1. Designing of clinical Microbiology laboratories

Microbiological investigation is becoming more and more important in infectious disease prevention and control. Standard Microbiological laboratories are essential to do these investigations. Standard Microbiological laboratories have to be specially designed. This guideline has been prepared to help in designing and construction of standard Microbiological laboratories in Sri Lanka.

Why a Clinical Practice Guideline

To improve the Microbiological services a standard working environment is essential. If the laboratory is not properly designed a safe and efficient working environment can not be provided to the laboratory personnel. Proper laboratory design ensures laboratory safety. It also reduces the risks that a laboratory may cause to the environment. Importance of correct laboratory designing has to be realized by the relevant authorities before they could plan and implement any development projects. In the existing laboratories too certain structural changes could bring improvements in the design. At this point of time a guideline on designing a laboratory in very much in need.

Who has developed this guideline?

This guideline has been developed by members of the Committee on Guidelines of the Sri Lanka College of Microbiologists. The Committee had a wide ranging representation of very senior to junior Microbiologists who had worked in different parts of the country at different levels of hospitals in order to ensure that the guidelines are applicable throughout the country.

For whom is this guideline intended?

It is intended to guide all the health care providers in institutions where Microbiological services are offered. It would provide guidance on three aspects in laboratory construction.

- Building of new laboratory facilities.
- Upgrading of existing laboratory facilities.
- Refurbishing of buildings to convert them into laboratories.

Although it is targeted for the institutions under the Ministry of Health this guideline may be used by any private health facility where Microbiological facilities are provided.

Objectives

- To provide evidence based recommendations to Microbiologists and other relevant personnel to choose the best course of plan to construct and manage the laboratories.
- To provide recommendations to the administration to help in the improvement of quality of service delivery.
- To provide recommendations to the Health Care Workers (HCW) in improving the quality of service they deliver while ensuring the safety of their work environment.
- Implement the health and safety standards in laboratory designing.

How are the guidelines structured?

Two different levels of institutions are identified in these guidelines for easy application. All institutions without specialist services are considered as one group (PU, DH). All institutions above these with specialist services are considered as another group.

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Designing of clinical Microbiology Laboratories

Introduction

A 'good' laboratory is a fundamental need in providing a 'good' diagnostic service to the population. Proper designing of the laboratory with technical guidance is one of the basic requirements of a 'good' or standard laboratory.

Lack of awareness and knowledge about laboratory designing creates many problems in building new facilities or refurbishing the buildings converting them into laboratories. Non availability of a national guideline is partly responsible for this.

The safe operation of the laboratories and the safety of the health care workers cannot be ensured in badly designed laboratories. Living in an era of emerging infections like "Bird flu", XDR tuberculosis (extreme drug resistant Tuberculosis) or Ebola haemorrhagic fever, the laboratory safety has become a very sensitive issue.

Therefore it is timely to have technical guidelines on the design and management of the laboratories and improve the laboratory infrastructure to meet with international standards of laboratory safety.

1.1 Definitions

Laboratory – the room in which biological agents are handled.

Laboratory suite – one or more laboratories, not necessarily of the same discipline or containment level, and ancillary rooms within a section or department.

Laboratory unit - separate building or self contained suite within a building containing one or more laboratories and with ancillary rooms.

Containment levels

Biological agents need to be managed in the laboratory environment so as to prevent / control the exposure of laboratory workers, other people and the outside environment to these agents. Laboratories can be classified according to their facilities to contain infectious agents.

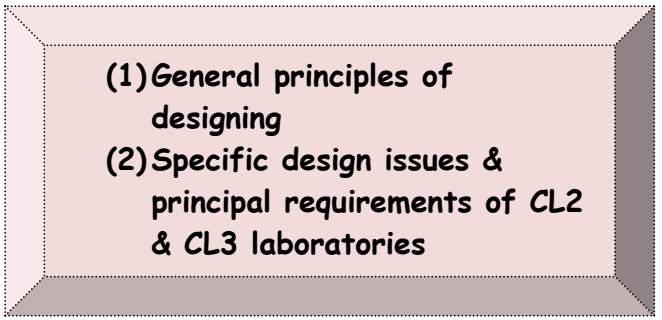
CL2 – Containment level 2

CL2 is the most commonly used containment level and is suitable for a broad range of clinical, diagnostic and research work with biological agents which, although capable of causing disease, only present a low or moderate risk to the employees.

CL3 - Containment level 3

CL3 laboratories must provide adequate protection to the employees and others from exposure to biological agents which are capable of causing severe disease and pose a serious hazard to employees.

The guideline covers two areas



1.2 GENERAL PRINCIPLES OF DESIGNING

1.2.1 Designing process

The designing process should be a collaborative work of the client and the designer. Therefore as a first step in building or refurbishing a laboratory a designing committee should be formulated before the work commences. (x)

1.2.2 Designing committee

i. Essential members

- Architect
- Administrative Head of the institution
- Construction Engineer
- Consultant Microbiologist of the institution / campaign
  - In the absence of an institution / campaign consultant Microbiologist the provincial consultant Microbiologist should be included.
  - If there is no consultant Microbiologist in the province an off-site consultant Microbiologist can be included.

ii. Project coordinator

- A project coordinator is necessary to liaise with the designing team, co-ordinate & oversee the project liaising with the building contractors.(x)
- He should coordinate well with the designing team and the building contractors.

- Supervising the building work / constructions carried out is essential to avoid delays in construction and to avoid reconstructions due to non-adherence to the design. (x)

1.2.3 General design considerations

There are a number of factors which need to be considered as appropriate, by the design team when setting the specifications of the new laboratory.

A. Issues to be considered

- User population
- Relationship between space and function
- Using centralized support facilities
- Comfortable working environment
- User friendliness
- Health and safety issues

B. In designing a laboratory the above issues should be matched with the following.

- Expected site of the laboratory
- Dimensions
- Sections and interior
- Commissioning

C. Siting / Location

The following points need to be considered in choosing a location.

- Laboratories providing routine microbiological services should be located in the main hospital laboratory complex (critical factor). (x)
- Off site locations should be reduced to a minimum or best avoided. (x)
- Should be easily accessible to patients(y)
- Should be away from the public traffic(x)
- Access to natural light should be available(x)
- Supportive services / facilities should be in the same premises / close proximity(x)
  Eg – incineration facilities, autoclaving facilities

D. Size / Dimensions

- Only broad generalizations can be made regarding laboratory size.
- In deciding the dimensions consider the nature of work, space required for placing the equipment for both free standing and bench mounted items and the amount of free air space required.

Definitions

- **Component dimensions**- relate to the size and position of equipment, furniture and fittings.
- **Activity dimensions** - define the user space, minimum space required to perform an activity.

- Design with more space than needed for current work load and types of services provided (include space for future expansion of services) (y)

- The volume of the room, when empty, divided by the number of people normally working in the laboratory should be at least 11 m^3. (x) However this is the minimum space required and may be insufficient depending on the layout, contents and the nature of the work.
- Bench space needed for each technologist to work is minimum of 50 ft^2 (y)
- The floor space allocated for the laboratory should be between 150 – 200 ft^2 per staff member.
- When determining the ceiling height, the need to install and remove the large items of equipment needs to be assessed. When the ceiling is more than 3 m high for volume calculations it should be counted as 3 m high.

E. Sections and Interior

- The laboratory sections should be decided depending on the services provided .This has to be dealt with in lay out.
- Designing should include an office / administrative support area, laboratory working area, staff welfare area / rest rooms (rest rooms should be located outside the laboratory working area) (x)
- Interior designing has to be done together with building construction designing to avoid delays in commissioning the laboratory.(y)
- The laboratory should be air conditioned. (y)

F. Commissioning

- Before the laboratory is brought into service, ensure the laboratory and the work that is to be carried out in the laboratory meet acceptable standards.(x)
- The laboratory (together with its equipment and procedures) should be tested in order to ensure that it

meets the standards specified in the design and construction. (X)

G. Maintenance

The laboratory should be designed for ease of cleaning and maintenance. Attention should be paid to sustainability of services.

1.3 SPECIFIC DESIGN ISSUES

1.3.1 Laboratory layout

Crucial for achieving the goals set for the laboratory.

Determined by the types of services provided, volume of work, physical constraints of the building and the resources available. Best approach is to use a generic design so that equipment, staff and processes can be moved as necessary. Areas that require bio-safety level 3 conditions cannot be moved easily, so that extra care should be paid in choosing the location.

1.3.2 CL2 laboratory

Safety considerations related to the practice of clinical microbiology can be achieved by designing the laboratory to meet bio-safety level 2 criteria and when necessary level 3 criteria.

In a CL2 laboratory

The entry doors should be spacious enough to accommodate equipment.

- **Main Areas**

a) Specimen reception
b) Report issuing counter
c) General laboratory bench space
d) Special laboratory bench space
e) Washing room and media preparation room
f) Storage
g) Offices & administrative support areas
h) Conference / teaching facilities
i) Staff welfare room

Other Important aspects to consider in designing are;

- Work flow and emergency exit
- Water and power supply
- Cleaning and waste handling
- Safety and security
- Communication facilities

Other facilities like patient waiting rooms, specimen collection rooms / areas, patient toilets should be incorporated in the design where appropriate.

H. Main Areas

i. Specimen reception

The designing committee has to consider the following.

location

- Near the laboratory entrance, easily accessible to the patients(X)
- Away from the public traffic and from the staff entrance (x)
- Ample bench top space to keep the samples (x)
- Counter to receive samples – height- preferably 3 ft
- Separate benches / tables for specimens and documentation (x)
- Wash basin near the door (y)
- Power supply for refrigerator, computers(x)

There is no single optimal design. It is necessary to design the place with knowledge of the volume of work and the types of specimens received at the laboratory. In place of manual transportation of specimens, ideally pneumatic system can be implemented according to the service requirements (Y)

ii. Report issuing counter

Report issuing counter should be adjacent to the reception.

iii. General laboratory bench space

- Work areas- linear / U shape modules (usually 10 ft x 10 ft) (y)
- Work bench – width 24 inches, height 30 inches (y)

a) Bench top should be covered with non-absorbable easily cleanable washable, stain and acid resistant material with continuous surface. Avoid tiling. (x)

b) Sinks for staining purposes can be incorporated depending on the requirement. (z)

c) Power supply for the necessary equipment should be placed at the correct positions. (x)

need within an arm's reach (y).

This area should have large doors to accommodate equipment (x).

iv. Special laboratory bench space

Need to be determined and designed depending on the service needs

Eg: Anaerobic bacteriology, Mycology etc.

v. Media preparation room

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- A separate room with enough space to accommodate equipment is necessary.
  a) Work benches and sinks need to be adequate.
  b) Power supply for the necessary equipment should be placed at the correct positions.
     eg- for autoclaves

vi. Washing room

- A separate room with enough space and liberal water supply (x).
- Water supply – ideally the washing room should have hot water supply (y)
- Bench tops should have enough space to accommodate equipment (x)
- Laboratory sinks need careful designing. They should be large deep acid resistant sinks. Storage facilities for washed materials until they are transferred to the work areas should be included in designing (y).
- Drainage system – a closed drainage should be in place (X). Should have large, wide–bore non corrosive piping without U bends.
- An exhaust fan should be in place (y).

vii. Storage

- Needs careful designing depending on the requirements.
- Separate stores for consumables and other items are preferred.
- Cold storage facilities should be made available in the laboratory.

viii. Office areas

- Should be separated from laboratory work areas. (x)

ix. Conference and teaching facilities

- Auditorium at teaching hospitals (X)
- Seminar rooms at other levels (X)

x. Staff welfare areas

- These must be located separately from the main laboratory working area. (x)
  Eg: rest room, tiffin room, toilet facilities

I. Other Important aspects to consider in designing a CL2 laboratory

i. Work flow and emergency exit

- It is preferable to have unidirectional work flow from specimen reception to reporting.
- The laboratory should have an emergency exit.
- The laboratory should have a safety shower, safety eye wash.
- Should have fire extinguishers and fire alarms.

ii. Walls & Floor

- Floor should be impervious to water, smooth but slip resistant.(x)
- Floor should never be carpeted with fabric material.(x)
- Walls should be smooth, easily cleanable and resistant to liquids and disinfectants in common use. Material which meet these criteria are epoxy / polyester coated plaster, rubberised paint etc.

iii. Water & power supply

- The laboratory should have a liberal uninterrupted water supply with adequate pressure. (x)
- There should be sufficient sinks to accommodate staining and hand washing.(x)
- To prevent laboratory acquired infections hand washing sinks should be designed with elbow or foot operated taps. / sensor taps. (y)
- Hand washing sinks should be located near the entry door of the laboratory to facilitate washing when leaving the laboratory. (y)
- Towel racks / shelves should be provided. Hand dryers are not recommended.(x)
- Laboratory sinks should be integral with the bench top. Poly propylene or epoxy resin bowls and drainers are preferable to acid resistant stainless steel because of their greater resistance to disinfectants.

Power supply has to be uninterrupted. Therefore a back up generator is necessary to cope up with power failures.

- Separate power line to the laboratory is preferable to avoid voltage disturbances to the laboratory. Voltage stabilizers should be available for the equipment.
- Electrical outlets should be liberal in number and in excess of the current need.

iv. Cleaning

- A clinical laboratory should be easily cleanable. (x)
- Materials used should withstand the use of disinfectants. (x)

v. Waste handling

There should be adequate designated space for waste handling in the laboratory. A storage facility for bio-hazardous waste (after rendering it non-infectious), infectious waste and general waste need to be provided near the laboratory and outside it till the waste is disposed. (x)

vi. Safety and security

Special attention need to be paid on the following.

- Limited access
- Use of a Bio Safety Cabinet (BSC)
- Adequate space and ventilation with fresh air

1.3.3 Containment level 3 (CL3)

- WORKING WITH BIOLOGICAL HAZARD GROUP 3 ORGANISMS REQUIRE CL3 FACILITY.
- DESIGNING OF THIS INCLUDES ALL THE REQUIREMENTS FOR CONTAINMENT LEVEL 2 MENTIONED ABOVE TOGETHER WITH SPECIAL FACILITIES / REQUIREMENTS MENTIONED BELOW

i. Entrance

- Separate access through two sets of self closing doors through a lobby / ante-room (x)
- Ideally the doors should be interlocking. (y)
- Sealable room for disinfection purposes. (x)
  (The gaseous formaldehyde fumigation need the room to contain the gas for 12 hours therefore sealability is essential to avoid leakages.)

ii. Space

- Volume of the room – should be $11m^3$ per person, ceiling 2.5- 3m high.
- Observation window (vision panel) for the room is needed (x)

iii. Air handling Ventilation

- When the laboratory is in operation, in relation to the surrounding parts of the laboratory suite negative air pressure should be maintained within the operating room (x)
- The typical values range from -30 to -50 Pa .
- The key issue is to ensure that there is a gradation of negative pressure with air flowing from outside, through the lobby and into the laboratory.

(The laboratory protection factor, LPF is directly related to the airflow through the door.)

- Ducted air system from bio-safety cabinets through HEPA filters should be in place. (x)
- The CL3 room should be air conditioned. (x)
- It is preferable to use a sealed type of unit.
- If the unit extracts air direct to the exterior this has to be HEPA filtered.
    - Location of the air inlet and the extract should avoid cross contamination. (x)
    - Air flow should not cause any turbulence near the safety cabinets. (x)
    - No air flow should be directed towards the entry door. (x)

iv. Authority to enter the Laboratory

- Access to the laboratory should be restricted to authorized personnel only. (x)
- A mechanism like digital lock entry or swipe card entry can be used to ensure the entry of only authorised personnel. (x)

v. Other safety issues

- BSC operating facility from outside is preferred. (Y)
- Alarm system should be in operation in the event of an emergency. (y)
- If some equipment is located outside the main containment area it should be located as close as possible to minimize movement of hazardous material. (x)
- A goods exchanging window is useful in a CL3 facility.

Testing of CL3 laboratories at 6 month – 1 year intervals is recommended.

1.4 References

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