C03 Laboratory Biological Safety Guidelines

1. Introduction

Biological hazards refer to any organisms or organic matters produced by these organisms that are harmful to human health. These include parasites, viruses, bacteria, fungi, toxins, etc. As laboratories involved in biomedical technology account for a majority of research laboratories at the Science Park, a great number of laboratory personnel are frequently exposing to biological hazards during their works. Biohazardous substances can enter into the human bodies via three major of routes, i.e. inhalation, ingestion and injection causing laboratory acquired infection. Laboratory personnel must exercise good biological safety practices to safeguard themselves. The laboratories shall also be equipped with proper biological safety equipment and facilities as essential biological safety measures.

2. Laboratory-Acquired Infections (LAIs)

Laboratory-acquired infections (LAIs) refer to infections acquired through laboratory or laboratory-related activities regardless of whether they are symptomatic or asymptomatic in nature. They may be resulted from occupational exposure to biohazardous substances or infectious agents via the following routes in the laboratories:

a) Inhalation (aerosols)
b) Percutaneous inoculation (needle and syringe, cuts or abrasions from contaminated items and animal bites)
c) Contact between mucous membranes and contaminated material (hands or surfaces)
d) Ingestion (aspiration through a pipette, smoking or eating)

As inhalation of contaminated aerosols accounts for a great number of LAI cases, infectious agents must be carefully handled to avoid the generation of aerosols in all laboratory procedures including centrifugation, sonication, homogenization, pipetting, mixing, shaking, and opening containers, etc.

3. Risk Grouping of Microorganisms

Microorganisms are classified into different risk groups by numerous government agencies based on their effects on humans, taking into consideration for the transmissibility, invasiveness, virulence, lethality of the specific pathogen and the availability of vaccines or therapeutic interventions. According to the “Laboratory Biosafety Manual” issued by the World Health Organization (WHO), there are four risk groups with the following definitions:

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a) **Risk Group 1** (no or very low individual and community risk): A micro-organism that is unlikely to cause human or animal disease.
b) **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 exposure may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
c) **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.
d) **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.

All microorganisms listed under Risk Groups 2 to 4 are known as pathogens while those classified as Group 1 are non-pathogens. Even though under the same principles of classification, different government agencies or international authorities may have developed their own list of microorganisms with different risk grouping. Research personnel shall adopt the corresponding biological safety measures for handling microorganisms in the laboratories.

Due to the health risk associated with **Risk Groups 3 and 4 organisms** and their potential health and safety impact to the community, they are currently **Not Allowed** to be handled in the laboratories at the Science Park.

4. Laboratory Biosafety Levels

In general, the biosafety level of a laboratory is the level of protection against the biohazard identified through the use of good laboratory practices, safety equipment and building facilities. Microorganisms of certain risk groups shall be handled only in laboratories of the required biosafety levels. The table below summaries the safety practices and equipment required for each biosafety level.

Risk Group	Biosafety Level	Typical Laboratory Types	Laboratory Practices	Safety Equipment
1	Basic Biosafety Level 1 (BSL1)	Basic teaching; research	Good microbiological techniques	None; open bench work

2	Basic Biosafety Level 2 (BSL2)	Primary health services; diagnostic; research	Good microbiological techniques; Protective clothing; Biohazard signs	Open bench + Biological safety cabinet for potential aerosols
3	Containment Biosafety Level 3 (BSL3) *(Not allowed at the Science Park)*	Special diagnostic; Research	As for level 2; + special clothing; controlled access, directional air flow	Biological safety cabinet for all activities
4	Maximum Containment Biosafety Level 4 (BSL4) *(Not allowed at the Science Park)*	Dangerous Pathogen Units	As for level 3; + air lock, shower exits, special waste disposal	Class III Biological safety cabinet, positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

As Risk Group 3 and 4 organisms are restricted at the Science Park, **Biosafety Levels 3 and 4 (BSL3 and 4)** laboratories are **Not Allowed** to be built and operated at the Science Park. For animal experiments associated with microorganisms, they must be conducted in laboratories of appropriate Animal Biosafety Levels. **Animal Biosafety Levels 3 and 4 (ABSL3 and 4)** laboratories are also currently **Not Allowed** at the Science Park.

For **clinical specimens** including human blood, blood products, body fluids, tissues and cells which may contain potentially infectious agents, they must be handled in **BSL2 containment** with **BSL2 practices** as the minimum requirement unless a higher biosafety level is deemed necessary due to the presence of known microorganisms of higher risk groups.

5. Risk Assessment

Laboratory Persons In-Charge of individual clients at the Science Park are required to conduct appropriate risk assessments before commencement of research projects involving microorganisms or other biohazardous substances. Risk assessment procedures are recommended as follows:

a) Identify the Risk Group that has been assigned to the biohazardous agent(s) involved with reference information from local authorities or international agencies.
b) Identify laboratory procedure hazards with particular attention to those procedures that may generate aerosols, pose hazards associated with needle-stick injury, animal bites, hazardous chemicals and radioactive substances, etc.
c) Determine the required biosafety level and other necessary safety measures.
d) Evaluate if existing safety measures suffice. If not, include additional measures.
e) Review the risk assessment periodically or whenever necessary.

The purpose of this risk assessment is to ensure that appropriate equipment and facilities are available to support the work being considered. In case of any queries arising from the process of risk assessment, the concerned Laboratory Person In-Charge should contact SHE Office for consultation.

6. Safety Measures for Biosafety Levels 1 and 2 (BSL1 and 2) Laboratories

The safety guidelines described here are applicable to both Level 1 and Level 2 laboratories. They are fundamental good microbiological practices, which should be practiced in all BSL2 laboratories as a basic minimum, and as far as possible in BSL1 laboratories.

6.1 General Rules

a) The international biohazard warning symbol and sign must be displayed on the doors of the rooms where micro-organisms of Risk Group 2 are handled.
b) Only authorized persons are allowed to enter the laboratory working areas.
c) Laboratory doors should be kept closed.
d) Animals not involved in the work of the laboratory should not be permitted in the laboratory.
e) Wear appropriate personal protective equipment such as gloves for hand protection; masks, protective eyewear or face shields for protection against splashes onto the mouth, eyes, or nose.
f) Remove all contaminated or potentially contaminated protective equipment before leaving the laboratory areas. Never take them home or outside the laboratories (such as during lunch or personal breaks).
g) Wash hands thoroughly before leaving the laboratories.
h) Do not eat, drink, smoke, or apply cosmetics in the laboratory areas.
i) Foods or drinks should not be kept in the laboratory areas except for experimental purpose.

j) Avoid mouth pipetting, recapping needles, or leaving unprotected any skin, membranes, or open cuts.
k) All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets. Procedures which may have an increased risk of aerosolization (e.g. centrifugation, grinding, blending, vigorous shaking or mixing, sonic disruption, opening ampoules containing infectious materials, etc.) should be conducted in a biological safety cabinet.
l) The laboratory should be kept neat, clean and free of materials that are not pertinent to the work.
m) Work surfaces must be decontaminated using appropriate disinfectants after any spill of biohazardous substances and at the end of the working day.
n) All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse.

6.2. Laboratory Design and Facility Requirements

a) Walls, ceilings and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratories. Floors should be slip-resistant.
b) Pipes and ducting should not be exposed, where possible.
c) Bench tops should be sealed to the walls, impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
d) Laboratory furniture should be sturdy. Open spaces between and under benches, cabinets and equipment should be accessible for cleaning.
e) Facilities for storing outer garments and personal items should be provided, preferably outside the laboratory working areas.
f) Hand washbasins, with running water if possible, should be provided in each laboratory room, preferably near the exit door.
g) Doors should have vision panels, be self-closing. They should have appropriate fire ratings.
h) An autoclave or other means of decontamination should be available for use at a convenient location.
i) Emergency shower and eyewash facilities should be available at a convenient location.
j) First-aid areas, or rooms suitably equipped and readily accessible, should be available.
k) Individual laboratory ventilation system should be such designed that the laboratory is maintained under negative pressure and laboratory air is not recirculated to other areas.
l) There should not be any cross connections between sources of laboratory water and drinking water supplies.
m) An anti-backflow device should protect the public water system.

n) There should be a reliable and adequate electricity supply and emergency lighting to permit safe exit. Back-up power is desirable for the support of essential equipment, such as incubators, biological safety cabinets, freezers, etc.

6.3 Essential Biosafety Equipment

a) Biological safety cabinets (BSC) – BSC is an essential biosafety equipment which offers a partially or fully enclosed work space for safe handling of biohazardous substances including microbiological agents and cancer cells, etc. According to international standards, there are different types of BSC with respect to the construction design as well as types and levels of protection. Laboratory personnel should use the appropriate type of BSC for their experimental works.
b) Pipetting aids – Use as a means to avoid mouth pipetting.
c) Plastic disposable transfer loops – Use to substitute metal inoculation loops in preventing aerosol production.
d) Electric transfer loop incinerators – Use to substitute gas burners in preventing aerosol production.
e) Screw-capped tubes and bottles – Avoid splashing of infectious materials in the tubes or bottles.
f) Autoclaves: Use for decontaminating infectious materials.
g) Plastic disposable Pasteur pipettes – Use whenever available to substitute glass pipettes.

Equipment such as autoclaves and biological safety cabinets must be validated with appropriate methods (preferably by a certified examiner) before being used. Re-certification should take place at regular intervals according to the manufacturer's instructions.

7. Handling, Storage and Disposal of Biological / Clinical Wastes

Biological or clinical waste is potentially dangerous because it can cause cuts and needle-stick injuries or transmit disease. According to the Waste Disposal (Clinical Waste)(General) Regulation (Cap. 354O, Laws of HKSAR), clinical waste means waste consisting of any substance, matter or thing generated in connection with:

a) A dental, medical, nursing or veterinary practice;

b) Any other practice, or establishment (howsoever described), that provides medical care and services for the sick, injured, infirm or those who require medical treatment;
c) Dental, medical, nursing, veterinary, pathological or pharmaceutical research; or
d) A dental, medical, veterinary or pathological laboratory practice.

Each laboratory operator at the Science Park that may generate clinical waste (as a clinical waste producer) shall obtain a premises code from the Environmental Protection Department (EPD) and follow all respective legal requirements in segregation, packaging, labelling, handling, storage, collection, transportation and disposal of clinical waste.

7.1 Segregation

Clinical waste must be segregated from municipal waste or general refuse and divided into six groups as described below which will be handled or treated differently.

a) Group 1 - Contaminated Sharps: Contaminated syringes, needles, cartridges, contaminated broken glass and other sharp instruments.
b) Group 2 - Laboratory Waste: Unsterilized laboratory stocks and cultures of infectious agents.
c) Group 3 - Human and Animal Tissue: All human tissue and animal carcasses from medical practices or research laboratories, whether infected or not, and items heavily contaminated with blood or blood products.
d) Group 4 - Infectious Material: Infectious material from patients under strict isolation.
e) Group 5 - Soiled Dressings: Soiled surgical dressings, swabs and all other contaminated waste from treatment areas and isolation rooms, assessed to be of significant risk by health care personnel.
f) Group 6 - Other Wastes: Other wastes that are likely to be contaminated with infectious materials or clinical waste and may pose significant health risk.

It should be noted that pharmaceutical waste and chemical waste which are potentially contaminated with infectious materials or clinical waste are classified as a special type of chemical waste and should be disposed of in accordance with chemical waste arrangements.

7.2 Packaging and Labelling

All clinical waste must be placed in a container or combination of containers that are leak resistant, impervious to moisture, strong enough to prevent tearing or bursting

under normal handling, and can be sealed securely. Containers shall be of one-trip type and under no circumstances should they be reused or recycled.
Bags and sacks should be colored RED and of high density polyethylene of a minimum gauge of 100 microns or equivalent strength. Group 1 waste should be disposed of in boxes or drums, which after sealing should be subsequently placed in plastic bags of the above specifications. Other groups of waste should be disposed of in plastic bags or plastic drums prior to dispatch for disposal.

Bags or sacks can be sealed by a "goose neck tie", and tied at the neck with adhesive tape. Bags or sacks should be sealed when they are no more than three-quarters full. Boxes and drums when closed must be further sealed with adhesive tape to ensure complete security of the aperture cover or lid prior to placing the container into a bag or sack, or prior to transportation in its original form, to storage and/or disposal. Sufficient space should be left in boxes or drums to ensure that they can be sealed securely. All containers should be conspicuously marked with the “Biohazard” symbol and labeled as “Clinical Waste” in both Chinese and English.

7.3 Handling

Personnel who may be required to handle or move bags of clinical waste by hand within a particular location should:

a) Check that storage bags, boxes and drums are effectively sealed;
b) Wear proper gloves and handle bags by the neck only;
c) Handle sharps containers and plastic drums safely;
d) Avoid damaging packaging by throwing, dropping, dragging it on ground or stepping on it;
e) Know the procedure in the event of accidental spillage and how to report accidents;
f) Check that the seal of any storage container is unbroken when movement is complete;
g) Understand the special problems related to special types of clinical waste, e.g. sharps, cytotoxic waste etc.

In the event of spillage of clinical waste, the clean-up operation should be conducted by workers trained for the purpose. The workers should be provided with absorbent materials, disinfectants, appropriate protective clothing, masks, eye protectors, gloves etc.

7.4. Storage

Clinical waste producers should provide suitable and adequate area for temporary onsite storage of clinical waste. The storage area should be located close to the

sources of waste generation so as to minimize waste handling and to facilitate management control.

The storage area should be enclosed on at least three sides by wall, partition or fence. As the quantity of clinical waste generated by most of the laboratories at the Science Park is not large, a small lockable cupboard with ventilation openings and proper signage can serve this purpose. For Group 3 clinical waste which contains human tissues or animal carcasses, they should be kept in dedicated lockable refrigerators or freezers to prevent obnoxious odor. Proper signage should also be displayed on the refrigerators or freezers.

7.5 Collection, Transportation and Disposal

Clinical waste producers must appoint a licensed clinical waste collector (list of licensed clinical waste collectors is retrievable from EPD's website) to collect the waste.

Licensed clinical waste collectors are required to use appropriate transit skips for collection and transportation of waste from the collection points to the dedicated vehicles for subsequent delivery to the licensed disposal facility.

In order to keep track of the waste movement in a waste consignment, EPD employs a "Trip Ticket" system to record and certify the quantity of clinical waste collected and delivered to the final destination. For each waste consignment, the licensed waste collector is required to provide a trip ticket copy to both the waste producer and the operator of the licensed disposal facility for checking and recording. Waste producers must keep such records for 12 months from the date of consignment / delivery for inspection by EPD.

8. Spillage and Decontamination

In the event of spillage of biohazardous or infectious agents, an assessment should be made so that suitable actions can be adopted for treating the spillage inside or outside of a biological safety cabinet.

8.1 Spillage inside a Biological Safety Cabinet

A spillage of infectious agents that is confined to the interior of a functioning biological safety cabinet should pose minimal risk to personnel in the area. However, the personnel involved should:

a) Stop any experimental works immediately;
b) Alert any nearby workers and notify the supervisor or Laboratory Person In-Charge;
c) Initiate decontamination procedures while the cabinet ventilation system continues to operate to prevent escape of contaminants from the cabinet;
d) Wear appropriate personal protective equipment including gloves, lab coat, goggles, and have the spill kit ready;
e) Cover the spill with paper towels or other absorbent materials and let the spill soak in;
f) Apply appropriate disinfectant such as 10% bleach from the outside to the inside of the spill;
g) Allow at least 20 minutes for disinfectant contact time;
h) Discard the paper towels into a clinical waste bag inside the cabinet;
i) Wipe up the spill area with clean paper towels and disinfectant for one or two more times;
j) Clean the area again using paper towels soaked with sterile water to remove any residual disinfectant;
k) Transfer all contaminated items into the clinical waste bag for disposal as clinical waste;
l) Upon completion of decontamination, report to the supervisor or Laboratory Person In-Charge for following up assessment if decontamination of the whole biological safety cabinet by fumigation is necessary.

8.2 Spillage outside a Biological Safety Cabinet

When there is an accidental spillage of infectious agents outside a biological safety cabinet, personnel involved should take the following emergency response procedures:

a) Alert all workers in the laboratory;
b) Hold the breath and evacuate the laboratory immediately followed by closing the door;
c) In case any body parts or clothing are contaminated, remove the contaminated clothing and flush the body parts with water using the nearby emergency shower;
d) Report the incident to the supervisor / Laboratory Person In-Charge as well as HKSTP by telephone following the general laboratory emergency procedures;
e) Proceed with decontamination procedures if considered manageable. Otherwise, stay in a nearby safe place and wait for assistance;

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f) Before re-entering the laboratory to carry out decontamination, stay outside for at least 30 minutes to allow droplets or aerosols to settle. Meanwhile, prepare for the spill kit and personal protective equipment;
g) Put on appropriate personal protective equipment such as gloves, lab coat, goggles, respirator and shoe covers;
h) Always work in a team by assigning personnel to control access to the site and personnel to do the cleanup.
i) Cover the spill with paper towels or other absorbent materials and let the spill soak in;
j) Apply appropriate disinfectant such as 10% bleach from the outside to the inside of the spill;
k) Allow at least 20 minutes for disinfectant contact time;
l) Discard the paper towels into a clinical waste bag;
m) Wipe up the spill area with clean paper towels and disinfectant for one or two more times;
n) Clean the area again using paper towels soaked with sterile water to remove any residual disinfectant;
o) Transfer all contaminated items including gloves, shoe covers and other protective clothing into the clinical waste bag for disposal as clinical waste;
p) Upon completion of decontamination, report to the supervisor / Laboratory Person In-Charge and HKSTP for following up assessment if the laboratory can be re-opened or further decontamination of the whole laboratory area by fumigation is necessary.