INFRASTRUCTURE PLANNING IN MEDICAL LABORATORY

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Objectives of the talk

- To list the **different types** of medical laboratory infrastructure
- To describe the **considerations** to be undertaken while designing a lab
- To understand the **layout and workflow** of laboratory
- To understand the specific **regulatory requirements** and **guidelines** laid down by NABL

Introduction

●A medical laboratory or clinical laboratory is a place where clinical investigations/tests are carried out on various clinical specimens .

●The results obtained from these tests help clinicians

- •make informed decisions regarding patient care
- •including selecting appropriate treatments
- • monitoring disease progression and
- •assessing the effectiveness of therapies

Functions of a medical laboratory

1. Provision of comprehensive and accurate analytical test results
2. Assistance in confirming/rejecting a diagnosis, prognosis and follow up therapy.
3. Detecting disease
4. Training and research

Different sections of a medical laboratory

- **Clinical Biochemistry**: This area typically includes automated analysis of blood specimens for assessments of electrolytes, enzymes, hormones, proteins, lipids, glucose, and other metabolites.

- **Anatomic pathology**: areas included here are histopathology, cytopathology, and electron microscopy.

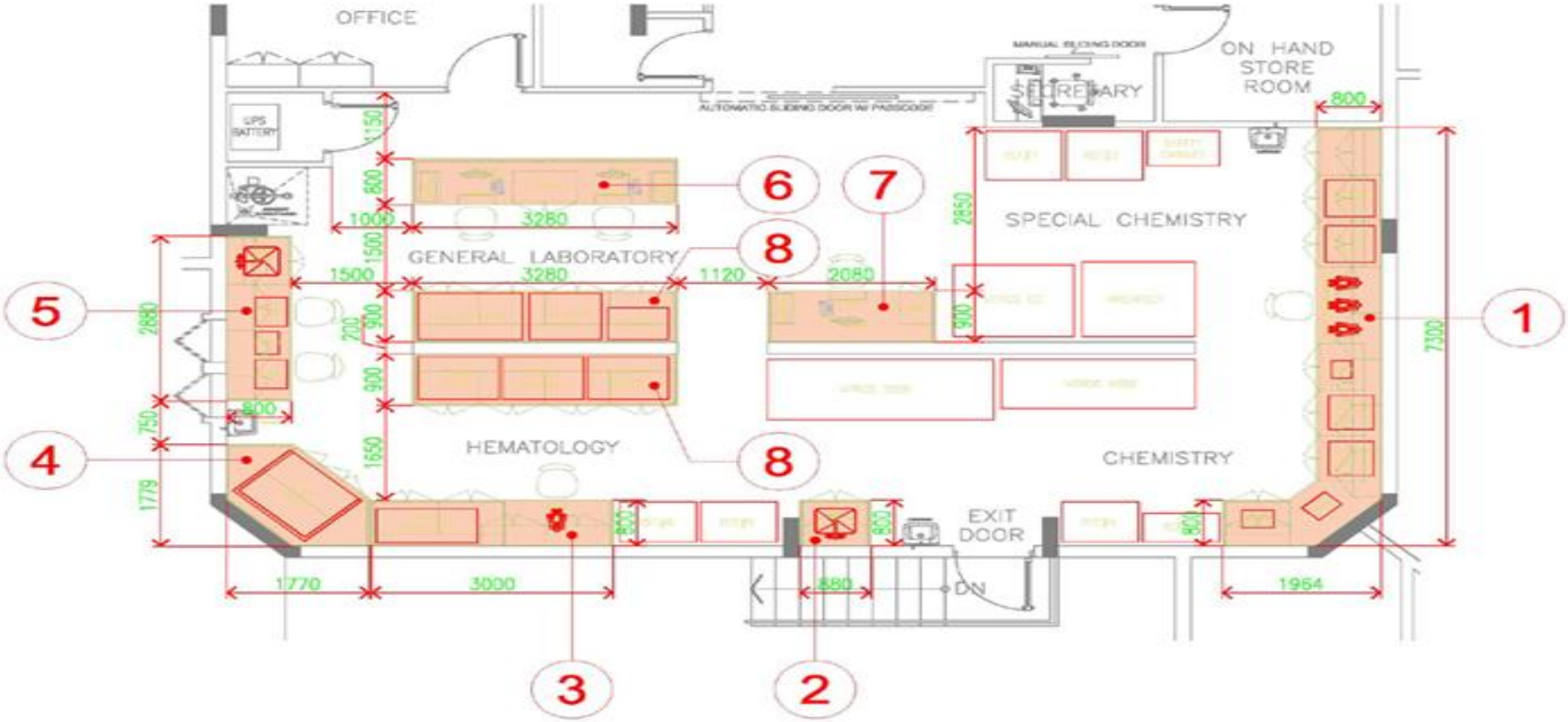
- **Hematology :** Hematology is the study of blood and blood-forming tissues. Hematology tests help diagnose blood disorders, anaemia, infections, and clotting abnormalities.

- **Clinical Microbiology**: This encompasses several different sciences, including bacteriology, virology, parasitology, mycology ,immunology and serology.

- **Blood Bank** involves the testing of blood specimens by blood typing, cross-matching, antibody screening, and infectious disease testing to ensure the safety and compatibility of blood products for transfusion.

- **Molecular diagnostics**

Medical laboratory design layout



Space requirements and location of laboratory

●Locations Laboratory should preferably be situated on the ground floor in close proximity to the ambulatory and acute patient care areas as well as in-patient areas.

●Space Requirements -Extent of automation and type of technology used are the main space determinant in a laboratory. Rule of thumb is 5-7.5 sq. ft/bed or 0.7-0.8 m / bed.

Space Planning

- Space planning is the most important part of laboratory design.
- There should be a staff member with laboratory experience and an architect
- Determine the total area available for the laboratory and allocate space for different sections based on their functional requirements.
- Ensure adequate space for workstations, equipment, storage areas, and circulation paths for staff and specimens.
- Consider future expansion needs and plan the layout to accommodate potential growth.

Spatial evaluation

- Before making the space allocation plan, we should make a comprehensive analysis of the factors such as the number of instruments and equipment, staff, workload, experimental methods and so on.
- The actual working space of the laboratory is the net area of the space.
- Net area is an effective functional part of the laboratory design. The net area of a region is calculated by dividing the total area by 1.35 (74%) to 1.55 (64%).
- Additional area refers to the mechanical, electrical, pump and infrastructure of the laboratory.
- The size of the workspace should ensure that the largest number of workers work at the same time.
    - clean area (office, rest room)
    - buffer area (storage area, supply area)
    - pollution area (work area, washing area, specimen storage area)

Workflow Optimization

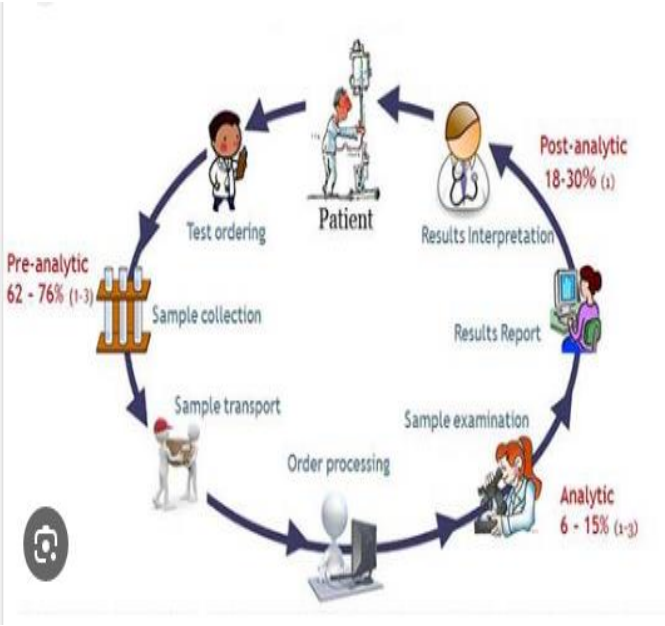
- Design the layout to facilitate a logical and efficient flow of specimens and personnel through the various sections of the laboratory.

- Minimize unnecessary movement and bottlenecks by arranging workstations and equipment in a sequential manner.

Zoning and Segregation

- Divide the laboratory into sections based on the types of tests performed and the disciplines involved (e.g., biochemistry, haematology, microbiology).

- Ensure proper segregation of pre-analytical, analytical, and post-analytical areas to prevent cross-contamination and maintain sample integrity.



Safety Considerations

- Laboratory design should strictly comply with the requirements of laws and regulations including those related to biohazardous materials, chemical storage, and emergency procedures.

- Incorporate appropriate engineering controls, such as fume hoods, biosafety cabinets, and safety showers, to mitigate occupational hazards.

- Provide adequate ventilation, lighting, and ergonomic design features to promote a safe and comfortable working environment for laboratory staff.

Equipment Placement

- Determine the **placement of analytical instruments**, such as analyzers, centrifuges, microscopes, and pipetting stations, based on workflow requirements and accessibility.
- Ensure **proper spacing** between equipment to allow for maintenance, calibration, and service activities.
- Provide **designated areas for equipment storage**, including dedicated bench-tops or shelves for reagents, consumables, and supplies.
- The **length, width, weight, power and ampere** of each instrument must be specified, and an instrument manual should be prepared.
- There should be space on the side and back of the instrument to facilitate **work ,repair and maintenance.**

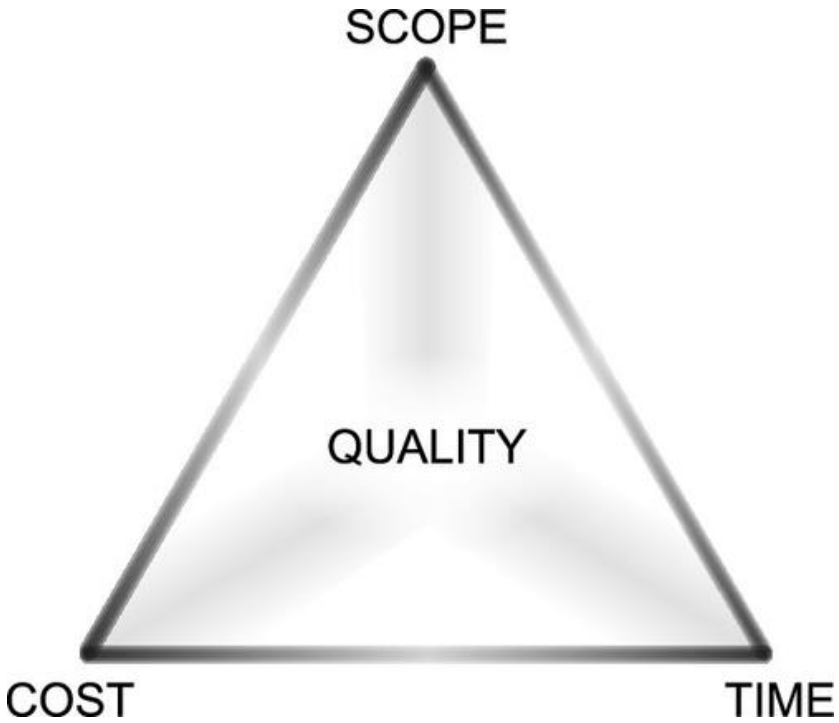
Ergonomics

- Design the layout to accommodate the needs of laboratory staff, including ergonomic **workstation design, adjustable seating, and accessible storage** solutions.

- Ensure that equipment and workstations are positioned at **appropriate heights and angles** to minimize strain and fatigue during repetitive tasks.

- **Aesthetic and Functional Design :**Choose durable and easy-to-clean materials for flooring, countertops, and walls to maintain cleanliness and hygiene standards.

The Project Management Challenge



Factors to be considered when designing a lab

1 Open-plan designs. wide-open spaces. With the open plan or big room concept, a lab is built with no interior walls to allow the layout to be reconfigured as necessary. Power, data and gases are mounted overhead, rather than provided through the floor or walls. Modular casework, which often is equipped with wheels for easy relocation, is used in place of fixed cabinetry.

2 Automated testing. Automated testing systems, an advancing lab technology, is facilitated by open-plan lab design. In an automated system, analyzers are arranged along a robotic track that operates much like a conveyor belt. Depending on the number of analyzers, automated systems may involve 50 to 60 feet of linear track bolted to the floor.

3. Organization of flows

4 Safety and containment strategy: Lab design is also being affected by a resurgence in BSL-3 containment.

The National Fire Protection Association (NFPA) codes give three classifications for labs depending upon the amounts of flammable and combustible chemicals that are stored.

Class A :High Hazard **10 to 20 gal**. of various flammable or combustible liquids allowed

Class B : Intermediate Hazard **5 to 10 gal**. of various flammable or combustible liquids allowed

Class C : Low Hazard **2 to 4 gal.** of various flammable or combustible liquids allowed

These classifications help in determining the necessary safety measures, such as proper storage, handling, and emergency preparedness protocols, to minimize the risk of incidents in laboratories.

Factors to be considered when designing a lab

5 Molecular testing. Another recent medical advance that's influencing the design of clinical labs is molecular testing. Molecular diagnostics and testing quickly are replacing traditional microbiology and are the fastest-growing areas of the clinical lab.

6. Cross contamination control

7. Regulatory impacts

8 Minimize transport and motion waste

Modular lab cabinets with wheels

Automated track system in lab

PLANNING PREMISES AND DESIGN CONSIDERATIONS

●Entry/ Reception area with patient waiting

●Specimen collection area including patient toilets (this area may also be located remotely in Ambulatory Care areas); the collection area shall have a workbench, space for patient seating and hand washing facilities

●Specimen Reception- registration and sorting area

PLANNING PREMISES AND DESIGN CONSIDERATIONS

- Support areas, including Clean-up, Sterilisation area
- Storage areas for reagents, appropriate storage for flammable liquids, general supplies, refrigerated storage for slides and reagents, disposal facilities for contaminated waste
- Restricted Access -Only authorized personnel should have access to examination area and record keeping area or information systems.
- Refrigerated blood storage
- Staff Areas including Offices, Meeting Rooms, Staff Room, Lockers and Toilets.

Histopathology - Electron Microscopy Room

●A separate room shall be allotted for tissue processing with a fume hood for handling osmium tetroxide.

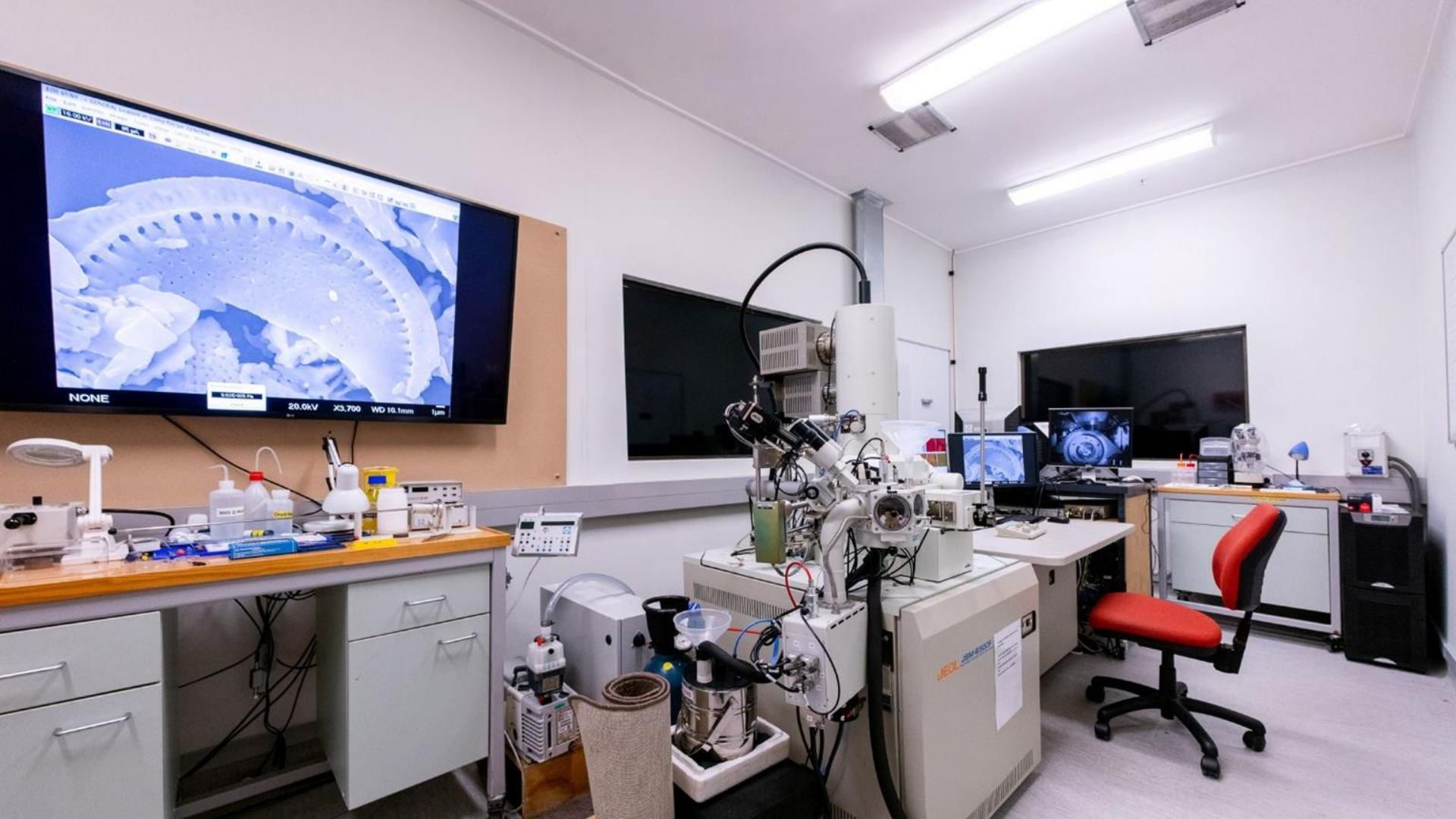
A separate dust-free facility, with air-conditioning shall be available for preparation of specimen and performing electron microscopy. The electron microscopy room shall have:

Facilities in place for temperature control and chilled water supply Ÿ Insulated cabling kept away from the work areas

Proper seating available to allow for optimal ergometric positioning of the person using the microscope

Dark room with adequate ventilation.

Warning light on the door of the dark room indicating usage.


NONE
20.0kV X3,700 WD 10.1mm 1μm

Cytopathology The laboratory shall have a dedicated space for FNAC procedure

NFPA- National Fire Protection Association) symbols

- NFPA symbols are typically diamond-shaped with four colored quadrants:
    - blue (health hazard)
    - red (flammability hazard)
    - yellow (reactivity hazard)
    - white (specific hazards) OX for oxidizers, ACID for acids, ALK for alkalis, COR for corrosives, etc.

NABL classification

a)Small sized: A laboratory receiving samples of up to 100 subjects per day

b) Medium sized: A laboratory receiving samples of up to 101- 400 subjects per day

c) Large sized: A laboratory receiving samples of more than 401-1000 subjects per day

d) Very large sized: A laboratory receiving more than 1000 subjects per day

e) Multiple location: A laboratory with more than one location in the same district with same legal identity

What does the NABL 112 standard say on the Infrastructure?

- The laboratory shall have effective separation for incompatible activities. The autoclave for sterile articles and for decontamination should be placed separately with proper exhaust.
- The laboratory shall have adequate lighting, power plugs and uninterrupted power supply. Use of exposed cables should be kept to a minimum.
- The laboratory shall ensure that adequate uninterrupted power supply is available so that there is no compromise of stored data.

What does the NABL 112 standard say on the Infrastructure?

- All **computers, peripherals, equipment and communication devices** shall be supported in such a way that service is not likely to be interrupted.

- The laboratory shall have procedures in **place to ensure the integrity of refrigerated and frozen samples / reagents / consumables** in the event of a power failure.

- Wherever possible the **sample processing area should be segregated / separated from the testing area.**

- In particular, **centrifuges** should not occupy the same working bench as testing instruments where **vibration** may interfere with the results e.g. centrifuges & balances / analytical instruments like automated analyzers

BIOLOGICAL SAFETY CABINET

- Microbiology :A separate biological safety cabinet, certified at least **annually to ensure that filters are functioning properly and that air flow rates meet** specifications, must be available for mycobacteriological work and for mycological work.
- The laboratory performing fungus culture shall be equipped with incubator to meet with the environmental conditions for the isolation of fungi.

Biosafety Cabinets

Class I

Class II

Class III

SUPPORTIVE SERVICES

- **Natural light** should be used for providing the requisite illumination.
- Fixtures should be positioned to provide **uniform, shadow-free and glare-free illumination** of the laboratory bench top.
- The light required is as under
  - Reception areas and stores : 200 lux
  - Offices : 400 lux
  - Working places : 600 lux

Note: One lux (Latin for “light”) is the amount of illumination provided when **one lumen** is evenly distributed over an **area of one square metre**.

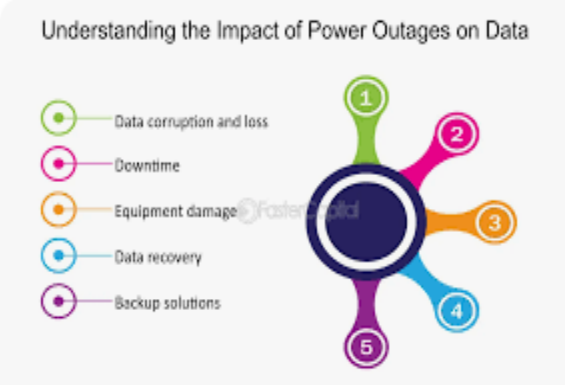
ELECTRICITY

●The laboratory shall ensure that adequate electrical service is available so that there is **no interruption in power supply** that may lead to compromise of stored data.

●All computers, peripherals, equipment and communication devices should be supported in such a way that service is not likely to be interrupted.

●The laboratory shall have procedures in place to ensure the integrity of **refrigerated and/or frozen stored samples/reagents/consumables** in the event of an electrical failure.

●The use of exposed cables should be minimum.



Examples of Electrical Hazards

Overhead Power Lines

Damaged/Faulty Tools & Equipment

Inadequate Wiring & Overloaded Circuits

Exposed Electrical Parts

Improper Grounding

Damaged Insulation

Wet Conditions

SafetyCulture

Floors

- It should be of materials that may be **cleaned and disinfected easily**.
- Flooring materials should be **non-absorbent, skid-proof, resistant to wear**, and resistant to the adverse effects of **acids, solvents, and detergents**.
- Materials may be monolithic (**sheet flooring**) or have a minimal number of joints such **as vinyl composition tile (VCT) or rubber tile**.
- Floor materials should be installed to allow for **decontamination with liquid disinfectants** and **to minimize the potential spread of spills**

Walls

●Wall surfaces should be free from **cracks, unsealed penetrations, and imperfect junctions** with ceiling and floors.

●Materials should be capable of **withstanding washing with strong detergents and disinfectants.**

Doors

- Laboratory doors should **not be of less than 1m wide**.
- Some **double doors** of **total width of 1.50 m** should be constructed one of the doors in these may be 1.0 m width and the other of 0.50 m.
- **Vision panels** are recommended for all laboratory doors.
- In laboratories where the use of larger equipment is anticipated, wider/higher doors should be considered.
- Laboratory doors should be recessed and swing outward in the direction of egress.
- Door assemblies should comply with all appropriate codes.

Doors

- Biosafety Level 2 (BSL-2) laboratories should have doors that are self-closing and have locks.
- to maintain room pressurization by affecting direction of airflow in combination with supply and exhaust ventilation rates
- controls the spread of fire and smoke to the lab; and
- secures the lab and its hazardous materials from unauthorized people.

Sinks

●Sinks Laboratories must have a sink for hand washing.

●The sink may be manually, hands-free, or automatically operated.

●Biosafety Level 2 (BSL-2) laboratories should have the sink located near the exit door.

●When a separate tissue culture room is located within a main lab room, there should be a hand washing sink located inside the tissue culture room

Emergency Showers and Eyewash Stations

- **At least one** emergency shower and eyewash station should be available in each laboratory. These emergency showers and eyewash stations should be **tapped to the laboratory water supply**.

- When installing showers**, the pull handle** should be located in direct proximity to the **shower head.**

- Safety showers should be no more than **25 feet from the chemical fume hood** or other area where corrosive chemicals will be used.

- An eyewash station must be readily available in all **Biosafety Level 2 (BSL-2)** laboratories.

- When a tissue culture room is located within a main lab room, the eyewash station should be installed next to the hand washing sink located inside the tissue culture room.

Emergency Eyewash

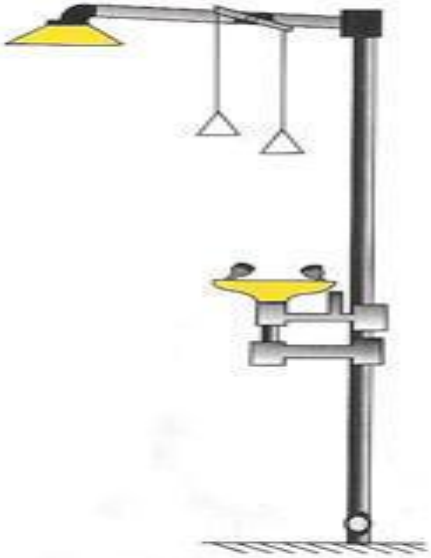
- Water remains on without use of hands (hands to hold eyes open)
- Goes from off to on in one second or less
- Large and easy to operate controls
- Delivers 0.4 gal of water per minute
- Water nozzles 33 to 45 inches above floor
- Visible sign
- Checked and flushed weekly

Emergency Shower should have following criteria

- Opens in one second
- Water remains on without use of hands
- Delivers 30 gal of water per minute
- Easy to locate and accessible controls
- Head at 84 inches from floor
- Adjustable water supply
- Visible sign
- Checked and flushed weekly

Hand Operated Safety Shower

Paddle Operated Safety Shower



Hand/ Pull Operated
Safety Shower

Spares for Eye Wash Fountain
(Bowl, Nozzel & Shower)

Paddle/Pull Operated
Safety Shower

Wall Mounted Eye Wash Shower

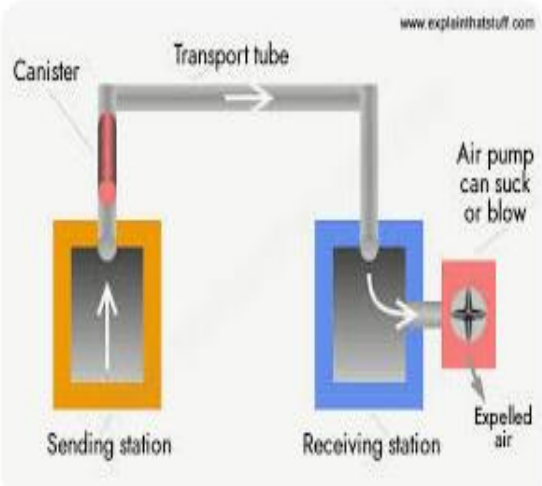
PNEUMATIC TUBE TRANSPORT SYSTEM

- The transportation of sample requires a reliable solution that ensures a **safe and efficient delivery**.

Rapid sample delivery systems, usually pneumatic tube system (PTSs), have been installed in hospitals **to transport blood specimens from the phlebotomy site to the core laboratory** and deliver **patient reports to clinicians**

- Transport of samples **for blood gas analysis** via a modern pneumatic tube system is safe when samples are correctly prepared.

- The use of rapid sample delivery systems can **signicantly reduce the turnaround times (TATs)** of results, which account for approximately 40% in the laboratory median TATs.



Ventilation

●Mechanical ventilation system is required with **10-15 air changes per hour** in areas where ferns are expected and **4-8 air changes** in other areas.

● Systems should have adequate ventilation capacity **to control fumes, odors, and airborne contaminants**, permit safe operation of fume hoods, and **cool the signicant heat loads** that can be generated in the lab.

Flammable Chemicals and Waste Storage

●Flammable-chemical storage cabinets should be placed in each laboratory and meet applicable fire safety requirements.

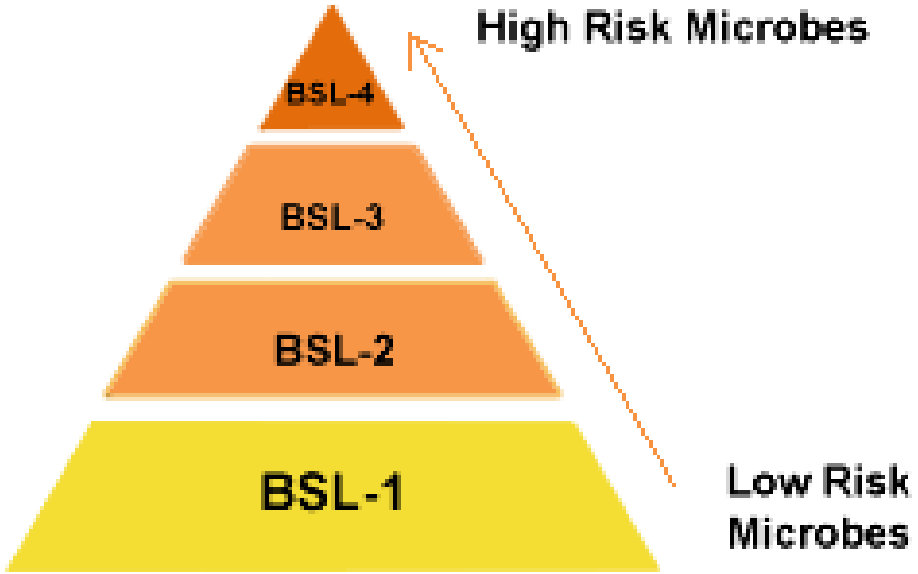
●Flammable storage cabinets **should not be located near exit doorways**, stairways, or in a location that would impede egress.

●Space should be allocated in each laboratory for storage of chemical waste

Biosafety levels in laboratory

- **BSL 1** - Infectious agents **not known to cause disease** in healthy adults
- **BSL 2** -Infectious agents associated with human disease. Ability to infect through **autoinoculation, ingestion, and mucous membrane** exposure .
  - eg:S. aureus,Salmonella ,Hepatitis B virus, HIV
- **BSL 3** -Infectious agents with potential for **aerosol transmission**. Effects may be serious or lethal
  - Mycobacterium tuberculosis,SARS-CoV-2
- **BSL 4** - Infectious agents which pose **high risk of life-threatening disease**, **aerosol transmitted** lab infections, or agents with **unknown risk of transmission .**
  - Ebola virus,NIPAH virus
  - BSL-4 laboratories are equipped with the **highest level of containment measures**, including **full-body suits, airlocks, and negative air pressure systems**

Biosafety levels in laboratory



Fire Extinguishers

●The distribution of fire extinguishers is **specified by fire code.**

● For example, a fire extinguisher must be **within 30 feet of a flammable liquid storage area.**

●Extinguishers should be conspicuously located where they will be **readily accessible** in the event of fire.

●They should be **located close to the exits** from an area and **along normal paths of travel.**

RESCUE

ALARM

CONFINE

EXTINGUISH

PULL THE PIN

AIM AT BASE OF FIRE

SQUEEZE HANDLE

SWEEP SIDE TO SIDE

ONE RACE YOU HAVE TO WIN!

Hazard Communication Signage

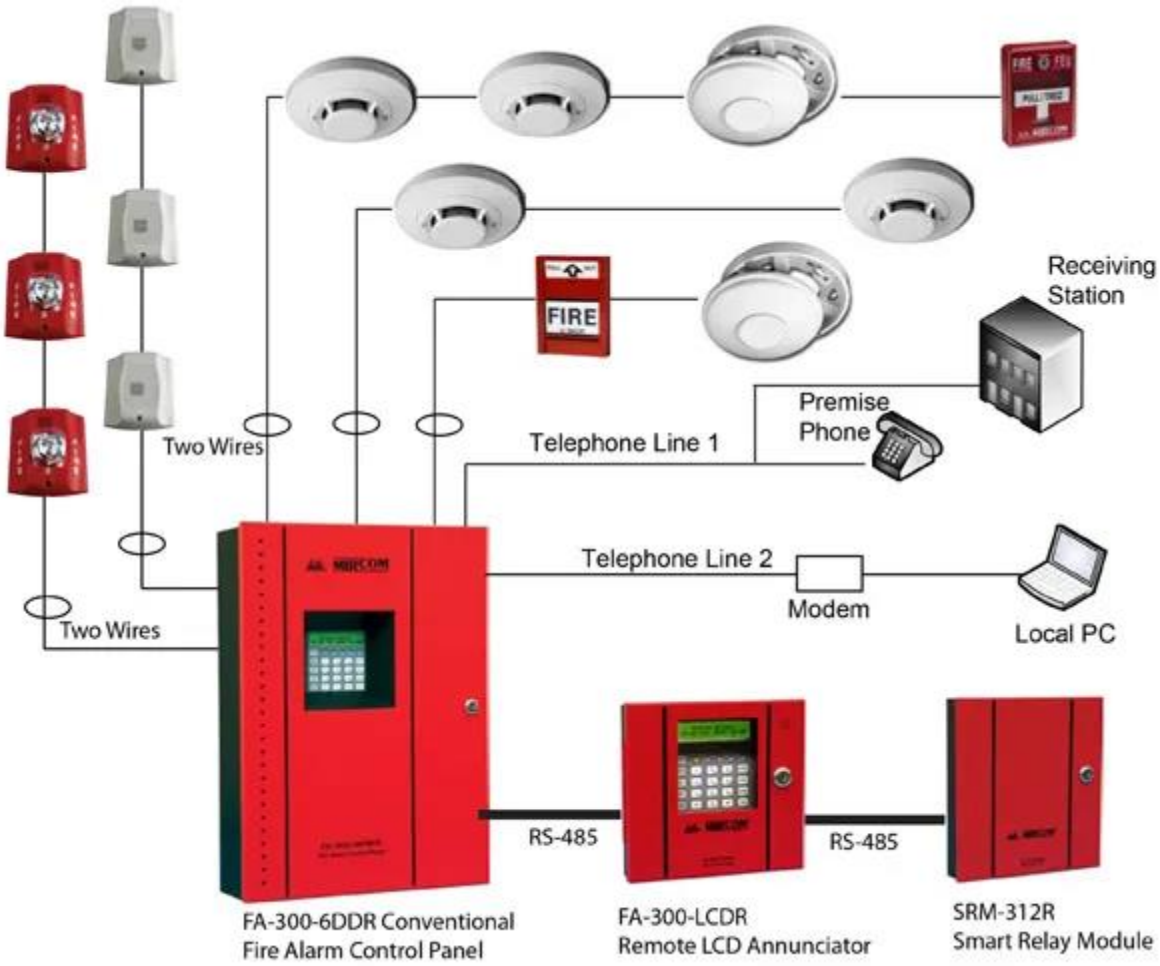
●Each laboratory should have a signage holder for prominently displaying hazard communication information at the entrance door.

●Individual labs should have signage holders that are consistent with the type used by other laboratories within each department or building.

Alarm and Monitoring Systems

●The increasing sophistication and fine control of laboratory instruments and the unique quality of many experiments **demand closely monitored and alarmed systems** that can be **connected to individual pieces of equipment or temperature-controlled rooms.**

●Several excellent monitoring systems are available for this purpose. They can be **connected to a central monitoring facility at several levels of observation** or can be used internally within a laboratory setting.


FIRE
Receiving Station
Premise Phone
Telephone Line 1
Telephone Line 2
Modem
Local PC
Two Wires
Two Wires
RS-485
RS-485
FA-300-6DDR Conventional Fire Alarm Control Panel
FA-300-LCDR Remote LCD Annunciator
SRM-312R Smart Relay Module

Foundations of Research

Building Operations & Renovations

- **CENTRAL UTILITIES**
  - *ELECTRICITY, STEAM, FIRE LOOP*
  - *CHILLED WATER, COMPRESSED AIR*
- **HVAC/ VENTILATION**
  - *FUME HOODS*
  - *LOCAL EXHAUST DEVICES*
- **PLUMBING**
- **STRUCTURAL ELEMENTS/ FURNISHINGS**
  - *CARPENTERS*
- **ELECTRICAL**
  - *DRIVEN BY ELECTRICAL CODE*
- **FACILITIES/ PROJECT MGMT**
- **GROUNDS/CIVIL CONSIDERATIONS**
  - *SEISMIC ENGINEERING*
  - *SITE-SPECIFIC CONCERNS (DRAINAGE)*

Scientific Support Services

- **CORE FACILITIES**
  - *ELECTRON MICROSCOPY*
  - *GLASSBLOWING*
  - *MAKERSPACE*
- **MATERIALS HANDLING**
  - *PACKAGE DELIVERY*
  - *SHIPPING*
- **IT/COMMUNICATIONS SUPPORT**
  - *MEDIA EQUIPMENT*
  - *NETWORKING*
- **INFRASTRUCTURE LAB**
  - *SPECIALTY GASES*
- **EHS SUPPORT**
  - *RESEARCH REGISTRATION*
  - *RISK ASSESSMENT*
  - *ENGINEERING CONTROLS*
  - *PPE SELECTION*
  - *Chem, Bio, Rad WASTE MANAGEMENT*

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