

Regulations Regarding Control of Radioisotopes, etc. at Kyoto University (established based on Notification 50, 2019)

(Purpose)

Article 1. These regulations (hereinafter referred to as “these Regulations”) aim to prevent radiation hazards and to ensure safety on and off campus by prescribing the ways of handling and use of Radioisotopes, Contaminated Objects, Radiation Generating Apparatuses, and X-ray Generator-related Apparatuses (as defined below) at Kyoto University.

(Definitions)

Article 2. In these Regulations, the following terms shall have the meanings specified below:

- (1) Radioisotopes: Defined in Article 2.2 of the Act on the Regulation of Radioisotopes, etc. (enacted in 1957, volume 167; hereinafter referred to as "the Act").
- (2) Contaminated Objects: Defined in item 2 of Article 1 of the Ordinance for Enforcement of the Act on the Regulation of Radioisotopes, etc. (originally enacted in 1960, volume 56; hereinafter referred to as "the Ordinance").
- (3) Radioisotopes, etc.: Radioisotopes and Contaminated Objects.
- (4) Radiation Generating Apparatus: Defined in Article 2.5 of the Act.
- (5) X-ray Generator-related Apparatus: An X-ray generating apparatus that is designated by the Agency for Health, Safety and Environment, Kyoto University (hereinafter referred to as "the Agency"). The Agency may designate any apparatus that generates X-rays with energies less than 1.0 mega-electron volts (MeV), other apparatuses that incidentally generate X-rays with energies less than 1.0 MeV and electron microscopes with a rated voltage of ≥ 100 kilo-electron volts (kV).
- (6) Establishment: Any establishment approved to use Radioisotopes according to Article 3.1 of the Act or has submitted a notification for the use of Radioisotopes according to Article 3-2.1 of the Act.
- (7) University Registered Radiation Handler: A faculty member or student of Kyoto University who is registered as a person authorized to handle, manage, or perform other tasks involving Radioisotopes, etc. or Radiation Generating Apparatuses by the Director of the Agency (hereinafter referred to as "the Director"). Such tasks are hereinafter collectively referred to as "Radiation Handling and Other Operations."
- (8) Non-university Registered Radiation Handler: A person who is not a faculty, staff member, or matriculated student of Kyoto University and is registered as a person authorized to perform Radiation Handling and Other Operations by the Director.
- (9) Registered Radiation Handler: University Registered Radiation Handler or Non-university Registered Radiation Handler.

- (10) Radiation Worker: A person who performs Radiation Handling and Other Operations at any Establishment at Kyoto University.
- (11) University Registered X-ray Handler: A faculty member or student of Kyoto University who is registered as a person authorized by the Director to handle or control an X-ray Generator-related Apparatuses. Such tasks are hereinafter referred to as "X-ray Operations."
- (12) Non-university Registered X-ray Handler: A person who is not a faculty, staff member, or matriculated student of Kyoto University and is registered as a person authorized by the Director to perform X-ray Operations at Kyoto University.
- (13) Registered X-ray Handler: University Registered X-ray Handler or Non-university Registered X-ray Handler.
- (14) X-ray Worker: A person who performs X-ray Operations at Kyoto University.
- (15) Worker: Radiation Worker or X-ray Worker.
- (16) Registered Handler: Registered Radiation Handler or Registered X-ray Handler.
- (17) Department: Any of the following organizations with one or more Registered Handlers: research departments (individual research divisions, individual attached laboratories, university libraries, the university hospital, and individual centers, etc. [facilities defined in Sections 7–11 of Chapter 3 of the Organizational Regulations of National University Corporation Kyoto University (hereinafter referred to as the "Organizational Regulations," Order No. 1 of 2004), including the administrative office of each department defined in Article 56-1 of the Organizational Regulations]), university headquarters, and joint administration offices.
- (18) Usage Facility: A facility where Radioisotopes or a Radiation Generating Apparatus is used.
- (19) Storage Facility: A facility where Radioisotopes are stored.
- (20) Disposal Facility: A facility where Radioisotopes, etc. are disposed of.
- (21) Radiation Facility: Usage Facility, Storage Facility, or Disposal Facility.

(Executive Vice President and the Agency)

Article 3. The Executive Vice President of Kyoto University in charge of matters on the environment, safety, and health shall oversee radiation safety at the University.

2. Under the supervision of the Executive Vice President, the Agency shall provide appropriate instructions on safety radiation control to Departments for the purpose stated in Article 1 of these Regulations.

(Heads of Departments)

Article 4. In coordination with the Agency, any head of each Department shall perform health management and other measures to ensure the health of the Department's Registered Handlers, X-ray Workers, and Radiation Workers for any Establishment of the Department. In addition, the head

of the Department shall endeavor to prevent radiation hazards.

2. Any head of a Department with any Establishment shall manage and operate Radioisotopes, etc. and Radiation Generating Apparatuses in a safe manner.

(Rules on Radiation Hazard Prevention)

Article 5. In accordance with all relevant laws and regulations, any head of a Department with any Establishment shall establish and conform to specific Rules on Prevention of Radiation Hazards (hereinafter referred to as "Prevention Rules").

2. Any head of a Department with any Establishment shall submit its Prevention Rules and any amendments to the Agency for approval prior to enacting.

(Guidelines on the Handling and Management of an X-ray Generator-related Apparatus)

Article 6. Any head of a Department whose Department houses any X-ray Generator-related Apparatus shall comply with all guidelines on handling and management of X-ray Generator-related Apparatus mandated by the Director.

(Radiation Handling Supervisor and Radiation Administrator)

Article 7. Any head of a Department with any Establishment shall appoint one or more Radiation Handling Supervisors for each Establishment (hereinafter referred to as "the Supervisor"). The Supervisor shall oversee the preventative measures against radiation hazards due to Radioisotopes, etc. or a Radiation Generating Apparatus.

2. Any head of a Department shall appoint one or more radiation administrators (hereinafter referred to as "the Administrator"). The Administrator shall perform administrative work related to the prevention of radiation hazards. One Administrator shall be assigned for each Establishment. If a Department does not have any Establishments, the Administrator shall be designated for the Department.
3. In addition to the above stipulations, a Department with any Establishment may appoint additional Administrators for the Department.
4. The Supervisor shall not serve concurrently as the Administrator.

(Duties of Supervisors and Administrators and Respect for Supervisor's Opinions)

Article 8. The Supervisor and Administrator shall perform radiation hazard prevention tasks mandated by the Director.

2. Any head of a Department with any Establishment shall respect the opinions of the Supervisor regarding preventative measures against radiation hazards.
3. The Supervisor may request the appropriate head of the Department to hold Committee meetings as

stated in Article 9.

(Establishment Committee)

Article 9. Any head of a Department with any Establishment shall establish a committee for each Establishment to investigate and deliberate on matters to prevent radiation hazards.

2. Notwithstanding the provisions of the preceding paragraph, any Department with two or more Establishments may set up a single committee to oversee multiple Establishments.
3. The Establishment's Prevention Rules shall specify the items necessary to organize the committee stated in the preceding two paragraphs.
4. At the Agency's sole discretion, any head of a Department without an Establishment shall establish a committee to investigate and deliberate on matters to prevent radiation hazards.
5. The Director shall mandate items necessary for the committee.

(Registration of University Registered Radiation Handlers and Non-university Registered Radiation Handlers)

Article 10. Any faculty member or student of Kyoto University planning to perform Radiation Handling and Other Operations as a Kyoto University task shall submit an application to register as a University Registered Radiation Handler.

2. Any person planning to perform any Radiation Handling and Other Operations as a Kyoto University Task but being unable to be qualified as an authorized person to perform Radiation Handling and Other Operations by his/her organization shall submit an application to register as a Non-university Registered Radiation Handler.
3. Any faculty member or student of Kyoto University planning to perform X-ray Operations as a Kyoto University task shall submit an application to register as a University Registered Radiation Handler or a University Registered X-ray Handler.
4. Any person planning to perform X-ray Operations as a Kyoto University task but being unable to be qualified as an authorized person to perform X-ray Operations by his/her organization shall submit an application to register as a Non-university Registered Radiation Handler or a Non-university Registered X-ray Handler.
5. The Director shall establish the rules for and accordingly perform the registration of University Registered Radiation Handlers, Non-university Registered Radiation Handlers, University Registered X-ray Handlers, and Non-university Registered X-ray Handlers.
6. The Agency shall record all registrations stated in the preceding paragraph.
7. Any person who is registered as a University Registered Radiation Handler or Non-university Registered Radiation Handler shall not be concurrently registered as a University Registered X-ray Handler or Non-university Registered X-ray Handler, and vice versa.

(Pre-registration Education and Training)

- Article 11. A person shall complete education and training upon submitting an application to register as a University Registered Radiation Handler or Non-university Registered Radiation Handler (hereinafter referred to as "Radiation Registration Applicants").
2. A person shall complete education and training upon submitting an application to register as a University Registered X-ray Handler or Non-university Registered X-ray Handler (hereinafter referred to as "X-ray Registration Applicants").
 3. The Director shall specify the contents, duration/number of hours, and exemptions of the education and training stated in the two preceding paragraphs.
 4. The Agency shall provide the education and training stated in paragraphs 1 and 2 of this Article. The Director shall be responsible for the education and training.
 5. Notwithstanding the provision of the preceding paragraph, if the Agency considers it appropriate, the education and training stated in paragraphs 1 and 2 may be provided by a Department. In such cases, the head of the Department shall be responsible for the education and training.

(Post-registration Education and Training)

- Article 12. Registered Radiation Handlers shall complete post-registration education and training before the end of the subsequent fiscal year of the last education and training (i.e., post-registration education and training must be completed once in each fiscal year.)
2. The Department that the concerned Registered Handlers belong to or are affiliated with shall provide post-registration education and training.
 3. Notwithstanding the provisions of the preceding paragraph, when a Registered Handler belongs to or is affiliated with a Department without any Establishment, the Agency shall provide the post-registration education and training.
 4. Other than those mandated in the preceding paragraph, the Agency may provide post-registration education and training for Registered Handlers on behalf of the Department when the Agency deems it necessary.
 5. For the case of paragraph 2, the head of the Department shall be responsible for the education and training, while for the cases of paragraphs 3 and 4, the Director shall be responsible for the education and training.
 6. The Director shall specify the contents and duration/number of hours of the post-registration education and training.

(Medical Examinations)

- Article 13. The Agency shall provide medical examinations for Radiation Registration Applicants, X-

ray Registration Applicants, and Registered Handlers according to the rules mandated by the Director.

2. The Director shall be responsible for the medical examinations mandated in the preceding paragraph.

(Procedures for Engaging in Radiation or X-ray Related Operations)

Article 14. Any head of a Department with any Establishment shall specify the procedures and necessary items for persons performing Radiation Handling and Other Operations in the relevant Prevention Rules.

2. The Director shall specify the procedures and necessary items for persons performing X-ray Operations at any Department at Kyoto University.
3. Registered X-ray Handlers are not allowed to engage in any Radiation Handling and Other Operations.

(Measurements)

Article 15. The Agency shall measure external exposure doses of Registered Handlers according to the rules mandated by the Director.

2. Notwithstanding the provisions of the preceding paragraph, any Department and Establishment may measure Workers' external exposure dose.
3. The Agency shall measure the atmospheric concentration of Radioisotopes in work rooms in which any unsealed Radioisotope is handled or at sites where there is a concern that any Radioisotope may be inhaled or ingested in accordance to the rules established by the Director.

(Creation, Renovation, and Abolition of Radiation Facilities)

Article 16. Any head of a Department shall submit an application to the Agency for approval when 1) making any modifications, including creation, renovation and abolishment, of any Radiation Facility; or 2) making any applications or notifications mandated by applicable laws and regulations such as notification of changes in the quantity of Radioisotopes, etc.

2. Any head of a Department shall notify the Agency before installing or disposing of any X-ray Generator-related Apparatus.
3. The Director shall establish the processes for the application and notification stated in the preceding two paragraphs.

(Maintenance of Radiation Facilities)

Article 17. Any head of a Department with any Establishment shall maintain the location, structure, and equipment of Radiation Facilities in the Establishment in accordance with the technical standards mandated by laws and regulations.

2. Any head of a Department with any X-ray Generator-related Apparatus shall maintain such Apparatus to ensure safe operations.

(Self-inspection of Radiation Facilities)

Article 18. Any head of a Department shall ensure that the Department conducts periodic self-inspections of appropriate preventative measures against radiation hazards and other inspection items and records results of inspections.

2. The Director shall specify the items to be inspected.

(Investigations and Inspections by the Agency)

Article 19. The Agency may inspect the maintenance status of Radiation Facilities, handling of Radioisotopes, etc., and Radiation Generating Apparatuses as well as the management of Workers by visiting the concerned Radiation Facilities of the Establishment or checking the work logs at fixed intervals and/or at any time.

2. The Agency may investigate and inspect the maintenance status of X-ray Generator-related Apparatuses and the management of Workers and Registered Handlers by visiting the concerned Department or checking work logs at fixed intervals and/or at any time.
3. The Director shall specify the timing, method, and items of the investigation or inspection.
4. Any head of a Department shall implement corrective actions as directed by the Agency based on the results of the investigation and inspection as mandated in paragraphs 1 and 2 promptly. The head of the Department shall report the outcomes of such measures to the Agency.

(Measures for Incidents and Disasters)

Article 20. In case of any radiation hazard or risk of occurrence due to 1) a theft, loss, or other incident of Radioisotopes, etc., Radiation Generating Apparatus, or X-ray Generator-related Apparatus or 2) earthquake, fire, or other disasters, the Department's notification, countermeasures, response measures, information sharing, and other operations shall comply with the Kyoto University Risk Management Regulations (established based on Notification 64, 2011).

(Reports)

Article 21. The Agency shall report all concerns of a suspected or actual significant breach of applicable laws and regulations in a certain Department to the President of Kyoto University. The Agency shall share its opinions on the necessary measures, including limited or suspended use of Radioisotopes, etc., Radiation Generating Apparatuses, or X-ray Generator-related Apparatuses by the Department, persons who belong to, or persons affiliated with the Department.

2. The Agency shall report all concerns of a suspected or actual significant breach of applicable laws

and regulations by a certain person, and its opinions on necessary measures, including limited or suspended use of Radioisotopes, etc., Radiation Generating Apparatuses, or X-ray Generator-related Apparatuses by the person to the President.

3. The Agency shall report all concerns of a suspected or actual radiation hazard in a certain Department, and its opinions on the necessary measures such as restricted access or closure of the site to the President.
4. Upon receiving any report stated in the preceding three paragraphs, the President shall provide instructions on necessary measures to the relevant head of the Department via the Director.

(Specified Radioisotopes)

Article 22. Any Department that owns “Specified Radioisotopes” as defined in Article 2.3 of the Act shall establish specified radioisotope security program and other control methods for the Designated Radioisotopes.

(Administrative Procedures)

Article 23. Administrative work regarding applications, notifications, and reports that must be performed according to applicable laws and regulations or under directions of a competent authority shall be done by the Agency.

(Exemptions for the Institute for Integrated Radiation and Nuclear Science)

Article 24. The Institute for Integrated Radiation and Nuclear Science is exempt from the provisions in Articles 5.2, 6, 8.1, 10 to 13, 14.2, 14.3, 16, 18.2, 19, and 20.

(Miscellaneous Rules)

Article 25. In addition to these Regulations and the Prevention Rules established by Departments with any Establishment, the Director shall mandate measures necessary to prevent radiation hazards at Kyoto University.

(Supplementary Provisions)

These Regulations shall be effective on August 1, 2019.

(Supplementary Provisions)

These Regulations shall be effective on September 1, 2019.