

Kyushu University Regulations for Safety Management of Research Microorganisms

Kyushu University Regulation No. 83 of 2004

Established: April 1, 2004

Last amended: June 29, 2018

(Kyushu University Regulation No. 16 of 2018)

(Purpose)

Article 1 These Regulations shall provide for matters necessary for the handling of research microorganisms and the assurance of their safety at Kyushu University (hereinafter referred to as the “University”).

(Definitions)

Article 2 In these Regulations, the meanings of the terms set forth in the following items are as provided respectively in those items:

- (i) research microorganisms: means bacteria, fungi, viruses, parasites, and toxins;
- (ii) specific pathogens, etc.: means, among research microorganisms, those specific pathogens, etc. as prescribed in Article 6, paragraph (19) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998; hereinafter referred to as the “Infectious Diseases Control Act”);
- (iii) pathogenicity: means to the ability of research microorganisms to cause harm to humans or animals by any mechanism;
- (iv) microorganism handler: a person who uses, stores, or supplies research microorganisms for experimental purposes;
- (v) designated laboratory: a laboratory in which experiments are conducted using Level 3 research microorganisms as defined in Article 5; and
- (vi) microorganism containment area: a specific area that includes designated laboratories and other rooms necessary for safety management.

(President)

Article 3 The President supervises the handling of research microorganisms and the assurance of their safety at the University.

(Safety Committee)

Article 4 (1) Matters relevant to the handling of research microorganisms and the assurance of their safety are to be deliberated at the Microorganism Research Safety Management Committee (hereinafter referred to as the “Safety Committee”) provided in Article 7, paragraph (1) of the Regulations for the Education and Research Council of Kyushu University (Kyushu University Regulation No. 6 of 2004).

(2) The Safety Committee may, when it deems necessary, provide advice or make recommendations to the President regarding the handling of research microorganisms and the assurance of their safety.

(3) The Safety Committee may, as necessary, request reports from the hazard prevention manager referred to in Article 9, paragraph (1), and the handling manager referred to in Article 12, paragraph (1).

(4) The organization, meetings, and other necessary matters relevant to the Safety Committee are as provided separately.

(Classification of Research Microorganisms)

Article 5 (1) Research microorganisms shall be classified into Levels 1 through 4 based on their pathogenicity to humans. Note that Level 4 research microorganisms may not be handled at the University.

(2) The Levels of research microorganisms specified in the preceding paragraph shall be provided separately.

(Responsibility of the Microorganism Handlers)

Article 6 Microorganism handlers, in handling research microorganisms, shall be fully aware of the importance of ensuring safety and shall exercise the necessary care, and shall, in advance, be well acquainted with and proficient in the standard laboratory methods for pathogenic microorganisms, as well as the procedures specific to the experiments and the related techniques.

(Responsibility of the Chief Administrator)

Article 7 The head of the department that manages a facility where research microorganisms are handled (hereinafter referred to as the “chief administrator”) must make efforts in safety assurance for the handling of research microorganisms conducted within that department.

(Responsibility of the Director of the Affiliated Division)

Article 8 The director of a division with which microorganism handlers are affiliated (hereinafter referred to as the “director of the affiliated division”) must make effort to ensure the health management of such microorganism handlers.

(Hazard Prevention Manager)

Article 9 (1) Each designated laboratory shall have a hazard prevention manager, who shall be appointed by the chief administrator from among the microorganism handlers.

(2) The hazard prevention manager referred to in the preceding paragraph shall endeavor to ensure the safe handling of research microorganisms within the designated laboratory and shall coordinate and supervise operations within the laboratory.

(Procedures for Handling Research Microorganisms)

Article 10 (1) When using or storing Level 2 research microorganisms for experimental purposes, a notification shall be submitted each fiscal year to the chief administrator. In addition, where a strain that differs significantly in pathogenicity from research microorganisms already notified is to be used, a new notification shall be submitted to the chief administrator.

(2) When using, storing, or providing Level 3 research microorganisms for experimental purposes, a notification shall be submitted to the President through the chief administrator each fiscal year and obtain the President's approval.

(3) When an application referred to in the preceding paragraph has been submitted, the President shall, after examination by the Safety Committee, decide whether to approve the application.

(4) Where the use and storage of research microorganisms that were notified pursuant to paragraph (1), or research microorganisms for which approval was obtained pursuant to paragraph (2), have been completed, a notification shall be submitted without delay to the chief administrator.

(5) When the chief administrator has accepted a notification under paragraphs (1) and (4), shall report the matter to the Safety Committee without delay.

(Handling of Specific Pathogens, etc.)

Article 11 When handling specific pathogens, etc., microorganism handlers shall comply not only with these Regulations but also with the Infectious Diseases Control Act, the Order for Enforcement of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Cabinet Order No. 420 of 1998), and the Enforcement Regulations of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Ministry of Health and Welfare Ordinance No. 99 of 1998).

(Handling Manager)

Article 12 (1) For each notification or application prescribed in the Article 10, a handling manager shall be designated from among the microorganism handlers.

(2) The handling manager shall, in close coordination with the hazard prevention manager, be responsible for the

handling of research microorganisms and shall perform the duties set forth in the following items:

- (i) comply with applicable laws and regulations and these Regulations with respect to the handling of research microorganisms, and to exercise appropriate management and supervision;
- (ii) provide microorganism handlers with the necessary guidance for handling the relevant microorganisms; and
- (iii) implement the necessary measures to ensure the safe handling of research microorganisms.

(Processing of Research Microorganisms)

Article 13 (1) Level 1 and Level 2 research microorganisms shall be processed using the disinfection or sterilization methods that are most effective for the relevant microorganisms.

(2) Level 3 research microorganisms shall be processed using the disinfection or sterilization methods approved pursuant to Article 10, paragraph (2).

(Signage for Microorganism Containment Area, etc.)

Article 14 (1) The chief administrator shall display the international biohazard symbol at the entrances of the microorganism containment areas.

(2) The chief administrator shall post a notice at the entrances of each designated laboratory, containing the required information in the prescribed form.

(Entry into Designated Laboratories)

Article 15 (1) No person other than microorganism handlers for whom approval has been obtained pursuant to Article 10, paragraph (2) may enter a designated laboratory.

(2) Notwithstanding the preceding paragraph, where it is necessary for persons other than the microorganism handlers referred to in the preceding paragraph to enter a designated laboratory for the purpose of maintenance of equipment therein, or for response to accidents or disasters, such entry may be permitted with the permission of the chief administrator and in the presence of the hazard prevention manager.

(Measures upon Accidents)

Article 16 (1) When any of the following occurs, it shall be deemed an accident, and except in the case set forth in item (vi), the handling manager shall be notified immediately:

- (i) theft or disappearance of research microorganisms;
- (ii) discovery of a serious defect in the functioning of safety facilities within a microorganism containment area;
- (iii) widespread contamination of a microorganism containment area caused by Level 3 research microorganisms;

- (iv) a possibility that Level 3 research microorganisms have entered the body of a microorganism handler due to injury or other causes;
 - (v) where, as a result of a health examination prescribed in Article 19, an abnormality caused by Level 3 research microorganisms is diagnosed, or where it can be clearly identified, through reports made immediately after the accident or otherwise, that a health impairment caused by Level 2 research microorganisms has occurred; or
 - (vi) where a report as prescribed in Article 20, paragraph (4), has been made.
- (2) The handling manager who has received the notification referred to in the preceding paragraph shall take the necessary measures and shall report the matter to the hazard prevention manager and the chief administrator. Furthermore, in the event of an accident involving specific pathogens, etc., the handling manager shall, in accordance with the provisions of the Infectious Diseases Control Act, report the matter to the police station without delay.
- (3) The chief administrator who has received the report referred to in the preceding paragraph shall, in cooperation with the hazard prevention manager, take the necessary emergency measures and shall immediately report the matter to the President.
- (4) The President who has received the reports referred to in the preceding paragraph and Article 20, paragraph (4), shall order the Safety Committee to take the necessary measures, and, when the President finds it necessary, may designate a hazardous area and prohibit the use of such area for a specified period.
- (5) When the President has designated a hazardous area pursuant to the preceding paragraph, the President shall notify the employees, etc. of the accident and the details of such designation, and shall cause the Safety Committee and other persons whom the President finds appropriate to conduct a follow-up investigation, and, upon confirmation that safety has been restored, shall lift the designation of the hazardous area and notify the employees, etc. to that effect.

(Measures in Emergency Situations)

- Article 17 (1) Where serious damage has occurred due to a disaster such as an earthquake or fire and the President determines that it is necessary, the President shall immediately establish an Emergency Response Headquarters.
- (2) Until an Emergency Response Headquarters referred to in the preceding paragraph is established, the Safety Committee shall take the necessary measures promptly in response to the emergency situation, and shall promptly report to the President the status of the damage and the details of the measures taken.
- (3) Where an infectious disease caused by specific pathogens, etc. has occurred or spread, or there is a risk thereof, due to a disaster such as an earthquake or fire, the handling manager shall immediately report the matter to the police station, and the President shall notify the Minister of Health, Labor and Welfare without delay.

(Emergency Response Headquarters)

Article 18 (1) The Emergency Response Headquarters prescribed in paragraph (1) of the preceding Article shall be composed of the President, the Chairperson of the Safety Committee, and other persons whom the President finds it necessary to appoint.

(2) The Emergency Response Headquarters shall direct or carry out the matters listed below:

- (i) measures to prevent the release of research microorganisms;
- (ii) measures for the prevention of contamination, and measures to be taken regarding contaminated locations and items;
- (iii) measures for the treatment of contaminated persons;
- (iv) designation of hazardous areas; and
- (v) safety inspections of hazardous areas and the lifting of the designation of hazardous areas.

(Health Management)

Article 19 (1) The President shall conduct regular health examinations of microorganism handlers.

(2) When the President finds it necessary, the President may require microorganism handlers to undergo health examinations on a temporary basis.

Article 20 (1) Microorganism handlers shall at all times endeavor to maintain their own health.

(2) Microorganism handlers, where infection with Level 3 research microorganisms is suspected, shall immediately submit a notification, through the handling manager, to the hazard prevention manager and the chief administrator.

(3) The chief administrator who has received the notification referred to in the preceding paragraph shall, as necessary and in cooperation with the hazard prevention manager, immediately conduct an investigation to determine whether infection with the relevant microorganisms has occurred.

(4) The chief administrator shall, where, as a result of the investigation referred to in the preceding paragraph, it is determined that infection with the relevant microorganisms has occurred, or where the infection status is medically unclear, immediately report the matter to the President.

(Miscellaneous Provisions)

Article 21 Necessary matters relevant to the implementation of these Regulations are specified by the President following discussions at the Safety Committee.

Article 22 An amendment to these Regulations needs to be discussed by the Safety Committee.

Supplementary Provisions

These Regulations come into effect as of April 1, 2004.

Supplementary Provisions (Kyushu University Regulation No. 250 of 2004)

These Regulations come into effect as of April 1, 2005.

Supplementary Provisions (Kyushu University Regulation No. 54 of 2005)

These Regulations come into effect as of April 1, 2006.

Supplementary Provisions (Kyushu University Regulation No. 131 of 2014)

These Regulations come into effect as of April 1, 2015.

Supplementary Provisions (Kyushu University Regulation No. 16 of 2018)

These Regulations come into effect as of July 1, 2018.