

LAW ON RADIATION PROTECTION AND SAFETY

I. GENERAL PROVISIONS

Article 1

This Law shall regulate the system of control of all ionizing radiation sources, as well as the protection of population and environment against the exposure or potential exposure to ionizing radiation.

This Law shall regulate also the management of radioactive and nuclear material, as well as the establishment of the measures of radiation safety and nuclear security.

Article 1-a

The objectives of this Law are:

- a. to provide for the adequate protection of population, society and the environment, against the harmful effects of ionizing radiation and for the safety of ionizing radiation sources and radioactive waste and the safety and the security of radioactive sources;
- b. to allow for the beneficial and peaceful uses of nuclear energy and its applications;
- c. to ensure that the Republic of Macedonia fulfils its obligations pursuant to the ratified international agreements.

Definitions

Article 2

Definitions and technical terms used in this Law shall have the following meaning:

1. **“Radiological emergency” means a situation that requires urgent action in order to protect workers and the population either partially or as a whole;**
2. **“Clearance levels” means values established by the competent authorities, and expressed in terms of activity concentrations and/or total activity, at or below which the ionizing radiation sources may be released from the control;**
3. **“Dose” means a measure of the average energy of ionizing radiation released in weight measurement unit from the radiated material or object.**
4. **“Irradiation” means exposure to ionizing radiation, which could be internal or external, depending if the ionizing radiation sources is in or out of the human body..**
5. **“Ionizing radiation“means electromagnetic, in the form of particles and any other radiation which in interaction with the substance directly or indirectly produces pairs of ions.**
6. **“Ionizing radiation source“means any equipment, installation or material which produces ionizing radiation, or releases radioactive substances.**
7. **“License” means an authorization granted by the competent authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied by the Licensee.**
8. **“Legal person” means the holder of a current license granted for a practice or a ionizing radiation source that has recognized rights and duties for the practice or the source, particularly in relation to protection and safety.**
9. **“Medical exposure” means exposure incurred by patients as part of their own diagnostic or treatment procedures; by persons, other than those occupationally**

exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programs of biomedical research involving their exposure.

10. **“Natural radiation sources” means ionizing radiation sources from natural terrestrial or cosmic origin.**

11. **“Notification” means a document submitted to the competent authority by a legal person to notify its ionizing radiation source.**

12. **“Population” means any member of the public or workers working with sources of ionizing radiation.**

13. **“Practice with sources of ionizing radiation” or “practice” means a human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure.**

14. **“Radiation protection” means a sum total of activities and means undertaken for protection of the life and health of the people and the environment against the harmful influence of the ionizing radiation.**

15. **“Safety” (nuclear or radiation) means sum of organizational and technical-technological measures which ensures optimal planned exposure and optimal risk from potential exposures of ionizing radiation, including measures of radiation protection, measures for preventing of radiological emergencies, as well as implemented measures for elimination of the effects in case that kind of event is included;**

16. **“Radioactive contamination” means the presence of radioactive substances in or on a material or human body, or other place, where they are undesirable or could be harmful.**

17. **“Radioactive waste“ means material in any physical form which is a residue of activities related to it or of interventions which are not anticipated for further use, which contains or is contaminated by radioactive materials and has activity or concentrations higher than the level which is not a subject of control and exposure to their radiation, shall not be excluded by this law and regulations adopted pursuant to this law.**

18. **“License” means document which gives the authorization from the competent authority as evidence that certain specific provisions for professional qualification and authorization for conducting of certain activities are fulfilled.**

19. **“Worker with ionizing radiation source” means any person who works, whether full time, part time or temporarily, for the legal person which conducts practice with ionizing radiation sources and who has recognized rights and duties in relation to occupational radiation protection;**

20. **“Occupational exposure” means all exposures of workers incurred in the course of their work, except the exposures excluded with the provisions of this Law and exposures from the exempted practices or sources with the provisions of this Law;**

21. **“Supervised area” means any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed;**

22. **“Activity” means the number of radioactive decays at a certain time;**

23. **“Decontamination” means the removal or reduction of the radioactive substances from the environment, the population, the equipment or the objects;**

24. **“Dose constraint” means a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimization is involved.**

25. **“Exemption” means decision adopted by the competent authority that the ionizing radiation source and/or the practice with the ionizing radiation source is no subject to a further control according to law. This decision is adopted by the competent authority in case the risk of exposure (including the potential exposure) is estimated as low and**

guarantees radiation safety and security without additional control from the competent authority;

26. “Exposure” means the process of being exposed to ionizing radiation.

27. “Exclusion” means the deliberate exclusion of a particular category of exposure from regulatory control;

28. “Disused source” means radioactive source which is no longer in use, nor there intention for its use for the practice of which is the license issued;

29. “Discharges” means planned and controlled release of liquid, gaseous or solid radioactive materials in the environment, within the limits authorized by the competent authority;

30. “Quality control” means part of quality assurance intended to confirm that the structures, the systems and the integrated components are in accordance with the established conditions;

31. “Quality assurance” means functional organization of management and practice of the legal person which conducts practice with ionizing radiation sources, which guarantees effective and quality application of the specific requirements in accordance with law;

32. “Controlled area” means defined area of practice with sources of ionizing radiation in which specific provisions and measures for radiation protection and safety are implemented, in order for controlling of the exposure of ionizing radiation, prevention of the spreading of the radioactive contamination during normal working activities and prevention or limitation of the extent of the potential exposures;

33. “Nuclear material” means:

1) plutonium-239 (Pu-239), uranium-233 (U-233), or uranium enriched in the isotopes uranium-233(U-233) or uranium-235 (U-235), where abundance ratio of the sum of these isotopes to the isotope 238 is greater than the ratio of the isotope 235 to the isotope 238 occurring in nature .

2) uranium depleted in the isotope U-235 and

3) thorium and any of the foregoing in the form of metal, alloy, chemical compound, or concentrate; as well as any other material containing one or more of the isotopes from the subparagraphs 1, 2 or 3;

34. “Nuclear and/or radiation security” means prevention or detection of, theft, sabotage, unauthorized access, illegal transfer or other malicious acts involving nuclear or other radioactive material, related equipment and associated facilities;

35. “Disposal” means the emplacement of radioactive waste in an appropriate facility without the intention of retrieval;

36. “Potential exposure” means exposure that is not expected to be delivered for certainty, with a probability of occurrence that can be estimated in advance;

37. “Occupational exposed person” means any person which during their work is permanently or periodically exposed on ionizing radiation, except for the exposures excluded with the provisions of this law and exposures from exempted practices and sources;

38. “Radioactive material” means material, in any physical form, which contains one or more radionuclides of which decay the ionizing radiation is produced.

39. “Public exposure” is exposure of the population on the ionizing radiation sources, except occupational and medical exposure and exposure from the normal natural radiation, but includes the exposure from the ionization radiation sources and practices with sources with license as well as emergency.

II. COMPETENT AUTHORITY

Radiation Safety Directorate

Article 3

For carrying out managing and professional activities in the area of radiation

protection a Radiation Safety Directorate shall be established (hereinafter: Directorate), **as independent government institution with attribute of legal person.**

The Directorate shall perform the following duties:

1. To conduct the sign up procedure, licensing and control of the ionizing radiation sources, in accordance with this law and regulations adopted pursuant to this law.
2. To establish the intervening levels and radiation protection and safety requirements;
3. **To issue and withdraw license for practice with ionization radiation sources;**
4. To undertake intervention measures in case of emergency;
5. To define exposure levels that **are excluded with general act adopted pursuant to this law** and exemptions of the ionizing radiation sources of low activity, as prescribed by general act adopted pursuant to this law;
6. To maintain National Registry on ionizing radiation sources and **occupational exposed workers, as well as register on nuclear material;**
7. To supervise, through authorised professional institution, the professional activities of the legal persons which work with ionizing radiation sources;
8. To cooperate with other governmental authorities and institutions on matters within the competence of the Directorate;
9. **To ensure training of the radiation protection officers and persons working with ionizing radiation sources;**
10. To initiate researches on radiation protection, **on radiation safety and nuclear security;**
11. To establish appropriate mechanisms for informing the population on the radiation protection;
12. **To determine the costs for issuing permit and license;**
13. **To maintain records and control of total nuclear material in the Republic of Macedonia;**
14. **To prepare Plan on protection of the population in case of radiological emergency in the Republic of Macedonia;**
15. **To verify certificates for presence of radionuclide in products;**
16. **To plan and conduct the international cooperation in the field of ionizing radiation;**
17. To conduct supervision; and
18. To undertake any other activities related to radiation protection.

Article 4

The Directorate shall be managed by a Director, **who shall be nominated and relieved by the government of the Republic of Macedonia.**

The Director shall be responsible for his work in front of the Government of the Republic of Macedonia.

Radiation Safety Commission

Article 5

The Directorate shall establish Radiation Safety Commission (hereinafter: Commission), as Advisory Body regarding relevant issues in the field of radiation protection and **on radiation safety and nuclear security.**

The Commission referred to in Paragraph 1 of this Article shall consist of representatives of the Ministry of Health, the Ministry of Environment and Spatial Planning, the Ministry of Education and Science, the Ministry of Agriculture, Forestry and Water-economy, the Ministry of Defense, the Ministry of Interior, the Ministry of

Transport and Communication, the Ministry of Foreign Affairs, **Rescue and Protection Directorate, Crisis Management Center and Ministry of Finance-Custom Administration**, as well as representatives of scientific and technical institutions, involved in ionizing radiation practices.

The Commission on proposal of the authorities and institutions from paragraph 2 of this article shall be established by the director of the Directorate.

The Commission shall establish roles of procedure.

Republic Institute of Public Health Protection

Article 6

Monitoring of the content of the radionuclide in water, air, soil and food, as well as the degree of public exposure shall be performed by the Republic Institute of Public Health Protection.

At the request of and under conditions prescribed by the Directorate, the Republic Institute of Public Health Protection shall provide the following technical services to the Directorate:

- 1) to prepare and propose expert grounds for preparation of sub-legal acts and standards in the area of radiation protection in accordance with the standards of the international organizations and the European Union;
- 2) to submit to the Directorate reports on the improvement of radiation protection related to practices under regulatory control;
- 3) to participate in conducting training regarding safe uses and management of ionizing radiation sources;
- 4) conducts measuring of the degree of the occupationally exposure, and population as well;
- 5) to perform assessment of the degree of exposure to ionizing radiation at work;
- 6) to conduct permanent medical surveillance of occupationally exposed persons and keep records thereof;
- 7) to conduct other activities related to the field of radiation protection;
- 8) to perform calibration on radiation protection measuring instruments.**

The Directorate may also request other expert institutions to provide expert services required for the enforcement of this Law, authorized by the Ministry of Environment and Spatial Planning, the Ministry of Health, **the Directorate** and the Ministry of Agriculture, Forestry and Water economy.

II-a AUTHORIZED TECHNICAL SERVICES AND LEGAL PERSON FOR PERFORMING DECONTAMINATION

Authorized technical services

Article 6-a

Monitoring of the content of the radionuclide in the products and raw material of animal or plant origin and consumer products, calibration on ionizing radiation intensity measuring instruments, and other technical measurements on ionizing radiation sources shall be performed by authorized technical services.

Legal persons may start to conduct the services from paragraph 1 of this article, only after obtaining a license for authorized technical services from the Directorate.

The Directorate shall issue the license from paragraph 2 of this article if the legal person fulfills the conditions prescribed in the article 9 of this Law.

The legal person shall be authorized to conduct the services from paragraph 1 of this article for period up to three years.

The procedure for renewing the license shall start at least two months before expire date of validity of the issued license.

Article 6-b

The authorized technical service shall be obliged to fulfill the following requirements for practice:

- qualified staff with appropriate education and work experience, trained for conducting and implementing measures on radiation protection, radiation safety and nuclear security,
- appropriate facilities and premises that fulfill the technical, safety and health requirements,
- Appropriate number and type of instruments, apparatus and equipment, and
- Accredited laboratory in Republic of Macedonia according accreditation provisions.

The authorized technical service may start to work after its registration in the Central Registry.

Along with the request for registering in the Central Registry shall be submitted the license obtained by the Directorate, as evidence in support of the fulfillment of the prescribed conditions for operating of the authorized technical service.

Article 6-c

The authorized technical service shall be obliged to keep records for the performed services from article 8 paragraph 1 of this law, and to submit monthly reports to the 20 of the month for the previous month, as well as annual report latest to the 31 of March of the present year for previous year to the Directorate.

On the request of the Directorate and in the case of emergency or increased radioactivity above the allowed level the authorized technical service shall inform the Directorate immediately.

Article 6-d

The Directorate shall conduct supervision on the authorized technical services.

In case the authorized technical service shall not conduct the services of which is authorized for in accordance with the provision set forth in this law or stop to fulfill the requirements set forth in this law, the director of the Directorate with decision shall withdraw the license for practice.

The Decision from the paragraph 2 of this article is final and against it may be taken legal action to the authorized court.

Legal persons for conducting decontamination

Article 6-e

Legal person may conduct decontamination of working premises or the environment, only after obtaining a license for conducting decontamination by the Directorate.

The Directorate shall issue the license from paragraph 2 of this article if the legal person fulfills the conditions prescribed in the article 13 of this Law.

The License from the paragraph 1 of this article shall be issued for period up to three years, and the procedure for renewing the License shall start at least two months before expire date of validity of the issued license.

Article 6-f

The legal person conducting decontamination is obliged to fulfill the following requirements for practice:

- **qualified staff with appropriate education and work experience, trained for conducting and implementing measures on decontamination,**
- **appropriate facilities and premises that fulfill the technical, safety and health requirements,**
- **Appropriate technical equipment for conducting decontamination.**

The legal person may start to work after its registration in the Central Registry.

Along with the request for registering in the Central Registry shall be submitted the license obtained by the Directorate, as evidence in support of the fulfillment of the prescribed conditions for operating of the authorized technical service.

Article 6-g

The legal person conducting decontamination is obliged to keep records for conducted decontaminations and to submit reports upon each decontamination to the Directorate.

Article 6-h

The Directorate shall conduct supervision on the authorized technical services.

In case the authorized technical service shall not conduct the services of which is authorized for in accordance with the provision set forth in this law or stop to fulfill the requirements set forth in this law, the director of the Directorate with decision shall withdraw the license for conducting the decontamination.

The Decision from the paragraph 2 of this article is final and against it may be taken legal action to the authorized court.

III. REQUIREMENTS FOR PRACTICE

License for practice

Article 7

Legal person may start with practice only after obtaining a license from the Directorate and after being recorded into the unique register of legal persons conducting practise with ionizing radiation sources, in accordance with the provisions of this Law (hereinafter: Register)

The License referred to in paragraph 1 above shall be granted, upon request, for a fixed term period up to 5 years, depending on the categorization of radioactive sources.

Any modification in the conditions for practice, as established by this law and provisions adopted pursuant to this law, may be made only on the basis of a permission granted by the Directorate and after their recording into the Register.

The License from paragraph 1 of this article shall not be transferred to other legal person

Article 8

The License of Article 7 hereof, may be issued only, if:

1. **the installations and facilities which are used for activities involving ionizing radiation sources and in which temporary storage or disposal of the ionizing radiation sources is being performed, as well as equipment, instruments and devices generating ionizing radiation shall meet the technical, safety and other requirements;**
2. **the persons working with ionizing radiation sources shall be provided with personal protection equipment, as well as with the required equipment for measurement of the radiation intensity;**

3. the persons working with ionizing radiation sources shall have adequate expert qualifications and shall meet the required health conditions for the work they shall perform;
4. **there is Radiation Safety Program that contains the Emergency Plan and the Program for Quality Assurance and Safety Control,**
5. **notify the ionizing radiation source with its technical and safety characteristics as well as safe handling, in accordance of this Law, as well as the provisions adopted according to it,**
6. **ensure radiation safety and nuclear security of the ionizing radiation sources from damaging, stealing, illegal behavior and transfer, lost or disappearing,**
7. **There are internal organizations that ensure:**
 - **precise determination of duties and responsibilities of all that work with ionizing radiation sources,**
 - **determination of Radiation Protection Officer,**
 - **appropriate control on the entrance of visitors in controlled and supervised area, concerning appropriate escort of the visitors in controlled and supervised area by the persons having needed knowledge in the field of protection and safety measures in that field and which may ensure appropriate information and guidance to the visitors that may influence their activities and**
 - **system for effectively informing for the conditions and the events of interests for protection and safety and**
8. measures were undertaken for the safe handling of radioactive materials in order to prevent possible contamination of the environment above prescribed limits.

The premises, devices, and the equipment, as well as the persons who work with ionizing radiation sources from paragraph 1 of this article, shall be closely prescribed by the Directorate.

Article 9

The Directorate shall not issue a license to a legal person which applies for a license for practice which does not justify the usage of ionizing radiation sources from a social, economic, medical or other aspect established by this law.

Article 10

The legal person, who works with ionizing radiation sources, shall cover the costs for the license issued by the Directorate, for disposal of the radioactive waste, as well as for the measurements carried out during the utilization of the sources, in accordance with this law.

The costs from the paragraph 1 of this law shall be prescribed by the Directorate.

Article 11

The procedure on issue of licenses shall be conducted pursuant to the rules on general administration procedure, if not otherwise stipulated by this law.

An Appeal against the findings and decisions **on issue of licenses** may be lodged to the Appeal Commission of the Government of the Republic of Macedonia, within 8 days, as of the day the decision has been received.

None of the aforementioned actions shall have a suspending effect.

Article 11-a

Supervision on the work of the legal persons which use ionizing radiation sources and have license for them performs the Directorate.

In case the legal persons that use ionizing radiation sources and have license for that shall not conduct the practice of which is authorized for in accordance with the provision set forth in this law or stop to fulfill the requirements set forth in this law, the director of the Directorate with decision shall withdraw the license for practice.

The Decision from the paragraph 2 of this article is final and against it may be taken legal action to the authorized court

IV. PROTECTION AND SAFETY REQUIREMENTS

General requirements

Article 12

The general requirements for radiation protection and ensuring security of the ionizing radiation sources should provide normal exposure within the limits of the doses prescribed by the Directorate and in accordance with the following basic principles of radiation protection:

1. Principle of justification– economic and social benefits yielded by all types of practices involving operation of ionizing radiation sources to individuals or society must outweigh the damage which may be caused by radiation to human health and environment;
2. Principle of optimization – any kind of exposure of individuals and society must be as low as reasonably achievable, economic and social factors being taken into account;
3. Principle of limitation of dose – the sum of total doses resulting from all types of practices with **ionizing radiation** sources may not exceed the established limits **by the Directorate**, with the exception of a personal dose received by a patient for his own health care and an individual helping a patient or participating in medical and biomedical research, as a volunteer.

Legal person Liabilities

Article 13

Legal person conducting practice in accordance with this Law, shall be obliged to establish and provide:

1. **Radiation Protection Program**, procedures and other organization activities for ensuring the protection of the **occupational exposed persons**, as well as for the workers of other institutions, working temporarily, in accordance with this Law, and the regulations thereto;
2. to prepare **Emergency Preparedness Plan**, defining the measures for protection of the population, as well as **the occupational exposed persons**, especially:
 - to define the sources that may require any intervention,
 - to define intervention levels of the corresponding radiation protection activities, their scope and time limit in regard to the intensity, and urgency for undertaking measures;
 - description of the methodology and instruments for appraisal of the **emergency** and the consequences of that event on the site, and out of it as well,
 - the time schedule, the manner and procedure to inform the Directorate, and
 - measures to provide optimal radiation protection in the frames of normal exposure for a certain group of persons expected to be exposed on radiation by a certain source, so that the total dose shall not exceed the determined maximum level of exposure of the population, workers with radiation sources

- or patients;
3. Corresponding area, equipment and staff for radiation protection of the population, **occupational exposed persons**, i.e. the patients;
 4. Register of the **ionizing radiation** sources;
 5. protection (personal protection devices, dose meters control, health control, degree of exposure of workers, ventilation, check of the contamination of persons and objects, facilities and air in the premises and regular check of the equipment and the protection devices), as well as training of persons involved in activities related with radiation protection of population, **occupational exposed persons**, i.e. the patients;
 6. **Program for Quality Assurance and Safety Control, as well as the equipment used for implementation of the program;**
 7. maintaining the activity and quantity of the radioactive waste at the lowest possible level through secure handling and deactivation;
 8. handling with the radioactive waste so that appropriate classification, allocation, proceeding, storing and disposal is provided;
 9. **appropriate efforts for treatment ,storage and disposal of the radioactive waste resulting by particular practice, on safe and secure manner;**
 10. decontamination of the environment contaminated by a ionizing radiation source or activity related to that source by its own service or **through authorized legal person for decontamination**, and
 11. Records of sources, staff and protection measures, as well as submitting reports in periods in accordance with the provisions set forth in this Law.

The legal persons referred to in paragraph 1 above shall also be obliged to inform the Directorate for any dislocation of an ionizing radiation source and of radioactive material.

The legal persons of paragraph 1 herein shall be fully responsible for protection and safe handling with the equipment which contains ionizing radiation source.

Exposure to Radiation

Article 14

According this Law, person may be exposed to ionizing radiation under different conditions, i.e. **occupational exposure**, public exposure and medical exposure.

The provisions of this Law shall also apply to potential exposure, and emergency exposure.

Dose limits, dose guidance levels and/or guidance for the application shall be prescribed by the Directorate.

Occupational Exposure

Article 15

Ionizing radiation source may only be operated by person having adequate qualifications and health requirements as prescribed by the Directorate.

The person referred to in paragraph 1 of this Article shall be subject to regular health surveillance, when employed, during working period and when leaving the duties.

Article 16

The following persons shall not be allowed to work with ionizing radiation sources:

1. persons under 18 years of age, **apart from students older than 16 years ,who are trained for work which include exposure to ionizing radiation. or utilizing ionizing radiation during their studies;**
2. **women during pregnancy, in case working on working places directly exposed to ionizing radiation;**
3. **women during breastfeeding in case working with open ionizing radiation sources and they are exposed on direct radioactive contamination and**
4. persons suffering certain diseases, to whom work with ionizing radiation sources is contra indicated.

Article 17

A person employed by a legal person licensed to conduct activities in accordance with this Law and **any temporary engaged person by the legal person** shall be obliged to apply the provisions on radiation protection, set forth in this Law and in any regulations related thereto.

Public Exposure

Article 18

A legal person shall be obliged to apply the requirements specified in this law and the regulations issued by the Directorate related to public exposure delivered by the utilization of the source for which the license is issued, unless the exposure is **excluded from regulatory practice or if the practice or the source delivering exposure is exempted from regulatory control and supervision.**

Should a practice or a source within a practice lead to the release of radioactive substances to the environment and thereby cause damage to human health or the environment, the legal person shall be held responsible and pay damages therefore.

Article 18-a

The legal person with a license for the ionizing radiation source shall ensure that radioactive substances from authorized practices and sources not be discharged to the environment, unless:

1. **either approval has been granted that radioactive substances are excluded from regulatory control or the discharge is within the permitted limits prescribed by the Directorate;**
2. **the discharges are controlled; and**
3. **the public exposures committed by the discharges are within the limits prescribed in accordance with this Law.**

The exposure limits for the population referred to in paragraph 1 of this Article shall be prescribed by the Directorate in accordance with the Ministry of Health.

Article 19

Monitoring and control over the allowed discharges of radioactive substances in the environment shall be carried out by the legal person **with a license for the ionizing radiation source** who shall notify the Directorate and the Ministry of Environment and Spatial Planning respectively.

Maximum allowed limits of discharge of the radioactive substances in environment, the manner of the monitoring and control over the allowed discharges, keeping evidence, as well as the manner of reporting shall be prescribed by the Directorate in accordance with the Ministry of Environment and Spatial Planning.

Medical Exposure

Article 20

Medical exposure should be justified by weighing out the diagnostic or therapeutic benefits it produces, against the radiation detriment it might cause, taking into account the benefits and risks of available alternative techniques not involving medical exposure.

Article 21

Regarding medical exposure the legal person shall ensure that:

1. no patient is administered a **diagnostic** or therapeutic medical exposure, unless the exposure is prescribed by a **family doctor or medical doctor-specialist**;
2. doctors are assigned the primary tasks and obligations of ensuring overall patient protection and safety in the prescription of, and during the delivery of medical exposure;
3. medical and paramedical personnel is available as needed (includes either health professionals or professionals that have appropriate professional training) to implement the assigned tasks related to the **diagnostic and/or therapeutic** procedures prescribed by a **family doctor or medical doctor-specialist**;
4. calibration of the sources, dosimetry and quality under supervision of a **medical physicist or specialist of medical nuclear physics**, during **diagnostic and/or therapeutic** application of ionizing radiation (including teletherapy, **radionuclide therapy** and brachytherapy) and
5. training of personnel is carried out in accordance with the provisions set forth by this Law.

The Directorate shall prescribe the method of implementation of the training stipulated under paragraph 1, item 5 of this article.

Potential exposure

Article 21-a

In case of the potential exposure, the Directorate shall perform supervision and monitoring of:

1. **the potential ionizing radiation sources and**
2. **the exposure of the natural radiation and exposure of radioactive materials that need to perform procedures for ensuring the reduction or prevention of the exposure.**

Radioactive Waste and Disused Sources of Ionizing Radiation

Article 22

The Legal person shall ensure that the activity and volume of any radioactive waste resulting from the sources for which for which the license is issued be kept as reasonably as achivable, and that waste be managed, i.e. collected, handled, treated, conditioned, transported, stored and disposed off in accordance with the provisions set forth in this Law and the regulations thereto.

The waste shall be managed, i.e. collected, handled, treated, conditioned, transported, stored and disposed off in accordance with the regulations prescribed by the Directorate.

Article 22-a

The import of radioactive waste and/or nuclear waste on the territory of the Republic of Macedonia is prohibited.

Article 22-b

The legal person or the physical person who possesses ionizing radiation source and/or radioactive waste not in accordance with the provisions of this law shall be obligated to cover the costs for the repossession, transport and storage.

Article 22-c

The transport and the storage of the orphan sources and/or radioactive waste shall be managed by the authorized technical services upon the request of the Directorate.

The costs for the transport and the storage of the orphan sources and/or radioactive waste from paragraph 1 of this article shall be covered by the Budget of the Republic of Macedonia.

Article 24

Disposal of the disused ionizing radiation sources and the radioactive waste shall be conducted in storage on a location established by the Government of the Republic of Macedonia upon the proposal of the Directorate, on the basis of the opinion of the Ministry of Environment and Spatial Planning and the Ministry of Health.

The costs for disposal of the disused ionizing radiation sources and/or the radioactive waste shall be covered by the legal person who possesses the source or the waste. Radioactive waste handling cost shall be established pursuant article 10 of this Law.

Radiological emergency

Article 25

The Government of the Republic of Macedonia upon proposal of the Directorate shall adopt a **Plan on protection of the population in case of radiological emergency in the Republic of Macedonia.**

The Government of the Republic of Macedonia shall proclaim a **radiological emergency** upon proposal of the Directorate.

The Plan on protection of the population in case of radiological emergency in the Republic of Macedonia shall be revised and set in accordance with the needs, as well as the new achievements in the field of the radiation protection and the radiation safety and **nuclear security**, depending on the assessment of the level of the radioactive contamination and in accordance with the international conventions.

Article 25-a

The legal person with a license for the ionizing radiation source shall be obliged to notify the Directorate promptly when a situation requiring protective action has arisen or is expected to arise, and shall keep them informed of:

- 1. the development of the situation,**
- 2. the measures taken for the protection of the population and**
- 3. the potential exposure.**

Radioactive and Nuclear Material

Article 26

Radioactive and nuclear material shall be used only in peaceful purposes and in accordance with the ratified international treaties.

Article 26-a

The legal persons may conduct import, export, transit and usage of radioactive and nuclear material only after obtaining a license from the Directorate.

Article 26-b

The legal persons may conduct scientific researches which are related on the usage of the radioactive and nuclear material only after written approval by the Directorate for conducting of these researches.

Measures for Radiation Safety and Nuclear Security

Article 26-c

The Directorate shall perform accounting and control over the radioactive and nuclear material subject of the measures for radiation safety and nuclear security and shall ensure compliance with the requirements prescribed with this Law.

The Directorate shall ensure the effective conducts of the measures for radiation safety and nuclear security by:

- 1. measurement of radioactive and nuclear material;**
- 2. evaluation of the measurement accuracy;**
- 3. review of the measurement differences,**
- 4. records of radioactive and nuclear material.**

Article 26-d

The legal person that uses, koristi and transport nuclear material shall be liable for the damage in amount of 100.000.000 Euro offset in denars according the average course of the National Bank of the Republic of Macedonia in case of nuclear incident.

The legal person from paragraph 1 of this article is obliged to submit financial security to the Directorate for compensation of the eventual damage.

IV-a. AUTHORIZATION FOR ISSUING REGULATIONS

Article 26-e

The director of the Directorate shall be authorized to issue regulations on:

- 1. the criteria for facilities, equipment and staff in the authorized technical services and the legal persons for decontamination, as well as the form and content of the application for the license and the form and content of the license;**
- 2. the types of training and the content of the program for training of the radiation protection officers and the persons working with sources of ionizing radiation;**
- 3. the form and content of the template of notification of the ionizing radiation sources, as well as the procedure of the notification;**
- 4. the form and content of the template of application for license, the form and content of the license, as well as the procedure for issuing of license;**
- 5. the content of the Radiation Protection Program, Emergency Plan and Quality Assurance Program;**

6. the dose limits and the conditions of exposure in special circumstances and in case of emergency;
 7. the criteria and measures for radiation protection for operating with X-ray units, accelerators and other units that generate ionizing radiation;
 8. criteria and measures for radiation protection during the practice with ionizing radiation sources;
 9. the health conditions for the work with sources of ionizing radiation, as well as measures, content and manner of the health surveillance of persons working with sources of ionizing radiation;
 10. the maximum permutable limits for discharge of radioactive materials in the environment, the manner of the monitoring, maintaining records and reporting;
 11. the maximum permitted quantities of radionuclide's in foodstuffs, water, air, soil, products and raw materials from animal and herbal origin, and consumer products;
 12. the maximum permitted quantities of radionuclide's in metal, construction materials, fertile lasers, ash from the thermo power plants and the waste from mines and melting industry;
 13. the criteria for the application of the ionizing radiation sources in the medicine, veterinary medicine, pharmacy and dentistry;
 14. the manner and the time frame for the control of the ionizing radiation sources, patients exposure measurement during diagnostic and therapeutic procedures, maintaining records and reporting;
 15. the manner and the measurement of the occupational exposure, maintaining records and reporting;
 16. the manner and the measurement of the public exposure, maintaining records and reporting;
 17. the manner of the transport of radioactive and nuclear material;
 18. the production, usage, handling, storage, as well as import and export of radiopharmaceuticals;
 19. the criteria for exemption of a ionizing radiation source and exclusion of a defined source from regulatory control;
 20. the categorization of the ionizing radiation sources, as well as the categorization of the radioactive and nuclear material;
 21. the categorization of radiation and nuclear threats;
- Regulations from paragraph 1 of this article the director of the Directorate shall issue upon the obtained opinion of the competent Ministries.

V. SUPERVISION

Article 27

The Directorate shall be responsible for the enforcement of this Law and any Regulations in relation thereto.

The Directorate shall perform supervision over the implementation of this law and regulations thereto through **radiation safety inspectors**.

Article 28

The inspector referred to in Article 27 of this Law shall be provided ID card issued by the Directorate.

The type and the content of the ID card referred to in paragraph 1 of this Article shall be prescribed by the Directorate.

Article 28-a

The inspector shall perform announced and unannounced inspection and at the

beginning of the inspection it is his duty to inform the responsible person of the legal person for the inspection and to legitimate himself.

Article 28-b

The inspection supervision shall be:

- regular inspection,**
- extraordinary inspection and**
- control inspection.**

Article 28-c

Regular inspection means inspection over the implementation of this law and the regulations thereto.

Extraordinary inspection means inspection based on initiations and proposals of governmental authorities, legal and physical persons, as well as in cases of doubt of the inspector.

Control inspection means inspection after the period determined with the decision of the inspector.

Article 28-d

Legal persons are obligated to ensure conducting of the inspection without any interruption in the premises where the practice is conducted and on request of the inspector to submit correct and true information and other documents, without cost and to ensure temporary taking of the documents and other objects which are may be used as evidence in court.

Article 28-e

In case the inspector during the inspection finds out that the activities are not in the compliance with this Law and regulations thereto and are committed offence or crime is obligated to submit the case to the court.

If for the committed offence or crime is entitled other governmental authority, the inspector is obligated to inform it immediately.

Article 29

In conducting the inspection, the inspector shall have the right to:

- 1) order elimination of certain irregularity in operating within a determined period;**
- 2) prohibit carrying out of practice or use of equipment;**
- 3) prohibit work of workers who do not fulfill the health conditions for operating with ionizing radiation sources;**
- 4) prohibit work of workers who do not fulfill the conditions set forth in this Law and the regulations thereto;**
- 5) prohibit operation with radioactive and nuclear material if not in accordance with this law and the regulations thereto;**
- 6) prohibit handling with radioactive waste if not in accordance with this law and the regulations thereto; and**
- 7) order other measures regarding radiation protection and safety of sources.**

For the activities referred to in paragraph 1 of this Article, the inspector shall make a decision.

Article 30

An appeal against the decision referred to in Article 29 paragraph 2 may be submitted to the competent Commission of the Government of the Republic of

Macedonia, within 8 days as of the day the decision has been received.
None of the aforementioned actions shall have a suspending effect.

VI. PENALTY PROVISIONS

Article 31

A Fee from 3.000 to 5.000 Euro offset in denars shall be levied upon a legal person, should it:

- 1) Start with practice without license (article 6-a, paragraph 2);
- 2) Start with practice prior to be registered into the Central Register (article 6-b, paragraph 2);
- 3) Fail to act in accordance with the provision set forth in Article 6-c of this Law;
- 4) Start conducting decontamination without license (article 6-e, paragraph 1);
- 5) Start operating prior to be subscribed into the Central Register (article 6-f, paragraph 2);
- 6) Fail to act in accordance with the provision set forth in Article 6-g of this Law;
- 7) start operating without a license or prior to be subscribed into the Register (Article 7, paragraph 1);
- 8) continue its operating after the granted period of the license is being expired (Article 7, paragraph 2);
- 9) carry out any changes in the requirements for practice without license (article 7, paragraph 3)
- 10) transfer the license to other legal person (article 7, paragraph 4)
- 11) fail to fulfill the obligations set forth in Article 13, paragraph 1 of this Law;
- 12) fail to inform the Directorate for dislocation of the ionizing radiation source or the radioactive material (Article 13, paragraph 2);
- 13) fail to provide complete protection and safe handling of the equipment (Article 13, paragraph 3);
- 14) fail to act in accordance with the provision set forth in Article 16 of this Law;
- 15) fail to act in accordance with the provisions on the public exposure set forth by this Law and the regulations thereto (Article 18, paragraph 1);
- 16) Fail to act in accordance with the provision set forth in article 18-a paragraph 1 of this Law;
- 17) Fail to conduct and report the monitoring and the control of permitted discharges of radioactive materials in the environment (Article 19, paragraph 1);
- 18) fail to act in accordance with Article 22, paragraph 1 of this law;
- 19) Fail to conduct import of radioactive waste in accordance with article 22-a of this Law;
- 20) fail to act in accordance with Article 22-b of this law;
- 21) Conduct disposal of radioactive waste out of the specified storage set forth in Article 24, paragraph 1 of this law;
- 22) Fail to act in accordance with the provision set forth in Article 25-a of this Law;
- 23) Fail to apply radioactive and nuclear material in accordance with the provision set forth in article 26 of this Law;
- 24) Conduct export, import, transit, or application of radioactive and nuclear material without license (article 26-a);
- 25) Conduct scientific researches without prior approval by the Directorate (article 26-b) and

26) Fail to act in accordance with the provision set forth in Article 26-d of this law.

For the activities referred to in paragraph 1 of this Article, besides the fee, sanction shall apply to the legal person- temporary prohibition of performing activity from three up to five years.

A Fee from 1.000 to 2.000 Euro offset in denars shall be levied for the activities referred to in paragraph 1 of this Article upon the responsible person of the legal person, as well as sanction- prohibition of performing a profession, activity or duty from 1 year to 5 years.

Article 32

A Fee from 2.000 to 4.000 Euro offset in denars shall be levied upon a legal person, should it employ a person to operate with ionizing radiation source that does not possess adequate qualifications and health condition, i.e. does not provide regular health surveillance (Article 15).

For the activities referred to in paragraph 1 of this Article, besides the fee, **sanction- temporary prohibition of performing activity from three up to five years shall apply to the legal person.**

A Fee from 800 to 1.500 Euro offset in denars shall be levied for the activities referred to in paragraph 1 of this Article upon the responsible person of the legal person, as well as sanction- prohibition of performing a profession, activity or duty from 1 year to 3 years.

Article 33

A Fee from 800 to 1.500 Euro offset in denars shall be levied upon the person employed by the legal person, should it fail to apply the provisions on radiation protection set forth in this Law and the regulations thereto (Article 17).

Article 33-a

Penalty procedure of breaking of rules envisaged in this Law is under authorized court.

Before undertaking the procedure of penalty procedure for breaking envisaged by the provisions of this Law, the Directorate undertakes the procedure for alignment according the Law of Misdemeanour.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 34

Pending organizational restructuring and the establishment of independent inspection functions within the Directorate, inspections shall be carried out by the:

- 1) State Health and Sanitary Inspectorate regarding the provisions of the Law on Sanitary and Health Inspections, applying to human health;
- 2) State Environmental Inspectorate regarding the provisions of the Law on Environment and Nature Protection and Improvement, applying to environment; and
- 3) Veterinary Inspectorate and State Inspectorate of Agriculture regarding the provisions of the Act on Veterinary Health Care, applying to the contents of radionuclides in fodder, plants, seeds and domestic animals.

Article 35

Based on the inspection carried out in accordance with Article 34 of this Law,

the Directorate shall be entitled:

- 1) to order elimination or correction, within a determined time period, of any infraction or adverse condition that could lead to harmful effects over the human health and safety, but does not represent immediate threat;
- 2) to suspend practice entirely or partially, use of equipment, as well as work of workers until the infraction or the safety condition, being potential for immediate threat to health and safety, is being corrected;
- 3) to prohibit any practice related to radioactive material, which is not in compliance with this Law and Regulation thereof;
- 4) to prohibit further use of an ionizing radiation source if not in compliance with the provisions of this Law, by the time the poor performance shall be set in accordance with the applicable Regulations;
- 5) to undertake other radiation protection measures.

Article 36

The legal persons conducting practice with ionizing radiation sources shall be obliged to set in accordance their practice with the provision of this law within a period of 1 year, as of the day this law shall come into force.

The legal persons, referred to in paragraph 1 of this article shall be obliged, as of the date of expiry of the period referred to in paragraph 1 of this Article, to submit a to the Directorate a request for new license for practice.

The legal person shall not have valid operating license, should it fail to submit the request referred to in paragraph 2 of this article within the determined period.

Article 37

By the time the location for the storage shall be established, the legal persons shall be obliged to dispose the radioactive waste in their own or other relevant storages, in a manner approved by the Directorate.

Article 38

Dismantling of the radioactive lightening rods shall be carried out following the provision of safety conditions for disposal of disused sources.

The legal persons possessing radioactive lightening rods shall commence dismantling them, following the approval issued by the Directorate.

Article 39

The Directorate shall start its operating as of the day of the appointment of the director.

The Government of the Republic of Macedonia shall appoint the director within 3 months, as of the day this Law shall come into force.

The Director of the Directorate shall enact the act on the organizational structure and on the staffing and job description within a period of 3 months, as of the day of his/her appointment.

The existing inspectors shall be undertaken by the Directorate within a period of 3 months, as of the day the acts referred to in paragraph 3 of this Article shall be adopted.

Article 40

In accordance with this law, the Directorate shall adopt the general acts within a period not exceeding 9 months, as of the day of the appointment of the director.

By the time the general acts referred to in paragraph 1 of this article shall be adopted, the existing regulations, not contrary to the provisions of this Law shall apply.

Article 41

The Law on Protection of Ionizing Radiation (Official Gazette of SFRY No. 53/91) shall not apply, as of the day this Law shall come into force.

In accordance with the provision of this Law, as of the day the Directorate shall start its inspection and supervision, the Law on Protection and Improvement of the Environment (Official Gazette of the Republic of Macedonia No. 69/96, 13/99 and 41/2000) and the Law on Sanitary and Health Inspection (Official Gazette of the Republic of Macedonia No. 19/95) i.e. their parts related to radiation safety, shall not apply.

Article 42

This Law shall come into force on the 8th day, as off the day it shall be announced in the “Official Gazette of the Republic of Macedonia”.

Article 43 (Article 46 in the Amendments)

The legal persons conducting practice with ionizing radiation sources shall be obliged to set in accordance their practice with the provision of this law within a period of 6 months, as of the day this law shall come into force.

Article 44 (Article 47 in the Amendments)

The Decisions for authorization issued to the legal persons and individuals before the establishment of the Directorate shall not be valid within three months of promulgation of this law.

Article 45 (Article 48 in the Amendments)

The procedures of issuing the licenses started before the promulgation of this Law shall be conducted in accordance with the Law on radiation protection and safety (“Official gazette of the Republic of Macedonia” No. 48/2002).

Article 46 (Article 49 in the Amendments)

The regulations prescribed with this Law shall be adopted within one year as of the day of the promulgation of this Law.

Article 47 (Article 50 in the Amendments)

The Legal Commission in the Parliament of the Republic of Macedonia is authorized to confirm consolidated text of the Law on Ionizing Radiation Protection and Safety.

Article 48 (Article 51 in the Amendments)

This Law shall come into force on the 8th day, as off the day it shall be announced in the “Official Gazette of the Republic of Macedonia”.