

SPECIFIC REQUIREMENTS FOR A CLINICAL AND BIOMEDICAL LABORATORY

A Clinical and Biomedical Laboratory shall be defined as a facility with the following minimum requirements as listed in sections A to G below:

A. Personnel

B. Services

C. Premises - Physical Design, Layout, Furnishing and Ancillary Facilities

D. Equipment Devices and Supplies

E. Safety and Security

F. Schedules

G. Records

A. Personnel

The minimum qualification for a person in charge of a laboratory shall be

- A qualified Medical Laboratory Scientist with a minimum of a first degree certificate as a medical laboratory scientist (with 5 years post qualification experience and in good standing with Allied Health Professions Council of Ghana).

Additional Staff

- Qualified Medical Laboratory Scientists with a minimum of a certificate as a medical laboratory scientist

B. Services

- Hematology;
- Clinical chemistry;
- Medical microbiology (Bacteriology, Virology, Parasitology, Mycology)
- Pathology
- Blood serology;
- Health Promotion and Preventive services
- Basic laboratory equipped to provide basic laboratory services

- Any other requirement that may be prescribed by the Board.

C. Premises- Physical Design, Layout, Furnishing and Ancillary Facilities

- Information desk
- A waiting and reception area;
- A functional laboratory with the relevant units
- Washable floors with floor drains
- Clean patients' toilet facilities with adequate water supply;
- Adequate general water supply
- Constant electricity supply with alternative power supply in good working condition
- Any other requirement that may be prescribed by the Board.

D. Equipment, Devices and Supplies

- Cubicle with a screen for attending to patients;
- Couch;
- Microscope;
- Weighing balance;
- Water bath;
- Centrifuge;
- Appropriate Analyzers (Haemoglobin electrophoresis machine etc.)
- Micro-haematocrit centrifuge and reader;
- Microbiological culture media;
- Spectrophotometer;
- Improved Neubauer counting chamber;
- Biochemistry reagents;
- Westergreen tubes and stand;
- Bunsen burner and gas cylinder;
- Laboratory glassware;
- Pipettes;

- Serology kits;
- Refrigerator;
- Procedures for processing (transport, disposal) of used medical devices, supplies and equipment
- Any other requirement that may be prescribed by the Board.

E. Safety and Security (Sections 1 to 12)

1. Structural

- a. Unobstructed access to facility
- b. Easily accessible to the disabled and aged
- c. Parking area
- d. Roof, walls and ceiling intact
- e. Windows and Doors for facility intact with mosquito netting
- f. Outer walls
- g. Facilities for storage of outer garments and personal items away from work area
- h. Adequate working space
- i. Clear separation of different general areas (reception, registration, laboratory)
- j. Separation of storage from process areas
- k. Separate work and storage areas are provided within the facility for processes/procedures, administration tasks and associated paperwork/reference material.

2. General

- a. Non-slip floors
- b. Unobstructed walkways, paths and corridors
- c. Adequate illumination
- d. Adequate ventilation

3. Signage

- a. Department/Unit Identification signs

- b. Directional signs
- c. Warning signs
- d. Health promotion/preventive posters
- e. Emergency evacuation diagram clearly displayed in all areas
- f. Entry and exit signs
- g. Hazard/safety signage on entrance/s clearly visible and contains information including:
 - i. Authorized access only
 - ii. No food or drink allowed
 - iii. Type of chemicals
 - iv. Lab supervisor details

4. Hygiene and Sanitation

- a. Fairly distributed number of pedal operated dust bins
- b. Means of decontamination of hands
- c. Posters on appropriate handwashing technique
- d. Posters on appropriate use of toilet facilities
- e. Signs for disposal of different types of waste
- f. Cleaning time tables for all rooms, offices and bathrooms

5. Protective Clothing and Gear

- a. Aprons
- b. Masks
- c. Gloves
- d. Covered shoes
- e. Goggles /Protective eye gear
- f. Protective hair nets
- g. Protective laboratory coats
- h. Protective feet covers
- i. Provision for washed and clean linen

6. Biohazards

- a. Procedures for handling, storage, treatment, transportation and disposal of waste (colour codes for different waste etc)

- b. Sharps disposal
- c. Consumables disposal
- d. Biological waste disposal
- e. Incineration procedures for biological waste
- f. Protocols and procedures for managing accidents with sharps
- g. Protocols and procedures for managing cross contamination
- h. Protocol and procedures for managing infectious samples

7. Emergency

- a. Exit doors clearly marked and can be opened from inside (not padlocked)
- b. Exit doors unobstructed from inside and outside the building
- c. Fire equipment (fire blanket, extinguisher, hose reel) is accessible and clear of obstruction
- d. Fire equipment (fire blanket, extinguisher, hose reel) have been inspected/tagged within the last 6 months.
- e. Fire exit and escape (for structures 2 storey and above) clearly marked and devoid of obstruction
- f. Smoke detectors are working and clear of obstruction.
- g. A first aid kit is located in the near vicinity.
- h. Safety shower and emergency eye wash station is functional and easily accessible.
- i. 'Experiments in Progress' are labeled with procedures outlining response in case of emergency

8. Biosafety

- a. Procedures in place to account for all samples, reagents or materials
- b. Protocol and procedures for prevention of spread of infectious diseases
- c. Protocol and procedures for managing patients with infectious diseases
- d. Appropriate biosafety signage at the laboratory entrance to applicable units and on storage room doors/vessels
- e. Biosafety cabinets, fume cupboards, and hoods present (if applicable)
- f. All cultures or biohazardous materials are correctly labelled.

- g. A supply of disinfectant for decontamination purposes is available and is clearly labelled.
- h. Instructions for dilution of disinfectant is clearly displayed e.g chlorine solution
- i. Diluted bleach is stored away from heat and is kept in lightproof containers with the preparation date displayed.
- j. Laboratory gowns stored in manner that prevents cross contamination
- k. A supply of hospital grade antiseptic for washing hands is available at laboratory exit.
- l. Laboratory gowns stored in manner that prevents cross contamination
- m. All keyboards have protective covers.
- n. Protocols in place for safe storage, handling and transport of dangerous substances and of waste containing dangerous substances

9. Biosecurity

- a. There is appropriate signage at the entrance to all areas.
- b. All GMO and Quarantine samples labelled appropriately
- c. All samples, reagents, liquids are appropriately stored in appropriate storage vessels and clearly labelled
- d. All samples are secondary contained (fridges and freezers count as secondary containment within a lab)
- e. Security arrangements are in place and various applicable areas have clearly marked restricted access
- f. Procedures are in place for the transport of materials
- g. All surfaces (including furniture) within the laboratory are smooth, impermeable to water and resistant to any decontaminant materials.
- h. There are locks on fridges and freezers.
- i. There are appropriate pest control procedures in place (spraying, weeding etc.)
- j. All windows and walls are intact and sealed and there are no gaps.

10. Chemicals, Handling and Storage

- a. Chemicals stored in appropriate containers.

- b. Containers are labelled correctly (e.g. not handwritten, label contains minimum chemical name and pictogram depicting hazard level).
- c. Chemicals are stored according to compatibility.
- d. Compatibility chart is readily available.
- e. Dangerous goods are stored under COSHH guidelines (Control of Substances Hazardous to Health).
- f. COSHH cabinets must be used, labelled and maintained in accordance with COSHH practices and other international best practices including but not limited to
 - i. Self-closing and close fitting doors
 - ii. Locking automatically (flammable)
 - iii. Locking mechanism in 2 or more places (flammable/corrosive)
 - iv. Self-releasing locking mechanism (oxidizing agents and organic peroxides)
 - v. Clearance from ignition/heat sources (flammable, oxidizing agents, organic peroxides)
 - vi. Ventilation
 - vii. COSHH approved labels for various hazards (toxic, danger to environment, corrosive etc.)

11. Flammable Liquids (if applicable)

- a. Must be stored in suitable closed vessels in limited quantities in fire resistant cabinets or bins designed to retain spills
- b. Cabinets to be located in designated well ventilated areas away from the immediate area for processing but not placed in a way to jeopardize the means of escape from other areas
- c. Must be stored away from other dangerous substances that can increase the risk of fire or compromise the integrity of the storage container or cabinet

12. Compressed Gas (if applicable)

- a. Compressed gas cylinder contents are appropriately identified.
- b. Cylinders are secured appropriately by bracket or chain.

- c. All cylinders are at least 3M away from ignition sources, combustible material and are stored according to dangerous goods class with compatible gases.
- d. Empty cylinders are separated from full cylinders and clearly labelled.
- e. Appropriate resources (e.g. cylinder trolley) are available for transporting gas cylinders.
- f. The regulator is appropriate for the gas being used (e.g. stainless steel for corrosive gases, brass for non-corrosive gases).
- g. Gas lines are labelled and free of leaks, kinks, signs of wear & tear.
- h. Gas use is confined to areas with good local exhaust ventilation.

F. Schedules

- Preventive maintenance schedules for the building housing the facility together with fixtures
- Preventive maintenance scheduled for equipment used in the facility
- Standard Operation Procedures
- Fire practices, drills, fire alarm tests and their results and action taken where applicable
- Any other applicable schedule or drill.

G. Records

- Facility equipment records;
- Facility inspection records;
- Waste tracking log book;
- Occupational log books to record results of all staff investigations;
- Log books for recording accidents and injuries at the facility;
- Log books for recording potential and actual infections
- Any other relevant records prescribed by the board