

REGULATION FOR SAFE MANAGEMENT OF RADIOACTIVE WASTE

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Chapter One

GENERAL PROVISIONS

Art. 1. This Regulation sets out the requirements, standards and rules for safety which apply to the activities and facilities for radioactive waste (RAW) management.

Art. 2. (1) This Regulation shall apply to:

1. Management of any solid waste that contains radionuclides in concentrations or activities above the levels for the release of radioactive material from regulatory control, established pursuant to Art. 11, par. 3, item 1 of the Regulation on Basic Standards of Radiation Protection, adopted by a Decree № 229 of the Council of Ministers in 2012 (SG issue. No. 76 of 2012);

2. Management of liquid and gaseous radioactive waste that are not released as authorized discharges.

(2) This Regulation shall not apply to:

1. Management of spent nuclear fuel, if it has not been declared as radioactive waste pursuant to Art. 75 of the Act on the Safe Use of Nuclear Energy (ASUNE);

2. Released from regulatory control under the ASUNE;

3. Permissible liquid and gaseous discharges;

4. Waste from the mining and milling industries;

5. Transport of waste off the site of the nuclear facility.

(3) The construction and commissioning of facilities for management of RAW is done in accordance with the applicable requirements of the Regulation on Ensuring the Safety of Nuclear Power Plants, adopted by a Decree № 172 of the Council of Ministers in 2004 (published SG No. 66/2004, as amended and supplemented in No. 46/2007, No. 53/2008 and No. 5/2010).

(4) The requirements for the decommissioning of facilities for treatment and/or storage of radioactive waste have been defined by the Regulation on Safety during Decommissioning of Nuclear Facilities, adopted by a Decree № 204 of the Council of Ministers of 2004 (SG. 73/2004).

Chapter Two.

NATIONAL STRATEGY

Art. 3. (1) The management of waste is carried out according to the Strategy for management of spent nuclear fuel and radioactive waste, adopted by the Council of Ministers pursuant to Art. 74 of the ASUNE hereinafter referred to as the "national strategy".

(2) The National Strategy applies to all types of radioactive waste, as well as to all stages in their management - from generation to disposal.

(3) The National Strategy is reviewed and updated periodically, taking into account as deemed appropriate the technical and scientific progress as well as the recommendations, lessons learned and best practices from peer reviews.

(4) The National Strategy includes:

1. the common objectives of the national policy on radioactive waste management;
2. the main stages and specific deadlines for their completion taking into account the leading objectives, as set in the national strategy;
3. inventory of all radioactive waste and forecasts of future quantities, including those from decommissioning, where their location is clearly indicated and the classification pursuant to art.6 is applied;
4. concepts or plans and technical solutions for the management of radioactive waste from generation to disposal;
5. concepts or plans for the post-closure period of the life cycle of the disposal facility, including the period during which an appropriate control is maintained and the means that are used to store information on the facility in a long term perspective;
6. scientific research, development and demonstration activities necessary for the implementation of the decisions on waste management;
7. responsibility for the implementation of the national strategy and key indicators to monitor the progress on its implementation;
8. cost estimates for the implementation of the national strategy, the basis and assumptions used for this assessment; the assessment must take into account the expected evolution of costs over time;
9. the funding schemes used;
10. international agreements in the field of radioactive waste management, including on the use of disposal facilities.

(5) The National Strategy should provide mechanisms and responsibilities, so that the information necessary for the management of radioactive waste will be available to the

responsible personnel and the population. Information is made public in accordance with the national legislation and international obligations, provided that this does not jeopardize other interests recognized in the national legislation or under international obligations.

(6) The national strategy should establish conditions so that the population should have the possibility to express freely their views and concerns on matters pertaining to radioactive waste management.

(7) The national strategy should include conditions that RAW is disposed of in a national repository, unless there is an enacted agreement to use a disposal facility in another country.

Chapter Three

MAIN OBLIGATIONS OF THE LICENSEE

Art. 4. (1) Activities on waste management can be carried out solely by a legal entity, which has received the appropriate license and/or permit, hereinafter referred to as the "licensee".

(2) The licensee assumes full responsibility for the safe management of RAW from the time of its generation until their release from regulatory control under the ASUNE or until their transmission to the State Enterprise "Radioactive Waste".

(3) The licensee must establish a safety policy, which should ensure priority to safety in waste management, as well as an organizational structure to ensure the implementation of the safety policy, with clearly defined responsibilities and levels of authority.

(4) The licensee must comply with the terms and conditions contained in the issued licenses and permits.

Art. 5. (1) The licensee shall ensure the following, namely:

1. generation of waste at a reasonably achievable minimum in terms of both activity and volume by means of suitable arrangements for the design and practice of operation and decommissioning, including recycling and the reuse of materials;

2. safe management of radioactive waste, including long-term, with elements of passive safety;

3. applying of a graded approach;

4. sufficient subcriticality and removal of residual heat;

5. maintaining of the effects of ionizing radiation upon the personnel, population and the environment as low as reasonably achievable;

6. implementation of evidence-based and documented process for decision making for all stages of RAW management;
7. characterization of waste;
8. bringing the waste to a safe passive form for storage and disposal in the shortest achievable time after their generation;
9. operation of facilities and implementation of the activities on management of RAW based on documented and approved limits and conditions of operation;
10. minimizing the final volumes of RAW for disposal;
11. reporting the relationships between all stages of generation and management of RAW;
12. application of the criteria for acceptance of waste;
13. traceability of RAW at all stages of its management;
14. sufficient financial resources needed to implement activities on waste management;
15. implementation only of those activities on management of RAW, which are pre-authorized by the Chairman of the Nuclear Regulatory Agency (NRA).

(2) The licensee is obliged to regularly assess, verify and continuously to improve within the reasonably achievable, the safety of the facility or the activity on RAW management in a systematic and verifiable manner. This is achieved by an appropriate safety assessment, other arguments and evidence, the extent of the safety demonstration corresponds to the complexity of the operations and the extent of the hazards associated with RAW and the relevant facilities and activities.

(3) The licensee is obliged to implement measures to prevent accidents and mitigate their consequences, including verification of the physical barriers and administrative procedures which in the case of their disruption could cause a situation in which the personnel and population would be significantly affected by the effects of ionizing radiation.

Chapter Four

CLASSIFICATION OF RADIOACTIVE WASTE

Art. 6. (1) A classification of RAW is introduced, which is based on the separation of solid RAW into categories and subcategories and is aimed at their long-term safe management and disposal.

(2) In accordance with the activity and their specific characteristics, solid RAW is classified as follows:

1. category 1 - waste containing radionuclides with low activity, which do not require the implementation of measures for radiation protection or do not need a high level of isolation and detention; RAW from this category is further divided into:

a) category 1a - waste that meets the levels for release and clearance from regulatory control under the ASUNE;

b) category 1b - very short-lived waste containing mainly radionuclides with short half-life (not more than 100 days), which activity decreases below the levels for release and clearance from regulatory control under the ASUNE as a result of appropriate storage on the site for a limited period of time (usually not more than several years);

c) category 1c - very low level waste with levels of specific activity exceeding by a minimal value the levels for release and clearance from regulatory control under the ASUNE and with a very low content of long-lived radionuclides, which represent a limited radiological risk; for this category of waste the application of specific measures for radiation protection are not required or such for isolation and detention;

2. category 2 - low and intermediate level waste: RAW containing radionuclides in concentrations that require measures for reliable isolation and retention, but do not require special measures for heat removal during storage and disposal; RAW from this category is further divided into:

a) category 2a - low and intermediate level waste containing mainly short-lived radionuclides (with a half-life not longer than that of cesium-137) as well as long-lived radionuclides at significantly lower levels of activity, limited for the long-lived alpha-emitters under $4 \cdot 10^6$ Bq/kg for each individual package and a maximum average value for all packages in the respective facility of $4 \cdot 10^5$ Bq/kg; for such RAW reliable isolation and detention is required for up to several hundred years;

b) category 2b - low and intermediate level waste containing long-lived radionuclides at activity levels of long-lived alpha emitters, exceeding the limits of category 2a;

3. category 3 - high-level waste: RAW with such a concentration of radionuclides in which heat removal must be taken into account when it is in storage and disposal, for this category a higher level of isolation and detention is needed compared to the low and intermediate level waste, through disposal in deep, stable geological formations.

(3) The classification pursuant to par. 2 applies to liquid and gaseous RAW depending on the characteristics and form of the suitable for disposal solid RAW that are expected to be generated after the conditioning of liquid and gaseous waste. When in the country there is no

technology available for conditioning of liquid or gaseous RAW, the classification shall be made taking into account the best modern technologies for conditioning.

(4) The classification pursuant to par. 2 does not take into account the non-radioactive hazardous constituents of the waste and their potential non radiological impact.

Art. 7. (1) According to the methods and approaches to the treatment of RAW, the licensee may introduce additional subcategories of RAW, which will support the management activities, and the operational use of the facility.

(2) The additional subcategories under par. 1 must be developed in such a way so as not to contradict the basic classification pursuant to art. 6 and to be substantiated in the programme pursuant to art. 12.

Chapter Five.

RADIATION PROTECTION REQUIREMENTS

Art. 8. For activities and facilities for RAW management, the following dose constraints are followed, namely:

1. the individual effective dose for the respective critical group of members of the population resulting from management activities of RAW and/or following the normal operation of all nuclear facilities on a single site can not exceed 0.15 mSv per year for the new facilities and 0,25 mSv per year - for existing facilities;

2. the individual effective dose for the respective critical group of members of the population resulting from a surface disposal facility for RAW after its closure can not exceed 0,1 mSv per year;

3. the individual effective dose for the respective critical group of members of the population as a result of a facility for geological disposal of RAW after its closure can not exceed 0,3 mSv per year.

Art. 9. In case of a design basis accident in a facility for radioactive waste management the assessed individual effective dose for the respective critical groups of the population on the border of the site cannot exceed 1 mSv per year.

Chapter Six

GENERATION AND TREATMENT OF RADIOACTIVE WASTE

Art. 10. (1) The licensee is obliged to implement measures to reduce the generation of RAW and to avoid their accumulation in a non processed form on the site.

(2) The licensee is obliged to:

1. apply technologies and methods, appropriate to maintain the generation of RAW to the reasonably achievable minimum in terms of their activity and volume;
2. prevent the spreading of radioactive contamination in the facility;
3. prevent the mixing of radioactive with non radioactive waste;
4. classify and sort the waste according to their radiological, physical and chemical characteristics and taking into account the provided options for further processing;
5. implement processing technologies to reduce the volume of radioactive waste;
6. perform decontamination based on analysis "cost/benefit";
7. provide appropriate conditions for storage of RAW subject to subsequent treatment, release from regulatory control or disposal.

(3) In accordance with the requirements pursuant to par. 1 and in order to ensure the subsequent management of disused sealed radioactive sources of ionizing radiation, the licensee is obliged to:

1. make an inventory of radioactive sources at least once an year in order to identify the sources that are not used regularly and are out of use;
2. include the disused sealed radioactive sources of ionizing radiation in the amount of radioactive waste;
3. undertake the measures that can be implemented for the return of the disused source to its supplier before reporting this source as radioactive waste;
4. ensure the continuity of surveillance after the radioactive sources have become obsolete;
5. submit timely all disused radioactive sources to the licensed facility for subsequent management unless the license is otherwise defined.

(4) The requirements pursuant to par. 1 must be considered at the stage of design, construction, operation and decommissioning of the nuclear facility as well as at the selection of appropriate methods, processes, technologies and materials for production of the equipment and the development of operational procedures.

Art. 11. (1) The RAW generated are treated timely for their adapting into a passively safe condition in order to avoid their spilling and scattering in the course of their handling during storage and disposal.

(2) The licensee is required at each stage of the management of RAW to apply methods and procedures for processing of RAW, facilitating their subsequent management.

(3) The choice of a method for processing of RAW should ensure that the resulting form of RAW, unpacked or packed meets the acceptance criteria for subsequent management and does not limit the possibilities for subsequent disposal.

Art. 12. (1) The licensee of a nuclear facility develops a programme for management of RAW, which describes and justifies the taken and planned activities on management of all generated RAW until their disposal, or release from regulatory control.

(2) The programme pursuant to par. 1 must contain as a minimum the following, namely:

1. scope and purpose of the programme;
2. evaluation of the sources, streams and characteristics of the generated RAW, including the disused sealed radioactive sources of ionizing radiation;
3. description of the selected management option for each stream of RAW, including a schedule of the activities on processing, storage and disposal and/or release from regulatory control under the ASUNE;
4. justification of the selected option for processing and storage, including analysis of the alternatives, criteria for selection of an option, the carried out fundamental assumptions and the availability of possibilities for disposal;
5. demonstrating compliance with the national policy and strategy for management of RAW and with the safety requirements for the management of RAW as defined in the ASUNE and in the regulations for its implementation;
6. principal risks and uncertainties identified by the programme, and evaluation of their impact upon its implementation;
7. description of the administrative organization established to implement the programme;
8. assessment of costs and sources of funding for the programme;
9. requirements for maintaining records of the implementation of the programme.

(3) The programme pursuant to par. 1 is reviewed in case of occurrence of significant changes in the methods, technologies and procedures used for RAW management and in case of change in the regulatory requirements for safety, but at least once every three years.

(4) If transfer of RAW to another licensee is envisaged, then the programme pursuant to par. 1 as well as its amendments shall be agreed with him.

Art. 13. (1) During preliminary treatment the waste is collected and sorted according to their characteristics that are important for their subsequent storage and processing,

including through separation of radioactive and non-radioactive streams and extraction of materials for recycling and reuse.

(2) During the processing of RAW, the requirements for reduction of the volume and/or extraction of radionuclides should be taken into consideration, as well as the change in their characteristics for facilitating their subsequent storage and/or conditioning.

(3) Radioactive waste is conditioned to evolve into a form that ensures the following, namely:

1. Physical and mechanical stability of the form of RAW and chemical compatibility between the waste, matrix and the container;

2. maximum homogeneity in the form of RAW;

3. minimum clear space in the container;

4. low level of the leaching rate of the form of RAW;

5. control over the content of complex formative and organic agents.

(4) the conditioned RAW must meet the acceptance criteria for storage and/or disposal.

(5) The licensee shall develop and implement technical specifications for the packages RAW, compliant with the requirements for handling and transportation and with the criteria for acceptance for storage and/or disposal.

Chapter Seven

STORAGE OF RADIOACTIVE WASTE

Art. 14. (1) Radioactive waste is stored in a manner that ensures adequate isolation from the environment and the population for the entire planned period of storage and facilitating the subsequent stages in its management.

(2) As far as it is practicable to be applied, RAW shall be stored in accordance with the following requirements for passive safety:

1. radionuclides should be in an immobilized form;

2. the form of RAW and the container for storage should be physically and chemically stable in the storage environment.

(3) Radioactive waste subject to subsequent release from regulatory control under the ASUNE, should be stored separately from other stored RAW and should be marked appropriately.

Art. 15. (1) The licensee, storing RAW develops and applies acceptance criteria for RAW storage.

(2) The acceptance criteria should be interconnected to the results of the safety assessment of the facility and should include, as a minimum, requirements towards the following, namely:

1. radionuclide composition of the package RAW, including the concentration of radionuclides in the package;
2. the equivalent dose rate of gamma radiation on the surface and at determined distances from the walls of the container;
3. chemical, physical, mechanical and biological properties of the form of RAW;
4. size and capacity of the container to retain its mechanical integrity and to ensure the isolation of RAW in normal and emergency conditions and for the envisaged period of storage.

Art. 16. (1) Radioactive waste is accepted for storage if they meet the acceptance criteria during the inspection of their relevant documentation.

(2) The licensee of the storage facility must have established procedures to carry out an inspection on the site to determine the compliance of RAW with the acceptance criteria for storage.

(3) In case the RAW does not meet the acceptance criteria, the licensee shall require application or shall take measures to eliminate or compensate the discrepancy or shall refuse the acceptance of RAW.

(4) The licensee shall monitor the condition of the stored RAW including, where applicable, through tests, measurements and sampling.

Chapter Eight

DISPOSAL OF RADIOACTIVE WASTE

Art. 17. (1) The disposal of radioactive waste must ensure the protection of the health of the personnel and the population and the environment during the operation of the facility for disposal and after its closure, preventing the uncontrolled distribution of radioactive substances and ensuring their isolation from the biosphere.

(2) The safe disposal of radioactive waste is provided by containing the radionuclides in the package and isolating RAW from the environment for the period of time during which the waste remains dangerous for the population. The immobilization and isolation of radioactive waste from the environment is ensured by successive engineering and natural barriers and means for monitoring of their integrity and efficiency at the maximum use of passive means.

(3) The licensee shall ensure the provision of the main safety functions both in normal evolution of the disposal system and for the planned in the design cases of failure of the disposal system.

Art. 18. The manner of disposal is based on the classification of RAW according to Art. 6 as follows:

1. radioactive waste from category 1a are released from regulatory control - no specific requirements for their possible disposal;

2. radioactive waste category 1b after reaching the levels for exemption and clearance from regulatory control also are subject to release from regulatory control – no specific requirements for their possible disposal;

3. radioactive waste category 1c are subject to conditional release from regulation - can be stored in surface depots in compliance with the conditions for release;

4. radioactive waste category 2a should be buried in surface engineering facilities for the disposal of radioactive waste;

5. radioactive waste category 2b and category 3 must be buried only in geological disposal facilities for radioactive waste.

Art. 19. The acceptance criteria for the disposal of radioactive waste shall be determined in accordance with the safety assessment and as a minimum include requirements for:

1. general and specific activity and radionuclide composition for the type of packaging;

2. form of the waste;

3. dose rate and contamination of the surface of the packaging;

4. content of materials, which may lead to processes such as the generation of gases and/or heat, corrosion and expansion of the packages or to accelerate the migration of radionuclides;

5. amount of free fluid in the packages;

6. content of chemical or biological hazardous substances;

7. flammability and pyrophoricity;

8. dimensions, weight, strength and other mechanical properties, important for the activities related with handling and placement in the facility;

9. markings and identification signs;

10. requirements for the form of RAW, the container for the packed RAW, package RAW and manipulation of RAW, arising from the safety analyzes of the facility.

Art. 20. In a facility for disposal of radioactive waste, are considered for disposal only RAW that undoubtedly meet the acceptance criteria for disposal.

Chapter Nine

FACILITIES FOR RADIOACTIVE WASTE MANAGEMENT

Section I

General provisions

Art. 21. (1) The life cycle of a facility for processing and/or storage of radioactive waste includes the stages of site selection, design, construction, commissioning, operation and decommissioning.

(2) The life cycle of a facility for disposal of RAW includes the stages of site selection, design, construction, commissioning, operation and closure.

(3) The safety of the facility for processing and/or storage of RAW must be provided for their entire life cycle and for the disposal facility – also for the period after its closure.

(4) A graded approach is applied for all stages of the life cycle of a facility for management of RAW. The graded approach is based on the degree of risk which the RAW represent. When applying a graded approach, the maximum possible consequences for the population and the environment are taken into account in case of failure of all protective barriers therefore release to the environment of the entire amount of radioactivity present in the facility.

Art. 22. (1) The safety of facilities for radioactive waste management is ensured by applying the concept of defense in depth, based on the following, namely:

1. system of physical barriers placed between the radioactive material and the environment;

2. system of technical measures and organizational procedures to protect the physical barriers and retain their effectiveness;

3. system of organizational and technical measures to protect the personnel, population and the environment in case of an accident.

(2) The system of physical barriers at each facility shall be determined by the design. The safety of the facility must not depend primarily on a single barrier.

(3) The concept of defense in depth is implemented in the design, commissioning, operation and decommissioning or closure and applies to all operating conditions of the facility.

(4) The safety of a disposal facility for RAW after closure should be ensured fully and solely by the passive engineering and natural barriers.

Section II

Site selection

Art. 23. The characteristics of the site of a facility for management of RAW are treated in accordance with the radiation risk from the facility and must meet the applicable requirements of the Regulation for ensuring the safety of nuclear facilities as well as the specific requirements of the regulation.

Art. 24. (1) The selection of a site for a facility for processing and/or storage of RAW is carried out based on an assessment of the following, namely:

1. quantity, characteristics and location of the existing RAW as well as the forecasts for the generation of radioactive waste;
2. specific characteristics of the site relevant to migration and accumulation of radioactive substances;
3. influence of the factors of natural and anthropogenic character on the safety of the facility;
4. radiological impact of the facility on the population and the environment;
5. possibilities for the application of protective measures for the population in case of an accident in the facility.

(2) The selection of a site for a facility for processing and/or storage of RAW should be done in such a way that the need for transportation of RAW is brought to a minimum.

(3) No additional requirements for characterization of the site of a facility for processing and/or storage of RAW are posed, which meets the following two conditions at the same time, namely:

1. the facility is located on the site of another nuclear facility, which has an issued license for operation pursuant to the ASUNE;
2. the facility is envisaged for management of RAW generated on the same site.

Art. 25. (1) The selection of a site for a facility for disposal of RAW is based on a comparative analysis of at least three alternative sites and is carried out in the following four phases:

1. developing of a concept for disposal and planning of the activities for site selection;
2. data collection and analysis of the areas, which includes the following, namely:

a) an analysis of the regions - an analysis and evaluation of the territory of the whole country is carried out, excluding large areas with unfavourable conditions for locating a facility for disposal of RAW and areas of analysis are identified, which represent large areas with favorable geological and tectonic, geomorphologic (topographic), hydro geological, engineering geological, hydrological, climatic and other characteristics;

b) selection of prospective sites - in the areas of analysis under item "a" are identified the potential sites that meet the criteria for location of a disposal facility and are determined the prospective sites for in-depth study;

3. site characterization – the determined under item 2 sites are researched profoundly and one site is selected;

4. confirmation of the site.

(2) The activities in each phase pursuant to par. 1 are planned and justified in a plan for the respective phase which includes the following, namely:

1. description of the objectives;

2. description of the main activities in their sequence;

3. description of requirements and recommendations of national and international documents which will be implemented during the activities;

4. list and description of the developed procedures, ensuring the practical application of the requirements and recommendations pursuant to item 3;

5. detailed schedule of the activities;

6. program of quality assurance;

7. estimate of the necessary financial resources and sources of funding.

(3) At the end of each phase pursuant to par. 1, a report is prepared with the results of the implementation of the plan under par. 2.

Art. 26. (1) The site of a facility for surface disposal of RAW must meet the following requirements:

1. the geological structure should contribute to the isolation of RAW and for the limiting of the migration of radionuclides to the biosphere, and also to provide stability of the disposal system and to possess the necessary geotechnical characteristics for the construction of the facility;

2. the hydro geological characteristics of the site should have a low speed and long paths of movement of the groundwater with the objective of limiting the migration of radionuclides;

3. the geochemical characteristics of groundwater and the geological environment should contribute to the limited release of radionuclides from the facility and should not significantly reduce the resource of the protective barriers;

4. the site must be located in an area of low tectonic and seismic activity that does not endanger the isolating capacity of the system;

5. processes occurring on the surface of the facility, such as erosion, landslides and flooding as well as extreme weather conditions should not affect the ability of the disposal system to perform the main functions of safety;

6. the site should be positioned in such a way, that the probability of failure of the isolating function of the site as a result of the activities of current or future generations at or in the vicinity thereof should be low.

(2) A facility for the disposal of high level RAW must be located in a suitable geological formation and at a sufficient depth, ensuring the isolation of the radioactive substances from the biosphere and the population for not less than 100 000 years.

(3) In selecting a site for the disposal of RAW, priority have the sites that require a minimum of geological and hydrological studies and are amenable to simple and reliable mathematical modeling.

(4) In the process of site selection is taken into account also the existing road infrastructure for ensuring the transport of RAW to the facility with minimal risk to the population.

(5) The investigation of the sites for disposal of RAW is conducted in such a way so as not to allow reduction of the confining and isolating properties of the natural barriers and not to alter adversely the characteristics of the sites.

Section III.

Design

Art. 27. The design basis determines the necessary qualities of the facility for management of RAW, which ensure that for all operational conditions and design basis accidents the established limits for internal and external exposure of the personnel and the population should not exceed the established limits as well as for the release of radioactive substances into the environment. The design basis includes design limits, operational conditions, safety classification of structures, systems and components (SSC), important assumptions in the design and in some cases special methods of analysis.

Art. 28. (1) The design of the facility for RAW management must take into account the national policy and strategy and should ensure the following, namely:

1. Fulfillment of the purpose of the facility, taking into account the relationships between all stages of generation and management of RAW;

2. Not exceeding the dose limits and restrictions under normal operation, anticipated operational events and design basis accidents, as well as after the closure of disposal facility at normal evolution of the disposal system;

3. The probability of a beyond design basis accident, and in the case of a disposal facility – failure of the functions for detention and isolation as a result of human interference or natural phenomena with a low incidence is reduced to a reasonably achievable minimum;

4. Correspondence of the developed technical solutions for management of RAW with the safety requirements.

(2) The design of the facility for management of RAW must classify the systems, structures and components (SSC) according to their relevance towards safety and should determine the operating conditions and the safety limits.

(3) A graded approach is applied towards the design solutions depending on the risk, which the RAW represent.

(4) The design solutions, technologies and procedures are defined and justified in accordance with the achievements of science and technology and of the internationally recognized operational experience.

Art. 29. (1) The design of the facility for management of RAW should through appropriate technical solutions ensure the prevention of the following, namely:

1. creating conditions for degradation and disruption of the integrity of the physical barriers, leading to failure of a physical barrier;

2. failure of one physical barrier as a result of the failure of another physical barrier.

(2) The design solutions, technologies and procedures must guarantee the retention of radioactive substances within the specified limits under all operating conditions and design basis accidents.

(3) The design of the facility for management of RAW should meet the applicable requirements of Chapter VII of the Regulation for Radiation Protection During Activities with Sources of Ionizing Radiation.

Art. 30 . The design limits shall include as a minimum:

1. criteria for acceptance of RAW;

2. dose limits for all operating conditions, design basis and beyond design basis accidents;

3. criteria for protection of the physical barriers;

4. criteria for liquid and gaseous radioactive discharges.

Art. 31. (1) To determine the boundary conditions in accordance with which are designed, produced and installed SSC important to safety, the initiating events for the expected operating conditions and design basis accidents must be defined in the project.

(2) The list of initiating events should cover the possible internal and external events for all operating conditions of the facility and should include the following, namely:

1. total or partial failure of the SSC;

2. human errors;

3. external events of natural origin or caused by human activity.

(3) The choice of postulated initiating events should be based on the use of deterministic methods and expert assessment and, where applicable – probabilistic methods.

(4) The design of a facility for management of RAW should take into account the following internal events, namely:

1. fire and/or explosion;

2. impact upon SSC as a result of the fall of heavy objects, shocks and others;

3. failure of SSC as a result of internal processes;

4. human errors, leading to loss of control over the technological process;

5. internal flooding due to ruptures and leaks of pipelines, pumps and valves;

6. other possible initiating events leading to disruption of the function of safety.

(5) The design of a facility for management of RAW should take into account the following external events and hazards specific to the site, namely:

1. extreme weather conditions;

2. earthquakes;

3. external flooding;

4. falling down of an average airliner;

5. industrial and transport activities in the vicinity of the site.

Art. 32 . (1) All SSC are classified into SSC important to safety and SSC not related to safety.

(2) For the SSC important to safety shall be determined the following, namely:

1. the applicable standards for design, manufacturing, installation, maintenance and inspection;

2. the degree of reserve, the requirements in terms of emergency power supply and the qualification for operation in normal operation and in emergency conditions;

3. the level of operational capacity which should be taken into account in the deterministic safety analyses.

(3) Structures, systems and components important to safety should withstand the conditions of postulated initiating events with a sufficient margin.

(4) For the determination of cases where it is necessary to implement the principles of diversity, redundancy and independence to achieve the necessary reliability, in the project should be analyzed and taken into account the possibilities for common cause failures.

(5) The failure of SSC which have no relation to safety should not lead to failure of SSC important to safety.

Art. 33. (1) The project will determine the procedures for qualification of SSC important to safety. With the procedures must be ensured the confirmation of the assigned functions for the entire design term of the facility, taking into account also the possible impacts from the environmental conditions (vibration, temperature, pressure, jet flows, aging, irradiation, humidity and the possible combinations thereof) that are expected during the operational conditions and the design basis accidents.

(2) The working conditions of SSC important to safety are imitated by tests and analyses or in a combination of both methods.

Art. 34. When designing a facility for processing of RAW the following requirements should be observed as well, namely:

1. physical separation of SSC important to safety;

2. providing radiation monitoring:

a) of RAW accepted for processing;

b) of the releases into the environment;

3. providing technological control over all operations for processing of RAW to ensure the following, namely:

a) monitoring of the parameters necessary for the management of processes and equipment;

b) protections and interlocks in all modes of operation;

c) functioning of technological systems in accordance with the design basis;

d) correspondence of the form of RAW received and/or packaging RAW with the technical specifications;

4. providing active ventilation systems.

Art. 35. (1) The design of a facility for storage of RAW should contain also technical solutions for the implementation of the following requirements, namely:

1. confinement of radioactive substances within the prescribed limits;
2. maintaining subcriticality (if applicable);
3. ensuring radiation protection by shielding of the direct irradiation and monitoring over the non spreading of radioactive contamination;
4. residual heat removal (if applicable);
5. ensuring a suitable environment for the storage of RAW through passive and/or active ventilation systems;
6. ensuring a possibility for viewing and inspection of the facility and the stored in it RAW;
7. ensuring a possibility for retrieval of the stored RAW and/or packaging RAW at any time;
8. providing a reserve capacity for storage or other technical measures to ensure a possibility for retrieval, inspection, technical maintenance or restoration activities.

(2) The design pursuant to par. 1 should have the inherent properties of passive safety, while the application of active systems to ensure safety must be brought to a minimum.

(3) The design pursuant to par. 1 should justify the lifetime of the facility.

Art. 36. The design for a facility for storage of liquid RAW should envisage technical resources for the following, namely:

1. representative sampling from the volume of the storage tank;
2. monitoring of the technological parameters;
3. separation of the sediments and residues;
4. monitoring over the content of hydrogen (if applicable);
5. protection against overpressure, vacuum and leaks in the equipment;
6. decontamination of storage tanks;
7. maintaining water chemistry regime, preventing intensive corrosion processes in the equipment.

Art. 37. (1) The main design features of the disposal facility are determined based on the assessment of safety during operation and after closure of the facility.

(2) The design of the disposal facility must take into account the results of the site investigations and should determine the following, namely:

1. the criteria for acceptance of waste;

2. the maximum activity - total and as per specific radionuclides, of the RAW for disposal on the site;
3. the composition and structure of the system of engineering barriers;
4. the requirements towards the materials of each barrier;
5. the minimum long term potential of each barrier;
6. the requirements for ensuring subcriticality, if applicable;
7. the maximum permissible specific heat release and the minimum necessary thermal conductivity between the package and the natural barriers, if applicable;
8. the requirements for monitoring and control over the non-proliferation of radionuclides during operation and during the period of active monitoring after the closure;
9. the possibility for retrieval of RAW packages during the stage of operation;
10. the size, location and depth of the facility ensuring the necessary degree of isolation of RAW from the biosphere;
11. temperature and radiation resistance of SSC and of the natural barriers.

Section IV.

Construction and commissioning into operation

Art. 38. (1) The construction and commissioning into operation of the facilities for RAW management is carried out in accordance with the applicable requirements of the Regulation on Ensuring the Safety of Nuclear Power Plants.

(2) The facility for RAW management is commissioned into operation in accordance with the program of the licensee, specifying the activities on verification of the correspondence of the constructed SSC with their design requirements. The program should include tests with imitators of RAW and real RAW.

Section V

Operation

Art. 39. (1) The licensee should ensure the safe operation of the facility in accordance with the requirements of ASUNE and the regulations for its implementation.

(2) During the operation of the facility, the following must be observed, namely:

1. the decisions related to safety shall be preceded by the respective research and consultations;
2. the personnel should be provided with the necessary resources and conditions for implementation of the activities in a safe manner;

3. the implementation of the activities related to ensuring the safety should be constantly monitored;

4. the own and international operational experience and the scientific and technical achievements in the field of nuclear technology must be systematically analyzed and used for continuous improvement of the activities.

(3) During the operation of the facility the licensee shall ensure also engineering support of the activities in order to analyze the behavior of SSC important to safety, justification of the proposed modifications in the design and the operational documentation, analysis of the operating experience and operating events, as well as the effectiveness of the system for management of RAW.

Art. 40. (1) The operation of the facility must be conducted by a sufficient number of personnel who possesses the necessary qualification.

(2) The necessary personnel and their qualifications are analyzed and verified according to a systematic and documented way.

Art. 41. (1) During normal operation of the facility, all physical barriers must be operable.

(2) The operation of the facility must be conducted in accordance with the limits and conditions for operation.

(3) The limits and conditions for operation must be defined and justified on the basis of the design, safety analyses and tests during commissioning into operation and periodically and in case of necessity to be revised in order to reflect the operational experience, the implemented modifications in the SSC important to safety, the new safety analysis and the development of science and technology.

(4) The licensee may establish also administrative control levels which shall be below the operational limits and which should be used as target values for improvement of the operation.

Art. 42. In the course of operation of a facility for management of RAW, the following should be ensured, namely:

1. constant radiation control in the premises and on the site, as well as control over the discharges;

2. periodic radiation control in the area for preventive protection activities and in the surveillance area;

3. incoming control of the accepted for processing or storage RAW for establishing their compliance with the acceptance criteria of the facility, including tests and monitoring of the processed RAW (or RAW packages) before their storage;

4. implementation of the activities on processing and storage of RAW in accordance with written procedures and instructions developed in accordance with the management system;

5. implementation of the activities in case of deviations from normal operation and emergency conditions in accordance with the emergency instructions;

6. conducting diagnostics, technical servicing, maintenance, testing and surveillance of SSC important to safety in accordance with schedules, maintenance and surveillance procedures and instructions for ensuring the design indicators for reliability and performance;

7. implementation of corrective measures to eliminate the lack of correspondence of the processed RAW or of the stored packages with the technical specifications;

8. analysis of the safety significant operational events, reporting them to the NRA and implementing corrective measures to prevent recurrence of operational events;

9. implementation of a program for feedback from operating experience with the purpose of recording, classifying, analyzing and archiving of technological and radiation parameters, failures of SSC, operational events and safety indicators;

10. emergency preparedness;

11. physical protection;

12. traceability of RAW and proper management of records and documentation.

Section VI.

Closure

Art. 43. (1) The closure of a facility for disposal of RAW is carried out in accordance with a detailed plan for closure of the facility.

(2) The plan pursuant to par. 1 must contain the following, namely:

1. description of the facility – site, areas with special statute, SSC important to safety, level of radioactive contamination of the SSC and the components of the environment;

2. operating history of the facility - a description of important operating circumstances and events related to the closure;

3. list of applicable standards;

4. complete inventory of the located in the facility RAW;

5. schedule of the stages and activities on the closure;

6. description of the decontamination and rehabilitation activities, referring to the radioactively contaminated SSC, soil and underground water;

7. classification of SSC in terms of their importance to safety in the course of the activities during closure;

8. description of the necessary major modifications in the existing SSC including the introduction of new SSC, if required specifically for the purpose of closure;

9. programme and schedules for surveillance and maintenance of SSC which have to be available in the process of closure;

10. description of the existing and planned technologies and technical means for dismantling of SSCs and in case of necessity their decontamination;

11. program for management of operational RAW, including until their disposal;

12. description of the management system, including for personnel management;

13. program for radiation protection of the personnel and the population and protection of the environment;

14. description of the organization and responsibilities for emergency planning and preparedness;

15. duties and responsibilities for ensuring the physical protection of the facility;

16. updated estimate of the costs for closure of the facility, mechanism for funding and available resources;

17. description of the monitoring programs, methods and technical means for inspection of the site after completing the process of closure;

18. defining the end point of the stage of closure of the nuclear facility;

19. schedule for reporting to the NRA of interim and final results from the closure.

Art. 44. (1) The activities on the closure of disposal facilities for RAW should include the following, namely:

1. decontamination and dismantling or sealing of all SSC used in the handling of RAW;

2. disposal of RAW generated as a result of the activities pursuant to item 1;

3. bringing the facility to the designed passive state for ensuring the long-term safety;

4. introduction of a comprehensive system for radiation monitoring;

5. updating and archiving of all operational information.

(2) The closure of a facility for disposal of RAW is based on a technical project for implementation of the activities and on a safety assessment of the facility after its closure.

Section VII.

Monitoring after closure

Art. 45. (1) The responsibilities for implementing the monitoring after the closure of the facility for disposal of RAW are determined by the decisions pursuant to Art. 74, par. 3 of the ASUNE or by a separate decision of the Council of Ministers.

(2) In the decisions pursuant to par. 1 shall be designated also the persons responsible for the determining of the necessity and for the implementation of active remediation activities and corrective measures on the site of the facility for disposal of RAW.

Art. 46. (1) The monitoring after the closure of the facility for disposal of RAW includes the following, namely:

1. active monitoring - by conducting monitoring, access control, maintaining the efficiency of certain SSC and maintenance of the infrastructure of the facility;

2. passive monitoring - through the application of administrative measures for restrictions with regard to the use of the site and adjacent areas.

(2) The duration of the post-closure monitoring is determined depending on the characteristics of the RAW and of the site, of the facility design, as well as on the demographic factors and is justified in the safety assessment of the facility.

(3) The duration of the active monitoring over a facility for surface disposal cannot be less than 50 years, and the total duration of the control is not expected to exceed 300 years.

Chapter Ten

MANAGEMENT SYSTEM

Art. 47. (1) The licensee shall document and implement an integrated management system that ensures the safety in the management of RAW.

(2) The management system should describe and systematize the actions for the implementation of the safety requirements in compliance with all other applicable requirements for the activities of the organization, so as to guarantee the priority of safety.

(3) The management system should cover the entire life cycle of the facility, as well as the entire length and scope of the activities performed on the management of RAW in all operational conditions and emergency situations.

Art. 48. (1) The licensee shall determine and distribute the policies of the organization in the various aspects of the activities with which to give the highest priority to safety and to undertake a clear commitment towards its continuous improvement. The implementation of the policies must be ensured by setting strategic objectives, developing of strategies and plans

and specific measurable objectives, including those related to improving the management of radiation risk.

(2) The licensee shall carry out the following, namely:

1. identify, disseminate and implement individual values, institutional values and expectations about the behavior of the personnel in terms of safety and to ensure that they are perceived and respected by all members in the organization;

2. provide sufficient resources (personnel, financial resources, infrastructure and working environment, information and knowledge) to ensure safety at every stage of the lifecycle of the facility and the implementation of the activities that constitute a radiation risk;

3. specify requirements for the competence of the personnel at all levels and provide training for the personnel to achieve and maintain the necessary competence.

(3) The management system should be based on substantiated organizational and management structure with clearly defined responsibilities, powers and links of interaction that are consistent with the policies and objectives of the organization and manage the process of decision-making in the everyday work.

Art. 49. (1) The processes of the management system must be developed, implemented, assessed and continuously improved. The coherence and synergies between them should be fixed so as to ensure the comprehensiveness of the control over their implementation and consistency in the process of decision making, including consideration of safety issues in making economic decisions.

(2) The requirements of the management system should be implemented in a graded approach in accordance with defined and documented principles and criteria that take into account the possible hazards and the extent of potential impact of the process or activity on safety.

(3) For each process must be determined the necessary inspections, tests, verification and validation, as well as the acceptance criteria, including the stages of implementation, the responsible persons or groups who are not directly involved in the implementation of the process.

(4) Any process, which may affect safety, must be performed under controlled conditions using validated and comprehensive internal documents, and the results must be recorded and evaluated. The documents must be appropriately validated and to undergo periodic review for relevance and applicability.

Art. 50. In the scope of the management system must be regulated the following as a minimum:

1. management of RAW and operation, technical maintenance and testing of SSC required for the management of RAW;

2. characterization of RAW in terms of: origin, flows, quantities, classification, methods for handling, storage, disposal; radiation, chemical, physical, mechanical, thermal, biological characteristics and properties;

3. establishment of criteria for waste acceptance and implementation of corrective measures in case of non-compliance;

4. inspections and tests during the management of waste, including of the end product for compliance with the technical specifications and acceptance criteria for its subsequent management;

5. monitoring over the storage of the packages, including measures in case of the deterioration of the characteristics of the packages;

6. recording and archiving of the main characteristics of RAW, including the ensuring of traceability of waste through a unique identification of the packages, permanent marking for the entire period of storage and the recording of their location;

7. management of records containing information on the results of activities on management of RAW and the operation of facilities for management of RAW;

8. measures for ensuring radiation protection;

9. management of measuring instruments;

10. configuration management, including the updating of operational records and the relevant training of personnel imposed by the introduced modifications in SSC of the facility and the design documentation;

11. periodic assessment of the safety of the facility.

Art. 51. (1) The management system should include effective measures for control in case of contracting external organizations to carry out certain processes and activities so as to ensure that the products and services that are important to safety meet the established requirements.

(2) The measures pursuant to par. 1 should include: defining the requirements towards the products and services in the delivery documents, as well as the requirements for reporting and resolving inconsistencies; selecting suppliers on the basis of certain criteria and assessment of their performance; obtaining evidence that the products and services correspond to the specified requirements before their use.

Art. 52. (1) The management system should provide conditions for the formation and development of a safety culture based on a set of beliefs and a way of behavior that reflect the proper attitude towards safety and are shared and followed by everybody in the organization, i.e. everyone works in such a way so as to ensure the principle of priority of safety.

(2) The heads of all management levels should demonstrate leadership skills and serve as role models by supporting and observing the accepted values and expected behavior, including in the decision making process, arising and solution of problems, transmission and dissemination of information.

Art. 53. (1) The effectiveness of the management system must be continuously monitored and measured in order to verify its ability to achieve the organization's goals and to determine the need for changes in the policy, objectives, strategies, plans, as well as in the processes and activities in such a way so as to provide improvement in safety in the management of RAW.

(2) The opportunities for improvement should be determined using various mechanisms, including self-assessment, independent assessment, review of the system by the management, management of inconsistencies, feedback from operational experience and use of the achievements and best practices in this field.

(3) The organization must use measurable indicators for monitoring and evaluation of the trends in the processes and for detecting early signs that may lead to the deterioration of the condition of safety with view of undertaking corrective measures following a proactive approach.

(4) The implementation and effectiveness of all planned and undertaken activities for improvement should be monitored and evaluated.

Chapter Eleven

SAFETY ASSESSMENT

Art. 54. (1) The licensee shall conduct safety assessments to assess the compliance of the facility or activity for RAW management with the objectives, requirements and criteria for safety and to determine whether an adequate level of safety has been attained.

(2) The safety assessment should include a systematic analysis of all radiation hazards to demonstrate the ability of the facility and of the established management system to ensure the safety during normal operation of the facility or the implementation of the activities, as well as in case of occurrence of anticipated operational events and design basis accidents.

(3) The safety assessment must determine the necessary measures for management of radiation risks in such a manner that ensures the protection of the personnel, population and the environment in accordance with the regulatory requirements.

Art. 55. (1) The scope of the safety assessment is determined by application of a graded approach depending on the level of radiation risk which the facility or the activity may cause.

(2) Upon application of a graded approach the following key factors are taken into account, namely:

1. the existing inventory of RAW and the potential radioactive discharges into the environment in all operational conditions and emergency situations, including for events of very low frequency of occurrence, but with significant radiological consequences;

2. the complexity of the facility and the carried out activities;

3. using proven in practice technologies and equipment, including the use of experience from similar facilities and activities and the availability of renowned designers and equipment manufacturers.

(3) The safety assessment should cover all stages of the lifecycle of the facility or activity and should include both the facility and the present in the facility RAW and their characteristics and packaging.

Art. 56. (1) The safety assessments of the facilities for management of RAW, as well as the design basis, technical and organizational measures ensuring the implementation of the concept of defense in depth shall be documented in a preliminary, interim and final safety analysis report, related to the licensing regime pursuant to the ASUNE.

(2) The licensee must maintain up to date the safety analysis report in accordance with the implemented modifications of SSC important to safety, the conducted new analyzes and the safety requirements in force.

(3) The safety analysis report is updated at the renewal of the license.

Art. 57. (1) To assess the safety of a facility for management of RAW should be applied deterministic methods.

(2) In complex facilities for management of RAW as an auxiliary method for assessment can be used the probabilistic approach.

Art. 58. (1) The assessment of the radiation exposure of the workers and the population are based on conservative assumptions.

(2) Realistic assessments can be performed to optimize the protection of the facility. In this case, the availability of specific data for the facility is taken into account as well as from the own and external operational experience.

(3) Methods with a lower degree of conservatism are applied in the modeling of scenarios and assessment of the consequences from beyond design basis accidents, including failure of the isolation properties of the disposal system as a result of human activity.

Art. 59. (1) The safety assessment of a facility for management of RAW should be based to a maximum degree on experimental data on the characteristics of RAW, the engineering barriers and the site.

(2) The safety assessment should include an analysis of the sensitivity of the used models and uncertainty analysis of the input data upon the received results.

Art. 60. (1) The safety assessment of a facility for the disposal of RAW should cover a period of time sufficient to reach the maximum estimated exposure dose of the population. The models used for safety assessment should be verified and evaluated to achieve confidence in their applicability for the assessed period of time.

(2) The safety assessment of a facility for the disposal of RAW should determine and justify the measures for limiting the spreading of radionuclides in the environment in case of human activity after the closure of a disposal facility.

(3) The safety assessment of a facility for the disposal of RAW after its closure should take into account also events with low probability of occurrence and human activity, that may affect the functioning of the facility. In these cases, as criteria for safety, are implemented the intervention levels established in the Regulation on Emergency Planning and Emergency Preparedness in Case of Nuclear and Radiological Emergencies.

Art. 61. (1) The licensee must carry out periodic safety assessment.

(2) The scope of the periodic safety assessment should include as a minimum the following areas of review:

1. the site characteristics considered in the design, and in case of necessity – their reassessment based on new data obtained and using new methods;

2. the condition of the physical and engineering barriers of the facility for management of RAW, taking into account the implemented modifications of SSC important to safety, the effects of aging and other effects that affect safety;

3. the existing analytical methods for safety analysis and the applicable new safety requirements;

4. the operational experience and the effectiveness of the feedback in the reviewed period;
5. the organization of the operation;
6. the safety indicators and the effectiveness of the management of safety and quality;
7. the quantity, level of training and qualification of personnel;
8. the acceptance criteria and each case of deviation of the stored RAW packages from these criteria;
9. emergency preparedness;
10. radiological impact of the facility on the environment.

(3) The periodic safety review must be carried out according to a systematic and documented methodology, which includes deterministic and, where applicable, probabilistic methods. The conclusions must justify the practically possible measures for improvements, taking into account the interrelationships between the identified deviations.

Additional provisions

§ 1. For the purposes of this regulation:

1. "Emergency conditions" are the deviations from normal operation, more severe than the anticipated operational events, including design basis and beyond design basis accidents.
2. "Barrier" means any physical (engineering or natural) barrier, which prevents or hinders the spreading of radioactive substances and protects the RAW from internal and external adverse effects as well as protection from ionizing radiation.
3. "Verification" means the process of determining whether the quality or the characteristics of a specific product (such as computer programs, analytical methods, models, procedures and guidelines) are such as declared, as intended or as required.
4. "Geological disposal" is the location of RAW in a stable geological formation at a depth of several hundred meters or more below the surface in order to provide for long-term isolation of the radionuclides from the biosphere.
5. "Operating conditions" are the conditions of normal operation and anticipated operational events.
6. "Operation" means all activities carried out to achieve the purpose for which the facility for management of RAW has been constructed, including testing, maintenance, repair, checks during work and other related activities.

7. "Discharges" are current and expected radioactive discharges of radionuclides from a source, released in the framework of the operation of a nuclear facility, such as gases, aerosols, liquid or solid substances into the environment.

8. "Conditioning of RAW" are the activities and operations as a result of which is received a RAW package, suitable for handling, transportation, storage and/or disposal. The conditioning of RAW may include: immobilization – transforming RAW into solid form by solidification, incorporation or encapsulation; packaging - placement of RAW in an appropriate container, and additional packaging – placement of one or more packages RAW in an additional external container.

9. "Container" means a volume, where RAW are placed for handling, transportation, storage and/or disposal, as well as the external barrier that protects RAW from external tampering.

10. "Criteria for acceptance of waste" are qualitative and quantitative criteria to be met by RAW in order to be accepted at the facility for management of RAW.

11. "Safety culture" is a set of characteristics and attitudes in the organizations and individuals, which indicate that the issues related to safety and security, have priority and receive due consideration in accordance with their importance.

12. "Beyond design basis accident" is an accident whose consequences are more severe than the design basis accident and for which are not provided technical resources in the design.

13. "Processing of RAW" is any activity resulting in a change in the characteristics of the waste, including pretreatment, treatment and conditioning.

14. "Package RAW" is a product of conditioning that includes the form of RAW and all containers and internal barriers (e.g. sorbent material and cladding) and is prepared in accordance with the requirements for handling, transportation, storage and/or disposal.

15. "Optimization of protection" is the process of determining the level of protection wherein the dose of irradiation, as well as the probability and extent of potential exposure are as low as reasonably achievable, taking into account economic and social factors.

16. "Quality Assurance" is a function of the management system, which gives confidence that the specified requirements will be fulfilled.

17. "Passive safe state" is a state that does not require direct action on the part of the operator or activities ensuing from feedback from operation, and it is relied both on the engineering components and systems, as well as on the known physical and chemical variables of the systems.

18. "Periodic safety review" is a systematic safety assessment of an existing facility or activity carried out at regular intervals to determine the impact of the cumulative effects of aging, implemented modifications, operational experience and technical achievements, which aims at ensuring a high level of safety throughout the service life of the facility and/or activity.

19. "Surface disposal" is a disposal of RAW in a facility, located on the surface or up to several tens of meters below it, through the use of engineering and/or natural barriers.

20. "Pretreatment" means any or all activities related to collecting, separating, altering the chemical composition and decontamination of RAW before their subsequent processing.

21. "Safety limits" are the specified in the design values of the operating parameters, within which it is proven that the facility is safe.

22. "Limits and conditions of operation" is a set of rules defining the limits of the parameters, functional capacities and ways of behavior of SSC and personnel which are adopted in the prescribed order to ensure the safe operation of the facility.

23. "Processing" are activities leading to change in the characteristics of the RAW with view of reducing the volume, extraction of radionuclides from the RAW and change in the composition. Such activities are pressing, burning, calcinations, melting, crushing, decontamination, etc.

24. "Design basis accident" are emergency conditions for which the facility has been designed in accordance with established criteria to the design of the facility, so that damage in the package or another barrier should not lead to the discharge of radioactive substances into the environment beyond the specified limits.

25. "Authorized discharges" are planned and controlled discharges into the environment of liquid and/or gaseous radioactive substances according to the legislative requirements and conditions of the license.

26. "Graded approach" is the application of nuclear safety requirements that are in accordance with the operational characteristics of the operational practice in the nuclear facility.

27. "Facility for the disposal of RAW" means any facility or installation the main purpose of which is the disposal of RAW.

28. "Form of RAW" is a physical and chemical state of RAW after processing and/or conditioning before packaging. The form of RAW is a component of the package RAW.

29. "Safety function" is the specific objective that must be achieved for ensuring of safety. The main safety functions of the facility for management of RAW are the isolation of RAW and the retention of radioactive substances.

30. "Characterization of waste" is the determining of the physical, chemical and radiation properties of RAW in order to establish the need for subsequent treatment or their suitability for subsequent handling, processing, storage or disposal.

§ 2. (1) This regulation introduces the requirements of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (OB, L 199/48 of 2.08.2011).

(2) Every three years, the NRA Chairman shall prepare a report on the implementation of the requirements of the Directive pursuant to par. 1 and shall coordinate it with the Minister of Economy and Energy with regard to the strategy pursuant to art. 74 of the ASUNE. The report is submitted to the European Commission. The specific deadlines are determined in accordance with the time periods for holding meetings to review the reports submitted under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of RAW Management.

Transitional and Final Provisions

§ 3. This Regulation is adopted pursuant to Art. 26, par. 2 of the Act on the Safe Use of Nuclear Energy.

§ 4. Within two years of the entry into force of this regulation the licensees must bring the operation of existing facilities and their management systems in accordance with the requirements of the regulation.

§ 5. (1) The state has the ultimate responsibility for the safe and responsible disposal of RAW, including of by-products when RAW is shipped for processing to another country.

(2) Radioactive waste generated in the Republic of Bulgaria, shall be disposed of on the Bulgarian territory, unless there is an enacted agreement to use a facility for disposal of RAW in another country. This facility must meet the established by the Commission criteria in accordance with Article 16 paragraph 2 of Directive 2006/117/EURATOM.

(3) The Republic of Bulgaria shall notify the Commission of the content of any agreement pursuant to par. 2 and ensures the following, namely:

1. the destination country has concluded an agreement with the Community for management of RAW or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of RAW Management;

2. the destination country has programs for management and disposal of RAW, aimed at achieving a high level of safety, equivalent to the established by this regulation, and

3. the disposal facility, where RAW are sent, has received a permit for acceptance of the sent RAW, has been commissioned into operation before their dispatch and is managed in accordance with the regulatory requirements of the destination country.

§ 6. The Minister of Economy and Energy shall notify the European Commission whenever a significant change of strategy has taken place pursuant to Art. 74 of the ASUNE.

§ 7. (1) The NRA Chairman provides guidance for the implementation of the regulation and issues guides, methodologies and other documents for its implementation.

(2) The Minister of Economy and Energy provides guidance regarding the national strategy adopted pursuant to Art. 73 of the ASUNE.