**IMPORTANT REMINDERS**

**General:**

1. This checklist shall be used as the minimum criteria for the certification of high containment (or BSL3) facilities. Additional checklists may be used only to supplement this checklist.
2. MOH officer(s) must be present during the independent measurements/tests and physical inspection phase of the certification or verification unless advised otherwise by MOH.
3. The Facility Operator (FO) and the MOH-Approved Facility Certifier (MOH-AFC) are both responsible for informing MOH of the certification schedule at least 1 month before the scheduled inspection.
4. MOH may introduce new measures or requirements on the certification scheme for the MOH-AFC.
5. The list of MOH-AFC may be updated from time to time.
6. The final outcome of the certification of the facility will be based on MOH’s decision and not solely based on the MOH-AFC's certification report.

**Facility:**

1. Facilities which plan to be certified without shutting down[[1]](#footnote-1) are required to:
2. Conduct a thorough risk assessment (RA), develop a risk management plan and implement all necessary risk mitigation measures to ensure the safety of ALL personnel (including laboratory personnel, MOH officers, certifiers, maintenance crew, etc.) involved in pre-certification maintenance, pre-certification and certification of the facility.
3. The RA and risk management plan must be reviewed and endorsed by the Biosafety Committee (BC), approved by the FO, and agreed upon by the certifiers. The certifiers reserve the right to reject the plan and/or decline to certify the facility if they assessed that the risk has not been adequately addressed.

The approved RA, risk management plan[[2]](#footnote-2) and all relevant documents must be submitted to MOH. The FO must inform MOH officers of any risks and/or potential hazards which the officers may be exposed to when carrying out their duties during the certification, and of any vaccinations that may be required prior to entering the facility.

1. Facilities which are being certified, should have the following in place:
2. Emergency response plan
3. The facility personnel must be able to demonstrate competency in responding to laboratory accidents (e.g. minor spills, etc.) or any procedural work upon MOH’s and/or MOH-AFC’s request, during certification.
4. Regular emergency drills shall be conducted together with the Singapore Civil Defence Force (SCDF). The presence of MOH officer/s is required during the drill as the conduct of the drill will be audited by MOH, unless advised otherwise by MOH. It is not required for this drill to be performed during the certification.
5. Red teaming[[3]](#footnote-3) program
6. An in-house red teaming (RT) exercise must be done annually.
7. A report using the template provided during the RT training course[[4]](#footnote-4) must be submitted to MOH by uploading the RT report in the Biosafety IT System (BiosIS).
8. The facility personnel may be interviewed by MOH officer with regards to the RT exercise.
9. Facilities which conduct activities involving animals are required to comply with Animal Veterinary Services (AVS) requirements and are responsible for co-ordinating MOH-AVS joint certifications where applicable.

**MOH-Approved Facility Certifier:**

1. MOH-Approved Facility Certifier (MOH-AFC) is advised to read and understand the requirements of the *Biological Agents and Toxins Act* (BATA) before carrying out any certification process.
2. The MOH-AFC will be liable for any intentional/unintentional changes made to the original “MOH Certification Checklist for High Containment Facilities” posted on [www.moh.gov.sg/biosafety](http://www.moh.gov.sg/biosafety) (e.g. result of editing or formatting/re-formatting).
3. The lead certifier must ensure that the certification team involve in the certification composed of at least one biosafety professional and one engineer who are both fully qualified and approved by MOH.
4. The MOH-AFC is responsible for informing MOH of any changes to its team members prior to certification and all changes are subjected to MOH's approval.
5. A certifier is not allowed to certify a facility if:
   1. The company or a member of the certifying team has provided maintenance services to the facility within 12 months preceding the certification date; and
   2. The company or a member of the certifying team has provided design, construction or commissioning services within 12 months preceding the certification date.
6. A MOH-AFC can only certify a facility for 2 consecutive years, otherwise, consent or approval from MOH is required.
7. The MOH-AFC must ascertain that the facility's engineering controls are equipped with sufficient redundancy[[5]](#footnote-5) and/or a system in place to ensure continuous and safe operation of the facility. Documentation of the tests performed must be recorded in the certification report. If the facility is unable to cater sufficient redundancy, the facility must implement administrative controls (e.g. Standard Operating Procedures [SOP]) to manage the failure scenarios and to ensure that the safety of the facility personnel, the community and the environment is guarded at all times.
8. The ventilation system of the facility being certified must be challenged with all probable failure scenarios including failure of the electrical system and Building Automation System (BAS). The list of scenarios which will be conducted on the day of certification, shall be provided to MOH, 2 weeks before the certification date. The ventilation system test script shall be endorsed by MOH.
9. The differential pressure for ALL rooms within the facility, shall be determined and measured in a quantitative manner using a calibrated instrument that can provide reliable and real time quantitative data. MOH-AFC must ensure that the calibration certificates (original hardcopy) of the instruments used for pressure measurement must be present on the day of certification. The measurements shall be recorded during normal operation, during challenge scenarios and upon resuming to normal operations. Qualitative tests such as smoke test may only be used as a supplementary method and cannot be used as a replacement of the quantitative method of measurement.
10. The MOH-AFC shall conduct all Air Conditioning and Mechanical Ventilation (ACMV) airflow (e.g. supply and exhaust diffusers in the facility), light and sound measurements, and to ensure they meet/achieve the intended designs and/or purposes.
11. The MOH-AFC shall provide expert advice/solutions to the problems identified during the certification process to the facility concerned.
12. MOH-AFC (with the relevant expertise) must be present for verification/re-verification process of issues identified during the certification[[6]](#footnote-6).
13. The validity of a MOH-AFC is determined at the discretion of MOH. MOH reserves the right to revoke the MOH-AFC’s approved status at any time when deemed necessary and the revocation decision is final.

|  |  |  |  |
| --- | --- | --- | --- |
| Facility Name: | Facility Type:  BSL3 Laboratory / ABSL3 laboratory | | Certification Date: |
| Facility Address: | | Facility status[[7]](#footnote-7) during certification: Hot / Warm / Cold  Date of submission of risk mitigation plan: | |
| Person-in-charge: | | Contact Details: | |

**Part 1: Facility Design, Fittings and Access Control**

A facility’s layout, design and installation are important in maintaining efficient containment (secondary containment) of infectious material, animal or toxin. This section of the checklist specifies the requirements of the different features which provide for containment, such as engineering, architecture (e.g. surface finishing, installations) and administrative controls.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Part 1.1 Air Conditioning and Mechanical Ventilation (ACMV)** | | | | | |
|  | The facility must have an ACMV system which maintains negative air pressure gradient relative to the non-containment area. |  |  |  |  |
|  | The ACMV system is designed: |  |  |  |  |
|  | 1. With directional airflow from the least to the most contaminated area; |  |  |  |
|  | 1. With differential pressure of 12.5Pa[[8]](#footnote-8) or more between pressure zones; |  |  |  |
|  | 1. With visual displays of differential pressure available at the entrance of each pressure zone |  |  |  |
|  | 1. With monitoring and alarm systems to alert users of system abnormalities and/or failure; and |  |  |  |
|  | 1. To ensure containment barrier is not compromised. This includes in the event of any ACMV failure scenarios. |  |  |  |
|  | Exhaust air of the facility is: |  |  |  |  |
|  | 1. Minimally filtered through high-efficiency particulate air (HEPA) filters before being discharged out; |  |  |  |
|  | 1. Discharged via an exhaust stack; and |  |  |  |
|  | 1. Discharged away from occupied areas and air intake points. |  |  |  |
|  | All HEPA filters are: |  |  |  |  |
|  | 1. In housings which have scanning and decontamination ports for HEPA testing and isolated HEPA decontamination respectively; |  |  |  |
|  | 1. Able to be isolated for decontamination; and |  |  |  |
|  | 1. Tested for integrity annually. |  |  |  |
|  | An alternate ACMV control system is available in the event of emergency situations (e.g. if there is a fire in the server room). |  |  |  |  |
|  | Duct work and interstitial spaces are not cluttered (e.g. not used as storage areas) and are free of trip hazards (or trip hazard is marked). |  |  |  |  |
| **Additional Requirements for Animal Work** | | | | | |
|  | An alert system is available in the event of failure and/or deviations from controlled environment settings for the experimental animals. |  |  |  |  |
|  | Backup systems or administrative controls are available to ensure normal facility operations, in the event of ACMV failures. |  |  |  |  |
| **Part 1.2 Physical Design and Fittings** | | | | | |
|  | Facility is away or separated from public access and thoroughfare. |  |  |  |  |
|  | Universal biohazard sign is posted at the entrance of the containment facility door. |  |  |  |  |
|  | Entry and exit to the facility are through an anteroom. |  |  |  |  |
|  | The entrance of areas where biological agents/toxins are handled are posted with (where applicable): |  |  |  |  |
|  | 1. Universal biohazard sign; |  |  |  |
|  | 1. Name of responsible personnel; |  |  |  |
|  | 1. Contact number of responsible personnel; |  |  |  |
|  | 1. Biological agent/toxin/animal handled within the area; and |  |  |  |
|  | 1. Any relevant safety measures |  |  |  |
|  | Hazard signage, in accordance to SS508[[9]](#footnote-9), are put up appropriately (e.g. entrances, on equipment) to warn facility personnel of hazards including: |  |  |  |  |
|  | 1. Biohazards; |  |  |  |
|  | 1. Chemical hazards; |  |  |  |
|  | 1. Radiological hazards; and |  |  |  |
|  | 1. Any other hazards, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | Doors into and within the containment are: |  |  |  |  |
|  | 1. Self-closing; |  |  |  |
|  | 1. Equipped with mechanisms to prevent simultaneous opening of doors which will compromise the containment barrier (e.g. between containment zones); and |  |  |  |
|  | 1. Installed with alarms to alert users if the door is not properly closed. |  |  |  |
|  | Emergency exit doors are available and unobstructed. |  |  |  |  |
|  | Windows within the facility are sealed and break resistant. |  |  |  |  |
|  | The facility is designed to include fire safety requirements and features (e.g. sprinklers) in accordance with SCDF’s Fire Code. |  |  |  |  |
|  | The facility is designed: |  |  |  |  |
|  | 1. For easy cleaning; |  |  |  |
|  | 1. With smooth surfaces (including furnishings, floor, walls etc. inside the facility) constructed of material which are resistant to moisture, scratches, chemicals and heat; |  |  |  |
|  | 1. With no trip hazards (or trip hazards are obviously marked); |  |  |  |
|  | 1. With no protruding sharp edges from furnishings and equipment; |  |  |  |
|  | 1. With sufficient storage space, and space usage is organised and not cluttered; |  |  |  |
|  | 1. With non-obstructed walkways (within the facility) of at least 1.2m width; and |  |  |  |
|  | 1. With means of observing work areas from outside of the facility. |  |  |  |
|  | Hands-free sink for handwashing is available at:   1. Each work zone; and |  |  |  |  |
|  | 1. Area before exiting from the containment facility. |  |  |  |
|  | Eyewash station shall: |  |  |  |  |
|  | 1. Be available for emergency use at each work zone; and |  |  |  |
|  | 1. Meet the specifications of ANSI/ ISEA Z358.1-2014 or equivalent. |  |  |  |
|  | Shower area (for showering out) is:   1. Available and well-maintained within the facility; |  |  |  |  |
|  | 1. Designed with a decontamination tank to hold run-off showering water; |  |  |  |
|  | 1. Designed to prevent overflow; and |  |  |  |
|  | 1. Procedure is in place to ensure effluent is decontaminated prior to release from the tank, and efficacy of the decontamination procedure has been validated. |  |  |  |
|  | All piping (e.g., drainage piping, supply piping and sanitary fittings) within the facility shall be: |  |  |  |  |
|  | 1. Designed to ensure that cup sinks or drains are not acting as air vents; |  |  |  |
|  | 1. Installed with backflow preventers, where appropriate; and |  |  |  |
|  | 1. In accordance with the requirements stipulated by the relevant national authorities (e.g. PUB). |  |  |  |
|  | Electrical points are designed to prevent potential hazards including: |  |  |  |  |
|  | 1. Overloading; |  |  |  |
|  | 1. Trip hazards; and |  |  |  |
|  | 1. Electrocution (e.g. electrical point located close to water sources). |  |  |  |
|  | Gas cylinders are: |  |  |  |  |
|  | 1. Secured and fitted with safety caps; and |  |  |  |
|  | 1. Kept outside of the containment area if they are not in use (e.g. storage, back up supply or empty). |  |  |  |
|  |  |  |  |  |  |
|  | Pass through chambers (e.g. pass boxes) are:  (a) Equipped with safety features to prevent simultaneous opening of doors; and |  |  |  |  |
|  | (b) Operate in a secure manner. |  |  |  |
|  | All seams, caulking and penetrations within the containment facility are sealed. |  |  |  |  |
|  | Intended penetrations (e.g. below the doors) within the facility are sealable for gaseous decontamination. |  |  |  |  |
|  | Adequate illumination is provided throughout the facility. |  |  |  |  |
|  | Containment and security of the facility shall be maintained, and facility design shall include the following: |  |  |  |  |
|  | 1. Sufficient redundancy is built into all critical systems (e.g. building automation system, ACMV) and equipment of the facility; and |  |  |  |
|  | 1. Emergency power supply and/or uninterrupted power supply (UPS) is available to support all the critical systems (e.g. building automation system, ACMV, security system) and critical equipment, in the event of power failure.   Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | 1. Testing of redundancy features supporting critical systems. Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  |  |  |  |  |  |
| **Part 1.3 Access Controls** | | | | | |
|  | Access into the following areas is restricted to authorised personnel only: |  |  |  |  |
|  | 1. Containment facility; |  |  |  |
|  | 1. Facility’s control rooms (e.g. Location of Building Management System, rooms housing control points of the security/ ventilation); and |  |  |  |
|  | 1. Voids of the facility (e.g. areas housing the ventilation and decontamination system, access areas to piping, conduit and ducts serving the containment facility, the interstitial spaces). |  |  |  |
|  | A policy and system are available and implemented for non-facility personnel to access the facility (e.g. visitor, housekeeping and maintenance personnel). |  |  |  |  |
|  | Specify security access system implemented for the following:   1. Containment facility   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  | 1. Facility’s control rooms   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | 1. Voids of the facility   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | An alternative override of access control system with tamper-proof features is available for the restricted areas (Part 1.3.3), for emergency situations. |  |  |  |  |
|  | Records of persons entering and exiting areas of restricted access areas (Part 1.3.1) are: |  |  |  |  |
|  | 1. Available and kept up-to-date; |  |  |  |
|  | 1. The records include specific location accessed, access time, purpose of entry and accompanying personnel, if applicable; and |  |  |  |
|  | 1. Being periodically audited. |  |  |  |
|  | Video surveillance system (VSS) or closed-circuit television (CCTV) is: |  |  |  |  |
|  | 1. Available and positioned at critical security points (e.g. access points, areas of storage and handling of biological agents/toxins); |  |  |  |
|  | 1. Resolution of video recorded is compliant to Singapore Police Force (SPF) VSS standards; |  |  |  |
|  | 1. Surveillance records are maintained for at least 30 days; and |  |  |  |
|  | 1. Records are audited and audits are documented to ensure proper functioning of the VSS/CCTV. |  |  |  |

**Part 2: Biosafety Equipment**

The use of biosafety equipment in the facility is intended for effective containment (primary containment) of infectious biological agents and toxins. Proper maintenance and use of biosafety equipment are vital to ensure a safe working environment for laboratory personnel. The list of biosafety equipment in this section is non-exhaustive, and the certifier is advised to expand the checklist, if deemed appropriate.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Part 2.1 Biosafety Cabinets (BSCs) other than Class III BSCs** | | | | | |
|  | BSCs are located at areas whereby their operations and airflows are not compromised (e.g. not in areas of high human traffic or near doors). |  |  |  |  |
|  | Please specify the type (e.g. Class II A1, Class II B2) and total number of units of BSCs in the facility.  Total units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  | Each BSC is:   1. Installed with interlock/fail safe mechanisms to ensure that mechanical failure (e.g. failure of BSC or ACMV exhaust fans) will not result in loss of air barrier (e.g. no reversal of airflow from BSC into the room); |  |  |  |  |
|  | 1. Fitted with monitoring system to alert user of malfunctions or deviations from operational settings; |  |  |  |
|  | 1. Certified annually or after repair, relocation or malfunction, whichever occurs earlier; and |  |  |  |
|  | 1. Certified by qualified/accredited personnel, and in accordance with manufacturer’s specifications. |  |  |  |
|  | All service and certification reports for all BSCs are maintained and kept up to date. |  |  |  |  |
|  | Any vacuum line attached to BSCs: |  |  |  |  |
|  | 1. Is fitted with an in-line HEPA filter and disinfectant trap; and |  |  |  |
|  | 1. In-line filter is maintained and inspected regularly. |  |  |  |
|  | Work space within the BSC is kept clean and tidy (e.g. not cluttered and front grills/exhaust filters are unobstructed). |  |  |  |  |
| **Part 2.2 Class III BSCs** | | | | | |
|  | All Class III BSCs are fitted with monitoring system to alert user of any malfunction or deviation from operational settings. |  |  |  |  |
|  | Each Class III BSC is: |  |  |  |  |
|  | 1. Certified at least annually, or after repair, relocation or malfunction, whichever occurs earlier; and |  |  |  |
|  | 1. Certified by qualified/accredited personnel and in accordance with EN12469 and/or manufacturer’s specifications. |  |  |  |
|  | All service and certification reports for Class III BSCs are maintained and kept up to date. |  |  |  |  |
|  | Integrity of gloves and arm sleeves are inspected and replaced regularly, in accordance with risk assessment. |  |  |  |  |
| **Part 2.3 Centrifuges** | | | | | |
|  | Centrifuge and/or its accessories (e.g. buckets) shall have aerosol proof features. |  |  |  |  |
|  | Centrifuges undergo regular preventive maintenance at least annually or in accordance with manufacturer’s recommendations, whichever occurs earlier. |  |  |  |  |
| **Part 2.4 Animal Cages (If applicable)** | | | | | |
| For small animals which are housed in **animal cages which act as the primary containment:** | | | | | |
|  | Animal cages are fitted/installed with: |  |  |  |  |
|  | 1. Its own individual ventilation system; |  |  |  |
|  | 1. Safety features to prevent cages from becoming positively pressured to the surrounding area; and |  |  |  |
|  | 1. A system which ensures that air released from the cages is HEPA filtered. |  |  |  |
|  | Animal cages and rooms are designed: |  |  |  |  |
|  | 1. To prevent animal escape (e.g. with locks, and locks are positioned to prevent from animal tampering); and |  |  |  |
|  | 1. With monitoring system to alert users of any malfunction or deviation from the operational settings. |  |  |  |
|  | Integrity of the animal cages is verified regularly, in accordance with risk assessment.  Specify the frequency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  |  |  |  |  |  |
| For large animals which are housed in **holding** **rooms which act as the primary containment:** | | | | | |
|  | Both animal cages and holding rooms are designed: |  |  |  |  |
|  | 1. To prevent animal escape (e.g. with locks, and locks are positioned to prevent from animal tampering); and |  |  |  |
|  | 1. With monitoring system to alert users of any malfunction or deviation from the operational settings. |  |  |  |
|  | Integrity of the animal cages is verified regularly, in accordance with risk assessment.  Specify the frequency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  | Integrity of the room (e.g. pressure decay or equivalent test) is verified annually and/or in accordance with risk assessment (*Note: with prior agreement from MOH if test is not done annually*). |  |  |  |  |
|  | Monitoring system is in place to alert users of any malfunction or deviation from the operational settings. |  |  |  |  |
|  | An effective effluent system is designed and validated to manage waste generated (e.g. animal excreta, carcasses or any other fluids or discharge), and shall also comply with all local requirements, including PUB’s and/or NEA’s requirements. |  |  |  |  |
| **Part 2.5 Other Safety Equipment (To be specified by certifier, as deemed necessary and appropriate.)** | | | | | |
|  |  |  |  |  |  |

**Part 3: Sterilisation, Decontamination and Waste Management**

Effective decontamination and management systems are necessary to ensure that all personnel (within or outside the facility) and the environment (within or outside the facility) are protected from unintentional exposure to hazardous materials. This section specifies the requirements for decontamination and waste management policies and procedures of a high containment facility.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Part 3.1 Decontamination and Waste Management Processes** | | | | | |
|  | A decontamination and waste management system are in place to: |  |  |  |  |
|  | 1. Ensure that all infectious materials are effectively decontaminated before removal or discharge from the facility; and |  |  |  |
|  | 1. Efficiently manage mixed waste (e.g. biological, chemical, radiological waste), whenever applicable.   Please specify the type of mixed waste, if any: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | Appropriate disinfectants and/or decontamination procedures are used for: |  |  |  |  |
|  | 1. Work and facility surfaces (e.g. BSC surfaces, work benches, floor); |  |  |  |
|  | 1. Reusable items (e.g. laboratory coats, respirators, laboratory equipment/accessories, racks, waste bin); |  |  |  |
|  | 1. Laboratory wastes (including waste from shower room); and |  |  |  |
|  | 1. Spill clean-up. |  |  |  |
|  | Effectiveness of the disinfectants and decontamination procedures are validated prior to use and reviewed by BC regularly, based on risk assessment. |  |  |  |  |
|  | Validation methods, results, and BC reviews are documented and maintained. |  |  |  |  |
|  | Appropriate waste bins and containers are used to contain waste and are clearly labelled with appropriate hazard signs. |  |  |  |  |
|  | All waste released from the facility into the common sewage or environment shall comply with the regulatory requirements of: |  |  |  |  |
|  | 1. PUB; |  |  |  |
|  | 1. NEA; and |  |  |  |
|  | 1. Any other relevant regulatory authority, if applicable. |  |  |  |
| **Additional Requirements for Animal Work** | | | | | |
|  | A system is in place to ensure: |  |  |  |  |
|  | 1. All waste generated from animal work (e.g. animal bedding, animal waste/excreta and from necropsy tables) and animal carcasses are decontaminated effectively prior to removal from the facility; |  |  |  |
|  | 1. Animal cages are effectively decontaminated prior to removal from the facility; |  |  |  |
|  | 1. Animal room used as a primary containment for infected animals is effectively decontaminated after each use; and |  |  |  |
|  | 1. All waste released from the facility into the common sewage or environment shall comply with regulatory requirements of: |  |  |  |
|  | * 1. PUB; |  |  |  |
|  | * 1. NEA; and |  |  |  |
|  | * 1. Any other relevant regulatory authority, if applicable. |  |  |  |
|  | Efficacy of all decontamination procedures used, are validated: |  |  |  |  |
|  | 1. Prior to use; |  |  |  |
|  | 1. When there is a change in parameter. Parameters for consideration include animal size, body weight, tissue type, number of animals per load; and |  |  |  |
|  | 1. Verified on a regular basis, based on risk assessment. |  |  |  |
|  | All validation and verification reports, as well as BC reviews of reports are documented and maintained. |  |  |  |  |
|  | An up-to-date record of the animal disposal is maintained and kept on file. |  |  |  |  |
| **Part 3.2 Autoclaves** | | | | | |
|  | Double door (pass-through) autoclave is designed with the following safety features: |  |  |  |  |
|  | 1. Dirty side of the door is located within the containment area, and clean side of the door is outside of the containment area; |  |  |  |
|  | 1. Doors cannot be opened simultaneously; |  |  |  |
|  | 1. Doors remain locked until sterilisation/decontamination process is completed; |  |  |  |
|  | 1. Autoclave is equipped with an air tight seal on the containment side of the autoclave (e.g. the intersection where autoclave passes through the containment barrier) |  |  |  |
|  | 1. The air-tight seal shall be maintained to be functional at all time when the facility is in operation; and |  |  |  |
|  | 1. System is available to detect and alert in the event of process failures/errors. |  |  |  |
|  | Efficacy of autoclave cycle is validated according to the autoclave cycle (e.g. Waste or reusable items) and load: |  |  |  |  |
|  | 1. Prior to use; |  |  |  |
|  | 1. When there is a change in parameter or waste load; and |  |  |  |
|  | 1. Verified on a regular basis, based on risk assessment. |  |  |  |
|  | All validation and verification reports, as well as Biosafety Committee reviews of reports are documented and maintained. |  |  |  |  |
|  | An up-to-date record of the autoclave usage is maintained and kept on file. |  |  |  |  |
|  | Autoclaves are maintained annually or as per manufacturer’s specification, whichever occurs earlier. |  |  |  |  |
|  |  |  |  |  |  |
| **Part 3.3 Tissue Digesters (If applicable)** | | | | | |
|  | Tissue digester is designed with: |  |  |  |  |
|  | 1. Safety features to ensure that door remains locked until the digestion process is completed; and |  |  |  |
|  | 1. Systems to detect and alert in the event of process failures/errors. |  |  |  |
|  | Efficacy of digestion process is validated according to waste load: |  |  |  |  |
|  | 1. Prior to use; |  |  |  |
|  | 1. When there is a change in parameter or waste load; and |  |  |  |
|  | 1. Verified on a regular basis, based on risk assessment. |  |  |  |
|  | All validation and verification reports, as well as BC reviews of reports are documented and maintained. |  |  |  |  |
|  | An up-to-date record of the tissue digester usage is maintained and kept up to date. The records shall contain the following: |  |  |  |  |
|  | 1. Date and time of use; |  |  |  |
|  | 1. Responsible person; |  |  |  |
|  | 1. Type of tissue/waste; and |  |  |  |
|  | 1. Date and time of completion. |  |  |  |
|  | All waste released from the digester into the common sewage or environment shall comply with the regulatory requirements: |  |  |  |  |
|  | 1. PUB; |  |  |  |
|  | 1. NEA; and |  |  |  |
|  | 1. Any other relevant regulatory authority, if applicable. |  |  |  |
|  | Tissue digesters are maintained annually, or as per manufacturer’s specification, whichever occurs earlier. |  |  |  |  |
| **Part 3.4 Effluent Decontamination System - EDS (If applicable)** | | | | | |
|  | Effluent decontamination system is designed with the following safety features: |  |  |  |  |
|  | 1. System to prevent effluent overflow; |  |  |  |
|  | 1. System to ensure effluent is decontaminated prior to release from the EDS; and |  |  |  |
|  | 1. System to detect and alert in the event of process failures/errors. |  |  |  |
|  | Efficacy of EDS is validated according to waste load: |  |  |  |  |
|  | 1. Prior to use; |  |  |  |
|  | 1. When there is a change in parameter or waste load; and |  |  |  |
|  | 1. Verify on a regular basis, based on risk assessment. |  |  |  |
|  | All validation and verification reports, as well as BC reviews of reports are documented and maintained. |  |  |  |  |
|  | All waste released from the EDS into the common sewage or environment shall comply with the regulatory requirements: |  |  |  |  |
|  | 1. PUB; |  |  |  |
|  | 1. NEA; and |  |  |  |
|  | 1. Any other relevant regulatory authority, if applicable. |  |  |  |
|  | An up-to-date record of EDS usage is maintained and kept on file. |  |  |  |  |
|  | The EDS is maintained annually or as per manufacturer’s specification, whichever occurs earlier. |  |  |  |  |

**PART 4: Administrative Control**

This section focuses on the requirements of the *Biological Agents and Toxins Act* (BATA) and administrative controls intended to mitigate risks associated with the work in the facility. The administrative controls to be introduced to the facility shall be based on thorough Risk Assessments (RAs), with the aim to protect the safety and security of facility personnel and the external environment.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Part 4.1 Biosafety Policies and Record Keeping Practices** | | | | | |
|  | A Biosafety Committee (BC) is appointed by the Facility Operator (FO) and consists of all the roles stipulated in BATA *(Note: Each personnel shall be appointed for only one stipulated role)* |  |  |  |  |
|  | A policy is available and states: |  |  |  |  |
|  | 1. The frequency and mode of BC meetings; and |  |  |  |
|  | 1. The requirement for document control and record retention for BC meeting minutes and other relevant records. |  |  |  |
|  | The policy/policies stated for Part 4.1.2 is implemented. |  |  |  |  |
|  | A biosafety management programme is in place and the programme shall comprise: |  |  |  |  |
|  | 1. A biosafety manual (including relevant SOPs) which is kept current and made readily available to all personnel working in the facility; |  |  |  |
|  | 1. Established procedures and safe work instructions which were devised, endorsed or reviewed by the BC and implemented by the biosafety co-ordinator; |  |  |  |
|  | 1. A system to ensure all facility personnel have read, understood and adhered to all the safe work instructions, and procedures (including safety and security practices/ procedures) of the programme; |  |  |  |
|  | 1. Records are available for (c), which shall be done annually or when there are changes made to the programme, whichever occurs earlier. |  |  |  |
|  | Risk assessment is carried out: |  |  |  |  |
|  | 1. On all proposed work activities in the containment facility prior to the commencement of the activities; |  |  |  |
|  | 1. Before any change is made to the established procedures of any activities; |  |  |  |
|  | 1. After any laboratory incidents or near misses; |  |  |  |
|  | 1. At least every 2 years or earlier, subjected to the occurrence of (a) – (c); and |  |  |  |
|  | 1. Records are available for all the above. |  |  |  |
|  | Risk assessment must cover all aspects, including safety, security of the biological agent, toxin and/or the project/work |  |  |  |  |
|  | Risk assessment and risk control measures are carried out/devised/reviewed (delete as appropriate) and approved by the BC (Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_). |  |  |  |  |
|  | All inactivation methods/procedures for biological agents and toxins: |  |  |  |  |
|  | 1. Are validated to be effective in rendering the biological agents non-replicative and non-infectious; |  |  |  |
|  | 1. Are validated to be effective in neutralising the toxicity of the toxins; |  |  |  |
|  | 1. Are accompanied with validation results and methods which are reviewed and approved by the BC; |  |  |  |
|  | 1. Are regularly reviewed and verified (specify frequency) for efficacy; and |  |  |  |
|  | 1. Are accompanied with validation/verification procedures and results which are documented and maintained. |  |  |  |
|  | All biosafety and biosecurity policies/programmes (e.g. Risk assessments, biosafety manual, inactivation methods etc.) are reviewed (by the BC) at a minimal frequency of 2 years or when changes are made to them, whichever occurs earlier. |  |  |  |  |
|  | Policy and system are in place for the transference of biological materials (including live and inactivated status) and toxins out of the containment area, both internationally and locally. |  |  |  |  |
|  | Availability of an up-to-date inventory system for all biological agents, toxins, inactivated biological agents and infectious materials in the facility. |  |  |  |  |
|  | Details of inventory (stock) shall include: |  |  |  |  |
|  | 1. Identity of the material (e.g. name of biological agent/toxin, clinical specimen positive for a biological agent); |  |  |  |
|  | 1. Location of the material; |  |  |  |
|  | 1. Material transaction activity (e.g. add on, remove) |  |  |  |
|  | 1. Material transaction date and time; |  |  |  |
|  | 1. Purpose of material transaction (e.g. lab use, disposal, transfer out); |  |  |  |
|  | 1. Laboratory personnel responsible for the material transaction; |  |  |  |
|  | 1. Identity of facility and recipient which biological agent/toxin is being transferred to/from (if applicable); |  |  |  |
|  | 1. Quantity of biological agent/toxin received/transferred out; and |  |  |  |
|  | 1. Status of biological agent/toxin being transferred out (e.g. inactivated, live); and |  |  |  |
|  | 1. Any other relevant information   Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
|  | A system is in place to track and/or account for working biological agent/toxin (e.g. biological agent as prevent in an infected animal or in a tissue culture flask). |  |  |  |  |
|  | Transport of biological agent/toxin (or infectious material) within the facility is performed in a secure manner, using a secondary container which is leak proof and break proof. |  |  |  |  |
|  | Policy and system are implemented for physical audit of inventory. |  |  |  |  |
|  | Physical audits of the inventory system is carried out regularly, and findings are documented and maintained. |  |  |  |  |
|  | Policy and system are in place for information security (including procedures to secure and assess sensitive information (e.g. inventory records). |  |  |  |  |
|  | Policy and system are in place to ensure all records pertaining to the compliances, operations, safety and security of the facility are maintained and kept up-to-date, with a minimum retention period: |  |  |  |  |
|  | 1. For at least 5 years for registered facilities; and |  |  |  |
|  | 1. For at least 3 years for de-registered facilities. |  |  |  |
| **Additional Requirements for Animal Work** | | | | | |
|  | Facilities engaged in animal work must comply with all policy and procedure requirements stipulated by AVS. |  |  |  |  |
|  | An up-to-date inventory with the following details regarding to animals used is maintained in the facility: |  |  |  |  |
|  | 1. IACUC’s approval number for the animal work; |  |  |  |
|  | 1. AVS’s approval/licence for the animal work; |  |  |  |
|  | 1. Person responsible for animal; |  |  |  |
|  | 1. Date of animal brought into facility; |  |  |  |
|  | 1. Type and number of animal/s brought into the facility; |  |  |  |
|  | 1. Location of the animal; |  |  |  |
|  | 1. Purpose of animal; |  |  |  |
|  | 1. Disposal or storage records of animal and its parts; and |  |  |  |
|  | 1. Health status report of animal, prior to the use and during use of the animal. |  |  |  |
| **Part 4.2 Occupational Health (OH) and Personal Protection Equipment (PPE)** | | | | | |
|  | An OH program is implemented according to the risk assessment conducted for all work carried out in the facility, including work involving: |  |  |  |  |
|  | 1. Biological agents; |  |  |  |
|  | 1. Toxins; |  |  |  |
|  | 1. Chemicals |  |  |  |
|  | 1. Radiological; |  |  |  |
|  | 1. Animal use; and |  |  |  |
|  | 1. Any other hazards (e.g., ergonomics) |  |  |  |
|  | All facility personnel are: |  |  |  |  |
|  | 1. Informed of the risk (or potential risk) associated with their work activities, including the handling of biological agents/toxins/animals/other hazardous materials; |  |  |  |
|  | 1. Trained and assessed to be competent to protect themselves from exposure to the hazards and response to incidents; |  |  |  |
|  | 1. Provided with the appropriate vaccination as indicated by risk assessment, and whenever available; |  |  |  |
|  | 1. Provided with the necessary PPE and PPE training as specified by risk assessment; |  |  |  |
|  | 1. Updated promptly and provided with the necessary training when there are procedural changes; and |  |  |  |
|  | 1. All the above is documented and maintained. |  |  |  |
|  | Where applicable, |  |  |  |  |
|  | 1. Mucosal membrane protection is used where there is a risk of exposure to splashes; and |  |  |  |
|  | 1. A respiratory protection fitting and training programme is implemented; and |  |  |  |
|  | 1. A vaccination programme is implemented. |  |  |  |
|  | A health monitoring system is implemented for surveillance and management of illness among facility personnel working with regards to the hazards identified. |  |  |  |  |
|  | Incident policy is implemented to: |  |  |  |  |
|  | 1. Document all incidents (including near misses) which occurred in the facility; |  |  |  |
|  | 1. Report incidents to internal authorities (e.g. senior management, FO); and |  |  |  |
|  | 1. Notify MOH (in a timely manner) of all the following incidents: |  |  |  |
|  | * + - All confirmed or suspected infections or illnesses acquired by any member of the staff of the facility in the course of carrying out any activity involving biological agents or toxins at the facility; |  |  |  |
|  | * + - All adverse incidents involving biological agents that may potentially cause transmission of any infectious disease; |  |  |  |
|  | * + - All adverse incidents involving toxins; |  |  |  |
|  | * + - All lost and/or unaccountable biological agents and toxins (whether through theft or otherwise); |  |  |  |
|  | * Any other incidents which the facility operator assessed to have adverse impact to the facility personnel, the community and/or the environment; and |  |  |  |
|  | 1. Notify all other relevant national authorities, whenever applicable. |  |  |  |
|  | A system is in place: |  |  |  |  |
|  | 1. For incident investigations and implementation of corrective actions to the identified root cause(s) for all incidents; |  |  |  |
|  | 1. For sharing of lessons learnt from incidents with all relevant personnel; and |  |  |  |
|  | 1. To document and maintain all record of incidents (include near miss). |  |  |  |

**PART 5: Personnel Training and Competency**

Personnel training is a crucial aspect in achieving a safe working environment of a high containment facility. While physical safeguards are in place, personnel entering the facility shall be aware of all the potential hazards and risks they may be exposed to and are equipped with adequate knowledge and skills to protect themselves and to respond to unforeseen incidents.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
|  | Training requirements/needs for each facility personnel are identified based on the facility personnel’s work duties. |  |  |  |  |
|  | Training modules include but are not limited to the following: |  |  |  |  |
|  | 1. Biosafety; |  |  |  |
|  | 1. Biosecurity (including information security); |  |  |  |
|  | 1. Dual - use awareness; |  |  |  |
|  | 1. Risk assessment and risk mitigation; |  |  |  |
|  | 1. Relevant biosafety and biosecurity legislations; |  |  |  |
|  | 1. Proper use of PPE; and |  |  |  |
|  | 1. Emergency evacuation and response procedures. |  |  |  |
|  | Refresher training (hands-on) is provided to facility personnel annually. |  |  |  |  |
|  | Training is conducted for all facility personnel, visitors and contractors who enter the facility (even for a temporary period), based on training requirement analysis. |  |  |  |  |
|  | A system is in place to assess training effectiveness and facility personnel competency. |  |  |  |  |
|  | Training and competency assessment records are maintained and kept up-to-date. |  |  |  |  |
|  | Training requirements of facility personnel are reviewed regularly based on risk assessment and/or when there is a change in facility personnel’s work duties, after a laboratory incident, whichever occurs earlier. These documented and records are maintained. |  |  |  |  |
|  | Facility trainers meet the following requirements: |  |  |  |  |
|  | 1. Have tertiary academic qualifications in Biomedical Sciences or equivalent field; |  |  |  |
|  | 1. Have significant experience and knowledge (minimum of 3 years) of managing/working a BSL3 (or higher) facility; |  |  |  |
|  | 1. Have significant work experience and knowledge (minimum of 3 years) in their training subject; and |  |  |  |
|  | 1. Evaluated to be competent by the BC to provide training. |  |  |  |
| **Additional Requirements for Animal Work** | | | | | |
|  | Facility personnel are trained in animal-related: |  |  |  |  |
|  | 1. Work procedures (e.g. use animal handling, use of animal restraint); and |  |  |  |
|  | 1. Emergency procedures (e.g. animal bites, animal escape). |  |  |  |

**PART 6: Laboratory Practices**

The use of safe work practices helps to protect personnel from exposure to infectious biological agents or toxins, and to prevent accidental release of hazardous materials into the environment. Safe work practices should be documented and adhered by all personnel.

| **S/N** | **Checked Item** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
|  | Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in the facility. |  |  |  |  |
|  | Personal belongings (e.g. jewellery, watches, etc.) are stored outside of the facility. |  |  |  |  |
|  | Open wounds and cuts are covered with waterproof dressing. |  |  |  |  |
|  | Mouth pipetting is prohibited, and mechanical pipetting equipment are readily available. |  |  |  |  |
|  | Procedures which present potential for creating infectious aerosols/splashes are carried out inside the BSCs and/or be handled with additional administrative controls. |  |  |  |  |
|  | Centrifugation of biological agents are carried out in sealed rotors/safety cups that are opened inside the BSCs. |  |  |  |  |
|  | When working in the BSC: |  |  |  |  |
|  | 1. Open flames are prohibited; and |  |  |  |
|  | 1. BSC is kept clean and tidy, not-cluttered, front grills and exhaust filters are not obstructed. |  |  |  |
|  |  |  |  |  |  |
|  | Sharps policy is in place: |  |  |  |  |
|  | 1. No sharp is allowed in the facility; or |  |  |  |
|  | 1. A sharps programme is implemented to ensure safe handling and disposal of sharps, and response to sharp incidents. |  |  |  |
|  | Active and effective pest control programme is in place. |  |  |  |  |
|  | Chemical policy is in place to ensure: |  |  |  |  |
|  | 1. Chemical stocks are stored in appropriate storage cabinets; |  |  |  |
|  | 1. Chemicals are properly segregated based on compatibility within their storage areas; |  |  |  |
|  | 1. No storage of hazardous chemicals above eye level; and |  |  |  |
|  | 1. All chemical containers/bottles are clearly labelled, in accordance to SS586[[10]](#footnote-10). |  |  |  |
|  | A two-way communication system is available between the facility personnel and personnel outside of facility. |  |  |  |  |
|  | Plans and procedures for emergency responses are available. |  |  |  |  |
|  | Emergency response exercises are conducted with Singapore Civil Defence Force (SCDF) on a regular basis. |  |  |  |  |
|  | Red teaming exercise is carried out annually. |  |  |  |  |
|  | Onsite demonstration – e.g., response to an emergency scenario, performing of a laboratory procedure, etc.   1. Specify the scenario/procedure; 2. Record of observations or findings from the demonstration; and 3. Assessment of facility personnel competency. |  |  |  |  |

|  |
| --- |
| **MOH Approved Certifiers’ Comments** |
|  |

|  |  |
| --- | --- |
| **Name of Certifier:** | **Certifier’s Signature:** |
|  |  |
|  |  |
| **Company Stamp:** | **Date of Certification Completion:** |
|  |  |

1. Shut down refers to complete cessation of all laboratory activities, with all biological agents and toxins stored within locked freezers, and that the facility is fully decontaminated. [↑](#footnote-ref-1)
2. FO must submit the RA and risk management plan to MOH prior to the estimated date of certification. The document submission must be done with adequate grace period to allow MOH officers to prepare for the certification (e.g. vaccination, PPE fitting, etc.). [↑](#footnote-ref-2)
3. Red teaming exercise refers to a variety of exercise activities which aim to test and/or identify the probable security vulnerabilities in a facility. [↑](#footnote-ref-3)
4. The Red teaming training course refers to the red teaming officer course held by Ministry of Home Affairs. [↑](#footnote-ref-4)
5. Examples of redundancy include emergency power supply, uninterrupted power supply, additional air handling unit and/or exhaust fans [↑](#footnote-ref-5)
6. Minor issues may be verified through other means (e.g. photograph), but this shall be agreed upon by MOH. [↑](#footnote-ref-6)
7. Facility status can be designated as (1) Shut Down and (2) Non-Shut Down. See definition of “Shut Down” in footnote 1. [↑](#footnote-ref-7)
8. NIH Design Requirements Manual Rev 1.4:4/24/2019 [↑](#footnote-ref-8)
9. Singapore Standards SS508:2016 Graphical symbols with appropriate safety signs and colours. [↑](#footnote-ref-9)
10. Singapore Standard SS586 – Globally harmonised system (GHS) and labelling of hazardous chemicals. [↑](#footnote-ref-10)