

RADIATION SAFETY DIRECTORATE

Pursuant to Article 26-e, paragraph 1, item 7 of the Law on Ionising Radiation Protection and Radiation Safety (Official Gazette of the Republic of Macedonia No. 48/02 and 135/07), the Director of the Radiation Safety Directorate hereby adopts a

RULEBOOK ON THE CRITERIA AND THE MEASURES FOR PROTECTION AGAINST IONISING RADIATION FOR PERFORMING WORK WITH X-RAY MACHINES, ACCELERATORS AND OTHER IONISING RADIATION-GENERATING DEVICES ⁽¹⁾

Article 1

This Rulebook shall prescribe the criteria and the measures for protection against ionising radiation for performing work with x-ray machines, accelerators and other ionising radiation-generating devices.

Article 2

X-ray machines, accelerators and other ionising radiation-generating devices may be used in medicine, stomatology, veterinary medicine, industry, science and other areas.

Article 3

X-ray machines, accelerators and other ionising radiation-generating devices may be used only in special facilities and premises designed and equipped in a manner that guarantees protection against ionising radiation for persons exposed thereto.

X-ray machines, accelerators and other ionising radiation-generating devices may also be used in fieldwork, provided the exposure doses are reduced to the minimum and do not exceed the dose levels established in accordance with the regulations on ionising radiation protection and radiation safety.

Article 4

The facilities and premises housing X-ray machines, accelerators and other ionising radiation-generating devices shall be designed, constructed and equipped depending on their intended purpose and on the exposure of the occupationally exposed persons and of the general public to ionising radiation.

The protection of premises housing X-ray machines, accelerators and other ionising radiation-generating devices shall be designed and constructed in such a manner that on the surrounding premises the dose levels for the general public and/or the occupationally exposed persons, established in accordance with the regulations on ionising radiation protection and radiation safety, are not exceeded.

When designing the protection referred to in paragraph 2 of this Article, dose limits shall be applied in order to reduce the doses to the minimum, at the same time taking into consideration the exposure to various ionising radiation sources.

Article 5

The dose limits referred to in Article 4 paragraph 3 of this Rulebook shall be as follows:

¹ This Rulebook is being aligned with the Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (CELEX number 31996L0029).

- 1) when operating diagnostic X-ray machines: 0,3 mSv per year for the general public, and
- 2) when operating radiotherapy devices:
 - 6 mSv per year for occupationally exposed persons, and
 - 0,3 mSv for the general public.

Article 6

X-ray machines, accelerators and other ionising radiation-generating devices shall be used in facilities and premises projected in a design plan that contains in particular:

- a draft of the facilities and premises that are intended to house X-ray machines, accelerators and other ionising radiation-generating devices, as well as of the technical specifications of the devices and their positioning;
- the projected thickness and type of materials for the walls, doors and other openings of the facilities and premises;
- determination of the controlled and supervised areas, and
- notes.

Article 7

Checks of the protection of facilities and premises housing X-ray machines, accelerators and other ionising radiation-generating devices shall be performed by measuring the ionising radiation dose rate on the work premises as part of the work environment monitoring, in accordance with the regulations on ionising radiation protection and radiation safety, before the premises are put into use.

Article 8

The premises housing X-ray machines, accelerators and other ionising radiation-generating devices shall have dimensions that correspond to their intended purpose, taking into consideration the size and number of the X-ray machines, accelerators and other ionising radiation-generating devices they contain, the need for setting up additional protective shields, the function of the devices and the need for the presence of individuals on the premises.

The floor of the premises where a stationary X-ray machine and an accelerator are being operated shall be made of an insulating material such as rubber, vinyl-asbestos, linoleum, etc.

Article 9

The premises housing an X-ray machine, accelerator or another ionising radiation-generating device may contain only equipment and objects necessary for operating the device.

High-voltage wires and other electrical conductors shall be connected to the corresponding parts of the X-ray machine and the accelerator through special conduits embedded in the floor.

Article 10

If the premises house several X-ray machines or other ionising radiation-generating devices or if any surrounding premises house several X-ray machines, accelerators or other ionising radiation-generating devices, the effect produced simultaneously by all of them shall be taken into consideration when determining the protection of the premises. X-ray machines, accelerators and other ionising radiation-generating devices shall be considered the sole source of exposure on the premises or surrounding premises where they are lodged.

In the case referred to in paragraph 1 of this Article, namely when the same premises house several X-ray machines and other ionising radiation-generating devices, the possibility of a simultaneous use of more than one X-ray tube with a regulated electrical wiring shall be

eliminated.

The provision referred to in paragraph 2 of this Article shall not apply to devices where two X-ray tubes are used for simultaneous radiation of the person who is being examined.

Article 11

Entries into the controlled area shall be marked with the ionising radiation warning sign, given in the Appendix which is a constituent part of this Rulebook. Where appropriate, the following flashing signal devices shall be placed in the immediate proximity to the door:

1. Yellow or white, accompanied by the explanatory wording "Equipment in use", when the device is ready for screening; and
2. Red, accompanied by the explanatory wording "Access prohibited", when the device is generating ionising radiation.

Article 12

The doors leading to the premises that house X-ray machines, accelerators and other ionising radiation-generating devices shall be locked and access to the keys shall be limited to the persons authorised to operate them.

Article 13

During the operation of the X-ray machine, accelerator or another ionising radiation-generating device, only the persons necessary for the operation of the device may be present in the controlled area.

The entry to the controlled area shall be such that prevents uncontrolled entry therein.

Article 14

Technical documentation, including a CE certificate of conformity and instructions for use and maintenance of the device, shall be necessary for the X-ray machine, accelerator and other ionising radiation-generating device; in addition, the device shall meet the criteria established in the regulations on ionising radiation protection and radiation safety.

By way of exception from paragraph 1 of this Article, the X-ray machine, accelerator and other ionising radiation-generating device for which there is no technical documentation, including a CE certificate of conformity and instructions for use and maintenance of the device, but which is already in use, shall meet the criteria established in the regulations on ionising radiation protection and radiation safety.

Article 15

The premises where X-ray machines, accelerators and other ionising radiation-generating devices are being operated shall have a waiting-room and locker-rooms for patients.

Article 16

The command device of the X-ray machine or another ionising radiation-generating device shall be placed in a protected cabin or in a different room.

If the command device referred to in paragraph 1 of this Article is in a special room, the visual contact with the room where the X-ray machine or another ionising radiation-generating device is situated shall be provided by means of an opening protected with a leaden glass or video surveillance.

In the case referred to in paragraph 2 of this Article, interphone communication between the

two rooms shall be compulsory.

If the command device is in a protected cabin in the same room, it shall be placed in the appropriate position and it shall be protected in such a manner that the exposure to ionising radiation of occupationally exposed persons is reduced to the minimum, below the dose limits established in Article 5 of this Rulebook.

Article 17

Accelerators, therapeutic X-ray machines and X-ray machines for computerised tomography, fluoroscopy and interventional radiology shall be placed in such a manner that the command device is in a room which is separate from the room which houses the device.

The visual contact in the case referred to in paragraph 1 of this Article shall be provided by means of an opening protected with leaden glass or video surveillance, whereby interphone communication between the two rooms shall be necessary.

The provision referred to in paragraph 1 of this Article shall not apply to therapeutic X-ray machines whose tube voltage does not exceed 50 kV.

Article 18

The leaden glass specifications referred to in Article 16 paragraph 2 and Article 17 paragraph 2 of this Rulebook shall provide that the exposure to ionising radiation of occupationally exposed persons is reduced to the minimum, below the dose limits established in Article 5 of this Rulebook.

The protective power of the leaden glass shall be made accessible and expressed in mm lead thickness equivalent on a visible spot.

Article 19

The room which houses the X-ray machine for diagnostics or therapy shall have ventilation or air-conditioning device separate from the ventilation device for the remaining parts of the facility. The efficiency of ventilation in therapy shall, if necessary, be subjected to occasional controls. The capacity of these devices shall depend on the type and intended purpose of the X-ray machine.

By way of exception from paragraph 1 of this Article, the ventilation or air-conditioning device of the room housing the X-ray machine for diagnostics may be the same as that of the remaining parts of the facility.

Article 20

Personal protective equipment such as a protective apron, protective gloves, protective thyroid collar, protective glasses and other equipment shall be used for occupationally exposed persons, patients and other persons that are of assistance to patients, where appropriate.

The protective apron, gloves and collar shall not be bent or twisted.

The protective apron shall cover the person's body from the collar-bone to the mid-shinbone, covering the thighs as well.

The protective gloves shall have a separate gap for each finger and shall cover the forearm up to the elbow.

The functionality and efficiency of the personal protective equipment referred to in paragraph 1 of this Article shall be subjected to regular checks.

Article 21

Occupationally exposed persons who in the process of performing their professional duties are in the controlled area shall not be exposed to the primary radiation beam and they shall handle the patients and screen cassettes during screening.

The leaden layer of the protective apron, gloves, thyroid collar and glasses for occupationally exposed persons shall have lead thickness equivalent of at least 0,25mm. When using X-ray tubes with a voltage higher than 100 kV, the leaden layer of the protective apron shall have lead thickness equivalent of at least 0,35 mm.

Article 22

Persons other than occupationally exposed persons who during screening handle immobile patients or other patients who are unable to keep the body position required for screening shall use the following personal protective equipment: a protective apron with a lead equivalent thickness of at least 0,5mm and, if necessary, protective gloves, protective collar and leaden glasses of the same lead layer with a lead equivalent thickness of at least 0,5 mm.

Article 23

Patients subjected to diagnostics or therapy with ionising radiation shall use personal protective equipment independent of the procedure being carried out, provided the application of such equipment does not impede the proper implementation of the procedure.

Personal protective equipment used for the purposes of paragraph 1 of this Article shall have a lead equivalent thickness of at least 0,5 mm.

Article 24

Mobile X-ray machines may be used in operating theatres, intensive care rooms and other premises intended for performing certain procedures.

When using mobile X-ray machines, if appropriate and necessary, in addition to personal protective equipment, protective shields shall be used, depending on the procedure.

During screening with mobile X-ray machines, moveable protective shields intended to protect the person operating the machine shall be used in hospital rooms. In exceptional situations, when other patients who are in the screening room cannot be removed from it, moveable protective shields shall also be used for their protection.

The lead layer of the protective shields referred to in paragraph 3 of this Article shall not be with a lead equivalent thickness smaller than 1mm.

Article 25

The command device of the X-ray machine shall have one built-in signal device indicating whether the machine is wired up and another one indicating the commencement, duration and termination of the X-ray tube operation. The command device of the X-ray machine may also have a built-in audio signal for the whole duration of the X-ray tube operation.

The command device of the X-ray machine shall also have a built-in switch for temporarily interrupting the flow of electricity to the machine.

Article 26

The electronic image intensifier of an X-ray machine used for screening patients placed in a vertical position shall have a protective shield on the side of the carrier as well.

The protective shield referred to in paragraph 1 of this Article shall have the same or larger width than that of the carrier of the electronic image intensifier and a length of at least 40 cm. The shield shall be designed with at least three parts in a manner that adjacent parts overlap by at least 1 cm.

If the X-ray machine is used for screening patients placed in a horizontal position, a protective apron shall also be used on the side of the person performing the screening.

The protective power of the apron referred to in paragraphs 1, 2 and 3 of this Article shall be equivalent to that of lead with a thickness of 0,5 mm.

Article 27

The provisions of Article 26 of this Rulebook shall not apply to X-ray machines with a remote control and to mobile X-ray machines used in operating theatres.

Article 28

When using an X-ray machine for screening in specific procedures such as angiography, monitoring the set-up of stents and other devices in the patient's body or other similar procedures, any persons present in the controlled area shall be provided with additional protective equipment such as shields, curtains and special lead padding offering protection equivalent to that of lead with a thickness of 0,25 mm.

Article 29

During the preparatory period after plugging the computed tomography device, while it is being heated and self-adjusted and the X-ray tube is emitting radiation, the room housing the device shall be completely evacuated.

During the period referred to in paragraph 1 of this Article, the person responsible for the computed tomography device shall be at the command device by the time the preparatory period is terminated.

Article 30

X-ray machines used for dental screening may be used in stomatological surgeries if the screening is performed only in the presence of the patient and of the person performing the screening and if the dose of exposure of the latter is reduced to the minimum.

Article 31

The primary radiation beam emitted from the X-ray machine used for dental screening shall not be directed towards the person performing the screening.

Article 32

The rooms intended for therapy with ionising radiation sources shall be projected and designed in a manner that the momentary dose rate in the rooms adjacent to the therapy room where persons are present does not exceed 20 μ Sv/h.

When determining the protection of rooms intended for therapy with ionising radiation sources, the energy, dose rate and field size resulting in the maximum dose rate outside the therapy room in a state of accelerator overcharge (maximum isocentre dose in water) of at least 800 Gy/per week shall be taken into consideration. When determining the protection of the primary radiation beam, the weakening of the beam on the part of the patient, phantom or therapeutic table shall not be taken into consideration. When determining the protection of scattered radiation, a water phantom sized 30 cm x 30 cm x 30 cm shall be used.

If the voltage of the therapy accelerator exceeds 10 MV, the contribution to the neutron dose rate shall be taken into consideration when determining the protection.

Article 33

The visual contact between the room housing the therapy device and the room housing the command device shall be realised by means of lead glass or video surveillance for devices with a voltage of up to 150 kV and by means of video surveillance for devices with a voltage above 150 kV.

The command device shall be placed in such a position that the operator monitors the entrance to the therapy room at all times.

Article 34

Signal lights shall be placed in the immediate proximity to the therapy room, in accordance with Article 11 of this Rulebook.

There shall be a red signal light or an audio signal in the therapy room, indicating that the equipment is emitting ionising radiation.

Article 35

Two mutually independent safety systems, intended to prevent radiation if there is unauthorised presence in the therapy room, shall be placed at the entrance thereto.

The safety systems referred to in paragraph 1 of this Article may be:

- A blocking system connected to the door, which disables activation of the equipment when the door is open or when the door system itself is not functional; and
- A photocell-based system, installed at the door, which disrupts the radiation procedure when the photocell is activated.

Both systems referred to in paragraph 2 of this Article shall be connected in a manner that when radiation is disrupted, it can be continued solely from the command device. The therapy room shall be equipped with a movement monitoring device (such as an infrared detector or video surveillance).

Article 36

The therapy room and the room housing the command device shall be equipped with a clearly visible activation switch to be used in exceptional circumstances or when necessary (urgency switch), which if activated disrupts the flow of electricity to the device, whereas only the command device makes possible the continuation of the therapy.

Article 37

The therapy room shall have only one entrance. Doors leading to the therapy room shall be opened from both sides. Entrance to and exit from the therapy room shall be also enabled in cases where the automatic door system is not functional.

Article 38

The keys for the radiotherapy equipment shall be kept in a manner that only persons authorised to operate the equipment have access thereto.

Article 39

No other person, apart from the patient undergoing therapy, shall be present in the therapy room during radiation.

Article 40

The main switch of the therapeutic X-ray machine shall be placed in the immediate proximity to the command device.

The command device shall display information on the filter, voltage and amperage used at any given moment.

Article 41

The entrance to the accelerator room shall be labyrinth-like.

Article 42

The accelerator room shall be equipped with a special ventilation and/or air-conditioning system, independent of the ventilation and/or air-conditioning system of the other rooms; the system's efficiency shall be subjected to occasional controls, if necessary.

Article 43

In veterinary medicine, the person holding the animal in the process of ionising radiation screening shall wear personal protective equipment, such as a protective apron, protective gloves and other protective equipment, if necessary, having a protective power equivalent to that of at least 0,5 mm lead.

No part of the body of the person holding the animal during screening shall be exposed to the primary radiation beam; when possible, the animal shall be sedated or immobilised during the X-ray screening.

Article 44

For the purposes of protection, when performing an activity with X-ray machines for crystallography, diffraction, spectral analysis, fluorescence, mobile fluorescent analysers and other similar devices, a dose limit of 0,3 mSv per year shall be used for the general public and the radiation dose rate at a distance of 5 cm from any available spot on the machine's surface shall not exceed 2,5 μ Sv/h.

In the case of the machines referred to in paragraph 1 of this Article, such as mobile fluorescent analysers, whose radiation beam is generated out of the machine's housing, the radiation emitted shall not exceed 25 μ Sv/h at a distance of 5 cm from any available spot on the machine's surface, when measured out of the radiation beam.

Article 45

X-ray machines that are used for control of packages, luggage and cargoes shall be positioned in a protective housing which provides minimal exposure to ionising radiation.

The entrance and exit openings of the X-ray machine for the packages, luggage and cargoes referred to in paragraph 1 of this Article shall have additional protection such as a lead curtain in the form of strips.

In the case of the machines referred to in paragraph 1 of this Article and similar X-ray machines used for quality controls or for the purposes of scientific research, whose X-ray tube and radiation beam are fully protected in the housing itself, whereas access to the object being screened is possible only when radiation is generated, a dose limit of 0,3 mSv per year shall be used for the general public and the radiation dose rate at a distance of 5 cm from any available spot on the machine's surface shall not exceed 5 μ Sv/h.

In the case referred to in paragraph 3 of this Article, the object shall be placed in the screening or analysis position before the radiation beam is generated or there shall be an automatic mechanism for putting the object in the appropriate position and back.

Article 46

Mobile X-ray machines and accelerators for package, luggage and cargo control may be used

in open areas as well. The controlled and supervised areas shall be determined before screening.

The controlled area shall be clearly marked by means of ionising radiation warning signs, in accordance with Article 11 of this Rulebook, as well as other barriers intended to prevent the presence of persons in the controlled area during screening. Access to the controlled area and the area itself shall be monitored throughout the screening.

Only the presence of the screening team members, classified as occupationally exposed persons, shall be allowed during screening.

When possible, in addition to the warning signs referred to in paragraph 2 of this Article, light signals placed on the X-ray machine and the accelerator, as well as audio signals, shall be used.

Article 47

X-ray machines used for quality controls by means of radiography (industrial radiography), X-ray machines used for examination, repairing and restoration of works of art and X-ray machines used as part of a production line shall be placed in at least two rooms. The ionising radiation generating device and the material examination table shall be placed in one room, whereas the command device or the timer regulating radiation shall be placed in another.

The visual contact between the two rooms referred to in paragraph 1 of this Article shall be provided by means of an opening protected with leaden glass or video surveillance.

The characteristics of the leaden glass referred to in paragraph 2 of this Article shall provide that the exposure of occupationally exposed persons and the general public to ionising radiation is kept to the minimum, below the dose limits of 6 mSv for occupationally exposed persons and 0,3 mSv for the general public.

By way of exception from paragraph 1 of this Article, X-ray machines used for quality controls by means of radiography may be used in fieldwork, production halls and storerooms.

Article 48

Blends used for adjusting the field size of the primary beam (collimators) shall be available during screening. The panoramic industrial radiography X-ray machines shall be equipped with collimators enabling orientation of the radiation beam in a specific direction.

Article 49

The control board and remote control of industrial radiography X-ray machines shall be located in a place from which the door to the room housing the machine is clearly visible. If there are other doors, they shall be locked during screening in a manner that opening them from the outside would be impossible. Before the screening, it shall be ensured that no person is inside the room.

Article 50

Before entering the screening room, after the screening has been terminated, the radiographer shall first make sure that the screening has been brought to an end.

Article 51

When performing screening during fieldwork or during a break, the industrial radiography X-ray machines shall be locked.

If a part of the radiation beam during fieldwork screening is transmitted behind the screened object, special protection shall be set up behind the object. When the X-ray tube is in the process of heating, its opening shall be blocked with a stopper.

Article 52

After terminating the fieldwork radiographic screening, the control board of the industrial radiography X-ray machine shall be checked in order to ensure that radiation has ceased.

Article 53

Before starting fieldwork screening with an industrial radiography X-ray machine, it shall be necessary to determine the controlled and supervised areas. The controlled area shall be clearly marked by means of ionising radiation warning signs, in accordance with Article 11 of this Rulebook, as well as other barriers intended to prevent the presence of persons in the controlled area during screening. Access to the controlled area and the area itself shall be monitored throughout the screening.

Article 54

In the course of fieldwork, one radiographer shall remain in the vicinity of the control board or the remote control throughout the screening in order to interrupt screening in the event of exceptional circumstances or if such an action is necessary.

Article 55

The dose rate in the area where radiographers perform their work shall be reduced to the minimum and it shall not exceed 20 $\mu\text{Sv/h}$ at any given moment.

Article 56

On the day of entry into force of this Rulebook, Articles 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 110, 111, 112, 113, 114 and 115 of the Rulebook on putting into circulation and using radioactive substances above the determined activity level, X-ray machines and other ionising radiation-generating devices, as well as on the measures for protection against such sources (Official Gazette of SFRY, No. 40/86 and 45/89) shall cease to apply.

Article 57

This Rulebook shall enter into force on the eighth day from the date of its publication in the Official Gazette of the Republic of Macedonia.

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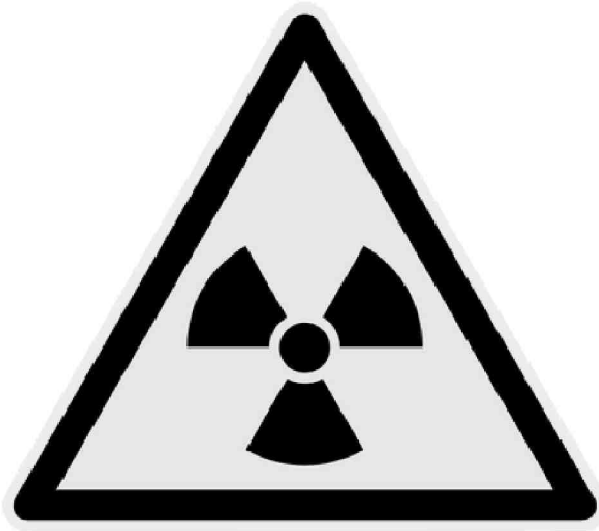
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Skopje

Director,
PhD. **Nuzi Shahin**

APPENDIX

Ionising radiation warning sign



IONISING RADIATION HAZARD