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FOREWARD

Optimal laboratory design requires a careful blending of many design elements, which can be effectively accomplished only if both potential problems and possibilities are well understood.

A good understanding of the design issues that affect space, cabinetry, ventilation, lighting, water supply, waste water removal, and storage encourages asking the right questions and facilitate wise choices during reviews of existent Laboratories and planning new or remodelling laboratories.

Many existent laboratories were designed when the requirements for each of these areas were different from what they are today. Thus, it is more important than ever that laboratories are designed so that they can more easily and effectively respond to operational and mission changes.

Due to the structural constrains of laboratory layout in most laboratories in Nigeria, the MLSCN developed this document to give general guidance in Laboratory design to ensure effective work flow and optimal safety at work place.

This Laboratory Design Guideline provides a foundation of information about laboratory design elements that can be used to help define the issues to be considered when designing a laboratory.

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LIST OF ABBREVIATIONS

CDC Centre for Disease Control

CLSI Clinical Laboratory Standards Institute
CQI Continuous Quality Improvement

EQA External Quality Assurance FMOH Federal Ministry of Health

ISO International Organization for Standardization MLSCN Medical Laboratory Science Council of Nigeria

POCT Point of Care Testing

QMS Quality management System SOP Standard Operating Procedures

TAT Turn-Around Time

WHO World Health Organization

ADA Americans with Disabilities Act

CDC Centers for Disease Control and Prevention
MLSCN Medical Laboratory Science Council of Nigeria

NIH National Institutes of Health

NIOSH National Institute for Occupational Safety and Health

OSHA Occupational Safety and Health Administration

CAD Computer-Aided Design

HVAC Heating, Ventilation, Air Conditioning

GSF Gross Square Feet
NSF Net Square Feet
NSM Net Square Meter

SF Square Feet

1. Terms and Definitions

Accreditation body – Authoritative body that provides third-party attestation that a laboratory fulfils specified requirements and is competent to perform specific tasks¹; NOTE: The authority of an accreditation body is typically derived from government.

Aerosol – System of respirable particles dispersed in a gas, smoke, or fog that can be retained in the lungs; NOTE: Aerosol particles range in size from 1 to 5 mcm.

Biosafety cabinet – Hood designed specifically to contain microorganisms; NOTE 1: They are designed to protect workers, the environment, and laboratory consumables from contamination; NOTE 2: They can also be designed to use small amounts of chemicals and to keep products in the hood clean.

Biosafety level (BSL) — Laboratory designation determined by risk assessment of the pathogenicity of the agent, mode of transmission, amount of the agent manipulated, and the nature of the work performed; NOTE: This is subdivided into four levels (BSL-1, BSL-2, BSL-3. BSL-4; PC Level 1, PC Level 2, PC Level 3, PC Level 4) for microbiological and biomedical laboratories.

Volts – a measure of the pressure in an electrical circuit.

Watts – a measure of electrical power that is determine by multiplying the voltage by the amperage.

2. Scope

Laboratory design includes many activities that, when thoughtfully and carefully applied, culminate in a well-conceived and highly functional laboratory. This document addresses selected, non-structural elements of laboratory design that affect the planning, layout, and safety of the clinical laboratory. These elements include space, workflow, casework, equipment, classifications, ventilation, lighting, plumbing, electrical, and communications. This document is intended to give general guidance in laboratory design for those working in and managing laboratories. Many important and specific issues that need consideration in a well-designed laboratory are beyond the scope of this guideline and are best worked through with the project's consultants, architects, and engineers.

3. Conversion Factors

Table: Conversion Factors. Area, Volume

To Convert	Into	Multiply by
Centimeters	Inches	0.394
	Feet	0.0328
	Millimeters	0.01
Meters	Centimeters	100
	Feet	3.281
	Inches	39.37
	Yards	1.093
Inches	Centimeters	2.54
	Feet	0.0833
	Meters	0.0254
	Yards	0.0278
Grams	Ounces	0.035
	Pounds	0.002
	Kilograms	0.001
Pounds	Grams	453.59
	Ounces	16
	Kilograms	0.454
Liters	Gallons	0.264
Gallons	Liters	3.785

Area

To Convert	Into	Multiply by
Square feet	Square meters	0.09290
Square meters	Square feet	10.76

Volume

To Convert	Into	Multiply by	
Cubic inches	Cubic centimeters	16.39	
Cubic feet	Cubic meters	0.02832	
Cubic meters	Cubic feet	35.31	

4. Design Process

A project begins with the creation of a project team representing the laboratory, administration, facilities (maintenance) department, the architects and/or laboratory design consultant, and the engineers. Each phase of the design works through the various issues affecting the facility, culminating in documents for the actual construction.

The complexity of laboratory design requires a structured approach to ensure project success. The flowchart in Figure 1 depicts the general phases of a design process.

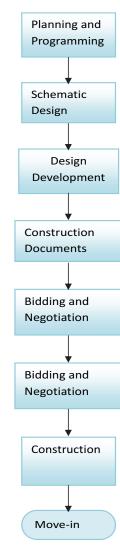


Fig. 1

5. The Project Team

The project team should include a careful selection of people who understand the laboratory, the facility, architecture, and engineering. There should be representatives from laboratory director/manager, laboratory staff, pathology staff, hospital/organization administration, and the facility department. The architectural and engineering team members should be experienced in clinical laboratory design.

It is very important to have the laboratory staff participating in the design process to ensure that specialized functions are not overlooked and to create consensus for new ideas and consolidations. Managers and supervisors from the various departments should participate in discussions of their particular areas and work together on shared spaces.

At the administration's discretion, selected staff members who actually work on the bench can be asked to participate in meetings. Posting drawings and design information in the laboratory where all staff members can comment is beneficial. It allows all of the staff to voice their concerns and ideas and keep track of the design progress.

The Laboratory departmental staff should be consulted on their particular areas of expertise. It is important that information on existing procedures and future plans is incorporated.

The architectural and engineering team (AE team) could consist of several members with various specialties. Consultants are common in a laboratory design project and should be used depending on the nature of the project. The AE team may be as follows:

- Architect of Record A state-licensed architect who will be stamping the drawings that go to contractors, as well as overseeing the construction process.
- Laboratory Design Consultant Someone who specializes in the design of clinical laboratories and can design the floor plans and elevations or can assist the Architect of Record in the design.

Engineers can consist of several specialties that are all important in the laboratory design: Structural engineer Plumbing engineer Electrical engineer Heating, Ventilation, Air Conditioning (HVAC) engineer

Other representatives of the organization and specialized consultants may be added to the team at various stages of the project. These might include the organization's maintenance department, infection control, security, and information technology personnel. Consultants may also include interior designers, workflow consultants, management consultants, equipment consultants, and manufacturers, representative for equipment and materials.

6. Planning and Programming

6.1 Develop Goals

Planning should start with the development of the overall goals of the project. What does the laboratory hope to achieve by redesign? Goals can be very general or specific. Look at existing problems and laboratory trends to establish goals. It is important not to be constrained by the existing facility and the workflow and staffing conditions that have developed over time.

This is good opportunity to inject operational changes into the organization that will require a different infrastructure to support those changes. The new design should also be capable of supporting future changes.

6.2 Collect and Analyze Facts

A large quantity of information needs to be collected to ensure that the construction process and resulting laboratory will work smoothly and efficiently.

A complete equipment list needs to be generated. This list needs to eventually have information on every instrument and device to ensure space and utilities are provided. It is also important to talk about future equipment that may be added to the laboratory. This might include

replacement analyzers, additional analyzers, equipment for new procedures, and automation systems.

Existing conditions in the laboratory are very important. The facilities department usually will have architectural and engineering drawings of the laboratory areas; these will show the structural, utility, and facility constraints that cannot be moved.

Conditions information is important in planning a new laboratory in a new space or building. This information can be obtained from the facilities department, a developer, or the architect who is designing the shell (exterior) of the building. Whether the building is new or a renovation of an existing building, columns, utility shafts, utility rooms, elevators, stairs, and other fixed elements will need to work around.

Another important step is to have the consultants, architect, and engineers tour the existing laboratories with laboratory staff members. The architects/consultants/engineers should be familiar with the existing laboratories and have problems pointed out to them before they start any design. Each laboratory has unique considerations; seeing these special conditions and problems is important in understanding the needs of the laboratory.

Interviewing the laboratory team members is the next step. The interview should highlight existing problems, staffing, future considerations, ideas, and concerns. There should be discussion of spaces that are important in the laboratory but that may not be associated with the equipment.- These might include manual testing areas (serology kit, blood cell differentials, plate reading), teaching/student stations (where applicable), and paperwork areas for clerical work, result verification, ordering, and quality control. Storage quantities and criteria to ensure space for the various types of storage should also be discussed.

A general process flowchart of the planning and programming process is provided in Figure 2.

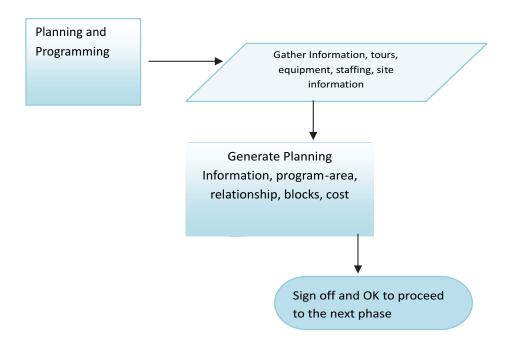


Figure 2: Planning and Programming Process

Interviews can go beyond the laboratory to include others who may be affected by changes in the laboratory.

- Internal customers nurses, doctors, medical records, etc.
- External customers outreach clients, remote laboratories, sister facilities

6.4 Uncover and Test Concepts

Planning should include a "brainstorming" step, in which team members may verbally and graphically generate ideas relating to the laboratory design. This early stage is the opportunity to try out any idea, no matter

how unusual it might sound. These ideas may develop into a unique solution to a common problem. It is important to think outside the existing conditions to be able to solve the problems those existing conditions have created.

6.5 Generate Information

The information that is ultimately generated in the planning processes should be as follows:

6.5.1 Equipment Information

Equipment lists and information by department can be done by the laboratory staff, the architect, the laboratory design consultant, or an equipment consultant. Information collected is as follows:

- Manufacturer's name and model and/or serial number;
- Dimensions (width, depth, height, and clearances required);
- Electrical information (volts, amps, emergency power, uninterrupted power, phases, special plugs/sockets);
- Data information [modem, laboratory information system (LIS) connection];
- HVAC information (heat generated in BTU'S, venting requirements;
- Plumbing information (type of water, drains, gases, wastes including acids); and
- General information (existing, new, future, who will purchase, who will install, association with other equipment, miscellaneous facts that are deemed important)

6.5.2 Program and Area Analysis

The program includes the laboratory spaces, offices, employee support, and base building support areas. Review with the laboratory representatives will highlight rooms that may have been missed, need to be added for expansions and technologies, or can be deleted and consolidated. Each of these rooms/spaces should have a square footage assigned to it.

Laboratory space square footage/square meters should be determined from the equipment needs, manual work areas, code requirements, and storage needs. Table 1 provides a sample program/area analysis).

There are no present benchmark numbers that illustrate square footage/meter requirements; this is due to the variety of instrumentation, procedures, and patient populations in various institutions.

Support spaces, employee spaces, and offices are generated from codes, quantity of staff, quantity of storage needs, and facility standards.

Table : Example Program/Area Analysis

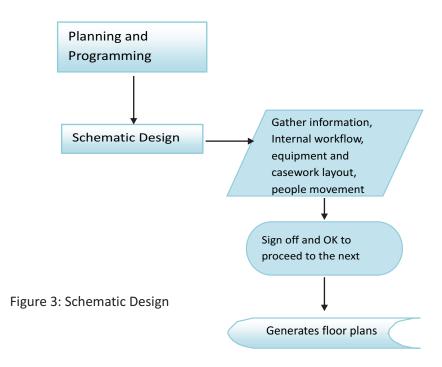
	Proposed Areas		NSF/NSM	Notes
1	ADMINISTRATION	Where Applicable	2630/235	
	1	Laboratory Director	150/14	
	2	Secretary	100/9	Keep copy machine/file room adjacent
	3	Laboratory Staff	120/11	
	4	Supervisors	480/45	4 people at 120 sf each
	5	QA Manager	120/11	
	6	Customer Service/	240/22	4 people at 60 sf each
	7	Transcription	340/23	5 people with mail, equip and files
	8	Cytology Screening	360/33	4 Cytotechs, one supervisor
	9	5-head-micrscope room	120/11	
	10	Meeting	300/28	
		Library	300/28	
II.	LABORATORIES		12184/1133	
	1	Accessioning	1520/141	
	2	Routine Medical Laboratory	3720/346	
	3	Development	With Routine	
	4	Blood Bank	1838/171	
	5	Microbiology	2310/215	

6	Fluorescent Microscopy	75/7	
7	TB/Fungi Culture	462/43	BSL-3 laboratory
8	Virology	288/27	BSL-3 laboratory
9	Gross Anatomy	407/38	laboratory
LABORATORY SUPPORT FACILITIES	WHERE APPLICABLE	3036/281	
1.	Walk-in-coolers	240/22	3 units each at 80 sf
2.	Sterilisation	64/6	
3.	LIS Server closet		80/7
4.	Bulk storage room	820/76	
5.	Biohazard/Trash/Recycle room	90/8	
6.	Record/File/Copy room	316/29	
7.	DI water closet	75/7	
8.	Gas storage closet	160/15	
9.	Clean laboratory coat closet	75/7	
10.	Flammable storage	128/12	
11.	Specimen storage/Recycle	238/22	
12.	Block and slide storage	750/70	
EMPLOYEE SUPPORT		1316/121	
1.	Multipurpose room (classroom)	500/46	
2.	Lockers	336/31	Acoustic division to divide room
3.	Lounge		
4.	Male shower with water closet	90/8	195 purse lockers
5.	Female shower with water closet	90/8	ADA accessible
6.	Unisex toilet	300/28	ADA accessible 6 ADA accessible
	Call Duty Rooms		
OUTPATIENT		330/31	
	7 8 9 10 LABORATORY SUPPORT FACILITIES 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. EMPLOYEE SUPPORT 1. 2. 3. 4. 5. 6.	TB/Fungi Culture 8 Virology 9 Gross Anatomy 10 Histology/Cytology LABORATORY SUPPORT FACILITIES 1. Walk-in-coolers 2. Sterilisation 3. LIS Server closet 4. Bulk storage room 5. Biohazard/Trash/Recycle room 6. Record/File/Copy room 7. DI water closet 8. Gas storage closet 9. Clean laboratory coat closet 10. Flammable storage 11. Specimen storage/Recycle 12. Block and slide storage EMPLOYEE SUPPORT 1. Multipurpose room (classroom) 2. Lockers 3. Lounge 4. Male shower with water closet 5. Female shower with water closet 6. Unisex toilet	TB/Fungi Culture

15

	1.	Phlebotomy room	112/10	
	2.	Fine-needle procedure	120/11	1 phlebotomy
	2.	room	120,11	station
	3.	Convenience room	50/5	Station
	4.	Waiting room	48/5	2 seats
	7.	Waiting room	40/3	2 3cdt3
VII	BASE BUILDING		350/32	
	1.	UPS system closet	100/9	
	2.	Janitor closet	50/5	
	3.	Electrical closet	100/9	
	_		100/9	
	4. RECAP	Communication closet	100/9	
	1	Communication closet	100/9	
	RECAP			
<u>l.</u>	RECAP ADMINISTRATION		2630/235	
II.	RECAP ADMINISTRATION LABORATORIES	l	2630/235 12 184/1133	
II.	RECAP ADMINISTRATION LABORATORIES LABORATORY SUP	PPORT	2630/235 12 184/1133 3036/281	
II. III. IV.	ADMINISTRATION LABORATORIES LABORATORY SUP EMPLOYEE SUPPO	PPORT	2630/235 12 184/1133 3036/281 1316/121	
II. III. IV. V.	ADMINISTRATION LABORATORIES LABORATORY SUP EMPLOYEE SUPPO OUTPATIENT	PPORT	2630/235 12 184/1133 3036/281 1316/121 330/31	
II. III. IV. V.	ADMINISTRATION LABORATORIES LABORATORY SUP EMPLOYEE SUPPO	PPORT	2630/235 12 184/1133 3036/281 1316/121	
II. III. IV. V.	RECAP ADMINISTRATION LABORATORIES LABORATORY SUP EMPLOYEE SUPPO OUTPATIENT BASE BUILDING	PPORT	2630/235 12 184/1133 3036/281 1316/121 330/31 350/32	
II. III. IV. V. VII.	ADMINISTRATION LABORATORIES LABORATORY SUP EMPLOYEE SUPPO OUTPATIENT	PPORT	2630/235 12 184/1133 3036/281 1316/121 330/31	*

Schematic Design Plan



In a laboratory project it is beneficial to show all major equipment, whether countertop or floor mounted in the schematic design. This assists in the discussion of specific workflows and staff movements. It also illustrates whether sufficient workspace is allowed for each instrument and procedure.

The project team will review and amend these plans until they are comfortable with the layout and workflow.

When the floor plan is acceptable to the design team, a sign-off is usually involved. Here, the laboratory representatives literally sign the floor plan. The signatures represent approval of the general layout presented and permission for the architects and engineers to proceed to the Design Development stage.

1. Laboratory Equipment

7.1 Equipment Documentation

Each type of laboratory relies on one or several equipment instruments or devices. Large analyzers can take up significant floor space as well as having many utility requirements, such as water, drains, special power, data connections, and vacuum. Small instruments and devices can easily accumulate and take up a large counter space and utilities, in addition to producing a large quantity of heat.

Documenting the specifics of each instrument and device is important for the architect or laboratory planner to determine square footage requirements and layout. The list should include any instrument or device, no matter what size, that requires any utility, such as electricity. This is also very important for the engineers when determining the utility requirements and heat loads for the laboratory.

This information should be part of the equipment list that is provided to the architect or laboratory planner.

7.2 Instrument Name

When listing equipment, note the general name of the instrument, or device (such as centrifuge, refrigerator, analyzer), the manufacturer of the instrument, or device, and the specific manufacturer's model number for the instrument, or device. This information is for the architects, laboratory planners, and engineers to look up additional information if needed. The manufacturer and model number allows them to call the manufacturer or go to the website to check specifics.

7.3 Size Information

When providing the dimensions of an instrument, width (side to side), depth (front to back), height and weight, are recorded.

Consideration should be given to whether the instrument is free-standing or mounted. Most laboratory equipment is placed on the countertop. Large instruments are placed on the floor. Occasionally, instruments and devices, such as a deionized (DI) water system, are actually mounted to the wall.

For instruments that weigh more than 300 lbs (136 kg), it is very important to ensure that the floor can support the load. For example, an irradiator can weigh as much as 5000 lbs. (2268 kg). The structural engineers will design the new floor support for extra weight to withstand instruments and devices that are very heavy.

A good instrument clearance is needed. This includes room to open the top of the instruments and devices, access to the sides for opening panels or hanging monitors, access to the back of the instrument for maintenance and troubleshooting, or manufacturer requirements for air ventilation around the analyzer. A good design solution is to keep an access to the back of the instrument of at least 30 inches (76 cm); this would give someone room to get to the back easily, as well as keep drains, reagents, and wiring out of a general walking path.

7.4 Electrical Information

Electrical needs for equipment can include the voltage, amperages, phases and watts. It will also include specialized features, such as whether or not it requires a dedicated circuit, uninterrupted power (UPS), emergency power, or a special type of connection (special outlet or hard wiring).

7.5 Networking Information

Laboratory information system (LIS), hospital information systems (HIS); and phone lines are generally referred to by engineers as "communications." Other systems may need connection to the LIS network or HIS network. Instruments and devices may also need telephone lines, so the manufacturer can be linked by a modem for troubleshooting.

NOTE: The information needs to be documented, so the engineers can provide a sufficient quantity of data outlets for the equipment.

2. Biohazards

8.1 Determining Biosafety Levels

Clinical laboratories receive samples for a variety of diagnostic and clinical support services. Typically, the infectious nature of the samples is unknown and is submitted for a wide range of microbiological examinations. The samples can be routinely processed at BSL-2, which meets the OSHA requirements for working with blood-borne pathogens. Work with certain pathogens such as tubercle bacilli should be performed in a BSL-3 laboratory. This is especially necessary in situations in which an aerosol may be created during manipulation of the pathogenic organisms such as in culture.

Some organisms that should be tested in BSL-3 include:

- Mycobacterium tuberculosis This organism is considered pathogenic for humans. The risk of acquiring the infection by laboratory personnel is quite high. Those working in mycobacteriology laboratories are three to five times at greater risk than other laboratory workers, and 100 times greater than the general population.
- Fungal agents such as Coccidioides immitis and Histoplasma capsulatum— BSL-2 is recommended for handling and processing clinical specimens; however, BSL-3 is recommended for propagating and manipulating cultures of these agents.
- Viral agents such as arboviruses, lymphocytic choriomeningitis virus, and Hantaviruses. Potentially infected samples should be handled in BSL-3 practices. Cell-culture virus propagation should be done in BSL-3.
- Recombinant DNA:- Experiments involving recombinant DNA requires BSL-3 containment.

8.2 Designing for Biosafety Levels

Biosafety levels are designated in ascending order by degree of protection provided to personnel, the environment and the community.

Biosafety Level 1 (BSL1) represents a basic level of containment that relies on standard microbiological practices with no special physical barriers.

2.2.1 Design Requirements for BSL 1:

- Doors for access control;
- Hand washing sink and located near the door.
- Bench tops: Impervious to water resistant, moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination.
- Sturdy laboratory furniture.
- Laboratory windows that open to the exterior should be fitted with screens
- No fabrics or carpeting

2.2.2 Design requirements: BSL 2

In addition to the BSL 1 above

• Laboratory doors should be self-closing and have locks in accordance with the institutional policies.

- Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
- The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
- Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
- Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens
- BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
- Vacuum lines should be protected with liquid disinfectant traps.
- An eyewash station must be readily available.
- There are no specific requirements for ventilation systems.
 However, planning of new facilities should consider
 mechanical ventilation systems that provide an inward
 flow of air without recirculation to spaces outside of the
 laboratory.
- HEPA filtered exhaust air from a Class II BSC can be safely recirculate back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
- A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

2.2.3 Design requirements: BSL 3

- Laboratory doors must be self-closing and have locks in accordance with the institutional policies. The laboratory must be separated from areas that are open to unrestricted traffic flow within the building. Laboratory access is restricted. Access to the laboratory is through two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
- Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated. It should be located near the exit door. If the laboratory is segregated into different laboratories, a sink must also be available for hand washing in each zone. Additional sinks may be required as determined by the risk assessment.
- The laboratory must be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces should be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.
- Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.
- Walls should be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
- Ceilings should be constructed, sealed, and finished in the same general manner as walls.
- Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs. Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment.
- Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment must be accessible for cleaning.
- Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- All windows in the laboratory must be sealed.

- BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily travelled laboratory areas, and other possible airflow disruptions.
- Vacuum lines must be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.
- An eyewash station must be readily available in the laboratory.
- A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.
- Laboratory personnel must be able to verify directional airflow. A
 visual monitoring device, which confirms directional airflow, must
 be provided at the laboratory entry. Audible alarms should be
 considered to notify personnel of air flow disruption.
- The laboratory exhaust air must not re-circulate to any other area of the building.
- The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations or the exhaust air must be HEPA filtered.
- HEPA filter housings should have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.
- BSC should be certified at least annually by a certified biomedical engineer and documented.
- A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).
- Equipment that may produce infectious aerosols must be contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.

- Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.
- The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.

3. Bioterrorism

Biological diseases and the select agents that might be used for terrorism are regulated by the Federal Ministry of Health. Public health and certain other laboratories have been identified as being capable of diagnosing and/or researching these agents. All laboratories possessing such agents are required to be registered and to strictly adhere to required BSLs, physical security standards, inspections, and personnel clearances by the relevant government agencies In the event of contamination with a suspected bioterrorism agent, there should be emergency shower facilities for the laboratory personnel. These are outlined by the CDC Anthrax Guidelines for Clinical Laboratories in their procedures for decontaminating after accidental exposure to anthrax or other bioterrorism organism. Providing a flood shower in the BSL-3 laboratory is a good practice, so staff can wash their outer clothing while still in the contained area. Outer clothing can be bagged, and the exposed individual should go to a locker room where a private shower is available. She/he should then disrobe, bag the remainder of the clothing, and shower thoroughly

4. Security

possible.

Security is an important issue in clinical laboratories due to the presence of biological, chemicals, and sharps. All of these can be used by people for illegal purposes and must be contained. Biological security considerations have been outlined in a recent CDC publication. Several issues are stressed:

with soap and water to remove as much of the contamination as

 Know the persons who have access to select agents and other highconsequence microorganisms.

- Isolate the laboratories working with these agents away from general traffic hallways and provide appropriate locks on the doors, such as locks requiring card keys access or cipher access. Doors should be locked when the laboratory is unoccupied.
- Closed-circuit TV monitoring, two-person access requirements and log books are often used for accountability.
- The level of vulnerability for a particular facility needs to be assessed by persons trained in laboratory security.
- The freezers containing stocks of high- consequence microorganisms should also be locked. Many laboratories also secure the stock vials inside lock boxes in the freezer.
- The laboratory should be locked at times when access into the facility cannot be monitored. This is good practice, but can be impractical when there is high traffic. Storage rooms for chemicals and areas that may contain sharps should be locked separately from the laboratory itself.
- In laboratory areas where forensic work is being performed there must be another level of security to protect the samples from being tampered with.. This would include locking and limiting access to the testing areas and all storage areas for specimens and files.

5. Space Determination

13.1 Working Laboratory Space

Laboratory space is currently determined based on the features of the laboratory itself. These would include the laboratory equipment, work areas, plumbing fixtures, aisles, and code clearances. Information used to determine the space or square footage requirements is gathered in the planning and programming stage of design. The necessary space for a particular laboratory requires an understanding of all its functions.

13.2 Floor Space Determination

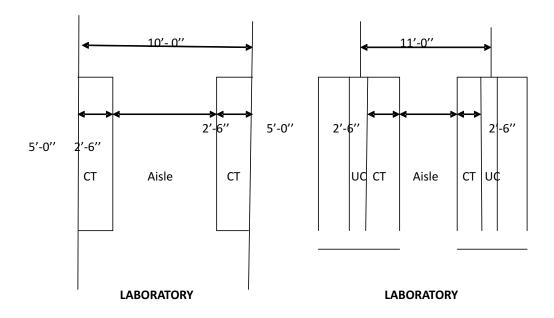
General space clearances are listed in Table 3 below:

Table: General Space Clearances

Minimum Clearance/space	Notes
Requirement	
at (5) and min	Consider minimum clearance in any walking area in the
	laboratory.
60" (152 cm) aisle	Consider minimum clearance between benches and
	equipment where people are working back to back.
18" to 24" (46 to 61cm) beside	Added to a 36" (91cm) door, this can increase the
doors	minimum corridor width to 60" (152cm)
44" (112cm) to 72" (183 cm)	Minimum clear corridor width where a patient bed or
corridor	stretchers would be used. Dependent on whether it is
	Institutional or Business occupancy.
96" (244 cm) corridor	Minimum clear corridor width where a patient bed or
	stretcher would be used.
30" (76 cm)	Consider minimum depth of countertop to
	accommodate laboratory equipment.

Laboratory features that are required by MLSCN need to be addressed when determining square footage. These include fixtures such as emergency eyewash stations, emergency floor showers, hand wash sinks, and fire extinguisher cabinets.

Space must be allowed for ease of manoeuvring throughout the laboratory, including the area between casework, in aisles, and around equipment (see Table 1). A typical laboratory model is between 10 to 11 feet (305 to 355 cm (see Figure 4). The 10-foot module includes countertop of 30 inches (76 cm) on each side and an aisle of 60 inches (152 cm). The 11- foot module has the same countertops and aisle, but also incorporates the utility core that is typical for many laboratory casework systems. This core is 12 inches (31 cm), and the module assumes half of the core on each side for a series of counters (see Figure 4).



LABORATORY
MODULENO UTILITY CORE

LABORATORY
MODULEWITH UTILITY CORE

CT-Countertop; UC-Utility core

Figure 4: Typical Laboratory Modules

Allowing space around equipment is necessary for proper ventilation and ease of maintenance. Equipment manufacturers will often note distances from walls that are required for particular instruments and devices. Ease of maintenance is achieved by leaving an aisle behind large instruments or placing equipments on procedure tables with lockable casters that can be wheeled out to expose the backs.

Disabled Employee Considerations

All public and common-use areas of new medical care facilities, as well as alterations of existing facilities, should be accessible, including outpatient and visitor areas. In the laboratory setting, this could include waiting, phlebotomy, toilet, and blood donation areas.

Areas that are designated employee-only work areas should be designed to allow an individual with disabilities to approach, enter, and exit. In the event that an employee is disabled, the laboratory should be revised to meet this employee's needs. The addition of casework that is flexible and can be adjusted in height allows the laboratory to easily adapt to both disabled and non-disabled employees.

2. Laboratory Support Spaces

13.1 Bulk Storage

The size and location of storage and support space have a significant effect on both laboratory functionality and laboratory safety. Laboratory employees use large quantities of consumables every day, including reagents and dry items, such as gloves, tubes, and paper products. Appropriate storage that is convenient to the laboratory must be provided. Locating bulk storage a long distance from the laboratory necessitates more storage within the laboratory space itself, which is more expensive and can constrain the work areas.

The quantity of space required for bulk storage is determined by noting the existing storage needs, providing sufficient space, and allowing for future expansion. If space is constrained, then the use of a high-density storage system, in which the storage shelves are on tracks can move and be stacked, should be considered.

The laboratory space should always contain some storage, which could be tall storage cabinets, under-counter cabinets and drawers, and wall cabinets. However, in-laboratory storage should not replace a bulk storage room.

13.2 Sample Storage

Some laboratory samples require retention for a week or more to allow repeat testing and future review; therefore, sufficient post-testing storage space must be planned. In clinical areas, conveniently located free-standing refrigerated units may be attached to the system for this purpose.

Many laboratory sections save slides in slide file drawers. Some laboratory sections are required to keep slides for ten years or more, thus creating a need for a very large amount of storage. Slide files are very heavy; therefore, bulk storage space should have sufficient structural capacity. Some slides (often two years worth) should be stored in the immediate area of the laboratory, as they will be accessed regularly.

Paraffin blocks are stored for ten years or more, and therefore require temperature control to ensure they do not melt. For their protection, the blocks should also be in an area that is free from rodent and insect infestation.

13.3 Autoclave/Sterilization

There must be facilities and equipment to sterilize contaminated samples before transportation. If the organization has on-site facilities for incinerating samples, the laboratory is required to have its own autoclave system.

Many microbiology areas prefer to have their own unit to allow for sterilization of some equipment or for media preparation. Depending on the use, this can either be a floor unit or a smaller countertop unit.

If a floor unit is to be installed, the manufacturer's specification should be consulted for clearances. It is advisable to place a canopy hood over the door of the unit to collect the heat and odour that will be generated. If the unit is placed in a service room, should be negatively pressurized to keep the odour from escaping into other areas.

13.4 Glass-wash Room

A glass-wash room is not a necessity for laboratories unless a large amount of recyclable glassware is used; most laboratories use disposable glass products. The small number of items that need washing can usually be accommodated by an under-counter laboratory glassware washer that is similar to a household kitchen dishwasher, which can be located in the laboratory itself or in a room with another function that is appropriate.

14. ELECTRICAL AND COMMUNICATIONS

14.1 Electrical

Laboratories should plan for supplying various types of electrical power and for future expansion. Information that can affect the electrical design of the laboratory includes the following:

- Volts
- Amps
- Phases
- · Watts
- Dedicated circuits
- · Uninterrupted power supply (UPS)
- Emergency power and
- Specialized plugs.

Equipment specifications and/or the unit itself should be checked for these requirements when determining power needs. This information should be part of the equipment list that is provided to the architect/consultant.

14.2 Volts

Typical levels of power are 110 to 120 v and 208 to 220 v. This should be adapted to meet in-country voltage requirement (220-240v)

Most laboratory analyzers and computers require UPS to control power surges and allow the instrument to run in the time between the laboratory's power going out and the emergency power starting. Units will note the amount of time they can run on the batteries. Either several small units should be provided for individual instruments and devices, or analyzers are often an option that can be purchased from the manufacturer.

If a large UPS system is part of the new laboratory, then a separate room should be allowed to accommodate it. These units tend to be very heavy, so it should be considered by the structural engineer and architect during design.

14.3 Emergency Power

Emergency power for laboratory equipment needs to be supplied by an emergency generator in the event of a power outage. Generators can only supply a limited amount of emergency power, and this should be carefully considered when requesting it for equipment. All refrigerators, freezers, and incubators should be connected to emergency power, so there is no loss of samples and reagents if the outage is extended. Other equipment to be connected should be those necessary for emergency testing. For other smaller units, such as microscopes, mixers, printer, etc., it is prudent to make sure that some emergency outlets are distributed around the laboratory to use if necessary. Often one extra emergency outlet per casework run can be enough. Instruments that could be harmed, or testing lost, when power supply is interrupted during testing should be equipped with loaded line phase shifter (LLPS) or battery backup.

When designing a new building, the quantity of emergency power is important, as quantity affects the size of the generator to be purchased. Extra capacity should be ensured to support future growth.

14.4 Communication

Computerization has revolutionized the way testing is done and reports generated. There is an ever-expanding need for connectivity to the laboratory information system (LIS) servers, hospital information system (HIS) servers, outside sources through modems, and to analyzers. There are also increases in the numbers of computers (either dumb terminals or PCs) and printers (report and label) needed. Providing the correct wiring and flexibility for expansion is very important.

Outlets for computer connections should be provided liberally throughout the laboratory and in the offices, not just where computers are shown on the plan, to allow the addition of other computers, analyzers, and printers in the future, as well as to permit flexibility for moving units as needs change.

14.5 Lighting

The clinical laboratory is not a static environment; its design and configuration change continually. These changes are precipitated by new instrumentation, computerization, and automation. Various types of lighting are normally included in a laboratory.

14.5.1 Lighting Levels

The amount of illumination (or lighting level) needed is determined by the task to be performed, the color of the adjacent walls and the ceiling, the distance from the lighting fixture to the work surface, and the spacing of the light fixtures (see Table 5).

Recommended lighting levels have been developed by the Illuminating Engineering Society of North America (IESNA). In the clinical laboratory, the various types of tasks and recommended levels are listed in the chart below. Laboratories generally require the Illuminance Category E. further information, refer to IESNA RP-29-95, Lighting for Hospitals and Health Care Facilities.

Table: Ranges of Illuminance

Type of Activity	Illuminance	Lux	Foot-	Reference Work -
	Category		candles	Plane
Performance of visual	D	100-150 –	10 – 15-20	Illumination on task
tasks of high contrast or		200		
large size				
Performance o f visual	Е	200-300-500	20-30-50	Illumination on task
tasks of medium				
contrast or small size				
Performance of visual	F	500-750-	50-75-100	Illumination on task
tasks of low contrast or		1000		
very small size				

Higher levels of light with good color rendering are needed in microbiology and anatomic pathology. This is accomplished by task lighting in the specific areas where increased light is needed; plate reading and gross anatomy cutting stations. Provision of flexible arm task lighting that allows each user to adjust the angle and height for his/her personal preference is beneficial to the staff.

14.5.2 Location of Lights

To achieve uniform distribution of light and to eliminate shadows, the ceiling lights should be mounted parallel to the work surface. Lights that are mounted perpendicular to the work surface can create a shadow, either from the person working at the bench or from overhead cabinets.

In areas containing overhead cabinets or shelves, use of task lights is advisable. Tasks light that are individually switched allow for turning the light off or on, depending on the task at the time. Several types of specialized task lights can be very useful in laboratories. The task lights should plug in instead of being hard wired, so they can be moved or eliminated if desired. Under-cabinet task lights that are magnetic instead of bolted to the cabinet can be moved wherever needed, adding to overall lighting flexibility.

Microbiology reading stations often need task lighting for close inspection of plates. A fluorescent light surrounding a magnifying glass is very popular. Histology cutting stations also need task lighting; an articulating arm fluorescent light works well in this situation, because it can be moved to eliminate reflections on the water baths.

Note that dark or off-white matte finish work surfaces reduce the amount of reflection and glare; however, dark work surfaces bounces less light to undersides of objects, making it harder to see.

15. Plumbing

15.1 Tap Water

Tap water is used in abundance in clinical laboratories for equipment, procedures, cleaning and personal use. Generally hot, cold, and temperate-regulated water should be provided where appropriate.

15.2 Deionized (DI) Water

DI water is required for many laboratory practices and analyzers. Either point-of-use DI system or a single loop system can be used to provide the proper water to all the laboratory areas requiring it.

The first step to determine what DI type and arrangement the laboratory needs is to obtain the specifics of the type of water and the quantity used from the manufacturers of the analyzers that use DI water. Most of the other laboratory uses are very small quantities for staining, reagent preparation, or glassware washers. The system should not be oversized or create loops that are infrequently used, as these will easily become contaminated and can be difficult to disinfect. Many laboratory glassware washers can be used with reverse osmosis (RO) water.

15.3 Sinks

Several types of sinks are used in clinical laboratories for various functions. The sinks are considered either dirty or clean, depending on their use.

Dirty sinks are used for testing, staining, and disposal of liquids other than DI water. They are usually made of epoxy resin or stainless steel. Integral sinks are integrated with the countertop surrounding them; drop-in sinks drop into a hole on the counter. Stainless steel sinks have the disadvantage of being corroded by some concentrations of bleach, so they should be used with caution where bleach is used for cleaning.

Sizes of dirty sinks are dependent on what the laboratory staff have found works well for their respective uses. Generally, laboratory sinks should be a minimum of 16 inches (41 cm) wide by 16 inches (41 cm) long by 6 inches (15 cm) deep. Some staining areas may use double sinks or deeper sinks. A larger and deeper sink should be considered for hand washing large cylinders and flasks, or pouring out of large containers. Occasionally, a very small sink is appropriate, such as when blood testing staff is pouring off supernatant from tubes. Many analyzers and strainers can drain into a cup sink.

Clean sinks are those designated for hand washing only and are required in clinical laboratories. Clean sinks can be used for pouring DI water, but cannot be used for any dirty procedures. In BSL-3 and BSL-4 laboratories the hand wash sink must be used hand-free, which can include foot pedal controls or electric eye operators. The hand wash sinks can be either countertop or separate, wall-hung lavatories. Room should be provided for paper towels, a soap dispenser, and an adjacent trash can.

16. Ventilation in laboratory Design

Ventilation is one of the most important elements in the design of a laboratory, and one of the most expensive. Proper ventilation rids the laboratory of biohazardous aerosols, noxious and/or toxic odours and vapours. It also promotes proper equipment functioning, maximizes temperature control, provides for the comfort of personnel, optimizes test performance, and facilitates a safe environment for personnel and patients both inside and outside the laboratory. Because ventilation is so important to the successful design of a laboratory, and because it is such an expensive component, it is vital that monies for ventilation be budgeted appropriately.

17. Temperature and Humidity

Temperature-control design criteria are affected by many factors, not the least of which is the operational tolerances of the equipment in the laboratory. A critical element of any laboratory design is the identification of the equipment that will be used in the area.

Several temperature guidelines are available. One is the US Department of Health standard, which uses $70\pm5^{\circ}$ F ($21\pm3^{\circ}$ C) as a guide. The IBC requires a minimum of 68° F (20° C) at 36 inches (914 mm) above the floor. Using all the recommendations and codes, it is prudent to ask for a range of 68° F (20° C) to 72° F (22° C) for the laboratory areas.

The optimal humidity level for a laboratory for both human comfort and equipment tolerances is 40 to 50%. Most laboratory equipment does not have major humidity requirement and accepts a wide range of tolerances, from 30 to 70%. There may be optimal humidity ranges noted in the operating manuals, especially for large analyzers. If no humidity range is noted, the manufacturer should be consulted to verify specifications.

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