

ROMANIA



National Report as required by Article 9.1 of the Council Directive 2009/71/EURATOM

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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, through the Department of Energy, establishes the energy national strategy and is the major shareholder of the nuclear energy production sector, nuclear research and engineering, nuclear fuel and heavy water production.

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 General Secretariat of the Government.

The Ministry of the Environment and Climate Change 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 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, is responsible for promoting the peaceful use of nuclear energy, for disposal of the radioactive waste and for the coordination, at national level, of the safe management of spent nuclear fuel and radioactive waste and decommissioning of nuclear installations.

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, through the Department of Energy.

The Autonomous Company for Nuclear Activities (RAAN) is also a State owned company, responsible for heavy water production. RAAN is subordinated to the Ministry of Economy. It manages the Heavy Water Plant (ROMAG - Drobeta).

There are two national research and engineering institutes in the nuclear power sector - the Institute for Nuclear Research (ICN - Pitesti), which operates a TRIGA research reactor, and the Centre of Technology and Engineering for Nuclear Projects (CITON – Bucharest, Magurele). 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 State-owned, 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. CNU is the supplier of sinterisable UO_2 power for the nuclear fuel manufacturer (FCN Pitesti).



Fig. 1.1 Location of nuclear installations and associated facilities

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 VVR-S Research Reactor under decommissioning 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.



Fig. 1.2a Cernavoda NPP Units 1 and 2



Fig. 1.2b Cernavoda NPP Units 3 and 4

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.

Cernavoda NPP Units 1 and 2 cover up to 19% 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. Cernavoda NPP is owned and operated by SNN, the license holder for Cernavoda NPP.

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.

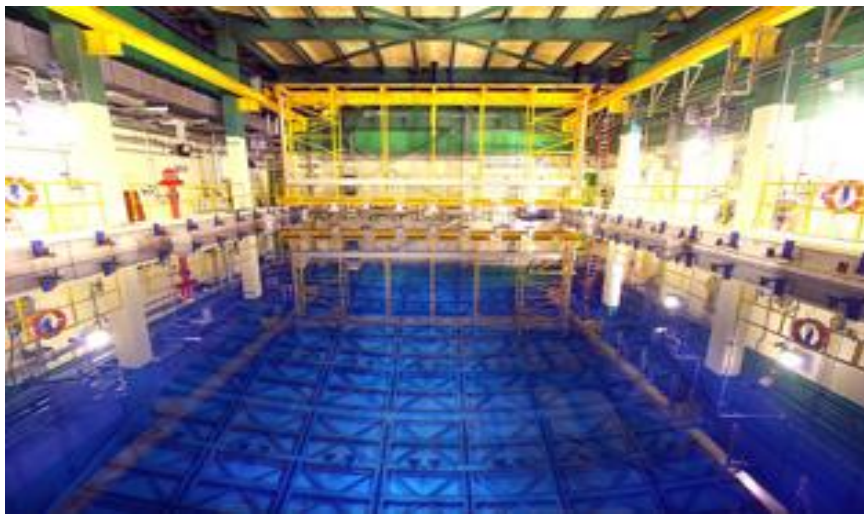


Fig. 1.3 Spent Fuel Bay

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 5 storage modules have been constructed and licensed for operation, with a total storage capacity of 60,000 spent fuel bundles.



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 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.

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 life extension 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; for the time being no spent fuel is stored in any of the racks, because the old HEU spent fuel has been shipped back in its country of origin under the provision of the US-DOE programme "Global Threat Reduction Initiative" completed in 2008.
- 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 nuclear fuel production in Romania has begun in 1980, when the Nuclear Fuel Element Manufacturing Section (NFEMS) was set up. In 1985, the nuclear fuel manufactured in NFEMS was certified in compliance with the national laws. In January 1992, NFEMS split from the Nuclear Research Institute (ICN) and developed into the Nuclear Fuel Plant (FCN). A technical and technological development program was implemented, assisted by the Canadian companies AECL (Atomic Energy of Canada Ltd.) and ZPI (Zircotec Precision Industries Inc.) between 1992 and 1994. On December 1995, FCN Pitesti obtained from AECL and ZPI the licence of supplier for CANDU 6 nuclear fuel in accordance with Canadian nuclear quality assurance standards. Starting with 1998, FCN Pitesti is part of SNN, together with Cernavoda NPP.

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 under decommissioning

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 foresees 3 phases, each consisting of different work packages. The VVR-S decommissioning is currently in phase 2. 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.

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 (hereinafter referred to as the 'national framework') for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall establish responsibilities for:

(a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;

(b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;

(c) the provision of a system of nuclear safety supervision;

(d) enforcement actions, including suspension of operation and modification or revocation of a licence.

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 latest revision of the Law was implemented to transpose provisions from the Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

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 the following activities and sources:

- a) 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;
- b) design, possession, siting, construction, assembly, commissioning, operation, preservation and decommissioning of installations for milling and processing of uranium and thorium ores and of installations for the management of wastes resulted from the milling and processing of uranium and thorium ores;
- c) 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;
- d) production, supply, and use of dosimetric equipment and ionising radiation detection systems, materials and devices used for the protection against ionising radiation, as well as containerisation or means of transport for radioactive materials, especially designed for such purposes;
- e) production, supply, leasing, transfer, possession, export, import and intra-community transfer of the materials, devices, and equipment specified in Annex 1 to the Law;
- f) possession, transfer, import, export and intra-community transfer of unpublished information related to materials, devices and equipment pertinent to the proliferation of nuclear weapons or other explosive nuclear devices, as specified in Annex 1 to the Law;
- g) manufacturing of products and supply of services designed for nuclear installations;
- h) manufacturing of products and supply of services designed for radiation sources, dosimetric control instruments, ionising radiation detection systems, materials and devices used for the protection against ionising radiation.
- i) orphan sources, from their detection to their final disposal as 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: “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 licence or permit. It also sets the general framework for the licensing process, including the licensing stages for the nuclear installations.

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, the licensing stages include, as appropriate: design, siting, construction, commissioning, trial operation, operation, repair and/or maintenance (as major refurbishment), modification (as major upgrades), preservation, decommissioning and closure.

Partial licences may also be issued to cover the construction or operation stages of nuclear and radiological facilities. Partial licences issued simultaneously or successively for one and the same stage may have the character of a provisional decision of CNCAN, if the applicant expressly requests so. In such a case their validity shall extend up to the issuing of the final licence of that type, but no more than two years with an extension right, on request, for two more years, when all necessary information is not available in due time. The partial licence can be withdrawn by CNCAN whenever it finds a lack of concern on the part of the licence holder for the completion of the necessary information in support of the application.

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;
- to prove that has obtained all the other licenses, agreements, approvals in accordance with the legislation in force, that are prerequisites for the licence issued by CNCAN.

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 disposition 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 - Attributions and Responsibilities

This chapter defines the attributions 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. Development of 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 discussed in common meetings. 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 Gazette of Romania. Besides publication in the Official Gazette, in order to provide for broader dissemination, CNCAN publishes the regulations separately in brochures, as well as on its website.

4.1.b. Overview of the licensing system

The practice for the licensing of the nuclear installations is based on the provisions of the Law and of the 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, as appropriate: design, siting, construction, commissioning, trial operation, operation, repair and/or maintenance (as major refurbishment), modification (as major upgrades), preservation, decommissioning and closure.

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 licences;
- IAEA Safety Standards;
- ICRP recommendations;
- Regulatory documents developed by CNSC and US NRC;
- WENRA Reference Levels;
- Applicable Standards and Codes (CSA, ANSI, ASME, IEEE, etc.);
- Safety related documentation produced by the licensees 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 (published) 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.

Control of licensing submissions is described in the management system of CNCAN, within the framework of which a set of procedures have been established that define the different activities and tasks performed by the different organisational divisions involved in the licensing process. The licensing process 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.

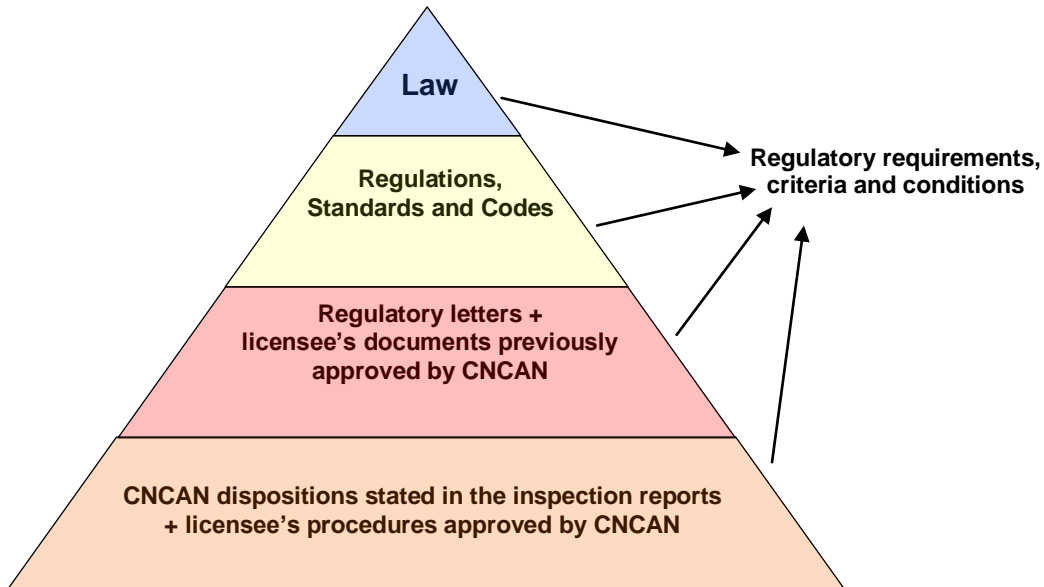


Fig. 4.1 - Documents containing requirements used by CNCAN in the licensing process

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 .

According to the Law, a licence for the quality management system has to be obtained from CNCAN, as pre-condition for the issuance of the construction / commissioning / operation / decommissioning licence. The licensing of the quality management systems is applied not only to the operators of nuclear installations but also to the suppliers of products and services for the nuclear installations.

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 granting practice permits to operating, management and specific training personnel of Nuclear Power Plants, Research Reactors and other Nuclear Installations”.

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 and Climate Change 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.c. Regulatory Assessment and Inspection

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 usually specified in the regulations.

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 manuals, different types of safety assessments and technical evaluations, information reports and procedures (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 division on a regular basis.

The key objective of 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.

Examples of 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 audits;
- review of temporary and permanent modifications to ensure they are consistent with the licensing basis and design basis for the installation;
- system inspections;
- regulatory inspections during planned outages, construction, pre-commissioning 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 operating practices and work;
- monitoring of the implementation of the licensees' training programmes;
- monitoring of emergency drills and exercises;
- monitoring of the radiological protection practices.

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;
- independent preliminary investigation of events significant for safety;
- inspections 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 maintenance activities, testing of the special safety systems, personnel training, quality assurance;
- monitoring of the emergency preparedness arrangements;
- surveillance of the performance of activities during the planned 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 (procedures, work plans, modification proposals, etc.);
- witnessing 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.d. Enforcement

In accordance with the provisions of the Law, CNCAN has in place a system to enforce compliance through graded measures. The 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;
- licence amendments;
- restricted 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 relevant for the nuclear field. Revisions and modifications to the Law are performed, as necessary, to take account of the changes in European and international legislation and 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), the feedback from the operators and the feedback from CNCAN inspectors based on their experience with the enforcement of the regulations.

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 that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.

3. Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the powers and resources to:

(a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;

(b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;

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

(d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

5.1 Description of the attributions 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 attributions and responsibilities of CNCAN are stipulated in the Law, and are further detailed in the Regulation for Organisation and Functioning of CNCAN, approved by Governmental Decision. The mandate of CNCAN can be summarised 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, approved by Governmental Decision.

- CNCAN is responsible to ensure, through the regulations issued and the dispositions arising from the licensing and control procedures, 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 attributions and responsibilities:

- 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 organisations specialised 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, attributions 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;
- Organises 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

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 are concerning solely the regulation, licensing and control of nuclear activities.

CNCAN reports to the Prime Minister, through the General Secretariat of the Government. 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, through the Department of Energy or to the Ministry of National Education.

CNCAN is chaired by a President nominated 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.

5.3 CNCAN Legal Powers

In accordance with the provisions of the Law, as described in this report in the chapter corresponding to article 4 of the Council Directive 2009/71/Euratom, 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 assessment and inspection activities;
- take enforcement actions, including restricting or suspending operation of nuclear installations.

5.4 CNCAN Organisational Structure and Human and Financial Resources

The organisational structure of CNCAN is shown in Fig. 5.1. The current total number of positions in CNCAN's structure, including the President, is 89.

The division in charge of the regulation, licensing and control of nuclear installations is the Nuclear Fuel Cycle Division, which has currently a total number of 28 staff positions and is composed of 7 units:

1. Nuclear Safety Assessment Unit;
2. Nuclear Regulations and Standards Unit;
3. Cernavoda NPP Residents Inspectors Unit;
4. Management Systems Oversight Unit;

5. Radiological Protection, Radioactive Waste Safety and Transport Unit;
6. Radiological Emergencies Unit;
7. Mining, Safeguards and Physical Protection Unit.

As described under Article 4, CNCAN staff evaluate and process applications for licences; develop and prepare licensing recommendations; administer CNCAN policies and procedures; monitor, audit and inspect nuclear facilities and activities; draft and administer licenses; evaluate the qualifications and performance of licensees and their staff; prepare documents and reports; review reports and records; develop and enforce regulatory standards and requirements.

CNCAN does not have a dedicated external technical support organisation, but, in specific cases, external consultants are employed to assist CNCAN staff in review and assessment activities or in the development of regulations. In addition, CNCAN benefits from external expertise, when necessary, through IAEA technical co-operation projects and bilateral agreements with regulatory authorities from other countries.

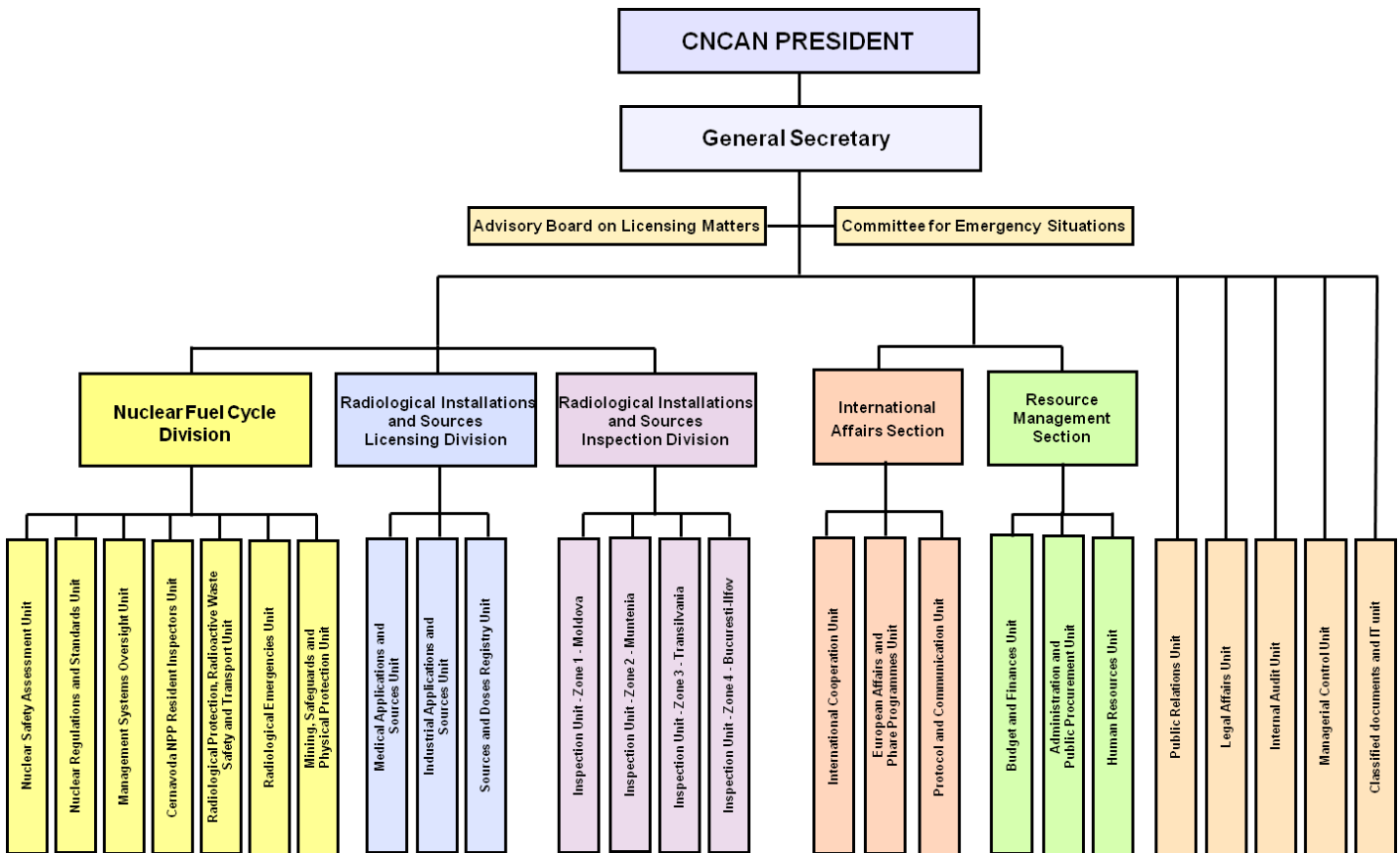


Fig. 5.1 CNCAN Organisational Structure

As regards the financing, before November 2009, CNCAN was collecting money for its budget from fees charged for performing inspection activities and technical assessments and for granting licences, permits and authorisations and was self-financed. Starting with November 2009, all the money collected from taxes and tariffs for CNCAN activities have become revenue to the state budget and CNCAN is currently financed from the state budget through the General Secretariat of the Government. CNCAN’s budget for 2013 has been of 9.516.000 lei (~2.143.243 Euro).

ARTICLE 6 - LICENCE HOLDERS

- 1. Member States shall ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.*
- 2. Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.*
- 3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.*
- 4. Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.*
- 5. Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.*

6.1 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 presented in this report in the chapter corresponding to article 4, in section 4.1.

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 attributions 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.

6.2 Safety assessment and verification and continuous improvement of nuclear safety

The obligation of the licensees to regularly assess and verify and continuously improve nuclear safety is stated in the specific regulations and 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 and components;
- periodic safety reviews, including through deterministic and probabilistic analyses, based on the regulatory specific requirements;
- in-service inspection, surveillance, functional testing of systems, maintenance;
- 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;
- emergency preparedness and response arrangements;
- management of suppliers.

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.

6.3 Safety review and assessment of defence-in-depth

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.

6.4 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 Quality 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 QMS 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 QMS. 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 QMS. The list of QMS 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 QMS 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.

6.5 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 the conditions of each of the licenses granted by CNCAN. For example, specific conditions 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.

Detailed information on Cernavoda NPP, as regards the design, operation, management system, resources and programmes of the licensee, is provided in the National Report under the Convention on Nuclear Safety, 6th edition, published in 2013 (<http://www.cncan.ro/assets/stiri/Romanian-Report-for-the-CNS-6th-Edition.pdf>).

ARTICLE 7 - EXPERTISE AND SKILLS IN NUCLEAR SAFETY

Member States shall ensure that the national framework in place requires arrangements for education and training to be made by all parties for their staff having responsibilities relating to the nuclear safety of nuclear installations in order to maintain and to further develop expertise and skills in nuclear safety.

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.

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 6.3 of this report.

Specific requirements for the licensees in the area of training and qualification are provided in the "Regulation on granting practice permits to operating, management and specific training personnel of Nuclear Power Plants, Research Reactors and other Nuclear Installations", the "General Requirements for Quality Management Systems Applied to the Construction, Operation and Decommissioning of Nuclear Installations" and in the "Specific Requirements for the Quality Management Systems Applied to the Operation of Nuclear Installations", as well as in the "Fundamental Requirements on Radiological Safety" and the "Regulations on issuing Working Permits for nuclear activities and designation of Qualified Radiological Protection Experts".

The above mentioned regulations establish:

- 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.

Detailed information on the training and qualification for staff with safety-related duties working in Cernavoda NPP is available in the National Report under the Convention on Nuclear Safety, 6th edition, published in 2013 (<http://www.cncan.ro/assets/stiri/Romanian-Report-for-the-CNS-6th-Edition.pdf>) in the chapter corresponding to article 11 of the Convention.

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 plan, elaborated by their respective line manager.

Training for CNCAN staff is provided either in-house or through technical cooperation programmes with the IAEA and with other states and organizations. Members of the technical staff attend training courses, workshops, technical meetings, expert meetings and conferences that are relevant for their professional development in relation to their current and foreseen duties. CNCAN has made arrangements for specific staff training using training courses and programs provided by international organizations such as the IAEA. Efforts are on-going for implementing a knowledge management programme and for formalizing the training and qualification programme for inspectors.

The “Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania” is currently in progress and aims to enhance the capabilities of CNCAN in eight specific functional areas of work through exchange of experiences, best practices and capacity building with the Norwegian Radiation Protection Authority (NRPA) and the IAEA. This project is under implementation until April 2016 and represents a continuation of the project conducted by CNCAN, NRPA, and IAEA during the previous cycle of Norway Grants in 2009-2011.

Priority sectors of this cooperation program include the following subprojects:

- CNCAN 1 - Enhancement of CNCAN capabilities for safety analysis;
- CNCAN 2 - Enhancement of CNCAN capabilities for integrated management systems and knowledge management;
- CNCAN 3 - Enhancement of CNCAN capabilities for inspections;
- CNCAN 4 - Enhancement of CNCAN capabilities for safety and security of transport and transit of radioactive and nuclear materials on the Romanian Territory;
- CNCAN 5 - Enhancement of CNCAN capabilities for emergency preparedness and response;
- CNCAN 6 - Enhancement of CNCAN capabilities for ionizing radiation sources control;
- CNCAN 7 - Enhancement of CNCAN capabilities for radioactive waste, spent nuclear fuel management and decommissioning activities;
- CNCAN 8 - Enhancement of CNCAN capabilities for safeguards.

Some of the most important activities of the projects are related to the development and updating of the Romanian regulations in line with the international standards and guidelines as well as to the training of CNCAN staff using effective knowledge transfer methods that will ensure sustainability.

ARTICLE 8 - INFORMATION TO THE PUBLIC

Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

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 111/1996 on the safe deployment, regulation, licensing and control of nuclear activities explicitly include:

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

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;
- annual reports on CNCAN's activity (<http://www.cncan.ro/informatii-de-interes-public/rapoarte/rapoarte-activitate-cncan/>);
- reports submitted to international organisations;
- information about the history, organization and functioning of CNCAN;
- information on licensed installations and activities;
- press releases and information about conferences;

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- forms for submitting requests for information.

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.

Requests for information have come mainly from non-governmental organisations 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 its activities are published on its website and summary reports are published also in the Official Gazette of Romania.

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

ENSREG – European Nuclear Safety Regulators Group

IAEA - International Atomic Energy Agency

ICRP - International Committee for Radiation Protection

NMC - Norms on Quality Management

NPP - Nuclear Power Plant

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

SNN - National Company “NUCLEARELECTRICA”

WENRA - Western European Nuclear Regulators Association

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