

MOH-APPROVED FACILITY CERTIFIER SCHEME (Explanatory Note)

Introduction

The MOH Biosafety Legislation Branch has a certification scheme to approve organizations with relevant experience in certification of a BSL-3 facility as MOH-Approved Facility Certifiers (AFC). The AFCs are to perform certification of BSL-3 facilities, which is **required under the Biological Agents and Toxins Act (BATA) 2005**.

The MOH certification checklist is based on the 3rd edition of the WHO Laboratory Biosafety Manual and also has incorporated our local requirements specified under BATA. The MOH certification checklist can be downloaded from URL: http://www.biosafety.moh.gov.sg/bioe/ui/pages/content/Certification_updated_v.2.pdf.

The requirements for an organization to apply for an AFC status are given in Annex 1 and 2. **Applicants should read and understand these requirements before submitting an application at www.biosafety.moh.gov.sg**

Application for AFC

1. An applicant who wishes to apply for an AFC must submit the following documents together with the application forms:
 - a) Testimonials from applicant's previous BSL-3 client(s) stating that the applicant had certified the BSL-3 facility. (At least 3 testimonials preferred);
 - b) Copies of the certifiers' *curriculum vitae* (including academic certificates, professional certificates, etc for verification purposes);
 - c) Certifier's internal standard operational procedures (SOPs) detailing methods to ascertain that a BSL-3 facility under certification has the necessary engineering and administrative control, as stated in the MOH certification checklist, to ensure safe practices; and
 - d) A brief description of the organization applying to be an approved certifier. The description shall include:
 - i) Organization background and history;
 - ii) Organization's experience in certifying and or commissioning any BSL-3 facilities; and
 - iii) Accreditation received (if any).

Conditions of approval

The conditions for approval are as follows:

- a) Certification of a BSL-3 facility using criteria specify by the Director;
- b) The approval should be tied to the company and the lead certifier;
- c) To prevent conflict of interests, no certifier shall be allowed to certify a BSL-3 facility, if he has commissioned it or provided maintenance services to the facility in the previous 3 years;
- d) Validity of the registration may be up to 5 years and is subject to the discretion of MOH.
- e) The Certifier's registration may be revoked if Director has reason to believe that certification criteria are not met; and
- f) Involvement of a MOH officer during the independent measurements/tests and physical inspection phase.
- g) The AFC must include at least a microbiologist and an engineer.

Submission of application form

Application is done online at www.biosafety.moh.gov.sg. Any supporting documents that were unable to be included in the online application should be sent to us via e-mail at moh_biosafety@moh.gov.sg or submitted to us in CD format by mailing it to:

Attn: Biosafety Legislation Branch
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

Please note that incomplete application forms or submissions would not be processed or considered.

Requirements for Application of Approved Certifier

General Requirements

1. Team requirement

- a) For team, one of the members must be the lead certifier; and
- b) Each team shall submit one copy of the company application together with particulars of each member of the certification team, as required in the online application.

2. Qualification and competence of certifier

- a) The certifier shall fulfill all the competencies as stated in Annex 2 and submit all the necessary documents stated in the annex;
- b) The team shall be competent in certifying all the items stated in the MOH certification checklist; and
- c) Only competent certifiers shall be approved and designated as approved certifiers.

3. The MOH certification checklist

- a) For the purpose of satisfying the requirements in 2(a) above, an applicant shall describe how every item in the MOH certification checklist is assessed. Please refer to the Introduction section on how to obtain a copy of the checklist; and
- b) Where necessary, internal SOPs to ascertain that a BSL-3 facility has the necessary engineering and administrative control as required in the checklist shall be included for our assessment.

4. Certification process

- a) The lead approved certifier shall ensure that the team members involved in the certification process are those approved by MOH;
- b) The approved certifier shall submit the schedule of certification at least 1 month in advance to the MOH Biosafety Legislation Branch; and
- c) During the certification process, the approved certifier shall:
 - i) Perform the certification according to paragraph 3 above;
 - ii) Involve a MOH officer for activities involving independent measurements/test and physical inspection; and
 - iii) Ensure that any problems identified are rectified and re-tested to be in satisfactory conditions before submitting the checklist and a final certification report to MOH.

5. Management of records

- a) The respective approved certifiers shall maintain all certification records; and
- b) The records shall be made available to the MOH Biosafety Legislation Branch upon request.

6. Indemnity issues

- a) The approved certifier shall fully indemnify MOH Biosafety Office and the Government against all costs, charges, actions, demands, claims and et cetera arising from or relating to any certification activities performed by the approved certifier.

7. Additional Requirements

- a) MOH Biosafety Legislation Branch reserves the right to amend or establish new requirements as and when needed. These requirements shall be communicated to the approved certifier for acceptance; and
- b) The approval of the certifier shall be revoked if the approved certifier refuses to accept the new requirements or subsequently fails to comply with such requirements.

8. Revocation of the approved certifier status

- a) The MOH Biosafety Legislation Branch reserves the right to revoke the status of an approved certifier if the certifier fails to comply with any requirements specified in this document; and
- b) Any decision of revocation shall be final.

ASSESSMENT CRITERIA

- 1) Relevant experience of the proposed agencies in certifying BSL-3 facilities in Singapore and/other countries. Documentary evidence of each agency's experience could include testimonials from previous clients;
- 2) Detailed CV/qualifications/training/work experience of the persons who would be carrying out the certification; and
- 3) Details of assessment criteria as well as the processes and Standard Operational Procedures (SOPs) that these persons would use to certify a BSL-3 facility using the MOH certification checklist.