

Guidelines for the Safe Management of High-Containment Laboratories at Academia Sinica

Approved on July 26, 2023

Amended on January 13, 2025

1. Academia Sinica (AS) has established these guidelines to ensure the safe management of high-containment laboratories (BSL-3 and ABSL-3 laboratories) under the jurisdiction of Institutes and Research Centers (hereinafter referred to as institutes/centers).
2. High-containment laboratories at institutes/centers may be activated only after being reviewed by the Academia Sinica Institutional Biosafety Committee (hereinafter referred to as the IBC) and approved by the Taiwan Centers for Disease Control, Ministry of Health and Welfare. (For ABSL-3 laboratories, the Animal and Plant Health Inspection Agency, Ministry of Agriculture shall also be notified).
3. The directors of institutes/centers shall support and provide the necessary resources for the operation of high-containment laboratories. The Biosafety Management Committee of the institutes/centers (hereinafter referred to as the Institute/Center Biosafety Committee) and the Academia Sinica Biosafety Office of the Institute shall oversee the biosafety and biosecurity management of the high-containment laboratories.
4. The responsibilities of supervisors of high-containment laboratories at institutes/centers (hereinafter referred to as "Supervisors") are as follows:
 - (a) Establish and maintain an up-to-date Laboratory Biosafety Manual.
 - (b) Ensure that personnel have completed the required training, passed the assessments, and been duly authorized.
 - (c) Ensure that laboratory equipment and infrastructure are maintained and serviced according to the planned schedule and comply with safety regulations.
 - (d) Ensure appropriate work scheduling for personnel; designate personnel to verify the accuracy of the inventory and quantities of stored pathogens at least quarterly, and maintain records for reference.
 - (e) In the event of an incident or accident in the laboratory, proceed

in accordance with Academia Sinica's disaster and accident response notification procedures.

- (f) Supervise and evaluate laboratory managers and staff to ensure the proper execution of their responsibilities and duties.

5. The responsibilities of the managers of high-containment laboratories at institutes/centers (hereinafter referred to as "Managers") are as follows:

- (a) Ensure the completeness of monthly laboratory project plans, usage schedules, and experimental work records, and maintain them for reference.
- (b) Ensure the proper functioning of the laboratory's software and hardware systems.
- (c) Ensure that the day's experimental work aligns with the scheduled plan.
- (d) Ensure that personnel entering the laboratory have been authorized by the Supervisors.
- (e) Ensure that personnel entering the laboratory are wearing personal protective equipment that complies with regulations.
- (f) Monitor the experimental procedures performed by laboratory personnel:
 - (1) Upon discovering that personnel violate biosafety standard operating procedures, promptly correct such behavior, document the incident, and report it to the Supervisors.
 - (2) Upon receiving a report from staff regarding an accident or incident during work hours, take immediate and necessary measures and notify the Supervisors. If the Supervisors cannot be contacted promptly, notify the institute/center's emergency response unit directly, followed by notification to the Supervisors.

6. Responsibilities of personnel working in high-containment laboratories at institutes/centers are as follows:

- (a) Complete education and training as required by regulations and laboratory protocols.
- (b) Adhere to the relevant standard operating procedures (SOPs) of the laboratory.
- (c) Shall not conduct unscheduled experiments or any unauthorized experiments or projects.
- (d) Immediately report any accidents or incidents occurring during experimental operations to the Managers.

7. The high-containment laboratories at institutes/centers may only conduct projects approved by the IBC. Conducting projects without such approval is strictly prohibited. Laboratory personnel may handle only a single species (including animals or pathogens) in the same area at the same time.
8. The high-containment laboratories of the institutes/centers shall be subject to inspections or internal audits conducted by the department's Biosafety Management Committee and the Biosafety Office. These inspections may include the review of surveillance footage and access control records. Avoidance, obstruction, or refusal of such inspections is strictly prohibited.
9. If the manager or personnel of the high-containment laboratories of the institutes/centers identify any violations of regulations, they may report or file a complaint to the director of the institutes/centers, the Chairperson of the Biosafety Management Committee, or the Biosafety Director of the Biosafety Office.
10. If personnel, managers, or supervisors of the high-containment laboratories of the institutes/centers violate the provisions set forth in Articles 4 through 7, and such violations are verified by the Academia Sinica Institutional Biosafety Committee, the matter shall be reported to Academia Sinica for disciplinary actions based on the personnel category and severity of the violation. The penalties may include one or more measures specified in Paragraph 2 or Paragraph 3.

Research Staff and Research Specialist :

- (a) Violations that do not result in personnel infection, illness, or pathogen leakage:
 - (1) For the first violation, a written warning will be issued, and the individual will undergo relevant biosafety education.
 - (2) For the second violation, an official reprimand shall be issued, access to relevant equipment will be suspended or the individual's qualification to enter high-containment laboratories will be revoked for one month, along with mandatory biosafety education.
 - (3) For the third and subsequent violations, in addition to the penalties outlined above, the following actions may also be taken:
 - Reduction or deduction of subsidies under the " Guidelines for Allowances for Personnel Working in High-Containment Laboratories at Academia Sinica " (hereinafter referred to as subsidies).

- Revocation or annulment of related awards previously conferred by the institution, with the recovery of any awarded funds.
- Rating of academic research performance at no higher than Level 2.
- Reassignment from high-containment laboratories.
- Placement on unpaid leave or early termination of the employment contract.

(b) In cases where the violation results in personnel infection, illness, or pathogen leakage, the following penalties may be imposed :

- Reduction or deduction of subsidies under the " Guidelines for Allowances for Personnel Working in High-Containment Laboratories at Academia Sinica " (hereinafter referred to as subsidies).
- Revocation or annulment of related awards previously conferred by the institution, with the recovery of any awarded funds.
- Academic research performance will not be graded above Level 2.
- Reassignment from high-containment laboratories.
- Placement on unpaid leave or early termination of the employment contract.

Contract-based Employee :

(a) Violations that do not result in personnel infection, illness, or pathogen leakage:

- (1)For the first violation, a written warning will be issued, and the individual will undergo relevant biosafety education.
- (2)For the second violation, access to relevant equipment will be suspended or the individual's qualification to enter high-containment laboratories will be revoked for one month, along with mandatory biosafety education.
- (3)For the third and subsequent violations, in addition to the penalties outlined above, the following measures may also be imposed:
 - Issuance of a demerit.
 - Year-end performance evaluation rated as Grade B or below.
 - Reduction or deduction of subsidies under the "Guidelines for Allowances for Personnel Working in High-Containment Laboratories at Academia Sinica."
 - Reassignment from high-containment laboratories.
 - Early termination of the employment (hiring) contract.

(b) In cases where the violation results in personnel infection, illness, or pathogen leakage, the penalties listed in Item (a)(3) above may be imposed.

- Issuance of a demerit.

- Year-end performance evaluation rated as Grade B or below.
- Reduction or deduction of subsidies under the " Guidelines for Allowances for Personnel Working in High-Containment Laboratories at Academia Sinica."
- Reassignment from high-containment laboratories.
- Early termination of the employment (hiring) contract.

11. If personnel, managers, or supervisors of the high-containment laboratories of the institutes/centers evade, obstruct, or refuse inspections, visits, or internal audits conducted by the department's Biosafety Management Committee or the Biosafety Office, and such actions are verified by the institution's Biosafety Committee, such conduct shall be deemed a violation and subject to penalties in accordance with Article 10.

12. If the Directors of institutes/centers, the Institute/Center Biosafety Management Committee, or the Academia Sinica Biosafety Office fail to comply with the provisions of Article 3, resulting in personnel infection, illness, or pathogen leakage, and such failure is verified by the Institutional Biosafety Committee, relevant personnel shall be disciplined in accordance with the " Code of Ethics for Academia Sinica Research Fellows and Research Specialists " and the " Guidelines for Handling Reward and Disciplinary Cases for Administrative and Technical Personnel at Academia Sinica."