

15 Annex - Energy

61. LAW ON IONIZING RADIATION PROTECTION AND RADIATION SAFETY

Pursuant to Article 95 item 3 of the Constitution of Montenegro, I hereby issue the

DECREE

**PROMULGATING THE LAW ON IONIZING RADIATION PROTECTION
AND RADIATION SAFETY**

(Official Gazette of Montenegro 56/09 of 14 August 2009)

I hereby promulgate the Law on Ionizing Radiation Protection and Radiation Safety, passed by the 24th Parliament of Montenegro at the third sitting of the first ordinary session in 2009 on 27 July 2009.

No: 01-2331/2

Podgorica, 5 August 2009

The President of Montenegro,

Filip Vujanović, m.p.

LAW

ON IONIZING RADIATION PROTECTION AND RADIATION SAFETY

I. BASIC PROVISIONS

Matter of Regulation

Article 1

This Law regulates protection of human life and health as well as protection of the environment against harmful effect of ionizing radiation, performing radiation activities, trade in ionizing radiation sources and radioactive materials, radioactive waste management, actions taken in case of radiation accidents, as well as other relevant issues for protection against ionizing radiation and safety of radiation.

This Law does not relate to ionizing radiation of natural origin from the space on the level of ground, earth crust and human organisms, if such radiation is not altered by human action.

Objectives

Article 2

Protection against ionizing radiation and provision of radiation safety is carried out through the following objectives:

- preservation and protection of life and health of present and future generations;
- working and living environment protection;
- security and safety of ionizing radiation sources;
- ensuring conditions for expert and rational utilization of ionizing radiation sources;
- raising the level of knowledge and consciousness in the field of ionizing radiation protection and provision of radiation safety.

Achievements

Article 3

Objectives of ionizing radiation protection and achievement of radiation safety laid down in Article 2 of this Law shall be achieved by:

- application of ionizing radiation in all activities for peaceful purposes;
- establishing a control system for ionizing radiation sources and radioactive materials;

- planning, monitoring, rational and expertise restriction of ionizing radiation source utilization;
- control of trade in ionizing radiation sources and radioactive materials;
- control of imported items and goods;
- ban on import of radioactive waste;
- radioactive waste management;
- providing working conditions for persons professionally exposed to harmful effects of ionizing radiation;
- timely and objective public information;
- enforcement of approved international conventions and other agreements from the field of ionizing radiation protection and radiation safety.

Basic Principles

Article 4

Basic principles applied when performing radiation activities are the following:

1) Justifiability of Application:

Each radiation activity should be planned and implemented in such manner that the use of ionizing radiation sources provides more benefit than the overall damage;

2) Optimization of Ionizing Radiation Protection:

Each radiation activity must be performed in such manner that the exposure to ionizing radiation shall be as low as objectively possible, considering economical and social factors;

3) Limitation of individual exposure:

Radiation activity must be planned in such manner that the individual exposures shall always be under prescribed limits.

Definitions

Article 5

Particular definitions, in the sense of this Law, shall bear the following meaning:

- 1) **Activity of certain amount of radioactive material** is the number of spontaneous nuclear break-ups in the time unit;
- 2) **Ambient dose equivalent** is such equivalent dose that can be produced by a corresponding radiation field of phantom reference;
- 3) **Absorbed dose** is fundamental dosimetric quantity and represents positive energy absorbed by certain substance per mass unit;
- 4) **Security** consists of: prevention, detection and action in case of theft, sabotage, unauthorized access, illegal trade or other malevolent activities including nuclear material, radioactive material or their facilities;
- 5) **Dose** is deposited energy of ionizing radiation within a facility;
- 6) **Decontamination** is removal or reduction of contamination level by physical, chemical and biological processes;
- 7) **Effective dose** is the sum of dose equivalent products in the tissue or organ of respective weight factor, throughout all exposed tissues and organs;
- 8) **Dose equivalent** is the product of the absorbed dose in the tissue or organ and so-called quality factor reflecting biologically harmful effect caused by particular type of ionizing radiation;

- 9) **Ionizing radiation exposure** is such situation or condition under which irradiation of a subject occurs;
- 10) **Population exposure** is such exposure to ionizing source, excluding professional or medical exposure and normal natural radiation (phon), including exposure consequent to radiation accident which can result in state of emergency;
- 11) **Source without owner (orphan)** is such radiation source that is not under control, because it was not under control or has been lost, stolen or displaced without adequate recording;
- 12) **Ionizing radiation sources** are substances, equipment or facilities emitting or able to emit ionizing radiation;
- 13) **Ionizing radiation** is electromagnetic or particle radiation that may produce ion pairs in biological material;
- 14) **Contamination** is an unplanned and undesired presence of radioactive material, as well as process leading to its presence on surfaces or inside solid, liquid or gaseous bodies (including human organism) above the prescribed limits;
- 15) **Quality control** is technical-technological control of system structure and components corresponding to requests previously determined by quality security programme;
- 16) **Ionizing radiation source user** may be a company, any other legal person or entrepreneur, in possession of ionizing radiation source;
- 17) **Use of ionizing radiation source is:** possession, work with such sources, conversion and change of technical characteristics, installation, servicing and storing;
- 18) **Medical exposure** is the exposure of patients and persons helping patients with medical application of ionizing radiation sources, and are not professionally exposed persons, as well as persons voluntarily included in medical research programmes with application of ionizing radiation sources;
- 19) **Monitoring** is measuring of dose of contamination with the purpose of estimation or control of exposure to ionizing radiation and radioactive materials, processing and interpretation of the results;
- 20) **Holder of licence for performing radiation activity** may be a company, any other legal person or entrepreneur, holding the radiation activity licence;
- 21) **Nuclear material** is plutonium, except for the one with isotopic concentration exceeding 80% Pu-238; uranium U-233; uranium enriched with content of U-235 or U-233 isotope; uranium containing isotopic mixture existing in nature, if its concentration is greater than the one found in ores or remains of processing, as well as mixture of aforementioned materials;
- 22) **Radioactive waste disposal** is permanent disposing of radioactive waste;
- 23) **Providing quality** includes all system measures necessarily needed for achieving adequate degree of reliability and security standard provision prescribed by relevant regulations;
- 24) **Open source** of ionizing radiation is such ionizing radiation source that is not a sealed source of ionizing radiation, and can be in solid, liquid or gaseous state;
- 25) **Professionally exposed persons** are persons working with sources of ionizing radiation or, are within the field of ionizing radiation while performing their work;
- 26) **Natural radionuclides** are radionuclides occurring in nature in significant quantities, i.e. not produced by human activity (uranium- 235, uranium-238, torium-232, kalium-40 and products of their degradation);

- 27) **Natural radioactive material** is a radioactive material whose radionuclide content does not significantly differ from natural radionuclides, as well as materials whose natural radionuclides specific activity changed during the course of technological procedures;
- 28) **Trade** implies supply, sale, import, export and transit of ionizing radiation sources and radioactive materials;
- 29) **Radiation activity** is each human activity dealing with ionizing radiation sources that may lead to increase of ionizing radiation exposure level or increase the number of people exposed to ionizing radiation;
- 30) **Radiation risk** is the probability of causing harmful effect to the health of an individual or a group of people and environment due to exposure to ionizing radiation;
- 31) **Radiation safety** presents a group of operating conditions, technical and organizational measures taken for prevention of radiation accidents or reducing the consequences of accidents, i.e. protection of professionally exposed persons, population and environment against radiation risk;
- 32) **Radiation accident** is any unintentional or unexpected event, including human error, equipment failure of other irregularities whose possible consequences are not neglectable regarding ionizing radiation protection and radiation safety;
- 33) **Radiation accident that may produce state of emergency** is an uncommon situation demanding fast reaction with primary goal to mitigate the risk or negative consequences for human health and safety, quality of life, property or environment;
- 34) **Radioactive material** is material containing one or more radionuclides whose total and specific activity exceeds prescribed limits;
- 35) **Radioactive waste** is radioactive material not planned for further use;
- 36) **Safety** encompasses measures that foresee reducing to least possible measure the probability of radiation accident including radioactive sources, and in case such an accident occurs, mitigation of its consequences;
- 37) **Radioactive waste storage** is storing of radioactive waste at a place under supervision of an authorized legal person;
- 38) **Radioactive material specific activity** is activity of mass unit of the said material;
- 39) **Radioactive waste management** consists of administrative and operative activities regarding handling, treatment, storage, transport and disposal of waste;
- 40) **High-level radioactive waste** is radioactive material with high level activity not planned for further use;
- 41) **Sealed source** of ionizing radiation is an ionizing radiation source sealed by impermeable coating of non-radioactive material (encapsulated) so that the radioactive material cannot escape and get in contact with the environment;
- 42) **Protection against ionizing radiation** is a group of measures for preventing harmful effects of exposure to ionizing radiation;
- 43) **Environmental protection** is taking measures and actions for prevention of ionizing radiation harmful effects to the environment and elimination of consequences of the radiation.

II. PROTECTION AGAINST IONIZING RADIATION

Strategy for Protection against Ionizing Radiation, Radiation Safety and Radioactive Waste Management

Article 6

For the purpose of providing conditions for implementation of the policy in the area of protection against ionizing radiation and radiation safety, the Government of Montenegro (hereinafter: the Government) adopts the Strategy for Protection against Ionizing Radiation, Radiation Safety and Radioactive Waste Management, with Action plan for its realization, at the proposal of the ministry competent for the affairs of environmental protection (hereinafter: the Ministry).

The strategy laid down in paragraph 1 of this Article determines plans and objectives regarding protection against ionizing radiation, radiation safety and radioactive waste management in accordance with standards and principles of international organization in this field, as well as undertaken international obligations.

Activities and measures for implementation of Strategy laid down in paragraph 1 of this Article shall be provided from the Budget of Montenegro in accordance with the law.

Competence of the Agency for Environmental Protection

Article 7

Professional, and to them connected management operation from the field of protection against ionizing radiation and radiation safety shall be carried out by the competent administrative body competent for the affairs of environmental protection (hereinafter: the Agency).

The Agency is competent to:

- perform systematic testing of radionuclide content in the environment (monitoring);
- perform analysis and prepare reports on state of radioactivity in the environment;
- collect and publish information of interest for the environment and human health;
- conduct information system on state of radioactivity in the environment;
- prepare programme for systematic analysis of radioactivity level in the environment;
- collect information on radiation accidents;
- Issue permits in accordance with this Law;
- Issue certificates on recorded ionizing radiation sources;
- Issue certificate of meeting requirements for professional qualification of the person responsible for ionizing radiation protection;
- keep records of applications and issued permits, confirmations of registration and certificates;
- establish and maintain the data base (central register) of ionizing radiation sources and users of these sources, radioactive materials, professionally exposed persons, radioactive waste and perform control of records kept by the users, as well as of other relevant data for ionizing radiation protection and radiation safety;
- perform control of meeting requirements according to which permits were issued;
- monitor the sources and use of ionizing radiation and radioactive materials in medical and non-medical purposes and their safe storage;
- order implementation of safety measures regarding ionizing radiation and radiation safety;
- participate in implementation of safety measures regarding ionizing radiation and radiation safety within its competence;
- independently, or in cooperation with competent state authorities cooperate with the International Atomic Energy Agency and other international bodies and competent other states' authorities concerning the implementation of the law;
- supply public media, competent state authorities and the International Atomic Energy Agency with relevant information from the field of ionizing radiation protection and radiation safety;

- provides opinion at request of competent state authorities regarding joining international conventions and other agreements from the field of ionizing radiation protection and radiation safety;
- perform other tasks determined by the Law.

Measures of Ionizing Radiation Protection and Radiation Safety

Article 8

For the purpose of human life and health protection as well as environmental protection against harmful effect of ionizing radiation the following measures shall be taken:

- systematic analysis of radioactivity level in the environment;
- determination of requirements for trade and use of ionizing radiation sources;
- use of ionizing radiation protection equipment and materials and control of efficiency of the said protection;
- restriction or ban of trade and use of products and raw materials for production, contaminated by radionuclides above prescribed limits;
- keeping records on ionizing radiation sources and radioactive materials;
- keeping records on materials whose natural radionuclide concentration increases above prescribed limits during technical-technological procedure;
- keeping records on ionizing radiation exposure of professionally exposed persons, patients and population;
- determination of working conditions and implementation of prescribed measures for ionizing radiation harmful effects safety at work;
- control and monitoring of professionally exposed persons' health;
- education and professional specialization of manpower in the field of ionizing radiation protection;
- personal and collective ionizing radiation human health protection;
- implementation and application of measures from the radiation accident safety action plan;
- secure and safe radioactive waste management;
- enforcement of programme for provision and control of ionizing radiation safety measures quality;
- radioactivity control at border crossings;
- decontamination;
- other measures providing ionizing radiation protection according to international standards.

Systematic Radioactivity Level Analysis in the Environment

Article 9

Systematic analysis of radioactivity level in the environment (hereinafter: radioactivity monitoring) shall be performed for determination of radionuclide presence in the environment and estimation of ionizing radiation exposure level of the population under normal conditions, as well as in case of a suspected radiation accident and during the course of a radiation accident.

Radioactivity monitoring referred to in paragraph 1 hereof, shall be performed in accordance with the Systematic Radioactivity Level Analysis in the Environment Programme passed by the Government, at the proposal of the Ministry, at latest till 1 December of current year for the following year.

The Programme referred to in paragraph 2 hereof determines locations, time intervals, types and manners of systematic radioactivity level analysis in the environment.

Costs of radioactivity monitoring activities and estimation of ionizing radiation exposure level of the population shall be covered from the Budget of Montenegro.

Allowed content of radionuclide in the environment shall be prescribed by the Ministry.

Report on Radioactivity Monitoring

Article 10

The legal person laid down in Article 32 of this Law implementing Systematic Radioactivity Level Analysis in the Environment Programme is bound to submit the Report on Radioactivity Monitoring to the Agency at latest till 1 March of a current year for the previous year, and in case of radiation accident or at request of the Agency, immediately.

According to the results of radioactivity monitoring referred to in Article 9 of this Law, the Agency shall monitor ionizing radiation exposure of population, order measures in case of increased radioactivity and perform evaluation of effective dose with the population.

Measurements for Purpose of Ionizing Radiation Exposure Level Estimation

Article 11

The holder of licence for performing radiation activity referred to in Article 21 of this Law is bound to perform the prescribed measurements for purpose of making an estimate of the level of ionizing radiation exposure of professionally exposed persons, persons attending schools and performing scientific research, patients and inhabitants.

Costs of measurements for purpose of ionizing radiation exposure level estimation referred to in paragraph 1 of this Article shall be covered by the holder of licence for performing radiation activity.

Types, manner and time intervals of measurements for purpose of making and estimate of the level of ionizing radiation referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Exposure Limits

Article 12

Professionally exposed persons, person attending schools and performing scientific research and population must not be exposed to ionizing radiation above the prescribed limits.

Exposure limits for professionally exposed persons, persons attending schools and performing scientific research and population, manner and time intervals of exposure level, manner and implementation of immediate control over ionizing radiation sources shall be prescribed by the Ministry, in cooperation with the ministry competent for health-related affairs.

Estimation of Medical Exposure Level

Article 13

For purpose of making estimate of ionizing radiation medical exposure, holder of licence for performing radiation activity referred to in Article 21 of this Law shall perform the prescribed measurements.

Types, exposure limits and manner of measurement for making estimate on ionizing radiation medical exposure shall be prescribed by the Ministry, in cooperation with the ministry competent for health-related affairs.

Systematic use of ionizing radiation sources for diagnostic purposes is not allowed, except for the cases where it is ordered by the ministry competent for health-related affairs.

Report on Estimation of Medical Exposure Level

Article 14

The legal person laid down in Article 32 of this Law performing measurements referred to in Articles 11 and 13 of this Law is bound to keep records on measurements and to submit the Report on the measurements to the Agency.

The contents of the Reports on the measurements referred to in paragraph 1 of this Article, manner of keeping and period of saving the records, as well as procedure of informing the competent authorities shall be prescribed by the Ministry.

Working Conditions of Professionally Exposed Persons

Article 15

Depending on type of business, professionally exposed persons must have prescribed professional qualification and be trained for providing ionizing radiation safety measures.

Professionally exposed persons must meet health requirements and are bound to carry out health examination prior to start of work, during the course of work in case of a radiation accident, and if required, upon termination of work with ionizing radiation sources.

Required professional qualification degree, health requirements that must be fulfilled by professionally exposed persons and time intervals of the examinations, contents, manner and periods of saving the data on the examinations, qualification for work and implementation of protection measures shall be prescribed by the Ministry, in cooperation with the ministry competent for health-related affairs.

Additional Training Programme

Article 16

For the purpose of additional training and periodic updating of knowledge in the field of ionizing radiation protection, the Ministry, in cooperation with the ministry competent for health-related affairs and ministry competent for educational affairs adopts the Additional Training Programme and training of professionally exposed persons responsible for implementation of ionizing radiation protection measures laid down in Article 15 of this Law.

The Programme referred to in paragraph 1 hereof shall be published in the "Official Gazette of Montenegro".

Activities referred to in paragraph 1 hereof shall be performed by a legal person meeting requirements prescribed by the Act of the Ministry in cooperation with the ministry competent for health-related affairs.

III. BANS

Ban of Nuclear Power Plants Construction

Article 17

Construction of nuclear power plants, plants for production of nuclear fuel and plants for treatment of used nuclear fuel is banned.

Ban of Work with Ionizing Radiation Sources

Article 18

Work with ionizing radiation sources is prohibited to:

- 1) persons under 18 years of age;
- 2) women during pregnancy;
- 3) women while breastfeeding – work with open sources of ionizing radiation.

Exposition to ionizing radiation is banned above limits prescribed for population younger than 18 year of age, except for persons above 16 years of age during the course of prescribed training for work with ionizing radiation sources within regular schooling.

Other Bans

Article 19

Every research and activity with the aim of development, production and use of nuclear weapons, as well as use of radioactive or nuclear material for production of mass destruction weapons is banned.

Import of radioactive waste, as well as processing, storing and disposal of radioactive waste of foreign origin at the territory of Montenegro is banned.

Trade in nuclear material on the territory of Montenegro is banned.

Installation of radioactive lightning rods at the territory of Montenegro is banned.

Installation of ionizing smoke detectors having a source of ionizing radiation in the gaseous state or ionizing radiation source whose break-up products in gaseous state are banned.

Adding radioactive substances in food, drinking water, medicines, tobacco and tobacco products, toys, jewellery, cosmetics, toiletries, construction material, animal fodder, ores, primary form metal products, mineral raw materials and consumer goods, as well as import, export and release of such products is banned.

IV. PERFORMING RADIATION ACTIVITY

Certificate of Registration

Article 20

Any user owning an ionizing radiation source with low radiation risk is bound to inform the Agency about it and obtain a Certificate of Registration from the Agency.

Manner of keeping record on users and ionizing radiation sources, criteria for determination of ionizing radiation source type and their categorization shall be prescribed by the Ministry.

Radiation Activity Licence

Article 21

Radiation activity may be performed exclusively by users of ionizing radiation sources having been issued the Radiation Activity Licence from the Agency.

The users of ionizing radiation source referred to in paragraph 1 hereof are bound to submit a request to the Agency for issuance of the Radiation Activity Licence.

According to the fulfilment of prescribed conditions, the Agency shall issue the Licence referred to in paragraph 2 hereof.

Licence shall be issued by a decision, within 30 days from the day of submitting the request for obtaining the licence.

The content of the requests referred to in paragraph 2 hereof and necessary documents for obtaining the Licence shall be prescribed by the Ministry.

Requirements for Performing Radiation Activities

Article 22

The Agency shall issue the Radiation Activity Licence to the source user if:

- 1) ionizing radiation source use satisfies the Principle of Justifiability;
- 2) facilities and rooms where ionizing radiation source is used, comply with technical, security and safety, sanitary and other prescribed requirements ensuring health protection of people and the environment against ionizing radiation;
- 3) professionally exposed persons are provided with adequate ionizing radiation means of protection, as well as equipment for radiation measurements;
- 4) the user ensures that professionally exposed persons have prescribed professional qualification and fulfil prescribed health requirements for work with ionizing radiation sources;

- 5) takes all prescribed measures for prevention of radioactive waste causing contamination of the environment above prescribed limits;
- 6) provides Attestation on technical-technological integrity of the ionizing radiation source from the authorized organization;
- 7) has a plan for action in case of radiation accident that may cause case of emergency, in compliance with health and safety methodology;
- 8) has Instructions for action in case of radiation accident;
- 9) has an employee in charge with protection against ionizing radiation laid down in Article 24 of this Law.

Detailed requirements for radiation activity referred to in paragraph 1 hereof shall be prescribed by the Ministry.

Temporary Performing Radiation Activity

Article 23

Users of ionizing radiation source registered outside of Montenegro may temporarily perform radiation activity when this is requested by a legal person or an entrepreneur registered in Montenegro.

A legal person or an entrepreneur referred to in paragraph 1 hereof is bound to submit a request to the Agency for obtaining a licence for temporary performing radiation activity.

The request referred to in paragraph 2 hereof, beside the evidence on satisfying criteria determined in Article 22 of this Law, shall be accompanied by:

- type and description of business for which the user of ionizing radiation source is to be engaged for temporary performing radiation activity in Montenegro;
- period of time during which the user of ionizing radiation source is to be engaged in Montenegro;
- decision brought by the competent state authority in which the user of ionizing radiation source is registered for performing activities referred to in indent 1 of this paragraph.

Based on submitted documents laid down in paragraph 3 of this Article, the Agency shall issue a licence for temporary performing radiation activity within 30 days from the day of submitting the request.

The licence referred to in paragraph 4 of this Article shall be issued by a decision and shall be limited to a period not longer than 12 months.

The contents of the request laid down in paragraph 2 of this Article as well as necessary documents for obtaining the licence for temporary performing radiation activity shall be prescribed by the Ministry.

Person Responsible for Ionizing Radiation Protection

Article 24

The person responsible for ionizing radiation protection referred to in Article 22 paragraph 1 item 9 of this Law is bound to: carry out internal supervision over application of ionizing radiation protection measures; take care of: supply of personal dosimeters and protective equipment, implementation of health examination of professionally exposed persons, professional qualification of employees for implementation of measures for ionizing radiation protection, regular control of ionizing radiation sources within prescribed time limits; encourage and organize taking protection measures in case of radiation accident; provide keeping records; attend inspection supervision and make declaration of the executed inspection; perform other activities concerning ionizing radiation sources defined by the Agency or which is obliged to perform according to this Law and regulations adopted based on this Law.

The person responsible for ionizing radiation protection laid down in paragraph 1 of this Article is bound to inform the Agency immediately of any failure to apply prescribed measures for ionizing radiation protection.

The Agency keeps record of persons responsible for ionizing radiation protection laid down in paragraph 1 of this Article.

Conditions for professional qualification of the responsible person referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Based on satisfied prescribed requirements, the person responsible for ionizing radiation protection shall be issued by the Agency the certificate on meeting the requirements for professional qualification.

Obligations of Licence Holder

Article 25

The holder of licence for performing radiation activity is obliged to:

- 1) regularly maintain and service ionizing radiation sources;
- 2) keep prescribed records on ionizing radiation sources;
- 3) report to the Agency all changes related to activity of ionizing radiation source;
- 4) report to the Agency termination of use of ionizing radiation source, as well as provide information on its keeping and storing;
- 5) report to the Agency all changes related to prescribed requirements based on which the licence was issued;
- 6) implement other measures of ionizing radiation protection determined by this Law.

The holder of licence for performing radiation activity is obliged to report immediately to the Agency any change laid down in paragraph 1 items 3 and 5 of this Article, and within 48 hours a change laid down in paragraph 1 item 4 of this Article.

Keeping records

Article 26

The holder of licence for performing radiation activity is obliged to keep records on ionizing radiation sources, on professionally exposed persons, as well as on radioactive waste.

The holder of licence for performing radiation activity in medical purposes is obliged to, besides keeping records referred to in paragraph 1 of this Article, keeps evidence on patients' exposure to ionizing radiation.

Form and contents of the records referred to in paragraphs 1 and 2 of this Article shall be prescribed by the Ministry, in cooperation with the ministry authorized for health-related affairs.

Quality control

Article 27

The holder of licence for performing radiation activity is obliged to establish and implement Programme for quality security and control of measures for ionizing radiation protection.

Depending on radiation activity performed by the licence holder, i.e. on tasks performed in the field of ionizing radiation protection by the legal person laid down in Article 32 of this Law, the Ministry shall prescribe the manner, types and time intervals at which measurements for quality control of measures for ionizing radiation protection are to be executed.

Decontamination

Article 28

In case a holder of licence for performing radiation activity should cause contamination, he is obliged to inform the Agency immediately and to implement decontamination through the legal person for performing decontamination laid down in Article 32 of this Law and bear the expenses of such decontamination procedure.

In such cases when the licence holder responsible for contamination cannot be immediately determined, the expenses of decontamination carried out by the legal person referred to in paragraph 1 of this Article as well as damage incurred shall be borne by the State, in accordance with specific regulation.

The Agency shall inform professionally exposed persons and public about possible harmful consequences of contamination.

Manner of carrying out decontamination, as well as requirements that must be satisfied by legal persons performing decontamination shall be prescribed by the Ministry.

Limitations in Use of Ionizing Radiation in Medical Purposes

Article 29

Ionizing radiation sources may be used in medical purposes in prescribed manner, if a medical practitioner of appropriate specialization performs estimate of medical justifiability of their use and approve the diagnostic or therapeutic procedure.

Conditions for use of ionizing radiation sources in medical purposes, as well as protection measures for the patients during medical exposure for implementation of diagnostic or therapeutic procedure shall be prescribed by the Ministry, in cooperation with the ministry authorized for health-related affairs.

Protection Level

Article 30

The holder of licence for performing radiation activity is obliged to provide such protection level that will prevent exposure above the limits prescribed for population.

Increase of Natural Radionuclide's Concentration

Article 31

A legal person or entrepreneur performing such technical-technological procedures that increase natural radionuclide concentration above the prescribed limits is obliged to keep records thereof and submit these records to the Agency annually.

The Agency shall define the list of legal persons and entrepreneurs referred to in paragraph 1 of this Article.

The Agency is obliged, based on submitted evidence, to estimate the degree of people's health and environment being endangered and to order execution of additional measures for ionizing radiation protection.

Contents and time limits for submission of evidence referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Costs of ionizing radiation protection measures implementation shall be borne by the legal person or entrepreneur referred to in paragraph 1 of this Article.

Legal Persons Performing Ionizing Radiation Protection Activities

Article 32

All the testings, measurements, control and other expert activities laid down in Articles 9, 11, 13, 27, 28 and 44 of this Law can be performed by legal persons holding the licence for performing ionizing radiation protection.

The Agency shall issue the licence referred to in paragraph 1 of this Article to the legal person satisfying the following requirements:

- 1) Dispose with adequate number and type of instruments, devices and equipment necessary for performing these activities;
- 2) Have facilities and rooms in accordance with technical, security and health protection requirements for protection of people and environment against ionizing radiation;
- 3) Dispose with adequate number of permanently employed persons with prescribed professional qualification and trained for performing measures for ionizing radiation protection and have adequate working experience;
- 4) Hold certificate on accreditation for analytical techniques and methods of testing required for this type of activities.

More detailed requirements referred to in paragraph 2 of this Article, that are to be fulfilled by the legal person for performing prescribed testing, measurements and other expert activities, as well as contents of the request form and necessary documents shall be prescribed by the Ministry.

Licence

Article 33

The licence referred to in Article 32 of this Law shall be issued in the form of decision and shall be published in the "Official Gazette of Montenegro".

The licence referred to in paragraph 1 of this Article shall be issued within 30 days from the day of submitting the request and documents proving meeting prescribed requirements.

The legal person referred to in Article 32 of this Law is obliged to report any changes in fulfilment of requirements according to which the licence was issued by the Agency.

V. ACTIONS TAKEN IN CASE OF RADIATION ACCIDENT

Obligations in the Event of Radiation Accident

Article 34

Any person who finds out about possible danger of increased ionizing radiation exposure of population and environment, is obliged, without postponing, to inform the ministry authorized for emergency situation and civilian safety, the Agency and other authorities.

A legal person or entrepreneur responsible for radiation accident is obliged, without postponing, to organize and carry out foreseen measures and procedures in case of accident and to mobilize people and means.

The obligation referred to in paragraph 2 hereof relates to legal persons or entrepreneurs not responsible for radiation accident, if consequences of the accident occur in their activity area.

Early Warning

Article 35

For the purpose of timely discovery of radiation accident that may produce state of emergency, and puts in danger or may endanger people's health and life as well as the environment, the ministry authorized for emergency situations and civilian safety shall establish the system of early warning, ensuring continuous measurement of gamma radiation ambient dose rate in the air.

According to the National Strategy for states of emergency, the ministry authorized for emergency situations and civilian safety, in cooperation with competent authorities, shall issue the National Action Plan for actions taken in the event of such radiation accident that may cause state of emergency.

National Action Plan

Article 36

The National Action Plan for actions taken in the event of such radiation accident that may cause state of emergency, in accordance with international Conventions.

The Early Warning Programme, issued by the ministry authorized for emergency situations and civilian safety, in cooperation with the Ministry, makes a constituent part of the Plan referred to in paragraph 1 of this Article.

The programme referred to in paragraph 2 of this Article contains number and distribution of measurement points, network of measurement points, sampling and measuring methodology, time limits, manner of data delivery and public informing.

The measurements expenses for early warning of radiation accident that may produce emergency state shall be provided from the Budget of Montenegro.

In case it is established that there is a hazard of radioactive contamination spreading from the territory of Montenegro towards neighbouring states, the Government shall inform thereof the International Atomic Energy Agency and the competent authorities of neighbouring states.

VI. RADIOACTIVE WASTE MANAGEMENT

Treating Radioactive Waste

Article 37

The holder of licence for performing radiation activities is obliged to collect, store, treat, record and dispose radioactive waste in the prescribed manner and under prescribed conditions, till its delivery to the legal person laid down in Article 38 of this Law.

The holder of the licence referred to in paragraph 1 of this Article is obliged to:

- 1) assure that the radioactive waste developed during the radiation activity is the least possible regarding activity and volume;
- 2) assure that facilities and rooms where radioactive waste is collected, kept, recorded and stored conform with technical, safety and other prescribed conditions providing ionizing radiation protection to people and the environment;
- 3) take measures for prevention of radioactive waste causing environmental contamination;
- 4) provide stored radioactive waste;
- 5) apply protection measures for radioactive waste management in Montenegro respecting internationally acknowledged criteria, standards and guidelines.

The holder of licence referred to in paragraph 1 of this Article is obliged to bear expenses of radioactive waste storage.

The expenses for storing orphan ionizing radiation sources and radioactive waste shall be covered from the Budget of Montenegro.

In case the owner referred to in paragraph 4 of this Article is determined subsequently, the State shall claim compensation for storing expenses.

More detailed conditions laid down in paragraph 2 of this Article and the manner of radioactive waste collecting, keeping, treating, recording and disposing shall be prescribed by the Ministry.

Storing of Radioactive Waste

Article 38

Radioactive waste, till establishing conditions for its disposal, shall be stored with a legal person holding the licence for radioactive waste storage management.

The legal person referred to in paragraph 1 of this Article is obliged to submit to the Agency the request for issuing the licence.

Based on meeting the prescribed requirements, the Agency shall issue the licence referred to in paragraph 1 of this Article.

The licence shall be issued by a decision, within 30 days from the day of submitting the request for issuing the licence.

The licence holder referred to in paragraph 1 of this Article is obliged to keep records on radioactive waste and to submit data from these records to the Agency within time limits and in manner prescribed by the Agency.

The expenses of maintaining the storage referred to in paragraph 1 of this Article shall be covered from the Budget of Montenegro.

Requirements of Storage Management

Article 39

The Agency shall issue licence for Management of radioactive waste storage to the legal person referred to in Article 38 hereof, provided the legal person:

- 1) disposes with adequate number of permanent employees with prescribed professional qualification and trained for carrying out measures of ionizing radiation protection and possess adequate working experience;
- 2) ensures that facilities and rooms where radioactive waste is stored, kept and recorded are in compliance with technical, safety and other prescribed requirements providing protection of people and environment against ionizing radiation;
- 3) secures the stored radioactive waste and takes all protection measures for prevention of radioactive waste causing environment contamination above prescribed limits, respecting internationally acknowledged criteria, standards and guidelines;
- 4) has a plan for action in case of radiation accident that may cause case of emergency, in compliance with health and safety methodology;
- 5) disposes with adequate number and type of instruments, devices and equipment necessary for performing these activities.

More detailed requirements laid down in paragraph 1 of this Article and the manner of radioactive waste storing, keeping, treating and disposing, as well as necessary documents for radioactive waste storage management shall be prescribed by the Ministry.

Highly Radioactive Waste

Article 40

Import, owning and using such radiation sources that after expiry of time foreseen for exploitation present highly radioactive waste is not allowed, unless an indisputable evidence is obtained that the source, after the expiry of the time shall be returned to the supplier outside Montenegro or shall abandon Montenegro in other way.

VII. TRADE IN IONIZING RADIATION SOURCES AND RADIOACTIVE MATERIALS

Trade Licence

Article 41

Trade in ionizing radiation sources and radioactive materials may perform such legal person or entrepreneur to whom the Agency issues the licence for trade in ionizing radiation sources and radioactive materials.

The legal person or entrepreneur referred to in paragraph 1 of this Article is obliged to submit to the Agency a request for issuing licence to perform trade in ionizing radiation sources and radioactive materials.

Based on meeting the prescribed requirements, the Agency shall issue the licence referred to in paragraph 1 of this Article.

The licence shall be issued by decision, within 30 days from the day of submittal of the request for licence issuing.

Trade in ionizing radiation sources and radioactive materials may be performed solely for the holder of licence for performing radiation activity referred to in Articles 21 and 23 of this Law.

Trade Requirements

Article 42

The Agency shall issue the licence to a legal person or entrepreneur trading in ionizing radiation and radioactive materials if measures prescribed by this Law are taken, and if such trade is performed in accordance with acknowledged international conventions.

The Agency shall issue the Licence for trade in ionizing radiation sources and radioactive materials to a legal person or entrepreneur if:

- 1) facilities and rooms where trading in ionizing radiation sources or radioactive material is performed comply with technical, security and safety, sanitary and other prescribed requirements ensuring health protection of people and the environment against ionizing radiation;
- 2) there is an employee in charge with protection against ionizing radiation;
- 3) persons operating ionizing radiation sources are provided with adequate ionizing radiation means of protection, as well as equipment for radiation measurements;
- 4) all persons operating ionizing radiation sources are provided with prescribed professional qualification and satisfy prescribed health requirements for work with ionizing radiation sources;
- 5) certificate on technical/technological integrity of ionizing radiation source is obtained by the competent authority;
- 6) there is an Instruction for action in case of radiation accident;
- 7) radioactive materials, x-ray devices or other devices producing ionizing radiation are secured in accordance with prescribed requirements for their trading.

Detailed requirements for trading in ionizing radiation sources and trading in radioactive materials and contents of the requirements and necessary documents that legal persons referred to in paragraph 1 and 2 of this Article must satisfy shall be prescribed by the Ministry.

Trade in ionizing radiation sources and radioactive materials

Article 43

The Agency shall issue the licence to a legal person or entrepreneur referred to in Article 42 of this Law performing export of ionizing radiation sources and radioactive materials only if the importer obtains an approval for such import from the competent authority of the state into which such export is performed.

If the exporter referred to in paragraph 1 of this Article must perform relapse of ionizing radiation sources and radioactive materials at the request of competent authority of the export state, the Agency shall issue the licence to such exporter.

Trading in ionizing radiation sources and radioactive materials may be performed solely across such border crossings where inspection monitoring is organized.

The importer of ionizing radiation sources and radioactive material is obliged to inform the Agency about arrival of goods at the border crossing within time period not shorter than five days and not longer than 60 days from the day of receipt of the goods.

Radioactivity Control of Goods being Imported, Exported and in Transit

Article 44

Drinking water, food, animal fodder, medicines, tobacco and tobacco products, cosmetics, toiletries and other general use products, as well as construction materials, ores, metal products, raw materials and other goods shall not be put on sale if they contain radionuclide content exceeding prescribed limits.

Allowed limits of radionuclide content, methods and manner of radioactivity control for products referred to in paragraph 1 of this Article shall be prescribed by the Ministry, in cooperation with competent ministries.

Trade in goods referred to in paragraph 1 hereof, not containing radionuclides above the prescribed limits may be performed solely at such border crossings where inspection monitoring is organized.

Detection and Prevention of Unauthorized Trade

Article 45

For the purpose of detection and prevention of unauthorized trade of radioactive and nuclear material across the Montenegrin border, ionizing radiation monitors shall be placed at border crossings, in accordance with the Act issued by competent authority for internal affairs and public management.

The Agency shall provide expert technical support in implementation of activities laid down in paragraph 1 hereof.

Expenses for placing ionizing radiation monitors laid down in paragraph 1 hereof shall be covered from the Budget of Montenegro.

Application of Law on General Administrative Procedure

Article 46

In the procedure of issuing licenses referred to in Articles 21, 32, 38 and 41 of this Law, the law regulating general administrative procedure shall be applied, unless differently regulated by this Law.

VIII. SUPERVISION

Administrative Supervision

Article 47

Supervision over implementation of this Law and of regulations adopted based on this Law shall be performed by the Ministry, unless differently regulated by this Law.

Inspection supervision over implementation of this Law and of regulations adopted based on this Law shall be performed by the Agency and other inspection authorities within their competences, in accordance with this Law and the law regulating inspection supervision.

Rights and Obligations of Inspector

Article 48

When performing supervision over implementation of ionizing radiation protection measures the inspector has rights and obligations to:

- order deflection of flaws regarding operation with ionizing radiation sources;
- suspend the operation of certain ionizing radiation sources and radioactive materials and revoke the licence for performing radiation activities until prescribed requirements are met;
- ban trade and use of ionizing radiation sources and radioactive materials until prescribed requirements are met;
- order deflection of determined flaws and fulfilment of prescribed requirements to legal persons performing activities in the area of ionizing radiation protection;
- ban activities of legal persons authorized for ionizing radiation protection till determined flaws are remedied i.e. till prescribed requirements are met;
- ban trade in ionizing radiation sources and radioactive materials over the Montenegrin border till prescribed requirements are met;
- order deflection of determined flaws and fulfilment of prescribed requirements for measurements at border crossings;
- order decontamination of environment;

- order keeping prescribed records;
- order prescribed disposal of radioactive waste;
- order meeting prescribed requirements and deflection of other flaws for which it is found that they may cause harmful effects to people's health or to the environment.

IX. PENALTY CLAUSES

Violation of Law

Article 49

Any legal person or entrepreneur shall be imposed fine in the amount of hundred percent up to three hundred percent of minimum national monthly wage for:

- 1) failing to submit to the Agency the report on radioactivity monitoring in the environment within due time, and in case of radiation accident, or upon request of the Agency, immediately (Article 10 item 1);
- 2) failing to execute prescribed measurements for estimation of ionizing radiation exposure level of professionally exposed persons, persons attending schools and performing scientific research, patients and inhabitants (Article 11 paragraph 1);
- 3) performing systematic use of ionizing radiation sources in diagnostic purposes contrary to prescribed requirements (Article 13 paragraph 3);
- 4) failing to keep records on performed measurements referred to in Articles 11 and 13 and to submit a report on the measurements to the Agency (Article 14 paragraph 1);
- 5) failing as professionally exposed persons to meet the requirements for operation with ionizing radiation sources pursuant to provisions of Article 15 hereof;
- 6) allowing ionizing radiation exposure to persons referred to in Article 18 of this Law or fails to prevent ionizing radiation exposure above prescribed limits for population (Article 18);
- 7) installing radioactive lightning protection rod or ionizing smoke detectors having ionizing radiation source in gaseous state or ionizing radiation source whose break-up products are in gaseous state (Article 19 paragraph 3 and 4);
- 8) failing to obtain from the Agency the certificate on record of a low radiation risk ionizing radiation source (Article 20 paragraph 1);
- 9) performing radiation activity without approval by the Agency (Article 21 paragraph 1);
- 10) failing to establish and implement Programme for quality security and control of measures for ionizing radiation protection (Article 27 paragraph 1);
- 11) causing contamination, and fails to inform the Agency immediately and to implement decontamination procedure in a prescribed manner. (Article 28 paragraph 1);
- 12) failing to provide such protection level that will prevent exposure above the limits prescribed for population (Article 30);
- 13) failing to keep records in case of increase of natural radionuclide concentration above the prescribed limits and to submit these records to the Agency annually (Article 31 paragraph 1);
- 14) performing testings, measurements, control and other expert activities without the licence issued by the Agency (Article 32 paragraph 1);
- 15) failing to report any change in meeting requirements according to which the licence was issued by the Agency. (Article 33 paragraph 3);
- 16) failing to collect, secure, record and store in the prescribed manner and under prescribed conditions, till its delivery to the legal person laid down in Article 38 (Article 37 paragraph 1);
- 17) managing the radioactive waste storage without the licence issued by the Agency (Article 38 paragraph 1);

18) failing to keep records on radioactive waste and to submit the data from these records to the Agency within time limits and in manner prescribed by the Agency (Article 38 paragraph 5);

19) performing trade in ionizing radiation sources and radioactive materials without the licence issued by the Ministry (Article 41 paragraph 1);

20) putting on sail the products laid down in Article 44 containing radionuclides above prescribed limits (Article 44 paragraph 1).

For violation referred to in paragraph 1 of this Article, the responsible person of the legal person shall be imposed a fine of minimum five times up to twenty times the minimum monthly wage in Montenegro.

X. TRANSITIONAL AND FINAL PROVISIONS

Secondary Legislation

Article 50

Secondary legislation for implementation of this Law shall be adopted within one year from the day of this Law's entering into force.

Till the adoption of the regulations referred to in paragraph 1 of this Article, secondary legislation adopted based on Law on Ionizing Radiation Protection shall be applied ("Official Gazette of FRY", No. 46/96), unless they are in collision with this Law.

Started Procedures

Article 51

Procedures started before this Law entering into force shall be completed in accordance with the Law on Ionizing Radiation Protection (Official Gazette of the Federal Republic of Yugoslavia 46/96).

Coordination of Legal Persons' Operation

Article 52

Legal persons and entrepreneurs are obliged to coordinate their business with this Law within six months from the day of adopting the Acts referred to in Article 50 of this Law.

Legal persons and entrepreneurs owning, respectfully using the ionizing radiation sources referred to in Article 19 paragraph 3 of this Law are obliged to remove them within two years from the day of this Law entering into force.

The expenses of removal of ionizing radiation sources referred to in paragraph 2 of this Article shall be covered by the legal person or entrepreneur owning, i.e. using such sources.

Reporting Sources

Article 53

Legal persons and entrepreneurs performing radiation activity are obliged to report to the Agency all ionizing radiation sources they possess, i.e. use, within six months from the day of this Law entering into force.

Cessation of Regulation Validity

Article 54

On the day of this Law entering into force, Law on Establishment of Authorities for Performing Activities in the Field of Ionizing Radiation Protection (Official Gazette of the Socialist Republic of Montenegro 13/89) shall cease to have effect and Law on Ban on Construction of Nuclear Power Plants (Official Gazette of the Federal Republic of Yugoslavia 12/95) shall cease to apply as well as Law on Protection against Ionizing Radiation (Official Gazette of the Federal Republic of Yugoslavia 46/96).

Entering into Force

Article 55

This Law shall enter into force on the eighth day following that of its publication in the Official Gazette of Montenegro.

SU-SK No 01-90/20

Podgorica, 27 July 2009

The 24th Parliament of Montenegro

The Speaker,

Ranko Krivokapić, m.p.