Ministry of Health Singapore
Certification Criteria for High (Biosafety Level 3) Containment Facility

General Instructions:

1. Certification of high containment facility shall be performed only by Ministry of Health-Approved Facility Certification Body (MOH-AFCB) and Certifiers (MOH-AFCs).
2. The MOH-AFCB's certification team shall comprise at least the following **TWO** MOH-AFCs: A lead biorisk management professional and a lead biocontainment engineering professional.
3. The certification shall encompass all safety and security aspects of the facility, focusing on biological related safety and security, and covering all compliance aspects of the facility's biocontainment and biorisk management systems.
4. Certification requirements shall be based on the **Singapore Standard 696:2023 Specifications for high containment (biosafety level 3) facility**. MOH-AFCB and MOH-AFCs may include additional requirements as assessed as appropriate.
5. MOH shall be notified of the certification at least ONE MONTH prior to the scheduled certification date, and **MOH officer/s shall be present on-site to observe the conduct of the certification process.** Both the facility and the MOH-AFCB are responsible in notifying MOH about the certification.
6. The certification report shall entail/include the following:
    a) Details of the participating certification team members which include the MOH-AFCs (lead certifiers) and any other persons who have supported the certification process (e.g. assistant certifier and the person who prepared/reviewed the report), and their names, designations and roles are clearly indicated.
    b) Details of the certification process, e.g. the date, time and duration of the on-site certification, the tests conducted, and if the certification was performed with the facility completely[1] or partially shutdown, or non-shutdown.
    c) Results/outcomes of the certification which include,
        (i) Checklist with checked items (and any other tests which are not included in the checklist) conducted/verified, and their corresponding outcomes, e.g. compliance, non-compliance, or findings, if any.
        (ii) Picture, table and/or chart presenting the testing/inspection results for the facility's ventilation and engineering system, containment equipment, and any other infrastructures/services. Assessments are to be conducted on all non-compliances and major findings to determine if they could compromise the containment integrity and security of the facility, and/or the safety of the workers and the environment.

[1] Complete shutdown 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.

(iii) Practical assessment of facility personnel in responding to work procedures, incidents, or emergency scenarios.

(iv) A list with all the findings and non-compliances identified in (i), (ii) and (iii) are clearly documented together with their required rectifications or follow-up actions and response timelines/deadlines.

(v) Relevant supporting documents, e.g. certificate of equipment used in the certification process.

d) The validity of the certification, which shall be **NO longer than 13 months from the certification date.**

7. MOH may introduce new certification criteria or requirements for the MOH-AFCB, MOH-AFC and the facility owner. The affected party will be notified prior to the implementation of such changes.

Specific Instructions to High (Biosafety Level 3) Containment Facility Owner:

1. Facility owner shall determine if the certification process is to be conducted with the facility completely[2] or partially shutdown, or not shutdown at all.

2. If the certification is to be conducted in a partially or non-shutdown manner, the facility owner shall ensure that:
   a) A thorough risk assessment is conducted, and a risk management plan is implemented to protect the SAFETY of ALL personnel (including laboratory personnel, servicing/maintenance crew, certifiers, MOH-officers, etc.) who will be involved/participated in the pre-certification maintenance, pre-certification and certification process.
   b) The risk assessment and risk management plan shall be:
      i. Reviewed and endorsed/approved by the biosafety committee.
      ii. Approved by the facility operator.
      iii. Endorsed and accepted by the MOH-AFCB and AFCs engaged for the certification service. The MOH-AFCB and AFCs reserve the right to reject the risk assessment and the risk management plan, and/or to decline providing certification service to the facility if they assessed that the risks have not been adequately identified and/or addressed.
   c) The finalised risk assessment and risk management plan including all relevant documents are to be submitted to MOH at least 1.5 months before the scheduled certification date.[3] The facility operator shall inform in writing of any risks and/or potential hazards which MOH officers may be exposed to when performing their duties during the certification, and of any vaccinations that may be required prior to entering the facility.

3. The facility shall have the following in place:
   a) Emergency response plan and procedures
      i. Facility personnel are available to demonstrate competency in responding to laboratory incidents (e.g. minor spills, etc.) and/or perform work procedures upon MOH-AFC's and/or MOH's request.
      ii. Policy to conduct regular/annual joint emergency drills with Singapore Civil Defence Force.
      iii. Audit reports (capturing the emergency scenarios, findings and lessons learned) for the joint emergency drills are available for review.
   b) Red teaming[4] programme

[2] Complete shutdown 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.
[3] The document submission must be done with adequate grace period to allow MOH officers to prepare for the certification (e.g. to be vaccinated, to perform mask fit testing, etc.).
[4] Red teaming exercise refers to a variety of exercise activities which aim to test and/or identify the probable security vulnerabilities in a facility.

i. Policy to conduct annual red teaming exercise.
ii. Reports (capturing the red teaming scenarios, findings and lessons learned) are available for review.

c) Public Utilities Board (PUB)'s Written Approval for the discharge of liquid effluent from the facility.

d) Compliance with MHA-Physical Security Work Group requirements, for facility gazetted as a Protected Place under the Infrastructure Protection Act.

4. The facility shall not engage a MOH-AFCB for certification if:

a) The company or a member of the certifying team has provided maintenance services or BRM programme/system development or any other biosafety/biosecurity related services to the facility within 24 months preceding the auditing date.

b) The company or a member of the certifying team has provided design, construction or commissioning services within 24 months preceding the auditing date.

c) The same MOH-AFCB has already certified the facility for two consecutive rounds, unless consent or approval from MOH has been obtained.

5. Facility involved in animal work is responsible to co-ordinate with AVS for the certification, whenever applicable.

Specific Instructions to MOH-Approved Facility Certification Body and Certifiers:

1. MOH-Approved Facility Body and Certifiers (MOH-AFCB and MOH-AFCs) are advised to read and understand the requirements of the ***Biological Agents and Toxins Act*** **(BATA)** and be familiar with the **Singapore Standard 696:2023 Specifications for high containment (biosafety level 3) facility** before conducting any certification process.

2. The team lead shall ensure that his/her certifying team comprise at least one lead biorisk management professional and one lead biocontainment engineering professional who are both MOH-AFCs.

3. The MOH-AFCB is responsible for informing MOH of any changes to its team members prior to the certification, and all changes are subject to MOH's approval.

4. A MOH-AFCB is not allowed to certify a facility if:
   a) The company or a member of the certifying team has provided maintenance services or BRM programme/ system development or any other biosafety/biosecurity related services to the facility within 24 months preceding the certification date.
   b) The company or a member of the certifying team has provided design, construction or commissioning services within 24 months preceding the certification date.

5. A MOH-AFCB may audit the same facility for a maximum of two consecutive rounds. Auditing beyond two consecutive rounds requires consent or approval from MOH.

6. The MOH-AFCB shall ascertain that the facility's engineering controls are equipped with sufficient redundancy[5] and/or a system is 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) to manage all possible failure scenarios and to ensure that the safety of the facility personnel, the community and the environment is protected at all times.

7. 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. The list of scenarios which will be conducted on the day of

[5] Examples of redundancy include emergency power supply, uninterrupted power supply, additional air handling unit and/or exhaust fans

certification shall be provided to MOH, 2 weeks before the certification date. The ventilation system test script shall be endorsed by MOH.

8. The differential pressure and/or pressure decay (if applicable) measurements for ALL rooms within the containment zone and along containment zone barrier, shall be determined in a quantitative manner using a calibrated instrument that can provide reliable and real time quantitative data. The measurements shall be recorded during normal operation, during challenge scenarios and upon resuming to normal operations. Qualitative tests such as smoke test cannot be used as a replacement of the quantitative method of measurement.

9. The MOH-AFCB shall conduct facility's airflow (e.g. supply and exhaust diffusers in the facility), light and sound measurements, and ensure they meet/achieve the intended designs and/or purposes.

10. All observations and findings collected from the certification process shall be properly recorded, documented, and communicated clearly to the facility owner and this shall include the required rectifications and/or follow up actions and their response timeline/deadline. The MOH-AFCB should provide expert insights to the facility owner with regards to the issues identified during the certification, without compromising the impartiality of the process.

11. MOH-AFC/s with the relevant expertise shall be present for verification/re-verification of the issues/findings identified during the certification.[6]

[6] Minor issues may be verified through other means (e.g. video or photograph), but this shall be agreed upon by MOH.