Agreement Concerning Radiation Apparatus

Determined by the Committee on Radiation Protection, May 2, 2008
Revised by the Expert Committee on Radioisotopes, April 24, 2013

(Terms)

1. Definitions of terms for this agreement are as follows:

a. The Law refers to the "Law concerning Prevention of Radiation Hazards due to Radioisotope, etc.".

b. The Regulation for Ionizing Radiation refers to the "Ordinance on the Prevention of Ionizing Radiation Hazards".

c. The Safety Law; *aneihou* refers to the "Industrial Safety and Health Law".

d. The University Regulations refer to the "Regulations for Prevention of Radiation Hazards at Kyoto University" (Notification No.11, April 10, 2001).

e. A radiation apparatus is defined in accordance with the Regulation. [1-1]

f. An X-ray generator is defined as an apparatus that generates X-ray produced by X-ray tube with a rated voltage of 10 kV or over. [1-2]

g. A charged particle accelerator is defined as a radiation generator in accordance with the Law. [1-3,5]

h. An instrument with radioactive materials is defined as an instrument equipped with radioactive material in accordance with the Regulation. [1-4,5]

i. An X-ray generator-related apparatus is defined as "an apparatus that does not fall under the category of a radiation apparatus" in accordance with Article 2.3 of University regulation. [1-6,7]

(Management Supervisor)

2. (1) In order to manage radiation apparatus and X-ray generator-related apparatus, a management supervisor must be allocated to supervise the prevention from radiation hazards at each apparatus. [2-1]

(2) The management supervisor must display the name of apparatus and management supervisor near apparatus. [2-2]

(X-ray Operation Supervisor)

3. (1) In order to conduct operations determined in the Safety Law and the Regulation for Ionizing Radiation, an X-ray operation supervisor (hereinafter "supervisor"; *shunin-sha*) must be allocated at each X-ray generator. [3-1]

(2) The management supervisor will appoint a supervisor from certified X-ray operation supervisors determined in the regulation for ionizing radiation.

(3) The management supervisor must display the name of the supervisor near the

apparatus. [3-2]
(4) Regardless of the Regulations in Paragraph (1), X-ray generators that meet all of the following conditions need not have a supervisor allocated to it. [3-3]
a. Those which do not necessitate external controlled areas.
b. Those which are equipped with safety functions such as an interlock that prevent entry into the generator while generating X-rays.
c. Those on which the safety functions of the preceding paragraph cannot be deactivated easily.

(Reporting Change)
4. (1) In the case of installing, modifying or removing of X-ray generator-related apparatuses, the management supervisor of use must submit the forms determined separately to the chairperson of the Sub-Committee on Radiation Protection (hereinafter "chairperson"; *iinchou*). [4-1, 2, 4]
(2) In the case of installing, modifying or removing of radiation apparatuses, the management supervisor must submit the forms determined separately to the chairperson in advance. [4-2, 3, 4]
(3) Procedure concerning the two preceding paragraphs is as shown in the accompanying fig. 1.

(Controlled Area)
5. (1) Any area in which the effective dose due to external radiation reaches a potential of over 1.3 mSv in three months must be designated a controlled area. [5-1]
(2) The controlled area boundaries must clearly display Sign 1 unless the relevant controlled area is the same as the controlled area determined by the Law. [5-2]

(Precautionary Notice)
6. In a prominent place within the controlled area (near the equipment in cases where external controlled areas are not necessary), the management supervisor must provide the necessary information for the prevention of radiation hazards such as precautions regarding installation of instruments for radiation measurement instruments, precautions for handling radioactive materials, and emergency measures to take when accidents occur. [6-1]

(Signage)
7. (1) The management supervisor must display Sign 2 and 3 on or near X-ray generators or X-ray generator-related apparatus.
(2) The management supervisor must display signs clearly with the classification of equipment, classification of radiation and maximum energy. For charged particle

accelerators; the classification of the equipment must be displayed in a prominent place near the instruments. Also, the classification, installation date and amount (unit: Bq) of radioisotopes equipped as radioactive materials, and the name or institution of ownership. [7-1]

(Radiation Apparatus Room)

8. (1) Radiation apparatuses must be installed in an exclusive-use room (hereinafter "radiation apparatus room"; *houshasen-souchi-shitsu*). [8-1] However, the following radiation apparatuses are excluded.

a. Those which necessitate frequent transfer.

b. Those which are highly difficult to install in a radiation apparatus room (and whose installation would curtail its purpose of use).

c. Those for which the effective dose rate due to external radiation is below 20 μSv/h.

(2) The management supervisor must display Sign 4 at the doorway of the radiation apparatus room (unless it is also a controlled area determined by the Law).

(3) The management supervisor must prohibit all unauthorized access.

(X-ray Generator Room)

9. (1) X-ray generators or X-ray generator-related apparatus that are not installed in radiation apparatus room must be installed in "X-ray Generator Room". [9-1]

(2) The management supervisor must display Sign 5 at the doorway of the X-ray generator room (unless it is also a controlled area determined by the Law).

(3) The X-ray generator room can have other experimental equipment installed but should not be used for any other purpose.

(Alarm Device and Others)

10. (1) The management supervisor must take measures to notify affiliates in the following cases. [10-1]

a. When the radiation apparatus (except instruments with radioactive materials) or X-ray generator-related apparatus are connected to a power supply.

b. When an instrument with radioactive materials is in operation.

(2) Notification per preceding paragraph shall be by an automatic alarm in the following cases.

a. When using machines in the radiation apparatus room.

b. When using X-ray generators with tube voltages of greater than 150 kV.

c. When using instruments with radioactive materials of greater than 400 GBq.

(3) In the case of frequent entry and exit, an interlock must be installed in any radiation apparatus room which has a charged particle accelerator or any instrument with radioactive materials greater than 100 TBq. [10-2]

(Records of Use and Access)

11. (1) The management supervisor of the use of X-ray generators or X-ray generator-related apparatuses must provide books to record each generator use and record the following items.

a. Name of apparatus (or model), place of use (installation room)

b. Date and time of use, name of user

c. Information about accelerating voltage, electric current and other details of usage

(2) The management supervisor must provide books to record access at the doorway of the radiation apparatus room and X-ray generator room. The following items must be recorded.

a. Name of room, name of apparatus (or model)

b. Date and time of entry/exit, name of person

(3) Regardless of the preceding paragraph, if all persons entering the radiation apparatus room record their name in the utilization book, it is not necessary to provide an access book. [11-1]

(4) Regardless of Paragraph 2, those who record his/her name in the utilization book, do not need to fill in the access book. [11-2]

(5) Regardless of Paragraph 2, it is not necessary to provide an access book for X-ray generator rooms which do not contain equipment necessitating an external controlled area. [11-3]

(6) Utilization and access books must be renewed annually and be kept on record for five years.

(Monitoring and Posting Notice)

12. (1) The management supervisor must monitor effective dose due to external radiation of controlled areas of X-ray generators and X-ray generator-related apparatuses (or monitor the surface of the apparatus when an external controlled area not necessitated) with an instrument for radiation measurement. This should be done regularly on a monthly basis (semiannually if the usage and the location of shielding of fixed X-ray generators are immobile), the following items recorded, then kept on record for five years. [12-1, 2]

a. Date and time of monitor, name of officer to carry out monitoring

b. Method of monitoring, classification, type and performance of instrument for radiation monitoring

c. Place, conditions for monitoring

d. Conclusions reached from monitoring, outline of any actions based upon monitor results

(2) The management supervisor must display the results of the monitoring as per the

preceding paragraph near the apparatus or controlled area boundaries.

(Guidance)
13. The chairperson is entitled to render advice to the management supervisor if necessary to ensure safety.

(Special Cases of Low-voltage Electron Microscopes)
14. (1) Article 6, Article 9 (1), Article 10 (1) a, Article 11, and Article 12 (1) shall not apply to Agency-approved electron microscopes among electron microscopes with an accelerating voltage of 300 kV or less (hereinafter referred to as "low-voltage electron microscopes"). [14-1]
(2) Low-voltage electron microscopes shall meet the condition that the effective dose measured in a position 10 cm away from their surfaces during rated operation shall be 600 nSv/hour or less.

Supplementary Provisions
1. The agreement concerning X-ray generators (Established April 1, 1995 by the Committee on Prevention of Radiation Hazards) is to be abolished.
2. This agreement shall come into force on May 2, 2008.
3. This agreement shall come into force on April 24, 2013.

Notes

[1-1] Radiation apparatuses determined in accordance with Article 15 of the regulation for ionizing radiation includes the following.

1. X-ray generators
2. Charged particle accelerators
3. Analytical instruments for equipment with X-ray tubes, Kenotron degassing or X-ray radiation generating capabilities
4. Instruments equipped with radioactive materials

[1-2] Apparatuses whose purpose is not X-ray generation, such as high-current vacuum tube or electron microscope, are to be administered as “X-ray generator-related apparatus”.

[1-3] While “Radiation generator” in Article 2.4 of the Law and “Charged particle accelerator” in Article 14 of the regulation for ionizing radiation are considered to be the same, the more precise definition of the law should be adopted. However, there are cases in which apparatuses that do not fall under the definition of a “Charged particle accelerator”, such as electron microscopes or ion implantation equipment, must be administered as “X-ray generator-related apparatus”.

[1-4] Radioactive material as determined in Article 2 of the regulation for ionizing radiation is the same as “radioisotope” in the law. “Equip” defines the state where radioactive material is habitually present in an apparatus. Therefore ECD for gas chromatograph corresponds whereas radioactive materials that are taken out from a storage box and other such container for each use -- such as a radiation source for calibration -- do not correspond.

[1-5] For controlling charged particle accelerator and instrument with radioactive materials based on the law, the additional articles to be met are Article 2, 4, 7 and 10 (only for automatic alarm when using instrument with radioactive materials with radiation below 400 GBq in radiation apparatus room).

[1-6] “X-ray generator-related apparatus” as determined in Article 2.3 of University regulation defines the apparatus generating X-rays below 1 MeV (including electron rays), an X-ray generator with a rated voltage of 10 kV or over or what incidentally generates equivalent X-rays -- and electron microscopes (excluding those with a rated voltage of less than 100 kV).

[1-7] To summarize: X-ray generators are classified as “radiation apparatus”. Electron microscopes with a rated voltage of 100 kV or over and apparatuses that incidentally generate X-radiation of 10 keV or over is classified as “X-ray generator-related apparatus”. Despite the inclusion of X-ray generators as X-ray generator-related apparatuses in the University Regulations, it is not included in this agreement.

[2-1] A management supervisor corresponds to the safety manager in the “Enforcement Guide for the Ordinance on Prevention of Ionizing Radiation Hazards” (Established

August 26, 2003 by the Sub-Committee on Radiation Protection) and the control manager in the Ministry of Health, Labour and Welfare Notification No. 253, 2001.
[2-2] Although the format is arbitrary, an example is given in ex.1.
[3-1] Only required for X-ray generator; no necessity for other instruments (other X-ray generator-related apparatus such as electron microscope or ion implantation equipment as well as radiation apparatus other than X-ray generator). When multiple X-ray generators are installed in one room, as long as they are within sight, one supervisor is sufficient. However, in principle, one supervisor cannot serve concurrently as the supervisor for equipment in another building.
[3-2] Although the format is arbitrary, an example is given in ex.2.
[3-3] Conditions a to c are based upon stipulations in the "Designation of Supervisors of X-ray Operation" (Established October 10, 2003 by the Sub-Committee on Radiation Protection), determined under consultation between the Safety and Health Department at Kyoto North Labor Standards Supervision Office and the chairperson of the Sub-Committee on Radiation Protection on October 3, 2003. The management supervisor will assess conditions. Body parts entering the generator refers to all parts, including fingertips.
[4-1] As X-ray generator-related apparatuses in this agreement are controlled independently by Kyoto University and not regulated the Safety Law nor the Regulation for Ionizing Radiation, submissions are accepted after the fact.
[4-2] The management supervisor will assess whether or not the equipment is an X-ray generator / X-ray generator-related apparatus, or whether it is relevant to this agreement (in the case that it is irrelevant, a proxy for the management supervisor will assess). The chairperson has the authority to give advice in accordance with Article 13.
[4-3] In accordance with Article 88.1 and 88.2 of the Safety Law. As a report must be submitted at least 30 days before the installation or modification, "in advance" should be understood as 45 days in advance considering the time required for University procedures, etc.
[4-4] All of the provisions of this agreement shall be observed even if no X-ray generator-related apparatus or radiation apparatus is used. Although the monitoring (mapping) of the effective dose stipulated in Article 12 is not required, a record and a sign showing that no X-ray generator-related apparatus or radiation apparatus are required. It is recommended to disuse apparatuses that have not been used.
[5-1] In accordance with Article 3 of the regulation for ionizing radiation. As the three month period is 13 weeks while a working week is 40 hours, "1.3 mSv per three months" is regarded as "2.5 μSv/h".
[5-2] As a charged particle accelerator and instrument with radioactive materials necessitate a controlled area in accordance with the law, this paragraph refers to an X-ray generator and X-ray generator-related apparatus. Ideally, the site of display

should be near the doorway and other possible entrance points. There is no need to display signs when an external controlled area is not necessitated.
[6-1] In accordance with Article 3 of the Regulation for Ionizing Radiation. As the notice contents match those of the law, in practice, the same applies to X-ray generators and X-ray generator-related apparatuses.
[7-1] In accordance with Article 14 of the Regulation for Ionizing Radiation.
[8-1] In accordance with Article 15 of the Regulation for Ionizing Radiation. This also applies to charged particle accelerators and instruments with radioactive materials.
[9-1] This does not to apply to charged particle accelerators and instruments with radioactive materials as they are within the controlled area determined by the law and their doorways are supervised.
[10-1] In accordance with Article 17 of the Regulation for Ionizing Radiation. "Measures to notify affiliates" defines, for example, a display of operation lamp (automatic alarm). These measures shall be posted near the doorway of the radiation apparatus room and near the controlled area boundary for the X-ray generator room (near the equipment when an external controlled area is not necessitated).
[10-2] In accordance with Article 17.2 of the Regulation for Ionizing Radiation. There is no need to install an interlock if it is not a radiation apparatus room even if the room is equipped with a radiation generator or instrument with radioactive materials. This is determined in the regulations for interlock exclusion of the law. (Article 14.6 of enforcement ordinance). This interlock refers to those installed on the door to a room, not those on the shielding cover or other similar part of X-ray generators.
[11-1] As the access book is intended to assess those entering the room, there is no need to provide access books when all relevant people are recorded in the utilization book. This paragraph does not apply to X-ray generator room because there are cases when people not using the equipment enter the room.
[11-2] This applies to the room with an access book.
[11-3] The management supervisor will assess the necessity for an access book. X-ray generator rooms necessitating an external controlled area must have an access book. X-ray generator rooms with no other experimental installations can be registered as a radiation apparatus room. In that case, Paragraph 3 will apply to the room and there is no need to provide access book.
[12-1] The monitoring is determined in Article 53 and 54 of the Regulation for Ionizing Radiation. Existing mapping for X-ray generator-related apparatuses must be continued. Radiation apparatuses besides X-ray generators are not included in this regulation as it is determined by the Law.
[12-2] (1) In principle, monitoring must take place under the rated conditions.
(2) When operating an X-ray generator-related apparatus or radiation apparatus below the rated conditions at all times, the maximum conditions to be used (hereinafter

referred to as “the maximum working conditions”) shall be entered in the precautionary notes. If the maximum working conditions are changed, the precautionary notes shall be revised accordingly.
(3) When using an X-ray generator under the maximum working conditions for the first time, or when changing the maximum working conditions to stricter conditions, a person certified as a supervisor of X-ray operations shall perform monitoring (mapping). This information and the name of the supervisor who performed the monitoring shall be entered in the precautionary notes.
(4) Monitoring that does not fall under the monitoring described in the preceding paragraph (second or subsequent monitoring of an X-ray generator under the maximum working conditions or monitoring of an apparatus other than X-ray generators) may be performed by a person who received guidance from the supervisor engaged in the monitoring described in the preceding paragraph.
[14-1] The items that do not apply to low-voltage electron microscopes (with a rated voltage of 300 kV or less) include the posting of precautionary notes, the installation of an X-ray generator room (a room that does not need an X-ray generator room sign and can be used as a habitable room), alarm devices, records of use and access, and the monitoring (mapping) and posting of external doses. Electron microscopes with a rated voltage of less than 100 kV are excluded from this agreement.