

## **Regulations Governing Management of Infectious Biological Materials**

Formulated and announced in 19 articles by the Department of Health, the Executive Yuan, on September 26, 2005, under Shu-Shou-Chi Order No. 0940000614; and implemented as of March 26, 2006.

Amended and announced Article 2-1 and Article 19 on April 11, 2006, by the Department of Health, the Executive Yuan, under Shu-Shou-Chi Order No. 0950000194

Amended the title (original title: Regulations Governing Management of Infectious Biological Materials and Collection of Specimens from Patients of Communicable Diseases) and 21 articles, and announced by the Ministry of Health and Welfare on March 11, 2014 under Bu-Shou-Chi Order No. 1030100208

Amended 21 articles and announced by the Ministry of Health and Welfare on December 13, 2016 under Bu-Shou-Chi Order No. 1050101528

**Article 1** This set of Regulations is formulated in accordance with regulations of Paragraph 3, Article 34 of the Communicable Disease Control Act (hereafter referred to as the Act).

**Article 2** Terms used in these Regulations are defined as follows:

1. " Entity" means an organization (institution), group or enterprise that keeps, stores, uses, disposes, exports or imports infectious biological materials and has set up a laboratory or storage facility for the safekeeping of biological materials.
2. "Laboratory" means a facility that conducts testing of communicable diseases or carries out storage, research, sharing and distribution of infectious biological materials.
3. "Storage facility" means a facility other than laboratory that stores infectious biological materials.
4. "High containment laboratory" means a biosafety level 3 (BSL-3) or above laboratory or an animal biosafety level 3 (ABSL-3) or above laboratory.

5. "Biosafety" means containment guidelines, technologies and rules implemented by a laboratory for preventing accidental exposure to or release of biological agents.
6. "Biosecurity" means protection and management measures implemented by a laboratory or storage facility for preventing unauthorized access, loss, theft, misuse, unauthorized transfer or intentional release of infectious biological materials.

Article 3 The pathogens referred to in Paragraph 4 of Article 4 of the Act, by their hazardous risks of pathogenicity, are classified into four risk groups:

1. Risk Group 1: such as *Escherichia coli* K-12, Adeno-associated virus and others that do not affect human health;
2. Risk Group 2: such as *Staphylococcus aureus*, hepatitis B virus, *Plasmodium falciparum* and others that produce slight effects on human health, and for them, there are usually prevention measures and treatment available;
3. Risk Group 3: such as *Mycobacterium tuberculosis*, Human Immunodeficiency Virus Type 1 and Type 2 and others that can produce severe effects on human health, which may even be fatal, and for them, there may be prevention measures and treatment available;
4. Risk Group 4: such as Ebola virus, Variola (major and minor) virus and others that can produce severe effects on human health, which may even be fatal, and for them, there are usually no prevention measures and treatment available.

The derivatives of pathogens mentioned in Paragraph 4, Article 4 of the Act refer to the purified or isolated components of pathogens or their secretory products, including nucleic acids, plasmids, proteins, biotoxins or other derivatives.

The directions for the classification, categories, packing and other matters concerning pathogens and biotoxins mentioned in the preceding two paragraphs shall be prescribed by the central competent authority.

Article 4 Pathogens and biotoxins mentioned in Paragraph 3 of the

preceding article that may be used as biological warfare agents or may pose a serious hazard to the society shall be classified as “select agents”.

The directions for the items, permissible amounts and other management matters concerning select agents shall be prescribed by the central competent authority.

Article 5 Laboratories, by their operational practices and associated risk of infection, are classified into four biosafety levels; laboratories that conduct animal experiments and research are classified into four animal biosafety levels.

The directions for operational practices of laboratories mentioned in the preceding paragraph and their biosafety level, practices, personnel protective equipment, safety equipment and facilities and other relevant matters shall be prescribed by the central competent authority.

Article 6 Entities shall set up an appropriate biosafety and biosecurity management mechanism.

For the management of Risk Group 2 and above pathogens and biotoxins, an entity shall set up a biosafety committee; if an entity which employees less than five persons may assign a person who is responsible for biosafety affairs (hereafter referred to as “biosafety staff”).

Members of the biosafety committee are as follows:

1. Director or deputy director of the entities,
2. Chief of laboratory or storage facility,
3. Management personnel, engineering personnel of the laboratory or storage facility, or other personnel with relevant professional knowledge.

Members of the biosafety committee shall receive at least 4 hours of training in biosafety and biosecurity; the biosafety staff shall possess relevant professional knowledge, receive at least 16 hours of training in biosafety and biosecurity, and have a minimum of three years of experience in laboratory work.

The entities must, within one month after the establishment of a biosafety committee or the assignment of a biosafety staff, report to the central competent authority for record with a copy sent to local competent

authority. The same shall apply to any changes thereafter.

When an entity closes or suspends its business, or is dissolved or merged by another organization, the entity shall assure that all infectious biological materials possessed, stored or used by it have been destroyed or properly disposed, and report to the central competent authority for record.

Article 7 Duties of the biosafety committee and the biosafety staff are as follows:

1. Establish laboratory biosafety and biosecurity management policies and rules;
2. Review the possession, storage, use, disposal, or import and export of Risk Group 2 and above pathogens or biotoxins;
3. Review the biosafety level of laboratories using Risk Group 2 and above pathogens or biotoxins;
4. Review the biosafety and biosecurity emergency response plans of laboratories or storage facilities;
5. Review the plans of building, reconstruction, extension, inception and termination of use of the laboratories or storage facilities;
6. Review matters concerning disputes about biosafety or biosecurity of laboratories or storage facilities;
7. Conduct annual internal audit of the biosafety and biosecurity of laboratories or storage facilities, and carry out improvement of deficiencies found in the audit;
8. Conduct biosafety and biosecurity training of laboratory or storage facility personnel; and assess laboratory employees' competence.
9. Plan or implement health examination of laboratory or storage facility personnel and establish a monitoring mechanism for personnel with abnormal health conditions.
10. Review and supervise other matters concerning management of infectious biological materials and biosafety and biosecurity of laboratories;
11. Handle, investigate and report biosafety and biosecurity accidents of

laboratories and storage facilities.

Article 8 Laboratories may possess, use, store or dispose Risk Group 2 and above pathogens or biotoxins only after passing the review conducted by the biosafety committee or the biosafety staff of relevant entity.

Laboratories may possess, store, or dispose Risk Group 3 and above pathogens or select agents by regulations of the preceding Paragraph; in addition, the entities shall report to the central competent authority for permission.

Article 9 Laboratories and storage facilities shall periodically make an inventory of the items and amounts of the Risk Group 2 and above pathogens or biotoxins in their possession or storage. If shortage, loss or other abnormalities are detected, the matter shall be reported immediately to the biosafety committee or the biosafety staff.

An entity shall immediately inform its biosafety committee or biosafety staff and, within 24 hours, report to the competent authority the detection of any shortage, loss or other abnormalities involving Risk Group 3 and above pathogens or select agents.

The biosafety committee or the biosafety staff shall complete investigation of the abnormal event within seven days from the next day the report is received; the established units shall, within three days from the next day the investigation is completed, submit the investigation report to the local competent authority for reference, copy to the central competent authority.

Article 10 Biosafety accidents of laboratories or storage facilities, by the degree of leakage of the infectious biological materials, can be classified into high, moderate, and low hazard levels:

1. High level: the leakage of infectious biological materials has spread to areas outside the laboratory or storage facility, and poses a threat of infecting or harming personnel on duty, personnel of other departments, or community people in the neighborhood.
2. Moderate level: leakage of infectious biological materials is confined within the laboratory area or storage facility, and poses a threat of infecting or harming personnel on duty.

3. Low level: leakage of infectious biological materials is confined to the safety equipment of the laboratory, and poses a threat of infecting or harming personnel on duty.

The directions for the reporting and management of biosafety accidents mentioned in the preceding paragraph shall be prescribed by the central competent authority.

The entities shall ensure that there is no fear of infectious biological materials leaking to cause infections, and set up a contingency plan in accordance with the hazard levels of biosafety accidents. The contingency plan shall contain the following particulars:

1. Emergency response team and tasks,
2. Appraisal of the level of accidents and risk assessment,
3. Warning, management and reporting mechanisms of accidents,
4. Inventory management of the emergency response supplies,
5. Procedures of emergency medical care and rescue,
6. Safety protection measures for response personnel,
7. Evacuation procedures for emergency response and other responsive measures,
8. Cleaning, disinfection, renovation of hazard areas, coordination with other personnel of the organization, rehabilitative measures, and investigation report.

The entities shall, each year by these contingency plans of the preceding Paragraph, conduct simulated response field drills.

Article 11 The entities shall carry out the following for the storage facilities of Risk Group 2 and above pathogens and biotoxins:

1. Assign a person to take charge of the management of storage facility;
2. Establish access control;
3. Keep stock inventories and records of retrieval and storage; and
4. Draw up biosecurity related management manual.

When necessary, the competent authority may conduct auditing in

coordination with organizations concerned.

Article 12 In the import and export of infectious biological materials, the entities shall, by regulations of Paragraph 2, Article 34 of the Act, submit applications and relevant documents to the central competent authority for permission.

In the event that the infectious biological materials imported or exported are Risk Group 2 and above pathogens and biotoxins, documentation of consent by the biosafety committee or the biosafety staff of the entity shall be enclosed with the application.

Article 13 For the need of disease control, the central competent authority may order the entities to, within specified time, self-destroy or collectively destroy certain infectious biological materials.

Article 14 In transporting infectious biological materials, an entity shall meet the triple packaging rules set forth by the central competent authority and transport the materials in appropriate vehicle in compliance with the rules and regulations of the transportation authority.

In the event where the infectious biological materials mentioned in the preceding paragraph involve select agents, the entity shall also report to the central competent authority as required.

In the event that the infectious biological materials leak or cause other accidents during the process of transportation, transportation-related personnel shall promptly undertake necessary measures, and report to the entities that entrust the transportation. Upon receipt of notice, the entity shall immediately inform the local competent authority at where the accident occurs.

Article 15 The central competent authority may conduct auditing of the entities with high-containment laboratories or storing or using Risk Group 3 and above pathogens or select agents.

Local competent authority may conduct auditing of entities in their locality with biosafety level 1 or level 2 laboratories, or storing or using Risk Group 2 pathogens or non-select agents; when necessary, the central competent authority may assign person for supervision or auditing.

When deficiencies are found in audits conducted pursuant to the preceding two paragraphs, the competent authority shall order the entity to take corrective actions in due time, and if deemed necessary, order the entity to stop using relevant infectious biological materials.

Entities may not evade, interfere with or refuse the supervision or audit of the competent authorities.

Article 16 Newly established high-containment laboratories and storage facilities storing select agents may be inaugurated for use after obtaining the consent of the biosafety committee of the entity, and obtaining approval from the central competent authority.

Article 17 When biosafety accidents occur or are feared to occur in laboratory of the entities, the competent authority may order the laboratory to suspend the use of relevant infectious biological materials.

When the laboratory safety concern in the preceding paragraph is properly addressed, which has also been confirmed by the biosafety committee or biosafety staff of the entities, the laboratory may resume operations again after reporting to the competent authority that all safety issues have been addressed for consent of re-operation.

Article 18 Biosafety level 2 and above laboratories shall indicate at a conspicuous place level of biosafety, bio-hazards signs, names of director and person-in-charge, telephone numbers, and emergency contact, and draw up a biosafety related management manual.

For personnel of laboratories using Risk Group 3 and above pathogens, the entities shall safe-keep their serum specimens for ten years after they have left the job. For personnel of laboratories using Risk Group 2 and below pathogens, their serum specimens and retention period shall be decided by the biosafety committee or biosafety staff.

Article 19 New employees of laboratories and storage facilities shall attend at least 8 hours of basic courses on biosafety and biosecurity. New employees of high-containment laboratories shall attend biosafety and biosecurity courses approved by the central competent authority.

Personnel of laboratories and storage facilities shall attend each year at

least 4 hours of continuing education courses on biosafety and biosecurity.

Article 20 The central competent authority may commission or entrust relevant organizations (institutions), juridical persons or groups to conduct matters mentioned in Article 8 through Article 17 and the preceding Article.

Article 21 This set of Regulations shall be implemented on the day of announcement.