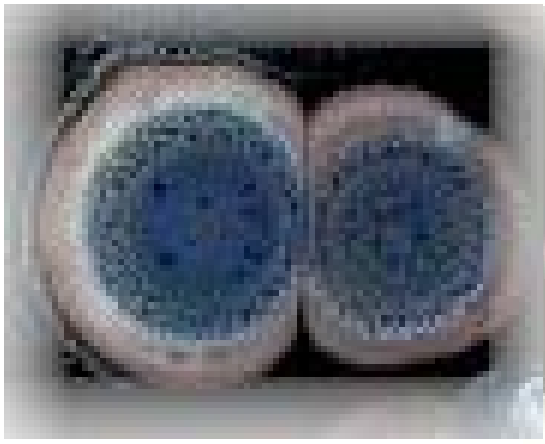
OSH GUIDELINES FOR LABORATORIES AND PRODUCTION FACILITIES



IN THE BIOMEDICAL SCIENCES INDUSTRY

Note :□

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These guidelines were developed □ to provide interim guidance on □ occupational safety and health in □ the biomedical sciences industry. □ You may wish to refer to the □ Ministry of Health website on the □ proposed Biological Agents and □ Toxins Act (BATA): □ http://www.moh.gov.sg/corp/about/□ newsroom/pressreleases/details.do

SAFE & HEALTHY WORKPLACE

MINISTRY OF MANPOWER

Updated on 21 April.2005

INTRODUCTION

Work in the biomedical sciences industry includes basic and clinical research, product and process development and diagnostic procedures which require handling of biological agents. Biological agents include microorganisms, cell-cultures and human pathogens, which may cause infection, allergy or toxic effects.

Other hazards likely to be present include chemical, mechanical and radiation hazards. It is important to bear in mind that any chemical, fire, electrical or radiation accident can result in breakdown of containment of infectious biological agents. Hence, for these hazards, high standards of safety must also be maintained.

The guidelines adopt current international and national containment requirements and operational practices for the control of biohazards. Also included are key features of the safety management system, which reflects occupational health and safety management philosophy, objectives and practices

SCOPE and APPLICATION

These guidelines apply to work in laboratories and production facilities in the biomedical sciences industry.

As exposure to biological agents is the most significant hazard encountered in this industry, the primary objective of the document is to give guidance on minimising such risks. For the control of chemical, fire, electrical and radiation hazards, the guidelines provide the key principles and make reference to relevant guidelines and legislation.

The work nature, size and safety and health risks in individual workplaces vary. The elements of the safety management system described in these guidelines should be applied as appropriate and integrated into any existing health, safety and environment management system. The guidelines should be customised for the individual workplace.

Where appropriate, other local legislation and available scientific information can be referred to for guidance. Some of the agencies involved include Ministry of Health, National Environment Agency, Agri-food and Veterinary Authority (AVA) and the Genetic Modification Advisory Committee (GMAC) These are listed in Appendix 1 of this document.

OSH ORGANISATION & SYSTEMS

- Employer's Responsibilities
- Safety Management System
  - Safety Policy and Organisation
  - In-house Safety Rules and Regulations
  - Safety Inspection
  - Hazard Analysis
  - Safe Work Practices
  - Control and Use of Hazardous Substances
  - Safety Training
  - Safety Meetings
  - Testing and Maintenance Programme
  - Evaluation, selection and control of contractors
  - Accident and incident investigation and analysis
  - Safety Promotion
  - Emergency, Preparedness and Plans
  - Document Control and Reviews
- Safety Personnel
  - Safety Coordinator (Biosafety)
  - Safety Officer
- Safety Committee
- Engineering & Other Supporting Services
- Safety Training
  - Training Requirements
- Health Surveillance and Immunoprophylaxis
  - Medical Monitoring
  - Immunoprophylaxis and Disease Notification
- Employee's Responsibilities

OSH ORGANISATION and SYSTEMS

Employer's Responsibilities

The employer has overall responsibility for assessing risks and determining the level of biosafety requirements relating to work practices, safety equipment and the facilities requirements for work involving biological agents.

The employer must ensure the effective implementation of the elements of the safety management system which are relevant to the set-up of the laboratory or facility. Standards on these elements should be established and can be integrated into existing safety framework in the workplace.

The employer should appoint relevant safety personnel to assist him in the implementation of the safety management system.

Safety Management System

The safety management system would normally cover the following elements:

- ### Safety Policy and Organisation

  An integral aspect of a safety management system is the top management's commitment and its overall safety philosophy.

  The successful implementation of a safety management system is facilitated if everyone understands his or her organisational role. The management should therefore issue a written safety policy comprising:

  - ❖ General statement pertaining to its overall safety philosophy for safety commitment; and
  - ❖ A description of a logical delegation of responsibility for safety and health from the top management to the workers.

- ### In-house Safety Rules and Regulations

  Written safety rules and regulations that are relevant to the organisation, and in compliance with legal requirements. This involves inculcating in employees, their roles and responsibilities in safety whilst performing their work in the laboratory.

- ### Safety Inspection

  An effective programme to carry out periodic inspection to spot-check, and correct unsafe work practices and conditions.

- **Hazard Analysis**

  Systematic procedures for identification, evaluation and control of hazards in the laboratory.

- **Safe Work Practices**

  Set of procedures to ensure that all work is carried out safely and the risks of injury to employees and property/equipment damage are eliminated or minimized.

- **Control and Use of Hazardous Substances**

  System for the identification and management of all hazardous agents and substances through the establishment of well-defined procedures for their receipt, issuance, storage, handling, use and disposal.

- **Safety Training**

  Provision of employee training relating to the operations, processes and work as well as maintenance of facilities and equipment to enable them to carry out their jobs safely and efficiently.

- **Safety Meetings**

  Adequate facilities and effective means for communicating the safety and health message, information and knowledge to all employees, including contractors. Employees at all levels should be encouraged to participate in regular discussion on safety and health issues arising from the workplace.

- **Testing and Maintenance Programme**

  Effective and practical maintenance regime for equipment and facilities to prevent occurrence of accidents.

- **Evaluation, Selection and Control of Contractors**

  System or procedures to evaluate, select and control contractors before any work is being awarded so as to ensure that they are aware of and meet their safety obligations.

- **Accident and Incident Investigation and Analysis**

  Procedures for ensuring that all incidents (accidents and near misses) are investigated promptly and effective and practical remedial measures are taken to prevent recurrence.

- **Safety Promotion**

Programmes and activities to create awareness of safety and health among all personnel, instill a positive attitude and behaviour, and help create a caring safety culture.

- **Emergency Preparedness and Plans**

Written response plan to mitigate consequences arising from potential emergency situations and to familiarize employees with the response procedures in the event of an emergency.

- **Document Control and Review**

Effective system to document and record the establishment and maintenance of all the elements in the safety management system. This is to facilitate easy and effective retrieval of relevant documents and also enhance the effectiveness of the system reviewing process

Safety Personnel

Safety personnel should be appointed to advise management on all occupational health and safety matters including biosafety issues.

- **Safety Coordinator (Biosafety)**

Production facilities and laboratories operating at BSL-2 and above should have at least a Safety Coordinator (Biosafety). The safety coordinator should have microbiology / biotechnology or equivalent biomedical education background with relevant working knowledge. He / she should have attended a recognised course in biosafety. The safety co-ordinator may be a senior staff in the laboratory who performs these duties on a defined part-time basis.

The safety coordinator can serve as technical advisor and liaison officer for existent site safety committee. He/she should help implement the relevant elements of the safety management system.

Safety Officer

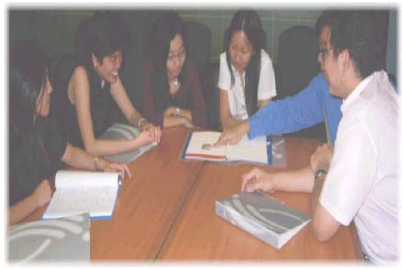
Production facilities are required to appoint a registered safety officer in accordance with criteria relating to number of employed persons, as specified in the Factories (Safety Officers) Order. The safety officer shall with assistance from the Safety Coordinator (Biosafety) or members of the safety committee:

- ❖ Implement safety training programs such as staff orientation, general safety and biosafety, usage of biological safety cabinet (BSC), animal biosafety, and containment suite training.

- ❖ Review safety aspects of all plans, protocols and operative procedures for work involving biological agents.
- ❖ Perform risk assessments and develop recommendations for biosafety improvements.
- ❖ Discuss infringements of safety code with appropriate persons and investigate accident and take preventive measures.
- ❖ Supervise the decontamination, disinfection, and disposal procedures for infectious waste in the facility or laboratory.
- ❖ Keep records of safe storage system for all infectious material entering the facility.
- ❖ Coordinate emergency response activities.
- ❖ Audit the effectiveness of the safety program at suitable regular intervals.

Safety Committee

Facilities handling biological agents employing 50 or more employees should form a safety committee. The committee should consist of the safety officer or coordinator (who will function as the committee secretary), members of the scientific and technical staff and representatives of the senior management. It may also include in its membership other departmental safety personnel or specialist and may at times require advice from independent experts in various associated fields, the local authorities and national regulatory agencies.



Smaller institutions or laboratories may group together to form the safety committee.

The functions of the committee include promotion of occupational safety and health, regular inspection of the workplace and investigation of incidents. The Committee should also oversee the overall facility's biological safety program by developing specific biosafety policies and programs to be used in all the laboratories in the facility.

Engineering and Other Supporting Services

Engineering, maintenance and cleaning personnel entering work area that handle biological agents should adopt the personal protection procedures in accordance with the biosafety level requirement. Preferably, these personnel should be staff of the laboratory who are familiar with the work operations and the safety requirements. However, when external personnel (e.g. contract cleaners, supplier service engineers) are engaged for the work, they should be made aware of the hazards and trained in the safe work procedures. External personnel entering and working in BSL 3 and 4 laboratories should work under the supervision of the safety coordinator or other competent laboratory personnel.

Safety Training

A continuous on-the-job safety training programme is essential among the laboratory and support staff. All employees should be equipped with the required skills, knowledge and safety information related to the operations, work processes and maintenance of facilities and equipment to enable them to carry out their jobs safely and efficiently.

The management with the assistance of the safety coordinator should analyse the occupational safety and health training needs for all employees.

A comprehensive safety-training programme should be established in the organization. This programme should include:

- New employee orientation
- Refresher training
- Safety awareness training
- Contractor briefing and training

Training Requirements

- **Safety Coordinator (Biosafety)**

Having attended and passed a recognised short course in biosafety. For safety coordinators operating at BSL-3, additional approved training is required.

- **Safety Officer**

Having attended and passed Safety Officer Training Certificate course

- **Laboratory Employees**

Having attended a minimum of 8 hours of training annually. Additional approved training is required for personnel responsible for managing operations in BSL-3 facilities.

- **Engineering and Other Supporting Personnel**

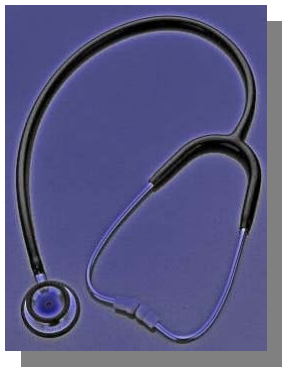
Having attended and passed a recognised short course in biosafety. For personnel responsible for supervising equipment and facility maintenance for BSL-3 facilities, additional approved training is required.

Health Surveillance and Immunoprophylaxis

Medical Monitoring

The objectives of the health and medical surveillance are to provide:

- a means of preventing occupationally acquired disease in healthy people by the exclusion of highly susceptible individuals as well as by regular review of those accepted for employment;
- active or passive immunisation where indicated;
- a means for the early detection of occupational disease including laboratory-acquired infections and
- to assess the efficacy of protective equipment and procedures.



To achieve the above objectives, a medical surveillance program should be established. The programme should include :

- identification of exposed workers
- arrangement for medical examinations in accordance with the kind of hazards they are exposed to.
- Evaluation of the results of medical examinations
- Maintenance of medical records.

All employees who are exposed to biological hazards should undergo appropriate pre-employment/pre-placement interview and immune status check for previous infection. Baseline serum sample may be obtained for employees exposed to microorganisms in Risk Group 2 and above with their consent. Employees who are immunocompromised should not be employed in a Biosafety Level 3 containment laboratory.

Women of childbearing age should be made aware of the risk to the unborn child of occupational exposure to certain microorganisms eg rubella virus. The measures taken to protect the foetus will vary depending on the microorganisms to which the women may be exposed.

Health surveillance medical record should be kept for at least 10 years following the end of exposure for employees handling microorganisms in Risk Group 3 and above.

Under the Factories (Medical Examinations) Regulations employees who are involved in activities where they are exposed to certain hazards listed in First Schedule would require to undergo compulsory medical examination. For those exposed to radiation medical examinations should be carried out in accordance with that which is stipulated in the Radiation Protection Act.

Immunoprophylaxis

When indicated, effective vaccines should be made available for those employees who are not already immune to the biological agent to which they are exposed or are likely to be exposed. Vaccination should be given prior to exposure and at specified intervals.

Recommendations for giving less efficacious vaccines and those associated with high rates of local or systemic complications should be carefully considered and not be required for employment.

A written organizational policy is essential. This should define at-risk personnel, specify risks as well as benefits of specific vaccines, and distinguish between required and recommended vaccines. Guidelines given in Ministry of Health's National Immunisation Programme and WHO may be adopted.

A complete record of vaccines received on the basis of occupational requirements or recommendations should be maintained in each employee's permanent medical file.

Disease Notification

Any worker suspected of suffering from any of the 31 notifiable diseases listed in the Sixth Schedule of the Factories Act should be notified to the Chief Inspector of Factories, Ministry of Manpower.

An employee who is found to be suffering from an infectious disease or is a carrier of the infectious disease should be notified to the relevant authority in accordance with the Infectious Disease Act.

Employee's Responsibilities

Safety and health is also the responsibility of all laboratory and facility employees (including support staff). Employees should not willfully interfere with or misuse any instruments or equipment, which are provided for the health and safety of those in the workplace. Safety devices and personal protective equipment should be used when they are provided. Safe work practices should be adopted so as not to endanger oneself and others. Unsafe acts or conditions should be reported to their superiors or safety personnel.

CONTROL OF BIOHAZARDS

- Classification of Biological Agents
- Risk Assessment
- Biosafety Levels
  - Biosafety Level 1
  - Biosafety Level 2
  - Biosafety Level 3
  - Biosafety Level 4
- Large Scale Production of Microorganisms
  - Biosafety Level (Large Scale) 1
  - Biosafety Level (Large Scale) 2
  - Biosafety Level (Large Scale) 3
  - Biosafety Level (Large Scale) 4
- Laboratory Animals
  - Animal Biosafety Level 1
  - Animal Biosafety Level 2
  - Animal Biosafety Level 3
  - Animal Biosafety Level 4
- Genetically Modified Organisms
- Certification of Facilities & Equipment
- Biohazard Signs & Labelling
- Biological Safety Cabinets

CONTROL OF BIOHAZARDS

Classification of Biological Agents

Biological agents are classified into four risk groups that are dependent upon a number of factors. Some of the most important ones are:

- the virulence, pathogenicity, biological stability, mode of transmission, and communicability of the agent;
- the endemicity of the agent;
- the availability of effective vaccines or therapeutic measures.
- the nature or function of the laboratory, the procedures and manipulations involving the agent;

A detailed description of the four risk groups are tabulated in Appendix 2.

Risk Group 1
(low individual and community risk)

A biological agent that is not known to consistently cause disease in healthy persons or animals.

Risk Group 2
(moderate individual risk, limited community risk)

A pathogen that can cause human or animal disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 3
(high individual risk, low community risk)

A pathogen that usually causes serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another. The disease can be treated by antimicrobial and anti-parasitic agents.

Risk Group 4
(high individual risk, high community risk)

A pathogen that usually produces very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission.

Risk Assessment

Detailed risk assessments shall be carried out for work involving biological agents classified under Risk Group 2 or higher, so as to determine the appropriate biosafety levels required. The risk assessment should take into account the inherent risk factor of the organism and the laboratory operations, which include the following:

- pathogenicity of the agent and infectious dose
- outcome of exposure
- route of infection
- stability of the agent in the environment
- concentration of the agent and volume of concentrated material to be manipulated
- information available from animal studies and reports of laboratory-acquired infections or clinical reports
- laboratory activity planned (concentration, sonication, aerosolization, centrifugation, etc.)
- any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens

Risk assessment should be conducted for all new biological agents to be used in the laboratory and should be reviewed periodically or whenever there is a change in the procedure or protocol that would result in significant deviation from the identified risk and the containment level assigned.

There are various methods of conducting risk assessment in workplaces. A useful reference is the risk assessment guidelines published by Centers for Diseases Control and Prevention (CDC), United States of America as given in http://www.cdc.gov/phppo/dls/pdf/irawwh.pdf

Specimens for which there is limited information

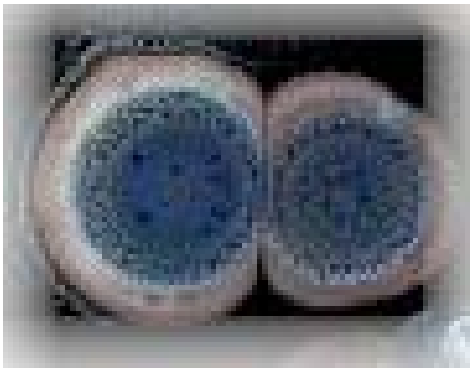
In situations when the information is insufficient to perform an appropriate risk assessment, a conservative approach to specimen manipulation should be taken. Universal precautions should always be followed, and barrier protection applied (gloves, gowns, eye protection), regardless of the origin of the samples.

Biosafety Level 2 should be the minimum requirement for the handling of such specimens.

The biosafety levels assigned are based on the assumption of typical activities handled by immunocompetent persons. Additional personnel precautions and increased levels of physical containment may be indicated where increased concentrations of biological agents are used or when they are handled by immuno-compromised persons. Special considerations should also be taken where experimental animals are used.

Biosafety Levels

Persons handling infectious agents can be exposed to these agents via numerous ways, such as ingestion, inhalation, contact with non-intact skin or transfer of microorganism to the eyes by contaminated hands. Thus, it is of high priority that these infectious agents must be effectively contained to prevent exposure during handling and transfer.



An important element in the containment of infectious agents or potentially infected materials is strict adherence to safe work practices and techniques. Persons working with these agents must be aware of the potential hazards and is trained and proficient in these practices and techniques required for safe handling. Each laboratory should develop or adopt a relevant biosafety manual that identifies the hazards that employees are exposed to or likely to be exposed to, and specifies practices and procedures to minimise or eliminate the exposure.

All work involving biological agents is classified into four biosafety levels. These biosafety levels describe the general work practices, safety equipment and the facility design required for the safe handling of biological agents.

Laboratories handling biological agents in volume less than 10 litres, should apply the appropriate work practices and requirements as given in this section (BSL). Production facilities and laboratories handling biological agents greater than 10 litres should also apply the requirements given under the Biosafety Level (Large Scale) (BSL).

However, the volume of 10 litres is used only as a general guide to differentiate between laboratory-scale and large-scale production. Where these work practices and requirements are not sufficient to control the hazards associated with any particular biological agent or procedures, additional measures should be adopted as necessary.

The following table is a summary of the requirements required for the different biosafety levels:

- **Biosafety Level 1**

The following procedures and requirements are for the manipulation of biological agents which are not known to result in or consistently cause disease in healthy persons or animals.

Safe Work Practices

- The laboratory should be kept neat, orderly and clean, and storage of materials not pertinent to the work should be minimised.
- Eating, drinking, handling of contact lenses, applying cosmetics, and storing of food for human consumption are not permitted in the work areas.
- Hands should be washed after handling of viable materials, removal of gloves and before leaving the laboratory.
- Mouth pipetting of any substance is prohibited.
- All procedures should be performed in a manner that minimises the creation of aerosols.
- Disinfectants effective against the agents in use must be available at all times within the laboratory area where biohazardous material is handled.
- Work surfaces must be cleaned and decontaminated with suitable disinfectant when work is completed, at end of the day and after any spill of viable material
- All cultures, stocks, and other regulated wastes must be decontaminated (e.g. by autoclaving) before disposal. Materials to be decontaminated at site away from laboratory should be placed in a durable, leak-proof secondary container or be double bagged
- Used gloves should be removed aseptically and autoclaved with other laboratory wastes before disposal
- An effective insect and rodent control programme must be implemented.
- Animals not involved in the work of the laboratory should not be permitted in or near the laboratory

Safety Equipment

- Protective laboratory clothing must be properly worn by all personnel entering or working in the laboratory and should not be worn in non-laboratory areas. Closed footwear should be worn.
- Eye and face protection devices must be worn when there is a risk of splashing hazardous materials, flying particles and harmful UV light or other rays.
- Gloves must be worn for all procedures that may involve direct skin contact with toxins, blood or infectious materials. Reusable gloves may be used only when necessary and must be appropriately decontaminated after each use.
- Special containment devices or equipment are generally not required for work with agents assigned to Biosafety Level 1.

Laboratory Facilities

- Laboratory should have impervious open bench top with sink.
- Hand washing facilities should be provided, with at least one preferably located near the exit door.

- **Biosafety Level 2**

Biosafety Level 2 requirements are for the manipulation of biological agents, which may result in human or animal disease, but under normal circumstances, is unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment. Furthermore, laboratory exposure rarely cause infection leading to serious disease. Effective treatment and preventive measures are available and the risk of spread is limited.

The procedures and requirements of Biosafety Level 1 shall apply to Biosafety Level 2. In addition, the following requirements should be included:

Safe Work Practices

- ❖ Access to the laboratory is limited to laboratory personnel and authorised persons only. Laboratory doors shall normally be closed when work is in progress.
- ❖ Biohazard signs should be posted on or near to the access door to the work area. Appropriate information supplementary to the warning sign should include the biosafety level required, the contact information supervisor or responsible person, the personal protective equipment and other essential information.

- ❖ Needles, syringes and other sharp instruments should be restricted for use only when there is no other alternative. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- ❖ Used disposable needles must be carefully placed in conveniently located puncture resistant containers used for sharps disposal. Non disposable sharps must be placed in a hard walled container for storage and transportation.
- ❖ Plasticware should be substituted for glassware whenever possible. Broken glassware should only be handled by mechanical means such as brush and dustpan, tongs or forceps and not directly by hand
- ❖ Culture shall be clearly labelled and dated and appropriately stored. They should not be stored for long periods on the bench and should be transferred to a dedicated storage area.

Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	• Safe Work Practices	• PPEs: laboratory coats; gloves; face protection as needed	• Impervious open bench top with sink • Handwashing facilities
2	Unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment They have potential for bloodborne transmission.	BSL-1 practice plus. • Limited access • Biohazard warning signs • "Sharps" precautions • proper storage of cultures	• Class I or II BSCs or other physical containment • devices used for all manipulations of agents that cause splashes or • aerosols of infectious materials; • Autoclave available	BSL-1 plus: • Laboratory design for easy cleaning • Bench top resistance to disinfecting chemicals • Eyewash available and in good condition
3	May result in serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another	BSL-2 practice plus: • Controlled access. • Entry and Exit protocol • Decontamination of all waste • Infectious agents to be securely sorted inside laboratory	• Class II or III BCSs or other physical containment • devices used for • manipulations of agents; • PPEs: Respiratory protection to be worn when aerosol cannot be safely contain within BSC • Decontamination of lab clothing before laundering	BSL-2 plus: • Physical separation from access • corridors • Self-closing, double-door access • Exhausted air not recirculated to other parts of the building • Directional airflow into laboratory. Supply and exhaust system designed to interlock • Drain traps filled with disinfectants • Structural designed and built to withstand pressure load
4	May result in very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • Only materials required are permitted • All material decontaminated on entry and exit from facility • Viable agents to be stored and transport on non breakable containers	All procedures conducted in Class III BSCs or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Access doors self locking and lockable • Hand washing sink and eyewash should be automatically operated • Liquid effluents to be decontaminated before discharge • Dedicated non recirculated ventilation system • Exhaust from general room facility to be treated before discharge

Safety Equipment

- Biological Safety Cabinets Class I or II (BSC) should be used for procedures with a potential for creating significant quantity of aerosols or splashes, high concentration or large volume of infectious agents
- Autoclave should be located within or near to the laboratory to provide convenient access and minimise the need for the transportation of materials

Laboratory Facilities

- Laboratory should be designed to facilitate easy cleaning. Furniture used in the laboratory should be made of material that can be easily decontaminated
- Bench tops should be impervious to water, resistant to acids, alkalis, organic solvents, moderate heat and the chemicals used for decontaminating their surfaces
- Eyewash should be readily available and in good operating condition.

Biosafety Level 3

Biosafety Level 3 requirements are for the manipulation of biological agents, which may result in serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another. The disease can be treated by antimicrobial or antiparasitic agents.

There should be a specific biosafety manual that outlines specific operative procedures. Laboratory personnel should be specifically trained in handling the agents and are supervised by competent persons who are experienced in working with these agents. The procedures and requirements of Biosafety Level 2 shall apply to Biosafety Level 3. In addition, the following requirements apply:

Safe Work Practices

- Access to the laboratory should be controlled and restricted to authorised personnel only. Laboratory doors should be kept closed when work is in progress and locked when the room is unoccupied.
- Entry and exit protocol for persons, animals, equipment, samples, wastes, etc. must be established and followed.
- Personal clothing and items should not be taken into the laboratory.
- Contaminated equipment, wastes, containers and other items should be decontaminated before removal from the laboratory
- All infectious agents should be stored inside the laboratory, unless the same level of biosecurity and biosafety is manintained at the alternative storage location.

Safety Equipment

- Biological Safety Cabinets Class II or III must be used for all manipulation of infectious materials whenever possible
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- For work performed outside Biological Safety Cabinet, appropriate personal protective equipment should be used in combination with other physical containment devices (e.g. centrifuge safety cup). Efficient respiratory protection e.g. cartridge respirator with High Efficiency Particulate Air (HEPA) filters, Self Contained Breathing Apparatus, powered air-purifying respirators should be worn when aerosols cannot be safely contained within the Biological Safety Cabinet.
- Equipment specified for Biosafety Level 3 requirements should be used for the process it is meant for in designated areas.
- Laboratory protective clothing must be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes. Front-buttoned standard laboratory coats are unsuitable.
- Laboratory protective clothing must not be worn outside the laboratory, and it must be decontaminated before it is laundered.

Facilities Requirements

- The laboratory should be separated from areas that are accessed by the general public. Access to the laboratory should be through a series of double self-closing doors.
- The interior surfaces of walls, floors and ceilings should be constructed to facilitate easy cleaning and decontamination. Walls, ceiling and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants used. Any penetrations and openings should be sealed or sealable to facilitate decontamination.
- Drain traps should be filled with approved disinfectant
- A ventilation system that establishes a negative pressure in the laboratory should be provided so that there is a directional airflow into the laboratory working area. The exhaust air should not be re-circulated to any other area of the building, and is discharged to the outside with proper filtration (HEPA)
- For laboratories having supply air systems, it should be designed such that the supply air and exhaust systems are interlocked to maintain inward airflow at all times. The proper directional air flow into the laboratory should be verified by regular airflow tests

- The exhaust air from Biological Safety Cabinets (BSC) should be discharged directly to the outside with proper filtration (HEPA). When the exhaust air is to be discharged through the building exhaust system, the air should be properly filtered and connected in such manner that avoid any interference with the air balance of the cabinets or building exhaust system (e.g. thimble unit connection).
- The exhaust air from biological safety cabinets may be re-circulated within the laboratory only if the work procedures do not include the usage of volatile or toxic chemicals and radionuclides. The discharged air must be adequately filtered. The cabinet should be operational and properly maintained.
- The structural design of all surfaces of the laboratory including windows should allow for all air pressure loads imposed by the ventilation fans during normal and restricted inlet operation
- The construction and finish of all of the room surfaces should be selected to ensure substantially airtight construction. Benches, cupboards and engineering services should be either sealed to the room surfaces or mounted on stand-off, thus permitting wipe down access for decontamination. Windows in the laboratory should be closed and sealed

- **Biosafety Level 4**

Biosafety Level 4 requirements are for the manipulation of biological agents, which may result in very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission. For such facilities, there should be a site-specific biosafety manual that outlines specific operative procedures. The procedures and requirements of Biosafety Level 3 shall apply to Biosafety Level 4. In addition, the following requirements apply:

Safe Work Practices

- Laboratory must adopt security practices to prevent unauthorised entry into work and storage areas, and the unauthorised removal of materials. Authorised persons must comply with all instructions and procedures for entry and exit
- Persons entering into containment laboratory must remove street clothing and change into dedicated laboratory clothing (including undergarments) and shoes. A decontamination shower is required on exit from the containment laboratory
- Materials not required for the experiment are not permitted in the laboratory
- Supplies and materials should be brought into and out of the laboratory via a pass containment barrier containing suitable decontamination facilities (e.g. double door autoclave, fumigation chamber, air lock or dunk tank)

- Materials that cannot be autoclaved (e.g. heat sensitive equipment) must be sterilised by other proven technologies for sterilization (e.g. chemical or gas sterilization)
- Biological materials in a viable or intact state are to be transferred to a non- breakable sealed primary container enclosed in a non-breakable sealed secondary container for storage and transportation

Safety Equipment

- Biological Safety Cabinet Class III should be used for all manipulation of infectious materials; or if Biological Safety Cabinet Class II is used, it should be used in conjunction with one-piece positive pressure suits

Facilities Requirements

- The laboratory shall either be a separate building or a clearly demarcated and isolated zone within a building. Entry into the laboratory should be via a minimum of double doors incorporating outer and inner change rooms, which should be separated by shower for personnel entering and leaving the laboratory.
- Double door autoclave should be located and sealed on to the outer wall of the containment facility. The autoclave is equipped with interlocking doors to prevent both doors opening at the same time.
- Access doors to the laboratory should be self closing and lockable.
- Windows should be break resistant.
- Hand washing sink and eyewash should be hands-free or automatically operated
- Internal facility such as light fixtures, air ducts, utility pipes, are to be arranged in such a way that they will minimise dust settling on their surfaces.
- Liquid effluents from laboratory sinks, Biological Safety Cabinets, floor drains and autoclave chambers are to be decontaminated by effective sterilization system (e.g. heat treatment) prior to discharge into the sanitary sewer.
- There should be a dedicated non-recirculated ventilation system. The system is balanced such that the directional airflow is from one with least potential hazard to one with greatest potential hazard. The differential pressure and directional airflow is continuously monitored with alarm to indicate malfunction of the system.
- The exhaust from the general room facility is to be treated by passing it through a HEPA filter prior to discharge to the environment. The discharge direction should be away from occupied spaces and air intakes. The HEPA filters should be located as near as practicable to the source so as to minimise the length of potential contamination to ductwork. The HEPA filter housing shall be designed such that the filters can be decontaminated prior to removal or removable in a sealed gas-tight container for subsequent decontamination or destruction by incineration. The design of the filter housing should facilitate validation of the filter installation

Large-scale Production of Microorganisms

Although large-scale production of microorganisms is not necessarily more hazardous than laboratory scale work, it usually poses a higher risk due to the large volumes of biological agents involved. Thus it is essential for large scale production facilities to ensure that proper containment and work procedures are established and implemented to minimise the potential risk of release and employees exposure.

The containment requirements for processes involving large-scale production of microorganisms are classified into four levels – Biosafety Level (Large-scale) 1 to 4. **These requirements are to be used in addition to the applicable requirements listed for the corresponding biosafety levels given.**

- **Biosafety Level (Large-Scale) 1**

  Safe Work Practices and Facilities Requirements

  - ❖ Culture of viable organisms is to be contained within a closed system or other form of containment equipment (e.g. biological safety cabinet) so as to reduce the release of aerosols.
  - ❖ Culture fluids that are required to be removed from a closed system shall be inactivated by a validated procedure.
  - ❖ Closed system or any containment equipment to be opened for maintenance or any other purposes should first be inactivated by a suitable procedure.
  - ❖ All exhaust from process equipment, closed systems and containment equipment shall be provided with suitable treatment (e.g. HEPA filter) to prevent the release of organisms.
  - ❖ Floors shall be designed to prevent the release of viable organisms into the sewer.

- **Biosafety Level (Large-Scale) 2**

  The procedures and requirements for Biosafety Level (Large Scale) 1 shall apply to Biosafety Level (Large Scale) 2. In addition, the following requirements apply:

  Safe Work Practices and Facilities Requirements

  - ❖ Entry to production area is to be limited to authorised personnel only.
  - ❖ Biohazard signs shall be posted on or near to the access door to the production area. The warning sign shall identify the agent, the biosafety level required and contact information of supervisor or responsible person
  - ❖ Personal protective equipment requirements is to be posted on or near to the access door to the production area.
  - ❖ Critical process equipment, closed systems and containment equipment should be equipped with devices to monitor the integrity and

set off alarm if any failure arises. Seals, pipework and valves should be designed to prevent leakage or be fully enclosed in ventilated housings.

- **Biosafety Level (Large-Scale) 3**

The procedures and requirements for Biosafety Level (Large Scale) 2 shall apply to BSL (Large Scale) 3. In addition, the following requirements apply:

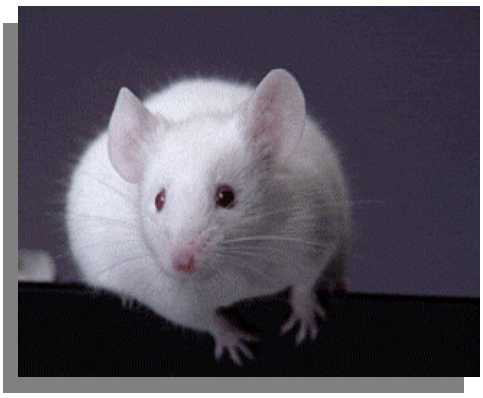
Safe Work Practices and Facilities Requirements

- ❖ Protective laboratory clothing and personal protective equipment must be available and properly worn by all personnel entering or working in the production area.
- ❖ Reusable protective clothing is to be decontaminated before leaving the BSL (large Scale) 3 facilities for laundry.
- ❖ Provision is to be made in the production area to contain the full volume of a release of process fluids.

- **Biosafety Level (Large-Scale) 4**

Laboratories intending to work with large-scale production of biological agents assigned to BSL 4 shall establish the employee safety requirements on a case-by-case basis through consultation with the Occupation Health Department, Ministry of Manpower

Laboratory Animals



Working with animals in laboratories poses a variety of hazards such as exposure to infectious biological agents, allergies, bites, scratches and even crushing risk by large animals. These laboratories shall provide the appropriate animal containment facilities and adopt safe work practices to minimise the risk to the laboratory personnel.

In general, facilities for laboratory animals shall as far as practical, be physically separated from other activities so as to allow for isolation and decontamination as required. The design should facilitate the ease of cleaning and housekeeping and should be located to minimise traffic flow so as to reduce the risk of cross contamination. An inventory of animals with details on animal movement in and out of the facility should be kept.

As with the classification of the biosafety levels for the manipulation of biological agents, handling of animals for laboratory experiment are classified into four levels – Animal Biosafety Level 1 to 4. These levels describe the animal facilities requirements and the safe work practices for working with animals infected with biological agents. **These requirements are to be used in addition to the applicable requirements listed for the corresponding biosafety levels given.**

- **Animal Biosafety Level 1**

  The following procedures and requirements are for the handling of animals infected with biological agents which are not known to result in or consistently cause disease in healthy persons or animals.

  Safe Work Practices and Animal Facilities Requirements

  - ❖ Animal cages are removed in such a manner as to minimise the creation of aerosols and dust
  - ❖ Cages washed in mechanical cage washer shall have final rinse at suitable temperature. (> 82 ^{o}C)
  - ❖ A hand washing sink should be made available in the animal facility
  - ❖ Animal carcasses and tissues must be incinerated or processed through proven technology (e.g. tissue autoclave). Carcasses must be transported in leak-proof containers that are properly labelled

- **Animal Biosafety Level 2**

  Animal Biosafety Level 2 requirements are for handling of animals infected with biological agents, which may result in human or animal disease, but under normal circumstances, is unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment. Furthermore, laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

  The procedures and requirements of Animal Biosafety level 1 shall apply to Animal Biosafety Level 2. In addition, the following requirements apply:

  Safe Work Practices and Animal Facilities Requirements

  - ❖ Animals not involved in the work process shall not be brought into the work area
  - ❖ Appropriate methods of restraint must be used to minimise risk of injuries and infection through scratches, bites and accidental self-inoculations.
  - ❖ Procedures to prevent animal escape must be established and implemented

- ❖ Doors to animal facility should be inward opening and self-closing and are closed when work is in progress. Access to the facility should be limited to laboratory personnel and authorised persons only
- ❖ Each animal room must be labelled with the unique hazards and entry requirements (e.g. respiratory protection requirement)
- ❖ Cages housing infected animals must be appropriately labelled
- ❖ Cages are to be decontaminated by suitable method (e.g. autoclaving) prior to cleaning and washing. Suitable temperature (> 82 ^{o}C) shall be used when washing cages in mechanical cage washer.
- ❖ Exhaust air should be discharged into the outside environment without being re-circulated to other rooms
- ❖ Drain traps must be filled with approved disinfectant

- **Animal Biosafety Level 3**

Animal Biosafety level 3 requirements are for the handling of animals infected with biological agents, which may result in serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another. The disease can be treated by antimicrobial or antiparasitic agents.

Laboratory personnel must be trained in handling the animals and are supervised by competent persons who are experienced in working with these animals.

The procedures and requirements of Animal Biosafety level 2 shall apply to animal biosafety level 3. In addition, the following requirements apply:

Safe Work Practices and Animal Facilities Requirements

- ❖ The animal facility doors shall be kept closed when work is in progress. Access to the laboratory is controlled and restricted to authorised personnel only. The laboratory doors shall be locked when the room is unoccupied
- ❖ The animal facility is to be separated from areas which are open to unrestricted human traffic within the building. The access to the facility should be via an airlock through two sets of doors
- ❖ The interior surfaces of walls, floors and ceilings should be water-resistant so that they can be easily cleaned
- ❖ Infected animals may be housed in containment systems (e.g. biological safety cabinets) to reduce the risk of spreading infectious aerosol
- ❖ When appropriate, respiratory equipment must be worn in rooms containing infected animals.

- **Animal Biosafety Level 4**

Animal Biosafety level 4 requirements are for the handling of animals infected with biological agents, which may result in very serious human or

animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission.

The procedures and requirements of Animal Biosafety level 3 shall apply for animal biosafety level 4. In addition, the following requirements apply:

Safe Work Practices and Animal Facilities Requirements

- The animal facility is located in a separate building or in a clearly demarcated and isolated zone within a building with strict access control. External animal facility doors should be self-closing and self-locking
- Personnel should enter and leave the facilities via changing room and shower room. Personnel should shower each time upon leaving the facility. Soiled clothing should be autoclaved before laundering or disposal
- Supplies and materials should be brought into the laboratory via a pass containment barrier containing suitable decontamination facilities (e.g. double door autoclave, fumigation chamber, air lock or dunk tank)
- All materials should be decontaminated by autoclaving prior to leaving the facility. Provision of equivalent decontamination method such as pass through dunk tank or fumigation chamber should be provided for materials that cannot be autoclaved
- Animals infected with biological agents assigned to BSL 4 should be housed in a class III BSC or equivalent containment systems.

Genetically Modified Organisms

Genetic modification of organism involves the alteration of the genetic composition of a living organism by techniques such as DNA technology. During such processes, strict care must be taken to ensure not only the safety and health of the persons working with the organisms, but also the release into the environment.

In general risk assessment of genetically modified organisms is based on the same principles as described for other biological agents. The containment level required for the genetically modified organism may be:

- equivalent to the risk group classification of the unmodified agent or
- raised or lowered as a result of consideration of the effects of the genetic manipulation

The Genetic Modification Advisory Committee (GMAC) recommends that, regardless of the size of the workforce, a biosafety officer and an Institutional Biosafety Committee (IBC) be appointed for laboratories or facilities working with genetically modified organisms (GMO).

For details on guidance regarding safe working with genetically modified organisms, please refer to guidelines published by the Genetic Modification Advisory Committee (GMAC).

Certification of Facilities and Equipment

The construction of the containment facilities and the performance of equipment should be verified with certification to ensure that they meet the requirements for the various classifications of laboratory. Certification should be carried out after the completion of construction or installation, and subsequently at regular intervals. A competent person with the relevant knowledge and experience should be appointed to conduct the certification process. A record of the certification and testing results must be kept and maintained. A list of facilities and equipment* that should be included in the certification is given below.

- Room Integrity
- Air Handling systems
- Interlocking systems
- Security System
- Biological Safety Cabinet
- HEPA Filter and Housing
- Eye Wash and Shower
- Other Critical Containment Components

* *the list is not exhaustive and should be reviewed according to individual laboratory set-up*
For detailed guidance, reference can be made to the Canadian Biosafety Guidelines.

Biohazard Signs and Labelling

For laboratory with BSL 2 and above, biohazard sign (See Fig 1) should be posted on or near to the access door to the work area. The warning sign shall identify the agent, the biosafety level required, contact information of supervisor or responsible person, personal protective equipment and other essential information

Fig.1 Biohazard Sign

All containers used to store or transport biological agents must be properly labelled to identify the biological agent, the risk group and the precautionary measures required for handling. Biological waste containers shall be affixed with warning labels to distinguish from other waste containers.

Biological Safety Cabinets

Biological Safety Cabinets (BSC) are designed to provide personnel, environmental and in some instances, product protection. When used in conjunction with safe work practices, they offer effective primary containment for work with infectious microorganisms. There are three classes of BSC designed to meet varying needs of research and clinical laboratories –

Biological Safety Cabinets Class I, II and III (See Appendix 3). The design, construction and testing of the biological safety cabinets should comply with any of the following standards or equivalent:

- **United States of America**
  - ❖ NSF/ANSI 49 – 2002 NSF International Standard / American National Standard for Biosafety Cabinetry - Class II (Laminar Flow) Biohazard Cabinetry
- **Australia**
  - ❖ AS 2252.1:1994 Biological safety cabinets (class I) for personnel protection and environmental protection
  - ❖ AS 2252.2:1994 Laminar flow biological safety cabinets (class II) for personnel, environment and product protection
  - ❖ AS 2647 Biological safety cabinets – installation and use, 1994
- **United Kingdom / European Committee**
  - ❖ BS EN 12469:2000 Biotechnology – Performance criteria for microbiological safety cabinets

The provision of Biological Safety Cabinets should be accompanied with instructions on good working techniques in the BSCs to provide effective containment of hazardous substances. In addition, considerations should be given to locate the BSC away from doorways, common passageways, direct overhead air diffusers or the likes of it so as to prevent significant distortion in the cabinet airflow.

Good techniques of working in BSCs are largely dependent on the procedures being carried out. However, some general principles for proper usage of BSCs are given below:

- BSC should be turned on for at least 15 minutes before the start of any procedure
- Operators should ensure that any arms movement in and out of the BSC should be done slowly and should be positioned such that it is perpendicular to the front opening. Furthermore, unnecessary movements across the front opening of the BSC should be minimised so as to prevent disruption to the air flowing into the BSC.
- Only materials and items required for the operation should be placed within the BSC. Aerosol generating equipment should be positioned towards the rear of the cabinet while bulky items such as biohazard bags should be placed to one side of the interior of the cabinet.
- When UV lights are being used in a BSC, they must be cleaned and checked frequently to ensure its proper functioning. UV lights must be turned off while the room is occupied to protect eyes and skin from inadvertent exposure.

- During operation, the sash height of the BSC should be positioned according to manufacturer's design criteria
- All required materials should be placed in the BSC before the start of the procedure to minimise in and out motion of the hand and arm
- The back/side air grills should not be blocked or obstructed such that air flow is restricted
- After working with procedures that generate aerosols, suitable period of time should be allowed for aerosols to settle before opening the BSC
- All items within the BSC should be surface decontaminated and removed while the BSC should be decontaminated by wiping down with suitable disinfectant after each operation
- Sump of Class II cabinets should be cleaned with suitable disinfectant regularly or following a known spillage.
- BSC should remain in operation for at least 15 minutes before switching off.

CONTROL OF OTHER HAZARDS

- Chemical Hazards
  - Handling & Storage of Hazardous Chemicals
  - Transportation of Chemicals
- Mechanical and Electrical Hazards
- Radiation Hazards
- Waste Treatment and Disposal
- Emergency Response Plan
- Documentation and Record Keeping

CONTROL OF OTHER HAZARDS

Chemical Hazards

The laboratory contains a wide range of potentially hazardous chemicals, which may be reactive, toxic, flammable or carcinogenic. It is therefore important that personnel who work in the laboratory are aware of the hazards and adopt the safe practices to avoiding chemical exposure. Some general safe practices of working with hazardous chemicals are given below:

- **Handling and Storage of Hazardous Chemicals**

  - ❖ Wherever possible, less hazardous alternatives to chemicals should be used
  - ❖ Work area involving hazardous chemicals should be designated and labelled
  - ❖ Chemical fume hood should be used for procedures that may result in the release of airborne contaminants or involve volatile chemicals. The weighing of hazardous chemicals should also be carried out in a chemical fume hood
  - ❖ Suitable and appropriate personal protective equipment should be provided when there is a risk of exposure
  - ❖ Whenever possible, hazardous chemicals should be stored at or below eye level to avoid accidental dropping and spillage from height.
  - ❖ Chemicals should be kept in storage places where unauthorised personnel have no access.
  - ❖ Chemical stores should be examined regularly. Chemicals that show signs of deterioration or are redundant must be disposed of through proper procedures.
  - ❖ Chemicals should be stored by hazard classification (e.g., oxidiser, combustible, corrosive, unstable, water reactive, etc) rather than alphabetical order in cabinets or shelves. Incompatible classes must be physically separated from each other such as by different shelves or by providing secondary containment.
  - ❖ Chemical hazard classification can be determined by checking the label for hazard information or consulting the Material Safety Data Sheet. The table below shows the examples of incompatible hazard classes.
  - ❖ Only capped small working bottles of flammable chemicals should be stored in a place where there is no likelihood of ignition from a naked flame. They must never be left open.
  - ❖ Unstable chemicals (e.g. chlorates (V), peroxides) should be stored in a flammable-storage cabinet, away from heat and moisture, and

subjected to regular inspection. It is always advisable to keep only a minimum amount sufficient for current use

- ❖ All chemical containers should be properly labelled with the following information:

  - ➢ identity of the chemical which may be a trade name and/or generic chemical name
  - ➢ hazard warning in words or symbol which provide information regarding the health hazard, flammability, reactivity of the chemical and personal protective equipment required.

Examples of Incompatible Hazard Classes

(Chemicals in List A are incompatible with those in List B)

LIST A	LIST B
Alkali and alkaline earth Carbides Hydrides Metals Oxides Peroxides	**Water** **Acids** **Halogenated organic compounds** **Oxidizing agents ***
Azides, inorganic	**Acids, Heavy metals and their salts, Oxidizing agents ***
Cyanides, inorganic	**Acids, Strong bases**
Nitrates, inorganic	**Acids, Reducing agents***
Nitrites, inorganic	**Acids, Oxidising agents***
Organic compounds Organic acyl halides Organic anhydrides Organic halogen compounds Organic nitro compounds	**Oxidizing agents *** **Bases, Organic hydroxy and amino compounds** **Bases, Organic hydroxy and amino compounds** **Group IA and IIA metals, Aluminum** **Strong bases**
Oxidizing agents * Chlorates Chromates Chromium trioxide Dichromates Halogens Halogenating agents Hydrogen peroxide Nitric acid Nitrates Perchlorates Peroxides Permanganates Persulfates	**Reducing agents*** **Ammonia, anhydrous and aqueous** **Carbon** **Metals** **Metal hydrides** **Nitrites** **Organic compounds** **Phosphorus** **Silicon** **Sulfur**
Reducing agents*	**Oxidizing agents*, Arsenates, Arsenites, Phosphorus, Selenites, Selenates, Tellurium salts and oxides**
Sulfides, inorganic	**Acids**
*The examples of oxidizing and reducing agents are illustrative of common laboratory chemicals; they are not intended to be exhaustive. From Prudent Practices in the Laboratory: Handling and Disposal of Chemicals, Committee on Prudent Practices for Handling, Storage, and Disposal of Chemicals in Laboratories, et al., National Academy Press, Washington, D.C., 1995.	

- **Transportation of Chemicals**

  - ❖ When transporting chemicals, precautions should be taken to avoid dropping or spilling chemicals.
  - ❖ Glass containers should be delivered in specially designed bottle carriers or leak resistant, unbreakable secondary containers.
  - ❖ When transporting chemicals on a cart, the cart should be suitable for the load and have high edges to contain leaks
  - ❖ For more information on the management of chemical hazards, please refer to MOM Guidelines on Prevention and Control of Chemical Hazards.

Mechanical and Electrical Hazards

Mechanical and electrical hazards are also present in all laboratories. Many such hazards are related to the release of stored energy. This often result in injuries to the personnel and damage to the facilities and equipment. Personnel should be trained in the proper usage and handling of equipment and well-versed with operating requirements of the laboratory equipment. General handling procedures of some of the more commonly used equipment is given in the following appendices:

- Safe Usage of Laboratory Equipment (Appendix 4)
- Compressed Gasses (Appendix 5)

Radiation Hazards

Many radioactive substances are also used in laboratories in the biomedical sciences industry. The Centre for Radiation Protection (CRP) is the national regulatory authority for ensuring the safe use of radiation in Singapore. It enforces and promotes the radiation safety of workers, the public and the environment. Under the Radiation Protection Act every licensee shall provide:

- a safe working environment to his employees such that they are protected from unnecessary exposure to radiation;
- training and supervision for employees so that they can perform their work safely;
- all employees with prescribed radiation monitoring equipment including personal monitoring devices; and
- all employees with prescribed medical examinations.
- For more information please refer to Centre for Radiation Protection (CRP)

Waste Treatment and Disposal

All waste generated should be segregated into various categories such as biological waste, chemical waste, sharps and non hazardous waste for proper treatment and disposal. The containers should be appropriate for the types of waste to be disposed and properly labelled.

During the collection and treatment of hazardous waste, care must be taken to ensure that the persons handling the waste are not being exposed to

potential safety and health hazards. Suitable personal protective equipment should be provided and personnel should be trained and competent in handling this waste on site.

A suitable area should be identified for the temporary storage of hazardous waste. Temporary storage of chemical waste should take into account the properties of the chemicals such as flammability and incompatibility with other chemical waste. The plan of storage should be submitted to the Fire Safety and Shelter Department for approval. . Such plans shall be prepared and submitted by Qualified Persons (QPs) which are registered architects or professional engineers

Spill kits suitable for the waste handled should be available. Personnel handling the waste should be competent in using the kits. Provision for a waste storage security system should be considered especially for biological waste from BSL 3 and 4 laboratories.

Biological Waste

Biological waste should be decontaminated to render them non-infectious before disposing as normal waste. In general, decontamination can be achieved by disinfection or sterilization.

- **Disinfection**

  This is normally carried out by applying liquid chemicals, usually for solid surfaces and equipment. The effectiveness depends greatly on the disinfectant used and the biological organism involved. However, as many of these chemical disinfectants are hazardous, safety precautions and care must be taken in applying them.

- **Sterilization**

  There are many methods of sterilization – by heat, vapour, gas or radiation. Autoclaving using steam is most commonly used for decontamination of biohazardous waste in the laboratory. However, certain wastes are not suitable for heat sterilization as hazardous by-product might be generated from the process (e.g. ammonia fumes may be generated when autoclaving urine samples).

Animal waste should be considered as infectious waste if it is derived from animals with zoonotic diseases or infected with agents infectious to humans. Carcasses, body parts, tissue, body fluid, excreta and bedding should be considered as infectious waste. Such waste should preferably be incinerated.

Biological waste contaminated with hazardous chemicals should first be suitably decontaminated and subsequently handled as chemical waste. However care must be taken to ensure that decontamination of one portion does not create a greater hazard due to the presence of the other portions. The collection, storage and transportation of the waste should be carried out

using durable, leak-proof containers with a secondary container or be double bagged. The plastic bags used must be tear resistant, leak resistant and sturdy enough to withstand normal handling. A flow chart of the decontamination process of the waste is given in Appendix 6.

For large volumes of waste generated, professional waste disposal companies may be engaged to manage proper disposal. For more information on the disposal of waste, please refer to the National Environment Agency.

Emergency Response Plan

The laboratory should establish emergency response plan to mitigate consequences arising from potential emergency situations. The plan should cover biological, chemical, mechanical as well as radiation risk, if applicable. The plan should be documented and effectively communicated to all levels of the organisation and a copy prominently located near the exits of each laboratory. Laboratory should establish procedures to:

- Identify emergency situations, such as accidents, spillages, failure of critical equipment and natural disasters (e.g. flood), and their impacts. This also includes biological, chemical, mechanical and radiation risks.

- Implement emergency response plans for each level of the organisation, with clear scope, roles and responsibilities.

- Identify emergency equipment requirements, including the provision for adequate first-aid facilities and trained first-aid personnel.

- Implement a programme of drills and exercises to familiarize the staff with the emergency procedures and assess the preparedness of the laboratory for prompt and effective response to emergency.

- Maintain an up-to-date emergency response plan.

The emergency response plan should include the following:

- Establishment of Emergency Teams and their duties and responsibilities

- Fire and other services should be involved and told in advance locations containing potentially infectious materials.

- Appointment of Safety Coordinator and/or Safety Officer to coordinate the emergency procedures in accordance with the requirements of the emergency response plan.

- Procedure for notification and raising of alarms. After a flood or other natural disasters, local or national emergency services should be warned of the potential hazards within and/or near laboratory buildings

- Procedure for initial response to emergency situations such as preliminary fire-fighting, first-aid and containment response.

- Procedure for evacuation, rescue and decontamination of personnel.

- Procedure for medical surveillance, clinical management and medical treatment of exposed and injured persons.

- Procedure for epidemiological investigation.

- Capability of in-house resources, such as rescue and medical facilities.

- Capability of nearest Government response agency, their roles and response time to emergency situations.

In addition, contact information of critical personnel (e.g. safety coordinator, safety officer, medical doctor), facilities and relevant authorities should also be prominently displayed at suitable locations such as the exit and near telephones.

Vandalism

Vandalism is usually selective (e.g. aimed at animal houses). Suitable defences are strong, heavy doors, good locks and restricted entry. Screened windows and intruder alarms are desirable. Action after vandalism is the same as that for other emergencies.

Documentation and Record Keeping

Record keeping is an integral component of the Safety Management System. Proper records would help in the evaluation of the effectiveness of the various components of the Safety Management System. The following is a summary of the types of records to be kept.

Items	Components to be included
Register Of Employees who are handling: a. Risk Group 2, 3 and 4 types biological agents b. Biological agents which can result in undiagnosable illness or with unknown effects c. Biological agents with long incubation period d. Biological agents which cause long-term sequelae.	• Type of work done • Biological agent exposed to • Nature of exposure and duration • Accidents and incidents as appropriate • Experience and training * To be kept 10 years following the end of exposure
Medical Records	• Pre-employment medical examination • Immune status to exposed agents • Vaccination records

	* To be kept 10 years following the end of exposure
Hazardous Substances Inventory	• Import and transport procedures • Storage system for hazardous substances • MSDS
Physical Facilities Commissioning / recertification of facilities	• Room Integrity • Air Handling systems • Interlocking systems • Security System • Biological Safety Cabinet • HEPA Filter and Housing • Eye Wash and Shower • Other Critical Containment Components
Equipment include installation, decontamination and maintenance schedule	• Biological Safety cabinets • Laminar Flow Cabinet • Fume hoods • Centrifuge cups/carriers/mixers • Autoclave • Conventional Oven • Incubator • Water bath • Chemical Fume Cupboard • Compressed gas cylinders • Personal protective equipment
Written Procedures	• Safety Management System • Emergency Planning • Risk Assessment • Waste disposal
Training Records	• Certificates • Training attendance

APPENDICES

Appendix 1:Related Legislation and Guidelines
Appendix 2:Classification of Microorganisms by Risk Group In Relation to Category of Laboratory
Appendix 3:Design of Biological Safety Cabinets
Appendix 4:Safe Usage of Laboratory Equipment
Appendix 5:Compressed Gases
Appendix 6:Contaminated Materials and Apparatus

RELATED LEGISLATION and GUIDELINES

Legislation

- The Factories Act and its subsidiary legislations
- The Factories (Medical Examinations) Regulations
- Infectious Diseases Act (Chapter 137) ,
- Private Hospitals And Medical Clinics Act (Chapter 248, Section 17)
- Animals and Birds Act (Chapter 7)
- Environmental Public Health Act (Chapter 95)
- Radiation Protection Act

Guidelines

Ministry of Health

- Guidelines for Preventing Transmission of Bloodborne Infections in a Health Care Setting 2000
- Guidelines under The Private Hospitals And Medical Clinics Act (1980) And Regulations (1991)
- Guidelines on the Import, Transport, Handling and Disposal of Human Pathogens for Diagnosis, Scientific Research and Industrial Uses in Singapore

Genetic Modification Advisory Committee A*STAR

- Singapore Biosafety Guidelines for Research involving Genetically Modified Organisms

Ministry of Education

- Life Sciences Laboratory Safety Guidelines for Primary and Secondary Schools, Junior Colleges and Centralised Institutes. 2002. Curriculum Planning and Development Division, Ministry of Education

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- Official Journal of the European Communities. Council Directive 90/679/EEC, 26 Nov1990

- NSF/ANSI 49 – 2002 NSF International Standard / American National Standard for Biosafety Cabinetry - Class II (Laminar Flow) Biohazard Cabinetry

- AS 2252.1:1994 Biological safety cabinets (class I) for personnel protection and environmental protection

- AS 2252.2:1994 Laminar flow biological safety cabinets (class II) for personnel, environment and product protection

- AS 2647 Biological safety cabinets – installation and use, 1994

- BS EN 12469:2000 Biotechnology – Performance criteria for microbiological safety cabinets

APPENDIX 2

CLASIFICATION OF MICROORGANISMS BY RISK GROUP IN RELATION TO CATEGORY OF LABORATORY

Risk Group	Handling Laboratory	Microorganisms		
		Viruses	Bacteria	Fungi
I. Low risk to individual and community	Teaching laboratories including schools.	Nil	*B. subtilis*, *E. coli* K12	Brewer's yeast
II. Moderate risk to individual, low risk to community	Laboratories with biohazard cabinets when required.	Myxoviruses, adenoviruses, human herpes viruses, enteroviruses, rhinoviruses, rubella, rotavirus, pox viruses except smallpox. Specimens from patients suspected of having hepatitis B and immunological deficiencies except for AIDS.	All bacteria, except for those mentioned below.	All fungi except for those mentioned below.
III. High risk to individual, low risk to community	Special diagnostic or research laboratories with containment facilities.	Arboviruses except those in IV. Rabies and specimens known to contain high titres of hepatitis B. All retroviruses and specimens from AIDS cases.	*Yersinia pestis*, *B. anthracis*, *Clostridium botulinum*, *Francisella tularensis Mycobacterium tuberculosis, Coxiella burnetii*	*Blastomyces dermatitidis*, *Coccidioides immitis*, *Histoplasma capsulatum*, *Paracoccidiodes brasiliensis*
IV. High risk to individual and community	Maximum containment laboratories.	Lassa, Marburg, Ebola, Crimean-Congo, Machupo and Junin haemorrhagic fever viruses, variola, Venezuelan equine encephalitis virus, simian herpes virus and Nipah virus.		

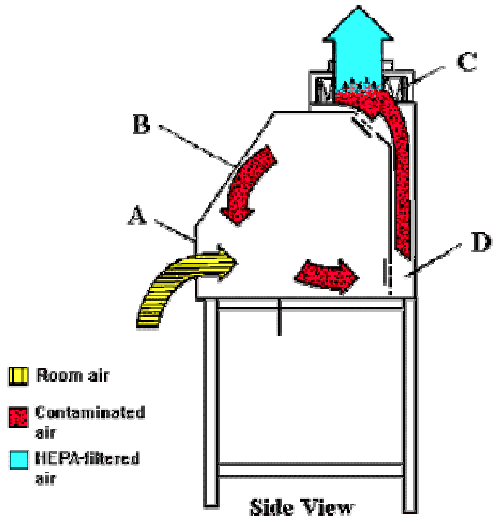
+Pathogenic microorganisms are classified into various categories ranging from those which could be adequately handled by routine service and research laboratories to those which should be totally prohibited from being imported into Singapore unless maximum containment laboratory facilities are available.

Source: Guidelines on the Import, Transport, Handling and Disposal of Human Pathogens for Diagnosis, Scientific Research and Industrial Uses in Singapore

APPENDIX 3

DESIGN OF BIOLOGICAL SAFETY CABINETS

Biological Safety Cabinets Class I (BSC I) have non-recirculated airflow away from the operator and is discharged through a HEPA filter into the laboratory or the environment. BSC I provide good operator protection against low and moderate risk micro-organisms but do not protect the material within the cabinets from contamination.



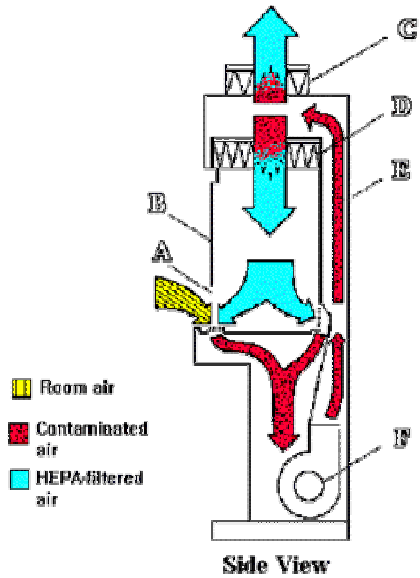
A - Front opening
B - Sash
C - Exhaust HEPA
D - Exhaust plenum

BSC I

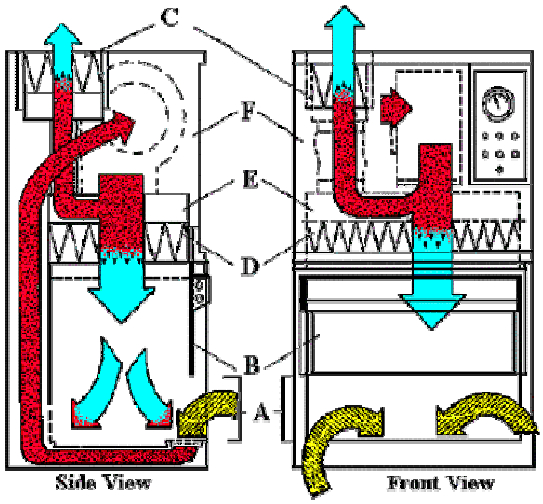
Biological Safety Cabinets Class II (BSC II) have inward airflow for personnel protection and the air is HEPA filtered before discharge into the environment. They are designed for working with Risk Group 2 and 3 microorganisms. BSC II are classified into two types (Type A and B) based on construction, airflow velocities and patterns, and exhaust systems.

Type A1 and A2 BSCs are suitable for work with procedures in the absence of volatile or toxic chemicals and radionuclides as the air is recirculated within the work area. The exhaust may be exhausted through HEPA filters into the laboratory or to the outside via a connection to the ductwork.

A - Front opening
B - Sash
C - Exhaust HEPA filter
D - Supply HEPA filter
E - Positive pressure plenum
F - Negative pressure plenum



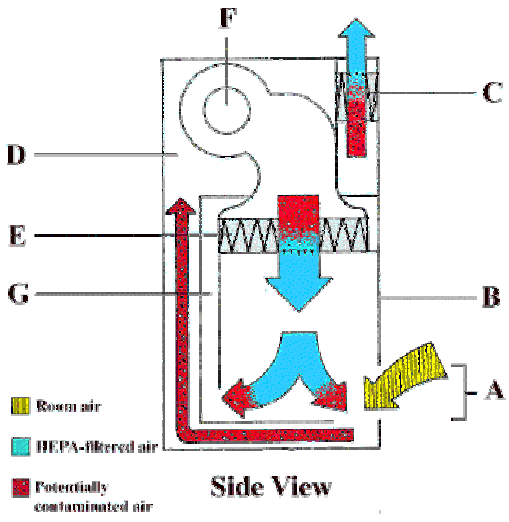
BSC II Type A



A - Front opening
B - Sash
C - Exhaust HEPA filter
D - Supply HEPA filter
E - Negative pressure exhaust plenum
F - Supply blower
G - Filter screen

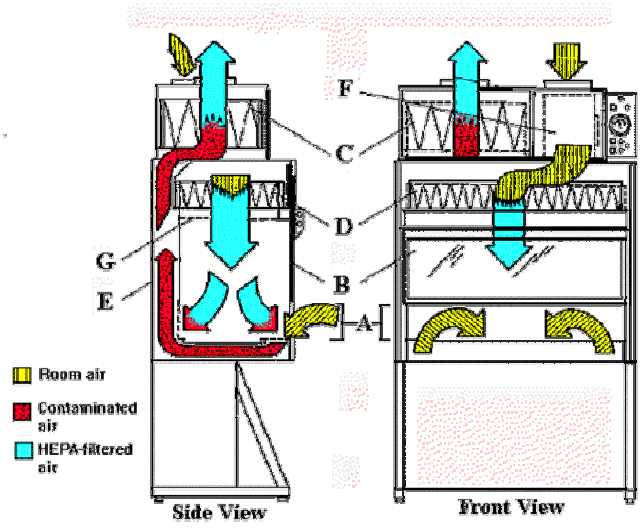
BSC II Type A2

Type B BSCs are further sub-typed into B1, B2 cabinets. These cabinets are suitable for use when manipulating small quantities of toxic chemicals when working with the mirco-organisms. Type B cabinets are directly connected to the exhaust system, and contain negative pressure plena. An alarm (audio and visual) should be provided to indicate the loss of exhaust flow from the building exhaust system. The cabinet should also be interlocked with the building exhaust system to prevent pressurization of the cabinet in the event of building fan failure.



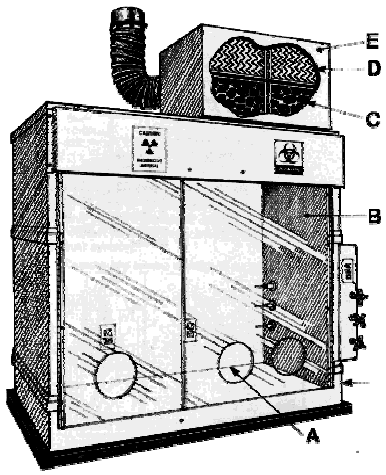
A - Front opening
B - Sash
C - Exhaust HEPA filter
D - Supply plenum
E - Supply HEPA filter
F - Blower
G - Negative pressure exhaust plenum

BSC II Type B1



BSC II Type B2

Biological Safety Cabinets Class III (BSC III) are totally enclosed and gas tight with HEPA filtered supply and exhaust air. Work is performed with attached long-sleeved gloves. The cabinet is kept under negative pressure, and airflow is maintained by a dedicated exterior exhaust system. BSC III provide the highest degree of personnel and environment protection from infectious micro-organisms that require Biosafety Level 3 or 4 containment.



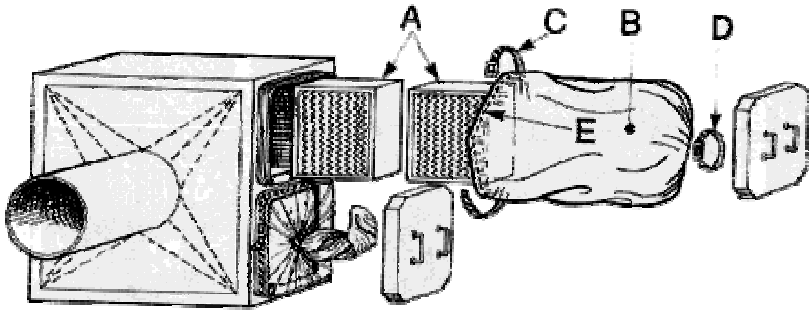
A - Arm holes
B - Hinged doors
C - Exhaust charcoal filter
D - Exhaust HEPA filter
E - Filter housing with required connection to building exhaust

BSC III

MAINTENANCE OF HEPA FILTER

For the proper functioning of the BSC, the HEPA filter would require periodic replacement or when the concentration of the contaminants causes insufficient airflow through the filter. During such maintenance or replacement work, care must be taken to ensure that the employees carrying out the job are not exposed to the trapped contaminants. Filters should be

decontaminated before removal. If this is not possible, a bag-in/bag-out (BIBO) assembly should be used.



Bag-in/Bag-out (BIBO) Assembly

A - filters
B - bags
C - safety straps
D - cinching straps
E - shock cord located in the mouth of the PVC bag restricts the bag around the second rib of the housing lip.

SAFE USAGE OF LABORATORY EQUIPMENT

General Operations

- Supervisors must demonstrate the proper and safe usage of equipment to new employees who are using the equipment for the first time.
- Equipment should not be moved around excessively so as to minimise damage to the equipment. If it is necessary to move the equipment around, the power supply must be switched off before moving.
- Equipment must not be left operating without any supervision.
- Equipment must be returned to its original state after use
- Equipment must be switched off at the end of the day.
- Equipment, switches and electrical cables must not be handled with wet hands.
- Equipment that malfunctions must be reported to the technician at once. The technician must switch off the equipment and remove the power plug from the main socket. A sign "FAULTY EQUIPMENT, DO NOT USE" must be placed prominently on or in front of the equipment.
- All instruction manuals accompanying the equipment must be filed and made accessible to all laboratory staff for their reference. It is advisable to have key steps and safety measures listed next to the equipment for quick reference.
- Instruments meant for laboratory activities must not be used for any other purposes to avoid spreading contamination. For example, a scalpel used in laboratory activities should not be used to sharpen pencils or to cut paper.

Sharp Objects

Examples of sharp objects include scalpel blades, hypodermic syringe needles and broken glass.

- Care should be taken when handling instruments with pointed ends or sharp edges. It is advisable that these instruments be kept in a safe storage box when not in use.
- Scalpel blades must never be pushed into the handle by hand. This should be done with the use of forceps. Used blades must always be removed with the use of forceps and disposed of immediately. Alternatively, blade removal apparatus could be used if available.
- If it is necessary to re-sheath a needle, the sheath must not be held towards the operator. The needle is guided into the sheath and lifted so that the sheath falls over it. Used needles must not be used for pinning down anything.

High Temperature Equipment

Autoclave

- Autoclaves can be dangerous unless properly used and serviced. Users should be adequately trained in their use and be aware that there are procedural differences among different makes and models.
- Foreign objects or substances must not be placed directly into the chamber. Baskets or buckets must be used for loading.
- Before use, the exhaust bottle must be filled with water to at least the "LOW WATER LEVEL" mark if applicable.
- Distilled water is preferred to chlorinated tap water to prevent corrosion of the chamber.
- Autoclave bags should be partially opened to prevent bursting and to allow steam circulation.
- Flasks and tubes placed in an autoclave must be loosely capped to avoid bursting, They must not be sealed with rubber or silicon caps
- Bottles, flasks and beakers must be loaded in their upright positions.
- The chamber lid must be securely sealed before the autoclave power is switched on. Failure to do so may cause steam to escape and this may injure the user.
- The door of the autoclave should be installed with tamper-proof interlocking device so that it cannot be activated if the door is not fully or securely closed.
- The autoclave must not be touched immediately after sterilisation and one should not go near the chamber lid to avoid being burnt by steam or injured by a flying lid in case of incomplete lid closing.
- Safety checks must be carried out on the autoclave at least once a year and the certificate for use of the autoclave must be renewed annually with the Ministry of Manpower.

Conventional oven

- Ovens must not be used for cooking food meant for consumption.
- Ovens must be cleaned and disinfected regularly, e.g. monthly.

Hot plate

- Heat sources must never be left unattended.
- When using hot plates, it must always be assumed that they are hot as there is no visible sign (e.g. red glow) to indicate the temperature of the plated.

Incubator

- The incubator must be cleaned and disinfected regularly, e.g. monthly.
- In the event of a spill of any material in the incubator chamber, it must be cleaned out immediately.

Microwave oven

- Microwave oven used for laboratory activities must not be used for cooking food meant for consumption.
- Metal components or parts must not be used in a microwave oven.
- Bottles or any containers used in a microwave oven should always be very loosely capped to prevent the building up of pressure due to hot air expansion.

Thermocycler

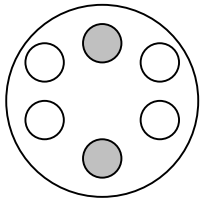
- The thermocycler should not be moved once installed. Should relocation be required, care should be taken to ensure that there is no obstruction to any air vents in the equipment for the purpose of heat transfer via airflow.
- The lid must be closed before starting an operation and should not be opened while the thermocycler is in operation.
- The programmable machine must be checked to ensure that it is programmed with the correct reaction cycles required for the specific experiment
- Caution should be exercised in removing thermocycler samples.
- Care should be exercised to avoid touching the tops of reaction vessels and the surfaces of the heated lid assembly (in particular the inner surfaces) as they can be very hot immediately after operation

Water bath

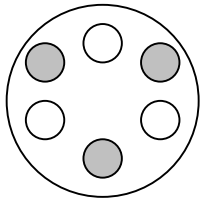
- Any bath fluids other than water should not be used. The water bath should be filled to at least half the height of the inner chamber before using.
- The water bath must be emptied, cleaned and disinfected regularly, e.g. monthly.
- In the event of a spill of any material in the water bath, it must be drained and cleaned out immediately.

Centrifuge and Mixer

- All users operating the centrifuge/micro-centrifuge must be shown the correct way to operate it.
- The instruction manual or an experienced colleague must be consulted of there is any doubt about the operation of the centrifuge.
- In most centrifuges, tubes, rotors and maximum speeds are specifically assigned and are not inter-changeable. Check this out in the instruction manual.
- Users must ensure that the tubes are balanced and the rotor is secured in the spindle. Dummy-tubes, if available, can be added for balance. Non-standard tubes must never be used. Two examples for the correct loading of tubes are shown below:



2 Tubes



3 Tubes

- Users must ensure that the safety catches are in place to prevent the opening of the centrifuge/micro-centrifuge lid while the rotor is moving.
- The centrifuge/micro-centrifuge should never be moved during an operation.
- The motor block must not be touched immediately after centrifuging, as it may be hot.
- If there is a power failure or a sudden stoppage of the machine, the main supply must be switched off. The rotor must come to rest before the lid can be opened (this may take a few minutes).
- After use, the centrifuge/micro-centrifuge must be cleaned and the rotor stored if appropriate. Any condensation must be wiped off from the centrifuge bowl. The lid should be left opened so that any film of moisture can evaporate off.
- The centrifuge/micro-centrifuge must not be operated if it is faulty. Any malfunction must be reported to the laboratory staff in charge. If there is any unusual noise produced while spinning, the rotor must be allowed to come to rest by switching off the machine.

Vortex mixer

- The vortex mixer must not be used next to any breakable item or flame as it causes vibration.
- Care must be taken to ensure that the content does not spill out of the container when the vortex mixer is used.

Electrophoresis apparatus

- The hazards of gel electrophoresis lie in the electricity used and the wet nature of the work. Care must be taken to only handle the leads one at a time with dry hands.
- While operating the apparatus for gel electrophoresis, the user must constantly ensure that there is sufficient buffer in the chambers and that there is no leakage.
- Electrodes must be connected to their respective sockets and the metal components must not be touched.

Laminar flow cabinet

At a glance, one may easily mistaken a laminar flow cabinet for a biosafety cupboard as they have a lot of similarities. Users should refer to the specifications in the instruction manual if in doubt.

- Biohazardous activities should never be carried out in the laminar flow cabinet as it offers no protection to the user. Also, the laminar flow cabinet should never be used as a fume cupboard or for storing biohazardous materials.
- UV lamps are sometimes added to the laminar flow cabinet. They should be switched off before using the laminar flow cabinet to prevent accidental burns. In the presence of fluorescent light or sunlight, it may not be noticeable that the UV lamp is on.
- The cabinet must not be used as a storage place as this may be hazardous.
- The biofilter in the laminar flow cabinet should be changed regularly.

Refrigerator/Freezer

- Refrigerators and freezers used for laboratory activities must not be used for storing food meant for consumption.
- Refrigerators and freezers must be cleaned and disinfected regularly e.g. monthly. It is a good practice to keep fixatives and microorganisms away from clean substrates such as tissue culture media. They should preferably be stored in separate refrigerators.

UV transilluminator

- A suitable facemask or visor must be worn when using a UV transilluminator. The UV light source must not be viewed directly without any eye and face shielding

COMPRESSED GASES

Compressed gas cylinders in the laboratory pose both chemical and physical hazards. Gases accidentally released can result in a depleted oxygen atmosphere which can lead to asphyxiation of laboratory personnel. Many gases used in laboratories also present a fire hazard due to their high degree of flammability. Finally, if a valve is damaged as the result of the tank being knocked over, the cylinder can become a projectile capable of causing severe injury.

Transporting Compressed Gas Cylinders

Compressed gas tanks should always be transported on cylinder carts which are equipped with straps or chains. It is always prudent to keep the valve cover in place while in transport and until the tank is secured in place and ready for use.

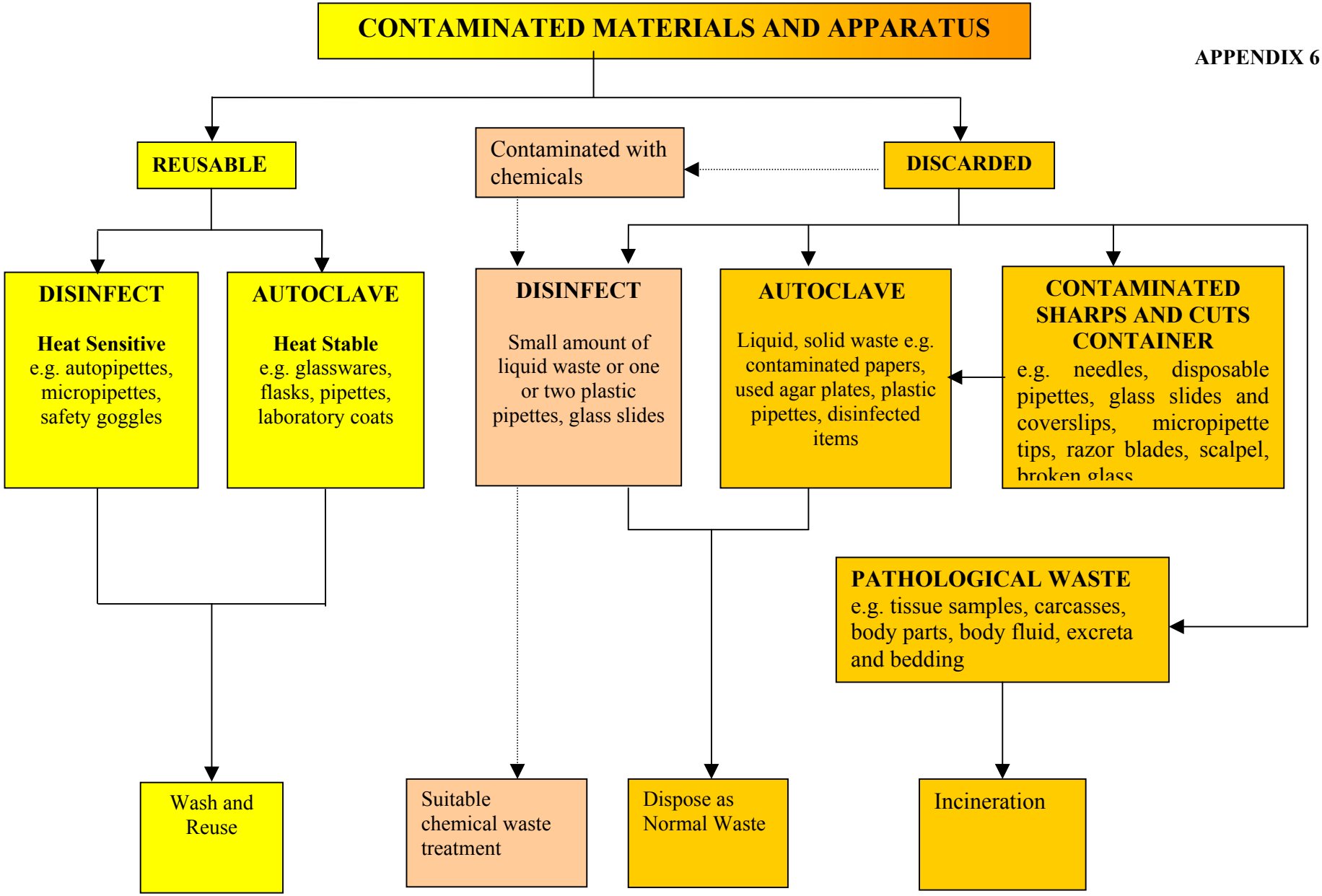
Storage Precautions and Procedures

The following are prudent work procedures for handling compressed gas cylinders in the laboratory.

- Cylinders should be secured by placing them into floor racks or by strapping the tanks to either wall mounts or clamping devices attached to work benches. Do not store tanks in public access areas.
- Cylinders of flammable gases should be stored away from all sources of ignition (i.e. bunsen burners, hot plates etc.).
- The colour on the cylinder should not be used to identify the gas. The labels should be checked.
- Only approved regulators should be used for the corresponding gas types.

- Valves should be closed when not in use.
- There should not be any self-attempt to refill tanks. The supplier will refill tanks and perform any needed repairs.

APPENDIX 6


CONTAMINATED MATERIALS AND APPARATUS
REUSABLE
Contaminated with chemicals
DISCARDED
DISINFECT
Heat Sensitive
e.g. autopipettes, micropipettes, safety goggles
AUTOCLAVE
Heat Stable
e.g. glasswares, flasks, pipettes, laboratory coats
DISINFECT
Small amount of liquid waste or one or two plastic pipettes, glass slides
AUTOCLAVE
Liquid, solid waste e.g. contaminated papers, used agar plates, plastic pipettes, disinfected items
CONTAMINATED SHARPS AND CUTS CONTAINER
e.g. needles, disposable pipettes, glass slides and coverslips, micropipette tips, razor blades, scalpel, broken glass
PATHOLOGICAL WASTE
e.g. tissue samples, carcasses, body parts, body fluid, excreta and bedding
Wash and Reuse
Suitable chemical waste treatment
Dispose as Normal Waste
Incineration

ACKNOWLEDGEMENTS

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Agri-Food and Veterinary Authority, AVA

Ministry of Health, MOH

National Environmental Agency, NEA

September 2003

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CHECKLIST FOR LABORATORIES AND PRODUCTION FACILITIES IN THE BIOMEDICAL SCIENCES INDUSTRY

This checklist is a guide to compliance of requirements in The "OSH Guidelines In Laboratories And Production Facilities In The Biomedical Sciences Industry". Sections A to G are basic general requirements that should be completed. Relevant sections from H to O should be completed for laboratories requiring higher or special containment.

Company	**Facility**	**Unit**
Address		
Name of person conducting checklist		
Date	**Signature**	

Description	**Yes**	**No**	**NA**	**Remarks**
A) OSH Organisation and Systems				
1) Is there adequate and effective Safety Management System?				
2) Is there a safety coordinator or safety officer appointed and trained in accordance to the guidelines				
3) Is there a safety committee for facilities employing more than 50 employees?				
4) Are all employees trained and equipped with the skills and knowledge to perform the work safely?				
5) Is there a health surveillance programme for employees exposed to biological agents?				
6) Are non-laboratory personnel (e.g. engineering and supporting services) made aware of the hazards and trained in the safe work procedures when required to work in the laboratories?				
B) Control of Biohazards				
1) Has risk assessment been carried out for work involving biological agents classified under risk group 2 or higher?				
2) Is there a laboratory procedural or safety manual?				

3) Biosafety Level 1 (all laboratories) 3.1) Have all practicable means been taken to ensure that no eating, drinking and storage of food is permitted in the work areas? 3.2) Are mechanical pipette aids used for pipetting? 3.3) Are procedures performed in manner to minimise the creation of aerosols? 3.4) Are effective disinfectants available within the laboratory? 3.5) Are work surfaces cleaned and decontaminated when work is completed, at the end of the day or after any spills? 3.6) Are all biological wastes (including used gloves) properly decontaminated before disposal? 3.7) Is the facility kept free of rodents and vermin? 3.8) Are the following personal protective equipment used as necessary? a) protective laboratory clothing b) closed footwear c) eye and face protection d) hand protection e) respiratory protection 3.9) Does the laboratory have impervious open bench top sink? 3.10) Is hand washing facility provided near to the exit door?				
C) Biological Safety Cabinets				
1) Does the design, construction and testing of the biological safety cabinets comply with any of the following standards or its equivalent? a) NSF/ANSI 49-2002 b) AS 2252.1/AS2552.2 / AS 2647 c) BS EN 12496:2000				

2) Is the re-certification of the biological safety cabinets performed by competent personnel and at least annually?				
3) Is a copy of the certification report with full details available?				
4) Are the general principles for the proper usage of biological safety cabinets being carried out and followed?				
D) Control of Other Hazards				
1) Is there an effective programme for handling, storage and disposal of hazardous chemicals?				
2) Are there clear instructions on the safe use of laboratory facilities & equipment?				
3) Is there a radiation safety programme?				
E) Waste Disposal				
1) Are waste properly segregated and collected in suitable containers specific to the hazard (e.g. biological, chemical, radioactive)?				
2) Are persons handling the waste competently trained and equipped with proper PPE?				
3) Are the spill kits available and easily accessible?				
4) Are all waste properly decontaminated and treated?				
F) Emergency response plan				
1) Is there an effective emergency response plan to cover potential emergency situations such as spillage, BSC failure, power failure, animal escape and others?				
2) Are Emergency Teams established and trained in handling the emergencies?				
3) Are there regular drills and exercises to familiarise the staff with the emergency procedures and to assess the preparedness of the laboratory?				

4) Is the contact information of critical personnel, facilities and relevant authorities posted at suitable locations?				
G) Documentation and record keeping				
1) Is there a proper system of documentation and record keeping?				
2) Is there a registry of personnel handling infectious pathogens?				
3) Is there a hazardous substances inventory?				
4) Are there detailed records of audit and certification of facilities and equipment?				
5) Is there a written schedule for installation, decontamination and maintenance of equipment?				
6) Are there written procedures for safety management system, emergency planning, risk assessment and waste disposal?				
7) Are there records on training?				
In addition to requirements in above sections, those in relevant sections below may need to be complied with according to hazard level				
H) Biosafety level 2 1) Is the access to the laboratory limited to authorised personnel only? 2) Are appropriate biohazard signs posted on or near to the access door? 3) Are used needles, syringes and sharps disposed in puncture-resistant containers? 4) Are culture media properly labelled and stored? 5) Is broken glassware handled by using mechanical means such as brush and dustpan instead of with hand? 6) Are procedures that create aerosols conducted within a biological safety cabinet (Class I)				

7) Is autoclave(s) conveniently located within or near to the laboratory? 8) Are bench tops impervious to water, resistant to chemicals and disinfectants? 9) Is the eye-wash in good working condition				
I) Biosafety level 3 1) Is access to laboratory controlled and restricted to authorised personnel only? 2) Is access to laboratory through a series of double self closing doors? 3) Is entry and exit protocol established and followed? 4) Are items not related to the work procedures not brought into the laboratory? 5) Are contaminated equipment and waste properly decontaminated before removal from the laboratory? 6) Are infectious agents stored only in the laboratory, unless the same level of biosecurity and biosafety is maintained? 7) Is the handling of infectious agents conducted within a biological safety cabinet (Class II)? 8) Are equipment dedicated for biosafety level 3 used only? 9) Is solid-front clothing or wrap around gown used instead of front-button lab coat? 10) Is laboratory clothing decontaminated before laundering? 11) Are drain traps filled with disinfectants? 12) Does the laboratory have ventilation system incorporated with interlocks to create and maintain directional airflow into the working area?				

13) Is the exhaust air properly filtered (HEPA filters) before discharge into the environment? 14) Is the laboratory structural design including windows able to withstand the air pressure loads? 15) Is the laboratory substantially airtight and its structural layout accessible for decontamination?				
J) Biosafety level (Large Scale Production) 1 1) Are the culture media contained in closed systems so as to prevent release into the environment? 2) Is there a validated procedure for inactivating culture fluids before removal from system? 3) Are floors designed to prevent release of culture into sewers?				
K) Biosafety level (Large scale) 2 1) Is the entry to production area limited to authorised personnel only? 2) Are appropriate biohazard signs and PPE requirement signs posted on or near to the access door? 3) Are critical processes equipped with suitable monitoring devices?				
L) Biosafety level (Large scale) 3 1) Are provisions made to contain the full volume of the release of culture fluids?				
M) Animal biosafety level 1 1) Is hand washing sink available in the animal facility? 2) Are animal carcasses and tissue waste incinerated or processed by proven methods?				
N) Animal biosafety level 2 1) Are animals not required for the work processes kept out of the work area? 2) Are there procedures to prevent animals from escaping?				

3) Are the cage housings of infected animals properly labelled? 4) Is the exhaust air discharged to the environment and not re-circulated into the room? 5) Are drain traps filled with disinfectants?				
O) Animal biosafety level 3 1) Is access to animal facilities restricted to authorised personnel only? 2) Are infected animals housed in containment facility to prevent risk of spreading?				

SIXTH SCHEDULE

Section 67

NOTIFIABLE INDUSTRIAL DISEASES

Aniline poisoning
Anthrax
Arsenical poisoning
Asbestosis
Barotrauma
Beryllium poisoning
Byssinosis
Cadmium poisoning
Carbamate poisoning
Carbon Bisulphide poisoning
Chrome ulceration
Chronic benzene poisoning
Compressed air illness
Cyanide poisoning
Epitheliomatous ulceration (due to tar, pitch, bitumen, mineral oil or paraffin or any compound, product or residue of any such substance)
Hydrogen Sulphide poisoning
Industrial dermatitis
Lead poisoning
Liver angiosarcoma
Manganese poisoning
Mercurial poisoning
Mesothelioma
Noise-induced deafness
Occupational asthma
Organophosphate poisoning
Phosphorous poisoning
Poisoning from halogen derivatives of hydrocarbon compounds
Repetitive strain disorder of the upper limb
Silicosis
Toxic anaemia
Toxic hepatitis

[S 145/95]

LABORATORY RISK ASSESSMENT

WHAT, WHY, AND HOW

Risk Assessment in the Infectious Disease Laboratory

Study Booklet

Revised October 1998
http://www.cdc.gov/phppo/dls/pdf/lrawwh.pdf

Accompanies the
Videotape of the July 23, 1998, Satellite Broadcast

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Acknowledgments

Special thanks to Elizabeth Franko, DrPH, Director, and the following staff of the Georgia Public Health Laboratory.

Karl Hoenes, MS Elizabeth Dennis, MA

Jenuryl Fluellen, MT (HEW); Ytisra Adams; Lexie Kreckman, AB; Abdal Mahdi, MT (AMT); Deborah Harris; Joseph Zambie, BS, MT(P); and Cindy Daniell, MLT (ASCP), MT(AMT)

Thanks also to the Association of Schools of Public Health for their continued support.

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INTRODUCTION

All workers in the United States are entitled to a safe and healthy working environment.* It is to this purpose that this program, Laboratory Risk Assessment: What, Why, and How, has been developed.

As new technologies and tests are introduced into the complicated arena of laboratory testing, it becomes increasingly difficult for regulatory and advisory agencies to provide specific safety regulations and guidelines for each new situation. It is, therefore, the responsibility of the laboratory itself to develop its own guidelines and work practices to ensure a safe work environment for all employees.

To develop effective strategies that continually guarantee employees a safe work environment, the performance of risk assessments must be an integral and on-going part of laboratory operation.

"Risk assessment" is a relatively new term, but one that is appearing more frequently in literature and in presentations dealing with laboratory safety. Although the term is used freely, many in the laboratory community are uncertain of (1) what the term means in reference to laboratory safety, (2) when and what kind of assessment should be performed, and (3) how to perform an assessment.

The satellite broadcast, Laboratory Risk Assessment: What, Why, and How, *Risk Assessment in the Infectious Disease Laboratory*, and the contents of this booklet are designed to provide you with tools for performing risk assessments in your facility.

**The Occupational Safety and Health Act of 1970, Executive Order Number 12196*

SPONSORS

This program, developed by the Office of Health and Safety and the Public Health Practice Program Office, Centers for Disease Control and Prevention (CDC), was funded by the National Center for HIV, STD, and TB Prevention, CDC.

PROGRAM DESCRIPTION

This training program consists of a videotape of the interactive satellite broadcast, *Laboratory Risk Assessment: What, Why, and How,* and a study booklet. Its purpose is to provide the learner with tools for performing risk assessments in infectious disease laboratories. The program provides learners with the opportunity to perform a risk assessment in a simulated mycobacteriology laboratory under the guidance of experts. Although a mycobacteriology laboratory is used for the training exercise, the principles and practices illustrated are applicable to other specialties as well.

TARGET AUDIENCE

This program is for infectious disease personnel working in public health, hospital, physician office, and research laboratories. Types of personnel include laboratory directors, supervisors, technologists, technicians, and researchers, as well as laboratory safety officers, trainers, laboratory designers and engineers, and administrators.

LEARNING OBJECTIVES

After viewing the videotape program, the learner will be able to--

- define risk and risk assessment
- list reasons for performing risk assessments in infectious disease laboratories
- define the selection and use of containment equipment
- perform a risk assessment of a simulated mycobacteriology laboratory
- identify resources for information on risk assessments and laboratory safety.

By applying the principles and practices detailed in the videotape program, study booklet, and suggested resources, you will be able to perform risk assessments effectively in your laboratory.

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RISK ASSESSMENT--THE *WHAT*

What is a risk assessment?

Performing a risk assessment of the workplace is the first step toward ensuring that all workers have safe and healthy working environments. Unfortunately, everyone in the laboratory community does not have the same understanding of what is meant by "risk" or "risk assessment." The following are selected definitions that will be used in this program:

> ***Risk*** is the chance of injury, damage, or loss.
>
> ***Chance*** means the probability of something happening.
>
> A ***Hazard*** is something that is dangerous--an object, a chemical, an infectious agent, or a situation. Hazards are categorized into three groups: ***Physical*** hazards**,** ***Chemical*** hazards, and ***Biological*** hazards. Here are some examples of hazards and the risks associated with each hazard.

Hazard	**Risk of that Hazard**
Careless handling of sharps such as needles	Sticking yourself (*physical*) Sticking and infecting yourself (*biological*)
Pouring hazardous chemicals while working on an open bench	Burning yourself with splashing chemicals (*chemical*)
Eating or drinking in the laboratory	Swallowing infectious material and getting sick (*biological*)

> ***Risk assessment*** is an action or a series of actions taken to recognize or identify hazards and to measure the risk or probability that something will happen because of that hazard. In evaluating risk, the severity of the consequences is also taken into account.

In the video is a scenario that focuses on a "wet spot" on the floor in a mycobacteriology laboratory. This scenario illustrates the progression in severity of the potential consequences that can result from broken test tubes. Crucial in determining the severity of risk due to the broken tubes are the contents of the tubes--from sterile media to cultures of *Mycobacterium tuberculosis.* For example:

> Breaking tubes of liquid media is more hazardous than breaking tubes of solid media because splashing liquid media can generate aerosols.

Breaking tubes of liquid media containing infectious agents is more hazardous than breaking tubes of sterile media because of the potential for becoming infected.

Breaking tubes of liquid media containing infectious agents that are transmitted by inhalation is more hazardous than breaking tubes of liquid media containing infectious agents that are transmitted by other means, such as ingestion, because of the potential for inhaling infectious aerosols.

Other factors to consider when doing a risk assessment of a spill include--

- the amount of material spilled
- the presence and number of infectious particles or the concentration of a hazardous chemical
- the nature of the ventilation in the room
- the personal protection equipment, such as a respirator, being worn by those in the room

Evaluations of risk may be only partly quantitative; complete assessment also requires--

- background information
- experience
- common sense
- ability to visualize potential outcomes

Tools useful in performing laboratory risk assessments are--

Reviewing laboratory records

Injury, illness, and surveillance reports
Equipment maintenance records
Employee training records
Environmental monitoring records

Inspecting the laboratory

Daily monitoring by employees
Periodic walk-throughs
Formal inspections by certifying agencies

Reviewing published materials

Equipment manuals
Manufacturers' bulletins and newsletters
Product inserts
Scientific journals
Published safety manuals and guidelines

Observing laboratory operation *(requires a knowledge of relevant literature and experience with similar activities)*

New procedures
New employees
New equipment
Work-flow

RISK ASSESSMENT--THE *WHY*

Why do risk assessments?

Risk assessments provide us with the information we need **to keep people safe**--people in the ***immediate laboratory***, people in the entire ***facility***, and people in the ***external environment***, i.e., the community.

Some ***additional benefits*** that can be derived from performing risk assessments include--

- Effective use of resources
- Identification of training needs and supervision
- Advance planning for renovations
- Evaluation of procedural changes
- Prevention of biohazard transmission to family members of employees
- Ensure compliance with governmental regulations
- Justification for space and equipment needs
- Cost effective laboratory operation
- Evaluation of emergency plans

RISK ASSESSMENT--THE *WHEN*

When should risk assessments be done?

Risk assessments should be done at ***regular intervals***, at least annually, but more frequently if problems are discovered.

A risk assessment should be done whenever ***a change occurs*** in the laboratory such as a--

- move or renovation
- new employee
- new infectious agent or new reagent
- new piece of equipment

RISK ASSESSMENT--THE *HOW*

How does one do risk assessments?

Maintaining a safe laboratory is the ***shared responsibility*** of both managers and employees; likewise, risk assessments are also a shared responsibility.

In an individual laboratory, the ***best assessors*** of risk are usually those who work in the laboratory, the first line supervisors, and others close to the situation.

Certain ***prerequisites*** are required before attempting to perform a risk assessment. These prerequisites include--

- A knowledge of biological, chemical, and physical hazards
- An understanding of the principles of biological, chemical, and physical safety
- A knowledge of the modes of transmission for the various infectious agents encountered in the laboratory

- An understanding of the importance of aerosols in the laboratory
  - *How aerosols act as modes of transmission for infectious agents and chemical vapors*
  - *What procedures are likely to generate aerosols*
  - *What methods can be used to reduce or contain aerosols*

- A knowledge of essential safety features of your facility
  - *The air handling system*
  - *The safety equipment available*
  - *The adequacy and limitations for decontaminating waste*

- A knowledge of the type of medical surveillance needed for each employee's job

- An understanding of how the facility, the equipment, the personnel, the procedures, and the hazardous materials must be integrated to create a safe working environment

- A knowledge of the local, state, and federal regulations under which the laboratory operates

Risk assessments must be done **systematically**. Before doing a risk assessment, you should make a check-list customized for your laboratory so that essential items are not overlooked.

Containment Equipment

The use of containment equipment is the primary mechanism for protecting employees from hazardous (*infectious or toxic*) aerosols. The two types of containment equipment most frequently used in the infectious disease laboratory are the biological safety cabinet (BSC) and aerosol-free centrifuge cups.

Other types of cabinets or hoods (as they are frequently called in the laboratory) are also available in addition to the BSC. Each type of cabinet, however, is designed for particular functions. The type of cabinet selected for use must match the type of hazardous material being manipulated. It is, therefore, essential that those who perform risk assessments in laboratories requiring containment equipment have a basic understanding of the types and functions of the various types of containment cabinets.

<u>Biological Safety Cabinets</u>

The BSC is the most important piece of equipment for containing infectious aerosols. Three kinds of BSCs have been developed to meet various needs. These have been designated Class I, II, and III. Class I cabinets protect the worker but not the product. Class III cabinets provide the maximum protection. They are tightly sealed, the front opening is closed, and a glove port provides access to the inside of the cabinet. Class III cabinets are typically used when working with highly infectious agents, such as Ebola virus or with an unknown pathogenic agent.

The most commonly used cabinet, the Class II, is further subdivided into types A, B1, B2, and B3. These variations reflect cabinet design, air flow, and installation mode. Most clinical laboratories use a Class II, Type A BSC. In a Class II, Type A BSC, room air enters the cabinet, mixes with filtered cabinet air, and passes through the intake grilles at the front of the cabinet. The air mixture is drawn up in an enclosed area (the plenum) behind the work space to the top of the cabinet. Seventy percent of the air mixture is pushed through the high-efficiency particulate air (HEPA) supply filters into the cabinet work area; the remaining 30% of the mixture is pushed through the exhaust HEPA filters. Class II type A cabinets are not suitable for working with chemicals.

Class II BSCs protect--
- the ***worker*** because the air flows into the cabinet
- the ***product*** because particulates have been removed from the air by the HEPA filters before flowing into the cabinet
- the ***environment*** because infectious particles have been removed from the air by HEPA filters before it is exhausted

BSCs are protective only if 1) they have been properly installed, 2) the appropriate air velocity is maintained during use, and 3) proper procedures are used when working in them. If any of these requirements are lacking, the BSC will not provide the intended protection. Performing a risk assessment should detect if any of these faulty conditions exist.

Chemical Fume Hoods

Chemical fume hoods are designed for working with chemicals that produce toxic fumes. Air enters through the front opening of the hood and exits through an exhaust duct without being filtered.

Chemical fume hoods protect--
- only the ***worker*** because the air flow is inward
- ***neither*** the product ***nor*** the environment because the exhaust air is not filtered

Clean Benches *(Vertical and horizontal laminar-flow cabinets)*

In clean benches, HEPA-filtered air moves across the work area either from the top- (vertical-flow) or from the back (horizontal-flow) of the cabinet. Clean benches are not suitable for work with infectious or toxic material. They are used primarily for working with or preparing sterile non-toxic media and reagents.

Clean benches protect--
- only the ***product*** because the air flowing over the work area is HEPA filtered
- ***neither*** the worker ***nor*** the environment because the air does not flow away from the worker nor is it filtered before it is exhausted

Performing a Risk Assessment

Risk assessments are a two-part process--first, identifying the hazards, and second, determining the degree of risk associated with each hazard. Only after these two steps have been completed can risk be effectively managed.

Performing risk assessments should not be limited to the immediate laboratory area. All parts of a facility must be a safe environment in which to work. As in the video walk-through, risk assessments begin with the arrival of the specimen at the facility. Below are some of the hazards or potential hazards seen in the video during the laboratory walk-through; you may have seen others as well.

- Confusion caused by a poor work flow creates conditions that could lead to workers ***colliding*** with other workers or with an object, resulting in the dropping, spilling, or breaking of potentially infectious material.

- Opening primary shipping containers which contain the specimen tube (or other receptacle) without using any barrier protection places workers at risk. If the specimen tube breaks, ***infectious aerosols*** could be generated. In addition, the worker's hands could become ***contaminated*** with infectious materials or ***cut*** with the sharp edges of the broken container.

- Using poor practices and techniques when working in the BSC can cause ***disruption of the air barrier*** allowing infectious aerosols to escape into the room.

- ***Failure to check the condition*** of the containment equipment before it is used may lead to working with equipment that is not safe. Safety equipment to be effective must not only be used properly, but must function properly as well.

- Use of the Bunsen burner in the BSC can ***disrupt the air flow,*** allowing escape of infectious material.

- Flaming wet smears can create potentially ***infectious aerosols***.

- Skin can be burned or damaged if not protected from possible ***carcinogens*** or other hazardous chemicals.

- Hazards associated with the use of the fluorescence microscope must be avoided or minimized--burns from contact with ***hot surfaces***; inhalation of ***mercury vapors*** from an exploding lamp; and ocular burns from exposure to ***ultraviolet light***.

- Overfilled sharps container creates the risk of being ***stuck with a contaminated needle*** and becoming infected with a pathogen.

- The ***spread of hazardous material*** via contaminated gloves to uncontaminated surfaces outside the BSC endangers all in the laboratory.

- ***Unfamiliar hazards*** may be associated with new procedures, new equipment, or new reagents.

- ***Improper use of chemical fume hoods*** can lead to escape of toxic vapors into the room.

- ***Pregnant women (or those that might be pregnant) should not be exposed*** to hazardous chemicals that might endanger the fetus.

- ***Improperly stored materials/supplies*** create unnecessary hazards for workers who might be injured if an objects falls on them or they collide with an object while moving about the laboratory.

- ***Wet spots*** on floors could cause someone to slip and possibly fall.

- ***Drinking, eating,*** or ***smoking in the laboratory*** provides a mechanism for ingesting infectious or toxic material.

- If ***emergency supplies are blocked***, they will be of little use if no one can get to them quickly.

- ***Improper disposal of waste*** endangers all in the laboratory--laboratory and non-laboratory staff.

- A ***malfunctioning door closure*** causes a disruption in all air-flow patterns and may allow laboratory air to escape into the hallway.

Once potential hazards are identified, the degree of risk must be determined for each hazard. Determining risks requires the integration of knowledge about the facility, the containment equipment, the personnel, and the infectious agents, chemicals, and other materials that are used in the laboratory. Following are some suggestions for laboratory features to be evaluated when performing risk assessments.

<u>Laboratory Features to be Evaluated</u>

- Physical facility (laboratory design, engineering controls)
  Air-flow
  Laboratory access
  Composition of ceiling, walls, and floors

- Containment equipment
  Biological safety cabinets
  Fume hoods
  Aerosol-free centrifuge cups/carriers

- Personnel
  - *Experience and training*
  - *Physical handicaps*
  - *Attitude*
  - *Immune status*

- Agents worked with in the laboratory
  - *Pathogenicity*
  - *Mode of transmission, e.g., inhalation, blood, ingestion, unknown*
  - *Information available, e.g., limited information on a new agent*

- Types of procedures performed
  - *Aerosol generating*
  - *Requiring use of syringes and needles*
  - *Requiring temperature extremes, e.g., ultra hot or ultra cold*
  - *Requiring dexterity and use of sterile techniques*

<u>Some Factors that Influence Risk</u>

- Mode of transmission, e.g., inhalation vs. ingestion

- Procedures that produce aerosols vs. procedures that do not produce aerosols

- Severity of the consequences of exposure, e.g., nontoxic/nonpathogenic vs. pathogenic/lethal

- Concentration of the pathogen or chemical, e.g., <10 (<1 log) infectious particles per milliliter vs. >1000 (>3 logs) infectious particles per milliliter

- Volume, e.g., <1ml vs. >10ml

- State or form of the agent, e.g., suspended in liquid vs. colonies on solid medium, lyophilized, or dried/fixed to a slide; clinical specimen vs. purified/concentrated suspension, etc.

A P P E N D I X

OBSERVATION WORKSHEET

PERFORMING A RISK ASSESSMENT

As you look at the video showing a walk through a simulated mycobacteriology laboratory, use this worksheet to indicate each time you identify a hazardous or potentially hazardous situation. Make note of any poor practices you might observe. In a second walk-through of the laboratory, the important hazards and poor practices will be identified and the risks of each discussed.

Specimen Path	Hazards/Poor Practices Identified	Discussion
Accession Area		
Laboratory: Specimen Processing Readying the BSC Processing the specimen		
Laboratory: Acid-Fast Microscopy Preparing smears Staining smears Examining smears		*continued next page*

Specimen Path	Hazards/Poor Practices Identified	Discussion
Laboratory: Inoculation of Culture Media (Isolation) Inoculation Incubation of Cultures Exiting the Laboratory		
Laboratory: Identification of Isolates (HPLC)		
Exiting the Laboratory		

Additional Notes:_____

The National Laboratory Training Network

The videotape of the July 23, 1998 satellite broadcast, “Laboratory Risk Assessment:What, Why, and How” is available for loan from the National Laboratory Training Network (NLTN). While on loan the videotape may be copied, but the original must be returned to the office from which it was borrowed.

Calling **1-800-536-NLTN** will automatically connect you with the office serving your state. Visit the NLTN web site @ http://www.cdc.gov/phppo/dls/nltn.htm

SUGGESTED RESOURCES

General Laboratory Safety

CRC Handbook of Laboratory Safety. Furr A.K. (ed.). CRC Press, Boca Raton. 1995. pp. 412-473.

Laboratory Safety: Principles and Practices, 2nd ed. Fleming DO, Richardson JH, Tulis JJ, Vesley D, eds., Washington, DC. American Society for Microbiology, 1994.

Physical and Biological Hazards of the Workplace. Wald, Peter H, Stave, Gregg M eds. Van Nostrand Reinhold, New York, 1994.

Preventing Occupational Disease and Injury. American Public Health Association, Washington, DC, 1991.

Biological Safety

AHIA - Biosafety Reference Manual. Heinsohn PA, Jacobs RR, Concoby BA eds. American Industrial Hygiene Association, Fairfax, 1995, pp 51-99.

Biohazards Management Handbook. Lieberman DF, ed. New York: Marcel Dekker, 1995; 173-192.

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Stern E, Johnson JW, Vesley D, Halbert MM, Williams IE, Blume P. Aerosol production associated with clinical laboratory procedures. Am J Clin Pathol 1974;62:591-600.

Mycobacteriology (TB) Laboratory Safety

CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. MMWR 1994;43(No. RR-13).

Heifets LB, Good RC. Current laboratory methods for the diagnosis of tuberculosis. In: Bloom BR, ed. Tuberculosis: pathogenesis, protection and control. Washington, DC: American Society for Microbiology Press, 1994:85-110.

Kent PT, Kubica GP. Public Health Mycobacteriology. A Guide for the Level III Laboratory. Atlanta: U.S. Department of Health and Human Services, Public Health Service, CDC, 1985.

Kubica GP, Dye WE. Laboratory Methods for Clinical and Public Health Mycobacteriology. Public Health Service Publication No. 1547. Washington, D.C. U.S. Department of Health , Education, and Welfare. United States Government Printing Office, 1967.

Richmond JY, Knudsen RC, Good RC. Biosafety in the Clinical Mycobacteriology Laboratory. Clinics in Laboratory Medicine 1996;16:527-550.

Chemical Safety

NIOSH/OSHA Pocket Guide to Chemical Hazards. NIOSH Publication No. 97-140, Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402,1997.

Prudent Practices in the Laboratory - Handling and Disposal of Chemicals. National Research Council, National Academy Press, Washington DC, 1995.

Physical Safety

Safe Handling of Compressed Gas in Containers. Compressed Gas Association, Inc., Publication No. P-I, 8th ed., 2235 Jefferson Davis Highway. Arlington. VA., 22207, 1991.

Ventilation and Safety Cabinets

American National Standards Institute. Laboratory Ventilation Standard, ANSI NO. Z9.5. 1992. American Industrial Hygiene Association, Fairfax, VA 1993.

American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE). 1995 Handbook - HVAC Applications. ASHRAE, Atlanta, GA 1995.

CDC/NIH. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets. U.S. Department of Health and Human Services, Public Health Service, CDC, 1995.

Kruse RH, Puckett WH, Richardson JH. Biological Safety Cabinetry. Clin Microbiol Rev 1991;4:207-41.

National Sanitation Foundation (NSF). Standard 49, Class II (Laminar Flow) Biohazard Cabinetry. Ann Arbor: 1992.

Web Sites

CDC Office of Health and Safety
http://www.cdc.gov/od/ohs/

APHL (*formerly, ASTPHLD*)
http://www.aphl.org

CDC Home Page
http://www.cdc.gov

Eagleson Institute
http://www.eagleson.org

HPLC Standardized Method Manual
http://www.cdc.gov/ncidod/publications/hplc.pdf

You will need an Acrobat Reader 3.0 to print the document. Acrobat Reader can be downloaded for free from http://www.adobe.com

List of Approved Respirators
http://www.cdc.gov/niosh/respinfo.html

National Laboratory Training Network (NLTN)
http://www.cdc.gov/phppo/dls/dlshome.htm

National Tuberculosis Center Homepage
http://www.umdnj.edu/%7entbcweb/ntbchome.htm

Self-Assessment Manual for the *Mycobacterium tuberculosis* Laboratory
http://www.cdc.gov/phppo/dls/ltapubs.htm

World Health Organization Homepage
http://www.who.ch/

Answers to Quiz

The quiz is on page 19. The answers are as follows: 1=D; 2=B; 3=C; 4=F; 5=B; 6=C; 7=A; 8=C; 9=B; 10=C; 11=B; 12=C.

QUIZ

Select the single best answer for each question. Answers are on page 18. If you do not score 100%, that is, answer all questions correctly, it is suggested that you view the video again.

1. Which of the following could be considered hazards?
   A. Carelessly handled sharps
   B. Dangerous chemicals on an open bench
   C. Eating or drinking in the laboratory
   D. All of the above
   E. None of the above

2. A complete risk assessment requires all of the following EXCEPT:
   A. Background information
   B. A substantial budget
   C. Experience
   D. Common sense
   E. The ability to visualize potential accidents

3. What is the primary reason for doing risk assessments?
   A. To analyze the cost-effectiveness of laboratory operations
   B. To save time when performing routine procedures
   C. To ensure the safety of laboratory personnel and protection of the environment

4. Risk assessments should be done—
   A. At regular intervals
   B. Whenever problems occur
   C. Anytime there is a change in the laboratory, e.g., new equipment
   D. Only before an inspection
   E. All of the above
   F. A, B, and C only

For questions 5 - 7, choose the most appropriate containment equipment from one of the following responses:

A = Class II, type A or B biological safety cabinet (BSC)
B = Fume hood
C = Clean bench

5. _____ Protects only personnel against toxic fumes

6. _____Protects only products from contamination

7. _____Protects personnel, products, and the environment against biohazards

8. In the laboratory walk-through, what color were the laboratory coats and gowns worn by the laboratorians performing the diagnostic tests?
   A. White
   B. Yellow
   C. Blue
   D. Green
   E. All of the above
   F. None of the above

9. Product information such as package insets and Material Safety Data Sheets (MSDS) should be kept in--
   A. The administrative area or office so they will not get damaged in the lab
   B. A central location in the lab so that everyone can find them quickly and easily
   C. Each lab worker's desk drawer

10. Which of the following is **NOT** a source for more information about risk assessments?
   A. Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual
   B. Internet
   C. Newspapers
   D. Peer-reviewed scientific journals
   E. Scientific meetings

11. The first time new equipment is used in the laboratory, actual testing samples should be used to see if the equipment is working properly.
   A. True
   B. False

12. Which of the following is **NOT** a tool to use when performing risk assessments?
   A. Reviewing equipment maintenance records
   B. Reviewing employee training records
   C. Wiping lab surfaces
   D. Reviewing published materials such as equipment manuals and package inserts
   E. Observing laboratory operations
   F. Reviewing injury and illness reports