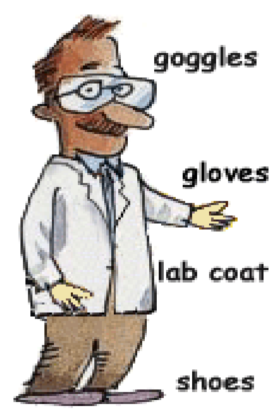
فكر مرة اخرى
لقد فكرت بعناية في جميع الزوايا.
لقد فعلت ذلك ألف مرة.
لا شيء يمكن أن يخطئ ، صحيح؟

- **Hand Washing**
1. Wash hands immediately after removing PPE (personal protective equipment)
2. Use a soft soap
3. A hand sanitizer can be used but wash with soap and water as soon as possible.

- **Personal Protective Equipment** (**PPE**)
1. PPE can become an important line of defence (last line of defence).
2. USE proper PPE

Spills

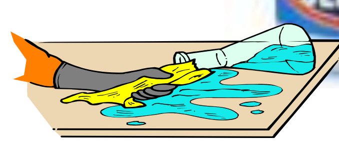
- Spill response will vary depending on:
  - What was spilled?
  - How much was spilled?
  - Where was the spill?
  - What is the potential for release to the environment?
- Spills should be cleaned up immediately to ensure proper decontamination.
- <u>All spills</u> are to be reported to the lab supervisor and Safety office.



When cleaning up surfaces use 10% bleach solution or approved disinfectant (<u>Mix bleach solution fresh each time</u>.)

- Put wipes or paper towel on top of the spill
- Spray and allow it to stand for at least ten minutes before wiping up.
- Dispose of all wipes in biohazard containers.
- Decontaminate any materials used to clean up blood or OPIM (mops, sponges, buckets, etc.)
- PPE should be removed and disposed of in biohazard containers.

➢ **Decontamination**



- Generally, for disinfection rather than sterilization
- Choice depends on;
  - Type of material to be disinfected
  - Organic load
  - Chemical characteristics
- Most common are chlorine compounds and alcohols (broad range)

Disinfection: What to use for my organism?
Bacteria
Vegetative bacteria (E. coli,)

- 2% domestic bleach
- 75% Ethanol
- Quaternary ammonia
- 6% formulated Hydrogen peroxide*

Mycobacteria and fungi

- 10% domestic bleach
- 75% Ethanol
- Phenolic compounds
- 6% formulated Hydrogen peroxide*

Spore forming bacteria (Bacillus)

- 10% domestic bleach
- Glutaraldehyde
- Formaldehyde
- 6% formulated Hydrogen peroxide*

➢ **Biohazardous Waste Containers**

- Biohazardous waste containers shall be clearly marked with the universal biohazard symbol.
- **Viruses**
- **Enveloped** (HIV, Herpes)
- 2% domestic bleach
- 75% Ethanol
- Quaternary ammonia
- 6% formulated Hydrogen peroxide*
- **Non enveloped** (Hepatitis, Adenovirus)
- 10% domestic bleach
- 6% formulated Hydrogen peroxide*
- Glutaraldehyde
- Formaldehyde

Biohazardous Waste Containers

- Biohazardous waste containers shall be clearly marked with the universal biohazard symbol.

- **Transportation**

Transportation of Dangerous Goods

- Ppackaging requirements (primary and secondary containers, dry ice etc.).
- Means and route of transportation (use of cart with guard rails, low traffic area etc.)
- Regulatory requirements (classification, labelling, signing, documenting)

With proper knowledge, planning and care, a biological exposure is avoidable.

Let Us be Safe !!!!!!!!!

Biosecurity

What is Biosecurity?

Biosecurity is a strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks for the environment. It is based on recognition of the critical linkages between sectors and the potential for hazards to move within and between sectors, with system-wide consequences. Reviewing national capacity provision for biosecurity as a whole help identify any gaps in regulations and monitoring. Also, as technologies for the detection of pests and disease develop, it is likely that synergies will emerge between sectors in areas such as virology or detection of low levels of chemical contaminants. Ultimately the aim is to enhance national ability to protect human health, agricultural production systems, and the people and industries that depend on them.

History of Biosecurity

First described in the agricultural and environmental Industries – Biosecurity is the protection of agricultural animals from any type of infectious agent—viral, bacterial, fungal, or parasitic. People can spread diseases as they move within a facility and from one to another.

The events of September 11, 2001, and the anthrax attacks in October of that year reshaped and changed, forever, the way we manage and conduct work in biological and clinical laboratories." Biosafety and biosecurity have dominated the policy discourse and the two have been inexorably intertwined. Biosafety and biosecurity are defined by the World Health Organization (WHO): **Biosafety** comprises "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release"; **Biosecurity** is defined as "the protection, control and accountability for valuable biological materials (including information) in laboratories in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release."

Biosecurity as the third component of biorisk management focuses on securing biological materials. The current focus on biosecurity evolved from a series of events that made the need for more focus on security around laboratories clear.

In 1984, members of the Rajneeshee commune in The Dalles, Oregon, purchased a strain of Salmonella from a medical supply company in Seattle, Washington to contaminate ten local salad bars, sickening over 750 individuals. Although not immediately recognized as an attack, this incident was a clear indication of the potential impact of the misuse of biological agents.

In 2001, at least five envelopes containing Bacillus anthracis spores (the etiologic agent of the disease anthrax) were mailed to U.S. Senators and media organizations. At least 22 individuals contracted anthrax as a result of the mailings; five of the individuals died.

Differentiating between biosafety and biosecurity

BIOSAFETY:

Describes the containment principles, technologies and practices that are applied to prevent the unintentional exposure to Biological agents and toxins or their accidental release

BIOSECURITY:

Describes protection, control and accountability for valuable biological materials within laboratories, in order to prevent their **loss**, **theft**, **misuse**, **diversion** of, **unauthorized access** or **intentional release**.

Biosafety *protects people from germs –* ***Biosecurity*** *protects germs from people.*

Goals of Biosecurity

The main aim of biosecurity is to protect human health and to increase and protect agricultural produce through the prevention, control and management of biological risk factors. Biosecurity also aims to protect against acts of bioterrorism and to prevent adverse biosecurity events as well as offering advice on appropriate interventions and political and social changes that should be adopted by government regulatory agencies.

Some factors influencing biosecurity:

1. Globalization
2. New agricultural production and food processing technologies
3. Increased trade in food and agricultural products
4. Legal obligations for signatories of relevant international agreements
5. Increasing travel and movement of people across borders
6. Advances in communications and global access to biosecurity information
7. Greater public attention to biodiversity, the environment and the impact of agriculture on both
8. Shift from country independence to country interdependence for effective biosecurity
9. Scarcity of technical and operational resources
10. High dependence of some countries on food imports.

What are the Biosecurity hazards?

A variety of biosecurity hazards threaten health and biosafety. Some of these are listed in the table below:

Table 1. Definitions of hazard as unlikable to different biosecurity sectors

Sectors	Definitions of hazard
Food safety	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
Zoonoses	A biological agent that can be transmitted naturally between wild or domestic animals and humans.
Animal health	Any pathogenic agent that could produce adverse consequences on the immuration of a commodity.
Plant health	Any species, strain or biotype of plant, animal or pathogenic agent injurious to octants or plant products (International Plant Protection Convention (IPPC).
Plant health quarantine	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (International Plant Protection Convention IPPC).
"Biosecurity" in relation to plants and animals	A living modified organism (LMO) that possesses a novel combination of relation to genetic material obtained through the use of modem biotechnology that is likely plants and to have adverse effects on the conservation and sustainable use of biological animals' diversity, taking also into account risks to human health (Cartagena Protocol on Biosafety'.
"Biosecurity" in relation to food	A recombinant DNA organism directly effecting or remaining in a food that relation to could have an adverse effect on human health (Cartagena Protocol on food Biosafety).
Invasive alien species	An invasive alien species outside its natural past or present distribution whose introduction and/or spread threatens biodiversity (CBD).

Biosecurity in laboratories

Pathological agents may be collected, grown, stored or handled in clinical laboratories, diagnostic facilities, public health laboratories, research centers and production facilities. All of these facilities are at risk of biosecurity incidents.

The term "biorisk" refers to the risk associated with biological substances and infectious agents. Biorisk assessments are carried out to identify the acceptable and unacceptable levels of these risks. The methods adopted to manage the occurrence of biorisks is an important field of research.

The reduction of biorisk involves the sharing of expertise and advice regarding the guidance and training that is needed for disease agents to be handled and controlled safely.

There are several non-legislated guidelines that set out the standard of conduct or behavior with respect to a particular biological activity. Organizations and individuals voluntarily agree to abide by these guidelines.

The term "biohazard" refers to a biological substance that poses a risk to health, particularly human health.

Laboratory biosecurity involves responsibility for the protection, control and accountability of biological materials within facilities to prevent their unauthorized access, theft, misuse, loss, or intentional release or exposure. Misuse refers to the use of biological materials for inappropriate or illegitimate purposes. Examples of biological materials that require this management include pathogens and toxins, as well as non-pathogenic organisms such as vaccines, genetically modified organisms (GMOs) and cell components or genetic elements.

While these objectives are related, and both are linked to the Convention, their purposes remain distinct. As a result, biosecurity concepts differ from biosafety concepts. The approaches used to achieve them are often similar or mutually reinforcing, but in some cases may conflict. A common example of conflict arises with the transport of dangerous pathogens: in the interests of biosafety, such pathogens should be clearly labeled during transport, but from a biosecurity perspective, labelling the pathogen being shipped may increase the risk of theft or diversion.

The two major biological threats that are faced in biosecurity include:

- Naturally occurring infectious diseases such as avian flu
- Biological weapons that are in the hands of states and terrorist organizations

These threats pose a challenge in national safety and providing protection against these them forms the basis of biosecurity.

<u>Laboratory Risks</u>

A broad spectrum of risks may be present in a typical biological laboratory, including risks to individuals working in the laboratory, to the community, and to the environment. To successfully mitigate these risks, it is critical to understand the components of risk. Risk, in general, is defined as a function of the likelihood an adverse event involving a specific hazard and/or threat will occur, and its consequences. Risk can also be defined more simply as a function of likelihood and consequences. Likelihood and consequences occur at two different time periods of risk. The likelihood of risk affects whether or not the incident happens, and thus precedes the event. The consequences of risk occur after the incident has happened and affects the severity of the incident. This concept is illustrated in Figure 1.

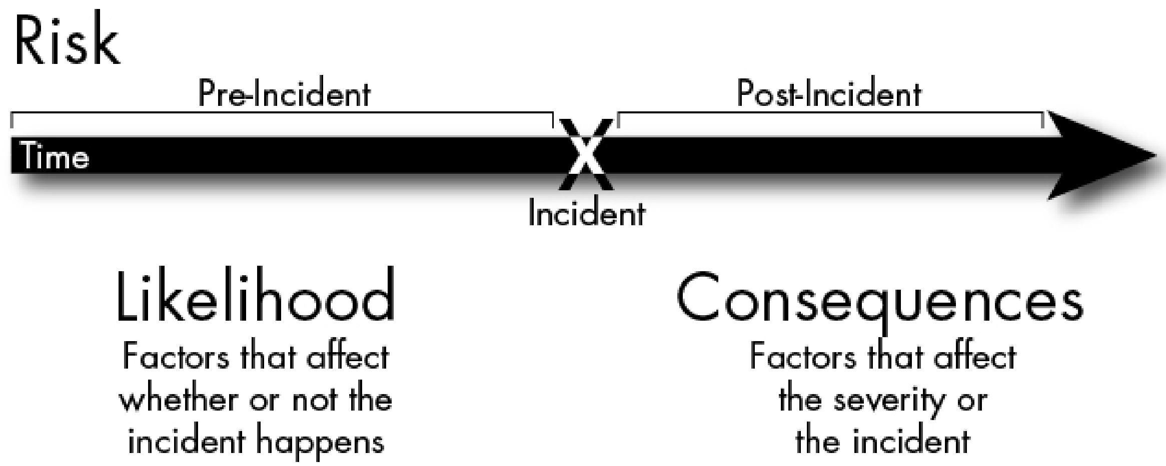


Figure 1. Likelihood and consequences of risk. The likelihood component of risk includes factors that affect whether or not the incident happens and occurs before the actual incident occurs; the consequences component of risk considers factors that affect the severity of an incident after it has occurred.

At the most basic level, understanding a particular risk, therefore, involves answering the following questions:

1. What can go wrong?

2. How likely is it?

3. What are the consequences?

For a laboratory, answering "what can go wrong?" can be a daunting task, but at the simplest level, these include risks posed by the biological agents themselves (e.g. infection via accidental or malicious exposure) and risk to the institution due to theft of intellectual property, valuable property, valuable biological materials, etc. There are also risks inherent to the activities of working with such agents, such as pricking or puncturing the skin with an infected needle or inhaling airborne pathogen particles from poor pipetting technique. All the risks present in a biological laboratory are collectively called "biorisks."

Biosecurity risks

Biosecurity risks are a type of biorisk based upon malicious intent. These risks are primarily focused on theft of a biological agent(s), equipment, or information, but can also include misuse, diversion, sabotage, unauthorized access, or intentional unauthorized release. The overall biosecurity risk varies with the intent of the adversary (or threat) aiming to do the malicious act. Factors that affect the likelihood and consequences of biosecurity risk are presented in Figure 2.

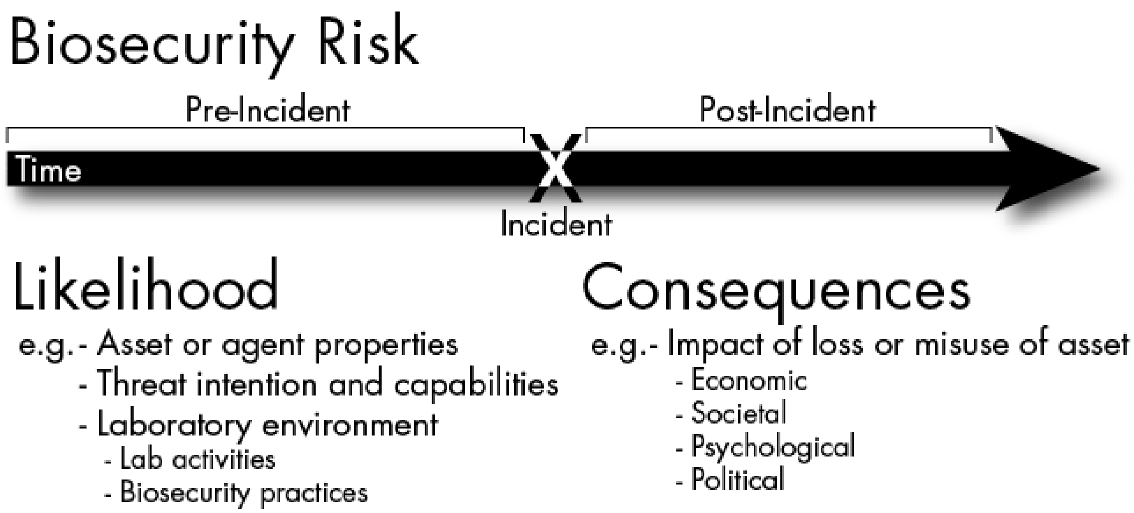


Figure 2: Biosecurity risk

In assessing a biosecurity risk, the malicious intent is typically focused upon an item of value, or asset, within the laboratory. In a biosecurity risk assessment, it is critical to define what assets exist within the laboratory. Once the assets are identified, a biosecurity risk can be defined as the likelihood that the asset can be acquired from a laboratory and the consequences of the loss of that asset (to include misuse of the asset following acquisition). Unlike biosafety risks, biosecurity risks are often difficult to identify and characterize because they are dependent upon intent of the individual(s) interested in illicitly attaining and/or using the asset (threat).

Some of the assets which may exist within a biological institution include VBM, VLM (e.g. equipment), intellectual property, informational assets, and intangible assets (such as the institution's reputation). There are many biosecurity risks based upon these assets in biological institutions, and depending upon the situation and the asset, the risks may impact the researcher(s), the facility, the human and animal community, and the economy.

For example, theft of equipment, such as a centrifuge, may present a significant risk to the laboratory researcher who routinely uses the centrifuge for his/her cutting-edge research.Without the centrifuge, the researcher cannot complete his/her work. The impact of this theft could include a financial risk to the researcher if the researcher purchased the centrifuge with his/her research funds. In addition, the loss would present a professional risk to the researcher as his/her work is subsequently halted until a new centrifuge is purchased or borrowed, and during this time, a competing researcher has completed and published the research results first. The biological facility would be impacted by a financial and operational loss. Additionally, the animal and/or human communities may also be at risk if the centrifuge was used maliciously to release an agent into the environment.

Category A Definition

The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.

Agents/Diseases

- Anthrax (Bacillus anthracis)
- Botulism (Clostridium botulinum toxin)
- Plague (Yersinia pestis)
- Smallpox (variola major)
- Tularemia (Francisella tularensis)
- Viral hemorrhagic fevers, including
    - Filoviruses (Ebola, Marburg)
    - Arenaviruses (Lassa, Machupo)

Category B Definition

Second highest priority agents include those that

- are moderately easy to disseminate;
- result in moderate morbidity rates and low mortality rates; and

- require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

Agents/Diseases

- Brucellosis (Brucella species)
- Epsilon toxin of Clostridium perfringens
- Food safety threats (Salmonella species, Escherichia coli O157:H7, Shigella)
- Glanders (Burkholderia mallei)
- Melioidosis (Burkholderia pseudomallei)
- Psittacosis (Chlamydia psittaci)
- Q fever (Coxiella burnetii)
- Ricin toxin from Ricinus communis (castor beans)
- Staphylococcal enterotoxin B
- Typhus fever (Rickettsia prowazekii)
- Viral encephalitis (alphaviruses, such as eastern equine encephalitis, Venezuelan equine encephalitis, and western equine encephalitis])
- Water safety threats (Vibrio cholerae, Cryptosporidium parvum)

Category C Definition

Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of

- availability;
- ease of production and dissemination; and
- potential for high morbidity and mortality rates and major health impact.

Agents

- Emerging infectious diseases such as Nipah virus and hantavirus

Laboratory biosecurity program

A comprehensive laboratory biosecurity program involves:

1. Identification of VBM.

2. Associated agent-based microbiological risk assessment and laboratory biosecurity risk assessment.

3. Bioethical and scientific analysis of research projects before they are authorized.

4. Allocation of responsibilities and authorities among staff and facility managers.

5. Communication between parties involved.

6. Development of and training on emergency plans.

7. Tailored biosecurity training for employees of the facility and for external first responders.

All these steps should be the result of a transparent and documented reasoning process that carefully evaluates the impact of biorisk management breaches, and prepares and plans for worst-case scenarios.

Responsibility for VBM (Valuable Biological Material)

Laboratory biosecurity should mainly be based on:

1. Control and accountability for VBM.

2. Defining their storage location.

3. Describing and scrutinizing their use; identifying personnel (and visitors) who should be granted access to them.

4. Documenting their transfer.

5. Certifying their inactivation and disposal.

6. Sharing this information with appropriate counterparts within the facility.

Laboratory biosecurity measures should be adapted to the needs of the institutions or facilities adopting them. Their identification should be the result of a biosecurity risk assessment that includes input from scientific personnel and laboratory management, biosafety officers, maintenance staff, IT staff, administrators and law-enforcement representatives.

Local law enforcement may be the police or other local, regional or national security force that is trained to manage security issues. Facilities that handle dangerous pathogens and toxins should ensure that all emergency response personnel, including local law enforcement, are aware of the safety issues on-site and the procedures to be followed if an incident occurs.

The facility should establish a clear working relationship with the local lawn forcemeat agency to provide a response to security incidents on-site. A clear protocol should be drawn up detailing the circumstances under which law-enforcement personnel may be summoned, the protocol to follow once on-site, and the scope of authority for all parties involved. Regular on-site training and orientation for the local law-enforcement agency is also recommended.

At facility level, it is recommended that the ultimate responsibility for VBM should lie with the laboratory/facility manager or director, who should be responsible for providing the appropriate conditions to minimize breaches in biosafety and laboratory biosecurity. The facility manager may delegate this responsibility to the principal investigator for routine activities. However, the facility manager will respond in case of biosafety or biosecurity breaches.

At international level, national authorities should be ultimately responsible for breaches in biosafety and laboratory biosecurity that may be at the origin of public health emergencies of international concern .

Elements of a Strong Biosecurity Program

1. Security Risk Assessment.
2. Threat Assessment.
3. Vulnerability Assessment.
4. Physical security (gates, guards, guns) .
5. IT (information technology) system security.
6. Employee security/ accountability.
7. Access control.
8. Transfer of agents.
9. Incident and injury policies.
10. Emergency response policies.
11. Security breach policies.
12. Intent?

The Virtual Biosecurity Center (VBC)

Founded in 2011, is a global multi-organizational initiative spearheaded by the Federation of American Scientists (FAS) committed to countering the threat posed by the development or use of biological weapons and the responsible use of science and technology. The VBC is the 'one stop shop' for biosecurity information, education, best practices, and collaboration.

The VBC offers:

- Comprehensive biosecurity news and events, an education center and library updated on a continuous basis with the most current information;
- The Global Forum on Biorisks, a collaborative online forum and tool for informing policy and empowering partnerships among professional biosecurity communities around the world;
- Calendar of global conferences to raise awareness and develop plans to address both current and future biosecurity issues;
- Outreach activities on cutting-edge topics with interactive webcasts;
- Education and partnership to bridge the gap between the scientific, public health, intelligence and law enforcement communities;
- Funding opportunities and coordination including graduate fellowships;
- Translations into more than 50 languages including the 6 UN languages.

The release of a dangerous biological agent, whether intentional, accidental or caused by a natural outbreak, could cause millions of casualties and result in far-reaching economic impacts. Now more than ever, biosecurity awareness, public health preparedness, and education on the responsible use of science and technology are crucial components for dealing with these threats. The VBC was developed with a grant from the National Counter Proliferation Center (NCPC) of the Office of the Director of National Intelligence (ODNI), and the Carnegie Corporation of New York.

Participating Organizations المنظمات المشاركة

Participating Organizations are governmental and non-governmental organizations, biosecurity policy centers, biosafety associations, and university policy centers from around the world that have agreed to share their activities and educational materials through the VBC.

Participating Organizations:

African Biological Safety Association (AfBSA).
American Association for the Advancement of Science (AAAS) .
American Biological Safety Association (ABSA).
Australian Biosecurity Intelligence Network (ABIN).
BIO (Biotechnology Industry Organization).
International Federation of Biosafety Associations (IFBA)
National Academy of Sciences (NAS)
National Biosafety Association (ANBio)
National Institutes of Health, Office of Biotechnology Activities
Organisation for Economic Co-operation and Development (OECD)

Developing a Biosecurity Program

The need for a biosecurity program should reflect actual risk management practices based on risk assessment at the specified location. A biosecurity risk assessment should be based on an analysis of the potential and consequences of the loss of ambiguity and potential use of pathogens and toxins. More importantly, the use of the BIO program should be used as a basis for decision making and risk management.

A Biosecurity Risk Assessment and Management Process

There are several models available for the **Biosecurity Risk Assessment** program. Most of these models share many characteristics such as asset identification, threat, vulnerability and side effects. Here is an example of how the BRA program works:

In this example, the risk assessment and management program are divided into five steps and each step-in turn can be divided into other secondary steps:

1. **Determination and prioritization of biomaterials and poisons**
2. **Identification and ranking of threats and risks from biomaterials and toxins**
3. **Risk analysis of specific security scenarios**
4. **Design and development of an integrated risk management program**
5. **Regular assessment of the objectives and protection standards of the institution concerned.**

Below we give an example of these five steps:

Step 1: Determination and prioritization of biomaterials and poisons

1. Identification of the biological materials found in the organization, in terms of form, location, and quantities, including non-divisible materials (ie toxins).
2. Assess the potential for abuse of these biological materials.
3. Assess the consequences of misuse of these biological materials.
4. Arrange biological materials on the basis of consequences of misuse (hazard of harmful use).

Step 2: dentification and ranking of threats and risks from biomaterials and toxins

1. Identification of types of insiders that may pose a threat to biological materials in the organization
2. Identification of species of strangers (if any) that may pose a risk to the biological material in the organization
3. Evaluate the motives, means and opportunities available to multiple opponents**.**

Step 3: Risk analysis of specific security scenarios

Develop a list of possible biosecurity scenarios, or undesirable events that

can occur within the organization (each scenario is a combination of the pathogen, the resistance mechanism, and the follower procedure): -

1. Access to the specific pathogen within the laboratory.
2. Preventive measures taken to prevent them
3. How current protection measures (vulnerabilities) can be breached

Step 4: Design and development of an integrated risk management program

1. The development of the management of the biosecurity risk profile and the documentation of any biosecurity scenarios represents unacceptable risks and should be mitigated against those risks that can be adequately addressed through existing protection controls.
2. The Department develops a biosecurity plan to describe how the institution deals with those unacceptable risks and how Mitigation including:

1. Written security plan, standard operating procedures, and incident response plans.
2. Written protocols to train staff on potential risks.

3. ensures that the resources needed to achieve and document protection measures are managed in the Biosecurity Plan

Step 5: Regular assessment of the objectives and protection standards of the institution concerned.

The Department regularly re-evaluates and makes the necessary adjustments to:

1. Biological Security Risk Statement.

2. Risk Assessment Process Biosecurity

3. Institution Plan for Biosecurity Program

4. Biosecurity Systems of the Enterprise

Applied biosecurity in practice

Implementing biosecurity encompasses many aspects of laboratory activities and resources. It aims to ensure the integrity and security of all pathogens, toxins and sensitive information. Applied biosecurity has a number of key components:

- Employee accountability.
- Material control.
- Development of standard operating procedures.
- Compliance with biosecurity procedures.
- Physical security.
- Access control.
- Information security.
- transport security;
- Proper routines for security-incident reporting and response.
- Maintaining continuous evaluation and revision.
- Providing training and education.

Employee accountability

Responsibility for biosecurity is shared by the employer and the employee. However, the facility director or head of department has the ultimate responsibility and accountability for the materials, equipment and information at a facility, the activities performed within it and the actions of the staff. It is difficult for one employee to have complete overview of all activities, and thus responsibilities are commonly delegated to laboratory managers and principal investigators. In turn, they can designate employees with proper qualifications and authorization to oversee specific agents or all agents in one laboratory. These employees must:

• oversee and manage infectious pathogens, toxins, sensitive information and equipment;

• ensure that these are accounted for at all times; and

• conduct record keeping, auditing and reporting.

Material control

Proper inventory practices are essential for effective material control and must cover pathogens and toxins from the time that they arrive at a facility or laboratory to their final destruction or shipping. Proper inventory practices must include the confirmation of receipt by the designated party. Proper biosafety practices and regulations do partially address inventory control, but this is far from common practice. Access to areas where biological materials are used or stored must be limited to those with proper clearance.

The employees who have access to and work with biological materials must be responsible for basic inventory tasks because they are familiar with the type and amount of biological materials present and their location and state. Rules and procedures for inventory control must be developed by laboratory managers or principal investigators, together with management and the biosafety and biosecurity officer. Inventories of pathogens and toxins vary in complexity, but they should

Include relevant information such as:

• Types of material (name, strain, serotype, taxonomy etc.);

• Forms of material (solution or pellet, freeze dried, paraffin embedded etc.);

• Quantities of material (number of vials, amounts of liquid, post-experiment quantities);

• Locations of material (in short- or long-term storage or in use);

• Contact or responsible employee;

• Employees who have access to the materials;

• Modifications of the original biological properties of material (i.e. genetically modified microorganisms and genetically modified organisms);

• Confirmation, date and method of destruction or inactivation of material; and

• Dates of transfer of material (delivery and departure) and end-user or recipient receipts.

Various methods can be used to coordinate and manage material inventories.

• Local laboratory lists of material can be created and managed by those accountable for them and passed on to an employee at a higher level of authority.

• A general material list for the whole facility can be maintained, coordinated and managed by the appointed biosafety and biosecurity officer.

Physical security

The aim of physical security is to restrict access to those with professional qualifications and who have the immunizations that allow them to work with specific pathogens and delay, deny and detect access by unauthorized individuals. Physical security is closely associated with biosafety and facility design. However, even the most sophisticated physical security is only one component of a secure workplace. The level of security of a laboratory or facility is ultimately determined by the employee's awareness of the need for security and behaviour that reflects such an awareness.

Physical security entails:

•monitoring and managing perimeters and security boundaries;

•establishing and enforcing access restrictions;

•installing and maintaining alarm and surveillance equipment;

•determining and preserving adequate containment levels; and

• provide prompt alerts of breaches or intrusions.

Information security

Information that enables access to a facility or to biological materials is sensitive and must be kept secure.19 Security measures may also be required for other sensitive information, such as:

• inventory lists of pathogens and toxins;

• sensitive equipment, including its location;

• security routines;

• access lists;

• patient sample data; and

• employee contact information.

Transfer and transport security

Transfers of dangerous pathogens and toxins must follow national and international guidelines that are based on the UN regulations for the two most hazardous categories of material (categories A and B).21 The UN regulations

focus on the safety of the employees involved in transporting the materials and the integrity of the containment (see case studies 3–6 for examples of violations of proper procedures or mistakes). Adequate containment must also be ensured for transports over shorter distances, such as between neighbouring facilities or within a facility. When materials are transferred in a facility or between facilities the properly packaged material must not be out of sight, even for a moment. This ensures the integrity of the transfer all the way to its final destination. Professional handling must be used for longer transports and there are many companies that handle dangerous goods and possess ADR (safe international transport of dangerous goods by road) certification. The primary security problem in long distance transfers is that the sender cannot personally supervise the transfer but must rely on the company to do so.

Case 1. Live *Bacillus anthracis* shipped by mistake In May 2004 live *Bacillus anthracis* was shipped from the Southern Research Institute in Frederick, Maryland, USA, to the Oakland Children's Hospital & Research Center in Oakland, California, USA. The sender had verified that the samples were not viable. However, the death of 49 mice that were infected using the *Bacillus anthracis* samples revealed the viability of the samples.

Case 2. British journalists order a sequence of modified smallpox DNA On 14 June 2006, *The Guardian* reported that journalists had successfully ordered online and received a plastic vial containing the 78bp sequence of DNA coding for the smallpox virus coat protein modified with three mutations from VH Bio Ltd. The vial, which arrived in an A5-size Jiffy bag, cost £33. The company was unaware that the sequence belonged to the smallpox genome.

Case 3. Bacillus anthracis requested from the University of Gothenburg The University of Gothenburg, Sweden, which has one of the largest bacteria depositories in the world, has on two occasions since the 2001 mailing of the anthrax-contaminated letters in the United States received requests for Bacillus anthracis that were deemed suspicious. The requests were forwarded to the Swedish security police for investigation. The University of Gothenburg has stated that its depository has never held or offered Bacillus anthracis.

Case 4. Yersinia pestis shipped to Tanzania In September 2002 Thomas Butler, a professor at Texas Tech University, Lubbock, Texas, USA, knowingly transferred the human pathogen Yersinia pestis (bubonic plague) to Tanzania without obtaining the required US Department of Commerce licence. He described the pathogen as ‘laboratory materials’ on the waybill and failed to fill out relevant sections of the Shipper’s Export Declaration requirement.

In such cases, the sender must establish a chain of custody that:

• identifies the individuals involved in the transfer.

• outlines the provisions to address potential problems.