

Laboratory Design; Approved Guideline— Second Edition

This document provides a foundation of information about laboratory design elements and guidance to help define the issues to be considered when designing a clinical laboratory.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



Clinical and Laboratory Standards Institute

Advancing Quality in Healthcare Testing

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Abstract

CLSI document GP18-A2—*Laboratory Design; Approved Guideline—Second Edition* is written for laboratory personnel responsible for, or involved in, the design of a laboratory. This guideline addresses selected nonstructural elements that affect the planning, layout, and safety of a clinical laboratory. The elements addressed include space, casework, equipment, classifications, health and safety, ventilation, lighting, plumbing, electrical, and communications.

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Foreword

Optimal laboratory design requires a careful blend of many design elements, which can be effectively accomplished only if opportunities, possibilities, and potential problems are well understood. A good understanding of the design issues that affect space, workflow, cabinetry, equipment, classifications, ventilation, lighting, plumbing, electrical, and data encourages asking the pertinent questions and facilitates wise choices during reviews of existing laboratories and planning of new or remodeled laboratories. Many existing laboratories were designed when the requirements for each of these areas were different. It is more important than ever that laboratories are designed to enable personnel to more easily and effectively respond to technological and procedural changes.

The advent of automation and instrument consolidation changes has permitted performance of more procedures in a smaller space. However, with the addition of new, specialized procedures and enhanced code requirements, overall scope of laboratory operations has generally expanded.

CLSI document GP18-A2—*Laboratory Design; Approved Guideline—Second Edition* provides a foundation of information about laboratory design elements and guidance to help define consideration of issues when designing a laboratory.

The content and organization of GP18-A2 is intended to encourage its frequent use throughout the laboratory design process. One aspect of this document that distinguishes it from other publications on laboratory design is the inclusion, where possible, of specific minimum and recommended guidelines. The minimum limits are limits at which laboratory safety or functionality begins to be compromised. Recommended guidelines are limits at which more acceptable levels of safety and functionality are attained. Many of the references cited in this document refer to US requirements; however, it is important for the laboratory consultants, architects, and engineers to consult specific codes and local authorities during the design process to ensure that all criteria are met for that particular region or country. This document is not intended to be an end to the process, but more a start in the right direction.

Key Words

Architecture, design, engineering, equipment, safety, space, utilities, workflow

Laboratory Design; Approved Guideline—Second Edition

1 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, nonstructural 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.

2 Introduction

Clinical laboratories are struggling to adapt and adjust to a myriad of changes that have come about through technological advances, increased computerization, and a decreased workforce. Laboratorians are confronted with new procedures and equipment that must be incorporated into their facilities to stay on the clinical and the competitive cutting edge. Many laboratory managers have found it necessary to either replace or remodel existing facilities to maintain the functional viability of their laboratories.

At this juncture laboratory managers encounter another legacy of change: the proliferation of building codes that must be addressed in the laboratory design process. A consequence of technologies that include chemicals and biohazards is the multitude of code requirements generated in response. More than an occupancy permit is dependent upon strict adherence to these codes; accreditation is also conditional on the incorporation of code requirements.

It is not reasonable to expect laboratory managers to be intimately familiar with thousands of pages of changing and seemingly contradictory regulations, or to master architecture and engineering in their spare time. That is the province of consultants, architects, and engineers who specialize in laboratory design, as well as code enforcement officers. It is preferable that managers have a general feel for space requirements, codes, and regulations that impact their laboratories. An awareness of the various regulatory agencies and the areas that they designate as hazardous will provide an alert to potential dangers and noncompliance in existing and new facilities.

3 Definitions

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

acids – chemicals with pH lower than 7; **NOTE:** Acids can cause serious burns on human skin and many other materials.

acoustics – the study of sound; **NOTE:** This is used in determination of the sound absorbance and transmission properties of various materials used in a construction project.

addendum//addenda – request for information adding to or clarifying the construction bidding documents; **NOTE:** These are generally issued during the bidding phase as part of the construction contract documents.

additional service – services of the architects and/or engineers that may be required for the project but were not originally specified in the contract; **NOTE:** These would only be done with authorization from the owner.

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 μm .

air changes – the amount of air it takes to replace existing air in a space over a specific time.

air pressure – the force exerted on a surface by the weight of air above it; more air is greater pressure, less air is lower; **NOTE:** Air pressure is used in HVAC to determine airflow from one area to another, as air will move naturally from areas of greater pressure to areas of less pressure.

aliquot – *in laboratory automation*, a portion of a sample placed in a separate container to facilitate concurrent testing or to hold in reserve for future use.

aliquotter – part of an automation line where the samples are separated into one or more secondary tubes.

alkalis – substance with a pH higher than 7; **NOTE:** Alkalis are also referred to as “bases” and can cause severe burns to the skin.

amps – short for amperes, which is a unit of measurement for electrical current.

anteroom – small room placed between two rooms or spaces that acts as an air lock or transition space between two areas of differential air pressure to reduce contaminated air from escaping one area and going into the other.

antifatigue mats – padded mats that are placed on floors in areas where staff must stand for long periods of time.

antifungal – agent that destroys or resists fungus; capable of destroying or inhibiting their growth.

antimicrobial – agent that destroys or resists microorganisms; capable of destroying or inhibiting their growth.

apheresis – the withdrawal of whole blood from the body, separation of one or more components, and return of remaining blood to the donor by transfusion.

backdraft – exhaust vents located at the back of the countertop, designed to take chemical fumes that are heavier than air out of a space.

backsplash – small strip placed on top of a countertop, at the back, to protect the wall.

benchmark – a standard or measurement that is used to compare with other similar situations.

bidding and negotiations – fifth design phase of the construction project, in which the drawings and specifications are sent to the contractor for bids on the overall project cost.

biohazard – a biological agent or condition that constitutes a hazard to human beings, animals, or their environment.

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.

bioterrorism – biological diseases and the select agents that might be used for terrorism; **NOTE:** Select agents are very varied and comprise viruses, bacteria, rickettsiae (microorganisms that have traits common to both bacteria and viruses), fungi, and biological toxins.

block diagram – graphic illustration of the spaces in a project and how they might fit into a designated area in the facility; **NOTE:** This is the very rough beginning of a floor plan.

blood-borne pathogens – pathogenic microorganisms that are present in human blood, blood products, or other potentially infectious material contaminated with blood, and can cause disease in humans or animals.

British thermal units (BTU) – the amount of heat required to raise the temperature of one pound of water by one degree Fahrenheit; **NOTE:** This measurement is used to describe the heating or cooling capacity of a system.

bubble diagram – graphic illustration, using circles, of the required relationships between various spaces in a project.

casework – premanufactured cabinet/countertop systems.

cell culture – technique for growing cells in a laboratory setting.

centrifugation – separation of solids from liquids using rotational forces.

change order – written order to the contractor to change something that was previously shown in the approved drawings or specifications.

clearance – open space allowed adjacent to equipment to allow access for maintenance or airflow; open space allowed for staff to move freely and to accommodate disabled people.

clinical laboratory automation systems – an assemblage of components that mechanically and electronically transfers, analyzes, and processes information and material related to clinical diagnostic testing of patient specimens, controls, calibrators, standards, and images.

codes – a collection of laws in writing.

combustible liquid – a liquid with a flash point of 100 °F (38 °C) or higher, but generally below 200 °F (93.3 °C).

constant air volume (CAV) – air supply and exhaust system where the airflow always stays the same.

construction administration (CA) – sixth and last design phase of a construction project, in which the actual construction is occurring; **NOTE:** The administration refers to the task of the architect in relation to construction.

construction documents (CD) – fourth design phase of a construction project, in which drawings and specifications, which tell the contractors exactly what to purchase and how they should be constructed, are prepared.

corrosive – a substance that can cause damage to human skin at the site of contact.

dead-end corridor – route that exceeds a specified length that does not lead to a fire exit; **NOTE:** Lengths are determined by fire codes for a specific building type.

decapper – part of an automation line at which the caps are taken off the specimen container.

decontamination – procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects; **NOTE:** Some disinfectants can be used for decontamination. These are intermediate- or low-level disinfectants and in the U.S. are regulated by the EPA for use on inanimate surfaces. They should not be used on medical devices that are used on patients; likewise, liquid chemical germicides formulated as sterilants or high-level disinfectants ordinarily are not used for purposes of decontamination because of the risk to personnel.

dedicated circuit – an independent electrical connection devoted to a specific piece of equipment.

deionized water (DI) – water resulting from the removal of ionized minerals and salts by ion exchange.

demolition – wrecking or removal of existing building components to allow new construction.

deoxyribonucleic acid (DNA) – a type of nucleic acid; a polynucleotide having a specific sequence of deoxyribonucleotide units (dNTPs) and serving as the carrier of genetic information.

design development (DD) – third design phase of a construction project, in which the plans generated in the previous phase (schematic design) are drawn in greater detail, more engineering information is incorporated, and the elevations are generated.

direct lighting – light that is directed downward towards the work surface.

directional airflow – air supply and exhaust system that is laid out to guide the movement of air in a specific direction.

downdraft – movement of air through exhaust vents located near the floor to take airborne particulates or chemical fumes that are heavier than air out of a space.

ducts – round or rectangular metal pipes for the distribution of air.

elevations – graphic illustration of the vertical elements of a design, including casework and millwork.

emergency power – back-up power system used in case of a public system outage.

emergency shower – see **flood shower**.

epoxy paint – paint that contains resins to allow more water and chemical resistance.

epoxy resin – a poured, molded, solid material used in laboratory countertops, floors, or other surfaces.

ergonomics – the study of the efficiency of persons in their working environment; **NOTE:** This term includes biomechanics, work physiology, anthropometrics, and man-machine interfaces.

exhaust air – air that is removed from an area.

extraction hood/fume hood – cabinet or cover above a laboratory device for the extraction of air or fumes directly to the exterior of a building, which prevents their general circulation.

eyewash station – unit designed to allow people to flush their eyes and face with water in case of a chemical or biological spill.

face velocity – the speed of the air moving into a cabinet or hood measured at the front opening.

fire egress – route used to get out of a building in case of a fire.

fire rating – rating of a wall or door used to protect an area from a fire for a certain amount of time; **NOTE:** Normally listed in hours of 1, 2, 3, or as smoke containment.

fixed casework system – premanufactured casework system that is fixed (bolted) to the floor, wall, and/or each other.

flammable liquid – a liquid with a flash point less than 100 °F (38 °C).

flash point – the lowest temperature that the vapor above a liquid will ignite when an ignition source is introduced.

flexible casework system – premanufactured casework system that is easily changeable in aspects, including countertop height and storage components.

flood shower – a shower located in laboratories that is used for emergency purposes, e.g., in case of accidental chemical spills, biological spills, or fire; **NOTE:** Also called an **emergency shower**.

floor plans – graphic drawings created to show the layout of a space from the perspective of looking down upon it.

foot-candle (fc) – unit of light on a surface one square foot in areas with a uniform distribution of a specific amount.

gross square feet (GSF) – square footage that includes usable space and the space necessary to accommodate walls, columns, shafts, plumbing, and other support features.

grossing station – equipment used in the dissection of gross anatomy specimens.

guidelines – principles and procedures to set basic requirements; recommended actions.

gypsum board – wall or ceiling sheets made from gypsum; **NOTE:** Also called “sheet rock.”

hands-free – operable without the use of a person’s hands; **NOTE:** The term is generally used to describe handwash sinks and can include electric-eye operators or foot pedal controls.

handwash sink – a sink that is dedicated to handwashing only and is not used for any procedural purposes.

hard ducted – air ducts that connect directly to an instrument, so fumes or contaminants can be transported directly to the outside of the building.

hard wired – electrical or communication wires directly connected to the unit instead of through an outlet.

high-density storage system – storage shelving that is stacked together in several rows with one or two aisles; **NOTE:** Units are moved to create access aisles as needed.

high-efficiency particulate air filter (HEPA) – used to remove from the air 99.97% of particulates having a diameter of 0.3 μm .

horizontal exit – route used to escape a fire that moves in a horizontal direction, such as a direct route to the outside or into another building through a fire-rated wall.

inactive leaf – door section that is normally fixed in a closed position unless manually unlatched to open.

indigenous – originating in a particular region or environment; occurring naturally in an area.

indirect lighting – lighting by lamps that direct the light upward towards the ceiling.

input station – part of an automation line at which specimens are placed to begin transport on line.

inside liquid storage room – one-hour fire-rated room suitable for storage of flammable liquids located inside a building.

integral – consisting of one piece, such as an integral baseboard with vinyl flooring, or an integral sink with countertop.

laboratory module – standard distance calculated from two work countertops and the aisle space between them.

lethal – an instrument of death, such as a toxin, organism, or weapon.

microorganism – microbiological entity, cellular or noncellular, capable of replication or of transferring genetic material (ISO 15190).¹

millwork – custom made cabinet/countertop systems.

modular casework system – prefabricated casework that comes in standard-sized modules; **NOTE:** This can be a fixed system or a flexible system.

monolithic – formed from or composed of a single material; seamless.

movement diagram – graphic illustration of a laboratory block plan that shows how samples, staff, waste, supplies, and visitors may move through the space.

negative pressure – room pressure below that of an adjacent space, causing air to flow into the room from the adjacent space.

net square feet (NSF) – usable square footage in a space.

net-to-gross factor – multiplier applied to net (usable) square feet to estimate the gross (total) square footage.

nonsprinklered – areas without a sprinkler system for fire control.

organic solvents – defined by the EPA as a volatile organic liquid that is used for dissolving or dispersing constituents in a coating or contact adhesive, adjusting the viscosity of a coating or contact adhesive, or cleaning equipment.

pathogens – *Risk Group 1 (low individual and community risk)*: This group includes those microorganisms, bacteria, fungi, viruses, and parasites that are unlikely to cause disease in healthy workers or animals; *Risk Group 2 (moderate individual risk, limited community risk)*: A pathogen that can cause human or animal disease but under normal circumstances is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment; **NOTE**: Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited; *Risk Group 3 (high individual risk, low community risk)*: A pathogen that usually causes serious human or animal disease; can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another; or can be treated by antimicrobial or antiparasitic agents; *Risk Group 4 (high individual risk, high community risk)*: A pathogen that usually produces very serious human animal disease, often untreatable; and may be readily transmitted from one individual to another (or from animal to human or vice-versa), directly or indirectly, or by casual contact; **NOTE 1**: In Europe, “Risk groups I, II, III, and IV” are termed “Hazard Groups 1,2,3, and 4.” For the purpose of this standard, the terms may be considered interchangeable and local usage will determine the actual terminology required; **NOTE 2**: Medical laboratories dealing with Risk Group III and IV infectious agents will need additional requirements to ensure safety.

percutaneous – parenteral inoculation of infectious material or transfusion of blood or blood products.

phasing – breaking a construction project into pieces to allow work around occupied areas or to allow breakdown of costs into smaller units.

phlebotomy – the puncture of a vein to collect blood.

planning and programming – first design phase of a construction project, in which the general project requirements are detailed, such as specific areas, square footage requirements, budgets, relationships, and equipment.

plastic laminate – a hard-surfaced, thin material made from melamine under high pressure and used for the finished surfaces of countertops, cabinets, and furniture.

polymerase chain reaction (PCR) – a technology used to synthesize multiple copies of a defined region of target DNA; **NOTE**: A common method of DNA amplification, using pairs of oligonucleotide primers as start sites for repetitive rounds of DNA polymerase-catalyzed replication alternating with denaturation in successive heating-cooling cycles.

polyvinyl chloride (PVC) – a plastic that can be used as edging material, e.g., in countertops or in plumbing applications.

positive pressure – room pressure above that of an adjacent space, causing air to flow out of the room into the adjacent space.

procedure tables – free-standing tables used as part of laboratory casework systems; **NOTE**: The tables can be adjustable height and on wheels or casters if desired.

radiant panel – heating panel usually mounted to a ceiling or wall that heats a small area in close proximity to as much as 20 °F warmer than the surrounding areas.

recapper – equipment to place caps back on specimens as part of an automation line.

recombinant DNA – DNA that has been altered by joining genetic material from two different sources.

refrigerated storage system (automated) – refrigeration unit for specimens attached to an automation line.

regulatory agency – a government agency with the assignment to enforce regulations passed by legislative process.

relative humidity – the ratio of water vapor in the air to the amount that would saturate it at a specific temperature.

reverse osmosis (RO) – process in which a solution under pressure is forced through a filter from a more concentrated to a less concentrated solution.

schematic design (SD) – second design phase of a construction project, in which information from the first phase (planning and programming) is used to create a floor plan.

sheet vinyl – flooring supplied in large sheets to minimize seams in the floor.

uninterrupted power supply (UPS) – battery backup system that safeguards against power fluctuations that can cause damage and/or loss of information by controlling the power going to equipment.

utilities – services, such as gas, electricity, water, drainage, telephone, and data.

variable air volume (VAV) – air supply and exhaust system in which the airflow requirements increase or decrease to provide only as much air as is required.

vinyl composition tile (VCT) – a common flooring tile that is commonly supplied in one-foot square pieces.

ventilation – movement of air into and out of a space.

vertical exit – route used to escape a fire that moves in a vertical direction, such as a stair tower.

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

watts – a measure of electrical power that is determined by multiplying the voltage by the amperage.

3.1 Acronyms

ADA	Americans with Disabilities Act
ANSI	American National Standards Institute
ASHRAE	American Society of Heating, Refrigeration and Air-Conditioning Engineers
BMBL	Biosafety in Microbiological and Biomedical Laboratories
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
DHHS	U.S. Department of Health and Human Services
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NFPA	National Fire Protection Association
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
SEFA	Scientific Equipment and Furniture Association

3.2 Abbreviations

CAD	computer-aided design
FNA	fine-needle aspiration
GSF	gross square feet
GSM	gross square meter
HVAC	heating, ventilation, air conditioning
IBC	International Building Code
MSDS	material safety data sheet
NSF	net square feet
NSM	net square meter
LLPS	loaded line phase shifter
UPS	uninterrupted power supply

3.3 Conversion Factors

To Convert	Into	Multiply by
Centimeters	Inches	0.394
	Feet	0.0328
	Meters	0.01
	Millimeters	10
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 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.

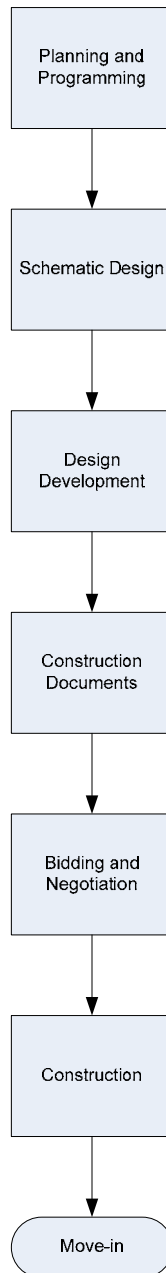


Figure 1. General Phases of the Design Process

4.1 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 administration, laboratory staff, pathology staff, hospital/organization administration, and the facility department. It is often helpful to include members of the medical staff at appropriate times during the project. The architectural and engineering team members should be experienced in clinical laboratory design.

The laboratory administration representative is often the laboratory medical director, laboratory manager or administrative director. This person should be able to participate in all meetings, be a negotiator, an arbitrator, and a decision maker.

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 to keep track of the design progress.

The pathologists, faculty, and support staff should be consulted on their particular areas. The pathologists and faculty will be concerned with the laboratory areas that support their 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:
 - Heating, Ventilation, Air Conditioning (HVAC) engineer
 - Plumbing engineer
 - Electrical engineer
 - Structural 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' representatives for equipment and materials.

4.2 Planning and Programming

4.2.1 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 a 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.

4.2.2 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. Architects and engineers work on computer-generated plans (CAD plans), and those drawings will be best if they are already in a CAD program. If they are not, recreate them into CAD. A survey of the site ensures that drawings are accurate.

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 be worked around.

Another important step is to have the consultants, architects, 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 testing, blood cell differentials, plate reading), teaching/student stations, 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; this is explored more fully in Section 8, Space Determination.

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

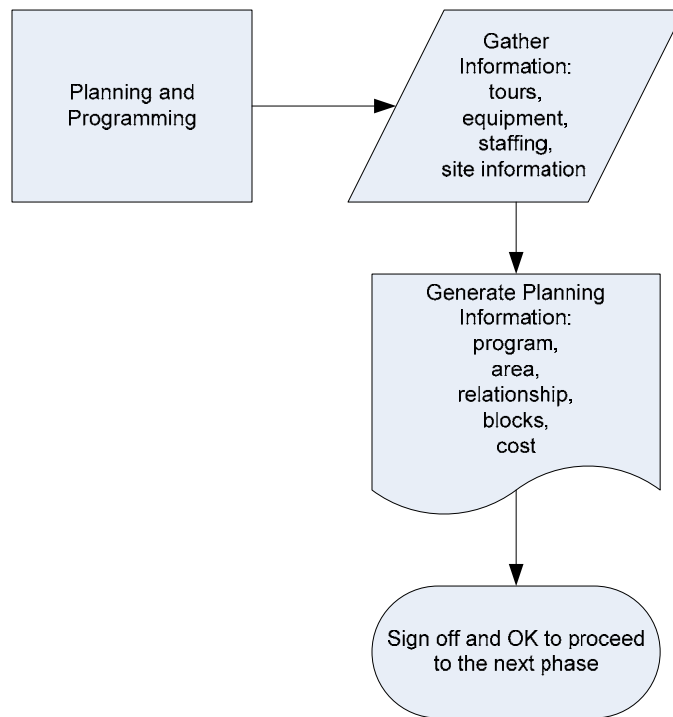


Figure 2. Planning and Programming Process

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

4.2.3 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 solution to a unique problem or 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.

4.2.4 Generate Information

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

4.2.4.1 Equipment Information

- *Equipment lists by department.* This can be done by the laboratory staff, the architect, the laboratory design consultant, or an equipment consultant. Information collected is as follows:
 - manufacturer 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 BTUs, venting requirements, air exchange requirements);
- plumbing information (type of water, drains, gases, acid waste); and
- general information (existing, new, future, who will purchase, who will install, association with other equipment, miscellaneous facts that are deemed important)

See Section 5, Laboratory Equipment, for more information.

4.2.4.2 Program and Area Analysis

The program includes the laboratory spaces, offices, employee support areas, laboratory support, and base building support areas. Review with the laboratory representatives will highlight rooms that may have been missed, need to be added for future 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 1. Example Program/Area Analysis

			Proposed NSF/NSM	Notes:
I.	ADMINISTRATION		3748/348	
	1	Medical Director	180/17	
	2	Pathologists	1350/125	9 offices at 150 sf each
	3	Administrative Director	150/14	
	4	Laboratory Secretary	100/9	keep copy machine/file room adjacent
	5	Manager	120/11	
	6	Supervisors	480/45	4 people at 120 sf each
	7	Customer Service	240/22	4 people at 60 sf each
	8	Transcription	348/23	5 people with mail, equip and files
	9	Cytology Screening	360/33	4 Cytotechs, one supervisor
	10	5-head-microscope room	120/11	
	11	Meeting/library	300/28	
II.	LABORATORIES		12 184/1132	
	1	Accessioning	1520/141	
	2	Routine Clinical Laboratory	3720/346	
	3	Development	with Routine	
	4	Blood Bank	1838/171	
	5	Microbiology	2310/215	
	6	Fluorescent Microscopy	75/7	
	7	TB/ Mycology	462/43	BSL-3 laboratory
	8	Virology	288/27	BSL-3 laboratory
	9	Gross Anatomy	407/38	
	10	Histology/Cytology	1564/145	
IV.	LABORATORY SUPPORT		3036/282	
	1	Walk-in coolers	240/22	3 units each at 80 sf
	2	Autoclave	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	

Table 1. (Continued)

			Proposed NSF/NSM	Notes:
V.	EMPLOYEE SUPPORT		1316/122	
	1	Multipurpose room (lounge, classroom)	500/46	acoustic division to divide room
	2	Lockers	336/31	195 purse lockers
	3	Male shower with water closet	90/8	ADA accessible
	4	Female shower with water closet	90/8	ADA accessible
	5	Unisex toilet	300/28	6 ADA accessible
VI.	OUTPATIENT PHLEBOTOMY		330/31	
	1	Phlebotomy room	112/10	1 phlebotomy station
	2	Fine-needle procedure room	120/11	
	3	Toilet room	50/5	
	4	Waiting	48/5	2 seats
VII.	BASE BUILDING		350/33	
	1	UPS system closet	100/9	
	2	Janitor closet	50/5	
	3	Electrical closet	100/9	
	4	Communication closet	100/9	
RECAP				
I.	ADMINISTRATION		3748/348	
II.	LABORATORIES		12 184/1132	
IV.	LABORATORY SUPPORT		3036/282	
V.	EMPLOYEE SUPPORT		1316/122	
VI.	OUTPATIENT PHLEBOTOMY		330/31	
VII.	BASE BUILDING		350/33	
	Subtotal NSF/NSM		20 964/1948	
	Net to Gross		1.40	
	Building GSF/GSM		29 350/2727	

Determination of space needs will be discussed in more detail in Section 8, Space Determination.

4.2.5 Relationship Diagrams

Relationship diagrams are often called “bubble diagrams” by architects. They graphically illustrate important proximities between the various program items. Figure 3 depicts a sample bubble diagram. The diagram should be reviewed with the laboratory representatives to make sure no relationships have been forgotten and to discuss new relationships that may benefit staffing and future technologies.

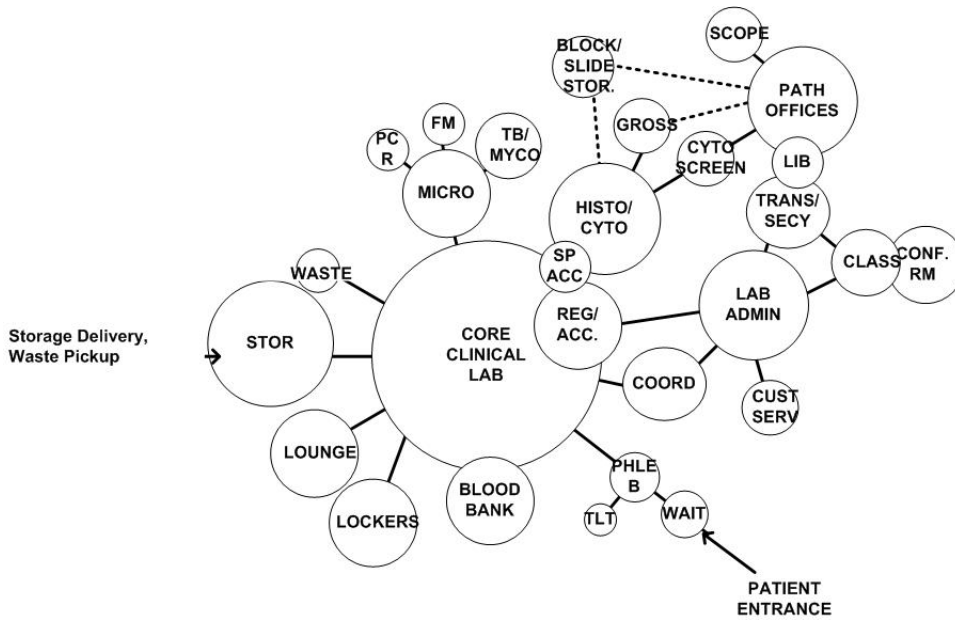


Figure 3. Bubble Diagram Example

4.2.6 Block Diagrams

Block diagrams are very general floor plans that show laboratory spaces as one block of space. There are no doors, equipment, or casework shown at this stage. A block illustrates the various options of how the laboratory spaces listed in the program can fit in the area or areas chosen for it. It also highlights the facility constraints can affect the layout of the various spaces and the relationships of the rooms in the space. Review of the block diagrams with the whole design team should be done to ensure consensus on the overall layout.

Movement diagrams build on the block diagrams and show generalized movement of the samples, staff, supplies, waste, and patients through the block diagram. Figure 4 depicts a sample block/movement diagram. This diagram can highlight possible traffic patterns and separations that can improve or disrupt efficiency in the overall layout. More specific movement inside the laboratory spaces should be discussed in the schematic design, which is the next phase.

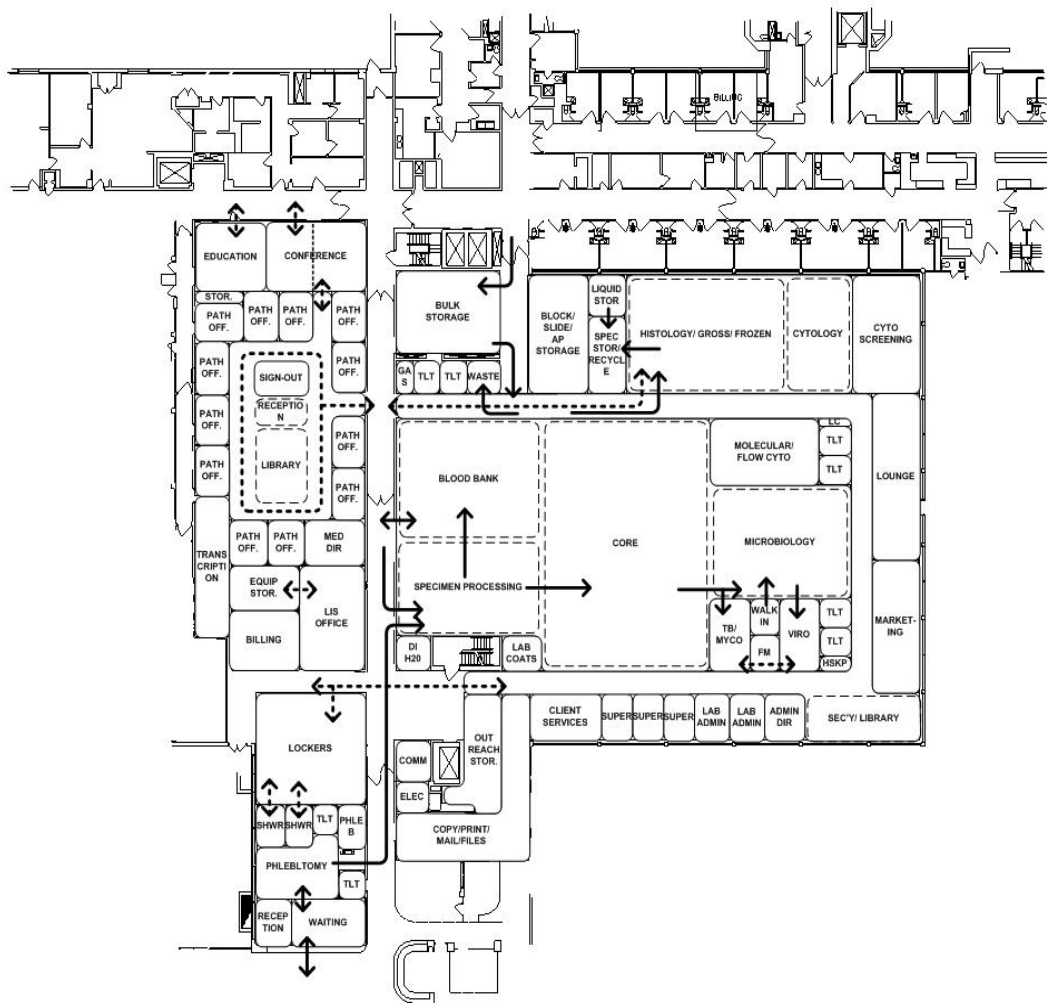


Figure 4. Block/Movement Diagram Example

4.2.7 Preliminary Opinion of Probable Construction Costs

The first cost estimate for a project is generated from the square footage of the various programmatic items. A generalized cost per square foot is assigned for the specific types of space. (See Table 2 for a sample opinion of probable project costs.) The built-in equipment items and base building items can be estimated and added to this cost. Determining the cost per square foot is variable and can be affected by the following:

- location;
- job market status;
- union status;
- existing facility differences and problems;
- size of the project (i.e., smaller projects tend to have a larger cost per square foot);
- new building versus renovation; and
- type of building to be constructed.

The cost per square foot/square meter also changes with inflation, so it is important to revisit the estimate if there is considerable time between planning and construction.

Table 2. Example Opinion of Probable Project Cost

Base Building		*Cost per Item in US Dollars				Total in US Dollars
Laboratory UPS system	allowance opinion - eng to verify					\$10 000
Laboratory DI water system	allowance opinion - eng to verify					\$15 000
Pneumatic tube	3	at	\$25 000	each	=	\$75 000
Square footage costs						
Laboratory space	12 650/1175	Sf/sm	at	\$180	per sf =	\$2 277 000
Laboratory flexible casework	12 650/1175	Sf/sm	at	\$50	per sf =	\$632 500
Office space	4990/464	Sf/sm	at	\$100	per sf =	\$499 000
Lounge/Lockers/Toilets/Other	1320/123	Sf/sm	at	\$100	per sf =	\$132 000
Phlebotomy/Donor	1473/137	Sf/sm	at	\$100	per sf =	\$147 300
Laboratory support space	3901/363	Sf/sm	at	\$50	per sf =	\$195 050
Corridor/Movement	1200/112	Sf/sm	at	\$75	per sf =	\$90 000
Equipment costs						
at						
Grossing stations	2	at	\$20 000	ea	=	\$40 000
Fume hoods/Biosafety hoods	9	at	\$9 000	ea	=	\$81 000
Walk-in refrigerator	3	at	\$20 000	ea	=	\$60 000
High-density storage	allowance opinion					\$50 000
Laboratory glassware washer	1	at	\$5 000	ea	=	\$5 000
Lockers	180	at	\$75	ea	=	\$13 500
Subtotal						\$ 4 322 350
Construction contingency						
						8.00%
Overhead and profit						15.00%
A/E fees						11.00%
TOTAL						\$ 5 791 949

*Dollar figures noted are for illustration purposes only.

4.3 Schematic Design

As each phase proceeds, the detail becomes greater. In schematic design, the floor plans are generated and reviewed. Figure 5 presents a flowchart of the schematic design process, and Figure 6 shows a sample schematic design. The general layout of blocks generated in planning is revised to become walls. Doors, windows, stairs, elevators, casework, sinks, and equipment are then added.

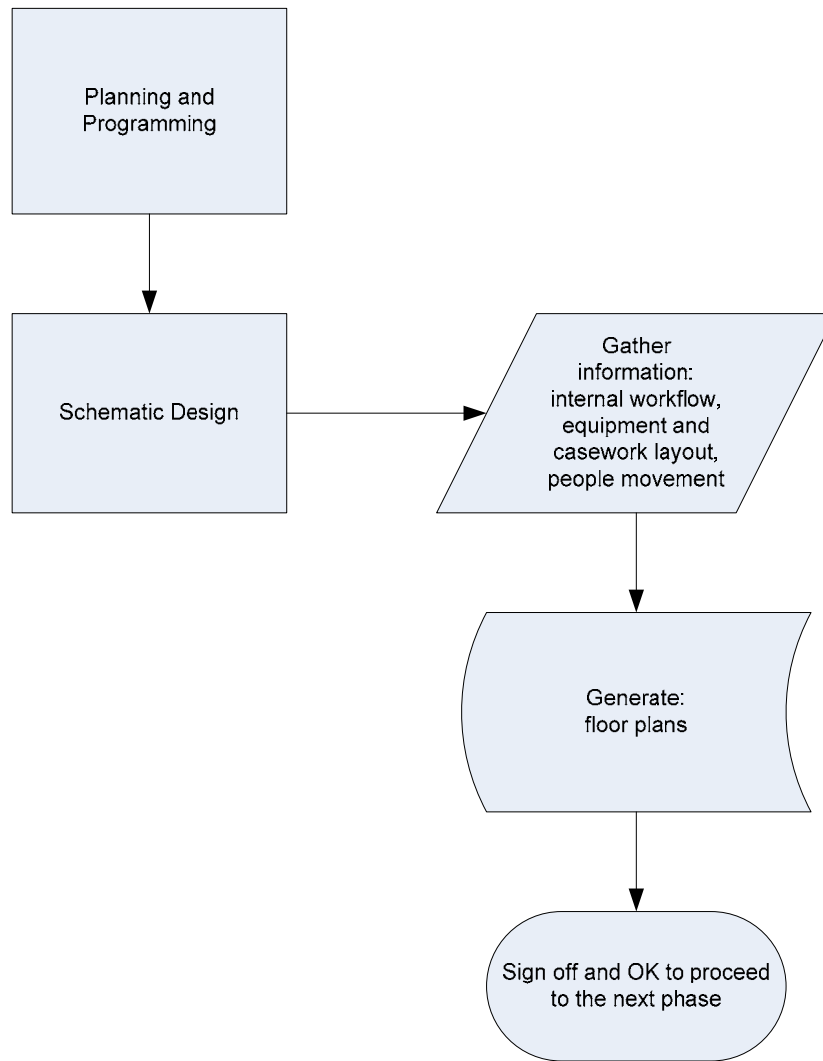


Figure 5. Schematic Design Process



Figure 6. Schematic Design Plan Example

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. The number of meetings depends on the complexity of the laboratory and facility. The first review of the floor plan should be held with the architect/laboratory consultant, so there is an understanding of the design intent and how to read the plan. After revisions from this first meeting, it is beneficial if the laboratory staff receives the plans before the next meeting to allow time to review the design and generate questions for the laboratory architect. It can be difficult for a staff member to fully review each item and be able to think about the implications within the short time normally allotted for a meeting.

Staff should be cautioned that the plans are more general at this stage, and that many details will be shown in later phases.

The design team should feel free to express concerns and discuss solutions, so they can be thoroughly understood by the laboratory architect and the staff members; a solution that works can then be created.

When the floor plan is acceptable to the design team, a sign-off is usually involved. Here, the laboratory representatives literally sign the schematic 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. The cost estimate may be revisited at the end of the Schematic Design stage to ensure that it has not changed significantly.

4.4 Design Development

The detail increases significantly in design development (see Figure 7). In this phase, more information on utilities, finishes, equipment, and design features can be seen.

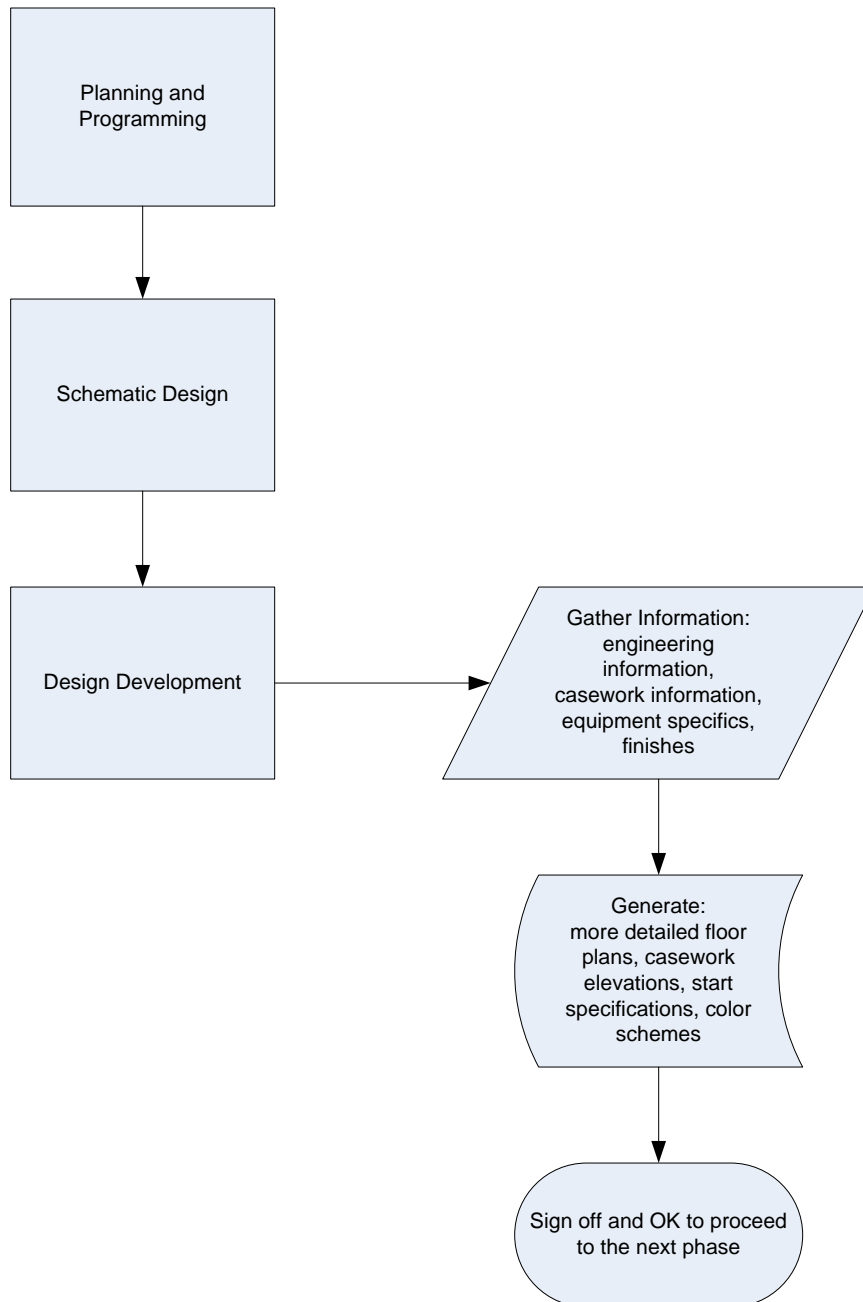


Figure 7. Design Development Process

The floor plans generated in the schematic design phase show items such as electrical outlets, telephones, data outlets, and floor drains. The engineers now become more involved in the design meetings to understand the laboratory's needs and the implications of equipment and layout on the utilities. This

information is used in specific requirements for emergency generators, air-handling equipment, piping, power systems, and many other features that affect layout, size, and operation of the building and the laboratory.

Furniture is shown either by the architect or by an interior designer assigned to the project. The architect or interior designer may work with the facilities department on furniture standards that are often adopted by institutions.

Discussion of finish type (i.e., paint, wall covering, flooring, countertops), colors, and floor patterns is started at this phase. Finishes are highlighted more specifically in Section 9, Finishes.

Laboratory casework is shown in much more detail on the plans, and elevations are drawn. Elevations are drawings that look at the casework as if one was standing in front of it (see Figure 8). Items such as knee spaces, drawers, cabinets, outlets, special features, and lights are shown. Elevations also show the overhead or wall cabinets. It is important to have the architect/consultant draw the equipment on the elevations to ensure it will fit under any wall and ceiling features.

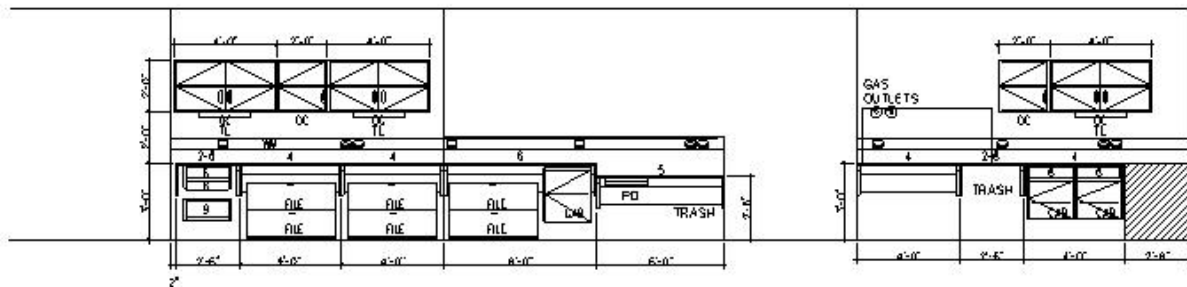


Figure 8. Elevation Sample

Plumbing items, such as sinks, emergency shower, emergency eyewash stations, and gas outlets, are added to the plan and reviewed with the staff. Many types of sink attributes such as size, material, and types of controls should be discussed to ensure that each sink meets the needs of the user.

Equipment purchased by the contractor needs to have written specifications. Specifications are the written detail of what the contractor is allowed to purchase, what options are included, and how it will be installed. Usually, equipment that is included in the construction is only that which is permanently connected to house utilities, such as water and ductwork. This equipment may include fume hoods, biosafety cabinets, grossing stations, walk-in coolers, laboratory dishwashers, and sterilizers. During design development the specific information for this equipment should be reviewed with the laboratory staff.

It is not unusual to have some adjustments to the plan as more engineering information is gathered and the systems designed.

The project team will review and amend the equipment, elevations, and plan details. Again, the number of meetings is very dependent on the complexity and size of the project.

The cost estimate may be revisited at the end of this stage to ensure that it has not changed significantly.

4.5 Construction Documents

The Construction Document phase shifts the life of the project into a purely technical mode (see Figure 9). Specific construction details for contractors are drawn, and specifications that outline material qualities and usage are written. This is the longest phase of the design process, due to the specific nature of the drawings.

No major design changes should occur in this phase. Because the overall design is not supposed to change, there are usually no meetings scheduled with the laboratory staff.

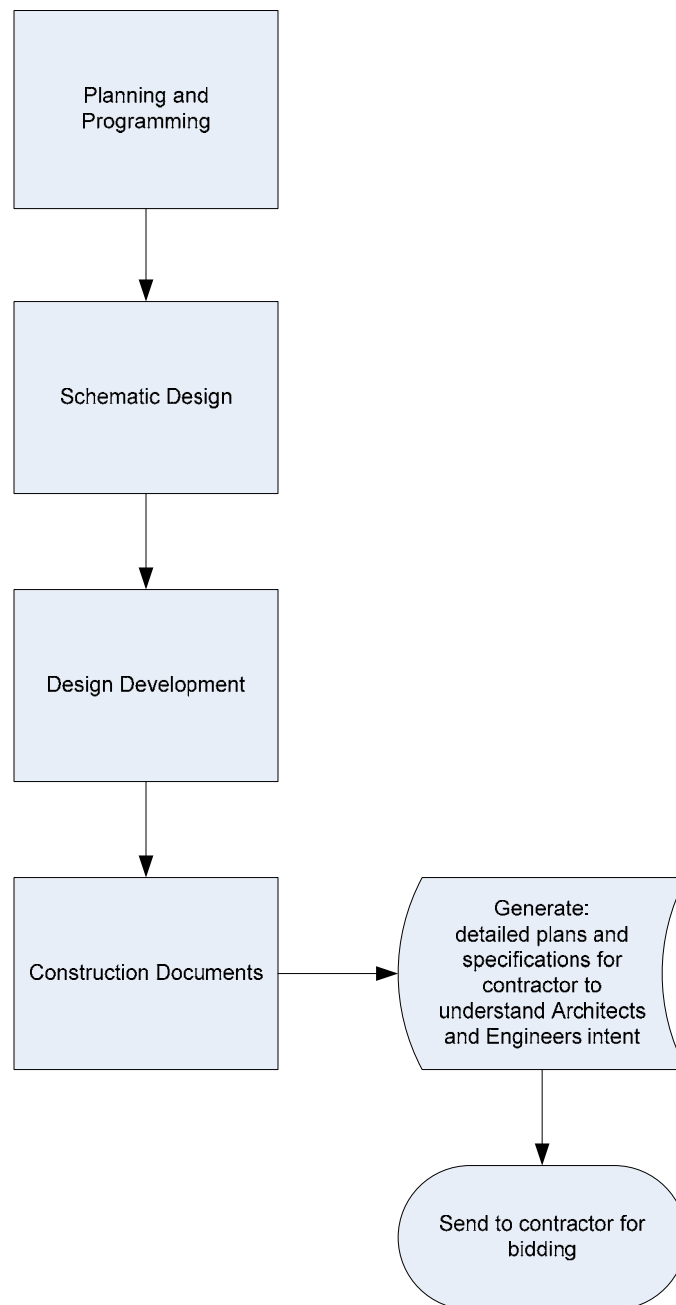


Figure 9. Process for Developing Construction Documents

4.6 Bidding and Negotiation

The construction documents are sent to contractors that are being considered for the project.

A review period of two to six weeks allows contractors time to contact subcontractors, estimate costs, ask any questions, and get clarifications from the architects and engineers.

A date is set for submission of construction bids; from those submissions the owners will select a construction company.

Addenda may be generated in this phase. An addendum is a supplemental drawing and information used by contractors that outlines changes requested by the facility, cost reductions required, mistakes made by the architects and engineers, or clarification needed by the contractors. The presence of an addendum may require meeting with the laboratory staff to review information, especially if items are being changed and deleted due to costs exceeding the allocated budget. The laboratory staff should keep costs in mind throughout the project and maintain a list of items for which compromise may be necessary.

A general flowchart for the bidding and negotiation process is shown in Figure 10.

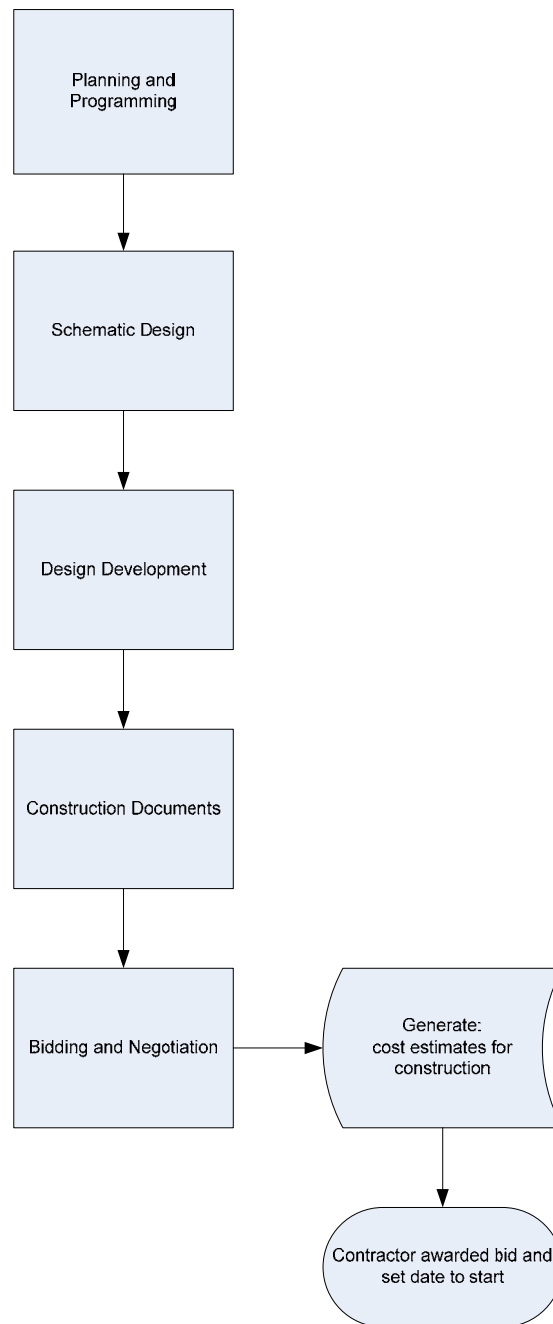


Figure 10. Bidding and Negotiation Process

4.7 Construction

The construction administrator, often one of the team architects and engineers but sometimes selected from another firm, acts as a liaison between the owners and the contractors. It is the construction administrator's responsibility to ensure that the physical construction in progress conforms to the construction documents. Construction documents are legal documents to which the contractor is required to adhere unless otherwise directed by the owners, architects, and engineers.

Weekly construction meetings usually are held among the contractors, the construction administrator, and a representative from facilities. Many laboratory administrators have found it beneficial to have a chosen laboratory representative participate in these meetings. This is a large responsibility and should be delegated to someone who understands construction, and can read and understand the plans.

See Figure 11 for a flowchart of the construction and move-in process.

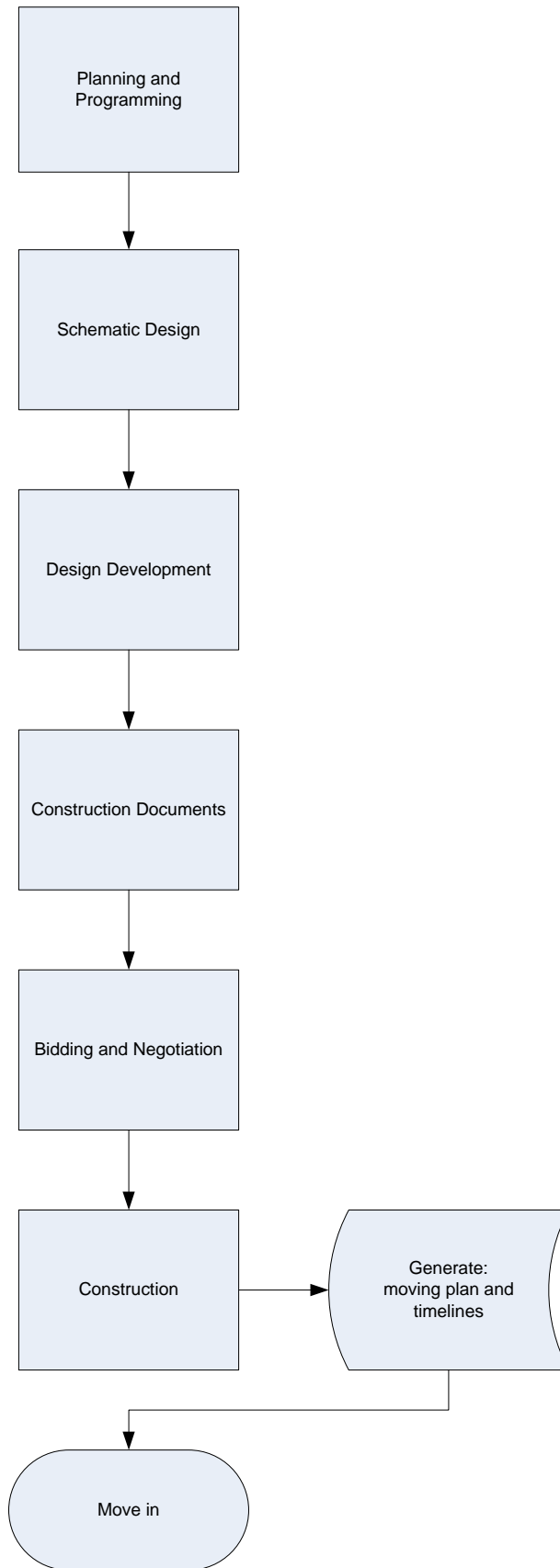


Figure 11. Construction and Move-In Process

4.8 Moving In

The laboratory should begin planning the move the first day the new laboratory design is started.

It can be useful to assign numbers from the equipment list directly onto the equipment itself for easy placement during the move. Some laboratories have used color codes and other organizational schemes to help move items from their existing location to the new location. There is no guarantee that the person moving the item will understand the requirements for placing them. Laboratory staff should clean house by discarding unused items and storing those that may be necessary later.

Manufacturers should be contacted for recommendations and requirements for moving items such as large analyzers, irradiators, and hoods. Many instruments and devices require decontamination and recalibration when moved; this can only be done by a manufacturer's representative. Instruments may require revalidation as well as recalibration because of temperature or airflow changes. These procedures can be done by laboratory staff and do not have to be done by service.

The evaluation of the cost of moving those items needs to be added to the budget. Moving costs should be a standard part of the laboratory's overall project cost estimate. Moving equipment such as irradiators can have significant costs. Any special moving costs should be verified with the equipment manufacturers.

4.9 Phasing

Phasing is an important aspect of design when the laboratory is constructed in the same space that it presently occupies. The layout must be organized to ensure that the laboratory can remain operational during construction. In phased construction, one area in the laboratory is enclosed with temporary partitions and that space is constructed. After completion, one section of the laboratory will move into that space, vacating the space they previously occupied. The vacated space is then enclosed and constructed. The process continues in this fashion until the entire laboratory has been renovated.

In some cases, there may be space available for a laboratory section to move into temporarily, allowing construction of their existing space. This is termed "swing space." Due to the utility demands of the laboratories, it is much easier and less costly if office and support areas can be moved into swing space.

Phasing a construction project takes more time and costs more than constructing a laboratory in an unoccupied space.

4.10 Lean Design Concepts

Lean is a quality philosophy that was developed in the manufacturing industry to optimize workflow and efficiency. These concepts have been adapted to the laboratory environment and should be considered when designing a new laboratory or renovating an existing one. The focus of Lean in the facility design is to:

- add value;
- remove wasteful practices with technologists/employees, reagents/samples/supplies, and equipment; and
- create a testing process toward single-piece flow.

Lean involves standardizing work practices to maximize the productivity of the constructed space and possibly minimize the amount of space constructed. For example, drawers are virtually eliminated, and storage cabinets and shelves are kept open and uncluttered. This has the added benefit of decreasing the cost of casework items, but forces the employees to keep their work areas neat and clean.

Within Lean there are several principals that must be adhered to achieve the optimal design:

- **5S of the laboratory area** - 5S stands for Sort, Store, Shine, Standardize, Sustain, and includes removal of all unnecessary and unused material from the work area, while standardizing what is done, where it is done, and how it is done.
- **Map the process being built** – This can start with a Value Stream map designed as a high-level process map, or be a very detailed step-by-step description of the entire process.
- **Build a control plan to keep the efficiencies in place** – This can be as simple as a five-minute meeting, or a more formal documentation plan with charts, graphs, and other visual feedback used on a daily basis for the life of the facility.
- **Review the workflow when new equipment or processes change** – Never make a change to the process without reviewing the effect on the physical layout of the laboratory. Change the physical layout of the laboratory to match the workflow. This does, however, require a very flexible design.
- **Move the product or service through the system at the speed the customer demands** - This is easier to achieve when nonvalue-adding activity has been minimized. Continually remove all nonvalue-adding activities (i.e., processes and items that are not required, and which clients are not willing to pay for).
- **Focus on data to make decisions** – Let the information mined from the process, rather than emotion, drive the decision.
- **Remove redundant processes** – Keep back-up equipment for processes that truly require it; avoid the “two or more of everything” syndrome. Store the back-up processes and equipment in locations that make sense, based on the frequency of use and criticality to the operations.
- **Minimal reagents and supplies stored at the bench** – Materials should be received into a warehouse or store room. Break down cases and cartons away from the work area, bringing only shelf packs into the testing area. This can reduce the amount of casework needed for storage in the laboratory space, which is much more expensive to construct than storage rooms and warehouses.

Standard work and performance measures are key to keeping a new facility “new.” The layout and workplace organization must facilitate repeatable processes. Operator workstations should be organized so that typical tools such as pipettes and pipette tips, loops, pens, computer keyboards, and computer mice are always located in the workspace that uses these items, so reaching, bending, or “borrowing” from another area can be avoided.

- Operator workstations should be organized so that tools and materials are located at the point of use or in sequence of use.

Informational aspects of standard work represent the best way to perform a process and to determine how long it should take to complete the process.

- Standard work should be used to measure daily performance and serve as a baseline for future improvements.
- The basic layout and design of the testing bench must support this performance measure.

In any Lean design, removal of waste is a key consideration. The aspects of waste to be considered in the design, and minimized if not removed, include:

- **overproduction** – doing more work than is necessary;
- **inventory** – storing or keeping close at hand more material than is necessary;
- **transportation** – moving samples and materials around within the laboratory or building without a clearly defined purpose;
- **inappropriate/unnecessary inspection steps** – performing more control steps than are necessary or required by regulatory bodies (this can add to mistakes and errors, simply because of confusion, and the belief that “someone else will catch it if I make a mistake”);
- **rework/repair** – repeating or reprocessing because of a failure in the original process (not to be confused with repeating a sample because it is “high” or diluting a “high value” and repeating);
- **motion** – employees moving around stored materials that are in the way, or running between benches that are kept separate because of leadership or political concerns);
- **waiting** - standing around and waiting for something to “happen” before beginning to work on what is already there; and
- **knowledge** – failure to ask the employees closest to the process or work area what really is going on.

All Lean engagements must:

- initiate single-piece flow;
- agree on what the customer really wants;
- understand the process;
- attack waste;
- install visual management control;
- minimize moving/standing operations;
- employ standard work; and
- employ “first in first out” (FIFO) for supplies and specimens.

Flexible choices include:

- how the work is done (steps in the process);
- materials employed and the sequence of using the materials;
- equipment, supplies, and materials;
- how visual control is employed;

- supplies and inventory are available; and
- employee walk paths.

As a result of employing Lean design in laboratory design, the following attributes can be added or improved:

- **Structure**
 - The work bench must direct the samples through the testing process.
 - Laboratory testing staff must use the same process.
- **Information**
 - Procedures and instructions must reflect the current (standard) work performed.
 - The work must be performed in the one best way.
- **Control Plan**
 - Measurement/metrics direct laboratory staff and identify root causes of any problems that are detected.
- **Space**
 - Relocation of critical testing with or to a core laboratory
 - Strategic planning for the appropriate testing location
 - Laboratory layout that reduces wasted space yet is flexible
- **Improved Work Flow**
 - Match the physical plan to the proposed workflow.
 - Create testing areas appropriate to the workflow.

Through the implementation of Lean in the laboratory, physical plans that support the mission, not only of the laboratory but the entire organization, can be developed. Testing patterns and workflow that are conducive to single-piece-flow in order to speed testing should be considered. The space will be developed around work patterns that are appropriate to the nature of laboratory samples, rather than creating processes around the space they inhabit. This will allow for special considerations for small sample volumes, shared samples, and test decision “on the fly.”

5 Laboratory Equipment

5.1 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 amount of 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. An example of an equipment list is shown in Table 3.

Table 3. Sample Equipment List

Instrument*	#	Wt.	Size	Volts	Amps	Watts	Network Connection	Alarm	Dedicated Circuit	UPS	Emerg. Power	Special Plug	BTU	Vent Out	Gas	Vac.	Drain	Water
Biosafety cabinet	1	598	78x33x96	115	20									X		X		
Centrifuge	1	114	22x26x37	115	15	466												
Processor	1	1365	91x37x68	208			X		X	X	X	X	8300		Air/H2			
GLC/HP	1	90	37x34x37	120	20													
Refrigerator	2	1100	59x36x85	120	10			X			X		4104					

*Include instrument model name here.

To locate this information, check the appropriate manufacturer's catalog for the specific instruments and devices. A catalog section often notes the specifications or installation information for the analyzer. If not, there may be a label on the instrument that includes some utility information. If all else fails, call the manufacturer's technical staff for the information.

It is important to note that information about a specific utility should only be included if the equipment is actually attached to that utility. If it is necessary to place an analyzer near a sink or near a telephone, then it may be noted as a separate remark, but it is not necessary to show it as an integral feature of the instrument or device.

Generally, any extra information that would be helpful to the placement of the instrument or device or to the design of the surrounding environment is good to add as a remark.

5.1.1 Instrument Name

When listing equipment, note the general name of the instrument or device (such as centrifuge, refrigerator, coagulation, 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.

5.1.2 Instrument Quantity and Status

Ensure that the list includes the number of each specific instrument and device, so sufficient space and utilities can be provided.

It is also important to note the status of the instrument and device. Status types include whether the existing equipment is relocated into the new laboratory, a new instrument or device will be purchased by the laboratory, or a new instrument or device will be purchased by the contractor as part of the laboratory construction. Generally, instruments and devices that are purchased by the contractor are those with hard connections to the utility systems, such as air handling or plumbing. These instruments and devices include fume hoods, grossing stations, autoclaves, and glassware washers.

5.1.3 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 and devices 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. In a renovation project, especially for older buildings, the existing floor supports may need to have added structure to allow instrument placement where needed.

The laboratory designer or architect must be aware of instrument clearances. 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. These should be noted separately, so it is understood where the

clearances should be kept in relation to the instrument itself. A good design solution is to keep an access aisle behind 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.

5.1.4 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).

Refer to Section 11, Electrical and Communications, for specifics on each of these items.

5.1.5 Networking Information

Laboratory information systems (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:** This information needs to be noted, so the engineers can provide a sufficient quantity of data outlets for the equipment.

Refer to Section 11, Electrical and Communications, for specifics on each of these items.

5.1.6 Ventilation Information

One of the most common complaints in a laboratory is the temperature, which can affect the operation of the equipment as well as the comfort of the staff. Providing information on the equipment heat loads can assist the engineers in the creation of a sufficient air-handling system.

The British thermal unit (BTU) is the amount of heat required to raise the temperature of one pound of water by one degree Fahrenheit. BTUs are used to describe the heating or cooling capacity of a system, such as analyzers. Engineers will use this information to determine the overall cooling or heating needed. If this information is not found for the instrument, it may be calculated from the instrument wattage as follows:

- 1 W is ≈ 3.4 BTU/hour.
- BTU per pound per degree F is the same as calories per gram per degree C.

Another important piece of information for the ventilation is whether or not an instrument needs venting to the outside of the building through separate ducts. Instruments and devices that could use this feature include fume hoods, biosafety cabinets, grossing stations, or atomic absorption analyzers. Separate ventilation requires special ductwork and can require extra equipment, such as blower placement on the roof of the building.

Refer to Section 10, Ventilation in Laboratory Design, for more information on the air-handling system.

5.1.7 Plumbing Information

Several items come under the heading of Plumbing, including water, drains, and gas lines.

Water needs for equipment may include tap water and deionized water. The engineers need to know any specific needs for the water. Tap water may be supplied as only cold, only hot, or tempered water, which is a mixture of hot and cold at a specific temperature.

DI water is normally specified as Type I or Type II. The manufacturers can give specific information on DI water and will often recommend manufacturers of DI water systems that can meet specific analyzers' requirements. This is important not only for the type of DI water, but also for the amount that the system needs to generate to support full operation of the analyzer. The size and type of the system, as well as specific utilities required to support it, need to be included in equipment information, so appropriate space can be planned. Please refer to the most current edition of CLSI document C3—*Preparation and Testing of Reagent Water in the Clinical Laboratory* for more detailed information.

In some cases, reverse osmosis (RO) water may be required.

Drains may be needed for some analyzers, incubators, stainers, glassware washers, and sterilizers. Some of the drains are for waste from analyzers, but others are provided for condensate from the instrument, or for emergency overflow precautions.

Gases can be those that are plumbed from exiting systems in the facility, such as air and vacuum. Gases from cylinders can also be plumbed into the new laboratory, and this has the benefit of keeping the tanks out of the laboratory itself. The separate gases should be noted for each instrument and device requiring them, whether or not it is a house system or a tank. A discussion with the design team should be held about the preferred way of supplying the gas. Information should include the number of spare tanks usually kept, so floor space can be planned appropriately.

Some instruments and devices also require specialized plumbing features, such as acid waste lines, steam, or a garbage disposal. These features should also be noted on the equipment list.

Refer to Section 13, Plumbing, for more information.

5.2 Automated Sample Handling Technology/Systems

5.2.1 Decision Points

The type and extent of automated sample handling technology for the laboratory is a decision based on many factors. The laboratory design will be significantly affected by the decision. It is important to have the information as soon as possible in the planning and design phase. Manufacturers of automation technology require specific information to assist with the decision on the size and scope of the system to meet the laboratory's needs.

5.2.1.1 Information for Manufacturers

- What analyzers are needed to interface with the system?
- How many sample containers per hour does the client want to process?
- What size sample containers are used?
- What is the average daily number of sample containers for chemistry, hematology, coagulation, immunology, and urinalysis (dependent on which analyzers are attached to the system)?
- What are the peak hour numbers of the sample containers?
- What is the number of sample containers not requiring centrifugation?
- What is the number of sample containers that need aliquotting, with average number of aliquots per container?

- Which LIS is used?
- What is the target turnaround time?
- What is the percentage of tests that are ordered *stat*?
- Is an automatic refrigerated storage system desired?

5.2.1.2 Information for Laboratory Planners, Architects, and Engineers

Once a decision has been reached with the manufacturer on the type or types of automated sample handling systems that are appropriate for the laboratory's needs, the information must be given to the design team.

The laboratory planner or architect would not actually design the automation system; he/she will use information from the laboratory and the manufacturer.

Information needed is as follows:

- Layout of the system with the analyzers
 - The manufacturer should send a CAD drawing to the architects for size planning and inclusion in the floor plan as soon as possible.
- Lists of utilities required, as well as sizes and weights for each instrument and device of the system
 - This should include any compressors or UPS systems that are also required by or provided for the system, but will not be located immediately adjacent with the system.

5.2.2 Layout Criteria

Placing an automated sample handling system in a new or existing laboratory poses many issues. Specific problems need to be addressed in the layout to ensure a good overall workflow for the laboratory and safety for the staff.

5.2.2.1 Workflow

Automation sample handling systems operate in a very specific configuration, such as clockwise or counterclockwise, depending on the manufacturer. This necessitates an arrangement of the various instruments and devices. Depending on the needs for the system, this arrangement could include centrifuges, decappers, aliquotters, recappers, and automated storage units.

The arrangement of the analyzers themselves will also have some strict guidelines.

- How does the analyzer interface with the sample handling system itself?
- In what direction does the analyzer face?
- What other parts of the system must be before and after the analyzer?

Once this information has been discussed with the manufacturer, layout of the remainder of the workstations can begin, so that the system works smoothly with the rest of laboratory.

- Are input stations easily accessible to the sample processing area?
- Are manual testing areas and support equipment close to associated analyzers?

- Can the analyzers on the sample handling system be run manually if the system is not operational?
- Can laboratory staff reach workstations without having to walk a very long distance to get around the system? (This is especially important for those shifts in which the staff is at a minimum.)

5.2.2.2 Safety

Fire egress is very important and should not be blocked by the sample handling system. Because they may occupy a large fixed area, these systems can create a division in movement through the laboratory. Criteria that need verification when the system is being drawn into the floor plan include:

- clearance to walk around the system and analyzers is no less than 44 inches (112 cm), preferably 60 inches (153 cm);
- doors that would be used to exit the laboratory in case of a fire are not blocked by the automation system; and
- the distance a person would have to walk to get from the most isolated corner of the laboratory to an exit door is regulated by IBC.² This criterion can be increased if the laboratory is in a business setting, not a hospital. It can also decrease if local fire codes are stricter. The rule is that the strictest code for the particular area needs to be followed. Refer to Section 7.4.1, Egress Path, for specifics.

5.3 Planning for Future Equipment

Equipment changes happen regularly in laboratories and can create problems for installation and use if some planning is not done.

5.3.1 Planning New Equipment

If new and additional instruments and devices in the laboratory are known or anticipated, the laboratory planner or architect needs to be informed, so planning for the space and utilities needed can be done at the beginning of the project. A discussion on the future growth of the laboratory should be held at the very beginning of planning. Laboratories do not grow in size by a percentage, but instead by the addition of instruments and workstations. It is possible that adding one analyzer can double the testing capability for several particular procedures.

When planning for new equipment, it is important to leave room for correlative studies that must take place before the instrument can be accepted as a replacement or as new testing. This extra room should include counter and floor area with access to electrical outlets at various amperages and a sink with tap water and DI water. Using procedure tables instead of fixed casework in this area will give the option of working on a large floor instrument/device or a smaller countertop instrument/device with minimum disruption.

The laboratory counters should be flexible in height adjustment as well as in ability to change storage components. This allows for the elimination of counters and storage with the addition of a floor-mounted analyzer, or for lowering the counters and adding knee space if necessary for a new countertop instrument/device.

Planning for utilities can be more difficult, because specific requirements may not be known. The laboratory should have extra electrical outlets and data/network outlets that will allow for additional instruments and devices. Access to a drain or a sink is needed in most of the casework groups. Floor drains that are capped off can be added in a new design, allowing the future addition of a sink or instrument requiring a drain.

If flexibility is planned in the beginning, it is much easier to reconfigure for the added or different equipment when the need arises. It will also be less expensive in construction costs and less disruptive to the laboratory staff.

5.3.2 Planning for Future Automated Sample Handling Systems

If the facility might add automated sample handling systems in the future, some measures can be taken to make the transition easier.

- Plan the analyzers in an arrangement that could allow the sample handling system to run adjacent as much as possible. This also allows the reuse of the floor drains and other utilities already in place for those instruments and devices.
- Use as flexible a casework system as possible. This minimizes demolition of counters that may be in the way of the sample handling system and also allows for the reuse of the casework in another location.
- Try to look at the layout of a manufacturer's automated sample handling system that is under consideration, and see how it might fit into the floor plan of the laboratory. It won't be a perfect solution but will help the later transition. Ask the laboratory planner or architect to draw the plan with and without an automation system to see the implications of the transition.
- Keep in mind where the main access aisles and the doors out of the laboratory are located, so they won't be blocked when the sample handling system is eventually installed. This can be difficult, as there are many options for configurations, which may change before the system is actually installed, but the manufacturers can help adjust the system to meet the laboratory's needs when the time arrives.

5.4 Summary Points

- Document each instrument and device in the laboratory, including small items, computers, printers, and equipment that is built in, such as fume hoods.
- Include the manufacturer's name and model number on the equipment sheet for each instrument or device.
- Provide catalog information with installation information if possible, especially for large analyzers and automation systems.
- Have the automated sample handling system manufacturer's representative work closely with the laboratory planner or architect as early in the project as possible to provide size, layout, and utility information.
- Plan the workflow to work with the system and not be interrupted by it.
- Do not block exit access in case of fire.
- Design the laboratory to be flexible to allow equipment to change.

6 Biohazards

In the United States the standard guidelines for biosafety are published by the US Department of Health and Human Services (CDC/NIH, *Biosafety in Microbiological and Biomedical Laboratories*, or *BMBL*³).

Similar guidelines have also been published in Canada⁴ and by the World Health Organization.⁵ Four biosafety levels (BSL-1 to -4) are outlined for working safely with microbial agents in laboratories. Each BSL is determined as a result of a risk assessment, which evaluates the pathogenicity of the agent, mode of transmission, amount of the agent manipulated, and the nature of the work performed. Biosafety levels are established as a combination of administrative controls, facility design, work practices, engineering controls, barrier protection, and containment needs.

6.1 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. These samples can be routinely processed at BSL-2, which meets the OSHA⁶ 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 samples, or if the pathogenic organisms are being replicated through procedures such as PCR.

Aerosols are possibly one of the major reasons for laboratory personnel infections. Aerosols are suspensions of finely dispersed particles in the air that can travel through the air and settle on surfaces. For example, aerosols are produced from either liquids or solids in the following ways:

- sizzling of liquids cultures or solid media on a hot wire loop;
- pipetting;
- centrifugation, vortex, mixing, shaking, stirring; and
- spills.

Lists of organisms that should be tested in higher biosafety levels are found in the CDC/NIH, *Biosafety in Microbiological and Biomedical Laboratories*, or *BMBL*³ manual. Some organisms that should be tested in BSL-3 include, but are not limited to:

- *Mycobacterium tuberculosis*—This organism is considered pathogenic for humans. The risk of contraction by laboratory personnel is quite high. Those working in mycobacteriological laboratories are at three to five times greater the risk than other laboratory workers, and 100 times greater than the general population.⁷ This organism is normally transmitted by aerosols and can be found in sputum, blood, body fluids, and tissues.
- 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-2 facilities following BSL-3 practices. Cell-culture virus propagation should be done in BSL-3.
- Recombinant DNA—Experiments involving recombinant DNA lend themselves to BSL-3 containment.

6.2 Designing for Biosafety Levels

Biosafety Level 1 (PC1) represents a basic level of containment that relies on standard microbiological practices with no special physical barriers. Such laboratories are commonly found in high schools, junior

or community colleges, and in undergraduate universities teaching introductory courses using microorganisms not known to consistently cause disease in healthy adult humans.

- Design Requirements:
 - doors for access control;
 - handwashing sink;
 - constructed for ease of cleaning;
 - bench tops impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination;
 - sturdy laboratory furniture;
 - screens on windows if they are operable. **NOTE:** Many laboratories do not have operable windows, as they can affect the pressurization of the room and the overall building HVAC system balance;
 - no fabrics or carpeting.

Biosafety Level 2 (PC2) represents a level of containment established by practices, equipment, and facility construction that is acceptable for clinical, diagnostic, teaching, and other laboratories working with indigenous agents that cause moderately severe illness and are usually found in the community. Many of the blood-borne pathogens (e.g., Hepatitis B virus, HIV, salmonella) can be safely manipulated in BSL-2 facilities. Accidental percutaneous, mucous membrane exposures or ingestion of infectious materials represent the primary hazards to laboratorians. Primary containment barriers, including biological safety cabinets, safety centrifuge cups, etc., are used to minimize aerosol or high splash potential. Handwashing sinks must be included in the laboratory spaces. Autoclaves or other waste decontamination equipment must be available in the facility.

- Design Requirements:
 - doors for access control (lockable door if housing restricted agents)⁸;
 - handwashing sink;
 - constructed for ease of cleaning;
 - bench tops impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination;
 - sturdy laboratory furniture;
 - screens on windows if they are operable. **NOTE:** Many laboratories do not have operable windows, as they can affect the pressurization of the room and the overall building HVAC system balance;
 - new laboratories located away from public areas;

- BSCs located so that fluctuations in air supply and exhaust or the operations of equipment do not alter the performance standard of the cabinet;
- eyewash station readily available;
- autoclave available in the facility;
- no fabrics or carpeting; and
- new facilities with inward airflow (negative pressurization) without recirculation of air outside the laboratory (100% outside exhaust).

Biosafety Level 3 (PC3) applies to a level of containment suitable for working with indigenous or exotic pathogens that have a potential for transmission by the aerosol route and that may cause serious and potentially lethal infections. More emphasis is placed on primary and secondary barriers to protect personnel and the environment. Primary barriers include equipment such as biosafety cabinets; secondary barriers include controlled access, sealed penetrations, and ventilation requirements to minimize release of infectious aerosols from the laboratory.

- Design Requirements:

- The laboratory is separated from public areas of the building.
- Entrance from public areas requires passage through two self-closing doors; a change room may be located in this passageway.
 - These rooms are called *anterooms*. The US Department of Justice⁹ and International Building Code (IBC)² require 48 inches (1219 mm) between the doors at a minimum, plus the width of the door swinging into the space. In essence this means that if there are two 36-inch (914-mm) doors swinging in the same direction (preferably towards the means of exit), then the total distance between the door faces would be 84 inches (2134 mm). The air in the anteroom must be inward (negative) from the public corridor, and the laboratory should be inward (negative) from the anteroom.
- The handwashing sink is hands-free and located near the exit door.
 - Hands-free can be foot pedal controls, electric eye, or hip controls.
- An eyewash station must be inside the room.
- All seams in walls, floors, or ceilings, if present, must be sealed. All surfaces should be smooth and impermeable to liquids and resistant to the chemicals used for decontamination.
- Floors are monolithic with coving at least four inches up each wall.
- Piping and other penetrations in floors, walls, and ceilings are sealed. Openings such as air ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.
 - Chairs should be covered with a nonfabric material that can be easily decontaminated. No fabric or carpeting is allowed.
- All windows are closed and sealed.
- An autoclave should be available and is best if it is within the laboratory area.

- Consideration should be given to installing a through-the-wall, double-ended autoclave.
- A ducted exhaust ventilation system that will provide directional inward flow of air (negative pressure) is required; exhaust air is not recirculated. HEPA filtration is optional.
 - It is best to have a visual monitoring device at the entrance to the laboratory to easily indicate directional airflow. Alarms that can be seen and heard by the staff are a good addition.
- The HEPA-filtered exhaust from the BSCs may be directed into the laboratory or to the building exhaust (either thimble connected or hard ducted).
- Continuous flow centrifuges and other aerosol-generating equipment must be contained in devices that exhaust air through HEPA filters before discharge into the laboratory.
- Vacuum lines are protected by HEPA filters (or their equivalent).
- The BSL-3 facility design and operational parameters must be documented before operation and annually thereafter.

Biosafety Level 4 (PC4) laboratories are designed and operated to provide maximum containment and protection from exposure to lethal pathogens. The basic means for accomplishing this is to conduct work inside Class III biological safety cabinets (glove boxes) or to place the worker inside a full-bodied positive pressure air-supplied suit. Either will provide maximum protection from these agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.

- Design requirements are documented elsewhere (see references).

Animal Biosafety Levels (ABSLs) have also been outlined in the *BMBL*. The US Department of Agriculture has also detailed animal biosafety levels – agriculture (BSSL-Ag),¹⁰ which focus additional attention on minimizing the potential for environmental release.

- Design requirements are documented elsewhere (see references).

6.3 Bioterrorism

Biological diseases and the select agents that might be used for terrorism are regulated by the DHHS¹¹ and USDA.¹² 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 Department of Justice.¹³

In the event of contamination with a suspected bioterrorism agent, there should be shower facilities for the laboratory personnel. These are outlined by the *CDC Anthrax Guidelines for Clinical Laboratories*¹⁴ in their procedures for decontaminating after accidental exposure to anthrax or another 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 then be bagged, and the exposed individual should go to a locker room where a private shower is available. He/she should then disrobe, bag the remainder of the clothing, and shower thoroughly with soap and water to remove as much of the contamination as possible.

6.4 Security

Security is an important issue in clinical laboratories due to the presence of biologicals, 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.¹⁵ Several issues are stressed:

- Know the persons who have access to select agents and other high-consequence 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 key access or cipher access. Doors should be locked when the laboratory is unoccupied. 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.
- 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 American Biological Safety Association recently published an excellent reference.¹⁶

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 tampering. This would include locking and limiting access to the testing areas and all storage areas for specimens and files.

6.5 Summary Points

- Provide appropriately designed laboratory areas for the type of agents being tested.
- Provide a safe environment and safety equipment for staff.
- Provide the security levels necessary for the facility based on chemicals or biologicals that could be used for illegal purposes.

7 Health and Safety

7.1 Laboratory Classification

7.1.1 Occupancy

Construction of laboratory spaces can vary, depending on the type of occupancy of the building in which the laboratories are housed. The National Fire Protection Association (NFPA 101¹⁷) has defined the various types of occupancies that can house laboratories as follows:

- *Health Care Occupancy* — the laboratory is part of a healthcare facility housed in the same building as patient activities;
- *Business Occupancy* — college and university instructional laboratories, ambulatory care center, medical clinics, and similar facilities for outpatients if separated from healthcare occupancy by not less than two-hour construction and not used for four or more litter-born patients;

- *Industrial Occupancy* — industrial laboratories; and
- *Mixed Occupancy* — must be separated from nonlaboratory areas by at least two-hour construction.

The IBC² also has specific classifications that will affect how a laboratory is constructed.

- *Group I (Institutional)* — an occupancy where people are cared for because of medical treatment. It is further subdivided into specific categories. I-2 includes hospitals.
- *Group B (Business)* — defined as a building or part of a building used for professional or service-type transactions. It includes testing and research laboratories.

In conjunction with the facilities department of the institution, the architects should determine the occupancy category for the building and design accordingly.

7.1.2 Fire Classification

The National Fire Protection Association has created specific classifications for laboratories that use chemicals (NFPA 45). They are based on the types and quantities of flammable liquids present in the laboratory (see Tables 4 and 5). There are three main classifications:

- *Class A* - high hazard;
- *Class B* - intermediate hazard; and
- *Class C* - low hazard.

The majority of clinical laboratories come under the Class C category, low hazard. This category allows specific types of storage for the following quantities of flammable chemicals (see Table 6):

- Two to four gallons (8 to 15 L) of flammable chemicals are allowed outside storage cabinets per 100 feet² (9 m²) of laboratory space.
- Three hundred to 400 gallons (1136 to 1514 L) of flammable chemicals, maximum per laboratory, including those inside storage cabinets.
- Additional quantities can be stored inside a flammable liquid storage room.
- Quantities are for sprinklered laboratories only and much less for nonsprinklered laboratories.

Table 4. Unsprinklered Laboratory Space

Laboratory Classification	Liquid Class	Gallons/ Liters allowed per 100 feet ² (9 m ²)of laboratory department space (including toilets, corridors, offices)	Total Gallons/ Liters allowed per laboratory
A	I	20/75	600/2271
	I, II, IIIA	40/ 151	800/3028
B	I	10/38	300/1136
	I, II, IIIA	20/75	400/1514
C	I	4/15	150/568
	I, II, IIIA	8/30	200/757

Table 5. Sprinklered Laboratory Space

Laboratory Classification	Liquid Class	Gallons/ Liters allowed per 100 ft ² (9 m ²) of laboratory department space (including toilets, corridors, offices)	Total Gallons/ Liters allowed per laboratory
A	I	20/75	1200/4542
	I, II, IIIA	40/151	1600/6056
B	I	10/38	600/2271
	I, II, IIIA	20/75	800/3028
C	I	4/15	300/1136
	I, II, IIIA	8/30	400/1514

Table 6. Flammable and Combustible Liquid Classifications

	Flash Points	Boiling Point
I - Flammables		
IA	<22.8 °C	<37.8 °C
IB	<22.8 °C	>37.8 °C
IC	≥22.8 °C	<37.8 °C
II - Combustibles	≥37.8 °C	<60 °C
III - Combustibles		
IIIA	≥60 °C	<93.4 °C
IIIB	>93.4 °C	

A complete list of flammable liquids, by department, should be developed and sent to the architect to ensure that fire construction meets the specific requirements for the laboratory.

7.2 Flammable Storage

Storage of the flammable liquids must meet the NFPA requirements as well as those for local agencies. After the list of flammable liquids kept and used by the facility has been developed, where and how these can best be stored should be determined with the architect. Criteria should include safety first and then efficiency for use in the laboratory.

A common misconception about flammable storage is that it is intended to keep a fire inside the cabinet or room from spreading into the surrounding space. These units are actually used to keep what is in the cabinet or room protected from a fire that is in the surrounding space, i.e., to keep possible fuel from feeding a fire.

7.2.1 Inside Liquid Storage Room

Laboratories that keep large quantities of flammable liquid should build an inside liquid storage room to house such liquids. An inside liquid storage room is a small room equipped with open wire shelving. The walls of the room are constructed with a one-hour fire rating to keep the flames away from the flammables for one hour. There should not be any electrical elements or outlets in this room. The light should be an explosion-proof unit, so there is no spark hazard.

NFPA 99¹⁸ states that an approved flammable or combustible inside liquid storage area that is designed, constructed, and operated in accordance with NFPA 30¹⁹ shall be available within any healthcare facility regularly maintaining a reserve storage capacity in excess of 300 gallons (1136 L). The criteria from

NFPA 30¹⁹ require that the walls, ceiling, and floors should have a one-hour fire rating if <150 feet² (14 m²). If larger than 150 feet² (14 m²), but less than 500 feet² (46 m²), the walls must have a two-hour fire rating.

When the laboratory is transferring flammable chemicals from a bulk stock container to a smaller container, it must be done in a flammable storage room, or within a fume hood. Many local codes will only allow bulk containers to a certain size, so the applicable code applies if this practice is used. If there are containers that are larger than 10 gallons (38 L), a curb or other means to keep the liquid out of adjacent spaces in the case of a spill should be provided.

Ventilation should be provided with the exhaust air taken out within 12 inches (30 cm) of the floor and going directly to the outside. Air movement should be arranged to prevent any accumulation of flammable vapors.

In the room there must be a minimum of a 48-inch (122-cm) wide aisle adjacent to the racks.

As the majority of clinical laboratories do not use combustible chemicals, it is not normally necessary to construct a combustible room. Again, the list of chemicals must be evaluated to determine what exactly the facility needs.

It is a good idea to keep a copy of the MSDS sheet in a remote location for Hazmat team access before they enter an affected area or zone.

7.2.2 Flammable Storage Cabinets

Flammable storage cabinets are found either in the laboratory itself or in a separate storage room. The cabinets are designed to keep the chemicals away from the fire for a specified time, depending on the construction of the cabinets.

Cabinets are designed with or without ventilation. Insurance companies test these cabinets with the vent holes plugged, and NFPA states that it is not necessary to vent the cabinets. NFPA 30¹⁹ notes that the storage cabinets do not require venting for fire protection, and that the vents shall be sealed shut with mechanisms provided by the cabinet manufacturer. It is permitted to vent cabinets, but the construction of the venting duct must be equal to the rating of the cabinet, and the cabinet must be vented directly to the outdoors. It must also be equipped with a mechanical blower to keep any fumes from accumulating in the vent ducts, or any air from blowing back into the cabinet itself.

Flammable cabinets must never be vented through a fume hood, because sparks from equipment or flames in the hood can cause a fire in the cabinet.

Flammable liquids that are stored in the laboratory space itself should be positioned to minimize possible fire hazards. They should not be:

- near Bunsen burners;
- near ovens;
- near hot pipes or valves;
- near other sources of heat; or
- in corridors.

7.2.3 Gas Cylinder Storage

Several common types of gas cylinders are present in a clinical laboratory. Some are considered flammable. Each cylinder should be marked for its flammability. A list of gas cylinders with their

respective flame ratings, whether the cylinders are attached or stored, and the equipment each cylinder is used for, should be given to the architect/consultant.

Any flammable gas cylinders used for a laboratory in a healthcare occupancy shall be in a separate room or closet that is two-hour rated and used only for that purpose. The room should be ventilated to ensure that staff members or vendors who may access that room will not be asphyxiated by the gas fumes that might escape the cylinders.

Many of laboratory gas tanks are listed as nonflammable. Such tanks can be kept in the laboratory area if so desired; however, more than one week's working supply should not be kept within the laboratory. The tanks must be secured in racks or with bolts and chains to the walls. Some reserve cylinders can be kept in the general laboratory work area, but not more than one extra cylinder for each cylinder that is actually connected and in use. If more tanks need to be kept on hand, these should be kept in a one-hour rated closet or storage room.

Overall, it is best to keep all the gas tanks in one tank closet or room that is constructed as a two-hour fire enclosure. This allows for the addition of tanks as necessary for increased quantities or different types of gas as procedures and needs change and has the added benefit of keeping the delivery of tanks in a corridor and not in the laboratory spaces where it could disrupt work.

Tanks must be stored securely to prevent them from tipping or falling. Should a tank fall, it is possible the valve assembly or "head" can be broken off, causing the affected cylinder to behave like a torpedo that could penetrate concrete block walls, causing significant damage and potential loss of life. Protecting tanks can be accomplished either by chaining them to a solid wall or installing specialized units that will securely hold the tanks. Full and empty gas tanks must be secured individually.

7.3 Wall Construction

Laboratories are considered hazardous; therefore, they must be constructed to contain fires, fumes, and biohazards.

The wall rating (how long it will contain a fire from the surrounding areas) is determined by the classifications noted in Section 7.1, Laboratory Classification. Classification is also affected by whether or not the laboratory is fully sprinklered (has a sprinkler system throughout that is connected to the fire alarm system).

If there are no sprinklers, a typical laboratory is required to have a one-hour fire rating on the surrounding walls, which means that a fire inside the laboratory would be contained in the space for one hour. This criterion also applies to the doors to that space, as they must also contain the fire. This criterion is adopted by OSHA⁶ as well as NFPA.²⁰

All laboratory walls should be extended to the underside of the floor slab above to maintain smoke and fire separation, as well as the pressurization of the room, and to minimize cross-contamination. It is also advisable to include sound insulation in the walls to keep surrounding offices and employee spaces comfortable and private.

7.4 Fire Egress

The ability of staff, patients, and visitors to get out of the building in case of a fire is critical and highly regulated. Laboratory regulations are particularly strict, as laboratories are considered hazardous areas due to the chemicals and gases that can be present.

Many agencies write regulations for fire safety; the most notable is the National Fire Protection Association (NFPA). However, state and local agencies also have strict codes, and the strictest code must be followed.

7.4.1 Egress Path

The path of egress is the path a person will take to get out of a room or building in case of a fire or emergency. The egress should be as easy and unencumbered as possible.

The corridor used for egress cannot house items that would feed the fire, including paper storage, waste items, electrical equipment, and even lockers, as they could contain flammable items. The width of this corridor is regulated by the IBC,² which allows a minimum of 72 inches (183 cm) for Group I (Institutional). For situations in which patient beds must move through the corridor in a Group I, the size increases to 96 inches (244 cm). For Group B (Business), the corridors can be a minimum of 44 inches (112 cm).

The aisles between laboratory casework and around equipment are considered egress for the people in that space. When looking at movement in the laboratory, the steps someone has to take if a fire breaks out in his/her area should be traced. Furniture, equipment, and wires should not be in this escape path.

The clearance between the casework and/or equipment should be a minimum of 44 inches (112 cm) as defined by NFPA.¹⁷ This minimum is for one person to escape the area, but is not sufficient for two people working back to back, so it is important to provide the proper clearance for the particular situation. Corridors that are used by many people have different criteria than those used only by laboratory staff, especially in a healthcare facility. If corridors are used only by staff members, they must be a minimum of 60 inches (152 cm). If patients in stretchers may use this corridor, then 96 inches (244 cm) must be maintained. Adding clearance next to a required door accessible to disabled persons must also be considered; this can add to the overall corridor size if the minimum amounts are being utilized.

Two or more exits from a laboratory are normally provided and are dependent on the size of the laboratory, the number of people in the laboratory, and the quantity of hazards. When there is a high hazard risk, it is prudent to provide a second door to exit the laboratory, even if it is a small space. This can be a concern in a BSL-3 laboratory, as staff should not contaminate the surrounding areas by exiting directly into a public corridor, and can be addressed through an alarmed door that would be used only in the case of an emergency.

A second exit from a laboratory area is required by NFPA¹⁷ if the area contains an explosion hazard that could block the exit; is high hazard and exceeds 500 feet² (46 m²), or low hazard and exceeds 1000 feet² (93 m²); if a hood is located next to the exit; or if there are compressed gas cylinders that are flammable or could prevent exit in the case of the gases being released. OSHA⁶ states this rule as arranging the access so one does not have to travel towards any area of high hazard. In the case of escaping a fire, a fume hood, gas cylinders, and flammable storage cabinets are considered high hazard; therefore, all of these should be kept away from exit doors.

The distance to an approved fire exit also is regulated by IBC.² A fire exit is defined as an opening out of the fire zone in which the laboratory is enclosed. This could be an enclosed stairway that opens to the outside (called a *vertical exit*) or the entrance into an adjacent building separated by a two-hour wall and door (called a *horizontal exit*). For I2 (Institutional), there is an allowance of 200 feet (61 m) in a sprinklered building and 150 ft (46 m) in a nonsprinklered building. Class B (Business) allows 300 feet (92 m) for sprinklered and 200 feet (61 m) for nonsprinklered buildings. Note that this distance is from the most remote point in the laboratory to the exit door, following the path someone could actually walk around equipment and casework.

One other aspect that often arises in a laboratory design is what is called a “dead-end corridor.” This is a hallway that does not lead to a fire exit. The allowed length by IBC² is no more than 20 feet (610 cm) for Class I2 and 50 feet (1524 cm) for Class B.

7.4.2 Doors

The type, size, number, location, and swings for doors must be specified during the design process and prior to installation.

Laboratory doors should be self-closing to keep the laboratory area contained from the surrounding areas. This is especially important in a nonsprinklered building, as the walls around the laboratory will be built to contain a fire and the doors are part of that containment. Any doors that are held open can only be done so by devices connected to the facility fire alarm system.

Having the doors open also raises HVAC concerns. With highly specialized systems and specific air changes and pressurization, keeping a laboratory door open can disrupt the balance of the system and make it ineffective.

Sliding doors are not considered self-closing; therefore, they are not appropriate for laboratory exit doors. The space that the door slides into is also a problem, because this area is very difficult to clean and thus can harbor bacteria and debris. Most facilities personnel do not like sliding doors, because they often fall off their tracks and become a maintenance problem.

The main laboratory doors should swing in the direction of travel such that when a person runs out of the laboratory away from a fire, he/she can just push the doors open and get into the corridor to get to the outside of the building. If the laboratory space is not a hazardous space, such as an office or storage room, the doors can open into the space. In any room where there are 50 or more people, the doors are required to open in the direction of egress travel (IBC²).

Doors cannot be less than 32 inches (81 cm) wide; this requirement is from the Americans with Disabilities Act (US Department of Justice⁹), as well as IBC.² These are actually fairly small doors, and are not useful for laboratories. At least one door, large enough to allow large instruments and devices to be brought in or taken out, should be provided to each area that houses equipment. A 4-foot, 0-inch (122-cm) door is useful, or a 36-inch (91-cm) door can be used with an extra 12-inch (31-cm) leaf or larger that can be opened when needed (called an “inactive leaf”).

Location of the doors is important to ensure that a person does not have to travel too far to get out of the space. NFPA requires that there is no more than 75 feet, 0 inches (23 m) of travel distance to any exit door from any point in a laboratory.

7.5 Fire Alarms

Fire alarms must be readily accessible in the laboratory area and can be located in or near the laboratory. When the alarm is pulled, notification to all areas must be visible as well as audible, so that someone who is hearing impaired can see the alarm and someone who is visually impaired can hear it. This is true in every area of the laboratory that might be occupied.

7.6 Fire Extinguishers

There must be a Class B fire extinguisher in all laboratories. This is an NFPA⁹ requirement. There are some arguments regarding the actual location. The College of American Pathologists (CAP) survey requirements state that fire extinguishers should be near the exit doors. Some laboratorians feel that

locating fire extinguishers near any hazard is safer, so staff members do not get trapped without escape and without an extinguisher.

Some specific laboratory areas that could use flammable chemicals might be required by local fire codes to have an extinguisher near that particular testing area. In all cases, consult local officials.

7.7 Hazardous Equipment

NFPA⁹ notes criteria for specific instrumentation, including hoods. Tissue processors and similar automated equipment that release flammable or combustible vapors must be operated at least 5 feet (152 cm) from the storage of combustible materials, unless separated by a one-hour, fire-resistant construction. This is important in histology areas, where it may be common to have tissue processors near flammable storage cabinets or large containers of flammable materials.

7.8 Handwashing

Handwashing facilities must be present in the laboratory. This requirement is cited by OSHA⁶ and most accreditation organizations. This specifically means ready access to running water, soap, and a way to dry hands.

Handwash sinks are considered dirty if they are used for any work; however, these sinks can be used for pouring clean liquids, such as distilled water. Providing a wall-hung lavatory, instead of a sink that is incorporated into the casework, may serve to highlight the sink as one specifically for handwashing.

In a Biosafety Level 3 room, handwash sinks must be located near the exit door of the laboratory and operable without the use of hands.³

7.9 Emergency Eyewash Stations and Flood Showers

The American National Standards Institute (ANSI²¹) has created very specific criteria for laboratory eyewash stations and emergency flood showers that have been adopted by OSHA⁶ as requirements.

The National Fire Protection Association (NFPA 99¹⁸) also includes the provision of eyewash station and emergency flood shower safety features in their criteria. NFPA states that wherever the eye or body of a staff member can be exposed to corrosive materials, appropriate facilities for flushing the eyes and rinsing the body must be provided in the work area.

Eyewash stations must be fixed bath units that meet the following criteria:

- The unit must allow a person to hold both eyes open while the water is running, i.e., the unit must remain on by itself, until someone purposely turns it off.
- The unit must go on in one second or less, usually interpreted as one movement.
- The height of the eyewash unit must be between 33 inches (84 cm) and 45 inches (114 cm) above the floor, and a minimum of 6 inches (15 cm) from any wall or obstruction on either side.
- The unit should be located so it takes no more than 10 seconds, or 100 feet (30.48 m) of travel from the hazardous area to reach it.

The installation of portable eyewash stations or those that are attached to a sink faucet cannot replace the fixed eye baths. They can be used as additional stations, as long as the approved fixture is still within the required distance.

Emergency showers must meet these criteria:

- The location of the showers is no more than ten seconds or 100 feet (30.48 m) from the hazardous area.
- The head of the shower should be between 82 inches (208 cm) and 96 inches (244 cm) from the floor.
- The water must remain on without the use of the person's hands, and stay that way until it is purposely shut off.
- It shall be able to go from ON to OFF in one second or less.

The location of the control is stated by ANSI²¹ as being not more than 69 inches (175 cm) above the floor. However, ADA⁹ guidelines require accessibility of controls from a wheelchair, i.e., no more than 54 inches (137 cm) above the floor, and of the type that can be pushed up to stop the water. Enclosures are not required. If the shower has an enclosure, it must be a minimum of 34 inches (86 cm) in diameter.

In both eyewashes and showers, OSHA's⁶ notation of availability for immediate use in a hazardous area should be interpreted to mean there are no doors between the hazardous area and the emergency facility. Areas where corrosive chemicals are used should have a shower and eyewash provided in the room itself.

7.10 Acoustics

As laboratories are housing more and more equipment, noise levels have risen. It is important to minimize the noise in the space to make it more comfortable for the employees.

White noise is the constant noise created by an object. Typically, in laboratories, these would be refrigerators, freezers, incubators, and analyzers. Other noise issues can be telephones, radios, and alarms.

White noise can be addressed with the use of mechanical sound masking. The overall white noise is measured, and the product generates specific frequencies of sound that can mask the noise. These will not address every noise, and a manufacturer/acoustic consultant must review and discuss what features they can mask.

General noises can also be addressed through the use of sound-absorbing materials in the laboratory. The designer must be careful to specify materials that meet the biosafety levels of cleanability. No fabrics are allowed in the laboratories; therefore, many of the traditional sound-absorbing materials are not appropriate. Some options that can be used are as follows:

- High sound-absorbance acoustic ceiling tiles (verify level of sound absorbance with manufacturer). **NOTE:** These cannot be used in BSL-3 or -4.
- Rubber flooring tiles (verify any acoustic properties for specific product with manufacturer). **NOTE:** These cannot be used in BSL-3 or -4.
- Cork has acoustic properties and is cleanable, antimicrobial, and antifungal. **NOTE:** These cannot be used in BSL-3 or -4.

Another means to address noise is to isolate some noisemakers without disrupting the efficiency of the laboratory; this may include creating a room for refrigerators and freezers, or partially isolating them with cork-covered acoustic panels, or wing walls and bulkheads.

7.11 Ergonomics

Creating a healthy environment for laboratory workers requires attention to specific areas that can contribute to ergonomic injuries; these can include sitting tasks, standing tasks, and lifting. Generally, ergonomic injury is caused by repetitive motion that cannot be addressed only through laboratory design features. Attention should be paid to employees who spend long periods of time doing the same task. Many laboratory administrators have worked with their facilities' physical therapy departments to identify areas of concern and possible changes to protect their staff.

The *NIEHS Ergonomics Guide*²² can provide information for other laboratory tasks that may be of concern.

7.11.1 Sitting Tasks

Sufficient knee and leg space needs to be provided where sitting tasks are performed. Staff members should not be sitting at an angle in front of cabinets or other storage components, such as situations in which knee spaces have been used to store boxes due to lack of appropriate storage facilities. A standard knee space should be approximately 36 inches (91 cm) clear width.

The chairs used in the laboratory should be ergonomically designed task chairs with adjustable features, so they can be customized to the unique requirements of each person who uses them. This could include height adjustment, back and seat angle adjustments, and adjustable arms. If the task is performed on a higher counter, an ergonomically designed stool with a footrest attachment should be provided.

A footrest under normal sitting height workstations can also be of benefit to those whose feet may not otherwise reach the floor.

Computer workstations are often a topic of ergonomic discussion. These should be provided with the appropriate knee space and ergonomic chair mentioned above. The computer monitor should have the capability of angling to reduce strain on the neck or eyes. A keyboard tray that can adjust may also be provided. The keyboard tray is not always appropriate for other laboratory tasks performed at the same time; therefore, each situation should be evaluated individually.

7.11.2 Standing Tasks

Much laboratory work is done while the technologist is standing. The strain on knees, backs, and legs can accumulate over time and may be especially problematic for older staff members. Either good antifatigue mats or comfortable flooring should be provided where long-term standing will occur.

7.12 Summary Points

- Determine the classification of the laboratory and build accordingly.
- Arrange the doors, aisles, equipment, furniture, and corridors to allow direct and rapid escape in case of emergency.
- Make sure doors are the correct type and arrangement.
- Keep hazards away from the doors and paths of egress.
- Ensure the proper storage facilities for flammables and gas tanks.

- Have fire alarms readily available and equipped with visible and audible alarms.
- Provide fire extinguishers.
- Provide clean handwash sinks throughout the laboratory, and at the exits in Level 3 rooms.
- Provide emergency eyewash stations and emergency showers that meet the ANSI criteria for type and location.
- Anticipate possible ergonomic issues and design the area to be as ergonomically correct as possible.

8 Space Determination

Allocation and organization of space are among the most controversial issues in laboratory design. Space inadequacies sufficient to present a safety hazard are often cited as deficiencies in inspections of clinical laboratories by accrediting bodies. Inspection agencies and accrediting bodies are concerned about lack of adequate space, because crowding and clutter may affect safety, as well as the quality of work performed in the laboratory.

8.1 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.

8.1.1 Floor Space Determination

Laws, codes, regulations, and requirements that pertain to space and access issues in public buildings in general, and laboratories in particular, can be found in consultation with federal, state, and local government agencies, accrediting organizations, and professional societies. The difficulty in assembling and understanding all the pertinent information is such that questions on space and access compliance are best referred to professionals, such as architects/consultants with experience in clinical laboratory design, who have access to the most recent information from all required sources. Code compliance can significantly impact laboratory design.

The majority of regulations and recommendations are for fire, life safety, and accessibility that require specific clearances. Table 7 should be referenced for the various criteria for clearances and clear widths. Keep in mind that many state and local jurisdictions have stricter codes than the federal ones. It is required that the strictest code in the area be met. General space clearances are listed in Table 7 below.

Table 7. General Space Clearances

Minimum clearance/space requirement	Notes
44" (112 cm) aisle	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 61 cm) beside doors	Added to a 36" (91 cm) door, this can increase the minimum corridor width to 60" (152 cm)
44" (112 cm) to 72" (183 cm) corridor	Minimum clear corridor width where a patient bed or stretchers would be used. Dependent on whether it is an Institutional or Business occupancy. See Section 7.4.1, Egress Path.
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 regulatory and accreditation agencies need to be addressed when determining square footage. These include fixtures such as emergency eyewash stations, emergency floor showers, handwash sinks, and fire extinguisher cabinets.

Space must be allowed for ease of maneuvering throughout the laboratory, including the area between casework, in aisles, and around equipment (see Table 1). A typical laboratory module is between 10 to 11 feet (305 to 355 cm) (see Figure 12). 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 12).

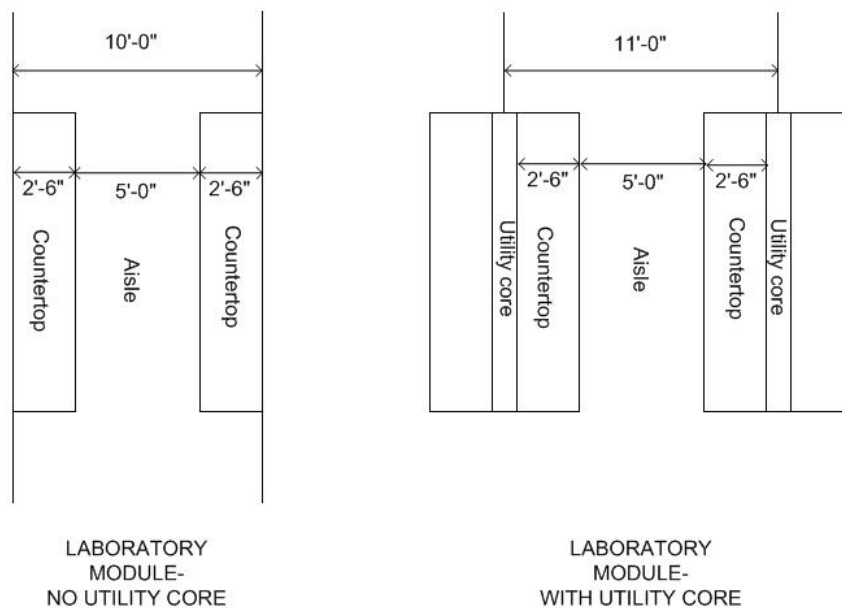


Figure 12. Typical Laboratory Modules

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 allowing space behind instruments for personnel to reach utilities and controls. This can be achieved by leaving an aisle behind large instruments or placing equipment on procedure tables with lockable casters that can be wheeled out to expose the backs (see Figure 13).

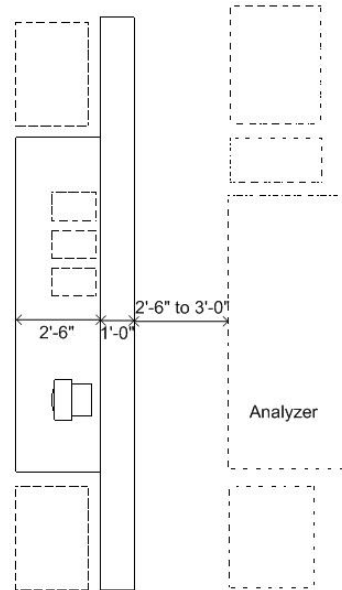


Figure 13. Example of Maintenance Aisle Behind Floor-Mounted Analyzers

8.1.1.1 Disabled Employee Considerations

All public and common-use areas of new medical care facilities, as well as alterations to existing facilities, should be accessible, including outpatient and visitor areas. In the laboratory setting, this could include waiting, phlebotomy, toilet, and blood donation areas. In the United States, the layout should adhere to regulations from the US Department of Justice⁹ regarding those who are physically challenged.

Areas that are designated as 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.

8.2 Specialized Laboratory Areas

Some laboratory areas have special space considerations due to the nature of the testing (e.g., biohazard level, environmental or security issue).

8.2.1 Sample Processing

Sample processing is very important in the overall workflow of the laboratory; therefore, placement should be where access to the laboratory analysis areas is as convenient as possible. When a laboratory has an automated sample handling system, it must be part of the open laboratory to allow the system to go from sample processing directly to the testing areas.

The sample processing area is considered Biosafety Level 2, as are most clinical laboratory areas. This area must be negatively pressurized in relationship to the corridor.

Most facilities have pneumatic tube stations in the sample processing area; therefore, space should allow for the tube stations and for storage of empty tubes. The number of tubes should be determined from an evaluation of the facility's need by a pneumatic tube manufacturer or consultant.

The use of couriers is an important consideration in laboratories, because samples coming from phlebotomy facilities remote from the laboratory and outside the facility are very common. Access to the sample processing area should be as easy as possible for couriers to drop off specimens and pick up supplies rapidly. A drop-off window can be convenient for the couriers, and also keeps the courier traffic out of the testing areas.

8.2.2 Hematology, Chemistry, Special Chemistry, Coagulation, Urinalysis, Immunology

These laboratory testing areas are very common to the clinical laboratory, and all require Biosafety Level 2 facilities. The space is determined from equipment, workstations, and code criteria. Workflow is important, from the sample processing perspective, as well as between the disciplines. These departments may have previously been housed in separate rooms, but the current trend is towards a large, open laboratory that will support cross-training, large analyzer cores, and automated sample handling systems.

8.2.3 Blood Bank

Blood bank or transfusion medicine can be part of the open laboratory, as long as it is in a location out of the main flow of traffic to minimize disruption.

Many laboratories take advantage of the reliability of pneumatic tube systems and send units of blood through it. If this is being considered, then the square footage should allow for the tube station and for storage of empty tubes. If a new system is being installed in the facility, then a six-inch tube system is best. A six-inch tube can accommodate one unit of blood at a time. The transport canister also needs to contain padding and sufficient absorbent material to soak up the entire contents of the unit in the event of a rupture.

A drop-off/pick-up window to the corridor is a convenience for blood banks that have units of blood delivered in large quantities to the laboratory, and that have hospital staff members come to the blood bank to pick up units for patient transfusions.

Drop-off windows should include, at minimum, sliding glass so the pressurization in the laboratory can be maintained. Note that all drop-off windows must meet fire safety codes for the locale, which includes a self-closing fire shutter that is linked to the fire alarm system.

Requirements for accommodating blood irradiators need to be considered. There are two types of irradiators—gamma ray and x-ray. Gamma irradiators (137 Cs or 60 Co) are very heavy (1250 lbs. [568 kg] to 4400 lbs. [1998 kg]) and need to be placed where the structure can support them, such as over a structural beam, adjacent to a support column, or in an area that has had the structural system augmented to support the additional weight. In some areas the NRC licenses require that irradiators be placed in an area of restricted access. Local requirements need to be considered and met. X-ray-based devices are significantly lighter and generally do not require the additional structural support or radiation isolation of the gamma irradiators.

8.2.4 Flow Cytometry

Flow cytometry can be part of the core laboratory if desired. It is considered a Biosafety Level 2. Flow cytometry should be located in a quiet corner of the laboratory, much in the same fashion as the blood bank, to minimize disruption.

8.2.5 Surgical Pathology

Surgical pathology, which can include histology, cytology, immunohistochemistry, gross anatomy, and frozen section, is also a Biosafety Level 2 laboratory. The square footage is determined in the same manner as for other laboratory areas.

The important distinguishing feature of the surgical pathology area is the large quantity of carcinogenic chemicals that may be used.

Formalin and xylene are heavier than air; therefore, traditional exhaust systems, in which the air is exhausted through ceiling vents, are not effective. Use of backdraft (in which air is exhausted at the back of countertop) or downdraft (in which air is exhausted near the floor) is more practical in removing the fumes.

8.2.6 Autopsy

Morgue/autopsy suites should be designed similar to Biosafety Level 3 laboratories in that they require an anteroom and a higher level of cleanability. Spaces required within the suite include the anteroom, housekeeping closet, body holding refrigerator, and autopsy room. Larger institutions often have separate autopsy rooms, one being reserved for isolation. A separate photography area and specimen storage room may also be included.

An important space consideration is the access for body stretchers into the anteroom, cooler, and autopsy suite. A considerable amount of space is necessary to allow the doors to close behind the stretchers, allow the stretcher to turn, and allow other doors to open.

The anteroom should be negatively pressurized in relation to the corridor, and the autopsy rooms should be negatively pressurized in relationship to the anteroom. If there is a separate isolation autopsy room, it should be negatively pressured to all the other rooms. A handwashing sink and some storage space for supplies, equipment, and samples must be provided in each autopsy room. A sink for washing large specimens is also required; this is usually done in a clinic sink that is equipped with a garbage disposal. Adding a garbage disposal is often questioned, because the frequency of clogs necessitates protection of the laboratory staff and maintenance staff from risking contamination to clean out the drains.

A room with a full shower for changing should be provided for the pathologists and dieners.

The Department of Health²³ requires that the morgue be accessible through an exterior entrance and located so that bodies do not have to be transported through public corridors.

8.2.7 Molecular Diagnostics

Most molecular suites contain five distinct areas where manual PCR testing is being performed, including a reagent preparation area; a specimen preparation area or pre-PCR; a product analysis area or post-PCR; a darkroom; and a technologist workroom. The actual square footage of each of these spaces is determined in the same manner as for other laboratory areas—based on equipment, work areas, and code clearances.

Anterooms, which are small, negatively pressurized rooms between the testing areas and the outside corridor, are also required. Anterooms need to be large enough for the door that will swing open into the space; a 5-foot (152-cm) wheelchair turnaround; and tall cabinets for protective clothing storage (see Section 10.4, Pressurization).

The reagent preparation area should be positively pressurized to keep out contaminants from other areas. This room can share an anteroom with the pre-PCR area. The pre-PCR space requires negative pressurization. The post-PCR room must open off a separate anteroom to avoid any cross-contamination with the pre-PCR room contents and must be negatively pressurized. The darkroom can open directly off the post-PCR area and should be light-tight. Newer procedures are removing the need for a darkroom and should be evaluated on a case-by-case basis.

New rapid response PCR analyzers have been developed that do the testing in an enclosed instrument. Most of these do not require housing in BSL-3 laboratory areas. However, samples for these analyzers need to be prepared in a small, isolated preparation room, which should be provided in close proximity to the counters where the analyzers are located.

A molecular diagnostic suite, where PCR replication is performed on organisms that are potentially fatal to humans, requires a Biosafety Level 3 construction because of the hazard of DNA and RNA aerosols. The level should be evaluated, keeping in mind what is being tested today as well as in the future of the facility.

Molecular diagnostics is a rapidly growing technology and has the potential to replace other existing procedures in the laboratory; thus, it is important to incorporate flexibility into the design.

8.2.8 Cytogenetics

Cytogenetics has specific criteria that are similar to those for molecular diagnostics. Several separate rooms need to be built to maintain the necessary environmental variables; these rooms would include clean tissue culture rooms with anterooms, a harvesting and staining room, and a room or area for image analysis.

Some laboratories are creating separate tissue culture rooms to separate fetal tissue and bone marrow samples. These rooms are positively pressurized to keep the tissue cultures from being contaminated by outside sources.

The harvesting and staining laboratory is a Biosafety Level 2 area and can house the equipment used in both bone marrow and fetal testing. Very strict environmental criteria exist for some of the procedures. Due to the difficulty of maintaining a constant temperature and humidity in a large institution throughout the seasons, it is advisable to include environmental chambers as part of the equipment.

The imaging area can be in an office-type area, or it can be part of the laboratory.

Additionally, there is usually the need for plenty of storage room for files and slides. This can be shared with other departments but should be located close to the cytogenetics laboratory (or department) due to the frequency of access.

8.2.9 Forensic Toxicology

Because of the legal implications of tampered with, lost, or mixed-up samples, a forensic technology area has strict security requirements that are not found in other laboratory areas. The laboratory must be in a separate lockable room. The Society of Forensic Toxicologists states in their *Laboratory Guidelines*²⁴ that the layout of the laboratory should be such that an unauthorized person cannot enter the laboratory undetected. The delivery of samples needs to go through as few hands as possible. A separate window for drop-off of toxicology specimens is best.

Inside the laboratory, space requirements are determined by the equipment, workstations, and codes needed. Space should be left for a sign-in/sign-out desk near the front door for anyone entering the laboratory. Sample log books are needed to document chain-of-custody samples.

Security is extended to the storage of samples and records. Separate refrigerators, coolers, and record storage areas need to be considered and can be housed in the toxicology laboratory itself, or by providing a separate locked area or cage in shared storage facilities.

8.2.10 Stem Cell Processing

Stem cell harvesting is becoming a common feature in the larger laboratory complexes. Requirements for this area are somewhat different from other laboratory areas.

Under Good Manufacturing Practice (GMP) requirements, separate rooms must be provided to avoid contamination of the samples. One room houses a large quantity of equipment, which includes several nitrogen freezers to store the stem cells. This room could also include space for the nitrogen tanks, or the freezers can be located in a room adjacent to a gas tank storage closet that houses the tanks. The distance from the tanks to the freezers should be minimized as much as possible. This room should be designed as a Biosafety Level 2 with negative pressurization. Procedures that do not require a clean environment can be housed in the same room.

The second room is the clean area, which should be separated from the equipment area described above to minimize any possible contamination of the cells and should be positively pressured. The two rooms may be separated by an anteroom. No water sources should be located in the clean area, to eliminate possible contamination that can be brought in through the tap. Handwash sinks and procedure sinks should be located right outside the room.

Criteria for stem cell areas can differ depending on the level of work performed in the institution. In some institutions there is only one room that houses all the testing as well as the storage equipment. However, in every situation, stem cell processing is performed in a separate laboratory area from other clinical testing.

8.3 Laboratory Support Spaces

8.3.1 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 that can move and be stacked, should be considered.

In a new building or renovation of an off-site building, space should be considered and allotted for a loading dock with the ability to accommodate parking needs of large trucks delivering supplies. This can take a considerable amount of space and have a significant impact on the positioning of a building on the site. Ideally, this dock should be adjacent to the bulk storage area; however, depending on the location of

the laboratories, the final dock location should be most efficient for the laboratory staff rather than the delivery staff.

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

8.3.2 Flammable Storage

There are still many flammable reagents used in clinical laboratories. Table 8 lists some of the more common chemicals and their flammability ratings from the NFPA.¹⁸ Each laboratory should create a list of the liquid flammables, by gallon, for the architect/consultant, so the laboratory can be constructed properly and the proper storage arrangements designed.

Table 8. Some Common Flammable Liquids Used in Clinical Laboratory Settings

Flammable Liquid	NFPA Classification
Acetone	I
Amyl acetate	I
Butanol	I
Ethyl alcohol	I
Formalin	I
Isopropyl alcohol	I
Methyl alcohol	I
Toluene	I
Xylene	I
Acetic acid	II
Alcoholic iodine	II
Glycerin	II

In most cases an “inside liquid storage room” is appropriate for the laboratory. Because clinical laboratories do not normally use combustible liquids, it is not necessary to design an explosion-proof room. The liquid storage room is a one-hour, fire-resistant room with open shelving. The size of the room is dependent on the quantity of chemicals stored there. For more information on the construction and requirements of inside flammable storage rooms, see Section 7.2, Flammable Storage.

Under-counter flammable storage cabinets should be located in the laboratory itself, preferably close to where the chemicals are used.

If a recycling system is used in the laboratory, large containers filled with recycled chemicals should be kept in the liquid storage room. However, the recycler itself, which uses electricity, cannot be placed in the liquid storage room; electrical equipment or outlets are not allowed in these rooms due to the possibility of sparks igniting the fumes.

8.3.3 Gas Tank Storage

Laboratories use many different gases in various procedures. Some gases usually used include CO₂, nitrogen, and anaerobic blends. Most of the gases used in laboratories are nonflammable, but flammable gases, such as acetylene, are used in atomic absorption.

The NFPA¹⁸ allows laboratories to keep tanks that are attached to instrumentation in the laboratory itself, as long as they do not interfere with exit from the laboratory in case of a fire. Full and empty gas tanks

must be secured individually with racks, chains or other fastenings, whether they are connected or not to either a manifold or a piece of equipment.

Spare gas tanks, as well as tanks that are considered highly flammable, should not be kept in the laboratory. Providing a fire-rated closet in which all gas tanks can be housed is safe and convenient. These tanks can be plumbed to provide outlets to where the gases are used. The closet also eliminates the need to move tanks around in the laboratory testing areas. For more information and requirements for gas cylinder storage, see Section 7, Health and Safety.

8.3.4 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 refrigerators or walk-in coolers are important. If a laboratory has an automated sample handling system, 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.

Surgical pathology departments save patient tissue samples for several days to several years. The length of time depends on the type of sample, the standards of the facility, and whether the samples are used for teaching. These samples may need refrigerated space or a room with shelving to allow a variety of container sizes. Most samples are stored in formalin; therefore, the storage area should be well ventilated.

Attention should also be paid to how the samples move from the work area to the storage area. Storage should be convenient to the testing space; the samples should not be transported through public areas.

8.3.5 Record Storage

Laboratories are required to keep extensive records on testing, equipment maintenance, employees, and quality control; therefore, room for files, record boxes, and electronic archival media is essential. Some locked files may be needed for sensitive materials.

Information is increasingly being saved in electronic media with off-site archiving; therefore, although the space needed for storing these records is shrinking, some space still needs to be provided to store computer disks and archival media, as well as for the equipment necessary to read them.

8.3.6 Refrigerated Storage

Walk-in refrigerators and freezers provide large, centralized storage areas for materials that need a temperature-controlled environment. Walk-in units are not as flexible as moveable refrigerators and freezers, but they can be moved and reused with some construction. The units themselves are standard, built-in modules that can be separated. If the unit has an insulated floor, either a ramp should be provided on the outside or inside, or the unit recessed into the floor slab. Remote compressor units can be considered if noise and heat reduction are an issue; however, the compressors must be located within a reasonable distance to the refrigerator/freezer unit.

Movable refrigerators and freezers are used widely in clinical laboratories and cannot be completely eliminated by the addition of walk-in refrigerators and freezers. Some refrigerated storage adjacent to analyzers or workstations will always be needed and can be accomplished with either full-size units or under-counter units. The decision is dependent on the capacity that needs to be immediately available and the distance to the walk-in unit to restock the supplies.

For large numbers of refrigerators and freezers that need not be adjacent to workstations, a separate room to house these could be considered and has the advantage of isolating the noise and heat load.

If locked refrigerated storage is necessary for forensic toxicology or general security, separate locked refrigerators, or locked cages in a shared walk-in unit, can be provided.

8.3.7 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 not required to have its own autoclave system. The facility, local authorities, and the waste transport company (if one is used) should be consulted if the laboratory staff is not familiar with local requirements.

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. Many of the newer units do not require steam lines, because they generate their own.

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 odors that will be generated. If the unit is placed in a service room, this room should be negatively pressurized to keep the odors from escaping into other areas.

8.3.8 Glass-wash Room

A glass-wash room is not a necessity for laboratories unless a very large amount of 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.

8.3.9 Waste Storage

Rooms for biohazardous waste, ordinary trash, and recycling may be necessary, depending on the housekeeping service for the area. If waste is generated faster than the staff can pick it up, it is prudent to create an area where the waste can be kept during the wait, especially for biohazardous material. An offsite laboratory space near the loading dock or an exterior entrance is appropriate.

Larger laboratories may need several spaces to minimize the distance a laboratory employee has to travel to transport waste containers. Typically, microbiology and anatomic pathology departments generate the largest amount of biohazardous trash.

Large bulk storage facilities generate an abundance of cardboard boxes that need to be discarded. Some facilities have incorporated trash areas adjacent to the storage facility with equipment that bundles the broken down boxes. Cardboard boxes should not be stored in exit corridors, because they are considered a fire hazard.

8.3.10 Pneumatic Tube Equipment Room

In buildings that do not have existing pneumatic tube service or in new construction, space should be reserved for the blowers that would support the tube system.

8.3.11 Utility Closets

In almost all situations, closets to house electrical panels, communication (telephone and data) panels, LIS panels, housekeeping; and possibly some mechanical support rooms need to be constructed. In new construction, the number of closets is usually larger than in existing facilities where some of the equipment is already located in other parts of the building.

8.4 Laboratory Employee Spaces

Employees need facilities for their personal needs and comfort, and these areas should be incorporated into the laboratory plan and space considerations. These rooms shall be convenient for the staff, but they do not have to be in the laboratory and can be shared by other departments. However, distance to the facilities is a serious consideration when looking at efficiency of staff time.

8.4.1 Lounge/Break Room

Lounges or break rooms are important for laboratory staff, especially during shifts for which there is a small staff available, such as second or third. These staff members need a space very close to the laboratory to eat their meals but still be able to monitor the laboratory for security, timed procedures, and emergencies. Ideally, this is a room with a window into the laboratory area for visibility during breaks. OSHA⁶ guidelines do not allow food or drink in the laboratory space itself—this also precludes walking through the space with food and drinks to access a lounge or break room, because blood-borne pathogens that may be present in laboratory spaces as aerosols can contaminate the food items as they pass through the area. When there is a door directly from the laboratory into a break room, there must be another door off a clean corridor to access the room, so food and drink can be brought in safely. The door to the laboratory should never be left open. Air should not move into the lounge from the laboratory space. This is accomplished by making sure the laboratory is negatively pressurized in comparison to the lounge itself. Handwashing facilities should be located close to the entrance to the lounge to encourage and maintain a pathogen-free environment.

Providing a lounge in close proximity to the laboratory is also important if the facility's dining area is so far away from the laboratory that it would prove very inefficient for the staff, or if the laboratory is in a separate building. Many stand-alone buildings provide lounges that include vending machines and appliances for food preparation when a cafeteria or food services are not available.

8.4.2 Lockers

Lockers are necessary for staff coats, boots, and personal items. The size of the locker is often regulated by facility standards, which should be verified. In areas where heavy winter clothing is normal, the lockers should be able to accommodate these items. Closets can be added unless there are security problems. Unisex locker rooms offer flexibility as the staff mix changes. However, if the staff changes clothes, then separate male and female locker rooms (or changing rooms) should be provided. If toilet rooms connect with the locker room, they can double as changing rooms.

8.4.3 Toilet Rooms

Convenient toilet rooms should be provided for the laboratory staff. The Department of Health *Guidelines for Design and Construction of Hospital and Health Care Facilities*²³ uses the National Plumbing Code

as a guideline. All of these areas have space determined by the number of staff that would be using them. Toilet rooms are in direct proportion to the maximum number of staff present at one time. The IBC² states that there should be a minimum of one toilet room for every 25 employees in a hospital setting. Another plumbing criterion calls for one male and one female toilet room for every 25 employees. Consideration should be given to any local codes, as well as percentages of males and females in the working areas.

8.4.4 Showers

If a microbiology department is part of the laboratory and includes a Biosafety Level 3 area, then there should be a shower room included in the locker room area. The CDC has issued guidelines concerning the possible contamination of a staff member with anthrax.¹⁴ Their process for decontamination includes removing the outer clothing, then proceeding into the locker room shower facility and removing the clothing to take a shower with soap and water. To minimize the distance that the contaminated person travels, it would be best if the laboratory locker room with shower facilities is located close to the BSL-3 facility and out of any public corridors.

8.4.5 Laboratory Coat Storage

Laboratory staff needs places for clean and dirty laboratory coats; this includes laboratory coat hooks inside the laboratory adjacent to exit doors, so that contaminated laboratory coats can be taken off before exiting. Dirty laboratory coats, when they are no longer going to be used, need to either be put in a laundry hamper if cloth coats are used, or in the trash if disposable coats are used.

Clean laboratory coats should be stored either in tall cabinets, if disposable or folded, or in closets if they arrive from the laundry on hangers. Some facilities use dispensing machines for either laboratory coats or scrubs.

8.4.6 Administrative Rooms

Administrative offices need to be provided, as well as space for clerical functions. Office sizes are often determined by a preset facility standard based on the organizational position of the person using the office. No code criterion exists that states the administrative offices must be located immediately adjacent to the laboratory. Office locations should be carefully evaluated for each situation. Typically, it is more efficient to locate offices to allow easy communication and access to the laboratory. Pathologists and laboratory administrative staff who also spend time in the laboratory work areas use most laboratory offices.

Some office functions, e.g., clerical, can be performed in open space, or at workstations for technologists who work in the laboratory but also need a clean desk area outside the laboratory. If staff requires quiet or a private situation for employee counseling, then a private room should be considered; some examples may include cytology screening rooms, transcription rooms, and some supervisory staff members.

To support various testing and organizational functions, a variety of office-type areas may be needed. A full list should be presented to the architect/consultant during the planning stage of design.

8.4.7 Conference, Teaching, and Library Facilities

Accreditation criteria require laboratory staff to continue their education; therefore, conference, training, and library space are needed. Facilities should be available that are large enough to gather laboratory staff for participation in continuing education programs, such as teleconferences or workshops. These rooms should also be provided with numerous data outlets for ongoing laboratory information systems (LIS) training.

Laboratory facilities contain many reference books, supply books, procedures manuals, pathology record books, and reference magazines. Bookcases should be provided in a convenient area that is used only by the laboratory staff. There should also be bookcases provided in the laboratory testing areas for those manuals and references used regularly during testing.

8.5 Patient Support Spaces

8.5.1 Phlebotomy

Areas for sample collection must be provided somewhere in the facility. A large number of patients may present at certain times of the day, and space should be provided that makes them as comfortable as possible while maintaining efficiency.

Waiting is determined by numbers of people at peak times. The areas should allow seating for patients and any accompanying family members. There must be public toilet rooms available in close proximity. The waiting area can be shared with other departments.

Occasionally, patients need to remove some clothing, or faint during phlebotomy, so privacy is important. This can be accomplished with cubicle curtains or partial walls. A private phlebotomy room should be provided for noisy pediatric patients or for patients who become sick. If the facility performs drug testing, then a private room is required to maintain patient confidentiality or to meet security needs.

Toilet rooms should be provided in numbers appropriate to the volume of patients. Each should be private and ADA⁹ accessible. If drug testing is performed, then at least one toilet room should have remote water shut-off so the samples cannot be diluted. Sample pass boxes are a convenience that minimizes patients' embarrassment from carrying the samples through an occupied area.

Facilities often provide a small phlebotomy area adjacent to the laboratory if the main phlebotomy area is located elsewhere and not staffed at all times. This is very efficient for weekends, holidays, and later shifts. Consideration must be given to how patients access this area without threatening the security of the rest of the laboratory and other surrounding healthcare areas.

Each area requires a countertop area, a phlebotomy chair, and a handwash sink. There must be an adjacent toilet room for urine and feces sample collection. Consideration should be given to including a cot or drop-down baby phlebotomy table, space for a computer terminal, an under-counter refrigerator for glucose tolerance supplies, and for phlebotomy supply storage. Because patients need access to the laboratory phlebotomy area, it must be fully accessible to disabled persons.

The phlebotomy room cannot open to the laboratory itself due to the Biosafety Level 2 nature of the testing areas. The possibility of aerosols that may harbor life-threatening organisms could be very hazardous to the patients.

8.5.2 FNA Room

Another room often associated with laboratories is a procedure room that can be used by the pathologists for fine-needle aspirations (FNA). These should be a minimum of 120 feet², which is a requirement for all procedure rooms by the US Department of Health.²³ The minimum dimension in any direction is 10 feet (305 cm). There should be a small counter, a handwash sink, and room for a cot. Room for a small rolling cart that holds equipment for the procedure should also be provided.

8.5.3 Donors/Apheresis

Blood donor and apheresis areas differ from traditional phlebotomy in that the blood donors are normally there for a much longer time. Space is calculated by the number of chairs required for the donors, along with equipment, storage, and staff areas. There must be handwash sinks readily available for the staff.

Both donor and apheresis areas should have space for some snacks for the donors that could include a small under-counter refrigerator and a clean sink, or for a seating area where the donors can relax for a few minutes while they have their snacks. A nice feature included by most facilities is some entertainment electronics for their donors, such as television, video/DVD players, or music provided as individual units or a larger unit that can be used by everyone.

A toilet room should be available that is accessible to physically disabled persons; it is preferable that it open off the donor/apheresis space itself.

A waiting area is needed in case the donors cannot go directly to one of the donor chairs and also if they have other people accompany them. Waiting rooms must have access to a toilet room, telephones, and a drinking fountain.²³ This area can be shared with another department if convenient.

Apheresis patients have special considerations that differ from donors. They may require stretchers and wheelchairs due to illness. As these patients may be ill, there should be means to keep them warm during their apheresis. Radiant panels, heated blankets, or heated donor chairs are considerations.

The design needs to include room for evacuation of these patients in case of fire. The corridors would have to be designed at 96 inches (244 cm) to accommodate any stretchers and allow for room to turn the patient around and get through doorways and around corners.

The blood donor and apheresis areas are both normally associated with the transfusion medicine service. Proximity to the department should be considered to efficiently transport the product and share staff.

8.5.4 Semen Sample Collection

In facilities that process a large number of fertility clinic samples, it is beneficial for the patients to have a separate, comfortable room for semen sample collection. This room should have a sink for handwashing and possibly a pass box, so the sample does not require transport by the patient to another location.

8.6 Utility Space

Room is necessary to house utilities required for the proper operation of the laboratory. These rooms can include an electrical closet, communication closet, pneumatic tube equipment closet, UPS closet, DI water closet, and various mechanical spaces, depending on what is already provided in the overall facility.

8.7 Net vs. Gross Square Feet

Actual functional workspace available in a laboratory, i.e., the net usable square footage of a space, will be less than the total square footage allocated. This departmental “net” square feet (DNSF) is the space that is used specifically for the various functions. Additional square feet that constitute gross square feet are those necessary to accommodate partitions; corridors; vertical transport; circulation; and mechanical, electrical, plumbing, and structural elements within the laboratory. These factors will vary from one site to another. When estimates of the area are being calculated, it is safe to use a multiplier of 1.3 to 1.5 to determine the gross departmental square feet (DGSF) that could be necessary.

In new construction, another net gross factor is added for the building itself. This could include space for stairs, elevators, corridors, structure, and utility needs. It is much the same as departmental criteria. The DGSF, multiplied by a factor of 1.3 to 1.5, yields the building gross square feet (BGSF). The DGSF and BGSF can easily take the usable space needed for constructing a laboratory and double the overall square footage needed for a building to house the laboratory.

8.8 Relationships

In the planning and programming stage of design, a chart or sketch, often called a “bubble diagram,” is created to show the relationships between the various laboratory areas. During discussion of the working areas and associated support spaces, the laboratory planning team should think about the arrangement of the laboratory areas to increase the efficiency of testing, staff, movement, and communication. Bringing areas closer together that may support each other and allow technologies to merge can help prepare the laboratory for future advances.

The relationships shown in the bubble diagram can be translated to the block diagram, allowing a better start to the actual design of the laboratory space. For an example of a bubble diagram and a block diagram, see Section 4.2, Planning and Programming.

8.9 Laboratory Casework

Casework is one of the big purchase items in a laboratory project and should be well thought out when a decision regarding type is made. Many reputable laboratory casework manufacturers can show their product before a decision is made—either in the facility with a mock-up, or by demonstrating the product at a similar site where it is already in use.

As laboratories are often operated 24 hours a day, 7 days a week, most custom-made cabinetry (called “millwork”) cannot withstand the rigors of the laboratory environment for as long as the casework systems can. Millwork can have exposed particle board from the construction method or from damage. This particle board provides a porous surface suitable for bacterial growth that can be dangerous for the laboratory staff. It also may not be able to withstand the chemicals and heat used in the laboratory on a daily basis. The cost of casework systems is traditionally higher than millwork, but the lifespan is much longer, and they are safer when constructed specifically for the laboratory environment.

8.9.1 Flexible Systems

When determining the layout of the laboratory it is important to prepare the design to adapt to future changes. The amount of flexibility incorporated into the design depends on the amount of change anticipated and the type of testing done. In a laboratory that is predominantly automated, the possibility of equipment changes is very high. Use of flexible casework would facilitate the installation of a new equipment and robotic sample handling system at minimal inconvenience and cost. Areas that perform mainly manual methods may not experience as much reshuffling.

Flexibility in the layout is accomplished through the use of a flexible casework system, instead of a typical floor-mounted modular system. Minimizing what is secured to walls and floors allows easier rearrangement in the laboratory. This can be accomplished on various levels.

A suspended casework system allows the removal of countertops and storage components in a very short time period, without construction. It also allows countertop height adjustment to meet the needs of that particular moment. Cores that are installed to attach the casework system in island or peninsula arrangements are normally bolted to the floor, unless they stay within a small module—usually 8 feet (244 cm) or less. This ensures stability, as well as the protection of utilities that may pass through the core. The bolted cores can be moved, but it often requires some mild reconstruction.

Using procedure tables instead of suspended countertops allows the users to move the work surface very easily. Most tables can be purchased with adjustable height capabilities; however, the location of the utilities is a constraining feature.

8.9.1.1 Flexible Casework Utilities

Many laboratories decide to use a combination of the various types of casework, including suspended tables and fixed casework. As the fixed casework typically is less expensive, this can lower the cost of the project. Keep in mind that any future changes can negate the savings of fixed casework.

It is important to ensure that all the utilities meet the changing needs of the people and equipment. These would include electrical, data, plumbing, and mechanical needs.

Electric and data wiring should be sufficient for present needs and should allow extra capacity and accessibility for adding or moving equipment. The location of relevant outlets should not be a constraint on the area in which a particular instrument is used. The profusion of computers and printers in the laboratory requires the ability to add and move them with ease. Incorporating organized wiring through the use of wire management and cable trays can ease the disruption that accompanies changes.

Plumbing is very difficult to move, due mainly to drain locations. It is prudent to add capped floor drain connections in the laboratory if budget permits, which will give some flexibility for moving sinks and for adding/moving analyzers requiring drains. Water and gas lines can be run above the ceiling and brought down in enclosures to the counters where needed. These features are helpful in renovation, since changes will not require walls to be opened or floors to be drilled.

Mechanically, the inclusion of flexibility is addressed through the type and capacity of the air-handling system and the accessibility of duct work for easy maintenance and rapid reconfigurations.

8.9.2 Weight Capacity

The ability to withstand the large weights of counter- or table-top laboratory instrumentation is important when considering casework systems. Many systems have a variety of support types and installations that should be considered. Laboratories should choose the heavy-duty support systems and tables that can withstand 300 pounds (136 kg) or more.

8.9.3 Height and Knee Space

As noted previously, the minimum depth of countertops in a working laboratory area should be no less than 30 inches (76 cm). Exceptions include situations in which countertop analyzers are deeper than this length. An example is a flow cytometer that would require a countertop of 36 inches (91 cm) in depth.

There must also be consideration given to clearances and sizes required for heights at workstations. There are two common countertop heights in most situations. The sit-down countertop is generally at 30 inches (76 cm) above the finished floor (AFF). The stand-up countertop is generally at 36 inches (91 cm) AFF. Sinks that are used for procedures should be installed 36 inches (91 cm) AFF, unless it is a specialized procedure during which the staff sits to use the sink. Inappropriate sink heights increase the possibility of back strain while using the sink.

Knee spaces are very common in laboratories and have clearance considerations. The ADA states that a knee space can be no less than 28 inches (71 cm) wide.⁹ In laboratory situations in which several instruments, devices, and equipment are used while sitting, the knee space should be larger. One example is a histology cutting area, where the technologist is using a microtome as well as a water bath and must

be able to access both comfortably; here, a minimum knee space should be 48 inches (122 cm). Teaching areas should have knee space large enough to comfortably accommodate two people sitting side by side.

8.9.4 Storage Components

The casework manufacturers offer many options for laboratory storage. These options usually are discussed in the project's design development stage, in conjunction with the casework elevations (see Section 4.4, Design Development). When choosing the storage components keep in mind that with a flexible system, the components can be moved as needs change, but in a fixed system construction will be required to change them.

Under-counter storage can consist of cabinets with doors; open cabinets; computer hard drive holders; drawers (in a variety of sizes); file cabinets; rolling carts; acid and flammable storage cabinets; keyboard trays; and specialized items for carboys, reagents, and equipment. Also to be considered are features that need to be under-counter but may not come from the casework manufacturer, such as refrigerators, freezers, glassware washers, gas tanks, carboys, and equipment and waste containers.

Wall storage components also are available in varieties to fit every need, including cabinets with doors (sliding, swinging, glass, solid), shelves, binder bins (used normally for file storage), peg boards, and components that can attach to rails for small items and special needs.

Tall storage cabinets should also be considered. These are very good for wheelchair-bound staff to access storage on the lower shelves. They are convenient, as they can be located throughout the laboratory to provide some point-of-use storage capabilities. They are also more ergonomic than wall cabinets, because one will not have to reach over counters and equipment to access supplies. NIEHS²² suggests that frequent use materials be stored no higher than shoulder height to avoid ergonomic injuries to employees. The cabinets can be purchased with doors (solid, glass, sliding, swinging) or without, which makes them useful as bookshelves in the laboratory. Open shelving also has the ability to allow employees to visually monitor the materials on the shelves, and to remove and replace items without moving or opening doors and drawers (this is one of the tenets of Lean, should Lean be incorporated in the design of the laboratory) but may not have the clean appearance of closed cabinets.

8.10 Summary Points

- Determine the type of casement system depending on budget and the need for flexibility.
- Visit sites or have a mock-up of the casework systems of interest.
- Verify heavy duty support to withstand instrument weight loads.
- Make sure countertops are no less than 30 inches (76 cm) deep.
- Consider the ergonomics of the situation when selecting casework systems.

9 Finishes

The selection of finishes for the laboratory is greatly affected by the biosafety level of the space. Other factors that can affect the selection are facility standards, budget, and color preferences. Generally, laboratory casework should be very cleanable, and the finishes should be able to withstand strong cleaning solutions and disinfecting. A rule of thumb is that there should be no fabrics in the laboratory, whether on the floor, furniture, or on partitions.

9.1 Casework

9.1.1 Countertops

Three typical countertop types used in laboratories can withstand the difficult environment: chemically resistant plastic laminate, epoxy resin, and stainless steel. Also, the construction of the top is available in several varieties. All three countertop varieties are acceptable in Biosafety Levels 1, 2, and 3. Epoxy resin is a good solution in areas where there are corrosive chemicals and in very wet areas, such as sinks. Stainless steel is good for glass-wash rooms and cold rooms.

Chemically resistant plastic laminate is usually the least expensive countertop material. It can be purchased in practically any color or pattern. Most manufacturers have standard colors with options; however, there may be cost differences between the various colors and patterns. Countertop construction is also offered in a variety of styles. Edges for plastic laminate are often offered in a standard edge (plastic laminate strip along edge), a band edge (a 3-mm strip of PVC edging), or a waterfall edge (curved continuous plastic laminate). The backsplash can be formed either as a butt curb (two separate pieces at right angles) or a form curb (continuous with a curve at the intersection).

Epoxy resin is a poured, molded, solid material. This type of countertop is now available in several colors, and the choice should be discussed with the manufacturer for options and costs. The edges can be a marine edge (curved up to contain liquids), a contoured edge (slight bevel at the corner), or a straight edge. Solid phenolic countertops are a type of black resin composite similar to epoxy resin, though it may not have some of the chemical resistance that the pure epoxy resin has. Varieties and ratings should be carefully investigated.

Stainless steel countertops are often the most expensive countertop material. They are practical for laboratory areas where there is high moisture and fire. Stainless steel should not be used if there is the possibility of exposure to bleach, as it will cause rust. A 16-gauge material that is reinforced and treated with sound-deadening should be used. Stainless steel is usually made with a marine edge. All edges should be rounded material and smoothed to avoid injury.

The use of stains in laboratories affects the type and color of countertops. Darker colors that can hide permanent stains are appropriate, especially in areas where staining sinks and automated stainers are used.

The Scientific Equipment and Furniture Association (SEFA) offers further information and some recommended practices for work surfaces in laboratories.²⁵

9.1.2 Sinks

The type of sink material used is often dependent on the type of countertop in which the sink is installed. With a plastic laminate countertop, a drop-in sink is used and can be either stainless steel (18-gauge) or epoxy resin. With an epoxy countertop, a drop-in sink of stainless or epoxy can be used, as can an epoxy integral sink (“integral” meaning that the sink and the countertop are constructed from one piece). A stainless countertop usually has an integral stainless sink. Providing an integral sink minimizes cracks that can allow water to leak or harbor microorganisms.

A freestanding handwash sink should be a porcelain wall-hung lavatory.

9.1.3 Cabinets

The material and finish of the cabinets, drawers, and shelves should be resistant to most chemicals and heat. It should also be easily cleanable.

SEFA has developed guidelines for qualities that are acceptable in laboratory casework,²⁶ including chemical resistance, hot water resistance, impact testing, paint adhesion, and paint hardness. When a decision is being made on the casework it is advisable to investigate these criteria with the manufacturers being considered.

9.2 Flooring

Laboratory flooring should be easily cleanable. Carpeting of any sort is not allowed in any BSL-2 or -3 laboratories.

In a BSL-2 typical laboratory, flooring can be either a tiled floor, such as vinyl composition tile (VCT) or rubber tiles, or monolithic flooring, such as sheet vinyl. BSL-3 laboratories must use flooring that has as few seams as possible and is not porous; this reduces the options to sheet vinyl or a poured epoxy only.

Floor bases used with any of the above flooring materials should be a coved rubber or vinyl. If sheet vinyl is used, a coved base that is integral with the flooring can also be used.

9.3 Walls

Walls should be easily cleanable and all penetrations from pipes, ductwork, or wires should be sealed. The walls themselves should go from the floor to the underside of the floor above to ensure that the laboratory is enclosed to maintain pressurization and fire resistance.

Paint should be the finish in laboratory spaces. In BSL-3 laboratories and in wet areas, epoxy paint should be used.

9.4 Ceilings

An acoustic tile ceiling is acceptable in most clinical BSL-2 laboratories. This type of ceiling should exhibit high sound absorbance ratings to minimize the noise in the laboratory. Open ceilings can be used, but exposed ductwork and lighting should be rounded and cleaned to minimize accumulation of dust.

In a BSL-3 laboratory the ceiling must be solid; a painted gypsum board ceiling is normally used. Penetrations should be kept to a minimum. Lighting should be surface mounted or sealed, and any access panels should be kept outside the room.

10 Ventilation in Laboratory Design

Ventilation is one of the most important elements in the design of a laboratory, and one of the most expensive. Indeed, the single largest demand for energy in the laboratory comes from the air-handling system. Proper ventilation not only rids the laboratory of biohazardous aerosols, noxious and/or toxic odors and vapors, but 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. The following information provides guidance on how to develop specifications for proper laboratory ventilation.

10.1 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. Particular attention is given to computerized and robotic equipment, which produce considerable heat and may have limiting operational tolerances.²⁷ Other important elements are the number of persons working in a room at one time and the influence of the exterior environment temperature (summer/winter factor). Only when this information is known can the mechanical engineer or industrial hygienist design the air-handling system to maintain appropriate temperature tolerances. Refer to Section 5.1.6, Ventilation Information.

Several temperature guidelines are available. One is the US Department of Health standard, which uses 70 ± 5 °F (21 ± 3 °C) as a guide.²³ The IBC requires a minimum of 68 °F (20 °C) at 36 inches (914 mm) above the floor.² ASHRAE cites a range of 70 to 72 °F (21 to 22 °C) as a comfortable range in all seasons.²⁸ 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%. In the United States, DHHS-acceptable ranges use 35% minimum for the winter and 55% maximum during summer months as a guide.²³ Most laboratory equipment does not have major humidity requirements and accepts a wide range of tolerances—from 30 to 70% in some cases—not difficult to maintain in most buildings.²⁰ 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.

10.2 Criteria for Supply and Exhaust

The size and number of air-handler units for a laboratory area depends on many factors: the size and volume of the area to be controlled; the heat production and operational tolerances for each instrument and device in use in the area; the number of personnel; the presence and characteristics of fume hoods and biosafety cabinets; the chemicals used in the area; and so on. Each space is unique, depending on the previously mentioned characteristics, and a mechanical engineer must take them all into account when determining the type, size, and placement of air handlers.

There are two primary types of air-handling systems in use. The first, and most common, is the constant air volume (CAV) type. The CAV system provides a relatively constant airflow based on the characteristics used to determine the area ventilation needs. The flow rate typically does not change unless major renovation of the laboratory or system occurs. The system is cheaper to install but more expensive to maintain due to its high energy consumption.

The second type of air-handling system, the variable air volume (VAV) system, provides greater flexibility in energy use because of its ability to adjust supply and exhaust air to an area, depending on changing needs, such as occupancy. A VAV system can be automatically adjusted, so it reduces supply and exhaust flow rates when the room is unoccupied, for example.

A number of factors should be used to determine the type of air-handling system for each laboratory. Both the CAV and the VAV can provide adequate air-handling systems. Decisions on the type of system depend on initial cost, ongoing maintenance, applications in use, expandability, the type of system in use throughout the rest of the facility, and other factors.

In accordance with NFPA and ANSI,^{18,20,29} because the clinical laboratory handles significant amounts of potentially biohazardous materials along with toxic and vaporous chemicals, air may not be recirculated except in an area where no chemicals or “biologicals” are handled, such as an office.

Laboratories are required to be built using 100% outside exhaust. In general, they can be constructed using the concept of 100% outside air/exhaust (also called “single-pass” air) in two ways:

- One hundred percent of the air comes into the laboratory from the outside, and 100% of the air is “exhausted” to the outside; and
- One hundred percent of the air is “exhausted” to the outside; however, the supply air may include some recirculated air from other nonhazardous areas that are permitted to recirculate air.

The latter approach enhances energy-conserving capabilities,²⁷ but requires careful planning by a mechanical engineer or industrial hygienist.

There are several reasons why 100% outside/exhaust air handling is the most desirable for laboratories, including:

- Rooms that contain fume hoods and/or biosafety cabinets, in which biohazardous materials are handled or animals are housed (rare in clinical laboratories), all require a single-pass air system.^{18,20}
- Rooms where autopsy, gross anatomy, and histology procedures are performed have a high level of aerosol and fume production and should have special ventilation requirements. Downdraft and backdraft ventilation should also be considered, because the xylene and formalin used in these departments are heavier than air. Heavier-than-air vapors do not exhaust well with the vents located on the ceiling.
- Laboratories that are built on the “open-laboratory” concept often support both hazardous and nonhazardous operations.
- One hundred percent outside exhaust prevents the transmission and recirculation of hazardous particulates, aerosols, fumes, and vapors.²⁸

Many laboratories have installed window air conditioning units to address heat loads that the house HVAC system cannot handle. Laboratories can use only those units that do not recirculate the air inside the room.

10.3 Air Changes

Air-exchange rates vary widely in the literature. For example, according to the American Institute of Architects,³⁰ the minimum total air changes per hour are six; however, this may be outmoded when one considers the computerized and robotic equipment that emit considerably more heat into the environment than previous equipment. In addition, concerns about indoor air pollution are causing an upward revision of the recommended air exchanges needed to create a more wholesome environment. However, these data are only guidelines for design. Local and state building codes, as well as specific equipment criteria, should also be consulted.

Air changes will remove biohazardous aerosols from the environment. In a study by the CDC and DHHS related to aerosols of mycobacterium in the laboratory, it was shown that 12 air changes removed 99% of the hazardous airborne particulates in 23 minutes, whereas six air changes took 46 minutes to remove the same amount.⁷

The American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHRAE) have established minimum air exchanges per hour for various types of laboratories. They suggest 6 to 10 air changes per hour in general laboratory areas (biochemistry), 12 in autopsy suites, and 10 to 15 in laboratory areas where animals are housed. OSHA⁶ requirements recommend 4 to 12 air exchanges per hour in laboratories with fume hoods, while other sources advise 10 or more air exchanges. Current thinking among ventilation designers supports the use of 10 to 12 air exchanges.²⁹ (See Table 9.)

Table 9. Minimum Suggested Ventilation Rates (Adapted from Richmond JY, ed. *Designing a Modern Microbiological/Biomedical Laboratory: Laboratory Design Process & Technology*: Washington, DC: American Public Health Association; 1997. Reprinted with permission from the American Public Health Association.)

Authority	Minimum Air Changes per Hour	Type of Area
ASHRAE	6-10	General laboratory areas
ASHRAE	12	Autopsy suites
OSHA ⁶	4-12	Areas containing fume hoods
DHHS/AIA ²³	6-10	All laboratory areas
Ventilation Designers	10-12	All laboratory areas

All these ventilation rates are to be considered minimums. In the design of the heating, ventilating, and air-conditioning (HVAC) systems for the laboratory, care is needed to thoroughly understand the following:

- the use to which each room will be put;
- the ability or capacity of the air-handling systems to cool, heat, humidify (or dehumidify), and cleanse²⁷ the air;
- the size of the space involved;
- the location of the laboratory;
- HVAC equipment within the facility;
- building constraints; and
- potential future needs.

To evaluate the efficiency of air handlers for each laboratory, consideration should be given to the development of performance standards for monitoring air exchange capabilities on a periodic basis.

10.4 Pressurization

In addition to providing for appropriate air exchanges, airflow into and out of an area is particularly important for a clinical laboratory. The overriding rule is that air should move from “clean to less clean” areas.³⁰ In other words, laboratories in general should be at a negative pressure to the corridors that serve them. Volatile and biohazardous areas within the laboratory should have air flowing into them from less hazardous areas.

The need to maintain directional airflow at all times and the magnitude of airflow needed will depend on individual circumstances. For example, “clean” rooms might have very strict positive airflow requirements. Rooms used for reagent preparation for molecular and tissue culture laboratories may also pose directional airflow concerns but require less extreme positive airflow requirements, whereas teaching laboratories might only need to maintain directional airflow during certain activities or emergency conditions. In the latter cases, one would simply use the appropriate offset to maintain directional airflow as needed and operational procedures during emergencies (e.g., close doors during a chemical spill).²⁹ Taking into account the use to which the room will be put is a key factor in determining pressurization needs. In addition, it is also important to consider the biosafety level (BSL) of each laboratory space. See Section 6, Biohazards.

10.5 Hood Types

Air that is contaminated by toxic or hazardous vapors, noxious odors, or biologic entities must be contained and eliminated. Contaminated air is handled by various types of fume hoods and biological safety cabinets.³¹

Many types of hoods are available for laboratories, including³²:

Canopy Hood: To remove odors, heat, and humidity, canopy hoods can be placed over large equipment or in areas where odors must be controlled, such as sterilizer areas or urine processing areas. Because vapors may be drawn across the worker's breathing zone before being vented, canopy hoods should not be used over areas where personnel routinely work with hazardous chemicals or severe biohazards. In addition, to maintain adequate exhaust velocity, canopy hoods require a significant quantity of room air. Some vapors tend to disperse in the air before they are exhausted; therefore, canopy hoods should not be used to exhaust toxic or flammable vapors.

Backdraft, Slot, or Spot Hoods: These hoods are extremely effective in pathology/histology areas where personnel work in close proximity to toxic/noxious vapors, e.g., while dissecting tissue, and staining and coverslipping slides. Similar to canopy hoods, these hoods use a large quantity of air, but vapors and odors are not drawn across the user's face. These hoods are placed at the back face of the workbench, usually not more than six inches above the backsplash. They are effective in removing the heavier-than-air vapors created in histology areas.

Fume Hood: Used for the removal of chemical vapors, this type of hood includes an overall enclosure with an adjustable safety glass sash and an exhaust blower-motor at the end of the system to maintain a negative pressure.

Because of their potential for explosion, most conventional hoods may not be used while handling perchloric acid when it is being heated above the ambient temperature, or if vapors are not trapped or scrubbed before entering the hood or its exhaust system. Simple activities, such as pouring perchloric acid, may be performed in a conventional fume hood.

Face velocity is the speed of the air entering the hood through the sash opening. A face velocity of 100 feet per minute (fpm) is considered the target to provide sufficient containment of fumes or vapors. Modifications to the speed should be made only after containment testing determines the actual optimal face velocity before use.

Three main types of fume hoods can be used in laboratories: the constant volume bypass fume hood; VAV fume hoods; and two-position, constant volume bypass fume hoods. Each has its advantages and its drawbacks. Decisions concerning the type of fume hood installed should be made with input from the mechanical engineer or industrial hygienist.

Lastly, whatever fume hood design is chosen, safety standards from OSHA, NFPA, ANSI/AIHA Z9.5, among others, require that the hood have a monitoring device to determine if the hood is functioning optimally and safely. There are many types available, and the decision should be made based on the use of the hood.

Exhaust ducts from laboratory hoods and other exhaust systems within the same laboratory unit may be combined within that laboratory unit and exhausted directly to the outside. However, no air exhausted from any laboratory hood may be recirculated.²⁰

Biological Safety Cabinets (BSC): The removal of infectious, biohazardous material from the air is paramount to protecting the health of laboratory employees and patients. Information regarding specific

standards for the various types of hoods should be obtained from specialized sources, depending on the use of the BSC. See Table 10 for a comparison of biosafety cabinet characteristics.

Table 10. Comparison of Biosafety Cabinet Characteristics (From Richmond JY, ed. *Designing a Modern Microbiological/Biomedical Laboratory: Laboratory Design Process & Technology*. Washington, DC: American Public Health Association. 1997:216-217. Reprinted with permission from the American Public Health Association.)

Laboratory Classification	Biosafety Level 1 / PC Level 1	Biosafety Level 2 / PC Level 2		Biosafety Level 3 / PC Level 3		Biosafety Level 4 / PC Level 4
		Low to Moderate <i>(Recommended for use with body fluids)</i>	Low to Moderate <i>(Recommended for use with body fluids)</i>	Moderate to High <i>(i.e., Carcinogens, HIV)</i>	Moderate to High <i>(i.e., HIV, TB)</i>	
Extent of potential laboratory hazard or risk to occupants:	None to very minimal	Low to Moderate <i>(Recommended for use with body fluids)</i>	Low to Moderate <i>(Recommended for use with body fluids)</i>	Moderate to High <i>(i.e., Carcinogens, HIV)</i>	Moderate to High <i>(i.e., HIV, TB)</i>	Very High <i>(Extremely lethal and exotic substances)</i>
Class and Type of Biosafety Cabinet Normally Required:	Class I <i>(Class I cabinets are frequently present, although they are not always necessary)</i>	Class II Type A	Class II Type B3	Class II Type B1	Class II Type B2	Class III
User protection provided by class and type of cabinet:	Good	Good	Better	Better	Better	Best
Minimum average face velocity of air entering through front cabinet:	75 fpm (0.38 m/s)	75 fpm (0.38 m/s)	100 fpm (0.51 m/s)	100 fpm (0.51 m/s)	100 fpm (0.51 m/s)	<i>(Not Applicable)</i> Fully Enclosed Cabinet
Amount of contamination protection the cabinet provides for the biological substance:	None*	Good	Good	Very Good	Very High	Absolute
Method of protection provided for the biological substance:	None	HEPA-filtered air stream composed of a mix of room and recirculated cabinet air.	HEPA-filtered air stream composed of a mix of room and recirculated cabinet air.	HEPA-filtered air stream composed of a mix of room and recirculated cabinet air.	HEPA-filtered air stream composed of non-recirculated room air containing no chemical vapors from within cabinet.	HEPA-filtered air stream composed of non-recirculated room air which is also environmentally conditioned.
Amount of toxic chemicals and/or radionuclides that may be used in the cabinet:	None	None	Minute quantities only	Minute quantities only	Minute quantities only	Quantities as needed

* Class I biosafety cabinets are often used to house equipment that generates aerosols, such as centrifuges and fermenters. They may be used in laboratories of biosafety levels, 1, 2 or 3 if no contamination protection is required for the biological substances within.

Table 10. (Continued)

Type of Biosafety Cabinet:	Class I	Class II Type A	Class II Type B3	Class II Type B1	Class II Type B2	Class III
Cabinet exhaust arrangement:	HEPA-filtered – Cabinet exhaust air may be returned to room or discharged outdoors via a hard duct connection.	HEPA-filtered – 30% of the cabinet exhaust air may be returned to room or discharged outside via a canopy connection. 70% is recirculated within the cabinet.	HEPA-filtered – 30% of the cabinet exhaust air is normally discharged outside via a canopy connection.** 70% is recirculated within the cabinet.	HEPA-filtered – 70% of the cabinet exhaust air is normally discharged outside via a hard duct connection. 30% is recirculated within the cabinet.	HEPA-filtered – 100% of the cabinet exhaust air is discharged outside via a hard duct connection. No air is recirculated within the cabinet.	HEPA-filtered – 100% of the cabinet exhaust air is discharged outside via a hard duct connection. No air is recirculated within the cabinet.
Environmental protection for air exhausted from cabinet:	Optional HEPA filter	HEPA-filtered	HEPA-filtered	HEPA-filtered	HEPA-filtered	HEPA-filtered
Amount of cabinet exhaust air that may be recirculated back into the laboratory room:	100%; however, most Class I applications do not recirculate the exhaust air.	30% Maximum	30% Maximum	None	None	None
Room makeup air requirements:	Must equal the amount exhausted outdoors – usually 100% of the face opening input airflow.	Must equal the amount exhausted outdoors – up to 70% of the face opening input airflow.	Must equal the amount exhausted outdoors – usually 70% of the face opening input airflow.	Must equal the amount exhausted outdoors – 100% of the face opening input airflow.	Must equal the amount exhausted outdoors – 100% of the intake airflow.	Must equal the amount exhausted outdoors – 100% of the intake airflow.
Nominal air consumption rates based on a 6-foot-wide cabinet and maximum allowable exhaust recirculation:	8”-High Opening 300 cfm 10”-High Opening 375 cfm	(Assuming outside exhaust) 8”-High Opening 210 cfm 10”-High Opening 265 cfm	8”-High Opening 280 cfm 10”-High Opening 355 cfm	8”-High Opening 410 cfm 10”-High Opening 515 cfm	8”-High Opening 900 cfm 10”-High Opening 1000 cfm	120 cfm

**If a cabinet is used in conjunction with chemicals and/or radionuclides, the exhaust connection should be a hard duct connection.

Biological safety cabinets contain potentially infectious material within the work chamber and protect the worker from aerosols. There are two general classes of BSCs: Class I and Class II. A Class I BSC operates strictly on negative pressure. Air is pulled in from the room and “exhausts” out the vent. The air quality is the same as the quality of the surrounding laboratory air, but the worker is protected from aerosols. This BSC must be vented to the outside. Class I biosafety cabinets are rarely used in clinical laboratories. Class II cabinets are divided into four subgroups: A1, A2 (formerly B3), B1, and B2. The planner should consult specialized sources for information regarding tuberculosis and other aerosol pathogen considerations in laboratory design.

Because of the use of high-efficiency particulate air (HEPA) filters, vertical laminar flow hoods (Class II BSCs) provide a low-particulate working environment within the chamber. When appropriate techniques are used, both the worker and the product inside the cabinet are protected from contamination. Class II BSCs are seen most often in clinical laboratories. Class A, A2, and B1 BSCs recirculate from 30 to 70% of the air through HEPA filters within the cabinet.

Class IIA BSCs need not be vented to the outside. Class IIB cabinets are often vented to the outside. It should be remembered that Class IA, B1, and B3 BSCs, which recirculate air into the room, should not be used with toxic, flammable, or explosive materials because of a potential buildup of hazardous materials within the cabinet or, in the case of BSC IIA, because materials are discharged back into the laboratory environment. While Class B2 cabinets exhaust all air, after filtration, to the outside, they do require a high-air demand, approximately 700 to 1200 cfm, (0.33 to 0.57 m³ per second) with concomitant-incurred energy requirements and operating costs.²⁷

Also note that only a flameless loop incinerator should be used inside BSCs, because a flame, especially from a large burner, may create turbulence and disrupt the downward laminar airflow.²⁷

The most common BSCs in use in laboratories are Class IIA and A2. The velocity of inward airflow varies from a minimum of 75 cfm (0.04 m³ per second) for Class I and Class IIA BSCs to 85 to 100 cfm (0.04 to 0.05 m³ per second) for all Class II and A2 cabinets.²⁷

Laminar Floor Hoods: Some laboratory tasks, such as large-scale media preparation, require a sterile field. A “clean room” is expensive to build and to maintain; therefore, a laminar flow hood, of the type used in the pharmacy for the sterile preparation of intravenous fluids, may be useful for a laboratory. Air flows outward from the hood and protects only the product from the environment. Because personnel are not protected, laminar flow hoods cannot be used when personnel are working with infectious, toxic, or otherwise hazardous materials. It should be noted that this type of laminar flow hood is not *required* for media preparation, and most laboratories that prepare certain media do so in Class IIA and B3 BSCs.

10.5.1 Layout Criteria

Attention should be paid to the placement of hoods in relation to doors, staff movement, and air registers. Hoods should be located away from doors and windows that could cause turbulence (NFPA 99¹⁸). The air turbulence caused by people walking past the face can also interfere with the laminar flow. It is best if hoods and BSCs are located in areas with as little traffic as possible. Air supply and return registers can cause disruption to the face flow in hoods. The engineers should locate the registers as remotely as possible. See NSF³³ for an example.

Because fume hoods often contain hazardous materials, they should not be located adjacent to or on the path to an exit door. If there are two doors in the laboratory, the hood may be on the exit path to one of them. This is noted more specifically in NFPA 99.¹⁸

10.6 Redundancy in HVAC Systems

The size of the air-handling equipment and the design of supply air ductwork must include expansion capabilities. For both the air-handling unit and accompanying ductwork, it is best to include a 15 to 25% growth in exhaust air quantities in any calculation. Future needs assessment should include design concepts that address the issues of flexibility, reliability, and potential retrofit in the laboratory air-handling systems.²⁷ For example, energy management systems are being retrofitted into air-handling systems because energy conservation and the associated cost savings are of increasing concern. If the energy management system is retrofitted without considering specialized air-handling requirements, the effectiveness of the ventilation systems could be seriously compromised.

Several different types of spot cooling devices are available, ranging in cost from relatively inexpensive to expensive. If supplemental cooling is required (for instance, in a computer room), factor its specifications into any ventilation calculations. Remember that the cooling unit itself will generate heat, take up valuable space, and be expensive to run. Air-cooled units generate the most heat, but water-cooled units are illegal in some jurisdictions. For those units that produce condensate on the cooling coils, one might place electric heat tape on the bottom of the drip pans to speed the evaporation of standing water. Spot cooling can be effective in newly expanded areas where the air-handling or exhaust system is unable to move air efficiently, in a computer room where specialized “extra” cooling is necessary, or as a temporary measure while awaiting construction of a laboratory addition.

10.7 Control

Regulation Devices: A number of control devices are available that should be accessible to appropriate personnel.

Thermostats: Because equipment varies from section to section, producing varying amounts of heat and having different operational tolerances, *each laboratory area should have its own thermostat control*. In addition, as equipment is added or removed, temperatures may need adjustment. It is not required, however, that control of the thermostats reside with the laboratory staff.

Other Controls: Other supply air-control devices should be placed to allow access for routine maintenance, performance testing, and other service activities. These include pressure-independent volume control dampers, variable air volume (VAV) dampers, reheat coils, humidifiers, filters, and other control dampers.²⁷ In addition, each air distribution system should have at least one manually operated accessible means, installed within an approved location, to stop the operation of supply, return, and, in some cases, exhaust fans in an emergency.³⁴

Some controls may be built into other operating systems. For example, an interlock device could connect lighting to exhaust fans, so when personnel are working in the area, the exhaust system is on and when the laboratory is closed and lights are off, the unneeded exhaust system is off, thus saving energy. Care must be taken to ensure that this lighting/exhaust system is off when not in use.

10.8 Code and Safety Issues

When designing a laboratory, use appropriate engineering controls.^a The use of personal protective equipment (PPE) should be the last line of defense in protecting employees from hazards. Examples of engineering controls include using sufficient air exchanges (at least 12 per hour) to keep air pure and using spot hoods to remove vapors that are heavier than air from the pathology/histology laboratory.

^a In the United States, appropriate engineering controls are required by OSHA.

Other examples could include using fume hoods and building shields into the work area, rather than relying on goggles or face shields to protect the laboratorian from aerosols.

The most common reason that formalin vapors exceed specified tolerances in pathology laboratories is due to the practice of “pouring off” formalin from sample containers before disposal. A low-lying vent close to or built into the disposal sink rectifies this problem.

When designing a laboratory, the maintenance workers who must perform their duties on the roof where air intake louvers and exhaust vents are located need to be considered. The placement of vents needs to be such that worker exposure to the material emitted from the vents is minimized.

The primary safety concern is keeping adequate levels of high-quality fresh air available, as well as removing fumes and heat from the laboratory. Additionally, temperature and humidity levels should be maintained at levels reasonable for both the comfort of the personnel and the optimal performance of equipment, test procedures, and other processes or products. Toxic or hazardous vapors and noxious odors need to be contained and eliminated in a manner that ensures that personnel have minimal-to-no contact with them. The aerosols of biohazardous materials need to be removed, so that personnel have no contact with them. Respirable elements need to be filtered out before air is dispersed within a laboratory area.

Care should be taken to keep air inlets away from helicopter pads, loading docks, and other areas where contaminated air may be introduced into the laboratory. It is not acceptable to “shut down” the air-handling system or the air intake system when helicopters are taking off or landing, as this can create a vacuum on the laboratory causing entry of dust and other environmental agents into the laboratory.

In the United States, the National Fire Protection Association (NFPA) and various national, state, and local building codes provide the fundamental precautions for laboratory ventilation. The following NFPA standards^b apply to laboratory ventilation:

- NFPA 90A, *Standard for the Installation of Air Conditioning and Ventilating Systems*, 2002 edition;
- NFPA 90B, *Standard for the Installation of Warm Air Heating and Air Conditioning Systems*, 2002 edition;
- NFPA 30, *Flammable and Combustible Liquids Code*, 2003 edition; and
- NFPA 45, *Fire Protection for Laboratories Using Chemicals*, 2000 edition.

These other authorities address laboratory ventilation:

- *OSHA Safety and Health Standards for General Industry*. Available from the Occupational Safety and Health Administration, US Department of Labor, US Government Printing Office, Washington DC, 20402. Published in the Federal Register, 29CFR1910, December 6, 1991;
- State and local building codes (usually based on one of the national codes);
- *Biosafety in Microbiological and Biomedical Laboratories*. HHS Publication No. (CDC) 93-8395, 1993. Available from the US Government Printing Office, Washington, DC;

^b Available from the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.

- *Heating, Ventilating, and Air Conditioning Systems*. American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc.; 1995.
- *Heating, Ventilating, and Air Conditioning Applications*. American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc.; 1996.
- *ASHRAE Laboratory Design Guide*. American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc.; 2001.

10.9 Summary Points

When designing the ventilation for a laboratory, keep the following points in mind:

- Factor in all equipment performance criteria, including heat exhaust and operating tolerances.
- Factor in the biosafety level for the area vented.
- There should be a **minimum** of 6 to 12 air exchanges per hour, depending on the use and contents of the space.
- There should be 100% exhaust to the outside for all technical work areas. Supply air may include air from other nonhazardous, nonlaboratory areas. Air from laboratories must not be recirculated within a facility.
- Laboratory areas should be at a negative pressure relative to corridors. The rule of thumb is that air should move from clean to less clean areas, with specific exceptions.
- There should be a thermostatic control for each laboratory area.
- Design in engineering controls for safety and protection of workers.
- Use backdraft and downdraft hoods for exhausting large concentrations of heavier-than-air vapors.
- Supply air should be filtered only for dust and should be brought in from a source away from any contaminated air. (The design characteristics of filtering systems and filter beds should be defined according to clinical needs.)
- The air-handling system should permit supplemental cooling (e.g., fan coil units) where heat load is high.
- Allow for growth of exhaust requirements (15 to 25%) for air-handling systems and accompanying duct work in the original design for ventilation.
- Locate hoods where the airflow will not be compromised.

11 Electrical and Communications

11.1 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.

11.1.1 Volts

Typical levels of power are 110 to 120 v and 208 to 220 v.

11.1.2 UPS

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 a large system should be used that will support the whole laboratory. The small units for 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.

11.1.3 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 items to be connected should be those necessary for emergency testing and those for which patient samples will be lost if the analyzer shuts off during testing. On smaller units, such as microscopes, mixers, printers, etc., it is prudent to make sure that some emergency power outlets are distributed around the laboratory to use if necessary. Often one extra emergency outlet per casework run can be enough. This should be discussed with the facilities engineers due to the limited capabilities of the generators and possible facilities standards. Instruments that could be harmed, or testing lost, when the generators are tested should be equipped with loaded line phase shifter (LLPS) or battery backup.

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

11.2 Communication

Computerization has revolutionized the way testing is done and reports are 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.

A meeting during the design stage (typically during design development) needs to include the engineers, the LIS representative, HIS representative, and laboratory personnel. LIS vendors or robotic sample handling manufacturers may also need to be included if the department representatives are unsure of the needs for the systems planned.

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.

Be sure to include requirements for networking and modems on the equipment list.

11.3 Summary Points

- Include electrical and data specifications on the equipment sheet.
- Analyze carefully the need for emergency power.
- Provide enough outlets and computer connections for expansion and flexibility.

12 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. Some specific standards for orientation and levels of lighting should be addressed.

12.1 Lighting Levels

The amount of illumination (or lighting level) needed is determined by the type of task to be performed, the color of the work surface, 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 11). The electrical engineer assigned to the project calculates this information and coordinates with the architect/consultant and the laboratory managers to ensure the light levels and types of lighting are appropriate for the procedures performed.

Recommended lighting levels have been developed by the Illuminating Engineering Society of North America (IESNA).³⁵ 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. For further information, refer to IESNA RP-29-95, *Lighting for Hospitals and Health Care Facilities*.³⁵

Table 11. Ranges of Illuminance

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

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.

Once these details are addressed and criteria are determined, an appropriate lighting fixture can be selected, which will establish the spacing and the number of fixtures needed to illuminate a specific area.

12.2 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. Task lights 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 bounce less light to undersides of objects, making it harder to see.

12.3 Light Fixtures

Lighting fixtures need to be easily cleanable and reduce glare.

Typically a recessed fluorescent fixture, either 24 by 48 inches (61 cm by 122 cm) or 24 by 24 inches (61 cm by 61 cm) with a parabolic lens is placed in the ceiling grid. These direct light fixtures are very

effective, because the parabolic lens reduces glare on computer screens, and all the light from the fixture points down directly onto work surfaces. The spacing and quantity of fixtures is determined by the engineer to provide the specific lighting level required.

A direct/indirect fixture is one that points up and down. This type of fixture throws some of the light down directly onto the work surface and throws other light up so it will reflect off the ceiling. For these fixtures, the ceiling should be light-colored to allow reflection of the light. The advantage of direct/indirect fixtures is that the balance of light eliminates shadows and dark spots that are created by having all the light point down. (Dark spots are those areas of light and dark on the ceiling that can be reflected on computer screens.) These fixtures require a higher ceiling height to allow 18 inches (46 cm) between the fixture and the ceiling above and still be high enough to clear head height, the tall cabinets, and tall laboratory equipment. The advantage of direct/indirect fixtures is the greater flexibility for the laboratory space and, due to the uniform overall light, the arrangement of the lights to minimize shadows is not critical. They have the disadvantage of being more costly than the recessed fluorescent fixtures.

Areas where microscopy is performed may benefit from dimmers on lights. Dimmers are often added to pathology offices, multihead microscope rooms, and cytology screening rooms, to allow the users to adjust the light level for more comfortable microscopy work.

The use of motion-activated lighting is particularly effective in areas that are intermittently occupied, such as support spaces and offices. This technology works well and, if installed correctly, eliminates wasted energy.

12.4 Expandability

The most successful method of providing for expansion or increased use of a specific area is to design a good uniform illumination system from the start, which allows for reconfiguration of the area but precludes having to pay a premium or being inconvenienced with costly shutdowns. Illumination levels can be occasionally augmented, without requiring additional overhead lights, by introducing additional task lighting at the work surface.

If the future functions of a specific area are known, empty conduits can be installed where additional luminaries might be required. When it becomes necessary to add lights, additional wires can be pulled into the empty conduit to accommodate the new lights. By wiring the original lights with flexible “pig tails” (where permitted by code) and using a lay-in ceiling, the spacing of existing lights can be easily modified at minimal cost.

To facilitate this process, it is necessary to provide additional capacity in the lighting panels to accommodate the increased electrical load.

12.4.1 Emergency Lighting

Emergency lighting is used to provide:

- evacuation in case of emergency; and
- life-support services to patients who are unable to be evacuated.

Evacuation lighting is usually provided at low levels that direct patients and staff to exit routes. In corridors and support areas evacuation lighting is usually set at 3 foot-candles; in the laboratory itself it is normally set at 5 foot-candles.³⁵

To support safety of the staff and patients, the laboratory must retain general illumination, even in the case of a catastrophic incident. Some emergency electrical outlets should be added that can be used to plug in task lights in the case of a prolonged power outage. These extra outlets should not replace the emergency outlets necessary for essential instrumentation.

12.5 Codes, Regulations, and Safety

The electrical engineer and the electrical contractor should ensure that fixtures and installation meet local, state, and federal codes.

12.6 Summary Points

- Provide proper light levels for the tasks.
- Arrange ceiling lights perpendicular to casework as much as possible.

13 Plumbing

13.1 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.

13.2 Deionized (DI) Water

DI water is required for many laboratory practices and analyzers. Either point-of-use DI systems 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 also be used with reverse osmosis (RO) water, which is easily provided by a point-of-use RO system adjacent to the unit.

Refer to the most current edition of CLSI document C3—*Preparation and Testing of Reagent Water in the Clinical Laboratory* for more detailed information.

13.3 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 usually are made of epoxy resin or stainless steel. Integral sinks are integral 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 handwashing large cylinders and flasks, or pouring out of large containers. Occasionally, a very small sink is appropriate, such as when blood bank testing staff is pouring off supernatant from tubes. Many analyzers and stainers can drain into a cup sink.

Clean sinks are those designated for handwashing only and are required in clinical laboratories.⁶ 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 handwash sink must be used hands-free, which can include foot pedal controls or electric eye operators. Such hands-free operators are not required, but very useful in all other laboratory areas. The handwash 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.

13.4 Emergency Eye Wash

Temperate water must be provided for emergency eyewash stations. This water temperature is not specific, but should be such that it is safe for the user. ANSI notes that a comfortable range is between 60 and 95 °F (15 to 35 °C). The water pressure from the eye wash cannot be so strong that it causes harm to the user's eyes. ANSI recommends 0.4 gallons (1.5 L) per minute.

13.5 Emergency Flood Shower

The flood showers should be set to deliver 30 gallons (114 L) per minute of temperate water. A comfortable temperature range is 72 to 74 ± 5 °F (40 to 41 ± 3 °C).²¹ Providing a drain for flood showers is not a requirement, but it is definitely a prudent practice. The drains should have a trap primer to ensure the drain does not dry out or allow insects or gases to escape into the laboratory area.

13.6 Gases

In the past it was typical to find natural gas, air, and vacuum in the clinical laboratory, and was in fact required by the US Department of Health for all clinical laboratories. This requirement has since been deleted.³⁰

Natural gas was used by Bunsen burners, which have been replaced by disposable wands or electric incinerators. Laboratories still using Bunsen burners should look at alternatives that allow their elimination, because the open flame is a fire hazard.

Compressed air is still used for centrifuges and automation systems. Centrifuge air can be provided by a small point-of-use air pump if that is the only need. Automation systems have specific criteria for air cleanliness; often the house systems do not meet these requirements. In such cases, the manufacturer usually can provide an air pump that meets specifications. Good practice is to provide a separate closet to house the pumps, which will isolate the noise and vibration.

Vacuum is still used for some methods and instruments. Point-of-use vacuum generators can be placed where needed when a house system is not available or is too expensive to install, such as in microbiology areas that use the vacuum to suction supernatant liquid from a sample.

Other gases are usually provided from gas cylinders that can be located adjacent to the equipment or in a fire-rated gas storage closet, where the gas is manifolded and plumbed to nozzles in the laboratory. Refer to Section 7.2.3, Gas Cylinder Storage, for specific information on safety for gas cylinders in the laboratory.

13.7 Waste Water

In today's clinical laboratory, fewer chemicals are going down the drains than in the past. The quantities are very small, and are generally heavily diluted with water before passing to the drains. There are exceptions, depending on the type of testing the laboratory is performing and the equipment used. It is important to analyze what types of waste are going down the drains and verify that the drain system can handle them properly. The local waste water authority should be consulted to ensure compliance with local rules and codes.

Many laboratories are required to recycle waste liquids and/or to empty them into carboys for proper disposal by local authorities. This method of waste liquid disposal should be verified during the design stage.

Where liquid waste is high in chemical and corrosive content, a holding and dilution tank with acid waste lines should be provided. If not, a standard plumbing arrangement can be used.

13.8 Sprinkler Systems

Sprinklers are very important in the laboratory, and construction must be handled differently when a system is not available. Some situations in which construction varies are noted in Section 7, Health and Safety.

When the laboratory is below-grade level, it must be provided with an automatic sprinkler system, whether or not the overall building has one.¹⁷⁻¹⁹ NFPA requires healthcare facilities to be sprinklered, as does IBC.² When the laboratory is located in a business-type occupancy, IBC does not require sprinklers, but they are encouraged.

13.9 Flexibility

Plumbing is probably the most difficult system for providing design flexibility; however, some methods can be used to make the changes easier.

The location of drains can be one of the biggest limiting factors in laboratory design, making otherwise flexible laboratory designs revolve around drain locations. When initially designed, the drains can be placed on a grid system, allowing for extra capped drains to permit more flexibility in the laboratory for moving drain-dependent instrumentation, or to add/move sinks with no or minimal construction.

Hot, cold, and DI water and gas lines should run through piping in the ceiling, and from there down to the sink or instrument. Casework manufacturers can provide ceiling enclosures that run from the ceiling to the casework or the floor just for this purpose; thus, it is much easier to access the plumbing lines when they need relocation.

13.10 Summary Points

- Provide appropriate DI water for the equipment and procedures with a full-house loop system or point-of-use systems.
- Provide dirty sinks for procedure effluent and clean sinks for handwashing.
- Provide proper water pressure and temperature for emergency showers and eyewash stations.

- Provide gases as needed from house systems, gas cylinders, or point-of-use generators.
- Be aware of and include design flexibility wherever possible.

14 Conclusion

Designing a laboratory is a highly involved and complex process. This CLSI guideline should be used to facilitate laboratory scientists', architects', and engineers' understanding of the design process and increase awareness of various criteria unique to laboratory design and construction. Additional regional, state, local, and private authority requirements related to laboratory design and construction and overall building construction must be addressed by architects and engineers in every project.

Appendix. Code/Design Resources

American Board of Forensic Toxicology

<http://www.abft.org/>

American National Standards Institute (ANSI)

American National Standard for Emergency Eyewash and Shower Equipment
11 W. 43rd Street
New York, NY 10036
www.ansi.org

American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)

1791 Tullie Circle, NE
Atlanta, GA 30329-8400
Tel: (404) 636-8400
Fax: (404) 321-5478
www.ashrae.org

Americans With Disabilities Act (ADA)

US Department of Justice
Disability Rights Section
P.O. Box 66738
Washington, DC 20035-6738
Toll Free: (800) 514-0301
TTY: (800) 514-0383
www.usdoj.gov/crt/ada/taprog.htm

ASHRAE Laboratory Design Guide

McIntosh IBD, Dorgan CB, Dorgan CE.
American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2001

Biosafety in Microbiological and Biomedical Laboratories; 4th Edition

CDC, NIH, US Department of Health and Human Services
US Government Printing Office, Washington, DC; 1999

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road
Atlanta, GA 30333
Tel: (800) 311-3435
www.cdc.gov

Clinical and Laboratory Standards Institute (CLSI)

Laboratory Design; Approved Guideline (GP18-A2)
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898
Tel: (610) 688-0100
Fax: (610) 688-0700
www.clsi.org

College of American Pathologists (CAP)

325 Waukegan Rd.
Northfield, IL 60093
www.cap.org

Design and Planning of Research and Clinical Laboratory Facilities

Mayer L.
John Wiley and Sons, Inc., New York, NY; 1995

Forensic Laboratories: Handbook for Facility Planning, Design, Construction, and Moving
Research Report
Office of Law Enforcement Standards, National Institute of Justice
April 1998
<http://www.ncjrs.org/txtfiles/168106.txt>

Guidelines for Design and Construction of Hospital and Health Care Facilities
The American Institute of Architects Academy of Architecture for Health, The Facilities Guidelines Institute,
US Department of Health and Human Services
The American Institute of Architects Press, Washington, DC; 2001

Guidelines for Laboratory Design: Health and Safety Considerations
Third Edition
DiBerardinis LJ, Baum JS, First M, Gatwood GT, Seth AK.
John Wiley & Sons, Inc, New York, NY; 2001

Illumination Engineering Society of North America (IES)
120 Wall St., 17th Floor
New York, NY 10005
www.iesna.org

Institute of Environmental Sciences and Technology
5005 Newport Drive, Suite 506
Rolling Meadows, IL 60008-3841
Tel: (847) 255-1561
Fax: (847) 255-1699
www.iest.org

International Code Council (ICC)
4051 W. Flossmoor Rd.
Country Club Hills, IL 60478
Tel: (708) 799-2300
Fax: (708) 799-4981
www.iccsafe.org

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
www.jcaho.org

Laboratories: A Guide to Master Planning, Programming, Procurement, and Design
Dahan FW.
W.W. Norton & Co, New York, NY; 2000

Lighting for Hospitals and Health Care Facilities, IESNA RP-29-95
IESNA Committee for Health Care Facilities
120 Wall St, New York, NY; 1995

Lighting Research Center
Rensselaer Polytechnic Institute
Troy, NY 12180
www.lrc.rpi.edu

National Fire Protection Association (NFPA)

- *45 Fire Protection for Laboratories Using Chemicals*
- *50 Flammable and Combustible Liquids Codes*
- *99 Health Care Facilities*
- *101 Life Safety Code*

1 Batterymarch Park
Quincy, MA 02269-9101
Tel: (617) 770-3000
Fax: (617) 770-0700
www.nfpa.org

National Institutes of Health (NIH)**NIH Design Criteria D37**

Spring 2003
9000 Rockville Pike
Bethesda, MD 20892
Tel: (301) 496-4000
www.nih.gov

Occupational Safety and Health Administration (OSHA)

US Department of Labor
200 Constitution Ave., NW
Washington, DC 20210
Tel: (202) 693-1999
www.osha.gov

Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets

CDC, NIH, US Department of Health and Human Services
US Government Printing Office, Washington, DC; 1995

Scientific Equipment and Furniture Association (SEFA)

1205 Franklin Ave., Suite 320
Garden City, NY 11530
www.sefalabs.com

Society of Forensic Toxicologists

P.O. Box 5543
Mesa, AZ 85211-5543
<http://www.soft-tox.org/>

United States Department of Health and Human Services (DHHS)

200 Independence Ave, SW
Washington, DC 20201
Tel: (202) 619-0257
Toll Free: (877) 696-6775
www.hhs.gov

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Clinical and Laboratory Standards Institute consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information, contact CLSI or visit our website at www.clsi.org.

Summary of Comments and Subcommittee Responses

GP18-A: *Laboratory Design; Approved Guideline*

General

1. Future laboratories will use robotics to increase efficiency. This will mean fewer people moving about the laboratory, less need for benches and storage, and thus a change in space requirements. Therefore, the working group may wish to address the topic of automation by reminding the laboratorians that future mechanization will require flexibility in design.
- **Concepts related to the introduction of automation and robotics in the laboratory have been introduced throughout the document.**

Summary of Delegate Comments and Working Group Responses

GP18-A2: *Laboratory Design; Approved Guideline—Second Edition*

General

1. There are a good number of laboratories that employ window air conditioners in testing areas. Could the working group address this directly?
 - **Information on installed window air conditioners has been added to Section 10.2.**

Foreword

2. Although the recommendations are based almost exclusively on USA building and safety codes, the foreword appropriately explains the practical necessity for this approach to provide useful guidelines and points out that other countries should refer to local codes and safety regulations. I have identified two places where further clarification is needed in the text.

Section 6.2, page 40, “42 CFR 72.6” is not an adequate reference to Federal Register for users outside the USA.

Section 10.1, page 72, second paragraph, add “USA” before Department of Health so the reader will know which country’s department is being referenced.

- **Suggested modifications to the referenced sections have been made to address the commenter's concerns.**

Section 3, Definitions

3. Technical laboratory terminology has not been used, e.g., centrifuge, corrosive, percutaneous are of a layperson level.
 - **The definitions included in GP18 are not geared towards laboratorians; rather towards lay readers instead as architects, engineers, facilities staff, and others in the construction industry will use this guideline as a reference.**

Section 4, Design Process

4. The laboratory medical director should be a decision maker in addition to the laboratory manager.
 - **As recommended, the laboratory medical director has been included as a representative of the laboratory administration portion of the design team.**

Section 4.2.4.1, Equipment Information

5. Add serial # or number of the instruments of the same model to information to collect.
 - **The bulleted text has been modified as suggested.**

Section 4.2.4.2, Program and Area Analysis

6. Please define “NSM.” This abbreviation appears in Table 1 next to “NSF.” It is not defined in either the text or table of contents. I inferred this abbreviation to mean “net square meters.” Is this correct?
 - **“NSM” is defined as net square meter. This abbreviation has been added to Section 3.2 on Abbreviations.**
7. Table 1: Use @ or “at” consistently.
 - **The term “at” has been introduced for consistency as recommended.**

Section 4.8, Moving In

8. Third paragraph—Instruments may require revalidation as well as recalibration because of temperature or airflow changes. These procedures can be done by laboratory staff and do not have to be done by service.

- **The text has been modified to address the commenter's concern.**

Section 4.10, Lean Design Concepts

9. Seventh bullet on “waiting”: correct the spelling of “and.”

- **This typographical correction has been made.**

Section 5.1, Equipment Documentation

10. There are some commercial manufacturers mentioned that need to be deleted to avoid the possible interpretation of endorsement by CLSI. Remove vendor names from Table 3 and use generic equipment names.

- **The text has been modified as suggested.**

Section 5.2.1.1, Information for Manufacturers

11. Eighth bullet: Remove parentheses around LIS.

- **The parentheses have been removed.**

Section 5.2.2, Layout Criteria

12. Instead of the word “one” replace with “laboratory.”

- **The text has been modified as suggested.**

Section 6.1, Determining Biosafety Levels

13. Second paragraph, second sentence: Use “dispersed” instead of “dispensed” to be consistent with aerosol definition.

- **The text has been modified as suggested.**

14. The set of bullets should state they are examples of typical ways to create aerosols. There are others, e.g., uncapping specimens.

- **The bulleted list has been qualified as examples to address the commenter's concern.**

Section 6.2, Designing for Biosafety Levels

15. This section states that there should be screens on windows. In a new or renovated laboratory, should there be windows that open?

- **The information about windows is taken directly from the CDC/NIH guidelines. Open windows with screens are permitted in BSL2 laboratories as noted. Text has been added to Section 6.2 for clarification.**

Section 7.2.3, Gas Cylinder Storage

16. It would be useful if the section on gas cylinder storage could address the issue of several gas cylinders bolted and chained to the wall together, i.e., one chain around multiple cylinders.

- **The text has been modified to address the commenter's concern.**

Section 7.9, Emergency Eyewash Stations and Flood Showers

17. Fourth and fifth bullet: There is an error that appears twice on page 51—100 feet equals 30.48 meters, not 2.54 meters.

- **The measurements have been corrected.**

Section 8.2.5, Surgical Pathology

18. Delete “have” from first line of third paragraph.

- **This editorial correction has been made.**

Section 10.1, Temperature and Humidity

19. Second paragraph, first sentence: Remove extra 5 after temperatures.

- **This typographical error has been corrected.**

Section 11.1.3, Emergency Power

20. Is there a definition of LLPS?

- **LLPS is an abbreviation for “loaded line phase shifter.” The abbreviation has been added to Section 3.2 and Section 11.1.3.**

Section 13.2, Deionized (DI) Water

21. This section includes an obsolete table (Table 12) describing types of DI water. The text should be corrected to reflect the newly published recommendations in CLSI C3-A4 which no longer uses that designation for water purity, nor the purity parameters included in the table. It would be satisfactory to delete the sentence beginning “Several types of DI water ...” and Table 12. The last sentence referring the reader to the most recent edition of CLSI document C3 is adequate.

- **The text has been modified as suggested.**

22. Table 12, Types of DI Water, contains errors.

- **Table 12 has been deleted in response to Comment 21 above.**

Appendix

23. There are some commercial manufacturers mentioned that need to be deleted to avoid the possible interpretation of endorsement by CLSI.

Delete Fisher Hamilton Product Specification Catalog. Delete US Filter Water Purification Products Catalog (also delete US Filter from Table 12 in Section 13.2 as mentioned in a separate comment).

- **The text has been modified as suggested. See also response to Comment 21 above.**

References

24. Please note that Reference 1 should be ISO/IEC 17011 and not ISO/IEC 1711.

- **The reference has been corrected.**

NOTES

The Quality System Approach

Clinical and Laboratory Standards Institute subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*. The quality system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any healthcare service’s path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are:

- | | | | |
|--|--|--|--|
| Documents & Records
Organization
Personnel | Equipment
Purchasing & Inventory
Process Control | Information Management
Occurrence Management
Assessment—External and
Internal | Process Improvement
Service & Satisfaction
Customer Facilities |
|--|--|--|--|

GP18-A2 addresses the quality system essentials (QSEs) indicated by an “X.” For a description of the other Clinical and Laboratory Standards Institute documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
											X GP17 M29

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Related CLSI/NCCLS Publications*

- C3-A4** **Preparation and Testing of Reagent Water in the Clinical laboratory; Approved Guideline—Fourth Edition (2006).** This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.
- GP17-A2** **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.
- M29-A3** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on U.S. regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents; and recommendations for the management of blood-borne exposure.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

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(Auckland, New Zealand)
North Shore-Long Island Jewish Health
System Laboratory (NY)
Northern Plains Laboratory (ND)
Northwestern Memorial Hospital (IL)
Ochsner Clinic Foundation (LA)
Oklahoma Heart Hospital, LLC (OK)
Onze Lieve Vrouw Ziekenhuis
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Center (CA)
Orlando Regional Healthcare System
(FL)
Overlook Hospital (NJ)
Palisades Medical Center (NJ)
Parker Adventist Hospital Laboratory
(CO)
Parkland Health Center (MO)
PathWest (WA)
Pathology Associates Medical
Laboratories (WA)
Pathology Associates of Boone (NC)
Pediatrix Screening Inc. (PA)
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(BC)
Physicians Reference Laboratory (KS)
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(CO)
PPD (KY)
Prince George Medical Lab (Prince
George, BC)

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Capistrano, CA)
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Arabia)
St. Anthony Hospital Central Laboratory
(CO)
St. Anthony Hospital North Laboratory
(CO)
St. Anthony's Hospital (FL)
St. Barnabas Medical Center (NJ)
St. Christopher's Hospital for
Children (PA)
St. Eustache Hospital (Quebec,
Canada)
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Center (MI)
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St. Joseph Medical Center (MD)
St. Joseph Mercy (WI)
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Center Laboratory (CO)
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Health Sciences Centre (Toronto,
Ontario)
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Canada)
Sydney South West Pathology Service
(Australia)

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Medicine
Temple Univ. Hospital - Parkinson Pav.
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Services (TX)
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(Canada)
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The Hospital for Sick Children (Canada)
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The Ottawa Hospital (Canada)
The Permanent Medical Group (CA)
The Public Health Laboratory, H47 (AR)
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