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برنامج إدارة مياه الشرب و الصرف الصحي
Water and Wastewater Management Program

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Biosafety of Microbiological Laboratory

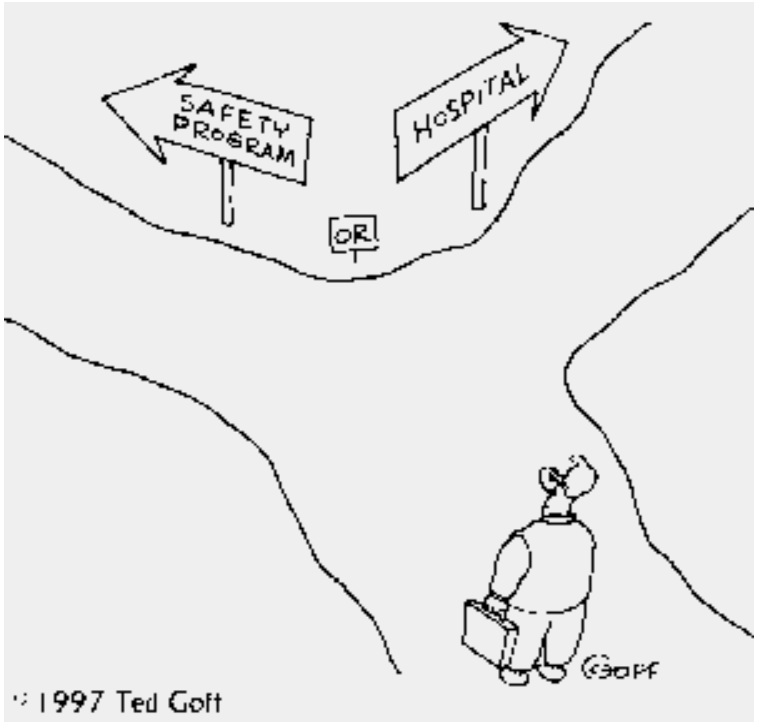
August 2009

Biosafety of Microbiological Laboratory

By Dr Fouad El Tahan

Introduction

- **Why Lab Safety?**
  - **Legal Reasons**
- **Moral Reasons**



Choices

- **The person best prepared to choose**
- **will know the likely outcome.**

1,141 laboratory associated infections 1979-2004 (aerosol route) the top ten are:

Mycobacterium tuberculosis	**199 cases**
Arboviruses (RVF, WNV)	**192**
Coxiella burnetti	**177**
Hantavirus	**155**
Brucella	**143**
Hepatitis B	**82**
Shigella spp.	**66**
Salmonella spp.	**64**
Hepatitis C	**32**
Neiserria meningitidis	**31**

Biological Safety, Principles and Practices. ASM Press. 2006

Why!!

- Transmissions from laboratory procedures may occur even if the disease is not transmitted by aerosol in the community.

- Laboratory procedures:
  - Higher concentration of organism
  - Procedures generate aerosols

- Throughout this presentation , references are made to the relative hazards of infective microorganisms by risk group

- (WHO Risk Groups 1, 2, 3 and 4).

- This risk group classification is to be used for laboratory work only.

Classification of infective microorganisms by risk group

- **Risk Group 1 (no or low individual and community risk)** A microorganism that is unlikely to cause human or animal disease.
- **Risk Group 2 (moderate individual risk, low community risk)**
- A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infectio, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

- **Viruses:** Influenza viruses types A, B, C other than notifiable avian influenza (NAI); Newcastle disease virus; Orf(parapox virus)

- **Bacteria:** Alcaligenes spp.; Arizona spp.; Campylobacter spp.; Chlamydophila psittaci (nonavian); Clostridium tetani; Clostridium botulinum; Corynebacterium spp.; Erysipelothrix rhusiopathiae; Escherichia coli; Haemophilus spp.; Leptospira spp.; Listeria monocytogenes; Moraxella spp.; Mycobacterium avium; Pasteurella spp.; Proteus spp.; Pseudomonas spp.; Salmonella spp.; Staphylococcus spp.; Yersinia enterocolitica; Yersinia pseudotuberculosis

- **Fungi:** Aspergillus fumigatus; Microsporum spp.; Trichophyton spp.

Classification of infective microorganisms by risk group

- **Risk Group 3** (high individual risk, low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
- **Viruses:** Rabies virus; Equine encephalomyelitis virus (Eastern, Western and Venezuelan); Japanese B encephalitis virus; Louping ill virus
- **Bacteria:** Bacillus anthracis; Burkholderia mallei (Pseudomonas mallei); Brucella spp.; Chlamydia psittaci (avian strains only); Coxiella burnetti; Mycobacterium bovis

Classification of infective microorganisms by risk group

- Risk Group 4 (high individual and community risk)

A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

classification of microorganisms, by risk group

- 1. Pathogenicity of the organism.
- 2. Mode of transmission and host range of the organism.

These may be influenced by

- existing levels of immunity in the local population,
- density and movement of the host population,
- presence of appropriate vectors,
- and standards of environmental hygiene.

classification of microorganisms, by risk group

- 3. Local availability of effective preventive measures.

These may include:

- prophylaxis by immunization
- administration of antisera (passive immunization);
- sanitary measures, e.g. food and water hygiene; control of animal reservoirs or arthropod vectors.

classification of microorganisms, by risk group

- 4. Local availability of effective treatment.

This includes:

- passive immunization,
- postexposure vaccination and use of antimicrobials,
- antivirals and chemotherapeutic agents,
- and should take into consideration the possibility of the emergence of drug-resistant strains.

classification of microorganisms, by risk group

- The assignment of an agent to a biosafety level for laboratory work must be based on
- a risk assessment.

- Such an assessment will take the risk group as well as other factors into consideration in establishing the appropriate biosafety level.

- For example,

- an agent that is assigned to Risk Group 2 may generally require Biosafety Level 2 facilities,

- equipment,

- practices

- and procedures for safe conduct of work.

classification of microorganisms, by risk group

- However, if particular experiments require the generation of high-concentration aerosols,
- then Biosafety Level 3 may be more appropriate to provide the necessary degree of safety,

Laboratory facilities are designated as basic

- Biosafety Level 1, basic
- Biosafety Level 2, containment
- Biosafety Level 3, and maximum containment
- Biosafety Level 4.

Biosafety level designations are based on a

- composite of the design features,
- construction,
- containment facilities,
- equipment,
- practices and operational procedures required for working with agents from the various risk groups.

Table 2. ***Relation of risk groups to biosafety levels, practices and equipment***

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

04-Aug-09

Table 3. ***Summary of biosafety level requirements***

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

classification of microorganisms, by risk group

- **Thus, the assignment of a biosafety level takes into consideration :**

- the organism (pathogenic agent) used,
- the facilities available,
- the equipment practices
- and procedures required to conduct work safely in the laboratory.

Biosafety guidelines

- By Dr Fouad El Tahan

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Biosafety guidelines

I - Microbiological risk assessment

II- Basic laboratories – Biosafety Levels 1 and 2

III -The containment laboratory – Biosafety Level 3

IV-The maximum containment laboratory – Biosafety Level 4

I- Microbiological risk assessment

- The backbone of the practice of biosafety is risk assessment.
- While there are many tools available to assist in the assessment of risk for a given procedure or experiment,
- the most important component is professional judgement.

I- Microbiological risk assessment

- Risk assessments should be performed by the individuals most familiar with :
- - the specific characteristics of the organisms being considered for use,

- the equipment and procedures to be employed,
- animal models that may be used, and
- the containment equipment and facilities available.

I- Microbiological risk assessment

- The laboratory director or principal investigator is responsible for ensuring that :

- adequate and timely risk assessments are performed,

- and for working closely with the institution's safety committee and biosafety personnel to ensure that

- appropriate equipment and facilities are available to support the work being considered.

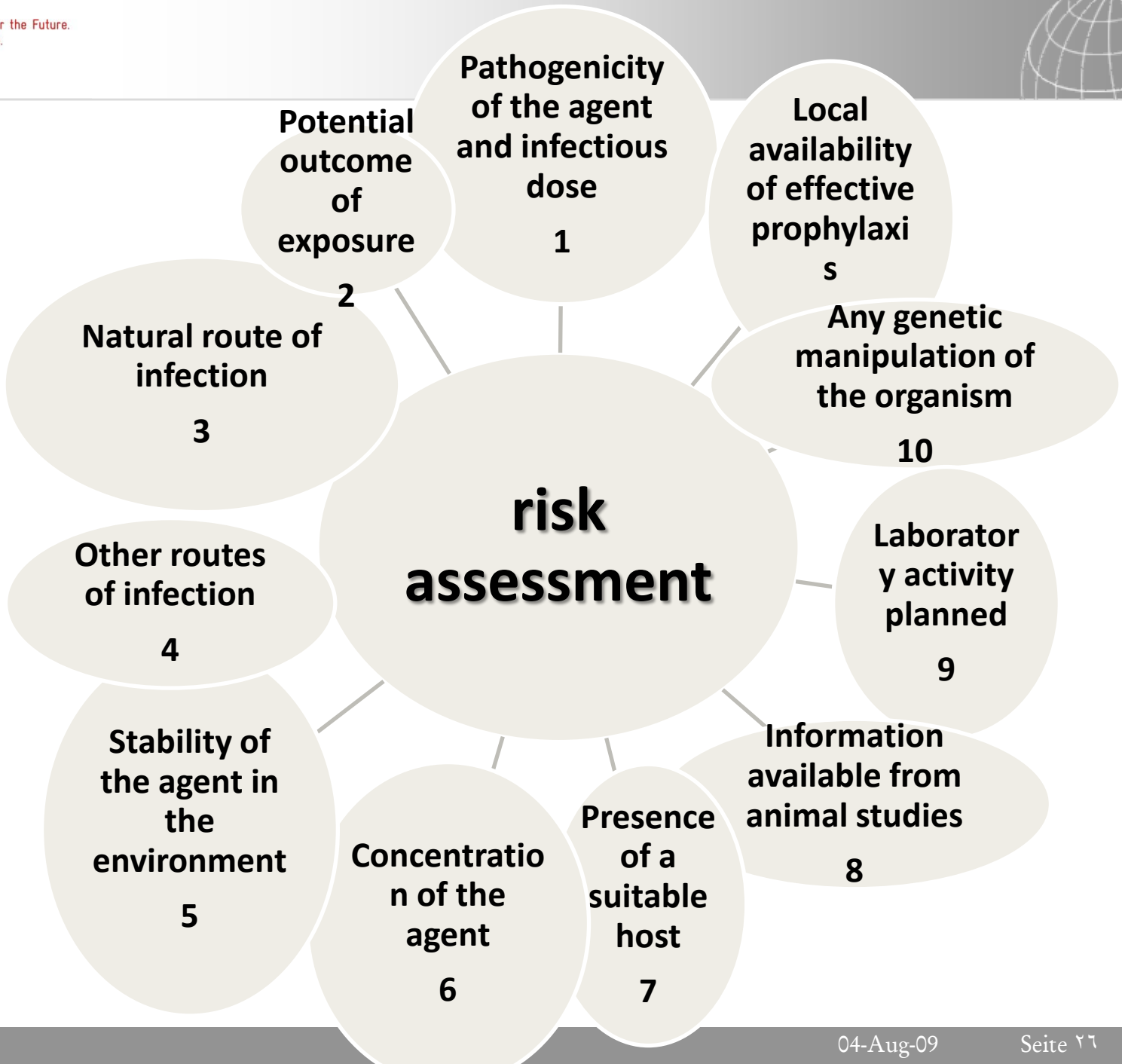
I – Microbiological risk assessment

- Once performed, risk assessments should be reviewed routinely and revised when necessary,

- taking into consideration the acquisition of new data having a bearing on the degree of risk and other relevant new information from the scientific literature.

I- Microbiological risk assessment

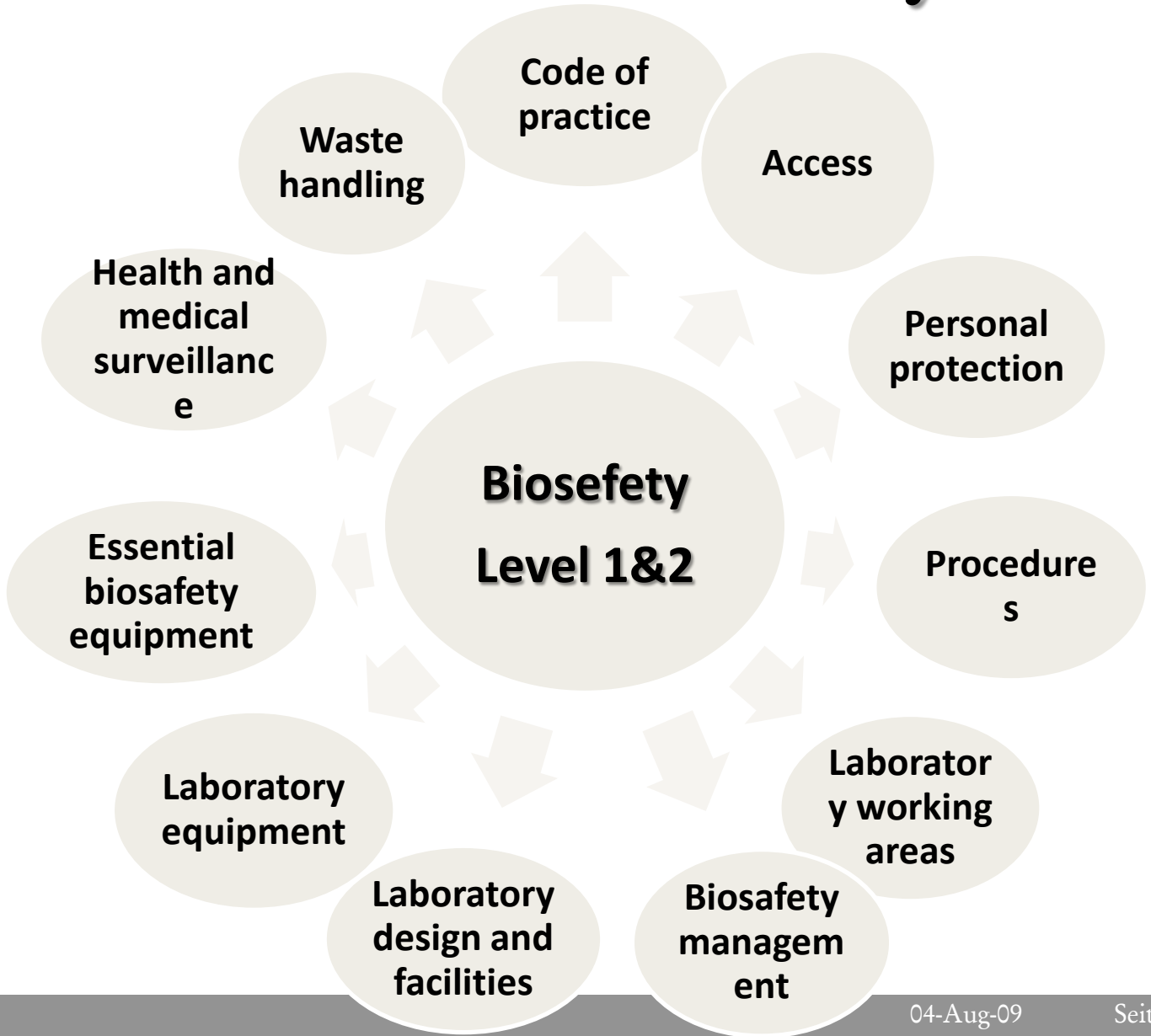
- One of the most helpful tools available for performing a microbiological risk assessment is the listing of risk groups for microbiological agents .
- However,
- simple reference to the risk grouping for a particular agent is insufficient in the conduct of a risk assessment.


risk assessment
Pathogenicity of the agent and infectious dose
1
Potential outcome of exposure
2
Natural route of infection
3
Other routes of infection
4
Stability of the agent in the environment
5
Concentration of the agent
6
Presence of a suitable host
7
Information available from animal studies
8
Laboratory activity planned
9
Any genetic manipulation of the organism
10
Local availability of effective prophylaxis

I- Microbiological risk assessment

- On the basis of the information ascertained during the risk assessment,
- a biosafety level can be assigned to the following:
- planned work,
- appropriate personal
- protective equipment selected,
- and standard operating procedures (SOPs) incorporating other safety interventions developed to ensure the safest possible conduct of the work.

II- Basic laboratories –Biosafety Levels 1 & 2



Code of practice

- In many laboratories and national laboratory programmes, this code may be used to develop written practices and procedures for safe laboratory operations.

- Each laboratory should adopt a safety or operations manual that identifies :

- known and potential hazards,
- specifies practices and
- procedures to eliminate or minimize such hazards.

Access

- 1- The international biohazard warning symbol and sign must be displayed on the doors of the rooms where microorganisms of Risk Group 2 or higher risk groups are handled.
- 2. Only authorized persons should be allowed to enter the laboratory working areas.
- 3. Laboratory doors should be kept closed.

Access

- 4. Children should not be authorized or allowed to enter laboratory working areas.
- 5. Access to animal houses should be specially authorized.
- 6. No animals should be admitted other than those involved in the work of the laboratory.

Access

Figure 1. ***Biohazard warning sign for laboratory doors***

Personal protection

- 1. Laboratory coveralls, gowns or uniforms must be wor at all times for work in the laboratory.

- 2. Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials
  - or infected animals. After use, gloves should be remove aseptically and hands must then be washed.

- 3. Personnel must wash their hands after handling infectious materials and animals, and before they leave t laboratory working areas.

Personal protection

- 4. Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation.

- 5. It is prohibited to wear protective laboratory clothing outside the laboratory, e.g. in canteens, coffee rooms, offices, libraries, staff rooms and toilets.

- 6. Open-toed footwear must not be worn in laboratories.

Personal protection

- 7. Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory working areas.

- 8. Storing human foods or drinks anywhere in the laboratory working areas is prohibited.

- 9. Protective laboratory clothing that has been used in the laboratory must not be stored in the same lockers or cupboards as street clothing.

Procedures

- 1. Pipetting by mouth must be strictly forbidden.
- 2. Materials must not be placed in the mouth. Labels must not be licked.
- 3. All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.
- 4. The use of hypodermic needles and syringes should be limited.
  - They must not be used as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals.

Procedures

- 5. All spills, accidents and overt or potential exposures to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents should be maintained.

- 6. A written procedure for the clean-up of all spills must be developed and followed.

- 7. Contaminated liquids must be decontaminated (chemically or physically) before discharge to the sanitary sewer. An effluent treatment system may be required, depending on the risk assessment for the agent(s) being handled.

- 8. Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.

Laboratory working areas

- 1. The laboratory should be kept neat, clean and free of materials that are not pertinent to the work.
- 2. Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day.
- 3. All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse.
- 4. Packing and transportation must follow applicable national and/or international regulations.
- 5. When windows can be opened, they should be fitted with arthropod-proof screens.

Biosafety management

- 1. It is the responsibility of the laboratory director (the person who has immediate responsibility for the laboratory) to ensure the development and adoption of a biosafety management plan and a safety or operations manual.
- 2. The laboratory supervisor (reporting to the laboratory director) should ensure that regular training in laboratory safety is provided.

Biosafety management

- 3. Personnel should be advised of special hazards, and required to read the safety or operations manual and follow standard practices and procedures. The laboratory supervisor should make sure that all personnel understand these.

- A copy of the safety or operations manual should be available in the laboratory.

- 4. There should be an arthropod and rodent control programme.

- 5. Appropriate medical evaluation, surveillance and treatment should be provided for all personnel in case of need, and adequate medical records should be maintained.

Laboratory design and facilities

- In designing a laboratory and assigning certain types of work to it,
- special attention should be paid to conditions that are known to pose safety problems. These include:
- 1. Formation of aerosols
- 2. Work with large volumes and/or high concentrations of microorganisms
- 3. Overcrowding and too much equipment
- 4. Infestation with rodents and arthropods
- 5. Unauthorized entrance
- 6. Workflow: use of specific samples and reagents.

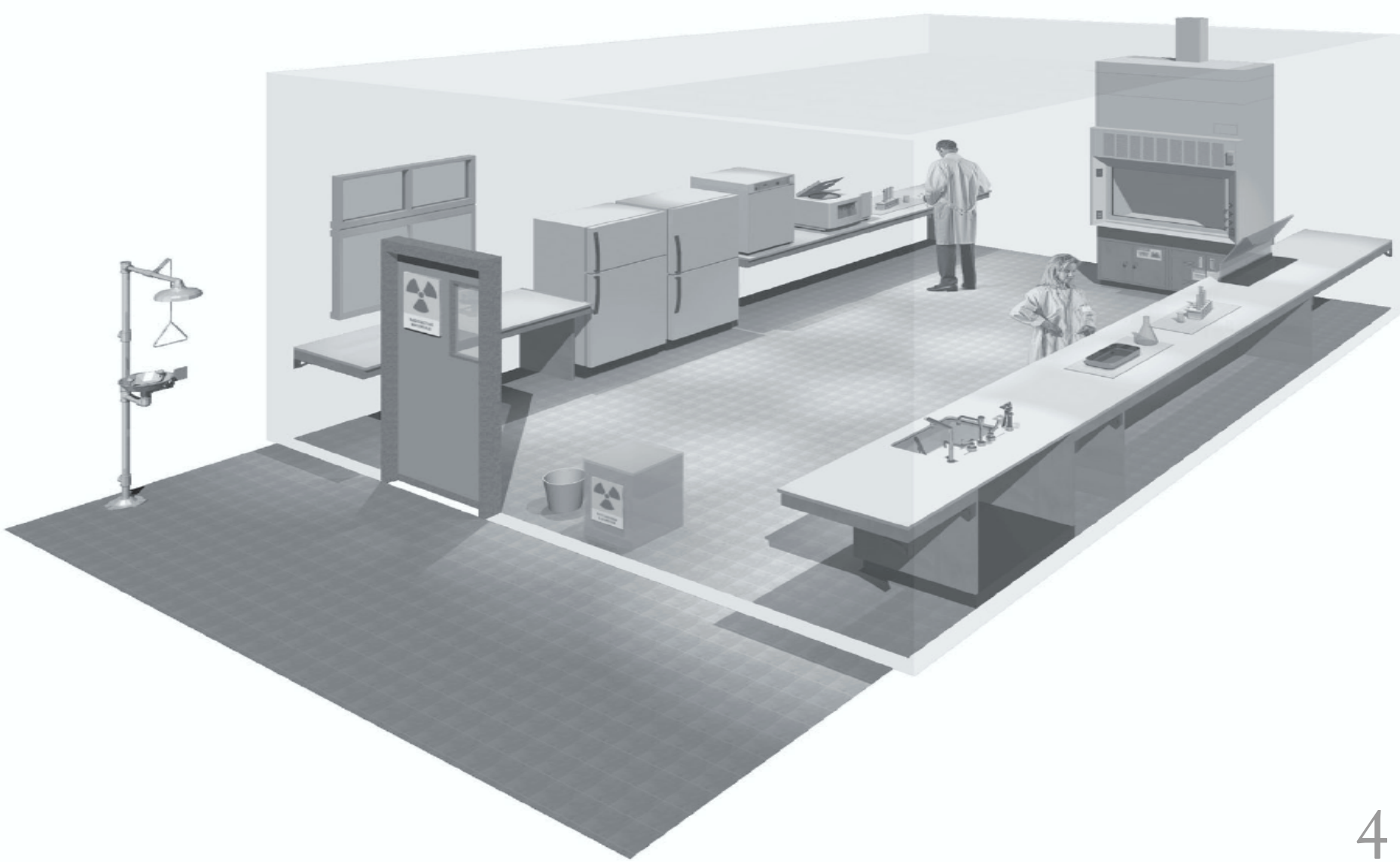
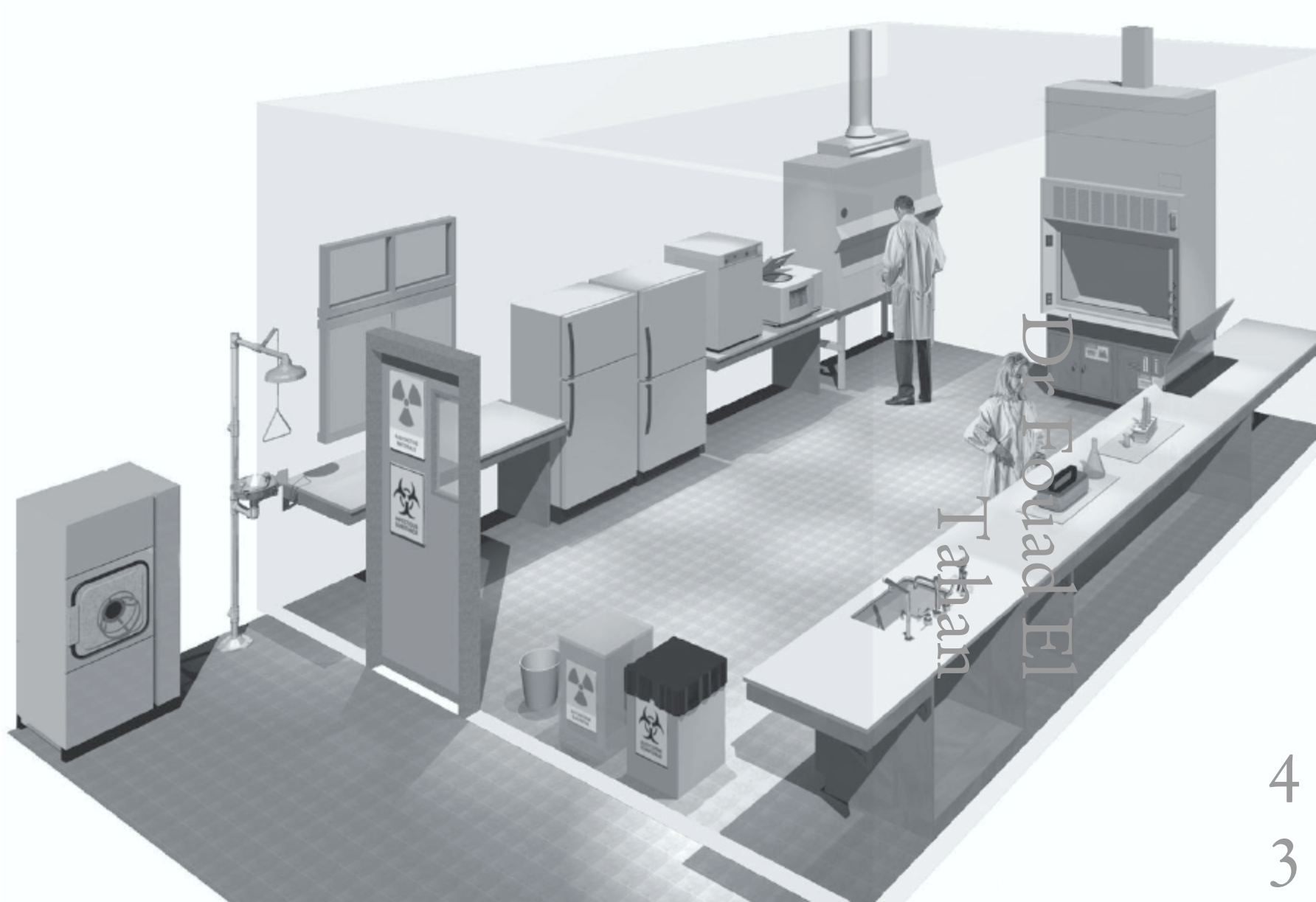
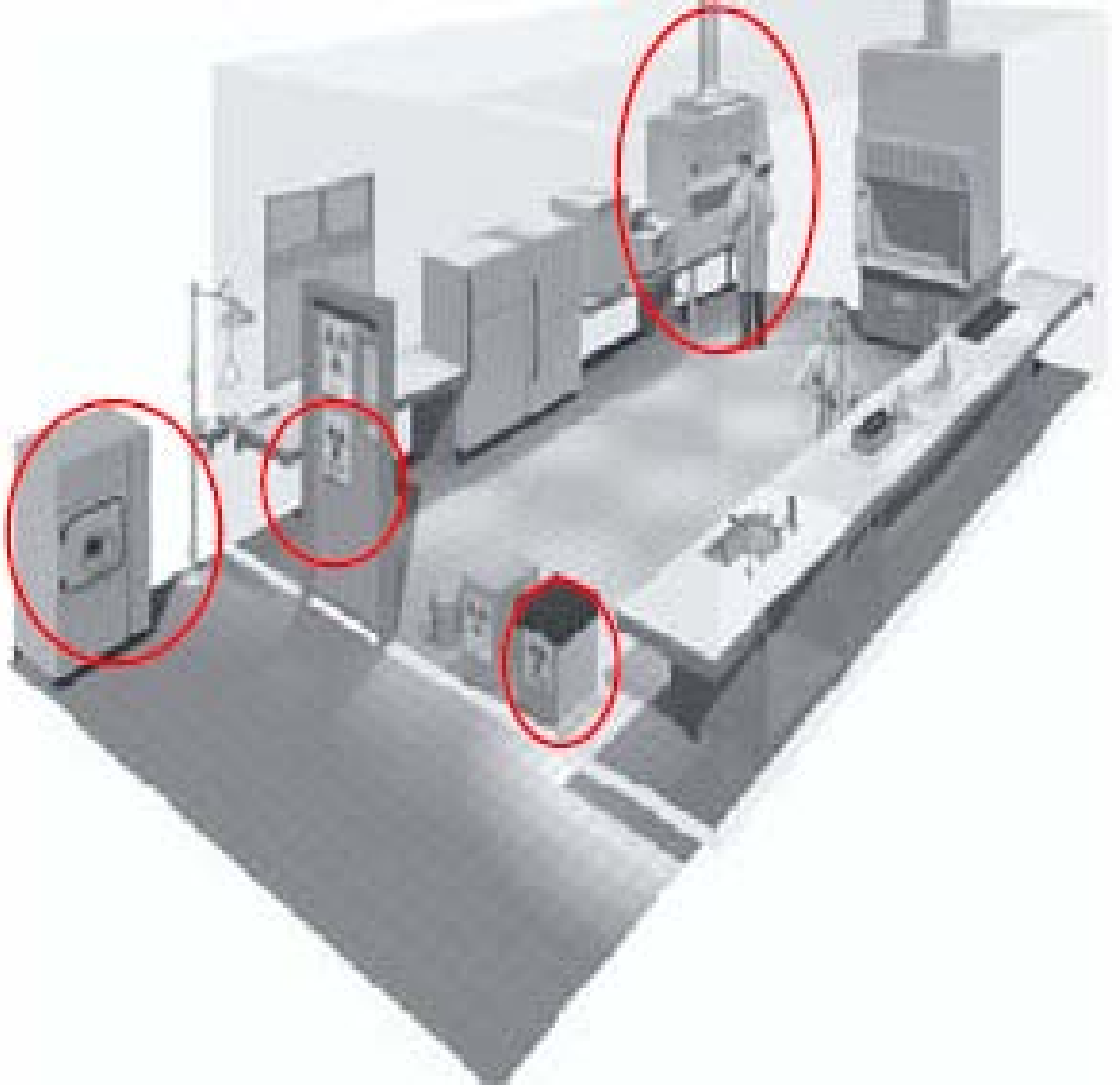


Figure 2. ***A typical Biosafety Level 1 laboratory***

3. BASIC LABORATORIES – BIOSAFETY LEVELS 1 AND 2





Design features

- 1. Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- 2. Walls, ceilings and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip-resistant.
- 3. Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.

Design features

- 4. Illumination should be adequate for all activities. Undesirable reflections and glare should be avoided.

- 5. Laboratory furniture should be sturdy. Open spaces between and under benches, cabinets and equipment should be accessible for cleaning.

- 6. Storage space must be adequate to hold supplies for immediate use and thus prevent clutter on bench tops and in aisles.

- Additional long-term storage space, conveniently located outside the laboratory working areas, should also be provided.

4

6

Design features

- 7. Space and facilities should be provided for the safe handling and storage of solvents, radioactive materials, and compressed and liquefied gases.

- 8. Facilities for storing outer garments and personal item should be provided outside the laboratory working areas.

- 9. Facilities for eating and drinking and for rest should b provided outside the laboratory working areas.

Design features

- 10. Hand-washing basins, with running water if possible, should be provided in each laboratory room, preferably near the exit door.

- 11. Doors should have vision panels, appropriate fire ratings, and preferably be selfclosing.

- 12. At Biosafety Level 2, an autoclave or other means of decontamination should be available in appropriate proximity to the laboratory.

Design features

- 13. Safety systems should cover fire, electrical emergencies, emergency shower and eyewash facilities.

- 14. First-aid areas or rooms suitably equipped and readily accessible should be available

- 15. In the planning of new facilities, consideration should be given to the provision of mechanical ventilation systems that provide an inward flow of air without recirculation.

- If there is no mechanical ventilation, windows should be able to be opened and should be fitted with arthropod-proof screens.

Design features

- 16. A dependable supply of good quality water is essential.
- There should be no cross connections between sources of laboratory and drinking-water supplies.
- An antiback flow device should be fitted to protect the public water system.

Design features

- 17. There should be a reliable and adequate electricity supply and emergency lighting to permit safe exit.
- 18. There should be a reliable and adequate supply of gas.

- Good maintenance of the installation is mandatory.

Design features

- 19. Laboratories and animal houses are occasionally the targets of vandals.
- Physical and fire security must be considered.
- Strong doors, screened windows and restricted issue of keys are compulsory.
- Other measures should be considered and applied, as appropriate, to augment security

Laboratory equipment

- Equipment should be selected to take account of certain general principles, i.e. it should be:

- 1. Designed to prevent or limit contact between the operator and the infectious material

- 2. Constructed of materials that are impermeable to liquids, resistant to corrosion and meet structural requirements

- 3. Fabricated to be free of burrs, sharp edges and unguarded moving parts

- 4. Designed, constructed and installed to facilitate simple operation and provide for ease of maintenance, cleaning, decontamination and certification testing; glassware and other breakable materials should be avoided, whenever possible.

Essential biosafety equipment

- 1. Pipetting aids – to avoid mouth pipetting. Many different designs are available.

- 2. Biological safety cabinets, to be used whenever:

- — infectious materials are handled; such materials may be centrifuged in the open laboratory if sealed centrifuge safety cups are used and if they are loaded and unloaded in a biological safety cabinet
  — there is an increased risk of airborne infection

Essential biosafety equipment

- — procedures with a high potential for producing aerosols are used;

  these may include :

- - centrifugation,
- - grinding, blending,
- - vigorous shaking or mixing,
- - sonic disruption,
- - opening of containers of infectious materials whose internal pressure may be different from the ambient pressure,
- - intranasal inoculation of animals,
- - and harvesting of infectious tissues from animals and eggs.

Essential biosafety equipment

- 3. Plastic disposable transfer loops. Alternatively, electric transfer loop incinerators may be used inside the biological safety cabinet to reduce aerosol production.
- 4. Screw-capped tubes and bottles.
- 5. Autoclaves or other appropriate means to decontaminate infectious materials.
- 6. Plastic disposable Pasteur pipettes, whenever available, to avoid glass.
- 7. Equipment such as autoclaves and biological safety cabinets must be validated with appropriate methods before being taken into use. Recertification should take place at regular intervals, according to the manufacturer's instructions

Health and medical surveillance

- the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel.
- The objective of such surveillance is to monitor for occupationally acquired diseases.
- to achieve these objectives are:
- 1. Provision of active or passive immunization where indicated
- 2. Facilitation of the early detection of laboratory-acquired infections
- 3. Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work
- 4. Provision of effective personal protective equipment and procedures.

Waste handling

- Waste is anything that is to be discarded.
  - In laboratories, decontamination of wastes and their ultimate disposal are closely interrelated.
- In terms of daily use, few if any contaminated materials will require actual removal from the laboratory or destruction.
- Most glassware, instruments and laboratory clothing will be reused or recycled.
- The overriding principle is that all infectious materials should be decontaminated, autoclaved or incinerated within the laboratory.

Waste handling

- The principal questions to be asked before discharge of any objects or materials from laboratories that deal with potentially infectious microorganisms or animal tissues are:

Waste handling

- 1. Have the objects or materials been effectively decontaminated or disinfected by an approved procedure
- 2. If not, have they been packaged in an approved manne for immediate on-site incineration or transfer to another facility with incineration capacity?
- 3. Does the disposal of the decontaminated objects or materials involve any additional potential hazards, biological or otherwise, to those who carry out the immediate disposal procedures or who might come into contact with discarded items outside the facility?

Decontamination

- Steam autoclaving is the preferred method for all decontamination processes.
- Materials for decontamination and disposal should be placed in containers, e.g.
- - autoclavable plastic bags, that are colour-coded according to whether the contents are to be autoclaved and/or incinerated.
- - Alternative methods may be envisaged only if they remove and/or kill microorganisms

Handling and disposal procedures for contaminated materials and wastes

- An identification and separation system for infectious materials and their containers should be adopted.
- National and international regulations must be followed. Categories should include:
- 1. Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste
- 2. Contaminated (infectious) "sharps" – hypodermic needles, scalpels, knives and broken glass; these should always be collected in puncture-proof containers fitted with covers and treated as infectious

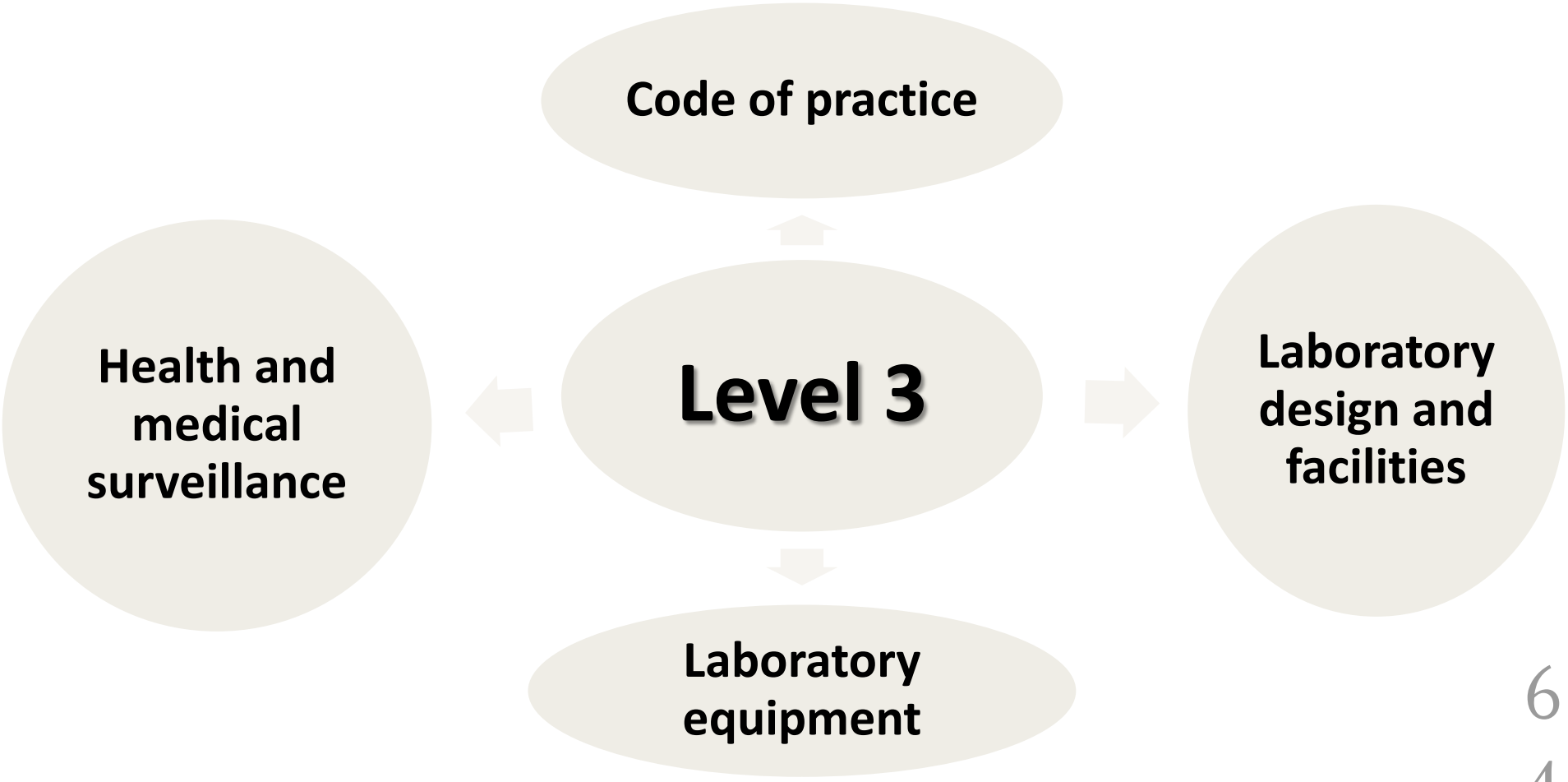
Handling and disposal procedures for contaminated materials and wastes

- 3. Contaminated material for decontamination by autoclaving and thereafter washing and reuse or recycling

- 4. Contaminated material for autoclaving and disposal

- 5. Contaminated material for direct incineration.

III-The containment laboratory – Biosafety Level 3



The containment laboratory – Biosafety Level 3

- The containment laboratory – Biosafety Level 3 is designed and provided for work with Risk Group 3 microorganisms
- and with large volumes or high concentrations of Risk Group 2 microorganisms that pose an increased risk of aerosol spread.
- Biosafety Level 3 containment requires the strengthening of the operational and safety programmes over and above those for basic laboratories

The containment laboratory – Biosafety Level 3

- **Biosafety Level 3. The major additions and changes are in:**
- 1. Code of practice
- 2. Laboratory design and facilities
- 3. Health and medical surveillance.

- **Laboratories in this category should be registered or listed with the national or other appropriate health authorities.**

Code of practice

- The code of practice for basic laboratories – Biosafety Levels 1 and 2 applies except where modified as follows.

- 1. The international biohazard warning symbol and sign displayed on laboratory access doors must identify the following:

- biosafety level

- the name of the laboratory supervisor who controls access,

- and indicate any special conditions for entry into the area, e.g. immunization.

Code of practice

- 2. Laboratory protective clothing must be of the type with solid-front or wrap-around
- gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or
- dedicated shoes. Front-buttoned standard laboratory coats are unsuitable, as are
- sleeves that do not fully cover the forearms. Laboratory protective clothing must
- not be worn outside the laboratory, and it must be decontaminated before it is
- laundered. The removal of street clothing and change into dedicated laboratory
- clothing may be warranted when working with certain agents (e.g. agricultural or zoonotic agents).

Laboratory design and facilities

- The laboratory design and facilities for basic laboratories – Biosafety Levels 1 and 2 apply except where modified as follows:
- 1. The laboratory must be separated from the areas that are open to unrestricted traffic flow within the building.
  - Additional separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition
  - and door or access through an anteroom (e.g. a double-door entry or basic laboratory – Biosafety Level 2),
  - describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space.
  - The anteroom should have facilities for separating clean and dirty clothing and a shower may also be necessary.

Code of practice

- 3. Open manipulations of all potentially infectious material must be conducted within
- a biological safety cabinet or other primary containment device (see also Chapter 10).

- 4. Respiratory protective equipment may be necessary for some laboratory procedures

  or working with animals infected with certain pathogens

Laboratory design and facilities

- 2. Anteroom doors may be self-closing and interlocking so that only one door is open at a time.
- 3. Surfaces of walls, floors and ceilings should be water-resistant and easy to clean. Openings through these surfaces (e.g. for service pipes) should be sealed to facilitate decontamination of the room(s).

Laboratory design and facilities

- 4. The laboratory room must be sealable for decontamination. Air-ducting systems must be constructed to permit gaseous decontamination.
- 5. Windows must be closed, sealed and break-resistant.
- 6. A hand-washing station with hands-free controls should be provided near each exit door.
- 7. There must be a controlled ventilation system that maintains a directional airflow into the laboratory room. A visual monitoring device with or without alarm(s) should be installed so that staff can at all times ensure that proper directional airflow into the laboratory room is maintained.

Laboratory design and facilities

- 8- The building ventilation system must be so constructed that air from the containment laboratory – Biosafety Level 3 is not recirculated to other areas within the building.
- Air may be high-efficiency particulate air (HEPA) filtered, reconditioned and recirculated within that laboratory. When exhaust air from the laboratory (other than from biological safety cabinets) is discharged to the outside of the building, it must be dispersed away from occupied buildings and air intakes. Depending on the agents in use, this air may be discharged through HEPA filters.
- A heating, ventilation and air-conditioning (HVAC) control system may be installed to prevent sustained positive pressurization of the laboratory.

Laboratory design and facilities

- 9. All HEPA filters must be installed in a manner that permits gaseous decontamination and testing.
- 10. Biological safety cabinets should be sited away from walking areas and out of crosscurrents from doors and ventilation systems .
- 11. The exhaust air from Class I or Class II biological safety cabinets
- which will have been passed through HEPA filters, must be discharged in such a way as to avoid interference with the air balance of the cabinet or the building exhaust system.

Laboratory design and facilities

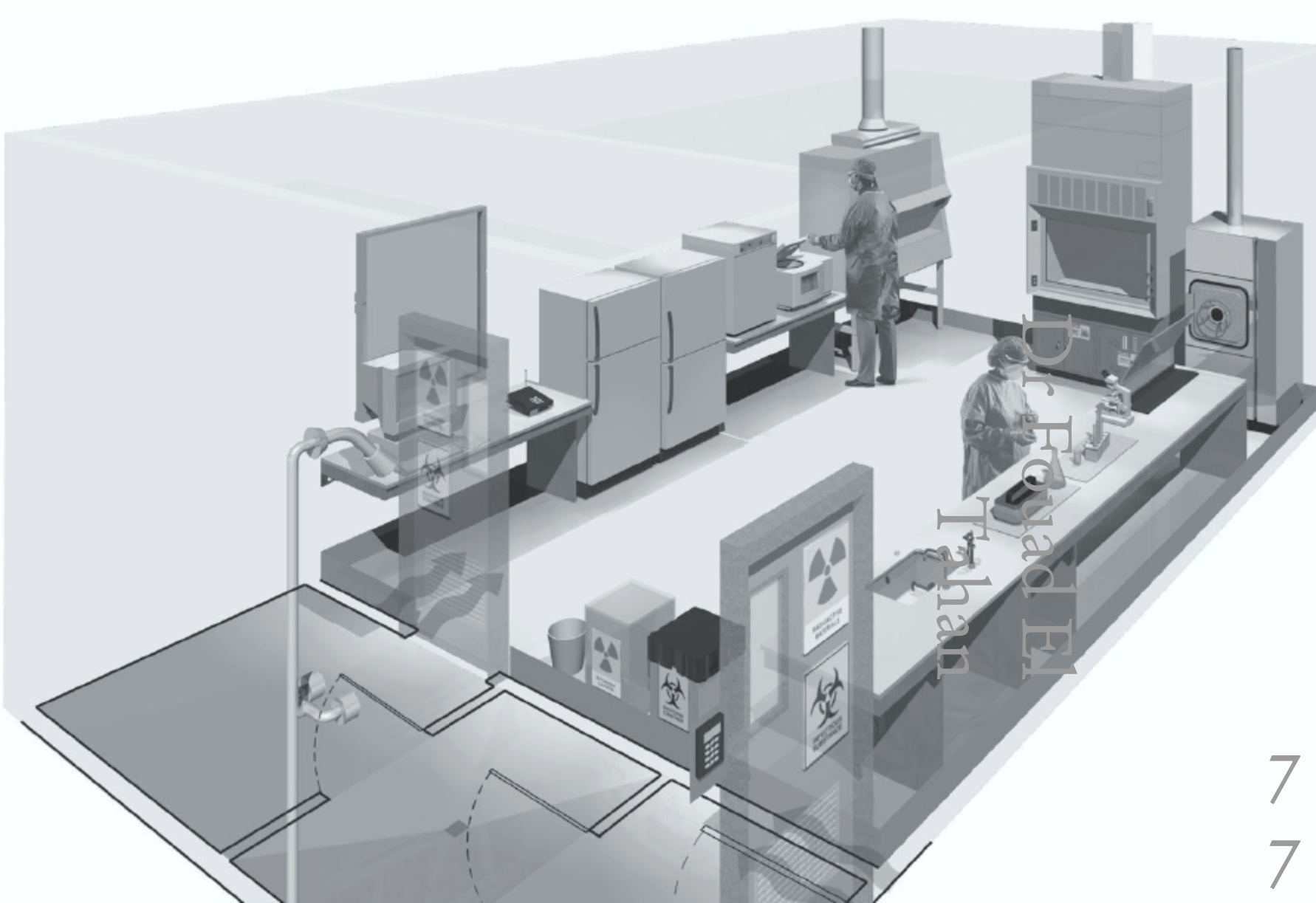
- An autoclave for the decontamination of contaminated waste material should be available in the containment laboratory.

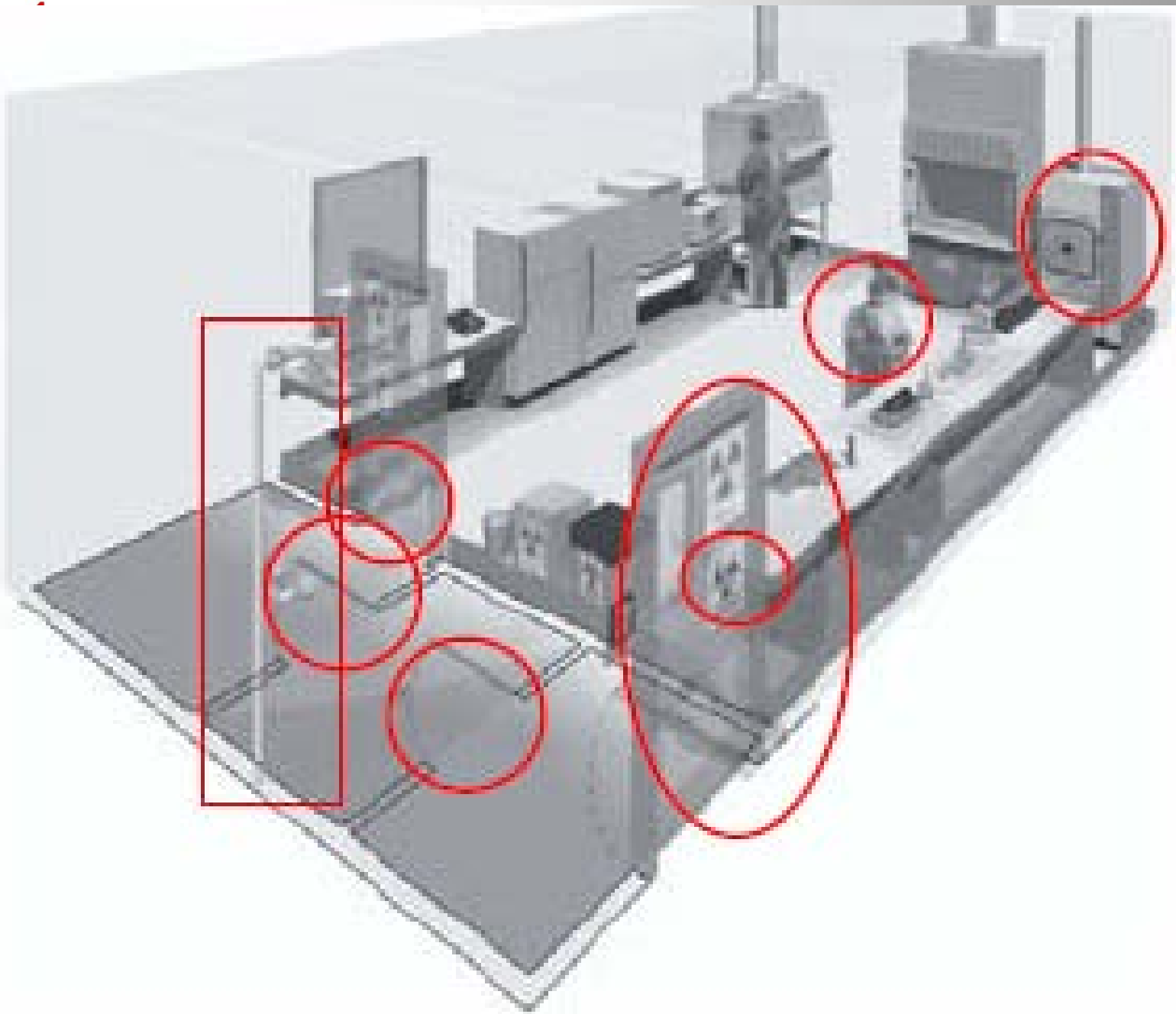
- If infectious waste has to be removed from the containment laboratory for decontamination and disposal, it must be transported in sealed, unbreakable and leakproof containers according to national or international regulations, as appropriate.

Laboratory design and facilities

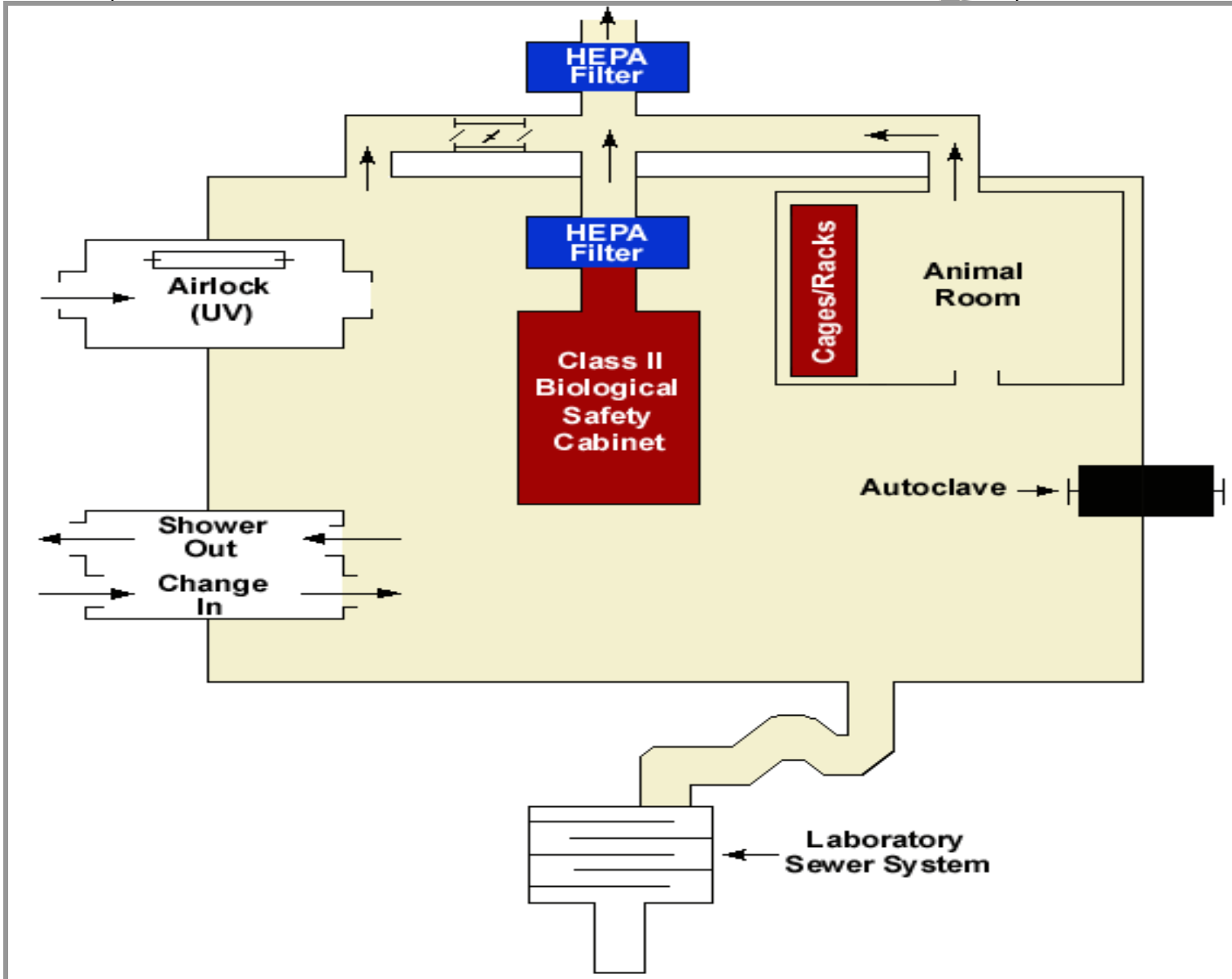
- 13. Backflow-precaution devices must be fitted to the water supply. Vacuum lines should be protected with liquid disinfectant traps and HEPA filters, or their equivalent.
- Alternative vacuum pumps should also be properly protected with traps and filters.

- 14. The containment laboratory – Biosafety Level 3 facility design and operational procedures should be documented.





Biosafety Level 3



Biosfatey level 3: facility design

- Requirements
- BSL-1 and 2 Facilities PLUS
  - Enclosures for aerosol generating equipment
  - Room penetrations sealed
  - Walls, floors and ceilings are water resistant for easy cleaning
  - BSC class II or III to manipulate infectious material
  - Separate building or isolated zone within a building
  - Directional inward airflow
  - Single-pass air; can be recirculated if HEPA filtered
  - Double door entry
  - BSCs mandatory
- Additional requirements depending on work and agents:
  - HEPA filtration of the exhaust
  - Effluent decontamination
  - Personnel showers

Lab. Bio-security

Follow the guidelines, regulations, Follow the guidelines, regulations, and site and site-specific risk assessment specific risk assessment for your unique situation

Biosafety Level 3

Standard and Special Practices, Safety Equipment and Facilities*

- Limited Access

(Double-door change room or Airlock)

- Exhaust Air Fan Interlocked with Supply Air Fan
- HEPA-Filtered Room Exhaust Air**
- Directional Airflow
- Protective Laboratory Clothing

* Plus criteria listed for BSL-2

** When working with certain Arboviruses

Biosafety Level 3

- Baseline serum samples are collected from laboratory workers.
- A biosafety manual, specific for that laboratory, is developed or adopted and biosafety precautions are incorporated into standard operating procedures.

- All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices.

Laboratory equipment

- The principles for the selection of laboratory equipment, including biological safety
- Cabinets are the same as for the basic laboratory – Biosafety Level 2.
- However, at Biosafety Level 3, manipulation of all potentially infectious material must be conducted within a biological safety cabinet or other primary containment device.

Laboratory equipment

- Consideration should be given to equipment such as centrifuges, which will need additional containment accessories, for example, safety buckets or containment rotors.
- Some centrifuges and other equipment, such as cell-sorting instruments for use with infected cells, may need additional local exhaust ventilation with HEPA filtration for efficient containment.

Health and medical surveillance

- The objectives of health and medical surveillance programmes for basic laboratories – Biosafety Levels 1 and 2 also apply to containment laboratories

- Biosafety Level 3,
- except where modified as follows:

Health and medical surveillance

- 1. Medical examination of all laboratory personnel who work in containment
- laboratories – Biosafety Level 3 is mandatory.
- This should include recording of a detailed medical history and an occupationally-targeted physical examination.

Health and medical surveillance

- After a satisfactory clinical assessment,
- the examinee may be provided with a medical
- contact card .
- stating that he or she is employed in a facility with a containment laboratory – Biosafety Level 3. This card should include:
- a picture of the card holder, be wallet-sized, and
- always be carried by the holder.
- The name(s) of the contact persons to be entered will need to be agreed locally
- But might include the laboratory director,
- medical adviser and/or
- biosafety officer.

A. Front of card

ILLNESS SURVEILLANCE NOTICE

Name _____

_____

Card holder's picture

TO THE EMPLOYEE

Keep this card in your possession. In case of unexplained febrile illness, present the card to your physician and notify one of the following in the order listed.

Dr _____ Tel (Work): _____

_____ Tel (Home): _____

Dr _____ Tel (Work): _____

_____ Tel (Home): _____

B. Back of card

TO THE PHYSICIAN

The holder of this card works in an area at _____
in which pathogenic viruses, rickettsia, bacteria, protozoa or helminths are present. In the event of an unexplained febrile illness, please call the employer for information on agents to which this employee may have been exposed.

Name of laboratory: _____

Address: _____

_____

_____

_____

Tel: _____

IV -The maximum containment laboratory – Biosafety Level 4

- The maximum containment laboratory – Biosafety Level 4 is designed for work with Risk Group 4 microorganisms.

- Before such a laboratory is constructed and put into
- operation, intensive consultations should be held with institutions that have had experience of operating a similar facility.

- Operational maximum containment

IV -The maximum containment laboratory – Biosafety Level 4

- laboratories – Biosafety Level 4 should be under the control of national or other appropriate health authorities.

- The following information is intended only

- - as introductory material.

- - Entities working to pursue development of a Biosafety Level 4
- - laboratory should contact the WHO Biosafety programme for additional information.

Level 4

- Code of practice
- The code of practice for Biosafety Level 3 applies except where modified as follows:

- 1. The two-person rule should apply, whereby no individual ever works alone.
- - This is particularly important if working in a Biosafety Level 4 suit facility.

- 2. A complete change of clothing and shoes is required prior to entering and upon exiting the laboratory.

Level 4

- Code of practice

- 3. Personnel must be trained in emergency extraction procedures in the event of personnel injury or illness.

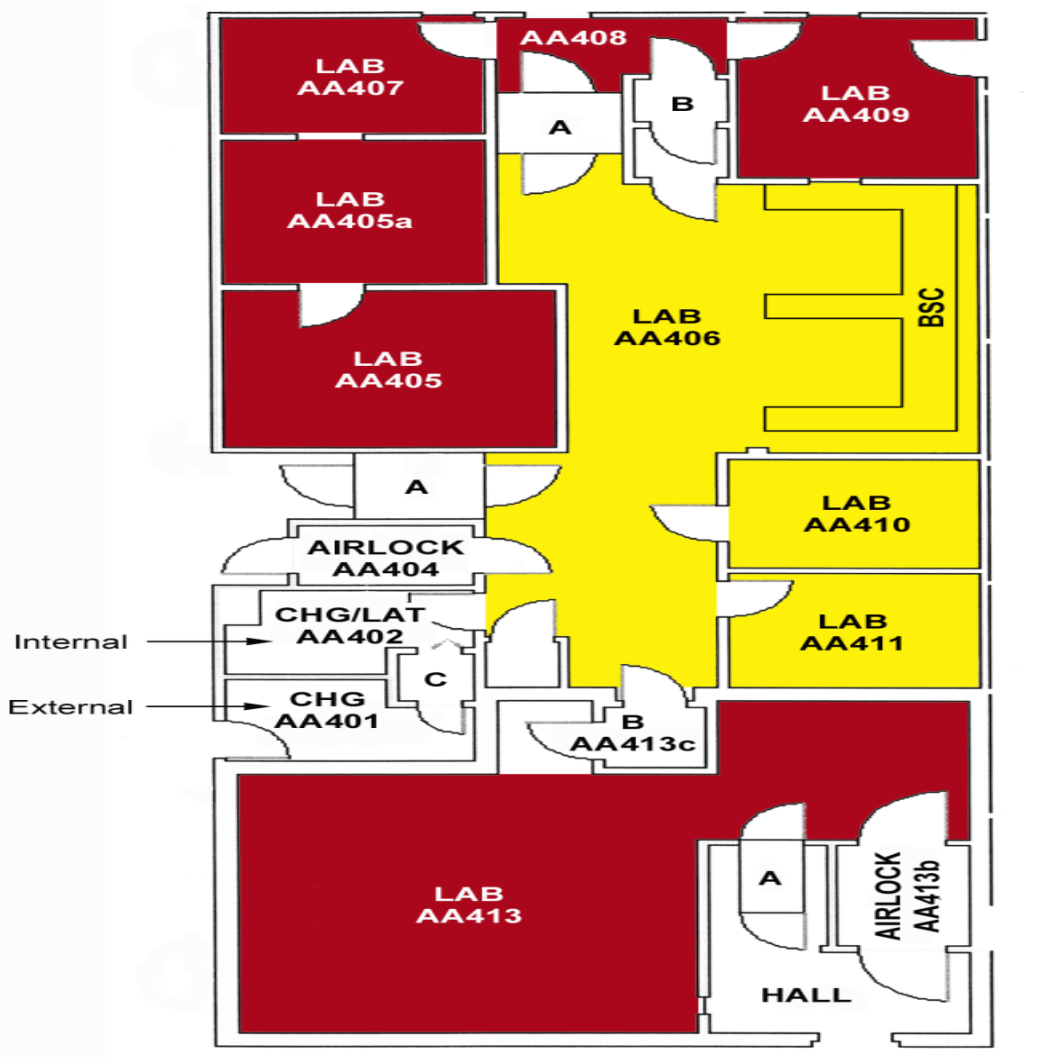
- 4. A method of communication for routine and emergency contacts must be
- established between personnel working within the maximum containment
- laboratory – Biosafety Level 4 and support personnel outside the laboratory.

Level 4

- **Laboratory design and facilities**

- The features of a containment laboratory – Biosafety Level 3 also apply to a maximum containment laboratory – Biosafety Level 4 with the addition of the following.

Biosafety Level 4



A - Autoclave
B - Chemical Disinfectant Shower
BSC - Class III Biological Safety Cabinet (hoodline)
BSL-4
BSL-3
C - Wet Shower
CHG - Change Room(s)
LAT - Latrine

Lab. Bio-security

Biosafety Level 4

Standard and Special Practices, Safety Equipment and Facilities*

- Limited Acces
(Double-door change room or Airlock
- Dedicated Laboratory Ventilatio
Syste
- Double HEPA-Filtered Exhaus
- Directional Ai
- Positive Pressure Personnel
or Class III

* Plus criteria listed

Biosafety Level 4

- Only persons whose presence is required for program or support purposes are authorized to enter the laboratory. Each entry is documented in a log-book.
- Supplies are brought in through the double-door autoclave, fumigation chamber, or airlock.

Biosafety Level 4

- Personnel enter and leave only through the clothing change and shower rooms. They take a decontamination shower every time they leave the laboratory.
- Airlock doors are to be used only in emergencies.

Level 4

- 1. Primary containment.

— Class III cabinet laboratory.

-Passage through a minimum of two doors prior to entering the rooms containing the Class III biological safety cabinet

- In this laboratory configuration the Class III biological safety cabinet provides the primary containment.

- A personnel shower with inner and outer changing rooms is necessary

- - Once the outer door is securely closed, staff inside the laboratory can open the inner door to retrieve the materials.

Level 4

- — Suit laboratory.
- - A protective suit laboratory with self-contained breathing apparatus
- - The rooms in the protective suit laboratory
- - A suit decontamination shower must be provided and used by personnel leaving the containment laboratory area.
- - A separate personnel shower with inner and outer changing rooms is also provided.
- -Personnel who enter the suit area are required to don a one-piece,
- - positively pressurized, HEPA-filtered, supplied-air suit.

Level 4

- - Entry into the suit laboratory is through an airlock fitted with airtight doors.

- - An appropriate warning system for personnel working in the suit laboratory must be provided for use in the event of mechanical system or air failure .

Level 4

2. Controlled access.

- - Biosafety Level 4 must be located in a separate building or in a clearly delineated zone within a secure building.
- - Entry and exit of personnel and supplies must be through an airlock or pass-through system.
- - On entering, personnel must put on a complete change of clothing;
- - before leaving, they should shower before putting on their street clothing.

Level 4

3. Controlled air system.

- - Negative pressure must be maintained in the facility.
- - Both supply and exhaust air must be HEPA-filtered.
- - There are significant differences in the ventilating systems of the Class III cabinet laboratory and suit laboratory:

4. Decontamination of effluents.

- - All effluents from the suit area, decontamination chamber, decontamination shower, or Class III biological safety cabinet must be decontaminated before final discharge.
- - Heat treatment is the preferred method.
- - Effluents may also require correction to a neutral pH prior to discharge.
- - Water from the personnel shower and toilet may be discharged directly to the sanitary sewer without treatment.

5. Sterilization of waste and materials.

- - A double-door, pass-through autoclave must
- be available in the laboratory area.
- - Other methods of decontamination must be available for equipment and items that cannot withstand steam sterilization.

Level 4

- 6. Airlock entry ports for specimens, materials and animals must be provided.
- 7. Emergency power and dedicated power supply line(s) must be provided.
- 8. Containment drain(s) must be installed.

Laboratory biosecurity

By Dr Fouad El Tahan

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Laboratory biosecurity concepts

The Laboratory biosafety manual emphasizes the use of :

- good microbiological work practices,
- appropriate containment equipment,
- proper facility design,
- operation and maintenance,
- and administrative considerations to minimize the risk of worker injury or illness.

Laboratory biosecurity concepts

In summary, security precautions should become:

- a routine part of laboratory work,
- just as have aseptic techniques and other safe microbiological practices.
- Laboratory biosecurity measures should not hinder
- the efficient sharing of reference materials,
  - clinical and epidemiological specimens
  - and related information necessary for clinical or public health investigations.

Laboratory biosecurity concepts

- Competent security management should not unduly interfere with the day-to-day activities of scientific personnel or be an impediment to conducting research.

- Assessment of the suitability of personnel,

-security-specific training

- and rigorous adherence to pathogen protection procedures

are reasonable means of enhancing laboratory biosecurity.

Laboratory biosecurity concepts

- All such efforts must be established and maintained through regular risk and threat assessments,
- and regular review and updating of procedures.
- Checks for compliance with these procedures, with clear instructions on roles,
- responsibilities and remedial actions, should be integral to laboratory biosecurity
- programmes and national standards for laboratory biosecurity.

biological safety cabinet

By dr Fouad El Tahan

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biological safety cabinet

- Biological safety cabinets (BSCs) are designed to protect the following :
- the operator,
- the laboratory environment
- and work materials from exposure to infectious aerosols
- and splashes that may be generated when manipulating materials containing infectious agents, such

biological safety cabinet

- primary cultures,
- stocks and diagnostic specimens.
- Aerosol particles are created by any activity that imparts energy into a liquid or semiliquid material,
- such as shaking, pouring, stirring or dropping liquid onto a surface or into another liquid.

biological safety cabinet

Other laboratory activities, such as:

- streaking agar plates,
- inoculating cell culture flasks with a pipette, using a multichannel pipette to dispense liquid suspensions of infectious
- agents into microculture plates,
- homogenizing and vortexing infectious materials,
- and centrifugation of infectious liquids, or working with animals, can generate infectious aerosols.

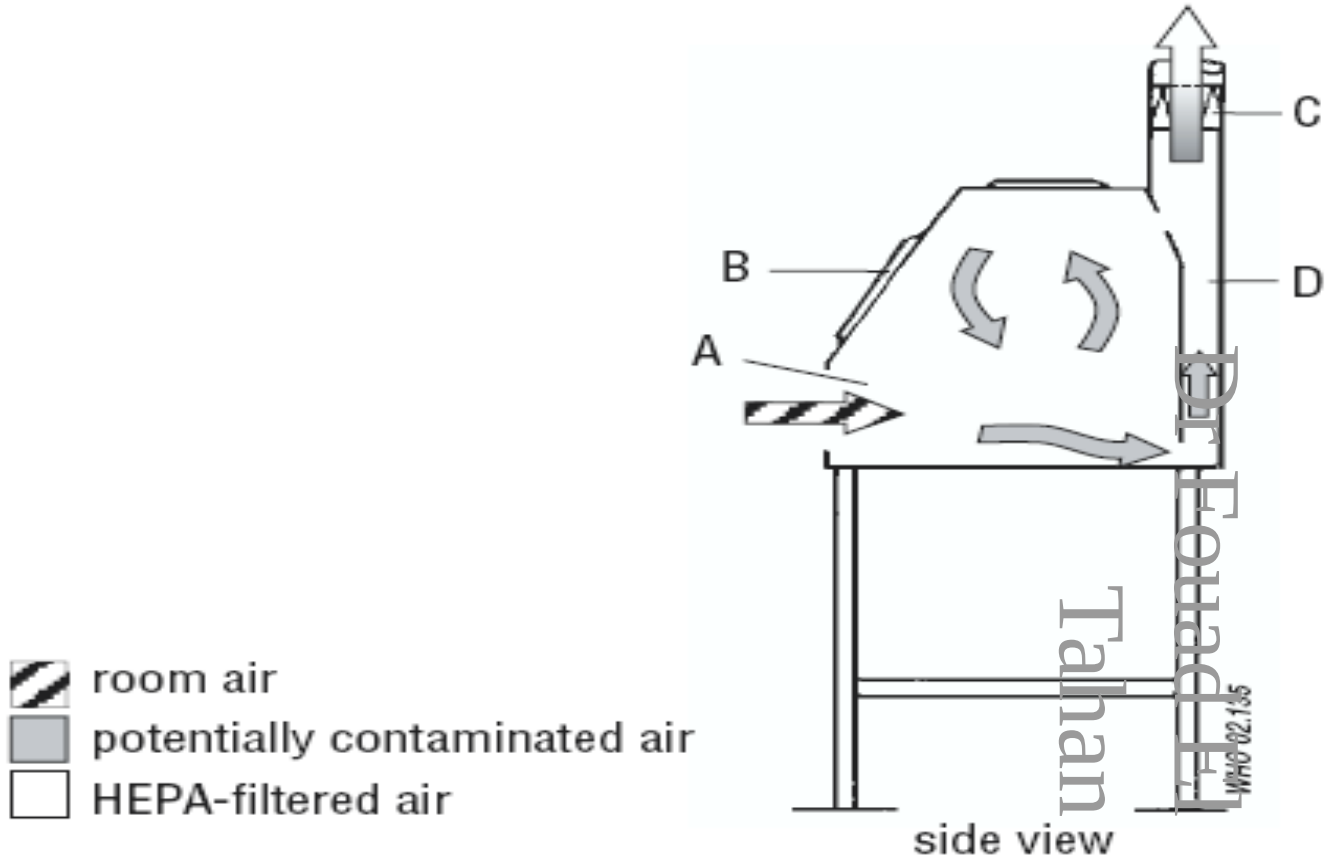
biological safety cabinet

- Aerosol particles of less than 5 μm in diameter and small droplets of 5–100 μm in diameter are not visible to the naked eye.

- The laboratory worker is generally not aware that such particles are being generated and may be inhaled or may cross contaminate work surface materials.

Table 8. ***Selection of a biological safety cabinet (BSC), by type of protection needed***

TYPE OF PROTECTION	BSC SELECTION
Personnel protection, microorganisms in Risk Groups 1–3	Class I, Class II, Class III
Personnel protection, microorganisms in Risk Group 4, glove-box laboratory	Class III
Personnel protection, microorganisms in Risk Group 4, suit laboratory	Class I, Class II
Product protection	Class II, Class III only if laminar flow included
Volatile radionuclide/chemical protection, minute amounts	Class IIB1, Class IIA2 vented to the outside
Volatile radionuclide/chemical protection	Class I, Class IIB2, Class III



Schematic diagram of a Class I biological safety cabinet.
A, front opening; B, sash; C, exhaust HEPA filter; D, exhaust plenum.

Class I biological safety cabinet

- Room air is drawn in through the front opening at a minimum velocity of 0.38 m/s,
- it passes over the work surface and is discharged from the cabinet through the exhaust duct.
- The directional flow of air whisks aerosol particles that may be generated on the work surface away from the laboratory worker and into the exhaust duct.

Class I biological safety cabinet

- The front opening allows the operator's arms to reach the work surface inside the cabinet while he or she observes the work surface through a glass window.

- The window can also be fully raised to provide access to the work surface for cleaning or other purposes.

Class I biological safety cabinet

The air from the cabinet is exhausted through a HEPA filter:

(a) into the laboratoryand then to the outside of the building through the building exhaust;

(b) to the outside through the building exhaust; or

(c) directly to the outside. The HEPA filter may be located in the exhaust plenum of the BSC or in the building exhaust.

Class II biological safety cabinets

The Class II BSC was designed not only to provide personnel protection but also to protect work surface materials from contaminated room air.

Class II BSCs, of which there are four types (A1, A2, B1 and B2),

Class II BSCs,differ from Class I BSCs by allowing only air from a HEPA-filtered (sterile) supply to flow over the work surface.

Class II biological safety cabinets

- The Class II BSC can be used for working with infectious agents in Risk Groups 2 and 3.

- Class II BSCs can be used for working with infectious agents in Risk Group 4 when positive-pressure suits are used.

Class II biological safety cabinets

Class II type A1 biological safety cabinet

- An internal fan draws room air (supply air) into the cabinet through the front opening and into the front intake grill.
- The inflow velocity of this air should be at least 0.38 m/s at the face of the front opening.
- The supply air then passes through a supply HEPA filter before flowing downwards over the work surface.

Class II biological safety cabinets

- As the air flows downwards it “splits” about 6–18 cm from the work surface, one half of the downwards flowing air passing through the front exhaust grill, and the other half passing through the rear exhaust grill.

- Any aerosol particles generated at the work surface are immediately captured in this downward airflow and passed through the front or rear exhaust grills, thereby providing the highest level of product protection.

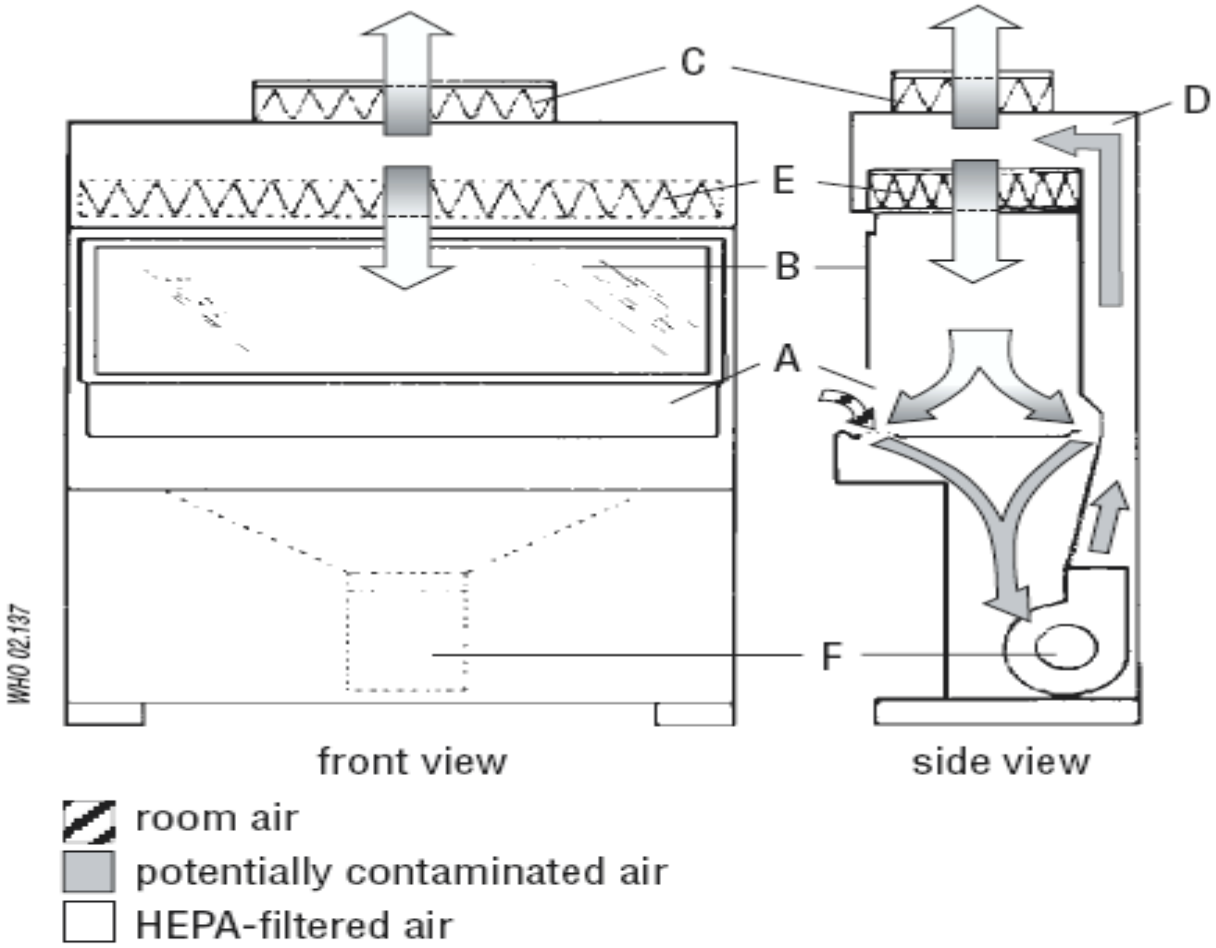
Class II biological safety cabinets

- The air is then discharged through the rear plenum into the space between the supply and exhaust filters located at the top of the cabinet.

Class II biological safety cabinets

- Owing to the relative size of these filters, about 70% of the air re circulates through the supply HEPA filter back into the work zone; the remaining 30% passes through the exhaust filter into the room or to the outside.

- Air from the Class IIA1 BSC exhaust can be re circulated to the room or discharged to the outside of the building through a thimble connection to a dedicated duct or through the building exhaust system.



Schematic representation of a Class IIA1 biological safety cabinet.
A, front opening; B, sash; C, exhaust HEPA filter; D, rear plenum; E, supply HEPA filter; F, blower.

Class II biological safety cabinets

Class II type A2 vented to the outside, B1 and B2 biological safety cabinets

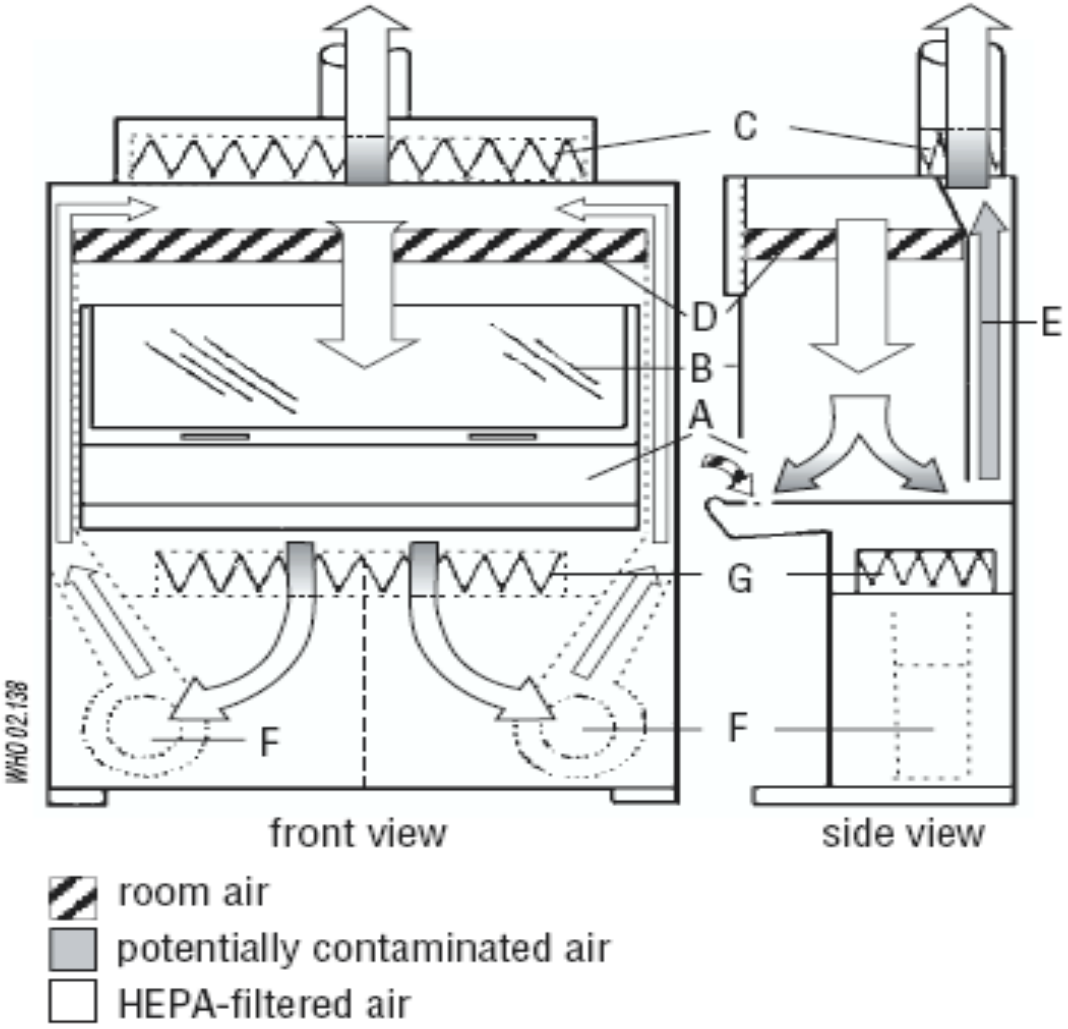
- Class IIA2 vented to the outside,
- These BSCs differ from one another in several aspects:

- the air intake velocity through the front opening;
- the amount of air recirculated over the work surface and exhausted from the cabinet;

Class II biological safety cabinets

- the exhaust system, which determines whether air from the cabinet is exhausted to the room, or to the outside, through a dedicated exhaust system or through the building exhaust;

- and the pressure arrangements



Schematic diagram of a Class IIB1 biological safety cabinet.
A, front opening; B, sash: C, exhaust HEPA filter; D, supply HEPA filter; E, negative-pressure exhaust plenum; F, blower; G, HEPA filter for supply air. Connection of the cabinet exhaust to the building exhaust air system is required.

Table 9. Differences between Class I, II and III biological safety cabinets (BSCs)

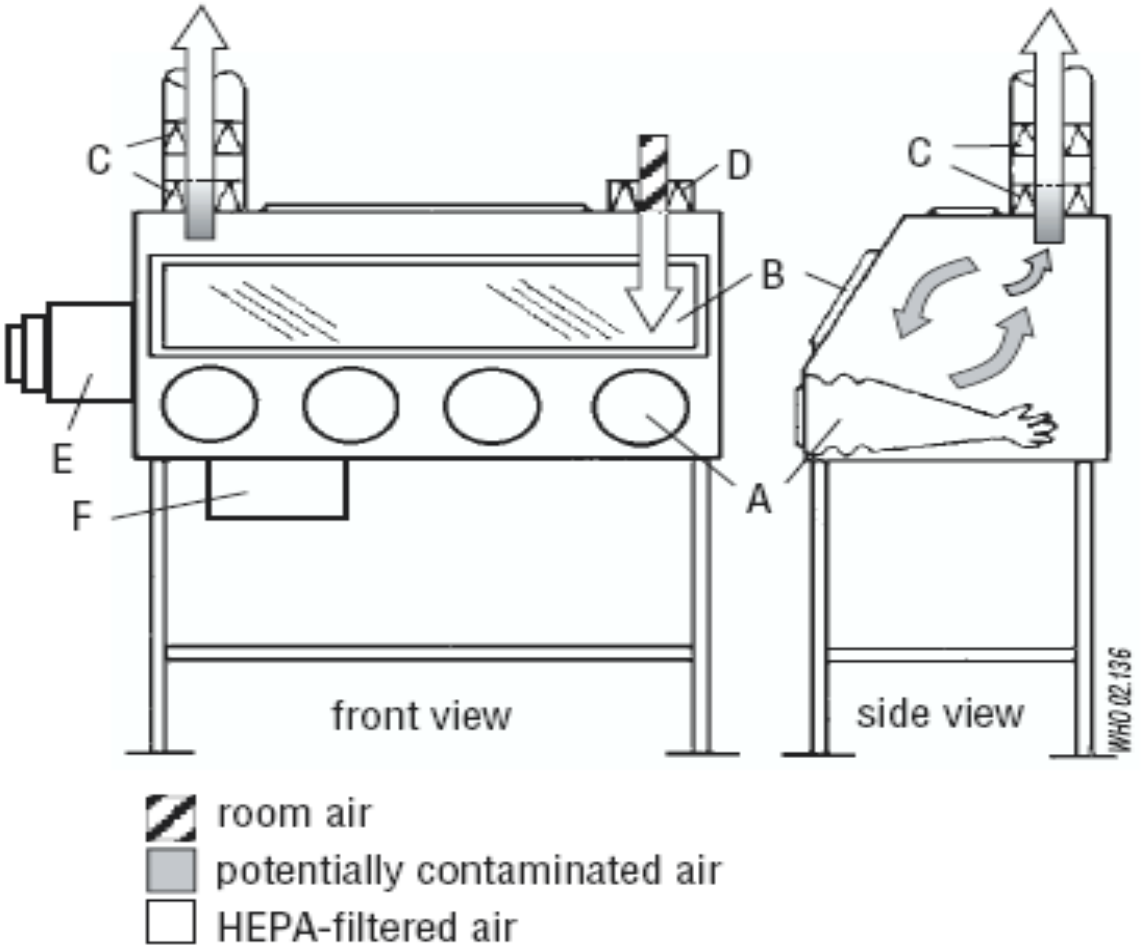
BSC	FACE VELOCITY (m/s)	AIRFLOW (%)		EXHAUST SYSTEM
		RECIRCULATED	EXHAUSTED	
Class I[a]	0.36	0	100	Hard duct
Class IIA1	0.38–0.51	70	30	Exhaust to room or thimble connection
Class IIA2 vented to the outside[a]	0.51	70	30	Exhaust to room or thimble connection
Class IIB1[a]	0.51	30	70	Hard duct
Class IIB2[a]	0.51	0	100	Hard duct
Class III[a]	NA	0	100	Hard duct

NA, not applicable.

[a] All biologically contaminated ducts are under negative pressure or are surrounded by negative pressure ducts and plenums.

Class III biological safety cabinet

- This type provides the highest level of personnel protection and is used for Risk Group 4 agents.
- All penetrations are sealed “gas tight”.
- Supply air is HEPA-filtered and exhaust air passes through two HEPA filters.
- Airflow is maintained by a dedicated exhaust system exterior to the cabinet,
- which keeps the cabinet interior under negative pressure



Schematic representation of a Class III biological safety cabinet (glove box).
A, glove ports for arm-length gloves; B, sash; C, double-exhaust HEPA filters; D, supply HEPA filter; E, double-ended autoclave or pass-through box; F, chemical dunk tank. Connection of the cabinet exhaust to an independent building exhaust air system is required.

Using biological safety cabinets in the laboratory

- Location
- Operators
- Material placement
- Operation and maintenance
- Ultraviolet lights
- Open flames
- Spills
- Certification
- Cleaning and disinfection
- Decontamination
- Personal protective equipment
- Alarms
- Supplementary information

Personal protective equipment and clothing

Barrier to minimize the risk

By Dr Fouad El Tahan

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General

- Protective clothing should be worn when working in the laboratory.
- Before leaving the laboratory, protective clothing should be removed,
- hands should be washed

Personal Protective Equipment

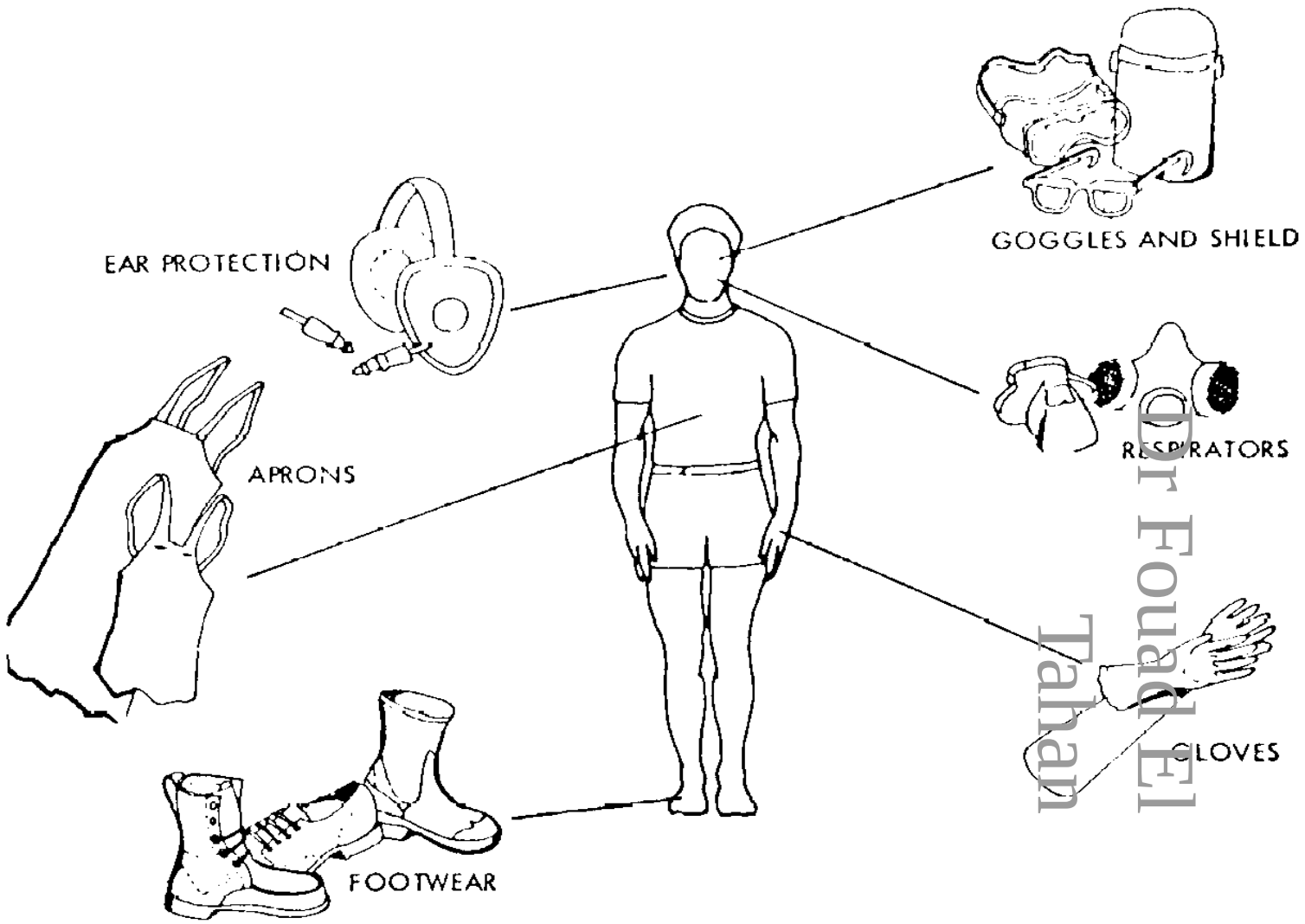
- Definition: specialized clothing or equipment worn by an employee for protection against infectious materials" (OSHA)

- The need for PPE and the type of PPE used is based on hazard present; each situation must be evaluated independently

Personal Protective Equipment

- Laboratory coats.
- Gowns.
- coveralls Aprons.
- Footwear
- Gloves
- Shoe Covers
- Boots

- Respirators
- Face Shields
- Face Masks
- Safety Glasses
- Safety Goggles



Factors Influencing PPE Selection

Type of exposure anticipated :

- Splash/spray versus touch
- Category of isolation precautions
- Durability and appropriateness for the task
- Fit

Personal Protective Equipment

For BSL 1 and 2

- Laboratory Coat
- Gloves
- Goggles or Face Shield

PPE Requirements General Conditions

- **Biosafety Level 3 Laboratories**

  - Safety glasses or goggles

  - Back-closing laboratory coat

  - Gloves (single pair at the time of entrance; double-gloved when working in the BSC or when transporting biological materials or chemicals)

Personal Protective Equipment

- For BSL 3
  - Back-closing laboratory coat or smock
  - Double Gloving
  - Shoe Coverings

For BSL 4

- Protective Suit Class III BSC

Clothing

- Laboratory coats should be fully buttoned.
- long-sleeved, back-opening gowns or coveralls give better protection than laboratory coats.
- Aprons may be worn over laboratory coats or gowns where necessary to give further protection against spillage of chemicals or biological materials such as blood or culture fluids

- Select appropriate type and size
- Opening is in the back
- Secure at neck and waist
- If gown is too small, use two gowns
  - Gown #1 ties in front
  - Gown #2 ties in back

Respirators

- Respiratory protection may be used when carrying out high-hazard procedures
- cleaning up a spill of infectious material.
- Place over nose, mouth and chin
- Fit flexible nose piece over nose bridge
- Secure on head with ties or elastic
- Adjust to fit
- Perform a fit check –
  - Inhale – respirator should collapse
  - Exhale – check for leakage around face
- Respirators are incompatible with facial hair

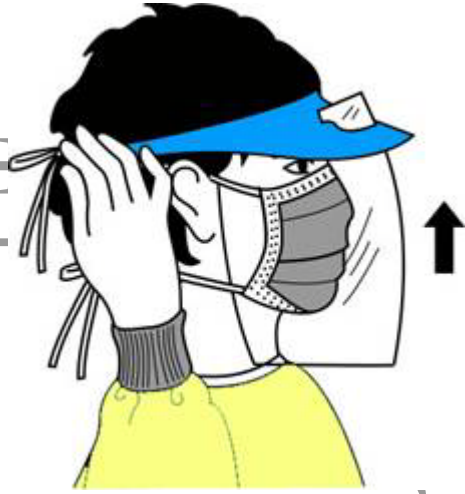
The choice of respirator

- will depend on the type of hazard(s).
- Respirators are available with interchangeable filters for protection against gases, vapours, particulates and microorganisms.
- It is imperative that the filter is fitted in the correct type of respirator.

Eye and Face Protection

- Position goggles over eyes and secure to the head using the ear pieces or headband

- Position face shield over face and secure on brow with headband

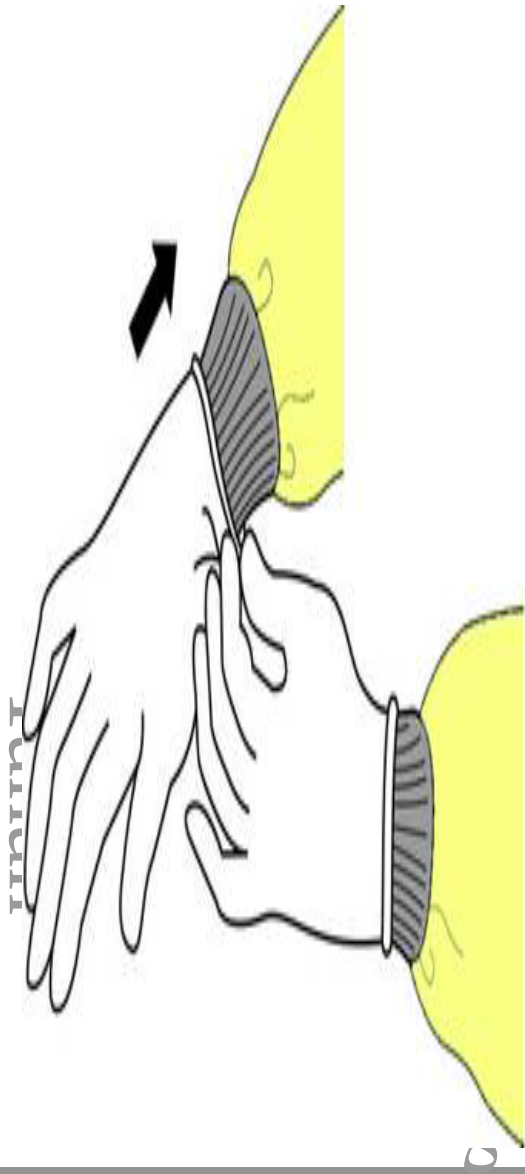


- Adjust to fit comfortably

Gloves

- Contamination of hands may occur when laboratory procedures are performed.
- Hands are also vulnerable to sharps injuries.

- put on gloves last
- Select correct type and size
- Insert hands into gloves
- Extend gloves over isolation gown cuffs
- Use two gloves over each other



Sequence for Donning PPE

- Mask or respirator
- Goggles or face shield
- Gown
- Over head
- Footwear
- Gloves

Disposable

- microbiologically approved latex, vinyl or nitrile surgical-type gloves are used widely for general laboratory work.

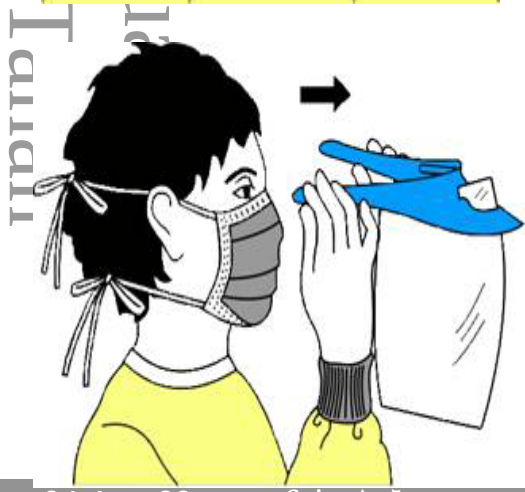
- They are used for handling infectious agents and blood and body fluids.

Removal

- **Sequence for Removing PPE**
  - Gloves
  - Footwear
  - Over head
  - ✓Gown
  - ✓Face shield or goggles
  - ✓Mask or respirator

Remove Goggles or Face Shield

- Grasp ear or head pieces with ungloved hands
- Lift away from face
- Place in disinfectant for reprocessing or dispose



Removing Isolation Gown

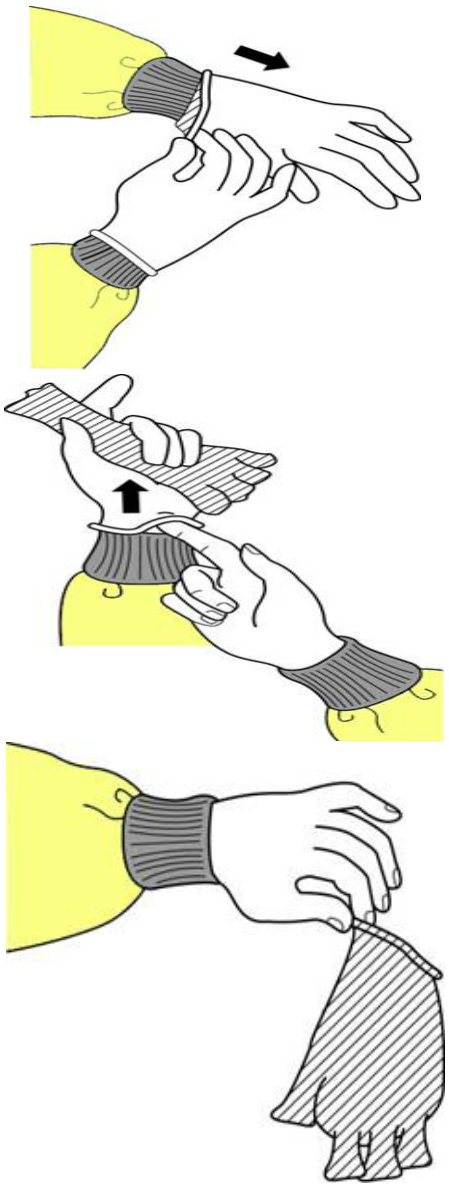
- Unfasten ties
- Peel gown away from neck and shoulder
- Turn contaminated outside toward the inside
- Fold or roll into a bundle
- Autoclave then discard

Removing a Mask

- Lift the bottom elastic over your head first
- Then lift off the top elastic
- Remove from face
- Autoclave then discard

How to Remove Gloves

- Grasp outside edge near wrist
- Peel away from hand, turning glove inside-out
- Hold in opposite gloved hand
- Slide ungloved finger under the wrist of the remaining glove
- Peel off from inside, creating a bag for both gloves
- Autoclave then discard



Hand Hygiene

- Perform hand hygiene immediately after removing PPE.
- Wash hands with soap and water or use an alcohol-based hand rub
- Ensure that hand hygiene facilities are available at the point needed, e.g., sink or alcohol-based hand rub

Biorisk management system

By Dr Fouad El Tahan

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Biorisk management system

- Management Systems Approach
- improves the organisation's effectiveness and efficiency.

Biorisk management system

Application of the management systems approach principle leads to the following actions:

- Defining the system by identifying or developing the processes that affect a given objective,
- Structuring the system to achieve the objective in the most effective manner,
- Understanding the interdependencies among the processes of the system,
- Continually improving the system through measurement and evaluation, and,
- Establishing resource constraints prior to action.

Biorisk management system

The management system approach enables an organisation to :

- effectively identify,
- monitor and control the laboratory biosafety
- and biosecurity aspects of its' activities.

Biorisk management system

- An effective management system approach should be built on :
- the concept of continual improvement through a :

- cycle of planning,
- implementing,
- reviewing and improving the processes , and
- actions that an organisation undertakes to meet goals.

Biorisk management system

- This is known as the PDCA (Plan-Do-Check-Act) principle;

- Plan: Planning, including identification of hazard and risk and establishing goals,

- Do: Implementing, including training and operational issues,

- Check: Checking, including monitoring and corrective action,

- In order to improve biorisk management the organisation needs to focus on :
- the causes of non-conformities
- and undesirable events.
- Systematic identification and correction of system deficiencies leads to improved performance and control of biorisk.

Keys to a successful biorisk management system.

1-Commitment by top management:

2-Focus on continual improvement:

3-Management system integration

4-Application

1-Commitment by top management:

Providing adequate resources, prioritisation and communication of safety and security policy;

Integration of biorisk management throughout the organisation;

Identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.

2-Focus on continual improvement:

- Making continual improvement an objective for every individual in the organisation;
- Using periodic assessment gainst established risk-criteria to identify areas for potential improvement;
- Continually improving the effectiveness and efficiency of processes;
- Promoting prevention activities;

2-Focus on continual improvement:

- Providing personnel in the organisation with appropriate education and training including the methods and tools of continual improvement;

- Establishing measures and goals for improvement;

3-Management system integration

- This Laboratory Biorisk Management Standard is compatible with
- the ISO 9001:2000 (Quality),
- ISO 14001:2004 (Environmental) and
- OHSAS 18001 (Occupational Health and Safety) management systems standards, in order to facilitate the integration of all such management systems of an organisation.

4-Application

- The requirements of this standard are generic and are intended to be applicable to all organisations handling
- pathogens and/or
- toxins, that is, microbiological containment laboratories, regardless of type, size and pathogens/toxins handled.

4-Application

- the organisation need to decide how they are to be implemented based on the available resources.

- The justification should be founded on an analysis of the potential gains in terms of
- improved control of risk.

4-Application

- Improvements may typically address issues like:
- Training and awareness programmes;
- Internal communication;
- Effectiveness of reviews;
- Preventive action;
- Effectiveness of follow-up activities;
- Documented procedures and instructions.

biorisk management system standard

Scope

- is to set requirements necessary to control risks associated with activities in microbiological containment laboratories,
- i.e., laboratories where biological agents and toxins are handled.

biorisk management system standard

Scope

The standard will enable organisations to:

- Establish and maintain a biorisk management system

to control or minimise risk to acceptable levels in relation to employees,

the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;

- Provide assurance that the requirements are in place and implemented effectively;

biorisk management system standard

- Scope

- Seek and achieve certification or verification of the biorisk management system by an external third party;
- Provide a framework that can be used as the basis for training and raising awareness of biosafety and laboratory biosecurity guidelines and best practices within the scientific community.

biorisk management system standard

Scope

The standard is performance-based and sets out requirements and places responsibility on organisations to

- demonstrate that appropriate and validated risk reduction procedures have been established and
- implemented.

Biorisk management system requirements

- 5 Biorisk management system requirements
- 5.1 General Requirements.
- 5.1.1 Biorisk Management System.

  - Shall establish, document, implement and maintain a biorisk management system with the requirments of this laboratory.

- 5.1.2 Continual Improvement.

- Use of policy, Objectives,self audit programme,audit results,analysis of data,risk assessment corrective and preventive avtions and management review

Biorisk management system requirements

- 5.2 Policy .
- 5.2.1 Biorisk Management Policy .

a. Protecting staff, contractors and visitors

b. Reducing the risk of unintentional release of biological agents and toxins,

c. Reducing the risk to an acceptable level

d. Complying with all legislation and other legal requirements applicable to the biological agents

e. Ensuring that the need for effective biorisk management

f. Effectively communicating individual obligations with regard to biorisk to all employees

g. Continually improving biorisk management performance.

Biorisk management system requirements

- 5.3 Planning.

5.3.1 Planning for Hazard Identification, Risk Assessment and Risk Control .

- Planning and Resources
- Assessment Timing and Scope
- Risk Identification
- Inherent Risk Assessment
- Identification of Treatment Options (or controls)
- Residual Risk

Biorisk management system requirements

5.3.2 Legal Requirements.

- shall ensure that all relevant legal requirements are identified within the biorisk management system.

5.3.3 Objectives, Targets and Programme .

- Biorisk Control Objectives and Targets
- Monitoring Controls

Biorisk management system requirements

- 5.4 Implementation and Operation.

5.4.1 Roles, Responsibilities and Authorities.

- Senior Management
- Biorisk Management Supervision
- Scientific Management
- Occupational Health
- Facility Management
- Security Management
- Animal Handling

Biorisk management system requirements

5.4.2 Personnel Training, Awareness and Competence .

- Recruitment [shall ensure that qualifications, experience and aptitudes relating to biorisk]
- Competence
- Continuity and Succession Planning
- Training

Biorisk management system requirements

5.4.3 Consultation and Communication .

- The organisation shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties.

5.4.4 Operational Control .

- The organisation shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied.
- The organisation shall plan these activities, including maintenance, and ensure that they are carried outunder specified conditions.

Biorisk management system requirements

- General Safety
- Biological Agents and Toxin Inventory and Information
- Work Programme, Planning and Capacity
- Change Management
- **Work Practices, Decontamination and Personnel Protection :**

a) Good Microbiological Technique
b) Inactivation of Pathogens and Toxins
c) Clothing and Personal Protective Equipment (PPE)

Biorisk management system requirements

- **Worker Health Programme**

a) Vaccination of Personnel

- **Human Factors and Control of Workers**

a) Personnel Reliability

b) Contractors and Suppliers

c) Exclusion

Biorisk management system requirements

- Infrastructure and Operational Management

a) Planning, Design and Verification

b) Commissioning and Decommissioning

c) Maintenance, Control, Calibration, Certification and Validation

d) Physical Security

e) Control of Supplies

Biorisk management system requirements

- Transport of Biological agents and Toxins
- Information Security

5.4.5 Emergency Response and Contingency Plans

Emergency scenarios

The organization shall ensure that all credible and foreseeable emergency scenarios that may impact on

Biorisk management system requirements

the organisation's biorisks have been identified.

a) Infected / potentially infected worker or other contact
b) Accident or illness to worker and need for evacuation;
c) Fire;
d) Flood;
e) Breach of security;
f) Explosion;
g) Potential loss of biological agents or toxins through theft or any other reason;
h) Unexpected virulence (unknown biological agents or biological agents expected to be avirulent);

Biorisk management system requirements

a) Physical facility and equipment failure, including control system failure;
b) Failure of disinfection regime;
c) Utility failure including electricity, gas, steam and water supplies;
d) Major spillage / aerosol release;
e) Environmental release;
f) Natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.);
g) Act of terrorism or deliberate vandalism;
h) Intense media attention.

Biorisk management system requirements

- Emergency Plans

The organisation shall ensure that biorisks are taken into account when preparing and implementing emergency plans.

- Emergency Exercises and Simulations

The organisation shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.

Biorisk management system requirements

- **5.4.6 Contingency Plans**

The organization shall ensure that in the event of an emergency, adequate contingency measures will be in place to ensure the safety and security of continued operations.

Biorisk management system requirements

- 5.5 Checking and Corrective Action .
- 5.5.1 Performance Measurement and Analysis of data .
- 5.5.2 Records, Document and Data Control.
- 5.5.3 Inventory Monitoring and Control .

Biorisk management system requirements

- **5.5.4 Accident and Incident Investigation, Non-conformances, Corrective and Preventive Actions.**
  - Accident / Incident Investigation
  - Control of non-conformities
  - Corrective action
  - Preventive action

Biorisk management system requirements

- **5.5.5 Inspection and Audit .**

The organisation shall ensure that a programme of inspection and audit is conducted which is appropriate to the risk associated with the facility.

Biorisk management system requirements

- **5.6 Management Review.**

5.6.1 Biorisk Management Review

Top management shall review the organisation's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

Biorisk management system requirements

- **The review input should include information on:**

a. Results of audits;

b. Compliance to SOPs and work instructions.

c. Status of risk assessment activities.

d. Status of preventive and corrective actions.

e. Follow-up actions from previous management reviews.

f. Changes that could affect the system.

g. Recommendations for improvement.

h. Results of accident / incident investigations.

Biorisk management system requirements

- **The review output should include decisions and actions related to:**

i. Improvement of the effectiveness of the biorisk management system.

j. Improvement related to the requirements and risk assessments;

k. Resource needs.

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