

THE NATIONAL COMMISSION FOR NUCLEAR ACTIVITIES CONTROL

Regulation on the radiological safety requirements for the disposal of radioactive waste

CHAPTER I. General provisions

Section 1

Objective, scope and definitions

- Art. 1** This regulation establishes the basic requirements to ensure radiological safety to the disposal of radioactive waste, in order to protect workers, population and environment in all phases of development, operation and closure of disposal facilities and after their closure.
- Art. 2** This regulation establishes requirements for licensing of disposal facilities in all phases of their development, operation and closure.
- Art. 3** The provisions of this regulation apply to the disposal of all types of radioactive waste, classified according to the Regulation on classification of radioactive waste, approved by Order CNCAN no. 156/2005, published in Official Bulletin of Romania, Part I, no. 571, from 04 July 2005, by means of their emplacement in solid or in solidified form in disposal facilities, as well as to the development, operation, closure and post-closure monitoring and control of disposal facilities.
- Art. 4** The provisions of this regulation does not apply to the approved direct discharges of radioactive effluents into environment, for which specific regulations apply.
- Art. 5** (1) This regulation only addresses the radiological impact from the disposal of radioactive waste.
- (2) The non-radiological impact aspects associated with the disposal activity are not addressed in the present regulation, but these shall be taken into consideration in all phases of development, operation and closure of disposal facilities and assessed in accordance with specific regulations.
- Art. 6** Within the scope of application of the provisions of this regulation, besides the terms defined into the Law 111/1996, on the safe deployment, regulation, licensing and control of nuclear activities, republished in the Official Gazette of Romania, Part I, no. 552 of 27 June 2006, with the subsequent modifications and completions, into the Fundamental Radiological Safety Regulation approved by CNCAN Order no. 14/2000, published in the Official Gazette of Romania, Part I, no. 404 of 29 August 2000, as well as in the Fundamental Regulation on the safe management of radioactive waste and spent nuclear fuel approved by Order no. 56/2004, republished in the Official Gazette of Romania, Part I, no. 223 of 28 March 2014, with subsequent modification and completions, there are terms and definitions used, provided in **Appendix no. 1**, which is part of this regulation.

CHAPTER II. Radiological safety criteria for disposal facilities

Section 1

Operational period

- Art. 7** The exposures associated with radioactive waste disposal activities are considered as planned exposures, for which radiological safety requirements and the related safety criteria are established in the Fundamental Radiological Safety Regulation approved by Order 14/2000 published in Official Gazette of Romania, Part I, no. 404 of 29 August 2000.
- Art. 8** (1) Protection of persons who are exposed as a result of disposal activities for radioactive waste shall be optimized with due regard to the dose constraint established by CNCAN from the beginning of the development phases of disposal facilities.
- (2) The optimization of radiological safety shall be considered in the design of the disposal facility and in the planning of disposal facility activities.

Section 2

Post-closure period

Art. 9 For the period after the closure of a disposal facility the following radiological safety criteria are applicable:

- a) The dose limit for members of the public for doses from all planned exposure situations is an effective dose of 1 mSv in a year and is not to be exceeded in the future.
- b) To comply with the dose limit provided at point a), a disposal facility, considered as a single exposure source, shall be designed so that the calculated dose to the representative person who might be exposed in the future as a result of possible natural processes affecting the disposal facility does not exceed a dose constraint of 0.3 mSv in a year, taking into account all possible ways of radiation exposure.
- c) In relation to the effects of inadvertent human intrusion after closure, if such intrusion is expected to lead to an annual effective dose of less than 1 mSv to those living around the site, then efforts to reduce the probability of intrusion or to limit its consequences are not necessary.
- d) If estimated doses from human intrusion lead to an annual effective dose of more than 20 mSv to those living around the site, then alternative options for waste disposal shall be considered, such as disposal of the waste below the surface, or separation of the radionuclide content giving rise to the higher dose.
- e) If estimated annual effective doses in the range 1–20 mSv are indicated, then arrangements shall be made at the stage of development of the facility to reduce the probability of intrusion or to limit its consequences by means of optimization of the facility design.
- f) The same requirements from d) apply where the relevant thresholds for deterministic effects in organs, may be exceeded, according to Fundamental Radiological Safety Regulation approved by Order 14/2000 published in Official Bulletin of Romania, Part I no. 404 in 29/08/2000.

Section 3

Graded approach

Art. 10 (1) The design, operation and closure of radioactive waste disposal facilities shall reflect proportionally the potential radiological impact of the radioactive waste disposed of.

(2) The applicant/licensee shall document in the radiological safety case how this graded approach concept has been used for all aspects of the disposal of radioactive waste and shall demonstrate that the level of analysis, documentation and other actions implemented to comply with the requirements in this regulation are commensurate with:

- a) the relative importance to radiological safety, safeguards, and security;
- b) the magnitude of any hazard involved;
- c) the lifecycle stage of a facility, status and condition of facility;
- d) the complexity of a facility;
- e) the particular characteristics of a facility;
- f) the relative importance of radiological and non radiological hazards;
- g) any other relevant factors.

(3) The graded approach shall be applied whenever important modifications occur in any aspect associated with the disposal facility.

CHAPTER III. Radiological safety requirements on disposal management

Section 1

Responsibility of the applicant/licensee for disposal activity

Art. 11 (1) The applicant/licensee shall ensure and demonstrate the safety of the disposal facility

until closure and thereafter.

(2) The applicant/licensee shall perform safety assessments and prepare, maintain and update the safety case of the disposal facility, as well as perform all necessary activities for siting, design, construction, commissioning, operation, closure, post-closure monitoring and control, until the release from CNCAN regulatory control.

(3) Responsibility for institutional control over the site after release of the facility from CNCAN regulatory control is established at national level, according to the national strategy for safe management of radioactive waste and spent nuclear fuel.

(4) Prior to the site being licensed for a disposal facility, the applicant/licensee shall make the necessary arrangements for institutional control after release of the facility from CNCAN regulatory control in consultation with the government and for the approval of CNCAN in the siting licence.

Art. 12 The applicant/licensee shall establish and implement a safety policy, taking due account of national and international standards and ensuring that matters related to safety of the disposal facility are given the highest priority.

Art. 13 The applicant/licensee shall make and implement programs and procedures necessary to maintain safety.

Art. 14 The licensee shall have in place a program for the continuous improvement of safety by, in particular, using experience feedback, advances in science and technology and the results of its own research programs.

Art. 15 The licensee shall ensure the availability of all necessary resources, including human, financial, and infrastructure necessary, for the safety of radioactive waste disposal activities at the time they are needed.

Art. 16 After closure the licensee shall carry out monitoring and control of the disposal facility and any necessary remediation in accordance with the safety case until release from CNCAN regulatory control.

Art. 17 The licensee shall ensure that all activities, including those carried out by contractors, are performed safely and properly controlled according to the licensee's management system.

Art. 18 The applicant/licensee shall ensure that interfaces between its responsibilities and those of any other organizations that have responsibilities relating to the waste to be disposed of are clearly defined, agreed and documented in the safety case, taking into account the interdependencies among all steps in the management of the radioactive waste.

Art. 19 The licensee shall set down requirements for waste acceptance criteria for the generators of radioactive waste for disposal.

Art. 20 The licensee shall verify the waste generator's management system will provide a high level of assurance of compliance with the waste acceptance criteria.

Section 2

Organizational structure

Art. 21 The applicant/licensee shall establish an organizational structure to enable its safety policy to be implemented with a clear definition of responsibilities, lines of authority and communication.

Art. 22 The applicant/licensee shall establish capabilities in terms of staffing, skills, experience and knowledge to build and maintain the competences required to undertake all relevant tasks related to radioactive waste disposal and adapt its organization progressively in accordance with future plans.

Art. 23 The applicant/ licensee shall define the necessary qualification, experience and skills for all staff involved with activities that may affect safety.

Art. 24 The applicant/licensee shall establish training programs to develop and maintain the professional skills of its staff and to ensure that personnel are appropriately trained before beginning each activity.

Art. 25 Where any activity related to safety is carried out by a contractor, the licensee shall retain within its organization the capability to assess the adequacy of the contractor's relevant resources and skills for ensuring safety and the quality of work undertaken.

Section 3

Management system

Art. 26 The applicant/licensee shall establish, document, implement, maintain, assess and continuously improve its management system to assure a high level of safety is achieved by bringing together in a coherent manner all the requirements for managing the organization by:

- a) Describing and implementing the planned and systematic actions necessary to provide adequate confidence that all safety requirements are satisfied;
- b) Ensuring that safety, health, environmental, security, quality and economic requirements are considered in an integrated manner and with a prime emphasis on safety;
- c) Promoting the development of a safety culture, which includes individual and collective commitment to safety and encourages a proactive, questioning and learning attitude at all levels in the organization;
- d) Developing and using in a graded and controlled manner of suitable documents: procedures, instructions, drawings or other appropriate documenting means in the organization processes deployment.

Art. 27 The applicant/licensee shall ensure that its management system takes into account safety for the entire lifecycle of the disposal facility, namely: siting, design, construction, operation, closure and after closure, as well as for any modification with safety significance.

Art. 28 The applicant/licensee shall ensure that its management system covers normal operation conditions, anticipated operational occurrences and possible accident situations.

Art. 29 (1) The licensee shall implement arrangements to review its management system at regular intervals and when needed, to ensure continuing suitability and effectiveness.

(2) The effectiveness of the management system shall be continuously monitored and assessed in order to verify and demonstrate 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 disposal of radioactive waste.

(3) The opportunities for improvement shall be determined using self-assessment, independent assessment, management of non-conformities and feedback from operational experience.

Art. 30 (1) The licensee shall have in place arrangements to ensure that relevant activities, systems, structures and components important to safety are identified on the basis of the results of systematic safety assessment.

(2) In case of contracting outside organizations to conduct certain processes or activities, the management systems of the licensee and contractor shall include effective control measures to ensure that relevant activities, systems, structures and components important to safety meet the established requirements.

(3) The control measures provided in paragraph (2) shall include:

- a) defining requirements for products and services, as well as requirements for reporting and treatment of non-conformities;
- b) establishing criteria for selection of the suppliers and evaluating their performance;
- c) obtaining evidence that products and services comply with the requirements established before their use.

Art. 31 The applicant/licensee shall document in its management system the following:

- a) Its safety policy;
- b) A description of its management system;
- c) A description of its organizational structure;
- d) A description of the financial management system addressing the collection of sufficient funds to cover the cost of excavation/construction, operation, closure and post-closure

- obligations;
- e) A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
 - f) A description of the licensee's interactions with contractors undertaking work important to safety, including the control of activities carried out by contractors;
 - g) A description of the licensee's interfaces between its responsibilities and those of the waste generator and processor, and any other organizations that have responsibilities relating to the waste to be disposed;
 - h) A description of the processes and supporting information that explain how work is to be prepared, carried out, recorded, assessed, reviewed, and improved;
 - i) A description of the provisions to record, update and long term keep knowledge, information and data about all aspects related to safety of the disposal facility, specifically:
 - i. Disposal facility concept development
 - ii. Selection and characterization of the site
 - iii. Detailed characterization of the selected site
 - iv. Design basis
 - v. Design
 - vi. As built construction of the disposal facility
 - vii. Operation including any operational occurrences and accidents
 - viii. Inventory and emplacement of the waste
 - ix. State of the disposal facility after closure
 - x. All documents relating to the safety case
 - j) A description of the provisions to ensure appropriate transfer of knowledge to its personnel throughout the different phases of the facility development and operation up until release from CNCAN regulatory control;
 - k) Any other provisions that influence safety.

Section 4

Record keeping and knowledge preservation

Art. 32 (1) The licensee shall retain all the information relevant to the safety case and the supporting safety assessment for the disposal facility and shall retain all the records, including inspection records, that demonstrate compliance with regulatory requirements and with the licensee's own specification.

(2) Information and records shall be retained, at least up until the time when the information is shown to be superseded, or until responsibility for the disposal facility is transferred to another organization.

Art. 33 (1) The timeframe for retention of different records shall be set down in the management system and justified in the safety case.

(2) The need to preserve the records for long periods of time shall be taken into account in selecting the format and media to be used for records.

Art. 34 The licensee shall put arrangements in place to ensure that, at release from CNCAN regulatory control, records on the site and on the as-closed state of the disposal facility are available for continuing preservation.

CHAPTER IV. Safety requirements for development, operation and closure of disposal facilities

Section 1

General provisions

Art. 35 (1) The applicant/licensee shall develop a disposal facility in a number of phases. The development phases of a disposal facility are:

- a) Siting;

- b) Design;
- c) Construction,
- d) Commissioning;
- e) Operation;
- f) Closure;
- g) Post-closure monitoring and control

(2) Prior to moving to the next phase of development, the applicant /licensee shall ensure that the safety requirements for the current phase have been fulfilled.

Art. 36 For each phase of the facility development process the applicant/licensee shall provide for the development of the safety case, for safety during operation and after closure, including:

- a) the collection, analysis and interpretation of the relevant scientific and technical data;
- b) the development of designs, operational limits and conditions and implementing procedures.

Art. 37 The applicant/licensee shall select the site, design, construct, operate and close the disposal facility in a manner which provides containment and isolation of the waste with a high level of confidence for a period of time compatible with its hazards.

Art. 38 (1) The applicant/licensee shall ensure that safety is provided by means of multiple safety functions and includes the use of multiple barriers and controls.

(2) The performance of these barriers shall be complementary and achieved by diverse physical and chemical means.

(3) The overall performance of the disposal facility shall not be exclusively dependent on any single safety function, in accordance with the defence in depth principle.

Art. 39 (1) The applicant/licensee shall demonstrate that after closure of the facility and after any subsequent period of post-closure monitoring and control, safety will be achieved by passive means.

(2) Passive means can include engineered barriers, natural barriers and drainage channels. Land use control can also be used as a long term control measure.

Art. 40 Throughout the process of development operation and closure of a disposal facility, the licensee shall provide an optimized level of safety, considering both operational and the post-closure phases.

Art. 41 (1) The applicant/licensee shall undertake research and development work necessary to demonstrate that the planned technical operations can be practically and safely accomplished.

(2) The research and development work provided in paragraph (1) shall be justified in the safety case.

Art. 42 (1) The applicant/licensee shall define and implement a programme of investigation to develop an understanding of the processes on which the safety of the disposal facility relies. (2) The applicant/licensee shall describe and justify in the safety case the program provided in the paragraph (1).

Art. 43 (1) The applicant/licensee shall identify the features associated with the facility and its host environment that provide for safety and features, events and processes that might be detrimental to the safety of the facility.

(2) The applicant/licensee shall demonstrate that the features, events and processes provided in paragraph (1) are sufficiently well characterized and understood.

Art. 44 (1) The applicant/licensee shall identify the range of possible features, events and processes mentioned in Art. 43 that could cause disturbance and could lead to significant loss of safety functions.

(2) The applicant/licensee shall take into consideration the range of possible features, events and processes provided in paragraph (1) in the safety assessment and shall present and justify it in the safety case.

Section 2

Site characterisation

Art. 45 (1) The applicant shall ensure that the selected site for a disposal facility will contribute to the safety performance of the facility.

(2) The applicant shall ensure that the location of the disposal facility is away from significant known mineral, geothermal, water and other valuable subsurface resources and shall be such as to reduce the risk of human intrusion into the site.

(3) The applicant shall ensure that the use of the surrounding area is not in conflict with the safety of facility.

Art. 46 (1) The licensee shall prepare and implement a program for characterization of the selected site.

(2) The program mentioned at paragraph (1) shall provide all the site information necessary for the development of the safety case and supporting operational and post-closure safety assessment, taking into consideration all the factors that could influence the safety of the disposal facility.

Art. 47 The licensee shall conduct characterisation of the selected site:

- a) To establish baseline values of conditions and parameters associated with the site and its environment that are relevant to safety;
- b) To anticipate and provide arguments to support an understanding of the anticipated normal evolution of the site characteristics;
- c) To identify any features, events and processes associated with the site that might disturb the anticipated normal evolution of the disposal facility;
- d) To identify and provide arguments to support an understanding of the effect on safety of any features, events and processes associated with the site.

Art. 48 Characterization of the geological aspects of the site and its environment shall include as a minimum investigation of:

- a) long term geological, geomorphological or topographical stability, as appropriate to the type of facility;
- b) faulting and the extent of fracturing in the host geological formation;
- c) seismicity;
- d) volcanism;
- e) the volume of rock suitable for the construction of disposal zones for a geological disposal facility;
- f) geotechnical parameters relevant to the design;
- g) groundwater flow regimes;
- h) geochemical conditions;
- i) mineralogy.

Art. 49 Characterization of the surface environmental features shall include at least the following aspects:

- a) hydrological and meteorological aspects
- b) flora and fauna
- c) human activities in the vicinity of the site, associated with the occupancy and land use
- d) industrial and agricultural activities
- e) the probable natural evolution of the site, including effects of erosion and climate change.

Art. 50 Site characterization shall be undertaken in an iterative manner with the safety assessment and the design, and shall provide input to and be guided by the safety case.

Art. 51 The licensee shall determine the extent of characterization necessary on the basis of the type of disposal facility, the type of waste and the site.

Section 3

Design

Art. 52 (1) The licensee shall develop a safety strategy for the design of the disposal facility.

(2) The safety strategy shall provide for both operational and post closure safety.

(3) It shall assure multiple safety functions, an adequate level of defence-in-depth, containment and isolation of radioactive waste and passive safety elements.

Art. 53 The licensee shall take into account the characteristics of the waste to be disposed of, the feasibility of the technical options available and the characteristics of the selected site.

Art. 54 The licensee shall establish a design basis for the facility taking into account normal operational conditions, anticipated operational occurrences and possible disturbing conditions derived from an analysis of the features, events and processes associated with the site.

Art. 55 The licensee shall design the disposal facility giving due consideration to both normal evolution of the disposal facility after closure and alternative evolution scenarios involving features, events and processes that might disturb the normal evolution of the disposal facility.

Art. 56 The licensee shall design the disposal facility giving due consideration to significant natural or human induced disturbances of the disposal facility whose consequences may affect post closure safety.

Art. 57 The licensee shall design the disposal facility to provide safety functions during the operational and post-closure phases that will provide for:

- a) control of the exposure of people and the environment;
- b) Containment and isolation of the waste;
- c) Control of sub-criticality, if applicable;
- d) Heat dissipation
- e) Control of gas generation and migration.

Art. 58 The licensee shall identify and classify engineered structures, systems and components in accordance with their importance for operational and post-closure safety.

Art. 59 In designing the facility, the licensee shall make use of applicable design and manufacturing standards, appropriately proven techniques and technology and the use of appropriate materials to ensure that the safety requirements will be met, throughout operation and post closure.

Art. 60 The licensee shall assure the identification of any conflicting design requirements from different radiological and non-radiological hazards, and seeking to resolve them.

Art. 61 The licensee shall establish design provisions to facilitate monitoring of the parameters important to both operational and long term safety.

Art. 62 The licensee shall make design provisions for maintenance, testing, inspection and monitoring of structures, systems and components important to safety, addressing also their ageing.

Art. 63 The licensee shall design the disposal facility and select handling and emplacement equipments taking into account radiation protection, ease of maintenance and inspection, minimization of the probability and consequences of anticipated operational occurrences and possible accidents.

Art. 64 The licensee shall design the disposal facility to ensure that any measures necessary for the purpose of monitoring, nuclear security or nuclear safeguards do not compromise operational and post-closure safety.

Art. 65 The licensee shall design the disposal facility so that the engineered components, including barriers, are physically and chemically compatible with each other, with the waste disposed and with the host environment.

Art. 66 The licensee shall incorporate into the design of the disposal facility passive safety features for post-closure safety and, as far as reasonably practicable, for operational safety.

Art. 67 For geological disposal and for the disposal of intermediate level radioactive waste, the passive safety features, including barriers, shall be sufficiently robust so as not to require repair or upgrading after closure.

Section 4

Information gathering and monitoring

Art. 68 (1) The licensee shall establish and implement a monitoring program that:

- a) Demonstrates adequate protection of workers, people and the environment and compliance with the regulatory requirements and licence conditions;
- b) Confirms that the disposal facility and system performs and evolves as expected in the safety case;
- c) Builds confidence in and refines the key assumptions and models made in the safety case;
- d) Enhances understanding of the environmental conditions and of the functioning of the disposal system;
- e) Acquires information for supporting decision making;
- f) Provides background information for post closure monitoring and control program and for the institutional control program.

(2) The licensee shall submit the monitoring programme for approval to CNCAN.

Art. 69 The monitoring programme shall commence in siting phase and will continuously evolve through the construction and during operation of a disposal facility and after its closure, as required in terms of the safety case and according with the specific requirements on monitoring.

Art. 70 The licensee shall design the monitoring program to collect and update information necessary for the purposes of protection and safety and information shall be obtained to confirm the conditions necessary for the safety of workers and members of the public and protection of the environment during the period of operation of the facility and after its closure.

Art. 71 The monitoring shall be carried out to confirm the absence of any conditions that could affect the safety of the facility after closure.

Art. 72 (1) For new facilities, the licensee shall perform, as part of the monitoring program, a background radiological survey of the site and its environment at the siting stage.

(2) The background radiological survey shall be updated prior to commissioning of the facility.

(3) For existing facilities for which no such background radiological survey has been made in the past, the licensee shall establish a reference background radiation level using data from analogous and undisturbed areas with similar characteristics.

Art. 73 Before starting construction, the licensee shall update and document the monitoring program to be implemented during construction, commissioning, operation, decommissioning, closure and after closure.

Art. 74 As part of the monitoring program, the site of a disposal facility shall be monitored after closure to confirm the performance of the safety functions associated with the facility.

Section 5 Construction

Art. 75 Prior to commencing construction activities the licensee shall provide evidence in the safety case that safety related design features:

- a) their construction is feasible;
- b) are robust;
- c) will perform effectively.

Art. 76 The licensee shall excavate the host environment and construct the disposal facility in accordance with procedures that will ensure compliance with the design, as described in the safety case.

Art. 77 The licensee shall construct the disposal facility in such a way as to preserve the post-closure safety functions of the host environment.

Art. 78 The licensee shall continue to gather information during excavation and construction of the facility to provide any further information required by the safety case in respect of:

- a) The intrinsic properties of the host environment;
- b) The response of the host environment to the presence of the disposal facility.

Art. 79 Excavation and construction activities shall be carried out in such a way as to avoid

unnecessary disturbance of the host environment.

Art. 80 If excavation and construction activities continue after the commencement of operation of part of the facility and after the emplacement of the waste, such overlapping of construction and operational activities shall be planned and carried out so as to avoid any degradation of the safety functions necessary both during the operational phase and after closure.

Section 6

Modifications during construction phase

Art. 81 (1) The licensee shall provide in the management system procedures for planning, assessing, documenting and implementing any modifications of design, construction procedures and methods that are necessary during construction of the facility, before operations commence, using arrangements consistent with the importance to safety of the modifications.

(2) The licensee shall ensure through this arrangements that the modifications will not have unacceptable effects on operational and post-closure safety.

Section 7

Commissioning

Art. 82 The licensee shall develop a commissioning program providing arrangements for commissioning all of the active systems and components of the disposal facility that are important to safety, including arrangements for receiving, controlling, handling and emplacement of waste before these activities are commenced.

Art. 83 The commissioning program shall, as a minimum, include:

- a) commissioning tests to be undertaken;
- b) the testing methodology to be used;
- c) the performance requirements for each system or component to be commissioned;
- d) the commissioning procedures to be used;
- e) the radiation protection program for commissioning;
- f) the management system requirements for the facility commissioning.

Section 8

Radioactive waste acceptance

Art. 84 (1) The licensee shall derive waste acceptance criteria from the operational and post-closure safety case.

(2) The licensee shall submit the waste acceptance criteria to CNCAN for approval in the application for the operation licence.

Art. 85 The licensee shall ensure that waste acceptance criteria specify limits, inter alia, on: radionuclide inventories and activity concentrations in individual waste packages, mass and dimensions of individual waste packages and non-radioactive content.

Art. 86 Waste acceptance criteria shall ensure that waste accepted for disposal is physically and chemically stable over a timescale consistent with the safety case and compatible with the other components of the disposal facility.

Art. 87 The licensee shall ensure that the management system of the organization submitting waste for disposal appropriately addresses quality issues on waste generation and treatment and compliance of the characteristics of waste with the waste acceptance criteria for disposal.

Art. 88 (1) Before accepting the radioactive waste, the licensee shall ensure that the waste is in accordance with the waste acceptance criteria for disposal.

(2) To fulfill the provisions of paragraph (1), the licensee shall perform a conformity assessment based on specific written procedures which include administrative procedures, inspections and/or tests.

Art. 89 (1) The licensee shall establish procedures for dealing with any waste arriving at the site that does not meet acceptance criteria for disposal.

(2) The licensee shall not accept waste that does not conform to waste acceptance criteria for disposal unless acceptability with regard to operational and post-closure safety has been

demonstrated on a case by case basis.

Art. 90 The licensee shall provide and implement a system for identification of the radioactive waste by assigning a unique identification for each waste package or batch of unpackaged waste and by tracing the location of waste disposed in the facility.

Section 9 Operation

Art. 91 The licensee shall operate the disposal facility in accordance with the design requirements, the limits and conditions of the licence and any other applicable legal and regulatory requirements so as to ensure and maintain safety during the operational phase, and so as to establish and preserve the post-closure safety functions claimed in the safety case.

Art. 92 The licensee shall establish, justify, document and implement operational limits and conditions to operate the disposal facility safely, to maintain the waste in a safe state during operation and to ensure compliance with the requirements for post-closure safety.

Art. 93 Before starting the emplacement of any waste, the licensee shall review and update the plan for closure and decommissioning of the waste disposal facility and post-closure monitoring and control.

Art. 94 The licensee shall develop procedures for operation of the disposal facility including for receiving, handling and emplacement of waste, before these activities are commenced.

Art. 95 (1) The licensee shall establish and maintain a program to measure and monitor the workers exposures and radioactive releases from the disposal facility, according to the specific regulations, and shall take any measures to ensure optimization of radiological safety.

(2) The licensee shall ensure that doses and releases are within the limitations established by CNCAN.

Art. 96 During the operation of the disposal facility, the licensee shall continue to gather information as required by the safety case to confirm:

- a) The intrinsic properties of the host environment;
- b) The response of the host environment to the presence of the disposal facility.

Art. 97 (1) The licensee shall establish and implement measures to ensure security and physical protection of the disposal facility, to prevent unauthorized access and unauthorized removal of radioactive materials from the facility.

(2) The requirements on the physical protection and security system are provided in the specific requirements issued by CNCAN.

Art. 98 The licensee shall manage the radioactive waste subject to nuclear safeguards control, in accordance to the specific regulations issued by CNCAN.

Art. 99 (1) The licensee shall make and implement arrangements to detect and respond to anticipated operational occurrences and possible accidents.

(2) The arrangements provided at paragraph (1) shall be compatible with operational and post-closure safety requirements.

Art. 100 (1) The licensee shall prepare and implement an on-site emergency plan to respond to possible accidents requiring protection of the site personnel and members of the public.

(2) The emergency plan provided at paragraph (1) shall be proportionate to the consequences of the possible accidents considered and shall provide for:

- a) Regaining control of the disposal facility in an emergency;
- b) Preventing or mitigating the consequences of any such emergency.

(3) If an off-site emergency plan is required in terms of the safety case, the licensee shall provide the technical basis for its development and implementation, with the approval by CNCAN in the operation licence.

Art. 101 For the purposes of emergency planning the licensee shall, as appropriate:

- a) Establish and implement the necessary organizational structure with a clear allocation of responsibilities and authorities;

- b) Ensure that, based on the on-site emergency plan, appropriate trained and qualified personnel, facilities and equipment needed to control an emergency will be available whenever they might be required;
- c) Establish arrangements as necessary for coordinating emergency activities and cooperating with external response organizations throughout all phases of an emergency.

Art. 102 (1) The licensee shall submit the on-site emergency plan to CNCAN, for approval in the operation licence.

(2) At regular intervals, the licensee shall carry out emergency exercises.

(3) Exercises shall, as appropriate, include the participation of external emergency response organizations.

(4) The plan shall be reviewed and updated in the light of the experience gained.

Section 10

Modifications during operation

Art. 103 (1) The licensee shall provide in the management system procedures for planning, assessing, documenting and implementing any modifications of design, structures, systems and components important to safety, operational limits and conditions and operating procedures during operation, using arrangements consistent with the importance to safety of the modifications.

(2) These arrangements shall ensure that the modifications will not have unacceptable effects on operational and post-closure safety.

Art. 104 (1) The licensee shall request approval from CNCAN for any proposed changes to waste acceptance criteria.

(2) The licensee shall fundament and justify any changes to waste acceptance criteria in terms of the safety case.

Section 11

Maintenance, periodic testing, inspection

Art. 105 The licensee shall establish and implement programs for maintenance, periodic testing and inspection, based on written procedures, in order to ensure and confirm that the structures, systems and components important to safety are able to function in accordance with the requirements for operational and post-closure safety, in normal operating and accident conditions.

Art. 106 (1) The licensee shall record and assess the results of maintenance, periodic testing and inspection of the structures, systems and components important to safety.

(2) The licensee shall periodically use the results derived from the programs provided in the **Art. 105** to review the adequacy of the design, construction and operation of the disposal facility and to identify any implications for post-closure safety.

Art. 107 The licensee shall periodically review and, as necessary, revise the program for maintenance, periodic testing and inspection of the structures, systems and components important to safety, to incorporate the lessons learned from experience.

Section 12

Closure

Art. 108 (1) The licensee shall plan the facility closure, including backfill, seal and cap designs, decommissioning and the arrangements for transition from active management of the facility.

(2) The plan shall be well defined and practicable, so that closure can be carried out safely at an appropriate time.

(3) Plans for closure shall be developed in the design phase and updated as the facility is developed and periodically during operation.

Art. 109 Before starting closure activities, the licensee shall define the corresponding program so that it takes into account, as appropriate:

- a) The state of the facility at the end of operation, including information on waste inventory and emplacement;
- b) Dismantling and removal of operational equipment;
- c) Remaining backfilling and sealing;
- d) Decommissioning of auxiliary structures;
- e) Environmental remediation as required;
- f) Programs for monitoring and surveillance;
- g) Programs for security and safeguards;
- h) Plans for preserving knowledge and records about the waste disposed of and the disposal facility.

Art. 110 The licensee shall perform decommissioning and closure activities so as to maintain safety during decommissioning and closure, and so as to establish and preserve the post-closure safety functions claimed in the safety case.

Art. 111 The licensee shall plan, assess, document and implement any modifications considered to be necessary to the decommissioning and closure procedures and methods, consistent with the importance to safety of the modifications.

Section 13

Post-closure monitoring and control and release from CNCAN regulatory control

Art. 112 (1) After closure the licensee shall implement a post-closure monitoring and control program until release from CNCAN regulatory control, to ensure and to demonstrate the performance of safety functions, as required in terms of the safety case.

(2) In the event that the results of the program provided in paragraph (1) demonstrate the need for remedial actions, the licensee shall implement such actions in a manner approved by CNCAN.

Art. 113 (1) For near surface disposal facilities, the post-closure monitoring and control program shall include inter alia:

- a) restrictions on access to the disposal facility;
- b) inspection of the physical condition of the disposal facility;
- c) retention of appropriate maintenance capabilities;
- d) checking whether performance of safety functions is as the design specifications.

Art. 114 For the release from CNCAN regulatory control, the licensee shall:

- a) Demonstrate that the results of the monitoring and control program are consistent with the assumptions of the safety case;
- b) Identify any restrictions on land use assumed in the safety case and details of the arrangements for institutional control and any information that might be necessary for the implementation of such control.

CHAPTER V. SAFETY VERIFICATION

Section 1

Preparation, scope and content of the safety case

Art. 115 The applicant/licensee shall prepare a safety case for the disposal facility and submit it for approval to CNCAN to demonstrate that operational and post-closure safety requirements are met.

Art. 116 The licensee shall develop and update the safety case before each of the major development phases of siting, design, construction, commissioning, operation, closure, monitoring and control and release from CNCAN regulatory control.

Art. 117 (1) The licensee shall update the safety case as soon as reasonably practicable and with consideration of the importance to safety, to reflect as a minimum:

- a) Changes to regulatory requirements and standards;
- b) Results from monitoring and control programs;
- c) Changes to the radioactive waste inventory to be disposed;

- d) Results from analysis of operational occurrences and accidents;
- e) Results of the periodic safety reviews
- (2) The licensee shall periodically update the safety case during operation and before any modifications important to safety
- (3) Documentation mentioned at paragraphs (1) and (2) shall be transmitted to CNCAN for approval both on paper and in electronic format.

Art. 118 The licensee shall provide assurance through the safety case that workers, members of the public and the environment are and will remain adequately protected against the hazards associated with the waste being disposed.

Art. 119 (1) The licensee shall include in the safety case a safety assessment that demonstrates conformity with the safety requirements.

(2) The licensee shall demonstrate that the design and the construction, operation, decommissioning, closure and post-closure monitoring and are feasible.

Art. 120 The licensee shall include in the safety assessment for the operational and post-closure phases an evaluation of the multiple safety functions providing defence-in-depth, the performance and robustness of the disposal facility and an evaluation of the radiological impact.

Art. 121 (1) The licensee shall describe in the safety case all safety important aspects of the disposal facility including the waste to be disposed, the site and the assumptions on its evolution in time, the design, the construction, operation, closure, decommissioning and post-closure activities.

(2) The licensee shall also describe in the safety case and justify the management system.

(3) The licensee shall describe in the safety case and justify the monitoring program.

Art. 122 (1) In the safety case the licensee shall analyse the impact of possible future human actions related to the site, including inadvertent human intrusion.

(2) Such analysis should focus on reducing the likelihood and potential consequences of inadvertent human intrusion.

(3) Any measures taken to prevent inadvertent human intrusion shall not compromise the operational or post-closure safety of the disposal facility.

Art. 123 The licensee shall ensure that the safety case provides a clear understanding of the safety arguments, is suitably comprehensive and documented with a content and level of detail appropriate to the phase reached in the disposal facility development.

Art. 124 The licensee shall ensure that the safety case provides clarity, justification and traceability of the assumptions, choices and decisions made.

Art. 125 The licensee shall consider in the safety case the features, events and processes specific for the site that influence safety and shall justify their choice and significance.

Art. 126 (1) The licensee shall identify all uncertainties significant to safety.

(2) The licensee shall demonstrate that the uncertainties provided at paragraph (1) are adequately taken into account in the safety case.

(3) As part of the safety case, the licensee shall describe a program for uncertainty management that includes identification, characterisation and reduction to the extent necessary and possible.

Art. 127 The licensee shall ensure that the safety case shows that the principle of optimization has been addressed in relevant choices and decisions on the disposal facility design and operation.

Art. 128 (1) The licensee shall present as part of the safety case the program, plans and provisions for closure of the disposal facility and for any post-closure monitoring and control.

(2) The licensee shall revise, update and use the program, plans and provisions provided in paragraph (1) in compliance with the requirements of the management system.

Art. 129 The applicant/licensee shall describe and justify the adequacy of the management system in the safety case, including the principles on which it is based, and how it will evolve

during future phases of development, operation and closure of the disposal facility.

Art. 130 The licensee shall use the safety case as the basis for operational limits and conditions and for assessing the safety implications of any changes to the disposal facility or its operation.

Section 2

Operational and post-closure safety assessment

Art. 131 The licensee shall consider in the operational safety assessment, both occupational exposure and public exposure resulting from normal operation, and anticipated operational occurrences and possible accidents.

Art. 132 The licensee shall include in the post-closure safety assessment a scenario analysis that considers the possible features, events and processes that might affect the performance of the disposal facility, including events of low probability.

Art. 133 The licensee shall justify in the safety assessment the level of defence in depth, the passive safety functions, the independence of the multiple barriers and their assigned safety functions.

Art. 134 The licensee shall justify the timescale over which the safety assessment is carried out.

Art. 135 In the safety assessment, the licensee shall use computer codes that have been verified and models that have been validated according to the specific regulations.

Section 3

Independent safety review

Art. 136 (1) The applicant/licensee shall make arrangements for independent review of the safety case and supporting safety assessment before each licensing step in the development process of the facility.

(2) Independent reviews shall focus on:

- a) the site selection, characterisation and evaluation process;
- b) the selection of design options;
- c) the adequacy of the scientific basis and analyses used in the safety assessment and compliance with safety standards and requirements;
- d) the establishment of waste acceptance criteria and other operational limits and conditions.

Section 4

Periodic safety review

Art. 137 (1) The licensee shall carry out at regular intervals a periodic safety review of the operational and post-closure safety of the facility, to confirm compliance with safety requirements and to update the safety case.

(2) The periodicity of the review shall not exceed 10 years.

Art. 138 The licensee shall define, justify and submit to CNCAN for approval the scope of the periodical safety review and shall ensure that, as a minimum, the following are taken into account:

- a) Review and analysis of operational experience on waste or waste package receipt, handling and emplacement;
- b) Review of monitoring, maintenance, testing and inspection activities;
- c) Review of operating experience in radiation protection aspects, occupational exposure, contamination levels and environmental radiation;
- d) Review of the waste acceptance criteria and the controls on the quality of radioactive waste packages or unpackaged waste information;
- e) Review of knowledge and experience of aspects affecting post-closure safety;
- f) Review of the assumptions made in the safety assessment to confirm that they are still valid;
- g) Review of compliance with current regulatory requirements.

Art. 139 The licensee shall document the results of the periodical safety review and develop

an action plan to implement all necessary improvements to safety and adequately update the safety case.

CHAPTER VI. LICENSING REGIME

Section 1

General provisions

Art. 140 The activities associated with the development phases in the lifecycle of a disposal facility specified in art. 35 shall require a licence issued by CNCAN, prior to the activity commencing.

Art. 141 (1) Before starting development of the disposal facility the applicant shall demonstrate that sufficient financial arrangements are in place to conduct all steps in the development of the disposal facility, including the post-closure phase.

(2) The proof of financial arrangements provided in paragraph (1) shall be a condition of licence.

(3) The financial arrangements provided in paragraph (1) shall be periodically reviewed and, where appropriate, adjusted according to the necessities.

Art. 142

Art. 143

Section 2

Siting

Art. 144 Prior to characterization of a potential site for waste disposal facility, the proposed characterization program shall be submitted to CNCAN for review and approval.

Art. 145 After obtaining the environmental agreement, the outcome of the characterization program shall be submitted to CNCAN in the application for a licence for siting.

Art. 146 In support to the application for a licence for siting the applicant shall provide the following information:

- a) Environmental agreement
- b) Status of the land ownership
- c) Arrangements for post-closure institutional control
- d) The safety case for the siting process which shall include as a minimum:
 - i. documents defining the management system for the siting phase
 - ii. the design concept, including the conceptual closure plan
 - iii. the radiological capacity of the facility
 - iv. the radioactive waste inventory: types of waste, volumes, radio-nuclides, half-lives
 - v. the detailed characterization program containing the proposed approach to site investigation and characterization, including monitoring
 - vi. a safety assessment for the siting process
 - vii. demonstration of compliance to legal requirements
 - viii. all authorizations/ permits/ certificates/ approvals issued by other authorities
 - ix. other information requested by CNCAN

Art. 147 (1) A siting licence shall be valid for a period of 5 years.

(2) Should application for a construction licence not be made within this period of validity, the licensee shall submit an updated safety case in support of a siting licence extension within the 5 years period.

(3) Failure to make such an application will invalidate the siting licence.

Section 3

Design

Art. 148 Prior to design activities being undertaken the applicant/licensee shall submit to CNCAN the application for a design licence.

Art. 147 In support of the licence application for design of the disposal facility the licensee shall submit to CNCAN the safety case for the design activity, containing as a minimum:

- a) the management system for the design phase;
- b) the design concept and safety strategy;
- c) the design of the monitoring program;
- d) the radioactive waste inventory;
- e) the proposed approach to design;
- f) a safety assessment for the design process;
- g) the safety optimization process;
- h) demonstration of compliance to the applicable legal requirements;
- i) all licences/ permits/ certificates/ approvals issued by other authorities;
- j) other information requested by CNCAN.

Art. 149 In the event that design work is subcontracted to another organization, the other organization shall meet the requirements provided in the CNCAN specific regulations on management systems including those for licensing the management system.

Art. 150 (1) A design licence shall be valid for a period of 3 years.

(2) Should application for a construction licence not be made within this period of validity, the licensee shall submit an updated safety case in support of a design licence extension within the 3 years period.

(3) Failure to make such an application will invalidate the design licence.

Section 4 Construction

Art. 151 Prior to construction activities being undertaken the licensee shall submit to CNCAN application for a construction licence.

Art. 152 In support of the licensing application for a construction licence the licensee shall submit to CNCAN the safety case for construction containing, as a minimum, the following information:

- a) the management system for the construction phase;
- b) the detailed design and the construction feasibility, including the updated conceptual closure plan;
- c) the construction methods and procedures;
- d) the safety assessment of the disposal facility for the construction phase;
- e) the updated monitoring program;
- f) other information asked by CNCAN;

Art. 153 In the event that construction work is contracted to another organization, the other organization shall meet the requirements provided in the CNCAN specific regulations on management systems including those for licensing the management system.

Art. 154 (1) The construction licence will have a period of validity set by CNCAN to cover the anticipated construction time.

(2) Should construction activities not commence within a period of 3 years from time of licence issue, the construction licence will become invalid.

Section 5 Commissioning

Art. 155 Prior to commissioning activities being undertaken the licensee shall submit to CNCAN application for a commissioning licence.

Art. 156 In support of the licence application for commissioning of the facility the licensee shall submit to CNCAN the safety case for commissioning containing, as a minimum, the following information:

- a) the management system for commissioning of the disposal facility;
- b) the detailed as built facility description;
- c) the commissioning program detailing the commissioning tests proposed, the testing methodology and performance requirements for each system or item to be commissioned;

- d) the operational limits and conditions for the commissioning of the facility;
- e) the facility commissioning procedures;
- f) radiation protection program for commissioning;
- g) the program of maintenance, testing and inspection of the structures, systems and components important to safety;
- h) the safety assessment of the disposal facility for the commissioning phase;
- i) an updated monitoring program;
- j) other information asked by CNCAN.

Art. 157 (1) The commissioning licence will have a period of validity set by CNCAN to cover the anticipated commissioning time.

(2) Should commissioning activities not commence within a period of 3 years from time of licence issue, the licence will become invalid.

Section 6 Operation

Art. 158 Prior to operational activities being undertaken the licensee shall submit to CNCAN an application for operation licence.

Art. 159 In support of the licensing application for operation licence of the facility the applicant shall submit to CNCAN the safety case for operation containing, as a minimum, the following information:

- a) the management system for the facility operation;
- b) the detailed as built facility description including any modifications undertaken during the commissioning phase;
- c) the safety assessment of the disposal facility for the operational and post-closure phases;
- d) the operational limits and conditions for the operation of the facility, including limits on the radiological inventory of the facility and the waste acceptance criteria;
- e) the facility operating procedures;
- f) radiation protection program for operation;
- g) an operational monitoring program;
- h) a modification control program;
- i) the program of maintenance, testing and inspection of the structures, systems and components important to safety;
- j) an incident reporting program;
- k) emergency plans and procedures;
- l) the revised closure plan;
- m) other information asked by CNCAN.

Art. 160 (1) The operating licence will have a period of validity of 10 years from time of licence issue.

(2) At least 2 years prior to the expiry date, the licensee shall make an application for renewal of the operating licence or make an application for closure of the disposal facility.

Section 7

Closure and post-closure monitoring and control

Art. 161 At least 2 years prior to closure activities being undertaken the licensee shall submit to CNCAN application for a closure licence.

Art. 162 In support of the licence application for closure of the facility the licensee shall submit to CNCAN the safety case for closure containing, as a minimum, the following information:

- a) The management system for closure of the disposal facility and the post-closure monitoring and control program until release from CNCAN regulatory control;
- b) A detailed description of the facility at the end of the phase of operation;
- c) The detailed closure plan, including the decommissioning plan for the auxiliaries, buildings

and facilities;

- d) Safety assessment for the closure and post-closure phase;
- e) The limits and conditions for closure and for post-closure monitoring and control, until release from CNCAN regulatory control;
- f) The post-closure monitoring and control program;
- g) The proposed institutional control program;
- h) The updated financial arrangements for the post-closure phase
- i) Other information requested by CNCAN

Art. 163 (1) The closure licence will have a period of validity as determine by CNCAN.
(2) At least 2 years prior to the expiry date the licensee shall submit to CNCAN application for renewal of closure licence or for release from CNCAN regulatory control.

Section 8

Release from CNCAN regulatory control

Art. 164 At least 2 years prior to the anticipated date of release from CNCAN regulatory control the licensee shall submit to CNCAN an application for the release.

Art. 165 In support of the application the licensee shall provide the safety case for the release from CNCAN regulatory control containing, as a minimum, the following information:

- a) A detailed description of the current state of the facility;
- b) The results of the post-closure monitoring and control program;
- c) The updated safety assessment for release from CNCAN regulatory control including the final results of the post-closure monitoring and control program;
- d) The institutional control program together with the detailed package of information that will be passed on to the government organization responsible for the institutional control, according to the National Strategy for the Safe Management of Radioactive Waste and Spent Nuclear Fuel, containing all the information about the facility, its history and the radioactive inventory;
- e) Details on any financial arrangements to provide for the period of institutional control
- f) other information requested by CNCAN

Section 8

Licensing extension

Section 9

Modifications

Art. 166 (1) Before starting any modification to a licensed disposal facility which can be of significant to safety, the licensee shall make an application to CNCAN for a modification licence.

(2) Such modifications shall include changes to: design, waste acceptance criteria, structures, systems and components important to safety, operational limits and conditions, operational methods and procedures with implications on safety of the facility.

Art. 167 In support of the application, the licensee shall submit to CNCAN the justification of the proposed modifications and the safety case updated and completed with: plans, programs, assessments, documents and procedures for implementing the modifications, the limits and the control program for implementation of the modifications in accordance with the approved management system.

Section 10

Transfer licence

Art. 168 (1) A licensee intending to transfer ownership of a licensed waste disposal facility to another owner shall apply to CNCAN for a transfer licence.

(2) The intended owner shall apply for a licence for the disposal facility.

Art. 169 The licensee who had the responsibility for the disposal facility shall transfer to the

new licensee the current safety case and all its supporting documentation, the disposal facility land and structures and any accumulated funds paid for the disposal of the waste in the facility.

Art. 170 The new facility owner shall verify that the information, the disposal facility land and structures and any accumulated funds paid for the disposal of the waste in the facility have been fully and legally transferred from the previous licensee.

Section 11

Existing disposal facilities

Art. 172 (1) For disposal facilities that exist at the time this regulation comes into force, the licensee shall assess the compliance with the safety requirements provided in this regulation and in the event of non-compliance shall establish an action plan to develop a safety case as required by the regulations and upgrade the facility as necessary.

(2) The action plan provided in paragraph (1) shall be submitted to CNCAN for approval.

Appendix no. 1 – Terms and definitions

Disposal facility – a radioactive waste management facility of which purpose is radioactive waste disposal. Such a facility is a designed repository or a particular location that may include safety elements, engineered and/or belonging to the natural host environment, named barriers, with functions of containment and isolation of radioactive waste. The facility can include the part where the radioactive waste is emplaced and the auxiliary parts needed for its construction, operation and closure.

Siting - the process of selecting and approving a site that is suitable for a disposal facility.

Commissioning - the process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

Containment - provisions of the disposal system to limit the discharge and dispersion of the radioactive substances.

Robustness (of a component or a system) - ability of a component or system to fulfil its assigned safety functions despite disturbing internal and external events and processes.

Safety case - collection of scientific and technical arguments and evidence in support of the safety of a disposal facility.

Safety assessment - systematic analyses of the safety performance of a disposal facility and confirming compliance with the safety requirements.

Closure - the completion of all operations at a certain time after the emplacement of radioactive waste in a disposal facility, including the final engineering and other necessary works required to bring the facility in a state that will be safe on a long term.

Human intrusion - any human activity after the closure of the disposal facility that will immediately damage the artificial and natural barriers of the disposal facility, favoring direct access to the radioactive waste. Distinction is made between advertent and inadvertent intrusion. According to requirements of present regulation, only inadvertent intrusion is considered.

Operational period – period comprising operation and closure phases of a disposal facility, for which was calculated, assessed and demonstrated the operational radiological safety

Post-closure period – period after closure of a disposal facility for which was calculated, assessed and demonstrated the post-closure radiological safety