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