

## THE NATIONAL COMMISSION FOR NUCLEAR ACTIVITIES CONTROL

### Regulation on the safety requirements for the predisposal activities of radioactive waste, disused radioactive sources and spent nuclear fuel

#### CHAPTER I. GENERAL REQUIREMENTS

##### Scope, objective, definitions

**Art.1.** This regulation establishes:

- a) the safety requirements for facilities and activities for predisposal of radioactive waste, disused radioactive sealed sources and spent nuclear fuel;
- b) licensing requirements for facilities and activities for predisposal of radioactive waste, disused radioactive sealed sources and spent nuclear fuel.

**Art.2.** This regulation shall apply to siting, design, construction, commissioning, operation, modification and permanent shutdown of facilities for the predisposal of radioactive waste, disused sealed radioactive sources and spent nuclear fuel.

**Art.3.** This regulation applies to:

- a) all nuclear activities which generate radioactive waste radioactive, disused sealed radioactive sources and spent nuclear fuel;
- b) all types of radioactive waste, disused sealed radioactive sources and spent nuclear fuel;
- c) all steps in the management of radioactive waste, disused sealed radioactive sources and spent nuclear fuel from generation up to its disposal.

**Art.4.** By exception from art. 3, this regulation does not applied to the activities and facilities for predisposal of radioactive waste from uranium and thorium mining, milling and fuel fabrication activities.

**Art.5.** This regulation shall apply both to independent facilities dedicated to the predisposal management of radioactive waste, management of disused radioactive sources and management of nuclear spent fuel, and to facilities within other nuclear or radiological facilities dedicated for other purposes.

**Art.6. (1)** This regulation does not regulate the non-radiological hazards or conventional industrial health and safety issues.

**(2)** The non-radiological hazards or conventional industrial health and safety issues shall be considered in all phases from planning to permanent shut down of the facility, as far as they may affect radiological safety.

**Art.7.** Within the scope of application of the this regulation, besides the terms defined in Law no. 111/1996, on the Safe Development, Regulation, Licensing and Control of Nuclear Activities, republished, with subsequent amendments and completions, in CNCAN Order no. 14/2000 approving the Fundamental Regulation on Radiological Safety, as well as in CNCAN Order no. 56/2004 approving the Fundamental Regulation on the Safe Management of Radioactive Waste and Spent Nuclear Fuel, republished, the other terms, definitions and abbreviations used are defined into Annex 1 which is integral part of this regulation.

## **CHAPTER II. GRADED APPROACH**

**Art.8. (1)** The predisposal activity of radioactive waste and associated documents shall be carried out and prepared, respectively, in accordance with the graded approach.

**(2)** The licensee shall demonstrate the graded approach concept used for all aspects of predisposal of radioactive waste and shall demonstrate that the level of analysis, documentation, and actions implemented to comply with a requirement in this regulation are proportionate to:

- a) the relative importance to 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 and
- g) any other relevant factors.

**(3)** The application of the graded approach shall be reassessed when important modifications of the facility take place.

## **CHAPTER III. REQUIREMENTS ON THE MANAGEMENT OF PREDISPOSAL ACTIVITY**

### **Section 1**

#### **Responsibilities of the licensee**

**Art.9.** The licensee shall be responsible for all aspects of nuclear and radiological safety, radiation protection and protection of the environment during predisposal management activity for radioactive waste, disused radioactive sources and during the storage of spent nuclear fuel.

**Art.10. (1)** The licensee is responsible for establishing and implementing an operational strategy for the management of radioactive waste, disused radioactive sources and spent nuclear fuel.

**(2)** For establishing of the strategy mentioned above in paragraph (1), the licensee shall consider the interdependences among all steps in waste management, the availability of disposal options and the national radioactive waste management policy and strategy.

**Art.11.** The licensee is responsible for providing the required financial resources for implementation of the own operational strategy for management of the radioactive waste.

### **Section 2**

#### **Integrated management system**

**Art.12. (1)** The licensee shall establish, implement, assess and continually improve a management system

covering all management of radioactive waste, disused sealed sources and spent nuclear fuel.

(2) The management system shall be aligned with the goals and objectives of the organization.

**Art.13.** To fulfil its prime responsibility for nuclear and radiological safety during predisposal of radioactive waste, the licensee shall establish and implement safety policies and ensure that safety issues are given the highest priority.

**Art.14.** The licensee shall establish an organizational structure for the management and implementation of predisposal activities, with the responsibility to ensure they will be conducted safely.

**Art.15.** The licensee shall establish an organizational structure to enable its safety policy to be delivered with a clear definition of responsibilities and accountabilities, lines of authority and communication.

**Art.16.** The licensee shall establish the skills needed for safe conduct of predisposal activity and shall determine the minimum number and qualification, training and skills requirements of staff that have overall responsibility for nuclear and radiological safety.

**Art.17.** The licensee shall establish requirements for qualification, training and skills of the staff who implement actions and tasks important for nuclear and radiological safety.

**Art.18.** The licensee shall establish, periodically update and implement training programs for staff.

**Art.19.** The licensee shall ensure that there is a clear allocation of authorities and responsibilities, together with the interfaces and communication routes that will be used especially when contractors or outside organizations are used.

**Art.20.** The licensee shall ensure that sufficient knowledge of the facility and technical expertise is maintained during the lifetime of the facility.

**Art.21. (1)** The licensee shall identify:

- a) the processes of the management system that are needed to achieve the goals,
- b) provide the means to meet all requirements, and
- c) how all activities important to safety are planned, implemented, assessed and continually improved.

(2) The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness.

**Art.22.** The licensee shall ensure that the documentation of the management system includes the following:

- a) the policy statements of the licensee;
- b) description of the management system;
- c) description of the organisational structure of the licensee;
- d) description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
- e) description of the interactions with relevant external organisations;
- f) description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.

### **Section 3 Safety culture**

**Art. 23.** The licensee shall promote and maintain a positive safety culture by having arrangement in place to:

- a) promote individual and collective commitment to protection and safety at all levels of the

organization;

- b) ensure a common understanding of the key aspects of safety culture within the organization;
- c) provide the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals and the technical and organizational aspects of their roles;
- d) encourage the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;
- e) ensure accountability of the organization and of individuals at all levels for protection and safety;
- f) encourage open communication with regard to protection and safety within the organization and with regulatory bodies, as appropriate;
- g) encourage a questioning and learning attitude and discouraging complacency with regard to protection and safety; and
- h) provide means by which the organization can continually develop and strengthen its safety culture including appropriate training.

#### **Section 4** **Record keeping system**

**Art. 24. (1)** On the entire lifetime of the facility, the licensee shall establish, implement, and maintain up to date a record keeping system on:

- a) the design and modifications of the design and facility;
- b) operating history;
- c) quantities, types (including disused sealed sources), characteristics and treatment methods of the radioactive materials and waste generated, stored in the facility, or transferred to another authorized facility;
- d) quantities, types, characteristics and control methods used for radioactive materials and waste released from regulatory control;
- e) discharges of radioactive effluents into environment.

**(2)** That recording system shall allow for traceability of radioactive waste from the point of its collection through to its long term storage and its disposal.

**(3)** The record keeping system shall consider the changes in the characteristics of radioactive waste due to their processing.

**Art.25.** The licensee who generates radioactive waste, disused radioactive sources or spent nuclear fuel which need transfer to another facility for treatment, conditioning, storage and/or disposal shall transfer them together with associated records.

**Art.26.** The licensee who receives radioactive waste for treatment, conditioning, storage and/or disposal shall define the records required for that radioactive waste and shall request them from the licensee who generated the radioactive waste.

**Art.27.** All records on the predisposal activity are permanent records and the licensee shall retain them according to the provisions of the integrated management system.

#### **Section 5** **Reporting to CNCAN**

**Art.28. (1)** The licensees shall establish and implement an events reporting system.

**(2)** The event reporting system needs to be approved by CNCAN.

**Art.29.** The licensees shall annually report to CNCAN by submitting a written report on:

- a) the progress of the predisposal management;

- b) anticipated future operations;
- c) the data needed for the national inventory of radioactive waste;
- d) the characteristics of the spent nuclear fuel, radioactive waste and disused radioactive sources, in particular the origin, physico-chemical form, quantity, activity, radionuclides, classification, non-radiological hazard associated with the waste, measures taken to avoid criticality and release of heat;
- e) data on control of the treatment, conditioning and packaging;
- f) the summary of the implementation of the training of personnel;
- g) the summary of the implementation of the maintenance programme;
- h) data on materials cleared from regulatory control;
- i) data on discharges of radioactive effluents into environment;
- j) the summary of the monitoring results on the exposure of the workers and public.
- k) any failure to comply with the radiological safety requirements and unplanned situations which affect the radiological safety of the facility;
- l) data on spent sealed sources transferred to original suppliers or to a specialized facility for treatment, conditioning and storage.

**Art.30.** Licensees shall ensure that information on abnormal performance conditions and events significant to nuclear and radiological safety are disseminated into the organization and made available to CNCAN.

## **Section 6**

### **Interdependences among steps in the predisposal management of radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.31. (1)** The licensee shall consider interdependences among all steps of predisposal of radioactive waste, disused radioactive sources and spent nuclear fuel management, as well as the impact of the anticipated disposal option.

**(2)** The demonstration of interdependences among the steps in predisposal management of radioactive waste, disused radioactive sources and spent nuclear fuel shall be presented in the safety case for the activities or facilities.

**Art.32.** The licensee shall select each step in the predisposal management of the radioactive waste, disused radioactive sources and spent nuclear fuel from generation to disposal, such that each step is compatible with the waste acceptance criteria for disposal when they exist, or the anticipated waste acceptance criteria of the most probable disposal option.

## **CHAPTER IV. SPECIFIC REQUIREMENTS FOR EACH STEP OF THE PREDISPOSAL MANAGEMENT**

### **Section 1**

#### **Control of generation of radioactive waste and disused radioactive sources**

**Art. 33. (1)** The licensee who generates radioactive waste and disused radioactive sources from its activities shall ensure that any radioactive waste generated is kept to the minimum practicable in terms of both volume and activity.

**(2)** The measures taken to minimize the generation of radioactive waste and disused radioactive sources

shall be presented and justified in the safety case for the activities or facilities.

**Art.34.** In fulfilling the provision of art. 33, the licensee shall ensure:

- i) proper design and construction of the facility;
- j) implementation of adequate practices for operation and decommissioning;
- k) selection and control of materials;
- l) recycling and reuse of materials including those released from regulatory control,
- m) implementation of operating procedures, including those for physical-chemical and radiological characterization as well as those for segregation of different types of materials and waste;
- n) minimization of quantities of radioactive materials used.

## **Section 2**

### **Characterization and classification of radioactive waste, disused radioactive sources**

**Art.35. (1)** The licensee shall establish and implement procedures for characterization of radioactive waste, disused radioactive sources;

**(2)** The characterization shall be done, at least for their physical, mechanical, chemical, radiological and biological properties in order to demonstrate the compatibility with the next predisposal steps.

**Art.36.** The licensee shall classify the radioactive waste and final waste package according to specific regulation issued by CNCAN.

## **Section 3**

### **Radioactive waste and disused radioactive sources acceptance criteria**

**Art.37. (1)** For each step of the predisposal activity, the licensee shall develop waste acceptance criteria specifying the required characteristics of waste and packages.

**(2)** The radioactive waste acceptance criteria shall be consistent with and presented in the safety case.

**Art.38.** The licensee shall establish an appropriate control system to ensure that radioactive waste and disused sources under its responsibility meet the applicable waste acceptance criteria.

**Art.39.** Licensees shall make provision for identifying, assessing and dealing with waste and/or waste packages that do not meet waste acceptance criteria for safe handling, transport, storage or disposal.

## **Section 4**

### **Collection, segregation, treatment and conditioning of radioactive waste and disused radioactive sources**

**Art.40.** Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, or clearance from regulatory control, shall be processed as radioactive waste in accordance with national radioactive waste management strategy.

**Art.41.** Licensees shall ensure that waste is collected, characterized and segregated, at the point of origin in accordance with:

- a) the licensee's established waste management strategy;
- b) the waste acceptance criteria defined for the next steps in the waste management process.



**Art.42.** During the waste collection phase the licensee shall ensure that containers:

- a) can be handled, transported and stored safely
- b) are compatible with characteristics, mass and volume of the waste;
- c) are mechanically and chemically resistant;
- d) can be sealed ;
- e) do not exceed regulatory limits;
- f) Are appropriately labelled.

**Art.43.** Licensees shall ensure that waste is rendered into a safe and stable form for storage or disposal in accordance with national radioactive waste management strategy.

**Art.44.** The licensee shall ensure that:

- a) the characterization of radioactive waste is done prior to the treatment;
- b) treatment and conditioning methods are selected on the basis of waste characteristics; waste acceptance criteria for further processing, storage or disposal; the limits, conditions and controls established in the safety case and in the assessment of environmental impacts.
- c) consideration has to be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is created during processing.

**Art.45.** Licensees shall ensure that waste is processed in such a way that the safety of the operations is appropriately ensured during normal operations, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur.

**Art.46.** Licensees shall ensure that radioactive waste is processed in such a way that the resulting waste form can be safely handled, stored and retrieved from the storage facility.

**Art.47** The licensee shall establish provisions for management of secondary waste resulting from processing radioactive waste.

**Art.48. (1)** The licensee shall establish a system for unique identification and durable labelling of waste and waste packages.

**(2)** The information contained on labels shall be sufficient to ensure the effectiveness and safety of the next step in the management process.

**Art.49.** In selecting a conditioning process, the licensee shall consider the following aspects:

- (a) the improvement of radiological safety of the waste form;
- (b) compatibility of the radioactive waste with the selected materials and processes;
- (c) the minimization of secondary radioactive waste.

**Art.50.** The licensees shall design and produce the waste packages so that radionuclides are confined under both normal conditions and accident conditions that may occur during handling, storage, and disposal.

**Art.51.** The licensee shall develop provisions and shall implement an adequate control system for meeting waste acceptance criteria for subsequent steps of storage and disposal.

**Art.52.** The arrangements and procedures for collection, segregation, treatment and conditioning of radioactive waste and disused radioactive sources shall be addressed in the licensee's waste management strategy which shall be presented and justified in the safety case.

## Section 6

### Storage of radioactive waste, spent nuclear fuel and disused sealed radioactive sources

**Art.53.** Prior to generating radioactive waste, spent nuclear fuel and disused sealed radioactive sources, the licensee shall ensure the availability of an appropriate storage facility within their own organization, or in another licensed facility.

**Art.54. (1)** Licensees shall establish and implement systems for verifying that the radioactive waste, collected or received in the storage facility, meets the waste acceptance criteria for storage.

**(2)** The waste acceptance criteria shall be defined and justified in the safety case.

**Art.55.** The licensee shall store the waste and waste packages safely and ensure:

- a) proper segregation;
- b) inspection, monitoring and retrieval;
- c) protection of workers, public and environment;
- d) a proper record of the waste is maintained;
- e) preservation of the waste and waste package integrity including ability to overpack, if necessary
- f) avoidance of accidents and mitigation of consequences where they do occur.

**Art.56.** The licensee shall periodically review the adequacy of the storage capacity, with account taken of:

- a) current and anticipated waste arisings;
- b) the expected lifetime of the storage facility;
- c) the availability of disposal options;
- d) any changes in safety standards.

**Art.57.** The safety arguments for the storage facilities for radioactive waste, disused radioactive sources and spent nuclear fuel shall be presented and justified in the safety case.

## Section 7

### Management of disused radioactive sources

**Art.58. (1)** Any person wishing to acquire a sealed radioactive source shall put in place a contract for return of the source to the supplier prior to acquisition.

**(2)** The contract and any financial arrangements necessary to enable return of the disused radioactive source to the supplier shall be verified by CNCAN in authorization process.

**Art.59.** Licensees who possess sealed radioactive sources shall notify CNCAN when a source becomes disused and provide the safety case for storage arrangements pending to return to the supplier or transfer to another licensed facility.

**Art.60.** Licensees shall not possess on their premises disused sealed sources for a period greater than 6 months, unless specifically authorized by CNCAN.

**Art.61.** The licensee shall establish provisions and implement control systems to avoid compaction, shredding or incineration of disused radioactive sources.



## CHAPTER V. REQUIREMENTS FOR THE DEVELOPMENT OF PREDISPOSAL RADIOACTIVE WASTE, DISUSED RADIOACTIVE SOURCES AND SPENT NUCLEAR FUEL MANAGEMENT FACILITIES

### Section 1

#### Location and design of the management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel

**Art.62.** The management facilities for predisposal radioactive waste, disused radioactive sources, and spent nuclear fuel shall be located and designed to ensure safety for the expected operating and decommissioning lifetime under both normal and accident conditions.

**Art.63.** The management facilities for predisposal radioactive waste, disused radioactive sources, and spent nuclear fuel shall be designed to fulfil the main safety functions:

- a) prevention of criticality;
- b) removal of heat;
- c) radiation shielding and contamination control;
- d) containment of radioactive material;
- e) retrievability

during normal operation, anticipated operational occurrences and design basis accident conditions.

**Art.64.** The management facility for predisposal of radioactive waste, disused radioactive sources, and spent nuclear fuel shall be designed for a specified lifetime and during normal operation shall:

- a) allow inspection and monitoring of the radioactive waste and packages;
- b) allow maintenance and repair of waste packages and overpacking of the radioactive waste;
- c) ensure containment of the waste, integrity of the waste form and of the packaging;
- d) allow retrieval and transport of waste and packages at any time;
- e) allow the timely decommissioning of the facility.

**Art.65.** The licensee shall design and operate the management facility for radioactive waste, disused radioactive sources, and spent nuclear fuel based on the principle of defence in depth, providing for multiple levels of protection against technical failures or human error:

- a) multi-barrier systems of several physical barriers on the migration pathway of the radionuclides to the environment;
- b) technical and organizational means for protection of the integrity and efficiency of the barriers;
- c) measures for protection of the public and environment in case of failure or damage to the barriers.

**Art.66.** At all stages of the lifetime of the management facilities for radioactive waste, disused radioactive sources and spent nuclear fuel the licensee shall apply the defence in depth principle through technical and organisational measures to achieve the following :

- a) prevention of deviation from normal operation;
- b) prevention of accidents;
- c) emergency planning for mitigation of consequences.

**Art.67.** The storage facility shall be designed to incorporate passive safety features as far as reasonably practicable.

**Art.68. (1)** The licensee shall identify and classify structures, systems and components (SSCs) important to the safety of radioactive waste, disused radioactive sources and spent nuclear fuel management

(2) The SSCs shall be presented and justified in the safety case.

**Art.69.** The management facility for predisposal of radioactive waste, disused radioactive sources, and spent nuclear fuel shall be designed to allow for safe access to the SSCs which require periodic maintenance, testing, examination and inspection.

**Art.70. (1)** The management facility for predisposal of radioactive waste, disused radioactive sources, and spent nuclear shall be designed taking into account all relevant postulated initiating events (PIEs).

(2) PIEs shall be presented and justified in the safety case.

(3) The list of potential PIE is provided in the Annex 2.

**Art. 71.** The licensee shall periodically review and assess the adequacy of the storage capacity, taking into account the national strategy and predicted radioactive waste, disused radioactive sources and spent nuclear fuel arising, expected lifetime of the facility and availability of disposal options.

**Art.72.** The arrangements for location and design of the management facility for predisposal of radioactive waste, disused radioactive sources, and spent nuclear shall be presented and justified in the safety case.

## Section 2

### **Construction and commissioning of management facilities for predisposal radioactive waste, disused radioactive sources, spent nuclear fuel**

**Art.73.** The management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel shall be constructed in accordance with the design as described in the safety case.

**Art.74. (1)** The commissioning of the facility shall be carried out to verify that the SSCs, and the facility as a whole, performs as planned.

(2) In cases when commissioning is carried out in several stages, each stage needs CNCAN approval.

**Art. 75. (1)** Upon the completion of commissioning, the licensee shall develop the final commissioning report.

(2) The final commissioning report shall describe the tests performed on the SSCs, their results, modifications performed in the facility and in the commissioning procedures, status of the facility as-built, and the evidence that the licensing conditions have been met.

(3) The final commissioning report shall be included in the safety case as the basis for further operation and for the development of the decommissioning plan.

**Art.76. (1)** The licensee shall plan, assess and review the modifications of the design, equipment, storage conditions, waste characteristics, in particular changes of SSCs, operational limits and conditions (OLCs) or operational procedures.

(2) The licensee shall ensure that the modifications mentioned in paragraph (1) will not impact adversely the safety of the facility or associated facilities or the further management of radioactive waste, disused radioactive sources and spent fuel.

**Art.77.** The licensee shall document any modification of the SSCs with safety functions implications and shall update the safety case accordingly.

**Art.78.** Before introducing a modification according to art. 77, the licensee shall appropriately train the personnel, and update all relevant documents necessary for facility operation.

### Section 3

#### **Operation of management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.79.** Prior to start of the facilities operation the licensee shall establish OLCs, including waste acceptance criteria, for all actions and activities relevant for the nuclear and radiological safety.

**Art.80.** The OLCs shall consider, in particular:

- (a) environmental conditions within the facility;
- (b) the effects of heat generation from waste and waste packages;
- (c) potential for gas generation;
- (d) criticality prevention;
- (e) suitability for handling and retrieval
- (f) control of discharges into environment
- (g) monitoring of the radiation levels in the environment.

**Art.81. (1)** The licensee shall develop procedures for demonstrating compliance with OLCs.

**(2)** The procedures mentioned in paragraph (1) shall be presented and justified in the safety case.

**Art.82.** The licensee shall establish programs for maintenance, testing and inspection to address the aging of SSCs and safety features of the facilities.

**Art.83.** The licensee shall have plans and establish appropriate contingency arrangements for waste that are not retrievable by normal means or show signs of degradation.

### Section 4

#### **Exposure during operation of management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.84.** During operation of the facility the radiological safety requirements for planned exposure situation according to CNCAN Order no. 14/ 2000 approving the Fundamental Regulation on Radiological Safety shall be applied.

**Art.85.** Radiation protection of persons who are exposed as a result of operation of the facility shall be optimized with due regard to the dose constraint established by CNCAN for each individual site in respect of public exposure.

### Section 5

#### **Planned discharges and their control during operation of management facilities for the predisposal of radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.86. (1)** The licensee shall set annual derived discharge limits for radioactive liquid effluents and gaseous effluents, ensuring optimization of protection and meeting of effective dose constraints established by CNCAN prior to start of the operation.

**(2)** The setting of the derived discharge limits for radioactive effluents into environment shall be done according to the specific regulations issued by CNCAN.

**Art.87. (1)** The licensee shall assess the radiological impact of the discharges of radioactive effluents resulting from the predisposal management of radioactive waste, disused radioactive sources and spent nuclear fuel.

(2) The assessment of radiological impact is part of the safety case.

**Art.88. (1)** The licensee shall re-assess periodically the discharges of radioactive effluents into environment in order to determine whether associated control measures and environmental monitoring programmes are remain appropriate, and if not the control measures shall be modified accordingly.

(2) Modification of the control measures and environmental monitoring programmes shall be approved by CNCAN

**Art.89. (1)** The licensee shall establish and implement programs for monitoring of radioactive discharges and monitoring of radioactivity on and off site.

(2) The monitoring program mentioned in paragraph (1) shall be established according to specific regulations issued by CNCAN.

## Section 6

### **Clearance of material and its control during operation of management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.90. (1)** The licensee shall establish and implement, procedures to ensure that the radioactive materials to be cleared comply with the requirements for release from regulatory control of radioactive materials.

(2) The requirements for release from regulatory control of radioactive materials are established by CNCAN in CNCAN Order no. 62/ 2004 approving the Regulation on the Release from Regulatory Control of Materials from Authorised Practices in the Nuclear Field.

**Art.91.** The licensee shall remove any radiation markings from any material which is released from regulatory controls.

**Art.92.** Deliberate dilution of radioactivity in the material with the view of changing the radioactive waste classification, other than the dilution that takes place in normal operations is forbidden.

## Section 7

### **Investigations and feedback of operating experience**

**Art.93.** The licensee shall have in place a programme to ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety are disseminated within organization or made available, as appropriate, to CNCAN.

**Art.94.** The licensee shall conduct an investigation for at least the following events:

- a) a quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions; or
- b) any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed any relevant limit or operating restriction.

**Art.95.** The licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of root cause, including a verification or estimation of any doses received and recommendations for preventing the recurrence of the event and the occurrence of similar events.

## Section 8

## **Shutdown and decommissioning of management facilities for predisposal radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art.96.** The licensee shall shut down and decommission the facility according with the specific requirements issued by CNCAN.

### **Section 9 Emergency preparedness and response**

**Art.97. (1)** The licensee shall prepare an on-site emergency plan for the management of predisposal facilities.

**(2)** The requirements for development of emergency response plan are established in the specific regulations issued by CNCAN.

### **Section 10 Physical protection and security**

**Art.98. (1)** The licensee shall establish and implement measures to ensure the physical protection and security at waste management facilities, which are compatible with safety requirements, to prevent the unauthorized access of individuals and the unauthorized removal of radioactive materials.

**(2)** The requirement for physical protection and security are established in the specific regulations issued by CNCAN.

### **Section 11 Nuclear safeguards**

**Art.99.** The licensee shall implement, in the design phase, the waste management facilities nuclear safeguards system in such a way as to be compatible with safety requirements and as:

- a) not to compromise the nuclear and radiological safety of the facility;
- b) to allow access to the material under nuclear safeguards;
- c) to limit the radiation exposure of the staff;
- d) not to compromise the isolation of the materials.

**Art.100.** The licensee shall manage the radioactive waste under nuclear safeguards according to the specific regulations issued by CNCAN.

### **Section 12 The transport of radioactive waste**

**Art. 101.** The transport of radioactive waste, disused radioactive sources and spent nuclear fuel from the generator to a treatment and storage facility, and from treatment and storage to a disposal facility shall be done according to the transport regulations issued by CNCAN.

### **Section 13**

## Existing facilities

**Art.102. (1)** The licensee of a predisposal facility in one of the phases of design, siting, construction or operation, shall verify the conformity with the safety requirements in this regulation, and if it is needed, shall establish an action plan to improve the radiological safety.

**(2)** In the event the compliance cannot be demonstrated with any of the requirements in this regulation, an equivalent level of safety shall be demonstrated.

**(3)** The action plan mentioned in the paragraph (1) needs to be approved by CNCAN.

## CHAPTER VI: VERIFICATION OF SAFETY

### Section 1 Safety case

**Art.103. (1)** The licensee shall develop a safety case in the planning phase and use it as a basis for demonstration of the safety throughout the lifetime of a predisposal facility.

**(2)** The licensee shall use the safety case also as a basis for assessing the safety implications of changes to the facility or to operating practices.

**(3)** The preparation of a safety case including the supporting safety assessment is a step by step development. The safety case is progressively refined as the predisposal facility is developed.

**Art.104. (1)** The safety case shall cover both the facility and the radioactive waste, disused radioactive sources and spent nuclear fuel and their relevant safety features.

**(2)** The safety case shall include a description of the context, the safety strategy, description of the site and facility, the safety assessment, the establishment of OLCs, the integration of the safety arguments, the management of uncertainties, application of the management system, the iterative approach of safety demonstration and the stakeholder involvement process.

**(3)** The content of the safety case is presented, but not limited to, the subject listed in Annex 3.

**Art.105.** The licensee shall update the safety case to reflect:

- a) modifications of regulatory requirements and international standards;
- b) results of the periodic safety review;
- c) results from analysis of incidents and accidents.

### Section 2 Safety assessment

**Art.106. (1)** In support of the safety case, the licensee shall prepare a safety assessment for the radioactive waste, disused radioactive sources and spent nuclear fuel management predisposal facilities, so as:

- a) to identify the possible exposure pathways;
- b) to determine the expected magnitude and likelihood of exposures in normal operational conditions and in incident and accident conditions;
- c) to assess the adequacy of the provisions for protection and safety.



- d) the site and facility engineering
  - e) the management system
  - f) non-radiological impacts of the facility.
- (2) The safety assessment shall be documented.

(3) The safety assessment shall be developed according to specific regulation issued by CNCAN.

**Art. 107.** The safety assessment shall include, as appropriate, a systematic critical review of:

- a) The OLCs for the operation of a facility;
- b) The ways in which the SSCs, including software with safety functions might fail and can lead to the elevation of exposure and the consequences of such events;
- c) The ways in which external factors could affect protection and safety;
- d) The implications for protection and safety of any modifications;

**Art.108.** The licensee shall take into account in the safety assessment:

- a) factors that could lead to a significant release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, could be released to the environment;
- b) factors that could lead to a lower but continuing release of radioactive material, and the measures available to detect, prevent or control such release;
- c) factors that could lead to unintended operation of any radiation sources or a loss of shielding, and the measures available to detect, prevent or control such occurrences;
- d) the extent to which the use of redundant and diverse safety features, that are independent of each other so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposure and it should be addressed in the safety strategy.

**Art. 109. (1)** The licensee shall have arrangements for analysis of the safety assessment conducted by an independent organization.

(2) The independent analysis shall be done by an organization recognized by CNCAN.

### Section 3

#### Periodic safety reviews

**Art. 110. (1)** The safety assessment and the integrated management systems within which it is conducted have to be periodically reviewed at least every 10 years.

(2) The licensee shall implement any necessary safety upgrades and any further requirements by CNCAN following this review.

(3) The results of the periodic safety review shall be included in the updated version of the safety case for the facility.

(4) By exception of the provision in paragraph (1) the safety assessment has to be reviewed and updated:

- a) when there is any significant change that may affect the safety of the facility or activity;
- b) when there are significant developments in knowledge and understanding arising from research or operational experience feedback;
- c) when there have been significant improvements in assessment techniques, computer codes or input data used in the safety analysis.

## **Section 1**

### **Licensing of predisposal management of radioactive waste, disused radioactive sources and spent nuclear fuel**

**Art. 111.** All predisposal activities and facilities shall be licensed by CNCAN, according to the provisions of art. 2 of the Law no. 111/1996, republished, with subsequent amendments and completions.

## **Section 2**

### **Licensing requests**

**Art. 112. (1)** The requesting of the licence shall be performed by submitting to CNCAN a licensing dossier that shall contain:

- a) application addressed to the president of CNCAN and signed by the legal empowered of the applicant;
- b) copies of the documents that prove that the applicant is a legal entity ;
- a) safety case for the stage of the facility development;
- b) list of staff with responsibilities on nuclear and radiological safety;
- c) copies of authorizations, approvals or the notices issued by other regulatory authorities necessary according to the law;
- d) the proof of the payment of taxes and evaluation tariffs for authorization.

**(2)** The licensing dossier shall be submitted to CNCAN both in printed and electronic form.

## **CHAPTER VIII. FINAL PROVISIONS**

**Art.113.** The licenses on the predisposal radioactive waste management activities issued by CNCAN prior to this regulation shall remain valid until expiration of current licence.

**Art. 114.** The Annexes 1-3 are part of this regulation.

**Terms, definitions, abbreviations**

*Graded approach to safety* - an application of safety requirements that is commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures.

*Predisposal activities* - Operations intended to benefit safety and/or economy developed before the disposal, and includes pre-treatment, treatment, conditioning and storage.

*License* - legal document granted by CNCAN by which allow to a licensee to conduct nuclear activities according to the Law no. 111/1996, republished, with subsequent amendments and completions.

*CNCAN* – National Commission for Nuclear Activities Control, the nuclear regulatory authority as defined in Law no. 111/1996, republished, with subsequent amendments and completions.

*Safety culture* - the assembly of characteristics, attitudes and behaviour of individuals, organizations and institutions which serves to support and improve the nuclear and radiological safety, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

*Radioactive waste* – radioactive material in gaseous, liquid or solid form for which the holder cannot demonstrate to CNCAN that it provides or considers other use and which contains radionuclides with concentrations or upper surface contamination values higher than levels established by CNCAN according to the provisions of the specific applicable regulations.

*Safety case* - a collection of arguments and evidence in support of the safety of a facility or activity.

*Safety assessment* - the assessment of all aspects of the site, design, operation and decommissioning of an authorized facility that are relevant to protection and safety.

*Event* (in the context of reporting and analysis of events) - an event is any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of

protection or safety.

*Safety function (of a system/structure/component)* - a specific goal which shall be fulfilled in order to ensure the safety.

*Incident* - any unintended event, including operating errors, equipment failures, initiating events, accident precursors, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

*Facility, nuclear or radiological* - a facility and its associated land, buildings and equipment in which nuclear materials are produced, processed, used, handled, and stored.

*Radioactive waste predisposal management facility* - any facility or arrangement which has the aim pre-treatment, treatment, conditioning and storage of radioactive waste.

*Spent nuclear fuel management facility* - any facility or any arrangement that has as main objective the management of spent nuclear fuel.

*Ageing* - general process in which characteristics of a structure, system or component gradually change with time or use.

*Management of ageing* - engineering, operations and maintenance actions to control within acceptable limits the ageing degradation of structures, systems or components.

*Structures, systems, components (SSCs) important to safety* - a general term encompassing all of the elements (items) of a facility or activity which contribute to protection and safety, except human factors. The structures are the passive elements: buildings, vessels, shielding, etc. A system comprises several components, assembled in such a way as to perform a specific (active) function. A component is a discrete element of a system.

*Licensee* - the legal person or any other legal entity having overall responsibility for a activity or nuclear or radiological facility licensed according to the Law no. 111/1996, republished, with subsequent amendments and completions. The term refers to a licensee of predisposal waste management of radioactive waste and covers also the applicant who requests a licence.

## Postulated initiating events

### External postulated events

#### Natural phenomena

- Extreme weather conditions;
- Flooding;
- Earthquake;
- Natural fires;
- Effect of terrestrial and aquatic flora and fauna;
- Combination of the natural phenomena.

#### Human induced phenomena

- Fire, explosion or release of corrosive/hazardous substance;
- Aircraft crash (accidents);
- Missiles due to structural/mechanical failure in surrounding installations;
- Flooding;
- Power supply and potential loss of power;
- Civil strife;
- Combination of the human induced phenomena.

### Internal postulated events

- Loss of energy and fluids: electrical power supplies, air and pressurised air, vacuum, super heated water and steam, coolant, chemical reagents and ventilation;
- Improper use of electricity and chemicals;
- Mechanical failure including drop loads, rupture, leaks, plugging;

- Instrumentation and control, human failures;
- Internal fires and explosions;
- Flooding, vessel overflows.

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## Components of the Safety Case

- 1) **Context for the safety case**
  - i) Purpose of the safety case
  - ii) Scope of the safety case
  - iii) Demonstration of safety
  - iv) Graded approach
- 2) **Strategy for safety**
- 3) **Description of the facility or activity and the waste**
  - i) Site conditions
  - ii) System description (description of the facilities and activities and of the waste)
  - iii) Type of Waste - description
- 4) **Safety assessment**
  - i) General
  - ii) Radiological impact assessment
  - iii) Site and engineering aspects
  - iv) Engineering analysis
    - (a) Passive safety
    - (b) Defence in depth
    - (c) Scientific and engineering principles
  - v) Quality of the site characterization
  - vi) Operational safety aspects
  - vii) Non-radiological environmental impact
  - viii) Management system
- 5) **Management of uncertainties**
- 6) **Iteration and design optimization**
- 7) **Identification of safety measures**
- 8) **Limits, controls and conditions**
- 9) **Integration of safety arguments**
- 10) **Comparison with safety criteria**
- 11) **Plans for addressing unresolved issues**
- 12) **Interacting processes**
  - i) Involvement of interested parties
  - ii) Independent review
  - iii) Management system