

RADIATION SAFETY DIRECTORATE

Pursuant to Article 26-e, paragraph 1, item 15 of the Law on Ionizing 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 MANNER AND MEASUREMENT OF THE EXPOSURE OF OCCUPATIONALLY EXPOSED INDIVIDUALS, KEEPING RECORDS AND SUBMITTING REPORTS

I. General provisions

Article 1

This Rulebook shall prescribe the manner and measurement of the exposure of occupationally exposed individuals, keeping records and submitting reports.

Article 2

Certain terms used in this Rulebook shall have the following meaning:

- 1) “Occupationally exposed individual” shall be an individual exposed to radiation in the course of his work.
- 2) “Dose equivalent” shall be a product of the absorbed dose in a given point in organ or tissue and the weighting factor appropriate for the type of ionizing radiation that leads to that dose. The dose equivalent represents a measure of the dose in organ or tissue that reflects the size of the damage done. The dose equivalent represents a quantity given by the International Commission on Radiation Units and Measurements in order to define the operational quantities: personal, ambient and directional dose equivalent. For the purposes of ionizing radiation protection, the quantity dose equivalent shall be replaced by the equivalent dose.
- 3) “Ambient dose equivalent $H^*(d)$ ” shall be a dose equivalent which is a result of the corresponding expanded and aligned field in a 30 cm diameter tissue equivalent sphere with a density of 1 g/cm^3 , mass composition of 76,2 % oxygen, 11,2 % carbon, 10,1 % hydrogen and 2,6 % nitrogen that represents an approximation of the human body in respect of absorption of ionizing radiation (hereinafter referred to as: ICRU sphere) at a depth d , on the radius opposing the direction of the field. The ambient dose equivalent is defined in a given point of the radiation field and represents a directly measurable quantity for the effective dose and is used when monitoring the exposure to external radiation. For strongly penetrating radiation a depth of 10 mm is recommended.
- 4) “Directional dose equivalent $H'(d,\Omega)$ ” shall be a dose equivalent which is the result of the corresponding expanded and aligned field in the ICRU sphere at a depth d , on the radius in a precise direction Ω . The directional dose equivalent is defined in a given point of the radiation field and represents a directly measurable quantity for the equivalent dose for the skin and is used when monitoring the exposure to external radiation. For weakly penetrating radiation a depth of 0,07 mm is recommended

5) "Personal dose equivalent $H_p(d)$ " shall be the dose equivalent in soft tissues at an appropriate depth d , below a specified point in the body. The personal dose equivalent is a directly measurable quantity for the equivalent dose in organ or tissue ($d=3$ mm for the lens of the eye) or (when $d=10$ mm) for the effective dose and is used in the individual monitoring of the exposure to external radiation. Recommended depth values are: $d=10$ mm for strongly penetrating radiation and $d=0,07$ mm for weakly penetrating radiation

II. Manner and measurement of the exposure of occupationally exposed individuals

Article 3

The measurement of the degree of exposure to ionizing radiation of occupationally exposed individuals, of school children and students over 16 and 18 respectively, during their training in the use of ionizing radiation sources, as well as of every temporary employee, shall be carried out by monitoring the working environment and by individual monitoring.

1. Working environment monitoring

Article 4

The working environment monitoring shall consist of measuring the dose rate of radiation within the working premises and of control of the contamination degree in the working premises and it shall be carried out by authorised expert technical services in accordance with the regulations on ionizing radiation protection and radiation safety.

Article 5

The check of the contamination degree in the working premises where open ionizing radiation sources are used shall be carried out by measuring:

- 1) The concentration of the separate radionuclides in the air in the working premises and in the exhaust valve of the ventilation system, and
- 2) The activity of a unit surface of separate radionuclides on the working surfaces, the equipment in the premise, protective means, walls, floors, ceilings, work clothes, shoes and other parts and items in the premise.

Article 6

The measurement of the radiation dose rate, as well as checking the contamination degree in the working premises where open radioactive sources are used, shall be carried out at least once a year.

The measurement of the radiation dose rate in the working premises where sealed radioactive sources are used, X-ray machines, accelerators and other ionizing radiation generating devices, shall be carried out at least once a year.

The measurements referred to in paragraphs 1 and 2 of this Article shall be carried out when a change in the use of the sources, significant in terms of ionizing radiation

protection and radiation safety occurs prior to the continuation of the operation with ionizing radiation sources.

Article 7

When carrying out working activities in accordance with the regulations on ionizing radiation protection and radiation safety the working environment monitoring, depending on the specificities of the working activity, shall adequately cover:

- 1) Gamma radiation dose rate measurement;
- 2) Activity of specific radionuclides per unit mass of the materials; and
- 3) Activity concentration in dust and aerosols.

The measurements referred to in paragraph 1 of this Article shall be used to assess the degree of exposure to ionizing radiation of the workers in situations when they are not subject to individual monitoring, and in this case all types of exposure to external and internal ionizing radiation should be taken into consideration, as follows: external gamma radiation exposure, internal exposure through inhalation of dust, ingestion of contaminated materials and inhalation of radon.

The working environment monitoring referred to in paragraph 1 of this Article, with the purpose of assessing the degree of exposure of workers to ionizing radiation shall be carried out in the first six months from the beginning of the work activity or after the entry into force of this Rulebook, and shall be repeated every five years or immediately after the occurrence of any change in the conditions of carrying out the work activity that are significant for the radiation protection.

2. Individual monitoring

Article 8

The individual monitoring shall be carried out with the purpose of determining the degree of exposure of the individuals referred to in Article 3 of this Rulebook, as a result of their internal and external exposure to ionizing radiation and shall be carried out by an authorised expert technical service in accordance with the regulations on ionizing radiation protection and radiation safety.

Article 9

The degree of external exposure to ionizing radiation of occupationally exposed individuals shall be measured with the help of a personal dosimeter.

The degree of external exposure to ionizing radiation of occupationally exposed individuals shall be measured on a monthly basis for occupationally exposed individuals of Category A, and once in three months regarding occupationally exposed individuals of Category B.

The period for measuring the degree of external exposure of occupationally exposed individual referred to in paragraph 2 of this Article regarding occupationally exposed individuals of Category A, may be longer than a month if the occupationally exposed individual is classified in Category A because of the risk from potential exposure, but

in this case the provision of Article 13 of this Rulebook shall apply.

In case of a reasonable doubt for uncontrolled exposure to ionizing radiation, the measurements of the degree of external exposure of occupationally exposed individuals may be carried out in a period shorter than the period specified in paragraph 2 of this Article.

Article 10

When the occupationally exposed individual in a legal entity, works at several working places with different ionizing radiation sources, this individual shall be obliged to use the same personal dosimeter.

When the occupationally exposed individual works with ionizing radiation sources in two or more legal entities, each of these legal entities should provide him with separate personal dosimeter.

Article 11

The measurement of the degree of exposure to neutrons shall be carried out using a dosimeter adequate for that purpose, when the dose is, or it is expected to be greater than 0,2 mSv during a month.

Article 12

The degree of external exposure to ionizing radiation of occupationally exposed individuals when carrying out activities with ionizing radiation sources or other work activities where the use of personal dosimeters for individual monitoring is inappropriate, or the reading of the personal dosimeter is prevented for any reason, shall be estimated on the basis of the results from the monitoring of the working environment or of the results acquired in respect of another adequate occupationally exposed individual.

Article 13

Except for personal dosimeters, for measuring the degree of external exposure to ionizing radiation of occupationally exposed individuals, alarm dosimeter or a dosimeter for direct reading of a dose or dose rate shall be also used in the following situations and activities with ionizing radiation sources:

- 1) In situations of potential exposure, when there is an exposure in particular cases, in accordance with the regulations on ionizing radiation protection and radiation safety or similar activities, and
- 2) In the industrial radiography, when working in plant for irradiation, during installation, repair and servicing, if there is a risk from exposure to the primary radiation thread of the device or similar activities.

Article 14

The personal dosimeter shall be worn on the working clothes at chest height and positioned on the body in such a manner as not to be hidden from any part of the body and clothes.

Article 15

When the occupationally exposed individual carries personal protective apparel (lead apron) the personal dosimeter shall be positioned under the protective apron, with the purpose of making an assessment of the whole-body dose.

In conditions where the exposure to ionizing radiation is high (in interventional radiology, when working with radioactive sources of Category 1, in accordance with the regulations on ionizing radiation protection and radiation safety), the occupationally exposed individual should also carry a second personal dosimeter over the personal protective apparel (lead apron) within a certain timeframe necessary to assess the exposure to ionizing radiation and establishment of the necessity to undertake additional protective measures.

In the case referred to in paragraph 2 of this Article, the authorised expert technical service shall determine the effective dose taking into consideration the protection being used, the working methods being applied and the working conditions.

Article 16

The doses in respect of the hands and fingers of the occupationally exposed individuals shall be measured with the help of a ring dosimeter in interventional radiology, when repairing and servicing, if there is a risk from exposure to the primary radiation thread of the device, when carrying out other working tasks where there is a risk from direct exposure to ionizing radiation and when treating patients with open ionizing radiation sources.

The ring dosimeter shall be worn on the middle finger, the detector pointed toward the side where the radiation is directed. The ring dosimeter can be worn in another place where there are grounds for supposing that the dose in the arms is significantly greater.

Article 17

When there is an exposure to photon radiation where there are grounds for suspecting that the dose received by the eyes may be substantial, it is necessary to make an assessment of the dose received by the eye through the personal dose equivalent $H_p(0,07)$ measured using the personal dosimeter carried over the protective apron.

When it is impossible to calculate the dose received by the eye with sufficient correctness of the measured personal dose equivalent referred to in paragraph 1 of this Article, a specific measurement of the dose received by the eye shall be carried out, with the help of a personal dosimeter worn at head height of the occupationally exposed individual.

Article 18

The measurement of the degree of internal exposure to ionizing radiation of an occupationally exposed individual shall be carried out when there is a risk of entry of radioactive substances in his/her organism by way of inhalation or ingestion.

As an exception from paragraph 1 of this Article, the determination of the degree of internal exposure to ionizing radiation of an occupationally exposed individual is not

necessary to be carried out when safe working methods of operation with open ionizing radiation sources are used, when regular checks of contamination of the working premises are carried out and when it is established that the contamination is negligible.

Article 19

The degree of internal exposure to ionizing radiation of an occupationally exposed individual carrying out an activity with open ionizing radiation sources shall be determined through establishment of the activity within the whole body or in the given organ or tissue, or through measuring the radionuclides concentration in biological samples taken from the body and on the basis of these results the corresponding expected dose is calculated in accordance with the regulations on ionizing radiation protection and radiation safety.

When there is a possibility of inhalation of radioactive substances, the quantity of radioactive substances inhaled in the organism may be assessed with the use of a personal device for taking samples of air where the adequate dose shall be calculated on the basis of the duration of the exposure.

Article 20

When the activity per unit volume of a radionuclide is established by the results from the working environment monitoring, then the degree of internal exposure to ionizing radiation of an occupationally exposed individual shall be determined using those results and calculating the adequate expected dose in accordance with the regulations on ionizing radiation protection and radiation safety.

Article 21

The degree of internal exposure to ionizing radiation of an occupationally exposed individual carrying out an activity with open ionizing radiation sources of Category 1 and 2 shall be determined once a year, and for sources that are not covered with category 1 and 2, once in three years.

Article 22

For occupationally exposed individual handling isotopes of iodine with significant volatility (in marking with iodine), determination of the activity of the iodine accumulated in the thyroid with the help of an appropriate device is necessary.

The value of the activity of the accumulated iodine in the thyroid shall be established on every two weeks when the marking with iodine is done more than once in a month. When the marking with iodine is carried out once a month or rarely, then the value of the activity of the accumulated iodine in the thyroid shall be determined after every marking process, 24 hours after finishing the marking process.

When the activity of the accumulated iodine in the thyroid exceeds 5 kBq, then an assessment of the dose of the thyroid that is a result of that activity is necessary and the result shall be submitted to the Radiation Safety Directorate.

Article 23

The authorised expert technical service referred to in Article 8 of this Rulebook shall immediately notify the Radiation Safety Directorate, when a determination of a dose in respect of the exposed individual that is significantly greater in a way that it reaches or exceeds the annual limit of a dose.

Article 24

When the individual monitoring establishes that the effective or equivalent dose within one dosimetric period of an exposed individual exceeds the investigation level, the legal entity shall conduct an investigation.

The investigation level referred to in paragraph 1 of this Article shall be determined by the legal entity for activity with ionizing radiation sources that it carries out, and this level should not exceed the value corresponding to 3/10 of the monthly value of the dose in accordance with the annual value of the dose prescribed by the regulations on ionizing radiation protection and radiation safety.

After the conducted investigation referred to in paragraph 1 of this Article, the legal entity shall submit a report to the Radiation Safety Directorate in respect of the findings from the conducted investigation, 15 days after completion of the same.

The investigation referred to in paragraph 1 of this Article shall be conducted also when there is a reasonable doubt (uncontrolled exposure to ionizing radiation) that the investigation level referred to in paragraph 2 of this Article have been exceeded.

Article 25

An occupationally exposed individual that temporarily works with ionizing radiation sources in another country and is subject to an individual monitoring in accordance with the applying regulations on ionizing radiation protection in the country of residence, the same individual, after returning to the Republic of Macedonia, reports the measured or estimated dose during the stay, to the Radiation Safety Directorate,

3. Manner of performing the working environment monitoring and the individual monitoring

Article 26

The measurement of the degree of exposure to ionizing radiation in the working premises and in the environment shall be carried out in a way determined by the Methodology for assessment of the degree of exposure to ionizing radiation, given in Annex No. 1 which is an integral part of this Rulebook.

III. Submitting reports and keeping records

Article 27

The authorised expert technical service referred to in Article 4 of this Rulebook shall submit the report regarding the performed monitoring of the working environment to the legal entity keeping records of the results from working environment monitoring.

The report referred to in paragraph 1 of this Article, depending on the activity with

the concerned ionizing radiation sources, should contain the following data:

- 1) Name and main office of the authorised expert technical service that performs the monitoring of the working environment;
- 2) Name and main office of the legal entity;
- 3) Date of performing the monitoring;
- 4) Characteristics of the ionizing radiation source or the working activity;
- 5) The measured dose or dose rate of the external radiation, as well as the type of radiation;
- 6) Radionuclides that have caused contamination, their activity per unit volume of air or surface unit, their physical or chemical form, when the presence of contamination in the working environment has been established.
- 7) The duration of the exposure to ionizing radiation of every occupationally exposed individual and of every temporary employee, when the results of the monitoring are used for assessing the received dose;
- 8) Assessment of the received dose;
- 9) Places where there are no indications on radioactive contamination or external radiation;
- 10) Other data, relevant for performing the monitoring of the working environment or for assessing the received dose.

Article 28

The authorised expert technical service shall submit the report for the performed individual monitoring in respect of every occupationally exposed individual subjected to an individual monitoring and every dosimetric period, to the legal entity keeping records of the results from the individual monitoring, 30 days after completion of the dosimetric period at the latest, containing the following data:

1. Dates of the start and end of the dosimetric period;
2. In case of internal exposure to ionizing radiation, the date of introduction the radioactive substance in the organism, if available; and
3. The measured or estimated dose.

In case of exceeding the investigation level within the dosimetric period, the authorised expert technical service shall submit the report referred to in paragraph 1 of this Article to the Radiation Safety Directorate.

The authorised expert technical service shall notify the Radiation Safety Directorate in respect of every measurement of external exposure to ionizing radiation in the cases referred to in Article 9 paragraph 4 of this Rulebook, without delay.

Article 29

The records kept by the authorised expert technical service and the legal entity in respect of the results from the individual monitoring of the occupationally exposed individuals, shall contain the following data:

1. Name and surname of the occupationally exposed individual;
2. Date and place of birth;
3. Sex;
4. Education;
5. Name and main office of the legal entity;
6. Category of the occupationally exposed individual;
7. Description of the work place with ionizing radiation sources;
8. Methods that are used in order to measure the degree of exposure to ionizing radiation;
9. Effective dose or personal dose equivalent $H_p(10)$ (regarding every dosimetric period)
10. Effective dose or personal dose equivalent $H_p(10)$ for neutron radiation (regarding every dosimetric period, if any)
11. Equivalent dose for the skin or personal dose equivalent $H_p(0,07)$ (if any);
12. Equivalent dose for the fingers recorded by the ring dosimeter (if any);
13. Expected effective dose from the internal exposure to ionizing radiation (data on the received radionuclides in the organism, if any)
14. Sum of the effective doses within a period of one year; and
15. Notes.

Article 30

The Register of the occupationally exposed individuals kept by the Radiation Safety Directorate, apart from the data referred to in Article 29 of this Rulebook, shall contain the following data:

1. Name and main office of the authorised expert technical service that has carried out the individual monitoring;
2. Date of starting the work with ionizing radiation sources in the legal entity;
3. Date of termination of the work with ionizing radiation sources in the legal entity;
4. Sum of the effective doses within a period of five years; and

5. Sum of the effective doses in respect of the overall working period.

Article 31

The registration level for the doses that are entered in the records referred to in Article 29 of this Rulebook, shall be as follows:

- 1) Effective dose Hp(10) for photons: 0,1 mSv/on a monthly basis;
- 2) Effective dose Hp(10) for neutrons: 0,2 mSv/on a monthly basis;
- 3) The equivalent dose Hp(0,07) and the dose for the fingers: 2 mSv/on a monthly basis; and
- 4) The expected effective dose: 0,1 mSv.

When a dose is under the registration level, the same is registered in the records. Doses not measured are registered as such.

IV. Transitional and final provisions

Article 32

With the day of entry into force of this Rulebook, the provisions of Article 28, 29, 30, 31, 32, 33, 34, 35 и 36 of the Rulebook on the limits over which the population and persons working with ionizing radiation sources must not be exposed to irradiation, in respect of the measurements of the degree of exposure to ionizing radiation of individuals working with ionizing radiation sources and in respect of the testing the contamination in the working environment, shall cease to apply ("Official Gazette of SFRJ", No. 31/89), as well as the provisions of Article 4 of the Rulebook on the manner of keeping records on the ionizing radiation sources and on the irradiation of the population and persons exposed to the activity of ionizing radiation when working ("Official Gazette of SFRJ", No. 40/86).

Article 33

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

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Skopje

Director
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**METHODOLOGY ON THE ESTIMATION OF THE DEGREE OF EXPOSURE TO
IONIZING RADIATION**

The degree of exposure to ionizing radiation of individuals working with ionizing radiation sources, the level of contamination of the working environment and the conditions for using the radiation sources shall be checked as follows:

X-RAY DIAGNOSTICS

1. The radiation doses of individuals carrying out illumination and of other individuals in the working environment shall be determined by applying high voltage of 90 kV and illumination power of 3 mA.

The distance of the back partition from the screen should be 25 cm, and the illuminated field on the screen.

For the measuring a water phantom with dimensions of is used.

2. The intensities of the absorbed radiation doses in the air at head height, sternum, ovaries-testicles and the hands of the doctor and his assistants shall be measured under the stated conditions.

The intensity of the absorbed dose in the air shall be determined in the direction of the central ray of the distance: focus – skin of the patient, with the help of thermoluminescent dosimeters or with ionization chamber.

The intensities of the absorbed doses of radiation in the air in the neighbouring premises should be measured at a distance of 1 m from the walls or the door, as well as in the waiting room and the patients changing room.

3. The radiation dose for the individuals carrying out x-ray examination and the individuals in the working environment shall be determined under the conditions applied most often in the diagnostic procedure with the x-ray machine (high voltage, power, duration, shutter opening, the distance focus-skin of the patient) and by using water phantom with dimensions of .

4. The radiation doses for individuals taking dental x-ray shall be determined by using water phantom with radius of 15 cm and a volume of 5 litres.

5. The radiation dose for individuals taking mammogram shall be determined with the use of plexiglass phantom with thickness of 5 cm.

6. Under the specified conditions of x-ray examination: the intensity of the absorbed doses of radiation in the air at head height, sternum, ovaries-testicles of the individuals carrying out the x-ray examination and of the other individuals in the working environment should be measured; the intensity of the absorbed dose of radiation in the air in direction of the central ray of the distance: focus-skin of the patient should be determined by thermoluminescent dosimeters or with ionization chamber and the intensity of the absorbed doses of radiation at the work places in the neighbouring premises should be measured, i.e. at a distance of 1 m from the external

wall surfaces and the door of the premise in which the x-ray machine is used, in the patient waiting room and patient changing room.

7. The radiation doses of the individuals carrying out diagnostic procedures shall be determined on the basis of the conducted dosimetric measurements and the number of diagnostic procedures that the individuals are carrying out during the month using the x-ray machine, and those values should be compared with the data of the personal dosimetry.

8. The concentration of liberated ions in the air should be checked at least once in two years in the premises in which x-ray machines for illumination, examination or treatment are used.

X-RAY THERAPY

9. The irradiation level of individuals working with therapeutic x-ray machines shall be determined during the therapeutic procedures in respect of the patient.

The intensity of the absorbed dose of radiation shall be determined in the air of the place where the individuals are handling the x-ray machine, of the work places, in the neighbouring premises and the waiting room.

The irradiation of the individuals working with the x-ray machine shall be calculated on the basis of the results, the number of performed irradiation procedures and their duration and the calculated value shall be compared with the data of the personal dosimetry.

APPLICATION OF RADIONUCLIDES IN MEDICINE

10. The irradiation level of individuals working with ionizing radiation sources in laboratories for application of radionuclides in medicine diagnostic and therapy shall be determined during every working operation (preparation and radiopharmaceutical preparations, measurements and application of the “dose” of activity for the radiopharmaceutical preparation, final measurements of the patient). The intensity of the absorbed dose of radiation in the air at head height (eyes), sternum, ovaries-testicles and hands of the individuals working with ionizing radiation sources shall be determined by thermoluminescent dosimeters or portable dosimeter. The measurements shall be also performed on the surface of the body of the patient who has received an application of the “dose” of the radiopharmaceutical preparation and of the distinct places in the waiting room.

11. The radiation dose of individuals working with radiation sources shall be calculated on the basis of the measurements and known values of the number and the type of the diagnostic or therapeutic procedures and the time necessary to perform separate working procedures and the resulting value shall be compared with the data from the personal dosimetry.

INDUSTRIAL RADIOGRAPHY

The level of the exposure to ionizing radiation of the individuals working with radiation sources in industrial radiography and of other people that may be exposed to this radiation shall be measured:

- by measuring the intensity of the radiation dose in places where those people may be exposed to the ionizing radiation during the performance of radiography;
- by evaluating the time of exposure to ionizing radiation in a particular period. The intensity of the radiation doses shall be measured in the most frequently appearing conditions, such as, despite other: the activity of the sealed radioactive source, anode voltage and the electricity in the device that produces ionizing radiation, the duration of the useful radiation thread and the place where the workers are exposed to radiation during the industrial radiography.

The intensity of the radiation doses shall be measured before issuing a license to use ionizing radiation sources and while using them, within the period provided for in this Rulebook.

PROCESSING TECHNIQUE AND AUTOMATICS IN INDUSTRY

The level of the exposure to ionizing radiation of the individuals handling and maintaining the devices with sealed ionizing radiation sources in the processing technique and industrial automatics, as well as of the other individuals that may be exposed to radiation of these sources shall be assessed:

- by measuring the intensity of the radiation doses in places where those individuals may be exposed to ionizing radiation while handling, maintaining and using the radiation thread;
- by assessing the time of exposure to ionizing radiation of those individuals. These measurements shall be conducted when using the useful radiation thread, in still position of the sources and during their maintaining.

The intensity of the radiation doses shall be measured before issuing a license for using ionizing radiation sources and while using them, within the periods provided for in this Rulebook.

DEVICES WITH SEALED RADIOACTIVE SOURCES IN MASS USAGE RADIOACTIVE LIGHTNING RODS AND IONIZATION SMOKE DETECTORS

The conditions for using radioactive lightning rods and ionization smoke detectors shall be checked:

- by measuring the intensity of the radiation doses around those devices;
- by control of the protection measures (technical correctness of the installation of those devices which may affect the safety of their use, the individuals responsible for these devices etc.).

The conditions for usage of radioactive lightning rods and ionisation smoke detectors shall be checked before issuing a license to use them and during their use, within the period provided for in this Rulebook.