

ROMANIA



**National Report as required by
Article 9.1 of the Council Directive
2009/71/EURATOM,
as amended by Council Directive
2014/87/EURATOM of 8 July 2014**

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INTRODUCTION

1. Current role of nuclear energy in Romania

The nuclear policy of Romania encompasses the development and use of nuclear energy and other nuclear fuel cycle activities in Romania as well as oversight of the development and enforcement of nuclear legislation and regulations to ensure that all nuclear facilities and activities are strictly regulated and controlled to the highest standards.

Long term commitment to nuclear power development, considered one of the drivers of the energy strategy of Romania, has been built based on the well-developed national nuclear infrastructure, proven and safe technology and excellent performance of Cernavoda NPP, as well as on the positive public perception of the nuclear energy.

2. Main governmental organisations with responsibilities in the nuclear sector

The Ministry of Economy, Energy and Business Environment establishes the national energy strategy and is the major shareholder of the nuclear energy production sector, nuclear research and engineering, nuclear fuel and heavy water management.

The National Commission for Nuclear Activities Control (CNCAN) is the nuclear safety and security regulatory authority of Romania, responsible for the regulation, licensing and control of nuclear activities, ensuring the peaceful use of nuclear energy and the protection of public and workers from the harmful effects of ionising radiation. CNCAN elaborates the strategy and the policies for regulation, licensing and control with regard to nuclear safety, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials, transport of radioactive materials and safe management of radioactive waste and spent fuel. CNCAN reports to the Prime Minister, through the Prime Minister's Chancellery.

The Ministry of the Environment, Water and Forests is the central authority for environmental protection and has specific responsibilities in the licensing and control of nuclear installations.

The State Inspectorate for Boilers, Pressure Vessels and Hoisting Installations (ISCIR), subordinated to the Ministry of Economy, Energy and Business Environment is responsible for the licensing and control of the pressure retaining systems and equipment, including those used in nuclear and radiological installations, with appropriate consultation and collaboration with CNCAN.

The Nuclear Agency and for Radioactive Waste (AN&DR), subordinated to the Ministry of Economy, Energy and Business Environment is responsible for promoting the peaceful use of nuclear energy and the related research and development programs and for the coordination, at national level, of the safe administration process of spent nuclear fuel and of radioactive wastes, including their disposal.

3. Main companies in the Romanian nuclear industry

The National Company "Nuclearelectrica" SA (Societatea Nationala Nuclearelectrica SA, further referred to in this report as SNN) is the owner and operator of Cernavoda NPP. The company includes two subsidiaries, one for nuclear power production (Cernavoda NPP) and one for nuclear fuel production (Nuclear Fuel Plant - FCN Pitesti), respectively. SNN is a government owned company, subordinated to the Ministry of Economy, Energy and

Business Environment. The company was listed on the Bucharest Stock Exchange in 2013 and, in its current shareholding structure, the Romanian state, through the Ministry of Economy, Energy and Business Environment, owns approximately 82.5 percent of the shares. The remaining percentage is owned by investment funds and other shareholders.

There are two national research and engineering institutes in the nuclear field - the Institute for Nuclear Research (ICN - Pitesti), which operates a TRIGA research reactor, and the Centre for Nuclear Projects Engineering (CITON - Bucharest). These two organizations are subsidiaries of the state owned company "Technologies for Nuclear Energy" (RATEN) which was established in 2013, by separation from the state-owned RAAN. RATEN is in charge of research and engineering activities devoted to the national nuclear power program. The two organizations are acting as scientific, technical and engineering support (technical support organizations) for the safe operation of Cernavoda NPP and for the other installations and projects that are part of the national nuclear power program.

The National Company for Uranium (CNU), also government owned and subordinated to the Ministry of Economy, Energy and Business Environment, is responsible for the administration of the national uranium mineral resources and performs geological research and exploitation activities for uranium ores, ores processing and concentrates refining, their transport and marketing.

4. Existing nuclear installations

In accordance with the provisions of Article 3.1 of the Council Directive 2009/71/Euratom, the following nuclear installations in Romania are under the scope of this report:

- Cernavoda Nuclear Power Plant (NPP) and its associated spent fuel storage and radioactive waste management facilities;
- The TRIGA Research Reactor and its associated spent fuel storage and radioactive waste management facilities;
- The Nuclear Fuel Manufacturing Plant and its associated radioactive waste management facilities;
- The decommissioned VVR-S Research Reactor in Magurele, near Bucharest, and its associated radioactive waste management facilities.

All these nuclear installations and their associated activities are licensed by CNCAN.

4.1 Cernavoda NPP

Romania has one nuclear power plant, Cernavoda NPP, with two units in operation, pressurised heavy water reactors of CANDU 6 design (CANadian Deuterium Uranium), each with a design gross output of 706.5 MWe. Unit 1 and Unit 2 started commercial operation on the 2nd of December 1996 and on the 1st of November 2007, respectively.

The plant was initially intended to have 5 units. The construction of the other three units on the site was stopped at different stages, and these units are currently under preservation. All units are pressurised heavy water reactors (PHWR), CANDU 6 type.



Fig. 1.2a Cernavoda NPP Units 1 and 2



Fig. 1.2b Cernavoda NPP Units 3 and 4

Cernavoda NPP Units 1 and 2 cover approximately 18% of Romania's total energy production. The Government has plans to further increase nuclear generating capacity through the resuming of construction and commissioning of Units 3 and 4 of the Cernavoda NPP. The decision to complete Units 3 and 4 was taken in June 2007. Pre-licensing reviews have been successfully completed, but no application for a construction license has been submitted yet.

The construction of Unit 5 has been cancelled by a decision of the General Shareholder Assembly of the National Company Nuclearelectrica, the owner and operator of Cernavoda NPP. The existing structures of Unit 5 will be used for different activities connected to the operation of Units 1 and 2 and, in the future, of Units 3 and 4.

Each unit is provided with a dedicated Spent Fuel Bay (SFB) for the spent fuel temporary storage. The SFB is designed to accommodate the fuel discharged during 8 years after its removal from the reactor core. After 6-7 years of cooling in the SFB, the spent fuel bundles are transferred to the on-site, naturally air cooled Intermediate Dry Spent Fuel Storage Facility (IDSFS) for the spent fuel long term storage.

The IDSFS is designed to provide safe, reliable and retrievable storage for spent fuel produced by the Cernavoda NPP Unit 1 and Unit 2 for a period of time of at least 50 years.

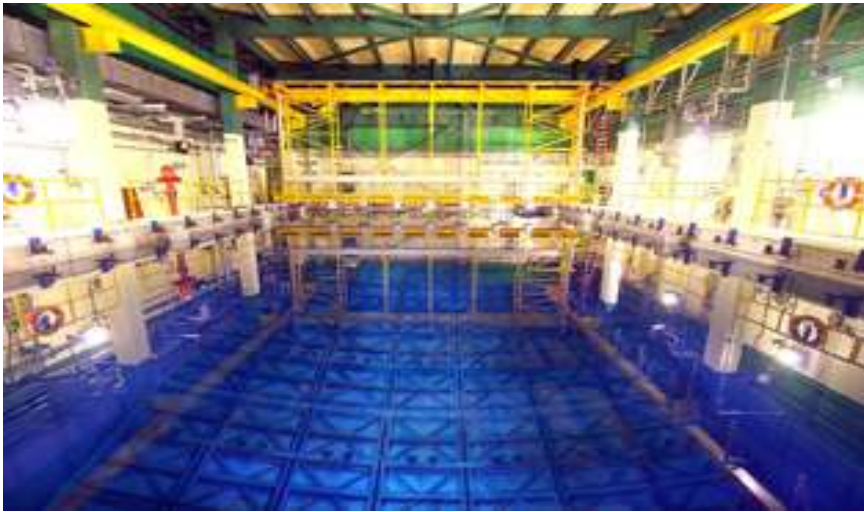


Fig. 1.3 Spent Fuel Bay

Intermediate Dry Spent Fuel Storage Facility on Cernavoda NPP site

The facility consists of seismically qualified MACSTOR 200 modules. The MACSTOR System consists of storage modules located outdoors in the storage site, and equipment operated at the spent fuel storage bay for preparing the spent fuel for dry storage. The spent fuel is transferred from the preparation area to the storage site in a transfer flask. The transportation is on-site.

Each MACSTOR-200 module is a parallelepiped structure made of reinforced concrete, which embeds 20 metallic storage cylinders positioned vertically. Once filled, the cylinder is covered with a reinforced concrete shield plug and a welded metallic cover plate, both of which are seal-welded to the upper flange of the storage cylinder. The fuel is air cooled, by natural convection. At present 11 storage modules have been constructed and are in operation.



Fig. 1.4 Intermediate Dry Spent Fuel Storage

Radioactive waste management facilities on Cernavoda NPP site

Cernavoda NPP has all operational arrangements including special designated facilities for proper current management of its gaseous, liquid and solid operational radioactive wastes, in order to assure the protection of the workers, the public and the environment.

The gaseous wastes are collected by ventilation systems, filtered and released through the ventilation stack under a strict control to minimize the environmental impact. The aqueous liquid wastes of NPP are collected and after adequate purification by using ion exchange resins (if necessary), are discharged in a controlled manner into the environment. Spent ion resins are collected and stored in vaults made of reinforced concrete lined with epoxy, located in the basement of the service building, in the proximity of the reactor building. The organic liquid waste is solidified in polymeric absorbent structure and stored on site. After pre-treatment (collection, segregation, decontamination) and treatment (compaction or shredding, as appropriate) the solid wastes are confined in 220L stainless steel drums (type A container) and transported to the Solid Radioactive Waste Interim Storage Facility which is located on the plant site and is designed for storage of low and intermediate level radioactive waste.

More detailed information on Cernavoda NPP design and operation is provided in the Romanian National Report for the Convention on Nuclear Safety, 8th edition, published in August 2019 (https://www.iaea.org/sites/default/files/romania_nr-8th-rm.pdf).

4.2. TRIGA Research Reactor of the Institute for Nuclear Research (Mioveni site)

Romania has one research reactor in operation. It is a dual core pool type TRIGA reactor, which has achieved the first criticality on the 18th of November 1979. The research reactor is primarily used for materials testing. The Institute for Nuclear Research (RATEN - ICN) in Pitesti is the operator of this research reactor.



Fig. 1.5 TRIGA Research Reactor

The reactor is composed of the following cores which are contained in the same pool:

- TRIGA SSR (Steady State Reactor) - 14 MW reactor; the conversion of the TRIGA-SSR Reactor started in 1992, from HEU fuel (Highly Enriched Uranium) to LEU fuel (Low Enriched Uranium) and was completed in 2006; the modernization of the reactor safety systems and of the control room has been completed in 2011 to support the long term operation of the facility;
- TRIGA ACPR (Annulus Core Pulse Reactor); the ACPR reactor, with LEU fuel, can be operated for a maximum pulse of 20.000 MW; it has a single large central irradiation channel for fuel and structural materials irradiations under pulsed modes.

The TRIGA research reactor has the following spent fuel management facilities:

- Spent Fuel Pool;
- Dry Storage Pits of the Post Irradiation Examination Laboratory, designed to receive experimental CANDU type irradiated fuel rods as well as fragments resulted from destructive testing of these rods.

ICN Pitesti has a Radioactive Waste Treatment Facility designated for treatment and conditioning of waste produced on site from research activities and from operation of TRIGA research reactor and for recovery of uranium from liquid effluents from fuel fabrication.

4.3. Nuclear Fuel Manufacturing Plant in Pitesti

The Nuclear Fuel Plant (FCN) in Pitești represents the national qualified producer of fuel bundles of type CANDU 6 for Cernavoda NPP. FCN is located on the same site with the TRIGA research reactor and the Institute for Nuclear Research (RATEN – ICN). The FCN Pitesti is part of SNN, together with Cernavoda NPP. SNN is the license holder for FCN.

FCN Pitesti produces the nuclear fuel for both Unit 1 and Unit 2 of Cernavoda NPP. The high quality of the defect free nuclear fuel manufactured by FCN Pitesti has been proven in operation.



Fig. 1.6 Nuclear Fuel Plant, Pitesti

FCN has its own designated facilities for the current management of its gaseous, liquid and solid wastes:

- The Gaseous Radioactive Waste System: air from potentially contaminated indoors areas (areas dedicated to the fuel manufacturing and laboratories) is collected, filtered with high efficiency prefilters and discharged through the plant's stacks.
- The Liquid Radioactive Waste Temporary Storage Tanks: the storage of the liquid radioactive wastes is provided in tanks located inside the basement of the plant building.
- The Solid Radioactive Waste Temporary Storage Platform: storage of low contaminated solid radioactive waste is provided on this platform on the ground located in the vicinity of the building of fuel manufacturing; it is dedicated to temporary storage of different categories of solid waste collected in the plant.

4.4. The VVR-S Research Reactor

The VVR-S research reactor has been located at Magurele site, outside Bucharest. It was a research reactor with a maximum thermal power of 2 MW, using distilled light water as moderator, coolant and reflector. The reactor was commissioned in 1957 and dedicated to nuclear physics research and radioisotopes production. Until 1984 the reactor was operated with nuclear fuel type EK-10. From 1984, this fuel was replaced with S-36, which was used until 1997 when the reactor was definitively shut-down. On average, the reactor was operated 5 days per week at full or variable power levels.

The reactor is under the administration of the Horia Hulubei National Institute of Research and Development in Physics and Nuclear Engineering (IFIN-HH). The decision for the decommissioning of the Nuclear Reactor VVR-S was taken in 2002. In the first phase of the decommissioning project, all the nuclear fuel of this reactor has been repatriated in the Russian Federation (the country of origin), before starting the dismantling and decontamination of the nuclear facility.

The decommissioning plan for the VVR-S reactor has been finalized and its building and site are currently in process of being released from regulatory control.

The radioactive waste resulting from the decommissioning of the VVR-S reactor is managed using the Radioactive Waste Treatment Plant on the same site and the National Repository for Radioactive Waste at Baita Bihor. All these facilities are managed by IFIN-HH, which is the holder of the respective licenses.

5. Preparation of the report

The present report has been prepared by CNCAN, following the ENSREG Guidelines regarding Member States Reports as required under Article 9.1 of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, as amended by Council Directive 2014/87/Euratom of 8 July 2014. The reports presents the main aspects that demonstrate the transposition and implementation of the requirements in these nuclear safety directives.

More detailed information on the nuclear installations described in the introduction and on the Romanian legislative and regulatory framework for nuclear safety is provided in the publicly available documents mentioned in the References section of this report.

ARTICLE 4 - LEGISLATIVE, REGULATORY AND ORGANISATIONAL FRAMEWORK

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework ('national framework') for the nuclear safety of nuclear installations. The national framework shall provide in particular for:

- (a) the allocation of responsibilities and coordination between relevant state bodies;*
- (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;*
- (c) a system of licensing and prohibition of operation of nuclear installations without a licence;*
- (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;*
- (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.*

The determination on how national nuclear safety requirements referred to in point (b) are adopted and through which instrument they are applied remains within the competences of the Member States.

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

4.1 Overview of the legislative, regulatory and organisational framework governing the safety of nuclear installations

The Law no. 111/1996 on the safe deployment, regulation, licensing and control of nuclear activities, republished with subsequent amendments, provides the legislative framework governing the safety of nuclear installations. In this report, it will be further referred to as "the Law".

The Law empowers the National Commission for Nuclear Activities Control (CNCAN), which is the national nuclear regulatory authority, to issue mandatory regulations, to issue licences for nuclear installations and activities, to perform assessments and inspections to verify compliance with the nuclear safety requirements and to take any necessary enforcement actions.

The current structure and content of the Law are described as follows.

Chapter I - General Provisions

This chapter defines the purpose of the Law, the activities which are within the scope of the Law, as well as the authority, mandate and responsibilities of CNCAN.

The Law applies to all activities involving or related to nuclear installations, radiological installations and ionizing radiation sources and generators, covering all the stages in their

lifetime.

The Law applies to research, design, possession, siting, construction, assembly, commissioning, trial operation, operation, modification, preservation, decommissioning or closure, import, export and intra-community transfer of nuclear installations, including of installations for the management of spent fuel. The Law also applies to the production, siting and construction, supply, leasing, transfer, handling, possession, processing, treatment, use, conditioning, temporary or permanent storage, decommissioning or closure, transport, transit, import, export and intra-community transfer of radiological installations, nuclear and radioactive materials, including radioactive waste.

In accordance with the Law, CNCAN is the national competent authority that exercises regulation, licensing and control attributions in the nuclear field. CNCAN is a public institution of national interest, with legal personality, having its headquarters in Bucharest, chaired by a President with the rank of State Secretary, coordinated by the Prime Minister. The first chapter of the Law also establishes the means of CNCAN financing.

The general dispositions also include statements with regard to the banning of nuclear proliferation activities and the banning of import, export and intra-community transfer of radioactive waste and spent fuel (with applicable exemptions).

Chapter II - Licensing Regime

This chapter is structured in two sections: “Notification, Registration, Licences and Permits” and “Licensing Conditions.”

The first section defines all the activities for which a formal authorization from CNCAN is needed, under the form of a notification, registration, licence or permit. It also sets the general framework for the licensing process, including the licensing stages that can be applied for the nuclear and radiological installations. The licensing stages applicable for each category of installations are established and detailed in the specific regulations.

The licences for nuclear installations are granted to legal persons, at their request, if they prove compliance with the provisions of the Law and specific regulations issued by CNCAN. According to the Law, the licences issued by the CNCAN shall be drawn up by levels of exigency, depending on the risks associated with the activities that are subject to licensing.

The licenses are applied for and issued, respectively, either simultaneously or successively, separately for each kind of activity or for each nuclear or radiological installation operating independently, belonging to the applicant’s property. The licensing of construction or operation phases for any nuclear or radiological facility may only take place if for the previous phases have been granted all the types of necessary licenses.

For a nuclear installation, in accordance with the specific regulation for the licensing of nuclear installations, the licensing stages include: design, siting, construction, commissioning, operation and decommissioning.

The licences and the permits are granted for a period established in accordance with the regulations developed by CNCAN. The licences and permits are not transferable.

Apart from situations when the licence holder is no more legally constituted or loses the legal personality, the licences can be suspended or withdrawn, partially or in total, for all cases of:

- non-compliance with the legal and regulatory provisions, or with the limits and conditions of the licence;
- failure to implement the corrective actions dispositioned as a result of the regulatory control;
- new situations, from technical point of view, or of other nature, that had been not known prior to the issue of the licence, and which could impact upon the safe deployment of the licensed activities;
- failure to meet the legal obligation with regard to providing funds for the safe management and disposal of radioactive waste and of spent nuclear fuel and for the decommissioning of nuclear installations or with regard to arranging indemnification for civil liability in case of nuclear damage.

The practice permits can be suspended or withdrawn for all cases of non-compliance with the provisions of the applicable regulations, as well as in case where the holder loses juridical capacity.

The second section of Chapter II provides the general conditions that an applicant shall meet for obtaining a licence, such as:

- to demonstrate the provision of adequate human and financial resources, technical and material means and the necessary technologies for carrying out the nuclear activities in a safe manner;
- to take all the necessary measures, at the level of the current technological and scientific standards, to prevent the occurrence of any damage that may result due to the construction and operation of the nuclear installation;
- to prove that has organisational capacity and responsibility in preventing and limiting the consequences of failures having the potential for a negative impact on the life and health of his own personnel, on the population, on the environment, on the property of third parties or on his own assets;
- to have arranged indemnification for liability in case of nuclear damage;
- to ensure that the decision-making process for safety matters in not unduly influenced by third parties;
- to have established arrangements, in accordance with the provisions of the specific CNCAN regulations, for ensuring radiological safety, physical protection, quality management, on-site emergency preparedness;
- to have established a system for the information of the public;
- to prove that has adequate and sufficient material and financial arrangements for the collection, transport, treatment, conditioning and storage of radioactive waste generated from the licensed activities, as well as for the decommissioning of the nuclear installation upon termination of operations, and has paid the contribution for the establishment of the fund for the management of radioactive waste and decommissioning.

Chapter III - Obligations of the Licence Holder

This chapter establishes the general obligations of the licence holders and responsibilities for the safety of their licensed installations, including nuclear waste management and decommissioning.

The licence holder has the obligation and the responsibility to take all necessary measures for:

a) ensuring and maintaining:

- nuclear safety, protection against ionising radiation, physical protection, on-site emergency preparedness and the quality assurance for the activities deployed and/or the associated radiation sources;
- a strict record of the nuclear and radioactive materials, as well as of all radiation sources used or produced in the activities under the licence;

b) complying with the technical limits and conditions stipulated in the licence and for reporting any deviations, in accordance with the specific regulatory requirements;

c) deploying only activities covered by the licence in force;

d) developing its own system of requirements, rules and instructions as to ensure that the licensed activities are carried out without posing an unacceptable risks of any kind;

e) ensuring and maintaining adequate human and financial resources.

The liability for nuclear damage, caused during or as a result of an accident that could arise from the deployment of the licensed activities or of other activities resulting in the death, injury to the corporal integrity or health of a person, destruction, degradation, or temporary impossibility of using any goods, rests entirely with the licence holder, under the terms established by law and by the international agreements to which Romania is a party.

The licensee has full accountability for the safety of the licensed installations and activities and the Law explicitly states that the licensee's responsibility for safety cannot be delegated.

For the deployment of any nuclear activities generating or having generated radioactive waste, the Law states that the licence holder shall:

a) be responsible for the management of radioactive waste generated by the licensed activities;

b) bear the expenses related to the collection, handling, transport, treatment, conditioning and temporary or permanent storage of the waste;

c) pay the legal contribution to the Fund for the management and final disposal of the radioactive waste and spent fuel and for the decommissioning of the nuclear installations.

The Law states that the licence holder shall:

a) develop and submit for approval to CNCAN a programme for the preparation of the decommissioning;

b) produce the proof of having paid the legal contribution to the Fund for the management and final disposition of the radioactive waste and spent fuel and for the decommissioning of the nuclear installations.

The Law also states that:

- the expiry, suspension or withdrawal of the licence does not exonerate the licence holder or the person having taken over the property title over the nuclear or radiological materials and installations covered by that licence, from the obligations stipulated in the Law, nor from those deriving from the conditions stipulated in the licence.
- prior to the termination of the activities or decommissioning of nuclear or radiological installations, as well as prior to any transfer, partial or whole, of the nuclear or radiological installations and materials, the licence holder shall apply and obtain, under the terms stipulated in the Law, a licence to own, preserve, decommission or transfer the respective installations and materials, as applicable.
- the licence or practice permit issued on the grounds of the Law does not exonerate the licence or permit holder from observing the legislation in force.
- the termination of nuclear activities shall take place in compliance with the provisions of the specific regulations issued by CNCAN.
- CNCAN establishes the concrete modality of application of the Law whenever its provisions cannot be applied simultaneously with other legal provisions in force, with the consultation of the relevant public administration authorities, giving priority to the observance of the conditions for the safe deployment of the nuclear activities.

Chapter IV - Control Regime

The legal provisions stated in this chapter empower CNCAN to carry out inspections at the licence holders as well as at the applicants for a licence, to control the application of the relevant regulatory requirements.

CNCAN inspectors are empowered to perform the necessary control activities at the site where the activities subject to licensing are deployed, as well as at any other location which may be connected to these activities, including the home or other location of any natural or legal person that may carry out activities related to nuclear and radiological installations or have possession of any nuclear or radiological materials, including related information.

The control activities are performed for any of the following situations:

- before granting the licence for which an application has been submitted;
- for the whole period of validity of the licence (periodic, as well as unscheduled or unannounced inspections);
- based on a notification/request made by the licence holder;
- for cases when it is suspected that installations, devices, materials, information, activities, etc., that are under the scope of the Law, exist or are performed without having been registered and subjected to licensing/authorisation process.

Following the control activities, CNCAN may disposition, if deemed necessary, the suspension of the activities and cease of operation / use of the respective installation, materials, devices, equipment, information, etc. that are possessed / operated / used without a licence or the operation/possession of which could pose a threat.

In exercising the control mandate, CNCAN representatives are empowered to:

- a) access any place in which activities subject to the control may be deployed;
- b) carry out measurements and install the necessary surveillance equipment;
- c) request the taking or receiving of samples from the materials or products directly or indirectly subject to the control;
- d) compel the controlled natural or legal person to ensure the fulfilment of the provisions mentioned under points a) – c) and to mediate the extension of the control to the suppliers of products and services or to their subcontractors;
- e) have access to all the information necessary for achieving the objectives of the control, including technical and contractual data, in any form, with observance of confidentiality if the holder makes explicit requests in this sense ;
- f) compel the licence holder to transmit reports, information, and notifications in the form required by regulations;
- g) compel the licence holder to keep records, in the form required by regulations, of materials, of other sources and activities subject to the control, and to control these records;
- h) receive the necessary protective equipment, for which the applicant or licence holder shall arrange.

For the whole duration of the control activities, CNCAN representatives have the obligation of observing the applicable licensing conditions, as imposed upon the personnel of the licence holder.

CNCAN representatives have the following responsibilities, to be exercised after conclusion of the inspection/control activity:

- a) to draw up a report stating the results of the control, the corrective actions requested, and the deadlines for their implementation;
- b) to propose the suspension or withdrawal of the licence or practice permit, under the terms of the Law;
- c) to propose the information of the legal prosecution bodies in the cases and for the violations specified under the Law;
- d) to request that the licence holder applies disciplinary sanctions to the personnel guilty of violations specified in the Law;
- e) to apply the sanctions for contraventions, as specified in the Law, to the persons vested with the statutory responsibility of representing the licence holder in the relation with the public authorities;
- f) to apply the sanctions for contraventions, under the terms of the Law, to the personnel guilty of commission of the respective violations.

Chapter V - Authority and Responsibilities

This chapter defines the authority and responsibilities of CNCAN, as well as those of the other governmental organisations that have different roles in the regulation, monitoring or control of the various nuclear activities.

The Law gives a list of authorities having attributions in controlling various aspects related to nuclear activities. The cooperation between CNCAN and the other governmental authorities (ministries and agencies) covers areas such as environment, health, transport, industrial safety, security, etc. Although their attributions and responsibilities are established by the legislation in force, CNCAN has also signed formal Memoranda of Understanding with each of the relevant authorities, for ensuring the prevention of potential gaps and overlaps in the implementation of their respective duties and responsibilities.

The provisions stated in Chapter V of the Law with regard to the specific responsibilities of CNCAN are described in this report under Article 5 – Competent Regulatory Authority.

Chapter VI - Penalties

This chapter defines the violations, including criminal offences, acts of terrorism and contraventions, and the respective penalties entailed, specifying that the offences of attempt are also subject to prosecution. The unauthorised deployment of any of the activities subject to licensing or approval under the terms of the Law constitutes a criminal offence.

Chapter VII - Provisional and Final Dispositions

This chapter includes provisions with regard to the validity of the licences and permits issued prior to the coming into force of the Law, the possibility of appealing against any regulatory decision claimed to have caused a prejudice, etc.

The Annexes to the Law include the following:

Annex 1: List of materials, devices and equipment pertinent to nuclear proliferation;

Annex 2: Definitions;

Annex 3: Authorities having various attributions in the review and inspection of nuclear activities.

Annex 4: List of organisations without legal personality, which can hold a licence under the terms of the Law.

4.1.a. Allocation of responsibilities and coordination between relevant state bodies

The allocation of responsibilities and coordination between relevant state bodies is specified in the Law 111/1996, Chapter V - Authority and Responsibilities and in the Annex 4.

CNCAN is the nuclear regulatory authority, in charge of regulation, licensing and control of all aspects relevant for nuclear safety, nuclear security and nuclear safeguards.

The Ministry of the Environment, Waters and Forests is the central authority for environmental protection and has specific responsibilities in the licensing and control of nuclear installations.

The State Inspectorate for Boilers, Pressure Vessels and Hoisting Installations (ISCIR), subordinated to the Ministry of Economy, Energy and Business Environment is responsible for the licensing and control of the pressure retaining systems and equipment, including those used in nuclear installations.

The Ministry of Labour and Social Protection, through the Work Inspectorate, is responsible for the regulation and oversight of industrial safety.

The Ministry of Internal Affairs, through the Department for Emergency Situations and the Romanian General Inspectorate for Emergency Situations, has specific responsibilities for the regulation and oversight of emergency preparedness.

CNCAN cooperates in good conditions with all these national authorities.

4.1.b. Development of nuclear safety regulations

CNCAN is empowered by Law to develop regulations in order to detail the general legal requirements as well as any other regulations necessary to support the licensing and control activities. All the regulations issued by CNCAN are mandatory and enforceable. The regulations are developed in observance of relevant international standards and good practices and in accordance with the provisions of the national legislation regarding the elaboration of normative acts.

The management system of CNCAN includes a procedure for drafting regulations and a process is in place to ensure internal consultation among CNCAN departments regarding the draft regulations. This is undertaken prior to the external consultation. The aim of the internal review is to provide an independent assessment of the scope, structure, content and implications of the regulatory documents, by persons not directly involved in their elaboration. In some cases, external experts are also involved in the review of the draft regulations developed by CNCAN staff. The correctness with regard to technical and legal aspects is observed.

The regulations in draft are published on the CNCAN website and are sent for external consultation to all interested organisations in order to receive feedback. The comments and suggestions received are analysed and also discussed in common meetings when necessary. As a consequence of this review process, the drafts may suffer some amendments. Subsequently, the final revision of a regulation is approved by the President of CNCAN and then submitted for publication in the Official Journal of Romania. Besides publication in the Official Journal, in order to provide for broader dissemination, CNCAN publishes the regulations on its website.

Currently there is in place a comprehensive set of nuclear safety regulations, covering all the most important aspects for all the stages of the lifecycle of nuclear installations.

4.1.c. Overview of the licensing system

The process for the licensing of the nuclear installations is based on the provisions of the Law and of the specific regulations issued by CNCAN.

The Law clearly stipulates that operation of a nuclear installation without a licence is prohibited and that the prime responsibility for the safety of a nuclear installation rests with the licence holder.

As required by the Law, a licence is needed for each of the stages of the life time of a nuclear installation. For a nuclear installation, the licensing stages include: design, siting,

construction, commissioning, operation and decommissioning.

The detailed regulatory requirements, as well as the assessment and inspection criteria used by CNCAN in the licensing process are derived from a number of sources, such as:

- Romanian regulations;
- Limits and Conditions specified in the different licenses;
- Regulatory guides;
- IAEA Safety Standards and Guides;
- ICRP recommendations;
- Applicable Standards and Codes (CSA, ANSI, ASME, IEEE, etc.);
- Safety related documentation produced by the licensee and approved or accepted by CNCAN (e.g. Safety Analysis Reports, Safety Design Guides, Design Manuals, reference documents, station instructions, operating manuals, technical basis documents).

Apart from the formally issued regulations, the requirements established by CNCAN in the licensing process are imposed through regulatory letters. Requirements and dispositions are stated also in the inspection reports. In order to facilitate the implementation of the requirements established in the regulations, CNCAN issues regulatory guides on various topics.

The licensing process is outlined in the Regulation on the licensing of the nuclear installations (NSN-22) and is documented according to CNCAN internal procedures.

The licensing submissions include, as the main document, a safety analysis report in accordance with the specifications established by CNCAN for each stage of the licensing process. In addition to the safety analysis reports, various supporting documents are submitted by the applicants to demonstrate the safety of the nuclear installation and the fulfilment of all the relevant legislative and regulatory requirements.

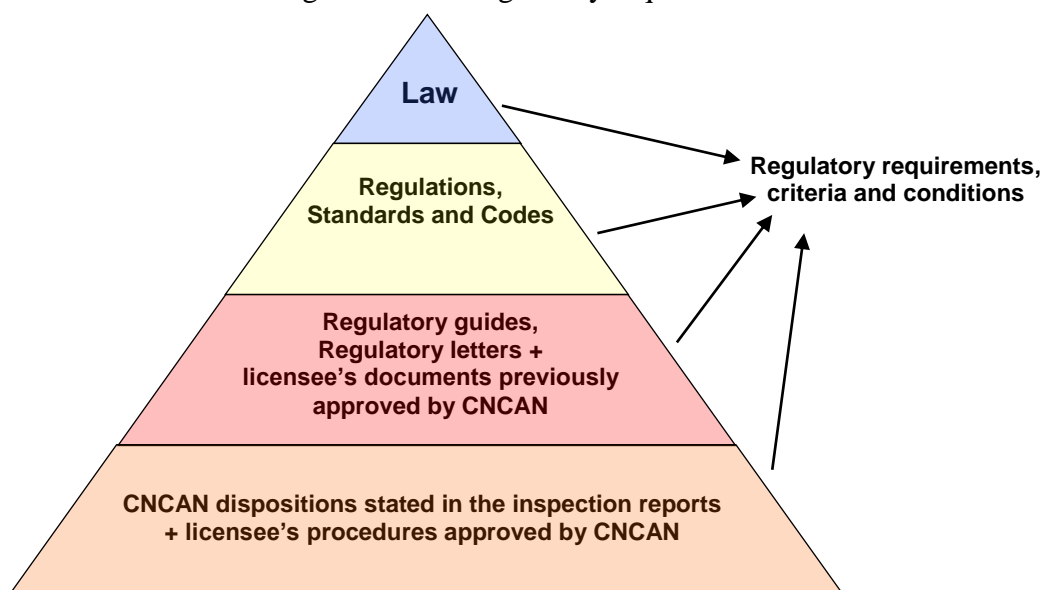


Fig. 4.1 - Documents containing requirements used by CNCAN in the licensing process

The review process performed by CNCAN is documented by one of the following means:

- evaluation reports;
- regulatory letters;
- inspection reports, containing findings and dispositions;
- written minutes as result of the licensing meetings (common meetings between CNCAN staff and the representatives of the licence holder or applicant).

If the review concludes that all the requirements have been met by the applicant, a licence is issued by CNCAN, for a specified period of time. All the limits and conditions derived for each specific case are clearly stated in the licence, which includes sections devoted to quality management, emergency preparedness, radiation protection, reporting requirements, compliance with licensing basis documents, the hierarchy of documents of the licensee, etc.

The typical content of a licence for operation of a nuclear installation includes, as applicable:

- facilities and activities covered by the licence;
- period of validity, provided that all conditions are met;
- general conditions specifying the documents on which the licence is based;
- specific conditions on the facility organisation and personnel;
- specific conditions for the operation (limits and conditions);
- specific conditions related to radiation protection of the personnel, public and environment;
- specific conditions regarding approvals for design changes and changes in the operating conditions;
- specific conditions for the management of records;
- specific conditions governing the procurement, possession, use, transfer, and storage of the nuclear fuel, of the nuclear and radiological materials, etc;
- specific conditions regarding safeguards;
- specific conditions regarding physical protection;
- specific conditions regarding quality management;
- reporting requirements (incident reporting, quarterly and annual reports);
- specific conditions regarding the periodic safety review;
- specific conditions regarding the emergency preparedness arrangements .

For detailing the requirements in the Law with regard to the issuance of practice permits, the procedures and conditions for issuing a practice permit for the personnel involved in the operation and management of the nuclear installations are established in the Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations (NSN-14 rev.1) and in the Regulation on the training, qualification and

authorization of nuclear installations personnel with nuclear safety related jobs (NSN-23). The processes implemented for the renewal of licences and permits are basically the same as those for the initial licensing.

All other authorisations granted by other governmental authorities are prerequisites to the CNCAN licences for nuclear installations, i.e. an applicant has to prove to CNCAN that it has obtained all the other licenses, agreements, approvals in accordance with the legislation in force. An exception would be the environmental authorisation issued by the Ministry of Environment, Waters and Forests after the issuance of the operation licence by CNCAN. The environmental agreement, issued by the same Ministry is however a prerequisite to the siting licence issued by CNCAN. The issues and conditions raised by the other national authorities are taken into account before licences are granted by CNCAN, providing that there is no conflict with the provisions of the Law and of the applicable CNCAN regulations.

4.1.d. Regulatory Control

Regulatory control exercised by CNCAN over nuclear installations comprises the review and assessment process and the inspection process.

In accordance with the provisions of the Law, CNCAN is empowered to request from the licensees, or from the applicants for a licence, all the documentation needed for the regulatory decision making process on safety related matters. The documentation that needs to be submitted to CNCAN for review and approval is generally specified in the regulations (e.g. safety analysis reports and reference documents).

Additional support documentation is requested on a case by case basis and specified in regulatory letters, minutes of the meetings between CNCAN staff and the representatives of the licensees/applicants, etc. According to the Law, the licensees and applicants have the obligation of facilitating CNCAN inspections and access to documentation and to provide all the information required by CNCAN.

The safety related documentation made available to CNCAN includes a large variety of documents, such as safety analysis reports, (quality) management system manuals, different types of safety assessments and technical evaluations, information reports and procedures (e.g. reference documents, station instructions, operating procedures, work plans, etc.).

The responsibilities for the review and assessment of the technical documentation submitted by the licensees or applicants are assigned to the different technical units within the organisational structure of CNCAN. The Nuclear Fuel Cycle Division of CNCAN is in charge of all aspects related to the regulatory control of nuclear installations.

The regulatory review activities are planned, performed and reported in accordance with internal procedures and instructions in order to assure the availability of internal resources and, as appropriate, external resources, and to establish interfaces with the licensees. Each technical unit has specific attributions and tasks and develops assessment and inspection procedures and plans in the respective areas under their responsibility.

For major reviews, such as those performed by CNCAN prior to granting a licence or an approval for a licensing milestone, interdisciplinary teams are established, which include

experienced staff from all the technical units involved in the licensing of a nuclear installation, with the necessary expertise for covering all the areas of review. Most of the experts responsible for the assessment of the safety related documentation are participating also in the teams that perform the inspections. The assessments and inspections performed in the framework of the major reviews mentioned above are performed supplementary to the assessment and inspection activities deployed by each technical unit on a regular basis.

The key objective of the CNCAN inspection programme for nuclear installations is to monitor compliance with the legal, regulatory and licensing requirements, and to take enforcement action in the event of non-compliance. The inspections are planned in a systematic manner by the staff from CNCAN headquarters and the resident inspectors, with the aim of ensuring a proactive identification of the deficiencies and deviations from good practices that could result in non-compliances. The inspection planning is periodically reviewed and modified as new information on the facility or organisation is obtained.

The inspections performed by CNCAN include:

- scheduled inspections, planned and performed either by each of the technical divisions, or jointly, with the occasion of the major licensing milestones;
- unscheduled and/or unannounced inspections, some of these being reactive inspections, in response to incidents;
- routines and daily observation activities performed by the resident inspectors for Cernavoda NPP.

Examples of review and inspection activities and tasks performed by CNCAN inspectors include:

- review of operation reports;
- review of progress on outstanding safety issues;
- review of the past safety performance of nuclear installations;
- review of the status of committed safety improvements;
- quality management system audits;
- review of temporary and permanent modifications to ensure they are consistent with the licensing basis and design basis for the installation;
- system inspections;
- inspections during planned and unplanned outages, construction and commissioning, as applicable;
- monitoring of the periodic safety review activities, as applicable;
- monitoring of the plant processes and programmes;
- monitoring of the conditions for nuclear installation safety assessment, as applicable;
- observation of operation and maintenance practices and work;
- observation of plant management meetings;
- monitoring of the implementation of the licensees' training programmes;

- monitoring of emergency drills and exercises;
- monitoring of the radiological protection practices;
- inspection of the validation of procedures for responding to transients, accidents and emergency situations;
- assessment and inspection of cyber security;
- analysis and investigation of operational experience events – reportable events and abnormal conditions;
- regulatory oversight of safety culture.

Resident inspectors in the Cernavoda NPP Surveillance Unit have a very important role in the daily observation and assessment of the activities on the NPP site. Examples of activities performed by the resident inspectors are given below:

- verification of the implementation of the dispositions and recommendations resulted from previous inspections;
- inspections in the main control rooms and in the field for observing and gathering information on the general progress of plant activities;
- detailed system inspections, for observing the performance of maintenance activities and the status of related documentation;
- daily verification of the various records and reports related to the operation of the plant;
- evaluation of the practices in different areas of activity to observe adherence to procedures, with focus on radiation protection aspects, preventive and corrective maintenance activities, testing of the special safety systems, personnel training, quality assurance;
- monitoring of the emergency preparedness arrangements;
- independent preliminary investigation of events significant for safety;
- surveillance of the performance of activities during the planned and unplanned outages with regard to configuration of the safety related systems, radiation protection of the personnel, work involving contractors, elaboration and review of the safety documentation (e.g. procedures, work plans, modification proposals, etc.);
- observing the performance of tests or other activities performed on safety related systems, usually according to an inspection plan that includes Witness Points (WP) and Hold Points (HP) (this approach is used mainly for monitoring the activities during planned outages).

A series of routine inspections is used by the Cernavoda NPP Surveillance Unit to monitor the physical state of the systems and the operating parameters, covering all safety relevant areas of the plant. Besides the routines, the resident inspectors perform daily visits to the control room, for verifying the main operating parameters and the different aspects related to work planning and control of temporary modifications.

The resident inspectors participate also as observers in the daily planning meetings of the plant management. Daily reports are elaborated by the Cernavoda NPP Surveillance Unit and forwarded to the CNCAN headquarters for information on the plant status and for ensuring awareness of any inspection findings.

The assessment and inspection activities performed by CNCAN staff are documented in assessment reports, inspection reports and written minutes of the meetings with the representatives of the licensees/applicants. These documents are also distributed to the licensees/applicants, in addition to the regulatory letters that summarise the main regulatory requirements and dispositions based on findings arising from the review process.

4.1.e. Enforcement

In accordance with the provisions of the Law, CNCAN has in place a system to enforce compliance through graded measures. Therefore, the possible actions that CNCAN can take in the event of non-compliance are:

- dispositions for licensee action (these are stated in each inspection report);
- action notices/directives stated in regulatory letters;
- fines / monetary penalties;
- license amendments;
- restricted reactor operation;
- revocation or suspension of the license;
- prosecutions.

The legal basis for the enforcement activities is covered by the provisions in Chapters IV (Control Regime) and VI (Penalties) of the Law. The enforcement process is described in the internal procedures that are part of the management system of CNCAN.

4.2 Review and update of the national framework

Romania has ratified all the relevant international conventions and treaties applicable for the nuclear installations and activities. Revisions and modifications to the Law are performed, as necessary, to take account of the changes in European and international legislation and standards, as well as of the regulatory experience feedback.

In accordance with the provisions of the Law, CNCAN has the responsibility for reviewing the regulations whenever it is necessary for these to be consistent with international standards and with relevant European and international legislation, and for establishing the measures for the application thereof.

Various sources of information relevant for updating the system of regulations and guides are used, including the development of international safety standards, international cooperation, the revision of the references levels adopted by WENRA (Western European Nuclear Regulators' Association), insights from safety analyses, studies and peer reviews, research and development activities, new technologies becoming available, the feedback from the operators and the feedback from CNCAN inspectors based on their experience with the enforcement of the regulations.

The current nuclear safety regulations and guides providing the basis for the licensing and regulatory oversight of the Cernavoda NPP include the following:

- NSN-01 - Nuclear safety requirements on siting of NPPs (2010);
- NSN-02 - Nuclear safety requirements on the design and construction of NPPs (2010);
- NSN-05 - Nuclear safety requirements on the operational limits and conditions for nuclear installations (2015);
- NSN-06 - Nuclear safety requirements for the protection of nuclear installations against external events of natural origin (2015);
- NSN-07 (rev.1) - Nuclear safety requirements on the response to transients, accident management and on-site emergency preparedness and response for NPPs (2020);
- NSN-08 - Nuclear safety requirements on probabilistic safety assessments for NPPs (2006);
- NSN-09 - Nuclear safety requirements on fire protection in NPPs (2006);
- NSN-10 - Nuclear safety requirements on periodic safety reviews for NPPs (2006);
- NSN-11 - Nuclear safety requirements on emergency core cooling systems for CANDU NPPs (2006);
- NSN-12 - Nuclear safety requirements on containment systems for CANDU NPPs (2005);
- NSN-13 - Nuclear safety requirements on shutdown systems for CANDU NPPs (2005);
- NSN-14 (rev. 1) - Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations (2014);
- NSN-16 (rev.1) - Nuclear safety requirements on surveillance, maintenance, testing and in-service inspections for nuclear installations (2020);
- NSN-17 - Nuclear safety requirements on ageing management for nuclear installations (2016);
- NSN-18 - Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations (2017);
- NSN-20 - Regulation on the nuclear safety policy and independent nuclear safety oversight for nuclear installations (2015);
- NSN-21 (rev.1) - Fundamental nuclear safety requirements for nuclear installations (2020);
- NSN-22 - Regulation on the licensing of the nuclear installations (2019);
- NSN-23 - Regulation on the training, qualification and authorization of nuclear installations personnel with nuclear safety related jobs (2017);
- NSN-24 - Regulation on deterministic nuclear safety analysis for nuclear installations (2019);
- NSN-25 - Requirements on the decisional transparency in licensing process for nuclear installations (2019);
- NSN-26 - Regulation on the interfaces between nuclear safety, radiological safety, physical protection, cyber security and nuclear safeguards (2019);
- NSN-27 – Regulation on the use of standards for the assessment and continuous improvement of nuclear safety for nuclear power plants (2020);
- NSC-01 - Regulation on the protection of nuclear installations against cyber threats (2014);

- GSN-01- Guide on the industrial codes and standards for nuclear power plants (2015);
- GSN-02 - Guide on the independent verification of nuclear safety analyses and evaluations (2015);
- GSN-03 - Guide on fulfilling the overall nuclear safety objective set in the fundamental nuclear safety requirements for nuclear installations (2018);
- GSN-04 - Guide on the format and content of the final safety analysis report for nuclear power plants (2015);
- GSN-07 – Nuclear safety guide for the preparation of nuclear installations refurbishment (2018);
- GSN-08 - Nuclear Safety Guide on restarting nuclear facilities after unplanned shutdowns (2019);
- GSN-09 - Nuclear Safety Guide on the development and assessment of the nuclear safety culture (2019);
- GSN-10 – Nuclear Safety Guide on Time-Limited Ageing Analyses (2020);
- A set of 13 regulations on quality management systems for nuclear installations and activities (issued in 2003–2005 and updated in 2014).
- Regulations on radiological protection, radioactive waste management, physical protection, nuclear safeguards, emergency planning and preparedness.

The complete set of regulations and guides applicable to nuclear installations is available on CNCAN's web site.

As it can be seen, many new regulations and regulatory guides have been developed and issued in the last reporting period, demonstrating a constant preoccupation for the improvement of the regulatory framework for nuclear safety.

ARTICLE 5 - COMPETENT REGULATORY AUTHORITY

1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.

2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

(a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organisation when carrying out its regulatory tasks;

(b) takes regulatory decisions founded on robust and transparent nuclear safety-related requirements;

(c) is given dedicated and appropriate budget allocations to allow for the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget;

(d) employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;

(e) establishes procedures for the prevention and resolution of any conflicts of interest;

(f) provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.

3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:

(a) propose, define or participate in the definition of national nuclear safety requirements;

(b) require that the licence holder complies and demonstrates compliance with national nuclear safety requirements and the terms of the relevant licence;

(c) verify such compliance through regulatory assessments and inspections;

(d) propose or carry out effective and proportionate enforcement actions.

5.1 Description of the authority and responsibilities of CNCAN

In accordance with the Law, CNCAN is the competent regulatory authority in the field of nuclear safety of nuclear installations.

The general authority and responsibilities of CNCAN are stipulated in the Law (as described in the section of this report corresponding to article 4 of the Directive) and are further detailed in the Regulation for Organisation and Functioning of CNCAN, approved by Governmental Decision.

The mandate of CNCAN can be summarized as follows:

- CNCAN is the national authority competent in exercising regulation, licensing and control in the nuclear field, for all the activities and installations under the scope of the Law.
- CNCAN elaborates the strategy and the policies for regulation, licensing and control with regard to nuclear safety, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials, transport of radioactive materials and safe management of radioactive waste and spent fuel, as part of the National Strategy for the development of the nuclear sector, approved by Governmental Decision.
- CNCAN is responsible to ensure, through the regulations issued and the dispositions arising from the licensing and control processes, that an adequate framework is in place for the deployment of activities under the scope of the Law.
- CNCAN is responsible for revising the regulations whenever necessary for the correlation with the international standards and ratified conventions in the nuclear field and for establishing the necessary regulatory measures for their application.

CNCAN has the following main responsibilities and authority:

- Initiates projects for normative acts in its areas of competence and issues regulations in the nuclear field, consulting as necessary the other authorities with attributions in this domain, according to the Law;
- Reviews and consents to all the normative acts with implications for the nuclear field, prior to their entering into force;
- Approves, in accordance with the law, the intervention plans for nuclear and radiological accident situations and participates in the intervention;
- Collaborates with the central authority for environmental protection and controls the implementation of the activities of the environmental radioactivity monitoring network;
- Requests to the competent authorities in the field of national security to perform the necessary checks for the persons with responsibilities in the field of nuclear activities, in compliance with the specific regulations;
- Initiates, with the consent of the Ministry of Foreign Affairs, activities for cooperation with IAEA and with other international organizations specialized in the nuclear field;
- Cooperates with similar institutions/authorities from other states;
- Controls the implementation of the provisions of international treaties and agreements in force, with regard to safeguards, physical protection, illicit trafficking, transport of nuclear and radioactive materials, radiation protection, quality assurance in the nuclear field, nuclear safety, safe management of spent fuel and radioactive waste, and the intervention in case of nuclear accident;
- Establishes and coordinates the national system for evidence and control of nuclear materials, the national system for evidence and control of radiation sources and of nuclear and radiological installations, and the national registry of radiation doses received by the occupationally exposed personnel;
- Cooperates with other authorities that have, according to the law, responsibilities

with regard to the safe operation of nuclear and radiological installations, correlated with the requirements for the protection of the environment and the population;

- Ensures public information on matters that are under the competence of CNCAN;
- Organizes public debates on matters that are under the competence of CNCAN;
- Represents the national point of contact for nuclear safeguards, for the physical protection of nuclear and radiological materials and installations, for the prevention and combat of illicit trafficking of nuclear and radioactive materials, and for radiological emergencies;
- Orders the recovery of orphan sources and coordinates the recovery activities;
- Licenses the execution of nuclear constructions and exercises control over the quality of constructions for nuclear installations;
- Carries out any other duties stipulated by the Law, with regard to the regulation and control of nuclear activities;
- Transmits notifications and presents reports to the European Commission on the status of the implementation of the Council Directives;
- Approves the national strategies for the development of the nuclear sector and for the safe management of the spent nuclear fuel and of the radioactive waste;
- Organizes periodically, at least once every 10 years, self-assessments and international peer-reviews of its activities, as well as of the national regulatory framework.

5.2 Independence of CNCAN

5.2.a. Functional separation from bodies and organisations involved in promotion or utilisation of nuclear energy

CNCAN is completely separated and independent from all the organisations concerned with the promotion or utilisation of nuclear energy. The responsibilities assigned to CNCAN by the Law concern solely the regulation, licensing and control of nuclear installations and activities.

CNCAN reports to the Prime Minister, through the Prime Minister's Chancellery. CNCAN exercises its functions independently from the ministries and other authorities of the central public administration which are subordinated to the Government. The companies and organisations that operate or own the main nuclear and radiological installations are subordinated to the Ministry of Economy, Energy and Business Environment or to the Ministry of Education and Research.

CNCAN is chaired by a President appointed by the Prime Minister. The position of the CNCAN President is assimilated to that of State Secretary. The President of CNCAN, with the advice of the General Secretariat of the Government, organises the subsidiary structures of the divisions of CNCAN depending on actual needs and conditions of the activities of CNCAN. The organisational structure of CNCAN and the modifications thereof are approved by Governmental Decision.

5.2.b. Basis for the regulatory decisions

The regulatory decisions that are taken by CNCAN in the area of nuclear safety comprise of the following:

- Licensing decisions (i.e. to grant a license or reject a licensing submission);
- Enforcement decisions (i.e. to direct compliance, apply penalties, amend, suspend or revoke licenses);
- Decisions to increase regulatory oversight of specific areas, based on licensees' performance, operational experience feedback and on regulatory experience feedback.

All the above mentioned decisions are based on requirements that are stipulated in the Law and in the nuclear safety regulations in force. As presented in the section of this report corresponding to article 4 of the Directive, the nuclear safety regulations are developed, revised and updated in a systematic manner and are transparent (being issued after a consultation process and being publicly available).

CNCAN is effectively independent from undue influence and has implemented sound regulatory decision-making processes, in line with the international standards and best practices.

5.3.c. Budget allocations

The money collected from tariffs for CNCAN activities (fees charged for performing inspection activities and technical assessments and for granting licenses, permits and authorizations) become revenue to the state budget. CNCAN is financed from the state budget through the General Secretariat of the Government (SGG). CNCAN is responsible for the implementation of its allocated budget.

5.3.d. Organisational structure and staffing

The current organisational structure of CNCAN is shown in Fig. 5.1.

The department in charge of the regulation, licensing and control of nuclear installations is the Nuclear Fuel Cycle Division, composed of the following sections:

- Nuclear Safety Assessment Section;
- Nuclear Reactors Regulation and Oversight Section, comprising of 2 units: Nuclear Regulations and Standards Unit and Cernavoda NPP Residents Inspectors Unit;
- Management Systems Control Section;
- Radiological Protection, Radioactive Waste Safety and Transport Section;
- Nuclear and Radiological Emergencies Section;
- Mining, Safeguards and Physical Protection Section.

There are currently 41 staff members working in the Nuclear Fuel Cycle Division of CNCAN, all of them involved in regulatory activities related to nuclear installations.

The total number of posts in the Nuclear Fuel Cycle Division is of 61, based on the analysis of current and future staffing needs. There are still 20 vacancies. Efforts are ongoing to staff all the available positions with personnel having adequate educational background, experience and qualifications and to improve staff retention.

In specific cases, external consultants are also employed to assist CNCAN staff in review and assessment activities. In addition, CNCAN benefits from external expertise, when necessary, through IAEA technical co-operation projects and bilateral agreements with regulatory authorities from other countries.

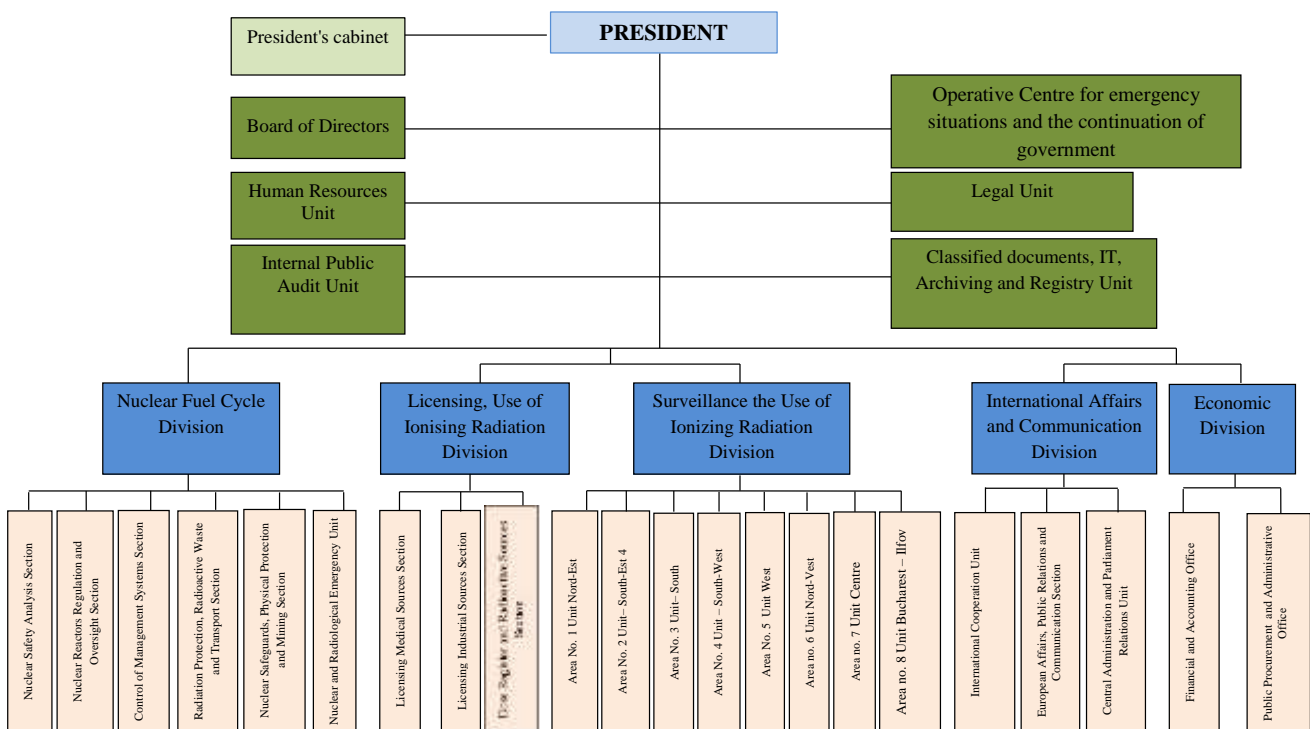


Fig. 5.1. – CNCAN Organisational Structure

5.3.e. Prevention and resolution of conflicts of interest

The prevention and resolution of conflicts of interest is done in accordance with national specific regulations on this aspect, which are applied for all employees of public authorities. CNCAN staff involved in licensing and control activities have to declare their revenues and their interests and these declarations are posted on the CNCAN public website and sent to the national authority in charge of monitoring public authorities' employees and performing verifications for conflicts of interest. CNCAN employees are legally forbidden to receive / obtain material advantages (e.g. money, gifts, etc.) from those impacted by their licensing and control activities.

Specific requirements have been introduced in the regulation NSN-21 (rev.1) - Fundamental nuclear safety requirements for nuclear installations (2020) to prevent the licensees from

appointing in executive positions persons that have worked for the nuclear regulatory authority (a “cooling-off” period of at least 1 year has been imposed). Specific requirements have been introduced in the regulation NSN-21 rev.1 also for preventing licensees from contracting organisations that provide the nuclear regulatory authority with advice or services. In practice, such situations have not been encountered. Similar explicit requirements will be established also for CNCAN, in line with the provisions of paragraph (9) of the preamble to the Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

5.3.f. Provision of nuclear safety-related information

CNCAN provides nuclear safety-related information to the public and to international organisations, in accordance with the provisions of the Law 111/1996, this being one of the regulatory responsibilities stipulated in this Law. No clearance has to be obtained from any other body or organisation, but information sensitive from nuclear security point of view is protected in accordance with the applicable legislation. More information of these aspects is provided in the section dedicated to article 8 of the Directive.

5.3 CNCAN Legal Powers

In accordance with the provisions of the Law, as described in this report in the section corresponding to article 4 of the Directive, CNCAN has all the necessary legal powers to:

- issue mandatory regulations establishing nuclear safety requirements;
- issue licences and permits for nuclear installations and activities, as legal instruments, with attached limits and conditions;
- require that the applicants and licensees demonstrate compliance with the requirements in the Law, in the regulations and in the relevant licences;
- independently verify compliance with the applicable requirements through regulatory assessment and inspection activities;
- take enforcement actions, including restricting or suspending operation of nuclear installations.

ARTICLE 6 - LICENCE HOLDERS

Member States shall ensure that the national framework requires that:

(a) the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;

(b) when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;

(c) licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner. That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions;

(d) licence holders establish and implement management systems which give due priority to nuclear safety;

(e) licence holders provide for appropriate on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences. Those shall in particular:

(i) be consistent with other operational procedures and periodically exercised to verify their practicability;

(ii) address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units;

(iii) provide arrangements to receive external assistance;

(iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;

(f) licence holders provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competences to fulfil their obligations.

6.a. Legal responsibilities of the licence holder

The Law clearly stipulates that the prime responsibility for the safety of a nuclear power plant rests with the licence holder and that this responsibility cannot be delegated.

As required by the Law, a licence is needed for each of the stages of the life time of a nuclear installation. The general conditions that an applicant shall fulfil in order to obtain a licence are stipulated in the Law and are detailed in the nuclear safety regulations. This information is presented in this report in the chapter corresponding to article 4.

Compliance with the general licensing conditions, as well as with all the provisions of the Law that are directed to the licensee, with the provisions of the applicable specific regulations and with the conditions embedded in the licence, is mandatory and enforceable. The clear definition of legal obligations ensures that by no means the licensee's responsibility for safety could be diminished or shifted towards the regulatory authority. Compliance with the legislative and regulatory requirements does not relieve the licensee of its responsibility to ensure that safety is maintained and continuously improved.

The attributions and responsibilities of CNCAN are also stated in the Law, defining the role of the regulator in ascertaining that the licensees are taking all the necessary measures to ensure and maintain the safety of the nuclear installations. The regulatory system and processes for licensing, review, assessment, inspection and enforcement, as well as the authority and responsibilities of CNCAN have been described under the articles 4 and 5.

The main responsibilities of the licence holder are stated in Chapter III of the Law and are further detailed in the specific regulations issued by CNCAN and in the conditions attached to each licence. In fulfilling its prime responsibility for safety, beyond simple compliance with the legislative and regulatory provisions in force, the licensees have developed and implemented their own systems of requirements, rules, procedures and instructions, with the objective of ensuring that any risks associated with its activities remain acceptable and are minimised to the extent possible. These systems are described in documents that form part of the licensing basis, for each stage of the lifetime of the nuclear installation, such as the Safety Analysis Reports and the Management System Manuals.

The legal and regulatory provisions require that all safety related activities contracted to the external organisations are effectively controlled by the licensees, who remain fully responsible for the implications of the work performed. The interfaces with the external organisations are described in the Management System Manuals and the licence holders have in place a system for selecting contractors, monitoring and assessing their performance and maintaining effective communication with the aim of ensuring the consistent application of high standards of safety and quality.

6.b. Demonstration of Nuclear Safety

The licensing submissions include, as the main document, a safety analysis report in accordance with the specifications established by CNCAN for each stage of the licensing process. In addition to the safety analysis reports, various supporting documents are submitted by the applicants to demonstrate the safety of the nuclear installation and the fulfilment of all the relevant legislative and regulatory requirements.

The nuclear safety regulations (e.g. NSN-21 rev.1, NSN-22) explicitly require and include specific provisions to ensure that the scope and level of detail of the safety analysis reports are commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site. Specific nuclear safety guides (GSN-04, GSN-05 and GSN-06) have been issued to facilitate implementation of these requirements. Compliance with the nuclear safety requirements is verified by CNCAN in the licensing process, as well as for the entire period of validity of the licenses.

6.c. Safety assessment and verification and continuous improvement of nuclear safety

The obligation of the licensees to regularly and systematically assess and verify and continuously improve nuclear safety, including the defence-in-depth provisions, is stated in the specific regulations (e.g. in NSN-21 rev. 1, NSN-22, NSN-27, NSN-24 and NSN-10) and in the license conditions.

The implementation of this obligation is verified by CNCAN through review and inspection activities on a current basis, as well as on the occasion of the renewal of the licenses for nuclear installations and on the occasion of the issuance of new or revised nuclear safety regulations.

The review and inspection activities performed by CNCAN staff cover areas such as:

- current design basis and associated safety analyses;
- current status of safety-related systems, structures, components and equipment;
- periodic safety reviews, including through deterministic and probabilistic analyses, based on the regulatory specific requirements;
- in-service inspection, surveillance, maintenance and functional testing of systems;
- ageing management;
- management system processes and documentation;
- use of operational experience feedback;
- training and qualification programmes;
- availability of sufficient competent human resources;
- modernization and upgrade programmes, including the associated design modifications;
- operating procedures for normal operation and abnormal conditions;
- procedures and resources for responding to transients and accident situations;
- emergency preparedness and response arrangements;
- management of suppliers;
- interfaces between nuclear safety and security;
- cyber security;
- conduct of the periodic safety reviews.

The licensees have to submit periodic reports to CNCAN in accordance with the conditions in the licences. The reports submitted to CNCAN include those detailing the outcome of self-assessments and independent assessments of the effectiveness of their management system processes in the continual improvement of nuclear safety. CNCAN also invites external safety review missions for nuclear installations and monitors the implementation of the resulting recommendations and suggestions.

The periodic safety assessments performed by the licensees include, as the main objective, the verification of the technical and administrative provisions that are part of the defence in depth concept for the nuclear installations, for both nuclear safety and nuclear security, in accordance with the requirements and criteria established in the regulations.

A specific regulation on the periodic safety review for nuclear power plants has been in force since 2006 and CNCAN has plans to extend the scope of this regulation to cover all nuclear installations. The general requirement for periodic safety reviews to be conducted every 10 years, for all nuclear installations, is stipulated in the NSN-21 rev.1 regulation.

Detailed regulations are in place for NPPs on siting, design, construction, commissioning and operation, covering all relevant aspects of defence-in-depth, both technical and administrative, including the associated deterministic and probabilistic safety analyses. The regulatory requirements for the research reactor and for the nuclear fuel plant are based on the general nuclear safety and radiological protection regulations, supplemented with requirements imposed by CNCAN through regulatory letters.

All the operating nuclear installations have adequate licensing and design basis documentation and are required to ensure that the actual configuration and operation are in conformity with the technical limits and conditions approved by CNCAN. All the licensees have procedures for normal operation, response to abnormal conditions and / or emergency operating procedures and emergency response plans and procedures. The maintenance of these procedures and plans, as well as the training of the staff, are ensured in accordance with the regulations issued by CNCAN and the management system requirements of the licensees.

The main responsibilities of CNCAN staff performing safety assessment activities in relation to the licensing and regulatory oversight of nuclear installations are:

- to determine whether the conceptual design is safe and meets applicable regulatory criteria;
- to determine whether the operating envelope is consistent with safety requirements, including regulatory requirements;
- to perform evaluations of proposed modifications to installations and associated operations;
- to provide the basis for the decision of issuing licences and approvals.

Safety evaluations of the safety documentation include the review of deterministic analyses, probabilistic analyses and reliability analyses, as well as review of emergency operating procedures.

The review and assessment activities have the objective of verifying compliance with the following:

- regulatory requirements, safety principles and design criteria;
- implementation of the defence in depth concept;
- safety-related systems design requirements;
- design codes, standards and safety guides

to provide the basis for the regulatory decision-making.

6.d. Management Systems

The Romanian legislative and regulatory framework relevant to quality assurance for activities related to nuclear installations has been subject to continuous development since

1982. A comprehensive framework is currently in place to govern the management systems for nuclear installations and associated activities and to ensure that the licensees give due priority to nuclear safety.

As required by the Law, any organisation deploying activities important to nuclear safety shall establish Management Systems (QMS) and shall submit an application to CNCAN for obtaining the relevant licence. In accordance with the provisions of article 24 of the Law, the MS in the nuclear field for the design, siting, procurement, construction, installation, commissioning, operation, decommissioning or conservation phases of a nuclear installation are subject to licensing.

The licences are granted by CNCAN in accordance with the provisions of the Law and the Romanian regulations on MS. The conditions that the applicant for a licence has to meet, as stated in the law, are:

- a) to demonstrate the professional qualification, for all job positions, of its own personnel, the personnel's knowledge of the nuclear safety requirements, as well as the probity of the personnel that have authority for decision making in managing the activities to be performed under the licence;
- b) to ensure that its own personnel involved in the activities to be performed under the licence has the necessary knowledge and awareness of the impact that the deviations from the quality standards and specifications for the products and services supplied to nuclear installations would have with regard to nuclear safety;
- c) to be accountable for the measures taken to ensure that the decision-making process related to licensed activities is not unduly influenced by third parties;
- d) to establish and maintain a controlled quality management system in its own activities, and to ensure that its suppliers of products and services, as well as their sub-contractors along the whole chain, establish and maintain controlled quality management systems.

All the above mentioned licensing conditions are further detailed and supplemented with specific requirements established through the set of regulations on MS and through the nuclear safety regulations (e.g. NSN-21 rev.1, NSN-22). The list of MS regulations is given as follows:

1. Licensing of the quality management systems applied to the construction, operation and decommissioning of nuclear installations (NMC-01);
2. General requirements for quality management systems applied to the construction, operation and decommissioning of nuclear installations (NMC-02);
3. Specific requirements for the quality management systems applied to the evaluation and selection of the sites for nuclear installations (NMC-03);
4. Specific requirements for the quality management systems applied to the research and development activities in nuclear field (NMC-04);
5. Specific requirements for the quality management systems applied to the design of nuclear installations (NMC-05);
6. Specific requirements for the quality management systems applied to procurement activities for nuclear installations (NMC-06);
7. Specific requirements for the quality management systems applied to the manufacturing

of products and the supply of services for nuclear installations (NMC-07);

8. Specific requirements for the quality management systems applied to the construction and assembling activities for nuclear installations (NMC-08);

9. Specific requirements for the quality management systems applied to commissioning activities for nuclear installations (NMC-09);

10. Specific requirements for the quality management systems applied to the operation of nuclear installations (NMC-10);

11. Specific requirements for the quality management systems applied to the decommissioning activities for nuclear installations (NMC-11);

12. Specific requirements for the quality management systems applied to the activities of producing and using software for research, design, analyses and calculations for nuclear installations (NMC-12);

13. Requirements for the establishment of classes for the graded application of the quality management system requirements for manufacturing of products and supply of services for nuclear installations (NMC-13).

The MS of each participant in a nuclear project (owners, operators, contractors, suppliers) are developed and implemented in accordance with the provisions of the above mentioned regulations, providing an adequate framework to ensure that all activities important to nuclear safety are properly managed throughout the life of a nuclear installation.

Several review mechanisms are used by CNCAN to evaluate compliance with the legislative and regulatory requirements:

- assessment of the Management System Manuals and the conduct of comprehensive audits and inspections prior to granting the licence for the respective phase of the nuclear installation;
- review and approval of the Management System Manuals and a range of documents referenced in these;
- evaluation and licensing of the personnel with major responsibilities in the establishment and development the Management Systems;
- the review of the arrangements for the quality assurance included in Safety Analysis Reports (PSAR or FSAR, depending on the stage in the lifetime of the installation);
- periodic audits, supplemented by inspections, to verify compliance with the licensing conditions and the arrangements made to ensure the continuous improvement of the management system;
- audits and inspections for verifying licensee's arrangements for the contracted work;
- audits and inspections at the various suppliers of products and services for the nuclear installation, and at their sub-contractors, to verify compliance with the conditions of their respective licences and with the provisions of the applicable regulations.

The requirements that licence holders establish and implement management systems which give due priority to nuclear safety are included also in the nuclear safety regulations NSN-21 rev.1 and NSN-20.

Compliance with the regulatory requirements is verified by CNCAN on a continuous basis.

6.e. On-site emergency procedures and arrangements

In accordance with the Law, CNCAN is empowered to issue regulations for the detailed specification of the general requirements on intervention in case of nuclear accidents. In this respect, the current specific requirements are provided in the following regulations, issued in alignment with the latest applicable international standards and European directives and reflecting the lessons learned from the Fukushima accident:

- Basic Requirements on Radiological Safety (BRRS, 2018);
- Regulation on the management of emergency situations specific to nuclear or radiological risk (2018);
- Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories I, II and III (2018);
- Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories IV and VI (2018);
- Fundamental Nuclear Safety Requirements (NSN-21 rev.1, 2020);
- Nuclear Safety Requirements on Preparedness for Response to Transients, Accidents and Emergencies at Nuclear Power Plants (NSN-07 rev.1, 2020).

All the requirements of the Directive concerning on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences have been included and detailed in the nuclear safety regulations (NSN-21 rev.1 and NSN-07 rev.1) and in the emergency preparedness and response regulations and licensees' compliance with these requirements is verified by CNCAN on regular basis through specific inspections, assessments and observation of emergency exercises.

6.f. Licensees' resources

As required by the Law, the licensee is responsible for ensuring both adequate financial and human resources to support the safety of the nuclear installation throughout its lifetime. Explicit requirements on the assurance of sufficient and adequate financial and human resources are established in the Law both for applicants (in article 18) and for licensees (in article 25). The above mentioned obligations are also stated and further detailed in nuclear safety regulations (NSN-21 rev.1, NSN-22) and in the conditions of each of the licenses granted by CNCAN. For example, specific conditions in the regulations and in the licenses require that the licensees submit to CNCAN for review and approval any organizational change with potential implications for safety, before implementation.

CNCAN requires the license holders to report periodically on their resources and the regulatory staff performs reviews and inspections to determine the actual status of the licensees' human and financial resources, as well as the associated changes and trends. The current regulations (NSN-21 rev.1) include provisions also on the licensees' responsibility for ensuring that their contractors and subcontractors have the necessary human resources with appropriate qualifications and competences to fulfil their obligations for nuclear safety related activities. These aspects are also covered by CNCAN's regular inspections and audits of both the licensees for nuclear installations and of their contractors and subcontractors.

ARTICLE 7 - EXPERTISE AND SKILLS IN NUCLEAR SAFETY

Member States shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness.

7.1 Licensees' training and qualification programmes

Legal requirements on the assurance of sufficient competent staff for all the phases of the lifetime of a nuclear installation are established in the Law and are supplemented by specific regulations (e.g. NSN-21 rev.1, NSN-22, NSN-23, NSN-14 rev.1).

Regulations related to training, qualification and retraining for operating personnel for research reactors and nuclear power plants have been in place in Romania since 1975. These regulations have been periodically reviewed and revised. For other nuclear installations, the requirements on training and qualification of staff with safety related duties are established in the regulations on quality management systems enumerated in section 6 of this report.

Specific requirements for the licensees in the area of training and qualification are provided in the following regulations:

- NSN-21 (rev.1) - Fundamental nuclear safety requirements for nuclear installations (2020).
- NSN-22 - Regulation on the licensing of the nuclear installations (2019).
- NSN-23 - Regulation on the training, qualification and authorization of nuclear installations personnel with nuclear safety related jobs (2017).
- Basic Requirements on Radiological Safety (BRRS, 2018)
- NSN-14 (rev. 1) - Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations (2014).
- NMC-10 - Specific Requirements for the Quality Management Systems Applied to the Operation of Nuclear Installations (2003)
- NSR-07 - Regulations on issuing Working Permits for nuclear activities and designation of Qualified Radiological Protection Experts (issued in 2002 and revised in 2018).

The above mentioned regulations establish:

- the categories of personnel with jobs important to nuclear safety, including emergency preparedness and response;
- the categories of licensed personnel for nuclear installations and the steps of the licensing process for each category;
- the qualification requirements for the operating personnel and the management personnel, starting from the commissioning phase of the nuclear installation up to complete removal of the nuclear fuel from the core, of the management personnel and the specific training trainers/instructors;
- the methodology of granting the practice permits for the above mentioned personnel categories, including assessment objectives, content and phases of evaluation, the examination process administered by CNCAN, criteria and performance indicators.

The examinations administered by CNCAN in order to verify the qualification of staff with safety-related duties and to grant practice permits are performed in accordance with the provisions of the regulations and of the internal procedures which are part of the management system of CNCAN.

The general topics for the examination of operating personnel for nuclear power plants and research reactors are chosen to be relevant for the knowledge of nuclear installation safety systems, operating limits and conditions, capabilities to operate under normal conditions, abnormal conditions or emergency conditions, team working skills, communication and coordination skills. The examinations consist of written and oral tests and practical examinations. For Cernavoda NPP operating staff, the practical examinations are performed at the full-scope simulator.

The examination objectives in the evaluation of managerial personnel are chosen to reflect the performance associated with the job at all three levels: organisational, as part of a process and at individual level. The content of the examination is established to give an overview of the candidate's knowledge, skills, attitudes and capabilities in specific areas of responsibility. The examination administered by CNCAN for different management positions for nuclear installations consist of an interview covering different aspects related to the organisational structure, responsibilities and levels of authority, decision making, human performance issues, safety culture, work planning, coaching and observation of their staff, lessons learned from operating experience, initiatives for the improvement of safety.

The practice permits granted by CNCAN following the satisfactory performance of the candidates in all the topics/tests of the examination, are valid for a definite period of time, provided that the licensed person has continuity in the same activity and a good performance on the respective job.

The training programmes for the licensed personnel are submitted to CNCAN for review and approval. The implementation of the training programmes for all personnel with duties important to safety and the observance of the station training policy are also extensively reviewed and assessed by CNCAN through periodic inspections and audits.

7.2 Training and qualification for the regulatory staff

CNCAN has a process to develop and maintain the necessary competence and skills of regulatory staff of the regulatory body, as an element of knowledge management. The required technical education, knowledge and experience, as well as the necessary skills and abilities are documented in the job descriptions for each job position with regulatory duties. To maintain an appropriate competence level, an annual plan for staff training is in place and each staff member has an individual training and qualification plan, elaborated by their respective line manager.

Training for CNCAN staff is provided either in-house or through technical cooperation programs with the IAEA and with other states and organizations. Members of the technical staff frequently attend training courses, workshops, technical meetings, expert meetings and conferences supported by the IAEA, that are relevant for their professional development in relation to their current and foreseen duties.

CNCAN is a beneficiary of technical cooperation projects managed by the IAEA, at national and regional level. Through these projects, CNCAN receives expert missions and support in the organization of international and national seminars.

In 2013, CNCAN and the Norwegian Radiation Protection Authority (NRPA) have agreed to fund an IAEA Extra Budgetary Program (EBP) on safe nuclear energy in Romania. The “Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania” started at the end of 2013 and was completed in 2017. The entire project was organized through an IAEA extra-budgetary program. The objective of the project was to enhance the capabilities of CNCAN in eight specific functional areas of work such as: safety analysis; integrated management systems and knowledge management; inspections; safety and security of transport and transit of radioactive and nuclear materials on the Romanian territory; emergency preparedness and response; ionizing radiation sources; radioactive waste, spent nuclear fuel management and decommissioning activities and safeguards activities. The project made a significant contribution to the improvement of CNCAN regulatory framework, processes and training of staff.

A new project, "Enhancement of Nuclear Safety and Security in Romania – Improvement of Disaster Resilience and Preparedness for Radiological and Nuclear Events" has started in 2019, as a continuation of the project implemented in 2013-2017. This project is being carried out in partnership with the Norwegian Radiation and Nuclear Safety Authority (DSA) and the International Atomic Energy Agency (IAEA), the national partners in Romania being CNCAN, as project promoter, together with the General Inspectorate of the Romanian Gendarmerie, the General Inspectorate of the Romanian Police, the General Inspectorate of the Romanian Border Police, General Inspectorate for Emergency Situations and the Ministry of Internal Affairs (MAI). The implementation period of this project is 4 years and is funded through the Norwegian Financial Mechanism 2014-2021 - Home Affairs Program. The main objectives to be achieved in the project include alignment of the national framework and regulatory practices with the latest international standards and European Union legislation in the field of nuclear safety and protection against ionizing radiation; the implementation of recommendations from the international missions in Romania on nuclear safety, detection and response to events involving nuclear and radioactive materials not subject to regulatory control, cyber security for nuclear installations and training and intervention in case of emergency; implementation of several activities of the national action plan associated with the National Strategy for Nuclear Safety and Security; the implementation of the new responsibilities that CNCAN has in managing the nuclear emergency situations, as well as improving emergency preparedness and response by implementing lessons learned.

CNCAN also receives assistance through the International Regulatory Development Partnership (IRDP), sponsored by the US NRC.

Training received through the IAEA technical cooperation programs and through the US NRC IRDP program are particularly valuable in keeping CNCAN’s technical staff up to date with the current international standards and good practices in nuclear safety and regulatory work, as well as with the relevant operating and regulatory experience.

ARTICLE 8 - TRANSPARENCY

1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:

(a) information on normal operating conditions of nuclear installations to workers and the general public; and

(b) prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.

2. Information shall be made available to the public in accordance with relevant legislation and international instruments, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments.

3. Member States shall, without prejudice to Article 5(2), ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.

4. Member States shall ensure that the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international instruments.

8.1 Legal provisions

The general Romanian legislation on public information and on transparency in the decision-making process of public authorities applies also to the regulatory activities of CNCAN. The main relevant laws are:

- Law 544/2001 on free access to public information;
- Law 52/2003 on decisional transparency in public administration.

In addition, the Law 86/2000 for ratification of the Convention on access to information, public participation in decision-making and to justice in environmental matters, done at Aarhus, on 25 June 1998 is also of relevance.

CNCAN responsibilities as established in the Law explicitly include:

- ensuring public information on matters that are under the competence of CNCAN;
- organizing public debates on matters that are under the competence of CNCAN.

For emergency situations, CNCAN has the responsibility to support the national authorities in providing the public with accurate, timely and comprehensive information regarding the emergency, through their representatives in the national committee for emergency situations.

The information that has to be supplied by the licensees to CNCAN in emergency situations is specified in the specific regulations on emergency preparedness and response and includes technical data and parameters that characterize the status of the nuclear installation and the fulfillment of safety functions (control of reactivity, cooling of the nuclear fuel, containment of radioactivity and the monitoring and support of these functions), as well as information on the actual or potential releases of radioactivity to the environment. CNCAN has an emergency response organization capable of performing nuclear safety and radiological protection assessments for emergency situations and of supporting the national response in such situations, including information and recommendations for the public.

Specific requirements have been stipulated in the nuclear safety regulation NSN-21 rev.1 and NSN-18 (Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations) to ensure that the license holders provide to the public the information required in accordance with the provisions of the Directive.

8.2 Public information on the regulatory activities

The main means used by CNCAN for the current information of the public on regulatory activities and developments is the website (<http://www.cncan.ro>). Information available on the website includes:

- laws, governmental decisions and regulations applicable to the regulatory activities;
- laws and regulations in force, applicable to nuclear installations and activities, as well as draft regulations in the phase of public consultation (in accordance with the Law 52/2003);
- annual reports on CNCAN's activity;
- reports submitted to international organizations;
- information about the history, organization and functioning of CNCAN;
- information on licensed installations and activities;
- press releases and information about conferences;
- forms for submitting requests for information of public interest (in accordance with the Law 544/2001).

Prior to the enactment of new or revised regulations, CNCAN posts the proposed drafts on its website and sends them for consultation to all interested organizations, for gathering information from the public, from licensees and applicants and from other interested parties, in accordance with the Law 52/2003.

Requests for information come mainly from non-governmental organizations and, to a lesser extent, from members of the public. CNCAN provides all the necessary data and clarifications, except for information that is classified due to security reasons.

The annual reports produced by CNCAN on the regulatory activities are published on its website and summary reports are published also in the Official Journal of Romania.

Information sensitive from nuclear security point of view is protected in accordance with the

applicable legislation.

8.3 Cooperation with regulatory authorities of other Member States

In the area of international cooperation and exchange of information, CNCAN maintains relations with a number of nuclear regulatory authorities and organizations worldwide, through bilateral arrangements and commitments under international conventions in the nuclear field.

The international activities in which CNCAN is involved include the participation in the activities of WENRA and its technical working groups, the annual meetings of the Senior Regulators from countries that operate CANDU NPPs, the biannual meetings of the European High Level Group on Nuclear Safety and Waste Management (ENSREG) and its working groups, the contribution to the initiatives at European Union level and the participation in various IAEA activities, as well as the participation in the NEA/OECD committees and working groups.

In order to ensure the exchange of information relevant to nuclear safety, CNCAN has a number of bilateral agreements with regulatory bodies from other countries. In particular, CNCAN maintains frequent communications on regulatory matters with the Canadian Nuclear Safety Commission (CNSC) and US Nuclear Regulatory Commission (NRC).

Also, CNCAN has established agreements with other nuclear regulatory authorities and arrangements with neighbouring countries on notification and assistance in case of nuclear accidents.

8.4 Public participation in decision-making process relating to the licensing of nuclear installations

The procedure for obtaining a construction license for a nuclear installation includes the obligation to perform and submit an environmental impact assessment (EIA). The neighbouring countries that could be affected by the installation are notified on the basis of the international Convention on Environmental Impact Assessment in a Transboundary Context (ESPOO Convention), to which Romania is a contracting party. This process for meeting the obligations under the ESPOO Convention is managed by the Ministry of Environment, Waters and Forests.

CNCAN is part of the Technical Analysis Committee established by the Ministry Environment, Waters and Forests for the environmental licensing of each nuclear installation, providing evaluations and feedback on any nuclear-safety related matter brought into discussion in the consultation processes, including the consultation under the ESPOO Convention.

In addition, CNCAN issued in 2019 a new regulation, NSN-25 - Requirements on the decisional transparency in licensing process for nuclear installations, that expands the opportunities that the general public has to participate effectively in the decision-making process for the licensing of nuclear installations, particularly in the area of nuclear safety.

ARTICLE 8a - NUCLEAR SAFETY OBJECTIVE FOR NUCLEAR INSTALLATIONS

1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

(a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;

(b) large radioactive releases that would require protective measures that could not be limited in area or time.

2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:

(a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;

(b) is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

8a – Nuclear Safety Objective for Nuclear Installations

The requirements in article 8a of the Directive are included in the nuclear safety regulations issued by CNCAN. For this purpose, the regulation NSN-21 rev.1 - Fundamental nuclear safety requirements for nuclear installations and the regulatory guide GSN-03 - Guide on fulfilling the overall nuclear safety objective set in the fundamental nuclear safety requirements for nuclear installations provide the respective requirements and safety goals.

The regulation NSN-21 rev.1 includes the following requirements:

“Art. 4. – (1) The general nuclear safety objective that shall be observed in the design, siting, construction, commissioning, operation and decommissioning of a nuclear installation is to reduce at the minimum the risks associated with the exposure to ionizing radiation for the personnel, population and the environment.

(2) The license holder, respectively the applicant for a license, shall take all the reasonable measures possible from technical point of view and practicable for the prevention of events which may lead to the exposure of the personnel, of the population and of the environment in excess of the limits established in the legislation. Also, all the reasonable measures, possible from technical point of view and practicable shall be taken for the limitation of the consequences of nuclear accidents, for the situations where such events may occur.

(3) For the purpose of fulfilling the general nuclear safety objective, the nuclear installations shall be designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

a) early radioactive releases that would require off-site emergency measures without sufficient time to implement them;

b) large radioactive releases that would require protective measures that could not be limited in area or time.

(4) The requirements established in paragraph (3) apply to nuclear installations at their first license for the phases of design, siting, construction and installation.

(5) The requirements established in paragraph (3) shall be used as a reference for the timely implementation of reasonably practicable safety improvements to nuclear installations already existing at the time of the entering into force of this regulation, including in the framework of their periodic safety review.”

The regulatory guide GSN-03, issued at the end of 2018 for facilitating the understanding and application of the requirements in article 4 of the regulation NSN-21, recommends the use of the following quantitative nuclear safety objectives:

a) Frequency of releasing into the environment a quantity of radioactive material that would require the temporary evacuation of the population from the vicinity of the nuclear site, quantified as the sum of the frequencies of all accident sequences with the source term higher than 1000 TBq of Iodine-131, to be less than 1E-5 / year. This quantitative objective aims at avoiding early releases of radioactive materials, which would require off-site emergency response measures without sufficient time to implement them. For accident sequences for which the source terms exceed 1000 TBq of Iodine-131, it should be demonstrated that the emission of radioactive material cannot occur in such a short time that it does not allow the population to be evacuated from the vicinity of the site.

b) Frequency of releasing into the environment a quantity of radioactive material that would require relocation of the population near the site, quantified as the sum of the frequencies of all accident sequences with the source term higher than 100 TBq of Cesium-137, to be less than 1E-6 / year. This quantitative objective aims at avoiding large releases of radioactive materials which would require protection measures that cannot be limited in space or time.

c) The cumulative frequency of all accident sequences that can lead to effective doses higher than 100 mSv in the first 7 days, for which the population in the vicinity of the nuclear facility is required to be evacuated in accordance with the generic criteria of the Regulation of Emergency Situations Management for nuclear or radiologic risk, to be less than 1E-5 / year.

d) The cumulative frequency of all accident sequences that can lead to effective doses higher than 100 mSv in the first year, for which temporary relocation of the population located near the site is required according to the generic criteria of the Regulation of Emergency Situations Management for nuclear or radiologic risk, to be less than 1E-6 / year.

No construction license has been granted for a new nuclear installation after 14 August 2014.

The nuclear safety objective and associated safety goals have been used in the periodic safety review of the operating nuclear installations.

In order to assess the fulfilment of the quantitative nuclear safety objectives, deterministic and probabilistic nuclear safety assessments have been further developed and revised, in accordance with the requirements and recommendations in the applicable CNCAN regulations, regulatory guides and internationally recognized standards and best practices. The analyses cover all operational modes of the nuclear installation and take into account all internal and external initiating events relevant to the installation and to site. Both design

basis accidents as well as the design extension conditions, including severe accidents, are considered in the analyses. Accident scenarios affecting several nuclear installations located on a common site are also considered.

Practical safety improvements have been identified and implemented. As the safety analyses are continuously revised and updated, any new opportunities for improvement identified will be taken into consideration and used for safety upgrades.

Safety upgrades for increased protection against severe accidents have been implemented in Cernavoda NPP. These include the following examples:

- Passive autocatalytic hydrogen recombiners;
- Water make-up to ensure in-vessel core cooling;
- Filtered containment venting system to preserve containment function;
- Mobile diesel generators to ensure the power supply in case of station blackout;
- Improved instrumentation for monitoring safety parameters in severe accident situations.

More details on the safety upgrades are provided in the national reports for the Convention on Nuclear Safety and on the action plans post-Fukushima (mentioned in the References).

ARTICLE 8b - IMPLEMENTATION OF THE NUCLEAR SAFETY OBJECTIVE FOR NUCLEAR INSTALLATIONS

1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:

- (a) the impact of extreme external natural and unintended man-made hazards is minimised;*
- (b) abnormal operation and failures are prevented;*
- (c) abnormal operation is controlled and failures are detected;*
- (d) accidents within the design basis are controlled;*
- (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;*
- (f) organisational structures according to Article 8d(1) are in place.*

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

- (a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(d);*
- (b) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;*
- (c) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority; and,*
- (d) arrangements for education and training, in accordance with Article 7.*

8b.1 – Implementation of the defence-in-depth concept

The requirements in the Directive concerning the defence-in-depth are stipulated in nuclear safety regulations (e.g. NSN-21 rev.1, NSN-02, NSN-07 rev.1) and are verified by CNCAN through assessments and inspections in the licensing process as well as on a regular basis for the entire lifetime of the nuclear installations. The regulations specified in the section corresponding to article 4 of the Directive contain specific provisions related to the various practical implementation aspects of the defence-in-depth concept. Particular focus has been given, post-Fukushima, to the regulatory oversight of severe accident management and design upgrades for preventing and mitigating severe accidents. These aspects, of particular relevance for nuclear power reactors, have been addressed in detail in the National Reports under the Convention on Nuclear Safety and in the National Action Plan post-Fukushima.

8b.2 – Effective nuclear safety culture

The main regulations supporting CNCAN's assessment of licensee's safety culture are:

- NSN-20 - Regulation on the nuclear safety policy and independent nuclear safety

oversight for nuclear installations (2015);

- NSN-21 rev.1 - Fundamental nuclear safety requirements for nuclear installations (2020);
- NSN-18 - Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations (2017);
- NSN-23 - Regulation on the training, qualification and authorization of nuclear installations personnel with nuclear safety related jobs (2017);
- NSN-27 – Regulation on the use of standards for the assessment and continuous improvement of nuclear safety for nuclear power plants (2020).

In 2019, CNCAN has issued a regulatory guide (GSN-09) on the development and assessment of nuclear safety culture, to facilitate the implementation of the regulatory requirements in NSN-20, NSN-21 and NSN-23, as well as to support the regulatory oversight activities of CNCAN in this area. The regulatory guide is applicable to all organisations operating nuclear installations and is based on the document INPO 12–012, Traits of a Healthy Nuclear Safety Culture, Revision 1, Institute of Nuclear Power Operations, 2013 and on the 37 attributes promoted in the IAEA safety guides on management systems for nuclear installations GS-G-3.1 and GS-G-3.5.

The regulatory guide GSN-09 recommends that each licensee performs a self-assessment to determine its own model of organizational culture and identifies the elements that support nuclear safety in the categories of artefacts, espoused values and basic assumptions, building on the model of organizational culture developed by Edgar Schein. The guide recommends that the traits of a healthy nuclear safety culture, outlined in the INPO document mentioned above, as well as the nuclear safety culture attributes promoted by the IAEA, are adopted by the licensee's organization and are used for the development of safety culture, as well as for self-assessment.

CNCAN has established and implemented a Management System in accordance with international standards and is currently revising it in order to implement the requirements in the IAEA GSR Part standard – Leadership and Management for Safety. The Management Manual of CNCAN describes the policies with regard to the regulation, licensing and control activities, the strategic objectives and plans, the interfaces at national and international level, the responsibilities of the organizational units of CNCAN, the mechanisms for measuring, evaluating and improving the effectiveness and efficiency of the regulatory activities and the principles, values and behaviours supporting nuclear safety culture. It also provides a set of general requirements applicable to the performance of activities within all organizational units and the specific requirements applicable to the assessment and inspection activities performed by the technical divisions.

ARTICLE 8c - INITIAL ASSESSMENT AND PERIODIC SAFETY REVIEWS

Member States shall ensure that the national framework requires that:

(a) any grant of a licence to construct a nuclear installation or operate a nuclear installation, is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a;

(b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.

8c. – Implementation of initial assessments and periodic safety reviews

As described in section 6 of this report, the licensing submission for a nuclear installation includes, as the main document (in conformity with the regulations NSN-21 rev.1, NSN-22), a safety analysis report in accordance with the specifications established by CNCAN for each stage of the licensing process. The safety analysis report is specific to the nuclear installation and its site, this requirement being stipulated in several nuclear safety regulations (NSN-01, NSN-02, NSN-06, NSN-21 rev.1, NSN-22, NSN-24) that have been mentioned in section 6 of this report. These regulations include detailed requirements and criteria on design and site related aspects important to nuclear safety. In addition, regulatory guides have been issued to facilitate compliance with the regulations. Compliance with the relevant requirements is verified by CNCAN in the licensing process.

The general requirement for periodic safety reviews to be conducted every 10 years, for all nuclear installations, is stipulated in the NSN-21 rev.1 regulation. Full-scope periodic safety reviews have been performed for Cernavoda NPP and reviewed by CNCAN. The safety improvements resulting from the PSR include revised safety analyses, design upgrades, procedural and organizational improvements. Work is ongoing for implementing this requirement and performing periodic safety reviews also for the other nuclear installations.

Detailed information on nuclear safety assessments for nuclear power plants is available in the Romanian National Report for the Convention on Nuclear Safety, 8th edition, published in August 2019 (https://www.iaea.org/sites/default/files/romania_nr-8th-rm.pdf), in the chapters corresponding to articles 14, 17, 18 and 19 of the Convention.

ARTICLE 8d - ON-SITE EMERGENCY PREPAREDNESS AND RESPONSE

1. Without prejudice to the provisions of the Directive 2013/59/Euratom, Member States shall ensure that the national framework requires that an organisational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the licence holder, and competent authorities and organisations, taking into account all phases of an emergency.

2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom.

8d – On-site Emergency Preparedness and Response

The requirements in the Directive concerning the on-site emergency preparedness and response are stipulated in the regulations mentioned in the section 6.e. of this report. These regulations have been revised and updated in the period 2018-2020, in accordance with the international standards and European directives.

The licensee is responsible to ensure that intervention plans are tested to an appropriate extent at regular intervals. Also, the licensee is responsible to notify immediately any radiological emergency occurring on site and to take all the necessary measures to reduce the consequences of the radiological emergency. For the adequate accomplishment of its own tasks concerning the intervention, the licensee has to perform an initial provisional assessment of the circumstances and the consequences of the radiological emergency and to communicate it immediately to the competent authorities. As a general principle, the intervention has to be focused on the source, to reduce or stop the direct radiation and radioactive emissions, to reduce the transfer of radioactive substances to the environment and to the individuals, to reduce exposure and organize the treatment of victims.

In accordance with the regulations, the analysis, approval and revision of the on-site emergency intervention plan shall be controlled and the responsible public authorities shall have the possibility to analyze each revision of the plan, to ensure the coordinated reaction to any emergency situation and at any moment.

CNCN performs regular assessments and inspections of the licensees' arrangements for on-site emergency preparedness and response and monitors the implementation of the improvement and corrective actions.

Examples of improvements in this area are provided for the most important nuclear installation – Cernavoda NPP.

In the last 3 years, Cernavoda NPP has revised the On-site Emergency Plan, in order to:

- define the emergency planning zones and distances in accordance with the current IAEA standards;
- introduce information about resources needed to support the on-site emergency response during the first 72 hours of an emergency;

- introduce information regarding the emergency equipment and facilities provided by Cernavoda NPP to support the off-site emergency response;
- introduce events that affect both units on the site;
- update protective actions if the projected dose exceeds the generic criteria.

Other relevant improvements in the area of emergency preparedness and response, implemented by Cernavoda NPP, include the following:

- Development of a software application for dose assessment for the intervention team members in case of severe accident;
- Supplemented the communication groups by the TETRA radio stations with a dedicated group for the monitoring teams;
- Concluded a contract for psychological counselling and psychotherapy services in case of emergency in order to provide psychological support to the intervention team members;
- Voice recorders in the On-site Emergency Control Centre and the Off-site Emergency Control Centre are in process of being procured, in order to record phone calls and verbal communication made during the emergency situations;
- Structural improvements to the On-site Emergency Control Centre and the Off-site Emergency Control Centre have been performed;
- The Diesel Generator for the fridge and cooking equipment in the canteen in the plant Campus is in process of being procured, in order to provide an auxiliary electrical power supply in the emergency food storage area.

Also, the emergency exercises carried out in the last 5 years at Cernavoda NPP have systematically included severe accident scenarios initiated by extreme external events, using lessons learned from the Fukushima accident.

ARTICLE 8e - PEER REVIEWS

1. Member States shall, at least once every 10 years, arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of such peer reviews shall be reported to the Member States and the Commission, when available.

2. Member States shall ensure that, on a coordinated basis:

(a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;

(b) all other Member States, and the Commission as observer, are invited to peer review the national assessment referred to in point (a);

(c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;

(d) relevant reports are published on the above mentioned process and its main outcome when results are available.

3. Member States shall ensure that arrangements are in place to allow for the first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.

4. In case of an accident leading to situations that would require off-site emergency measures or protective measures for the general public, the Member State concerned shall ensure that an international peer review is invited without undue delay.

8e – Peer Reviews

The necessary provisions for supporting the implementation of the peer reviews have been included in the Law 111/1996 and in the nuclear safety regulations (e.g. NSN-21 rev.1). CNCAN has also issued a specific procedure for the management of the peer reviews.

Romania has a long tradition in inviting and receiving peer-review missions in the areas relevant for nuclear safety, with regard to both regulatory activities and licensees' activities. The missions received include specific review missions conducted by the IAEA, such as IRRS (Integrated Regulatory Review Service), OSART (Operational Safety Review Team), EPREV (Emergency Preparedness Review), IPSART (International Probabilistic Safety Assessment Review Team), SEDO (Safety Evaluation of Fuel Cycle Facilities during Operation) and peer review missions conducted by WANO (World Association of Nuclear Operators).

The last IRRS mission received by CNCAN was a follow-up IRRS conducted in October 2017. The IRRS team found that Romania had systematically addressed the findings made by the previous mission, implementing most of its recommendations and addressing the lessons learned from the 2011 Fukushima Daiichi accident. The follow-up IRRS report has been made public on the IAEA website: https://www.iaea.org/sites/default/files/documents/review-missions/irrs_follow-up_mission_rep_romania_2017.pdf.

Romania has participated in the first EU Topical Peer Review on Ageing Management for Nuclear Installations and issued a National Action Plan based on the outcome of the TPR.

LIST OF ACRONYMS

CANDU - Canadian Deuterium Uranium Reactor
CNCAN - National Commission for Nuclear Activities Control
CNU - National Uranium Company
IFIN – HH - R&D Institute for Physics and Nuclear Engineering “Horia Hulubei”
ISCIR - State Inspectorate for Boilers, Pressure Vessels and Hoisting Installations
IRRS - Integrated Regulatory Review Service
ENSREG – European Nuclear Safety Regulators Group
GSN – Nuclear Safety Regulatory Guides
EPREV - Emergency Preparedness Review
IAEA - International Atomic Energy Agency
ICRP - International Committee for Radiation Protection
INPO – Institute of Nuclear Power Operations
IPSART - International Probabilistic Safety Assessment Review Team
NMC - Norms on Quality Management
NPP - Nuclear Power Plant
NSN – Nuclear Safety Regulations
OSART - Operational Safety Review Team
PHWR - Pressurised Heavy Water Reactor
PSA - Probabilistic Safety Assessment
PSR - Periodic Safety Review
QMS - Quality Management System
RATEN - Technologies for Nuclear Energy State Owned Company
RATEN - CITON - Centre of Technology and Engineering for Nuclear Projects
RATEN - ICN – Institute for Nuclear Research
SEDO - Safety Evaluation of Fuel Cycle Facilities during Operation
SNN - National Company “NUCLEARELECTRICA”
TPR – Topical Peer Review
WANO - World Association of Nuclear Operators
WENRA - Western European Nuclear Regulators Association

REFERENCES

1. Romanian National Report for the Convention on Nuclear Safety, 8th edition, August 2019, https://www.iaea.org/sites/default/files/romania_nr-8th-rm.pdf ;
2. National Report of Romania under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. 6th edition (2017) <http://www.cncan.ro/assets/Informatii-Publice/06-Rapoarte/Rapoarte-2019/RomaniaJC6thNational-Report2017.pdf>
3. National Stress Test Reports <http://www.ensreg.eu/EU-Stress-Tests/Country-Specific-Reports/EU-Member-States/Romania>
4. National Report for the the Ageing Management Topical Peer Review <http://www.ensreg.eu/country-specific-reports/EU-Member-States/Romania>
5. National Action Plan for the Ageing Management Topical Peer Review <http://ensreg.eu/tpr-national-action-plans/EU-Member-States/Romania>
6. IRRS Report for Romania https://www.iaea.org/sites/default/files/documents/review-missions/irrs_follow-up_mission_rep_romania_2017.pdf
7. CNCAN annual reports <http://www.cncan.ro/informatii-de-interes-public/rapoarte/rapoarte-activitate-cncan/>
8. CNCAN regulations <http://www.cncan.ro/legislatie/norme/>