

Administrative Regulations for Operators of Radioactive Material or Equipment Capable of Producing Ionizing Radiation

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Article 1

These regulations are stipulated pursuant to Article 31, Paragraph 3 of the Ionizing Radiation Protection Act (hereinafter referred to as “this Act”)

Article 2

The radiation related certificates stipulated in the proviso of Article 31, Paragraph 1 of this Act refers to one of the following:

1. Radiology or nuclear medicine specialist license.
2. License issued in accordance with the Medical Radiologist Act.
3. Authorization certificate of radiation protection personnel issued in accordance with the stipulations of Article 7, Paragraph 3 of this Act.
4. Certificate of operators issued in accordance with the stipulations of Article 29, Paragraph 5 and Article 30, Paragraph 2 of this Act.

Article 3

Persons engaged in operation training under the direction of qualified personnel, based on educational need, as stipulated in the proviso of Article 31, Paragraph 1 of this Act, are the following:

1. Teachers, researchers and students of middle schools, colleges and universities and academic research institutions.
2. Students at radiation protection training institutions authorized by the Competent Authority.
3. Doctors or dentists receiving clinical training or students or graduates of a medical school with a hospital practicum.
4. New recruits who are receiving pre-employment training.

Personnel referred to in the preceding paragraph shall, before operating radioactive material or equipment capable of producing ionizing radiation, attend lectures on operating procedures and radiation protection planned by qualified personnel. However,

when operating radioactive material or equipment capable of producing ionizing radiation for which the Competent Authority has issued a certificate of permission it shall still be necessary to be directly supervised by qualified personnel.

The lectures on operating procedures and radiation protection referred to in the preceding paragraph shall not be less than three hours. Except for operation training done at middle schools, colleges, and universities in courses approved by the educational competent authority, academic research institutions, hospitals and medical facilities shall keep on file for reference for a period of three years on information including title of lecture course, instructors, location, and names of trainees.

Article 4

Personnel operating radioactive material or equipment capable of producing ionizing radiation shall, except for the conditions stipulated in the proviso of Article 31, Paragraph 1 of this Act, meet one of the following important conditions and obtain certification; following testing and qualification by the Competent Authority, said personnel shall fill out an application form and send to the Competent Authority requesting the issuance of a radiation safety certificate:

1. Undergo training from a radiation protection training company that is authorized by the Competent Authority in line with procedures stipulated in Table 2 of the Regulations for Administration of Radiation Protection Service Related Business.
2. Obtain more than four credits in radiation safety, health physics, physics of radiology, radiobiology, radiation measurement, radiation dosimetry or any other relevant coursework related to radiation protection authorized by the Competent Authority taken at a Taiwan public or legally registered private college or university or a foreign college or university that meets Ministry of Education recognition requirements.
3. Attend an ionizing radiation protection lecture course authorized or commissioned by the Competent Authority prior to the coming into force of this Act.

The training referred to in Subparagraph 1 of the preceding Paragraph may not be substituted by the training stipulated in Article 6, Paragraph 1, Subparagraph 1.

When, in fulfilling the requirements of an agreement for contracting, buying and selling, technical cooperation, a foreigner does work in the ROC within the scope of said agreement and must operate radioactive material or equipment capable of producing ionizing radiation, the facility operator who has made the agreement shall submit a photocopy of foreign certification of operating or radiation protection training for said foreigner, apply to the Competent Authority for review and obtain qualification before

said foreigner may engage in said work.

Article 5

The specific radioactivity or specific energy levels stipulated in Article 31, Paragraph 2 of this Act are as follows:

1. For a toxic-gas detector, the radioactivity level of Americium-241 contained in any component is 10 MBq, the surface dose rate at an accessible distance of 5 cm is 5 micro-sieverts (μSv) per hour.
2. Radioactive material that forms a component of an instrument or manufactured product and that has a radioactivity less than 1,000 times that of the exemption level and the surface dose rate at an accessible distance of 5 cm is 5 microsieverts (μSv) per hour.
3. The radioactivity of Nickel-63 contained in a gas chromatography instrument or explosive detector is 740 MBq.
4. The radioactivity of Americium-241 contained in a lightning rod is 370 MBq.
5. Radioactive materials besides those mentioned in the preceding four subparagraphs with a radioactive level of 100 times that of the exemption level.
6. For equipment capable of producing ionizing radiation, the nominal voltage is 150 kV or the particle energy is 150 keV.
7. Cabinet or baggage inspection X-ray machine, ion implanter, electron beam welding machine or static eliminator, the surface dose rate at an accessible distance of 5 cm is 5 micro-sieverts (μSv) per hour.
8. Other material or equipment as designated by the Competent Authority.

Article 6

The training stipulated in Article 31, Paragraph 2 of this Act refers to one of the following, and with training certification:

1. Training in accordance with the stipulations of Table 2 of the Regulations for Administration of Radiation Protection Service Related Business conducted by a radiation protection training company authorized by the Competent Authority or conducted by the facility operator.
2. Obtain more than two credits in radiation safety, health physics, physics of radiology, radiobiology, radiation measurement, radiation dosimetry or any other relevant coursework related to radiation protection authorized by the Competent Authority taken at a Taiwan public or legally registered private college or university or a foreign college or university that meets Ministry of Education recognition requirements.

Prior to conducting the radiation protection training referred to in Subparagraph 1 of the

preceding paragraph, facility operator shall submit the names of trainees, time and place of training, training course and number of hours, and instructor qualifications to the Competent Authority for reference. Related information shall be recorded and kept on file for at least ten years.

Article 7

The radiation safety certificate is valid for a period of six years. Within three to six months prior to its expiration, the applicant may fill out an application form and attach **the following proof of training or credits of totaling more than 36 hours** during the radiation safety certificate's period of validity and apply to the Competent Authority for a certificate renewal:

1. radiation protection training conducted by a radiation protection training company authorized by the Competent Authority;
2. **academic activity or continuing education credits as stipulated in Article 7, Paragraph 1 of Administrative Regulations for Radiation Protection Personnel; and**
3. regular educational training as stipulated in Article 14, Paragraph 4 of this Act.

If the radiation safety certificate has expired, **the applicant may fill out an application form and attach the documentary proof of above-mentioned training or credits of totaling more than 36 hours in recent 6 years and apply to the Competent Authority renewedly for a certificate renewal.**

Article 8

For a request to replace a valid lost or damaged radiation safety certificate, an application form shall be filled out, with the relevant documentary proof attached and application made to the Competent Authority for a certificate replacement.

For a request to modify information on a valid radiation safety certificate and issue a renewal, application form shall be filled out, with the relevant documentary proof attached and application made to the Competent Authority for a certificate renewal.

For replacements and renewals referred to in the preceding two paragraphs, the period of validity will be the same as for the original certificate.

Article 9

If any one of the following situations obtains for the holder of a radiation safety certificate the Competent Authority may revoke or terminate said certificate:

1. Documents attached to the application for a radiation safety certificate contain false information.
2. The radiation safety certificate has been leased or lent for use to another person.
3. A crime has been committed in the course of business relating to Article 38 or

39 of this Act.

4. Any other situation determined by the Competent Authority to be a major violation.

If a radiation safety certificate has been revoked or terminated by the Competent Authority, a renewed application may not be made within one year after the effective date of revocation or termination.

Article 10

Those who, before the implementation of this Act, have obtained an operating license from the Competent Authority, or before the implementation of this Act have obtained a formal notification of passing an examination for a non-medical operating license or have obtained a completion certificate for a lecture course in medical ionizing radiation protection, shall within two years of this Act coming into force fill out an application form and attach the original operating license, formal notification of passing an examination for a non-medical operating license or the original of a completion certificate for a lecture course in medical ionizing radiation protection and apply to the Competent Authority for a **replacement** of the radiation safety certificate.

The **replaced** radiation safety certificate stipulated in the preceding paragraph is valid from the date this Act comes into force.

Those who have **not** applied for a **replacement within** the period stipulated in Paragraph 1 shall fill out an application form and attach the documentary proof of Paragraph 1 and the training and credits received as listed in Article 7, Paragraph 1 and apply to the Competent Authority renewedly for a radiation safety certificate:

1. Those who are not exceeding 4 years from the date of this Act comes into force shall attach the documentary proof of totaling more than 12 hours from the date of this Act comes into force;
2. Those who exceed 4 years but less than 6 years from the date of this Act comes into force shall attach the documentary proof of totaling more than 24 hours from the date of this Act comes into force; and
3. Those who exceed 6 years from the date of this Act comes into force shall attach the documentary proof of training totaling more than 36 hours in recent 6 years.

Article 11

The format of all documents and forms stipulated in the regulations shall be determined by the Competent Authority.

Article 12

These regulations shall take effect on the day of promulgation.