LABORATORY BIOSAFETY MANUAL
FOURTH EDITION
AND
ASSOCIATED MONOGRAPHS

LABORATORY DESIGN AND MAINTENANCE

World Health Organization

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Laboratory design and maintenance

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Glossary of terms

Accident: An inadvertent occurrence that results in actual harm such as infection, illness, injury in humans or contamination of the environment.

Accreditation: The assessment and attestation of competency.

Aerosol: Liquid or solid particles suspended in air and of a size that may allow inhalation into the lower respiratory tract (usually less than 10 micrometres in diameter).

Biological agent: A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants.

Biological safety cabinet (BSC): An enclosed, ventilated working space designed to provide protection to the operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Containment is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Exhaust air is passed through a high-efficiency particulate air (HEPA) filter before recirculating into the laboratory or into the building's heating, ventilation and air conditioning system. There are different classes (I, II and III) of BSCs that provide different levels of containment.

Biosafety: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

Biosecurity: Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release.

Bunding: A tank of a minimum height used to contain spills which can then be drained or pumped under control. It is usual to provide bunding which has a volume equivalent to 110% of the potential spill volume.

Calibration: Establishment of the relationship between the measurement provided by the instrument and the corresponding values of a known standard, allowing correction to improve accuracy. For example, laboratory equipment such as pipetting devices may need calibration periodically to ensure proper performance.

Certification: A third-party testimony based on a structured assessment and formal documentation confirming that a system, person or piece of equipment conforms to specified requirements, for example, to a certain standard.

Clean: Visually free of soil and below specified levels of analytes.

Commissioning: Process of bringing an item into operation and ensuring that it is in good working order. On building projects, commissioning refers primarily to building services.

Commissioning agent: Individual or company independent of the builder that does the commissioning work.

Consequence (of a laboratory incident): The outcome of an incident (exposure to and/or release of a biological agent) of varying severity of harm, occurring in the course of laboratory operations. Consequences may include a laboratory-associated infection, other illness or physical injury, environmental contamination, or asymptomatic carriage of a biological agent.

Containment: The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

Contamination: The introduction of undesired biological agents into tissues and specimens or onto surfaces.

Core requirements: A set of minimum requirements defined in the fourth edition of the World Health Organization (WHO) *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

Decommissioning: Process of stopping work, decontaminating and making safe a facility such that residual risk in the facility is reduced to an acceptable risk. Decommissioning may be followed by re-commissioning, repurposing or demolition.

Decontamination: Reduction of viable biological agents or other hazardous materials on a surface or object(s) to a pre-defined level by chemical and/or physical means.

Design features: Practical and commonly used design solutions used to meet and satisfy stated design requirements. This could be a hand-washing basin with a knee-operated water tap, or a window allowing vision through a door or into a space.

Design requirements: Stated features required by a needs assessment which must be included in the design and which are set out in the user requirement specification.

Design team: A group of (professional) people brought together with the main purpose of designing a building, including specifications and drawings, schedules and programmes. They may be the same as, different to, or part of a construction team.

Directional airflow: Air moving from an active (caused by an intentional force) or passive (air movement as a secondary effect) air source to an active extraction location.

Disinfectant: Agents capable of eliminating viable biological agents on surfaces or in liquid waste. These will have varying effectiveness depending on the properties of the chemical, its concentration, shelf life and contact time with the agent.

Emergency response: An outline of the behaviours, processes and procedures to be followed when handling sudden or unexpected situations, including exposure to or release of biological agents. The goal of an emergency response is to prevent injuries or infections, reduce damage to equipment or the environment, and accelerate resumption of normal operations.

Engineering controls: Risk control measures that are built into the design of a laboratory or laboratory equipment to contain the hazards. Biological safety cabinets (BSCs) and isolators are forms of engineering control in order to minimize the risk of exposure to and/or unintended release of biological agents.

Exposure: An event during which an individual comes in contact with, or is in close proximity to, biological agents with the potential for infection or harm to occur. Routes of exposure can include inhalation, ingestion, percutaneous injury and absorption and are usually dependent upon the characteristics of the biological agent. However, some infection routes are specific to the laboratory environment and are not commonly seen in the general community.

Fumigation: Use of a poisonous gas or vapour to remove contamination of a biological agent from a surface, piece of equipment or area.

Good microbiological practice and procedure (GMPP): A basic laboratory code of practice applicable to all types of laboratory activity with biological agents, including general behaviours and aseptic techniques that should always be observed in the laboratory. This code serves to protect laboratory personnel and the community from infection, prevent contamination of the environment and provide protection for the work materials in use.

Handover: An important and irreversible event when ownership of and all responsibility for the project passes from the builder to the user or owner.

Hazard: An object or situation that has the potential to cause adverse effects when an organism, system or (sub)population is exposed to it. In the case of laboratory biosafety, the hazard is defined as biological agents which have the potential to cause adverse effects to personnel and/or humans, animals, and the wider community and environment. A hazard does not become a "risk" until the likelihood and consequences of that hazard causing harm are taken into account.

Heightened control measures: A set of risk control measures as described in the WHO *Laboratory biosafety manual* that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a risk that cannot be brought to an acceptable risk with the core requirements only.

High efficiency particulate air (HEPA) filter: These filters are composed of many randomly oriented fibres that create a fibrous matrix through which air can pass. Particles travelling with the air may be captured by the fibres, effectively filtering the air.

Inactivation: Removal of the activity of biological agents by destroying or inhibiting reproductive or enzyme activity.

Incident: An occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm.

Infectious dose: The amount of biological agent required to cause an infection in the host, measured in number of organisms. Often defined as the ID_{50}, the dose that will cause infection in 50% of those exposed.

Inward airflow: Passive or active airflow that comes from outside a room or device.

Likelihood (of a laboratory incident): The probability of an incident (that is exposure to and/or a release of a biological agent) occurring in the course of laboratory work.

Maximum containment measures: A set of highly detailed and stringent risk control measures described in the fourth edition of the WHO *Laboratory biosafety manual* that are considered necessary during laboratory work where a risk assessment indicates that the activities to be performed pose very high risks to laboratory personnel, the wider community and/or the environment, and therefore an extremely high level of protection must be provided. These are especially needed for certain types of work with biological agents that may have catastrophic consequences if an exposure or release were to occur.

Needs assessment: A structured analysis to determine what purpose the proposed building and its systems are required to serve based on all planned activities to be carried out.

Personal protective equipment (PPE): Equipment and/or clothing worn by personnel to provide a barrier against biological agents, thereby minimizing the likelihood of exposure. PPE includes but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators.

Procurement: The process of purchasing goods or services. There are many different routes by which the design and construction of a building can be procured.

Project manager: A project manager is a specialist adviser who represents the laboratory management/facility owner and is responsible for the day-to-day management of a project.

Qualification: A performance ensuring process typically associated with validation of complex systems and equipment.

Redundancy: Repetitions of systems or parts of a system to provide protection in the case of a primary system failure. For example, a series of high efficiency particulate air (HEPA) filters in case one or more fail when used to move laboratory air to the outside environment.

Residual risk: Risk that remains after carefully selected risk control measures have been applied. If residual risk is not acceptable, it may be necessary to apply additional risk control measures or to stop the laboratory activity.

Risk: A combination of the likelihood of an incident occurring and the severity of the consequences (harm) if that incident were to occur.

Risk assessment: A systematic process of gathering information and evaluating the likelihood and consequences of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk to an acceptable risk.

Risk control measure: Use of a combination of tools, which include communication, assessment, training, and physical and operational controls, to reduce the risk of an incident/event to an acceptable risk. The risk assessment cycle will determine the strategy that should be used to control the risks and the specific types of risk control measures required to achieve this.

Safety culture: A set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting atmosphere by individuals and organizations working together to support or enhance best practice for laboratory biosafety, irrespective of whether it is stipulated in applicable codes of practice and/or regulations.

Sharps: Any device or object that is a puncture or wound hazard because of its pointed ends or edges. In the laboratory, sharps can include needles, syringes with attached needles, blades, scalpels or broken glass.

Soap: A water soluble cleaning compound used for cleaning skin and other materials. Note, soap does not necessarily inactivate biological agents.

Standard operating procedures (SOPs): A set of well-documented and validated stepwise instructions outlining how to perform laboratory practices and procedures in a safe, timely and reliable manner, in line with institutional policies, best practice and applicable national or international regulations.

Sterilization: A process that kills and/or removes all biological agents including spores.

Testing (of laboratory design features and equipment during construction and/or maintenance): A physical check that an entity meets a specified need or target figure. Testing is normally included with other activities such as commissioning, validation and verification. For example, tests can be of water pressure, water quality and/or light level.

Transmission: The transfer of biological agent(s) from objects to living things, or between living things, either directly or indirectly via aerosols, droplets, body fluids, vectors, food/water or other contaminated objects.

User requirement brief: An outline documented statement defining the requirements identified by the user that must be fulfilled by the completed project.

User requirement specification: A detailed documented statement defining all the requirements identified by the user (during the needs assessment) that must be fulfilled and verified by the completed project.

Validation: Systematic and documented confirmation that the specified requirements are adequate to ensure the intended outcome or results. For example, in order to prove a material is decontaminated, laboratory personnel must validate the robustness of the decontamination method by measurement of the remaining biological agents against the detection limit by chemical, physical or biological indicators.

Verification: Confirmation that a given item (product, process or system) satisfies the specified requirements. For example, verification that the performance of an autoclave meets the standards specified by the manufacturer should be performed periodically.

Workflow (laboratory workflow): A stepwise analysis of planned processes in the laboratory that enables understanding and communication of the sequential steps in each process and what facilities, services, systems and space are required at each step. The workflow can be further broken down into the flow of personnel, specimens, materials and waste.

Executive summary

The planning, design, construction, operation and maintenance, as well as the renovation and repurposing, of laboratories is a vast subject that requires input from many professionals working in a wide range of disciplines, including science, finance, human resources, architecture, engineering and construction. Therefore, a clear, objective, pragmatic and realistic understanding of the needs driving the laboratory project must be set out. Building a new or refurbishing an existing laboratory is an infrequent event and the resultant facilities need to remain usable and sustainable for the life of the laboratory, normally decades. It is therefore vital that decisions are taken with clarity of purpose to realistically and pragmatically address the function required from the laboratory project. This monograph describes the design features or design considerations that apply to different types of facility, including laboratories with core requirements and facilities needing heightened control or maximum containment measures. The targeted readership for this monograph is people involved in the risk assessment and in the laboratory design or renovation, such as senior management, laboratory manager, biosafety officer, architects, designers, construction engineers and builders.

The information in this monograph on laboratory design and maintenance is designed to accompany and support the fourth edition of the WHO *Laboratory biosafety manual* (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable. Emphasis is placed on the importance of a "safety culture" that incorporates risk assessment, good microbiological practice and procedure and standard operating procedures, relevant training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions. This new approach aims to facilitate laboratory design and ways of operating that ensure greater sustainability while maintaining adequate and appropriate control of biosafety.

The other associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment, biological safety cabinets and other primary containment devices, personal protective equipment, decontamination and waste management, biosafety programme management and outbreak preparedness and resilience.

This monograph focuses on the planning, design, construction, operation and maintenance of laboratory facilities. These facilities are most likely to be laboratories with core requirements. However, the monograph also gives advice if the risk assessment determines that heightened control measures or maximum containment measures are needed. Information on decommissioning a laboratory is also provided.

SECTION 1

INTRODUCTION

1.1 Laboratory design features

When designing a laboratory, determining the biological, radiological and chemical hazards, the type of work to be performed and the implementation of risk control measures are fundamental considerations. In order to determine how the work can be performed safely and effectively, a risk assessment and a needs assessment must be completed to assess the types of laboratory activities planned. While much of the facility design will be dictated by the placement of the equipment and systems required to perform laboratory procedures, biosafety and biosecurity must be considered when selecting the facility design and its features. This section provides an overview of the facility design features that are necessary for building and operating laboratories that best facilitate and fulfil biosafety requirements.

Section 2 covers the design features for core requirement laboratories that must be incorporated in all laboratories. For laboratories where a risk assessment has determined that heightened control measures are required for some laboratory processes, additional risk control measures, design features or modifications may be necessary to maintain a safe working environment. These additional considerations are described in section 3. Where the risk assessment indicates maximum containment measures are required, the design features are outlined in section 4.

1.2 Risk assessment and needs assessment

Biological laboratories must be designed, constructed, operated and maintained to fulfil their intended role and to keep laboratory personnel, the environment and the wider community safe from the risks associated with handling biological agents.

The information in this monograph on laboratory design and maintenance is designed to accompany and support the fourth edition of the WHO *Laboratory biosafety manual (1)* (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable.

The other associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment *(2)*, biological safety cabinets and other primary containment devices *(3)*, personal protective equipment *(4)*, decontamination and waste management *(5)*, biosafety programme management *(6)* and outbreak preparedness and resilience *(7)*.

When building a new laboratory, or repurposing or renovating an existing laboratory, those responsible for the ownership and management of the laboratory must determine how to manage biological and chemical hazards by the implementation of risk control strategies; which should then drive the planning and design of the facility. To accomplish this goal, before starting the design process for the construction, repurposing or renovation, a thorough risk assessment is required to identify the hazards and decide the risk control measures that need to be incorporated into the design. A needs assessment should also be performed to define any other laboratory design features required to reduce the risks or facilitate needed functions.

The likelihood of an incident (such as an exposure to and/or release of a biological agent) and the severity of the consequences are analysed in the risk assessment. This risk assessment must consider, for example, the biological agents to be handled, procedures to be performed and the workflow of the procedures (including specimens, personnel, consumables, waste).

Depending on the type and magnitude of risk identified, core requirements, heightened control measures or maximum containment measures may be necessary to control the biological risks. More information on conducting risk assessments can be found in section 2 of the fourth edition of the WHO *Laboratory biosafety manual (1)* and in *Monograph: risk assessment (2)*. The risk assessment monograph provides risk assessment templates to help support and justify decisions on laboratory requirements.

The necessary risk control measures and design features that are identified should be the basis for design professionals to plan the design, construction, repurposing or renovation of the laboratory. Sections 5 to 10 outline basic principles of the phases of laboratory construction projects, including performing the initial risk assessment, typical design stages, and construction, commissioning, operation and maintenance of a new, repurposed or renovated facility.

SECTION 2

DESIGN CONSIDERATIONS – CORE REQUIREMENTS

2.1 Facility space

2.1.1 Laboratory floor space

The planning phase of laboratory design is the most important step in ensuring the site of the laboratory has enough floor space for the intended laboratory activities. Adequate movement and working space are important considerations in any laboratory facility. The space must be sufficient to accommodate all the required design features of a core laboratory, including hand-washing basins, benches, sinks and worktops as well as equipment such as refrigerators and freezers. Furthermore, the workflow associated with laboratory processes (number of specimens, personnel, waste) must be considered at the start of any design process. In addition, the space to house all the furnishings and equipment, including ancillary and mobile equipment, and accommodate all personnel must be considered. Furthermore, the floor space allocated must be adequate for the laboratory activity to be conducted safely. When considering the allocation of floor space, the following conditions must be met.

- The laboratory activities can be performed safely, efficiently and ergonomically.
- The normal movement of personnel, specimens, materials and waste can be performed safely without disturbing or affecting ongoing work in laboratories.
- In case of an emergency, there is sufficient space for personnel to move quickly, or be assisted, carried or even dragged if illness or injury has occurred.
- Hidden spaces or surfaces, such as behind or underneath furniture and equipment, can be accessed for maintenance, cleaning and decontamination.
- There is adequate space and access for any necessary safety equipment, such as isolation switches, fire extinguishers and safety showers.

2.1.2 Corridors and doors

Corridors, doors and laboratories must be of sufficient width to allow easy delivery, removal and replacement of laboratory equipment. Ensure mandatory requirements are in place for emergency exit and for access by emergency services by designing corridors, doors and laboratories of a minimum width – wide enough for the planned laboratory operations (for example, for big trolleys, if used) and compliant with any national regulations.

These corridors and exits must be kept clear at all times to allow emergency exit; they must not be used as storage locations. Similarly, do not use technical areas and plant rooms (for example, wastewater treatment areas) as extra storage areas.

2.1.3 Floor space for other facilities

Floor space must be allocated for additional facilities for personnel use, such as toilets/bathrooms, eating/drinking areas and office facilities. This space must be located outside of the working space of the core requirement laboratory. Spaces for personnel to leave and store personal items, outer garments (coats) and clean laboratory coats must be provided.

2.2 Storage

2.2.1 Consumables and reagents

Sufficient floor space and/or shelving must be available to house consumables and reagents safely and securely in the long and short term. To prevent clutter, bench tops, shelves and aisles must not be used to hold supplies other than those for immediate use. Long-term storage spaces outside of the laboratory should be provided. Pest control measures should be taken based on the local circumstances to protect consumables and reagents.

2.2.2 Chemicals

Specialized storage cabinets need to be available for hazardous reagents and chemicals, such as those with flammable, oxidizing or corrosive properties. Space for emergency supplies such as eye washes, first-aid materials and biological or chemical spill kits must also be provided and be appropriately located.

2.2.3 Specimens

Specimen storage may require large amounts of refrigerator or freezer space within the facility. Electrical supplies to refrigerators and freezers, their resilience to interruption, the likely additional heat gain as well as temperature monitoring of these devices and associated alarms need to be taken into consideration. Physical security of specimens may also need to be considered depending on associated biosecurity requirements, any mandatory legislative requirements and a biosecurity risk assessment.

2.2.4 Waste

Enough floor space must be provided to enable safe and secure storage of waste before it is decontaminated or transported for disposal. Space must also be provided to facilitate waste movement, which may include the use of trolleys or the loading of waste disposal trucks; therefore, doorways and corridors must be sufficiently wide to accommodate these needs.

The location of waste and/or waste decontamination units (such as autoclaves) must be considered so that odour and excessive heat generated do not affect other areas or personnel in the laboratory. Where an incinerator is available onsite or where waste is collected and disposed off-site, consideration needs to be given to necessary segregation, secure storage and, importantly, custody of any sensitive or infectious waste before decontamination, destruction or final disposal. Further information on waste disposal can be found in *Monograph: decontamination and waste management (5)*.

2.3 Surfaces and finishes

2.3.1 Walls and floors

- Walls and floors must be smooth and continuous surfaces. This may require the use of coving, whereby curved edges (rather than corners or crevices) are introduced using mouldings between the floor and walls, and, where needed, between walls and walls or walls and the ceiling.

- Materials used for walls and floors must be easy to clean, and impermeable and resistant to the chemicals and disinfectants used in the laboratory. For example, vinyl or linoleum are suitable materials for floors.

- If used, tilework must be sealed to avoid dirt and other contaminants accumulating in the grouting and seams.

- Floors must be of sufficient load-bearing capacity to hold the furnishings, equipment and personnel. They should also keep the risk of slipping low in normal use.

- Walls must be solid and properly finished according to function. For example, wall protection may be required to prevent damage by trolleys, or splash backs may need to be placed behind sinks and hand-washing basins.

- Floor drains in the laboratory must include grills or water traps to prevent insects, rodents or other vermin entering.

2.3.2 Windows

- Windows should normally be sealed but may be openable when the laboratory is designed to be naturally ventilated.

- If openable, they must be designed to prevent insects or vermin entering the laboratory, and they should be lockable.

- Openable windows should be easily operated and remain easily accessible to facilitate opening and closing as needed.

- Natural ventilation design should avoid strong air movements and draughts that might interfere with the proper functioning of equipment.

2.3.3 Doors

- Doors to the core requirements laboratory must be lockable and must have a vision panel to see into the laboratory. Internal laboratory doors must be fitted with vision panels so that workers are visible and to prevent collisions.

- Doors must be compliant with applicable building regulations (for example, fire ratings), should preferably be self-closing, and wide enough to move equipment, materials or waste easily.

- Doors should be appropriately labelled. At a minimum they should have:

  - the international biohazard symbols where biohazardous materials are handled or stored,

  - the contact details of the responsible person for the laboratory, in case of an emergency, and

  - an indication that access to the area is restricted.

- External doors and windows should be secured against the entry of pests and wildlife based on the local circumstances.

2.4 Furniture

Consider the following specifications for furniture in the laboratory.

- Furniture must be easily cleanable, appropriate (in size and function) and sufficiently robust to withstand planned use.
- Furniture must not include any fabric surfaces which may absorb and hold contaminants.
- Furniture on lockable wheels can be easily moved, allowing easy access for cleaning and/or decontamination.
- Furniture with ergonomic adjustment features allows for comfort while working and can help reduce the possibility of incidents/accidents.
- Curtains and blinds with absorbent surfaces must not be used as they may accumulate dust and are not easily cleaned if material is spilled on or near them.
- Carpets and rugs must not be used including carpet tiles.

Consider the following specifications for bench tops.

- Bench tops must be impervious to water and resistant to heat and the chemicals and disinfectants that may be used in the laboratory, for example, acids, alkalis and organic solvents.
- Wood, tile, metal, concrete or painted bench tops are acceptable if they are appropriately sealed so that they are easily cleanable and resistant to the chemicals used in the laboratory.
- Bench tops should have curved edges wherever possible for easy cleaning.

2.5 Facilities and systems

2.5.1 Hand washing

Hand-washing facilities must be provided in each room of the laboratory where procedures, including waste handling, are performed. These facilities should be located as close as possible to the exit door. This area should be dedicated to hand washing only and kept separate from any sinks where chemicals or contaminated liquids are processed. Running water must be available, preferably operated by a hands-free mechanism (elbow, wrist, knee or foot). Soap (in dispensers), or an equivalent product, must also be provided. Provision of dermatological products such as hand lotions/moisturizers should be considered.

2.5.2 Electrical supplies

Electrical supplies must be of sufficient capacity and reliability for safe and effective operation of all electrical and electronic devices. These supplies include cabling, fuses and outlets, which must be earthed to prevent shocks in case of malfunction. The electrical supply must be sufficiently stable to sustain the laboratory equipment used. Where necessary or recommended, installation of an uninterruptable power supply system or stabilizers may be considered to minimize voltage spikes and to reduce interruptions to the electrical supply. In some cases, an electrical generator may also be needed where interruption happens frequently. Electrical supplies should be placed away from wet processes and in accordance with local electrical safety requirements.

2.5.3 Lighting

Lighting must be adequate for all activities. The specific lighting needs may vary for different areas of the laboratory. Therefore, the lighting requirements of procedures should be assessed so that those needing more light (or low light levels) can be appropriately lit (or shaded) using artificial means, while using natural daylight wherever possible to save energy. Undesirable shadows, reflections and glare should be avoided. The direction of light sources must be designed so that personnel can avoid working in their own shadow. Emergency lighting needs to be bright enough and available long enough to ensure safe exit from the laboratory and also containment of the current work if the situation allows. It is also important to consider glare from daylight through windows as well as undesirable solar heat gain.

2.5.4 Environmental controls

Environmental controls, including comfort cooling and/or heating systems (to provide a comfortable temperature) and air conditioning (to control of the condition of the air), may be necessary as a temperature and/or humidity control measure to ensure a comfortable working environment for personnel to perform their tasks safely and with optimal efficiency.

These systems should be selected, designed and installed in such a way as to avoid undesirable airflow or turbulence on and around working surfaces. Care should be taken when installing supplementary wall mounted comfort cooling systems or adding ceiling fans and/or using fixed and oscillating desk or pillar fans which can produce high velocity and turbulent airflows as such airflows often conflict directly with biosafety needs.

2.5.5 Safety systems

Safety systems are dictated by the needs assessment and must comply with government regulations and/or applicable building regulations. Installation of safety systems for fire, including fire alarms, and for laboratory gases, where applicable, must be considered.

2.6 Laboratory equipment

Many specialized tools and items of equipment are required to carry out modern laboratory processes and operations. The space required to accommodate this equipment and necessary utilities (such as water, electricity, gas, drainage, telephones) should be considered during the early stages of the laboratory design. This planning is necessary to ensure that adequate floor space is provided for safe use of the equipment. The space required for effective equipment cleaning, decontamination and maintenance must also be considered. In addition, sufficient space along the route needed for the initial delivery of the equipment to the facility and/or its final removal from the facility must be ensured. The manufacturer's instructions for the positioning of each piece of equipment must always be followed before incorporating it into the laboratory design so that it can be operated safely.

Where high heat loads or airflows are emitted, supplementary systems to facilitate cooling and/or heat removal should be considered. Equipment producing high airflows should be sited with due consideration to equipment and work that may be sensitive to room airflows, for example, open bench work.

SECTION 3

DESIGN CONSIDERATIONS – HEIGHTENED CONTROL MEASURES

3.1 Selecting heightened control measures

When selecting laboratory risk control measures, national regulations and guidelines must always be consulted first to ensure compliance.

For most laboratory activities, the likelihood of exposure to and/or release of a biological agent is rare or unlikely, with a negligible to minor severity of consequences. Such activities do not need added risk control measures beyond the core requirements. Where the risk assessment for laboratory activities indicates a higher risk, the laboratory design needs to consider heightened control measures in addition to the core requirements to ensure a safe working environment. Information on and templates for risk assessments can be found in *Monograph: risk assessment (2)*.

The heightened control measures implemented should be appropriate and sufficient to reduce the specific risks that contribute to the likelihood and/or consequence of an exposure and/or release. For example, a procedure with an aerosol risk should have a risk control measure that is effective in reducing aerosol exposure to the person performing the procedure and other laboratory personnel and/or the environment. For this reason, the most appropriate heightened control measure will vary considerably depending on the biological agents being handled, laboratory activities being performed and potential transmission routes. Heightened control measures will have advantages and disadvantages that must be carefully evaluated when selecting the appropriate ones to bring risks to acceptable risks. Where the risks evaluated are considered high, cost–benefit analyses should be performed to assess options such as outsourcing the work. In addition, a detailed evaluation should be made of heightened control measures that could be implemented to improve the laboratory facility. The risk control measures chosen will be most effective when they are selected to meet local needs and have been adapted to meet the local availability of equipment, materials and skills.

Usually, heightened control measures should be selected based on a risk assessment and the available evidence of their effectiveness, either through peer-reviewed studies or other reliable sources of information. Where reliable information does not exist, in-house validation of risk control measures may be required. Where applicable, publishing in-house validation studies in peer-reviewed journals should be considered so that others can benefit from the conclusions of such studies.

This information includes new data, previous incidents and the effectiveness of the risk control measures. More information on heightened control measures can be found in section 4 of the fourth edition of the WHO *Laboratory biosafety manual (1)*.

Where heightened control measures are applied, it is important to reassess the residual risk after the risk control measure is selected and estimate whether this measure has effectively bought the residual risk to an acceptable risk.

3.2 Additional separation and design features

Laboratory activities for which a risk assessment suggests the need for heightened control measures may require greater separation from more populated areas to reduce the risk of exposure to and/or release of a biological agent. Different facility design features and techniques may need be used to achieve this additional separation.

3.2.1 Site selection

During the laboratory planning process, it is essential to consider the physical location of the laboratory build site.

Where the laboratory is part of a larger facility, such as a hospital, or an academic or research institution, the build site of the laboratory may be in a separate building. If a separate building is not possible, then the laboratory may be in an area located behind or away from common walkways between other rooms or buildings of the facility.

Where the laboratory must share a building with other departments or faculties, consider placing the laboratory at the end of a corridor with no onward access, and/or constructing wall(s) and/or doors to separate the laboratory from unrestricted areas of traffic.

Where specific procedures are being conducted within the laboratory, physical separation may also be achieved by building additional rooms or by incorporating a primary containment device (such as a BSC) into the laboratory design. In addition, separating the heating ventilation and air conditioning system could be considered.

3.2.2 Anterooms

An anteroom is an intermediary room used to create an additional layer of separation and safety between the heightened control measures laboratory and outside rooms or the general laboratory. Anterooms are commonly used as a changing area, where laboratory coats and other PPE that are to be used inside the laboratory are put on. This room provides personnel with a place to remove and store personal clothing before putting on the dedicated laboratory clothing that may be potentially contaminated once in the laboratory. Laboratory clothing must be stored separately from personal clothing. The anteroom may also be used to house a hand-washing sink and as a storage room for the laboratory.

In rare cases, where considerable aerosol generation in the laboratory is expected, the anteroom can act as part of a pressure cascade to prevent any backflow of air. For more information on pressure differentials, refer to subsection 3.4.

Anteroom doors should normally be opened one door at a time so that both the outer and inner doors are never open at the same time, with the inner door opening into the laboratory space. This sequential opening may be specified as a required procedure that all personnel must adhere to. Alternatively, an electronic interlocking system can be installed. In this case, it is important to consider emergency escape procedures, should this automated system fail. Self-closing doors may also be helpful.

3.2.3 Controlled access systems

In addition to physical segregation, control devices should be considered to ensure that only appropriately trained and authorized personnel can access the laboratory. Controlled access systems will also address biosecurity concerns.

Controlled access systems vary in method and complexity. Generally, the simpler the controlled access system, the more likely it is to be used and maintained effectively. Examples of controlled access systems that may be used in the facility design include non-reproducible keys, card pass readers, access code key pads or a reception and/or security desk.

It is important to note that any controlled access system must also have an appropriate monitoring and management system if they are to be used effectively. Procedures must be in place for detection and follow-up of failures, accidents or breaches. As the need for heightened control measures increases, it is important to ensure that the access systems log both entry to and exit from the facility, and are designed to allow entry and exit of only one person at a time to prevent unauthorized access.

3.2.4 Additional design features

Some types of heightened control measures that could be included in a laboratory design are outlined below. It should be noted that the list is not definitive and simply offers some insight into possible measures.

- Windows in a laboratory with heightened control measures should be closed and sealed.
- Where gaseous disinfection (fumigation) is selected as a heightened control measure for decontamination, the airtightness of the laboratory room or space will need to be enhanced. This enhancement can be achieved by sealing all surfaces and/or laboratory penetrations (passageways in the wall, floor, ceiling or other surface) to prevent the escape of hazardous gases.
- The laboratory exhaust airstream should be designed to discharge in a way that reduces the likelihood that any people, animals and/or the outside environment will be exposed to the exhaust air; for example, by discharging exhausts away from air intake vents. Alternatively, or additionally, exhaust air can be filtered before exhausting.
- Provide sufficient space for the onsite treatment of laboratory waste, or provide dedicated secure storage for laboratory waste until it can be transported off-site for decontamination.

3.3 Laboratory equipment

The following safeguards may need to be considered for the equipment being used during the laboratory procedures:

- fitting additional containment accessories to the equipment, for example, safety buckets or containment rotors in centrifuges;
- using additional safety features on equipment, such as automatic shutdown on centrifuges or bead beaters;
- dedicating equipment (in dedicated rooms) for use only for tasks with infectious material to avoid cross-contamination; and
- using additional, dedicated safety equipment to protect against infectious aerosols.

The most commonly used engineering control for limiting aerosol risks is a primary containment device, for example, a BSC. In addition to reducing exposure to aerosols, these devices also act to isolate aerosol-generating work or equipment from other areas of the laboratory.

Different types of BSCs are available. Other non-standard designs of primary containment devices have come into use for several reasons, including cost, portability and requirements for a customized design.

Workflow steps where there is a risk of generating aerosols are often conducted inside a BSC (or other primary containment device) that is held at a pressure lower than the laboratory space (negative pressure). In open-fronted devices, this pressure difference causes air to be drawn into the front opening in a laminar flow and at a velocity which will normally prevent the release of most of an aerosol from the cabinet, assuming correct use. Air is passed through a series of HEPA filters and then exhausted back into the room or to the outside atmosphere depending on the type of cabinet and installation arrangement. In order to provide protection to the user of the BSC, other laboratory personnel and the wider environment, the BSC must be:

- set up and used correctly,
- in good working order, and
- certified or validated and the certification must be up to date.

The protection factor of the safety cabinet must not be compromised by room airflows, including those generated by supplementary ventilation and cooling systems, other machinery or movement (for example, of people or the use of laboratory doors).

More information on the types, functions and uses of BSCs and other containment devices can be found in *Monograph: biological safety cabinets and other primary containment devices (3)*.

3.4 Directional airflow and inward airflow

Where a risk assessment determines that a risk of exposure to aerosols exists, directional airflow or a pressure cascade may be used to protect against aerosols containing biological agents and direct them away from people or objects that may otherwise become exposed. Directional airflow at the equipment level is commonly used by primary containment devices, such as BSCs. With an open-fronted device (for example, Class I and II BSC), the effect on the surrounding area of a BSC is called inward airflow. All workflow steps where a risk of aerosol generation is present must be conducted inside the BSC. In very rare situations, where aerosol generation occurs outside BSCs, a pressure cascade or directional airflow at the room level may be required.

3.4.1 HEPA filters

HEPA filters capable of trapping microorganisms are integrated in risk control measures *(8)*; for example, in BSCs. These filters ensure filtration of air to remove biological agents and support product protection (that is protection from contamination of the specimen or material handled). When a facility has HEPA filtration on either a direct/exhaust air distribution system or a passive system (air transfer ports, pressure differential lines) in a laboratory using heightened control measures, the laboratory designer should consider the needs for maintenance, testing, validation, decontamination and access when deciding on a location for the HEPA filter(s) and housing.

3.5 Waste disposal

When incorporating decontamination and waste management into facility design, it is important to ensure sufficient space for waste storage, movement and/or decontamination systems such as autoclaves. Further information on waste disposal can be found in *Monograph: decontamination and waste management (5)*.

The movement of contaminated waste should be kept to a minimum, especially when the risks associated with handling waste from biological agents increase, either because the biological agents have more severe consequences or the likelihood of exposure increases. When the risks of handling contaminated waste are high, barrier type decontamination systems (double-ended autoclaves) may be needed, and even incinerators. Note that national or international regulations and standards may require local decontamination of potentially infectious waste.

Enhanced autoclave functions include double-ended machines with hermetic barriers and special programmes, cycles and test functions. Where such enhanced functions are indicated by the risk assessment, it is essential to ensure that these functions are specified in detail in the user requirement specification. In addition, care must be taken in the formal process of qualification and validation, including all necessary and rigorous factory testing together with onsite acceptance and performance testing.

In a small number of cases, and in line with the risk assessment, a dedicated liquid disposal sink and drain may be required for liquid waste in order to prevent the release of potentially contaminated liquid waste outside the laboratory. Alternatively, an effluent decontamination system can be used for larger volumes where high-risk liquids cannot practically be collected and treated in small volumes. An effluent decontamination system helps decontaminate potentially contaminated liquids using either heat or chemical treatment before disposal into a sink or public sewer system. Heat decontamination is usually more expensive to install and maintain. However, the effectiveness of chemical decontamination may be difficult to monitor, and corrosion of the drains or tanks is common. Decontamination may be done immediately, as the liquid enters the system, or the liquid may be collected and stored in specialized tanks and then decontaminated in bulk before disposal into normal waste systems. Devices to prevent backflow, including deep seal syphons, which take into consideration pressure cascades and ventilation systems, may also be used to prevent any contaminated liquids, aerosols, vapours or chemicals from moving back up the drain.

3.6 Laboratory emergency response

Introducing additional segregation, separation and access controls to the facility design can also result in barriers and challenges to emergency response to deal with adverse events that may occur. The installation of systems that allow monitoring of the safety of the personnel working inside should be considered. As with controlled access systems, these systems should be complemented by procedural controls to ensure that monitoring is effective and emergency responses are initiated when necessary.

An emergency escape route from inner segregated areas must be established and communicated to personnel to enable them to use it effectively. If electronically controlled access systems are used, contingencies for emergency response must be considered in case the access system fails; for example, if there is power failure. In case of a medical emergency, personnel inside the facility must be able to call for help. Emergency systems, and associated monitoring and response procedures, are particularly important if a laboratory allows personnel to work alone.

The medical emergency response team (onsite or external) should be informed about the risks of the biological agents that are handled in the laboratory and the medical equipment that is accessible close to the laboratory. Furthermore, the response team must be instructed on the emergency entry and exit routes and procedures to be taken in case of a medical emergency.

SECTION 4

DESIGN CONSIDERATIONS – MAXIMUM CONTAINMENT MEASURES

For the majority of laboratory activities, laboratory facilities will be designed to perform work safely under core requirements, or with certain heightened control measures in accordance with the risk assessment. However, in exceptional circumstances, a facility designed with maximum containment measures will be required to control the highest risks. These high risks arise from work with biological agents that have severe consequences and when there is a high likelihood of exposure to and/or release of these biological agents.

It is important to understand that laboratories requiring maximum containment measures are very expensive to plan, design and build. They are also very expensive to operate and maintain. The high-risk operations often mean these laboratories will fall under national regulations and oversight mechanisms for biosafety and biosecurity. This means special permits or approvals must be sought even before starting the planning process for such a laboratory. These facilities require a very high level of technical expertise and experience, not only for their planning, design and construction, but also for their operation and maintenance. It is essential before starting such a project to ensure that trained and experienced personnel are available for all aspects of the project, including the design, construction, operation and maintenance. For these reasons, before building a maximum containment facility, other options for the work must be considered such as the use of an alternative biological agent or procedure where possible, or the outsourcing of work to another appropriate facility.

The following information on facilities with maximum containment measures is not exhaustive and is intended only as introductory material. Before such a laboratory is constructed and put into operation, intensive consultations should be held with national authorities, biosafety experts and other institutions that have had experience in operating similar facilities to determine the exact design specifications.

4.1 Additional separation and design features

Facilities with maximum containment measures are designed around the use of primary containment systems within which all procedures with biological agents are performed. The intention of risk control

measures used in laboratories requiring maximum containment measures is to place an impermeable physical barrier (provided by a full body suit or by a Class III BSC) between the laboratory personnel undertaking the work and the biological agent which they may otherwise be exposed to while performing that work. Two main systems are currently used in laboratories with maximum containment measures. These systems are the so-called cabinet line laboratory and suit laboratory.

4.1.1 Cabinet line laboratory

A cabinet line laboratory is one where work is performed using more than one Class III BSC or isolator acting as a sealed primary containment device. The cabinets or isolators are interconnected in a cabinet line configuration which is used to house all the laboratory equipment and working space required. Secure access to controlled inner and outer changing rooms is required for entry and exit to the laboratory, with personnel making a complete change of clothing on entering and exiting the room containing the cabinet line. A minimum passage through two interlocking doors must exist, forming an additional anteroom/airlock, before entering the rooms containing the BSCs or isolators (cabinet room). A shower room is situated between the changing areas which should be used on each exit or in the event of emergencies depending on the risk assessment.

Supplies and materials brought into the cabinet line must be introduced through an integral double-door, pass-through autoclave, dunk tank or fumigation chamber. Once the outer door of the transfer device is securely closed, personnel inside the laboratory can open the inner door to bring the materials into the cabinet line. The doors of the autoclave or fumigation chamber should also be interlocked in such a way that the outer door cannot open again (after the inner door has been opened) unless the autoclave has been operated through a sterilization cycle or the decontamination chamber has been successfully decontaminated.

4.1.2 Suit laboratory

A suit laboratory for work with biological agents requires personnel to first put on a one-piece, positive-pressure protective suit complete with a separate breathing air supply, which is fully isolated from the room air. The breathing air system must provide adequate airflow and pressure to meet the manufacturer's specifications for the suits. Furthermore, the quality of the air must be monitored continuously for toxic gases and annually for several other contaminants.

The breathing air system must be equipped with a back-up system (typically bottled air or large reservoirs of compressed air with a fail-safe connection to the breathing air line) to allow for a safe exit from the laboratory should the primary breathing air system be compromised. A decontamination shower in an airlock is also needed for safe exit from the suit laboratory before removal of the suit.

As with a cabinet line laboratory, there must be effective systems to allow for the safe introduction of materials and specimens into the laboratory. Again, this can be through double-ended autoclaves, dunk tanks and fumigation chambers.

4.2 Controlled access

The laboratory using maximum containment measures must be in a separate building or in a clearly delineated zone within a secure building. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel must put on a complete change of clothing. Before leaving, they should remove the laboratory clothing and take a full body shower before putting on their personal clothing.

4.3 Directional airflow

Negative pressure must be maintained inside the facility. Both supply and exhaust air must be HEPA-filtered. All protective HEPA filters need to be tested and certified annually. The HEPA filter housings may be designed to allow the filter to be decontaminated in place before removal. Alternatively, the filter can be removed in a sealed, gas-tight primary container for subsequent decontamination and/or destruction by incineration.

There are significant differences in the ventilating systems of the cabinet line laboratory and suit laboratory:

4.3.1 Cabinet line laboratory

- The laboratory room must be maintained at negative pressure supported by a pressure cascade through the entrance rooms and anterooms. There must be a dedicated system with alarms and monitoring covering all critical system and operating conditions.
- The laboratory ventilation must have HEPA filtration of both the supply and exhaust air (normally double HEPA).
- Redundant exhaust fans are required to provide a back-up to ensure that the facility remains under negative pressure at all times even in the event of an exhaust fan failure. The supply and extract systems must be interlocked to prevent over-pressurization.
- The cabinet line must be operated at negative pressure to the surrounding laboratory at all times.

- The supply air to the cabinet line may be drawn from within the room through a HEPA filter mounted on the cabinet or supplied directly through the supply air system (but always through a HEPA filter).

- Exhaust air from the cabinet line must pass through a minimum of two HEPA filters before release outdoors.

The containment system must have adequate back-up systems to ensure maintenance of negative pressure under foreseeable failure conditions.

4.3.2 Suit laboratory

- Dedicated room air supply and exhaust systems are required. The supply and exhaust components of the ventilating system are balanced to provide directional airflow within the suit area from the area of least risk to the area(s) of greatest risk.

- Redundant exhaust fans are required to provide a back-up, thereby ensuring that the facility remains under negative pressure at all times even in the event of an exhaust fan failure. There should also be redundancy within the power supply to the facility to ensure continuous operation.

- All critical ventilation, pressure differential, life safety and operational systems must be continually monitored and have alarms. An appropriate system of controls must be used to prevent positive pressurization of the suit laboratory.

- HEPA-filtered supply air must be provided to the suit area, decontamination shower and decontamination airlocks or chambers. The exhaust air from these areas must be passed through two HEPA filters in series before release outdoors.

- Exhaust air from the suit laboratory must be passed through two HEPA filters in series before release outdoors. Alternatively, after double HEPA filtration, exhaust air may be recirculated, but only within the suit laboratory.

- Under no circumstances should the exhaust air from the maximum containment suit laboratory be recirculated to other areas. Great care must be taken if air within the suit laboratory is to be recirculated.

- The build-up of chemical fumes from disinfectants and other activities must be taken into account if considering any recirculation of air. The possible impact to animal rooms on recirculation of air must also be considered.

- The protective suits will require a dedicated, breathing air system, with multiple layers of redundancy to ensure personnel safety all times.

All protective HEPA filters need to be tested and certified annually. The HEPA filter housings may be designed to allow the filter to be decontaminated in place before removal. Alternatively, the filter can be removed in a sealed, gas-tight primary container for subsequent decontamination and/or destruction by incineration.

4.4 Waste disposal

The objective of maximum containment measures is to maintain at all times a physical, impermeable barrier between the biological agent and the laboratory personnel, and the wider community and environment. This objective applies from initial specimen receipt through to final decontamination and disposal. Waste disposal requirements will vary from facility to facility, but it is widely acknowledged that no waste must leave the laboratory unless having first been fully decontaminated. The risk assessment also helps to identify the most suitable decontamination method.

All liquid waste (effluents) from the suit area, autoclave, decontamination chamber, decontamination shower and cabinet line must be decontaminated before discharge. Heat treatment is the preferred method since it can be validated more consistently and reliably than chemical treatment. Effluents may also require adjustment to a neutral pH and temperature reduction before discharge. Backflow prevention mechanisms should be installed in all effluent drains as well as deep siphons to prevent backflow of air and aerosols. These siphons should be deep to cope with normal pressure and loss of negative pressure in the room. As with room ventilation, HEPA-protected drainage vents will require two HEPA or equivalent filters in series to prevent release of drainage vapours and aerosols to atmosphere. Depending on the results of the risk assessment, water from personal showers and toilets in the outer changing area, which are outside the containment measures, may be discharged directly to the sewer system without treatment. The personal hygiene shower in the cabinet line facility may be treated in an effluent treatment plant depending on the risk assessment.

A double-door, pass-through autoclave must be available in the laboratory area for decontamination of laboratory materials, equipment and solid waste. Other methods of decontamination must be available for equipment and items that cannot withstand steam sterilization. These other methods include gaseous decontamination (such as hydrogen peroxide or formaldehyde) or chemical decontamination in a barrier dunk tank.

4.5 Laboratory emergency response

No individual should work alone and unattended in facilities with maximum containment measures. Working in laboratories using maximum containment measures relies on a buddy system where pairs of individuals enter and leave the facility together. This system allows each individual to check the protective equipment of their partner and that protection systems are correctly used. Personnel working in the laboratory should be visually monitored at all times. Therefore, the facility must be equipped with well-designed vision panels allowing a full and clear view of all spaces at all times. Where this cannot be achieved by windows alone, a combination of mirrors and/or video surveillance may be used.

As restricted entry controls may be numerous, emergency extraction of personnel presents challenges. Therefore, personnel must be trained in emergency extraction procedures in the event of personnel injury or illness. Protocols for emergency response procedures must be developed, simulated and practised so that emergency response personnel can navigate the facility design and controls and deliver an appropriate response. This protocol should be developed in conjunction with local authorities, and communication to the emergency response personnel of the risks and value of life versus biosafety for these situations should be considered.

A method of communication for both routine use and in emergencies must be installed, so that personnel working within the maximum containment facility and laboratory/support personnel stationed outside the laboratory can communicate without difficulty.

SECTION 5

FRAMEWORK OF A LABORATORY PROJECT

The process of a typical project to build, renovate or repurpose a laboratory begins with the facility idea or requirement, proceeds through planning to design, construction, commissioning, operation and maintenance. While this conceptual framework outlines the typical steps and stages of most laboratory construction projects, it is a guide only and the framework may vary widely depending on place and time, governance, procurement methods, markets and many other factors. The steps and stages in the framework are expanded and illustrated at each main stage in the following sections. Some important elements require careful attention, especially budgets, personnel and schedules.

Details of the planning, layouts and design requirements adopted for the facility are determined directly by the risk assessment and needs assessment. Therefore, before the construction, repurposing or renovation process can begin, a detailed risk assessment must be carried out in order to determine the specific risk control measures that need to be implemented. In addition, a facility-specific needs assessment is required to define all other design features needed for the laboratory.

SECTION 6

PLANNING

To facilitate the process of planning, designing, constructing, operating and maintaining a laboratory or facility, it may be useful to use a model approach to help map out and understand the various stages and activities that are required. Various models, including nationally recognized systems, exist that outline work stages and detail the tasks and outputs required at each stage. Those involved in the planning should identify useful model resources and/or consult their national architect´s organization and building regulatory agency early in the planning phase.

Planning (Figure 6.1) can be divided into two parts: the pre-planning phase and the planning phase. The pre-planning phase comprises everything that precedes and leads up to the start of the project; it includes the initial idea, the identification of need at the senior level and the agreement to proceed in a particular direction. The main activity of the planning phase is to bring together a team of relevant experts to perform a risk assessment and a needs assessment. The risk assessment identifies the need for risk control measures and indicates if core requirements are enough for the planned laboratory or if heightened control measures or even maximum containment measures are advisable. The needs assessment will establish the nature and purpose of the laboratory and define the details of the work that will be performed there and all the equipment required.

It is important during the planning phase that realistic costs are determined, and that key deliverables are established that support project goals and serve as progress milestones.

The following national planning tools were reviewed during the development of this monograph:

- the Royal Institute of British Architects (RIBA) plan of work – 2013 *(9)*, and
- the American Institute of Architects. AIA Document D200™ – 1995 *(10)*.

Other national systems and concepts exist and can be used as planning tools. In the absence of a nationally recognized system, one or both of the above-mentioned tools can be accessed online and are free of charge to use (see references and the further reading/information section).

Planning phase

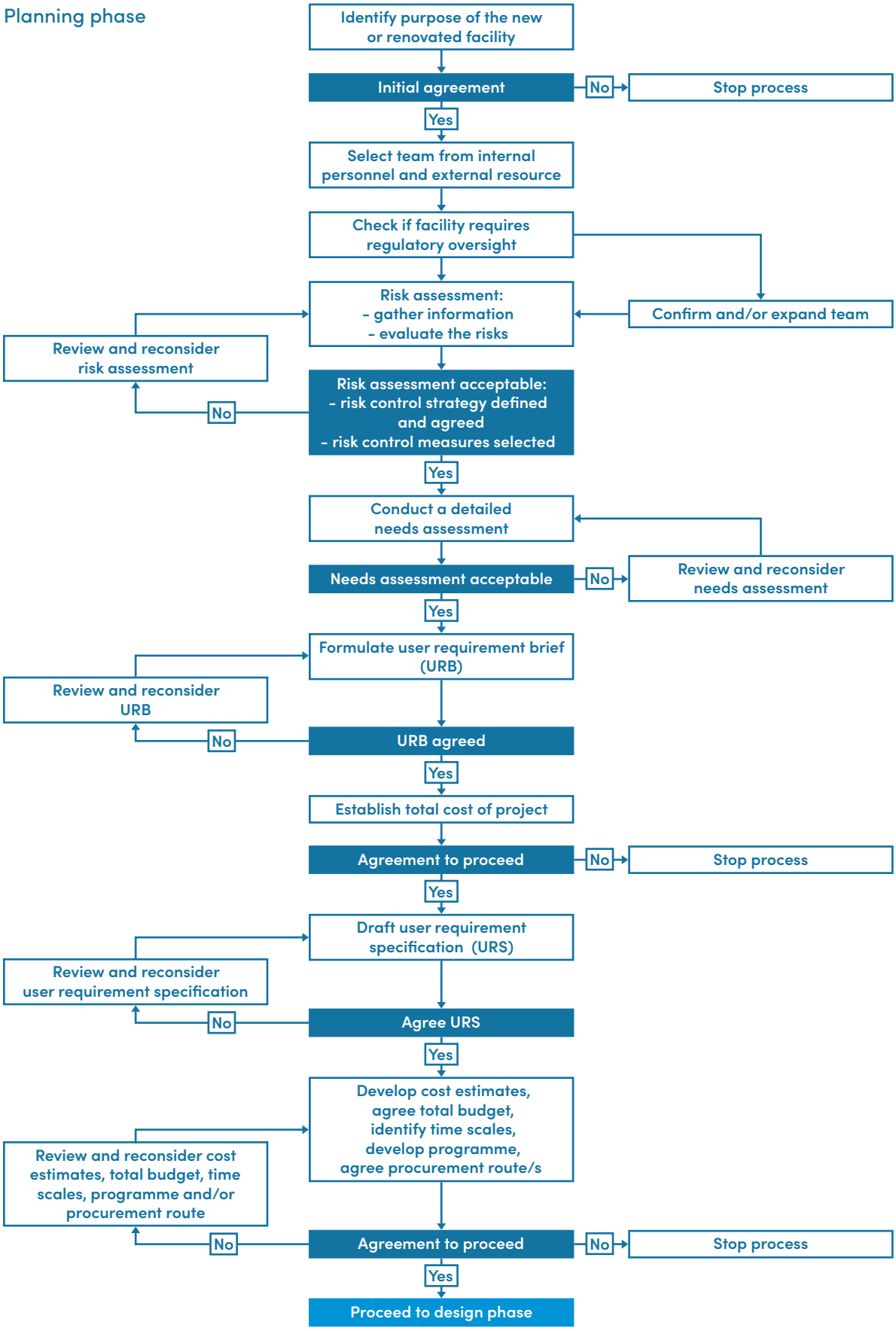


Figure 6.1 Project flowchart, planning phase

6.1 Planning team

In order to conduct a thorough and effective risk assessment and a comprehensive needs assessment, a strong team of knowledgeable individuals with experience in laboratory design, operation and management is needed. The following subsections outline the people, or groups of people, who are important contributors to the planning phase of the laboratory project. The number of individuals involved in the planning process will depend on the size of the project and the complexity of the work that is to be performed in the laboratory.

The project team will initially include selected members of the organization for which the facility is being constructed. Construction professionals can be added later and are often appointed by the organization undertaking the design-related tasks. Afterwards, the project team may expand further as builders and subcontractors are employed to carry out the construction and commissioning work.

6.1.1 Senior management or facility owner

The senior management or the facility owner is the authority from a public or private organization in need of the new, renovated or repurposed laboratory. The senior management may designate a senior administrator, laboratory director, departmental head or similar to be its representative. This person is responsible for leading, or monitoring the effectiveness of, the risk assessment and the associated needs assessment. This individual is also responsible for managing the formulation of the user requirement brief and user requirement specifications, and determining and overseeing the project budget. This person is often referred to as the project sponsor.

6.1.2 Laboratory management and biosafety professionals

The laboratory management includes the people who have thorough and specialist knowledge of the intended function of and procedures planned in the laboratory. In many cases, these people are already performing this kind of work in their everyday jobs. The main responsibility of this group of experts is to perform the risk assessment. This assessment includes defining: the laboratory activities that will be performed; the biological agents that will/may be used; the properties of the specimens that will/may be used; the equipment required; and the workflow of the laboratory activities. The outcome of the risk assessment will inform the risk control measures needed and the facility design. For this reason, laboratory management should include experts in the risk assessment process and implementation of its outcomes. Ideally, individuals who are familiar with standards/regulations specific to biosafety and laboratories should also be part of the laboratory management team. Biosafety professionals may be the most suitable candidates to fill these roles, although other laboratory personnel and support personnel may be suitable too.

6.1.3 Project manager

The field of architecture and construction can be unfamiliar to scientific and laboratory personnel. Therefore, a project manager is essential to take on coordinating activities. The project manager acts as the senior management's representative, prioritizing the interests of the management when dealing with the various actors in the design and construction process, such as the architects, engineers, builders and subcontractors. The project manager is normally responsible for overseeing and managing all phases of the project, including procurement, design, construction, installation, commissioning, handover and operational training of users of the completed laboratory. The project manager can also support the development of a budget to secure enough funding to complete the laboratory and put it into operation.

6.1.4 Design team

The design team may be made up of design professionals including architects, engineers and surveyors. Appointment of the design team can begin during the planning phase. It is important to engage design professionals with laboratory design and construction experience. If this is not possible, professionals who have done similar work to similar standards may be suitable, such as those with experience of hospital design and construction projects.

6.2 Risk assessment and needs assessment

Once the project team is assembled, the purpose and the functions of the laboratory must be agreed upon. This part of the process involves considering and listing the many factors that contribute to the operation of a successful laboratory. It is important to make this assessment as detailed as possible so that the designs that are developed are closely aligned with the needs and intended functions of the laboratory. This assessment will also ensure that the costs of the project are properly justified by the needs of the laboratory.

Information on performing a risk assessment (Table 6.1), can be found in *Monograph: risk assessment (2)*. This monograph includes short and long risk assessment templates and associated guidance.

A needs assessment should consider the following issues (among others).

- Planned purpose of the laboratory; for example, as a diagnostic, research, pharmaceutical or reference laboratory.
- Requirements for national or international laboratory accreditation/certification or legislative requirements.

- Reasons for the repurposing/renovation/construction; for example, need for increased safety measures following the outcome of the risk assessment, or need for additional space because of an increased number of duties.
- Processes that require rooms; for example, animal work, sterilization work, or work needing aeration or controlled temperatures.
- Amount of space required, based on, for example, the expected number of personnel.
- Nature of specimen (organs, liquids, specimen in sealed tubes, microbial culture) and analysis methods to be used (for example, culture, polymerase chain reaction, serology) and their related requirements (for example, separate rooms for different tasks).
- Adjustments required in the specimen workflow; for example, separate specimen reception or space, and equipment for specimen storage.
- General building regulations; for example, fire alarms or sprinkler systems.
- Adequate availability of utilities; for example, sufficient power supply, water supply, wastewater treatment and removal, waste discard and similar requirements for autoclaves.
- Locally available maintenance and service expertise.
- Necessary environmental control systems.
- Personnel facilities; for example, toilets, rooms for breaks, or office spaces separate from laboratory working spaces.
- Floor space requirements for all physical elements (equipment, personnel, biosafety controls), for facilitating movement (walkways, hallways), for storage of consumables and reagents and for additional facilities (toilets, rooms for breaks, offices).
- Technical space for the location of the building engineering services, as well as space for services to pass between floors in multistorey buildings – riser space.
- What currently exists; for example, laboratories embedded in hospitals, and comparison with needs assessment.

Table 6.1 Risk control measures needed based on a risk assessment and the related needs based on a needs assessment for an antibiotic testing laboratory for tuberculosis

CHARACTERISTICS OF THE BIOLOGICAL AGENT		
Biological agent(s)	*Mycobacterium tuberculosis*	
Expected specimens	Sputum, urine, other body fluids or infected tissues	
Route of transmission	Airborne, percutaneous routes, ingestion, contact/fomites	
Infectious dose (ID)	ID_{50} estimated to be < 10 bacilli	
Treatment/preventive measures	Effective immunization is not routinely available. Antibiotics are available for post-exposure prophylaxis. Multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis strains exist and specimens containing these strains are expected to be received. Susceptible to 5 000 ppm hypochlorite, 10 minutes exposure time and autoclave at 121 °C for 15 minutes	
Pathogenicity	Highly transmissible	
FACTORS CONSIDERED IN RISK ASSESSMENT	**RISK CONTROL MEASURES**	**RESULTS OF NEEDS ASSESSMENT**
Laboratory procedures ▪ specimen receipt and recording ▪ direct smear microscopy to detect acid-fast bacilli ▪ autoclaving and disposal of waste (by external contractor) ▪ decontamination of laboratory after any spills **Equipment to be used** ▪ PPE (personal protective equipment) (laboratory coats, latex gloves) ▪ Equipment (refrigerator, heat block/flame, microscope, sharps container, autoclave) ▪ sealed transport container ▪ incubator	▪ disinfection ▪ autoclaving ▪ PPE ▪ sharps container ▪ first-aid kit ▪ autoclave ▪ sealed containers for transport	▪ space for specimen reception including data entry, microscopy, slide staining, autoclave, storage of waste and storage of disinfectant ▪ power and water supply for autoclave ▪ adequate and correctly located sockets ▪ environmental control for special storage conditions for disinfectant, such as temperature, humidity ▪ hooks for laboratory coats separate from personal clothing, space for laundry outside laboratory ▪ hand-washing basin for hand hygiene after glove removal and water supply ▪ space and workflow for equipment placement (autoclave, incubator, analyser) ▪ space for first-aid kit, short-term waste storage before and after autoclaving ▪ space for cleaning, disinfection and storage of transport containers

Table 6.1 Risk control measures needed based on a risk assessment and the related needs based on a needs assessment for an antibiotic testing laboratory for tuberculosis (continued)

FACTORS CONSIDERED IN RISK ASSESSMENT	RISK CONTROL MEASURES	RESULTS OF NEEDS ASSESSMENT
Other factors that may affect laboratory operations ▪ occasional crime in the area	▪ ensure restricted access	▪ need for system that ensures only authorized personnel have access (such as keys, key cards) ▪ bars to windows on the ground floor
Potential situations in which exposure or release could occur ▪ aerosol exposure to and/or release of *M. tuberculosis* from a spill ▪ contact with contaminated surfaces ▪ improperly treated waste	▪ BSC (to process suspected or documented specimens of MDR-TB and XDR-TB) ▪ respiratory protective equipment ▪ gloves, gowns and respiratory protective equipment when handling waste and decontaminating spills	▪ space, electric supply and exhaust for BSC ▪ consideration of workflow (for example, avoiding placing BSC in high-traffic areas) ▪ space to store respiratory protective equipment and other PPE

BSC = biological safety cabinet; MDR-TB = multidrug-resistant tuberculosis; PPE = personal protective equipment; XDR-TB = extensively drug-resistant tuberculosis

6.3 User requirement brief

Once the risk assessment and needs assessment have been performed, an outline document should be developed to communicate the outcomes of these assessments to the designers. This document is the user requirement brief. Further input may be required by specialists with experience in laboratory design and the planned laboratory work and processes to help develop the user requirement brief into a more detailed and comprehensive set of user requirement specifications (discussed in the subsection 7.1). These specialists can be from within or outside the group for whom the facility is being designed/constructed. An example of a user requirement brief can be found in Annex 1.

6.4 Costs

Planning a new facility or the refurbishment or repurposing of an existing facility normally requires a business case to justify the need for the proposed laboratory project and to secure the required funding. This business case will be built on the risk assessment and needs assessment and should demonstrate the benefits that will be produced by the facility against the estimated cost of building/renovating/repurposing it. It is fundamental to identify all the anticipated costs that will be incurred during planning, designing, constructing, commissioning, delivering, operating and maintaining any new, refurbished or repurposed facility.

These costs include the following:

- cost of the land on which to build (if applicable), and any services and access improvements required;
- cost of permissions and licencing required for construction to proceed (if applicable);
- cost of the time of various teams/people required at each of the following stages
  - planning
  - design
  - construction
  - training – training required for all laboratory users and technical and maintenance support personnel (ongoing)
  - preparatory (pre-operation) – for example, writing SOPs
  - operation – for at least the first 5 years of occupancy and use
  - maintenance – including specialists for certification and validation, and for the first 5 years of occupancy and use;
- materials costs – all the building materials required to construct the building;
- equipment costs – all the equipment required to fit out the laboratory;
- consumables costs – all of the items consumed by the laboratory daily/weekly (for example, pipettes, gloves, slides, waste bags, reagents, PPE) for the first 5 years;
- training costs – training courses (onsite and off-site) and training placements;
- development costs – development of laboratory policies, standards and guidance, including SOPs;

- operating costs – costs besides staffing time/costs, that is spare parts and other consumables (oils, gaskets, filters) for the first 5 years;
- cost of operating the facility including miscellaneous costs (for example, cost of activities not directly related to the laboratory work such as specimen transportation or specimen collection) for the first 5 years;
- maintenance costs – above the base level laboratory operating cost, including planned preventative maintenance and periodic shutdowns as and when required;
- energy and utility costs
  - energy and utilities required to construct the facility
  - energy and utilities required to operate the facility (ongoing for the first 5 years); and
- other costs not listed above but which may be specific to the project, country or region.

It is advisable also to include a contingency allowance in the estimation of costs. This allowance is a percentage figure added to the total cost to cover unforeseen events and changes, or anything missed or not fully considered. As the project progresses, the costs become more certain and the contingency allowance can be reduced accordingly.

6.5 Time scale

Deciding on a time scale is a complex task and has critical consequences if not done correctly. For each project activity, a finite time must be allocated, and the risks and consequences of delays must be evaluated. Developing an initial schedule will normally be the responsibility of the project manager. This schedule will then be confirmed or adjusted on appointment of a builder.

Establishing a schedule may be based on a required or fixed end date or, more realistically, on time blocks with the end date predicated on the start date which is finalized only once a contract is in place with a builder. Any fixed end date chosen must be realistic.

Construction contracts once signed will normally be based on an agreed price and a fixed schedule with a start date and an end date. Changes to these dates will generally have a financial impact.

However, as the project progresses, small delays will inevitably occur. Delays are cumulative and consequently the remaining tasks will need to be done in less time if the end date is to be met. This often has an adverse effect on the installation quality and on the testing and commissioning activity. Under such time pressure, the installation and subsequent testing and commissioning activities may be poorly executed which may undermine the previous work and result in trouble and danger for the users. It is therefore essential for all laboratory projects to ensure that the construction schedule is practical and realistic, and includes contingencies for expenditure and delays. Time allowed for testing and commissioning must be realistic and strictly defended by the project manager.

6.6 Quality

Quality is of key importance in the design and construction of a laboratory facility. The quality of design, workmanship and finishing are fundamental elements and must meet the requirements of the risk assessment, needs assessment and the articulation of the user requirement brief and user requirement specification. The quality of the final designs and specifications, the accuracy of the schedule and budget, and the quality of the project management are all vital components of the total quality. Quality management should run through the project from beginning to end. If quality is taken into consideration at all stages of the project, it will help ensure that the final product meets the required standard.

SECTION 7

DESIGN

Once all of the elements of the risk assessment and needs assessment have been fully considered and defined, a comprehensive list of all the facility's needs will emerge. From this list, a user requirement brief (subsection 6.3) and then a user requirement specification (subsection 7.1) must be developed that communicate to the design team and subsequent construction team what requirements define the project (Figure 7.1)

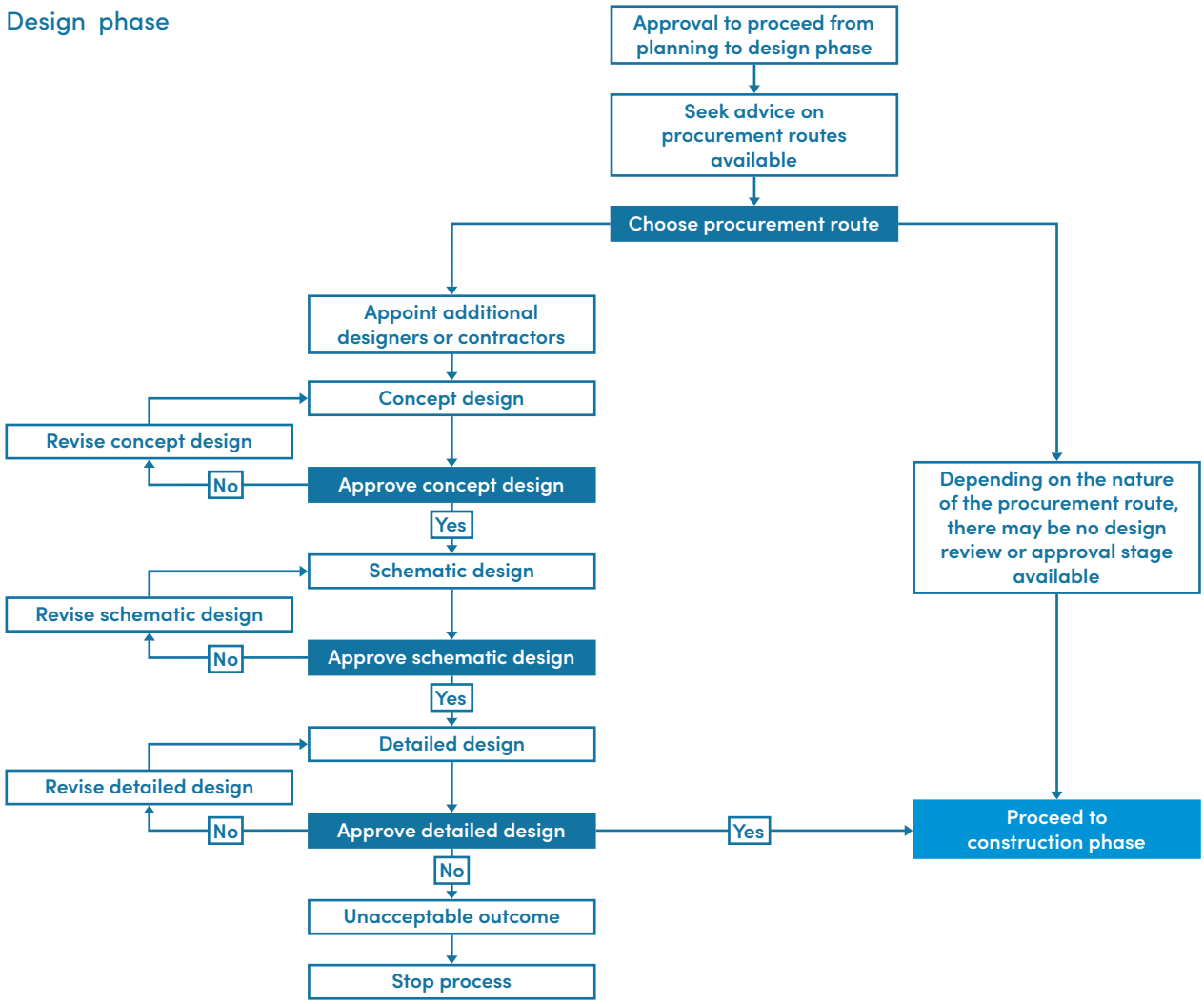


Figure 7.1 Project flowchart, design phase

7.1 User requirement specification

The user requirement specification may be developed by an architect or designer for small or simple projects or by a larger design team for more complex projects. There are likely to be several rounds of discussion between the senior management, the laboratory management, the project manager and the design team to agree on the most appropriate final user requirement specification to inform the facility design and layout. Other issues also need to be considered, such as materials to be used, surface finishes, laboratory furniture, even colour schemes and the appearance of the finished laboratory. The architect or laboratory designer must be informed of the planned laboratory workflows so they can understand all required spatial dependencies and so that any proposed design solutions are tailored to the planned needs of the laboratory. This can sometimes be facilitated by the design team appointing their own consultant laboratory professionals in support.

An example of a user requirement specification can be found in Annex 2.

When a final design and layout have been agreed upon, more specific design work may be necessary for the technical aspects of the facility. Detailed design drawings, specifications and equipment schedules, and later shop drawings, may be needed for laboratory furniture, fixtures and fittings, mechanical and electrical components, static load-bearing components, and plumbing and air conditioning systems, among others. The finalized designs must consider ergonomics for the laboratory users in all planned workflows. In addition, careful attention should be paid to ensure maintenance can be carried out effectively. It is a good idea to obtain an independent review or peer review at each stage of the design (subsection 7.3.4) and also to carry out benchmarking. Benchmarking is a way of assessing other existing facilities that perform the same or similar functions and evaluating and reviewing the risk control measures they use in order to establish a clear target for the level of quality to be achieved for the project.

7.1.1 Design review and benchmarking

In order to perform a design review, a consultation process or activity may be facilitated through national and international professional networks such as biosafety organizations or through organizational and institutional networks or government departments, depending on each individual circumstance. For the purpose of benchmarking, it can be useful to arrange fact-finding visits to reference projects to exchange experiences, data and knowledge. It is important to share both positive and negative experiences as well as knowledge, so that valuable lessons can be shared, similar outcomes can be anticipated and designs adjusted to correct any deficiencies.

Benchmarking must allow an optimized user requirement specification to be reached that is most functional and cost-effective to meet the requirements informed by the risk assessment and needs assessment.

7.2 Workflow diagrams

Workflow diagrams are valuable communication tools enabling the laboratory management and the design team to communicate effectively on a common platform. They are simplified plans that illustrate the laboratory process steps. Workflow diagrams change, and several revisions may be needed to achieve an optimum arrangement that can be used in the final architectural laboratory floorplan, general arrangement and/or design drawings.

Figure 7.2 gives three examples of workflow diagrams that illustrate layouts for laboratories requiring core requirements, common heightened control measures, and more comprehensive heightened control measures.

7.3 Typical project design stages

Depending on the size, scale and complexity of the project, there may be distinct design stages or these stages may merge. There are many design approaches and procurement methods, but the following design stages are common to most procurement routes – although sometimes they are named differently.

7.3.1 Concept design

The concept design (also known as outline design) is the first step in the design process and gives an impression or vision of the project. It contains the risk control measures to be included as defined by the risk assessment. The concept design is the first opportunity for the design team members to study the design and provide feedback based on their understanding of the needs of the users as articulated in the user requirement brief or user requirement specification. This design stage helps refine project cost data and project time scales and can inform stakeholders what to expect of the planned facility.

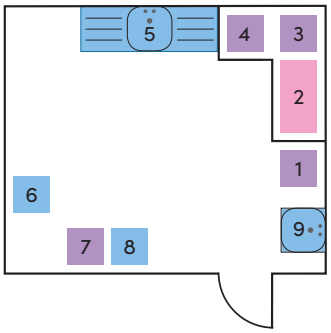
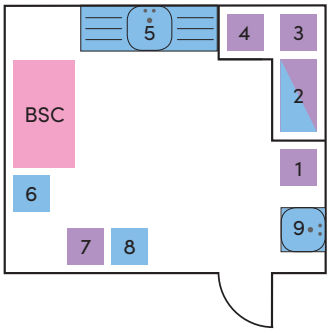
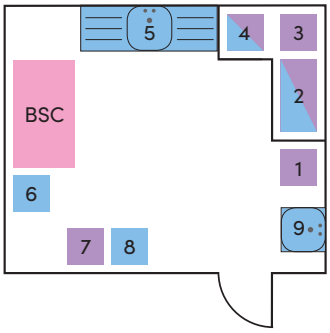
7.3.2 Schematic design

During the schematic design (also known as developed or scheme design), the concept design is developed in more detail. However, the level of detail is still insufficient to construct the facility. Depending on the chosen procurement route, the builder could be appointed to complete the detailed design. Costs and time scales are further refined.

No handling of biological agents

Handling of biological agents in containment

Open handling of biological agent

	Core requirements laboratory example	**Heightened control measures laboratory example** + BSC	**Heightened control measures laboratory example** + BSC, safety buckets in centrifuge, second inactivation step of the biological agent, autoclave
			
Laboratory equipment	**Features of the laboratory equipment in a core requirements laboratory**	**Features of the laboratory equipment in a heightened control measures laboratory**	**Features of the laboratory equipment in a heightened control measures laboratory**
Specimen storage	1 refrigerator	1 refrigerator	1 refrigerator
Workbench	2 open specimen handling	**2 no open specimen handling**	**2 no open specimen handling**
Centrifuge	3 normal	3 normal	**3 with safety buckets**
Heatblock	4 only inactivation method	4 only inactivation method	**4 plus second inactivation method**
Sink and drainer	5 preparation of disinfection solution	5 preparation of disinfection solution	5 preparation of disinfection solution
Biological safety cabinet	no	**yes – open specimen handling**	**yes – open specimen handling**
Processed specimens storage	6 freezer	6 freezer	6 freezer
Waste management	7 waste storage	7 waste storage	**7 autoclave**
Storage of consumables	8 shelf	8 shelf	8 shelf
Hand wash basin	9 hand hygiene	9 hand hygiene	9 hand hygiene

Core requirements **Heightened control measures**

Figure 7.2 Examples of workflow diagrams for laboratories with core requirements and heightened control measures as informed by the outcome of a risk assessment. These laboratories have similar laboratory activities but different risks. The core requirement laboratory works on biological agents that can be handled without containment. The laboratory with common heightened control measures includes a biological safety cabinet (BSC). The laboratory with additional heightened control measures for handling more hazardous infectious biological agents has a BSC, uses two inactivation methods, safety buckets in the centrifuge and waste inactivation by an autoclave. In the table below the workflow diagrams, the laboratory equipment needed for the core requirements is in black text, and the additional equipment for heightened control measures is in orange text.

7.3.3 Detailed design

Detailed design (also known as technical design) is the final step of the design process. In this stage, detailed drawings, specifications, schedules and lists needed to facilitate the construction process are produced. This design should clearly describe in detail all the elements, systems and equipment that will be built and installed to form the functioning facility.

Further information will still be needed to enable the final manufacture and installation of some parts – such as steelwork and ductwork shop drawings – but the completion of the detailed design allows the construction phase of the project to start.

7.3.4 Support activities for design

During each of the design stages, it can be useful to continue to build on earlier information gathering and fact-finding activity (see subsection 7.1.1), which may include further benchmarking exercises. This can be especially useful where new information is obtained or where similar projects are ongoing but are already at an advanced stage or have faced problems.

It can also be useful to seek independent peer review of the new laboratory design proposals; this can be done at each design stage. Peer review takes time and involves financial costs, but such review is essential as the complexity of the design increases. Peer reviews can be undertaken by suitably experienced in-house personnel, or by independent specialists and experts.

7.4 Budget

Finalization of the user requirement specification should allow the design team to produce an accurate estimate of the facility's final construction cost. It is important to consider this before moving forward so that the costs can be justified to those funding the project. The finalization process requires a person skilled in estimating the costs associated with various design features, risk control measures, and/or resources being requested, and taking account of the needs specified in the user requirements.

During this stage, a contingency allowance should be considered. About 10–15% of the estimated facility cost may be added during the construction process to cover changes or adjustments that will almost certainly need to be made. Furthermore, costs must also be added to finance parallel and post-construction activities, such as commissioning and training activities. These activities will ensure that the constructed facility is not only finished, but functional and able to be used and maintained. Refer also to subsection 6.4.

In many cases, a fixed budget is provided (by government, for example) or is available (through a donor, for example), which can be a constraint for the project. Under such circumstances, it is essential to define the laboratory activities of the planned facility and to assess if it will fully meet the requirements of the risk assessment and needs assessment.

It is important to realize that a construction process, a renovation or a repurposing could take several years from planning to handover. In this time, equipment from manufacturers can become obsolete and/or be replaced by new models. It is therefore important to include such contingencies in the budget and to track these changes with equipment manufacturers and the design team or builders who are providing the infrastructure support.

Excessively long planning and building processes may result in unnecessary cost increases, which can reduce the viability of the laboratory project. Similarly, if a budget is not available or is insufficient, or if the targets of the user requirements are too high, then the project may need to be stopped or substantially revised at this stage, or even earlier in the planning and design process.

Further iterations of the user requirement specification may be required to ensure that the project design matches the approved budget, or the budget may need to be adjusted. Engineering options may need to be discussed and equivalent alternatives for a given product or system explored to balance cost. However, quality and performance should match the original design requirement; otherwise any savings made in capital costs could be lost because of increased owning and operating costs. Cheaper but potentially inferior system components should be avoided, as they may in fact turn out to be far more expensive in the medium and long term with increased breakdown frequency and higher ongoing maintenance and repair costs.

7.5 Procurement

Procurement is a broad topic. Rules and requirements governing procurement may vary from country to country and organization to organization. Rules for procurement in the public sector may not always be fully compatible with the complex needs of a successful laboratory project.

If procurement rules allow, it is safer to complete the design as an independent and separate preliminary activity and have it fully costed and peer reviewed before the appointment of the construction company (the so-called design–bid–build approach). The independent design team can be retained by the laboratory management or facility owner to manage the quality controls throughout the construction phase and advise the laboratory management on the completeness of the testing, commissioning, documentation and training needed before the formal handover.

Another procurement route is the so-called design and build route, where the design and construction phases are undertaken by one company. Any changes made to the design tend to incur substantial costs, and these generally increase more as the project moves closer to completion. In addition, a decrease in quality is common in design and build with inevitable consequences on critical completion activities, such as testing and commissioning. Appointing and authorizing an independent body to undertake quality control may help here.

SECTION 8

CONSTRUCTION

With appropriate commitment to a realistic budget and approval of the preceding planning and design phases, builders and/or their subcontractors can be engaged to execute the project construction phase, typically overseen and managed by the project manager. Key to good project management is facilitating effective communication and documentation processes. As construction moves towards completion, commissioning is undertaken to ensure that the finished construction is in line with all of the original user requirement specifications and the detailed design drawings and specifications made by the design architects and engineers.

The construction phase (Figure 8.1) normally starts on a fixed date and has a fixed schedule or programme, which is one of the conditions of the contract between the senior management/owner and the builder (or principal contractor).

The builder will typically take possession of the site at the start of construction, which becomes their legal responsibility, and which is returned only at completion and handover of the project. The builder is responsible for security of the site during the construction phase. The builder will also become responsible for the health and safety of all workers and visitors to the site as well as all people in the vicinity of the site including the general public.

8.1 Site investigations

As required, the builder may appoint subcontractors, such as plumbers, electricians and air conditioning companies. The builder may also carry out additional site investigations and surveys, as needed. The need for further site investigations in the construction phase assumes that an appropriate level of site investigation was already done during the design stage and may be complete before the appointment of a builder. However, some work may be required that was not possible to carry out earlier because of, for example, lack of availability of the site, or the occupancy and use of an existing building. If a design and build route is followed, this work may needs to be done during this stage of the project.

Some preliminary tests may also be performed to confirm design assumptions (for example, capacity of the electrical supply, water supply, drainage and sewerage systems and other utilities), especially on existing equipment, services or utility supplies where refurbishment, repurposing or expansion is being undertaken.

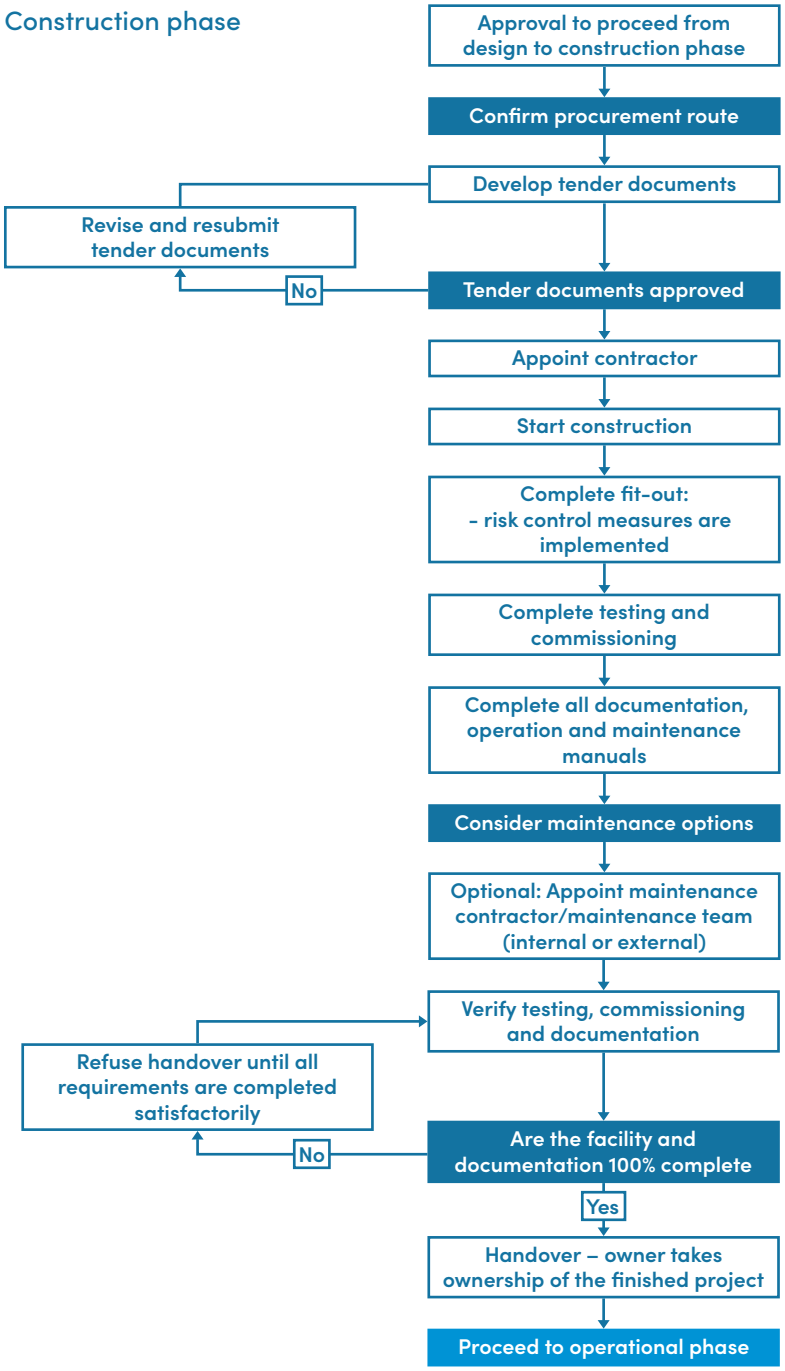


Figure 8.1 Project flowchart, construction phase

Further detailed construction and engineering work may also be required involving the following areas:

- layout of laboratory rooms, location, size and layout of technical spaces, support areas and plant rooms (where not included at the design stage);
- shop drawings, for example, of specialized equipment, ducts and steelwork;
- calculations for system components (where not included at the design stage);
- specialist installations, for example, air handling units and autoclaves;
- water supply;
- electricity supply including various voltages, mono and triphase supplies; and
- wastewater effluents requiring special treatments such as biological inactivation or chemical detoxification for biosafety and environmental reasons.

8.2 Products and materials: quality control

Samples of materials should be submitted to demonstrate the required (specified) and agreed quality. Sample products and workmanship can be provided and or constructed and approved. These approved sample elements can then be used to measure the quality of subsequent workmanship and/or materials against. This work can be in one part of the construction or even part of a separate mock-up construction. The more complex or critical the needs of the finished facility are, the more a separate mock-up of key components, finishes and features can contribute to the success of the project and is well worth the investment.

In complex laboratories, the movement of materials through the facility spaces, as well as the planned movement of people, specimens containing biological agents and associated waste streams can also be mocked up and physically tested.

One quality control measure that is vital in all laboratory construction projects is the continuous protection of all surfaces, finishes and installed equipment. If they are not protected during construction, they can be damaged. The integrity of the finished flooring, for example, will considerably affect facility cleaning or decontamination and durability. The same is true for walls and for benches and other surfaces. Good management at all levels and clear specifications for protection can help reduce all but accidental damage, which should always be rectified before final handover.

8.3 Documentation

If the planning and design phases have been carried out effectively, clear and detailed documentation (drawings and specifications) should be available to direct the construction team to accurately complete the laboratory project construction. Communication, coordination and management of the various actions and actors is an important part of the process and is key to success in construction. Scrutiny of everything and at every level by those responsible for the design, its proper functioning and its formal sign off should be ensured at all stages of the project.

Detailed records should be kept of all meetings and all decisions that are mutually agreed. The project manager should discuss and collectively agree with the builder and subcontractor(s) their specific roles and responsibilities. This agreement should be recorded in a formal contract before the beginning of the construction process. Additional methods of accountability may need to be implemented, such as the use of signature sheets for builders and/or subcontractors to acknowledge when they have reviewed and agreed with any discussions, and/or other written documentation described in Table 8.1. Control of changes is important as almost all changes will affect costs and may also affect project time schedules.

In Table 8.1 some common formal documented communication and recording methods are explained. These are not the only methods used. Documented communications may vary by name and purpose depending on the time and place and the type of contract being used. Documents may also include instructions of the project manager, early warning notices and technical queries.

Table 8.1 Common documented communications and recording methods

DOCUMENT	DESCRIPTION
Request for information	Documents provided from builder to the senior management/owner or their design team asking for a clarification or additional supplementary information relating to a question over the design or user requirement specification which they believe is unclear
Request for approval	When approval is required to conduct a certain action
Change control order	To track changes and associated costs and possible delays
Technical submittal	When approval is required for proposed components and systems by the builder
Defect notice	A document indicating that an item has been rejected and must be made good or replaced by the builder/installer
As-built drawing	An update that reflects all changes made by the builders
Technical documents (as part of the operating and maintenance manuals)	A document from the builder on deliverables which outlines the specifications of the system or feature, how to use it and how it must be maintained to function effectively.

8.4 Testing and commissioning

During the construction activity, there may be a requirement for specific testing, verification and recording of issues such as ground conditions, reinforcing steel and concrete strength. These tests and test results must be inspected, authorized and signed off by the project manager or other design team members before further work proceeds. As construction progresses, it will be necessary to check and inspect the quality of workmanship of the work before it is covered or enclosed. Steelwork and concrete reinforcement, for example, must be checked and approved, and brickwork and blockwork walls will need to be checked before render or plaster is applied. Any hidden features (pipes, wires and ducts) will need to be checked and tested before being covered or enclosed. This inspection, checking and testing must be written into the project specifications by the designers and the quality control process must be carefully followed throughout. Some specific construction features may need to be inspected several times including firebreaks and partitions to ensure that the lives of the people using the building will not be at risk during use.

When the construction phase comes to an end, the facility or the renovated/repurposed laboratory must be thoroughly inspected and checked for quality, compliance and functionality against the design documents before it is handed over to the senior management and it becomes operational. Other approval processes may be necessary before full operation (licensing, for instance). Depending on the size and purpose of a laboratory, it might be necessary to check and test elements at both the beginning and the end of the construction phase. Any defects should be identified in the testing and commissioning phase by the project manager and design team and must be satisfactorily corrected by the builder/subcontractor prior to final handover.

Commissioning involves the testing of all items constructed, fitted or installed to show that they are complete and functional according to previously agreed specifications. Commissioning should occur throughout the construction phase, checking, testing and approving what is being executed, against the user requirement specification and/or the more detailed project design drawings and specifications. Commissioning is usually carried out by the person responsible for installation, checking is performed by a commissioning engineer, and verification and scrutiny by the designer (or an independent entity). On more complex projects, an independent commissioning agent can be used to carry out this function and should be engaged to advise from early in the design phase.

As changes may be required and made throughout the construction process, commissioning agents (and/or the project manager and design team) must review all written communications and technical documentation for conformity and alignment with the design specifications.

Handover of any construction project is a milestone and responsibility shifts from the builder back to the senior management/facility owner and laboratory manager. It is essential in all laboratory projects that the facility is completely finished before the handover is agreed.

8.5 Acceptance and handover

The builder is responsible for the quality of the completed facility in accordance with the contract, the design drawings and the contract specifications. As construction reaches completion, the senior management/laboratory manager must accept the work and take over responsibility for the oversight of the facility and its function. This is a formal contractual process and with a formal handover. All contract work must be completed, inspected, verified, accepted and signed off by a competent person or persons acting directly for the senior management.

At the handover, functional testing of all equipment and systems must be complete and inspected, and fully signed off against all technical documentation. In addition, all construction design features must be approved as they are specified in the as-built information. If these elements are not completed satisfactorily, then handover should be delayed until the project manager has received the needed approvals from the design team and/or the commissioning and validation team as described in the list below.

The responsibility of the project manager is to ensure that all the testing, commissioning, validation, verification and qualification tasks – however simple or complex – are complete, specifically in the opinion of a suitably qualified and competent person undertaking the inspection. It is also important that the as-built information and the operation and maintenance manuals (see subsection 9.3) are complete, comprehensive, accurate and useful. These will underpin all the operation and maintenance of the laboratory. Scrutiny at this stage of the project must be complete.

When evaluating the completed laboratory systems for acceptance, in addition to installation quality, the following points may also need to be considered/tested:

- repeatability of the system operation under various outside influences, such as temperature, humidity and pressure;
- operational stability of the system for a period of time consistent with the intended operation of the laboratory (usually at least a day but it could be longer);
- stability, accuracy, reliability and repeatability of control systems;
- responsiveness of systems to changing environments and other varying laboratory conditions, including normal, emergency and recovery modes of operation;
- efficiency of the operation of the systems, consistent with predicted criteria of operating costs; and
- ability to maintain systems, including proper and safe access to components and owner training, to ensure a long-term, high-level performance; this might include safe 24-hour access to such systems and necessary normal lighting and emergency lighting.

8.6 Accreditation and certification

If required, a well-recognized standard should be chosen that is suited for the intended purpose and is specified for either certification or accreditation. The assessment body providing certification should be properly accredited by authoritative national bodies or competent authorities to carry out the particular assessment formally.

Formal assessment of laboratory processes for biosafety vary around the world and are most often found in countries with national oversight systems. In these cases, inspectors (authorized by the national authority or another competent authority) inspect laboratories against an acceptable standard (often a national biosafety standard). If the laboratory meets the standard, it may be certified. Many countries do not certify and simply authorize activities in laboratories that have been found to meet the national standard.

To identify necessary certification, national regulations can give guidance. National regulations should be consistent with standards of the International Organization for Standardization and the International Electrotechnical Commission.

8.6.1 Certification of engineering controls

Beyond laboratory certification, specific certification exists for engineering controls. A good example is the certification of BSC by field testing. Various standards exist for the certification of BSC *(11,12)*. A field-testing certifier should be accredited by the accrediting body. Determining if a certifier is qualified requires verification of the certifier's credentials, references, work history, accreditation and any other relevant factors.

SECTION 9

OPERATION AND MAINTENANCE

Well-functioning laboratory equipment and systems contribute to biosafety of the laboratory. Maintenance plays an important role in keeping the laboratory equipment and systems reliable (Figure 9.1). There are two types of maintenance: planned maintenance (predictive maintenance and preventative maintenance) and unplanned maintenance (breakdown maintenance or emergency maintenance, also called corrective maintenance) – see subsections 9.5 and 9.6.

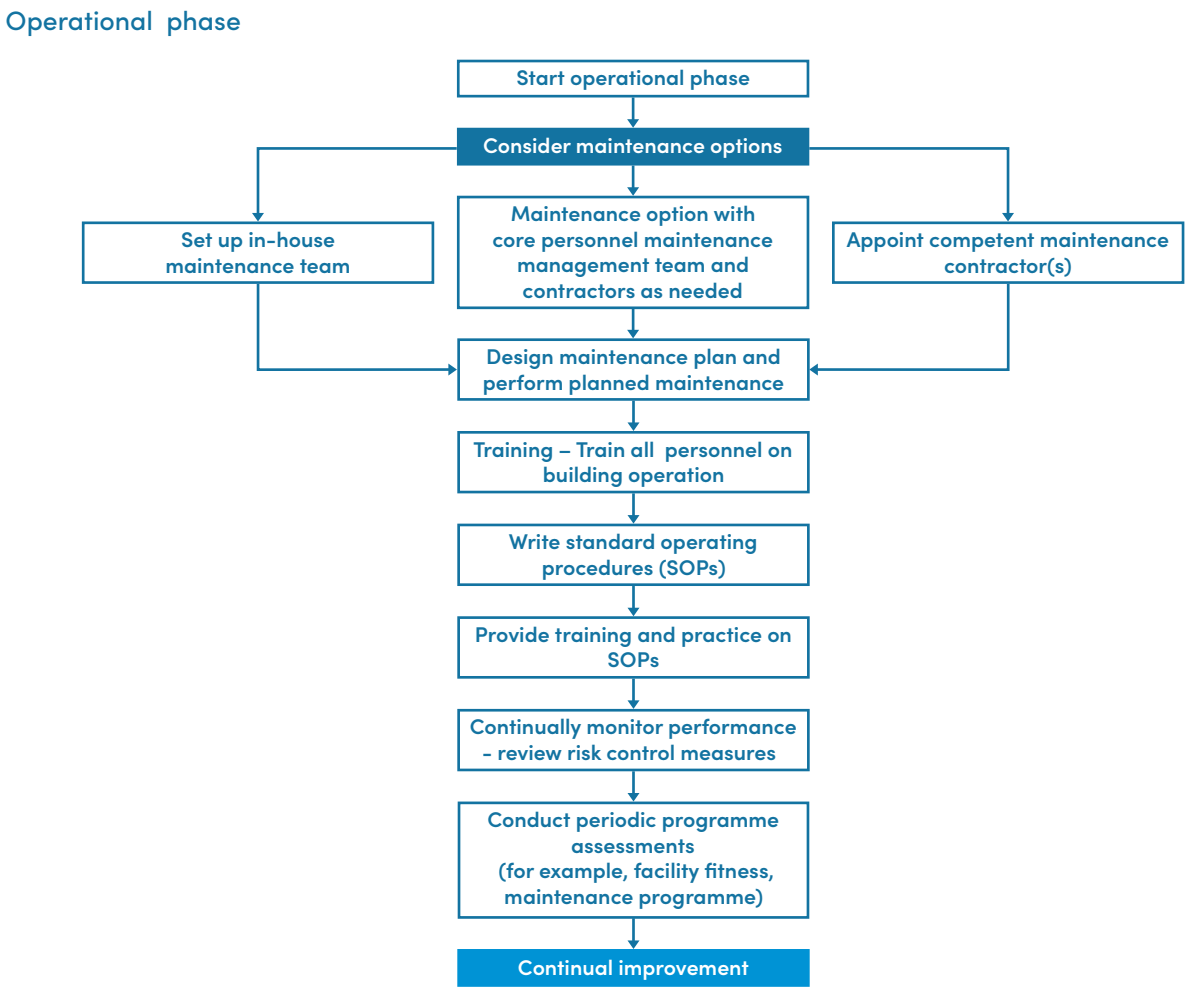


Figure 9.1 Project flowchart, operational phase

A detailed maintenance plan should minimize problems and help avoid common and predictable breakdowns. Maintenance will require a trained knowledgeable and competent team supplied with the correct tools and spare parts.

9.1 Safety of maintenance personnel

The safe and optimum operation of a laboratory is dependent on support personnel, and such personnel must be given appropriate safety training.

Skilled engineers and trades people who maintain and repair the structure, facilities and equipment of the laboratory should have knowledge of the nature of the work of the laboratory, and of the importance of safety regulations and procedures. Testing of engineering controls after servicing, for example, testing the efficiency of BSC after new filters have been fitted, may be carried out by or under the supervision of the biosafety officer. Ideally the hazards of the laboratory should be removed or isolated before engineering or repair work is undertaken. Engineering and maintenance personnel may need to enter laboratories with clearance and supervision by the biosafety officer and/or the laboratory manager. Establishing SOPs can standardize and facilitate common understanding and execution of laboratory entry and exit procedures for non-laboratory personnel.

9.2 Design for maintenance

As with all key elements of the process required to plan, design, construct, operate and maintain laboratory facilities discussed throughout this monograph, good maintenance begins in the early planning and design stages. Depending on the level of complexity of the facility and required design features, the need to facilitate the appropriate maintenance of the structure, its envelope, its finishes, fixtures and fittings, and of course its engineering services will vary. Access space is also essential to maintain, service, calibrate, and validate or certify key biosafety equipment such as BSCs and autoclaves. Systems should be retested and checked before work with biological agents starts.

Where possible, maintenance services and systems should be located outside the main laboratory space, even for core requirement laboratories, to avoid the need for maintenance personnel to enter the laboratory. This reduces the risk to these personnel and minimizes interruptions to the laboratory work.

The following example for HEPA filter maintenance illustrates what needs to be considered to maintain this equipment (based on the risk assessment and/or needs assessment).

- Clearly define minimum clearance requirements around the housing (typically provided or recommended by the manufacturer) to ensure sufficient space to test and remove the HEPA filter or any associated housing components.
- Clearly label the HEPA housing with biohazard symbols to ensure that it is obvious to anyone who has access to the technical space that the HEPA filter housing is potentially contaminated. Ideally, access to any plant room containing such equipment should be controlled and restricted.
- Clearly identify the HEPA housing and which areas of the containment space it serves so that it can be referenced in a maintenance/testing schedule.
- The HEPA housing should have a visual monitoring device to provide an indication of both the performance and state of the HEPA filter in use (such as a pressure differential monitoring gauge across the HEPA filter).
- The HEPA housing should be designed to withstand structural changes from pressure fluctuations and not be distorted during filter installation due to over tightening.
- The HEPA housing should be mounted to a solid frame such as the floor in a plant room, or a steel frame in the ceiling space with appropriate vibration restraints to withstand any structural shifts.

9.3 Operating and maintenance manuals

The detailed design, specifications and drawings should always include clear requirements addressed to all manufacturers, suppliers, builders and installers to ensure that complete operating and maintenance instructions are provided for the finished facility. These operating and maintenance manuals should include the complete set of as-built drawings, schedules and all necessary information required to develop a comprehensive planned preventative maintenance schedule for all elements of the facility. In addition, operating and maintenance manuals should cover only the specific components and systems that are finally installed or fitted and refer only to those specific elements that are part of the finished facility. The contract documents should also state the date of delivery of these manuals. Manuals should always be provided early enough to enable full scrutiny, checking and review before any proposed completion and handover date. Complete, well-drafted, understandable and approved operating and maintenance manuals must be a prerequisite to handover (see subsection 8.5).

9.4 Maintenance contracts

Laboratories must strictly follow maintenance manuals for all laboratory equipment, systems, and/or engineered facility components. As a minimum, this maintenance includes annual maintenance procedures. Maintenance contracts for the technical systems and laboratory equipment may need to be agreed with relevant engineers or manufacturers. Laboratory equipment is becoming more and more complex, and regular maintenance, calibration and validation are needed to ensure accurate diagnostic results. Specialist technicians trained in the specific equipment are needed for such work.

When preparing maintenance contracts (for the facility and/or for scientific machinery and equipment), consideration may be given to the following questions.

- Does the system or equipment have a manufacturer warranty and what is its duration? Do not pay for something to be serviced or repaired that is already covered by a warranty.
- What is the availability of parts and consumables? How long would parts take to be delivered?
- Is a spare parts kit available which would allow certain preventative maintenance to be done in-house?
- After the warranty period expires, what service contractors are available and at what cost?
  - What terms and conditions can be negotiated in the service contract?
  - Is the service contract long or short term?
  - Is there an automatic renewal clause?
  - Are there cancellation fees?
  - Is there a guaranteed response time by the supplier/manufacturer?
  - Are parts and travel included in the costs of the service contract?

9.5 Planned maintenance

Maintenance plans should have lists of tasks that need to be done for all cycles and all items that require maintenance, including inspections, routine checks, maintenance and replacements. Each system (for example, heating, ventilation and air conditioning, pressure systems, wastewater treatment) can be broken down into appropriate parts and a unique plan made for each part.

Table 9.1 Example of planned preventative maintenance – external rainwater drainage system

PLANNED PREVENTIVE MAINTENANCE TASK LIST NO: A001			
ELEMENT: EXTERNAL ENVELOPE ITEM: RAINWATER DRAINAGE SYSTEM			
TIMING	**INSPECTION**	**ACTION**	**COMMENTS/INSTRUCTIONS**
Daily	N/A	N/A	Daily frequency not required
Weekly	Visual inspection only	Report obvious obstructions, arrange safe access and clear.	Visual inspection from ground level; look over entire system and identify any problems.
Monthly	Check all downpipes, hoppers, gullies and junctions	Clear away obvious obstructions and collections of debris. Report any obstructions or blockages requiring further action/equipment and arrange action to clear.	Using safe temporary access equipment and working in a buddy system, inspect key locations in rainwater guttering system; if required use additional safety equipment. Where further action is indicated arrange safe work\ access.
Quarterly	As monthly	As monthly	As monthly
Six-monthly	Full inspection to be completed, all gutters and hoppers	Clean all guttering, hoppers, gullies, junctions and downpipes.	Using contract-hired access equipment (cherry picker or scaffolding), make safe access available to complete system, carry out full cleaning, condition inspection and report; select seasonal inspection dates.
Annually	As six-monthly	As 6-monthly; in addition, take a photographic record of condition.	As six-monthly
5-yearly	As annually	As annually; in addition, check all fixings, remediate and replace as necessary, and identify and remediate any corrosion.	As annually
Exceptional	Visually check operation and or general condition.	Report function and/or observed damage.	To be done during and after periods of exceptionally high rainfall or before and after severe (tropical storms, and significant climatic or geographical events, such as earthquakes.

N/A = not applicable.

The plan will typically cover the tasks and timing of inspections: daily, weekly, monthly, yearly, and 5 –, 10 – or even 15–yearly or longer depending on the manufacturer's or supplier's advice. Six-monthly, bimonthly and quarterly timings are also common. The example of planned preventive maintenance given in Table 9.1 is for a rainwater and drainage collection system.

Equipped with such plans for building elements, services and equipment, from the simple to the complex, a comprehensive planned preventative maintenance schedule can be carried out that will ensure correct, safe and reliable operation of all building systems.

9.6 Breakdown maintenance

Unplanned maintenance events, breakdowns and emergencies are unavoidable – but they should occur rarely in a well-maintained and operated facility. However, plans should be made for such events. This planning might include the availability of: spare components and tools; personnel (technicians on call); and back-up systems, fixed or portable. The ability to react well to unplanned maintenance events can be enhanced by good training and supported by good design for both access and lighting. Lighting for maintenance should include fixed emergency lighting, portable emergency lighting and torches/flashlights in technical areas. Avoid placing key equipment and machinery outdoors where the weather could make such items more difficult to maintain.

9.6.1 Spare parts and tools

Common spares that may be held for such critical breakdowns include fan and motor belt drives, fuses, possibly motors for critical equipment, and consumables such as light bulbs, filters and strainers. Spare parts must be catalogued, stored appropriately and, importantly, located for easy access and use.

Other parts and tools could be similarly stored, which will help the technician to rapidly respond to and resolve the emergency or breakdown. Shadow boards for organizing a set of tools are common in many industries. In secure technical areas and locked plant rooms, such boards are an effective and inexpensive way of managing tools needed for maintenance. Alternatively, if feasible, a mobile tool station can be useful.

In addition to having obvious spare parts and consumables and the necessary tools, repair kits for specific systems, such as water pipe networks, may be useful. For smaller pipes, repair kits can include some spare pipe and fittings as well as some proprietary repair kits. For larger pipes, temporary repairs may be done with tapes and bands to resolve the problem until a more permanent repair can be undertaken. The time between temporary repairs and final repair must be kept short. A well-trained, responsive and reactive technical team must be available to respond to this type of problem.

9.6.2 Flooding and leaks

Potential leaks and floods caused by emergency breakdowns must be considered in the design phase of the project. Areas can be designated for the location of wet services and have waterproof flooring, bunding, drainage systems and, if feasible, leak detection systems. Other design measures can help minimize the risk of failures and consequent flooding, such as the appropriate: selection and specification of materials; location of header tanks and water feeds; specification of installation quality; and final testing. These measures should be combined with rigorous quality control, witness testing and scrutiny.

9.7 Maintenance records and inspections

As well as maintenance planning, detailed and accurate records are needed using manuals, log books, journals and schedules.

In addition to normal planned maintenance, it is good practice to conduct regular housekeeping visits. A housekeeping visit or inspection is a planned walk through a plant room or technical space by maintenance personnel on duty, which looks carefully for problems and listens for unusual sounds and noises. In addition, strange smells, especially of smoke or drains, should be investigated.

A well-established process to manage maintenance, monitoring and repair records might be necessary to support the requirements for laboratory quality management. Laboratory users are important in supporting this process. A laboratory maintenance system includes:

- regular walk-through inspection
- log book
- laboratory personnel observation/notification.

A laboratory quality management system or a suitable log book can be used to record observations which should be acted upon as necessary based on a supervisory review by the laboratory manager or maintenance supervisor. All personnel working in the laboratory can be involved in laboratory quality management, including safety and security personnel. Laboratory users should identify and record simple issues such as: peeling paint, peeling sealants, wet patches, water marks or traces of water leaks, rusty pipes and smoke or odd smells. A mechanism is needed to notify maintenance personnel of such observations so as to prevent bigger problems occurring later. An inventory template and a self-inspection checklist can be found in *Monograph: biosafety programme management (6)*.

SECTION 10

DECOMMISSIONING LABORATORY FACILITIES

Laboratory facilities can include many different types and sizes of laboratory in different locations, from a small one-room laboratory space to an entire campus, and can include animal housing facilities and manufacturing facilities. These facilities can also have specialist facilities or equipment such as autoclaves, effluent decontamination systems and incinerators. For decommissioning, the same basic process can be followed and adapted to fit the situation at hand. The key to successful decommissioning is sound and thorough risk assessment, good planning and meticulous documentation.

Risk evaluations (as part of the risk assessment) that are carefully and thoroughly carried out should identify all risks associated with the planned decommissioning of a laboratory facility and its equipment. Most laboratory equipment and the laboratory space itself can generally be rendered safe by following the existing SOPs used for routine periodic maintenance or planned shutdowns. When GMPP have been consistently applied in the facility, the risk of contamination should be low and restricted to known locations.

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Further information

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ANNEX 1. EXAMPLE OF A USER REQUIREMENT BRIEF

Sample User Requirement Brief (URB)

Title	Laboratory upgrade: central diagnostic laboratory and national reference laboratory
Location	Central Public Free Hospital, Medical Avenue, Midtown.
Date	30 February 2020.
Purpose:	To refurbish, update and upgrade the central diagnostic laboratory facility and national reference laboratory in line with published government plans to meet the guidelines of the fourth edition of the WHO *Laboratory biosafety manual*. This has been facilitated with support of WHO and the World Bank.
Funding	Funding will be from the central government (70%) supported by the World Bank (30%).
Budget	Project construction and commissioning budget 125 000.00 to project completion, + 25 000/year for the first 4 years operational budget (total budget 250 000).
Contracting authority	Ministry of Public Works on behalf of the Ministry of Health.
Background	The central diagnostic laboratory and national reference laboratory located at the Central Public Free Hospital in Midtown was originally constructed in 1905. Since opening, it has provided a key diagnostic service to the central hospital and all outlying hospitals in Midtown district and region. Although some improvements were made in the 1970s, a lack of funding since then, combined with substantial underinvestment in facility maintenance (including the loss of 60% of trained hospital maintenance personnel), has led to an obvious decline in standards at the facility which fall below core laboratory requirements.
Criticality	During all refurbishment works, the central diagnostic laboratory and national reference laboratory must continue to operate at full capacity. To allow the laboratories to continue work, space has been set aside in an adjacent building in which a temporary facility can be set up and to which personnel and equipment can be moved during the main construction work.
Requirements	
1	The project should start the construction phase on 30 February 2021.
2	The project should complete the construction phase on 30 February 2023.
3	Design and planning phases will start immediately on receipt of this URB.
4	Detailed programmes to prepare a temporary facility and move personnel, including refresher training, should be created and agreed to align with the project time schedule.
5	The refurbished facility will be required to operate for a minimum of 30 years with correct planned preventative maintenance. An allowance for the first 4 years of operation including maintenance is included in the budget indicated above.
6	The temporary facility should be fitted out in accordance with the risk assessment and needs assessment governing the temporary facility needed to maintain diagnostic service.
7	The refurbished facility should be fitted out in accordance with the risk assessment and needs assessment governing the facility needed to provide full diagnostic services.
8	The project risk assessment are appended to this URB. Questions and requests for direction in relation to this assessment should be addressed only to the designated laboratory management and laboratory management team.

Sample User Requirement Brief (URB) (continued)

Title	Laboratory upgrade: central diagnostic laboratory and national reference laboratory
9	The project needs assessment are appended to this URB. Questions and requests for direction in relation to this assessment should be addressed only to the designated laboratory management and laboratory management team.
10	Usable area: existing usable area is 50 m^2 including specimen receipt and three laboratory rooms.
11	Personnel numbers: five laboratory personnel, two support personnel and one maintenance technician.
12	Specimen throughput (average) is 50 specimens per day.
13	Nature of specimens: typical diagnostic specimens generated from hospital patient care, including blood, sputum, urine, stool and biopsy tissues. Often heightened control measures are necessary.
Project manager	Responsible project manager, senior project manager, Ministry of Public Works.
Important	Address all project questions to the project manager first; all project decisions must be signed by the project manager only.

WHO = World Health Organization.

ANNEX 2. EXAMPLE OF A USER REQUIREMENT SPECIFICATION

Sample User Requirement Specification (URS)

Title	Laboratory upgrade: central diagnostic laboratory and national reference laboratory
Location	Central Public Free Hospital, Medical Avenue, Midtown
Date	31 April 2020
Purpose	To refurbish, update and upgrade the central diagnostic laboratory facility and national reference laboratory in line with published government plans to meet the guidelines of the fourth edition of the WHO *Laboratory biosafety manual*. This has been facilitated with support of WHO and the World Bank.
Funding	Funding will be from central government (70%) supported by the World Bank (30%).
Budget	Project construction and commissioning budget 125 000.00 to project completion, + 25 000/year for first 4 years operational budget (total budget 250 000).
Contracting Authority	Ministry of Public Works on behalf of the Ministry of Health.
Background	The central diagnostic laboratory and national reference laboratory located at the Central Public Free Hospital in Midtown was originally constructed in 1905. Since opening, it has provided a key diagnostic service to the central hospital and all outlying hospitals in Midtown district and region. Although some improvements were made in the 1970s, a lack of funding since then, combined with substantial underinvestment in facility maintenance (including the loss of 60% of trained hospital maintenance personnel), has led to an obvious decline in standards at the facility which fall below core laboratory requirements.
Criticality	During all refurbishment works, the central diagnostic laboratory and national reference laboratory must continue to operate at full capacity. To allow the laboratories to continue work, space has been set aside in an adjacent building in which a temporary facility can be set up and to which personnel and equipment can moved during the main construction work.
Requirements	
1	Follow guidance of the WHO *Laboratory biosafety manual* and its associated monograph on laboratory construction.
2	Materials of construction – use locally available materials wherever possible that meet the requirements of both the risk assessment and needs assessment attached to the URB (issued 29 January 2020).
3	Surfaces and finishes – use locally available materials wherever possible that meet the requirements of both the risk assessment and needs assessment attached to the URB (issued 29 January 2020).
4	Correct application – ensure that manufacturers' data sheets and installation/application instructions are always fully followed when applying substrates (plaster) and all paints or similar finishes. Ensure the correct environmental conditions exist before application/construction and that the correct drying times are adhered to.

Sample User Requirement Specification (URS) (continued)

5	Mechanical and electrical services – use locally available equipment and systems wherever possible that meet the requirements of both the risk assessment and needs assessment attached to the URB (issued 29 January 2020).
6	Maintenance provision – ensure sufficient access to all equipment that requires maintenance inside the laboratory and serving the laboratory (including a demonstration on completion).
7	External design conditions: • Summer maximum temperature 35 °C • Summer maximum humidity 85% relative humidity • Winter minimum temperature 5 °C • Winter minimum humidity – saturated (100%).
8	Internal design conditions: • Winter – temperature 18 °C and relative humidity 30–70% • Summer – temperature 25 °C and relative humidity 30–70% • Lighting – average illuminance 400 lux with task illumination at workbenches 500 lux • Uniformity of lighting generally 80%, avoid glare and ensure shadowing on worktops is eliminated • Noise – noise rating 45 (fixed machinery and equipment only, excluding scientific machinery).
9	Emergency lighting – maintained illuminance of 5 lux for 30 minutes to facilitate safe shutdown of work and safe exit from the laboratory facility (use distributed battery units not central system).
10	Fire protection: • Provide fixed fire detection and alarms with strobes and sounders in laboratory rooms; ensure correct selection of detectors (heat, smoke or combined) based on area served • Ensure all construction meets local fire codes and compartmentation and resistance times. • Ensure all fire and life safety systems are signed off by authorized signatory from the Ministry of Public Works.
11–99	**Many more such requirements between 11 and 99 – not shown in this sample URS**
100	Concrete testing – all concrete must pass the Ministry of Public Works laboratory test, TOC_LAB_rev002C
101	Slip resistance test – test floors in laboratory against Ministry of Public Works slip test: ST001_LAB_Rev001
102	Commissioning and testing – Commission and test all mechanical and electrical equipment in line with Ministry of Public Works testing and commissioning guidance: TCT001_LAB_Rev005B
103	Final documentation – All testing, commissioning and completion documentation must be complete and submitted to the Senior Project Manager, Ministry of Public Works no later than two weeks before planned project handover. This is to allow a two-week trouble-free operating period to pass before the project is formally signed off and handed over. Failure to submit complete documentation and/or failure to obtain Ministry of Public Works approval shall prevent handover.
104	Operating and maintenance manuals – These manuals are to be submitted in final draft as part of the final documentation mentioned above but must be completed six weeks before handover (except for completed testing and commissioning sections).
Project manager	Nadia Sharif, Senior Project Manager, Ministry of Public Works
Important	Address all project questions to the project manager first; all project decisions must be signed by project manager only.

URB = user requirement brief; WHO = World Health Organization.

World Health Organization