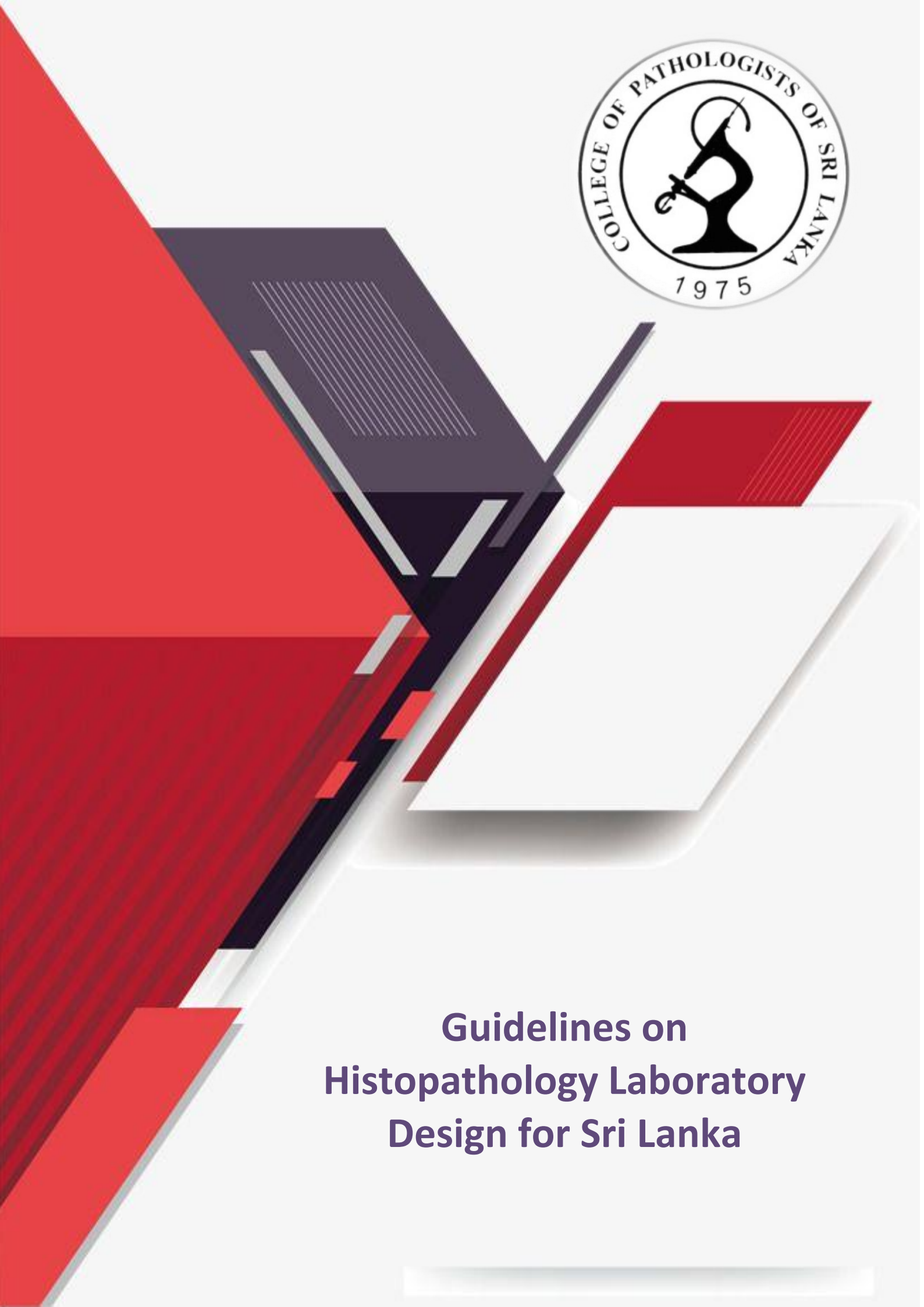

Guidelines on Histopathology Laboratory Design for Sri Lanka

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Guidelines on Histopathology Laboratory Design for Sri Lanka

Introduction

This document is a basic guide to planning and designing a histopathology laboratory in Sri Lanka using the Lean Design Concept. (Lean is a quality philosophy that was developed in the manufacturing industry to optimize workflow and efficiency). This concept has been adopted for laboratory design in many countries. The histopathology laboratory is designed to create the histopathology testing process towards a single-piece flow, to introduce effective practices, utilize maximum work capacity of human and physical resources and to add quality and value to the laboratory premises. It also involves standardizing work practices to maximize productivity.

Key factors considered in this laboratory design

1. Location of the histopathology laboratory in the hospital.
2. Designing of the laboratory layout (Schematic representation of layouts of different sections of a histopathology laboratory).
3. Space and capacity determination of the laboratory**.**
4. Growth prediction of the laboratory.
5. Determination of the bio-safety level of the histopathology laboratory.
6. Laboratory construction with priority for health and safety measures.
7. Maintenance of adequate ventilation.
8. Correct placement of laboratory equipment.
9. Special considerations for electrical and communication network design.
10. Special considerations for lighting.
11. Special considerations for plumbing.
12. Storage facilities.
13. Waste management.

These key factors will be discussed in detail in the next part of this document.

1. Location of the histopathology laboratory in the hospital

Histopathology laboratory should be located close to the operating theaters of the hospital. Easy accessibility to the autopsy room should also be considered.

2. Designing of laboratory layout

Physical layout of the laboratory should match the work flow (e.g. Single piece flow). The entire histopathology laboratory should be located on the same floor of the building. Design should have the flexibility to accommodate anticipated future changes in new technology and increased workload. (A semi flexible design is recommended for histopathology laboratories while a highly flexible design is recommended for chemical pathology laboratories where changes in technology occur more frequently)

Facilities for disabled persons should be considered when planning and constructing new medical care facilities. Laboratory work areas should be designed to allow an individual with disabilities to approach, enter and exit. If facilities to accommodate a disabled employee are not available, the laboratory settings (e.g. equipment, work benches, floor arrangements) may need re-arrangement to meet the needs of such employees. (e.g. adjustable work benches can be designed to allow a comfortable working height for both disabled and non-disabled employees).

Histopathology laboratory layout

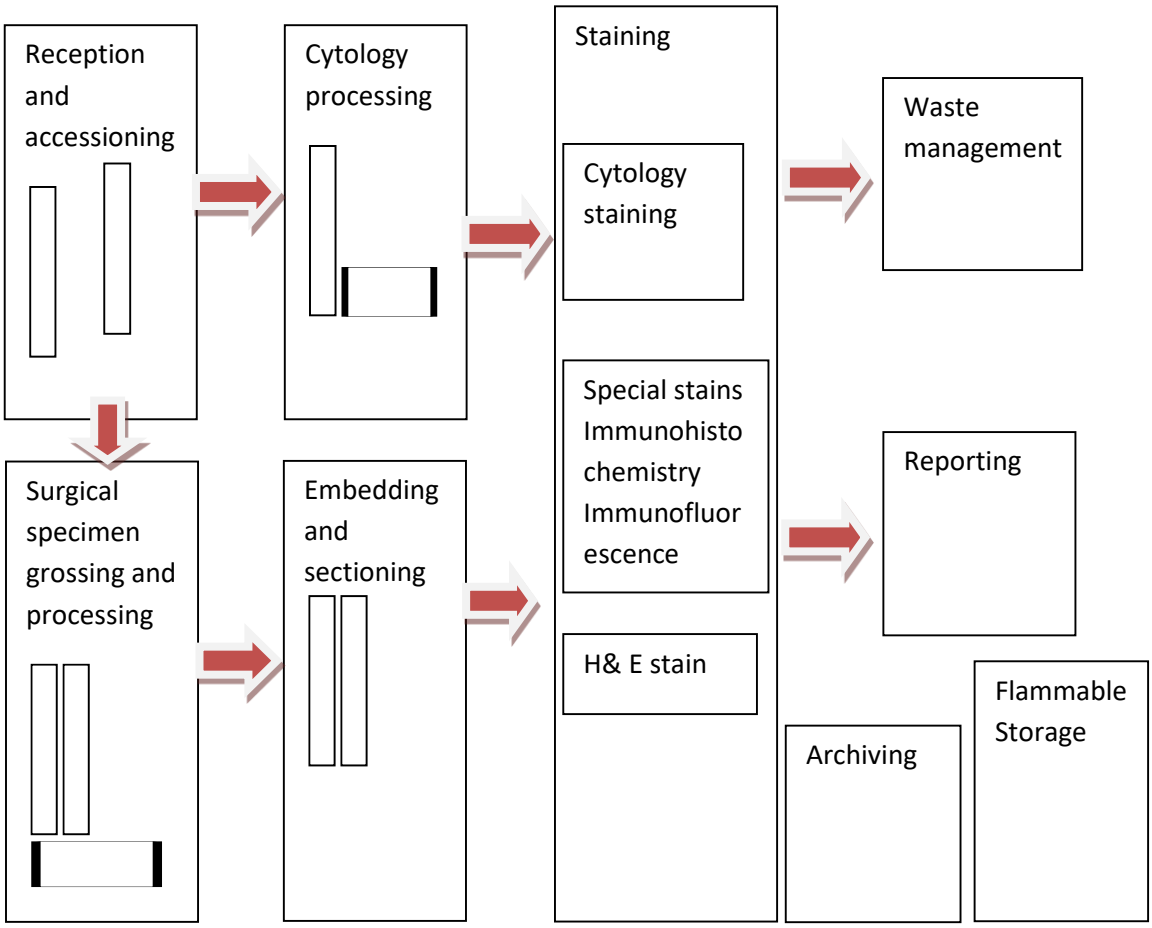
Space layout should be organized and arranged based on the workflow of the laboratory so that there is maximum efficacy and minimum crossing of paths at different points in the handling process.

Given below are two types of layouts recommended when designing a histopathology laboratory.

Layout 1

This layout (Figure 1) was extracted from the document on *Guide for establishing a pathology laboratory, in the context of cancer control, WHO, 2019* and modified accordingly by the accreditation committee of the College of Pathologists of Sri Lanka.

Figure 1: Layout 1**;** *Guide for establishing a pathology laboratory, in the context of cancer control, WHO, 2019* and modified accordingly.



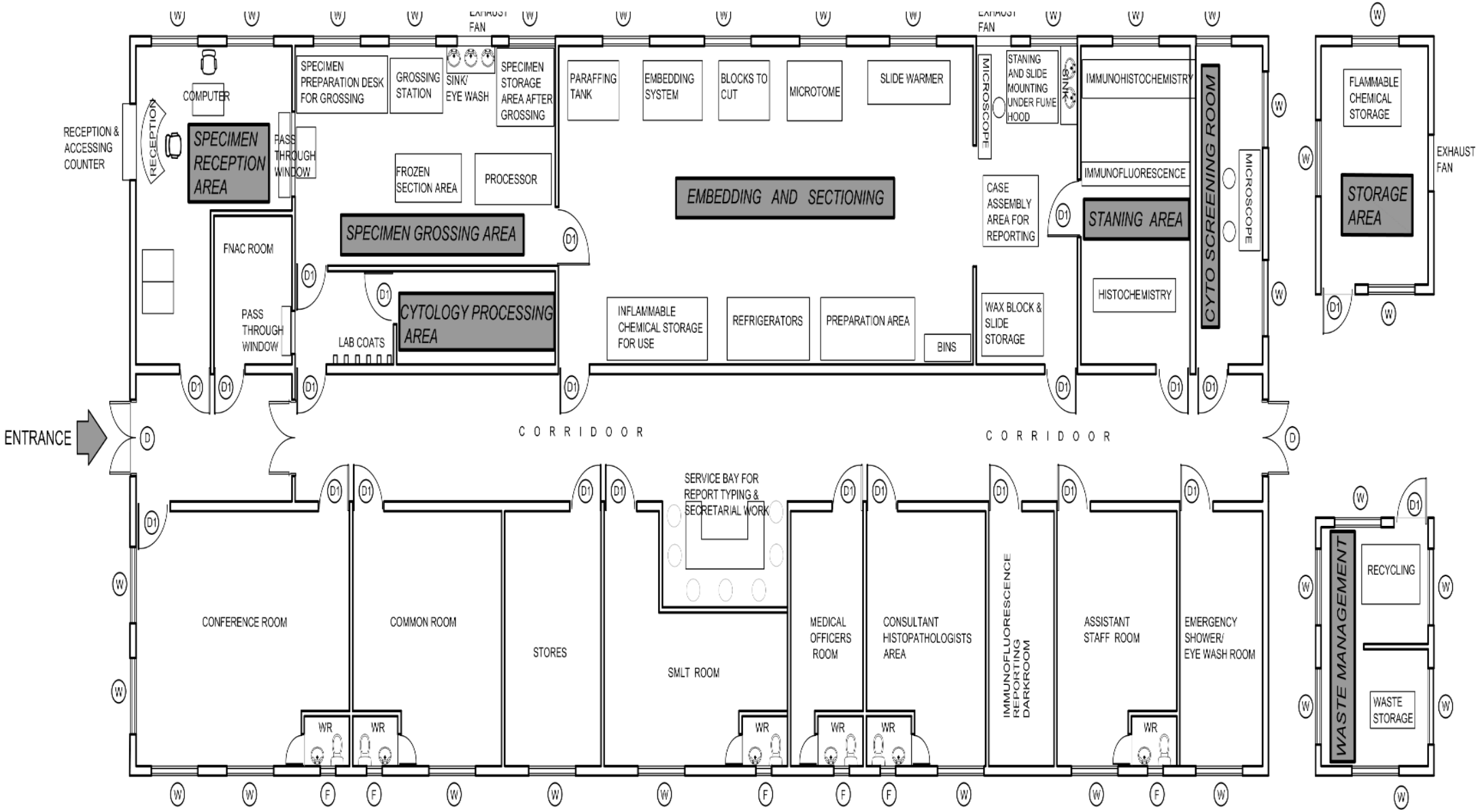
Layout 2: Standard layout for a histopathology laboratory recommended by the accreditation committee of the College of Pathologists of Sri Lanka.

Layout 2, given below (Figure 2) is a plan recommended by the Accreditation Committee of the College of Pathologists of Sri Lanka for histopathology laboratories. However, space calculation, architectural design, electrical design, plumbing, communication systems and relevant modifications need to be planned according to the individual requirements of each laboratory in consultation of relevant experts including engineers, architects, technical officers and consultant histopathologists.

Note 1:

Laboratory work areas should be modified accordingly. Staining and mounting should be done in separate areas if a fume hood is not available. A designated storage room should be designed to store used chemicals prior to recycling or disposal.

Figure 2: Layout 2; standard layout for a histopathology laboratory recommended by the accreditation committee of the College of Pathologists of Sri Lanka.



3. Space and capacity determination of the laboratory

Routine surgical pathology work includes histology, cytology, histochemistry, immunocytochemistry, immunohistochemistry, immunofluorescence and frozen section. For surgical pathology laboratories (e.g. histopathology laboratories), Bio Safety Level 2 laboratories are recommended.

Workspace should be sufficient enough for individual workers to perform anticipated tasks. Space determination should be done considering the current requirement as well as future proposed advancements. Factors to be considered include the number of employees, number of equipment, equipment clearance (e.g. distance between equipment) recommended by the manufacturers for operation and maintenance, location of storage spaces and future service projection. Safety should be given priority over efficiency, and space allocation must allow easy function and free movement throughout the laboratory.

Separate rest rooms and common rooms can be arranged within the laboratory but these areas must essentially be located away from the work benches. These should have designated food refrigerators, and eating and drinking should be discouraged inside the laboratory.

The square foot area is determined in the same manner as for other laboratory disciplines. As the histopathology laboratory uses carcinogenic chemicals during routine work, space should be allocated to minimize exposure to these carcinogens. Adequate spacing of the equipment is necessary for proper air circulation as well as for maintenance.

Table 1: General space clearance

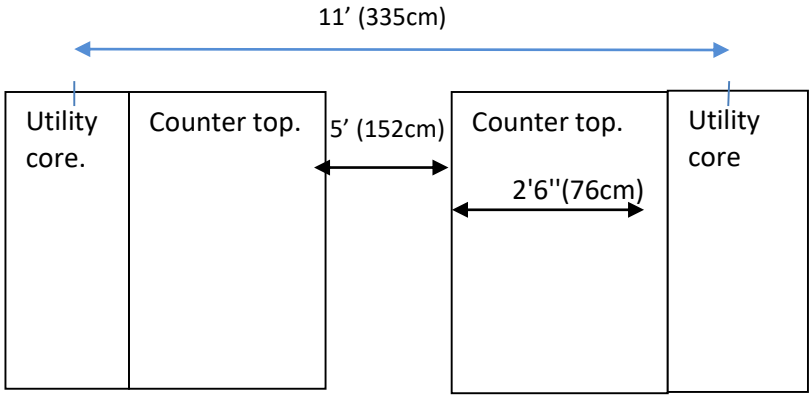
Description	Minimum Clearance/Space requirement
Minimum clearance in any walking area of the laboratory	112cm - aisle
Minimum clearance between two benches and equipment. Note: Adequate space should be allocated for wheel chair access for disabled persons.	152cm- aisle
Corridor where a patient bed or stretchers would be used.	244cm
Minimum width (depth) for countertop to accommodate laboratory equipment.	76cm

Work station design

Designing good workstations is essential for a comfortable, healthy and task-efficient laboratory.

Laboratory module with utility core.

Figure 3



Height and knee space

Height To avoid back strain, appropriate heights should be designed for working areas.

For sit-down counter tops - Recommended height from the floor-76cm

For stand-up counter tops- Recommended height from the floor - 91 cm

Knee space

This space should not be less than 71cm.

In the histopathology grossing area (e.g. microtome, water bath usage area), recommended minimum knee space is 112cm.

FNAC Room

Recommended area is 120 square feet. The minimum dimension in any direction should be 10 feet (305cm)

4. Growth prediction of the laboratory

These should be developed for a minimum projected duration of 10 years and should be documented in the laboratory design/ plan.

5. Determination of bio safety level of the laboratory.

Bio safety level 2 (BSL2) is recommended for histopathology laboratories.

(Annexure 1)

6. Laboratory construction with priority for health and safety measures.

Doors and aisles should be of sufficient width for transportation of standard laboratory carts and equipment without any obstruction.

Staff should have dedicated closets, and/or hanging areas for lab coats and for personal items and clothing. Lab coat hangers should be located near the entrance of the laboratory.

6.1 Wall construction

As laboratories are considered hazardous, the walls must be constructed to withstand and contain fire, fumes and other biohazards.

If water sprinklers are not available, the laboratory walls should have a one hour fire rating to the surrounding walls (this means that in the event of a fire inside the laboratory, it will be contained in that space for one hour)

All laboratory walls should be extended to the underside of the slab of the next floor to contain smoke and fire and to maintain the pressure limit of the laboratory space.

It is advisable to include insulation in the walls to keep working areas sound-proof, comfortable and private.

Walls of the laboratory should be designed to facilitate easy cleaning. Wall penetrations made for electrical circuits should be tightly sealed. It is recommended that glass or transparent panels should be used for partition of the working areas wherever possible to facilitate observation of the working areas as well as to ensure integrity and visibility among laboratory workers.

Epoxy paints are recommended for laboratory walls.

6.2 Doors

The type, size, number, location and placement of swing doors must be specified during the design process. Laboratory doors should be of the self-closing type to keep the laboratory area contained from the surrounding environment. Sliding doors are *not* recommended.

The main laboratory door should swing in the direction of travel, out of the laboratory. (e.g. a person should be able to easily push open the door and escape out of the laboratory in case of an emergency).

It is recommended to provide glass panels or viewing ports for doors of the working areas to facilitate observation of the work benches.

A self-closing door mechanism is recommended for entry doors and inner laboratory doors. Automated door opening systems are recommended to facilitate movement of materials and carts across the corridors. However, the main entry door should have restricted access.

A standard 8.5” x 11” inch, clear, plastic sign holder with the ‘laboratory door sign’ should be displayed outside each door.

If the space is not hazardous (e.g. office rooms, rest rooms), doors can be opened to the exterior.

The doors should open in the direction of fire egress travel in rooms occupied by 50 or more people. When designing the access, consideration must be given to the disabled, and the door width should not be less than 81cm.

There should be at least one large door for large instruments to be moved in and out.

Travel distance to an exit door from any point of the laboratory should not be more than 23 meters. (75 feet)

6.3 Windows

It is recommended to have closed windows that can be opened in the event of an emergency.

6.4 Flooring

Floor surfaces should be smooth to facilitate easy cleaning.

Material used for cleaning should be non-porous and have few seams.

Carpets of any sort are *not* allowed in Bio safety level 2 (BSL 2) laboratories.

All floor penetrations should be sealed to prevent spread of spillages in the event of a spill or a flood.

Walking floor surfaces should be designed to provide stable, firm and slip-resistant surfaces. Special slip-resistant floor material needs to be used for areas where the wax is handled.

Surfaces that are likely to be wet in the laboratory should have a Dynamic Coefficient of Friction of 0.42 or greater (e.g. high traction surface).

Raised platforms and special drainage facilities should be provided in places where wet procedures are performed.

Materials recommended for flooring

Use of non-asbestos flooring materials should be ensured.

Sheets : Vinyl and poured epoxy are the best recommended material.

Tiles : Vinyl composition tile (VCT) or rubber tiles are recommended.

6.5 Ceiling

Acoustic tiles with a high sound absorbance rating are recommended for ceilings.

Open ceilings can also be used, provided that the exposed duct systems and lighting systems have rounded surfaces for easy cleaning and to minimize accumulation of dust. Recessed light fittings are preferred over suspended light fittings.

Placement of lights directly above lab benches should be avoided.

Energy-efficient lighting should be used whenever possible.

6.6 Fire egress

The fire escape routes of the laboratory should be designed meticulously to facilitate easy access to laboratory staff to escape out of the building in case of a fire or an emergency. The fire egress must be free of all obstructions.

6.7 Egress corridors

Furniture, wires and equipment should not block the fire escape path.

Corridors should be free of items that can feed the fire (e.g. paper, storage, waste items, electrical equipment and inflammable items).

It is recommended to have two or more fire exists depending on the size and the number of employees in the laboratory.

6.8 Fire alarms

Fire alarms must be readily accessible in the laboratory area and can be located in or near the laboratory. When the fire alarm is pulled, notification must be visible *and* audible to all the laboratory areas.

6.9 Fire extinguishers

Class B fire extinguishers are recommended to all laboratories.

These should be located near all exit doors.

Fire extinguishers should be located close to places where flammable chemicals are in use. (e.g. Processor, cut up areas.)

6.10 Hazardous equipment

Tissue processors should be operated at a minimum distance of 5 feet (152cm) from flammable storage areas.

6.11 Chemical and flammable storage

See section on storage facility (12)

6.12 Hand washing

Recommended type is a wall-hung lavatory instead of a sink.

6.13 Emergency eye wash stations and flood showers

Emergency eye wash should be located at a height of 84cm-114cm above the floor level.

Emergency eye wash and emergency shower should be located at a point within 10 seconds reach from a hazardous area.

6.14 Acoustics

It is important to minimize noise in the laboratory. Use of sound absorbent material for walls and the ceiling is recommended. (Note: use of fabrics such as curtains are not allowed in the laboratory)

The following are recommended;

- High sound absorbent acoustic ceiling tiles.
- Rubber flooring tiles. (Note: these cannot be used in Bio safely level 3 or 4 laboratories)
- Cork - Cleanable, antimicrobial and antifungal. (Note: this cannot be used in Bio safely level L3 or 4 laboratories)

Alternatively, noise producing equipment can be isolated or cork-covered acoustic panels can be used (e.g. for refrigerators, freezers).

7. Maintenance of adequate ventilation

Proper ventilation is one of the most important elements in the design.

Following factors should be considered to ensure adequate ventilation.

- Removal of noxious odour and vapour generated in the laboratory.
- Ensure proper functioning of equipment.
- Provision of a comfortable and a healthy working environment for the laboratory staff.
- Optimize work performance.

There should be 100% exhaust to the exterior in all technical working areas (e.g. a single-pass air system without recirculation or re-use of laboratory exhaust)

Recommended target

- For occupied rooms - 8-10 air changes per hour
- For unoccupied rooms - 4-6 air changes per hour.

Ideally the laboratory area should be negatively pressurized compared to the corridor areas and surrounding rooms.

Note:
In rooms containing fume hoods and grossing rooms, there is a high level of aerosol generation and fume production. This air should not be recirculated or circulated to other areas in the hospital.

For exhaust fumes heavier than air generated in histopathology laboratories, (e.g. formalin and xylene vapour) backdrafts, slots, spot hoods and downdrafts are recommended as these heavy vapours do not exhaust through vents located on the ceiling or upper levels of walls.

These hoods are extremely effective in laboratory areas where laboratory staff work in close proximity to equipment or carry out procedures that generate toxic or noxious vapours. (e.g. grossing area, staining, area where cover slips are placed etc.). Similar to canopy hoods, these hoods use a large quantity of air and prevent vapours and odours being drawn across the face. These hoods are placed at the back-face of the workbench, usually not more than six inches above the backsplash.

Fume hoods, biosafety cabinets and grossing stations need venting to the exterior of the building through a separate duct system. (Note: These may require special duct systems and extra equipment).

Hoods should be located where the air flow will not be compromised.

7.1 Temperature and humidity control

To design temperature and humidity control, the type and the number of equipment in use and the number of persons working in the area should be considered.

Temperature

A temperature of 20^0C - 22^0C is recommended for the laboratory area.

Optimal humidity

It is recommended to have 40-50% humidity in the laboratory area. The instrument manuals should be referred to maintain optimum humidity.

The size and the number of air conditioners

These depend on many factors including the size and the volume of the area, the amount of heat produced, operational tolerance of instruments used in the area, number of staff members, requirements of the fume hoods/ bio safety cabinets and the nature of chemicals used in the area.

Recommended types of air conditioners

- CAV (Constant Air Volume) system or VAV (Variable Air Volume) system air conditioners can be used.
- Window air conditioning units can also be used to address heat loads as far as they do not re-circulate the air inside the room.

8. Correct placement of laboratory equipment

A list of all equipment in the laboratory should be maintained with the anticipated future additions. It is recommended to accommodate future additions anticipated for a minimum of 10 years. Documentation of specifications for each instrument with utility requirements such as electricity and water supply is important for the architects and engineers to determine the footage requirements and to plan the layout of electricity, plumbing and heat emission of the laboratory.

Information of instrument size

Width, depth, height and weight of all instruments should be taken into consideration. For instruments that weigh more than 136kg, new floor support may be needed, especially if the planned laboratory is located above the ground floor.

Space for instrument clearance should be considered. (Note: It is recommended to keep a distance of at least 76cm behind each instrument).

Counter tops

When selecting counter tops and table tops, consideration should be given to the weight-bearing capacity. These should be able to withstand a weight of 136kg or more. Counter tops used in the laboratory should be made of sturdy, durable material and be able to withstand hard use.

The following types of material are recommended for counter tops.

1. Stainless steel
2. Chemically resistant plastic laminate
3. Epoxy resin

Drawers must be eliminated wherever possible.

Storage cabinets and shelves should be designed to be kept open, to reduce cost as well as to motivate the laboratory staff to keep their work area neat and clean.

Cabinets

Material should be resistant to chemicals and heat and should be easily cleanable.

Shelves

These can be installed as wall-mounted shelves and above-bench shelves to maximize accessible storage space.

Surfaces should be chemical resistant.

Shelf lips should be designed to reduce accidental slides or fall of bottles off the shelves.

Shelves should be fixed at a reachable distance for the workers' height. Use of portable ladders and climb steps to access the materials on shelves in routine work should be discouraged.

Shelves for storage of laboratory material should be located at a distance of 18 inches from the ceiling to allow fire sprinkler clearance.

9. Special considerations for electrical and communication network design in the laboratory

9.1 Installation of a maximum number of separate circuits to avoid overloads.

Electricity requirement for the laboratory equipment has to be defined in the design including the voltage, amperages, watts and phases. Maintenance of an uninterrupted electric power supply to the laboratory should be ensured by installing an emergency power supply, a special type of connection (e.g. special outlet or a separate wiring system) or a generator.

Extra power outlets, switches and plug points need to be planned in the original electrical layout, labeled and covered to be utilized later with the future developments.

An adequate number of grounded outlets on multiple circuits should be planned to minimize the need for power outlet strips and extension cords.

Power disconnects, switches, and circuit panels must be clearly marked and centrally located for prompt access.

9.2 Communication

Laboratory information system (LIS), hospital information system (HIS) and phone lines should be included in the design.

10. Special considerations for lighting

There are specific standards for the lighting plan of a laboratory.

10.1 Lighting level

Higher intensity lighting with a colour that is comfortable to the eye is recommended for the histopathology laboratory and for the technical work stations. Low intensity lights can be used for the pathologist's office, room housing the multi-header microscope and in the cytology screening room. Non explosive lights should be used in storage areas.

10.2 Location of lights

Recessed light fittings are preferred over suspended lights. Placement of lights directly above laboratory benches should be avoided. Ceiling lights should be mounted parallel to the work surface to maintain uniform distribution of lighting and to eliminate shadows. Energy efficient lighting systems should be used whenever possible.

10.3 Task lights

Plug-in type lights are recommended so that these can be mobilized when required. (e.g. This type is useful for the microtomy and the grossing areas)

Light fixtures -These should be easy to clean and designed to reduce glare.

11. Special considerations for plumbing

Type of water needed in the laboratory should be defined according to the requirement of equipment. (e.g. Distilled water).

Some instruments require specialized plumbing features such as acid waste lines, steam, and a garbage disposal. These requirements should be noted.

Special attention should be given during plumbing to create dedicated drainage systems and storage tanks to collect and recycle used toxic chemicals (e.g. formalin). A plumbing system can be created to deliver gas into the laboratory. (This has the benefit of keeping the gas tanks out of the laboratory premises)

12. Storage facilities

Storage area should be decided according to individual laboratory requirement.

12.1 Chemical storage

There should be a dedicated space for chemical storage.

This can include free-standing, flammable and corrosive chemical storage cabinets or shelves.

Flammable storage cabinets

Flammable storage can be kept inside the laboratory or in a separate storage room.

The cabinets must have self-closing and self-latching doors.

These must be labeled as “Flammable - Keep away from fire.”

Flammable storage cabinets can be designed with or without ventilation. Cabinets do not necessarily need separate venting. If vented, it should be vented directly to the exterior and never vented through a fume hood.

Cabinets must be labeled to identify whether or not they are connected to an exhaust.

These must have doors raised at least two inches above the cabinet bottom to retain spilled liquid within the cabinet and should be designed to contain the chemicals within the cabinets for a specified period of time in the event of a fire.

Cautions when storing flammable material.

Flammable material should not be stored

- near Bunsen burners.
- near ovens.
- near other heat sources.
- in the corridors.

13. Waste management

Sufficient space must be allocated for collection and storage of laboratory waste.

Space should be allocated in each laboratory area for all chemical waste. These must be kept in a room at or near the point of waste generation.

Fume hoods should not be used to collect generated waste.

Space should be allocated either on or below bench tops for medical waste and sharps containers for easy access.

Each floor should have space allocated for storage of waste bins.

Each laboratory should have space to collect and store general waste.

Laboratory recycling containers should be in place where applicable.

Note: Please refer the following documents for further details.

- CPSL-GL-02 on *Guidelines on Waste Management in Histopathology.*
- Annexure I on BSL-2 (Bio-safety level -2) laboratory guidelines.

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Annexure 1

A basic outline for operation of a Bio Safety Level 2 (BSL2) laboratory

Laboratory practices	Standard microbiological practices are followed. Work can be performed on an open laboratory bench or table.
Training	All lab staff must complete lab-specific safety training and should demonstrate laboratory proficiency.
Access	Access to the laboratory is restricted. The laboratory should have doors to separate the working space from the rest of the facility. Doors must be of self-closing type. Display a BSL-2 biohazard warning sign while infectious agents are in use.
Facilities	Chairs and other furniture should be covered in a non-fabric, non-porous material. No carpets or rugs are permitted. Sinks must be available for hand washing. Eye wash must be readily available.
Personal Protective Equipment (PPE)	Appropriate PPE should be worn when working with infectious agents. Laboratory PPE should consist of lab coats, gloves, eye protection goggles and face shields. PPE should NOT be worn in public areas.
Decontamination	Decontaminate all biohazard waste prior to disposal using appropriate method. (eg: autoclaving or chemical disinfection). Decontaminate work surfaces and lab equipment after completion of work and after spills or splashes.
Sharps	Collect sharps in a red, plastic sharps container. Pack non-disposable sharps in a hard-walled container for decontamination.
Transport	Place biohazardous waste in a leak-proof secondary container labeled with a biohazard symbol. Decontaminate the outer surface of the container prior to transport. PPE is not required for transport.