

Safety Regulations for Medical Ionizing Radiation

I. Safety regulations for X-ray installations

(1) General regulations

i. Diagnostic-type protective tube housing

For a therapeutic X-ray tube in use, its leakage radiation shall not exceed 2.58×10^{-5} coulomb (100 mR/hr (R)) every kilogram per hour at 1 meter away from the target.

ii. Therapeutic type protective tube housing

For a therapeutic X-ray tube in use, its leakage radiation shall not exceed 2.58×10^{-4} coulomb (1 Roentgen (R)) every kilogram per hour at 1 meter away from the target. Furthermore, its leakage radiation shall not exceed 7.74×10^{-3} coulomb (30 Roentgen (R)) every kilogram per hour at 5 cm away from the protective tube housing and facing the patient.

iii. Personnel monitoring

For work personnel in the controlled area, if the dosage received can reach one-fourth of the maximum permissible dosage, they shall carry a personnel detector (such as a plastic badge or dosage pen). The maximum permissible dosage is stipulated according to regulations of safety standards for protection against ionizing radiation by the Atomic Energy Council (AEC) of the Executive Yuan.

iv. Buildings with X-ray machines

For buildings of facilities with X-ray machines installed, their internal and external maximum permissible dosage of radiation shall be in accordance with regulations of safety standards for protection against ionizing radiation by the Atomic Energy Council (AEC) of the Executive Yuan.

(2) Regulations on special utilities

i. Medical fluoroscopic installations

(a) The distance from the target to the table surface shall not be less than 30.38 cm (12 inches).

(b) All of the permanent filters of the useful beam shall not have less than a 2.5 mm thickness of aluminum equivalent or its half-value layer shall not have less than a 2.5 mm thickness of aluminum.

(c) The entire section of the useful beam will be weakened through the primary barrier. When the voltage peak value is 100 thousand volts (kVp), the thickness of the primary barrier shall have at least a 1.5 mm thickness of lead equivalent; when the voltage peak value is 125 thousand volts, it shall be at least 1.8 mm thick, and when the voltage peak value is 150 thousand volts, it shall be at least 2 mm thick.

(d) The exposure switch must be the dead-man type and be attached with a fixed-hour timer. Thus, it will stop automatically when time is up, and the longest period of time shall be 5 minutes.

(e) The collimator used to limit the size of the useful beam shall be equipped with adjustable diaphragms, or shutters, and it shall at least be equipped with a certain thickness of lead equivalent. When the voltage peak value is 100 thousand volts, it shall be at least 2 mm thick; shall be 2.4 mm thick for 125 thousand volts, and 2.7 mm thick for 150 thousand volts.

(f) For routine work, the exposure rate at the table surface shall not exceed 2.58×10^{-3} coulomb (10 mR, Roentgen (R)) every kilogram per minute.

(g) In between the patient and the operator of the fluorescent plate, there shall be a barrier of at least a 0.25 mm thickness of lead equivalent, while the gap of the screen shall also have a 0.25 mm thickness of lead equivalent.

(h) The safety measures for mobile fluoroscopic equipment shall be the same as the above-mentioned measures for fixed fluoroscopy equipment.

ii. Medical radiographic installations

(a) All of the permanent filters of the useful beam shall not have less than a 2.5 mm thickness of lead equivalent or its half-value layer shall not have less than a 2.5 mm thickness of aluminum.

(b) It shall be equipped with a suitable collimator or cone that can restrict the useful beam.

(c) The height of the protective barrier shall reach at least 2 meters above the ground.

(d) The position of the operator shall be behind the protective barrier.

iii. Mobile diagnostic equipment

(a) The distance from the target to the skin shall be no less than 30 cm, and the section of useful beam shall be the same as the one needed for diagnosis.

(b) The distance between the operator and the patient shall be no less than 180 cm.

(c) If the mobile diagnosis treatment is always used at a certain fixed location, it shall be considered fixed equipment.

iv. Photofluorography installations

(a) The collimator has to be able to limit the section of useful beam projected onto the fluorescent plate.

(b) The subject whose photo is to be taken must be equipped with a suitable barrier to prevent their reproductive organs from being exposed to the useful beam during photo-taking.

v. Dental radiographic installations

(a) The diameter of the useful beam to the tip of the cone shall not be greater than 7.6 cm.

(b) The distance from target to skin: When the voltage peak value is 50 thousand volts, it shall be no less than 18 cm, and when it is less than 50 thousand volts it shall, be no less than 10 cm.

(c) When the voltage peak value has reached 70 thousand volts, all of the permanent filters of the useful beam shall have at least a 1.5 mm thickness of aluminum equivalent; when it is well over 70 thousand volts, it would need more than a 2.5 mm thickness of aluminum equivalent.

(d) The exposure switch must be the dead-man type.

(e) The distance between the operator and the patient shall not be less than 180 cm, or there must be a suitable barrier.

(f) Fluoroscopy cannot be used on dental diagnosis.

vi. Therapeutic X-ray installations operated at potentials operated at up to 3000Kv

(a) The tube housing has to be therapeutic.

(b) For adjustable diaphragms or removable beam-defining diaphragms or cones, when they are under the context of using the highest voltage and maximum therapeutic filter, the useful beam that passes through the diaphragms shall not exceed 5% of the original value.

- (c) Effused radiation from the filter slot shall not exceed 2.58×10^{-4} coulomb (1R, Roentgen (R)) coulomb at 1 meter away every kilogram per hour, and at 5 cm outside the opening of the filter slot shall not exceed 7.74×10^{-3} coulomb (30 mR, Roentgen (R)) every hour per kilogram.
- (d) Detection equipment for the useful beam, a position indicator of the shutter, and primary and secondary barrier, as well as windows and mirrors for observation, CCTV and other equipment shall be provided.
- (e) Lead rubber and lead sheets used to restrict the section of the useful beam shall not permit the beam to exceed 5% of the original value of the useful beam after passing through the lead sheet.
- (f) When voltage peak value is more than 125 thousand volts, a mobile lead barrier is not allowed to be used.
- (g) When voltage peak value has reached higher than 150 thousand volts, the control station has to be behind a protective barrier or in a neighboring room.
- (h) It shall be equipped with interlock, so that when the therapy room is opened, the X-ray machine will turn off automatically, or it will render the amount of average radiation within the therapeutic room to be less than 5.16×10^{-7} coulomb (2 mR, Roentgen (R)) every hour per kilogram; the greatest amount of radiation shall not exceed 2.58×10^{-3} (10 Roentgen (R)) every hour per kilogram in any place 1 meter from the target.

vii. X-ray therapy equipment operated at potentials of 60 Kv and below

- (a) Should the distance from the target to skin be less than 3cm, it has to be equipped with barrier to shield from useful beam.
- (b) Leakage radiation from surface of tube housing shall not exceed 2.58×10^{-5} coulomb (100 mR, Roentgen (R)), every hour per kilogram and it shall be equipped with 0.5mm of cap of lead equivalent so that ~~it can~~ the aperture window can be covered when it is not in use.

II. Safety regulations for isotopes (isotopes in these regulations refer to unsealed radiation nuclides used on tasks for diagnosis and therapy or medical research)

(1) Necessary basic detection equipment to be equipped

- i. Personnel monitor
- ii. Area monitor

(2) Safety for isotope chambers or hot laboratories :

- i. Locations processing high-level radiation and low-level radiation have to be separated.
- ii. They must be equipped with a fume hood with exhaust equipment.
- iii. They must be equipped with a special sink for dumping radioactive waste liquid and washing contaminated glass containers.
- iv. Delivery of a radiation isotope within the room is best to be done with a wheeled table.
- v. Powder radioactive isotopes shall not be sterilized with heat, and one shall take special caution when sterilizing them with chemicals.
- vi. They must be a place to store radioactive materials, with suitable protective barriers and adequate management.
- vii. The walls and ceiling inside the room shall be coated with painting that is hard, hole-less, and easy to wash. As for the floor, materials not liable to leaking and that can be cleaned of dirt easily shall be used;

as for furniture, they shall be as little as possible, and their surfaces shall be covered with materials that will not leak easily. The radioactive waste bucket shall employ a step-type bucket, while the inside shall be lined with a hole-less plastic bag.

viii. Utensils for surgery shall be placed within a stainless steel, aluminum, or nylon plate lined with absorbent paper; liquid samples shall be placed within containers not liable to break. Utensils used in the isotope room shall not be mixed with others and shall be placed in a fixed location.

(3) Transportation container

For transportation of utensils, one shall follow the Regulations for the Safe Transport of Radioactive Material by the AEC of the Executive Yuan.

(4) Operation tools

- i. The tools shall include clamps and forceps of suitable sizes and others.
- ii. One must not use his/her mouth to suck the pipette.

(5) Regular health care :

- i. It shall be equipped with rubber gloves, plastic gloves, and working clothes, etc.
- ii. It is strictly prohibited to drink and eat, smoke, or store food inside the radioactive isotope room.
- iii. If radiation contamination is found, one shall deal with it immediately.

(6) Radiation Survey :

A measurement of radiation shall be taken regularly (at least once a month), and a detailed record of the measurements shall be kept.

(7) Signs :

- i. There must be a radiation sign.
- ii. There must be a warning sign.

(8) Standards for removing radioactive contamination:

- i. In a space with an area between 900 and 1600 square centimeters, when the count rate has dropped to five times that of the background count rate, it has then reached the decontamination standard.
- ii. In a space with an area of 100 square centimeters, when the count rate has dropped to ten times that of the background count rate, it has then reached the decontamination standard.
- iii. For general contamination spots, when its count rate is 10 times higher than the background count rate, it shall first be stored in an appropriate location, and when it has decayed naturally and its count rate has dropped to 10 times of the background count rate, the operation of decontamination can then be conducted.

(9) For processing of radioactive waste: when radioactive waste is placed at the periphery outside of the location, processing shall be conducted according to the following listed regulations:

i. Processing for the public sewage system

- (a) Radioactive material must be easily dissolved or diffused in water before it can be discharged into the

public sewage system.

- (b) The discharge amount of radioactive waste shall not exceed the greatest value from the following listed regulations stipulated.

Radioactive waste discharged must be diluted with water discharged daily every day from the sewage system and its concentration shall not exceed the highest permissible concentration stipulated in the 9th column of Table 4 of the Safety Standards for Protection against Ionizing Radiation by the AEC of the Executive Yuan.

Radioactive liquid waste discharged must be diluted with the average water discharged every day from the sewage system and its concentration shall not exceed the highest permissible concentration in water stipulated in the 9th column of Table 4 of the Safety Standards for Protection against Ionizing Radiation by the AEC of the Executive Yuan.

Radioactive liquid waste discharged every year shall not exceed 3.7×10^{10} Bq (1 Curie).

The above-mentioned constraints are not applicable to patient excrement with medical therapy by isotope.

ii. Soil-burial processing

For processing the burial of waste material, the site of the land burial shall first submit the information regarding the site and peripheral official chart of location, depth of ground water, velocity, and flow direction and then request the AEC of the Executive Yuan for approval. Then the AEC of the Executive Yuan can respectively appoint the greatest intensity for land burial in processing waste material in every occasion.

iii Incineration processing

When waste material is dispersed into the air after burning, its average concentration every year shall not exceed the highest permissible concentration stipulated in the 7th column of Table 4 of the Safety Standards for Protection against Ionizing Radiation by the AEC of the Executive Yuan.

(10) Carcass processing

- i. For a carcass that contains less than 1.1×10^9 Bq (30 mCi), injection asepsis can be used. For a carcass that contains more than 1.11×10^9 Bq (30 mCi), there shall be radiation protection personnel on site for instruction during processing.
- ii. For a carcass that contains more than 1.85×10^8 Bq (5 mCi), there shall be radiation protection personnel on site for instruction during autopsy.

III. Safety regulations for sealed radiation sources (the so-called sealed radiation in these regulations refers to radioactive isotopes that are contained within metal or metal alloy containers. The well-contained radioactive material will not have contact with external air, and what the staff bears is merely the radiation emitted from the isotopes in the container.

(1) Therapeutic radiation sources for the body and body surfaces:

- i. Usually, the barrier has a 5 mm thickness of lead equivalent, and it shall not exceed the following figures every week within the smallest distance of 30 cm:
Radium as 5.92×10^9 Bq (160 mCi) per hour, Co-60 as 3.7×10^9 Bq (100 mCi) per hour, and Cs-137 as 1.332×10^{10} Bq (360 mCi) per hour.

ii. Operation must be conducted under the guidance of a physician or dentist with an operating license.

iii. Medicinal Application

Regarding operation of the above-mentioned various kinds of radiation sources for treatment, it is best to be conducted within a single operation room. If a person

contains a sealed radiation source inside their body, the patient shall be placed in a single ward. Furthermore, the location of a sickbed and its distance from other patients and medical staff shall have an adequate barrier such that meets the stipulations of Safety Standards for Protection against Ionizing Radiation by the AEC of the Executive Yuan.

iv. Storage

A radiation source shall be well stored within utensils of lead quality or raw materials with favorable protection function, so that staff working in the area affected by radiation will not exceed the greatest permissible dosage; the storage room shall also be equipped with ventilation equipment.

v. Transportation

The transportation of radiation sources shall meet the Regulations for the Safe Transport of Radioactive Material.

vi. Maintenance

Whether during storage, transportation, or clinical application, radiation sources shall remain intact from damage, and should any breakage occur, it shall be stopped of employment at once with suitable safety measures taken for processing. At the same time, the AEC of the Executive Yuan shall be informed immediately.

vii. Users of a radiation source shall always conduct self-checks and accept regular examinations by the AEC of the Executive Yuan.

viii. Smear tests shall be conducted regularly to measure if there is any leakage.

(2) Radiation source for long-distance therapy

- i. Smear tests shall be conducted regularly to measure if there is any leakage.
- ii. For protective housing, it has to render the greatest and average exposure rate with a distance of 1 meter from the radiation source not in excess of 2.58×10^{-6} coulomb (10 mR, Roentgen (R)) every hour per kilogram and 5.16×10^{-7} coulomb (2 mR, Roentgen (R)) every hour per kilogram.
- iii. During operation, the leakage radiation shall not, at 1 meter away from the radiation source in use, exceed one thousandth of the useful beams.
- iv. During operation, the useful beam that penetrates the adjustable controller shall not exceed 5%.
- v. The door in the therapy room, if one loses his/her way, must have a 1.5 mm to 3 mm thickness of

lead equivalent.

IV. Fire prevention and radiation safety

(1) Definition

- i. Building
It must be fixed to the ground, found with roof-top, walls, or pillars, and it also includes construction equipment.
- ii. Houses
Those entire houses for accommodation, work, gathering, entertainment, and other activities are considered to belong to this category.
- iii. Primary structures
All the walls, pillars, ground surfaces, girders, roofs, and stairways are considered to belong to this category.
- iv. Fire-proof structure
All those fire-proof materials, such as steel, concrete, or brick and other structures as stipulated in legal provisions by government construction law, belong to this category.
- v. Non-combustible materials
All those non-combustible materials, such as concrete, brick stone, tile, asbestos, steel, aluminum, glass, ceramics, trinity mixture fill and other non-combustible materials, are considered to belong to this category.

(2) Fire-proof buildings that use radiation sources

- i. Houses shall use mainly fire-proof and non-combustible construction materials; but under following listed scenarios the main structure shall employ primarily with fire-proof structure, while the rest will not have to be non-combustible materials.

Classification	1	2	3	4
Type	^{90}Sr and isotopes emitting α radiation	Isotopes whose half-life is greater than 30 days (^3H , ^7Be , ^{14}C , ^{35}S , ^{55}Fe , ^{59}Fe , ^{90}Sr , and not including isotopes emitting α radiation)	Isotopes whose half-life is less than 30 days (^{18}F , ^{51}Cr , ^{71}Ge , ^{201}Tl , ^{55}Fe , ^{59}Fe , ^{35}S and not including isotopes emitting α radiation)	^3H , ^7Be , ^{14}C , ^{18}F , ^{51}Cr , ^{71}Ge , and ^{201}Tl

Installed with ventilation and contamination detection equipment	Less than 3.7×10^6 Bq (100 μ Ci)	Less than 3.7×10^7 Bq (1 mCi)	Less than 3.7×10^8 Bq (10 mCi)	Less than 3.7×10^9 Bq (100 mCi)
Not installed with ventilation and contamination detection equipment	Less than 3.7×10^5 Bq (10 μ Ci)	Less than 3.7×10^6 Bq (100 μ Ci)	Less than 3.7×10^7 Bq (1 mCi)	3.7×10^8 Bq (10 mCi)

ii. Houses shall be equipped with adequate fire-fighting equipment.

(3) Fire-fighting organizations that use radiation sources

- i. Utility units shall have adequate fire-fighting and self-defense organization for fire-fighting.
- ii. Self-defense organization for fire-fighting and radiation protection personnel shall work and cooperate with each other in terms of fire-fighting and fire-prevention.
- iii. Radiation protection personnel of utility units shall be responsible for making contact with each of the relevant fire-fighting and fire-prevention authorities to ensure safety of radiation protection.

(4) Radiation safety during a fire

- i. Sealed and non-sealed isotopes
 - (a) Inflammable objects, fire-triggering items, and explosive in the area of isotopes shall be removed quickly.
 - (b) Exhaust and ventilation systems shall be turned off immediately to prevent proliferation of air pollution.
 - (c) Power and gas shall be cut off at once.
 - (d) Isotope rooms shall be equipped with adequate extinguishers, such as carbon dioxide or powder extinguisher.
 - (e) Isotopes shall be quickly placed in the storage room.
 - (f) If the storage room is on fire, isotopes shall be moved to other safe places.
 - (g) Isotope containers shall be made of non-combustible materials that will not break easily, and during transportation one shall be cautious of the solution leaking. There must also be suitable signs to prohibit approach by any third party.
 - (h) If it is impossible to move the isotope, it shall be placed within a non-combustible container to avoid contamination.
- ii. Coordination during a fire-fighting
 - (a) Radiation dosage in the area of the fire shall be detected at all times and any unconcerned party shall be strictly prohibited to get close.
 - (b) Suitable ways of fire-fighting are suggested to prevent fire-fighters to be exposed to over dosages and to avoid proliferation of contamination.
 - (c) If necessary, fire-fighters shall carry personnel detectors and wear protective clothing.
 - (d) Inspect the contamination conditions of fire-fighters.

iii. Dealing with the aftermath

- (a) The aftermath dealing of the isotope room is considered a top priority.
- (b) Decontamination and prevention of the proliferation of contamination with patients.
- (c) Re-zoning of restricted areas.
- (d) Inspection of isotope containers, barrier, and if there is any damage or leakage with other radiation protection equipment.