# GENERAL GUIDELINES
## ESTABLISHMENT OF BIOSAFETY LEVEL-3 LABORATORY

INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH & FAMILY WELFARE
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# PREFACE

Globally, there is a strong perception that studies on microbial agents need more care and caution to avoid health hazards to the laboratory personnel and the community. Emerging and newly emerging diseases caused by unknown as well as known pathogens occur unpredictably worldwide. These often appear in epidemic forms and are very difficult to diagnose and manage.

It is pertinent to have laboratories with high containment facilities (BSL-3) and protocols to deal with such threats. The institutes with a mandate to investigate such outbreaks are required to be in a state of preparedness. It is also mandatory that storage of these pathogens be done in appropriate biosafety laboratories. Diseases of global public health significance are tackled by forming international networks of laboratories having suitable infrastructure and trained manpower, and there is an increasing need for containment facilities. The containment facilities are also required to enhance countries' capacity on preparedness in term of diagnostics and vaccines.

Biosafety policies and procedures are designed to safeguard personnel and the environment from biologically hazardous materials and to comply with regulatory requirements. Containment science emerged as an important branch of science in recent times. There were no national guidelines for establishment, operation and maintenance, auditing and validation of containment laboratories. Therefore, according highest priority to establishing such facilities becomes laboratory management's responsibility and lacunae in knowledge to execute such projects become biggest hurdles.

In most of the developing countries, the awareness about bio-containment has increased but planning, designing, constructing and operating BSL-3 laboratories needs regular updates and clear definitions of risk groups and their handling.

Realizing the importance of containment science these National Guidelines are developed to benefit principal investigators, engineers, architects and management in conceptualizing the concept, layout to final drawing, developing cost estimate to the execution of project. It has incorporated the hand-on experiences of the contributors in establishing containment facilities in this country as well as in many SEAR countries. This also has compiling the right information on a large number of areas that needs tremendous attention during establishing such facilities.


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# FOREWORD

Biosafety and biosecurity are essential pillars of international health safety. In today's interconnected world, there is an ever-present threat of emerging, re-emerging and newly emerging viruses and other pathogens that are capable of causing outbreaks & epidemics. Such emerging pathogens can potentially and rapidly spread due to very fast air-transit and increasing urbanization in the era of globalization. Many of these zoonotic viruses and other infectious etiologies are highly pathogenic and transmissible in humans with high consequences.

High containment laboratories like Biosafety level-3 and -4 levels and specialized know-how for handling these highly pathogenic micro-organisms and viruses are very essential in the developing world, which faces the major brunt of infectious diseases and many of the outbreaks due to emerging and re-emerging pathogens.

In Indian settings, recent outbreaks due to emerging viruses such as Nipah virus, arboviruses such as Crimean-Congo hemorrhagic fever virus (CCHF) have led to increased emphasis on having high containment facilities for the preparedness to handle outbreaks due to highly infectious pathogens. Several high containment BSL-3 facilities have been established or currently in the planning or execution phase. It is recognized that highly specialized expertise required for establishment, maintenance and operation of high-containment facilities at BSL-3 and BSL-4 levels laboratories.

Currently, there is no existing guideline for establishing BSL-3 facilities for biomedical research and diagnostic laboratories from the South Asian or South-East Asian region.

The Department of Health Research and the Indian Council of Medical Research has taken an initiative to develop "General Guidelines for Establishment of Biosafety Level-3 Laboratories".

The first edition of guidelines on establishment of BSL-3 laboratories will be a useful reference to institutions in India and SEAR countries. It is hoped that these guidelines will act as a standardized set of guidelines useful at the national level and the regional level for other countries in South-East Asia as well as for other developing countries elsewhere.

Among many essential aspects covered in this guideline are clarifications on different biosafety levels, objectives and scope of BSL-3 laboratory facilities, specific laboratory designs, considerations in construction, staffing as well as pertinent issues related to operation and maintenance of these facilities.

The guideline is timely and essential in the backdrop of outbreaks of emerging and re-emerging highly-pathogenic viruses and micro-organisms such as Nipah virus, Avian influenza virus, SARS and CCHF virus and drug-resistant mycobacteria in India and the South-East Asian region.

These guidelines will play an important role in the current efforts by the Government of India to enhance biosafety and biosecurity in the country in accordance with the International Health Regulations (IHR).

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# CONTENTS

# INTRODUCTION

India, like many other progressing nations, faces a formidable challenge of infectious diseases and especially of viral infections. Despite a few major successes such as the elimination of wild polio virus, the country continues to suffer substantial morbidity and mortality from both emerging and re-emerging pathogens. The recent establishment of a 3-tiered network of Virus Research and Diagnostic Laboratories (VRDL) across the country has greatly facilitated the timely diagnosis of viral infections. These laboratories are equipped with facilities at the Biosafety Level 2 (for handling pathogens causing moderate risk to humans and low risk to the community), while a few of them have the capability to handle some of the high-risk pathogens. Building preparedness against the emerging high-risk pathogens is a need of the hour in all parts of the country, and the establishment of more high containment laboratories would be a critical step to achieve this goal.

A high containment Biosafety level 3 (BSL-3) laboratory would be mandatory for all clinical, diagnostic, teaching & research facilities that perform work involving agents that cause serious or potentially fatal disease in the workers through inhalation or lead to environmental contamination with these. All the work would be performed in bio-contained environments with appropriate engineering controls. Work would be performed only by specifically trained personnel and supervised by scientists competent in the handling of infectious agents.

## Key elements of Biosafety level-3 (BSL-3) laboratory

Following are the key elements for the establishment of BSL-3 laboratory,

- *a) Biorisk assessment*
- *b) Specialized physical, engineering infrastructure and environment (Annexure-1)*
- *c) Safety equipment (Primary and secondary containment barriers) and other supplies*
- *d) Training of human resource for special practices*

## Importance of these key elements are described and discussed in relevant sections below:

The following guidelines are to summarize the practical approaches for the establishment, commissioning, operationalization, requirement of validation and functionality of a BSL-3 laboratory. These guidelines mainly assist the VRDL network for establishing BSL-3 laboratories for expanding their diagnostic and research capabilities in handling high risk pathogens.

## General considerations in the establishment of a Biosafety Level 3 (BSL-3) laboratories

An in-depth analysis of the scientific framework, objectives, pre-requisites (availability of manpower, funding and space) as well as plan of proper utilization of the facility is a critical requirement prior to decisions on development of a biosafety level 3 laboratory.

## Following essential steps are involved in establishing BSL-3 laboratory (Figure-1)

**Identifying pre-requisites for the construction**

**Defining basic objectives and scope of work**

**Preparation of pre-design, construction site selection and risk assessment of area**

**Preparation of BSL-3 laboratory design based on risk assessment**

**Construction of BSL-3 laboratory**

**Commissioning of laboratory**

**Validation of the laboratory**

**Operation and maintenance**

# 1. IDENTIFYING PREREQUISITES FOR THE CONSTRUCTION



The first step in initiation for executing the thought of establishing BSL-3 laboratory is identifying the pre-requisites/assessment of proposed facility for the construction is based on

- *Defined comprehensive outline of scientific framework*
- *Specific objectives, pre-requisites (manpower, space and funding)*
- *Plan for proper utilization of the facilities*
- *Assessment of scientific and biosafety strength*
- *Identifying the breach of biosafety with existing protocols*
- *Preparation of preliminary flowchart for laboratory work*
- *Specifying the need of engineering controls, Administrative controls and Personal protective equipment (PPE) to accomplish the desired task.*

## Assessment of biorisk:

Based on the severity of infection caused by the pathogens to individuals and to the communities, microbes are divided into four risk groups (Annexure-2a). Identifying the risk group of the pathogens and other associated factors would be helpful in proper risk assessment.

Assessment of biorisk plays a key role in defining biosafety infrastructure, requirement of engineering controls and safety equipment, hence in establishing BSL-3 laboratory.

## Specifically, assessing the biorisk involved

- *In work protocols and high-risk pathogens to be handled.*
- *With other factors: Pathogenicity, infectious dose, Natural route of infection, Potential outcome of exposure, pathogen stability, availability of effective prophylaxis or therapeutic interventions.*
- *During specimen handling, packaging and transport of high-risk pathogens in animal experiments to be conducted*
- *During discarding, disinfection and decontamination procedures*

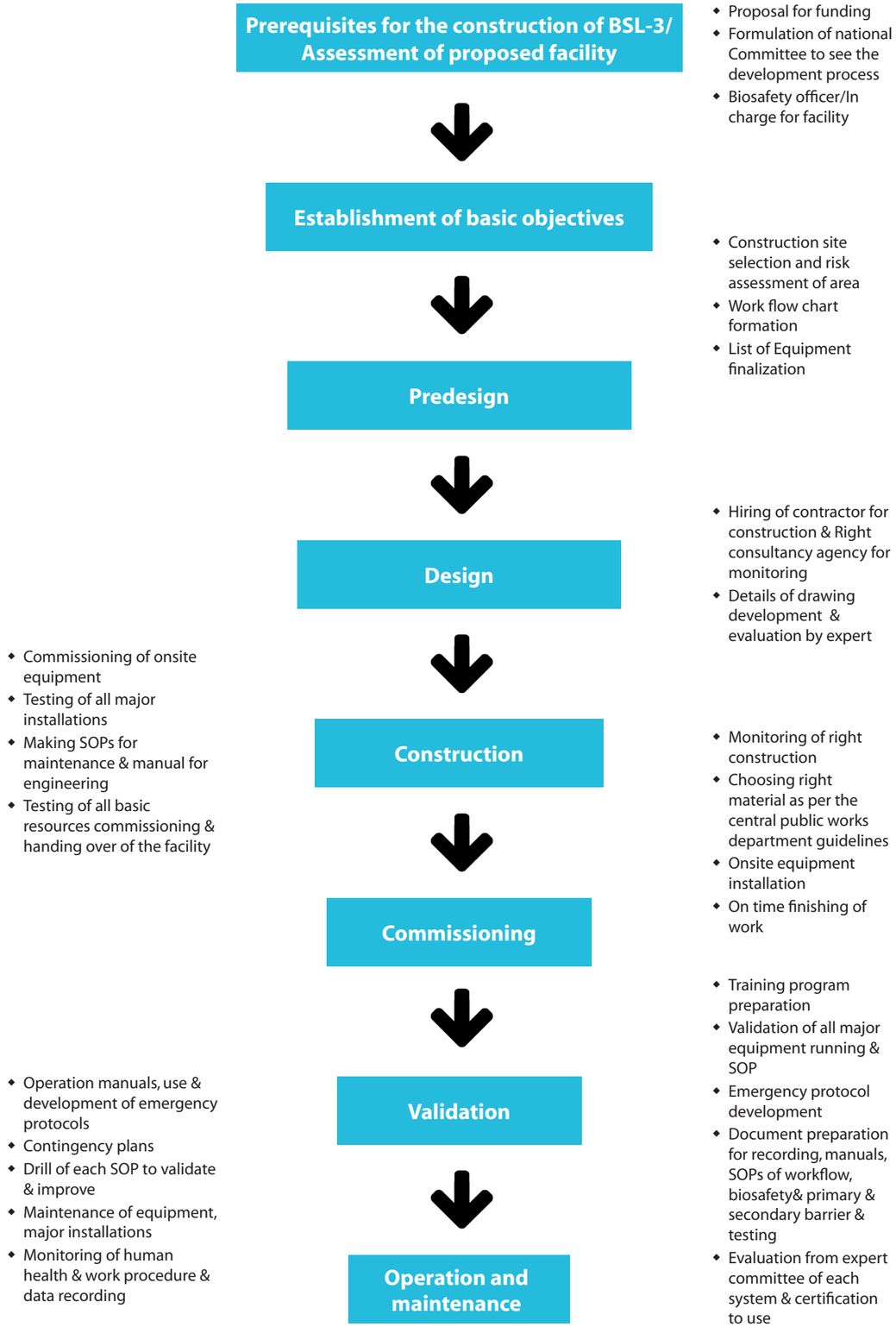



Figure: -1 Essential steps involved in establishing BSL-3 laboratory
Source: Mourya DT et al., (2014)



Further, understanding the relationship of risk groups to biosafety levels, practices and equipment to be used (Annexure-2b) in laboratory procedures will help in understanding the requirements and practices for risk reduction and containment of pathogens. Key steps involved in risk assessment are represented in Figure-2 and important points to be considered during risk assessment process and risk prioritization matrix is represented in Annexure-3.

Based on the above considerations a detailed conceptual proposal needs to be prepared including budget estimation for funding, simultaneously formulation of national committee that will help in monitoring of developmental process.

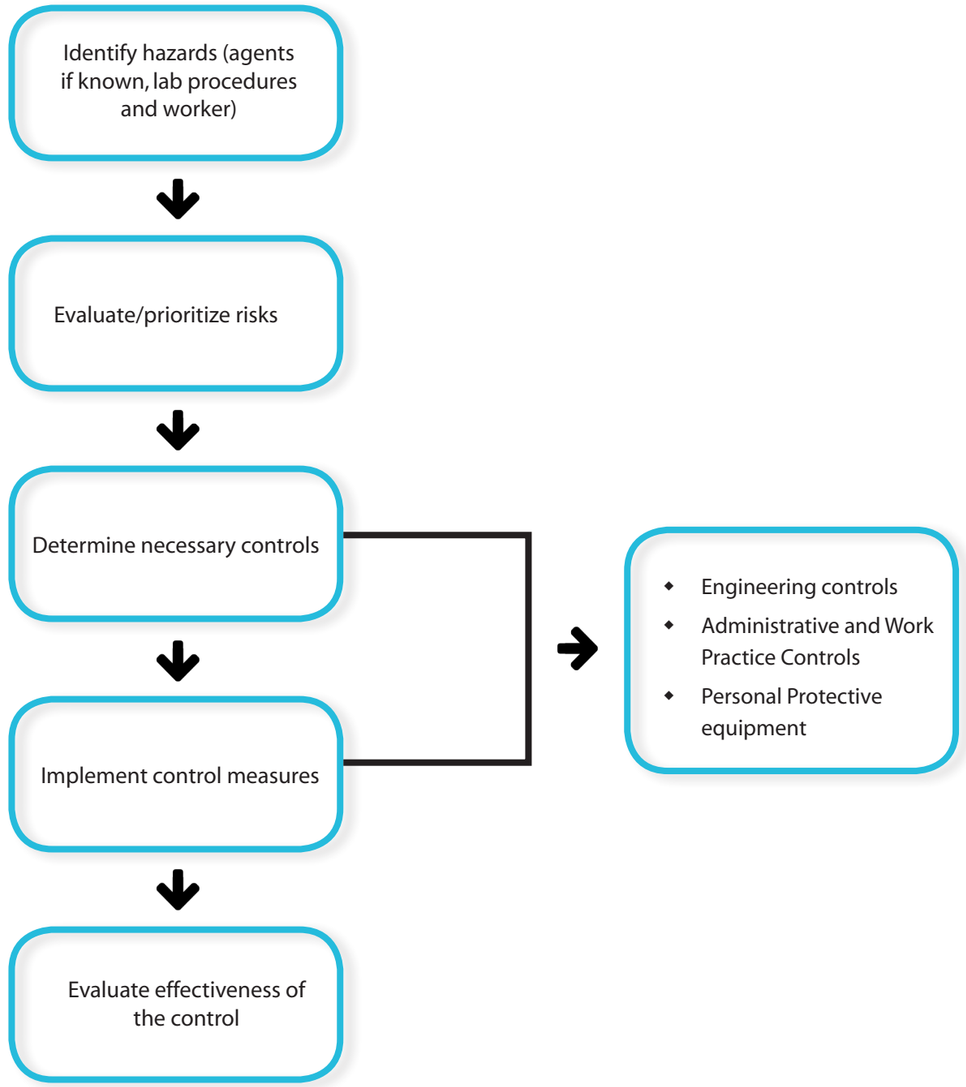



Figure: -2 Risk Assessment process flowchart

# 2. DEFINING BASIC OBJECTIVES AND SCOPE OF WORK



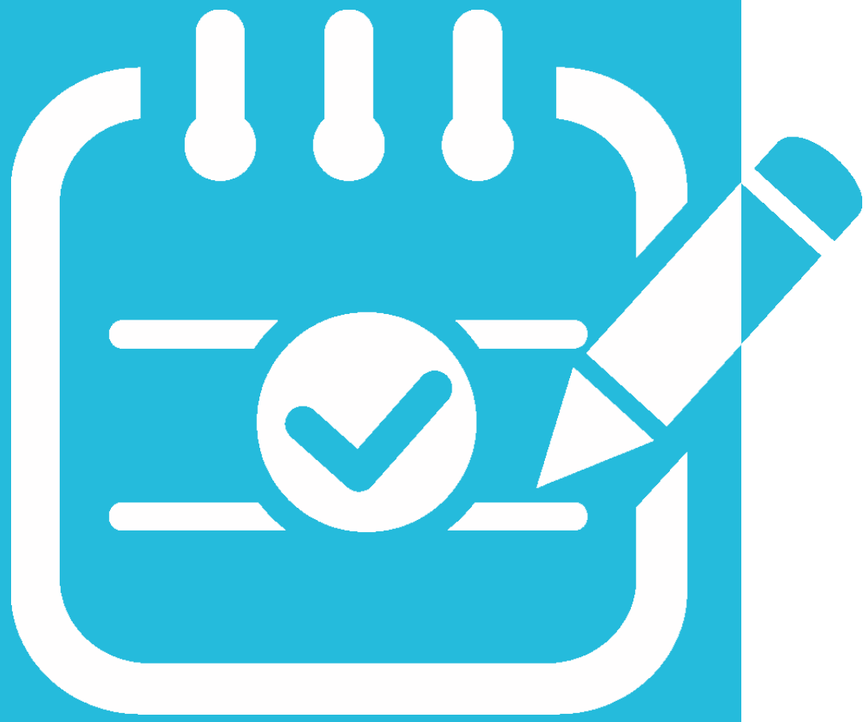
The basic objectives for establishment of containment laboratories for handling risk group-III agents include:

- Handling of clinical samples of patients infected with high risk pathogens during routine diagnostic testing or outbreaks.
- Conducting basic, applied or clinical research, or a combination of these on high risk pathogens.
- Creating safe environment for detection, identification, propagation, manipulation of such organisms in the laboratory; as well as maintaining safety of the community and the environment.
- List of probable high-risk pathogens on which laboratory propose to work along with their relative importance in terms of human morbidity and/or mortality in the region should be included in the scope.

Further, considering the futuristic approach, scope of work intended to be performed in the BSL-3 laboratory has to be discussed thoroughly among the scientific/Biosafety officer and administrative heads of the institution.Specifically, assessing the biorisk involved.

**Defining basic objectives and scope of work**

# 3. PREPARATION OF PRE-DESIGN



During preparation of pre-design of the BSL-3 laboratories there are several criteria which play critical role in pre design preparation that should be understood (Annexure-4a, b, c). Further knowing different types of BSL-3 described below and their important features will ensure correct pre-design development.

## Types of BSL-3 laboratories

Multiple designs of BSL-3 laboratories exist, varying in the overall layout, area, infrastructure and cost input. In any format, these laboratories are sophisticated, expensive establishments, and the choice of the design depends on several factors: the overall mandate, objectives and scientific framework of the laboratory, the frequency of occurrence of high-risk pathogens in the region, clinical-scientific, administrative and financial commitment, availability of expertise, laboratory space and funding support. The features of the different types of BSL-3 laboratory and the factors to consider in their choice are summarized in Table-1.

## Selection of construction site and risk assessment of the area

- BSL-3 laboratory should be ideally located in separate building or it must be separated from the general traffic flow and accessed through an anteroom/air lock facility within a building.
- Hence, for construction of BSL-3 laboratory a new stand-alone facility of the institutional site should be selected. The construction site should meet the basic criteria of uninterrupted supply of water and electricity, easy connectivity to the nearest airport and feasibility for a 3-tiered security system.
- An in-depth risk analysis should be done in the area selected, for susceptibility to natural disasters like landslides and earthquakes. The risk for possible damage to the site from occurrences like landslides, heavy rains and flooding should be systematically evaluated.
- The proposed site should be subjected to excavation to a depth of 2 meters to detect possible presence of 'borehole logs'. Detailed analysis of soil properties at the site also needs to be undertaken in order to evaluate the suitability for construction.

## Defining workflow for diagnostic/research procedures

Defining the work flow and preparation of flow charts based on mandate along with the utility of the BSL-3 laboratory plays a primary role in enhancing the safety and effectiveness of development of pre-design.

- Identify the workflow, prepare required flow charts for each routine diagnostic and research procedures.

## Identifying the list of equipment

- Equipment are the integral part of the BSL-3 laboratory for the conduct of experiments/ procedures.
- Based on the workflow and the flow charts prepared for the conduct of tests, identify the equipment required for specific work.
- Finalize the list of equipment required and identify the rooms/space where these equipments should be placed (Table-2).
- Other equipment and accessories required for environment protection and personal protection should also be listed for pre-design preparation i.e.: use of HEPA filtration of exhaust air, effluent decontamination or chemical kill tank, personnel shower in the changing area, etc. inner and outer change rooms for showers, to allow easy entry and exit protocols for the laboratory personnel.

# 4. PREPARATION OF BSL-3 LABORATORY DESIGN



In this phase, complete design with action plan for constructing a BSL-3 laboratory should be crystallized which mainly include:

## Developing an action plan

A complete action plan for constructing the BSL-3 laboratory should be developed during the planning phase. This involves preparing a detailed flowchart of the construction work and a schematic drawing to enable detailed planning.

- *A detailed drawing of development of the entire facility should then be prepared, in order to monitor the work progress.*
- *The drawings must depict the layout of all laboratory areas to facilitate placement of essential on-site and stand-alone equipment (including autoclaves, biological liquid effluent decontamination plant/chemical kill tank, air handling units, exhaust filters).*
- *The plan should also indicate the placement of safety equipment, such as fire extinguishers etc. within the facility. A detailed concept proposal with detailed drawings, plans as per requirements and abiding the biosafety regulations should be developed.*
- *Preparation of detailed construction document with final specifications*
- *Finalizing the engineering controls*

## Hiring of contractor/agency for construction

- *Hiring qualified, experienced architects, engineers to prepare design and construction of the project in addition to finding the right construction agency/contractor.*
- *Construction agency should have (i) the minimum average annual turnover during the last three financial years (as per their audited balance sheets)- this ensures the ability of agency to complete the project. (ii) Successful and timely completion of at least one similar project, which involved construction, testing,*

*commissioning and validation of BSL-2 /or BSL-3 laboratory including civil works, electrical works, HVAC works, Building Management System, door interlocks, access control system, primary barrier containment equipment, decontamination system, etc., during the previous five years.*

- *The ability of construction agency for designing and planning, correct evaluation of architectural layout plans, men and material movement plans, zoning plans, specialized systems and services schemes, services and utilities schemes, laboratory commissioning and validation protocols, laboratory security protocols, integration of laboratory and equipment should be assessed.*
- *The most important part is providing correct magnitude/valuation of the project and completion on time, customer satisfaction, cost overrun, if any and litigation, if any.*



## Evaluation of design by expert committee

- *Constitution of a Project Implementation Committee*
  *A Project Implementation Committee (PIC) should be constituted, with expert members from scientific, technical or engineering & architecture background, holding an extensive experience in design and commissioning of biosafety laboratories.*
- *This committee shall have the overall accountability and authority for construction of the laboratory. A crucial member of this committee would be the official who holds the responsibility for the overall functioning and safety of the laboratory.*
- *The committee would recognize the amount of work involved before laboratory design is -initiated.*
- *In view of the scarcity of advanced biosafety expertise in the country, a few members with scientific and engineering background could be trained in currently existing BSL-3 laboratories, to gain exposure and experience.*
- *All members of the PIC should gain familiarity with the information relevant to the project. The team should meet at least once every month, for discussions to evolve the criteria for the proposed laboratory, based on priorities and requirements.*
- *An evaluation of the prepared drawings should be done by an expert committee to review whether the proposed design is as per the requirements and also complies with the "General Guidelines of Biosafety and Biosecurity" for the BSL-3 laboratories in state/country.*
- *Design should also consider placing vibration-sensitive instruments such as microscopes etc. away from structural columns or over slab-on-grade.*
- *The engineering staff associated with the laboratory should gain experience in modern mechanical systems, including Building Management Systems that would be installed in the laboratory.*
- *Design should also include those for electrical supply of transient or voltage fluctuations with harmonics along with adequate voltage requirement of uninterrupted power supply (UPS).*
- *Identification and appointment of staff who would perform specific responsibilities in the laboratory needs to be done at this stage. Preliminary finish schedules and material selection for hardware and construction requirements should be finalized. The recommendations also include developing an Engineering Manual for the operation of the facility.*

Defining all the above factors will help in monitoring the progress of the work and successful, timely completion of the project.

# 5. CONSTRUCTION



An important aspect in the construction of the BSL-3 laboratory is putting forward the conceptual proposal with detailed drawings and plans, justifying the objectives for the construction as per the requirements along with abiding with the national and international guidelines of biosafety.

- *A construction document with final specifications is to be prepared at this stage. The final proposal with detailed drawings and equipment specifications should submitted for release of funds so that tenders can be invited.*
- *Tender must be prepared to select agencies/organizations experienced in similar works earlier, and with proven track record.*
- *The tender should include the general conditions of contract, description and scope of work, qualification criteria, instructions to bidders and evaluation of bids, in addition to the notice inviting the tender.*
- *Some of the construction documents setting basic criteria and requirements for this facility should be part of the tender document.*
- *A credible agency and contractor with successful track record in undertaking similar works should be identified as described in laboratory designing phase.*
- *Awarding the tender to agency, hiring a consultant agency for supervising the quality of construction as per the requirements recommended in national and international standards.*
- *Tender must be customized to select a professional organization, having experience of constructing this kind of laboratory.*
- *An agreement should be signed specifying all the requirements and guidelines to be followed, mentioning the time limit given for the completion of the project and the penalty clause, if not completed in time.*

## Monitoring of precise construction

- *It is important to monitor precise construction by Identifying project management consultant.*
- *Given the scarcity of regulations, codes and standards for high containment laboratories in the country, and the complexity of the international standards, a competent agency or group of engineers should supervise the quality of construction process.*
- *The local engineering department may ensure supervision of construction. Installation of integral equipment and procurement of accessory equipment required for the laboratory could proceed along with the construction work.*
- *The team members should possess a thorough understanding of the features of the equipment being procured and the essential requirements for their installation, calibration and routine maintenance.*
- *Selection of correct material as per international guidelines is the prime requirement during construction phase.*

## Installation and testing of equipment

- *The placement and installation of all on-site equipment like autoclaves, Biological Liquid Effluent Decontamination (BLED) plant/chemical kill tank, air handling units, exhaust filters within the facility must be identified.*
- *Placement of all safety equipment like fire extinguishers etc. within the facility should also be incorporated in the detailed drawing.*
- *Approvals should also be taken at this stage from the local fire departments, so that at later stages facility can pass the fire norms. Complete Heating Ventilation Air Conditioning (HVAC) design calculations for maintenance of unidirectional airflow and negative pressure as compared to the ambient within the facility and air flow diagrams must be prepared.*
- *Adequate considerations must be given to the ability of the laboratory facility engineering staff to start learning to operate modern mechanical systems as soon as these are installed in the laboratory.*
- *During planning with various laboratory work flowcharts, on-site and stand-alone equipment and the requirement of electrical supply of transient or low voltage fluctuations with low harmonics along with adequate voltage requirement of uninterrupted power supply (UPS), should be taken care of.*
- *At this stage, staff that will be required for working in the facility must be identified and trained for carrying out specific responsibilities.*
- *Developing an "Engineering Manual" for the operation of the facility is also recommended.*

# 6. COMMISSIONING

The process of laboratory commissioning plans ideally should start in the design phase and continue throughout the construction process.

## The commissioning process of the laboratory includes three phases:

*(i) Testing and commissioning of "on-site" equipment– this should be initially performed by the construction contractor alone. It should be repeated and demonstrated to an authorized person or project management consultant for the facility.*

*(ii) Testing and validation of the commissioning process of equipment are performed in presence of the facility In-charge and Biosafety Officer.*

*(iii) Final testing and commissioning should take place in presence of committee / project team. On completion the laboratory is to be made functional, ready for takeover.*

- *Commissioning procedure for the laboratory should be well designed and implemented to verify the safe facility operation.*
- *Testing and commissioning of some of the elements are crucial to the proper functioning of the containment, such as airflow patterns and pressures within isolators and biosafety cabinets, temperature profiles in autoclaves, procedures for decontamination and sterilization, verification of light lux level (must be between 300-600 lux), operation of HVAC systems, capacity calculations of HVAC systems plant, chilled water pumps capacity, air quantities at outlet diffusers / grilles, and air compressor, testing air curtains, steam boiler, clean room garment storage cabinet, floor traps, drains, dunk tanks, checking of ceiling panels, pass box, shower cabinets/air shower, water outlets, air leak in ducts as well as plenums, doors and view panels along with functioning of all the alarm systems.*
- *Taking over the facility includes verifying all the basic requirements as per the approved layouts, electrical connections (raw, essential and UPS), local area network (LAN) connections, servers, water connections, sewage connection, hardware fitting, telephones and intercoms, functioning of the BMS with all the desired parameters, fine setting of access control and all the inventories.*

## Staff Pattern in a BSL-3 Laboratory and Preparation of Training program

- *A multi-disciplinary team of specially trained staff, consisting of clinical/scientific, engineering, administrative and support staff is integral to the functioning of a BSL-3 laboratory.*
- *An experienced and qualified Biosafety Officer and a Scientist-in-Charge would be responsible for the overall functioning of the facility. The objectives of the laboratory and the specific projects to be undertaken in the laboratory would be important considerations in deciding the pattern of scientific and technical team.*
- *Staff requirement would also include an officer-in-charge for maintenance, one technician each for HVAC, electrical systems, instrumentation and the staff for general building and service maintenance.*
- *On-site training on relevant aspects could be considered for the project staff, at other laboratories.*

## Preparation of Training program

All personnel recruited in the BSL-3 laboratory must successfully complete a comprehensive training program on BSL-3 laboratory functioning.

- *This training program should be developed keeping in mind the mandate and specific requirements of the laboratory; this training should cover the concepts of biosafety and biosecurity and safe working within the BSL-3 laboratory.*
- *The Biosafety Officer and Scientist-in-charge of the facility shall be responsible for the development and implementation of the training programs and protocols.*
- *In addition to the initial training, refresher trainings on biosafety (along with safety drills) should be conducted every six months.*
- *Records of orientation and refresher training for staff should be maintained along with the list of trainees and results of assessment/competency evaluation.*

## Development of Standard Operating Protocols (SOPs)

- *SOPs should be developed for use of all laboratory equipment, general laboratory work, processing of clinical samples and diagnostic assays performed.*
- *Development and validation of SOPs for emergency protocols in the laboratory is another important concern, and should be considered from the beginning of laboratory construction.*
- *The SOPs developed should also be validated by a designated officer.*

## Testing of all resources and handing over of laboratory

After completing commissioning process all resources including SOPs should be tested before taking over the laboratory from the construction agency to ensure and understand practical functionality as well as user acquaintance of the BSL-3 facility.

# 7. VALIDATION OF THE LABORATORY



Approval from local statutory authorities like the Fire Department and Municipal Corporation should be obtained before commencing operation of the laboratory for validation. Staff training should be reinforced and mock drills along with validation of SOPs should be conducted at this stage. Upon completion of these processes, the validation process for the laboratory can be started.

## Preparation of essential documents and program for laboratory validation

Important step at this phase would be the preparation of documents certifying compliance with the international guidelines. A document describing the mandate and features of the laboratory would be a primary requirement.

- *In addition, commissioning reports of major equipment, SOPs of laboratory workflow, use of equipment and engineering controls (including records of operation of AHU and change of filters), user log books of all equipment, certification details, maintenance reports should also be prepared and maintained in the laboratory.*
- *The records for entry/exit, printouts of shower entry, records of daily checks, requisition file, and file of calibration of equipment should be prepared and maintained.*
- *Documents in support of validation of decontamination processes (e.g., spore strip test for validation of autoclaves, records of area fumigation and surface swab tests), record of performance of Building Management System, room pressure, temperature and humidity should also be prepared.*
- *Documents related to the inventory of samples and other material (stored in laboratory refrigerators, -20˚C and -86˚C freezers and liquid nitrogen storage) and backup plans should be developed.*
- *Facility and Operation Manuals explaining biosafety aspects as well as maintenance of engineering systems should also be prepared.*
- *A Technical Manual should also be developed for the facility.*
- *Validation of the laboratory should be conducted by internal and external expert committees in liaison with the Facility-in-Charge and/or Biosafety Officer, construction agency and project management consultancy.*
- *The validation process aims to ensure biosafety and biosecurity concerns to the workers, work and the environment as well as adherence to the work flow program.*

# 8. OPERATION AND MAINTENANCE

The laboratory would commence the safe operation mode upon completion of the validation process and obtaining the certificate to use the facility.

- *The contingency plan for emergencies needs to be reviewed during the regular operation mode, to prevent biosafety breaches with respect to the building management systems, UPS, DG set and autoclaves.*
- *All organizations which undertake work involving microorganisms/genetically engineered organisms should constitute an Institutional Biosafety Committee which should prepare an updated site emergency plan as per recommendations given in the Review Committee on Genetic Manipulation (RCGM), and also evaluate the biosafety concerns arising from experimentation and containment issues.*
- *Operation and comprehensive maintenance contract for day to day (24Hr) operation of BSL-3 lab should be undertaken in advance with the suppliers for all major equipment to ensure prompt service. A contract should also be undertaken for maintenance of the facility with the facility contractor to ensure engineering support.*
- *Finally, Memoranda of Understanding should be executed with the contractor and subcontractors to ensure uninterrupted provision of spares and services, for a minimum period of 5 years.*

After successful competition of all the phases involved in establishment of BSL-3 laboratory, during routine usage of the facility, the laboratory persons have to self- assess the biosafety parameters (Annexure-5) in the laboratory. Further to generate systematic documented evidence, every BSL-3 laboratory should develop a format for capturing basic laboratory safety check points (Annexure-6).

In conclusion, for achieving biosafety and biosecurity during handling high risk pathogens, multifactorial assessment of biorisk, infrastructure, safety equipment, Good Laboratory Practices, trainings etc. is mandatory as described in these guidelines.

# FURTHER READING


- *Mourya DT, Yadav PD, Majumdar TD, Chauhan DS, Katoch VM. Establishment of Biosafety Level-3 (BSL-3) Laboratory: Important criteria to consider while designing, constructing, commissioning & operating the facility in Indian setting. Indian J Med Res 2014; 140:171-83.*
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- *Regulations and guidelines for recombinant DNA research and bio contentment 2017. Accessible at: http://www.dbtindia.nic.in*

## Annexure-1: BSL-3 Laboratory Infrastructure And Environment

| Sr.# | BSL-3 laboratory infrastructure and environment | Remarks |
|---|---|---|
| 1 | Controlled access | |
| 2 | Physical separation from access corridor | |
| 3 | Personnel shower | Optional, as/risk assessment |
| 4 | Anteroom; two self-closing interlocked doors | |
| 5 | Single pass air directional air flow | |
| 6 | Air pressure differential (ranging from -10 to -60 Pa, as per the risk assessment) | |
| 7 | Exhaust system independent from remainder of the building | |
| 8 | Supply system independent from remainder building | |
| 9 | Single HEPA filtered exhaust | Depending upon the size of the lab., multiple HEPA filters at exhaust points are necessary. Thus, HEPA SAFE CHANGE BOX could be considered connected with a single suitable blower with 100% redundancy |
| 10 | Supply exhaust fans interlocked with supply fans | |
| 11 | Redundant exhaust fan (N+1) | |
| 12 | Utilities backflow prevention | |
| 13 | Minimum 6-12 air changes per hour | |
| 14 | Autoclaves available in facility | Within facility preferable |
| 15 | Sealed windows | |
| 16 | Sealed penetrations | |
| 17 | Seamless floors | |
| 18 | Monolithic ceiling | |
| 19 | Chemical resistant floors, walls, ceiling, doors and frames | |
| 20 | Chemical resistant piping, fixtures and casework | |
| 21 | BSL-3 laboratory on emergency power | |
| 22 | Laboratory lighting and biosafety cabinets on emergency Inverter/UPS | Preferred to avoid blackout |
| 23 | HVAC failure alarm | |
| 24 | Pressure differential monitors | |
| 25 | Deep sealed floor traps | |
| 26 | Hand wash sinks and emergency eye wash | |
| 27 | Surface mounted sealed lighting | |
| 28 | Less than 60 db. noise level | |
| 29 | Lighting (300-600 lux) | |
| 30 | BSC shall be located out of the mainstream of traffic | |
| 31 | Isolation dampers in ventilation system | |



## Annexure-2A: Classification Of Infective Microorganisms By Risk Group

| | |
|---|---|
| **Risk Group 1 (No or low individual and community risk)** | A microorganism that is unlikely to cause human or animal disease |
| **Risk Group 2 (Moderate individual risk, low community risk)** | A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment.<br>Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited. |
| **Risk Group 3 (High individual risk, low community risk)** | A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another.Effective treatment and preventive measures are available. |
| **Risk Group 4 (High individual and community risk)** | A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. |

## Annexure-2B: Relationship Of Risk Groups To Biosafety Levels, Practices And Equipment

| Risk Group | Biosafety level | Laboratory Type | Laboratory practices | Safety equipment |
|---|---|---|---|---|
| 1 | Basic Biosafety level 1 | Basic teaching, research lab | Good Microbiological Techniques (GMT) | None: open bench work |
| 2 | Basic<br><br>Biosafety level 2 | Primary health,<br><br>services; diagnostic, services, research | GMT plus protective clothing, biohazard sign | Open bench plus biological safety cabinet (BSC) for potential aerosols |
| 3 | Containment Biosafety level 3 | Special diagnostic services, research | As level 2 plus special clothing, controlled access, directional airflow | BSC & other primary devices for all activities |
| 4 | Maximum Containment Biosafety level 4 | Dangerous pathogen units | As Level 3 plus airlock entry, shower exit, special waste disposal | Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double ended Autoclave (through the wall),<br><br>filtered air |

# Annexure-3:
## Points To Be Considered During Biological Risk Assessment

- *The backbone of the practice of biosafety is risk assessment.*
- *While there are many tools available to assist in the assessment of risk for a given procedure or experiment, the most important component is professional judgment.*
- *Risk assessments should be performed by the individuals most familiar with the specific characteristics of the organisms being considered for use, the equipment and procedures to be employed, animal models that may be used, and the containment equipment and facilities available.*
- *The laboratory director or principal investigator is responsible for ensuring that adequate and timely risk assessments are performed, and for working closely with the institution's safety committee and biosafety personnel to ensure that appropriate equipment and facilities are available to support the work being considered.*
- *Once performed, risk assessments should be reviewed routinely and revised when necessary, taking into consideration the acquisition of new data having a bearing on the degree of risk and other relevant new information from the scientific literature.*
- *One of the most helpful tools available for performing a microbiological risk assessment is the listing of risk groups for microbiological agents. However, simple reference to the risk grouping for a particular agent is insufficient in the conduct of a risk assessment.*
- *No one standard approach or correct method exists for conducting a risk assessment.*
- *However, several strategies are available, such as using a risk prioritization matrix, conducting a job hazard analysis; or listing potential scenarios of problems during a procedure, task, or activity.*



## Other factors that should be considered as appropriate include:

- *Pathogenicity of the agent and infectious dose*
- *Potential outcome of exposure*
- *Natural route of infection*
- *Other routes of infection, resulting from laboratory manipulations (parenteral, airborne, ingestion)*
- *Stability of the agent in the environment*
- *Concentration of the agent and volume of concentrated material to be manipulated*
- *Presence of a suitable host (human or animal)*
- *Information available from animal studies and reports of laboratory-acquired infections or clinical reports*
- *Laboratory activity planned (sonication, aerosolization, centrifugation, etc.)*
- *Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens*
- *Local availability of effective prophylaxis or therapeutic interventions.*
- *On the basis of the information ascertained during the risk assessment, a biosafety level can be assigned to the planned work, appropriate personal protective equipment selected, and standard operating procedures (SOPs) incorporating other safety interventions developed to ensure the safest possible conduct of the work.*
- *Each laboratory should adopt a safety or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards.*



## Risk Prioritization Matrix

- *The process involves the following five steps:*
- *Identify the hazards associated with an infectious agent or material.*
- *Identify the activities that might cause exposure to the agent or material.*
- *Consider the competencies and experience of laboratory personnel.*
- *Evaluate and prioritize risks (evaluate the likelihood that an exposure would cause a laboratory-acquired infection and the severity of consequences if such an infection occurs).*
- *Develop, implement, and evaluate controls to minimize the risk for exposure.*

| Likelihood | Consequences | | | | |
|---|---|---|---|---|---|
| | Insignificant | Minor | Moderate | Major | Severe |
| Almost certain | M | H | H | E | E |
| Likely | M | M | H | H | E |
| Possible | L | M | M | H | E |
| Unlikely | L | M | M | M | H |
| Rare | L | L | M | M | H |

## Annexure-4a: Criteria for BSL-3 laboratory

| Overall guidelines | High Containment Laboratory (HCL) |
|---|---|
| Containment barrier outlined and appropriate | Yes |
| Office area located outside of laboratory Equipped with computer control for restricted access | Yes |
| Clean/Dirty change area separated by a walk-through shower | Yes |
| Double door pass-through autoclave with interlocking doors or visual/audible alarm | Yes |
| Large door to allow entry of equipment | Yes |
| Interlocking door system (Computer control access with manual override) | Yes |
| Room pressure to be monitored either by differential pressure gauge or other means of display of pressure. | Yes |
| Decontamination ports, Dunk tank, Pass through | Yes |
| Surfaces having Epoxy and Polyurethane coating, Able to withstand disinfectants, No porous joints | Yes |
| Impact resistant material | Yes |
| All penetrations are sealed (water plumbing/ducts/cables etc.) | Yes |
| Air Handling separate from other areas of lower/non containment, Motorized bubble tight damper or HEPA filter for backdraft protection. Bubble tight damper for gaseous decontamination. Exhaust completely sealed and ducked out | Yes |
| Location of supply does not interfere with inlets and outlets; different users properly designed hence not applicable | Yes |
| All inlets and outlets are computerized to control and balance the negative pressure | Yes |

## Annexure-4b: Criteria for BSL-3 laboratory

| Laboratory Services | High Containment Laboratory (HCL) |
|---|---|
| Communication system (Direct telephone line, Intercom, LAN network connections and CCTV etc.) | Yes |
| Water supply provided with backflow preventers at containment barrier | Yes |
| Full-fledged shower facilities | Yes |
| Drainage traps with double U traps and filter mechanism | Yes |
| Effluent piping to be heat and chemical resistant | NA |
| Autoclave condensate drain located on dirty side (leading to either BLED tank or Chemical Kill Tank) | Autoclave condensate drain located on dirty side |
| List of equipment on the emergency generator (specifications) | AHU with twin motors, Access control, Isolators, Computers & LAN system, BSCs, Emergency lights and other important equipment are backed by inverter & UPS. Whole electrical system has back-up to back-up DG sets. |
| Emergency lighting to be provided | Supported by Inverters and UPS |

## Annexure-4c: Criteria for BSL-3 laboratory

| HEPA Housings | High Containment Laboratory (HCL) |
|---|---|
| Provided with a bubble tight damper for isolation on inlet and outlets | Yes |
| Provided with fumigation ports upstream and downstream | Yes |
| Provided with upstream injection port and downstream access port for scanning purposes | Yes |
| Leak tight | Yes |
| **Biosafety cabinets (BSCs)** | |
| Type and class of BSCs (thimble, hard-ducted, recirculated, charcoal filter, etc.) | Class-II, B2 type with HEPA in and HEPA out filters. 100% exhaust. Chemical resistant (high density polyurethane material) used for ducting |
| Located 1.5m from supply/exhaust ducts, doors, air generating equipment | Exhaust completely sealed and ducted out |
| 30 cm clearance between exhaust outlet and ceiling | Yes |
| 30 cm around cabinet for access | Yes |

## Annexure-5: Self-assessment of Biosafety

| Self-assessment of Biosafety | |
|---|---|
| ◆ Proper engineering controls are being used and are functioning adequately as designed | |
| ◆ Appropriate site and protocol specific administrative controls are in place | |
| ◆ Personal protective equipment is appropriate for the tasks being performed | |
| ◆ Decontamination of waste and materials has been adequately considered and proper waste management procedures are in place | |
| ◆ Proper procedures for general laboratory safety, including physical, electrical and chemical safety are in place. | |
| Administrative Controls and Documentation | All the manual, protocols & other material available to lab persons |
| Authorization for protocols on file | Certain restricted protocols & other confidential material available to specified persons on password digitized files |
| Biosafety Manual and SOPs | Biosafety Manual and SOPs are available to lab persons |
| Emergency Response Plan including spill contamination | Present in the lab, available to lab persons |
| Documented Biosafety training for all personnel | Present in the lab, available to lab persons |
| Laboratory Facilities | |
| Biosafety Sign posted on entrance | Yes |
| The laboratory has a sink & soap for hand washing | Yes |
| Emergency shower/eyewash facility is available | Yes |
| Windows that open to the outdoors are fixed w/ screens | Windows in the main lab not open able, others with grill |
| First aid kit readily available | Present in the lab, available to lab persons |
| Safety Equipment – Primary Barriers | |
| Biological safety cabinets (BSCs) are used whenever procedures with potential for creating infectious aerosols or splashes are conducted | Yes, have separate BSC for clean & infected work. |
| BSCs located away from doors, heavily traveled areas, etc. to maintain air flow | Yes, location is secured place |
| BSC has been certified within the past year | Yes, under AMC and checked twice in a year |
| Centrifuge safety containment cups or sealed rotors with O-rings available | Yes, also separate centrifuge for clean & infected work |
| Lab coats are not taken home by lab personnel | Yes, not to be taken out of working area |
| Autoclave | |
| **Self-assessment of Biosafety** | |
| Is autoclave QC log kept | Yes, the chemical indicator always used |
| Appropriate autoclave bags are used | Yes, autoclavable bags are used |
| The autoclave is monitored with biological indicators | Yes, once in a year |
| Standard Microbiological Practices | |
| Access to laboratory is restricted | Yes |
| Containers properly labeled | Yes, for discarding infectious material, broken glasses, waste gels etc. |
| Lab personnel receive appropriate immunizations or tests for agents handled | All the persons immunized with KFD killed vaccine, other immunizations not in the institute's general policy |
| Insect and rodent control program available | Yes, in place |
| Eating or drinking and the storage of food are prohibited | Yes, have defined area for eating and drinking |
| Mechanical pipetting devices are used | Yes, rubber bulb or battery-operated device |
| Cultures and stocks decontaminated before disposal | Yes, autoclaved before disposal |
| Plasticware substituted for glassware when possible | Yes, mostly disposable plasticware are used |
| Used needles, syringes and other sharps placed in appropriate sharps containers | Used needles should be destroyed using needle cutter before discarding it in the sharps container |
| Pasteur pipettes properly disposed | Disposable plastic pipettes used |
| Broken glass is not handled directly but by mechanical means | Yes |
| Work surfaces are decontaminated daily and following spills | Yes |
| All bio-waste is properly disposed | Yes, as per the corporation norms for disposal of bio-waste |

## Annexure-6: Format for Biosafety Level 3 [Basic laboratory safety survey]

| Location: _____ Date: _____ | | | |
|---|---|---|---|
| **Person in charge of laboratory:** | | | |
| **Laboratory** | **Yes** | **No** | **N/A** |
| Proper signage: ultraviolet light, laser, radioactive material, etc. | | | |
| Appropriate biosafety guidelines available and followed | | | |
| Laboratory equipment properly labelled (biohazardous, radioactive, toxic, etc.) | | | |
| Laboratory design | | | |
| Designed for easy cleaning | | | |
| Room ultraviolet lights on interlock switch | | | |
| All shelves secured | | | |
| Bench-tops waterproof and resistant to acids, alkali, organic solvents and heat | | | |
| Adequate illumination provided | | | |
| Adequate storage space available and appropriately used | | | |
| Gas cylinders (Should be housed outside BSL-3 core area, tubings should be in embedded condition) | | | |
| All cylinders secured | | | |
| Caps on reserve cylinders | | | |

| | | | |
|---|---|---|---|
| Asphyxiating and hazardous gases only in ventilated rooms | | | |
| Excess or empty cylinders present | | | |
| Chemicals | | | |
| Flammables stored in flammable storage cabinet | | | |
| Peroxide formers double-dated (received and opened) | | | |
| Chemicals properly segregated | | | |
| Hazardous chemicals stored above eye level | | | |
| Chemicals stored on the floor | | | |
| Chemical containers left open | | | |
| All solutions properly labelled | | | |
| Mercury thermometers in use | | | |
| Refrigerators/freezers/cold rooms | | | |
| Food for human consumption present | | | |
| Flammables in explosion-proof/-safe units labelled externally if containing carcinogens, radioactivity and/or biohazards | | | |
| Cold-room has emergency release | | | |
| Electrical equipment | | | |
| Extension cords present | | | |
| Outlets earthed/grounded and with proper polarity | | | |
| Connections by sinks, under showers, etc. | | | |
| Equipment with frayed or damaged wiring | | | |
| Overloaded outlets or electrical strips | | | |
| Power strips mounted off the floor | | | |
| Proper fuses in conduits | | | |
| Electrical outlets near water sources meet local codes | | | |
| Earths/grounds present on electrical cords | | | |
| Portable space heaters | | | |
| Personal protective equipment | | | |
| Eyewash available in laboratory | | | |
| Safety shower available | | | |
| Personal protective equipment available (gloves, gowns, goggles, etc.) | | | |
| Occupants properly attired | | | |
| Laboratory coats, gowns, smocks, gloves and other personal protective clothing not worn outside the laboratory | | | |
| Personal protective equipment available for cryogenic storage | | | |
| Waste management | | | |
| Evidence of improper waste disposal | | | |
| Wastes segregated in proper containers | | | |
| Chemical waste containers tagged, labelled, dated and kept closed | | | |
| Chemical waste containers appropriately handled and stored | | | |
| Sharps containers used and disposed of properly | | | |
| No trash on floor | | | |
| Waste disposal procedures posted in laboratory | | | |
| Occupational health and safety programs available | | | |



| | | | |
|---|---|---|---|
| Hazard communication | | | |
| Respiratory protection | | | |
| Hearing conservation | | | |
| Formaldehyde monitoring | | | |
| Ethylene oxide monitoring | | | |
| Anesthetic gas monitoring | | | |
| General engineering controls | | | |
| Laboratory airflow is negative to general occupancy, corridor and office areas | | | |
| Cup sinks or drains acting as vents | | | |
| Sink available for hand-washing | | | |
| Exposed machine parts (pulleys, gears) | | | |
| Vacuum line has filters and traps on laboratory benches | | | |
| Backflow hazards to water supply | | | |
| Distilled water systems in good condition | | | |
| Active and effective arthropod and rodent control program | | | |
| General practices and procedures | | | |
| Food for human consumption stored outside the laboratory | | | |
| Microwave oven(s) clearly labelled "No Food Preparation, Laboratory Use Only" | | | |
| Eating, drinking, smoking and/or applying of cosmetics occurring in the laboratory | | | |
| Pressurized glass containers taped or shielded (i.e. vacuum traps) | | | |
| General practices and procedures | | | |
| Mouth pipetting prohibited | | | |
| Mechanical pipetting devices available and used | | | |
| Protective laboratory clothing stored separately from street clothing | | | |
| General laboratory housekeeping | | | |
| Glass containers stored on the floor | | | |
| Trip hazards evident | | | |
| Clean absorbent pads on work surfaces | | | |
| Broken glassware handled by mechanical means (brush and dustpan, tongs, etc.) | | | |
| Fire protection | | | |
| Fire suppressor gas system heads free and unobstructed | | | |
| Open penetrations in walls, ceiling, floor, etc. | | | |
| Wiring or tubing through door openings | | | |
| Minimum passage width of 1 m in laboratory | | | |
| Storage observed on ductwork or light fixtures | | | |
| Heated constant temperature baths | | | |
| Equipped with low water level and overheat shutoff | | | |
| Constructed of non-combustible materials | | | |

| Biological safety cabinet (BSC) Location: | : | | |
|---|---|---|---|
| Brand | : | | |
| Type | : | | |
| | Serial no.: | | |
| | Yes | No | N/A |
| BSCs located away from doors, heavily travelled areas, etc. to maintain air flow | | | |
| Certification within last year | | | |
| BSC surface wiped down with appropriate disinfectant at beginning and end of each procedure | | | |
| Front grill and exhaust filter unobstructed | | | |
| Open flames used inside cabinet | | | |
| Vacuum lines have in-line filters and disinfectant traps in use | | | |
| BSC compromised by room air or location | | | |
| BSC used when there is potential for creating aerosols | | | |
| Laboratory | | | |
| Access limited and restricted to authorized personnel | | | |
| Entry limited to personnel advised of all potential hazards | | | |
| Biohazard sign posted on laboratory door as appropriate | | | |
| Information on sign accurate and current | | | |
| Sign legible and not defaced | | | |
| All doors closed | | | |
| Decontamination | | | |
| Decontaminant specific to the organism(s) in use | | | |
| All spills and accidents involving infectious materials reported to the laboratory supervisor | | | |
| Appropriate decontaminant used during spill clean-ups | | | |
| Work surfaces decontaminated before and after each procedure, daily and after spills | | | |
| Handling of contaminated waste | | | |
| Infectious waste containers properly used | | | |
| Containers not overfilled | | | |
| Containers properly labelled and closed | | | |
| Culture stocks and other regulated waste properly decontaminated before disposal | | | |
| Materials decontaminated outside the laboratory transported in closed, durable, leakproof containers according to local rules and regulations | | | |
| Mixed waste biologically decontaminated prior to disposal as chemical or radiological waste | | | |
| Personal protection | | | |
| Laboratory personnel reminded of appropriate immunizations/tests for agents handled | | | |
| Appropriate medical services contacted for medical evaluations, surveillance and treatment of occupational exposures | | | |



| Gloves worn when handling infectious material or contaminated equipment | | | |
|---|---|---|---|
| Face protection provided when working outside the BSC with infectious material | | | |
| Hands washed after removing gloves, after working with infectious agents, before leaving the laboratory | | | |
| Antimicrobial agent available for immediate first aid | | | |
| Practices | | | |
| BSC used when potential for creating infectious aerosols/splashes exists | | | |
| Biosafety manual prepared and adopted | | | |
| Personnel read, review and follow the instructions on practices and procedures, including safety or operations manual (required for all personnel annually) | | | |
| Procedures performed so as to minimize aerosols/splashes | | | |
| Needle-locking syringes/single-use needle syringe units used with infectious agents | | | |
| Centrifuge cups and rotors opened only in a BSC | | | |
| Infectious specimens transported outside a BSC in approved containers following approved transport regulations | | | |
| Facility | | | |
| Hand-washing sink available near laboratory exit | | | |
| Laboratory separated from unrestricted traffic flow in building | | | |
| Access to laboratory through an anteroom with self-closing doors | | | |
| All penetrations in laboratory sealed or sealable for decontamination | | | |
| Room exhaust air single-pass and exhausted away from occupied areas | | | |
| Controlled ventilation system to monitor directional airflow available | | | |
| Personal protection | | | |
| Closed-front gowns worn in laboratory | | | |
| Protective laboratory clothing worn only in laboratory areas | | | |
| Hand-washing sink foot, elbow or automatically controlled | | | |
| Hand protection | | | |
| Double gloves worn when handling infectious material, potentially contaminated equipment and work surfaces | | | |
| Respiratory protection | | | |
| Respiratory protection worn by all personnel in the laboratory when aerosols are not safely contained in a BSC | | | |
| Practices | | | |
| Mucous membrane protection provided when working with infectious material outside a BSC | | | |
| Personnel advised of special hazards associated with the agent(s) | | | |
| Personnel required to read and follow all instructions on practices and procedures, including safety or operations manual | | | |
| Personnel received annual updates/additional training for procedural changes | | | |
| All contaminated waste autoclaved prior to disposal | | | |

## Annexure-7: BSL-3 Construction related information

CIVIL WORK

Doors

Windows

Walls & Ceiling Panels

Epoxy Based Joint Less Flooring & Covings

Plumbing & Sanitary Installations

ELECTRICAL & ASSOCIATED WORKS

Internal Electrification of Building

Main/Sub Distribution MV Panels

Telephone System

Cables

Earthing

Fire Detection & Alarm System

HVAC & ASSOCIATED WORKS

System Design

Drawings

HVAC System based on of design

Operating Rooms / Zone Pressure

WATER CHILLING MACHINE

Water Chilling Unit

Compressor

Condenser (Air Cooled Type)

Chiller

Refrigerant Piping

Motors & Starters

Refrigerant Circuit Accessories

Control Panel

AIR HANDLING UNITS

WATER CIRCULATION EQUIPMENT

Monobloc Type Pump Set

Pump Accessories

FILTERS

Prefilters, Fine Filters & HEPA

Filter Plenums

HEATING & REHEATING SYSTEM

Electric Heaters & Heater Frames

Contactors

Heating Thermostats

Humidistat

Pan type humidifier

CONTROLS

Air Handling Unit Controls

Condensing Unit Controls

Centrifugal Blowers

Blower Drive Assembly

MOTOR & SWITCHGEARS & MOTOR STARTERS

Control Panel

Cable Termination

Indication

Subsidiary Panels

Contactor Starters

Squirrel Cage Induction Motors

DUCT WORK & OUTLETS

Duct materials & Installations

Dampers

Grilles & Diffusers

Testing

PIPE WORK

Pipes

Fittings

Flanges

Valves

Balancing Valves

Strainers

Jointing

Hangers & Supports

Sleeves

Insulation Materials

Chilled/Hot Water Piping

Walls & Ceiling Acoustic Treatments of Plant Rooms & A.H.U. Room

ELECTRIC WIRING

Control Wiring

Compressors Condensers/Chillers/Evaporators/Pumps etc.

Air Handling Units

Piping System

Duct Work



## Annexure-8: Conceptual BSL-3 drawings

[Diagrammatic depiction, how the lab area can be accommodated if the proposed lab is in an already existing building]

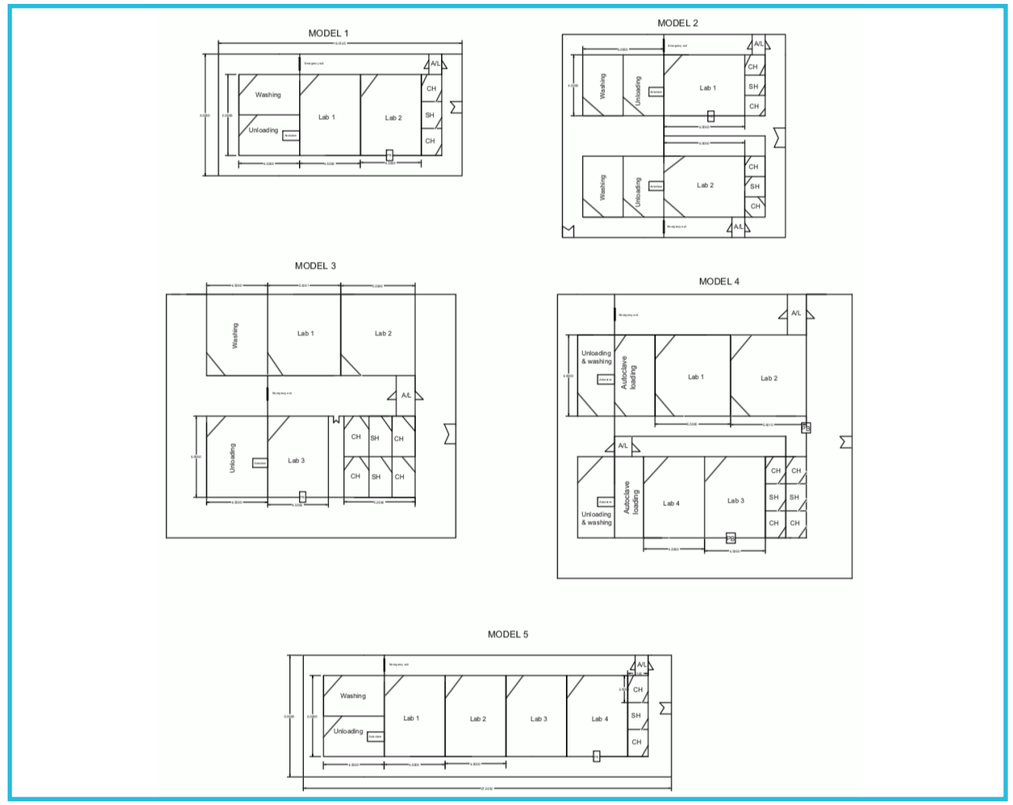

**Table-1: Categories of laboratory and secondary barrier requirements**

| Facility Type (Areas of Utilities) | Primary Containment | Eye-wash | Hand wash | Shower | On-site Autoclave | Ventilation 100% Fresh air | Ventilation Recirculatory (30% Fresh air) | Air changes /Hr. [ACPH]** | Effluent Decontamination System | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Chemical Type | Steam Type |
| BSL-2, Type-1 (Basic laboratory for laboratory diagnosis [serological & molecular] for RG-2 agents) | Class II A2 | * | * | NM | NM [vertical autoclave may be considered] | As per risk assessment | May be considered as per risk assessment | 4-6 | NM | NA |
| BSL-2, Type-2 (Laboratory with facility for propagation of infectious agents [serological & molecular] for RG-2 agents) | Class II A2 | * | * | NM | NM [vertical autoclave may be considered] | As per risk assessment | May be considered as per risk assessment | 4-6 | NM | NA |
| BSL-2, Type-3 (Laboratory with facility for propagation of infectious agents in vitro & in vivo for RG-2 agents) + equipped for providing diagnosis for MDR & X-TB | Class II A2 | * | M | NM | NM [vertical autoclave may be considered] | As per risk assessment | May be considered as per risk assessment | 4-6 | M* | NA |
| ABSL-2, (Laboratory with facility for maintaining arthropods colony and performing vector biology work on infectious agents of RG-2 agents) + equipped for processing pools for the surveillance of routine public health vector borne diseases like Dengue, Chikungunya, Scrub typhus etc. | Class II A2 | * | M | NM | NM [vertical autoclave may be considered] | As per risk assessment | May be considered as per risk assessment | 4-6 | M* | NA |
| BSL-3, Type-1 (Basic laboratory for laboratory diagnosis [serological & molecular] for RG-3 known public health disease agents) | Class II A2 | M | M | NM | NM [vertical autoclave may be considered] | M* | NA | 8-12 | M* | NA |
| BSL-3, Type-2 (Laboratory with facility for propagation of infectious agents in vitro & in vivo for RG-2 agents) + equipped for providing diagnosis for MDR & X-TB | Class II A2 | M | M | NM* | NM [vertical autoclave may be considered] | M | NA | 8-12 | M* | NA |
| BSL-3, Type-3 (Laboratory for laboratory diagnosis and with mandate of in vitro propagation of specific infectious agents for RG-2 related to DNA recombination technologies or RG-3 / MDR & X-TB agents) | Class II A2 | M | M | NM* | NM [vertical autoclave may be considered] | M | NA | 8-12 | M* | |
| BSL-3, Type-4 (Laboratory for laboratory diagnosis and with mandate of in vitro and in vivo propagation of specific infectious agents for RG-3 related to DNA recombination technologies or RG-3 /MDR & X-TB agents). Animal with experimentation with RG-3 agents up to mice, chickens and rodents. | Class II A2 + IVC | M | M | M | NM [vertical autoclave may be considered] | M | NA | 8-12 | NA | M |

| Facility Type (Areas of Utilities) | Primary Containment | Eye-wash | Hand wash | Shower | On-site Autoclave | Ventilation 100% Fresh air | Ventilation Recirculatory (30% Fresh air) | Air changes /Hr. [ACPH]** | Effluent Decontamination System | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Chemical Type | Steam Type |
| BSL-3, Type-5 (Laboratory for laboratory diagnosis and with mandate of in vitro and in vivo propagation of specific infectious agents for RG-3 related to DNA recombination technologies or RG-3 /MDR & X-TB agents). Animal with experimentation facility with RG-3 agents equipped with animal challenge experimentation with RG-3 agents | Class II A2 + IVC | M | M | M | NM [vertical autoclave may be considered] | M | M | 10-12 | NA | M |
| ABSL-3, (Laboratory for vector biology experimentation and for the surveillance of agents of vector borne diseases of RG-3 level or dealing with arthropods with infectious agents for RG-2 level related to DNA recombination technologies with facility to maintain small animals for experimentation facility with RG-3 agents) | Class II A2 + IVC | M | M | M | NM [vertical autoclave may be considered] | M | M | 10-12 | NA | M |

* Preferred, however depends on risk assessment for mandated work

NA: Not applicable

NM: Not mandatory, depends on risk assessment for mandated work

M: Mandatory

**: Air Changes depends on risk assessment for mandated work

NB: If mandate of the laboratory includes processing & propagation [in vitro] of unknown samples from known or unknown high-risk group agents' outbreak/ unusual outbreaks or regional VRDL: it is advised to follow BSL-3, Type-5 standards. However: If mandate of the laboratory includes processing & propagation [in vitro & in vivo] of unknown samples from known or unknown high-risk group agents' outbreak/ unusual outbreaks or regional VRDL: it is advised to follow ABCL-3 standards.



## Table 2. Onsite equipment in the laboratory

| Equipment | Remarks |
|---|---|
| Biosafety Cabinet | Class-II (A1/A2/B1/B2) or Class-III, based on risk assessment |
| Autoclave | Yes |
| | Size and configuration shall be based on the program/laboratory's needs. Sterilization/ decontamination cycles and options are program driven. Autoclave integrated with the containment barrier of the BSL-3 laboratory shall provide bio-seal. |
| Dunk Tanks & Pass Boxes | Size and location of dunk tank/s and pass boxes shall be determined by the program and shall be integral to the containment barrier. The depth of partition must exceed the expected maximum pressure differential. |
| Chillers for HVAC | Capacity will depend on the total area of the facility. |
| *Boiler facility may be required if autoclaves operate on steam | |

## Table-3: Thumb-Rule Calculations for Understanding Estimated Budget of Proposed Laboratory

| Item | Work description | Qty | Unit | Unit rate** | Amount |
|---|---|---|---|---|---|
| Civil Work | Doors | 12 | Nos. | 32,000 | 3,84,000 |
| | Windows | 5 | Nos. | 15,000 | 75,000 |
| | Walls & Ceiling Panels | 2400 | f2 | 3,000 | 72,00,000 |
| | Epoxy based joint less flooring & covings | 243 | m2 | 900 | 2,18,700 |
| | Plumbing & Sanitary Installations | 1 | Job | | 2,20,000 |
| Electrical & Associated Works | Internal electrification of building | | | | 2,50,000 |
| | Main/Sub Distribution MV Panels | 3 | Nos. | 1,500 | 4,500 |
| | Telephone System | 6 | Nos. | 2,000 | 12,000 |
| | Cables | | | | |
| | Earthing | 2 | Nos. | 18,000 | 36,000 |
| | Fire Detection & Alarm System | | | 15,00,000 | 15,00,000 |
| HVAC & Associated Works | System Design | | | | |
| | Drawings | | | | |
| | HVAC System based on the design and area of the laboratory | | | | |
| | Operating Rooms / Zone Pressure<br>++: Based on the design and area of the laboratory. | | | | |
| Water Chilling Machine | Water Chilling Unit [based on the design and area of the laboratory] | 50 | Tr | 40,000 | 20,00,000 |
| | Compressor | | | | |
| | Condenser (Air Cooled Type) | | | | |
| | Chiller | | | | |
| | Chiller Piping | | | | 15,00,000 |
| | Motors & Starters | 3 | Nos. | 30,000 | 90,000 |
| | Refrigerant Circuit Accessories | | | | |
| | Control Panel | | | 25,000 | 25,000 |
| Air Handling Units | Air Handling Units | 18 | Tr | 35,000 | 6,30,000 |
| Water Circulation Equipment | MoNobloc Type Pump Set | 2 | Nos. | 20,000 | 40,000 |
| | Pump Accessories | | | | |
| Filters | Prefilters | 3 | Nos. | 3,000 | 9,000 |
| | Fine Filters | 3 | Nos. | 4,000 | 12,000 |
| | High Efficiency Particulate Air (HEPA) filters | 6 | Nos. | 38,000 | 2,28,000 |
| | Filter Plenums | 6 | Nos. | 1,00,000 | 6,00,000 |
| Insulation | Includes: Other materials, Chilled/Hot Water Piping, Walls & Ceiling Acoustic Treatments of Plant Rooms & A.H.U. Room, Acoustic Treatment Installation etc. | 300 | f2 | 500 | 2,70,000 |
| Building Management System | ++: Cost will depend on the area of the laboratory, which company? & critical requirements of the specific laboratory. | 1 | Job | 25,00,000 | 25,00,000 |
| Specialized Equipments & Systems | ++: Depends on the requirements of the laboratory. | | | | |
| Hot Water Shower System | ++: Cost will depend on the number of shows required in the laboratory, which make? | 1 | Job | 3,50,000 | 3,50,000 |
| Hot Water Generator | ++: Cost will depend on the capacity required depending on the number of showers in the laboratory, which make? | 1 | No. | 4,00,000 | 4,00,000 |
| Bio-Safety Doors | ++: Cost will depend on the number of biosafety doors required in the laboratory, which make? | 4 | Nos. | 35,000 | 1,40,000 |
| Double Door Pass Box | ++: Cost will depend on the number of Double Door Pass Box required in the laboratory, which make? | 1 | No. | 40,000 | 40,000 |
| Double Door Pass Box (Dynamic Type) | ++: Cost will depend on the number required & which make? | 1 | No. | 60,000 | 60,000 |
| Steam Autoclave / Sterilizer | ++: Depends on the requirements of the laboratory. | 1 | No. | 12,00,000 | 12,00,000 |
| Biosafety Cabinet | ++: Depends on the requirements of the laboratory. | 3 | No. | 7,50,000 | 2,25,000 |
| Pre-Fabricated Shower Cubicle | ++: Depends on the requirements of the laboratory. | 574 | f2 | 3,000 | 17,22,600 |
| CCTV System for Surveillance | ++: Depends on the area & the requirements of the laboratory. | 1 | Job | 10,00,000 | 10,00,000 |
| **Total** | | | | **82,05,900** | **2,29,41,800** |

**=Unit cost for each item is non-realistic. These are given only to understand the process of calculation and represent only rough estimates. However, many items are not available on government e-procurement sites like CPWD Manual Site etc. These can also be obtained from local contractors or may be searched on the websites.

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