

Indian Institute of Technology Hyderabad

Biosafety Handbook 2024

Version - 1



భారతీయ సాంకేతిక విజ్ఞాన సంస్థ హైదరాబాద్
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CONTENTS

S. No.	Title	Page Number
1.	Chapter I - About IBSC handbook	07
1.1	Overview of biosafety	07
1.2	Scope of biosafety handbook	07
1.3	Implementation of the biosafety practice	08
1.4	Regulatory Frame	08
1.5	Other biosafety guidelines	08
2.	Chapter II - Roles and Responsibilities	
2.1	Responsibilities of the Principal Investigators	10
2.2	Responsibilities of the Research scholars & Staff	11
2.3	Responsibilities of the Head of Department	11
2.4	Responsibilities of the IITH Administration	11
3.	Chapter III - IBSC Rules and Regulations	
3.1	Institutional Biosafety Committee (IBSC)	13
3.2	Present IBSC Committee Members	13
3.3	Responsibilities of the IBSC at IITH	13
3.4	Procedure for IBSC approval at IITH	14
3.5	Import, export & exchanges of biohazard materials	15
3.6	When Do I need to get an IBSC approval for my project	17
4.	Chapter IV Biosafety levels and equipment requirement/ specification for biosafety operation	
4.1	Biological safety cabinets	19
4.2	Universal precautions for biological laboratory workers	27
4.3	Personal Protective Equipment (PPE)	28
4.4	Facility Design and Maintenance	30
4.5	Maintenance of the BSC, Autoclave and fume hoods	34
4.6	Risk group and containment facilities	34
4.7	Risk Classification	35
4.8	Risk Assessment	36
4.9	Good Laboratory Practice and Procedure (GLPP)	37
4.10	Good Cell culture Practices (GCCP)	37
4.11	Laboratory Inspection and Audits	38
4.12	Corrective action and follow up procedures	38
4.13	Record keeping and Documentation	38
4.14	Incident report & Investigation	39
4.15	Emergency Provisions	39
5	Chapter V	
5.1	What is biomedical waste	41

5.2	Segregation & Disposal of Biomedical waste at IITH	41
5.3	Responsibilities of the research scholars for Biomedical waste	42
5.4	Liquid Biomedical waste treatment	43
5.5	Disinfection & Decontamination	43
5.6	Categories of Decontamination	44
5.7	Hand Hygiene	45
5.8	Biohazard events	45
5.9	Spill Response	46
5.10	Spill Kit	47
6	Chapter VI – Biosafety Training at IITH	49
7	Chapter VII – Standard Operating Procedures (SOPs)	
7.1	SOP for the Biosafety cabinets	51
7.2	SOP for the Autoclave	53
7.3	Biosafety guidelines for the Fumigation	56
7.4	SOP for the HCHO based Fumigation	57
8	Frequently Asked Questions (FAQ)	60
9	Glossary of Terms	64
10	References	66
11	Acknowledgement	66

S. No.	Name of the Table	Page No.
Tables 1.	Categories of GE experiments & Approval requirements	14
Tables 2.	Categories of GE experiments & Biosafety level requirements	15
Tables 3.	list and quantities GE organisms and their products use in R&D purpose not meant for release in the environment	16
Tables 4.	Risk Group Classification	33

Abbreviations

ABSL - Animal Biosafety Level.

AqBSL – Aquatic Organism Biosafety Level.

BioRRAP – Biological Research Regulatory Approval Portal.

BMW – Biomedical Waste Management.

BSC - Biosafety Cabinets.

BSL – Biosafety Level.

CBWTF – Common Biomedical Waste Treatment Facility.

CPCB – Central Pollution Control Board.

DBT - Department of Biotechnology.

DGFT - Directorate General of Foreign Trade.

DLC – District Level Committee.

DNA – Deoxy Ribonucleic Acid.

EPA – Environmental Protection Act.

GCCP - Good cell culture practices.

GE – Genetically Engineered.

GEAC – Genetic Engineering Appraisal Committee.

GLPP – Good Laboratory Practices and Procedures.

GMO - Genetically Modified Organisms.

GOI – Government of India.

HMO – Hazardous Micro Organisms.

IBKP – Indian Biosafety Knowledge Portal.

IBSC – Institutional Biosafety Committee.

LD – Lethal Dose.

LMO – Living Modified Organisms.

MoEF & CC - Ministry of Environment, Forest and Climate Change.

NaOCl - Sodium hypochlorite.

PBSL – Plant Biosafety Level.

PI – Principal Investigator (R & D /Industry/ Others).

PPE - Personal Protective Equipment.

PPM - Parts Per Million.

RCGM – Review Committee on Genetic Manipulation.

RDAC - Recombinant DNA Advisory Committee.

rDNA – Recombinant DNA.

RG – Risk Group.

SBCC – State Biotechnology Co-ordination Committee.

SCOMET - Export of Special Chemicals, Organisms, Materials, Equipment and Technologies.

SDN - Site Directed Nucleases.

SOP – Standard Operating Procedure.

UV – Ultraviolet.

CHAPTER – I

About Biosafety Handbook

About biosafety handbook

In today's rapidly evolving research environment, maintaining strict biosafety standards is crucial. As researchers explore the cutting edges of biology, biotechnology, and life sciences, they encounter a wide array of hazards, both known and unexpected. Whether working in laboratories, field studies, or R&D facilities, including incubation centers, the risks posed by biological agents require careful management and strict protocols.

This handbook is an essential resource for researchers, laboratory staff, policymakers, and anyone involved in biological research or biotechnology. It aims to provide a foundational understanding of biosafety principles, practices, and regulations, empowering individuals and laboratories to carry out their work safely and responsibly.

In this handbook, you'll find concise explanations of key biosafety guidelines established by the Department of Biotechnology, along with insights on risk assessment and containment. It also offers practical advice on laboratory design, personal protective equipment, emergency response, good laboratory practices, and biomedical waste management procedures.

As biological research advances with new technologies and discoveries, our approach to biosafety must also adapt. Therefore, this handbook is not a static reference but a living document, regularly updated to reflect the latest best practices, regulations, and innovations in the field.

Our shared commitment to biosafety is not only a legal obligation but also essential for preserving the integrity of scientific research and protecting public health and the environment. By following the principles outlined in this handbook and fostering a culture of safety, we can minimize risks, prevent accidents, and ensure that our scientific efforts positively impact society.

We encourage you to explore the "Biosafety Handbook" and join us on the path toward safer, more responsible scientific practices. Together, we can create a future where innovation and safety are intertwined, advancing knowledge and discovery for the betterment of humanity.

1.1. Overview of Biosafety

Biosafety refers to the set of practices, protocols, and measures implemented to ensure the safe handling, containment, and control of biological agents and hazardous materials in laboratory and research settings. It encompasses basic procedures designed to protect researchers, laboratory personnel, the community, and the environment from potential risks associated with working with living organisms, including bacteria, viruses, fungi, and Genetically Modified Organisms (GMOs).

Key aspects of biosafety include bio-risk assessment, containment strategies, laboratory design, Personal Protective Equipment (PPE) usage, decontamination procedures, waste management, and emergency response protocols. Biosafety measures are essential for preventing laboratory-acquired infections, minimizing the release of harmful agents into the environment, and maintaining the integrity of scientific research while ensuring ethical conduct and compliance with regulatory standards.

1. 2. Scope of Biosafety Handbook

The Biosafety Handbook serves as a comprehensive guide to overview of the safe handling, containment, and disposal of biological agents and materials across various settings. It aims to promote safety awareness, standardize procedures, and ensure compliance with national and international biosafety regulations.

This book gives you a brief information about biosafety, various levels of biosafety cabinets good laboratory practices and Biomedical waste management etc., Do not consider this is complete guideline for the Biosafety management in the laboratory. Each laboratory working different level of hazards hence biosafety precautions may vary based on hazard type and nature.

1.3. Implementation of Biosafety Practice:

This biosafety handbook is applying to all IITH fraternity (**faculty, staff, students, researchers, and visitors**) who engaged in activities involving biological materials within the Institute facilities. It encompasses laboratories, research facilities, teaching environments, and any other areas where hazardous biological agents/ materials are handled or stored as per the guidelines framed by the Department of Biotechnology, Govt. of India.

1.4. Regulatory Frame

In India, all activities related to Genetically Engineered organisms (GE organisms) or cells and non-GE hazardous microorganisms and products thereof are regulated as per the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (known as 'Rules, 1989') notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC) & Department of Biotechnology, Government of India, under the Environment (Protection) Act, 1986 (EPA 1986).

1.5. Various biosafety guideline

RCGM, Department of Biotechnology, a nodal agency under the Ministry of Science and Technology, Govt of India, frame, regulates and enforce the various guideline on biosafety and related areas.

The following are main guidelines related to Biosafety.

1. Regulations and guidelines for Recombinant DNA Research and Biocontainment 2017
2. Handbook for Institutional Biosafety Committee (IBSC) 2011 & 2020.
3. List of Infective Microorganisms corresponding to different Risk Groups, 2021.
4. Biomedical waste management rules 2016.

Link for all regulatory documents <https://biorrap.gov.in/Home/RegulatoryDocuments>

CHAPTER – II

Role and Responsibilities

Roles and Responsibilities

2.1 Responsibilities of the Principal Investigator (PI)

1. The **Principal Investigator** or a Laboratory Director is the utmost authority within the facility or laboratory to implement all biosafety related measures and adhere to the biosafety policies of the Institute. He/she will be responsible personnel to implementing all biosafety measures and addressing any deviation if these measures are not followed.
2. It is the responsibility of PI obtain the IBSC certification before commencement of work using biohazard materials (body fluids such as blood, saliva urine, etc., tissues, DNA, cell lines, pathogenic microorganisms' insects, and others).
3. Ensuring that adequate and timely resources are made available for the elements of the biosafety program (for example, essential PPE kits, other pathogen specific protective measures and all the instruments calibrated and serviced based on the manufacturer's instructions of which biohazard materials are used such as biosafety cabinets, centrifuge, autoclave etc.).
4. Contributing to the development of facility or laboratory-specific Standard Operating Procedures (SOPs), ensuring that all personnel comply with safety policies and procedures, and promoting ongoing communication between senior management, the biosafety officer, and laboratory personnel.
5. The Principal Investigator has the responsibility and authority for assessing risks, establishing laboratory policies and procedures, training lab personnel, and maintaining laboratory facilities and equipment.
6. Performing an appropriate initial risk assessment of research projects. The biosafety level should depend on the hazard associated with the organism under study. Each evaluation should be completed before work is undertaken and the project should be reassessed periodically as new data is obtained.
7. Working closely with biosafety personnel to ensure that appropriate risk control strategies are implemented.
8. No human or animal pathogen should be studied without prior written approval of the Institutional Biosafety Committee IBSC of the IIT Hyderabad.
9. Instructing students and staff of potential hazards and the application of appropriate safety practices and procedures within their laboratories.
10. Ensuring the laboratory staff are vaccinated as per the guideline while working with biohazardous agents.
11. Supervise laboratory staff to ensure that the required safety practices and techniques are employed. **All the PhD students and JRF/SRF/RA/PDF must be starting the work after completion of the biosafety training.**
12. Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., purity and genotypic and phenotypic characteristics).
13. Comply with permit and shipping requirements for biological materials.
14. Maintaining a liaison with the Biosafety Office.
15. Report any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the Institute Biosafety Guidelines, or any significant research-related accidents and illnesses to the IBSC Committee, Safety committee Chairmen, and as applicable, the Biological Safety Officer, and other appropriate authorities.
16. Ensure the biomedical waste is segregated and collected as per the guideline of IITH biomedical waste management.

All other laboratory personnel within the organization, including personnel, students and volunteers, are responsible for supporting and contributing to a robust biosafety programme. Personnel has a responsibility to adhere to institutional policies; complete required training; follow SOPs and other operational working practices; and report to the biosafety officer any contravention of these procedures and practices, any areas for improvement, or any incidents with hazardous biological materials.

2.2 Responsibilities of the Research Scholar & Staff:

1. All the newly joined PhD students/ JRF/SRF/RA/PDF and Staff after joining the Institute if their work is fall under the biohazard related work first complete the biosafety training before commencement of the research work.
2. Must be aware of the Biosafety policy and handbook of the Institute.
3. Familiar with themselves about Biosafety cabinets and its classes.
4. Familiar with the biomedical waste disposal plan and guidelines of the IITH.
5. Maintains the records of the Biomedical waste disposal records and autoclave of the laboratory and hand it over to the biosafety office.
6. Familiar with Good Laboratory Practices (GLP) and other general safety practices.
7. Utilizing Personal Protective Equipment (PPE): Proper use of lab coats, gloves, goggles, shoes, face shields, and other PPE to minimize exposure to hazardous materials.
8. Maintains laboratory list of biohazard materials available in the lab and labelled properly based on Risk Groups (RG) and requirements of biosafety levels.
9. Must maintain the records of the biosafety cabinet user records, safety training, vaccination if any, instruments calibration (biosafety cabinets, autoclave and centrifuge, etc) and spill incidents & other incidents related to biosafety and security.
10. Make sure biosafety symbols are pasted all the instruments and main door entrance and wherever the biohazard materials handled in the laboratory.

2.3 Responsibilities of the Head of the department

1. Make sure all the biosafety guidelines are adhered within the departmental facilities and support and implement institutional biosafety policies.
2. Ensure all biosafety practices in places time to time.
3. Arrange awareness and training programs if required in addition to the training received from the Biosafety office.
4. Speedy approval of the fund any other approvals required for biosafety practices within the department.

2.4 Responsibilities of the IITH Administration

1. Implementation and enforcement of the biosafety policies as per the guidelines of the Union Government.
2. Allocate the required funds for all biosafety related operations as per the guidelines mentioned in the Biomedical waste management rules 2016.
3. Allot a housekeeping staff member for the collection and disposal of biomedical waste from the laboratory premises to the interim transport and final disposal to the vendor.
4. Arrange a vehicle to transport biomedical waste from various departments to the interim biomedical waste storage shed as needed.

CHAPTER – III

IBSC (Function & Responsibilities)

IBSC (Composition, Function and Responsibilities)

In compliance with Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells 1989 (known as Rules 1989) under the Environmental (protection) Act 1986 (EPA 1986), an Institutional Biosafety Committee (IBSC) is to be constituted by every organization engaged in research, use an applications activities related to GE organisms (organism include microorganisms, animals, plants, arthropods, aquatic animals, etc.) and hazardous microorganisms (includes parasites, protozoa, algae, fungi, bacteria, virus, prion etc.) and products produced through exploration of such organisms.

3.1 Institutional Biosafety Committee (IBSC)

IBSC serves as the nodal point within an organization for the implementation of the biosafety regulatory framework.

The Institutional Biosafety Committee (IBSC) is solely responsible:

- To implement and respond to biosafety and biosecurity at the Institution level and
- Evaluation of applications/reports related to rDNA technology work involving the GE organisms and non-GE hazardous microorganisms in an organization.

3.2 Present IBSC committee members

The IBSC committee constituted by the Institute every three years as per the “Biosafety handbook guidelines 2020”.

Serial No.	Name of the Member	Designation
1	Prof. B.S. Murty, Director, IIT Hyderabad	Chairperson
2	Prof. Jyotsnendu Giri, Dept. of BME, IIT Hyderabad	Member Secretary
3	Prof. Sharmistha Banerjee, Dept. of Biochemistry University of Hyderabad	DBT Nominee
4	Dr. Girish K Radhakrishnan Scientist F, NIAB, Hyderabad	Representative of DBT/ External experts
5	Dr. Raja Adharath, SMO, Health Center, IIT Hyderabad	Biosafety officer (Medical qualification)
6	Dr. Suhanya Duraisamy, Asst. Professor, Dept. of Chemical Engg. IIT Hyderabad	Internal Member
7	Dr. Sandipan Ray Assistant Professor, Dept. of Biotechnology, IIT Hyderabad	Internal Member
8	Dr. Indranil Malik, Dept. of Biotechnology, IIT Hyderabad	Internal Member
9	D Anbumani Technical officer (Biosafety), Dept. of BME, IIT Hyderabad	Internal Member

3.3 Responsibilities and functions of IBSC at IIT Hyderabad as per IBSC handbook 2020.

The primary function of the IBSC is to implement and ensure compliance of provisions of Rules 1989 and amendment thereafter at the Institutional Level. These functions include:

Implement	Evaluate/ consider/ review	Report	Approve
<ul style="list-style-type: none"> • Biosafety guidelines • On site emergency plans • Biosafety Training • Health surveillance 	<ul style="list-style-type: none"> • Application/ Activities* • Physical safety and security measures • Applications/ activities for approval 	<ul style="list-style-type: none"> • Compliance to Rules 1989 • Biosafety/ biosecurity threats and management 	<ul style="list-style-type: none"> • Category I/ II Genetic engineering • Import, export, transfer, receive as per Simplified guidelines

*Activities include import, export, transfer, receive, contained (laboratory), and confined R & D involving GE organisms and/or hazardous microorganisms.

TABLE 1. Categorization of GE Experiments and approval requirements

Category	GE experiments	Activities	Approval requirements	IBSC
1	Risk Group 1 organisms (microorganisms, animals, plants, insects and aquatic animals).	Insertion genes, gene knockout, experiment on approved host/ vector system provided donor is from RG1 group. Self-cloning, fusion of protoplasts between non-pathogenic organism, etc	An investigator should intimate the IBSC of the study objectives and experimental design along with organisms involved.	IBSC should review the same as and when convened for record purpose, monitoring, or action to be taken, if any.
2	Risk Group 2 organisms (microorganisms, animals, plants, insects and aquatic animals).	Experiments on non-approved host system, Experiments with GE animals, GE arthropods and GE aquatic animals and associated materials, that do not cause diseases to plants and animals, Lower eukaryotes host, etc from RG2 groups each category.	An investigator requires prior authorization from IBSC before the commencement of the experiments.	Committee will discuss in the IBSC meeting and inform the decision to the PI
3	Risk Group 2 & 3 organisms (microorganisms, animals, plants, insects and aquatic animals).	Gene insertion directly linked to toxin production, allergen, antimicrobial compounds, Experiments with animals infected with GE microorganisms that fall under RG3. GE plants, arthropods and aquatic animals containing genes from RG 3 category organisms where the genetic engineering positively affects environmental fitness and virulence challenged.	An investigator requires prior authorization from IBSC and subsequent approval from RCGM before the commencement of experiments.	Committee will discuss in the IBSC meeting and send to RCGM for approval.

Table 2. Category of experiments, GE organism involved and Biosafety Level Facility Requirements

Category	GE Microorganisms	GE Animals	GE plants	GE Insects	GE Aquatic organisms
Category I	BSL-1	ABSL-1	PBSL-1	IBSL-1	AqBSL-1
Category II	BSL-2	ABSL-2	PBSL-2	IBSL-2	AqBSL-2
Category III and above	BSL-3/BSL4	ABSL-3	PBSL-3	IBSL-3	AqBSL-3

3.4 Procedure for IBSC Approval at IITH

Use Form C1 to be used for all the project seeking IBSC approval and must completed all aspects. Additional documents can be submitted based on the requirements.

Avoid using not applicable in the application form.

Section 3 of the Form C1 to be filled out after getting a project code from the Biological Research Regulatory Approval Portal (BioRRAP).

For this purpose, Biosafety office already has username and password, it will be issued all the principal Investigators. Not mentioned here due to policy privacy.

Forms to use import, export, and exchange of the hazardous organisms

Form B1: Application to RCGM for Import of HMOs/GMOs/LMOs and product(s) thereof for research and development purpose.

Form B3: Application to RCGM for export of HMOs/GMOs/LMOs and product(s) thereof for research and development purposes.

Form B5: Application to RCGM for receiving HMOs/GMOs/LMOs and product(s) thereof for research and development purposes within India.

Form B7: Application to RCGM for transfer HMOs/GMOs/LMOs and product(s) thereof for research and development purposes from within India.

The link for all the template form is <https://ibkp.dbtindia.gov.in/Content/ApplicationFormats>

3.5 Import, export, and exchange of the hazardous organisms

As per the RCGM the small quantities of GE organisms and their products import, export and exchange are done with prior approval of the Institute Biosafety Committee IBSC.

Link for all regulatory documents <https://biorrap.gov.in/Home/RegulatoryDocuments>

Table 3: list and quantities GE organisms and their products use in R&D purpose not meant for release in the environment:

S. No.	Category	Characteristics	Quantity proposed
1.	Purified Nucleic acids Nucleic acid/ polynucleotides/ plasmid vector/ genetic constructs of natural/ synthetic/ recombinant origin and not present within or containing any host (living microorganisms/ cells).	A. Cannot independently produce infectious biological agents (viruses) in animals, permissive cells, or in vitro systems, with or without rescue plasmids or other exogenous factors. B. Upon translation in vivo or in vitro within a vector or recombinant host genome, it does not produce a toxin with an LD ₅₀ less than 1 µg/kg in vertebrates. C. Has not been modified or treated to penetrate cell membranes independently.	1 mg
2.	Proteins A purified form (Antigen, antibodies, vaccines, enzymes, toxins, hormones, etc of synthetic / recombinant form.	A. Not toxic at LD ₅₀ of less or equal to 1 microgram per kilogram body weight. B. Not toxic at LD ₅₀ of less than or equal to 200 microgram per kilogram body weight.	100 grams 20 grams 100 grams
3.	Drug products/ Substances/ API /process intermediates	A. Do not contain living microorganisms. B. Do not contain biological ingredients that render harmful to humans.	1 Kg (concentration between 0.05 – 180gm/L).
4.	Non-GE microorganism (bacteria, viruses, fungi, mycoplasma, cell lines, algae, protozoans and nematodes).	A. belongs to Risk Group 1 and 2 B. could be handled in BSL1 and BSL 2 facility.	Cell lines 500 ml (10 ⁶⁻⁸ cells/ml) in liquid form Microorganisms other than cell lines 200 ml (10 ⁶⁻⁸ cells/ml) in liquid form 100gm lyophilized dry form
5.	GE Microorganisms That deliberately modified using rDNA technology.	Refer Recombinant DNA Research and Biocontainment guidelines 2017.	GE cell lines 500 ml (10 ⁶⁻⁸ cells/ml) in liquid form 500 gm lyophilized dry form. GE Microorganisms 200 ml (10 ⁶⁻⁸ cells/ml) in liquid form 200 gm lyophilized dry from.

The exchange of regulated items within India (Transfer & Receive) for Biopharma drugs (R & D) shall not require approval from RCGM. The exchange of materials may take place with the approval from the respective IBSCs of the organizations involved in transfer/receive before commencing the activity.

Import and export of regulated items not specified or not covered in the above table will require prior approval of IBSC followed by RCGM.

All the materials belong to RG3 and RG4 require prior approval of IBSC followed by RCGM for transfer/exchange/ R&D.

The applicant shall apply, duly filled in every aspect, to RCGM through the Indian Biosafety knowledge portal.

The link for the detailed guidelines available in the DBT website.

3.6 When do I need to get IBSC approval for my project or work?

As per the guidelines of the IBSC handbook 2020 the principal investigator responsible for getting approval from the IBSC if the projects fall under the following categories:

S. No.	Activity Involved	Approval requirement
1.	Working with human body fluids (blood samples, urine, lymph, CSF), tissue samples including stem cell.	Must obtain the IBSC approval prior to the commencement of the work
2.	Working with bacterial samples and AMR, Biofilm related work.	Must obtain the IBSC approval prior to the commencement of the work
3.	Working with algae, yeast & fungi, other eukaryotic organisms	Must obtain the IBSC approval prior to the commencement of the work
4.	Working with viruses, cell lines both human and animals' cells, epigenetic modification related works	Must obtain the IBSC approval prior to the commencement of the work
5.	Experiments using Drosophila and zebra fish models	Must obtain the IBSC approval prior to the commencement of the work
6.	Working with aquatic and contaminated or polluted water samples related works	Must obtain the IBSC approval prior to the commencement of the work

The complete details are available 'Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017'<https://ibkp.dbtindia.gov.in/Content/Rules>

CHAPTER – IV

Biosafety level, PPE, Risk classification and Assessment & Spill Management

Biosafety Cabinets and Equipment's for Biosafety Operation

4.1 Biological Safety Cabinets (BSC)

Biological safety cabinets (BSCs), isolators and local exhaust ventilators are enclosed, ventilated working spaces that can be used in laboratories as primary containment devices. These devices protect the operator, the laboratory environment and/or the work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing biological agents.

Containment is achieved by segregation of the work from the main area of the laboratory and/or using 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.

BSC facilities are the fundamental laboratory structures for containment purposes.

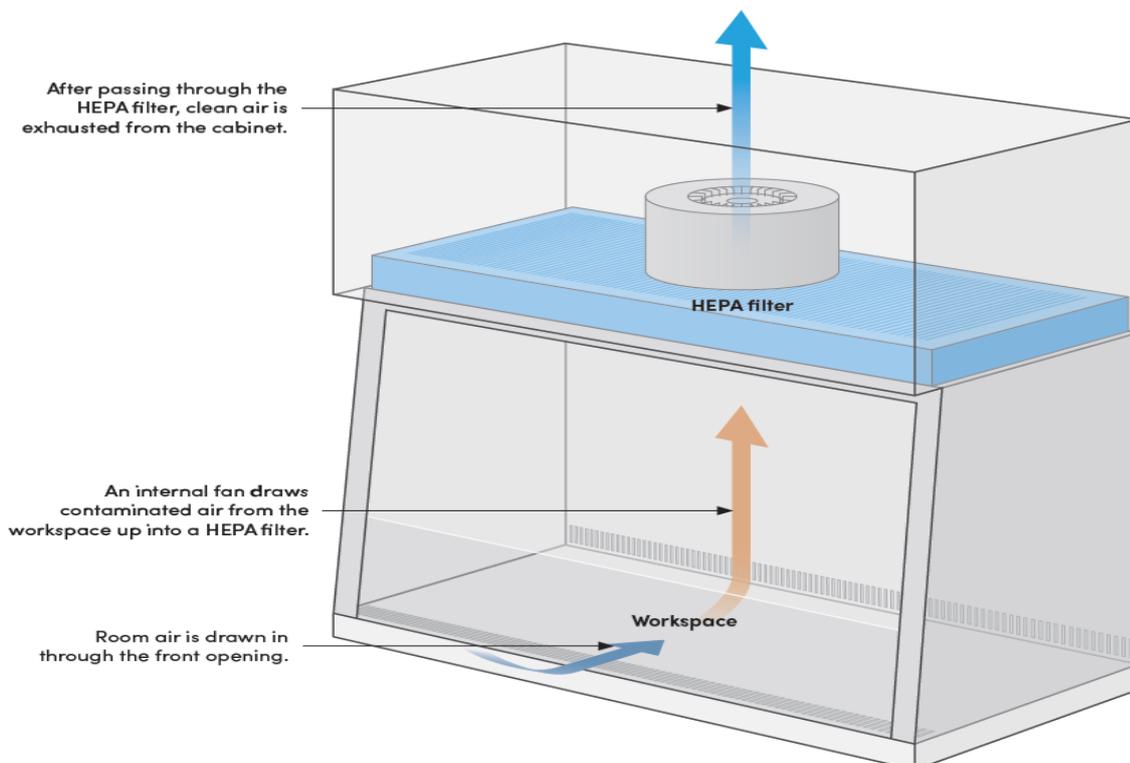
Such facilities will be suitable for:

- a. Isolation, cultivation and storage and experiments on hazardous microorganisms.
- b. Genetic engineering of organisms and their safe handling.
- c. Handling of toxins, tissues, cell lines etc.

4.1.1 BS Class 1

The class I BSC provides personnel and environmental protection, but no product protection. It is similar in terms of air movement to a chemical fume hood but has a HEPA filter in the exhaust system to protect the environment.

Before commencement of Category I GE experiments, the investigator should intimate the IBSC about the objective and experimental design of the study along with organisms involved. IBSC should review the same as and when convened for record or action if any. It is desirable to designate a separate area in the facility with proper labelling for Category I GE experiments to avoid any chances of contamination



Operational guideline for class BSC-1 Facility

A. Facility Design

1. Facility should be a fully enclosed space bounded by walls, doors, windows, floors, and ceilings.
2. Ample space must be provided for the safe conduct of laboratory procedures.
3. Walls, ceiling, and floors should be smooth, easily cleanable, impermeable to liquids, and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip resistant. Exposed pipes and ducting should stand clear of walls. Horizontal runs should be avoided to prevent dust collection.
4. Adequate illumination should be ensured for carrying out all activities. Undesirable reflection is to be avoided.
5. Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents, and moderate heat.
6. Laboratory furniture should be sturdy and open spaces between and under benches, cabinets and equipment should be accessible for cleaning.
7. Storage space must be adequate to hold supplies for immediate use and thus prevent clutter on bench tops and in the aisles. Additional long-term storage space, conveniently located outside and working areas, should also be provided.
8. Washbasins, with running water, should be provided in each laboratory room, preferably near the exit.
9. Doors should have appropriate fire ratings, be self-closing, and have vision panels.
10. There are no specific ventilation requirements. In planning new facilities, consideration should be given for providing a mechanical ventilation system that provides an inward air flow and exhaust without recirculation. If there is no mechanical ventilation, windows should be openable, preferably having fly proof screens. Skylights should be avoided.
11. Drainage exits should be fitted with barriers to prevent entry of arthropods and rodents.
12. Space and facilities should be provided for the safe handling and storage of solvents, radioactive materials, and compressed gases.
13. Safety systems should cover fire, electrical emergencies, emergency shower and eyewash facilities.
14. First-aid areas or rooms suitably equipped and readily accessible should be available.
15. A good-quality and dependable water supply is essential. There should be no cross-connections between sources for laboratory purposes and the drinking water supply. The public water system must be protected by a back-flow preventer.
16. A reliable electricity supply with adequate capacity should be available. There should be emergency lighting to permit safe exit. A standby generator with automatic cut-off is desirable for the support of essential equipment-incubators, freezers, etc.
17. There should be an insect and rodent control measures.
18. Facilities for storing outer garments and personal items and for eating and drinking should be provided outside the working areas.
19. **“No Smoking” “No Eating” and “No Drinking” signs should be displayed clearly inside and outside the laboratory.**
20. Access to the laboratory area should be designed to prevent entrance of free-living arthropods and other vermin.

B. Safety Equipment

1. Pipetting aids-to replace mouth pipetting.
2. Screw-cap tubes and bottles - to provide positive specimen containment.
3. Disposable Pasteur pipettes, whenever available, to avoid glass.
4. Sterile plastic disposable transfer loops and spreader etc. to avoid incineration of regular loops, glass spreader etc.

C. Personal Protective Equipment

Working in BSL-1 laboratory do not require any personal protective equipment (PPE), although care should be taken to avoid spillage of biological material on street clothing for which use of apron is recommended.

D. Procedures

1. Mouth pipetting should be prohibited.
2. Eating, drinking, storing food, and applying cosmetics should not be permitted in the laboratory work area.
3. Avoid touching various body parts while handling the microorganisms.
4. Wash hand after entering, post work and before leaving the laboratory with sanitizing agents.
5. The laboratory should be kept neat, clean and free of materials not pertinent to the work.
6. Work surfaces should be decontaminated at least once a day and after any spill of potentially dangerous material.
7. Members of the staff should wash their hands after working before leaving the laboratory.
8. All technical procedures should be performed in a way that minimizes the creation of aerosols.
9. Laboratory doors would be kept closed when work is in progress.
10. Children are not permitted in laboratory working areas.

E. Laboratory Monitoring

1. There should be no unauthorized entry in the laboratory.
2. Only the trained personnel to enter the laboratory.
3. Entry and exit should be limited when work is in progress.
4. Immediately after work, the workplace and the used instruments should be cleaned with a disinfectant and the materials used in work should be placed back to its position.
5. No viable cultures are left unattended and either stored or incubated as per need.
6. Record of work should be duly registered in the register available.

F. Waste Management

As per the IITH Biomedical waste management

G. Health and Medical Surveillance

These microorganisms are unlikely to cause human or animal diseases of veterinary importance. Prompt reporting of illness or laboratory accident is desirable and all the staff members should be made aware of the importance of maintaining good laboratory safety practices.

H. Emergency procedures

All spills, accidents and overt or potential exposures to infectious materials should be reported immediately to the laboratory supervisor. A written records should be prepared and maintained. Appropriate medical evaluation, surveillance and treatment should be provided.

4.1.2 BSC Class II

The Class II BSC is designed to provide personnel and environmental protection as well as protection for work surface materials from potentially contaminated room air. The airflows inside Class II BSCs are considerably more complex than in other BSC classes because of the addition of airflows designed to provide product protection.

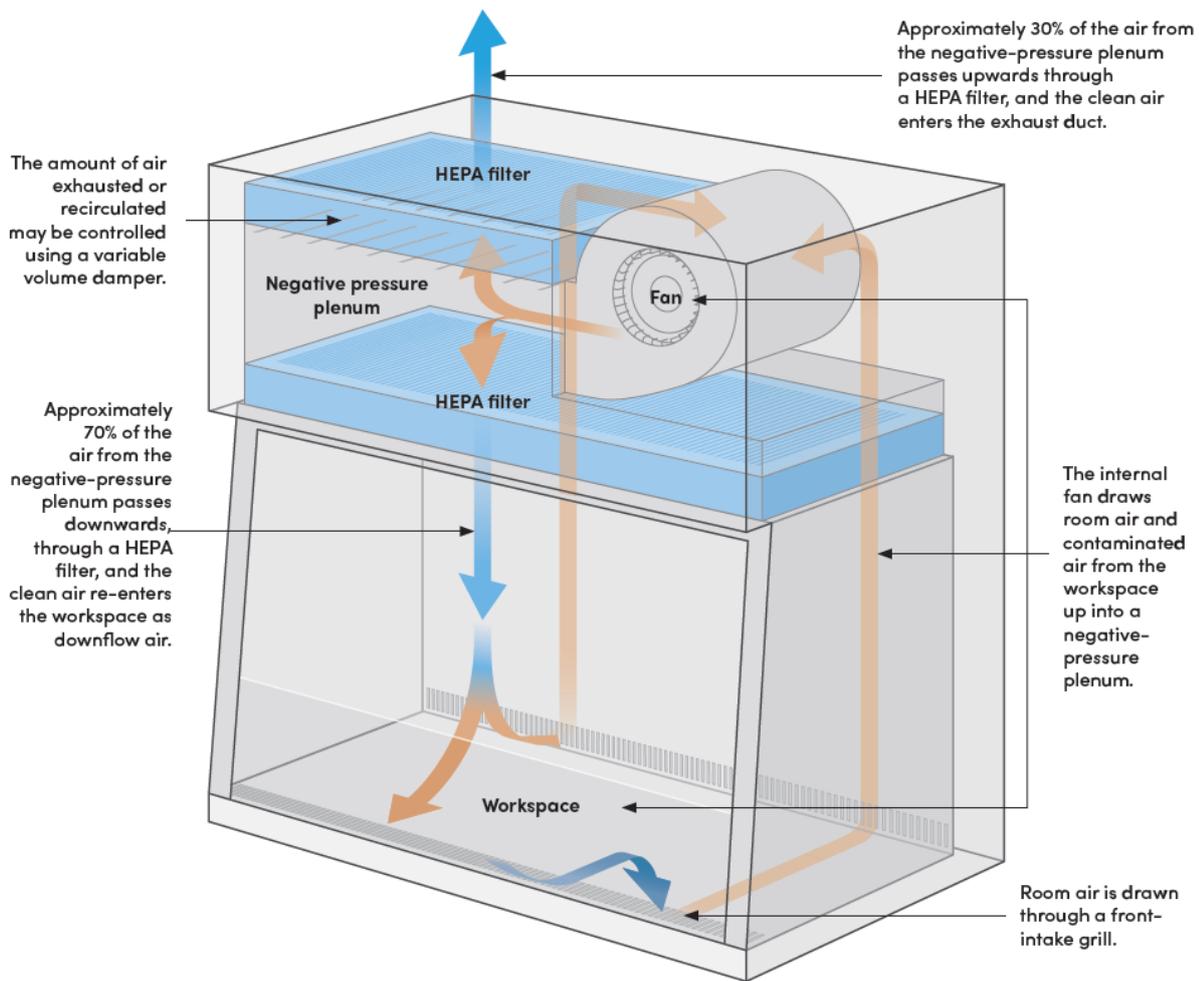
HEPA filtered air is driven as a downward airflow from the top of the cabinet onto the work surface. This is in addition to the inward flow of air at the front opening, which provides operator protection in a similar way to Class I BSCs. This system often involves partial recirculation of air within the cabinet; filtered air is divided between an exhaust and the downward flow mechanism.

Five types of Class II cabinets currently exist they are A1, A2, B1, B2 and C1.

BSC-2 will be applicable for:

- a. Isolation, cultivation, and storage of RG 2 microorganisms.
- b. Handling of environmental samples collected from environment that is unlikely to contain pathogens. Isolation of microorganisms from those samples and subsequent experiments.

- c. Experiments on RG 2 microorganisms or isolates from environment mentioned above, provided that the experiments will not increase environmental fitness and virulence of the microorganisms.



Category II genetic engineering experiments on microorganism:

These experiments may pose low-level risk(s) to laboratory workers, community, or the environment.

Experiments involving the use of infectious or defective RG 2 viruses in the presence of helper virus.

1. Work with non-approved host/vector systems where the host or vector either:
 - does not cause disease in plants, humans, or animals; and/ or
 - can cause disease in plants, humans, or animals but the introduced DNA is completely characterized and will not cause an increase in the virulence of the host or vector.
 - experiments using replication defective viruses as host or vector.
2. Experiments with approved host/vector systems, in which the gene inserted is:
 - a pathogenic determinant.
 - not fully characterized from microorganisms which are able to cause disease in humans, animals, or plants, or an oncogene.
3. Modification leading to persistent transient disruption of expression of gene(s) that are involved directly or indirectly in inducing pathogenicity, toxicity, survival, or fitness. Modification should be well characterized, and the gene functions and effects are adequately understood to predict safety.
4. Work involving fragments of Transmissible Spongiform Encephalopathy (TSEs) proteins or modified TSEs proteins that are not pathogenic and is not producing any harmful biological activity.

5. Experiments in which DNA from RG 2 or 3 organisms are transferred into non-pathogenic prokaryotes or lower eukaryotes. However, handling of live cultures of RG 3 organism should be performed in BSL-3 laboratory.

All category II GE experiments require prior authorization from IBSC before the commencement of the experiments through submission of information in the prescribed proforma. It is desirable to designate a separate area in the facility with proper labelling for Category II GE experiments to avoid any chances of contamination.

Operational guide for BSL-2 Facility

The operational program for BSL-1 laboratory will be also apply to Biosafety level 2 laboratory, with additional modifications as follows:

A. Facility design

1. An autoclave for decontamination of potentially hazardous laboratory wastes should be available in the same building as the laboratory.
2. Biological safety cabinets for handling of risk-inherent microorganisms of RG 2 should be used.
3. Laboratory may be kept under constant CCTV surveillance.
4. The biohazard warning symbol and sign (must be displayed on the door(s) of the rooms where microorganisms of RG 2 are handled.

B. Safety instruments

1. Autoclave to sterilize contaminated material.
2. Biological safety cabinets to be used whenever
 - a. Procedures with a high potential for creating hazardous aerosols. These may be including centrifugation, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers harbouring hazardous materials, whose internal pressure may be different from the ambient pressure, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.
 - b. High concentration or large volumes of hazardous microorganisms are handled. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

C. Personal protective Equipment

1. The use of laboratory coats, gowns or uniforms is required to prevent contamination of street clothing.
2. Goggles and face protection must be used when there is a potential for splashes of
3. microorganisms or other hazardous materials.
4. Face mask and appropriate gloves may be worn as protection while handling animals.
5. Appropriate gloves should be worn for all procedures that may involve accidental direct contact with blood, infectious materials, or infected animals. Gloves should be removed aseptically and autoclaved with another laboratory wastes before disposal. When disposable gloves are not available, re-usable gloves should be used. Upon removal they should be cleaned and disinfected before re-use.
6. All PPE should be removed so that the transfer of infectious materials to areas beyond where they or animals are being handled is minimized.
7. Used disposable PPE should be disposed of with other contaminated waste and reusable PPE (i.e., goggles) should be appropriately decontaminated before reuse.
8. Reusable protective clothing should be laundered through laboratory laundry facility only and it must not be taken home. If visibly contaminated, laundry should be placed in a biohazard bag before being placed with other items to go to laundry.

D. Procedure

1. All contaminated liquid or solid materials should be decontaminated before disposal or reuse; contaminated materials that are to be autoclaved or incinerated at a site away from the laboratory should be placed in durable leak-proof containers, which are closed before being removed from the laboratory.
2. Containers used to collect, handle, process, store, or transport within a facility, potentially infectious materials must be durable, leak-proof and have a lid. The containers must be properly labelled with the contents and a biohazard symbol.
3. Laboratory coats, gowns, or uniforms should be worn in the laboratory; laboratory clothing should not be worn in non-laboratory areas; contaminated clothing should be disinfected by appropriate means.
4. Safety glasses, face shields and other protective devices should be worn to protect eyes and face from splashes and impacting objects.
5. Only persons who have been advised of the potential hazards and meet any specific entry requirements (immunization) should be allowed to enter the laboratory working areas.
6. Hypodermic needles and syringes should not be used as a substitute for automatic pipetting devices in the manipulation of infectious fluids. Cannulas should be used instead of sharp needles wherever possible.
7. Never wear contact lenses when working with infectious microorganisms.
8. Add disinfectant to water baths to contain spread of infectious substances.
9. Use sealed rotors, sealed buckets, or a guard bowl cover complete with gasket as well as safety centrifuge tubes (tube or bottle carrier with sealable cap or "O" ring cap) for potentially infectious samples/otherwise hazardous samples. Before use, tubes should be checked for cracks.
10. All technical procedures should be performed to minimize the formation of aerosols and droplets. Whenever there is an increased risk(s) of aerosolization, work should be conducted in a biological safety cabinet.
11. Always use secondary leak-proof containers when transporting samples, cultures, inoculated Petri dishes, and other containers of hazardous microorganisms. Packages containing viable microorganisms must be opened in a facility having an equivalent or higher level of physical containment unless the microorganism is biologically inactivated or incapable of reproduction.

E. Laboratory Monitoring

1. Only highly trained personnel are entering in the facility.
2. Person working in the facility are not transporting the laboratory materials including hazardous organism outside the laboratory environment either without permission or without proper transport strategy with prior approval from competent authority.
3. Person working in the laboratory are aware about the microorganism(s) to be handled and its associated risks.
4. Accidental spill or splashes are cleaned immediately, reported, and recorded.

F. Waste Management

As per the IITH Biomedical waste management Policy.

G. Health and Medical Surveillance

1. Pre-employment health surveillance is necessary. This screening should include the past medical history. A clinical examination and the collection of a baseline serum sample would be advantageous and, in some cases, may be necessary.
2. Records of illness and absence should be kept by the facility in-charge, and it is the responsibility of the laboratory worker and his own medical officer to keep the facility in-charge informed of all absences due to illness.
3. Women of child-bearing age should be made aware, in unequivocal terms, of the risk(s) to the unborn child of occupational exposures to hazardous microorganisms, such as Rubella, Cytomegalovirus, etc. The precise steps taken to protect the foetus will vary, depending on the microorganisms to which exposure may occur.

H. Emergency Procedure

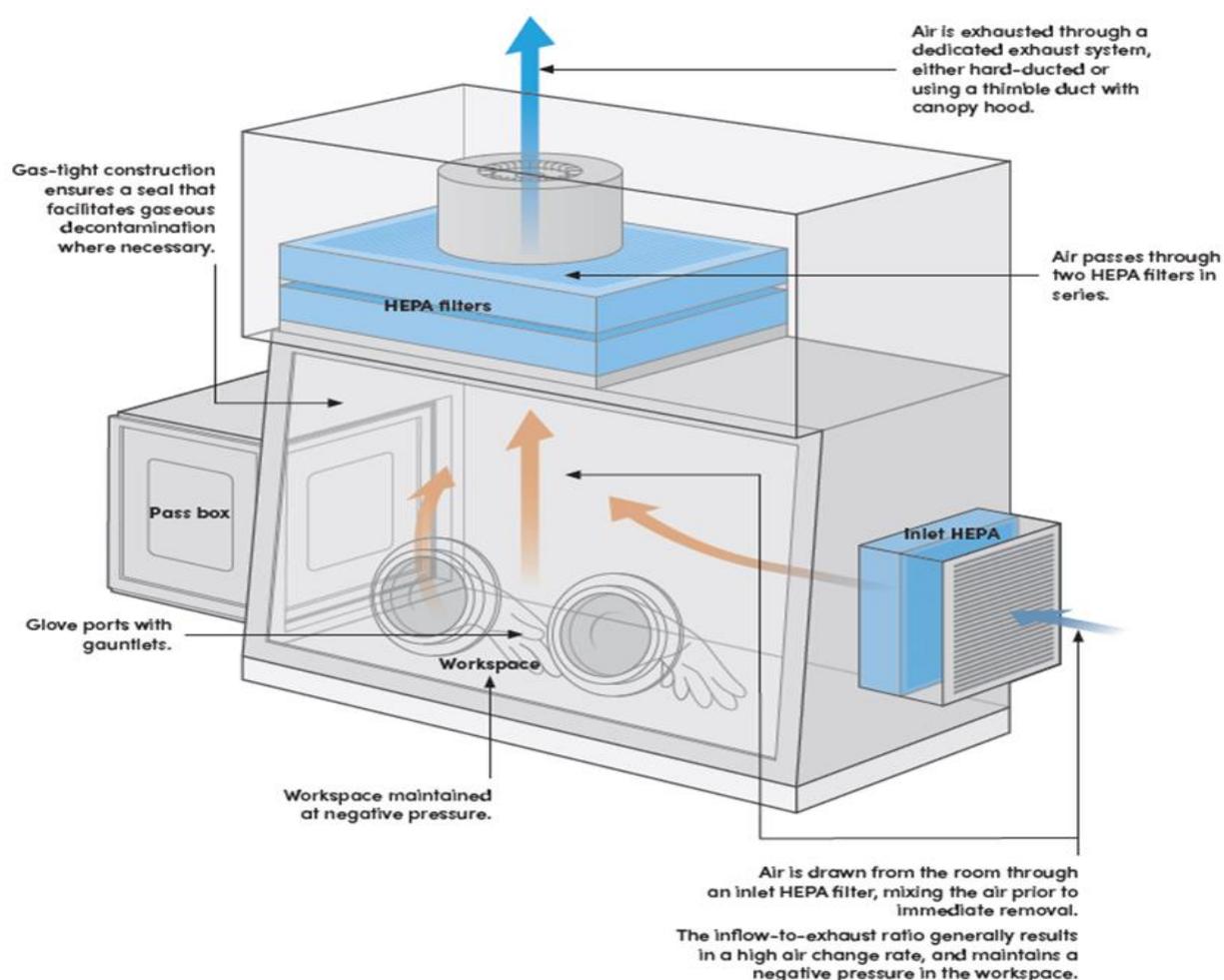
Same as BSL-1 additionally any accidental incident reported to Biosafety officer in addition to Laboratory supervisor.

4.1.3 BSC Class 3

The Class III BSC is designed to provide the highest level of protection to personnel. These cabinets are leak-proof and will be stringently tested to check leakage rates for the completed system at commissioning and installation.

Both the supply and exhaust air are HEPA-filtered, and the rate of air change within the cabinet is normally high. Airflow is maintained by a dedicated exhaust system outside the cabinet, which keeps the inside of the cabinet under negative pressure to the surrounding laboratory space.

Access to the work surface is by means of heavy-duty, chemically resistant gauntlets or sleeves with integrated gloves, which are attached to ports in the cabinet.



BSL-3 will be applicable for:

1. Isolation, cultivation, and storage of RG 3 microorganisms.
2. Handling of environmental samples collected from environment that is likely to contain pathogens of potential disease consequences. Isolation of microorganisms from those samples and subsequent experiments.
3. Experiments on RG 3 microorganisms or isolates from environment mentioned above provided that the experiments will not increase environmental fitness and virulence of the microorganisms.
4. Category III and above genetic engineering experiments on microorganism:

These kinds of experiments pose moderate to high risk(s) to laboratory workers, community, or the environment.

Examples are:

- a. Experiments on RG 2 and RG 3 microorganisms where insertion of gene directly involved in production of toxin or allergen or antimicrobial compounds.
- b. Insertions of gene into RG 3 microorganisms from any source, deletions, or rearrangements that affect the expression of genes, whose functions or effects are not sufficiently understood to determine with reasonable certainty if the engineered organism poses greater risk(s) than the parental organism.
- c. Insertions of nucleic acid from any source, deletions, or rearrangements that have known or predictable phenotypic or genotypic consequence in the accessible environment that are likely to result in additional adverse effects on human and/or animal health or on managed or natural ecosystems, e.g., those which result in the production of certain toxins.
- d. Research involving the introduction of nucleic acids (recombinant or synthetic) into RG 3 organisms or organisms listed in SCOMET items (<http://dgft.gov.in>).
- e. Genetic engineering of organisms isolated from environment where there are reported cases of disease prevalence and possibility of presence of infectious microorganisms.

All category III and above GE experiments require prior authorization from IBSC and subsequent approval from RCGM before commencement of the experiments through submission of information in the prescribed proforma.

4.1.4 BSC Level 4

BSL-4 laboratory is the maximum containment laboratory. Strict training, strictly restricted access and supervision are required, and the work must be done under stringent safety conditions and positive pressure personnel suits. BSL-4 will be suitable for

1. Isolation, cultivation, and storage of RG 4 microorganisms.
2. Handling of samples collected from environment/patients that are likely infected with RG 4 organisms with serious/fatal health effects.
3. Experiments on RG 4 microorganisms or isolates from environment/patients mentioned above to find remedial measures.
4. Category III and above genetic engineering experiments on microorganisms involving introduction of nucleic acids (recombinant or synthetic) into RG 4 microorganisms or exotic agents.

Note:

1. BSL facilities are not meant for Permanently housing/keeping/rearing of any animals, arthropods, or aquatic organisms for longer than the time required to complete laboratory procedures on them.
2. The growing of any plants, except those in tissue culture bottles or fully contained in a plant growth chamber.
3. Genetic engineering experiments not covered under any of the above four categories will require case by case evaluation for selection of appropriate containment strategies. Prior approval and/or permission from the IBSC and/or the RCGM shall be required to initiate such experiments. Few examples are:
 - a. Clubbing of experiments pertaining to different categories.
 - b. Any experiments involving primates, dogs, large animals, and human participants within the laboratory.

- c. Experiments involving the use of infectious or defective RG 3 and above viruses in the presence of helper virus.
- d. Experiments using DNA which encodes a vertebrate toxin having an LD50 of less than 100 µg/kg.
- e. Experiments with genes that alter the growth status of cells such as oncogenes, cytokines, and growth factors.
- f. Experiments aimed at controlling natural populations.

All existing BSL-3 and 4 facilities must be certified by RCGM. A format for certification is available in this guideline.

The new BSL-3 and 4 facilities shall require certification at the time of commissioning operations as per the format.

4.2 Universal precautions for the biological laboratory workers

Universal precautions are a set of guidelines designed to protect laboratory workers and others from exposure to infectious agents, particularly those found in human blood and body fluids. Here are the key universal precautions for biological laboratory workers:

Prioritize Health

If performing studies with human participants or with blood and other potentially infectious materials, reducing transmission of diseases is a top priority, regardless of diagnosis or presumed infection status.

Treat All Human and Animal Material as Infectious

Disease spreads by direct contact with sick individuals or infectious materials, or through indirect contact with contaminated surfaces or objects. By using universal precautions and treating all materials as infectious, the likelihood of exposure to an infectious agent is reduced.

Hand Hygiene

Wash Hands Frequently: Before and after handling any biological materials, after removing gloves, and whenever there is a potential for contamination.

Use Hand Sanitizers: If soap and water are not available, use an alcohol-based hand sanitizer.

Personal Protective Equipment (PPE)

Gloves: Always wear disposable gloves when handling biological specimens or potentially infectious materials. Change gloves between tasks and dispose of them properly.

Lab Coats/Gowns: Wear lab coats or gowns to protect your skin and clothing. These should be removed before leaving the laboratory.

Eye Protection: Use safety goggles or face shields to protect against splashes or aerosols.

Masks/Respirators: Use masks if there is a risk of inhalation of infectious agents, particularly during procedures that generate aerosols.

Safe Handling of Sharps

Use Needles and Sharp Instruments Carefully: Avoid recapping needles and ensure that sharps are disposed of in designated sharps containers.

Dispose of Sharps Properly: Use puncture-resistant sharps disposal containers for needles, scalpel blades, and other sharp objects.

Proper Disposal of Biological Waste

Segregate Waste: Dispose of biological waste in appropriate biohazard containers. Follow the IITH biomedical waste disposal guidelines for waste segregation.

Decontaminate Before Disposal: Decontaminate waste by autoclaving or using chemical disinfectants before disposal, as per the lab's procedures.

Perform Routine Sanitation

Maintain a clean workspace to prevent the risk of exposure and transmission of infectious agents. Regularly disinfect personal lab spaces, reusable equipment, and commonly touched surfaces.

Work Practices

Avoid Eating, Drinking, and Applying Cosmetics: Do not eat, drink, apply cosmetics, or handle contact lenses in the laboratory.

Minimize Aerosol Generation: Perform procedures in a way that minimizes the production of aerosols. Use biological safety cabinets when handling potentially infectious materials.

Decontaminate Work Surfaces: Regularly clean and decontaminate work surfaces with appropriate disinfectants, especially after spills or contamination.

Vaccinations

Immunizations: Ensure you are up to date with vaccinations, particularly hepatitis B and any other vaccines recommended for the agents you may encounter in the lab.

Reporting and Managing Exposures

Report Incidents Immediately: Report any exposure to biological agents, including needlestick injuries or splashes, to your supervisor or the designated health officer.

Follow Post-Exposure Protocols: Follow the lab's protocols for managing exposures, which may include immediate washing of the area, seeking medical attention, and reporting the incident.

Training and Awareness

Regular Training: Participate in regular training sessions on biosafety and infection control.

Stay Informed: Keep yourself informed about the pathogens you work with and the associated risks.

By following these universal precautions, biological laboratory workers can significantly reduce the risk of exposure to infectious agents and ensure a safer working environment.

4.3 Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE) is crucial in biological labs to protect personnel from potential exposure to hazardous biological agents and to prevent contamination of experimental samples.



The overview of the essential PPE for biological laboratories:

1. Lab Coats or Gowns

Purpose: Protects the skin and personal clothing from biological and chemical exposure.

Types: Disposable or reusable, made from fluid-resistant materials.

2. Gloves

Purpose: Protects hands from exposure to biological agents, chemicals, and other hazardous materials.

Types: Latex, nitrile, or vinyl gloves, chosen based on the specific needs of the lab.

3. Safety Goggles or Face Shields

Purpose: Protects eyes from splashes, aerosols, and other hazardous materials.

Types: Safety goggles for full eye protection; face shields for additional facial protection.

4. Respiratory Protection

Purpose: Protects the respiratory system from inhaling hazardous biological agents.

Types: Surgical masks, N95 respirators, or powered air-purifying respirators (PAPRs), depending on the level of risk.

5. Footwear

Purpose: Protects feet from spills and contamination.

Types: Closed-toe shoes, often with shoe covers in high-risk areas.

6. Head Covers

Purpose: Prevents contamination from hair and protects the head from exposure.

Types: Disposable bouffant caps or hoods.

7. Sleeve Covers

Purpose: Provides additional protection to arms when working with hazardous materials.

Types: Disposable, fluid-resistant sleeve covers.

8. Aprons

Purpose: Offers additional protection, especially during procedures with a high risk of splashes.

Types: Disposable plastic aprons or reusable fluid-resistant aprons.

9. Hearing Protection

Purpose: Protects against noise hazards in environments with loud equipment.

Types: Earplugs or earmuffs.

10. Specialized PPE

Purpose: Provides protection tailored to specific lab tasks and hazards.

Types: Cryogenic gloves for handling extremely cold materials, cut-resistant gloves for tasks involving sharp instruments, etc.

Note: Depending on the work and hazard type, laboratory workers can choose one or more types of PPE. It is not necessary to wear all the PPE all the time.

Selection of PPE

Proper selection of personal protective equipment is crucial for minimizing the risk of exposure to biological agents. The selection process should consider factors such as the type of biological material being handled, the potential routes of exposure, and the activities being performed. Common types of PPE may include gloves, lab coats, safety goggles, face shields, respirators, and shoe cover.

Proper Use and Maintenance

Personnel must be trained on the proper use, fitting, and maintenance of PPE to ensure its effectiveness. This includes instructions on how to properly don, doff, and dispose of PPE, as well as procedures for cleaning and disinfecting reusable PPE.

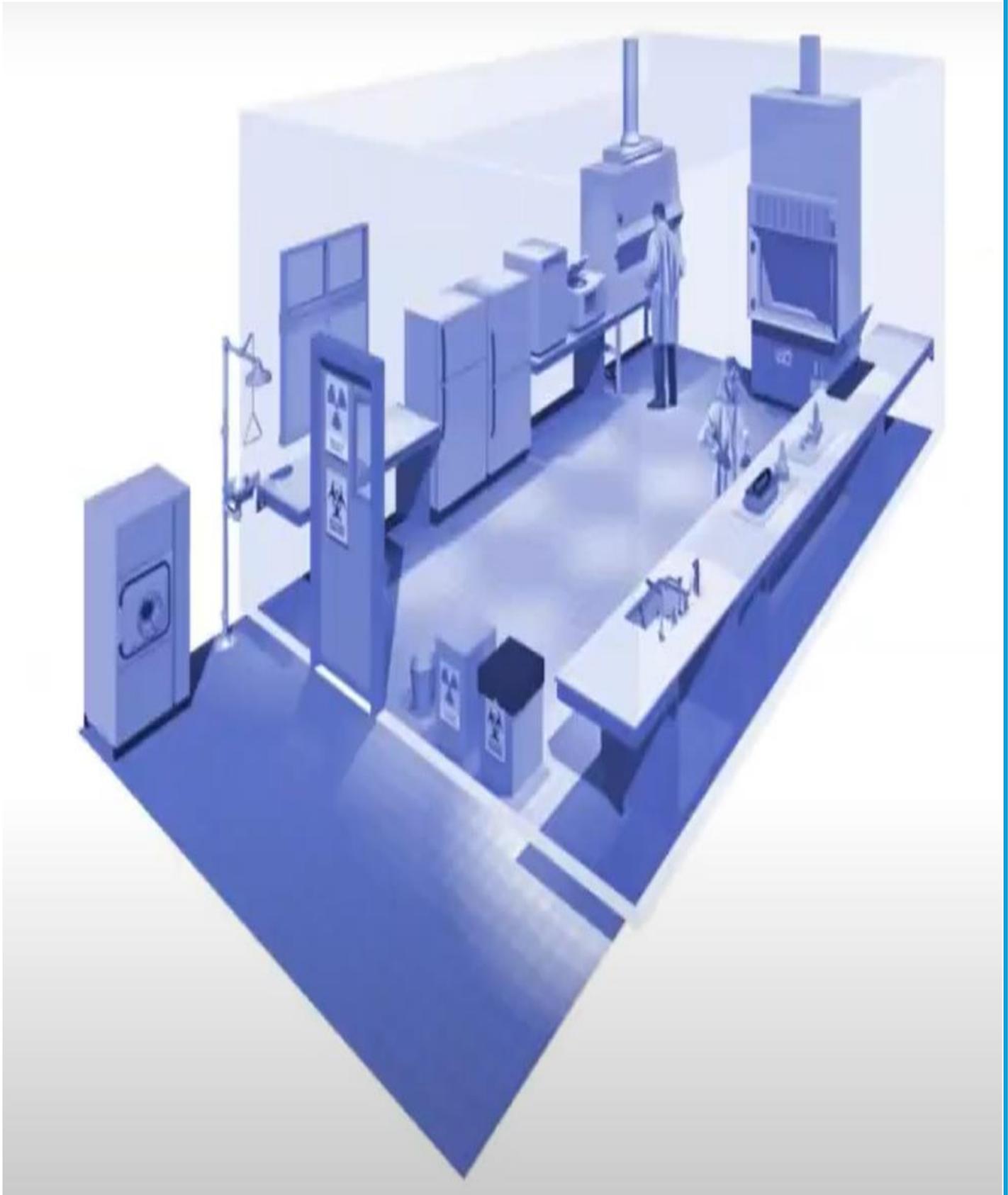
4.4 Facility Design and Maintenance

Facility Requirements for Biosafety Levels

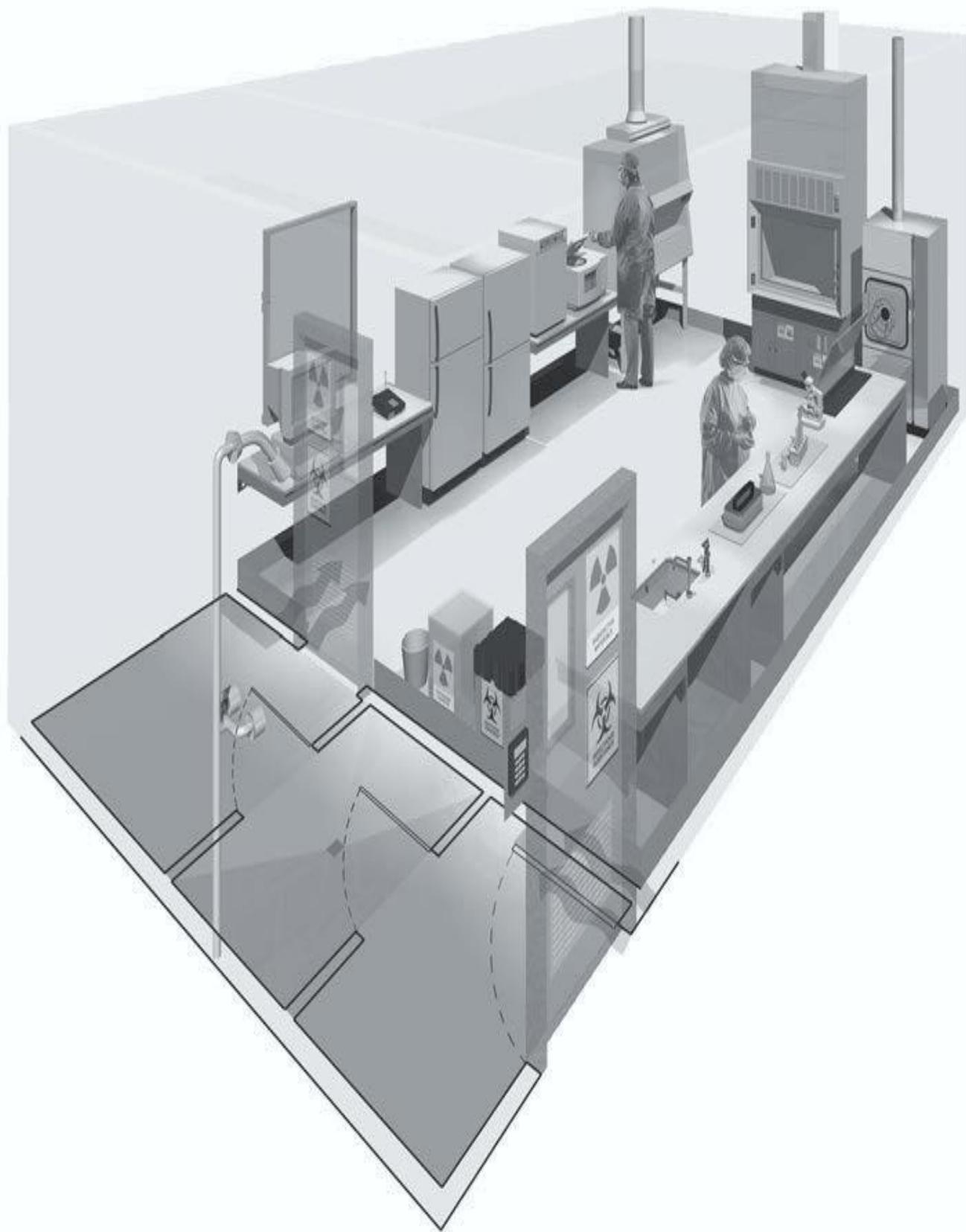
The design and maintenance of laboratory facilities must align with the biosafety level requirements established for the types of biological agents being handled. This includes considerations such as the layout of laboratory spaces, airflow patterns, containment equipment, and decontamination systems.

Model layout of the BSL 1 and BSL 2 laboratory is given below.

Layout of the of the BSL 2 facility



Layout of the BSL3 facility



4.5 Maintenance of the BSC, Autoclave and fume hoods

Engineering controls, such as biological safety cabinets, autoclaves, and fume hoods, play a crucial role in containing biological agents and minimizing the risk of exposure. These controls must be properly installed, maintained, and operated to ensure their effectiveness.

Regular maintenance of equipment is essential for identifying and addressing potential hazards or malfunctions. All laboratories must maintain all equipment used to handle biohazards according to the manufacturer's instructions, and this maintenance should be documented. Any issues should be promptly addressed to prevent disruptions to biosafety practices.

4.6 Risk group and containment facilities

In general, biosafety begins with ensuring that the workplace (whether it is a laboratory, fermentation plant or open field) is safe for the working staff, the public and the environment by proper containment/ confinement.

Containment includes combination of facilities, practices, and procedures for managing risk-inherent microorganisms, GE organisms or cells where they are being handled or maintained for reducing the exposure, preventing their escape within establishment and/ or in natural environment.

The selection of containment facilities depends upon the risk category of microorganisms.

The Risk Groups with details of microorganisms falling into each category and required containment facilities for each group are published separately by the Department of Biotechnology through the OM No. PIB-15011/1/2020-PPB-DBT Dt. 09.12.2021 and amendment thereafter. <https://ibkp.dbtindia.gov.in/Registration/Index>

The list provided is indicative but not exhaustive and will be updated periodically. However, for working with organisms not listed in these guidelines, it is the responsibility of the investigator to determine appropriate risk groups and containment level in consultation with IBSC/RCGM.

4.6.1 Risk group of microorganisms

In case of microorganisms, the pathogenicity of the organism is extremely important for the risk assessment and its subsequent categorization. Infection by a microorganism followed by disease depends on its ability to multiply in the host and on the host's ability to resist or control the infection. Classification of microorganism into risk groups is based on:

1. Pathogenicity of the organism towards humans/animals/plants.
2. Modes of transmission and host range of the organism.
3. Availability of effective preventive treatments or curative medicines.
4. Capability to cause epidemics.

TABLE 4: Risk Group (RG) classification

Risk Group (RG)	Description
RG 1 (no or low individual and community risk)	Microorganisms that are unlikely to cause human/ animal/plant disease
RG 2 (moderate individual risk, low community risk)	Microorganisms that can cause disease in human /animal/ plants. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited

RG 3 (high individual risk, low community risk)	Microorganisms usually cause serious or lethal human/ animal/ plant disease but do not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
RG 4 (high individual and community risk)	Microorganisms usually cause 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.

4.7 Risk Classification

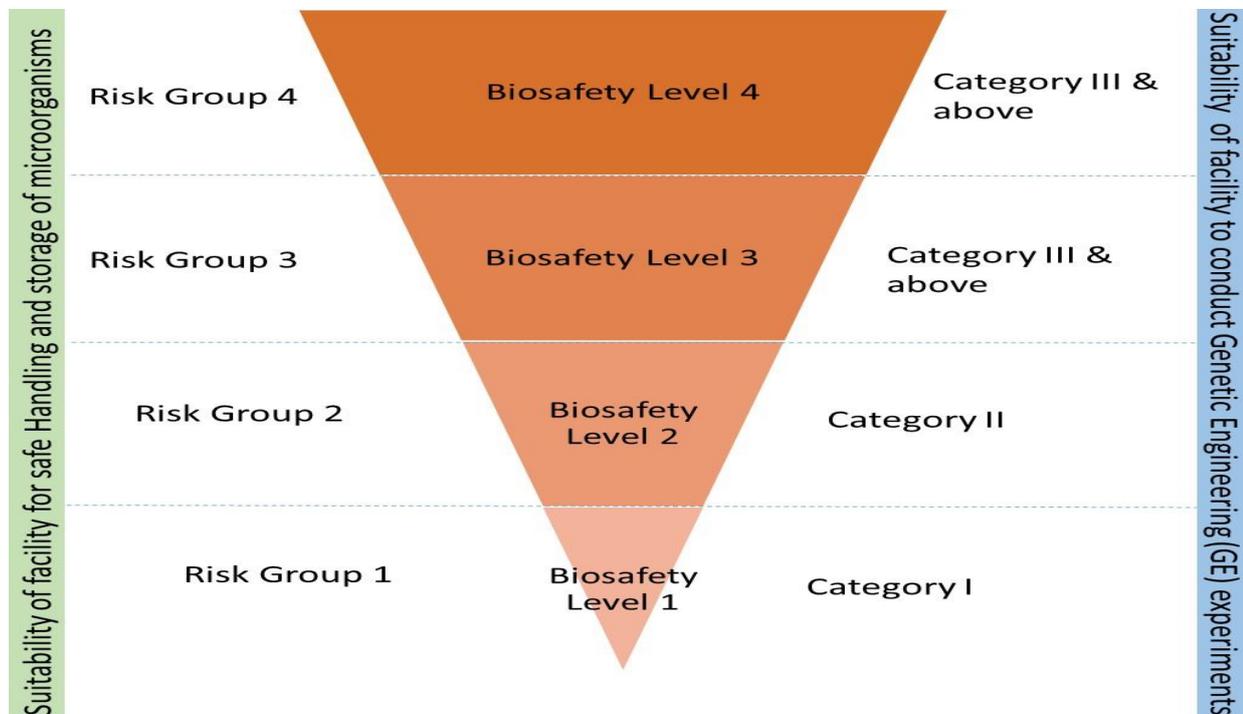
Considering fact that genetic engineering can alter/change the overall risk of an organism, a risk re-evaluation approach has been mentioned in these guidelines for the selection of appropriate containment facility.

Operational details that are not specified in these handbooks shall be as per International best practices wherein the proposals shall be taken up in the IBSC meeting(s) for proper deliberations and approval before commencement of the work.

Further, request for any change of an operational parameter(s) of a containment facility shall be evaluated by IBSC in the same manner before approval to ensure that the change does not affect the biosafety and biosecurity concerns that may arise while working in the facility.

Higher the risk group that the organism belongs to, higher is the risk involved:

A guide for selection of appropriate containment facility for handling and storage microorganisms and conducting GE experiments is shown in below:



Guide for selection of appropriate biosafety level laboratory for handling microorganisms and conducting GE experiment

4.8 Risk Assessment

Principles of risk assessment

Risk assessment is a systematic process for identifying, evaluating, and mitigating potential hazards associated with working with biological materials. It involves assessing the likelihood and consequences of exposure to biological agents and implementing control measures to minimize risks.

Risk assessment must be conducted before the commencement of research activities to identify the hazards and control measures to be adopted to prevent laboratory associated infections.

Risk assessment must be carried out in the following steps:

Identify the hazards related to with pathogen/human/animals' cells being handled

The hazardous characteristic of the pathogen includes

- Routes of transmission
- Infective dose
- Stability in the environment
- Host range and its endemic nature
- Method of treatment available

The probable routes of transmission in the laboratory are

- Exposure of the agent through the skin, eyes, and mucous membranes
- Parenteral inoculation by a syringe needle or other contaminated sharp.
- Bites, scratches from infected animals.
- Ingestions of liquid suspension of an infectious agent.
- By contact of the contaminated hand to mouth exposure.
- Inhalation of infectious aerosols.

Identify the hazards related to laboratory procedure

Processes that generate aerosols must be taken into consideration as they remain invisible to personnel in the laboratory and there is a risk of infection to everyone present or entering the lab.

The risk involved is greater if the pathogen is capable of being transmitted through the respiratory passage in the form of aerosols.

Experimental animals can transmit zoonotic agents through saliva, urine or faeces.

Genetic manipulation could increase an agent's pathogenicity or affect its susceptibility to antibiotics or other effective treatments. The risk involved in experimental alteration of virulence genes may lead to increased risk.

Technical proficiency in the use of microbiological practices, the person's training, experience in handling infectious agents must also be taken into consideration.

Pre-existing disease, medications and pregnancy can increase exposure to infants are examples of some of the conditions that may increase the risk of an individual for acquiring laboratory acquired infectious.

Determine the appropriate biosafety level and determine the precautionary measures to be adopted

The inputs obtained from risk assessment can be used in determining the biosafety level and associated precautions for the same.

Review the risk assessment

The risk assessment that is done must be reviewed and modified whenever there is a change in the agent used, modification of practices and equipment or on availability of new information of the hazard.

While carrying out risk assessment, the lab personnel must discuss with the Principal Investigator and Co PI, other experienced personnel having competency in the area, refer literature providing information on the hazards of the agents and exposures that have been happened in the past, etc.,

The existing systems, facilities, and control measures available in the laboratory must also be taken into consideration.

Documentation and record keeping

Records of risk assessments, including identified hazards, control measures, and residual risks, must be maintained for reference and review.

4.9 Good Laboratory Practices and Procedures (GLPP)

1. Don't store food or drink, or personal items coats, and bags in the laboratory.
2. No eating, drinking, smoking, or applying cosmetics in the laboratory.
3. No pens, pencils, or gum, in the mouth; Never pipette by mouth.
4. Wash hands thoroughly, preferably with warm running water and soap.
5. Shake the broth cultures in a manner that avoids wetting of the cotton plug/cap.
6. No open flames or heat sources near the flammable supplies and are never left unattended.
7. Must cover the cuts or broken skin are covered before entering the laboratory.
8. Make sure laboratory equipment and consumables, including reagents, PPE, and disinfectants available in sufficient quantity before the start of work
9. Proper label all biological agents and chemical and radioactive material is mandatory.
10. The work is performed with care and without hurrying.
11. Avoid working when fatigued.
12. Keep the work area clean and free of non-essential objects and materials.
13. Avoid using earphones because they distract personnel and prevent equipment or facility alarms from being heard.
14. Cover or remove any jewellery that could tear gloves.
- 15. Avoid using mobile or telephones, tablets, laptops, flash drives, memory sticks, cameras, or other portable devices, including those used for DNA/RNA sequencing) during the laboratory procedures being performed.**
16. Keep portable electronic devices in areas where they cannot easily become contaminated or act as fomites that transmit infection.

4.10 Good Cell Culture Practices (GCCP)

Cell culture work falls under BSL-2 category labs and cell culture labs need approval from IBSC. Work in cell culture should provide product safety and personal safety.

BSL-2 is appropriate for activities with all primate cell lines, all tumour and lymphoid cells derived from primate origin; all cells derived from human origin; cells exposed to or transformed by a primate oncogenic virus etc. Good cell culture practices include but are not limited to.

1. All cell and tissue work should be performed in a Class II BSC
2. A strict quarantine procedure, including suitable precautions to prevent the spread of potential contamination.
3. Horizontal laminar flow cabinets should not be used when handling cells, as such cabinets are designed to protect only the work area, and the air flow is directed toward the user. Hence use vertical laminar flow cabinets.
4. It is recommended that, as a minimum and where advisable, mycoplasma testing should be carried out on all samples received.

5. Hands should be washed or disinfected before and after handling cells. An appropriate gown or laboratory coat should be worn when entering and removed when leaving the laboratory.
6. Personal accessories (rings, watches), which might compromise cell and tissue culture activities, should be removed, or covered up to prevent contamination. Gloves should be worn and replaced immediately if torn or punctured or during extended work sessions.
7. When handling cell and tissue cultures, workers must avoid transferring contamination on the hands from the culture work to unprotected body parts (for example, eyes or mouth), clothing or items in the open laboratory environment.
8. Mouth-pipetting must be strictly prohibited, always use mechanical pipette aids.
9. All procedures should be undertaken by using methods that minimize the production of aerosols that might spread contamination by micro-organisms or cells.
10. All work surfaces should be cleaned with an appropriate disinfectant, usually 70% alcohol, before and after use.
11. All cultures should be clearly and unambiguously labelled.
12. The use of sharps should be avoided as far as is possible. Any used sharps should be disposed of safely into sharp containers.
13. All liquid waste, except for sterile media or solutions, should be either chemically inactivated by bleach or autoclaved.
14. All solid waste contaminated with tissue culture liquid and/or cells should either be autoclaved before leaving the laboratory, or should be placed in rigid, leak-proof containers before being transported elsewhere for autoclaving or incineration.

4.11 Laboratory inspections and audits

Annual Biosafety audits take place all the labs registered with IBSC in all the department. Regular inspections may be scheduled or unscheduled and should cover all aspects of biosafety, including facility design, equipment maintenance, PPE use, waste management, and adherence to SOPs.

4.12 Corrective actions & Follow-up procedures

Any deficiencies or non-compliance identified during inspections will be documented, and corrective actions should be implemented promptly to address the issues. Corrective actions may include retraining personnel, repairing, or replacing equipment, updating SOPs, or revising protocols to improve safety practices.

Follow-up inspections may be conducted to verify that corrective actions have been completed satisfactorily and that compliance has been restored. Documentation of follow-up inspections and verification of corrective actions are essential for demonstrating continuous improvement in biosafety practices.

4.13 Record keeping and Documentation

Documentation Requirements

Records of the SOP, incident reports, inspection findings, Import, export of the Biohazard substances, vaccination, logs, of the autoclave records of the decontamination of the biomedical waste, calibration and maintenance of the Biosafety cabinets and vaccination if any must be documented in the respective labs all these verified by the Biosafety officer during the inspection.

Access to Records

Access to biosafety records should be restricted to authorized personnel with a legitimate need to know, such as members of the IBSC, biosafety officers, regulatory agencies, and institutional administrators. Measures should be implemented to ensure the confidentiality, integrity, and security of biosafety records.

4.14 Incident reporting and investigation

All biosafety incidents, near misses, and accidents must be promptly reported and investigated to determine the root cause and implement corrective actions. Incident reports should include details such as the nature of the incident, individuals involved, and any corrective measures taken to prevent recurrence.

All the biological hazard related incidents must be reported to Biosafety officer and IBSC.

4.15 Emergency provisions

All labs should have emergency contact details for Biosafety, Fire Safety, Security, and the Principal Investigator posted on the doors, both outside and inside the laboratory along with biosafety level of lab

Building: XXXXXXXXXXXX		OFFICE OF THE BIOSAFETY	
Department: XXXXXXXXX		భారతీయ సాంకేతిక విజ్ఞాన సంస్థ హైదరాబాద్	
Lab Name: XXXXXXXXXX		भारतीय प्रौद्योगिकी संस्थान हैदराबाद	
		Indian Institute of Technology Hyderabad	
CAUTION: The following Hazard may be Present			
	Biological Hazard(s) in Use:		Contact Information:
	<input type="checkbox"/> Infectious Agents Risk Group <input type="checkbox"/> Human Derived Materials <input type="checkbox"/> Acute Biological toxins <input type="checkbox"/> Potentially infectious Biological Specimens <input type="checkbox"/> Human /Animal cells <input type="checkbox"/> Any other Hazard: Live bacteria and yeast		Lab In-charge: XXXXXXXX Secondary Contact: XXXXXXXX Emergency contact: Biosafety office: 9790241480 IITH Security: XXXXXXXX Fire Safety: XXXXXXXXX Emergency Response: XXXXXXXX
Biological Safety Level BSL I			
Laboratory Requirement:			
DO NOT EAT OR DRINK IN THE LAB			
<ul style="list-style-type: none">▪ PPE (Gloves, lab coats, etc.) must be worn when handling biohazards or biohazard-labelled equipment.▪ Wash hands after glove/personal protective equipment removal and before exiting the lab▪ In case of any spill/adversity inform the lab PI and Biosafety officer immediately.			

Emergency response

In the event of a biosafety incident or emergency, personnel must be familiar with emergency procedures and know how to respond effectively. This includes protocols for evacuating the area, containing spills, providing medical assistance to exposed individuals, and notifying appropriate authorities such as the Principal Investigator and biosafety officer.

CHAPTER – V

Biomedical waste Management & Disinfection methods

Biomedical Waste Management (BWM)

5.1 What is biomedical waste?

Biomedical waste means any waste, which is generated during the diagnosis, treatment or immunization of human or animals or research activities pertaining thereto or in the production or testing of biological camps.

Bio-medical waste includes all the waste generated from healthcare facility and research laboratory which can have any adverse effect to the health of a person or to the environment in general if not disposed properly.

All such waste which can adversely harm the environment or health of a person is considered as infectious and such waste must be managed as per the **Biomedical Waste Management Rules 2016 (BMWM 2016)** and amendment thereof time to time.

Occupier means a person having administrative over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

Categories of Biomedical Waste at IITH

YELLOW		RED	WHITE	BLUE
<p><u>Solid Waste</u></p> <ul style="list-style-type: none"> • Human anatomical waste • Animal Anatomical waste • Soiled waste • Expired or discarded medicines • Cytotoxic drugs including all items contaminated with cytotoxic drugs alongwith glass or plastic ampoules, vials etc. • Chemical waste • Soiled Linen, Mattresses and Beddings • Microbiology, Biotechnology and other clinical laboratory waste. • Blood bags 	<p><u>Liquid waste</u></p> <ul style="list-style-type: none"> • Chemical liquid waste— Liquid waste from • OT/Lab • Floor washing • Cleaning • Housekeeping • Infected secretions • Discarded disinfectants • Silver X-ray film developing liquid • Aspirated body fluids 	<p><u>Recyclable Plastic Waste</u></p> <ul style="list-style-type: none"> • Tubings • Bottles • Intravenous tubes & sets • Catheters • Urine bags • Syringes without needles & fixed needle syringes • Vaccutainers • Gloves (Including Soiled Gloves) 	<p><u>Waste Sharps including metals</u></p> <ul style="list-style-type: none"> • Needles • Syringes with fixed needles • Needles from needle tip cutter or burner • Blades • Scalpels • Other contaminated sharp object that may cause puncture and cuts 	<ul style="list-style-type: none"> • Glassware <ul style="list-style-type: none"> ➤ Broken or Discarded Glass ➤ Contaminated Glass ➤ Medicine vials and Ampoules (Except those contaminated with cytotoxic waste) • Metallic Body Implants

5.2 Segregation and Disposal of Biological Waste at IITH

Steps involved in Biomedical Waste collection and Disposal

1. As per the BMWM 2016, the first five steps (**Segregation, Collection, Pre-treatment, Intramural Transportation, and Storage**) are the exclusive responsibility of the Research Laboratory or Healthcare facility within the Institute.
2. At IITH, segregation and pretreatment are done in the respective labs, followed by collection and transportation is carried out by the biosafety office and treatment and disposal are primarily the responsibility of the CBWTF.
3. Biomedical waste should be segregated at the point of generation by the person who is generating the waste (**Research laboratory / Health care Center**) in designated color-coded bins/containers and perform pretreatment.
4. Biomedical waste and general waste shall not be mixed.
5. **The pretreatment, include disinfectant followed by autoclaving must be done as early as possible preferably same day or within 24 hours and deposit big collection bin installed in the corridor of the floor.**

6. Ensure barcodes are labelled on all color-coded bags or containers and paste the details lab information, type of waste and tag in the bags.
7. **Storage time of waste should be as less as possible so that waste storage, transportation and disposal is done within 48 hours.**
8. to a CBWTF (Dharma & Co.).

BIOMEDICAL WASTE SEGREGATION



5.3 Research scholars /student's responsibilities for biomedical waste management

1. All research students and staff must follow the institutional policies and procedures of IITH for biomedical waste management.
2. Training is mandatory before handling any biomedical waste.
3. Segregate waste at the point of generation according to type (e.g., sharps, pathological waste, contaminated plastics, chemical waste, etc.) and use the correct color-coded bags/containers (Red, Yellow, Blue, and White) as per the regulatory guidelines of IITH.
4. Do not mix biomedical waste under any circumstances.
5. Do not mix solid and liquid biomedical waste.
6. A segregation chart provided by the biosafety office must be posted on the wall where the biomedical waste bin is placed in the laboratory.
7. Autoclave biomedical waste using a chemical indicator (autoclave tape) for all cycles.
8. Maintain records of biomedical waste disposal, autoclave logs, and biosafety cabinet usage.
9. Ensure all color-coded (Red, Yellow, Blue) QR code-labelled plastic bags are adequately numbered and maintained in the lab.
10. After autoclave all biomedical waste deposited based on the colour in the BINS INSTALLED on the corridor.
11. Do not discard anything other than biomedical waste in the outside bins.

5.4 Treatment for liquid biomedical waste

1. All microbiological liquid biohazardous waste generated in BSL-2 labs (spent liquid growth culture media containing microbial or human/animal cells, diluted blood and tissue fluids, plasma, etc.) should be autoclaved and then disposed of in the sanitary sewer system.
2. The steam from the autoclave must come into direct contact with the solution to be disinfected, so the containers holding the liquid waste should not be sealed.
3. Do not autoclave solutions containing significant (high) amounts of hypochlorite, ethanol, or formaldehyde, as they can become volatile and exceed acceptable air concentration levels when the autoclave is opened.
4. All liquid biomedical waste generated in BSL-1 labs must be treated with a 1–10% sodium hypochlorite solution (bleach), based on the amount of microbial load present, before disposal into the sewer line (sink). Records of such treatments must be maintained for a period of three years. The biosafety office will verify these records from time to time.

5.5 Disinfection and Decontamination

Disinfection: A process to eliminate viable biological agents from items or surfaces for further safe handling or use.

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.

Antiseptic: Is a chemical germicide formulated to be used on skin or tissue.

Sterilizer: Is intended to destroy all microorganisms (viruses, bacteria, fungi, and bacterial or fungal spores) on inanimate surfaces.

Chemical disinfection

Biological agents will show different resistance or sensitivity to chemical disinfectant depending on the presence or absence of a cell wall skeleton, lipid membranes, layers of polysaccharides and peptidoglycan.

Generally, higher concentrations of highly active disinfectants are required to inactivate spores than enveloped viruses.

Typically, a solution of sodium hypochlorite (NaClO) containing 1000 ppm (parts per million) available chlorine will be suitable for general surface disinfection, but stronger solutions (for example, 5000 ppm or 10 000 ppm) are recommended when dealing with heavy contamination, the presence of organic matter or disinfectant-resistant biological agents.

Types of chemical Disinfectant

1. **Chlorine compound** (Sodium hypochlorite, Calcium hypochlorite, Sodium dichloroisocyanurate, Chloramine Chlorine Dioxide)
2. **Phenols**
3. **Peroxides** (Hydrogen peroxide & Peracetic acid),
4. **Aldehydes** (Formaldehyde, Glutaraldehyde)
5. **Quaternary ammonium compounds**
6. **Alcohols** (Ethanol, Propanol/ Isopropanol)

Gaseous disinfection

In a limited number of situations mainly in laboratories with maximum containment measures the risk assessment determines that gaseous disinfectants also known as fumigants, are required to decontaminate the laboratory space, furniture and/or equipment.

Types

1. Hydrogen peroxides
2. Chlorine dioxide
3. Formaldehyde

Heat disinfection

Heat is the most common physical method used for the decontamination of biological agents. Both dry and moist heat can be used.

The contact of the biological agents with water is essential for steam sterilization, that is, the steam must reach all the surfaces or materials to be sterilized or disinfected.

Moist heat is most effective when used in autoclaving.

Dry Heat incineration and Hot air oven.

Decontamination

Decontamination is the process of reducing 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.

The specific decontamination requirements depend on the nature of the biological agents being handled.

A basic knowledge of the laboratory personnel about cleaning, disinfection and sterilization is therefore crucial for biosafety in the laboratory.

The choice and use of a decontamination method, either chemical or physical, will depend on the application.

Methods of Decontamination

Cleaning: The removal of foreign material (e.g., soil, organic material) from objects and surfaces.

Disinfection: Use of chemical agent to eliminate viable biological agents.

Sterilization: Complete elimination or destruction of all forms of microbial life including spores.

The correct sequence for successful disinfection is:

(i) clean to remove dirt and organic matter, (ii) apply the disinfectant and (iii) after a pre-determined contact time, wipe with water to remove chemical residues, if necessary.

5.6 CATEGORIES OF DECONTAMINATION

Chemical		Physical
Gas/ Vapour	Liquid	Heat
Formaldehyde	Phenols	Autoclave
Hydrogen peroxide	Peroxides	Incineration
Chlorine dioxide	Hypochlorite's	Hot air oven
	Chlorine dioxide	Boiling
	Peracetic acid	
	Formaldehyde	
	Glutaraldehyde	
	Quaternary ammonium compounds	
	Alcohols	

5.7 Hand Hygiene

There are two types of laboratory hand hygiene

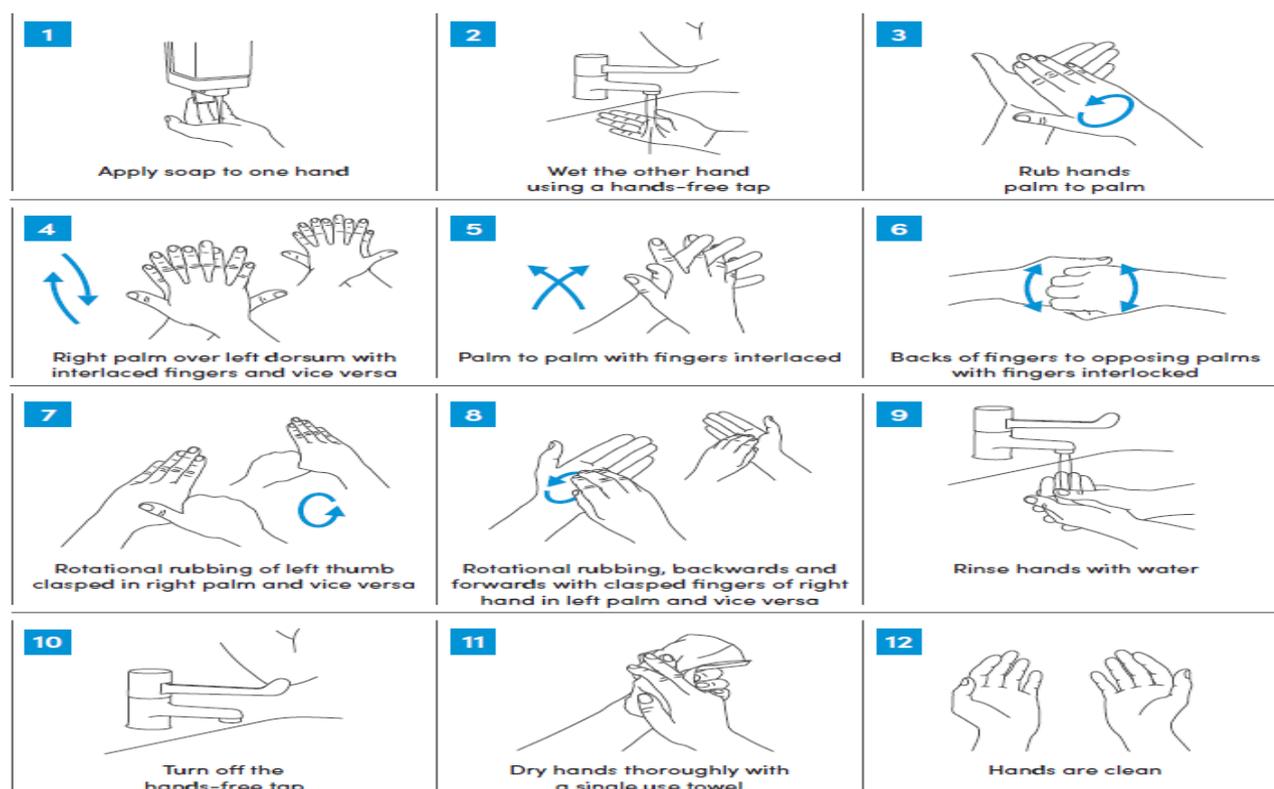
Handwashing

A short (about 20 seconds) but thorough handwash with soap and running water will efficiently remove laboratory-acquired contamination.

Alcohol hand rub

Alcohols (ethanol, propanol, or isopropanol) at concentrations between 60% and 95% applied to the hands and rubbed to dryness can be effective in removing microbial contamination acquired during laboratory work.

A Technique for effective hand washing shown below:



5.8 Biohazard events

Refer to incidents involving biological agents that pose a risk to the health of humans, animals, or the environment. These events can occur in settings such as laboratories, healthcare facilities, research and development set up, and other places where biological materials are handled. Biohazard events can include:

1. **Exposure to Pathogens:** Accidental exposure to harmful microorganisms, such as bacteria, viruses, fungi, or parasites. This can occur through inhalation, ingestion, skin contact, or injection.
2. **Spills and Releases:** Unintentional release of biohazardous materials, such as during the handling, transport, or disposal of biological agents.
3. **Needle Stick Injuries:** Incidents where individuals are accidentally pricked by needles or other sharp objects that have been used with biological materials.
4. **Containment Breaches:** Failures in containment systems, such as biosafety cabinets or containment facilities, that lead to the release of hazardous biological agents.

5. **Infections in Laboratory Workers:** Occurrences were laboratory personnel contract infections due to inadequate biosafety practices or accidental exposure.
6. **Improper Disposal:** Incorrect disposal of biohazardous waste, leading to environmental contamination or exposure to the public.

5.9 Spill Response

In the event of a spill or release of biological material, personnel must follow established spill response procedures to contain the spill, mitigate the spread of contamination, and protect themselves and others from exposure.

BIOHAZARD SPILL CLEAN UP PROCEDURES:

Spills in a biological safety cabinet

1. Leave the BSC running.
2. Wipe down all interior surfaces with appropriate disinfectant.
3. Determine if spill has gone beyond the work surface such as on the grilles or inside seams. If yes, disassemble as much of BSC as possible for decontamination.
4. If the BSC has a catch basin below the work surface that may be involved in the spill, flood the basin with disinfectant. Do not use alcohol, as a large quantity of alcohol presents a flammable hazard. Clean basin after 30 minutes.
5. Wipe down all items in BSC with disinfectant and some items sterilized by autoclaving
6. Clean up the BSC surface with 70% ethanol
7. Let BSC run for at least 10 minutes after cleanup.

Small spill outside a Biological Safety Cabinet

1. Remain calm and leave the room immediately if no other workers are present. Otherwise: Warn others to stay out of the spill area to prevent spread of contamination.
2. Post a sign stating: “DO NOT ENTER, BIOHAZARD SPILL, and block off area as possible.
3. Remove any contaminated clothing, ensuring that clothing is not pulled over the face, and put into a biohazard bag for later autoclaving.
4. Wash hands, eyes, and exposed skin.
5. Notify the principal investigator or supervisor.
6. Wait for 30 minutes before re-entering the contaminated area to allow for dissipation of aerosols.
7. Meanwhile, put on protective clothing (lab coat, gloves and, if necessary- respirator, eye protection, shoe covers) and assemble clean-up materials.
8. Cover the spill with paper towels and gently apply disinfectant, proceeding from the outer edge of the spill to its Center. Leave in place for 20 minutes.
9. Collect all treated material and discard in a biohazard container.
10. Pick up any broken glass with forceps and place them into a sharp’s container. Never use hands.
11. Re-wipe the spill area with disinfectant and wash hands thoroughly at completion of clean-up.

Large spill outside or inside the biological safety cabinet

Remain calm and leave the room immediately if no other workers are present. Otherwise: Warn others to stay out of the spill area to prevent spread of contamination

Post a sign stating: “**DO NOT ENTER, BIOHAZARD SPILL**, and block off area as possible.

Notify the principal investigator and Biological Safety Office to take further action

Biological Spill in a Centrifuge

1. Leave the lid closed to allow aerosols to settle for a minimum of 30 minutes.
2. Notify others and post warning sign on the centrifuge that equipment is contaminated.
3. If possible, remove rotor and/or swinging buckets and transfer to the BSC

4. Disinfect all parts with freshly prepared 1 in 10 dilution of household bleach (or other appropriate disinfectant).
5. Carefully retrieve any sharp objects by mechanical methods and transfer to a red sharps container.
6. Thoroughly wipe down the inside of the centrifuge and all parts with freshly prepared 1 in 10 dilution of household bleach (or other appropriate disinfectant).
7. Rinse all parts with either water or 70% ethanol if bleach was used, this is to minimize corrosion.

5.10 Spill Kit:

In biosafety management, a spill kit is a collection of supplies and equipment designed to safely and effectively clean up and contain spills of hazardous materials, including biological substances. Spill kits are crucial for preventing the spread of contamination, protecting personnel, and ensuring compliance with safety regulations

Required in all labs conducting research involving potential bio-hazardous agents

A spill kit in biological laboratories is a collection of tools and materials specifically designed to manage and clean up spills involving biological materials safely and effectively.

These materials can include pathogens, cell cultures, bodily fluids, or other potentially infectious substances.

The primary purpose of a biological spill kit is to protect laboratory personnel, prevent the spread of contamination, and ensure proper disposal of hazardous materials.

Components of Spill Kit

1. Personal Protective Equipment (PPE)
2. Gloves: Usually, nitrile or latex to protect hands from exposure.
3. Face Shield or Goggles: To protect eyes from splashes.
4. Disposable Lab Coats or Aprons: To protect clothing and skin.
5. Disposable Shoe Covers: To prevent contamination from spreading.
6. N95 Masks or Respirators: For respiratory protection when handling certain biological agents.

Cleanup Materials

1. Absorbent Materials: Such as spill pads, paper towels, or absorbent granules to soak up the spill.
2. Disinfectants: Commonly bleach solution, ethanol, or other appropriate disinfectants for the specific biological material.
3. Appropriate Biohazard Bags: For the safe disposal of contaminated materials.
4. Sharps Container: For safe disposal of broken glass or other sharps.
5. Forceps or Tongs: For picking up contaminated debris without direct contact.
6. Dustpan and Brush: Disposable or easily decontaminated tools for gathering solid waste.
7. Spill Control Pillows or Booms: For containing larger spills.

Usage of a Biological Spill Kit

1. Assess the Spill: Determine the type and extent of the spill and any immediate hazards.
2. Protect Yourself: Don the appropriate PPE before approaching the spill.
3. Contain the Spill: Use absorbent materials and spill control items to contain and prevent the spread.
4. Clean Up: Apply disinfectants and use cleanup tools to remove the spill.
5. Dispose of Waste: Place contaminated materials in biohazard bags and dispose of according to regulations.
6. Decontaminate Area: Thoroughly clean and disinfect the affected area.
7. Report and Document: Complete spill report forms and log the incident in the logbook.
8. Restock Kit: Replenish any used items to ensure the kit is ready for future use.

By having a well-equipped spill kit and following proper procedures, biological laboratories can effectively manage spills, minimizing the risk to personnel and the environment.

CHAPTER VI

Biosafety Training

Biosafety Training at IITH

Training and Education (Research Staff and Students):

Office of the biosafety IITH provides the training and education for person who work and engage in biohazard substances.

The biosafety and biomedical waste management training is mandatory for all personnel who work in the research and teaching laboratory, including PhD students, JRFs, SRFs, RAs, PDFs, and research staff, working with biological materials.

This training covers fundamental concepts of biosafety, appropriate use of PPE, emergency procedures, waste management, and strategies to reduce biomedical waste generation in the lab.

No one is allowed to work in the laboratory without completing this training. The Principal Investigator (PI) must ensure that all laboratory staff and students are thoroughly trained before they begin work with biohazards.

There is an assessment post biosafety training.

Frequency of Training:

- Training is currently conducted monthly or as on need.
- It is also provided during the admission of new students.

All the researchers are encouraged to attend online training courses conducted by Center for Disease Control (CDC) to gain more knowledge on area of biosafety and biosecurity.

The link for CDC training <https://reach.cdc.gov/training>

CHAPTER – VII

Standard Operating Procedures for Biosafety Cabinets & Autoclave

Common Standard Operating Procedures for biological laboratory

7.1 SOP for Biosafety Cabinets

TITLE: Biological Safety Cabinets (BSCs)

SCOPE: Biomedical Research Personnel

RESPONSIBILITY: Facility In-charge, Head of the Department and Biosafety Officer

PURPOSE: To outline the proper procedures for the use and maintenance of Biological Safety Cabinets (BSCs)

I. PURPOSE

This procedure outlines the use and maintenance of BSC to obtain the optimum control over product quality while reducing the potential for exposure of both product and personnel to airborne biological or particulate chemical agents in low to moderate risk-hazard research and product operations.

II. RESPONSIBILITY

1. The Facility in charge / Principal Investigator ensures that all equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.
2. It is the responsibility of the Biosafety officer to ensure that all research and technical staff using this equipment are adequately trained and experienced in the use of the BSC.
3. It is the responsibility of the Researchers (students) and technical staff using a BSC to read, understand, and follow the procedures outlined below.

III. EQUIPMENT APPLICATION

The Biosafety cabinet is a product resulting from the development of the “laminar flow” principle and the application of environmental control as required in the field of biological research and chemical containment.

IV. Before the Beginning of the work.

Recommended minimum attire includes a lab coat, gloves, and safety glasses. Additional PPE and procedures may be required based work/procedure to be carried out.

V. EQUIPMENT USE/ OPERATION PROTOCOL

1. Turn on the cabinet blower and lights and check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
2. Allow the blower to operate for a minimum of **FIVE** minutes before starting the aseptic manipulations within the biosafety cabinet. **As per the manufacturer's instructions.**
3. Disinfect all interior work surfaces by wiping them down with 70% ethanol. This practice eliminates the need for UV lights, whose primary purpose is to inactivate surface contamination.
4. Place only the necessary materials onto the cabinet work surface.
5. **Do not place any items over front to rear intake grills. Ensure that all activities are conducted at least 4 inches within the air curtain of the biosafety cabinet (i.e., greater than the height of a cage card holder).**

6. Make sure the viewing window is set to the recommended working height before initiating any procedures. Audible and visual alarms are present on some models to warn the user of the inappropriate window height.
7. Separate contaminated materials on the cabinet work surface to minimize movement.
8. Allow 2-3 minutes after the apparatus and materials are placed into the cabinet.
9. Minimize movement within the BSC and within the room to reduce airflow and use the proper aseptic technique.
10. Allow 2-3 minutes before removing materials from the cabinet.
11. Do not use constant flame gas burners or any flammable substances inside the biosafety cabinets.
12. Disinfect all interior work surfaces by spraying and wiping down with 70% ethanol
13. Note: Specific disinfectants may be required for decontamination of specific biological agents. Refer to biohazard signage or MSDS to determine which chemical disinfectant to use.
14. Chlorinated disinfectants (bleach) use can cause corrosion of equipment and must be followed with a final rinse/wipe with 70% alcohol.
15. Turn off blowers and lights.

VI. MAINTENANCE

1. Inspect the condition of the unit and electrical cord/plug to ensure safe operation. Equipment determined to be unsafe will be removed from service immediately.
2. Perform the weekly disassembly, cleaning, and disinfection of the BSC as per the manufacturer's instructions and **record in the logbook**.
3. Annual routine maintenance with an authorized/experienced person as per the manufacturer's instructions.
4. Any additional maintenance/service should be performed by authorized personnel and the unit re-certified in writing.
5. Certification is documented by labelling the equipment with the date of certification and the date when certification is due.
6. The facility in charge is responsible for maintaining current records of division-owned equipment inspections, calibrations, maintenance, non-routine repairs, and current inventory for their facility on the Division's Equipment Maintenance Logs.

VII. Special precautions for Ultraviolet (UV) lamps

- Post a warning sign on the front of the BSC indicating the presence of UV light hazards.
- The sign must say CAUTION: Turn off the UV light before working.

Take precautions during work:

- Turn off UV lamps while the lab is occupied. The stainless-steel interior of the BSC can reflect potentially hazardous illumination out of the opening of the cabinet.
- Never have the UV lamp on while an operator is working in the cabinet.

Maintenance:

Because UV lamp intensity (its destructive power) decreases with time, proper maintenance is critical for decontamination purposes.

- Follow the manufacturer's instructions for the periodical replacement of bulbs and cleaning.
- Before replacing bulbs, clear the BSC of equipment and material, disinfect it with 10% bleach and then clean it with 70% ethanol.
- Install the bulb with gloved hands to prevent oil buildup.
- Disinfect lamp bulbs before disposal as universal waste.

- Check lamp efficiency monthly with a UV meter or monitoring strip.

Log sheet for BSC

BIOSAFETY CABINET LOG SHEET

BSC make/model:				Location (building/room number):	
Lab/Facility name:				Principal Investigator/ Supervisor name:	
Person responsible for BSC(IF ANY) :				Phone number:	
Date	Time	Temperature & Airflow	Disinfectant used	Name of the User	Activity/comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

7.2 SOP for Autoclave

GENERAL AUTOCLAVE SAFETY GUIDELINES

An autoclave is capable of rendering items sterile of any living organisms by using hot, pressurized steam. Biomedical research laboratories use autoclaves to sterilize glassware and instruments, media and solutions, and biohazardous waste.

The hazards associated with autoclave use include heat, steam, and pressure. Familiarize yourself with the hazards and know how to protect yourself before operating an autoclave.

Do not operate an autoclave until you have been trained on how to do so safely.

Personal Protective Equipment (PPE)

1. Always use PPE such as a lab coat, heat-resistant glove, and safety goggles when using an autoclave.
2. Be sure arms are covered by a lab coat and longer heat-resistant gloves to prevent burns from heat and steam.

PREPARE THE AUTOCLAVE

1. Inspect the door gasket (seal) for any cracks or bulges. The gasket should be smooth and pliable.
2. Clean the drain screen of debris if necessary.
3. Check the water level as per the manufacturer's instructions. If needed add deionized water only.
4. If any problems are found, contact the responsible person before using the autoclave.
5. Turn the autoclave on and allow time for the jacket to reach sufficient temperature and pressure.

PREPARE ITEMS

1. Do not autoclave flammable, combustible, reactive, corrosive, toxic, or radioactive materials.
2. Check that plastics are compatible with the autoclave. Not all plastics can be autoclaved.
3. Polypropylene or stainless-steel tubs are typically used for secondary containment.
4. Inspect glassware for cracks. Do not autoclave cracked or compromised glassware.
5. For liquids, leave caps loose or cover with foil to allow steam penetration and prevent explosion.
6. For bagged items, loosely tape or tie closed. Leave an opening for steam to penetrate the bag.
7. Check the water level. Always use deionized or distilled water.
8. Make sure a logbook is available for recording the time and temperature.

LOAD

1. Inspect for spills or debris inside the autoclave, check door gasket for cracks or bulges.
2. Ensure that the jacket has reached sufficient pressure to start a cycle.
3. Place items in an autoclave tub on a rack and paste the indicator one of the materials.
4. Never place items directly on the autoclave bottom or floor.
5. Do not overload the autoclave. Allow sufficient space between items for steam.
6. Add water if needed.
7. Always use secondary containment in case of spillover.

OPERATE

1. Follow the manufacturer's user manual and laboratory SOP for operating the autoclave.
2. Close and lock the door. Ensure the door is secure before starting a cycle.
3. Select the appropriate cycle given below (e.g. dry heat, sterilize media, sterilize biohazardous waste).
4. Record run on log sheet.
5. Do not open the autoclave door during a cycle! If necessary, abort the cycle and wait until the chamber depressurizes.
6. If the cycle fails, notify the person responsible for the autoclave. Items may not be sufficiently decontaminated if the cycle is not complete.

Sterilizer	Temperature	Pressure	Time
Sterilization	121°C	15-pound psi	20
Biomedical waste	121°C	15-pound psi	60
Biomedical waste	135°C	31-pound psi	45
Biomedical waste	149°C	52-pound psi	30

UNLOAD

1. When the cycle is complete, verify that the chamber temperature has dropped, and the pressure is zero.
2. Wear appropriate PPE to protect yourself from heat and steam (e.g. heat-resistant gloves, lab coat, safety glasses).
3. Slowly open the door to allow steam to escape gradually. Keep your face away from the door.
4. Allow items to stand in the autoclave for 10 minutes.
5. Cautiously remove items and place them in a safe area to cool. Do not agitate containers as boiling or superheated liquids can explode if moved too quickly.
6. Record the cycle on a log sheet or logbook.

7.3 Biosafety guideline for the Fumigation

Objective:

To ensure the effective fumigation of laboratory spaces to eliminate pests, pathogens, or other contaminants, thereby maintaining a safe and clean working environment for personnel and preventing the spread of biological agents.

Equipment and Materials:

1. Fumigant (appropriate for the target pathogen and compliant with regulatory requirements)
2. Fumigation chamber or enclosure (e.g., sealed laboratory space)

PPE during fumigation process to wear:

1. Respirator with appropriate filter cartridges, Chemical-resistant gloves safety goggles or face shield and Lab coat or protective clothing.
2. Closed-toe shoes
3. Warning signs or barricades to restrict access to fumigated areas Timer or alarm clock.
4. Ventilation system (if applicable).

Preparation:

1. Ensure the laboratory space to be fumigated is clear of personnel, animals, and sensitive equipment.
2. Seal all openings, gaps, and cracks in the laboratory space to prevent fumigant leakage.
3. Post warning signs or barricades to restrict access to the fumigated area.
4. Put on appropriate PPE, including respirator, gloves, goggles/face shield, lab coat, and closed-toe shoes.
5. Ensure adequate ventilation in the laboratory space, if applicable.

Fumigant Preparation:

1. Follow manufacturer instructions for preparing the fumigant solution or gas mixture.
2. Transfer the fumigant into the fumigation chamber or enclosure, taking care to avoid spills or leaks.
3. Measure the appropriate quantity of fumigant based on the volume of the laboratory space and the recommended concentration for effective fumigation.

Fumigation Process:

1. Activate the fumigation system according to manufacturer instructions, ensuring that all necessary safety precautions are followed.
2. Start the timer or set an alarm to monitor the fumigation duration.
3. Monitor the fumigation process from a safe location outside the fumigated area, using remote monitoring devices if available.
4. Do not enter the fumigated area until the specified exposure time has elapsed, and the fumigant has dissipated to safe levels.

Ventilation and Aeration:

1. Once the fumigation process is complete, ventilate the laboratory space to remove residual fumigant and ensure air quality meets safety standards.
2. Open windows, doors, and ventilation systems to facilitate air exchange and accelerate the dissipation of fumigant gases.
3. Monitor air quality and fumigant concentrations during the ventilation process to ensure safety.

Post-Fumigation Inspection:

1. After ventilation is complete and the laboratory space is deemed safe for entry, conduct a visual inspection to ensure no signs of fumigant residue or contamination are present.
2. Remove warning signs or barricades and restore access to the fumigated area.
3. Document the fumigation process, including fumigant used, duration of exposure, ventilation procedures, and any observations or incidents encountered during the process.

Decontamination:

1. If necessary, decontaminate surfaces or equipment that may have been exposed to fumigant residues using appropriate cleaning agents or procedures.
2. Dispose of any waste generated during the fumigation process according to regulatory requirements for hazardous materials or chemical waste.

Safety Precautions:

1. Always wear appropriate PPE during fumigation activities to minimize exposure to fumigant gases or residues.
2. Follow manufacturer instructions and regulatory guidelines for handling and using fumigants safely.
3. Ensure adequate ventilation during fumigation and post-fumigation aeration to prevent respiratory hazards.
4. Keep unauthorized personnel away from fumigated areas by posting warning signs or barricades.
5. In the event of a spill, leak, or other fumigation-related incident, follow emergency procedures and report the incident to designated personnel immediately.

7.4 Standard Operating Procedure (SOP) for Formaldehyde (HCHO) Fumigation

Purpose

This SOP outlines the procedure for the safe and effective fumigation of an area using formaldehyde (HCHO) to ensure decontamination of biological agents and other hazardous materials.

Scope

This procedure applies to all personnel involved in the fumigation process in laboratories, clean rooms, or other controlled environments requiring decontamination.

Safety Precautions

1. Personal Protective Equipment (PPE):
2. Full-body protective suit
3. Chemical-resistant gloves
4. Respiratory protection (formaldehyde-rated respirator)
5. Safety goggles or face shield

Ventilation:

Ensure proper ventilation during and after fumigation to avoid formaldehyde exposure.

Use exhaust fans and fume hoods if available.

Emergency Procedures:

Have formaldehyde spill kits and neutralizing agents (e.g., ammonia solution) readily available.

Ensure eye wash stations and emergency showers are operational.

Materials and Equipment

1. Formaldehyde solution (37% formaldehyde) Vaporizer or fumigation device
2. Sealable plastic sheeting and tape Warning signs Formaldehyde detector or monitoring device
3. Neutralizing solution (e.g., ammonia solution)
4. Decontamination equipment (mop, bucket, cleaning agents)

Procedure

Preparation:

1. Notify all personnel of the fumigation schedule.
2. Remove all non-essential items from the area to be fumigated.
3. Seal all windows, doors, and ventilation ducts with plastic sheeting and tape to contain the fumigant.
4. Place warning signs on all entrances to the area indicating that fumigation is in progress and access is restricted.

Fumigation:

1. Calculate the amount of formaldehyde needed based on the volume of the area (approximately 0.3 mL of 37% formaldehyde solution per cubic meter).
2. Pour the required amount of formaldehyde solution into the vaporizer or fumigation device.
3. Activate the vaporizer to disperse formaldehyde vapours evenly throughout the area.
4. Allow the area to remain sealed for a minimum of 6 hours to ensure thorough decontamination.

Post-Fumigation:

1. After the fumigation period, turn off the vaporizer and begin the ventilation process.
2. Open all windows, doors, and ventilation ducts to allow fresh air to circulate.
3. Use exhaust fans and fume hoods to expedite the ventilation process.
4. Monitor formaldehyde levels using a formaldehyde detector to ensure they fall below permissible exposure limits (0.75 ppm over an 8-hour time-weighted average).

Neutralization and Cleanup:

1. If necessary, apply a neutralizing solution (e.g., ammonia solution) to areas with high formaldehyde concentrations.
2. Clean all surfaces with water and a mild detergent to remove any residual formaldehyde.
3. Dispose of all cleaning materials and PPE according to hazardous waste disposal regulations.

Documentation:

1. Record the fumigation date, time, and personnel involved.
2. Document the amount of formaldehyde used and the duration of exposure.
3. Maintain records of formaldehyde monitoring results and any incidents or deviations from the SOP.

Emergency Procedures

1. In case of a spill, evacuate the area immediately and follow the spill response protocol using the formaldehyde spill kit.
2. If exposed to formaldehyde, seek immediate medical attention and follow the decontamination procedures (e.g., rinse eyes with water for at least 15 minutes if contact occurs).

Review and Training

1. Review this SOP annually and update as necessary.

2. Provide training to all personnel involved in the fumigation process on the proper use of PPE, handling of formaldehyde, and emergency procedures.

By adhering to this SOP, the risks associated with formaldehyde fumigation can be effectively managed, ensuring a safe and decontaminated environment.

Frequently Asked Questions (FAQ)

FAQ on Biosafety

1. What personal protective equipment (PPE) is required when working with cell cultures, and how often should it be changed?

Wear gloves, lab coat, and safety goggles. Gloves should be changed between tasks or if contaminated. Lab coats should be washed regularly, and safety goggles should be decontaminated after each use.

2. What precautions should be taken to minimize the risk of aerosol generation when working with infectious biological agents?

Perform procedures that could generate aerosols (e.g., pipetting, vortexing) inside a BSC. Avoid splashes and use sealed containers or equipment with built-in filters.

3. How should biological spills (e.g., blood, cell culture media) be handled to prevent contamination and ensure proper decontamination?

Cover spills with absorbent material, then apply disinfectant (e.g., 10% bleach) for at least 10 minutes. Clean the area thoroughly with additional disinfectant and dispose of materials in biohazard bags.

4. How should biohazardous waste, such as contaminated gloves, pipette tips, and culture flasks, be segregated and disposed of?

Place all contaminated items in clearly marked biohazard bags. Sharps (e.g., needles, broken glass) should be disposed of in puncture-resistant sharps containers. Autoclave all waste before final disposal.

5. What are the guidelines for working with potentially infectious agents like bloodborne pathogens to minimize exposure risk?

Follow universal precautions, assuming all blood samples are infectious. Use PPE, work in BSCs, and follow proper handwashing and decontamination procedures after handling.

6. What procedures should be followed to properly store biological samples and cell cultures to prevent contamination?

Label all samples clearly with date, type, and risk level. Store samples in designated refrigerators or freezers, separate from food and chemicals. Regularly clean and decontaminate storage areas.

7. What training and certifications are required for lab personnel working with biological hazards such as blood, cell cultures, and infectious agents?

Personnel should undergo biosafety training, including handling bloodborne pathogens, proper waste disposal, and emergency response. Depending on the risk level, additional certifications (like BSL-2 or BSL-3 training) may be required.

8. What are the minimum PPE requirements for a biological lab?

Full-covered shoes, high-quality gloves, lab coat, goggles, and face masks if necessary for aerosols or chemicals.

9. What are the biosafety requirements for handling blood samples at IIT Hyderabad?

Blood samples must be handled under BSL-2 conditions due to the potential risk of exposure to bloodborne pathogens (e.g., HIV, hepatitis B and C). Researchers are required to use personal protective equipment (PPE), such as gloves, lab coats, and face shields, and work within a Biological Safety Cabinet (BSC) when processing samples.

10. What is the vaccine requirement working with blood samples

Researcher who working with blood samples must vaccinated and adhere all the biosafety guidelines and must use BSL -2 facility.

11. How should blood samples be stored at IIT Hyderabad?

Blood samples should be stored in properly labelled, sealed containers, and kept at appropriate temperatures (e.g., refrigerated at 2-8°C or frozen at -20°C or lower). Storage areas should be clearly marked, access should be restricted, and records of sample storage should be maintained.

12. What are the biosafety protocols for handling bacterial samples at IIT Hyderabad?

Bacterial samples, depending on the pathogen involved, are generally handled under BSL-1 or BSL-2 conditions. Researchers must use appropriate PPE, work within a BSC for BSL-2 pathogens, and ensure that all materials are properly sterilized before and after use.

Check link provided for under which category of Risk category the microorganisms used in the laboratory <https://biorrap.gov.in/Home/RegulatoryDocuments>

13. How are bacterial samples stored?

Bacterial cultures should be stored in labelled, airtight containers at the appropriate temperatures (e.g., refrigeration for short-term storage, -80°C for long-term storage). The storage area must be secure, with restricted access to authorized personnel only.

14. What biosafety precautions should be followed when working with bacterial cultures?

Wear PPE (lab coat, gloves, goggles). Use a BSL-2 cabinet, follow aseptic techniques, and autoclave waste before disposal. Ensure proper labelling and storage.

15. Does IIT Hyderabad have specific biosafety policies?

Yes, IIT Hyderabad has biosafety policies that align with the Department of Biotechnology (DBT) guidelines. These policies are designed to ensure the safe handling of biological materials, particularly in research involving genetically modified organisms (GMOs) and other biohazards.

16. What are the biosafety considerations for working with cell cultures at IIT Hyderabad?

Cell cultures, especially those derived from human or animal sources, are handled under BSL-2 conditions due to the potential presence of infectious agents. PPE, including gloves, lab coats, and eye protection, is mandatory, and work should be conducted in a BSC.

17. How should cell cultures be maintained and stored?

Cell cultures should be maintained in sterile conditions, typically in an incubator at specific conditions (e.g., 37°C with 5% CO₂ for mammalian cells). For long-term storage, cell cultures can be cryopreserved in liquid nitrogen or at -80°C.

FAQ on Biomedical waste management

1. How is biomedical waste disposed of IIT Hyderabad?

Biomedical waste at IIT Hyderabad is disposed of in accordance with the Biomedical Waste Management Rules, 2016. The waste is segregated into color-coded containers (red, blue, yellow, and white) at the point of generation. It is then pre-treated (autoclaved) and stored in dedicated biomedical waste bins installed on each floor of the buildings. The Biosafety team collects the waste and hands it over to an authorized Common Bio-medical Waste Treatment Facility (DHARMA & Co.).

2. How long the biomedical waste stored in the laboratory?

As per Biomedical Waste Management Rules 2016, waste must be disposed of within 48 hours after segregation and pretreatment (autoclave), collection and intramural transport and disposal.

3. What precautions should be followed when working with blood samples?

Treat all samples as infectious (Hepatitis B, C, HIV), use PPE, and work in a Biosafety Cabinet Class II. Ensure Hepatitis B vaccination and properly disinfect surfaces and dispose of sharps.

4. What are biosafety levels are available at IIT Hyderabad?

IIT Hyderabad has laboratories equipped to handle work at various biosafety levels, primarily BSL-1 and BSL-2. These labs are used for research that involves low to moderate risk biological agents.

5. What are the most effective disinfectants for decontaminating work surfaces after handling biological materials?

Use 70% ethanol or a 1:10 dilution of bleach for general disinfection. Ensure proper contact time (at least 10 minutes) for thorough decontamination.

6. Who is responsible for biomedical waste management at IIT Hyderabad?

Proper segregation and pre-treatment are responsible for the research laboratory and health centre. Collection and intramural transport, hand it over to the CBWPC is responsibility of Biosafety office.

7. What are the disposal procedures for blood samples at IIT Hyderabad?

Used blood samples and associated waste (e.g., syringes, gloves) must be disposed of as biomedical waste. These items should be placed in yellow color-coded bags and treated as per the guidelines. Liquid waste containing blood should be treated with a suitable disinfectant before disposal.

8. What precautions are taken to avoid contamination when working with blood samples?

To avoid contamination, strict aseptic techniques must be followed, including sterilization of equipment, use of disposable materials, and working within a BSC. Spill kits and emergency procedures should be readily available in case of accidental spills.

9. What are the disposal procedures for bacterial samples?

After experimentation, bacterial cultures and contaminated materials should be autoclaved to ensure complete inactivation of the organisms before disposal. Autoclaved waste can then be disposed of in red color-coded bags designated for recyclable biomedical waste.

10. What steps are taken to prevent cross-contamination between bacterial samples?

To prevent cross-contamination, strict aseptic techniques are followed, including the use of dedicated tools for each bacterial strain, sterilization of surfaces and equipment between experiments, and working with only one bacterial strain at a time in the BSC.

11. How microorganisms such as yeast or bacteria be properly disposed of to ensure environmental safety?

Autoclave contaminated materials before disposal. For liquid cultures, disinfect with bleach before draining. Solid materials (e.g., plates, pipette tips) should be placed in biohazard waste bags for autoclaving.

12. How is waste from cell culture experiments disposed of?

Waste from cell culture experiments, including media, pipettes, and flasks, should be treated with a disinfectant (e.g., 10% bleach solution) before disposal. Solid waste should be autoclaved and disposed of in red bags, while liquid waste can be decontaminated and flushed according to lab protocols.

FAQ on IBSC

13. How does IIT Hyderabad ensure compliance with biosafety regulations?

IIT Hyderabad ensures compliance through its Institutional Biosafety Committee (IBSC), which reviews and approves all research proposals involving biological materials. The committee also monitors ongoing projects and inspect the facility 'for adherence to biosafety protocols and provides training to researchers.

14. How often does the IBSC at IIT Hyderabad meet?

The IBSC at IIT Hyderabad meets regularly, typically twice in a year, or more frequently if there are urgent matters to address, such as the review of a new research proposal or an incident report.

15. How can a researcher/PhD student submit the project proposal for IBSC clearance at IIT Hyderabad?

Researchers at IIT Hyderabad must prepare a detailed proposal in consultation with their Principal Investigator (PI) and submit it to the Institutional Biosafety Committee (IBSC) through the PI, who acts as the official applicant. The proposal should include the objectives, methodology, and proposed biosafety measures, and be accompanied by Form C1 as well as Form B5 or B7. This submission can be made either through the designated online or offline process, after which it will be reviewed by the IBSC and feedback provided. As per the latest guidelines first submit the project to the BIORAPP portal and get the project code same will be mentioned in the section 3 of the FORM C1. Additional documents can be requested by the committee.

16. What kind of training does the IBSC provide at IIT Hyderabad?

The IBSC provides training sessions every month on biosafety practices, emergency procedures, waste management, and compliance with regulatory requirements. These sessions are mandatory for all researchers working with biological materials.

Glossary of Terms

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

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).

Aerosol/airborne transmission: The spread of infection caused by the inhalation of aerosols.

Aerosol-generating procedure: Any procedure that intentionally or inadvertently results in the creation of liquid or solid particles, which become suspended in the air (aerosols).

Antimicrobial: An agent that kills microorganisms or suppresses their growth and multiplication.

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.

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

Biosafety committee: An institutional committee created to act as an independent review group for biosafety issues, reporting to senior management. The membership of the biosafety committee should reflect the different occupational areas of the organization as well as its scientific expertise.

Biosafety officer: An individual designated to oversee facility or organizational biosafety (and possibly biosecurity) programs. The person fulfilling this function may also be termed a biosafety professional, biosafety advisor, biosafety manager, biosafety coordinator, or biosafety management advisor.

Biosafety program management: The development, implementation, and oversight of biosafety at the organizational level using a variety of information that includes institutional policies, guidance documents for practices and procedures, planning documents (training, recruitment, emergency/incident response) and record-keeping (personnel, inventories, incident management).

Disinfection: A process to eliminate viable biological agents from items or surfaces for further safe handling or use.

Dual use items: Certain materials, information, and technologies that are intended for benefit, but which might be misapplied to harm.

Emergency/incident 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/incident response is to prevent injuries or infections, reduce damage to equipment or the environment, and accelerate the resumption of normal operations.

Good microbiological practice and procedure (GMPP): A basic laboratory code of practice applicable to all types of laboratory activities 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.

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 that 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 considered.

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 below the risk tolerance level with the core requirements only.

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 the number of organisms. Often defined as the ID 50, the dose that will cause infection in 50% of those exposed.

Laboratory-associated infection: Any infection acquired or reasonably assumed because of exposure to a biological agent during laboratory-related activities. A person-to-person transmission following the incident may result in linked secondary cases. Laboratory-associated infections are also known as laboratory-acquired infections.

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 is 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 exposure or release were to occur.

Pathogen: A biological agent capable of causing disease in humans, animals, or plants.

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.

Primary containment device: A contained workspace designed to protect its operator, the laboratory environment, and/or the work materials for activities where there is an aerosol hazard. Protection is achieved by segregation of the work from the main area of the laboratory and/or using controlled, directional airflow mechanisms. Primary containment devices include biological safety cabinets (BSCs), isolators, local exhaust ventilators, and ventilated working spaces.

Prophylaxis: Treatment is given to prevent infection or to mitigate the severity of the disease if infection were to occur. It can be delivered before possible exposure or after exposure before the onset of infection.

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

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 practices 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.

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 practices, and applicable national or international regulations.

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.

Validation: Systematic and documented confirmation that the specified requirements are adequate to ensure the intended outcome or results. For example, to prove a material is decontaminated, laboratory personnel must

validate the robustness of the decontamination method by measuring 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.

Zoonotic disease (zoonosis): Infectious disease that is naturally transmitted from animals to humans and vice versa.

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