

Kyushu University Regulations for Safety Management of Experiments involving genetic modification

Kyushu University Regulation No. 82 of 2004

Established: April 1, 2004

Last amended: March 31, 2022

(Kyushu University Regulation No. 121 of 2021)

(Purpose)

Article 1 These Regulations shall provide for necessary matters relevant to safety assurance that should be observed when planning and implementing genetic modification experiments (hereinafter referred to as “experiments”) at Kyushu University, pursuant to the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003; hereinafter referred to as the “Act”) and the Ministerial Order Providing Containment Measures to Be Taken in Type-2 Use of Living Modified Organisms for Research and Development (Order of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of the Environment No. 1 of 2004; hereinafter referred to as the “Ministerial Order”).

(Definitions)

Article 2 Beyond what is provided in the Act and the Ministerial Order, the meanings of the terms set forth in the following items in these Regulations are as provided respectively in those items:

- (i) Experiment staff: persons who implement an experiment;
- (ii) The Principal Investigator: a faculty member of Kyushu University who is responsible for the execution of an experimental plan.
- (iii) Experimental facility administrator; a faculty member of Kyushu University who is responsible for facility management for each facility where an experiment is carried out.

(President)

Article 3 The President supervises the planning and implementation of experiments carried out at Kyushu University and safety assurance therefor.

(Safety Committee)

Article 4 (1) Matters relevant to safety assurance for experiments are to be deliberated at the Genetic Modification Experiment Safety Committee (hereinafter referred to as the “Safety Committee”) provided in Article 7, paragraph (1) of the Kyushu University Education and

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Research Council Regulations (Kyushu University Regulation No. 6 of 2004).

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

(Safety Administrators)

Article 5 (1) Kyushu University has in place several safety administrators for genetic modification experiments (hereinafter referred to as “safety administrators”), and the President appoints them from among faculty members of Kyushu University who have achieved a high level of proficiency in the knowledge and skills required for preventing the occurrence of biohazards as well as related knowledge and skills.

(2) Safety administrators assist the President and perform the duties set forth in the following items:

(i) confirm whether an experiment is carried out properly in accordance with the Ministerial Order and these Regulations and other rules;

(ii) provide guidance and advice to the Principal Investigator;

(iii) handle other necessary matters relevant to safety assurance for experiments.

(3) The term of office of a safety administrator is a period not exceeding two years as specified by the President; provided, however, that if a vacancy arises in the office of a safety administrator, the term of office of the successor is the remaining term of office of the predecessor.

(4) Safety administrators may be reappointed.

(5) In performing their duties, safety administrators shall fully communicate with the Safety Committee and report necessary matters to the Safety Committee.

(Responsibility of the Director of the Management Division)

Article 6 The director of a division that manages a facility that is used for experiments (hereinafter referred to as the “experimental facility”) (hereinafter referred to as the “director of the management division”) must make efforts in safety assurance for experiments carried out at the experimental facility.

(Responsibility of the Director of the Affiliated Division)

Article 7 The director of a division with which experiment staff are affiliated (hereinafter referred to as the “director of the affiliated division”) must make efforts in safety assurance for experiments carried out respectively by the experiment staff.

(Responsibility of the Principal Investigator)

Article 8 (1) The Principal Investigator must perform the following duties:

(i) in creating and implementing an experimental plan, administer and supervise the experiment as

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a whole appropriately in compliance with related laws and regulations and these Regulations and other rules and in close communication with the safety administrator;

(ii) before commencement of an experiment, provide the experiment staff with education and guidance necessary for implementing the experiment; and

(iii) implement other necessary matters relevant to safety assurance for experiments.

(2) If any knowledge that could affect the policy of safety assurance for experiments is obtained or if an accident or any other event occurs during an experiment or during the transport of a living modified organism to be used in an experiment, the Principal Investigator must immediately report this to the safety administrator and also report the same to the President via the director of the affiliated division or the director of the management division.

(3) The Principal Investigator may designate an acting the Principal Investigator from among faculty members who are experiment staff.

(4) If the Principal Investigator is unavailable to perform their duties due to travel, illness, or any other reason, the acting the Principal Investigator provided in the preceding paragraph shall perform the duties on behalf of the experiment administrator during the period of unavailability.

(Responsibility of Experiment Staff)

Article 9 (1) In planning and implementing an experiment, experiment staff shall fully become aware of and give due consideration to safety assurance, and shall, in advance, achieve mastery of and proficiency in standard experimental methods relating to organisms as well as operational methods specific to the experiment and related experimental methods.

(2) If an experiment falls within the category of animal experiments provided in Article 2, paragraph (1) of the Kyushu University Regulations for Animal Experiments (Kyushu University Regulation No. 129 of 2014; hereinafter referred to as the “Animal Experiments Regulations”), experiment staff must implement the experiment based on the Animal Experiments Regulations in addition to these Regulations.

(3) Beyond what is provided in the preceding paragraph, in implementing an experiment in which attention should be paid to safety management, such as one that uses physically or chemically hazardous materials or pathogens subject to control under laws and regulations, etc., experiment staff must implement the experiment properly pursuant to related laws and regulations and Kyushu University’s regulations and rules.

(Examination Procedure and Examination Standards for Experimental Plans)

Article 10 (1) The Principal Investigator must file an application with the President via the director of the affiliated division to obtain approval for an experimental plan. The same applies if the experiment administrator seeks to change an approved experimental plan.

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(2) If an application referred to in the preceding paragraph is filed, the President shall decide whether to approve the experimental plan, following examination by the Safety Committee. In this case, if an experimental plan requires confirmation by the Minister of Education, Culture, Sports, Science and Technology, the President shall obtain the Minister's confirmation in advance.

(3) The Safety Committee shall examine an experimental plan based on its conformity with the standards for containment measures, the degree of training and experience of experiment staff, etc., and other factors.

(Application for Establishment, Change, or Notification of Closure of Experimental Facility)

Article 11 (1) When a division director seeks to establish or change an experimental facility, the director must file an application with the President to obtain approval.

(2) If an application referred to in the preceding paragraph is filed, the President shall have the Safety Committee examine the experimental facility in the application and shall grant approval or dismiss the application based on the committee's advice.

(3) If a division director has closed an approved experimental facility, the director must notify the President of the closure.

(Responsibility of Experimental Facility Administrator)

Article 12 (1) The experimental facility administrator must manage and preserve an experimental facility according to the containment measures provided in related laws and regulations.

(2) The experimental facility administrator may designate an acting experimental facility administrator from among faculty members who have taken the educational and training programs referred to in Article 21.

(3) If the experimental facility administrator is unavailable to perform their duties due to travel, illness, or any other reason, the acting experimental facility administrator provided in the preceding paragraph shall perform the duties on behalf of the experimental facility administrator during the period of unavailability.

(Safety Assurance for Experiments)

Article 13 (1) The Principal Investigator must inspect the safety of experiments and the status of management and preservation and other matters regarding the experimental facility.

(2) If the Principal Investigator has found any abnormality in the case referred to in the preceding paragraph, the experiment administrator shall take necessary measures and report this to the director of the affiliated division or the director of the management division.

(Entry into Experimental Facility)

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Article 14 Any person who enters an experimental facility must obtain permission from the responsible personnel of experiments and the experimental facility administrator.

(Sign on Experiments)

Article 15 While an experiment that requires containment measures of P2 or higher level or LS1 or higher level is ongoing, the Principal Investigator must put up a sign on the experimental facility to indicate this fact and the level of containment measures taken for the experiment.

(Records of Experiments and Preservation Thereof)

Article 16 The Principal Investigator must prepare and preserve records of the type of the donor organism used in the experiment, the recipient organism, the vector, the living modified organisms, and the period of the experiment (hereinafter referred to as “experimental records”).

(Handling of Samples Containing Living Modified Organisms)

Article 17 (1) The Principal Investigator must have experiment staff strictly confirm that the type of the donor organism used in the experiment, the recipient organism, and the vector constantly satisfy the conditions for containment measures before the commencement of an experiment and during an experiment.

(2) The Principal Investigator must prepare and preserve records of the storage and disposal of samples containing living modified organisms. In this case, the experimental records may be used in place of the records of storage and disposal.

(3) Each time when conveying samples and waste materials containing a living modified organisms, the experiment administrator must prepare and preserve records of the name and quantity of the living modified organism, as well as the name of the institution that is the destination of conveyance and the name of the person responsible for the institution. In this case, the experimental records may be used in place of the records of the conveyance.

(4) Beyond what is provided in the preceding three paragraphs, in handling samples and waste materials containing living modified organisms, experiment staff must comply with the containment measures provided in the Ministerial Order.

(Transfer of Living Modified Organisms)

Article 18 (1) A person that seeks to transfer a living modified organisms shall transfer it after confirming that the transferee has a clear use plan and has in place an appropriate management system, and at the time of making a transfer, shall provide information to the transferee and notify the President of the transfer via the director of the affiliated division.

(2) The Principal Investigator who receives the transfer of a living modified organisms shall follow

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the procedure provided in Article 10, paragraph (1) with regard to an experiment that uses the living modified organisms, and at the time of receiving a transfer, shall notify the President of the transfer via the director of the affiliated division.

(Report of Conclusion or Suspension of Experiments)

Article 19 If the Principal Investigator has concluded or suspended an experiment, the experiment administrator must immediately report this to the President via the director of the affiliated division.

(Preservation of Materials Relevant to Mass Cultivation Experiments)

Article 20 In the case of implementing a mass cultivation experiment, the President must preserve relevant materials.

(Education and Training)

Article 21 (1) The President shall provide educational and training programs on the following matters to people, including those who intend to carry out experiments and those who are to become experimental facility administrators:

- (i) technology for handling organisms safely according to the degree of hazard;
 - (ii) knowledge and technology relevant to physical containment;
 - (iii) knowledge and technology relevant to biological containment;
 - (iv) knowledge relevant to the degree of hazard of an experiment to be implemented; and
 - (v) knowledge relevant to measures to be taken in the event of occurrence of an accident (including consideration to be given to measures such as sterilization by chemical treatment in the event of leakage of a culture fluid containing a living modified organisms in mass cultivation).
- (2) The President may have experiment staff and experimental facility administrators (hereinafter referred to as “experiment staff, etc.”) take educational and training programs as necessary.
- (3) The educational and training programs referred to in the preceding two paragraphs shall be organized by the Safety Committee, and the content and other details of implementation of these programs are specified separately by the Safety Committee.

(Health Management)

Article 22 (1) The President shall conduct necessary health management for experiment staff.

(2) Ordinary periodic health checkups provided in Article 12, paragraph (1), item (ii) of the National University Corporation Kyushu University Rules for Safety and Health Management for Employees (Kyushu University Employment Regulation No. 23 of 2004) may be provided to experiment staff who are employees and periodic health checkups for students may be provided to

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experiment staff who are students, in place of health checkups.

(3) In the case of handling microorganisms pathogenic to humans in an experiment, the Principal Investigator shall consider measures for the prevention and treatment of infection before the commencement of the experiment and report these measures to the President via the director of the affiliated division. In this case, the President shall, following discussions at the Safety Committee, have the director of the affiliated division and the Principal Investigator prepare an antibiotic, vaccine, blood serum, and the like as necessary.

Article 23 (1) If an experiment staff member falls under any of the following items, the director of the affiliated division shall immediately investigate the fact and take necessary measures:

(i) the experiment staff member has swallowed or inhaled a living modified organisms by mistake;
(ii) the experiment staff member has had their skin stained by a living modified organisms and the stain cannot be removed, or there is a risk that a living modified organism causes an infection; or
(iii) the experiment staff member was present at a laboratory and experiment area or mass cultivation experiment area when the area was extremely contaminated by a living modified organisms.

(2) If there is a risk of infection in a laboratory or a mass cultivation experiment area, the director of the affiliated division shall immediately conduct a health checkup and take appropriate measures.

(3) The director of the affiliated division must immediately report to the President about matters, including the measures taken due to the occurrence of the circumstances set forth in the preceding two paragraphs.

Article 24 (1) Experiment staff shall constantly make efforts for their own health management.

(2) If an experiment staff member notices any changes in their health or suffers a serious or long-term illness, the experiment staff member must immediately report this to the director of the affiliated division. A person other than the experiment staff member who learns this fact shall also report it.

(3) If the director of the affiliated division has received the report referred to in the preceding paragraph, the director must immediately take necessary measures and report this to the President.

(Measures to Be Taken upon the Occurrence of Emergency)

Article 25 (1) A person who has discovered that an experimental facility has been abnormally contaminated by a living modified organisms or that a fire or any other disaster has occurred or is likely to occur in an experimental facility must immediately notify the Principal Investigator and the experimental facility administrator of such situation.

(2) If the Principal Investigator and the experimental facility administrator have been notified as

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referred to in the preceding paragraph, they must make the occurrence of an abnormal situation known to people around the site and take necessary measures to prevent the disaster, and must immediately notify the safety administrator and the director of the management division of this.

(3) The director of the management division who has been notified as referred to in the preceding paragraph must immediately notify the President of this and take necessary measures.

(Measures to Be Taken When Accident, etc. Is Reported)

Article 26 (1) If an accident, etc. is reported pursuant to these Regulations, the President shall take necessary measures based on discussions at the Safety Committee, such as having the experiment suspended or having the related experiment staff, etc. take educational and training programs under Article 21, paragraph (2).

(2) If an accident that could affect an external environment, etc. is reported, the President must immediately report the status of the accident and an outline of the measures taken to the Minister of Education, Culture, Sports, Science and Technology.

(Miscellaneous Provisions)

Article 27 Necessary matters relevant to the implementation of these Regulations are specified by the President following discussions at the Safety Committee.

Article 28 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. 251 of 2004)

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

Supplementary Provisions (Kyushu University Regulation No. 3 of 2005)

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

Supplementary Provisions (Kyushu University Regulation No. 53 of 2005)

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

Supplementary Provisions (Kyushu University Regulation No. 1 of 2006)

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

Supplementary Provisions (Kyushu University Regulation No. 112 of 2006)

1. These Regulations come into effect as of April 1, 2007.

2. The term of office of safety administrators to be appointed after these Regulations come into effect until July 1, 2008, ends on March 31, 2009, notwithstanding the provisions of Article 5, paragraph (3) of the Kyushu University Regulations for Safety Management of Experiments Involving Genetic Modification as amended by these Regulations.

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Supplementary Provisions (Kyushu University Regulation No. 130 of 2014)

1. These Regulations come into effect as of April 1, 2015.
2. An experimental facility that was approved by the Safety Committee for establishment or change is deemed to have been approved pursuant to the provisions of Article 11, paragraphs (1) and (2) of the Kyushu University Regulations for Safety Management of Experiments Involving Genetic Modification as amended by these Regulations.

Supplementary Provisions (Kyushu University Regulation No. 81 of 2015)

These Regulations come into effect as of April 1, 2016.

Supplementary Provisions (Kyushu University Regulation No. 80 of 2016)

These Regulations come into effect as of March 23, 2017.

Supplementary Provisions (Kyushu University Regulation No. 121 of 2021)

These Regulations come into effect as of April 1, 2022.

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