Guidelines on Radiation Control

July 25th, 2019

Established by the Director of the Agency for Health, Safety and Environment, Kyoto University

(Purpose)

Article 1. These Guidelines aim to prevent radiation hazards and to ensure safety on and off campus by prescribing detailed operational procedures for the safe management of radiation pursuant to the Regulations Regarding Control of Radioisotopes, etc. at Kyoto University (established based on Notification 50, 2019, hereinafter referred to as "the Regulations").

(Definitions)

- Article 2. In these Guidelines, in addition to the terms defined in Article 2 of the Regulations, the following terms shall have the meanings specified below:
 - (1) X-ray Generating Apparatus: Any apparatus that generates an X-ray with energy less than 1.0 mega-electron volts (MeV) and a rated voltage of 10 kilo volts (kV) and above.
 - (2) Specified Electron Microscope: An electron microscope with a rated voltage exceeding 300 kV or an electron microscope with a rated voltage between 100 kV and 300 kV and a maximum measured effective dose rate at 10 cm from the device surface during rated operation exceeding 600 nanosieverts per hour (nSv/h).
 - (3) Ion Accelerating Apparatus: An apparatus that accelerates ions with an acceleration voltage exceeding 30 kV and with a maximum effective dose rate at a 10 cm height from the surface of the apparatus during rated operation exceeding 600 nSv/h excluding a Radiation Generating Apparatus.
 - (4) Handling and Other Operations: Handling, managing, or performing other tasks involving Radioisotopes, etc. or Radiation Generating Apparatuses.
 - (5) X-ray Operations: Handling or controlling of any X-ray Generator-related Apparatuses.
 - (6) Non-university Radiation Applicant: Any person who is not a faculty, staff member, or student of Kyoto University and is planning to receive permission to perform Handling and Other Operations at a Kyoto University Establishment other than Non-university Registered Radiation Handlers.
 - (7) Non-university Radiation Worker: A Non-university Radiation Applicant who has received permission by an Establishment to perform Radiation Handling and Other Operations at a Kyoto University Establishment.
 - (8) Non-university X-ray Applicant: Any person who is not a faculty, staff member, or

student of Kyoto University and is planning to receive permission by a Department to perform X-ray Operations at the Department other than Non-university Registered Radiation Handlers or University Registered X-ray Handlers.

- (9) Non-university X-ray Worker: A Non-university X-ray Applicant who has received permission by a Department to perform X-ray Operations at a Department.
- (10) Radiation Registration Applicant: A person who submits an application to register as a University Registered Radiation Handler or a Non-university Registered Radiation Handler.
- (11) X-ray Registration Applicant: A person who submits an application to register as a University Registered X-ray Handler or a Non-university Registered X-ray Handler.
- (12) Applicant: Radiation Registration Applicant or X-ray Registration Applicant.
- (13) Approved Devices with Certification Labels: Defined in paragraph 2 of Article 12-5 of the Act on the Regulation of Radioisotopes, etc. (enacted in 1957, volume 167; hereinafter referred to as "the Act").
- (14) Department with an Establishment: A Department that has an Establishment defined in the Regulations.
- (15) Department with X-ray Apparatus: A Department that manages an X-ray Generatorrelated Apparatus other than a Department with an Establishment.
- (16) Department without X-ray Apparatus: A Department other than a Department with an Establishment or Department with X-ray Apparatus.
- 2. The term "X-ray Generator-related Apparatus" shall refer to any apparatus that falls under any of the following items: [1]
 - (1) X-ray Generating Apparatus
 - (2) Specified Electron Microscope
 - (3) Ion Accelerating Apparatus
 - (4) Apparatus for degassing of X-ray tubes or kenotrons or for performing inspection of such equipment that involves any generation of X-rays.
 - (5) Any apparatus that incidentally generates X-rays or other radiation and has a maximum effective dose rate at a 10 cm height from the surface of the apparatus during rated operation exceeding 600 nSv/h excluding any apparatus listed in the preceding items or a Radiation Generating Apparatus.

(X-ray Generator-related Apparatuses)

Article 3. A Department Head whose Department houses an X-ray Generator-related Apparatus shall appoint a person who is responsible for use of the apparatus, for each one of the X-ray Generator-related Apparatuses (hereinafter referred to as an "X-ray Apparatus Manager"). 2. Details for handling and management of an X-ray Generator-related Apparatus shall be stipulated by the Radiation Hazards Prevention Subcommittee (hereinafter referred to as "the Subcommittee").

(Education for Radiation Protection Supervisor)

- Article 4. The periodic training that is required to be taken by Radiation Protection Supervisors (hereinafter referred to as the "Supervisor") under paragraph 1 of Article 36-2 of the Act (hereinafter referred to as "the Training" in this Article) shall be provided as follows:
 - (1) A person who has not received the Training after being appointed as a Supervisor (excluding those who have received the Training within a year before the appointment) shall receive the Training within a year from the date of appointment as a Supervisor.
 - (2) A Supervisor (excluding the person stated in the preceding item) shall receive the Training within three years beginning on the start date (April 1st) of the subsequent fiscal year of the last Training.

(Radiation Protection Supervisor and Radiation Administrator)

- Article 5. The Agency shall, according to reports from Departments, prepare and maintain a list of the Supervisors, their proxies, and the radiation administrators (hereinafter referred to as the "Administrators").
- 2. The Agency shall make a prescribed notification to the Nuclear Regulation Authority (hereinafter referred to as "the NRA") when 1) receiving a report from a Department with an Establishment that it has appointed or dismissed a Supervisor or proxy or 2) receiving a report from a Department that a proxy is going to represent the Supervisor for more than 30 days at the Department.
- 3. The Administrator shall have a First-class Radiation Protection Supervisor certificate. However, this requirement shall not apply if the Subcommittee is satisfied that there is a reasonable reason to not have a certificate.

(Duties of Supervisors and Administrators)

- Article 6. The duties of a Supervisor of an Establishment or a Department with an Establishment are listed in column (i) of Table 1.
- 2. The duties of a Radiation Protection Administrator (hereinafter referred to as "the Administrator") of an Establishment or a Department with an Establishment are listed in columns (ii) and (iii) of Table 1, respectively.
- 3. The duties of the Administrator of a Department with X-ray Apparatus and a Department without X-ray Apparatus are listed in columns (iv) and (v) of Table 1, respectively.

(Committee Organization in a Department without an Establishment)

- Article 7. A committee that is established for any Department without an Establishment (referred to as "the Committee" in this Article) under paragraph 4 of Article 9 of the Regulations, shall be composed of the following members:
 - (1) The Department Head
 - (2) The Administrator of the Department
 - (3) Other persons deemed necessary by the Department Head
- 2. The Committee shall have a Chair. The Department Head shall be the Chair.
- 3. The Chair shall call and chair meetings of the Committee.
- 4. The Committee shall be responsible for deliberating the following items:
 - (1) A plan that is important for radiation hazard prevention
 - (2) Investigation of cause(s) of any abnormality or accident
 - (3) Other items that are stipulated by the Committee
- 5. The Committee shall coordinate with the Agency in the prevention of radiation hazards at the relevant Department as needed and shall ask for advice or direction from the Agency, when necessary.
- 6. In addition to those listed in the preceding paragraphs, items that are necessary for the Committee shall be set by the Committee.

(New Registration)

- Article 8. Any person planning to register as a University Registered Radiation Handler or a University Registered X-ray Handler for the first time at Kyoto University shall submit an application to the Department to which the person belongs with documentation including the information listed in Table 2(i). If the person has a record of the information listed in Table 2(iii), the person shall also submit a copy thereof.
- 2. Any person planning to register as a Non-university Registered Radiation Handler or a University Registered X-ray Handler for the first time at Kyoto University shall submit an application to the Department to which the person belongs with documentation including the information listed in the Table 2(ii). If the person has a record of the information listed in Table 2(iii), the person shall also submit a copy thereof.
- 3. Upon receiving an application made under the preceding two paragraphs, the head of the Department to which the person who made the application belongs or affiliates with shall have the person receive pre-registration education and training and a pre-handling medical examination.
- 4. A head of the Department to which the person who made the application belongs or affiliates with shall communicate to the Director about persons who have received both

pre-registration education and training and a pre-handling medical examination. The Director then shall register the reported persons as Registered Handlers.

5. The registration as a Registered Handler shall be effective during the fiscal year.

(Renewal of Registration)

- Article 9. Any University Registered Radiation Handler or University Registered X-ray Handler planning to renew their registration for the subsequent year of the registration shall submit an application to the Department to which the person belongs with documentation including the information listed in Table 2(i).
- 2. Any Non-university Registered Radiation Handler or Non-university Registered X-ray Handler planning to renew their registration for the subsequent year of the registration shall submit an application to the Department to which the person belongs with documentation including the information listed in Table 2(ii).
- 3. The applications stated in the preceding two paragraphs shall be made by the end of the fiscal year of the current registration. However, if the head of the Department to which the person who made the application belongs or affiliates with considers that there is an unavoidable reason, the application may be made in the subsequent fiscal year of the registration.
- 4. When a Department receives an application made under paragraph 1 or 2, the Department Head shall report that to the Director and the Director shall renew the registration of the Applicant.
- 5. The Director shall not register any person who made an application under paragraph 1 or 2 if the person has not received any mandatory education and training or a medical examination during a fiscal year in which the person was registered. However, if the Department Head communicates to the Director the reason why receiving the education and training was impossible and the Director thinks it reasonable, this shall not apply.

(Suspension of Registration)

- Article 10. A Department Head may advise suspending the registration of a Registered Handler to the Director if they find any safety-related problems associated with a Registered Handler, for example, when a Registered Handler has not received the latest mandatory education and training or a medical examination.
- 2. Upon receiving the advice made under the preceding paragraph, the Director shall suspend the registration of the concerned Registered Handler.
- 3. After confirming the resolution of the safety-related issue(s), the Director may cancel the suspension of the registration under the preceding paragraph.

(Pre-registration Radiation Education and Training)

- Article 11. The content and hours of the education and training that should be provided for Radiation Registration Applicants pursuant to paragraph 1 of Article 11 of the Regulations are listed in column (i) of Table 3. [2]
- 2. Notwithstanding the provision of the preceding paragraph, for a Radiation Registration Applicant who has requested an exemption for some of the mandated education and training due to any of the reasons listed below and is recognized to have enough knowledge and skills about the content listed in column (i) of Table 3 by the Subcommittee chair, the content listed in the column may be exempted partially or in full. [3]
 - (1) The Applicant has previously received the education and training mandated by paragraph 1 of Article 11 of the Regulations.
 - (2) The Applicant has a First-class Radiation Protection Supervisor certificate.
 - (3) The Applicant has received education and training that is equivalent to that mandated by paragraph 1 of this Article at any organization other than Kyoto University.
 - (4) The Applicant is deemed by the head of the Department to which the Applicant belongs as a person who has enough knowledge and skills on the items stated in the preceding paragraph and the Department Head's judgement is approved by the Subcommittee chair.
- 3. The results of the education and training provided under paragraph 1 of Article 11 of the Regulations and the results of the determination of an exemption pursuant to the preceding paragraph shall be recorded and kept by the Agency.

(Special Radiation Education and Training)

- Article 12. The Agency may provide any person who has received the education and training mandated by paragraph 1 of Article 11 of the Regulations with practice on items listed in column (i) of Table 3 due to a request from the head of Department to which the person belongs.
- 2. The content of the practice provided under the preceding paragraph shall be prescribed by the Subcommittee.

(Pre-registration X-ray Education and Training)

- Article 13. The content and hours of the education and training that should be provided for X-ray Registration Applicants pursuant to paragraph 2 of Article 11 of the Regulations shall be as follows:
 - (1) The radiation effects on human bodies: 30 min
 - (2) Safe handling of X-ray Generator-related Apparatuses and past examples of radiation accidents: 1 hour

(3) Relevant laws and regulations and the University's internal rules: 1 hour

- 2. Notwithstanding the provisions of the preceding paragraph, for an X-ray Registration Applicant who has requested an exemption for some of the mandated education and training with documentation that includes the information listed below and is recognized to have enough knowledge and skills on X-ray Operation, the content listed in the items 1 and 2 of the preceding paragraph may be exempted subject to the approval of the Subcommittee chair.
 - (1) The date of receipt and the registration number of an Operations Chief of Radiography with X-rays certificate, if the applicant has one.
 - (2) When the applicant has performed any tasks involving X-rays previously, the name of the organization for which the applicant performed the tasks and a copy of the record of education that the applicant has received on content stated in items 1 to 3 of the preceding paragraph.
- 3. The results of the education and training provided under the paragraph 2 of Article 11 of the Regulations and the results of the determination of exemption pursuant to the preceding paragraph shall be recorded and kept by the Agency.

(Pre-registration Education and Training Provided by Department)

- Article 14. A Department Head shall obtain approval from the Agency on the content of the education and training before providing any education and training pursuant to paragraph 5 of Article 11 of the Regulations.
- 2. The education and training provided pursuant to paragraph 5 of Article 11 of the Regulations shall be as listed in column (i) of Table 3 for education and training mandated by paragraph 1 of Article 11 of the Regulations and shall be as listed in paragraph 1 of Article 13 for education and training mandated by paragraph 2 of Article 11 of the Regulations.
- 3. A Department Head shall, when having provided the education and training pursuant to paragraph 5 of Article 11 of the Regulations, report the date and participants to the Agency.
- 4. The results of the education and training provided by the Department under paragraph 5 of Article 11 of the Regulations shall be recorded and kept by the Agency.

(Post-registration Education and Training)

- Article 15. The content and hours of the post-registration education and training provided by the Agency or a Department shall be as listed in column (ii) of Table 3.
- 2. For any University or Non-university Registered Radiation Handler who has requested an exemption for some of the mandated education and training and is recognized as having enough knowledge and skills on all content listed in column (ii) of Table 3 by the

Subcommittee chair shall be deemed to be a person who has completed the postregistration education and training.

3. The results of the post-registration education and training shall be recorded and kept by the Agency (for persons who are deemed to have completed post-registration education and training under the preceding paragraph, this information shall be recorded).

(Special X-ray Education)

- Article 16. When a law or regulation involving an X-ray Generator-related Apparatus is amended or established, or any accident occurs, or the Director confirms the necessity to raise awareness regarding the safe use of X-ray, the Director may have Registered X-ray Handlers receive special X-ray education while communicating the reasons for the necessity.
- 2. The participants, items to be learned, and method of education shall be stipulated by the Subcommittee.
- 3. The results of the education provided under paragraph 1 of this Article shall be recorded and kept by the Agency.

(Medical Examinations)

- Article 17. Applicants shall receive a pre-handling medical examination that is provided by the Agency.
- 2. All Registered Handlers shall receive a regular medical examination once every six months, beginning April 1st and October 1st every year.
- 3. Notwithstanding the provisions of the preceding two paragraphs, the pre-handling medical examinations and regular medical examinations can be substituted by any medical examination provided by any organization other than the Agency that has the same check items.

(Items of Medical Examinations)

- Article 18. Items to be checked in the pre-handling and regular medical examinations provided by the Agency shall be:
 - (1) White blood cell count and white blood cell percentage
 - (2) Red blood cell count and hemoglobin content or hematocrit
 - (3) Eyes with regards to cataracts
 - (4) Skin
- 2. Items to be checked in an interview session of the pre-handling and regular medical examinations shall be as follows:
 - (1) Presence of exposure history

- (2) Amount of exposed radiation; location, content, and timing of the work causing exposure; presence of radiation injury; and other items related to radiation exposure for persons with a history of exposure
- (3) Subjective symptoms
- 3. In a pre-handling medical examination, when confirmed by a doctor based on the results of interview performed under the preceding paragraph, the items listed in item 3 of paragraph 1 of this Article can be exempted.
- 4. In a regular medical examination, when confirmed by a doctor based on the results of interview performed under the paragraph 2 of this Article, the items listed in paragraph 1 can be exempted partially or in full.

(Special Medical Examinations)

- Article 19. When someone falls under one of the following conditions at any site within any Establishment under the control of a Department, the Department Head shall have the person receive a medical examination without delay.
 - (1) The person has accidentally inhaled or ingested Radioisotopes.
 - (2) The person's skin is contaminated by Radioisotopes to the degree exceeding the surface density limit and the contamination cannot be easily removed.
 - (3) The person has or may have a surface wound on the skin that is contaminated by Radioisotopes.
 - (4) The person's internal exposure dose exceeds 2 mSv per 3 months.
 - (5) The person's external exposure dose exceeds 5 mSv per 1 month.
 - (6) The sum of the person's internal and external exposure doses exceeds 20 mSv per 1 year.
 - (7) The person has or may have been exposed to radiation beyond the effective dose limit or equivalent dose limit.
- 2. When someone falls under any condition stated in items 5 or 7 of the preceding paragraph due to an X-ray Generator-related Apparatus under control of a Department, the Department Head shall have the person receive a medical examination without delay.
- 3. A Department Head shall report to the Director the results of a medical examination performed under the preceding two paragraphs (hereinafter referred to as the "Special Medical Examination") and shall take the necessary measures directed by the Director for ensuring the health of the person(s) involved.
- 4. The items to be checked in the Special Medical Examination shall be determined by the doctor who performs the diagnosis.

(Records of Medical Examinations)

- Article 20. The Agency shall record the following information every time when providing a pre-handling or regular medical examinations or when receiving a report of results of a special medical examination from a Department Head.
 - (1) Date, month, and year of the medical examination
 - (2) Full name of the subject
 - (3) Full name of the physician who conducted the medical examination
 - (4) Results of the medical examination
 - (5) Measures that have been taken due to the results of the medical examination
- 2. The Agency shall keep the records stated in the preceding paragraph permanently.
- 3. The Agency shall, each time it provides a medical examination to a person, give a copy of the record of the medical examination results according to the paragraph 1 to said person.

(Procedures for X-ray Workers)

- Article 21. Any person planning to perform X-ray Operations at a Department shall submit an application form for each of the X-ray Generator-related Apparatuses that the person is going to handle in the operation to the relevant X-ray Apparatus Manager.
- 2. Upon receipt of an application form made under the preceding paragraph, the X-ray Apparatus Manager shall confirm that the Applicant meets the following criteria:
 - (1) The applicant has received the education and training equivalent to that stated in paragraph 1 of Article 13.
 - (2) The applicant has received a medical examination equivalent to the pre-handling or regular medical examination since the start date (April 1st) of the fiscal year preceding the date of the application.
- 3. The application shall include the following information: the Applicant's full name, date of birth, sex, the Department or institution to which the applicant belongs or affiliates with, title, the Applicant's registration number if the applicant is a Registered Handler, and the name and registration number of the X-ray Generator-related Apparatuses that the Applicant will handle.
- 4. Any Non-university X-ray Applicant shall attach documentation that proves that the Applicant satisfies the conditions stated in paragraph 2 to the application form submitted under paragraph 1.
- 5. The X-ray Apparatus Manager shall provide education to ensure the safety of the person who made the application under the paragraph 1 including these Guidelines, safety instructions on the X-ray Generator-related Apparatus, and other necessary information for ensuring safety (hereinafter referred to as "Pre-use Education").
- 6. When an applicant under paragraph 1 performs radiophotography, the relevant X-ray Apparatus Manager shall provide the person with education on the content listed below.

Content that has been covered by the education and training stated in paragraph 1 or 2 of Article 11 of the Regulations or the Pre-use Education and training that the applicant previously received can be omitted.

- (1) Method of performing radiophotography: 1 hour 30 min
- (2) Structure and method of handling of X-Ray Generating Apparatus: 1 hour 30 min
- (3) The effects of ionizing radiation on living bodies: 30 min
- (4) Relevant laws and regulations: 1 hour
- 7. When receiving an application made under paragraph 1 of this Article, the X-ray Apparatus Manager shall allow the applicant, when the applicant has satisfied each item of paragraph 2 and received the education stated in the preceding two paragraphs, to serve as an X-ray Worker. The X-ray Apparatus Manager also shall make a list of Pre-use Education performed for each fiscal year.
- 8. The permission stated in the preceding paragraph shall be effective only during the fiscal year when the permission is issued.

(Measurement of External Exposure by the Agency)

- Article 22. The Agency shall, upon a request by a Registered Handler, measure external exposure of the person using a personal dosimeter.
- 2. The measurement stated in the preceding paragraph shall be performed using the following methods:
 - (1) 1 cm and 70 μ m dose equivalents shall be measured at the chest for men and at the abdomen for women.
 - (2) If the exposure dose is expected to be high at any sites other than those stated in the preceding item, 1 cm dose equivalent for those sites shall be also measured.
- 3. The duration of the measurement stated in paragraph 1 shall be while the Registered Handler is within any Controlled Area or while they are performing X-ray Operations. The results of the measurement shall be summed up and recorded every month and kept by the Agency.
- 4. The results of measurements of Registered X-ray Handlers performed under paragraph 1 of this Article shall be confirmed by the Supervisor of the Establishment of the Department to which the concerned person belongs or affiliates with. However, when the Department is a Department with X-ray Apparatus or a Department without X-ray Apparatus, the results shall be confirmed by the Supervisor of the Radioisotope Research Centre.

(Measurement of External Exposure by a Department)

Article 23. When a Department measures the external exposure dose of an X-ray Worker or

Radiation Worker, a personal dosimeter that will be provided by the Department, such as a glass dosimeter and a pocket dosimeter, shall be used.

- 2. Notwithstanding the provision of the preceding paragraph, calculated exposure values may be deemed as measured exposure values when measurements with a personal dosimeter is significantly difficult.
- 3. A Department Head shall obtain approval of the Subcommittee about the measuring method when performing any measurement under the preceding two paragraphs.
- 4. The measurement stated in paragraph 1 shall be performed while the Registered Handler is within any controlled area or while they are performing X-ray Operations. The results of the measurements shall be summed up every month.
- 5. The results of the measurements performed under paragraphs 1 and 2 shall be confirmed by the Supervisor of the Establishment of the Department to which the subject belongs or affiliates with. However, when the Department is a Department with X-ray Apparatus or a Department without X-ray Apparatus, the results shall be confirmed by the Supervisor of the Radioisotope Research Centre.
- 6. When a Department has performed any measurements under paragraph 1 or 2, the Department shall record the results of the measurements. The recorded results shall be kept by the Agency. However, records of measurement results of any persons other than Registered Handlers shall be kept by the Facility Director.
- 7. When any measurement performed under paragraph 1 or 2 finds any exposure that exceeds 0.1 mSv per 1 month, the relevant Department Head shall promptly report it to the Agency.
- 8. When receiving a report made under the preceding paragraph, the Agency shall record the content of the report and keep it permanently.

(Measurement of Internal Exposure)

- Article 24. The Agency shall, pursuant to Article 55 of the Ordinance on Prevention of Ionizing Radiation Hazards (Ordinance of Labor volume 41 of 1972), measure the atmospheric concentration of Radioisotopes in work rooms in which any unsealed Radioisotopes are handled or at sites where there is a concern that any Radioisotopes may be inhaled or ingested (hereinafter referred to as "Work Room, etc.") at least once a month.
- 2. The Agency shall record the date of the measurement performed under the preceding paragraph, the full name of the person who performed the measurement, the concentration of Radioisotopes, and the type and model of radiation measuring apparatus used, and communicate this record to the Facility Director of the Establishment that houses the relevant Work Room, etc.
- 3. The method for calculating the internal exposure dose of a person who performs Handling

and Other Operations in Work Room, etc. based on the measurement results stated in paragraph 1 shall be stipulated by the Subcommittee.

4. The calculation results of internal exposure doses notified by Facility Directors shall be kept by the Agency.

(Record of Exposure Measurements and Provision of Measurement Results)

- Article 25. The Agency shall calculate the effective dose and the equivalent dose based on the results of the measurements and calculations performed under Articles 22 to 24. The Agency shall also record and permanently keep the full name of Registered Handlers for whom the calculation was performed, the calculation dates, the full name of personnel who performed the calculation, the period for which the calculation was performed, the calculated effective dose and equivalent dose, and the organization the subject affiliates with.
- 2. The Director shall confirm the results of the calculation performed under the preceding paragraph and give the calculation results to the person with results of measurement and calculation performed under Articles 22 to 24.

(Creation, Renovation, and Abolition of Radiation Facilities)

- Article 26. A Department Head shall, when 1) creating, renovating, or abolishing any Radiation Facility or 2) making an application or notification mandated by the relevant laws and regulations (e.g. on the changes in the quantity of Radioisotopes, etc. in the Facility), submit an application form that includes the details of the intended creation, renovation, abolishment, or the quantity change to the Agency attaching a draft of the application form to be submitted to the NRA pursuant to relevant laws and regulations.
- 2. When receiving the application made under the preceding paragraph, the radiation safety department of the Agency shall review the submitted application and attached draft application to the NRA and give direction to the contact person written in the application form to correct the application, if necessary,
- 3. When the review performed under the preceding paragraph confirms the appropriateness of the application and the drafted application to the NRA, the Agency shall approve the application made under paragraph 1.
- 4. A Department Head shall, when installing, renovating, or abolishing any X-ray Generating Apparatus, notify the Agency using a form specified by the Subcommittee 45 days before the date of the installation or disposal.
- 5. A Department Head shall, when having installed any one of the apparatuses listed below, make a notification using a form designated by the Subcommittee to obtain a confirmation that the apparatus is not an X-ray Generator-related Apparatus.

- (1) An electron microscope with a rated voltage between 100 kV and 300 kV other than Specified Electron Microscopes.
- (2) Any apparatus for accelerating charged particles other than Radiation Generating Apparatuses or electron microscopes; or any apparatus that incidentally generates Xray or other radiation that has a maximum effective dose rate at 10 cm height from the surface of the apparatus during rated operation not exceeding 600 nSv/h.

(Frequency and Items of Inspection)

- Article 27. The frequency of the inspection required by Article 18 of the Regulations (hereinafter referred to as "Periodic Self-inspection") shall be twice a year.
- 2. The items to be checked in a Periodic Self-inspection at facilities shall be stipulated by the Subcommittee and communicated to the Department Heads.

(Investigations and Inspections by the Agency)

Article 28. The Subcommittee shall specify the timing, method, and items of the investigation and inspection performed under paragraphs 1 and 2 of the Article 19 of the Regulations.

(Radiation Control Status Report)

Article 29. The Agency shall submit radiation control status reports that are submitted by Establishments to the NRA by the deadline stipulated by the relevant laws and regulations.

(Measurement of Amount of Radiation)

- Article 30. The methods for measurement of the amount of radiation at an Establishment shall be stipulated by the Subcommittee.
- 2. Notwithstanding the provision of the preceding paragraph, an Establishment may measure the amount of radiation with a method other than the measurement methods that are stipulated by the Subcommittee under the preceding paragraph.

(Measurement of Contamination)

- Article 31. The measurement method for the amount of radiation and the status of contamination by Radioisotopes, etc. at locations where radiation hazards may occur (referred to as "State of Contamination" in this Article), the methodology for determining the significance of contamination, and actions to be taken when the presence of contamination is confirmed shall be stipulated by the Subcommittee.
- 2. Notwithstanding the provision of the preceding paragraph, an Establishment may

measure the State of Contamination or determine the significance of contamination with a method other than the measurement methods that are stipulated by the Subcommittee under the preceding paragraph.

(Compliance)

Article 32. The Facility Director shall stipulate the following items:

- (1) General items: The method for confirming the conditions described in the certificate of approval of the Establishment, such as places, conditions, quantity, etc. under which Radioisotopes or Radiation Generating Apparatus can be used; the response to personnel with inexperienced personnel; the obligation to keep work sites tidy; the prohibition of carrying unnecessary devices etc. to the work site; the obligation to wear a personal dosimeter; the measures to reduce exposure; the obligation of recording; the prohibition of eating, drinking or smoking in the work site; and emergency responses.
- (2) Items regarding usage of unsealed Radioisotopes: inspection of contamination during experiments, containment of contamination, and inspection of contamination before exiting the site.
- (3) Items regarding usage of sealed Radioisotopes: method for checking the presence of damage after using a radiation source, and ways to communicate the position of safety equipment such as interlocks and how to escape from a room in case of emergency (the two latter are only for applicable radiation sources).
- (4) Items regarding usage of Radiation Generating Apparatus: ways to communicate the position of safety equipment such as interlocks and how to escape from a room in case of emergency (these are only for applicable Radiation Generating Apparatuses).

(Calculation of concentration in emission gas)

- Article 33. The methods for measuring the level of Radioisotopes in exhaust gas with calculation shall be stipulated by the Subcommittee.
- 2. Notwithstanding the provision of the preceding paragraph, any Establishment may measure the level of Radioisotopes in exhaust gas with the calculation method stipulated by the Committee established for the Establishment pursuant to Article 9 of the Regulations.

(Approved Devices with Certification Labels, etc.)

Article 34. Any faculty members and students of Kyoto University, Non-university Registered Radiation Handlers, Non-university Registered X-ray Handlers, Nonuniversity Radiation Workers, and Non-university X-ray Workers may use Approved Devices with Certification Labels and sealed Radioisotopes not exceeding the Minimum Quantity.

2. Items needed for use under the preceding paragraph and the management thereof shall be stipulated by the Subcommittee.

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

Article 35. In addition to the provisions stated in Article 24 of the Regulations, the Institute for Integrated Radiation and Nuclear Science is also exempt from Articles 23.3, 23.6, 24.4, and 25 of these Guidelines.

(Supplementary Provisions)

These Guidelines shall be effective on August 1st, 2019.

(Supplementary Provisions)

These Guidelines shall be effective on September 1st, 2019.

(Supplementary Provisions)

These Guidelines shall be effective on November 28th, 2019 and shall apply on and after August 1st, 2019.

(Supplementary Provisions)

These Guidelines shall be effective on April 1st, 2020.

Notes

- [1] Though the Ionizing Radiation Prevention Ordinance defines radiation generating apparatuses as the following four apparatuses, we exclude all of the apparatuses listed in 4) and Radiation Generating Apparatus (included in 2)) from the scope of "X-ray Generator-related Apparatus" because they are controlled by the Radiation Hazards Prevention Act. In addition, we include apparatuses that can incidentally generate radiation in X-ray Generator-related Apparatuses. Radiation Generating Apparatuses thus differ from X-ray Generator-related Apparatuses.
 - 1) X-ray Generating Apparatuses
 - 2) Apparatus that accelerates charged particles
 - 3) Apparatus for degassing of X-ray tubes or kenotrons or for inspecting such equipment that involves generation of X-rays.
 - 4) Apparatus that is equipped with Radioisotopes.
- [2] Recommendations of the Japanese Society of Radiation Safety Management: (a) 30 min or more, (b) 1 hour or more, (c) 30 min or more plus unsealed radioisotopes: 30 min, sealed: 30 min, Radiation Generating Apparatus: 30 min, animal experiments: 30 min, and hospital: 1 to 3 hours.

[3] In case of a short stay by international personnel, (3) and (4) of paragraph 2 shall apply.

Table 1

		The Administrator				
	(i) The	(ii)	(iii)	(vi)	(v)	
Content of Duties		Establishmen	Department	Departmen	Departmen	
	Superviso	t	with an	t with X-	t without	
	r		Establishmen	ray	X-ray	
			t	Apparatus	Apparatus	
(1) Preparation of a						
draft of the						
Establishment'						
s Radiation	0	—	—	—	—	
Hazards						
Prevention						
Program						
(2) Development of						
a plan that is						
important for						
radiation						
hazard prevention at	0	o —	_			
the						
Establishment						
(2) Development of						
a plan that is						
important for						
radiation	0	—	0	0	0	
hazard						
prevention of a						
Department						
(3) Application,						
notification and						
report made at						
the						
Establishment	0	_	_	_	_	
according to						
relevant laws						
and regulations						
L	1			1	1	

		The Administrator			
		(ii)	(iii)	(vi)	(v)
Content of Duties	(i) The	Establishmen	Department	Departmen	Departmen
	Superviso	t	with an	t with X-	t without
	r		Establishmen	ray	X-ray
			t	Apparatus	Apparatus
(3) Application,					
notification and					
report made at					
the					
Department	_	—	0	0	0
according to					
relevant laws					
and regulations					
(4) Supervision of a					
site inspection	0	0	_	_	_
by NRA etc.					
(5) Investigation of					
cause(s) of any					
abnormality or	0	0	—	—	—
accident at the					
Establishment					
(5) Investigation of					
cause(s) of any					
abnormality or	0	—	0	0	0
accident at the					
Department					
(6) Offering opinion					
on radiation					
safety to a	0	0	0	0	0
Department					
Head					
(6) Offering opinion					
on radiation	_	~	<u>_</u>	_	_
safety to the		0	0		
Supervisor					

		The Administrator			
	(i) The	(ii)	(iii)	(vi)	(v)
		Establishmen	Department	Departmen	Departmen
Content of Duties	Superviso	t	with an	t with X-	t without
	r		Establishmen	ray	X-ray
			t	Apparatus	Apparatus
(7) Audit of status					
of usage,					_
facilities,					
logbooks, etc.	0	_	_	_	
at the					
Establishment					
(8) Confirmation of					
compliance		— о	_	_	_
with laws and					
regulations at	_				
the					
Establishment					
(8) Confirmation of					
compliance with					
relevant laws and	0	—	0	0	0
regulations at the					
Department					
(9) Safe					
management of					
Radiation	0	0	—	—	—
Workers at the	rkers at the				
Establishment					
(9) Safe					
management of					
X-ray Workers	0	—	0	0	—
at the					
Department					

		The Administrator			
Content of Duties	(i) The Superviso r	(ii) Establishmen t	(iii) Department with an Establishmen t	(vi) Departmen t with X- ray Apparatus	(v) Departmen t without X-ray Apparatus
 (9) Safe management of Registered Handlers at the Department 	0	Ι	0	0	0
(10) Advice, recommendation, and direction to related personnel	0	0	0	Ο	0
(11) Help the Supervisor	_	0	_	_	_
 (12) Other items that are deemed necessary by a Department Head on prevention of radiation hazards at the Department and the Establishment 	Ο	0	0	Ο	Ο

Table 2

(i)	Full name, name of the Department to which the person belongs, title, date of		
	birth, sex, contact information, type of registration (University Registered		
	Radiation Handler or University Registered X-ray Handler).		
(ii)	Full name, name of company or organization to which the person belongs, title,		
	date of birth, sex, contact information, type of registration (Non-university		
	Registered Radiation Handler or Non-university Registered X-ray Handler).		

(iii)	Records of radiation exposure history, medical examinations, and education and
	training received.

Table 3

Items to be learned	(i) Pre-	(ii) Post-
	registration	registration
	Radiation	Education and
	Education and	Training
	Training	
(a) Radiation effects on human bodies	30 min	15 min
(b) Safe handling of Radioisotopes, etc., a	3 hours (1)	30 min
Radiation Generating Apparatus, and an		
X-ray Generator-related Apparatus, and		
past examples of radiation accidents		
(c) Relevant laws and regulations and	30 min	15 min
Radiation Prevention Program		
established by the Agency		

(1) Fundamental knowledge about safe handling of radiation, 1 hour; safe handling of sealed Radioisotopes, 30 min; safe handling of unsealed Radioisotopes, 30 min; safe handling of a Radiation Generating Apparatus and an X-ray Generator-related Apparatus, 30 min; and past examples of radiation accidents, 30 min

А	Registered X-ray Handler of	The Agency	Recorded by the Agency
	the Department		
В	Non-university Workers of	Establishment (Stipulated in	Recorded by the Establishment
	the Establishment	the Program)	
С	Non-university X-ray	Department (stipulated in	Recorded by the Department
	Workers of the Department	Guidelines)	
D	Department's own X-ray	Department (submit an	Recorded by Department and by
	Workers	application to the	the Agent if significant
		Subcommittee)	
Е	Establishment's own	Establishment (Stipulated in	Recorded by Department and by
	Workers	the Program)	the Agent if significant