

Ministry of Health Singapore

Audit Criteria for Biosafety Level 2 Facility

General Instructions:

1. Ministry of Health-Approved Facility Certification Body (MOH-AFCB) and Certifiers (MOH-AFCs) shall be engaged to perform audit for Biosafety Level 2 (BSL2) facility.
2. The MOH-AFCB's audit team shall comprise at least **ONE MOH-AFC** who is a **lead biorisk management professional**.
3. The audit 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 biorisk management system.
4. The Enhanced BSL2 Laboratory (Uncertified Facility) Audit/Inspection Checklist shall be used for the audit process. MOH-AFCB and MOH-AFCs may include additional requirements as assessed as appropriate.
5. MOH shall be notified of the audit at least ONE MONTH prior to the scheduled audit date, and **MOH officer/s shall be present on-site to observe the conduct of the audit process**. Both the facility and the MOH-AFCB are responsible in notifying MOH about the audit.
6. The audit report shall entail/include the following:
 - a) Details of the participating audit team members including the MOH-AFC (lead certifier) and any other persons who have supported the audit 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 audit process, e.g. the date, time and duration of the on-site audit and the audit tasks conducted.
 - c) Audit results/outcomes which include:
 - (i) Checklist with checked items (and any other tests which are not included in the checklist) audited/verified, and their corresponding outcomes, e.g. compliance, non-compliance, or other findings, if any.
 - (ii) Picture, table and/or chart presenting the audit observations/findings. Assessments are to be performed 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.
 - (iii) Practical assessment of facility personnel in responding to work procedures, incidents, or emergency scenarios.
 - (iv) A list with all 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 audit, which shall be **NO longer than**

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- (i) **25 months** from the audit date, for facility involving **large-scale production of biological agent**, or
- (ii) **37 months** from the audit date, if NO large-scale production of biological agent is involved in the facility.

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

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Specific Instructions to Biosafety Level 2 Facility Owner:

1. The facility shall have in place the following:
 - a) Emergency response plan and procedures with facility personnel available to demonstrate competency in responding to laboratory accidents (e.g. minor spills, etc.) and/or perform work procedures upon MOH-AFC's and/or MOH's request.
 - b) Red teaming¹ programme for facility gazetted as a Protected Place under the Infrastructure Protection Act.
 - i. Policy to conduct annual red teaming exercise.
 - ii. Red Teaming Reports (capturing the red teaming scenarios, findings and lessons learned) are available for review.
 - c) Compliance with MHA-Physical Security Work Group requirements for facility gazetted as a Protected Place under the Infrastructure Protection Act.
2. The facility shall not engage a MOH-AFCB for audit 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 audited the facility for **two consecutive rounds**, unless consent or approval from MOH has been obtained.
3. Facility involved in animal work is responsible to co-ordinate with AVS for the audit, whenever applicable.

¹ Red teaming exercise refers to a variety of exercise activities which aims to test and/or identify the probable security vulnerabilities in a facility.

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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 **auditing requirements for BSL2 facility (refer to Annex A)** before conducting any audit process.
2. The team lead shall ensure that his/her certifying team comprise at least ONE lead biorisk management professional who is a MOH-AFC.
3. The MOH-AFCB is responsible for informing MOH of any changes to its team members prior to the audit, and all changes are subject to MOH's approval.
4. A MOH-AFCB is not allowed to audit 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 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.
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. All observations and findings collected from the auditing 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 timelines/deadlines. The MOH-AFCB should provide expert insights to the facility owner with regards to the issues identified during the audit, without compromising the impartiality of the process.
7. MOH-AFC/s with the relevant expertise shall be present for verification/re-verification of the issues/findings identified during the audit.²

² Minor issues may be verified through other means (e.g. photograph), but this shall be agreed upon by MOH.