



**MINISTRY OF HEALTH**  
SINGAPORE

# **NATIONAL BIOSAFETY STANDARDS FOR MAXIMUM CONTAINMENT FACILITIES**

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# INTRODUCTION

1. This document sets the requirements for facilities handling highly dangerous biological agents, which includes Second Schedule biological agents under the *Biological Agents and Toxins Act (BATA)*. These biological agents are generally regarded as risk group 4 agents and pose a high risk to individuals as infections may lead to life-threatening diseases. The requirements are aimed at protecting personnel who work with, or come into contact, directly and indirectly with the biological agents, and to prevent the release or spread of such biological agents into the environment.
2. Compliance with these requirements is not sufficient by itself to gain approval to possess and to use Second Schedule biological agents under the *BATA*. Additional considerations include those related to public health, national safety and security, and building codes which are not covered in this document. Users are advised to refer to the *BATA* for detailed regulatory requirements of the Ministry of Health, and to note that compliance with the requirements of other local regulatory authorities or committees such as the Ministry of Home Affairs, the Ministry of Manpower, the Animal and Veterinary Service, the National Environmental Agency, the Public Utilities Board and the Genetic Modification Advisory Committee, may also apply.
3. This document covers the design principles, management and operating policies, performance testing and good practices for facilities handling highly dangerous biological agents. The scope of this document includes the use of animals that can be handled safely within primary containment cages. Users are advised to seek guidance from the relevant authorities for work involving animals that cannot be placed within primary containment cages.

## LIST OF ABBREVIATIONS

|        |   |
|--------|---|
| ACMV   | Air Conditioning and Mechanical Ventilation                       |
| ANSI   | American National Standards Institute                             |
| ARA    | Activity-based Risk Assessment                                    |
| AVS    | Animal and Veterinary Services, Singapore                         |
| BASS   | Breathing Air Supply System                                       |
| BATA   | Biological Agents and Toxins Act                                  |
| BC     | Biosafety Committee   |
| BMS    | Building Management System  |
| BRM    | Biorisk Management  |
| BSC    | Biosafety Cabinet   |
| EDS    | Effluent Decontamination System                                   |
| FO     | Facility Operator   |
| HEPA   | High Efficiency Particulate Air                                   |
| IDA    | Inward Directional Airflow  |
| IEST   | Institute of Environment, Science and Technology                  |
| IPA    | Infrastructure Protection Act                                     |
| MCF    | Maximum Containment Facility                                      |
| MHA    | Ministry of Home Affairs, Singapore                               |
| MOH    | Ministry of Health, Singapore                                     |
| MOM    | Ministry of Manpower, Singapore                                   |
| OSH    | Occupational Safety and Health                                    |
| PAPR   | Powered Air-Purifying Respirator                                  |
| PM     | Post Mortem   |
| PPE    | Personal Protective Equipment                                     |
| PUB    | Public Utilities Board, Singapore                                 |
| SCDF   | Singapore Civil Defence Force                                     |
| SMACNA | Sheet Metal and Air Conditioning Contractors National Association |
| SOP    | Standard Operating Procedure                                      |
| UPS    | Uninterrupted Power Supply  |
| w.g.   | Inches of water gauge (unit of pressure; 1 in. w.g. = 250 Pa)     |
| WSH    | Workplace Safety and Health                                       |
| WSHA   | Workplace Safety and Health Act                                   |

## DEFINITIONS

| Term                   | Interpretation   |
|------------------------|--|
| Airtight door          | This door is designed to ensure that air is not able to leak through under normal operating conditions and to withstand pressure decay test requirements. Airtight doors can be achieved with inflatable or compression seals.   |
| Animals                | Refer to animals which can be fitted into airtight primary containment cages such as animal isolators or individually ventilated/contained cages. For animals which do not fall under this definition, please refer to AVS requirements.   |
| Anteroom               | A separate room located at entry/exit points of and within the containment facility. This space may have specific containment functions and may contain personal shower facilities and change areas.   |
| Authorised personnel   | Staff or individuals who have been granted access by the management of the containment facility and have been cleared by the regulatory authorities.   |
| Authorised visitor     | Individuals who have been granted access by the management of the containment facility but may not necessarily have been cleared by the regulatory authorities.  |
| Backdraft preventer    | An installation or system which prevents the clean air supply from being contaminated in the event of airflow reversal from the containment area. HEPA filters or isolation dampers are common choices of backdraft preventers.  |
| Backflow preventer     | An installation or system which prevents the contamination of the clean water supply leading into the containment area in the event of back pressure or back siphonage from the containment area during extreme pressure conditions. Backflow prevention devices shall incorporate test ports so that their functionality can be verified.     |
| Biological agent       | Any microorganism (including any bacterium, virus, fungus, rickettsia and parasite), any infectious substance (including prion), or any component of a microorganism or an infectious substance (but not including toxin) that is capable of causing death, disease or other biological malfunction in humans, as defined in the <i>BATA</i> . |
| Biological agent waste | Any unwanted, unused or obsolete biological agent or any material or waste contaminated with any biological agent, as defined in the <i>BATA</i> .   |
| Biosafety committee    | Biosafety committee appointed under section 39 of the <i>BATA</i> .  |
| Biosafety              | Specific for laboratory settings and refers to laboratory containment principles, technologies and practices which are implemented to  |

| Term                                  | Interpretation   |
|---------------------------------------|--|
|                                       | prevent unintentional exposure to, and accidental release of biological agents and toxins.   |
| Biosecurity                           | Specific for laboratory settings and refers to the protection, control and accountability for biological materials and sensitive information within laboratories in order to prevent unauthorised access, loss, theft, misuse, diversion or intentional release of either the biological materials or information.   |
| Certified facility                    | A facility certified under section 51 of the <i>BATA</i> .   |
| Clean area                            | Area which has not been exposed to biological agents/toxins and therefore shall not pose any biohazardous risk to individuals.   |
| Commissioning                         | A process whereby a newly constructed containment zone, or a newly modified containment zone is subjected to a series of performance tests to verify that the containment facility (including equipment, mechanical and engineering systems), operates in accordance with the planned design and specifications.   |
| Containment barrier                   | A designated physical boundary which separates the clean and dirty areas.  |
| Containment zone                      | A physical area which suffices the requirements for containment of biological agents/toxins. The containment zone may be a single room, a collection of co-located rooms (e.g. several non-adjoining but lockable containment laboratory work areas), or several adjoining rooms (e.g. a single laboratory with dedicated suites and separate animal rooms). Other than the laboratory area, the support area (including anteroom) may also be considered as part of the containment zone. |
| Critical door                         | Any door directly located at the containment barrier of a containment zone where inward directional airflow is required.   |
| Decontamination                       | Procedures which aim to remove or reduce biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects.  |
| Deep seal trap                        | A plumbing drain trap that has an effective depth for the maintenance of a water seal in accordance with air pressure differentials (i.e. water is neither siphoned into the room nor pushed through the trap).  |
| Dirty area                            | Area where infectious biological agents, toxins, and/or infected animals are handled and stored, and thus posing a risk or potential risk. The dirty change area shall be considered to be contaminated or potentially contaminated during normal operations.  |
| Effluent decontamination system (EDS) | A system/equipment used to decontaminate (via heat or chemical or both means) the effluent (liquid waste) prior to release from the EDS.   |
| Facility                              | Any premises or conveyance that is being used for:<br>(a) The storage of any biological agent or toxin; or   |

| Term  | Interpretation  |
|---|---|
|   | (b) The carrying out of any activity involving any biological agent or toxin;<br>as defined in the <i>BATA</i> .  |
| Facility operator (FO)                        | Used in relation to a facility. Refers to the person who operates the facility or who has the management or control of the facility, as defined in the <i>BATA</i> .  |
| High efficiency particulate air (HEPA) filter | A filter that is capable of demonstrating a minimum efficiency of removing 99.97% of 0.3µm diameter airborne particles, in accordance with the <i>ANSI N511</i> or equivalent industry standards.   |
| Highly dangerous biological agents            | Biological agents which can cause severe, life threatening, often fatal human infections with limited or no available effective prophylaxis or vaccines. These biological agents are easily transmissible on a widespread scale and pose a serious risk to public health. These include biological agents which are listed under the Second Schedule of the <i>BATA</i> , and are often categorised internationally as Risk Group 4 biological agents.  |
| Inactivated                                   | Used in relation to a biological agent, means that the biological agent has been rendered non-infectious and unable to replicate itself under any condition, as defined in the <i>BATA</i> .  |
| Isolation damper                              | An extremely low leakage device which provides a physical separation between designated areas in the ductwork of the air conditioning and mechanical ventilation (ACMV) system, for the following purposes (but not limited to):<br>(a) To prevent cross contamination of air between different levels of the containment zone in the event of an ACMV system failure; and<br>(b) To facilitate gaseous decontamination for designated spaces and HEPA filters.<br>An isolation damper may also be used as a backdraft preventer within the ACMV system (e.g. bubble-tight damper). |
| Pass-through equipment/fixture                | Equipment or fixtures with double-door compartments situated on a containment barrier that allow the safe movement of materials in and out of the containment zone. Examples include double door barrier autoclaves, pass-through chambers, dunk tanks, barrier cage washers and feed chutes, in which the interior door opens to the containment area while the exterior door opens to the non-containment area.   |
| Personal protective equipment (PPE)           | Equipment and/or clothing worn by personnel to provide a barrier against infectious material or toxins, thereby minimising the risk of exposure. PPE may include laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators.   |



| Term                             | Interpretation  |
|----------------------------------|---|
| Primary containment cages        | Sealed or sealable devices or equipment which provide an enclosure for laboratory animals, providing them with individual self-contained environments which are separated from the general laboratory environment. Air from within the containment cages shall be filtered through a HEPA filter before release.  |
| Second Schedule biological agent | Any biological agent specified in the Second Schedule of the <i>BATA</i> .  |
| Staff                            | Used in relation to any facility:<br>(a) Any person employed at the facility to do any work under a contract of service;<br>(b) Any consultant assisting the operator of the facility in the carrying out of any activity involving any biological agent or toxin at the facility; and<br>(c) Any other person (including any student or intern) authorised by the operator of the facility to carry out any activity involving any biological agent or toxin at the facility;<br>as defined in the <i>BATA</i> . |
| Sterilisation                    | Process that completely eliminates or destroys all living microorganisms, including bacterial spores, by means of physical or chemical methods.   |
| Toxin                            | Any poisonous substance that is produced and extracted from any microorganism, as defined in the <i>BATA</i> .  |
| Validation                       | The act of confirming that a method achieves its objective by observing that specific parameters have been met. For example, using biological indicators to confirm that a set autoclave cycle can decontaminate a representative load of waste in a given facility.  |
| Verification                     | The routine monitoring of equipment and processes to ensure continued efficacy between validations.   |

## PRINCIPAL REQUIREMENTS

These requirements cover physical design, containment management and operating practices of a maximum containment facility (MCF), which is equivalent to a containment level 4 (CL4), biosafety level 4 (BSL4), and physical containment level 4 (PC4) facility.

A MCF is required for all activities involving highly dangerous biological agents because they pose a high risk to individuals through infections which may result in life-threatening, frequently fatal diseases with limited or no available effective vaccines or treatments. This also includes dangerous biological agents with uncertain risk of transmission. All staff working in such facilities must understand the primary and secondary containment features provided by the laboratory design and containment equipment. Laboratory staff must be trained in standard and special practices related to the containment facility, and demonstrate competency for all activities involving highly dangerous and exotic biological agents.

There are two models of MCF:

- a) Primary containment facility - commonly known as cabinet or cabinet-line facility, where all work involving highly dangerous biological agents and toxins are performed within a totally enclosed primary containment system, such as in a Class III biosafety cabinet (BSC); and
- b) Suit facility - laboratory staff wearing a positive pressure air-fed suit to manipulate highly dangerous biological agents within a BSC or other primary containment equipment.

The requirements for both cabinet and suit MCFs are specified in the following parts:

- I. Physical containment requirements;
- II. Management and operational practice requirements; and
- III. Performance verification and testing requirements.

In the following parts, the criteria or requirements shall apply to both cabinet and suit facility, unless otherwise specified. Where the word “must”, “is/are to be” or “shall” is used, the requirement is mandatory.

Users of this document are also advised to refer to all legislations, guidelines and documents which are relevant and applicable to a MCF, as stipulated by the respective local regulatory authorities.

**PART I**  
**PHYSICAL CONTAINMENT REQUIREMENTS**

# PART I

## PHYSICAL CONTAINMENT REQUIREMENTS

Part I describes the physical containment requirements designed to mitigate the risks associated with the use, handling or storage of highly dangerous biological agents, toxins and related infectious materials. Physical containment is achieved through specific physical barriers provided by facility design and engineering controls. This part is divided into the following sections:

1. Location and structure;
2. Layout;
3. Containment barrier;
4. Access points and controls;
5. Surface finishes and casework;
6. Air ventilation system;
7. Facility services; and
8. Laboratory safety equipment.

### 1.0 Location and Structure

The following factors shall be taken into consideration when selecting a suitable location, design and structure for a MCF:

- (a) National regulatory requirements;
- (b) Nature of work activities and the impact of possible biological agent and toxin release into the surrounding environment;
- (c) Availability of resources to support construction of the facility, and to sustain the functionality and operation of the facility; and
- (d) Any possible or foreseeable natural disasters and security threats.

Prior to the commencement of the facility construction, users or organisations should be clear about the intended scope of work to be conducted within the facility and to perform thorough risk (including health, safety and security) assessments of all the work activities. Thereafter, users or organisations shall seek to incorporate building and engineering solutions at the beginning of the design phase to ensure that building requirements are met and planned designs are targeted at mitigation of all potential risks.

- 1.1 The MCF shall be built in a separate building or isolated area/floor within a building with controlled access. The location selected for the facility must be away from public areas or thoroughfare.
- 1.2 Physical structure of the MCF shall be designed to withstand internal stressors which may include possible extreme negative and positive pressure exerted on the facility, especially in the event of a failure of the air handling system, during gaseous

decontamination, ventilation system failure testing, as well as external environmental stressors (e.g. water, moisture) and any other foreseeable issues.

- 1.3 The MCF should adopt a “box-in-a-box” design whereby:
  - (a) The outer (or secondary barrier) wall is located at an appropriate distance away from the building’s external walls or facade to prevent potential issues, such as condensation and water seepage; and
  - (b) Such a design can serve as an additional layer of barrier in the event of the positive pressurisation of rooms, or the reversal of airflow.
- 1.4 Administrative areas such as offices shall be located outside of the MCF. Dedicated paper/computer work stations within the containment zone should be segregated from laboratory work areas and/or animal holding rooms.
- 1.5 Technical control and support service areas (including areas or rooms housing the building management system (BMS), air handling system, laboratory exhaust air filtration system, effluent decontamination system (EDS), breathing air supply system (BASS), chemical disinfectant supply system to shower room, etc.) shall be located in close proximity to the laboratory area for convenience, as well as to reduce the distance of potentially contaminated services or areas, and to minimise flow and pressure drop at the terminal units (of water/gas supply).
- 1.6 The facility must be gazetted as a protected place under the *Infrastructure Protection Act (IPA)* under the Ministry of Home Affairs (MHA) and must meet the requirements set forth in the *Fire Safety Act, Codes and Regulations* by Singapore Civil Defence Force (SCDF), MHA.

## 2.0 Layout

Thorough considerations and planning of the facility’s layout is essential to ensure that spaces are efficiently utilised, operationally feasible, ease of maintenance (of the facility), and most importantly, provide a safe and secure working environment for those who are working in the facility, and protect those who are outside of the facility and the external environment.

- 2.1 A **cabinet facility** shall compose of at least an anteroom, a clean change room (which can also be used as or be shared with the anteroom), a personal body shower room, a dirty change room, and laboratory areas containing Class III BSCs. Rooms in the facility shall be arranged to ensure sequential exit through a dirty change room, a personal shower and a clean change room. Figure 1 illustrates an example of a simple cabinet facility layout.

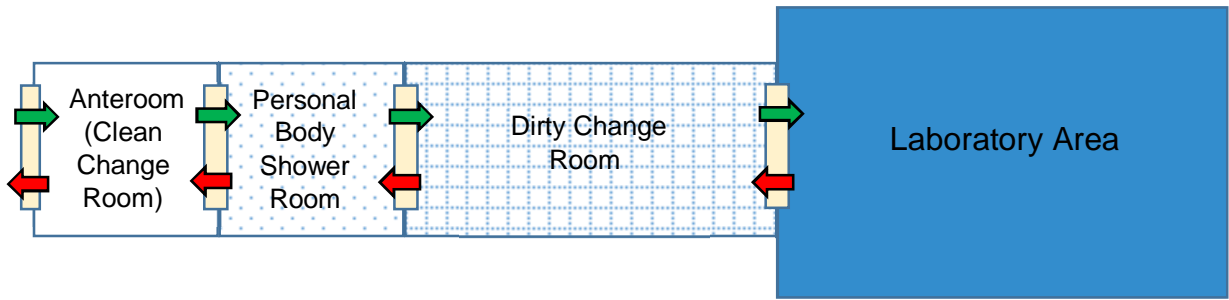




Figure 1: Simple schematic diagram of a cabinet containment facility. Entry into  facility; Exit from  facility. (Adapted from *Biological Agents: The Principal, Design and Operation of Containment Level 4 Facilities*. Advisory Committee on Dangerous Pathogens, United Kingdom.)

2.2 A **suit facility** shall compose of an airlock anteroom, a clean change room (which can also be used as or be shared with the anteroom), a personal body shower room, a suit room (a room for storing, donning and doffing positive pressure suits) which also serves as a dirty change area, a chemical decontamination shower room (fitted with airtight doors), and laboratory areas. Depending on the laboratory activities and functions, the facility may have multiple anterooms, e.g. additional anterooms for animals. Rooms in the facility must be arranged to ensure sequential exit through the chemical shower, suit and dirty change room, personal body shower, and clean change room. The requisite for airtightness for other rooms (other than the chemical decontamination shower room) shall be based on the MCF's risk assessment. Figure 2 illustrates an example of the layout for a simple suit facility.

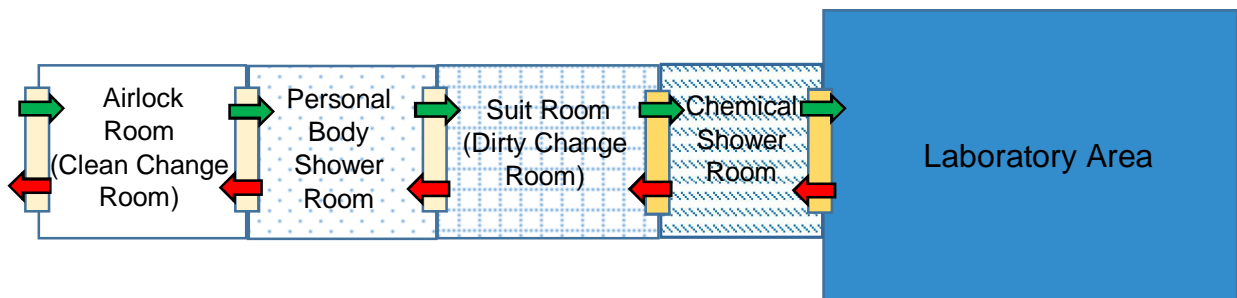




Figure 2: Simple schematic diagram of a suit containment facility. Entry  into facility; Exit  from facility. (Adapted from *Biological Agents: The Principal, Design and Operation of Containment Level 4 Facilities*. Advisory Committee on Dangerous Pathogens, United Kingdom.)

### 3.0 Containment Barrier

A containment barrier demarcates the boundary between clean and dirty areas of a MCF. While a containment barrier is predominantly established by physical structures (e.g. walls, doors, floors and ceilings), it is supported by inward directional airflow (IDA) maintained via

negative air pressure differentials. Points of access through the containment barrier are provided through doors and anterooms. Equipment like dunk tanks, pass-through chambers and double door autoclaves are examples of penetrations on the containment barrier.

- 3.1 Windows and vision panels on the doors and barrier walls shall be sealed, break-resistant and meeting the security requirements of a protected place, as prescribed by the MHA.
- 3.2 All doors are sealable for gaseous decontamination.  
***Additional requirement for suit facility*** - doors of critical rooms, including doors of the chemical decontamination shower room or doors to the containment zone, doors of inner anteroom(s) for animal rooms, and doors directly at the containment barrier must be airtight.
- 3.3 Doors of all critical rooms situated at the containment barrier (e.g. doors of anteroom, doors of chemical decontamination shower) shall incorporate an interlocking system to prevent simultaneous opening of doors that may lead to a compromised containment barrier. Interlocking doors shall have manual overrides or alternative means for emergency exit.
- 3.4 Pass-through double doors autoclave, dunk tank, fumigation chamber<sup>1</sup>, or an equivalent decontamination methods must be provided at the containment barrier for the passage of materials, supplies, or equipment in and out of the facility. They shall be installed in a manner that maintains the integrity of the containment barrier. All the pass-through equipment or fixtures shall be equipped with interlocking doors and visual/audio alarms to prevent simultaneous opening of both doors. Access to the external (exterior side) of the pass-through shall be limited to authorised personnel.
- 3.5 All penetrations of the containment barrier, including conduits and wiring, are to be sealed with a non-shrinking sealant which is compatible with the disinfectant(s) used.

## 4.0 Access Points and Controls

Restriction of access to the facility is an important safety and security measure. Only well-trained, competent and security cleared personnel are to be allowed access and work in the facility.

- 4.1 Biohazard warning signage, containment level, name and telephone number(s) of contact person(s) must be posted at the main entry to the MCF. Additional information including entry requirements (e.g. personal protective equipment, PPE), shall be

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<sup>1</sup> Dunk tanks and fumigation chambers are used for the removal of materials (which cannot be decontaminated through autoclave) from the facility.

posted at the point(s) of entry to the containment zone. Where unique hazards exist, relevant hazardous signage (e.g. radiation) or project-specific signage shall be posted at the relevant point(s) of entry or area.

- 4.2 All doors should be of a solid finish construction, chip and crack-resistant, and compatible with the decontamination chemicals used in the MCF. The size of the doorway should be sufficient to allow passage of equipment used in the MCF. The door frame shall be flushed with the walls. Both door and frame must be smooth and easily cleaned. External doors are to be fire and forced entry resistant, in accordance with the MHA's requirement.
- 4.3 All doors providing access to the facility shall be locked at all times. Access into the facility and the respective rooms within the containment zone shall be limited to authorised personnel, through a controlled access system with at least two layers of security access control, such as card and pin-code, biometric and pin-code, or any other combinations. If an electronic locking system is used, the main entry/exit of the facility shall be back up with an alternate controlled access system such as physical key-lock, with non-reproducible keys.
- 4.4 All doors providing accessing to the containment zone shall be fitted with audible/visual alarms to warn personnel inside and outside of the containment facility when any of the doors are not closed properly. There shall be continuous monitoring of the door access system at all times.
- 4.5 Anteroom shall serve as the entry/exit point for the containment zone. There shall be a dedicated change area for staff entry to the containment zone and to allow for separation of personal clothing (i.e. clean change area separated from dirty change area). Space shall be provided for the storage of personal clothing (e.g. street clothes, scrubs) and PPE.
- 4.6 The MCF shall comply and meet all of the MHA's physical security requirements for a protected place. In addition, the facility shall have in place:
  - (a) A system for identifying and responding to unauthorised entry to the facility including outside of office hours; and
  - (b) Closed circuit television cameras which are strategically sited to monitor all points of access to the facility and its support areas as well as sites where highly dangerous biological agents are stored or handled (e.g. freezers, incubators, pass-through facilities, cages or areas housing infected animals).

## **5.0 Surface Finishes and Case Work**

Use of appropriate surface finishes and materials facilitates the maintenance, cleaning, and decontamination of surfaces within the facility and will prolong its lifespan. In the selection of



materials and finishes, the factors that should be taken into consideration include: repeated exposure to fumigant or decontamination chemicals, material strength required for experimental activities and ease of maintenance.

- 5.1 Interior surfaces and coatings, including the walls, floors, ceilings, work surfaces, installations and furniture of the containment facility, shall be smooth, impervious, non-absorbent, cleanable and resistant to chemical, heat, scratch, stains, moisture, impact, and repeated decontamination or cleaning. Material compatibility with chemicals used for gaseous decontamination shall also be taken into consideration.
- 5.2 Material for floors shall be durable, waterproof and slip resistant. Floor drains or traps are highly discouraged in the containment zone. If unavoidable, they must be sealable for room fumigation and are designed to prevent accidental release of untreated fluid out of the facility.
- 5.3 Interior surfaces and installations of the facility shall be seamless and continuous with adjacent materials (e.g. where the floor meets the wall and where the wall meets the ceiling). All penetrations must be fully sealed to facilitate effective gaseous decontamination and prohibit animal and insect intrusion. Openings around doors must also be sealable for gaseous decontamination.
- 5.4 Laboratory installations and furniture including benches, shelves, handles and corner guards shall have smooth rounded corners/rims to prevent potential cuts and injuries. Furniture must be capable of supporting the anticipated loading. Under-bench storage should be kept to a minimum.
- 5.5 Adequate spaces shall be provided between laboratory installations, equipment and fixtures to allow easy access for cleaning and maintenance.
- 5.6 Extra considerations shall be made to ensure hollow structures, such as adjustable mounting tracks or open-ended pipes, can be infiltrated by decontamination gases during fumigation.

## **6.0 Air Ventilation System**

Air ventilation system (commonly known as air conditioning and mechanical ventilation system or ACMV in local context) is a critical engineering component of a containment facility. The system shall be designed and operated to minimise accidental release of biological agents into the environment, through the creation of an IDA into the facility, and the exhausting of containment zone's air through high efficiency particulate air (HEPA) filters before release into the environment.

- 6.1 A dedicated, independent and non-recirculating ventilation system shall be provided for the MCF. Supply and exhaust ventilation systems should not be shared with lower containment areas. If unavoidable, a thorough risk assessment must be carried out and effective risk management implementations (e.g. installation of gas-tight dampers and HEPA filters for isolation of the individual containment systems) must be in place. The design and risk management implementations must be reviewed and approved by independent, qualified and competent biocontainment engineers and biosafety professionals, prior to the construction of the facility. Airtightness and functionality of the gas-tight dampers and the efficiency of HEPA filters shall be monitored and tested on a regular basis, at least annually.
- 6.2 The supply and exhaust components of the ventilation system must be designed to maintain the containment facility at negative pressure<sup>2</sup> to the surrounding areas, and to provide differential pressure or IDA, as appropriate. Sufficient safeguards<sup>3</sup> shall be built into the system to prevent sustained positive pressurisation of the containment zone in the event of ACMV system failure.
- 6.3 Monitoring device(s) with visual display(s) of pressure differential(s), must be provided for each of the containment zone. Pressure differential monitoring lines penetrating the containment barrier shall be installed with HEPA filters or other acceptable alternatives. Monitoring devices shall be connected to an alarm system (audible and visual), which will alert personnel (inside and outside of containment zone) in the event of improper ACMV system operation or deviation(s) from the designed parameters.
- 6.4 The supply air ductwork located between the containment barrier and backdraft protection (e.g. HEPA filter), and the exhaust ductwork located between the containment barrier and HEPA filter(s) or downstream isolation damper(s) shall be made of stainless steel, and the joints (if any), are to be fully welded. These areas of the ductwork system must be designed to be adequately airtight in accordance with *ANSI/SMACNA 016 Seal Class A*, or equivalent.
- 6.5 Effective airflow control devices are to be provided on both the supply and exhaust air system, with flowrate sensors installed (for quick identification of discrepancies in airflow or pressure along the ducts) at strategic locations along the exhaust duct. The real time data should be relayed to a central monitoring system (e.g. BMS) and the responsible personnel shall be alerted immediately of any abnormality in the readings.

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<sup>2</sup> The pressure differential value chosen shall create sufficient and sustainable directional inward airflow (e.g. -30Pa or more negative), which does not impede the facility's operations or biosafety safeguard features. It is to note that with the use of a low differential pressure, facility doors may be opened with ease but this may result in the IDA being easily breached. In turn, if a high differential pressure is used, very high negative pressures are created at the centre (or most inner zone) of the facility and may have an impact on the structure of the facility (e.g. walls, windows and doors).

<sup>3</sup> Examples: Automatic (mechanical or electronic) interlocking of supply and exhaust air systems, and appropriate level of redundancies (e.g. redundant exhaust fans, supply fans, stand-by power supply and uninterrupted power supply).

- 6.6 Supply air shall pass through at least one HEPA filter and the exhaust air must pass through two HEPA filters in series, with the first HEPA filter placed as close to the containment barrier as possible. All exhaust air (100%) shall be discharged directly to the outdoors with exhaust fans which are capable of discharging the air at least 3 metres above the discharge nozzle, or the highest point of any neighbouring environment of the same building, and away from any air intakes of a building.
- 6.7 All HEPA filters shall be resistant to heat and high temperature, of H13 grade (or higher), or equivalent as described in industry standards such as *IEST-RP-CC001.5*. The filters should be located as near as practicably possible to the cabinet and laboratory area in order to minimise the length of potentially contaminated ductwork.
- 6.8 HEPA filters shall be placed in HEPA filter housings which are designed to:
- a) Withstand structural changes at applied pressure of 1000 Pa, in accordance with *ASME N511 and AG-1*; and
  - b) Have bubble-tight isolation dampers, decontamination ports, filter scanning ports and be designed with features to facilitate *in-situ* filter isolation, decontamination and filter leak detection (e.g. using Dioctyl Phthalate or Poly Alpha Olefin).
- 6.9 HEPA filter loading should be monitored using differential pressure sensors fitted across HEPA filters. It is recommended that airflow and pressure drop data from the sensors be monitored through the BMS, and the responsible personnel be alerted immediately of any abnormality in the readings.
- 6.10 Sections of the supply and exhaust air systems located outside the containment barrier shall be accessible for maintenance and repair. The ventilation system should be designed in such a way (e.g. through the use of manual or electrically operated mechanical dampers) that will allow the facility or the containment zone, and the exhaust ducts to be isolable and sealable for fumigation.

## 7.0 Facility Services

Other facility services that support the functions and operations of the containment facility include plumbing, electrical, fire suppression, communication and information technology systems.

### 7.1 Water, fire suppression and drainage systems

7.1.1 Emergency eyewash stations in the MCF shall meet performance standards stated in *ANSI/ISEA Z358.1-2014*

- (a) For **cabinet facility** - emergency eyewash stations must be readily available in all laboratory areas.

- (b) For **suit facility** - emergency eyewash stations must be readily available for use, such as during maintenance and repair periods. To avoid contaminating the eyewash, a portable eyewash station is recommended.
- 7.1.2 Hands-free sink must be provided near the door of the anteroom to facilitate hand washing before exit from the MCF.
- 7.1.3 For **cabinet facility** - additional hands-free sinks should be provided near the door of the laboratory area or cabinet room(s) and in the clean change room. All sinks in the laboratory areas with Class III BSC or where biological agents may be handled (e.g. freezer room) shall be made of durable and chemical (or disinfectant) resistant materials and be connected to the facility's effluent decontamination system (EDS). No untreated (or non-decontaminated) liquid waste is to be flushed down the sinks.
- 7.1.4 For **suit facility** - hands-free sinks or disinfectant sinks/containers shall be provided for decontamination of suit outer gloves and/or suit footwear at strategic locations, such as within the experimental procedure rooms, in accordance with the containment zone activities. Such sinks/containers shall be made of durable and chemical (or disinfectant) resistant materials and be connected to the facility's EDS. No untreated (or non-decontaminated) liquid waste is to be flushed down the sinks.
- 7.1.5 Chemical decontamination shower must be provided in a **suit facility**. The chemical shower room and associated fittings (e.g. chemical holding tank, plumbing, switches, lights, etc.) shall be made of materials that are resistant to the chemical (or disinfectant) used in the shower, and be designed to ensure sufficient capacity for all personnel working in the facility. A device or mechanism with double redundancy should be in place to alert operators of low levels of chemical. A back up chemical decontamination shower shall be designed for the event of failure of the chemical shower system or emergency exit for decontaminating positive pressure suit.
- 7.1.6 All plumbing services that penetrate the containment walls, floors, or ceiling must be fitted with isolation valves and at least one backflow prevention device, such as a reduced pressure dual check valve. The backflow preventer(s) shall be located outside of the containment zone and is/are subjected to annual certification. Atmospheric plumbing (or drainage) venting systems must be fitted with two HEPA filters in series and be sealed up to the second filter. The filters should be designed to enable isolation for decontamination.
- 7.1.7 All floor traps and drainage pipes serving areas inside the containment barrier shall be independent from those of lower containment areas and be directly

connected to an EDS. All drainage and associated piping (including plumbing vent lines) connected to the EDS shall be airtight (in accordance with PUB standards), chemical resistant, compatible with gaseous decontamination, and located in areas which facilitate inspection and maintenance.

7.1.8 Drains and traps are to be equipped with deep seal traps of sufficient depth to maintain a water seal which is stable under designed pressure differentials, under normal and failure conditions of ACMV system. The liquid column within the traps shall be determined by taking into consideration the possible extreme room pressure generated in the drain pipe, for example, in the event of a failure of supply air handling unit with exhaust fans continuing to run, or vice versa.

7.1.9 The facility must comply with *Fire Safety Act, Code and Regulations*, and a system shall be in place to manage the water released from the firefighting provisions (e.g. fire sprinkler discharge). Discharge of the water into the main sewage or watercourse shall be done in accordance with PUB's requirements and the *Environmental Protection Management Act*.

## 7.2 Electrical and power supply

7.2.1 All services and equipment critical to maintaining containment and security of the facility shall be supported by an automatically activated emergency power source. In the event of an electrical power loss, the emergency power must be able to support all fail-safe and fail-secure<sup>4</sup> requirements of the MCF, as determined by risk assessment. Uninterrupted power supply (UPS) shall be available to ensure smooth transition of electrical supply to emergency power during power failure. Critical equipment and services may include ACMV system, life support system (*for **suit facility***), alarms, lights, entry and exit controls, BMS (or automation system), security system, door gaskets (if airtight doors are sealed pneumatically) and BSCs.

7.2.2 The BMS system should be designed in such a way that the pre-programmed values/parameters/set points will not be affected in the event of a power failure. For instance, in the event of a power failure, the system is able to restart when the power supply is restored, without the need for the user to reset or re-programme the parameters.

7.2.3 Exposed conduits, piping, and other services shall be mounted in a manner which allows for effective decontamination of all surfaces. All penetrations

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<sup>4</sup> Examples of fail-safe requirements/features include biosafety cabinets remaining functional to avoid puff-back, ensuring that the containment facility does not become positively pressured or maintains pressure neutrality relative to the external environment during ACMV failure; while fail-secure requirements/features include ensuring doors providing accessing to the containment facility remain locked during power failure, and access into the facility or to the freezers housing the biological agents remains restricted.

(arising from electrical and other conduit services) shall be sealed with non-shrinking sealants.

### 7.3 Communication system

7.3.1 A communication system shall be provided for laboratory personnel within the facility and to communicate with personnel at support facilities or outside the containment facility. Cordless hands-free telephones with voice activated transmit features should be considered. If a two-way communication system is used, measures shall be implemented to safeguard the communication of sensitive information.

7.3.2 ***Additional consideration for personnel working in suit facility*** — as air-fed positive pressure suits can be excessively noisy during use, direct communication between laboratory personnel can be difficult. Thus, this shall be taken into consideration when selecting a suitable communication equipment for the facility.

### 7.4 Information technology system

In planning for the provision of an information technology (IT) system to support the MCF operations, consideration should be made in terms of IT security (e.g. linkage to an independent secure server) and suitability of platforms. IT systems may include ACMV system, BMS and networks for information transfer.

### 7.5 Central vacuum system

The use of a **central vacuum system** is not recommended in the containment facility. However, if there is a central vacuum system, the system must not serve areas outside the containment facility. Two in-line HEPA filters must be placed near each use point and the filters shall be installed to permit in-place decontamination and replacement.

## 8.0 Laboratory Safety Equipment

Laboratory safety equipment refers to equipment or devices used to protect or minimise direct contact and/or exposure of laboratory staff and environment to biological agents, toxins, and other dangerous materials through the formation of a barrier. Commonly used laboratory safety equipment in a containment facility include primary containment devices such as BSCs, isolators, centrifuges with sealable cups, ventilated cage racks, and equipment supporting the sterilisation/decontamination and waste management (e.g. pass-through autoclaves, fumigation chambers, dunk tanks and EDS). Facility operators shall ensure that sufficient redundancies and/or appropriate measures are in place to manage all foreseeable equipment failures.

## 8.1 Biosafety cabinet

### 8.1.1 For *cabinet facility*

- (a) **Class III BSC** (individually or in series) must be provided for the handling and manipulation of infectious biological agents and toxins.
- The BSC shall be designed such that the sample/waste exit point is attached to an autoclave, a pass-through dunk tank, a fumigation chamber or an equivalent decontamination chamber;
  - The BSC must have a HEPA filter on the supply intake, and the backflow preventer device in the supply duct must be provided in a manner that prevents positive pressurisation of the cabinet;
  - The air from the BSC must be directly, and independently exhausted through two HEPA filters in series (on the exhaust outlet of the unit);
  - Airtight dampers must be installed in both the supply and exhaust ducts of the BSC to permit gas or vapour decontamination of the unit. Ports for injection of test mediums must be available in a manner that allows for testing of individual filters within the housing;
  - The interior of the BSC shall be constructed with stainless steel material, be fully welded and have smooth finishes that can be easily cleaned and decontaminated. All sharp edges on cabinet finishes must be eliminated to reduce the potential for cuts and tears of gloves. Equipment to be placed in the cabinet should also be free of sharp edges or other surfaces that may damage or puncture the cabinet gloves. Should the design of the BSC allow any of the panel(s) to be opened for purposes such as for loading and unloading of laboratory equipment, the panel(s) shall be secured; and
  - The BSC shall be placed in a manner which ensures that there is sufficient space within and outside of the BSC to enable personnel to work in a safe manner.
- (b) **If Class II BSC** is used in the cabinet facility, it shall comply with international standards such as *NSF49*, *BS EN12469* or *BS5726*. Provisions shall be in place to ensure proper safety cabinet performance and the air system operation must be verified.
- (c) **All BSCs** (Class II and III) shall be equipped with a real time monitoring and warning system to alert users when pressure differential of the cabinet system falls out of the safety range.

### 8.1.2 For *suit facility*

- (a) Suitable types of BSCs shall be made available for the handling and manipulation of infectious biological agents and toxins, in accordance with risk assessments and work activities.
- (b) Class II BSC must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations, and it shall be

located away from doors, heavily travelled laboratory areas, and other possible airflow disruptions.

- (c) For Class III BSC, the supply air duct shall be provided with backflow prevention device and supply air shall be filtered through HEPA filter in such a manner that prevents positive pressurisation of the cabinet.
- (d) Exhaust air from all BSCs (Class II and III) shall pass through two HEPA filters in series.
- (e) BSC (Class II and III) shall be installed in a manner that facilitates isolation and fumigation of the unit (e.g. installation of airtight damper along the exhaust duct of ducted BSC).
- (f) The interior of the BSC (Class II and III) shall be constructed with smooth finishes that can be easily cleaned and decontaminated.
- (g) Re-circulation of HEPA filtered exhaust air from the Class II BSC back into the laboratory shall be determined based on risk assessment.
- (h) Potential for air excursion from Class II BSC into the room during a failure of ACMV system or the BSC exhaust fan, shall be eliminated through engineering design. If the potential for airflow reversal cannot be totally eliminated, the risks associated with air excursion shall be mitigated through physical and operational means.
- (i) All BSCs (Class II and III) shall be equipped with a real time monitoring and warning system to alert users when BSC operations deviate from safety mode.
- (j) All Class II BSCs shall comply with international standards such as *NSF49*, *BS EN12469* or *BS5726*.
- (k) It is recommended the use BSCs with designed models which have been tested/certified directly by the respective BSC certifying body, in accordance with their standard requirements.

## **8.2 Pass-through autoclaves**

8.2.1 A double door pass-through autoclave must be available at the containment barrier for decontaminating materials passing out of the facility. The interface between the interior door of the autoclave and the physical wall of the containment shall be sealed hermetically and the seal must be durable, airtight and water tight, and is capable of expansion and contraction. The autoclave doors must be interlocked so that only one door can be opened at any time, and be automatically controlled so that the outside door (at the clean side of the autoclave) can only be opened after the decontamination cycle has been completed.

8.2.2 Gas and liquid discharge from the autoclave chamber must be decontaminated. Autoclave decontamination processes shall be designed so that unfiltered air or steam exposed to infectious material cannot be released directly into the environment. Autoclaves designed with appropriate filtration of exhaust gases



and containment of condensates are recommended for this purpose. Otherwise, autoclave condensate drains located outside the containment barrier shall have a closed connection to the drain piping, serving areas inside the containment barrier.

8.2.3 Control systems and utility connections of the pass-through autoclave should be easily accessible from the non-containment zone for maintenance and repair purposes.

8.2.4 If larger equipment is to be autoclaved, roll-through type of autoclaves should be considered. This is to minimise other hazards created from lifting contaminated equipment into the autoclave.

### **8.3 Breathing air supply system for suit facilities**

8.3.1 The BASS shall be a dedicated and standalone system which cannot be shared with other supply air systems of the facility. There shall be sufficient breathing air supply and air hose connections provided in strategic areas and locations where positive pressure suits are worn. The number of connection points should be sufficient to avoid the air hose from being excessively stretched or tangled. Each air hose is only connected to one suit. The piping of the BASS is to be fitted with two (in series) backflow prevention devices to ensure that no backflow from the laboratory occurs.

8.3.2 A BASS shall be available for personnel wearing positive pressure suits. The quality of breathing air supplied by the BASS<sup>5</sup> shall comply with SS511:2010<sup>6</sup> or its equivalent internationally accepted air quality standard. Checks shall be carried out to ensure an acceptable quality of air is supplied as per requirements.

8.3.3 In the case when a fuel generator is used, efforts shall be made to avoid air-intake near the exhaust outlet.

8.3.4 All exposed piping and mechanical parts servicing the BASS shall be adequately shielded and protected (e.g. using guards) to avoid being compromised or accidentally damaged, such as during routine maintenance of the surrounding systems or services.

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<sup>5</sup> Oil-free compressor is recommended as this will help to reduce the likelihood of incomplete oil combustion which is a source of carbon monoxide content in the breathing air.

<sup>6</sup> SS511:2010 (Singapore Standards - Code of practice for diving at work) stipulates that the breathing air quality shall (a) have no objectionable or nauseous odour; (b) contain not less than 20% and not more than 22% by volume of oxygen; (c) contain not more than 11mg/m<sup>3</sup> of carbon monoxide (10ppm by volume); (d) contain not more than 900mg/m<sup>3</sup> of carbon dioxide (480ppm by volume); and (de) contain not more than 0.5mg/m<sup>3</sup> of oil.

- 8.3.5 The BASS shall be equipped with system failure alarms, with audible and visual warning alarms. The alarms shall be connected to the BMS that is monitored by competent personnel outside of the containment zone. An automatic switch-over redundancy system and independent backup system shall be in place.
- 8.3.6 The BASS must be designed to have adequate capacity (e.g. back up supply system) for emergency evacuation of all personnel in areas where positive pressure suits are worn. Calculations for the estimation of breathing air capacity shall include time for shutting down experiments safely and decontaminating before leaving the laboratory area.
- 8.3.7 Where electric air compressors are used, in addition to the standard emergency power supply, the BASS shall also be supported with an alternative power supply (double redundancy of power supply). The use of compressed air cylinders as the backup air supply system may help to circumvent the need for a double redundancy power supply.

#### **8.4 Positive pressure suit for suit facilities**

- 8.4.1 The positive pressure suit should be one piece of full encapsulated garment that is made of chemical (including disinfectant used for decontamination) and puncture resistant plastic material. The suit should be equipped with a wide field vision visor, heavy duty zipper with sealable flap, internal air distribution manifold and molded cuffs. The air system serving the suit shall incorporate an in-line HEPA filter for the air supply, coupling connectors and one-way valves for both exhaust and supply air hoses. It is recommended that the suit be designed with integrated boots and according to individual wearer's size.
- 8.4.2 Positive pressure suits shall operate in accordance with the manufacturer's specifications and are capable of maintaining a positive pressure within the suits when the material is compromised.
- 8.4.3 Noise levels within the suits should not exceed the permissible exposure limit of 85dB(A) over an 8-hour workday. Otherwise, effective hearing protection shall be implemented.

#### **8.5 Effluent decontamination system**

All liquid waste (or effluent), which include run-off waste from the decontamination shower, autoclaves, laboratory sinks, hand-wash sinks, floor drains in the containment zone, and the autoclave drains, must be collected in an EDS where it is treated before being released from the EDS.

- 8.5.1 An EDS must be installed to handle the liquid effluent generated from the MCF. It shall be a dedicated system and shall not be shared with a facility of lower containment level. Both batch and continuous EDS have their advantages and disadvantages. Facilities shall conduct an assessment to decide on the system which is most appropriate for their needs.
- 8.5.2 The EDS shall be designed to cater for sufficient redundancy, for both the holding and treatment tanks, whenever necessary. It is recommended that liquid effluent be gravity fed to the tanks. These tanks shall have the capacity to contain the full volume of the operation capacity with redundancy considerations. The EDS shall also be designed with sufficient preventive features to ensure that there is no occurrence of accidental discharge of untreated effluent.
- 8.5.3 EDS tanks shall be fitted with devices or mechanisms to prevent blockages and accidental overfilling of the EDS tanks, and alarms must be available to alert operators of excess filling of the holding tank. The inclusion of an automatic shut-off valve to the laboratory water supply would prevent this from happening and should be considered. The EDS shall be bunded to contain spillage up to the full capacity of the EDS with redundancy considerations (e.g. the total volume of the tanks plus an additional 20% redundancy).
- 8.5.4 The EDS (including its connecting piping, valves and tanks) shall be constructed with materials which are heat and chemical resistant. The system should be completely sealed and leak- proof with minimal joints. The joints must be fully welded.
- 8.5.5 The design of the EDS shall provide the means to verify the inactivation of biological agents/toxins, and be equipped with an alarm system to warn users of failure of a decontamination process. Thermally controlled EDS shall be equipped with temperature monitoring devices which are calibrated at least annually or as recommended by the manufacturer, whichever occurs earlier. EDS vent lines shall be provided with two stages of HEPA filtration.
- 8.5.6 EDS shall be located as close to the discharge point as possible to reduce the risk of contaminating pipes. Drain piping shall be directly connected to the EDS and should be sloped to ensure gravity flow, towards the EDS tank. All piping of the EDS should be readily accessible for routine inspection and should not be buried or enclosed. Double-wall containment piping may be considered with leak-detection systems enclosed within the cavity. The network of pipes shall be connected by means of full weld.

8.5.7 The EDS should be housed in a room with the following features:

- (a) Lockable doors;
- (b) Doors with biohazard signage;
- (c) With an anteroom;
- (d) With IDA;
- (e) Exhaust air to be filtered via a HEPA filter;
- (f) Vent pipes with 2 stages of HEPA filtration;
- (g) Fitted with leak monitoring devices (for liquids);
- (h) Sealable for gaseous decontamination;
- (i) Waterproof floor and appropriate height for the wall (especially if the EDS room is situated above other sensitive areas or materials); and
- (j) A spillage response procedure must be in place for the room and all relevant equipment shall be easily accessible.

8.5.8 All discharge from the EDS shall comply with the relevant national regulations.

**PART II**  
**MANAGEMENT AND OPERATIONAL PRACTICE**  
**REQUIREMENTS**

## PART II

# MANAGEMENT AND OPERATIONAL PRACTICE REQUIREMENTS

Part II describes the management and operational practice requirements aimed at mitigation and control of risks associated with the use, handling or storage of highly dangerous biological agents and toxins, including infected animals in the MCF. Effective risk management and operational practices can be achieved through the development and implementation of a biorisk management (BRM) programme. A comprehensive BRM programme shall encompass the following aspects:

1. Administrative controls;
2. Risk assessment and planning;
3. Biosafety and biosecurity manual;
4. Occupational safety and health programme;
5. Personnel training programme;
6. Personal protective equipment;
7. Entry and exit of personnel and material movement;
8. Work practices;
9. Housekeeping and general maintenance;
10. Animal work considerations;
11. Decontamination and waste management;
12. Emergency response plan and procedures;
13. Incident investigation and reporting;
14. Records and documentation; and
15. Continual improvement.

### **1.0 Administrative Controls**

Under the *BATA*, it is the responsibility of the facility operator (FO) to safeguard the safety and security of all biological agents and toxins under his/her possession, and to ensure that all individuals (e.g. laboratory personnel, visiting workers, service engineers) entering and/or working in the facility, and members of the public, are protected from all potential hazards arising from activities conducted in the facility.

- 1.1 The FO shall establish a BRM programme and is accountable for the proper implementation of the programme.
- 1.2 The FO shall appoint a biosafety committee and a biosafety coordinator to effectively implement the BRM programme. The duties of the biosafety committee and the biosafety coordinator shall include:

- (a) Conducting laboratory biosafety and security risk assessment; devising laboratory biosafety and security risk management policies, measures and procedures; devising training programmes; implementing policies and programmes; monitoring and reviewing the effectiveness of such policies and programmes;
  - (b) Verifying the accuracy and completeness of all approval/permit/license applications required by, or obtained from, the respective regulatory authorities, including under the *BATA*;
  - (c) Communicating with the relevant authorities on behalf of the FO, whenever applicable;
  - (d) Ensuring and monitoring compliance with all applicable legislations, (including the *BATA*, *IPA* and *WSHA*), guidelines (e.g. *Singapore Biosafety Guidelines for Research on GMOs*) and institutional/MCF's policies, guidelines and relevant standard operating procedures (SOPs).
- 1.3 The FO may delegate the responsibilities of the day-to-day management of the BRM programme to suitable personnel who are competent and possess the necessary qualifications. In assigning of critical roles and responsibilities, considerations shall include potential areas with conflicts of interest. Reference shall be taken from the *BATA* which details the responsibilities of the FO, biosafety committee, biosafety coordinator and all other administrative controls requirements.
- 1.4 All individuals (e.g. laboratory personnel, visiting workers, service engineers) with access to the facility and highly dangerous pathogens must be authorised by the FO. The FO shall also ensure that these individuals have been security cleared by the relevant regulatory authorities, whenever applicable (see details in Part II 7.1.2).
- 1.5 In the MCF where the *BATA* Second Schedule biological agents are handled, changes in the programme intent, or deviations in the use, activities, SOPs and/or any other matters which may impact public health, biocontainment, biosafety or biosecurity must be submitted to the MOH for review and approval prior to implementation.

## **2.0 Risk Assessments and Planning**

- 2.1 An overarching risk assessment shall be conducted to identify all hazards and threats, as well as to document the appropriate mitigation strategies for the facility where activities involving biological agents or toxins are carried out. The risk assessment and mitigation strategies shall be documented clearly and records kept.
- 2.2 An activity-based risk assessment (ARA) shall be conducted and documented to examine each activity involving biological agents or toxins, ensuring risks are identified, and risk mitigation measures are incorporated in the development of safe and secure work practices. The ARA shall thoroughly reflect the nature of the work being assessed,

covering all aspects of risk including biological (safety and security), physical, chemical, radiation, mechanical, electrical and ergonomic. The risk assessment shall take into consideration personnel directly involved in the work and those not directly involved in the work but may also be affected, such as engineers and visitors. A training needs assessment (see Part II Section 3.6) shall be conducted for all workers.

- 2.3 The risk assessment shall be reviewed at least biennially, or when there is a change in activity procedures/equipment/infrastructure, occurrence of an incident or when there is an emergence of new security threats, whichever occurs earlier. The review should ensure that all of the hazards and security threats associated with the work and the MCF operations have been identified and that the measures put in place to prevent or control exposure are suitable and sufficient.
- 2.4 A system shall be in place to ensure that no experimental work is performed until all documentation relating to the process has been approved by the biosafety committee and the FO.

### **3.0 Biosafety and Biosecurity Manual**

- 3.1 A biosafety/biosecurity manual shall be developed, implemented and kept up to date. The manual shall be read and understood, made available, accessible and followed by all personnel. The manual shall cover the institutional biosafety policies, programmes and plans, based on overarching risk assessments and ARAs. The manual shall include at least:
- (a) The programme intent;
  - (b) A brief description of the physical design and operation parameters of the containment zone and systems;
  - (c) A description of:
    - Biosafety programme;
    - Biosecurity plan;
    - Occupational safety and health surveillance programme;
    - Personnel training programme;
    - Decontamination and waste management programme;
    - Requirements, workflow and procedures for inactivation and/or removal of biological agents and toxins from samples;
    - Emergency response plan (ERP) and incident management (which includes reporting) procedures;
    - Housekeeping programme, including pest management;
    - Facility and equipment maintenance programme for components of the containment zone, including integrity and performance testing of primary containment devices;
    - Monitoring of the biorisk management system of the facility; and



- (d) SOPs for safe working practices specific to the containment zone.
- 3.2 A biosecurity plan shall be developed based on a security risk assessment, and subsequently be implemented, evaluated and improved as necessary, and kept up to date. The biosecurity plan shall include mitigation strategies which comply with the *IPA* requirements and for risks associated with:
- (a) Physical security;
  - (b) Personnel suitability and reliability;
  - (c) Accountability for biological agents, toxins, and other regulated infectious materials (including the use, storage, transfer and transport of such materials);
  - (d) Information (security sensitive or confidential information such as information pertaining to the inventory and storage location of the biological agents and toxins, and access codes to the freezers where biological agents or toxins are stored);
  - (e) Information technology system (e.g. ACMV and BMS); and
  - (f) Incidents and emergency response.
- 3.3 An occupational safety and health programme, based on overarching risk assessments and ARAs, shall be developed, implemented, and kept up to date.
- 3.4 A hazardous chemical management programme shall be implemented, where applicable.
- 3.5 A respiratory protection programme shall be in place when respirators are in use. This shall include respiratory protection compatibility.
- 3.6 A training programme shall be developed based on a training needs assessment, and subsequently be implemented, evaluated and improved as necessary, and kept up to date.
- 3.7 A system shall be in place to ensure all methods and procedures for inactivation and/or removal (e.g. through the use of filtration) of biological agents, toxins or samples are adequately validated to be effective, reviewed and approved by the biosafety committee prior to use. To ensure continuous effectiveness, the approved inactivation and removal methods and procedures shall be verified regularly as determined by risk assessment. Conditions for revalidating the methods and procedures shall also be determined. All validation, revalidation and verification results are to be documented and kept on file.
- 3.8 SOPs specific to the nature of the work being conducted in the containment zone shall be developed and documented, including:
- (a) Use of PPE;
  - (b) Entry/exit procedures for personnel, animals, and materials (including consumables, live or inactivated biological or related materials);

- (c) Use of primary containment devices;
- (d) Decontamination and waste management procedures;
- (e) Procedures for transferring and transportation of infectious materials and toxins;
- (f) Animal work procedures, if applicable;
- (g) All other procedures or tasks involving infectious materials, toxins, and/or infected animals, as determined by an ARA; and
- (h) Emergency response procedures.

## **4.0 Occupational Safety and Health Programme**

The occupational safety and health (OSH) programme aims to prevent, detect and manage illnesses related to personnel exposure to biological agents or toxins, and all other hazards as identified through risk assessment. It should detail response mechanisms through which potential infections, ill-health and injuries can be efficiently identified and have personnel treated before serious injury, illness or disease is sustained, or transmission to the public occurs.

- 4.1 Laboratory personnel and support staff must undergo occupational medical consultation and/or assessment by an occupational health physician and be offered all available immunisations for agents handled or potentially present in the facility, prior to starting work.
- 4.2 A system must be established for reporting and documenting laboratory accidents, exposures, employee absenteeism and medical surveillance of potential laboratory-associated illnesses. An essential adjunct to such an occupational medical services system is the availability of a facility for isolation and medical care of personnel with potential or known laboratory-acquired infections.
- 4.3 Facility should consider the need for collection and storage of serum samples from at-risk personnel.

## **5.0 Personnel Training Programme**

Working in a MCF can be physically rigorous and demanding, and requires a high level of technical expertise. It is important for staff to be equipped with the appropriate knowledge and skills, and be competent in performing their duties in the facility.

- 5.1 A detailed, well-documented training programme must be in place, to ensure staff:
  - (a) Have a clear understanding of all identifiable risks to their health and safety arising from the work and the working environment;

- (b) Acquire the relevant knowledge and skills regarding the concepts, tools and practices which will protect them from exposure to the hazards; and
- (c) Are aware of the appropriate actions to be taken in dealing with unforeseen situations which may result in exposure.

5.2 Staff training shall include the following:

- (a) Biosafety/biosecurity manual and SOPs, as determined by the training needs assessment;
- (b) Potential hazards (including biological, chemical, radiological, ergonomic, mechanical and electrical hazards and physical hazards such as fire, noise, etc.) associated with the work involved, including the possible symptoms of illness caused by infectious materials or toxins in use, and the precautions to prevent exposure, release of biological agents or any other hazards from the facility;
- (c) Relevant facility design and operations of the containment zone and containment systems;
- (d) Correct use and operation of laboratory equipment, including primary containment devices;
- (e) Good laboratory techniques, special techniques (e.g. technique to handle and restrain animals) and any other subjects as determined by the training needs assessment; and
- (f) Emergency response procedures.

5.3 Visitors, maintenance and janitorial staff, contractors, and individuals who require temporary access to the containment zone shall undergo the stipulated training requirements and/or be accompanied in accordance with their anticipated activities in the containment zone.

5.4 A system shall be in place to assess staff competency. Trainees are to be supervised by authorised personnel when engaging in activities with infectious biological agents or toxins until they have fulfilled the training requirements and are assessed to be competent in performing the activities.

5.5 Staff training needs assessment shall be reviewed at minimum, annually. Additional or refresher training is to be provided as determined by the review process or when warranted by a change in the BRM programme.

5.6 Refresher training shall include emergency response procedures and be conducted on a regular basis, in accordance with the training needs assessment. All laboratory personnel shall participate in emergency response training.

## **6.0 Personal Protective Equipment**

Personal protective equipment includes protective equipment and clothing which are designed to minimise the risk of personnel exposure to biological agents and toxins. PPE usually serves as a last line of defence to prevent exposure in the event of failure in the administrative or engineering controls. However, in places like animal cubicles and post mortem (PM) rooms, PPE could become the primary defence for personnel against exposure. Selection of PPE is determined by an ARA and is specific to the biological agents and toxins being handled and the work activities performed.

### **6.1 Cabinet facility**

- 6.1.1 Personnel in the containment zone must wear protective laboratory clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. All protective clothing must be removed in the dirty change room before personal body showering and/or exiting the facility. Reusable clothing must be autoclaved prior to removal from the facility for laundering.
- 6.1.2 Disposable gloves must be worn underneath cabinet gloves to protect the worker from exposure if the cabinet gloves are compromised. Potentially contaminated disposable gloves must not be worn outside of the containment zone.
- 6.1.3 Face and eye protection should be used where there is a risk of exposure to splashes or flying objects.
- 6.1.4 Respiratory protection should be worn where there is a risk of exposure to infectious aerosols which can be transmitted through the inhalation route, as determined by an ARA.

### **6.2 Suit facility**

- 6.2.1 Positive pressure suits must be worn before entering the containment zone. Beneath the positive pressure suit, workers shall wear the appropriate laboratory clothing (such as scrub suits) and at least a pair of inner disposable gloves to protect against breaking or tearing in the outer suit gloves.
- 6.2.2 Personnel working in animal rooms, animal cubicles, or PM rooms shall wear dedicated protective footwear (whenever applicable), and/or any additional protective equipment such as bite proof gloves, as determined by an ARA.
- 6.2.3 Decontamination of outer suit gloves should be performed during laboratory operations to remove gross contamination and minimise cross contamination

within the laboratory. Inner gloves and laboratory clothing are to be removed following a chemical shower and prior to entering the personal body shower.

## **7.0 Entry and Exit of Personnel and Materials Movement**

The operational practices for entry/exit of personnel and materials are critical in maintaining containment integrity. Within the containment zones, adherence to operational procedures allows IDA to be maintained and keeps contaminated or potentially contaminated PPE inside the containment barrier.

### **7.1 Personnel access and authorisation**

7.1.1 The MCF and the premises housing critical supporting services (e.g. plant room, mechanical and electrical services room, effluent decontamination room) must be gazetted as a protected place under the *IPA*.

7.1.2 All doors leading to the facility, the containment zone or rooms or suits within the facility and premises housing the supporting services are to be kept closed at all times. Access to these areas or premises shall be limited to authorised personnel and authorised visitors.

- Authorised personnel's security clearance must be granted by the MHA, through the MOH;
- Authorised visitors must be escorted in and out of the facility, and be accompanied by an authorised personnel at all times while in the facility and its supporting services premises; and
- All persons entering the facility must be advised of the potential hazards and shall meet the entry requirements in accordance with the institutional or facility policies.

7.1.3 An individual's authorisation to access the facility or any part of the facility must be promptly removed when the individual no longer requires access to the facility or to that part of the facility, or when the individual no longer holds a valid clearance from the MHA. The MOH shall be updated promptly of changes to the list of authorised personnel.

7.1.4 Entry into the facility and the supporting areas must be limited by means of at least 2 layers of secured and locked doors. A system shall be in place to log and track (date and time) all persons entering and leaving the premises. If an electronic door lock system is used for entry/exit door of the facility and the supporting areas, the outermost doors must have an alternative locking mechanism (e.g. key and a key lock).

## 7.2 Personnel entry procedures

- 7.2.1 There shall be current entry requirements posted at all point(s) of entry to the facility, containment zone, and experimental, animal or other rooms within the containment zone. All individuals entering the containment zone must don appropriate laboratory clothing and PPE. Personal belongings not needed for work in the containment zone must be kept outside of the containment zone, or in the change areas outside the containment barrier.
- 7.2.2 Personnel shall doff personal clothing and footwear and don dedicated laboratory clothing and PPE before entering the containment zone. Performance of mechanically powered PPE (e.g. powered air-purifying respirator (PAPR), positive pressure suit) must be verified prior to donning and use. Personnel are to verify correct reading of monitoring device(s) that visually demonstrates IDA prior to entry into an area where IDA is provided.

## 7.3 Personnel exit procedures

- 7.3.1 *For cabinet facility* - all persons shall doff all PPE before exiting the containment zone, in a manner that minimises contamination of any body parts including the skin and hair. Personnel belongings which have been brought into the containment zone (e.g. eyeglasses) shall be decontaminated at the containment barrier prior to exit. Personal body shower shall be taken, if indicated by ARA.
- 7.3.2 *For suit facility* - all personnel shall disinfect their outer suit gloves, up to the forearm, before exiting any experimental room. Disinfection of footwear is recommended if open cages animals are handled in the room. The person in positive pressure suit is required to undergo a chemical decontamination shower, followed by a personal body shower before exiting the facility.

## 7.4 Materials movement

- 7.4.1 Supplies and materials shall be brought into the containment zone via the change room or alternative routes, such as through the fumigation chamber or airlock rooms. After securing the outer doors, personnel within the containment zone or laboratory area may retrieve the materials by opening the interior door of the autoclave, fumigation chamber, or airlock. These doors must be secured after materials are brought into the facility.
- 7.4.2 Only necessary equipment and supplies shall be stored inside the facility. All equipment and supplies inside the facility must be decontaminated before removal from the facility.

- 7.4.3 Viable biological materials being removed from the facility must be packed into a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. These materials must be transferred through a disinfectant dunk tank, fumigation chamber, or decontamination chamber. Once removed, packaged viable biological materials must not be opened until they arrive at the designated destination (e.g. another facility with the same containment capability). Packaging, transport and shipment of the materials shall comply with national (i.e. the *BATA (Transportation) Regulation*) and international regulations, whenever applicable.
- 7.4.4 Inactivated materials shall be validated to be effectively inactivated prior to removal from the facility. The inactivated materials are to be packed appropriately as approved by the BC, and be transferred out of the facility through a disinfectant dunk tank, fumigation chamber, or decontamination chamber. Transportation of the materials shall comply with the *BATA (Transportation) Regulation*.

## **8.0 Work Practices**

The use of safe work practices helps prevent personnel exposure to infectious biological agents or toxins, and prevents their release into the environment. In containment zones where biological materials and toxins are handled or stored, safe work practices shall include the proper use and maintenance of biocontainment systems (e.g. ACMV system), biosafety equipment (e.g. BSCs, centrifuges), and other general aspects of containment zone maintenance (e.g. tidiness, clutter). Safe work practices documented in the SOPs should be written in a clear and comprehensive manner to allow proper implementation by all personnel.

- 8.1 Daily inspections of essential containment (e.g. BSCs, autoclaves and ACMV system) and life support systems (e.g. BASS and chemical shower for suit laboratory) must be completed and documented before laboratory work commences. This is to ensure that the facility is operating in accordance with the established parameters.
- 8.2 The MCF shall ensure that regular preventive maintenance checks for critical PPE such as PAPR and positive pressure suits, are performed to verify the PPE's integrity and functionality, or in accordance with manufacturer's recommendations. Additionally, prior to each use, laboratory personnel shall verify that these PPEs function within their operational parameters.
- 8.3 All alert alarms which are meant to warn personnel of physical containment deviations, irregularities and emergency situations shall be linked to the BMS, whereby the BMS is designed with the feature to immediately send alerts to designated responsible personnel.

- 8.4 Whenever there are personnel working within the facility, support personnel shall be available outside of the containment zone but within the building to respond to alarms and to render support, whenever needed.
- 8.5 The facility shall implement a buddy-system for personnel working inside the containment zone.
- 8.6 All personnel shall be familiar with, and adhere strictly to the facility's policies and procedures, including all the following standard laboratory practices:
- 8.6.1 No eating, drinking, smoking, handling of contact lenses, application of cosmetics, and storage of food in the facility. All unnecessary personal belongings (e.g. jewelry and watch) are to be removed before entering the containment zone.
- 8.6.2 Hair must be tied up or covered appropriately to prevent contact contamination. All open wounds, cuts, scratches, and grazes must be covered with waterproof dressings.
- 8.6.3 Mouth pipetting is prohibited.
- 8.6.4 All activities involving open vessels of infectious biological materials must be performed in a BSC or other appropriate primary containment device. All procedures involving biological materials must be performed in a manner minimising the creation of splashes and/or aerosols.
- 8.6.5 Centrifugation of biological agents shall be carried out in sealed safety cups (or rotors) which are loaded and unloaded only within a BSC.
- 8.6.6 Open flames shall not be used inside the BSC.
- 8.6.7 Procedures involving the movement of biological agents and toxins shall include preventive measures or implementations, as determined by an ARA, to prevent unintentional incidents such as leaks and spillage.
- 8.6.8 Traffic flow patterns from areas of lower contamination (i.e. clean) to areas of higher contamination (i.e. dirty) shall be established and followed, as determined by an ARA.
- 8.6.9 Dedicated paper/computer work areas shall be utilised for paperwork and report writing. These areas shall be clearly demarcated. Papers cannot be brought out from the facility unless they are verified to be successfully decontaminated. Information written on the papers can be sent out of the facility via alternative ways such as by fax or email.



8.6.10 Work surfaces shall be cleaned and decontaminated with a disinfectant effective against the biological agent(s) or toxin(s) in use, frequently, to minimise the potential of exposure to infectious or toxic materials.

8.7 Use of needles, syringes, and other sharps shall be prohibited when suitable alternatives are available. If unavoidable, policies for safe handling of sharps must be developed and implemented. Personnel involved in sharps handling shall receive the appropriate training and must be assessed for competency prior to the commencement of procedures involving sharps.

## **9.0 Housekeeping and General Maintenance**

9.1 Containment zone (including the floors) are to be kept clean, free from obstructions, and free from materials that are in excess, not required, or that cannot be easily decontaminated.

9.2 Routine cleaning (including the floor, furniture and equipment), as described in the SOPs, are to be carried out by containment zone personnel or other personnel trained specifically for this task.

9.3 An effective pest control programme shall be maintained.

9.4 Water seals in drainage traps shall be maintained through regular usage or filled with appropriate disinfectant.

9.5 There shall be a system in place to maintain, service and test all critical equipment and facility engineering in the facility. The maintenance frequency and schedule should be determined, based on the risks which arise in the event of failure, and/or according to the manufacturer's requirements. All maintenance personnel must be competent in carrying out their assigned jobs. All maintenance and servicing findings and reports shall be recorded and properly filed for reference.

9.6 A basic tool kit should be available inside the containment zone.

## **10.0 Animal Work Considerations**

Working with biological agents involving live animals increases risk due to the unpredictable behavior of animals and high volumes of contaminated waste generated in the animal containment zones. Special considerations and handling techniques for work with animals helps prevent personnel exposure or release of biological agents from animals which are infected or potentially infected, or are asymptomatic carriers of human pathogens. Safe

practices for animal work shall be established and documented in SOPs. The SOPs shall be comprehensive and implemented by all personnel.

- 10.1 Primary containment cages housing infected animals shall be identified with labels.
- 10.2 Appropriate methods shall be used to minimise scratches, bites, crushing injuries, and accidental self-inoculation. Handling procedures employed shall aim to minimise the creation of aerosols and dissemination of dust from cages, refuse, and animals. Animals shall be disinfected and/or cleaned at site of injection or exposure, following inoculation or aerosol challenge with biological agents or toxins.
- 10.3 Inoculation, surgical, and necropsy procedures with animals shall be carried out in a BSC or other appropriate primary containment device.
- 10.4 Animals shall be properly secured during transportation into, out of, and within the containment zones. All animal carcasses must be decontaminated (e.g. autoclaving or digested) before leaving the containment zone and facility. The decontamination methodology must be validated to be effective.
- 10.5 Refer to AVS for additional requirements and practices for all work related to animals, particularly for animals which cannot be placed/fitted in primary containment cages and are not covered under this Standard.

## **11.0 Decontamination and Waste Management**

- 11.1 The facility must be sealable to permit effective gaseous decontamination and ensure no escape of gaseous fumigant. Procedures shall be in place to validate the efficacy of the decontamination process.
- 11.2 Decontamination protocols shall be in place for both routine use (including a chemical decontamination shower for the suit facility) and spillage incidents. The protocols shall document the assessment of disinfectant efficacy under in use conditions. Efficacy may be determined by:
  - (a) Examining the manufacturer's literature;
  - (b) Examining relevant peer-reviewed literature; and/or
  - (c) In-house validation - the protocol should indicate the type of disinfectant, storage conditions, working concentrations and contact times that are effective for the biological agents or toxins that may be present in the facility.
- 11.3 All waste from the facility must be treated, preferably by steam sterilisation (or autoclave) and/or heat or chemical treatment before removal or discharge from the facility.

- (a) Policies and methods for the treatment and disposal of waste must be identified and put in place before work begins;
  - (b) Performance of all the waste treatment equipment (e.g. autoclave, EDS) shall be assessed and documented as part of the facility commissioning. Additionally, periodic review of waste treatment equipment performance shall be performed (see details in Part III);
  - (c) Waste treatment SOPs shall incorporate risk assessment of the biological agents likely to be present in the wastes, the types of waste (e.g. liquid, solid, animal carcass) and quantity of waste per load. All waste treatment SOPs documentation shall state the parameters used, corresponding to the respective conditions; and
  - (d) For mixed waste, all hazards (e.g. biological and chemical) present in the waste must be treated appropriately in accordance with the hazards.
- 11.4 Sharps (if any) shall be discarded in containers that are leak-proof and puncture-resistant, or specially constructed for the disposal of sharps waste.
- 11.5 All equipment or materials (other than waste) shall be thoroughly decontaminated at the containment barrier and labelled as decontaminated prior to removal from the facility.
- 11.6 Decontamination equipment and processes shall be validated at commissioning, when significant changes are implemented or when new biological agents or toxins are introduced. The validation process shall take into consideration the type of biological agent or toxin, the form it exits (e.g. in liquid, solid, animal carcass) and the load (of waste). If a surrogate agent is used for the validation process, it shall be more hardy or resistant than the agent itself.
- 11.7 Decontamination processes shall be routinely verified, as described in SOPs. Frequency of verification shall be determined by an ARA.

## **12.0 Emergency Response Plans and Procedures**

- 12.1 The facility must draw up plans and procedures for response to all possible and foreseeable emergency situations. Examples of emergency situations include medical emergencies, fires, chemical and biological spills, power failure, loss of facility containment (e.g. failure of the ACMV system), malfunctions of facility services (e.g. loss of water supply, facility flooding, failure of positive pressure suit, BASS and chemical decontamination shower), failure of primary containment devices (e.g. BSC malfunction and puff-back of Class II BSC) and PPE (e.g. PAPR or positive pressure suit), escape of animals, loss, theft or diversion of biological agents or toxins, security breaches and natural disasters.

- 12.2 Emergency plans should provide sufficient details regarding:
- (a) All foreseeable incidents that may affect the safety and security of the personnel, the community and the environment, and the immediate mitigation steps to be taken;
  - (b) Organisations involved in emergency situations, including identities and contact of key personnel, their responsibilities and liaison arrangements with them;
  - (c) Communication links;
  - (d) Key information about the site; and
  - (e) Evacuation arrangement.
- 12.3 Emergency procedures shall be documented and regularly practised to ensure that all personnel are familiar with the actions to be taken during emergencies. The procedures shall include:
- (a) Roles and responsibilities of individuals during an emergency, including the first point of contact;
  - (b) Emergency procedures training requirements for staff;
  - (c) Contacts and procedures to activate external assistance (e.g. institutional emergency response team, SCDF or HazMat team, medical care);
  - (d) First-aid arrangements, which may include the availability of post-exposure prophylaxis, if appropriate;
  - (e) Procedures for reporting accidents involving laboratory staff and non-laboratory staff (e.g. visitors); and
  - (f) Arrangement for the investigation of incidents.
- 12.4 The emergency procedures and staff preparedness shall be tested through regular emergency drills, at least annually. All staff are required to participate in the drills.

## **13.0 Incident Investigation and Reporting**

Incidents involving biological agents, infected animals, or failure of containment systems or control systems shall be reported immediately to the appropriate internal authority, the MOH and any other regulatory authorities, whenever applicable. Incident investigation shall be conducted and documented in order to determine the root cause(s) and to devise corrective or preventive measures.

- 13.1 The MOH must be informed immediately via the submission of a notification report following:
- (a) Exposure to a biological agent or toxin;
  - (b) Release of a biological agent or toxin into the external environment;
  - (c) Loss, theft or diversion of a biological agent or toxin;
  - (d) Failure to receive biological agent or toxin during scheduled transfer or import;
  - (e) Personnel who present signs and/or symptoms corresponding to possible exposure to a biological agent or toxin handled in the facility; or

- (f) Any incident that the facility assessed to have adverse effects on the laboratory personnel, the community or the environment.
- 13.2 An exposure follow-up report documenting the completed investigation is to be submitted to the MOH within 15 days of the submission of the notification report.
- 13.3 The FO shall also adhere to the Ministry of Manpower *WSHA and WSH (Incident Reporting) Regulations* for reporting of work related accidents, dangerous occurrences and occupational diseases.

## **14.0 Record and Documentation**

- 14.1 All records pertaining to the facility, including records of the BRM programme shall be kept for as long as the facility is in operation, or for a minimum of 10 years following the deregistration of a facility.
- 14.2 All records shall be documented, kept on file, updated and made available for internal and external inspection or audit. Records shall include:
- (a) All training records;
  - (b) Inventory of biological agents and toxins (including critical information, e.g. identity of the biological agents or toxins, inactivation process, storage location, quantity, responsible personnel, use/activity, movements or transfer within, in and out of the facility);
  - (c) Records and documentation pertaining to the approvals, import permits or licenses for the possession and/or activities involving biological agents and toxins;
  - (d) List of personnel authorised to have access to the facility, and log records of individuals accessing and leaving the facility;
  - (e) Risk assessment records;
  - (f) Incident records (including investigation reports and records of follow-up actions);
  - (g) Occupational health assessment and PPE suitability records (e.g. mask/respirator fitting);
  - (h) Medical surveillance records;
  - (i) Biological agent inactivation (and/or removal), validation and verification records;
  - (j) Minutes of biosafety committee meetings and all relevant correspondences;
  - (k) Drawings and physical specifications (including “as built” drawings of all structures and services pertaining to the containment zone, and any modifications made to the facility or the engineering system) and reports of performance and verification tests of the containment systems;

- (l) Records of inspections (internal and external) of the facility/support facilities and laboratory activities (e.g. laboratory practices, red teaming, emergency response drill, inventory audit), their findings and follow-up actions;
- (m) Records of MCF and equipment maintenance, repair, inspection, testing, or certification (including performance verification and testing records);
- (n) Calibration certificates of instruments used for performance verification and testing of containment systems and essential biosafety equipment; and
- (o) Records of validation and routine verification of decontamination equipment and processes.

14.3 Access to records and documentation pertaining the MCF and activities conducted within shall be restricted to authorised personnel.

## **15.0 Continual Improvement**

The biorisk management system is dynamic and requires continuous assessment and review to ensure ongoing and sustained improvement. The MCF's management should strive for continuous development and refinement of the system in place, and create opportunities to identify areas of improvement and implementations.

- 15.1 The MCF's management should establish and document the objectives and targets (qualitative and quantitative) for the BRM programme.
- 15.2 There should be a system in place to assess the effectiveness of the BRM programme and workflow processes, such as through monitoring of the relevant indicators in accordance with the set objectives and targets, with the aims to ensure:
  - (a) All personnel perform their tasks competently, in a safe and secure manner;
  - (b) All aspects of the physical containment (including equipment and PPE) are maintained to function safely and optimally; and
  - (c) All work activities and processes are progressing as planned and areas of improvement are identified and implemented.
- 15.3 The FO shall ensure that periodic reviews (at least biennial) are performed on the BRM programme and all high risk work processes, and to verify that risk mitigation implementations effectively satisfies the MCF's BRM policies and objectives.

**PART III**  
**COMMISSIONING TESTING AND PERFORMANCE**  
**VERIFICATION REQUIREMENTS**

# PART III

## COMMISSIONING TESTING AND PERFORMANCE VERIFICATION REQUIREMENTS

Commissioning testing and performance verification of all physical and engineering components are essential to ascertain that a MCF is operating within its design specifications and is compliant to all relevant regulations. Part III specifies the required commissioning, performance validation and maintenance verification (with respect to the applicable standards and test frequencies) for all critical physical containment features and laboratory safety equipment in the facility. This part is divided into the following sections:

1. Commissioning requirements; and
2. Performance verification requirements.

### 1.0 Commissioning Requirements

Commissioning testing must be carried out once for all newly constructed or renovated containment facilities to ensure that all physical and engineering components, systems and features of the facility meet the design specifications and/or intended purposes, and are functioning safely and optimally as per requirements, prior to its operations. All findings and commissioning reports shall be documented and filed properly. Validation reports are required for newly commissioned containment facilities or when there are changes/modifications made to the existing facility and/or engineering design. All reports shall be filed properly as specified in Part II, Section 14.1.

#### 1.1 Structural strength of facility and integrity of containment barrier

1.1.1 Tests (excluding the HEPA housing) shall be carried out to verify the facility's endurance to withstand the (possibly anticipated) extreme pressure during ventilation failure<sup>7</sup>. All data must be documented.

1.1.2 ***For suit facility (or facility with pneumatically sealed doors)***

Integrity of the containment barrier/s (e.g. chemical decontamination shower, and/or experimental rooms) shall be subjected to the pressure decay test.<sup>8</sup>

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<sup>7</sup> For example, a suit facility is tested to be able to withstand an extreme pressure of -1200 Pa and +1500 Pa.

<sup>8</sup> Acceptance criteria: Two consecutive testing with no more than 50% of loss in pressure from an initial 500 Pa over a 20-minute period, in accordance with the Canadian Biosafety Standards 2<sup>nd</sup> Edition Section 5.3.5.



## 1.2 Air conditioning and mechanical ventilation systems and high efficiency particulate air filter housing

- 1.2.1 ACMV systems and controls are to be tested during normal operation and with all possible scenarios simulating failure of system components, including facility exhaust fan(s), facility supply fan(s), power supply, BSC exhaust fan(s), as determined by containment zone design<sup>9</sup>.
- 1.2.2 Supply air ductwork located between containment barrier and backdraft preventer is verified to be sealed airtight in accordance with *ANSI/SMACNA 016 Seal Class A* or equivalent standards, and tested *in situ* by pressure decay<sup>10</sup> in accordance with *ASME N511/ASME AG-1*.
- 1.2.3 Exhaust air ductwork located between containment barrier and HEPA filter or isolation damper has to be sealed airtight in accordance with *ANSI/SMACNA 016 Seal Class A* or equivalent standards, and tested *in situ* by pressure decay testing<sup>10</sup> in accordance with *ASME N511/ASME AG-1*.
- 1.2.4 HEPA filter housings are to be tested *in situ* by pressure decay testing<sup>10</sup> in accordance with *ASME N511 /ASME AG-1* or other equivalent methods.

## 1.3 Drainage system

All drain piping leading to the EDS shall be tested with a minimal testing pressure of 35,000 Pa (i.e. 141 inches of water gauge).<sup>11</sup> MCF shall also perform drain piping tests as required by other national regulatory authorities.

## 1.4 Commissioning of critical safety equipment and supporting services

In addition to the above, all critical safety equipment and supporting services shall be tested in accordance with the respective standards, and must be verified to be operating within their specifications. Commissioning reports of laboratory safety equipment, including the following, shall be documented and made available upon request.

- (a) Class II and Class III BSCs;
- (b) Pass-through autoclaves/fitting (including Ministry of Manpower [MOM] pressure vessel examination report);
- (c) Fire alarm system and fire suppression system;
- (d) BASS (including MOM pressure vessel examination, if applicable);

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<sup>9</sup> Acceptance criteria includes: IDA is maintained during normal operation; reversal of IDA is not observed at any critical doors during the stimulated failure scenarios; Class II B2 BSC puff-back is minimised, and ACMV system alarms and interlocks operate as intended.

<sup>10</sup> Acceptance criteria: Rate of leakage not more than 0.1% volume/minute at 1000 Pa/1000Pa, in accordance with *ASME N511/ASME AG-1*.

<sup>11</sup> In accordance with Canadian Biosafety Standard 2nd Edition Section 5.3.1

- (e) Emergency and uninterrupted power supply;
- (f) Chemical shower system;
- (g) EDS; and
- (h) Security system.

## 2.0 Performance Verification Requirements

Performance verification is to be conducted at regular intervals to ensure that the physical and engineering systems of the containment facility are appropriately maintained and consistently operate according to design specifications. This aims to ensure that the safety and security of the containment facility can be maintained at all times. All verification results are to be documented and filed properly, as specified in Part II, Section 14.1. In the following sections, unless specified, the performance verification is to be conducted annually.

### 2.1 Structural integrity and tightness

#### 2.1.1 For **cabinet facility**

All penetrations and seals in the containment facility shall be inspected for leakage, faults and/or deterioration.

#### 2.1.2 For **suit facility** and/or **facility with sealed doors**

Integrity of containment barrier shall be pressure decay tested<sup>12</sup> at least annually or when rectifications are made to the facility (especially if rectifications potentially affect the integrity of the containment facility), whichever occurs earlier.

### 2.2 Air conditioning and mechanical ventilation systems and high efficiency particulate air filters

2.2.1 All HEPA filters (including seals and fittings) within the ACMV system shall be inspected and tested at least annually or when rectifications are made, whichever occurs earlier. Testing shall be in accordance with *IEST-RP-CC034.3* or other equivalent standards.

2.2.2 All sensors, devices, displays and alarms designed to control and/or monitor the performance of the ACMV system (e.g. differential pressures which created the IDA) shall be verified to function as intended.

2.2.3 All fail-safe and interlock controls incorporated in the ACMV system to manage system failures shall be verified to function as intended. Example: Perform testing at all critical doors (or doors between a differential pressure zone) in the

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<sup>12</sup> Acceptance criteria: No more than 50% of loss in pressure from an initial 500 Pa over a 20-minute period.

facility where IDA is provided, and to verify (using real-time quantitative devices) that IDA is maintained in accordance with intended design, during normal operation as well as in the event of ACMV system failure (all possible failure scenarios).

## 2.3 Facility services

Numerous systems work together to enable the smooth operations of the MCF, and these include the access control and security systems (e.g. intrusion detection system) of the facility. These systems must be verified to function as designed or intended. These verifications include:

- 2.3.1 Inspection of interlocking function mechanisms of all critical doors, which should be performed weekly.
- 2.3.2 Verification of the integrity of all in-line filters fitted within the containment facility.
- 2.3.3 All plumbing backflow prevention devices shall be certified in accordance with *CAN/CSA B64.10-11/B64.10.1-11* or equivalent standards.
- 2.3.4 Verification of the performance of the low level alarm and parametric monitoring and recording devices of the chemical decontamination shower system (*for suit facility*).
- 2.3.5 Inspection of leak-tightness of piping leading to the EDS, periodically, or as indicated by risk assessment.
- 2.3.6 Testing of the emergency power and UPS, under representative electrical load.
- 2.3.7 Testing of all emergency lighting, alarm systems, communication system and security system (e.g. closed circuit television cameras and the intrusion detection system) in the facility.

## 2.4 Laboratory biosafety equipment

### 2.4.1 Biosafety cabinet (BSC)

All BSCs shall be certified before use and at least annually or when there is a malfunction in operations, in accordance with *NSF49*, or other equivalent internationally recognised standards. Certification of BSCs shall be performed only by competent personnel (e.g. *NSF 49* field certifier).

### 2.4.2 Pass-through autoclave

- (a) The pass-through autoclave shall be tested and calibrated annually or according to manufacturer's specifications, whichever occurs earlier.

The testing and calibration shall encompass operational parameters, including seal tightness, interlocking door mechanisms and sensors;

- (b) The pass-through autoclave shall also be registered and inspected as per *WSHA* and *WSH (General Provisions) Regulations*.
- (c) Effectiveness of the autoclave shall be verified at applicable autoclave cycles for full operating loads (e.g. waste, re-usable consumables, animal carcasses and laboratory scrubs, etc.) using biological agents (e.g. *Geobacillus stearothermophilus* with minimum load of  $10^6$ ) every 6 months. When changes in the process are made (e.g. new packaging protocol, new autoclave parameters), revalidation has to be done; and
- (d) If the in-line HEPA filter is included in the autoclave for filtering exhaust air, the efficiency of HEPA filters shall be verified and/or replaced according to manufacturer's recommendation.

#### 2.4.3 Breathing air supply system and positive pressure suit (For **suit facilities**)

- (a) The BASS and backup BASS shall be verified according to manufacturer's specifications;
- (b) The BASS system failure alarms shall be verified to function as intended;
- (c) The breathing air quality shall be tested at least once every 6 months for compliance with Part I, Section 8.3.2;
- (d) Should standby compressed gas cylinders be used, the maintenance and labelling of the cylinders should be in accordance with SS639<sup>13</sup>;
- (e) The positive pressure suits shall be maintained and inspected before each use to ensure:
  - The integrity of the suit is not compromised; and
  - The positive pressure in the suit meets manufacturer's requirements and/or function as intended (e.g. pressure and noise level, see Part I, Section 8.4.3).

#### 2.4.4 Effluent decontamination system

- (a) EDS warning alarms (e.g. sterilisation failure, equipment error, leakage and system deviation from normal operations) to be verified to function as intended; and
- (b) All devices (e.g. sensors) designed to monitor and/or detect the performance of the EDS (e.g. sterilisation process) and/or leakage of EDS or piping connected to EDS are to be verified.

#### 2.4.5 Other primary containment devices

Integrity of other primary containment devices other than BSCs (e.g. process equipment, closed systems, primary containment caging) shall be verified in

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<sup>13</sup> SS639:2018 – Singapore Standard for Code of practice for the filling, inspection, testing and maintenance of gas cylinders for the storage and transport of compressed gases.

accordance with testing procedures and acceptance criteria appropriate for the equipment and design, whenever applicable.

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Users are advised to refer to the relevant local legislations, regulations and/or guidelines through the respective regulatory authorities' contact or website.