



**INTEGRATED  
REGULATORY  
REVIEW SERVICE (IRRS)  
MISSION  
TO  
ROMANIA**

Bucharest

*17 to 28 January 2011*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



**INTEGRATED REGULATORY REVIEW SERVICE (IRRS)**  
**REPORT TO**  
**THE GOVERNMENT OF ROMANIA**

*Bucharest, Romania*  
*17 to 28 January 2011*



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**Mission date:** *17 to 28 January 2011*

**Regulatory body:** *CNCAN*

**Location:** *Bucharest, Romania*

**Regulated facilities and practices:** *Nuclear power plants; research reactors; fuel cycle facilities; medical, industrial and research facilities, radioactive waste facilities, decommissioning and remediation.*

**Organized by:** *International Atomic Energy Agency (IAEA)*

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**The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

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## EXECUTIVE SUMMARY

At the request of the Government of Romania, an international team of fifteen senior experts in safety regulation visited the National Commission for Nuclear Activities Control (CNCAN) of Romania from 17 to 28 January 2011 to conduct an Integrated Regulatory Review Service (IRRS) mission

The purpose of this IRRS mission was to review the framework for regulating safety of nuclear facilities and activities and radioactive sources in Romania and the effectiveness of regulatory functions implemented by CNCAN and other regulatory bodies. The review was carried out by comparison against IAEA safety standards – IAEA Safety Fundamentals and Safety Requirements and Safety Guides – and the Codes of Conduct on the Safety and Security of Radioactive Sources and on the Safety of Research Reactors as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS review team members and the Romanian counterparts in the areas covered by IRRS.

The IRRS Review Team consisted of thirteen senior regulatory experts from twelve Member States, two staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review of CNCAN and other regulatory bodies in all relevant areas: responsibilities and functions of the Government; global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body, the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development of regulations and guides; emergency preparedness and response; transport of radioactive materials safety; and the interface between safety and security.

The IRRS review addressed facilities and activities regulated by CNCAN, including the operation of nuclear power plants, research reactors, fuel cycle facilities, industrial, medical and research facilities, and waste management facilities. The review also addressed implementation of the Codes of Conduct on Safety and Security of Radioactive Sources and on the Safety of Research Reactors. To help assess the effectiveness of the regulatory system, the mission included observations of inspection activities at a variety of nuclear and radiological facilities, covering the key activities regulated by CNCAN. In addition, four policy issues were addressed and discussed with CNCAN management and staff: Independence of the Regulatory Body; Openness, Transparency and Public Communication, Regulatory Approach, and Human Resources and Knowledge Management.

CNCAN provided the IRRS Team with initial documentation as advanced reference material including the results of its self-assessment. Additionally, the team took into account recommendations from the previous IRRS mission conducted in January 2006.

In several areas of regulatory responsibility, CNCAN has made significant progress from the previous IRRS mission. Additionally, the team highlighted the following:

- A comprehensive legal infrastructure that addresses all relevant international conventions and obligations is in place. In addition, the regulatory framework establishes CNCAN as the sole competent authority with the necessary powers to effectively implement its regulatory obligations.
- CNCAN staff demonstrated a high level of competence and dedication. This should be regarded as a valuable asset for maintaining nuclear and radiation safety in Romania.
- CNCAN conducts its activities with its stakeholders in an open and transparent manner,
- CNCAN properly coordinates and integrates safety and security matters.

A number of areas were identified where improvements are necessary or desirable to enhance the effectiveness of Romania's regulatory performance in accordance with IAEA Safety Standards. The following key issues should be urgently addressed:

- Completion by the Government of the development and implementation of the national policies and strategies for the nuclear sector.
- Provision by the Government of adequate financial and human resources to CNCAN so it can discharge its regulatory responsibilities.
- Provision by the Government of greater flexibility for CNCAN to manage its own organizational structure and resources.
- Consistent implementation by CNCAN of the graded approach in its regulatory activities.

In addition, CNCAN should address, as a matter of priority, the following issues:

- Complete the review and revisions, as necessary, of regulations
- Development and implementation of its integrated management system

CNCAN staff expended a huge effort for the preparation of the mission. Throughout the mission, the administrative and logistical support was very good. The IRRS review team was given full cooperation in technical, regulatory, and policy discussions. The counterparts were receptive to opportunities for improvement.



## I. INTRODUCTION

At the request of the Government of Romania, an international team of fifteen experts in nuclear, radiation and radioactive waste safety visited CNCAN from 17-28 January 2011 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the Romanian nuclear regulatory framework and its effectiveness. In early September 2010, a preparatory meeting was conducted in Bucharest to discuss the objective and purpose of the review as well as to finalize the scope of the mission.

The IRRS Review Team consisted of 13 senior regulatory experts from 12 Member States, 2 staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review of CNCAN in all relevant areas: responsibilities and functions of the Government, nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development of regulations and guides; emergency preparedness and response; transportation of radioactive material safety; and the interface between safety and security.

The IRRS review addressed facilities and activities regulated by CNCAN including the operation of nuclear power plants, research reactors, fuel cycle facilities, industrial, medical and research facilities, and waste management facilities. The review also addressed implementation of the Codes of Conduct on Safety and Security of Radioactive Sources and on Research Reactor Safety.

In addition, four policy issues were addressed and discussed with CNCAN management and staff: Independence of the Regulatory Body, Enhancing Regulatory Effectiveness and Competence, Regulatory Approach, and Human Resources and Knowledge Management.

CNCAN prepared substantial documentation as advance reference material for the mission including its self-assessment. During the mission the IRRS review team performed a systematic review of all topics using the advance reference material, conducted interviews with management and staff from CNCAN and other governmental authorities involved in regulation of the areas stated above, and performed direct observation of the working practices during inspections carried out by CNCAN.

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Romania nuclear regulatory framework and regulatory activities as applied to regulated sources, facilities and activities; to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards (Appendix VI) and the Codes of Conduct on the Safety and Security of Radioactive Sources and of Research Reactor.

It is expected that the IRRS mission will facilitate regulatory improvements in Romania and throughout the world from the knowledge gained and experiences shared by CNCAN staff and the IRRS reviewers and through the evaluation of the effectiveness of the Romanian nuclear regulatory.

The key objectives of this mission were to enhance nuclear and radiation safety and nuclear security by:

- ✓ Providing CNCAN, through completion of the Self-Assessment Tool questionnaires, with an opportunity for self-assessment of its activities against international safety standards;
- ✓ Providing CNCAN (and other governmental authorities on a limited scope) with a review of their regulatory programmes and policy issues relating to nuclear and radiation safety;
- ✓ Providing Romania and CNCAN with an objective evaluation of their nuclear and radiation safety regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting the sharing of experience and exchange of lessons learned;
- ✓ Providing reviewers from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- ✓ Providing key staff with an opportunity to discuss their practices with reviewers who have experience with other practices in the same field;
- ✓ Providing CNCAN with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review.

### **III. BASIS FOR THE REVIEW**

#### **A) PREPARATORY WORK AND IAEA REVIEW TEAM**

At the request of the Romanian government authorities, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 2 to 3 September 2010. The preparatory meeting for the mission was carried out by the appointed Team Leader Mr Greg Rzentkowski, Deputy Team Leader Ms Olga Makarovska, and the IRRS IAEA Team Coordinator Mr David Graves.

The IRRS mission preparatory team had extensive discussions regarding regulatory programmes and policy issues with the senior management of CNCAN represented by Mr Lucian Biro, Director General of CNCAN, and other senior members of CNCAN senior management and staff.

The Liaison Officer for the IRRS mission was Mr Lucian Biro. The discussions resulted in the following areas to be covered by the IRRS mission:

- Nuclear power plants;
- Research reactors;
- Fuel cycle facilities;
- Medical, industrial and research facilities and activities;
- Waste management facilities;
- Code of Conduct on Safety and Security of Radioactive Sources;
- Code of Conduct on the Safety of Research Reactors
- Emergency preparedness and response;
- Interface between safety and security
- Selected policy issues.

Mr Biro and the CNCAN staff made comprehensive presentations on the current status of CNCAN, the self-assessment results to date, and the status of actions taken to address previous mission recommendations and suggestions. IAEA staff presented the IRRS principles and methodology, including the self-assessment phase. This was followed by a discussion on the work plan for the implementation of the IRRS in Romania in January 2011.

The proposed IRRS Review Team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS Review Team was confirmed. Logistics including meeting and work space, counterpart identification, lodging and transportation to accommodate site visits and observations were also addressed.

In November 2010, CNCAN provided IAEA with the advance reference material for the review, including the self-assessment report.

#### **B) REFERENCES FOR THE REVIEW**

The most relevant IAEA safety standards used as review criteria are: GSR Part 1, Safety Requirements on Governmental, Legal and Regulatory Framework for Safety; GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency; GS-R-3, Safety Requirements on The Management System for Facilities and Activities; the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS); the Code of Conduct on the Safety and

Security of Radioactive Sources; and the Code of Conduct on the Safety of Research Reactors. Many other Safety Standards were used as review criteria and are listed in Appendix VI.

### **C) CONDUCT OF THE IRRS REVIEW**

The initial IRRS Review Team meeting and briefing was conducted on Sunday, 16 January 2011 in Bucharest. The briefing was conducted by the IRRS Team Leader, the IRRS Deputy Team Leader, the IRRS IAEA Team Coordinator and the IRRS IAEA Deputy Team Coordinator to discuss the specifics of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and evaluation among all reviewers.

The opening remarks were given by Mr. Greg Rzentkowski, IRRS Team Leader. The Liaison Officer, Mr Lucian Biro, was present at the meeting in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 17 January 2011 with the participation of CNCAN senior management and staff. Opening remarks were made by Mr. Lucian Biro and by Ms Borbala Vajda, President of CNCAN, and Mr Greg Rzentkowski, the IRRS Team Leader.

During the mission, a systematic review was conducted for all the review areas with the objective of providing CNCAN and other government authorities with recommendations and suggestions for enhancing nuclear and radiation safety regulation as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to relevant organizations and direct observations regarding the national practices and activities.

The IRRS Review Team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 28 January 2011. The opening remarks at the exit meeting were presented by Ms Vajda. The results of the IRRS mission were presented by Mr Greg Rzentkowski. The closing remarks were made by Mr Pil Soo Hahn, Director of IAEA's Division of Radiation, Transport and Waste Safety, and Ms Vajda from CNCAN.

## 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

### 1.1. NATIONAL POLICY AND STRATEGY

The Law no. 111/1996 (“the Law”) on the safe deployment, regulation, licensing and control of nuclear activities, amended on the 27<sup>th</sup> of June 2006, provides the legislative framework governing the safety of nuclear and radiological installations and it creates (Art 4) the National Commission for Nuclear Activities Control (CNCAN) as the competent national authority for nuclear activities. The law stipulates (article 5(2)) that CNCAN is responsible for the preparation of the strategy and the policies for the nuclear safety, including regulations, authorization and control, 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. The strategy and the policies prepared by CNCAN are approval by the Government Decision, as part of the National Strategy for the development of the nuclear sector in Romania.

The National Strategy for the development of the nuclear sector in Romania is to expand the existing fleet of CANDU 6 Nuclear Power Plants (NPP) at the Cernavoda site from two to four operational units (two new units are currently in conservation and construction resumption is pending). The fundamental objectives of the proposed strategy for the nuclear safety, formulated by CNCAN, are aligned with the mandate of the Law. They are:

- Ensuring adequate staffing to enable effective discharge of the regulatory duties in all areas of activity, with particular focus on the regulation and oversight of nuclear installations safety, taking account of the development of national nuclear power programme;
- Ensuring the transposition and implementation of all the provisions of the new European Directive, 2009/71/Euratom of 25 June 2009, establishing a Community framework for the nuclear safety of nuclear installations;
- Modernisation of the regulatory framework and of the assessment, review and inspection practices applying the latest IAEA Safety Standards and completion of the revision of the nuclear safety regulations, in order to fully cover the reference levels established by WENRA;
- Implementation of all the actions arising from external review missions conducted by the IAEA and from peer-reviews under the relevant safety Conventions to which Romania is a contracting party;
- Maintaining good co-operation with other national authorities with responsibilities in the nuclear field and with the stakeholders, as well as with regulatory bodies of other countries and with international organisations having competence in radiological protection, nuclear safety and security.

The IRRS team noted that, at the time of the IRRS mission, the strategy and the policies elaborated by CNCAN for the next five year period were undergoing the consultation process within the government, and the National Policy had not been promulgated as a statement of the Government’s intent. As the strategy and the policies elaborated by CNCAN were under development, the Team did not review it in order to provide comments on its elements and on the implementation of a graded approach. At the same time, according to the requirements of GSR- Part 1 paragraph 2.3 the national policy and strategy shall take into account the fundamental safety principles established in the Fundamental Safety Principles. This requirement should be implemented during finalizing of the national strategy and policy for safety.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	(1) <b>BASIS:</b> Req.1 GSR, Part 1 states that <i>“The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.”</i>
R1	<b>Recommendation:</b> The Government of Romania should issue the national policy and the strategy for safety, and implement them in accordance with a graded approach.
	(1) <b>BASIS:</b> GRS - Part 1, paragraph 2.3 of the Req. 1 states that <i>“In the national policy and strategy, account shall be taken of the following: (a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles...”</i>
S1	<b>Suggestion:</b> The government should consider all fundamental safety objectives and principles, established in the IAEA Fundamental Safety Principles document, when finalizing the national policy and strategy.

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Law on the safe deployment, regulation, licensing and control of nuclear activities, republished in the Official Gazette no. 552/27.06.2006 (the Law) provides the legislative framework governing the safety of nuclear installations and empowers CNCAN to issue mandatory regulations and 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 Law also clearly states the responsibilities of the licence holders.

The provisions of the Law apply to the following activities and sources:

- research, design, possession, siting, construction, assembly, commissioning, trial run, operation, modification, conservation, decommissioning, import and export of nuclear facilities;
- design, possession, siting, construction or assembly, commissioning, operation, conservation and decommissioning of the mining and milling facilities for uranium and thorium ores and of the waste management facilities of the waste resulted from the mining and milling of uranium and thorium ores;
- production, siting and construction, supply, leasing, transfer, handling, possession, processing, treatment, use, temporary storage or final disposal, transport, transit, import and export of radiological installations, nuclear and radioactive materials, including nuclear fuel, radioactive waste and ionizing radiation generating devices;
- production, supply, and use of dosimetric equipment and ionizing radiation detection systems, materials and devices used for the protection from ionizing radiation, as well as packaging or conveyance for radioactive materials, specially designed for such purpose;
- production, supply, leasing, transfer, possession, export, import of the materials, devices and equipment provided in Appendix no. 1 to the this Law;
- possession, transfer, import and export of the unpublished information, relating to materials, devices and equipment pertinent to the proliferation of nuclear weapons and other explosive nuclear devices, as stipulated in Appendix no. 1 to the this Law;
- manufacturing of products and provision of services designated for nuclear facilities;

- manufacturing of products and provision of services designated for radiation sources, dosimetric control instruments, ionizing radiation detection systems, materials and devices used for the protection from ionizing radiation; and
- orphan sources, from their detection to the final disposal as radioactive waste.

Following the IRRS Mission conducted in Romania in 2006, the Government amended the Ordinance No. 7/2003 approved by the Law 321/2003 and gave the Nuclear Agency sole responsibility for promotion of nuclear activities under the subordination of Ministry of Economy and Finances. However, the IRRS Team observed that the recommendation to repeal of overlapping sections of Articles 9 of Ordinance 11/2003 approved by the law 320/2003, and related government decisions and rules, is outstanding because by the Governmental Decision 1437/2009 (Article4(2)n) issued in 2009 the Nuclear and Radiation Wastes Agency, under the Ministry of Economy, Trade and Business Environment, has the legal responsibility for issuing regulations for safe management of radioactive waste (see Article4 (2) n and r). It thus follows that CNCAN doesn't currently have the only responsibility for establishing safety principles, criteria, and regulations for safe management of spent nuclear fuel and radioactive waste.

The IRRS Team also noted overlapping responsibilities between CNCAN and the Ministry of Health. Recently, the Ministry of Health issued regulations no. 1224/2010 on staffing requirements in medical institutions, including medical physicists. These regulations contradict the Norms for Medical Exposure on medical physicists in diagnostic radiology that were jointly issued by the Ministry of Health and CNCAN in 2006. CNCAN was not consulted and contacted the Ministry of Health on 19.10.2010 in to clarify the contradiction. No response was provided yet.

The IRRS Team concluded that the legislative and regulatory framework for nuclear safety in Romania is well established, and contains an appropriate range of instruments allowing for an effective legal regime. Responsibilities are generally clearly allocated within this framework with some exceptions of competences, for example, with the Nuclear and Radiation Wastes Agency under the Ministry of Economy, Trade and Business Environment. However, there are no administrative provisions to maintain an appropriate legislative and regulatory framework, and avoid legislative amendments that can affect its effectiveness.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Requirement 2 states that *“The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”*

R2 **Recommendation:** The Government should ensure that there is no duplication in responsibilities between CNCAN and other government organizations for establishing safety principles, criteria, and regulations for nuclear safety and radiological protection.

### 1.3. ESTABLISHMENT OF A REGULATORY BODY

The Law establishes that CNCAN is the national nuclear regulatory body and provides it with the legal authority to discharge its statutory responsibilities. The legislation gives CNCAN the authority to:

- apply regulations, licensing and control in the nuclear field, for all the activities and installations under the scope of the Law;
- elaborate the strategy and the policies for regulation, licensing and control with regard to nuclear safety, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials, transport of radioactive materials and safe management of radioactive

waste and spent fuel, as part of the National Strategy for the development of the nuclear sector, approved by Governmental Decision;

- 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; and
- amend the regulations, when necessary, or the purpose of harmonization with the international standards and ratified conventions in the nuclear field, and for establishing the necessary regulatory measures for their application.

The senior organisational structure of CNCAN, and the modifications thereof, is approved by the Governmental Decision. In addition the General Secretariat of the Government on the basis of propositions of the President of CNCAN, decides on the detailed organizational structure of the CNCAN divisions, depending on operational needs and economic conditions.

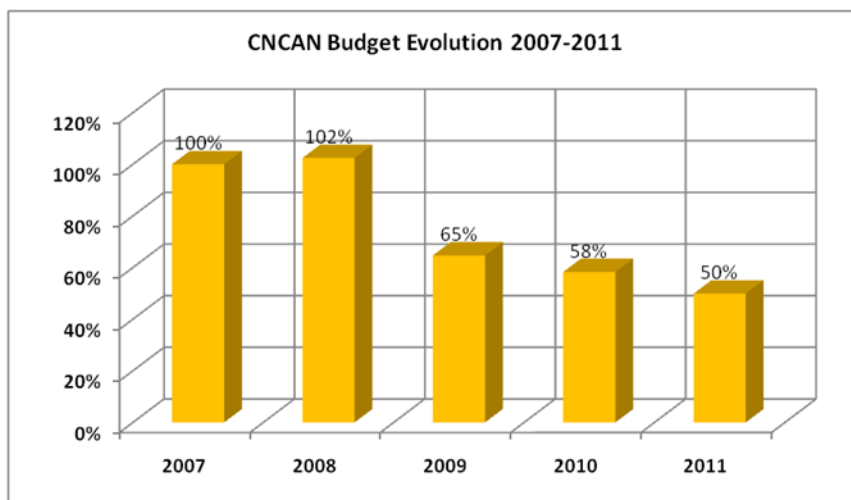
During the period from 2008 to 2011, CNCAN was restructured four times due to drastic measures taken by the Romanian Government to mitigate the consequences of the economic crisis.

- In December 2008, CNCAN was reorganized by creating two General Divisions, one dealing with the technical aspects and one with the support aspects. The Technical General Division was the General Division for the Regulation, Licensing and Control of Nuclear Activities (DGRACAN) and the Support General Division was the general Division for Resources Management (number of staff in the organizational structure was 171);
- In June 2009, at the request of the Prime Minister/State Counsellor coordinator, the number of positions in CNCAN's organisational structure was reduced from 171 to 137, by eliminating the vacant positions and by forced retirement of staff meeting the conditions for retirement.
- In November 2009, the Parliament issued a law for the reorganisation of some public authorities and institutions and for rationalisation of public spending which affected both the human and financial resources of CNCAN. As a result, CNCAN was not allowed anymore to directly recover operational costs from fees charged for performing inspection activities and technical assessments, and for granting licences, permits and authorisations. CNCAN is now financed from the state budget through the General Secretariat of the Government (SGG) and all CNCAN expenditures have to be approved by SGG. This led to significant reduction of the CNCAN budget and, as a consequence, the number of position was reduced from 137 to 103.
- In January 2011, the position of the Director General of the General Division for the Regulation, Licensing and Inspection of Nuclear Activities was replaced by the newly created position of the General Secretary who will be appointed by the Prime Minister. This organizational change was published in the Official Gazette no. 26/2011 on January 18, 2011 and implemented during the IRRS mission. There was no direct impact on CNCAN staffing level.

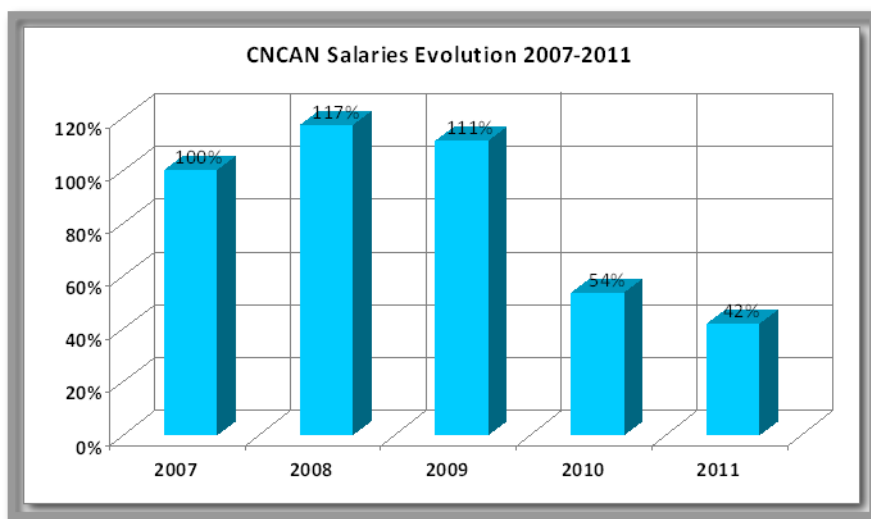
In November 2009, the Parliament issued the Law 329/2009 for the reorganisation of some public authorities and institutions and for rationalisation of public spending. Furthermore, in the first quarter of 2010, a law providing for a single framework for the salaries in the civil service entered into force which led to a significant reduction of the salaries of CNCAN.

Figures 1 and 2 show the changes in the CNCAN operating and salary budget, respectively, since 2007 to 2011. These figures demonstrate that over this time period the CNCAN overall budget decreased by 50%, while the salary budget decreased by 58%.





**Figure 1: The CNCAN operating budget 2007 to 2011**



**Figure 2: The CNCAN salary Budget 2007 to 2011**

The IRRS Team noted that recent measures taken by the Romanian Government led to the serious limitation of regulatory resources of CNCAN, both financial and human. The problem is further compounded by staff retention issues due to low salaries and continuous expansion of the nuclear sector e.g. the restart of construction of Cernavoda Units 3 and 4 and the new radioactive waste repository in Saligny and tritium removal facility.

The IRRS Team concluded that CNCAN is currently challenged with the existing resources to fulfil its statutory obligation for the regulatory control of facilities and activities. These changes could impact the existing framework for safety, and may also affect, on a longer term, the planned expansion of nuclear energy generation (it should be noted that the process of rebuilding the competence of nuclear regulatory organizations may take several years).

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 1, Requirement 3 states that *“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfill its statutory obligation for the regulatory control of facilities and activities.”*
- R3 **Recommendation:** The Government should provide CNCAN with the financial and human resources necessary to fulfill its statutory obligation for the regulatory control of facilities and activities.

### 1.4. INDEPENDENCE OF THE REGULATORY BODY

CNCAN is empowered by the Law to regulate, authorize and control nuclear activities, as well as to suspend, revoke and amend their authorizations on its own notion. The 2006 amendment of the Law was issued to ensure an effective separation of the regulatory CNCAN from the organisations mandated by the government with the promotion or utilisation of nuclear energy.

As stipulated in the Law, CNCAN has the statutory authority to exercise its regulatory decisions independently from the ministries and other authorities of the central public administration, subordinated to the Government. The state owned companies and organisations that operate or own the main nuclear and radiological installations are subordinated to the Ministry of Economy, Commerce and Business Environment and to the Ministry of Education, Research, Youth and Sports. The main organisation responsible for the promotion of nuclear activities for peaceful purposes and for Radioactive Waste is also subordinated to the Ministry of Economy Commerce and Business Environment.

Changes to the CNCAN organizational structure, including all management positions and staffing levels, are typically proposed by the CNCAN President and must be approved by the Prime Minister. The last change in the organizational structure, published in Official Gazette no. 26/2011 on January 18, 2011, abolished the post of Director General and created the post of the Secretary General. The Secretary General is a position that can be occupied only through a competitive selection (including satisfactory passing of an examination) organized at the national level. It is not intended to be a political appointment.

The IRRS Team concluded in 2006 that the process for implementation of changes in the organizational structure may have serious implications on the responsiveness and adaptability of the regulatory body to political decisions, and recommended that the Government of Romania amend Governmental Decision 1627/2003 in order to provide CNCAN with greater flexibility in the management of its organizational structure. This has not been implemented.

The IRRS Team noted that this situation is even more pronounced today. The Team noted also that CNCAN does not have a sufficient level of staffing and financial resources for the proper discharge of its assigned responsibilities, as discussed in Section 1.3.

The IRRS Team concluded that the recent changes in the CNCAN organizational structure, leading to reduction in the level of staffing and financial resources, may compromise the technical capability for the regulatory decision making.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Requirement 2.8 states that *“To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities.”*

R4 **Recommendation:** The Government should provide CNCAN with adequate financial and human resources, and authority in the management of its organizational structure.

### 1.5. PRIME RESPONSIBILITY FOR SAFETY

Article 25 of the Law expressly discharges the responsibility for nuclear safety in relation to the activities authorized by the licence on the licence holder, including the responsibility for nuclear damage caused by accidents or problems generated by wrong actions by third parties, such a service provider or supplier to the facility. In addition, the Law shall grants the regulatory body the authority to require the licence holder to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.

The Law includes provisions stating 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.

The IRRS Team, following the mission conducted in 2006, recommended, in light of the need to clearly transfer the prime responsibility of safety to the licensee, that in order to clearly place prime responsibility on the operator for ensuring quality assurance of component suppliers and subcontractors, the present Romanian Legislation should be modified so that CNCAN is released from its obligation to issue quality assurance authorizations for component suppliers and subcontractors. This recommendation still applies, as CNCAN continues to issue separate authorizations to suppliers and subcontractors. CNCAN responded that this approach should not be considered as having the potential for diminishing the licensee’s responsibility, as it only constitutes an additional mechanism to provide confidence that the specified requirements for all activities important to nuclear safety are satisfied.

The IRRS Team concluded that clear definition of the legal obligations in the Law ensures that the licensee’s responsibility for safety could not be relinquished or shifted towards the regulatory authority or any other party. Furthermore, the Law extends the responsibility of the licensee beyond the validity of the licence to deal with the liabilities created during the conduction of the activity.

### 1.6. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

The Law clearly stipulates the responsibilities of the licensees and that the responsibility cannot be delegated to third parties. Compliance with regulations, as required and enforced by CNCAN, does not relieve the licensee from complying with the legal requirements, including the conditions stated in the licence. This extends to all stages in the lifetime of facilities and the duration of activities.

The IRRS Team noted that the licensees understand their obligations and responsibilities with respect to safety.

## 1.7. COORDINATION OF DIFFERENT AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

The licensing framework is administered by CNCAN in cooperation with other governmental authorities (ministries and agencies) in such areas as environment, health, transport, labour, security, etc. The issues, authorizations or requirements raised by these authorities in respect to a nuclear activity are taken into account before licences are issued by CNCAN, providing that there is no conflict with the provisions of the Law and the CNCAN regulations.

Authorizations granted by other governmental authorities, having partial responsibilities for safety within the regulatory framework, are prerequisites for the granting of a licence by CNCAN. The only exception is the environmental authorisation issued by the Ministry of Environment and Forests after the issuance of the operation licence by CNCAN. The environmental agreement issued by the same Ministry is, however, a prerequisite to the siting licence issued by CNCAN.

As per Articles 36 – 42 of the Law, some responsibilities to control various aspects related to nuclear activities are given to the following authorities:

- National authority for boilers and hoisting equipment;
- Central environment protection authority;
- Ministry of Public Health;
- Ministerial Committee for Emergency Situations within the Ministry of Administration and Interior;
- Department for Export Control – ANCEX (former National Agency for Exports Control); and
- National Customs Authority within the Ministry of Public Finance

Although the responsibilities of these authorities are clearly established by the legislation in force, CNCAN has also signed formal Memoranda of Understanding with some of these organisations and other authorities to clarify the roles and responsibilities for safety within the regulatory framework, and to ensure prevention of potential gaps and overlaps in the discharging of their respective mandates. They are:

- Memorandum of Understanding between the National Commission for Nuclear Activities Control, the Division of Preventive Medicine of the Ministry Health and General Inspectorate of Police.
- Memorandum of Understanding between the Romanian Legal Metrology Bureau and National Commission for Nuclear Activities Control for the uniform application of the Law and Government Ordinance no. 20/1992, 1997.
- Memorandum of Understanding on exchange of information in the area of transfers of strategic products, including nuclear products between the Department for Export Control – ANCEX (former National Agency for Exports Control) and the National Commission for Nuclear Activities Control, 2001.
- Memorandum of Understanding between Custom National Authority and the National Commission for Nuclear Activities Control, 2005.
- Memorandum of Understanding between the National Commission for Nuclear Activities Control and the General Inspectorate for Emergency Situations (IGSU), 2006.
- Memorandum of Understanding between the National Meteorological Administration and the National Commission for Nuclear Activities Control, 2007.
- Memorandum of Understanding between Custom General Inspectorate of the Border Police and the National Commission for Nuclear Activities Control, 2007.

- Memorandum of Understanding between Romanian Intelligence Service and the National Commission for Nuclear Activities Control for the prevention and combating terrorism, 2008 – classified.
- Memorandum of Understanding between Ministry of Administration and Interior and the National Commission for Nuclear Activities Control, 2008 – classified.
- Memorandum of Understanding between the Romanian Gendarmerie and the National Commission for Nuclear Activities Control, 2010.
- Memorandum of Understanding between the General Inspectorate of Romanian Police and the National Commission for Nuclear Activities Control, 2010.

The IRRS Team noted that no memorandum of understanding has been signed with the Ministry of Environment and Forest. This could lead to conflicting regulations and requirements issued by two independent authorities, undermining the authority of the regulatory body and causing confusion on the part of the authorized party or the applicant. As an example, in September 2010 the Ministry of Health issued regulations on staffing requirements for facilities using nuclear equipment which conflict with the staffing requirements imposed by CNCAN for the same facilities.

The IRRS Team noted also that no agreements have been made by CNCAN with other regulatory authorities to carry out joint inspections in the areas where their mandates overlap to optimize the regulatory effort and minimize undue duplication on common areas of regulatory compliance. In addition the team identified insufficient coordination in regulatory activities in areas such as Emergency preparedness and Transport.

### Conclusion

The IRRS Team concluded that CNCAN has made considerable progress in coordinating regulatory activities with other authorities, having responsibilities for nuclear safety. However, some overlapping provisions in their mandates still exist and further work is required to avoid conflicting requirements being placed on authorized parties by either streamlining the legislative framework or by improving their cooperation.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Requirement 7 states that *“Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.”*

R5 **Recommendation:** The Government should make provisions for effective coordination of regulatory functions between CNCAN and other authorities.

### 1.8. PROVISION FOR DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL

The main legislative framework for the management of radioactive waste and spent fuel is provided by the Law and Governmental Ordinances no. 11/2003 regarding the management of nuclear spent fuel and radioactive waste, including their disposal, with subsequent modifications and completions and no. 7/2003 regarding the use of nuclear energy in exclusive peaceful purposes, with subsequent modifications and completions. In September 2007 the Government adopted Decision No. 1080 establishing the

financial contributions for setting up the financial resources for decommissioning and disposal of radioactive waste.

The Nuclear and Radioactive Waste Agency (AN&DR) is responsible for disposal of the radioactive waste and supervising decommissioning of nuclear facilities. AN&DR is responsible for the development the national strategy for radioactive waste management and is responsible for its implementation together with the licensees. AN&DR administrates the funds for radioactive waste management and decommissioning, and produces the five-year Nuclear National Plan and the Annual Plan for Nuclear Activities which includes radioactive waste management concrete measures.

According to the national strategy, the near surface repository should be in operation in 2014. This target date will likely be postponed. The target date for the operating deep geological repository is 2050.

Plans for a disposal facility in deep geological formations were declared in the Third Romania National Report of Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. It was planned that ANDRAD (now AN&DR) will issue site investigation program on preferred site for three geological formations. These plans are not yet released.

The objective of Romanian radioactive waste management policy is to assure safe management of radioactive waste. Some specifics of the radioactive waste management policy are summarized below.

- By the legislative and regulatory framework, spent fuel from CANDU reactors is considered to be another form of radioactive waste. Legislation and policies on managing radioactive waste apply equally to spent fuel.
- Radioactive waste management, including the transport, shall be authorized, and shall be performed according to the provisions of the applicable laws and regulations, assuring safety of facilities, protection of human health and environment (including protection of future generations);
- The licensees have the responsibility for management of radioactive waste arising from operation and decommissioning of their own nuclear and radiological facilities, up to disposal. They shall bear the expenses related to the collection, handling, transport, treatment, conditioning, storage and disposal of the waste they have produced;
- The licensees shall pay the legal contribution to the fund for management of radioactive waste and to the fund for decommissioning of nuclear installations;
- CNCAN has the responsibility for radioactive waste regulatory policy;
- Nuclear and Radioactive Waste Agency has the responsibility for disposal of the radioactive waste;
- The import of radioactive waste is prohibited;
- The timing for decommissioning and radioactive waste disposal shall assure, as far as applicable, the requirements for not imposing undue burden on future generations;
- Spent fuel produced by NPPs shall not be reprocessed;
- According to international agreements signed with neighbour countries, the protection of human health and environment beyond national borders shall be assured in such a way that the actual and potential health effects will be not more detrimental that those accepted for Romania.
- The discharge of gaseous and liquid radioactive effluents from any nuclear facility shall be limited, according to derived emission limits approved by CNCAN, and further reduced, according to optimization principle.

- By conditions set in the operating authorization, and by regulatory dispositions, the holder of authorization is requested to transfer the radioactive waste (including the spent sources) for treatment and disposal or long term storage at dedicated facilities.
- Any nuclear and major radiological facilities shall have a decommissioning generic plan; for new facilities, this requirement applies from the design stage, when the application for the siting authorization is submitted to CNCAN.

CNCAN is responsible for radioactive waste regulatory policy.

At the moment there is a national strategy for the safe management of radioactive waste and nuclear spent fuel approved by Order No. 844/2004 of the President of the Nuclear Agency (AN). The strategy contains some policy elements.

The IRRS Team observed that the national strategy does not reflect the existing situation. For example, the near surface repository for radioactive waste scheduled for operation in 2014 may now be delayed until 2019.

As part of a strategy, before a repository starts operation, a treatment and conditioning facility needs to be designed, constructed and commissioned to produce the waste packages meeting the repository waste acceptance criteria.

During the meeting with AN&DR, the IRRS team was informed by the AN&DR that the draft strategy being prepared as part of the updated National Strategy for the Development of Nuclear Sector considers all of the stages of radioactive waste and spent fuel management.

### Conclusion

The revised strategy for radioactive waste and nuclear spent fuel management is not approved by the government.

The team concluded that CNCAN is the competent authority responsible for establishing requirements for the decommissioning of nuclear facilities and for the management of radioactive waste and spent fuel and for verifying and enforcing compliance with such requirements. Also CNCAN has the legal authority to issue licences for decommissioning and for the management of radioactive waste and spent fuel. The licensees are responsible for implementing decommissioning plans.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 1, Requirement 10, paragraph 2.28. states that *“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility between successive authorized parties.”*

- R6 **Recommendation:** The Government should issue and implement a revised national strategy for radioactive waste and nuclear spent fuel management as part of the overall Nuclear Strategy for the Development of Nuclear Sector

## 1.9. COMPETENCE FOR SAFETY

The Government of Romania continues to emphasize the need for building and maintaining competences in the nuclear field. The National Policy, however, has not made clear provisions for building and maintaining the competence of all parties, having responsibilities related to safety of facilities and activities. The fundamental objectives of the proposed strategy for the nuclear safety, formulated by CNCAN and included in the National Policy, are intended to ensure adequate staffing to enable effective discharge of the regulatory duties in all areas of activity, with particular focus on the regulation and oversight of nuclear installations safety, taking account of the development of national nuclear power programme

The IRRS Team noted that there are no systematic measures taken by the Government to address the need for maintaining sufficient number of suitably qualified and experienced staff in the field of nuclear safety, as well as the need for enhancing research and development capabilities in support of a nuclear sector. Furthermore, the number of applicable training courses through academic institutions and other learning centres is rapidly decreasing.

Article 18 in the Law makes provisions on the required professional qualification of licence holders' personnel for each position, their knowledge of the requirements of the regulations on nuclear safety and protection from ionizing radiation, as well as the probity of the persons who, during the construction and operation of a nuclear or radiological plant, manage other nuclear activities among those mentioned under the article. The regulations require that all licensee personnel in certain positions (such as reactor operators, supervisors, certain management positions, quality assurance staff, radiation protection personnel, training instructors, etc) must be licensed/authorized by CNCAN. More details are provided in Section 5 of this report.

The IRRS Team concluded that the Government has not implemented systematic measures for maintaining sufficient number of suitably qualified and experienced staff in the field of nuclear safety. If corrective actions are not taken, this situation can impact development of the nuclear sector. CNCAN, however, has put in place the programs to ensure that the operating organizations' key positions for nuclear and radiation safety are staffed by competent personnel.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR- Part 1, Req. 2.34 states that *“As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.”*

R7 **Recommendation:** The Government should establish a national policy and strategy to develop and implement the necessary training program for maintaining and enhancing the competence of a sufficient number of suitably qualified and experienced staff employed in the nuclear sector.

## 1.10. PROVISION OF TECHNICAL SERVICES

Relevant provisions for technical services relating to safety, such as services for personal dosimetry, environmental monitoring and calibration of equipment are set in regulations issued by CNCAN (e.g. Norms on individual dosimetry and Norms on the designation of notified bodies in nuclear field). Such services are subject to regulatory authorisation, in accordance with the relevant provisions of the Law (e.g. article 2 d), g) and h)).



The IRRS Team concluded that technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment are available, and are authorized by CNCAN.

## 2. GLOBAL NUCLEAR SAFETY REGIME

### 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Romania is a contracting party to all relevant international conventions that establish common obligations and mechanisms for ensuring protection and safety, such as, for example:

- Convention on Early Notification of a Nuclear Accident,
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency,
- Vienna Convention on Civil Liability for Nuclear Damage, as amended in 1997,
- Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention,
- Convention on Physical Protection of Nuclear Material as amended in 2005
- Convention on Nuclear Safety,
- Convention on Supplementary Compensation for Nuclear Damage,
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management,
- Treaty on Non-Proliferation of Nuclear Weapons,
- International Convention for the Suppression of Acts of Nuclear Terrorism.

Romania made political commitments to the Codes of Conduct that promote the adoption of good practices in the relevant facilities and activities, namely:

- Code of Conduct for the Safety and Security of the Radioactive Sources and supplementary Guidance; and
- Code of conduct on the safety of Research Reactors.

Romania is a member of the Western European Nuclear Regulators Association (WENRA) since 2003. CNCAN participates in WENRA to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety in applicant countries and to participate in a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues.

Romania is also member of European Nuclear Safety Regulators Group (ENSREG) which was established in 2007. CNCAN participates in ENSREG to support establishment of the conditions for continuous improvement and to reach a common understanding in the areas of nuclear safety and radioactive waste management.

Through commitments under international conventions and bilateral arrangements, CNCAN maintains relations with a number of nuclear regulatory authorities and organisations worldwide, including Greece (1992 and 1997), Hungary (1997), Bulgaria (1997), Russian Federation (2002), Slovakia (2002), Ukraine (2004), Turkey (2008); for other safety related issues: Korea (1997, prolonged in 2006), Hungary (1997), Germany (1998), Canada (1997/ 2003 / 2010), USA (2000/ 2005), Italy (2009), Argentina (2009), and Macedonia (2010).

To discharge the existing commitments to the Global Nuclear Safety Regime, 5% of the CNCAN annual budget is allocated to contributions to international conventions and organizations, and 3.5% to international travel. This has resulted in limited participation by staff in international activities.

CNCAN also takes an active part in the international peer reviews of the regulatory control and safety of facilities. It is important to note that CNCAN has received several peer review missions, including an International Regulatory Review Team (IRRT) mission in 2002 and an IRRS mission in 2006 (a follow-

up mission to the IRRT). However, the IRRT Team noted that the implementation of recommendations from these peer reviews has been limited to those of particular importance to enhancement of the regulatory regime in Romania due to limited resources available at CNCAN. As a result, many recommendations made by the IRRS Team in 2006 remain outstanding, hindering CNCAN efforts to harmonize its practices with those already implemented by international community.

The Law on the safe deployment, regulation, licensing and control of nuclear activities, republished on the 27th of June 2006, provides the legislative framework governing the safety of nuclear installations. The Law empowers CNCAN to issue mandatory regulations on nuclear safety, and clearly establishes an obligation to harmonize these regulations with IAEA safety standards. Specifically, Article 5(6) of the Law reads: “The Commission shall review the regulations whenever it is necessary for these to be consistent with international standards and with ratified international conventions...”. The IRRS Team noted that CNCAN extensively uses IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices.

The IRRS Team concluded, based on the review of documents and discussions with counterparts, that the Romanian government effectively fulfils its international obligations, participates in the relevant international arrangements, including international peer reviews, and promotes international cooperation to enhance safety globally. However, the ability of CNCAN to maintain and further enhance international cooperation seems to be restrained by budgetary and administrative restrictions.

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

As a part of bi-lateral agreements with regulatory bodies from other countries, CNCAN made several arrangements for the exchange of information relevant to nuclear safety, including:

- Participation in the annual meetings of the CANDU Senior Regulators Group,
- Participation as a member of WENRA technical working groups,
- Participation in the biannual meetings of the European High Level Group on Nuclear Safety and Waste Management (ENSREG) and its working groups,
- Participation as an observer in the annual session of the Nuclear Law Committee (NLC) of the NEA/OECD (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development), and
- Acceptance as an observer in the Committee of Nuclear Regulatory Activities (CNRA) and Committee on the Safety of Nuclear Installations (CSNI) of NEA/OECD.

Furthermore, CNCAN participates in the exchange of regulatory and operating experience through the IAEA International Reporting System (IRS) and through the EU Clearinghouse (European Union operating experience feedback which is closely linked to IRS). Recently, CNCAN reported to IRS on the development and implementation of the corrective action plan by the licensee in response to the event reported by US NRC (7950/13.11.2008). In this case, the licensee took the initiative to analyze the event, to identify the lessons to be learned and to develop a corrective action plan. The implementation of the corrective action plan was verified by CNCAN site inspectors.

The IRRS Team noted that there is no process owner and no group assigned to event investigations, including the analysis to be carried out to identify the lessons learned and the dissemination of this information to other relevant authorities. Reports received from international forums, or from the licensees, are circulated inside CNCAN for information only. There was only one example of a corrective action given, stemming from the CANDU Senior Regulators Group meeting, which was

requested by CNCAN and led to safety improvements at the Nuclear Power Plant in Cernavoda and enhancement in regulatory practices in response to information received.

The IRRS Team concluded that sharing of operating and regulatory experience with the international community is currently restricted due to decreasing human and financial resources provided to CNCAN. The Team believes that more intensive exchange of operating experiences could further enhance the nuclear safety in Romania, and could be beneficial in preparation for the construction of new power plants in Romania. A consideration should thus be given to the creation of a separate event investigation group within CNCAN responsible for an independent analysis of events, identification of lessons learned, development of corrective action plans, and dissemination of related information. Development of supporting processes and procedure should also be considered.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR-Part 1, Requirement 15 states that *“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”*

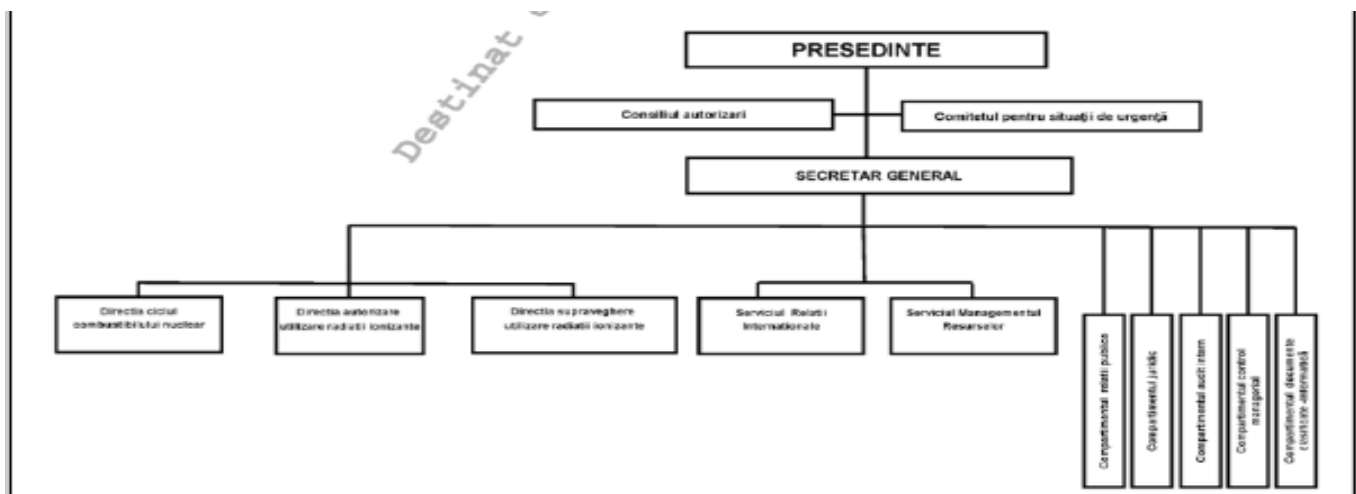
R8 **Recommendation:** CNCAN should make arrangements for independent analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community.

### 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

#### 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

CNCAN reports directly to the Prime Minister through the General Secretariat of the Government (State Counsellor). The President of CNCAN has the rank of State Secretary and is nominated by the Prime Minister.

During the period from 2008 to 2011, CNCAN was restructured four times. The current organizational structure of CNCAN is depicted in Figure 3. The President and the General Secretary are appointed by the Prime Minister. The General Secretary directs both Regulatory and Administrative Branches. The regulatory functions of CNCAN are effectively discharged by 3 divisions.



**Figure 3: Organizational Structure of CNCAN as of January 2011**

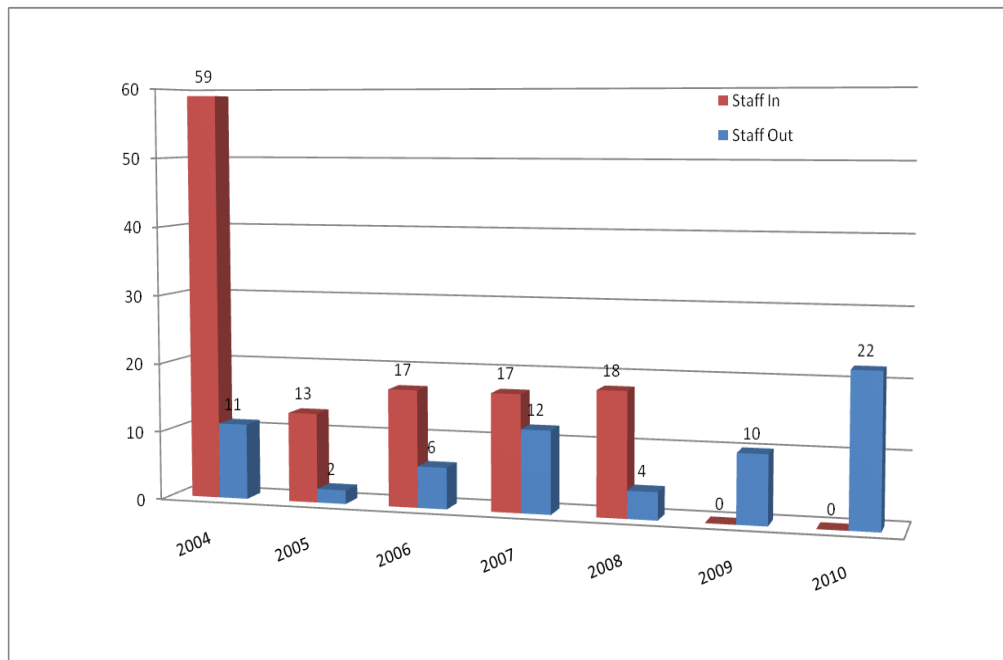
Table 1 provides details on changes in technical and administrative staff positions in CNCAN since 2008 that resulted from the recent reorganization of public organizations. The number in brackets indicates the actual staffing levels, excluding vacancies that couldn't be filled due to governmental restrictions of public spending. It is important to note that the number of technical positions was reduced from 117 to 75 over this time period. This represents a reduction of about 40%.

##	Year	Technical staff positions (occupied)	Administrative staff positions (occupied)	Total authorized personnel
1.	2008	117	54	171
2.	2009	95 (87)	42 (38)	137
3.	2011	77 (75)	26 (26)	103
From 2008, the total reduction of personnel is 40%, while technical personnel was reduced by 34%				

**Table 1: Changes in the complement of CNCAN technical staff since 2008**

In November 2009, the Parliament issued the Law 329/2009 for the reorganisation of some public authorities and institutions and for rationalisation of public spending. Furthermore, in the first quarter of 2010, a law providing for a single framework for the salaries in the civil service entered into force which led to a significant reduction of the salaries of CNCAN staff.

Through these reorganizations, the President of CNCAN attempted to preserve the technical expertise and the competence residing at CNCAN, and to maintain the staff’s focus on performing its functions in relation to safety, irrespective of difficult economic conditions. Despite the President’s efforts, the number of technical position was reduced. As shown in Figure 1, over the past years 32 employees have left CNCAN and no new employees were attracted to fill vacant positions.



**Figure 4: CNCAN Staff Retention Trend during 2004-2010**

In February 2010, the President of CNCAN submitted to the Government a detailed report describing the potential risk resulting from the reduction of CNCAN’s resources, including the risk to its ability to discharge its statutory obligations. As of January 2011, the Government had not provided a response to this report.

The IRRS Team noted that CNCAN has limited authority in structuring its organization and managing its available resources, as any changes to its structure and all management positions must be approved by the Government. As a result, CNCAN has no formal action plan for prioritization and optimization of activities to address the current staffing and budgetary constraints.

The IRRS Team noted also that, although human and financial resources of CNCAN may not be sufficient to effectively discharge its statutory obligations, there is an opportunity for a more efficient use of available resources. For example, in 2010, 1715 authorizations were issued. More than 7000 related submissions, in addition to 1098 exercise permits, were reviewed by the 75 technical staff members of CNCAN in 2010. In the same year CNCAN staff conducted 2029 inspections (an average of about 10 per day). CNCAN should use its resources in a manner that is commensurate with the radiation risks associated with facilities and activities. In particular, CNCAN should consider extending the length of the re-licensing period (currently two years), eliminating some low-risk authorization and qualification

approvals that have little benefit to nuclear safety, and assessing the possibility to exempt specific activities of low radiological risk from some or all aspects of regulatory control.

### Conclusion

The IRRS Team concluded that CNCAN has limited authority in structuring its organization and managing its available resources. As a result, some regulatory functions are not being effectively discharged, although an adequate level of safety is maintained. This situation, however, may impact the implementation of the national strategy for the nuclear sector.

The IRRS Team also concluded that there is an opportunity for a more efficient use of available resources by CNCAN that should be commensurate with the radiation risks associated with facilities and activities.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Requirement 16 states that *“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”*

R9 **Recommendation:** CNCAN should implement measures for managing available resources in a manner commensurate with the radiation risks associated with facilities and activities.

### 3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

CNCAN has limited authority in structuring its organization and managing its available resources, as any changes to its structure and all management positions must be approved by the Government. In Section 1.4, the Team concluded that the recent changes in the CNCAN organizational structure leading to reduction in the level of staffing and financial resources, may negatively impact the capability for regulatory decision making.

CNCAN exercises its authority to intervene in connection with any facilities or activities that present significant radiation risks, irrespective of the possible costs to the authorized party. For example, CNCAN several times delayed start of NPP units operation after outage for safety reasons, irrespective of the economic consequences of these decisions.

The IRRS team noted that CNCAN staff is competent, focused and very dedicated to performing all its functions in relation to safety. This gives the review team confidence that the technical assessments and inspections are carried out by CNCAN staff with no undue interference in their independent decisions. However, as reported in Section 1.3, the Government is not providing CNCAN with the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.

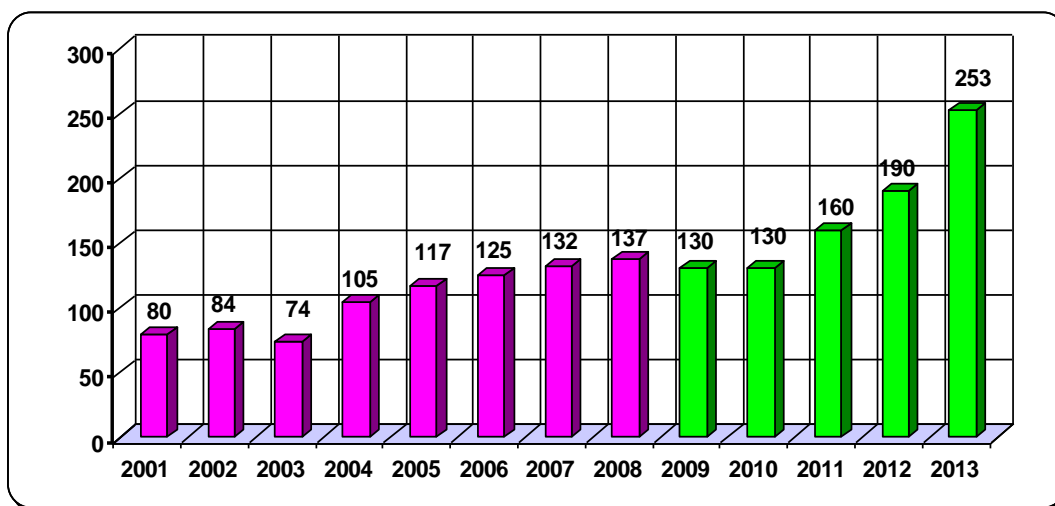
The IRRS Team concluded that CNCAN is performing its functions in a manner that does not compromise its effective independence in its decision making. To maintain this independence, it is important that the recent reorganization of CNCAN not adversely affect the current independence in the staff’s decision making.

### 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The responsibilities assigned to CNCAN in the Law, the number of regulated facilities and activities, the regulatory requirements placed on these facilities and activities, the safety documentation submitted for review, and the scope of the inspections to be performed have determined the resources needed to perform the work (including the competences required).

The IRRS Team, following the mission conducted in 2006, recommended that CNCAN should take all necessary steps to ensure that the vacant positions are filled by suitably qualified and experienced persons. The conditions of CNCAN staff should be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of the standards. The implementation of these recommendations has been delayed by the Government due to current economical restrictions.

In February 2010, CNCAN submitted a report on CNCAN Current Status and Perspectives to the Prime Minister and Ministry of Finance/Labour and to the General Secretariat of Government, proposing creation of a Centre of Excellence for Nuclear Safety and Security. CNCAN forecasted the need to employ 150 staff members (current level is 103) to maintain necessary competency for safety, given the current work demands, and an additional 100 staff members (for a total of 250) to implement the necessary regulatory framework for construction of Cernavoda units 3 and 4 (see Figure 3). The Government had not yet responded to this proposal.



**Figure 5: CNCAN Historical and Proposed Staffing Levels (from 2009)**

CNCAN uses a process to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. The necessary knowledge, skills and abilities are documented in the job descriptions for each job position. Training is provided either in-house or through technical cooperation programmes with other States or the IAEA. Efforts for implementing a knowledge management programme are on-going. To maintain an appropriate competence level, an annual plan for staff training is in place and each staff member has an individual training plan. The plan, however, is not implemented because there is no sufficient training funding provided to CNCAN. Instead, CNCAN has made some arrangements for staff training, using training courses and programs offered by other Member States or provided by international organizations. This training is provided predominantly with the economic support from outside of the country.

The IRRS Team noted that no adequate human resources plan can be implemented for CNCAN to achieve the desirable level of staffing and competencies under the current budgetary constraints. Without the Government implementing timely corrective actions such that the situation and challenges can be properly addressed, CNCAN may have difficulty meeting its statutory obligations.

The IRRS Team concluded that, although CNCAN is currently satisfying its legal requirements, due to



resources limitation and the lack of capacity to develop required competencies, CNCAN will continue to have difficulty properly meeting its statutory obligations.

#### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

CNCAN has no technical support organizations and no external advisory bodies. The Advisory Board on Licensing Matters is an internal board comprised of the heads of the technical divisions. External experts might be invited to give an opinion on specific matters, but they have no role in decision-making.

#### 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

CNCAN liaises with authorized parties to achieve common objectives in ensuring safety. The main liaison activities consist of:

- Regulatory inspections;
- Interaction during the documentation review and approval process;
- Licensing meetings;
- Examinations in view of issuance of practice permits;
- Investigations related to abnormal occurrences;
- Meetings for discussion of draft regulations;
- Development of Licensing Basis Documents and Licensing Programmes for new installations;
- Regular information meetings for discussing the progress of various programmes implemented by the licensees, etc.

#### **Conclusion**

Licensees at the facilities visited by IRRS Team members concluded that their interface with CNCAN provides full understanding and gives opportunity to discuss the arguments of each party on safety related issues. It was found that mutual understanding and respect on the part of authorized parties exists although relationships stay formal.

CNCAN decisions are justified as appropriate. The basis for the regulatory decisions is clearly identified, documented in CNCAN reports, in the authorisations issued and in the inspection reports. The basis for the decisions is explained.

#### 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The principles and criteria for review and assessment as well as for inspection and enforcement are based on the provisions of the Law and of the regulations used by CNCAN. Applicants and licensees are kept informed of these principles and criteria as well as of the format and content of the licensing submittals through regulatory letters and by means of licensing meetings (especially in the case of nuclear installations). In case there is a change proposed to the existing body of regulations, this is submitted for external consultation with the stakeholders. CNCAN justifies its decisions in internal reports and in the documentation provided to applicants/authorization holders.

The IRRS team reviewed procedures that ensure the stability and consistency of regulatory control and prevent subjectivity in decision-making by the individual staff members of the regulatory body.

Authorization decisions proposed by individual staff members of the regulatory body have to be independently reviewed by at least one other member of staff with expertise in that respective area and also by the managers of the technical divisions. This measure prevents to some extent subjectivity in decision-making by individual staff members of the regulatory body.

The IRRS Team noted that the regulatory process is not fully formalised in procedures. This issue was also highlighted by the IRRS mission conducted in 2006, which made a number of recommendations to formalise the regulatory processes. They can be summarized as follows:

- CNCAN should review and, as appropriate, revise or develop new procedures to review and assess applications for authorization (other than nuclear installations);
- CNCAN should establish a process for regulating, authorizing, inspecting all the different types of radioactive waste management activities and facilities, including decommissioning;
- CNCAN should complete its internal review and assessment procedures, concentrating on assessment of compliance with the technical requirements contained in relevant regulations;
- CNCAN should implement a procedure for a second review of submitted documentation in support of the request for authorization in combination with the findings of a pre-inspection before the authorisation is granted.

According to GSR Part 1, paragraph 4.34, the regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization.

The IRRS Team concluded that CNCAN does not have a comprehensive set of procedures for all elements of regulatory processes. Also although CNCAN does not provide applicants/licensees with the comprehensive set of guidance for the format and content of the documents to be submitted by the applicant in support of an application for an authorization, certain guidance is provided via regulatory dispositions. These procedures and guidance should address the requirements of the approved regulation on the given practice, indicating the main safety criteria to be taken into account in the review process.

Additional information is given in the Section 4 and 8.1.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- |     |   |
|-----|---|
| (1) | <b>BASIS:</b> GSR Part 1, Requirement 22, Paragraph 4.26 states that: <i>“The regulatory process shall be a formal process... and follows specified procedures...The process shall ensure the stability and consistency of regulatory control and shall ensure the stability and consistency of regulatory control...”</i>            |
| R10 | <b>Recommendation:</b> CNCAN should identify and, if necessary, issue and implement a comprehensive set of procedures for the regulatory processes and provide applicants/licensees with the comprehensive set of guidance for the format and content of the documents to be submitted by the applicant in support of an application. |

### 3.7. SAFETY RELATED RECORDS

CNCAN has established a system to keep a register of radiation sources. This system is maintained only on one of CNCAN’s Headquarters three sites. There are plans to expand the informational system for the nuclear safety divisions.

CNCAN further maintains a dose register (records of occupational doses) as a part of regulatory activities information system in the sphere of radiation sources management regulation. Summary reports on doses received by radiation workers are sent to the technical compartments of the Nuclear Fuel Cycle Division.

All review and assessment activities, as well as inspection activities, have to be documented in internal reports and inspection reports. Also all the basis for regulatory decisions are documented in internal reports, letters sent to licensees and in the licences / authorisations issued. All these documents are kept in accordance with internal procedures for archiving (based on general Romanian legislation on archiving,

not specific to nuclear). Records relating to the safety of facilities and activities, records of events, including non-routine releases of radioactive material to the environment are maintained in the paper form, which complicates exchange of regulatory information between divisions of CNCAN (these are not available on the intranet). From the other hand, joint data base with Cernavoda NPP of all safety related documentation is very useful instrument.

The authorized party maintains all the records necessary for the safe operation of facilities and the safe conduct of activities. This includes maintaining records that might be necessary for the shutdown and decommissioning (or closure) of facilities, and an inventory of radioactive sources and inventories of radioactive waste and of spent fuel, as well as records of occupational doses.

The archiving requirements appear to conform to the requirements of the regulations but the records are not easily retrievable. More details of this issue are provided under Section 4, Management System Resource Management section.

IRRS Team concluded that all the records required in paragraph 4.63 of GSR Part 1 are available to CNCAN, either in its own databases or, upon request, from the licensees, who are legally required to maintain such records. Under the archiving process the records are not easily retrievable.

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

In communication, good cooperation with the media is emphasized with the objective of reaching all citizens. The CNCAN website provides easy access to current information on CNCAN's field of activities, and to documentation on radiation and nuclear safety. The website is also used for collecting comments and suggestions (as part of a consultation process or otherwise).

Each year CNCAN produces and broadly disseminates its annual report about nuclear and radiation safety regulation in Romania. The report is disseminated in several formats. Especially attractive for the public format is a small brochure with a summary of regulatory activities and an enclosed CD with full text of the report. Also, it is mandatory that the annual reports be published in the Official Bulletin of Romania Part III. Due to lack of funds, the number of disseminated report copies was decreased from 400 to 100.

The IRRS team visited the Nuclear and Radioactive Waste Agency, AN&DR, and interviewed the President and Vice President regarding the regulatory relationship with CNCAN. AN&DR reported that it has good communications with CNCAN and a clear understanding of all regulatory requirements.

The IRRS Team concluded that CNCAN disseminates information and consults interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.

## **4. MANAGEMENT SYSTEM OF THE REGULATORY BODY**

### **Background**

The management system of CNCAN is currently being revised under the framework of the IAEA Extra Budgetary Programme, funded by CNCAN and NRPA (the regulatory body of Norway), with the objective of implementing the requirements set out in GS-R-3 “Safety Requirements – The Management System for Facilities and Activities”. The old management system was developed with the provisions of the ISO 9001:2000 standard as a basis. Therefore the majority of the procedures currently in place have been developed under the quality management system previously implemented by CNCAN.

On the basis of the GS-R-3 requirements a management system manual was developed and formally signed by the President and the six senior managers of CNCAN on 05 January 2011.

### **Management system**

The present management system is a Quality Assurance system consisting of 184 procedures and instructions. The documents are clearly indicated and the system contains a number of general procedures and instructions. Although these are referred to as procedures the majority of them are detailed working instructions describing routine activities, activities to be performed in the inspection of a specific system, for example in the Cernavoda NPP, or detailed work instructions for activities to be carried out during an emergency situation. If no detailed procedure is available for a certain inspection activity, for example in the research reactor or in another nuclear facility, the procedures for the NPP are taken as guidelines.

The Management System Manual describes in general terms the majority of the key elements of GS-R-3. Key processes, which are split up into Management Processes, Core Processes and Supporting Processes, of CNCAN are also identified. The requirements for the development and the implementation of the processes are also described. The five core processes are described in more detail while the six management processes are divided in 20 sub processes, which are not further described. No further detail is provided for the 10 identified support processes.

A gap analysis, by external experts, has only been performed between GS-R-3 and this Management Manual. In the introduction, of the external experts’ report, it is stated that the lower tier implementation processes and procedures were not included in the review and also, in the review comments, it is stated that the Management System Manual meets the requirements. The gap analysis does not indicate the status of the implementation of the manual and it could therefore be concluded that the majority of the key elements of GS-R-3 are satisfied. However a number of requirements of the Management Manual are yet to be implemented and the identified omissions are not yet incorporated in a controlled action plan. Neither has a responsible staff member for this activity been appointed.

In the framework of the Norwegian project an extended safety culture programme is being implemented for the regulatory oversight of licensees’ safety culture, in which the CNCAN management and technical staff participate. The safety culture is also clearly addressed in the management system manual and a draft guideline for regulatory oversight (MC-XX-xx) has been developed.

### **Management responsibility and process implementation**

Although two staff members are assigned with a number of tasks related with the presently available Quality Assurance system, no individual reporting directly to CNCAN senior management for the coordination of the development and the implementation of the management system, as it is described in the Management System Manual, is yet assigned. Also no process owners for the processes as specified in the Management System Manual have been appointed. Consequently no project plan is available, for example, for the development of the processes, the review of the present procedures and instructions, the gap analyses and the adaptation of the old procedures and instructions to the processes where needed.

CNCAN recognizes the short comings in this area and is committed to further work on its integrated management system.

### **Resource Management**

General resource management within CNCAN is subject to the Government's constraints in relation to its organisational structure and budget. (This has already been discussed in Sections 1 and 3).

In addition to the general implications of these resource constraints very limited resources are available to establish, implement, assess and continually approve the management system. Specifically there are no resources, as yet identified and assigned, to develop an Integrated Management System (IMS), which will deliver and implement CNCAN's intent to have an IMS that fulfils the requirements of GS-R-3.

Current arrangements for determining 'post profile' and related competences and subsequent individual training needs are structured around individual job descriptions and performance appraisals. Each Division is responsible for preparing an annual training plan. The training plan of 2010 for the Nuclear Fuel Cycle Division [4] showed the competences and skills to be acquired for the junior staff, staff with 1-3 years of experience and staff with more than 3 years of experience. The majority of the skills and competences are gained through on the job training and self-study. For some technical areas CNCAN make extensive use of IAEA Technical Co-operation Programme(s). Also an overview of courses is presented, but current resource and budget constraints limit their implementation. CNCAN recognise the shortcomings in the knowledge management, competence specification (post profile) and training areas and, supported by external support from experts contracted under the IAEA Extra Budgetary Programme funded by CNCAN and NRPA (the regulatory body of Norway), are actively working to bring these areas up to the standards required by GSR Part 1 Requirement 18 and the related requirements in GS-R-3.

### **Generic Management System Processes**

Procedure MC-PQ-06 defines the structure, content, numbering system to be applied for documents. But the numbering and the prescribed authorization date and prescribed number of pages are not always indicated on the index. All the documents are available on INTRANET of CNCAN.

The available management system documents are verified, approved and duly signed. They are also all endorsed by the President of CNCAN. Although procedure MC-PC-01 of 01.02.2002 requires that every head of an organizational prepares an annual plan for the drafting and revision of management system documentation, the last plan revision which could be shown to the team was nota 30452 of 03.05.2004 presenting 27 actions, including the responsible staff member and the planned completion date. None of the planned actions resulted in a formal revision of the indicated document(s) nor the preparation of a new document. More than 90% of the documents currently within CNCAN's management system are older than 5 years.

The documents that have been issued (produced or updated after review) in the last 5 years have followed the same review and approval route as the original ones adapted to the extant organisational structure in place at the time. However many existing documents have not been revised to reflect the many organisational changes that CNCAN has experienced, particularly in the last five years. Consequently the documents do not reflect the present organisational structure and corresponding responsibilities. Although it is not therefore possible to fully comply with the procedures and instructions as written none the less the technical content is still being used effectively particularly in various areas of licensing, assessment and inspection.

The archiving requirements are specified in procedure MC-PL-01, which is based on a governmental regulation "Nomenclatorul Arhivistic" of 07.12.2004. The procedure describes the layout of the archiving lists and the expiration time of the different documents. The archiving lists, which have been observed,

appear to conform to the requirements of the regulations. The documents are being archived in the cellar of the CNCAN head office. There is no uniform method applied to store the documents and neither is the specific storage location indicated on the archiving lists. Consequently the records are not easily retrievable. No fire detection equipment appears to have been installed in the cellar and the identification of more than 20% of the files are not clearly indicated or are subjected to degradation.

The organizational structure of CNCAN has been changed 4 times the last two years. A documented evaluation of the tasks and responsibilities, and the consequences of the changes and classification according to their importance to safety could not be presented to the team.

### Measurement, Assessment and Improvement

Within the current existing resource and budget constraints senior management and management at all levels undertake reviews and assessment to evaluate the performance of CNCAN against the goals and objectives of the organisation. This includes the preparation of and performance reports for the Government (undertaken at least on an annual basis).

However the current constraints mean that there is no current or systematic review or arrangements for:

- Monitoring and measuring the effectiveness of the management system and identifying opportunities for improvement
- Independent Assessment
- Management System Review
- Non-conformances and Corrective and Preventive Actions
- Improvement

### Conclusion

Although the CNCAN staff is highly motivated and professional, current resources and budget constraints are adversely affecting the amount of resource that can be applied to implementing the organisation's aspiration of having an IMS which fulfils the requirements of GS-R-3.

This review, (and CNCAN's self assessment), has revealed that there are significant elements and requirements of GS-R-3 which are not currently met.

Therefore the current management system in CNCAN cannot be considered to meet GS-R-1 Requirement 19: that "The regulatory body shall establish, implement, and assess to improve a management system that is aligned with its safety goals and contributes to their achievement."

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Requirement 19 states that "*The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.*"

R11 **Recommendation:** CNCAN should develop and implement an Integrated Management System satisfying the requirements set out in GS-R-3.

## 5. AUTHORIZATION

### 5.1. GENERAL

According to the Law three types of authorizations are granted by CNCAN:

- an authorization for “a facility or activity”;
- a “practise permit for personnel involved in authorized activities” and;
- a “quality assurance authorization of supply, designing, manufacture, construction-installation, repair and maintenance activities for products, services and systems classified as important for the safety of the nuclear facility”.

The general requirements applicable to the licensing process are set in the Law. More detailed requirements on licensing, for the different types of facilities and activities subject to regulatory control, are set in the specific regulations issued by CNCAN and are supplemented, as necessary, by means of regulatory letters sent to applicants and licensees. There are no specific regulations for licensing of radioactive waste facilities, though some requirements are established in Norms on Surface Repository of Radioactive Waste (2006).

Control of licensing submissions is described in the Quality 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. Formal record of the reasons for the regulatory decision is different for different practice. For example, for NPP it is done in initial reports, for radiological facilities it is done directly in the license. The depth of assessment is decided by the senior management by instructing reviewers on case by case basis.

The general process (the process is adjusted to each licence/permit type) followed upon receipt of an application for a licence includes:

- specification and/or clarification of the applicable regulatory requirements (if these are not already known to the applicant);
- review and assessment of documentation submitted to CNCAN;
- request for additional information, when necessary;
- performance of regulatory inspections to verify compliance with the legal and regulatory requirements (including the issuance of regulatory dispositions, as appropriate);
- integrated review of data from the safety documentation submitted by the applicant and of the findings of the regulatory inspections (including of the implementation of any corrective actions required);
- examinations (written and/or oral, plus simulators for nuclear operators) administer to each permit applicant;
- documentation of the basis for issuing the licence (or for refusing to grant a licence, if that is the case);
- issuance of the licence, stating the licensing basis and the limits and conditions to be observed by the licensee.

The licensing process encompasses the authorisation of certain activities of the licensee, and the issuance of permits for certain categories of licensee's staff, in accordance with the provision of the Law.

The licences 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 CNCAN shall be drawn up by levels of exigency, depending on the risks associated with the activities that are subject to licensing.

The licences/authorizations issued by CNCAN have a period of validity in the range of from 2 to 5 years. For activities which are limited in time by nature, the term of license validity depends on the activity as proposed by the applicant and assessed by CNCAN. For other types of facilities and activities, the validity is prescribed and is independent of the reviewer/inspector view. The licensing procedures for radiological facilities allows for operating of facilities for up to 2 months beyond the expiry of the license, provided that it has submitted an application for renewal in time. However there are a few cases, where this 2 month time limit was not respected.

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;
- 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.

The practice permits can be suspended or withdrawn for all cases of non-compliance with the provisions of the applicable regulations. In 2010 licensed were suspended 2 times and revoked 1 time [REF: SAT, the IAEA Self Assessment Tool, Country Information].

The Law provides (in article 18) the general conditions that an applicant shall meet for obtaining a licence, such as:

- to demonstrate the provision of adequate resources for carrying out the 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.

The main responsibilities of the licence holder are stated in Chapter III of the Law (articles 25 – 28) and are further detailed in the specific regulations issued by CNCAN and in the conditions attached to each licence.

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 same applies to the QMS established by the suppliers of products and services to be used in nuclear installations and classified as important for nuclear safety. All the above mentioned licensing conditions are further detailed and supplemented with specific requirements established through the set of regulations on QMS.

Pursuant to Article 18 of the Law, before being granted an authorization, the licensee has to demonstrate the financial arrangements and material means for the decommissioning of the installation after the stoppage of the authorized activity. The licensee has also to demonstrate payment of the prescribed contribution to ensure availability of financial sources for the management and final storage of radioactive waste and spent nuclear fuel and for the decommissioning of nuclear facilities. Article 27 of the Law stipulates that every licensee shall develop a programme for the preparation of the decommissioning and submit it for approval to CNCAN and shall demonstrate he paid the legal contribution to the fund for the management and final storage of radioactive waste and spent nuclear fuel and for the decommissioning of nuclear facilities. Also, Article 28 of the Law stipulates that, on termination of the activity or at decommissioning of nuclear or radiological facilities, as well as in case of transfer of radiological or nuclear installations or materials, the licensee shall be under the obligation to obtain first, under the terms provided by the law, an authorisation to hold, preserve, decommission or transfer them, as appropriate.

The IRRS Team has observed that the graded approach to the authorization process is not fully implemented. Specific examples include:

- For radiological facilities and activities, Article 39(1) of the licensing procedures [Reference: licensing procedure for sources] include a list of facilities and activities for which authorization in all stages is compulsory. This list includes high risk practices as well as practices of relatively lower risk such as diagnostic radiology.
- For nuclear installations, permits for Nuclear Installation Training Instructors are required in the regulations (i.e. the instructors to be licensed by CNCAN). In the past this regulation was not enforced because no applications were submitted by the licensee for the authorization of instructors. However, applications for this type of permit have now been received and are currently under review by CNCAN. CNCAN had accepted the status-quo for 5 years, because it was considered that sufficient assurance regarding the quality of the licensee's arrangements for training is obtained through the routine inspections on training as well as through the authorization of operating staff (control room operators and shift supervisors) and management staff (including

the training manager) and because the instructors are not considered as staff performing activities having a direct impact on the installation.

This, combined with the high number of authorization renewals has generated an administrative burden and workload of CNCAN staff in charge, in many cases that it is not commensurate with the radiological risk associated with the facility or activity being licensed.

### Conclusion

1. Authorization by the regulatory body, including specification of the conditions necessary for safety, is prerequisite for all those facilities and activities that are not either explicitly exempted.
2. The applicants are required and submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.
3. There are no specific regulations for licensing of radioactive waste facilities and this issue is addressed in details in the section 5.6.
4. The IRRS Team has observed that a significant number of authorizations and permits issued by CNCAN pursuant the requirements in the Law do not appear to apply a graded approach.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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|-----|---|
| (1) | <b>BASIS:</b> GSR Part 1, Requirement 4.33 states that “.... <i>The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach</i> ” |
| R12 | <b>Recommendation:</b> CNCAN should revise its system for authorization in accordance with a graded approach  |

### 5.2. NUCLEAR POWER PLANTS

The current licensing practice for Cernavoda NPP is based on the provisions of the Law and of the regulations issued by CNCAN. The licensing stages include design, siting, construction, commissioning, trial operation, operation, repair and/or maintenance (as major refurbishment), modification (as major upgrades), preservation and decommissioning.

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 (design manuals, operating manuals, etc.)

If the review concludes that all the requirements have been met by the applicant, a licence is issued by CNCAN, for a limited period of time (usually 2 years). 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.

For example, the content of a licence for operation includes:

- facility 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 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;
- status of emergency preparedness arrangements (to be described in quarterly reports).

For all nuclear facilities (including reactors, fuel fabrication, etc) CNCAN licences certain positions. For example, in nuclear installations, about 150 operating staff and management positions are licensed in all nuclear reactors (NPPs and RRs). The permit/authorization process requires the review of training programs, training records and administration of exams. Exams are administered by a board, formed by CNCAN management with the support of resident inspectors for NPPs. The procedures and conditions for issuing a practice permit for the personnel involved in the operation and management of the nuclear installations are established by the “Regulation on granting practice permits to operating, management and specific training personnel of Nuclear Power Plants, Research Reactors and other Nuclear Installations”. This regulation defines the conditions relating the issuance of the practise permit for operating personnel, management personnel and specific training instructors, who carry on any specific nuclear activities in a NPP, research reactor or in another nuclear installation.

The practice permits granted by CNCAN following the satisfactory performance of the candidates in all the subjects/tests of the examination, are valid for a definite period of time, as stated in the regulation (e.g. in case of operators, 2 years since the first licensing and 3 years after renewal), provided that the licensed person has continuity in the same activity and a good performance on the respective job.

Graded approach has not been formalised, but resources are allocated function of the work required in any particular area. For example, the safety documentation to be reviewed in the regulation of the nuclear power plant is obviously far more complex that the safety documentation reviewed for a radiological installation used for medical purposes. Generally, the allocation of resources is influenced by the safety reviews and inspections to be performed, which depend on the safety cases produced by the licensee for every facility and activity, these being commensurate with the risks associated.

The licences/authorizations issued by CNCAN have a period of validity of 2 to 5 years, but the bases for this validity are not established in the regulation. Also guidelines issued by CNCAN or CNCAN internal procedures don't have instructions how to determine the period of validity of licence. The determination of the period is part of licensing process and depends on the performance of facility, safety important programs and processes and other important issues connected to the nuclear safety and raised during licensing process.

### 5.3. RESEARCH REACTORS

The TRIGA reactor was recently modernized. Its operating license expired in 2009, as well as its design lifetime of 30 years. The licensee decided to prolong its operating lifetime. They performed the analyses for remaining design lifetime in the request for licence for trial operation after modernization. The licensing review process is on-going.

The licensing process and the licensing stages for research reactors are similar to the one implemented for nuclear power plants.

The re-licensing support documents for research reactors shall address mainly the following aspects:

- Description of the operating activities from the previous licensing period
- Status of compliance with Operating Limits and Conditions (OLCs)
- Significant events during operation
- Installations modifications and Operating Procedures modifications
- Organizational changes and personnel responsibilities
- Radiation exposure personnel from nuclear unit
- Radioactive waste management
- Maintenance and repair activities performed at reactor installations
- Assessment of testing and inspection program results
- Report on the fulfilment of CNCAN dispositions following CNCAN inspections
- Technical assessment of quality assurance

The new regulations set general principles on the siting, design and construction of nuclear power plants. In the new regulations are also requirements regarding format and content of safety analysis report. Format and content of safety analysis reports for research reactors have been specified in a regulation (Nuclear Safety Republican Norms - Nuclear Reactors and Nuclear Power Plants (1975)) applicable to both research reactors and nuclear power plants (general requirements) and have been detailed in regulatory letters in the licensing process.

#### 5.4. FUEL CYCLE FACILITIES

The licensing process for fuel cycle facilities is based on the provisions of the regulation “Radiological Safety Norms – Authorization Procedures for Uranium and Thorium Mining and Milling”, which establishes:

- the basic objectives, concepts and principles of the authorization procedures for Fuel Cycle Facilities
- the activities requiring authorization (geological prospecting, exploration and mining exploitation, milling of the uranium and thorium ore, activities similar to those that are carried out for other ores associated with uranium and thorium in contents that exceed excepting authorizing limits, processing of uranium concentrates, CANDU fuel fabrication, preservation and decommissioning Fuel Cycle Facilities);
- the phases of Fuel Cycle Facilities requiring authorization (design, siting, construction, commissioning, operation, conservation, decommissioning);
- the detailed content and format of authorization documentation for each phase;
- the responsibilities of involved parties in the process (applicant and regulatory authority); and
- the conditions, the limits and technical documentation needed in an authorization process.

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- the detailed content and format of authorization documentation for each phase;
- the responsibilities of involved parties in the process (applicant and regulatory authority); and
- the conditions, the limits and technical documentation needed in an authorization process.

The requirement that the SAR forms the basis for establishing the OLCs for the fuel cycle facility is not explicitly stated in the current regulations. Nevertheless each facility has established their applicable OLCs according to IAEA requirements.

The requirement that the SAR cite the technical literature in the form of references that may be necessary for a thorough review and assessment process is not explicitly stated in the current regulations. However the licensing documentation includes adequate references to supporting documents during the authorization process.

## 5.5. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

### **Findings**

Requirements for authorization of radiological facilities and activities are included in the Law, in the licensing procedures and in the specific regulations. The IRRS team observed that the provisions for authorization in the hierarchy set of regulations are not fully consistent. For example, bullet item 5 of article 26 of the specific regulations on radiation safety in diagnostic and interventional radiology includes a provision that decommissioning is not required for diagnostic radiology.

The IRRS team observed also that some phases of the authorization specified in article 8 (bullet item 8) of the Law have not been issued at all, e.g. conservation authorization, and that there is no provision in any of the documents presented to the IRRS team which makes this legally possible.

The licensing procedures set up the authorization process for the different types of authorizations. These procedures were issued in 2001, and have not been reviewed after the law revision in 2006.

Article 7 of the licensing procedure states that the authorization system includes registration. According to article 11, registration is applicable to the use of certain types of sources as listed there. However, the IRRS team observed that in certain cases CNCAN accepts application for authorization in activities, for which only registration is required. For example, it was found that 44 authorizations were issued in 2010 for facilities having only intraoral radiation generators, and consequently should have registration only.

Article 55 of the licensing procedures establishes a time limit of two months for CNCAN to decide on the application for authorization, provided that the applicant has submitted all necessary documents. Internally, the head of the licensing division prescribes time limits for each step in the process of review and assessment. Formal checklists are used for reviewing the applications for licenses.

Authorization validity is specified in article 74 to 77 of the licensing procedure. However, these articles specify the maximum duration of the license, and this is interpreted by CNCAN as the authorization validity.

According to article 82 of the licensing procedures, facilities can continue their activities for up-to 2 months after authorization expiry, provided that they have submitted the application for renewal in advance in accordance with the prescribed time limit of 45 days. However, it was observed in a field inspection that CNCAN allows for longer period of operation beyond the 2 months limit. The IRRS team was informed that there is a few cases like this.

Bullet item (1) of article 87 of the licensing procedures specifies the cases in which a licensee should apply for modification of the authorization. In particular, changes in the limits or conditions of the

authorization should trigger the authorization modification. The IRRS team observed however, that CNCAN includes too many details in the authorization limits and conditions, changes in which do not trigger authorization modifications (For example, limits and conditions include serial numbers of each component of diagnostic X-ray generators including the table; and serial number of each electronic personal dosimeter).

In the following sub-sections, observations on specific types of authorizations are presented.

### **Radiation Safety Approval (ASR)**

Before issuing an authorization to any facility or activity involving radiation sources and equipment, a radiological safety authorization (ASR) for the type of that source or equipment has to be obtained.

The ASR for a certain type of equipment is required from each supplier or importer of equipment of that type. Consequently, it is likely that multiple ASRs are issued for the same type of equipment. In fact the IRRS team noticed that 6 types of equipments received multiple ASRs, and in one case there were 7 ASRs for the same type of equipment.

For equipment originating from EU countries, ASR is not mandatory. However, in this case suppliers of such equipment have to notify CNCAN on the technical details and confirmation of compliance with EU standards for each piece of equipment they supply, which is an administrative burden that makes some of the suppliers preferring to apply for an ASR. In fact, CNCAN has issued 95 ASR for equipment originating from EU countries, and 84 for equipment from non EU-countries.

### **Siting and Construction Authorization**

Siting and construction authorizations can be combined. Article 39 of the licensing procedures specifies cases where this is possible. However, the IRRS team observed that, in practice, the combination of siting and construction authorizations is not fully in accordance with these provisions. For example, siting and construction authorizations for diagnostic radiology are combined into one authorization, which is not fully in line with the licensing procedures.

Verification of construction is done in the context of the next stage of authorization.

Construction authorization allows installation of equipment or source in the constructed building according to item (1) (b) of article 37 of the licensing procedures (see also Commissioning below).

### **Commissioning Authorization**

The commissioning authorization was first requested in 2004 and included in the 2006 revision of law (article 8, para 8).

Commissioning is also addressed in specific regulations. For example, the specific regulations on radiotherapy require commissioning authorization. The scope of commissioning in this case covers mainly tests to medical aspects on newly installed teletherapy equipment. In 2010, two commissioning authorizations were issued in 2010.

Specific regulations on diagnostic radiology, nuclear medicine and non-destructive testing do not refer to commissioning. It's not clear how CNCAN implement the commissioning provision in the law for those practices, for which no specific regulations exist, such as irradiators.

Prior to issuing the commissioning authorization, an initial inspection is required. This is the first interface between authorization and inspection in the regulatory control during the life time of radiological facilities or activities.

## **Leasing Authorization**

According to article 2(c) and article 8 of the law, a leasing authorization can be issued by CNCAN. The authorization holder is in this case the financial institution providing the funds in the leasing contract, which will be in the same time the owner of the source or equipment

In addition to the leasing contract, and simultaneously with it, a possession authorization is issued to the financial institution.

In 2010, 168 leasing licenses were issued to 144 agents, involving 478 X-ray generators. Although no applications for authorization for leasing of radioactive sources have been submitted so far, it would be possible according to the existing framework.

In the view of the IRRS team, this practice raises concern about assignment of responsibility for safety in some phases during the duration of the leasing, in particular in the period between issuing the possession authorization and the actual transfer of the source to the user, and in cases where the user fails to fulfill the conditions of the leasing contract.

## **Import and export authorizations**

For radioactive sources, import authorization is only issued if the end-user is specified and if he has an authorization enabling him to receive the source. For the import of X-ray generators, this is not necessary, but if the end-user is not specified, then the importer has to have a possession authorization. CNCAN import authorization is a condition for the customs clearance.

Importers have to notify CNCAN within 48 hours after the actual import. However, in cases that the import authorization expires without receiving a notification from the importer, CNCAN does not systematically investigate whether the import has taken place or not. Data cross-checking with the information received from the end-users, or with the annual reports sent by the suppliers, are not consistently applied.

Although MoU with the National Customs Administration exist (2005), it seems that no arrangements are in place to receive notification from the customs on import or export of radiation sources. The IRRS team was informed that arrangements have been made to provide CNCAN access to the customs online system, through which CNCAN will be able in the near future to follow up import and export of sources.

Romania has supported the Guidance on Import and Export of Radioactive Sources (GIERS) in 2006, and it nominated points of contact in this regard.

GIERS provisions regarding the import of category 1 or 2 sealed sources seem to be implemented by CNCAN within the general framework of conducting regulatory activities. However, there seem to be no arrangements to implement GIERS provision related to the export of category 1 and 2 sources.

## **Conclusion**

Provisions for authorization are not entirely consistent in the hierarchy of regulations. Related recommendation is in section 9.1

In certain cases regarding ASR, registration and authorization, CNCAN does not strictly follow the related provisions in the licensing procedures

In certain cases, CNCAN permits operation of facilities after authorization expiry beyond the time limit prescribed in the licensing procedures.

CNCAN approach to setting limits and conditions in the authorization is too detailed, making it not always feasible to modify the authorization upon changes in these limits and conditions. Consequently,

CNCAN does not adhere to the legal provisions in case of such modification in these limits and conditions.

CNCAN does not have procedures in place to ensure that import and export of category 1 and 2 sources are in accordance with the Guidance on the Import and Export of Radioactive Sources.

Cross-checking of data received from different information sources is not consistently applied.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<b>BASIS:</b> GSR Part 1, Paragraph 4.26 states that: <i>“The regulatory process shall be a formal process that follows specified procedures as established in the management system...”</i>
R13	<b>Recommendation:</b> CNCAN should ensure that its implementation of authorization processes of <u>radiological facilities and activities</u> is consistently in accordance with the provision of the law, regulations and procedures.
(1)	<b>BASIS:</b> <i>Romania’s commitment to implement the Code of Conduct on the Safety and Security of Radioactive Sources, signed in 2004, and to the on the Import and Export of Radioactive Sources, signed in 2006.</i>
R14	<b>Recommendation:</b> CNCAN should establish procedures for the import and export of radioactive sources in accordance with the provisions of the Guidance on the Import and Export of Radioactive Sources
(1)	<b>BASIS:</b> GSR Part 1, Requirement 25 states that: <i>“The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization...”</i>
S2	<b>Suggestion:</b> CNCAN should consider establishing mechanisms for assessing all relevant information received from different sources to ensure its consistency.

## 5.6. WASTE FACILITIES

### Findings

CNCAN as a regulatory body is empowered with the regulatory authorization and control of nuclear facilities. General conditions for authorization are provided in the Law and its amendments, Chapter II, Section 2, Article 18 - “Authorization conditions”. Taking into account that each authorization is issued for one specific purpose and site, the content of the license issued by CNCAN is adapted for each type of nuclear installation in order to specify clearly the authorization conditions. Every license is limited to a fixed number of years. According to the Law, for a new license an inspection is required. CNCAN issues license for deployment of the nuclear activities in different stages of a nuclear installation in a multi-stage authorization process.

CNCAN has issued The Norms (NDR-02) on Clearance from Regulatory Control of the Materials Resulted from Authorized Practices, by Order of CNCAN President No. 62/2004. According to the norms, the unconditional clearance levels are those levels provided for exclusion in the Fundamental Norms for Radiological Safety issued in 2000. Higher levels can be accepted for unconditional clearance



if the amount of ingestion and inhalation is limited due to the low quantity of contaminated material and/or its physical and chemical form. Conditional clearance can be granted on a case by case basis.

The NDR-02 does not apply to uranium and thorium mining and milling, where the specific regulation (NMR-03) establishes the clearance levels for those materials. The regulation in force does not stipulate if recycling of materials is allowed.

The report of the 2006 IRRS Mission stated that there is a need for a clear procedure on how to proceed with clearance, discharge and its control and record keeping. So far no practical guidelines have been issued.

Legal provisions for dealing with past practices, abandoned sites, or facilities still remain partially unsolved since the 2002 IRRS mission. The joint order 89/2010 for the monitoring of scrap metal was issued by CNCAN, the Ministry of Interior and Administration and the National Agency of Customs. This order details the general regulations only for management of orphan sources found in scrap metal. Regulations for abandoned sites and installations have not been developed.

Order 56/2004 demands radioactive waste to be processed based on the appropriate consideration of its characteristics and the demands of the different steps of waste managing. So far general licenses have been granted but no decisions as a result of a national strategy have been taken. According to the results of the interviews, CNCAN has no personal capacity for the granting of new licenses according to a national strategy.

Regulations for decommissioning of research reactors do not include all necessary safety criteria, and regulations for the decommissioning of NPPs have not been issued. So far no safety requirements regarding decommissioning are implemented. As a result of a WENRA mission these safety requirements are to be implemented in 2013.

Interdependencies along all steps of predisposal management are legally taken into account however they are not practically implemented. This results from a lack of practical guidance and resources.

No guidelines exist to prevent the degradation of existing waste packages. For new waste packages the necessary type approvals include these requirements. This is not required according to the Romanian legislation. It is implemented by the regulatory authority on a case by case basis applying the safety standards of the IAEA and the EU.

Radioactive waste is generally classified according to the requirements of the IAEA which were implemented into a national regulation by Order 156/2005 on the classification of radioactive waste. To cover possible needs for predisposal, radioactive waste is classified differently by producers and/or by the predisposal operator. Even if it is the legal basis, at the major producer, Cernavoda NPP, the general classification is not implemented yet. In order to report to the IAEA Net Enabled Waste Management Database (NEWMDB) a generic matrix is used but it seems to be not very accurate.

According to the Law, the licensee shall keep and maintain the records of radioactive waste produced by its own activity. There is no any obligation of licensees to report the inventory to the regulatory authority. According to the Ordinance 11/2003 the AN&DR (former ANDRAD) is responsible to develop and maintain the national data base for radioactive waste and spent nuclear fuel. In order to report the national inventory to IAEA NEWMDB, CNCAN, based on disposition letters, requested to licensees to report their inventory. Even if there is the legal basis for licensees to report their inventory to AN&DR, this seems to be difficult to be enforced without an agreement with CNCAN which has the power to enforce the law.

No requirements exist for the authorization and review of predisposal facilities. The published guidelines for small producers (CNCAN Order No 366, 22 Sept. 2001) are used for all facilities. Requirements used

by the regulatory body also are taken from IAEA Safety Standards. There is no published document explaining this procedure. Applicants prepare and CNCAN reviews the application according to the experience of the involved experts. It is planned to implement legislation for predisposal in 2012.

In order to fill the gap of the regulatory framework, CNCAN, on case by case basis, issues the specific requirements which are enforced by a regulatory letter. This is the case of content and format of safety assessment on predisposal facilities requested by the AN&DR, or content and format of the decommissioning plan requested by Cernavoda NPP.

The requirements for the authorization of near surface disposal facilities are laid down in Order 400/2005, published in official journal, part I no. 345 from 17/04/2006. According to Article 9, licenses need to be given for different activities:

- Siting
- Construction
- Operation
- Closure
- Active institutional control

There is a given timeframe established for response by the regulatory body to any request of the licensee or of any applicant. After all necessary documents have been received the licensing decision for a repository has to be taken within 6 month, 2 month for decommissioning of facilities and one month for other activities (Order 400/2005, Article 5-10, Annex 1.).

There is no explicit concept of a safety case, however the set of documents and safety assessments that have to be presented according to order 400/2005 by the applicant may be equivalent to a safety case.

The post closure phase is not addressed in detail in the license. The protection of barriers in repositories is not required for the post closure phase.

No requirements exist for geological disposal.

No training program for the staff is implemented though it is planned to do so.

Several recommendations and suggestions from the 2006 IRRS mission are not completely implemented.

These recommendations covered the following points:

- CNCAN should develop guidelines and practices for clearance
- CNCAN should develop legal provisions dealing with past practices
- CNCAN should develop requirements on the qualification and experience of personnel
- CNCAN should develop Guidance on the application of exclusion levels
- CNCAN should review existing regulations for decommissioning in order to include safety assessment for decommissioning
- CNCAN should consider relevant IAEA safety standards for predisposal and disposal

## **Conclusion**

The national strategy does not reflect the existing situation and future prospective of Romania.

Legal provision for dealing with past practices, abandoned sites or facilities still remain partially unsolved since the IRRRT 2002. Regulations for abandoned sites and installations have not been developed.

No regulations exist for the authorization of predisposal facilities. The application process relies on the experience of the involved experts and the application of regulations from different fields and IAEA-Safety-Standards. Though geological disposal is planned there are no regulations for geological disposal. Regulations for decommissioning of research reactors and partly for the decommissioning of NPPs are not implemented. The protection of barriers of repositories is not required for the post closure phase.

The time limit is 30 days for granting the license or sending a written official reply. After all necessary documents have been received for a disposal facility the licensing decision has to be taken within 6 month. The 6 month time limit is too short a time period to assess the calculations presented in a safety case for a disposal facility.

At the major waste producer, Cernavoda NPP, the general classification is not implemented yet. In order to report to IAEA NEWMDB a generic matrix is used but it seems to be not very accurate.

No clearance levels for uranium and thorium in mining and milling exist. The regulation in force does not stipulate if recycling of materials is allowed. There is no clear procedure on how to proceed with clearance, discharge and its control and record keeping.

Interdependencies along all steps of predisposal management are not taken into account. This results from a lack of practical guidance and resources. No training program for the staff is implemented

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1, Requirement 2 states: <i>“The government shall develop and maintain an appropriate governmental, legal and regulatory framework for safety.”</i>
R15	<b><u>Recommendation:</u></b> CNCAN should establish and implement authorization processes and procedures for all radioactive waste management and decommissioning activities.
(1)	<b>BASIS:</b> WS-R-1, Requirement 12.5 states that <i>“Special attention should be given to changes in the barrier design.”</i>
R16	<b><u>Recommendation:</u></b> The regulator should change the requirements in a way that attention should be given to changes in the barrier design.
(1)	<b>BASIS:</b> GSR part 1, Requirement 32 states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based.”</i>
R17	<b><u>Recommendation:</u></b> CNCAN should develop regulations for dealing with legacy waste, abandoned radioactive material, source, sites or facilities.
(1)	<b>BASIS:</b> GSR Part 1, Requirement 4.38 states <i>“The safety assessment may need to be repeated or reaffirmed by the regulatory body in support of its decision.”</i>
S3	<b><u>Suggestion:</u></b> The regulatory authority should consider to eliminate or extend the time limit of 6 month for the licensing of disposal facilities.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 5, Requirement 9 states: *“Radioactive waste shall be characterized classified in accordance with requirements established or approved by the regulatory body.”*
- S4 **Suggestion:** The regulatory body should consider taking steps to adjust the waste classification at Cernavoda NPP to be in line with the national waste classification system.

## 6. REVIEW AND ASSESSMENT

### 6.1. GENERAL

In accordance with provisions of the Law, CNCAN is empowered to request from the licensees, or from the applicants for a license, 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, license conditions, regulatory letters, and inspection reports. Additional support documentation is requested on a case by case basis and specified in regulatory letters, minutes of meetings between CNCAN staff and licensee's representatives, etc.

The responsibilities for the review and assessment of the technical documentation submitted by the licensees or applicants are assigned to the various technical divisions within CNCAN.

Each of the technical divisions and organisational units having roles in the review and assessment process is responsible for the development and implementation of specific procedures suitable to their particular area of activity.

The regulatory review activities are planned, performed and reported as per internal procedures and instructions in order to assure the availability of internal resources and, as appropriate, external resources and to establish efficient interfaces with the licensees.

For major reviews, such as those performed by CNCAN prior to granting a license, or periodic safety reviews, or an approval for a licensing milestone in the case of nuclear installations, interdisciplinary teams are established. These teams include experienced staff from the technical divisions and units involved in the licensing of nuclear installations, to ensure the necessary expertise is applied to all the areas of review. Most of the experts responsible for the assessment of the safety related documentation also participate in the teams that perform the inspections. The assessments and inspections performed as part of the major reviews mentioned above are supplementary to the assessment and inspection activities deployed by each division on a regular basis. In some specific cases, assistance from external specialists is required to supplement the assessment needs of CNCAN.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1, Paragraph 4.4 states that <i>“Requirement 3 establishes that the government shall be responsible for ensuring that the regulatory body has sufficient resources to fulfil its statutory obligations.”</i>
R18	<b>Recommendation:</b> CNCAN should include in its request to the government that adequate financial resources are allocated and provided in CNCAN's budget in order to allow acquiring sufficient resources and necessary analytical tools supporting nuclear safety assessment and emergency preparedness, as well as for securing sufficient numbers of staff specialized in safety assessment
(1)	<b>BASIS:</b> GSR Part 1, Requirement 26 states that <i>“Review and assessment of a facility shall be commensurate in accordance with a graded approach”</i>
R19	<b>Recommendation:</b> The regulatory body should formalize the graded approach for review and assessment

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 4, Requirement 21 states that <i>“The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body.”</i>
R20	<b>Recommendation:</b> CNCAN should establish requirements for the operating organizations to carry out an independent verification of safety assessments, in accordance with the graded approach before it is used by the operating organization or submitted to the regulatory body.
(1)	<b>BASIS:</b> GSR Part 1, Paragraph 4.41 states that <i>“Technical and other documents submitted by the applicant shall be reviewed and assessed by the regulatory body to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety.”</i>
S5	<b>Suggestion:</b> CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment for all nuclear facilities.

### 6.2. NUCLEAR POWER PLANTS AND RESEARCH REACTORS

#### Findings

Legal provisions governing the review and assessment process are established in the set of regulations for the design (CANDU type) of NPPs, CNCAN regulations on quality management system and other regulations. They contain provisions related to the nuclear safety, design, periodic safety review, quality assurance and safety of operation, maintenance, in-service inspections, testing, modifications, etc. There are also other regulations containing requirements for specific areas of review and assessment (e.g., fire protection, radiation protection, etc.). The regulations are updated whenever needed to adhere to recent developments in Romania in requirements for nuclear safety and radiation protection in the European Union (EU) and IAEA.

The principles and criteria used in the review and assessment of NPPs and research reactors are mainly those set in the Law and regulations, supplemented, as necessary, with principles and criteria derived from other documents (i.e., IAEA Safety Standards, regulations of other countries, accepted codes and standards, etc.), of which the licensees are informed through formal regulatory letters. If the safety principles and criteria are stated in or based on a regulation, feedback is obtained first in the consultation process prior to the formal issuance of the regulation, then from experience with the application. If the review principles and criteria are solely based on other documents (i.e. IAEA Safety Standards, regulatory requirements from other countries, etc.), CNCAN informs the licensees/ applicants of its intention to use these in the review and the applicability and suitability of the principles and criteria are discussed and agreed, together with the details on the safety documentation that needs to be submitted to demonstrate compliance.

Romanian regulation (NMC-10, article 165) requires a periodic safety review (PSR) to be conducted for NPPs every ten years, without explicitly mentioning its role in the licensing process. The regulation is based on the IAEA Safety Guide NS-G-2.10, having the 14 “safety factors” defined as “areas of review”, for each of these having specified most of the “generic review elements” given in the Appendix to the IAEA guide. In 2007, CNCAN has approved the scope and programme of the PSR for Cernavoda NPP Unit 1, together with the Quality Assurance plan. The second phase that represents the main activity of the PSR, covering the preparation of the Discipline-Based Reports and Topic Reports, is in progress. The outcome will be a PSR Main Report outlining the current plant safety status, that it is expected to be

submitted to CNCAN in 2011. However, there is no regulatory requirement for periodic safety reviews of research reactors as required by the Code of Conduct on the Safety of Research Reactors, item 20(c).

CNCAN prepares a program for the review and assessment of the facilities, activities and practices related to the safety. The program is tied with inspection program and both are dependent on the licensing. The program for the review and assessment is communicated and agreed with facility and consequently implemented.

A set of internal procedures establishing the administrative rules for conducting review and assessment activities is issued and they are included in the CNCAN quality management system manual. The internal regulatory review and assessment procedures cover construction, commissioning and operation stages of NPP lifetime. The siting and design are not covered. The owners of internal procedures currently are not identified, and many internal procedures have not been revised since 2002.

Guidance concentrated on technical details of the review and assessment exists only for some areas, e.g. for the fire hazard analysis, periodic safety review, probabilistic safety analysis or new developed guide for the safety culture. Complementing existing procedures with a guidance to ensure the technical quality of the review and assessment, will allow CNCAN further increase its effectiveness. This finding was also identified in IRRS mission conducted in 2006 (R14) but has not been fully resolved.

CNCAN developed a guideline for regulatory oversight of safety culture in licensees' organizations. The guideline aims at establishing a structured process for the identification collection and review of data relevant to the safety culture. This guideline is intending to be used in a flexible manner, as an aid for the CNCAN inspectors. The proactive approach it is considered when practices, processes, procedures and other aspects are observed and evaluated with the aim of identifying areas for improvement. This type of assessment finalizes with recommendations and in particular cases with dispositions. These kinds of assessment are usually convenient for the facilities because they are independent assessments even if they come from regulatory authorities. This will improve nuclear safety by observing weak areas and processes and by recommending improvements.

The scope of technical expertise covered by the staff in CNCAN Nuclear Fuel Cycle Division, as well as in other divisions involved in review and assessment of nuclear power plants is broad and covers both deterministic and probabilistic analyses, normal and fault conditions for all operational states and regimes. It was generally sufficient for ensuring that all major areas of review and assessment are properly covered. However, lately, due to restrictions in resources, CNCAN has limited the review to the methodologies, verification of hypotheses used by NPP during analyses, verification of computer code model assumptions, verification of validity of input and output data against the design specifics, and conservative hand calculations. CNCAN does not systematically perform its own computer aided safety analyses, due to the lack of specialized personnel and computer codes. Insufficient financial resources do not allow to contract external organizations to support review and assessment activities. These findings were also identified in IRRS mission conducted in 2006 (R15 and R16) but have not been fully resolved. Even with resources available, there are limited possibilities to find independent expertise in Romania (the expertise available with research and design institutes is used by the licensees). CNCAN uses external consultants in limited extent to assist CNCAN staff in licensing activities of NPP and research reactors. Use of external consultants covers a small part of CNCAN activities. Hiring and training of new staff and purchasing up-to-date analytical tools are needed (estimation for achieving good level for review of safety analyses is minimum 3 years). In addition to training of new staff and purchasing up-to-date analytical tools, present practice with the utilization of IAEA, EU and other foreign projects should continue. Co-operation and information exchange with experts in the country of origin or with other regulatory bodies in countries operating CANDU reactors should be supported. Resources for contracting

domestic or foreign organizations should also be increased. The review and assessment process of NPPs in CNCAN is well managed and recorded in CNCAN internal documents.

The internal review and assessment procedures mostly deal with the organization and process of the review, flow of the information, completeness of required components of the analysis, and control of steps to be performed. A system of check-lists to record the activity performed and made the review and assessment process more transparent and traceable is not fully applied. A system for categorization of regulatory findings arising from the review and assessment is neither fully formalized nor implemented.

CNCAN requires and verifies that the technical solutions used in a nuclear power plant, in particular any novel features, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety. The verification requirements are identified in the engineering quality plans implemented during manufacturing, construction, commissioning and operation stages. These plans identify the design activities to be verified, the extent of verification, persons involved in verification, methods and position in the design cycle, etc. All the above requirements are covered by specific verification procedures. Any improvements to an existing design or redesign of the systems or components are subject to the same verification as the original design in order to confirm that all the existing analyses are valid and the design is correct. The design activities can be performed only by organizations recognized or licensed by CNCAN. When the design activities are contracted to other design organizations, the contractors shall be licensed or agreed by CNCAN, or it shall be ensured by other means that the design work is verified in the same manner as mentioned above. The Design Authority for the plant has the responsibility to check that the contractors have performed such design verifications and that the particular designers have used correctly the design inputs.

The process of review and assessment of operational events occurring at nuclear facilities is well established. Requirements on reporting of operational events are fixed in the operational license of the NPP. There is a NPP procedure for reporting of events, which is in compliance with the approved by CNCAN quality management system manual. 34 categories of events are specified for reporting. Over the few years, there were about 30 events reported per year, but currently 1-2 events per year is being reported by CNCAN to IAEA Incident reporting system (IRS). No INES 2 event has occurred in Cernavoda NPP. The NPP has a commission for the analysis of events, and CNCAN staff attends meetings of the commission as considered important. Similarly as for NPP, licenses for other nuclear facilities, e.g. research reactors, include requirements for reporting of operational events and, in accordance with their quality management system, operators of those installations have procedures for reporting. CNCAN has an internal procedure for assessment of operational events in NPPs (MC-PA-01, issued in 2002). Another procedure is available for assessment of emergency situations. The same procedure as for NPP is used for the assessment of events in research reactors and fuel cycle facilities. CNCAN reviews the procedure for collecting operating experience both from licensees' own facilities and from other facilities, as applicable, assesses the INES classification, studies direct and root causes, reviews the action plan, and verifies its implementation. Site inspectors receive the list of corrective actions and monitor their implementation. Site inspectors also collect required information from the NPP needed for any review and assessment. CNCAN does not perform its own evaluation of operational events.

## **Conclusion**

In general, the legislative basis for review and assessment of nuclear power plants and research reactors in Romania is established. Some guidelines specifying technical requirements contained in regulation are missing. The scope of technical expertise covered by CNCAN staff is broad. The regulatory review and assessment activities are planned, performed, and reported as per internal procedures and instructions in order to assign internal resources and, as appropriate, external ones. The interface with utility is assured.



Most of IAEA requirements for the review and assessment are fulfilled. However, the limited resources (human and financial) available at CNCAN do not allow performance of review and assessment as required nor in full scope. Hiring and training of new staff and purchasing up-to-date analytical tools are needed. International co-operation and information exchange on expert level should be enhanced. Resources for contracting domestic or foreign organizations should also be increased. An independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body is not common practice.

### 6.3. FUEL CYCLE FACILITIES

#### **Findings**

In recent years an in-depth review of regulations and regulatory requirements/ safety criteria for the fuel cycle facilities has been performed. The review was done by German company under international project. Proposed upgrade of the regulations is in progress now in order to adhere to the recent developments in the requirements for the safety and radiation protection of nuclear facilities in the European Union (EU) and IAEA. The updated regulations should also include a requirement on the evaluation of potential impact of the contamination of surface water and ground water on the public and environment. Corresponding analyses for the fuel cycle facilities are not submitted to CNCAN.

Regulatory requirements for the procurement are stipulated in details in the national regulation – Specific requirements for the quality management systems applied to procurement activities for nuclear installations (NMC-06). CNCAN verified application of relevant requirements through the inspections. CNCAN inspectors review the procedures for procurement, the selection and evaluation of contractors and the reports elaborated by the licensees to document acceptance of a product or a service.

Generally, the scope of technical expertise covered by the staff in CNCAN Nuclear Fuel Cycle Division, as well as in other divisions involved in review and assessment of fuel cycle facilities, is broad and includes siting, design, construction, and operation stage of lifetime of fuel cycle facility. However, the commissioning stage is not covered. CNCAN should extend its capabilities for performing review and assessment to all stages of lifetime of fuel cycle facilities including commissioning.

CNCAN does not assess the capability of a licensee for a fuel cycle facility of performing adequate safety reviews and verifications and of maintaining of valid safety case for the installation and activities covered by the licensee.

Although the specification of regulatory requirements for the licensee or applicant in letters is a practice in Romania, the scope and content of safety analysis report (SAR) should be provided in a generally binding legal document (regulation), which could be further developed in the regulatory guide.

Requirements on periodic safety review (PSR) for the fuel cycle facilities are provided in the national Romanian regulation (NMR-02, article 65). Required scope of PSR corresponds to a scope suggested in the IAEA guideline on PSR (NS-G-2.10). PSR for the fuel cycle facility is performed in 5-year interval, without explicitly mentioning its role in the licensing process.

Currently, CNCAN staff has not enough capacity/ capability to perform in-depth review of all fuel cycle facility's submissions. The review activities are limited to a review of the methodologies, verification of hypotheses used, verification of used data against the design specifications, and conservative hand calculations. The potential interaction between the fuel cycle facility and site seismology, geology, local and regional hydrology, which may affect the safety of facility, is reviewed in simple way. Human factors and man-machine interface is not reviewed at all. CNCAN relies on facility's conclusions. External expertise is not used. Insufficient financial resources do not allow to contract external organizations to support review and assessment activities. These findings were also identified in IRRS mission conducted

in 2006 (R15 and R16) but have not been fully resolved. Hiring and training of new staff is needed. Practices with the utilization of IAEA, EU and other foreign projects should be enhanced. Co-operation and information exchange with experts from other regulatory bodies and particularly regulatory bodies in countries operating CANDU reactors should be established. Resources for contracting domestic or foreign organizations should be increased. Practices with the utilization of IAEA, EU and other foreign projects should be maintained.

There have been only few events identified for fuel cycle facilities till now. Separately, case by case, CNCAN inspections review each individual event and corrective actions, but this is not systematic approach. The regulatory body review of the feedback of operating experience in fuel cycle facilities is not perform in systematic way.

The review and assessment process of fuel cycle facilities is recorded in internal documents.

### Conclusion

The legislative basis for review and assessment of fuel cycle facilities in Romania is in process of updating after its international review. The regulatory review and assessment activities are planned, performed, and reported as per internal procedures and instructions. The interface with utility is assured. Most of IAEA requirements for the review and assessment are fulfilled. However, due to the limited resources (human and financial) available at CNCAN, review and assessment is not performed as required nor in full scope, specifically for the commissioning stage. Some specific areas of facility's submissions are reviewed only formally or review is limited to a CNCAN inspection at the site. Hiring and training of new staff are needed. Co-operation and information exchange with experts from other regulatory bodies or relevant international organizations has a potential for enhancement. Resources for contracting domestic or foreign organizations should also be increased. An independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body is not a common practice. The regulatory body review of the feedback of operating experience in fuel cycle facilities is not performed in a systematic way.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** NS-R-5, Requirement 3.9 states that *“Irrespective of the differences between national practices, a detailed demonstration of safety in the form of licensing documentation shall be submitted by the operating organization, and shall be reviewed and assessed by the regulatory body before progress of the project to the next stage is authorized (specific requirements addressed to the fuel cycle facility for commissioning are provided in IAEA NS-R-5, paragraphs 8.1-8.18).”*

R21 **Recommendation:** CNCAN should perform review and assessment of all stages of lifetime of fuel cycle facilities including commissioning.

### 6.4. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

#### Findings

The licensing division is in charge of review and assessment of all radiological facilities and activities. Review and assessment is mainly conducted in conjunction with the applications for authorization. Article 55 of the licensing procedure set a time limit of 2 months for CNCAN to complete the review and assessment process.

The result of review and assessment conducted by CNCAN is formally recorded, and used as basis for decision to approve or reject the application for authorization.

Periodic review and assessment of radiological facilities and activities is associated with the authorization renewal, which is usually 5 years for use authorizations. Significant modifications to the facility or activity require modification of the authorization and, consequently, initiate a review and assessment process.

Copies of the reports of regular inspections are always sent to the licensing division. However it seems that there no arrangements to trigger a review and assessment process based on the findings and conclusion in the inspection report.

Although the content and depth of the review and assessment is related to the radiation risk associated with facilities and activities.

The IRRS report of 2006 included recommendation relating to the revision of the procedure on review and assessment in the context of CNCAN quality management system (REF: R8, R9 and R14 of IRRS 2006 report). Implementation of these recommendations is ongoing.

### Conclusion

Beside the authorization process, no provisions are in place to conduct review and assessment periodically or in connection with information received from inspection reports or otherwise.

Recommendations of previous IRRS report regarding improving the review and assessment procedures in the context of CNCAN management system have not been fully implemented yet.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GSR Part 1, Paragraph 4.43 states that *“The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.”*

S6 **Suggestion:** CNCAN should consider improving its procedures for review and assessment by including provisions for periodic review and assessment and identifying situations that trigger review and assessment process.

### 6.5. WASTE FACILITIES

#### Findings

No specific requirements exist for the authorization and review of predisposal facilities. The published guidelines for small producers (CNCAN Order No. 366/22 Sept. 2001) are used for all facilities.

According to the organizational chart and the results of the interviews there are no responsible experts for evaluating the safety assessments of the operators. Due to a lack of resources no external experts can be consulted. In the authorization-process the presented calculations of the operator are the basis for licensing.

As a result of the 2006 IRRS mission CNCAN actively participated in the IAEA-coordinated research-program, but for the last 2 years these activities stopped, however, several recommendations and suggestions from the 2006 IRRS-Mission are not completely implemented.

These recommendations covered the following points:

- CNCAN should establish regulations including safety criteria for decommissioning
- CNCAN should establish regulations for the decommissioning of NPPs
- CNCAN should systemize the practice of the formally recording of the review process
- CNCAN should develop mechanisms to demonstrate the compliance with appropriate training and staff development programs
- CNCAN should consider active participation in international research programs such as ASAM and SAWDRMS

No formal system exists for the record keeping of the review process and the basis for its decision.

### **Conclusion**

There exists no graded approach for review and assessment. The regulations do not state how review and assessment are to be adjusted to the nature of the hazard associated with the particular facility or activity (no graded approach).

Due to the number of experts and the lack of resources for external experts no assessment of the calculations of the applicants for nuclear facilities can be done.

The participation in IAEA coordinated research programmes has stopped.

No regulations and guides exist for the review of predisposal facilities. The published guidelines for small producers (CNCAN Order No. 366/22 Sept. 2001) are used for all facilities.

There are no periodic safety review periods for waste management facilities.

## **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

(1) **BASIS:** GSR Part 1, Paragraph 4.43 states that *“The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.”*

R22 **Recommendation:** CNCAN should improve its procedures for review and assessment, including provisions for periodic verifications, and whether radiation risks are as low as reasonably achievable.

## 7. INSPECTION

### 7.1. GENERAL

This section considers inspection for each type of nuclear installations, medical practices, industrial and research practices and waste facilities.

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 general roles, authority and responsibilities of CNCAN inspectors are set in the Law (Chapter IV - Control Regime).

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

CNCAN inspectors are empowered to perform the necessary inspections 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.

Inspections are performed for any of the following situations:

- before granting the license for which an application has been submitted;
- for the whole period of validity of the license (periodic, as well as unscheduled or unannounced inspections);
- based on a notification/request made by the license 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.

CNCAN inspectors are empowered to:

- access any place in which activities subject to the control may be deployed;
- carry out measurements and install the necessary surveillance equipment;
- request the taking or receiving of samples from the materials or products directly or indirectly subject to the control;
- compel the controlled natural or legal person to ensure the fulfilment of the provisions mentioned under the 3 points above and to mediate the extension of the control to the suppliers of products and services or to their subcontractors;
- 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 ;
- compel the license holder to transmit reports, information, and notifications in the form required by regulations;
- compel the license 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;

- receive the necessary protective equipment, for which the applicant or license holder shall arrange.

CNCAN inspectors have the following responsibilities and authorities, to be exercised after conclusion of the inspection activity to:

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

The management structure is involved in planning and implementing inspections, however, the CNCAN inspection program is not fully defined according to the potential magnitude and nature of the hazard associated with the facility or activity.

The existing inspection procedures do not address the establishment of the CNCAN inspection programme considering for example the results of previous inspections, the safety analysis performed by the operator and the results of regulatory review and assessment, performance indicator programmes or any other systematic method for the assessment of the operator's performance, operational experience and lessons learned from operating the facility and other similar facilities as well as results of research and development (GS-G-1.3, § 4.5)

The management structure operates satisfactorily from the point of view of planning and implementing inspections. However this process relies sometimes on informal co-operation between the management persons and sometimes the inspectors.

Each technical division has specific roles in the inspection process and develops assessment and inspection procedures and plans in their respective areas of responsibility. The assessment and inspection criteria are usually specified in the internal procedures of CNCAN.

The inspections performed by CNCAN include:

- scheduled inspections, planned and performed either by each of the technical divisions, or in the case of Cernavoda jointly, with the on-site inspector;
- unscheduled and/or unannounced inspections, some of these being reactive inspections, in response to incidents;
- routines and, in the case of Cernavoda, daily observation performed by the on-site inspectors.

According to the Law 252 (Article 2, version 10.06.2003) every inspection has to be recorded in an internal register of the operator. This is no specific requirement only for nuclear installations.

At the end of the inspection, CNCAN formalizes the main findings of the inspection and decides the dispositions to be implemented by the licensee to solve these findings if needed (a timeframe for resolution is specified in writing and agreed to). This official report named “process-verbal” is signed by the inspectors, the management and the persons contacted during the inspection of the facility concerned. This document is the only official document specifying CNCAN findings after an inspection. On a case-by-case basis, inspectors can produce a more detailed internal inspection report. Time devoted to the elaboration of the “proces-verbal” can be short and, depending on the situation, the inspector may not be in a favorable position to issue a comprehensive “proces-verbal” including all the inspection findings. The current inspection process in some cases does not allocate sufficient time to the inspectors for a more in-depth work on the inspection findings and for a more detailed official report to the licensee after the inspection.

In discussions with a CNCAN legal advisor, the IRRS team was informed that the signature by the representative of the facility has no legal meaning but acknowledgement of the findings and taking note of the conclusions.

CNCAN does not have any formalized system for inspection action follow-up. The follow-up relies on inspectors’ individual practices. The Cernavoda site inspectors itemize and track inspection findings and resolution/closeout, but it is an informal system with no procedures.

CNCAN requires appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis. There is no core group at CNCAN trained to perform independent root cause assessment. Procedures for event investigations should be developed and implemented.

CNCAN does not have any formalized training courses for its new staff or existing inspectors, in particular on the radiation protection and the broader aspects of regulation to enable safety judgments to be made on a sound priority basis. Furthermore, CNCAN does not implement any qualification / requalification systems for its technical staff nor inspectors. It was observed by the IRRS team that the CNCAN inspection staff is extremely qualified, competent and dedicated to safety.

CNCAN did not implement any formalized process for inspection finding sharing between inspectors, in particular to coordinate CNCAN inspector activities, to collect feedback information and to use it to improve the regulatory process.

## **Conclusion**

- There is no structured training program for CNCAN inspectors, and no qualification process for either initial qualification or requalification.
- Inspection planning is not a formalized process for certain facilities and activities, and there is no formalized graded safety approach to the prioritization of inspections based on the safety significance and available resources. In addition, in certain instances (e.g., fuel cycle facilities), inspections are generally performed in response to a request for an authorization change.
- CNCAN did not develop any comprehensive list of the inspections carried out annually in order to provide pertinent input for the definition of annual inspection programmes.
- Inspection reports issued subsequent to “proces-verbals” are not decided upon in a consistent manner.
- There is no systematic approach to the sharing of inspection information among the various CNCAN units.

- Particularly for the Cernavoda reactors, there is no integrated review of licensee operational performance

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1, Paragraph 4.11 states that <i>“The regulatory body has to have appropriately qualified and competent staff.”</i>
R23	<b>Recommendation:</b> CNCAN should establish a consistent and comprehensive inspector training programme and qualification process.
(1)	<b>BASIS:</b> GSR Part 1, Paragraph 4.50 states that <i>“The regulatory body shall develop and implement a program of inspection of facilities and activities,... in accordance with a graded approach”</i>
R24	<b>Recommendation:</b> CNCAN should establish a systematic and comprehensive inspection programme based on a graded safety approach and formally describe its processes in procedures for consistency of regulatory practices.
(1)	<b>BASIS:</b> GS-G-1.3, Paragraph 2.4 states that <i>“A programme to monitor and follow-up inspection findings should be in place.”</i>
S7	<b>Suggestion:</b> CNCAN should consider including in its procedures a programme to monitor, share and follow-up inspection findings.
(1)	<b>BASIS:</b> GS-G-1.3, Paragraph 4.1 states that <i>“To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail.”</i>
S8	<b>Suggestion:</b> CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment and for inspection for all nuclear facilities.

### 7.2. NUCLEAR POWER PLANTS

On-site inspectors have a very important role in the daily observation and assessment of the activities on Cernavoda site. The most experienced senior inspector left in 2010 but he anticipated his replacement and took time to train the two other inspectors.

Responsibilities of both on-site inspectors and CNCAN headquarters are laid down in a specific procedure (MC-PI-01, version 2, 08/03/2005). Communication channels between on-site inspectors and CNCAN headquarters are specified in another procedure (MC-PC-05, version 1, 01/02/2002).

Besides the routine inspections, 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 for information on the plant status and for ensuring awareness of any inspection findings.

The senior inspector sends daily reports (one page report) and annexes with shift supervisors logs to the Division director and his adviser and attaches the daily report made by the Cernavoda site management for information on the plant status and for ensuring awareness of any inspection findings.



Once sent, CNCAN has not established any process for disseminating this information or compiling it for experience feedback sharing.

On-site inspectors are also in charge of the definition of the inspection annual programme according to systems to be inspected. The draft programme is sent to the division for approval. The division can also propose modifications.

In 2010, CNCAN had three on-site inspectors at Cernavoda and implemented a programme of 102 man/day inspection programme. For 2011, CNCAN proposes a significantly more ambitious annual programme based on about 400 man/day inspections despite the fact that CNCAN only have two on-site inspectors at Cernavoda site. Furthermore, this plan does include inspections to be carried out during Cernavoda 2 reactor outage in 2011.

The inspection programme of Cernavoda site is currently based on two inspection programmes respectively dealing with (1) nuclear safety and safeguards and (2) environment, radiation protection and emergency preparedness. In the field of nuclear safety, inspections planned in 2011 are focused on safety systems and PSR.

CNCAN has prepared thorough practice-specific checklists and procedures for inspections. Check-lists are also distributed to the licensee. The topics included in the checklist are very different and the information about them should be received by different person with different responsibilities (such as: responsible for radiological safety, legal representative, etc.).

The IRRS team observed an onsite inspection at Cernavoda. Team members visited the Cernavoda site, accompanied by two CNCAN counterparts. These team members evaluated inspection and enforcement, regulations and guides, and waste management. Interviews were conducted with the two Cernavoda CNCAN site resident inspectors, waste management technical experts, and a separate meeting was held with the Director CNE.

There are presently two CNCAN site resident inspectors assigned fulltime at Cernavoda. This is a reduction from previous years staffing of 3, in that the previous senior inspector retired in September 2010. These inspectors live in the vicinity of Cernavoda, report to the site each working day, and are available and respond to the site afterhours for reactive inspections. They also perform routine scheduled inspections outside normal working hours and on weekends.

A documented inspection plan for 2010 was completed; the inspection plan for 2011 was prepared by the site inspection staff and reviewed and approved by the Director CNCAN. The plan is based on previous findings, operational experience, licensee abnormal condition reports, and focuses on the important safety systems. It is, however, not prioritized, and is extremely ambitious in terms of scope and resources needed, and also is a significant increase in effort from 2010, made more extreme due to the reduction in inspection staff.

Both of the resident inspectors are very experienced and qualified, having worked for contractors onsite during the construction and commissioning of Unit 2. They attend daily licensee plan-of-the-day meetings, and provide written reports to CNCAN management daily. They were observed by the IRRS team members to work well together as an efficient team. The IRRS team members observed the performance of two inspections: a surveillance test on the emergency diesels; and control room daily status for Unit 2. The inspectors were well-prepared for the inspections, used prepared checklists, employed excellent questioning attitudes, interfaced well with licensee subject matter experts, and pointed out areas for improvement during the inspections.

The IRRS team members interfaced with several licensee employees. This included security staff upon arrival and entrance into the facility and during a site tour, technical experts, the on-shift shift manager,

control room operators, refuelling control room operators, and administrative staff. All licensee staff exhibited the appropriate focus on safety. They were knowledgeable of the facility and the regulatory requirements. They responded properly to questioning by the CNCAN site inspectors. All licensee staff showed the proper respect for safe operation and security of Cernavoda Units One and Two and the onsite waste storage facility.

A separate meeting was held with the Director CNE Cernavoda. He stated there is a good working relationship between his staff and the CNCAN site resident inspectors. The inspectors are welcome at all licensee meetings, and add value to the safety discussions. He interacts periodically with CNCAN management.

## **Conclusion**

- At Cernavoda there is a large number of inspections given the number of on-site inspectors.
- The Cernavoda site resident inspectors do not schedule and conduct regularly scheduled interface meetings on a routine schedule with senior licensee management.

### **7.3. RESEARCH REACTORS**

CNCAN has developed a set of procedures for research reactor inspections (Procedures MC-RC-01 to MC-RC-05 and MC-RC-08, 01/02/2002). They have not been revised since 2002. CNCAN issues quarterly inspection programmes. Usually, the inspection programme is issued at the beginning of the quarter addressed in the inspection programme.

The IRRS team observed an inspection carried out at the TRIGA research reactor located in Pitesti.

The inspection was prepared using 2 existing procedures for NPP. All of the reference documentation was listed in the inspection plan. The plan was sent to the licensee 2 days in advance. At the entrance meeting, a check list was provided to the licensee. The inspection scope was presented at the entry meeting. Site management was involved, including the Director of the Institute, and senior managers of the facility.

Facility management representation during the review was good at all times. Records were made available and licensee responded all questions diligently. During this meeting, several discussions and clarification on the requirements took place, many related to the use of NPP requirements and interpretation by CNCAN staff's and application of a graded approach. Records were verified in detail.

The inspector checked housekeeping and some equipment calibration. He also took pictures using the licensee's cameras. Several questions were asked to address concerns or for clarification. CNCAN drafted the report in a 30-60 minute meeting with licensee staff present in the room. The IRRS team did not observe this activity and the level of discussions to reach agreement on findings of the report.

At the exit meeting, the report was presented to senior managers of the Institute. Five findings and corresponding corrective actions were presented.

Inspectors recognized that the 2 year modernization process may have caused some slippage of actions. Some findings/observations made by one inspector did not find their way into the list of findings in the report. Apparently, explanations were given by the licensee during the drafting of the report, and they were dropped on promises by the licensee that they will be resolved. An action plan was requested by February 15.

Some clarifications were given by the Deputy Director of Nuclear Safety of the institute. He stated that some of the findings were a consequence of the lack of time and by not having the documentation available for the inspectors. They have a DB based system, and stated that the system is working. He recognized that a procedure needs revision.

Inspector stated that the requests will help the licensees to improve. The findings were considered non-critical, and the report was signed by the 2 parties at the end of the meeting.

#### 7.4. FUEL CYCLE FACILITIES

The IRRS team reviewed the inspection carried out in the framework of the Feldioara facility application for a facility modification.

- The Feldioara facility sent an official application for the facility modification on 30 September 2010 (CNCAN document 52541).
- After the review of the request, CNCAN performed an announced inspection on 28 October 2010.
- The findings of this inspection were documented to the site on 29 October 2010 (CNCAN document 52721 – proces verbal) and to the licensee on 3 November 2010 (CNCAN document 52745).
- The licensee responded with an amended application on 8 December 2010 (CNCAN document 53033).
- The licensee submitted the payment on 17 January 2011.
- The CNCAN authorization for the facility modification is under process and is expected to be issued in January 2011.

The expertise and the experience of the individual reviewers played a key part in ensuring an adequate safety assessment of the modification assessment during a short time frame. This is in spite of the lack of guidance for review of such applications and the apparent administrative complexity of processing such applications.

CNCAN has a general procedure (PC-DMS-02, version 0, 12/01/2006, not revised since 2006) for preparing and carrying out inspections in the field of mining (Natural Uranium and Thorium). This general procedure is also used for fuel fabrication facilities. This procedure includes:

- Inspection planning,
- Inspection structure (preparation, announcement, implementation, documentation, follow-up)
- Inspection documents to be produced (process-verbal contents, report)
- Actions to be launched after the inspection.
- Enforcement

CNCAN does not have any specific guidance for inspections to be carried out in fuel cycle facilities and in mining facilities in force. However, some guidance is being developed (ex. *Methodology for the inspection and the assessment of long term stability of closed mine tailing facilities* – Ref RO – 2007/19343.06.04), but no schedule for implementation was provided.

CNCAN issues a quarterly inspection programme approved by management. Usually, the inspection programme is issued at the beginning of the quarter addressed in the inspection programme.

In August 2008 the EC under the article 35 of the EURATOM treaty carried out an inspection at Crucea and Fedioara facilities. A report was issued (réf. RO-08/6) and mentions that dispositions implemented are adequate. The scope of the inspection was the environment monitoring dispositions set up in the country. Romania gave comments on the draft document and the final version has been sent. No action plan has been issued. The deadline for issuing the action plan is July 2011. However, some of the actions are part of the inspections carried out on the site and identified in the process-verbal.

#### **Conclusion**

- There is no CNCAN guidance for inspection of the fuel cycle facilities, or for development of an annual inspection program for fuel cycle facilities.

- CNCAN has not formalized the follow-up on the recommendations from previous program assessments, including those performed by external organizations (e.g. Euratom).
- There are only two inspectors for the fuel cycle facilities.

## 7.5. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

### Findings

Inspection is performed in accordance with the provisions included in chapter IV of the law and the CNCAN inspection procedures.

In each region, a group of about 200 facilities are assigned to each inspector. In the current situation, inspections are performed by one inspector only. The workload for inspections is in average about 8 to 10 inspections per month per inspector.

Inspectors are provided with a red inspector pass showing their IDs, duties and powers.

There are no requirements for initial and refresher training of inspectors. (discussed in Section 4)

Frequencies of regular inspection are specified in the inspection procedures based on, the type of facility and activity. Although related to the facility type, the inspection frequencies seem high and not commensurate with the risk associated with the facility or activity in accordance with a graded approach. This observation was also made in the IRRS report of 2006.

The inspection program is done on a monthly basis. The inspection procedures setup criteria and principles for preparing the inspection program, which take into account the risk of the facility and optimizing the use of available inspection resources. It was observed that the regular inspections do not fully comply with the frequency provisions prescribed in the inspection procedures. CNCAN attributed this fact to the high workload of inspectors, however, in the IRRS team view, this fact can also be attributed to the lack of the application of the graded approach.

As for initial inspections, the IRRS team observed that inspectors have little information in advance on the specificity of the new facility to be inspected. The applicant's file is kept in the licensing division. This file is accessible by the inspectors in Bucharest but there is no formal and systematic procedure to consider that file by the inspectors before the inspection. Moreover, regional inspectors can't access that file at all unless they come to Bucharest. In many cases, the only left opportunity for the inspectors to learn the details of the facilities is onsite where they have access to the applicant's copy of the technical file. Consequently, regional inspectors have limited opportunities for preparation of initial inspections.

The IRRS team observed field inspections in the radiotherapy department of the Oncology Institute in Bucharest, and in the Laboratory of Radiation Metrology, Testing and Dosimetry of the Horia Hulubei National Institute of Physics and Nuclear Engineering (IFIN-HH).

In general, the inspectors followed prescribed procedures using detailed checklists. After the inspection, inspectors prepared the inspection report onsite. They were equipped with office devices enabling them to put the inspection report in the prescribed template (The IRRS team was informed that in the near future, inspectors will have online access to CNCAN database and will be able to fill-in the report through a web form).<sup>1</sup> and to print hard copies that are signed by the licensee and by themselves. The IRRS team got the impression that the conditions for preparing the inspection onsite are not very comfortable and puts unnecessary pressure on the inspectors.

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<sup>1</sup> The IRRS team was informed that in the near future, inspectors will have online access to CNCAN database and will be able to fill-in the report through a web form.

In the field inspection to the Oncology Institute, a Co-60 teletherapy equipment was inspected and several non-compliances were discovered. The equipment didn't meet a technical limit specified in the specific regulation on safety in radiotherapy. However, this non-compliance was not addressed in the final inspection report. The IRRS team was informed that this was a conscious decision by the inspector based on his judgment. The authorization to operate this equipment was expired since May 2010, but CNCAN didn't consider this non-compliance under the justification that the facility's application to renew the authorization is in progress. This will be further discussed in section 8.5 on enforcement.

In the field inspections it was observed also that house-keeping issues were raised. The IRRS team was informed that this is not based on regulatory requirements, but is addressed by individual inspectors based on their experiences.

Additionally, the IRRS report of 2006 recommended CNCAN to prioritize its inspection plans so as to focus on safety significant issues. According to CNCAN self-assessment, the implementation of this recommendation is ongoing.

### Conclusion

Inspection frequencies seem high and are not commensurate with the radiological risk associated with the facilities or activities in accordance with a graded approach. Inspection program is not fully consistent with the inspection frequency.

For initial inspections, regional inspectors outside Bucharest have little opportunity and little information for proper inspection preparation.

In certain cases, the circumstances at the end of field inspections may impose unnecessary pressure on the inspector during preparation of inspection report.

In certain cases, inspection findings are based on individual inspector view rather than regulatory requirements.

In certain cases of non-compliances, inspectors do not request corrective actions or impose enforcement actions in accordance with the provisions of the law and regulations (see section 8.5).

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
(1)	<b>BASIS:</b> GSR Part 1, Requirement 27 states that: <i>“Inspection of facilities and activities The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.”</i>
(2)	<b>BASIS:</b> GSR Part 1, Paragraph 4.26 states that: <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body...”</i>
R25	<b>Recommendation:</b> CNCAN should improve its inspection system as to ensure that the inspections are done in full compliance with the regulations and procedures and that subjective judgment is avoided.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-G-1.3, Paragraph 4.14 states that “*Before an inspection is carried out, the inspection personnel should be thoroughly prepared for the task. The type of preparation will depend on the type and method of inspection*”

S9 **Suggestion:** CNCAN should consider enhancing its procedures to support its regional inspectors undertaking their inspection duties to ensure proper preparation of initial inspections.

### 7.6. WASTE FACILITIES

#### Findings

There is no requirement for the number of inspections. If and how many inspections are carried out between the licensing processes is decided by the inspectors of CNCAN. There is no requirement for the development of an inspection plan. Nevertheless every year an inspection plan is developed in the responsible department.

Inspections can be carried out announced and unannounced. In practice most inspections are carried out announced.

Inspections are carried out following an internal guideline of CNCAN. No legal requirements exist. The results of every inspection are communicated immediately by the inspectors to the management of the inspected facility.

According to Article 2 of Law 252 from 10.06.2003, every inspection has to be registered in an internal register of the operator. This is no specific requirement only for nuclear installations.

The regulatory body does not require that the waste is stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. This was already identified as a result of the IRRS mission in 2006. The implementation of this requirement for the time being does not seem to be possible for the NPP storage facilities due to limited available place in the facility, and no regulatory actions have been taken.

#### Conclusion

There is no requirement for the development of an inspection plan. However, an inspection plan is developed every year in the responsible department by its own initiative.

In practice nearly all inspections are announced.

The regulatory body does not require that the waste is stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management.

## 8. ENFORCEMENT

### 8.1. GENERAL

Chapter VI of the Law (“Penalties”) 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.

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

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

The enforcement process is similar for all facilities and activities regulated.

CNCAN developed a specific procedure (MC-PC-11, version 0, 01/02/2002) addressing the main provisions of the law (findings justifying prosecution, information to be included in the process-verbal, in the fine and the final document which includes resolution of the sanction).

CNCAN does not implement any specific administrative procedures and guidelines for the use and the implementation of enforcement actions. CNCAN inspectors have neither any formalized training on the CNCAN enforcement policy in place nor any refresher training for staff including the latest regulatory developments.

In discussions with a CNCAN legal advisor, the IRRS team was informed that inspectors are obliged to record any identified non-compliances in the inspection report and to request corrective actions as needed. Imposing contravention measures is however subject to their judgments.

### APPEAL PROCESS

There are no specific provisions on appeal in the law. However article 51 refers to the Government Ordinance No. 2/2001 on the legal status of infringements. Article 54 of the law provides for appeal in the case of ‘...abuse made by the Commission or another body provided under this Law’.

The CNCAN legal advisor informed the IRRS team that appeal measures are within the general legal framework of Romania and that:

- No appeal is possible in case of rejection of an application for authorization
- No appeal is possible if no contravention measures, i.e. penalties, are imposed. For example, facilities can’t challenge corrective actions requested by inspectors
- If contravention measure is imposed in inspections, an appeal to the court of justice can be initiated within 15 days from the date of communication or delivery.

## Conclusion

- There is no detailed CNCAN guidance for implementation of the enforcement provisions of the Law and there is no associated training.
- CNCAN did not develop any specific training courses on its enforcement policy in the general process for the inspector qualification. This will also promote consistent implementation.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1, Requirement 30 states that <i>“The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to noncompliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”</i>
R26	<b>Recommendation:</b> CNCAN should develop and implement administrative procedures and guidelines to clarify its enforcement policy. The enforcement procedures should ensure that: (1) enforcement measures are consistently applied in accordance with a graded approach (2) subjective decision making with respect to enforcement is avoided (3) all non-compliances are properly addressed in the enforcement process (4) all enforcement actions are clearly based on regulatory requirements
(1)	<b>BASIS:</b> GSR Part 1, Paragraph 2.5 states that: <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: ...</i>  <i>(11) Provision for appeals against decisions of the regulatory body...”</i>
R27	<b>Recommendation:</b> The government should ensure full provisions are provided for appeal of all decisions by CNCAN.

## 8.2. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

### Findings

A list of enforcement actions in 2010 was presented to the IRRS team. 80 sanctions of different types were imposed, totaling to 21000 Euros; 4 court prosecutions were initiated (2 wins, 2 are pending).

In certain cases, the inspection division may propose suspension or withdrawal of the license. There is no formal process for consultation with the licensing division in such cases. Decisions on suspension or withdrawal of the authorization are made by CNCAN management [REF. law article 32(b) and inspection procedures section 6.2.3.8].

Theoretically, the licensing division has also the power to undertake enforcement actions, if it discovers non-compliances by any means. But there were no cases like this since it was established through the revised organizational structure in 2008. There are no provisions to coordinate such actions with the inspection division.

As mentioned earlier in section 7.5, following observation relating to enforcement were made during the site inspection to the Radiotherapy Department of the Oncology Institute:

1. On-the-spot enforcement actions were made in areas, for which no clear regulatory requirements exist, such as house-keeping issues.



2. A Co-60 teletherapy unit was operational although the related authorization expired in May 2010. However, CNCAN accepted this fact and imposed no enforcement action. CNCAN argued that this is permissible according to article 53(1) of the licensing procedure because the facility has submitted an application to renew the authorization well in advance according to the licensing procedure, and that CNCAN has requested actions which couldn't be completed until Dec 2010.
3. An observed deviation of the source from the prescribed limits in the regulations was omitted in the inspection report.

### **Conclusion**

Different organizational units in CNCAN may be involved in enforcement, however no provisions are in place for information exchange and cooperation among those units.

Onsite requests for corrective actions and enforcement actions are, in certain cases, based on individual inspector's judgment rather than regulatory requirements. Additionally, in certain cases, no actions are undertaken to correct non-compliances with regulatory requirements.

Facilities and activities can only appeal to the court of justice in case of contravention measures. In all other cases, except those covered by article 54 of the law, facilities and activities have no options to challenge regulatory decisions.

## 9. REGULATIONS AND GUIDES

### 9.1. GENERAL

The Law (which was modified and complemented through Law No.16/1998, Law No 384/2001 and Law No. 193/2003) regulates the use of nuclear energy and empowers CNCAN to issue regulations in fields of its competence. The ordinary Law No.24/2000 on “Legislative technique for elaboration of the normative acts” and Governmental Decision HG 561/2009 “Appointing a Regulation regarding procedures for submitting draft normative acts to governmental endorsement” establish the provisions, technical rules and administrative procedures for the development of regulations (normative acts) in Romania. Development of all regulations should fulfill the mandatory steps prescribed in Law no.24/2000.

In development of regulations, a large number of CNCAN experts are involved. On a case by case basis, external consultants can also be involved in drafting regulations (funding by the European Commission). In the field of Fuel cycle facilities and radioactive waste, a huge work of revision of the Romanian regulation has been performed by foreign consultants before assessing to the European community (2007). According to the Romanian regulation, these regulations will have to be revised before 2012. To date, the revision process has not been launched.

There is an internal CNCAN Quality Assurance procedure on drafting regulations (MC-PC-11). According to this procedure, a process is in place to ensure internal consultation among CNCAN units regarding the drafting regulations.

The 2 year validity of licenses for installations for the fuel cycle is specified in the regulatory norm “procedure for the authorization” (NMR – 04). This norm has been revised, but not issued.

CNCAN is empowered by the Law to develop any regulations necessary to support the licensing and control activities.

The Law 24/2000, republished in 2010, on “Legislative technique for elaboration of the normative acts” and the Governmental Decision HG 561/2009 on the approval of the Regulation regarding the procedures for the development of public policy documents, establish the general provisions, technical rules and administrative procedures for the development of all Romanian regulations (normative acts).

All regulations issued by CNCAN are mandatory and enforceable. The regulations are developed in observance of relevant international standards and good practices.

A process is in place to ensure internal consultation among CNCAN departments regarding draft regulations. 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 production. In some cases, external experts are also involved in the review of the draft regulations developed by CNCAN staff. The conformity with technical and legal requirements is verified.

The draft regulations are sent for external consultation to all interested organizations in order to receive feedback. The comments and suggestions received are analyzed and discussed at meetings with interested parties. As a consequence of this review process, the proposed regulations may be revised. Subsequently, the final version of the 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, CNCAN publishes its regulations separately in brochures and on the CNCAN website in order to provide for broader dissemination,

In accordance with the provisions of the Law, CNCAN is responsible for reviewing the regulations whenever it is necessary for these to be consistent with international standards or with ratified international conventions, 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 international cooperation as well as feedback from licensees and from CNCAN inspectors based on their experience with the enforcement of the regulations.

The core process implemented for the development of regulation and guides is applicable to all technical divisions of CNCAN. However, each technical division and organisational unit involved in the development of regulations and guides may produce and implement specific procedures suitable to their particular area of activity (e.g., for developing nuclear safety regulations, regulations on radiological protection, regulations on transport of radioactive materials, regulations on medical applications of ionising radiation, etc.).

The IRRS team noticed that the format and content of SARs for nuclear installations other than NPPs should be addressed separately in appropriate regulations.

### Conclusion

- There is no guidance for the generation of regulatory guidance, and there are no plans in place to review regulations as necessary as specified in the law.
- Fuel cycle facility guidance is presently in draft form.
- There are no procedures for interaction among the various Ministries.
- The existing set of regulations related to radiation safety has not been formally and consistently reviewed in light of the changes which have occurred over the last years such as the revision of the law in 2006 and Romania commitment to implement the code of conduct in order to identify need for revisions.
- As explained in section 5.5, the provisions for authorization are not entirely consistent in the hierarchy of the existing regulations (law, licensing procedures and specific regulations).

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1, Requirement 32 states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
R28	<b>Recommendation:</b> CNCAN should identify, complete and issue those regulations for safety upon which regulatory judgements and actions are based.
(1)	<b>BASIS:</b> GSR Part 1, Requirement 33 states that <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.”</i>
R29	<b>Recommendation:</b> CNCAN should review and revise as necessary, its regulations and guides for completeness and consistency.
(1)	<b>BASIS:</b> GSR Part 1 – Paragraph 4.62 states that <i>“The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R30 **Recommendation:** CNCAN should ensure that all provisions related to authorization are consistent across the entire set of regulations and procedures

### 9.2. NUCLEAR POWER PLANTS

No additional specific findings have been identified in this section.

### 9.3. RESEARCH REACTORS

No additional specific findings have been identified in this section.

### 9.4. FUEL CYCLE FACILITIES

In addition to general findings reported in section 9.1., it was noted that the regulation of Fuel cycle facilities by CNCAN includes interactions with other ministries (Ministry of Environment, Ministry of Health, Ministry of Industry), including for regulation issuance. The unit in charge of fuel cycle facilities do not have any formalized procedure for the interaction with other ministries.

#### **Conclusion**

CNCAN should consider the formalization of interactive procedures between these administrative bodies.

### 9.5. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

#### **Findings**

In addition to the general findings reported in 9.1, CNCAN demonstrated several examples, in which it prohibited further use of certain types of sources due to unjustified risk, such as fluoroscopy X-ray generators, which are not equipped with image intensifiers. These regulations were associated with the implementation of the European directive no. 97/43/Euratom (1997) related to protection in medical exposure in Romania.

#### **Regulations related to Safety and Security of Radioactive Sources**

Romania committed itself to the implementation of the code of conduct on safety and security of radioactive source in 2004, but since then, no formal and consistent analysis was made to identify the need to review the existing regulations accordingly.

Romania applies also the European HASS directive.

CNCAN order no 40/1990 includes criteria for establishing radiation risk for practices. However, none of the existing regulations include provisions on the categorization of sources in accordance with the associated radiation hazard. The new information system, which was adopted recently by CNCAN provides for categorization of sealed sources in accordance with the HASS directive as well as the IAEA categorization of sources. However, information on all sources in Romania is not yet included in this information system. This observation was made also in the previous IRRS in 2006 and it was recommended to upgrade the national inventory of sources.

It is requested that authorization holders provide for the disposal of disused sources in a safe and secure manner such as Article 77 of and Article 108(3) of the Law. This can be ensured by means of a contract to return the source to the supplier or by arrangements to domestically dispose the disused source as radioactive waste.

Information related to security of sources is considered confidential according to article 51 of the licensing procedures. Additionally, article 31(1)(e) of the law provides inspectors the power to access information with observance of the confidentiality.

CNCAN has issued regulations relating to orphan sources, jointly with the ministry of interior and National Customs administration. If a source is detected at border, it has to be sent back to the country of origin (Romania has established memoranda of understanding with some neighboring countries to accept receiving back of sources detected at border). Customs have the capacity to temporarily store the source in a safe and secure manner until it is sent back.

If an orphan source is detected inside country in a public area, then CNCAN is in charge of managing the source in a safe and secure manner. Funding may be provided through the fund established under article 16(2) and article 20 of the governmental ordinance no. 11/2003 with subsequent modification and completion.

CNCAN has issued regulations related to controlling scrap yards with respect of potential orphan sources. Owners of Scrap yards have to have appropriate radiation monitors according to the amount of scrap they deal with. They shall also provide adequate space for temporarily storing discovered orphan sources in a safe and secure manner.

### Conclusion

There are no clear provisions in the existing regulations on the categorization of sources based on associated radiation risk.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<b>BASIS:</b> <u>RS-G-1.9</u> Paragraph 3.2 states that “ <i>The regulatory body should use the categorization system described in this Safety Guide to provide a consistent basis for implementing these requirements in different area</i> ”
S10	<b>Suggestion:</b> CNCAN should consider amending the regulations to include the categorization of sources in accordance with the associated radiation risks.

## 9.6 WASTE FACILITIES

### Findings

The Law on the safe deployment regulation, authorization, and control of nuclear activities and Fundamental Regulation on Radiological Safety, respectively the Fundamental Norms for Safe Management of Radioactive Waste (Order no. 14/2000 - and 56 /2004 - of CNCAN president) provide regulation principal on the radioactive waste management. Specific regulations on waste management and decommissioning such as Order no. 62/2004(Clearance), 156/2005(Waste Classification), 221/2005(limiting of effluents), 400/2005(Near surface disposal), 181/2002(Decommissioning), etc. are established to enforce the principal of laws and fundamental regulation to the facilities.

The general system of regulations, despite the deficiencies identified in the earlier chapters, seems to be structured appropriately.

As mentioned before, appropriate regulations do not exist for all facilities (predisposal management of radioactive waste).

Generally non-mandatory guides are developed when necessary. However, especially for disposal facilities for radioactive waste, some gaps were identified.

The Romanian national strategy for disposal of NPP's low and intermediate-level radioactive waste was targeted for completion in 2014 by the AN&DR (Nuclear and Radioactive Waste Agency), and the target date for repository operation was postponed to 2019. The site license application of the Saligny for the disposal waste of NPP that was proposed in 1997 was reviewed by CNCAN and resulted in a number of requirements and comments. As a result of that, the partial license was issued in 2008 and renewed in 2010. However, the standard review plan that describes the detail criteria and review procedure on the application of the radioactive waste disposal facility may need to be developed prior to the final siting licensing and design of the disposal facility.

The regulatory authority should review whether non-mandatory regulatory guides exist in a sufficient manner in all fields.

Due account is taken of internationally recognized standards and recommendations, such as IAEA safety standards. Safety standards are used to compensate gaps in the national legislation.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 5, Requirement 11, states that *“Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment.”*

S11 **Suggestion:** The regulatory body should consider developing the standard review plan that describes the detailed criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility.

## **10. EMERGENCY PREPAREDNESS AND RESPONSE**

### **10.1. EMERGENCY PREPAREDNESS AND RESPONSE**

#### **10.1.1 BASIC RESPONSIBILITIES**

##### **National Framework**

Emergency preparedness and response in Romania is organized starting with 2004 as an integrated system for prevention and mitigation of any type of emergency that could occur or have impact on the Romanian territory.

At national level, the responsibilities for preparedness and response in case of a nuclear or radiological emergency are clearly defined and allocated in the following documents:

- GO No.21/2004, regarding the National System for the Management of emergencies;
- GD No.1489/2004 regarding the organization and functioning of the National Committee for Emergencies;
- GD No.1491/2004 for the approval of the frame Regulation on the structure, attributions, functioning and endowment of the committees and operative centres for emergencies;
- GD No.1492/2004 on the organizing and functioning principles and attributions of the professional emergency services;
- GD No.2288/2004 for the approval of the nomination of the main support functions which the ministries, state authorities and non-governmental organizations have to perform in order to prevent and manage emergency situations;
- Law No.111/1996 republished with amendments on the safe deployment of nuclear activities;
- GO No.242/1993 “Nuclear safety republican regulations on planning, preparedness and intervention in nuclear or radiological emergencies”;
- Basic radiation protection safety regulations, CNCAN, 2000
- Governmental Decree No.223/1990 for the Romania’s accession to the IAEA Conventions on Early Notification of a Nuclear Accident and Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Bilateral early notification agreements with Bulgaria, Greece, Hungary, Slovakia, Russian Federation, Ukraine and Turkey.

According to the current legislative framework, the National System for the Management of Emergencies is composed from three types of structures:

- the decisional structure – the committees for emergencies,
- the executive structure – the General Inspectorate for Emergencies (IGSU) and the county and local inspectorates for emergencies (as public professional emergency services);
- the operational structure – the operative centres for emergencies.

All the decisional, executive and operational structures are established on three levels: national, county and local. As a decisional structure, at national level is organized the National Committee for Emergencies. The National Committee for Emergencies is set-up under the co-ordination of the Prime

Minister and managed by the Minister of Administration and Interior. At the level of central public authorities there are established Ministerial Committees for Emergencies. At the level of local public authorities there are established County and Local Committees for Emergencies which are directed by the county Prefect / local mayor. All the Ministerial, County and Local Committees are subordinated to the National Committee for Emergencies.

According to the current legislation, the Ministry of Administration and Interior (MAI) is responsible for the prevention and management of nuclear and radiological emergencies.

As an executive structure, at national level is established the General Inspectorate for Emergencies (IGSU), a specialized organization in the Ministry of Administration and Interior. IGSU has the responsibility of permanent co-ordination of the prevention and management of emergencies, at national level. The IGSU has county structures called County Inspectorate for Emergencies (42 units) which are having the responsibility of permanent co-ordination of the prevention and management of emergencies at local level, as well as for the control and periodic assessment of the local off-site emergency plans.

As an operational structure at national level functions the National Operative Centre of IGSU. Operative centers are established at county and local level, and also at the level of central public authorities.

IGSU-MAI and National Commission for Nuclear Activities Control (CNCAN) are according to the current legislation, the national competent authorities in case of nuclear or radiological emergency.

According to GD No.2288/2004 provisions, CNCAN functions at national level are:

- Monitoring of specific dangers and risks, together with their associated negative consequences.
- Informing, notifying and alerting.

### **Legal responsibilities of the Regulatory body**

As nuclear regulatory authority, CNCAN has the responsibility to control, evaluate and approve the emergency plans of the licensees (Law No.111, Article 40; MO No.242 Article10). In the process of authorization, all practices necessitating an emergency intervention are identified by CNCAN and when applicable, the Radiological Safety Report of the licensee includes an Emergency Intervention Plan. Basically, all licensees in Romania have to present to CNCAN their emergency arrangements as part of the authorization process. Further on, requirements for the setting in operation of the Emergency Plan and for the notification of the regulatory body are specifically given in their license. One of the licensing conditions is the obligation of the applicant to establish and maintain its own system for the intervention in case of radiation emergencies.

The specific Regulation on Nuclear Safety Republican Regulations on Planning, Preparedness and Intervention in Case of Nuclear and Radiological Emergencies, approved by Ministerial Order No.242/1993 is including detailed requirements for the Regulatory Body, but also for the licensee and for the public authorities, in connection to planning, preparedness and response in following situations:

- nuclear accidents at nuclear installations;
- radiological emergencies as a result of authorized nuclear activities;
- radiological emergencies as a result of some transboundary effects or as a result of other cases, such as cosmic objects falling.

According to the Law (Article 35) and MO No. 242 (Article 10), CNCAN has to participate in any radiation emergency as technical adviser for the decision makers at national level.



For the planning phase, Articles 35 and 40 of the Law stipulates that CNCAN has to collaborate with the Ministry of Administration and Interior for the approval of planning at national level. According to the current legislation (GO No.21/2004, GD No.2288/2004, MO No.242 Article 3), CNCAN has to establish its own Operative Centre for Emergencies, its own Committee for Emergencies and to have in place its own Emergency Response Plan for Radiation Emergencies.

The collaboration between CNCAN and the Ministry of Administration and Interior is considered as a very good approach in the field of emergency preparedness and response

### 10.1.2. ASSESSMENT OF THREATS

Considering the categories of radiation-related threats for the purpose of emergency preparedness and response [GS-R-2] Romania has facilities and activities in all threat categories:

<b>THREAT CATEGORY</b>	<b>FACILITY</b>
<b>I</b>	Cernavoda NPP with two CANDU reactors
<b>II</b>	TRIGA Reactor in Pitesti (14 MWth)
<b>III</b>	Facilities on the site of the Institute for Nuclear Research (INR) in Pitesti, e.g. the nuclear fuel factory, the gamma irradiation facility and the radioactive waste treatment section
<b>IV</b>	Different types of activities throughout the country with the use radioactive sources (e.g. medical, industrial radiography, etc.)
<b>V</b>	Applicable to Romania also

The National Nuclear and Radiological Emergency Plan is considering all threat categories. Nevertheless the assessment of radiation related threats at national level has been not reviewed in accordance with the present situation (mainly in relation to accidental events that might happen abroad and have radiological impact on the Romanian territory) and the National Registry of Radioactive Sources has been not fully completed.

As stipulated in Chapter X of the Basic Radiation Protection Safety Regulation, in order to obtain a license from CNCAN for any practice the applicant shall take into consideration all types of radiological emergencies which could arise from the practice, assesses the spatial and temporary distribution of radioactive substances dispersed in case of emergencies and, consequently the corresponding potential exposures. Based on these evaluations, the applicant shall elaborate an adequate intervention plan, at all necessary levels, commensurate with the extent of all possible types of radiological emergencies. The assessment of the radiological threat is based on the type and activity of the source, design base accidents for specific sources, exposure pathways and propagation of the contamination in the environment.

### Conclusion

For facilities belonging to threat category I in the specific regulation NSN-08 "Norms regarding the probabilistic safety assessment for Nuclear Power Plants" is stipulated that the authorization holder is responsible for conducting the probabilistic safety analysis. CNCAN's role is to review the probabilistic safety assessment as part of the licensing support documentation for facilities in threat category I. The

Regulatory Body does not perform probabilistic safety analysis for facilities belonging to threat category I.

## RECOMMENDATIONS

(1) **BASIS:** GSR-2, Requirement 3.15 states that *“The full range of postulated events shall be considered in the threat assessment. In the threat assessment, emergencies involving a combination of a nuclear or radiological emergency and a conventional emergency such as an earthquake shall be considered.”*

R31 **Recommendation:** The government should finalize the radiation threat assessment at the national level for all postulated nuclear and radiological emergencies for all nuclear facilities and activities.

### 10.1.3. ESTABLISHING EMERGENCY MANAGEMENT AND OPERATIONS

According to the new legislation (2004), Ministry of Administration and Interior is responsible for the management of nuclear or radiological emergencies. Ministry of Administration and Interior through the General Inspectorate for Emergency Situations is responsible for the activation and coordination of the response at national level.

At the county level, each Inspectorate for Emergency Situations sets-up an Operative Centre for Emergencies. The primary function of the centre is to activate the emergency organization in case of an accidental event. These Operative Centres for Emergencies receive notifications for all types of emergencies, including radiation events. There are similar operational centres set up at the national levels for these emergencies, which is the National Operative Centre of IGSU.

In order to fulfill the legal responsibilities in case of a nuclear or radiological emergency, CNCAN has established (2004) its own Emergency Response Centre (ERC), as part of the National System for the Management of Emergencies (PHARE Project RO/RA/02 “Transfer of western European methodology to the nuclear safety authority of Romania” and CNCAN President Order No.209 / 24.06.2004). CNCAN-ERC acts as a support centre performing technical analysis and prognosis of the emergency situations with focus on the nuclear safety, radiation protection and radiological consequences, in nuclear and radiological emergency:

- independent analysis,
- technical recommendations in the nuclear safety field,
- technical recommendations in the radiation protection field,
- environmental radioactivity measurements (field and laboratory measurements)

A Protocol between CNCAN and IGSU is in place since 2006, with specific provisions regarding collaboration and support in the planning phase but also in response in case of nuclear or radiological emergencies. The CNCAN-ERC is connected also through this Protocol to the National Operative Centre.

### 10.1.4. IDENTIFYING, NOTIFYING AND ACTIVATING

At national level, there are established two National Contact Points, one in relation to European Union ECURIE system and one in relation with IAEA - ENAC system for early notification. The National Contact Point in relation to ECURIE system is organized under the General Inspectorate for Emergencies. CNCAN is the National Contact Point in relation with IAEA, in respect with the provisions of IAEA

Conventions for Early Notification and Assistance (Law No.111/1996 amended in 2003 and IAEA letter EPR/CP(0100) from 16/11/2000), with the following functions (as defined in ENATOM, 2000):

- National Warning Point;
- National Competent Authority for a Domestic Accident;
- National Competent Authority for an Accident Abroad.

Both National Contact Points act on a 24-hour basis, for receiving / sending notifications inside the country. The information flow in between the two National Contact Points is coordinated through the Protocol of collaboration of CNCAN and IGSU (No.9120/V.Z./05.06.2006).

All types of events at nuclear installations or sites using radioactive sources, radiological emergencies with radioactive sources and/or scrap metal processors and/or at borders, transport accidents with radioactive sources and/or materials are notified at CNCAN-ERC. The notification system is established in the Emergency Plans of the authorization holders and public authorities. Exercises and communication tests are performed between the operative centres of the National System. CNCAN-ERC is testing every week the communication lines with Cernavoda NPP Units 1 and Unit 2 by using pre-defined forms. With international organizations and neighboring countries, the testing of communication lines is performed irregular, mainly before having national / international exercises.

In case of a nuclear incident / accident at a nuclear facility, the response actions should begin without any delay and be coordinated from the beginning. To facilitate this, an event classification system is established by the On-Site Emergency Intervention Plan of each nuclear installation, in order to predefine the response actions for each emergency class. The events are classified on the basis of the actual or potential consequences for the public, environment, personnel and property. In case of radiation emergencies with off-site effects, the operator is responsible for initiating notification of the public authorities and for elaborating first recommendations on protective actions for the population in the affected area.

The emergency notifications are sent by the Regulatory Body to the General Inspectorate for Emergencies, through the operative centre established in Central Commission of Experts (CANUR).

The notifications are received / sent by fax. Procedures are in place at CNCAN-ERC for sending / receiving notifications. Additional to fax, the ENAC web site of IAEA is used for sending notifications to the international organizations and foreign countries with which Romania has agreed bilateral treaties for early notification in case of nuclear or radiological emergency.

A special Procedure MC-PP-MU-CU 01 (revision 11) "Working procedure at the National Contact Point of CNCAN-ERC" has been developed".

In case of radiation emergencies with off-site effects, Cernavoda NPP is responsible for notifying the public authorities and making recommendations on protective measures for the population.

In all phases of an emergency, notification forms are sent by fax to CNCAN-ERC and to public authorities involved in the intervention off-site, as follows:

- "Radiation Emergency Notification" form, sent as soon as possible after the declaration of the incident;
- the "Source Term Description" form is used only if the containment is boxed-up; the form is sent when enough data are available and, after this, each hour or when situation changes;
- the "Radiological Information" form is sent when a radiological release from the containment is in progress and data from the stack and/or from the On-site/Off-site Monitoring Team are available;

after that, it is sent each hour or when the situation changes;

- the “Radiation Emergency Termination” form is sent when the Emergency Manager declare the termination of the emergency.

The Regulatory Body has in place a system for activating its own emergency organization (Procedures code MC-PP-MU-CU 03). Decision on activating the emergency organization is taken by CNCAN President. There are two levels of activation:

- partial activation – usually in radiological emergencies, when the mobile team of CNCAN has to go to the affected area;
- full activation – when it is a significant accident at a nuclear installation; the full activation in such cases might start with a partial activation, depending on the emergency situation.

In present, CNCAN-ERC is operated on a 24/7 basis by CNCAN staff of Section for Radiation Emergencies (3 persons) in collaboration with the personnel operating the Environmental Radioactivity Station belonging to the Bucharest Environmental Protection Agency. CNCAN staff is operating the CNCAN-ERC during office hours. Based on a common Agreement between CNCAN and Bucharest Environmental Protection Agency, for the rest of the time, the notifications are received by the personnel of the Environmental Radioactivity Station which is functioning inside the CNCAN-ERC. As modifications in the program of Environmental Radioactivity Station are envisaged for the near future, CNCAN may not be able to provide appropriate staffing for this important function on a 24/7 basis. CNCAN should consider these probability and for example implementation an on-call system coordinated by the staff of the Section for Radiation Emergencies.

#### **10.1.5. MITIGATORY ACTION**

According to the current legislation CNCAN has responsibilities to support public authority with technical expertise in radiation protection and nuclear safety matters (MO No.242, Article 10).

A Protocol is in place between the General Inspectorate for Emergency Situations (IGSU) and CNCAN for cooperation and technical support in case of radiation emergencies. At local level, according to the same protocol CNCAN inspectors are supporting with technical expertise the representatives of County Inspectorates for Emergency Situations.

The County Emergency Plans for Radiological Accidents, elaborated in the last years, specify the way to obtain expertise and services in radiation protection field, at local level, in a timely manner. CNCAN provides examples of incidents and accidents, and copies of new regulations for the training materials for all persons undergoing examinations for work permits (renewed every 5 years). Training, exercises and equipment are still necessary at local level.

When situation impose, CNCAN inspectors are coming at the place of the accident for radiological investigations. Arrangements are in place between CNCAN and the General Inspectorate for Emergency Situations (No.9120/V.Z./05.06.2006) and between CNCAN and General Inspectorate of Romanian Police (No.1195/V.B./11.03.2010) for intervention in case of any radiation emergency.

#### **10.1.6. TAKING URGENT PROTECTIVE ACTION**

Generic intervention levels (GIL) are defined in the current legislation (Ministerial Order No.242/1993 “Nuclear safety republican regulations on the planning, preparedness and intervention in case of nuclear or radiological emergencies”, which is under revision). After the revision of the above mentioned regulation CNCAN proposals regarding new GILs will be subject to the analysis of public authorities, inside the National System for the Management of Emergencies.

In order to take protective actions for the affected population at national level is established the National Centre for Intervention Co-ordination in case of a nuclear or radiological emergency (CNCCI), where representatives of central public authorities are activated in case of an emergency. In case of a severe nuclear accident within the National Centre is functioning a Central Commission of Experts (CANUR) that has the responsibility of assessing the emergency and give technical recommendations to national decision makers. The Regulatory Body is involved in formulation of recommendations for urgent protective actions off the site. One main role of CNCAN - ERC is to deliver, in case of a radiation emergency, recommendations for protective actions for the population to CANUR and to the national decision makers from CNCCI.

According to the Emergency Response Plan provisions (code MC-PP-MU 001 Revision 2/2011), at CNCAN - ERC a *Radiological Consequences Assessment Group* is acting in case of a full activation of the emergency organization. The Group is responsible to make dose assessments and to deliver recommendations for urgent protective actions to the population. The recommendations are sent to CANUR, where they are analyzed and commonly agreed by all experts and then sent to CNCCI where the decision is taken at national level.

### **10.1.7. PROTECTING EMERGENCY WORKERS**

Dose levels for the emergency workers are already established in MO No.242 (Articles 102 and 103). New provisions (generic action levels for the intervention personnel) will be adopted when MO No.242/1993 will be revised, accordingly with the international recommendations. In the revision of MO No.242/1993, additional dose levels will be proposed by CNCAN and adopted after consultations with IGSU and the organizations belonging to the National System for the Management of Emergencies.

In the specific regulation MO No.242/1993, “Nuclear safety republican regulations on the planning, preparedness and intervention in case of nuclear or radiological emergencies” there are provisions related to the dose limits for workers in intervention (off-site):

- for the emergency workers shall be applied the dose limits for occupational exposure;
- in special situations for life saving actions and in actions performed to prevent or stop the development of catastrophic conditions in installation there is stipulated that “the exposure of emergency workers could be above the occupational dose limits, but shall be kept below the thresholds for deterministic effects”.

On the site, under emergency situations, all possible efforts are made to keep the emergency exposures of the intervention personnel below the legal dose limit of 20mSv/y. It is allowed to exceed the legal dose limit in the following situations: saving life or preventing serious injury, averting a large collective dose or preventing the development of catastrophic conditions. For these situations, the Emergency Manager approves the dose exceeding. All reasonable efforts will be made to keep doses below 100mSv, except for life saving actions, in which the dose limit is 500mSv. Workers who undertake actions in which the dose may exceed the maximum single year dose limit shall be volunteers, clearly and comprehensively informed in advance about the associated health risk and as much as possible, trained in the actions that might be required.

CNCAN is responsible for managing the doses received by its own personnel in intervention and for maintaining the registry for all occupationally exposed personnel involved in authorized practices. For other emergency workers the responsible organization is Ministry of Health.

### **10.1.8. ASSESSING THE INITIAL PHASE**

No Operational Intervention Levels (OILs) are established at national level. Nevertheless, according to the MO No.242/1993 provisions, under the emergency intervention plans, optimized intervention levels

shall be established, based on particular locations and circumstances of each nuclear installation, taking into consideration radiological factors, as well as financial and socio-economical factors.

OIL's are established for Cernavoda NPP under the On-site Intervention Plans, in terms of measured values of measurable quantities (dose rates, activity concentrations, etc.). The model and hypotheses used to derive this OIL's are described under the On Site Intervention Plan. In the first phase of the emergency, the NPP decides on protective actions by comparing the measured dose rates with the OIL's calculated during the emergency planning process. After the information about the emergency conditions and about the source term released into environment becomes available, some OIL's are recalculated, according to specific health physics procedures. Then, protective actions are established comparing the measured dose rates with the new values of the OIL's.

### Conclusion

At national level, as the Regulatory Body has responsibilities to adopt regulations in the field of emergency preparedness and response, then the adoption of OIL's which are to be used in the initial phase of a radiation emergency should be part of this process. Therefore, OIL's will be adopted at national level when MO No.242 will be revised.

In order to support to local officials and first responders during the initial phase of a radiation emergency, CNCAN participates in radiological investigations with the mobile team, composed of CNCAN inspectors in territory and personnel from CNCAN headquarters.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-2, Requirement 3.4 states that *“Legislation shall be adopted to allocate clearly the responsibilities for preparedness and response for a nuclear or radiological emergency and for meeting the requirements established in this Safety Requirements publication.”*

R32 **Recommendation:** CNCAN should update ministerial order No.242/1993 and implement it in accordance with the requirements of GS-R-2.

### 10.1.9. KEEPING THE PUBLIC INFORMED

According to the current legislation CNCAN has the responsibility to provide information to the public in radiation emergencies (MO No.242, Article 10). At national level, the information includes aspects regarding the status of the nuclear / radiological facility and to the status of planning / implementing the protective actions for population. The Public Information Officer of CNCAN has to deliver the information to the Public Information Group at CNCCI, in order to have joint press releases and instructions to the public.

The On-site Radiation Emergency Plan of the operator and the Off-site Radiation Emergency Plans of the public authorities establish the responsibilities, the resources and the interfaces required for informing the public in case of a nuclear emergency. Joint information centres, staffed by representatives of the nuclear facility and of the public authorities, are established at the local and national levels. At local level, the information includes instructions and warnings for the population in the affected area.

CNSU at national level and the County Committees for Emergencies at local level are responsible to give instructions and information to the public. The local and national TV and mass-media are used to keep the public informed about the accidental radiological event.

CNCAN and also the operator have the responsibility to support the public authorities in informing the public with accurate, timely and comprehensive information regarding the emergency. CNCAN and the

operator have representatives at national level in CNSU and at local level in the County Committees for Emergencies. In this respect during an emergency the link between NPP and the public authorities is ensured through the Cernavoda NPP representatives at Local (in Cernavoda town) and County (in Constanta town) Committees for Emergencies as member of these committees. From these structures, Cernavoda NPP Public Relations Officers will ensure accurate and reliable technical information, in a timely manner, for the mass-media and population.

According to its specific role in informing the public during radiation emergencies, CNCAN should enhance its own capabilities for public information in general (in routine conditions also, not only in emergencies). Specific public information procedures should be in place at CNCAN – ERC for emergency situations. The general requirements for developing specific procedures are included in section 4 under ‘Management System of the Regulatory Body’.

#### **10.1.10. TAKING LONG TERM PROTECTIVE ACTIONS**

As national competent authority, CNCAN is responsible for recommending long term protective actions based on measurements in the affected area and based on plant status.

In the post-accidental phase CNCAN retains the responsibility for ensuring that the NPP licensee appropriately initiates actions to recover the nuclear installation, the resuming of operating activities or the decommissioning, as appropriate (MO No.242, Article 10). In addition, regarding radiation protection aspects, CNCAN has to monitor the radiation levels in the environment, to assess the long term exposure to radiation for the population, and to recommend protective and follow-up actions.

CNCAN has also responsibilities for controlling the safe and effective management of radioactive waste resulting from an emergency. CNCAN requires and verifies the management and the handover of the radioactive waste resulting from an emergency to a facility authorized for radioactive waste management.

Current provisions are stipulated in MO No.242/1993 for taking long-term protective actions. Generic action levels for foodstuffs are established. These levels are in compliance with the levels recommended by IAEA. Provisions are stipulated in the National Intervention Plan for Cernavoda NPP and also in the County Intervention Plan for Dolj – Bechet area in relation to the implementation of long-term protective actions.

#### **10.1.11. CONDUCTING RECOVERY OPERATIONS**

CNCAN supports the local and/or national officials in the recovery phase for removal of restrictions and return to normal conditions in the affected area.

As mentioned CNCAN has the responsibility to advice the national officials after the ending of emergency, for recovery actions in order to return to normal conditions in the affected area, with recommendations in the field of competence: nuclear safety and radiation protection matters.

#### **10.1.12. ORGANIZATION**

##### **Routine Organizational framework**

CNCAN ERC is organized in conformity with the approved “Strategy for CNCAN emergency response centre” (PHARE Project RO/RA/02 “Transfer of western European methodology to the nuclear safety authority of Romania”) and CNCAN President Order No.209/24.06.2004.

Currently CNCAN – ERC is operated and maintained by the personnel acting in the Section for Radiation Emergencies, subordinated to the Division for Nuclear Fuel Cycle, which is under the General Division for Regulation, Authorization and Control of Nuclear Activities. Section for Radiation Emergencies has 3 full-time staff (1 physicist, 1 chemist and one IT expert) which has responsibilities for preparedness and planning activities of CNCAN for radiation emergencies.

Because of lack of human resources in Section of Radiation Emergencies, the routine monitoring activities have been slowly stopped starting with 2008, as well as the planning and training activities suffered in last years.

### **Emergency Organization**

The emergency organization of CNCAN was established in 2005, and is part of the Emergency Plan of CNCAN for radiation emergencies (code MC-PP-MU 001 Revision 2/2011). The emergency organization of CNCAN acts during emergencies at CNCAN -ERC. CNCAN - ERC is part of the National System for the Management of Emergencies. CNCAN - ERC is connected to other important centres of the National System: CANUR, CNCCI, NPP-ERC.

The emergency response organization of CNCAN is structured in dedicated groups, performing the following tasks:

- Management Group;
- Secretariat;
- Communications Group (National Contact Point including CNCAN Notification Team);
- Nuclear Safety Assessment Group (including a Nuclear Security component);
- Radiological Assessment Group (including CNCAN Intervention Unit and Laboratory Measurements);
- Technical (Logistic Support) Group and
- Public Information Officer.

During a radiation emergency, the main duties of CNCAN - ERC are the followings:

- notify an emergency to national and international organizations;
- create, update and disseminate information inside the country and outside (through IAEA and bilateral partner States) on the overall view of the safety state of the nuclear installation / radiological facility and on the radiological situation;
- technical assess and advise the national decision makers on the safety state of the nuclear installation / radiological facility;
- technically advise and supervise the public authorities and the licensees on nuclear/ radiological safety issues;
- provide advice to licensees, as necessary, on additional steps to be taken to mitigate the consequences of the accident and avoid harm to the public and the environment;
- recommend to national decision makers the protective actions for the population in case of an emergency;
- participate, in radiological emergencies (transport accidents, loss of a dangerous radioactive source, recovery of an orphan source) with the mobile team, performing environmental monitoring and radiological investigations at the affected location;
- assess and advise the national decision makers on the appropriate information which are to be distributed to the media and the general public for accurate, timely and comprehensive information regarding the emergency;



- assess and advise national decision makers on the appropriate long term post-emergency protective actions;
- advice for protective measures for industry, trade, traffic and customs.

The CNCAN ERC organization has been recently revised and a “command and control” style has been adopted, in accordance with European recommendations obtained by CNCAN under the framework of PHARE Project 5812.06.01 “Technical Assistance for the Romanian Regulatory Emergency Centre”. A Strategy for the operation of CNCAN – ERC has been adopted by CNCAN President after the completion of the PHARE Project (Order No.93/29.02.2008). The “command and control” unit includes now the following posts:

- Emergency Controller;
- Assistant to the Emergency Controller;
- Head of Nuclear Safety Assessment;
- Head of Radiological Assessment;
- Head of Communications;
- Public Information Officer.

The Head of Nuclear Safety Assessment, Head of Radiological Assessment and Head of Communications are each supported by the corresponding Group and the Assistant to the Emergency Controller provides the principal interface with the Technical (Logistic Support) Group. A nuclear security component within the nuclear safety assessment group is considered, when appropriate.

### **Conclusion**

The entire resources of CNCAN which are available are activated in the event of an emergency to ensure that decisions are made from a wide spectrum of experts, and to afford relief from fatigue for the “duty” emergency team members. Nevertheless, because of lack of human resources, CNCAN has not assigned sufficient qualified personnel in each position of the emergency organization.

### **10.1.13. PLANS AND PROCEDURES**

The Regulatory Body has its own emergency plan "Emergency Response Plan of CNCAN for radiation emergencies", code MC-PP-MU 001, Revision 2/2011. The "Emergency Response Plan of CNCAN for radiation emergencies" includes 5 chapters:

- Introduction - with Scope, Purpose, Legislative framework and Relation with other plans;
- Planning basis - with dangers and risks, roles and responsibilities at national level, CNCAN's roles and responsibilities, CNCAN emergency organization, human and material resources for emergency situations;
- CNCAN response in radiation emergencies;
- Planning and preparedness for radiation emergencies;
- National and international cooperation in EPR field.

Procedures, tools and computer programs are in place for performing dose assessments in accidental events: RASCAL 4.0, HOTSPOT, RODOS (installed at the beginning of 2011). A software is under development with the contribution of BMU and BfS Germany for the management of all information

received / sent inside the National System in case of a radiation emergency - ELAN - E for Romania ("Electronic Situation Display for Radiation Emergencies").

A software application is developed by Cernavoda NPP for the transmission in real time of all technical parameters of the plant to the CNCAN – ERC. The parameters will be used by CNCAN experts for making nuclear safety analysis in emergency situations.

### Conclusion

The Regulatory Body has the necessary procedures, analytical tools and computer programs in order to be able to perform the response functions during an emergency. Although procedures, analytical tools and computer programs are in place in order to perform the response functions during an emergency, there is still a need for developing new procedures, tools and computer programs for nuclear safety analysis and radiation protection assessments. The general requirements for developing specific procedures are included in section 4 under ‘Management System of the Regulatory Body’.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(1) <b>BASIS:</b> GS-R-2, Requirement 5.25 states that <i>“Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation ... shall be provided for performing the functions specified in Section 4<sup>78</sup>. .... These support items shall be located or provided in a manner that allows their effective use under postulated emergency conditions.”</i>
S12	<b>Suggestion:</b> CNCAN should consider the finalization of the implementation of common software platform for data and information exchange during emergencies (ELAN system) and maintain the system operational in CNCAN–ERC.
S13	<b>Suggestion:</b> CNCAN should consider the completion of the development of the software application for data transmission from Cernavoda NPP to the CNCAN-ERC and maintain it in proper conditions to be used in exercises and real situations.
G1	<b>Good Practice:</b> CNCAN’s involvement in the development of a common software platform for data and information exchange during emergencies.

### 10.1.14. LOGISTICAL SUPPORT AND FACILITIES

CNCAN has three different locations where personnel of the organization are working. One of the CNCAN locations hosts the Emergency Response Centre in Afumati, Bucharest. With respect to this requirement, the Regulatory Body has adequate facilities for performing the assigned response functions.

Following implementation of the PHARE Project RO 5812.06.01 “Technical Assistance for the Romanian Regulatory Emergency Centre” (2005 – 2007), the ERC has the following facilities:

- Guaranteed electrical supplies (including on-site Diesel Generator and Uninterruptible Power Supply for computer equipment);
- Emergency lighting and access control equipment;
- Computer hardware and software and associated peripheral;
- Laboratory equipment for radioactivity analysis;
- Field equipment (portable dosimeters RADIAGEM 2000, Eberline, Automess, portable spectrometers Inspector 1000, HPGe detector, Rn monitor);

- Communication equipment;
- Various diagnostic aids and other equipment;
- An equipped Intervention Mobile Laboratory.

Although communications means are in place, there is still a need for developing and improving the communication system (video conference system for example).

A variety of communication channels is used at CNCAN - ERC: terrestrial telephone / fax lines, GSM telephone / fax lines, satellite telephone / fax lines. Internet availability is continuously assured by employing two providers using different infrastructure types at a constant available high speed bandwidth.

New developments are under progress for connecting CNCAN - ERC and the other facilities of CNCAN at the national special infrastructure created and maintained by the Romanian Special Telecommunications Service.

Service agreements are in place for maintaining the communications systems, and for maintaining the IT capabilities at CNCAN. CNCAN has also few employees responsible for maintaining the IT equipment at CNCAN, and, respectively, at CNCAN Emergency Response Centre.

The personnel of Section for Radiation Emergencies is responsible for CNCAN - ERC maintenance and for emergency preparedness and planning activities (preparation of emergency plans, training of post-holders, ensuring the readiness of the ERC, maintaining the ERC facilities). Constant efforts should be put to maintain all facilities / equipment / tools and to develop the logistics at CNCAN - ERC

#### **10.1.15. TRAINING, DRILLS AND EXERCISES**

The training of personnel is performed by the current staff of Section for Radiation Emergencies in CNCAN. The training is irregular and intensive usually before conducting national or international exercises. Nevertheless, specific training for different positions in the emergency organization has been conducted in last years in the field of radiation measurements, source identification, first responders and medical response in radiation emergencies. Specific training is scheduled for the beginning of 2011 in the field of public information and expanded response in radiation emergencies.

Once in a few years, all the responsible organizations participate in the national large scale exercises organized by IGSU-MAI. The frequency of the training and exercises became constant in the last 3 – 4 years with at least one per year major international exercise and one major national exercise being organized by CNCAN in partnership with national and international institutions.

For Cernavoda NPP general exercises are organized by the operator in collaboration with the local and national public authorities every 3 years, and include mobilization of the emergency personnel and the appropriate resources and organizations in order to verify the response capability for an accident scenario (on-site and off-site).

For the influence area of Kozloduy NPP, IGSU-MAI is responsible with the organization of national exercises, with a periodicity of maximum 5 years.

CNCAN staff has participated in and continues to participate in numerous national and international training activities and emergency preparedness exercises.

The exercises are followed by a post-exercise report (Exercise Evaluation Report) in order to evaluate the ability of the various organizations involved and to recommend measures for improving the response.

## Conclusion

There is no specific internal exercise program in place for testing CNCAN staff for their role in the emergency organization. Nevertheless, CNCAN personnel have been tested in last years in national and international exercises. The training of CNCAN staff is tested also in the preparation and participation to yearly exercises organized by the major nuclear installations in Romania.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-2, Requirement 5.33 states that *“Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals<sup>84, 85</sup> ...”*

R33 **Recommendation:** CNCAN should develop and implement internal training and exercise program for the personnel with assigned responsibilities in the emergency organization.

#### 10.1.16. QUALITY ASSURANCE PROGRAMME

A quality management program is in place in CNCAN. Procedures, equipment, services are considered in the quality management program of CNCAN.

All arrangements that have an impact on the quality of products and services offered, both in preparedness and response are in accordance with the relevant standard ISO9001. It is the responsibility of the permanent staff of CNCAN - ERC to perform evaluations and improve the systems used at the ERC location. The systems are evaluated, reviewed and, if necessary, revised after every response (exercise) which lasts for more than one working day.

Every exercise is evaluated at the end. Feedback and results from training activities and exercises are considered and used for making improvements and developments at CNCAN - ERC.

#### 10.2. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISK

A system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events is in place in Romania, in accordance with current legislative provisions. The system is consistent with the principles of justification and optimization in radiation protection, as being part of the National System for the Management of Emergencies.

Concerning intervention mechanisms (including request of assistance), same legislative framework applies to the management of radiation emergencies arising from facilities and activities which are under the control of the Regulatory Body and to any other emergencies that might produce unacceptable radiation risks as a consequence of an accident, a discontinued practice, or inadequate control over a radioactive source or a natural source which is not under the control of the Regulatory Body.

Concerning planning mechanisms, some specific regulations are in place for imposing regulatory control over protective actions in situations arising from non-nuclear practices. Two main activities are envisaged by CNCAN in this area: radiation monitoring of scrap metal during the reprocessing cycle in order to search for and secure orphan sources and the use and impact of NORM activities in the country.

A regulation has been issued in 2010 containing specific requirements and criteria for protective actions for authorities, facilities and stakeholders having activities in the reprocessing cycle of scrap metal. The “Regulation on radiation monitoring of scrap metal during the reprocessing cycle” has been issued by

common Order of CNCAN President (No.89/08.04.2010), Minister of Administration and Interior (No.117/19.05.2010) and President of National Authority of Customs (No.21.707/14.04.2010). For issuing the regulation, CNCAN collaborated with all other responsible authorities and with stakeholders in the field of reprocessing of scrap metal.

If necessary, special restrictions are prescribed by CNCAN, proportionally with the exposure risk involved the following measures (Article 129 form the NSR-01):

- a) demarcation of the interest perimeter;
- b) assurance of a system of exposure monitoring;
- c) assurance of an corresponding intervention measures, taking account of the real characteristics of the situation;
- d) regulation of the use of the lands or the buildings situated in the delimited perimeter, as well as of the access in that interior.

### Conclusion

Concerning intervention mechanisms (including request of assistance), same legislative framework applies to the management of radiation emergencies arising from facilities and activities which are under the control of the Regulatory Body and to any other emergencies that might produce unacceptable radiation risks as a consequence of an accident. CNCAN should consider finalizing the regulation on radiological safety of working activities involving enhanced natural radioactive material

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-Part 1, Requirement 2.25 states that *“Radiation risks may arise in situations other than in facilities and activities that are in compliance with regulatory control. In such situations, if the radiation risks are relatively high, consideration shall be given to whether protective actions can reasonably be taken to reduce radiation exposures and to remediate adverse conditions...”*

S14 **Suggestion:** CNCAN should consider finalizing the regulation on radiological safety of working activities involving enhanced natural radioactive material.

## 11. TRANSPORT OF RADIOACTIVE MATERIAL

### 11.1. INTRODUCTION AND BACKGROUND

The transport of radioactive material in Romania is well established and a legislative infrastructure is in place to protect people and the environment. The main categories of radioactive materials transported in Romania are: a) radioactive waste, treated, packaged and transported to the National Repository, Baita b) uranium ore from the Crucea Mine to the Processing Uranium Ore Plant, Feldioara; c) uranium concentrate from Feldioara to the CANDU Nuclear Fuel Plant, Pitesti; d) fresh CANDU nuclear fuel from Pitesti to the NPP CANDU Cernavoda; e) spent nuclear fuel (SNF) from NPP Kozloduy (Bulgaria) to Ukraine (Russian Federation) and WWER fresh nuclear fuel from Russian Federation to Kozloduy NPP (Bulgaria), via the River Danube, trans-boundary transport; f) radioactive sources used for industrial purposes for example in irradiation facilities, industrial radiography, well-logging and in portable gauges ; g) radioactive sources used in nuclear medicine facilities (diagnostic and therapeutic) and for educational and research purposes.

The activity of the radioactive sources ranges from very low quantities to large quantities which are shipped by various modes of transport, i.e. road, rail, air (no internal flights), and inland waterways (Danube River). There has been no transport by sea and none is scheduled in the near future. Radioactive material is shipped in excepted packages, industrial packages, Type A packages and Type B packages which are of Romanian or external origin.

The National Commission for Nuclear Activities Control - CNCAN (Comisia Nationala pentru Controlul Activitatilor Nucleare) - is the nuclear safety authority of Romania, responsible for the regulation, licensing and control of nuclear activities, ensuring the peaceful use of nuclear energy and the protection of the 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, as part of the National Strategy for the development of the nuclear sector. CNCAN reports to the Prime Minister, through the General Secretary of the Government.

The work of the CNAN in the area of transport of radioactive material among other items includes the assessment of applications and the associated technical documentation for licensing, assessment of applications and associated technical documentation for issuing of type approval certificates for packages type B(U), B(M) and fissile material, verification and validation of type approval certificates for different package types (Type B(M), Type C and fissile material), inspection of facilities and enforcement as required.

The review undertaken for transport safety as part of this IRRS mission was based upon the information provided by CNAN staff through the IAEA Self Assessment Tool, presentations, reports, interactions, discussions and visits to representative facilities. It is a follow-up mission to a previous IRRS mission held in January 2006 where transport was also included in the scope.

### 11.2. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES IN TRANSPORT

A comprehensive and sound legislative/governmental regulatory structure clearly exists defining the responsibilities of CNCAN in regulating the safe transport of radioactive material in Romania.

CNCAN 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.

The principal regulations for the safe transport of radioactive material in Romania are:

- Law No. 111/1996 which is the fundamental law regarding the safe deployment of nuclear activities; and Order No. 357/ 2005 published in the Official Bulletin of Romania No. 1152 of 20December 2005 (NTR-01) approving the Norms on the transport of radioactive materials.
- Order No. 443/2008 published in the Official Bulletin of Romania No.797 of 27 November 2008 (NDR-06) approving the Norms on the supervision and control of international shipments of radioactive waste and spent fuel involving the Romanian territory.

This norm applies to the transport of radioactive materials by all transport modes: on road, water and in the air and which involve radioactive materials, including transport which is incidental to the use of the radioactive material. Transport comprises all operations and conditions associated with and involved in the movement of radioactive material. These include the design, manufacture, maintenance and repair of packaging, the preparation, handling, loading, shipment, transport including temporary storage, unloading and receipt at the final destination of radioactive material and packages. Romania has legally adopted the various conventions and thereby the corresponding modal agreements for the safe transport of dangerous goods (ADR, RID, ICAO-TI, and the IMDG-Code). The Standard document for the shipment of sealed sources between Member States of the European Union pursuant to Council Regulation No. 1493/93 is also used in practice. There is also evidence that there is co-operation regarding regulator to regulator consent for the shipment of IAEA Category 1 and 2 sources under the IAEA Code of Conduct for the shipment of these sources. The European Directive 2006/117 Euratom on shipment of radioactive waste and spent fuel is also applied in practice.

Noting recommendation R62 from the IRRS Mission 2006 that the cooperation with the Ministry of Transport and Infrastructure should be enhanced and formalized it acknowledged that steps to enhance the co-operation with the Ministry of Transport, Buildings and Tourism have been initiated by CNCAN.

## Conclusion

Based on a review on the information provided, the legislative and statutory framework established to regulate the transport of radioactive material is comprehensive and covers the relevant modes of transport.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 1 Section 2, 2.18 states that *“The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: safety in the transport of dangerous goods, including nuclear material and radioactive material.”*

R34 **Recommendation:** CNCAN should enhance and rejuvenate co-operation with the Ministry of Transport and Infrastructure at the highest level.

### 11.3. REGULATORY BODY RESPONSIBILITIES AND FUNCTIONS

For an introduction to the regulatory body responsibilities and functions, please refer to section 1.3 and section 3.0 of this report. Radiological safety standards applicable to the transport of radioactive material in the State are issued by CNCAN, in accordance with the provisions set in Article 5 of the Law. CNCAN is responsible for the publication and periodic revision of national regulations for safe transport of

radioactive material. National regulations are revised and updated in consultation with relevant stakeholders as appropriate, when the international regulations (TS-R-1) are revised.

CNCAN is responsible for assuring compliance with the regulations for safe transport of radioactive material. The compliance assurance programme developed and implemented includes:

- the assessment of technical documentation in order to issue the validation of the type approval certificate for a particular package design
- the assessment of technical documentation and the inspection of the design and testing of the packages in order to issue the type approval certificate
- the assessment of technical documentation and inspections in order to issue the transport authorization
- the assessment of technical documentation and inspections in order to issue shipment certificates
- the assessment of technical documentation and inspections in order to issue the shipment certificate for special arrangements
- the assessment of technical documentation and inspections in order to approve the radiation protection programme for special use vessels

The key functions of CNCAN includes the issue of approvals required in TS-R- 1 (2005) and the inspection of premises and conveyances associated with the safe transport of radioactive material.

In the area of international cooperation and exchange of information, CNCAN maintains relations with a number of nuclear regulatory authorities and organisations worldwide, through bilateral arrangements and commitments under international conventions in the nuclear field. The international activities in which CNCAN is involved include the participation in the activities of WENRA and its technical working groups, the annual meetings of the Senior Regulators from countries that operate CANDU NPPs, the biannual meetings of the European High Level Group on Nuclear Safety and Waste Management (ENSREG) and its working groups, the contribution to the initiatives at European Union level and the participation in various IAEA activities. CNCAN also participates, as observer, in the annual session of the Nuclear Law Committee (NLC) of the NEA/OECD (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development). Since 2010, CNCAN has been accepted as an observer in the CNRA (Committee of Nuclear Regulatory Activities) and CSNI (Committee on the Safety of Nuclear Installations) committees of NEA/OECD.

CNCAN liaises with regulatory bodies in other countries and takes part in the meetings of the European Association of Competent Authorities for the Safe Transport of Radioactive Material. Experts from Romania have also attended IAEA TRANSSC meetings in the past and this should be continued. There are general collaborations between CNCAN and similar bodies of other countries particularly the Russian Federation that also affect the activities carried out by CNCAN regarding transport. There are no exclusive formal agreements on transport-related subjects. Nevertheless, CNCAN has collaborated in a case-by-case basis with the regulatory bodies of other countries in transport package approval processes.

A review of NTR-01 indicates that the practical methodologies/guidance is available in the annex; however no supporting guidance documents are available or have been adopted with respect to the transport of radioactive material.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 1, Section 4, Paragraph 4.61 states that *“The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides.”*



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S15 **Suggestion:** CNCAN should consider adopting international best practice safety guidance relating to the transport of radioactive material.

### 11.4. ORGANIZATION OF THE REGULATORY BODY

For detailed information on the organizational structure of the regulatory body and allocation of resources, reference should be made to section 3.1 of this report. The staff members working on transport of radioactive material are in the Unit (compartment) for Radiological Protection and Radioactive Waste Management (one staff member) (duties relate to fresh and spent fuel, high activity sealed radioactive sources and carriers) and in the Unit for Safeguards, Transport and Physical Protection (one staff member)(mining), both of which are part of the Nuclear Fuel Cycle Division. This Division is one of three Divisions part of the General Division for the Regulation, Licensing and Inspection of Nuclear Activities. There are two staff members covering transport (industrial, medical, and many other responsibilities) in the Radiological installations and source Licensing/ inspection Division. Recommendation R63 from the IRRS Mission 2006 ‘CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team’. It was also reported that currently the resources for transport of radioactive and nuclear material are considered appropriate. The proposed suggestion in this area has been incorporated in the general recommendation on resources in section 3.1.

### 11.5. AUTHORIZATION PROCESS, REVIEW AND ASSESSMENT

The licensing system is administered by CNCAN in cooperation with other governmental authorities (ministries and agencies) in such areas as environment, health, transport, labour, security, etc. The issues raised by these authorities are taken into account before licenses are issued by CNCAN, providing that there is no conflict with the provisions of the Law and CNCAN regulations. All other licenses granted by other governmental authorities are prerequisites to the CNCAN licenses. An exception would be the environmental authorisation issued by the Ministry of Environment and Forests after the issuance of the operation license by CNCAN. The environmental agreement, issued by the same Ministry is however a prerequisite to the siting license issued by CNCAN.

The Law gives a list of authorities having attributions in controlling various aspects related to nuclear activities. Although their attributions and responsibilities are established by the legislation, CNCAN has also signed formal Memoranda of Understanding with each of these organisations, for ensuring the prevention of potential gaps and overlaps in the implementation of their respective duties and responsibilities. For ensuring transparency of its activities and decision making process, CNCAN routinely consults with and ensures information of all the organisations that have an interest in its regulatory activities, including licensees and other nuclear industry representatives, governmental, local and municipal authorities, departments and agencies as well as interest groups and individual members of the public.

The approval/authorisation requirements for transport activities are clearly specified in Chapter VIII of Order No 357/ 2005 (NTR-01). General provisions are outlined in Article 801, 802 and 803. CNCAN approval / authorization is required for the following:

- a) The transport activity for the radioactive materials (see Articles 804, 805, 806)
- b) Designs for:

- i. Special form radioactive material (Articles 807, 808 and 818);
  - ii. low dispersible radioactive material (Articles 807 & 808);
  - iii. packages containing 0.1 kg or more of uranium hexafluoride (see Articles 810, 811)
  - iv. all packages containing fissile material unless excepted by para. 672 (see Articles 813, 816, 817, 820)
  - v. Type B(U) packages and Type B(M) packages (see Articles 810, 813, 816, 817, 820)
  - vi. Type C packages (see Article 812);
- c) Special arrangements (see Articles 822-823)
  - d) Certain shipment of radioactive materials (see Articles 820, 821)
  - e) Radiation protection programme for special use vessels (see Article 575 a))
  - f) Calculation of radionuclide values that are not listed in Table I (see Article 402).

The request for approvals/authorizations to CNCAN is undertaken in accordance with the provisions included in Annex No. 2 to norm NTR-01. CNCAN issues five types of approval certificates: for special form radioactive material, for low dispersible radioactive material, for special arrangement, shipment and package design. It also indicates in the package design approval certificate that the design meets the specific requirements and gives it an identification mark according to Article 825.

A detailed authorization methodology of the transport activity is provided in Annex No 2 of NTR-01. These articles present what information is required to be submitted to CNCAN and in what format. Details of the technical documentation and specific information required for various scenarios (for example, special arrangements, package design, shipment authorization, re-authorization or extension of validity etc) are also presented.

Guidelines on the content of the transport authorization and of approval certificates are provided in Annex No. 3 of NTR-01. This includes specific details of what each authorization includes, for example, identification mark, list of regulations, date of entry into force and expiry, conditions imposed and any potential restrictions on modes of transport, personnel with responsibilities, UN numbers, design specifications etc.

The authorization process as outlined essentially reflects the IAEA Regulations for the Safe Transport of Radioactive Material. It is clear that the requirements and controls for transport as specified in NTR-01 generally reflect the requirements specified in the relevant provisions of the IAEA TS-R-1.

Based on the information provided, the review and assessment process of the regulatory body to regulate the transport of radioactive material is in general satisfactory. Any suggestions other than those presented have been incorporated into sections 5.1 and 6.1 of this report.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** TS-R-1 2009 Edition, 308 states that *“The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards.”*

S16 **Suggestion:** CNCAN should consider performing a periodic assessment of the radiation doses received by persons involved in the transport of radioactive material, to ensure that the system

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

of protection and safety complies with the provisions within the Fundamental Norms on Radiological Safety and of the applicable relevant norms on nuclear safety as well as the IAEA TS-R-1.

### 11.6. INSPECTION AND ENFORCEMENT

For background information on inspection and enforcement, refer to section 7.1 and 8.1.

The transport related inspections performed by CNCAN include:

- Scheduled inspections, planned and performed either by each of the technical divisions;
- Pre-authorization / licensing inspections;
- unscheduled and/or unannounced inspections, some of these being reactive inspections, in response to incidents;
- Transit inspections at the borders only.

Recommendation R65 from the IRRS Mission in 2006 indicated that ‘CNCAN should develop and implement a systematic inspection plan for the transport, in order to assure compliance with the relevant transport regulations.’ The subsequent reported analysis of this showed that the establishment of an inspection plan was more efficient if undertaken in accordance with the varied schedule of transports, and authorization requests received. Recommendation R63 from the IRRS Mission 2006 indicated that ‘CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team’. It was also reported that currently the resources for transport of radioactive and nuclear material are considered appropriate.

While there is no specifically planned inspection programme, inspections are undertaken based on the number of transport authorizations received. It is also a licence or authorization condition that the licensee must notify CNCAN at least 72 hours in advance of the date of entry into Romanian territory of any shipment of high activity sealed radioactive material, fresh or spent fuel so that CNCAN experts can escort the shipments. There are typically up to 10 of these escorts per year. Twenty transport related inspections were undertaken in 2010 covering new authorizations (industrial, pharmaceutical, foreign carriers, and fresh nuclear fuel), modifications to existing authorizations (industrial – relating to personnel and vehicles), inspection of fresh fuel transport by inland waterway and an in-transit inspection of high activity radioactive sources being transported across Romania. Inspections typically take about 1 day but some regarding inland waterway shipments can take several days.

During a site visit to and observation of a partial inspection of the Oncological Institute, it was noted from discussions with staff that arrangements in place for the transport of sources used in brachytherapy, nuclear medicine, iodine therapy and teletherapy are consistent with requirements of IAEA TS-R-1 and the Romanian Transport Norm NTR-01.

A second inspection was also observed at the National Institute for Physics and Nuclear Engineering. The Waste Management department facilitates the packaging and transport of disused radioactive sources from industrial and medical licensees to the storage facility in Magurele. The inspection of the relevant authorizations, documentation and vehicles approved for transport was well structured using a standard control check-list. All documentation was readily available by the facility and the designated drivers. Overall, the inspection was undertaken in a professional manner covering all the required items under the ADR and the transport NORM.

Any suggestions raised in this section have been incorporated into section 7.1 (Inspections). While there is an enforcement system in place, it has not been necessary to undertake any enforcement measures in the transport area to date. Further information on enforcement is presented in section 8.1.

#### 11.7. DEVELOPMENT OF REGULATIONS AND GUIDES

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. The ordinary Law 24/2000, republished in 2010, on “Legislative technique for elaboration of the normative acts” and the Governmental Decision HG 561/2009 on the approval of the Regulation regarding the procedures for elaboration of public policy documents, establish the general provisions, technical rules and administrative procedures for the development of all Romanian regulations (normative acts). All the regulations issued by CNCAN are mandatory and enforceable. The regulations are developed in observance of relevant international standards and good practices. Various sources of information relevant for updating the system of regulations and guides are used, including international cooperation as well as feedback from the operators and from CNCAN inspectors based on their experience from the enforcement of the regulations.

While the definition of ‘regulations’ in the Law (definition 24) includes ‘the technical, methodological rules, guidebooks, instructions, procedures or technical-organizational conditions concerning the authorization and control of nuclear activities, that are mandatory in the nuclear field, issued by the competent authority under Article 5 of the law’ and noting that methodologies for authorization for various transport activities are given in Annex 2 of NTR-01, there are no specific guidance documents for example on compliance assurance for the safe transport of radioactive material, the management system for the safe transport of radioactive material, radiation protection programmes applicable to transport, approval of packages not requiring competent authority approval, security in the transport of radioactive material, planning and preparing for emergency response to transport accidents involving radioactive material etc for CNCAN staff, licensees, or stakeholders.

Any suggestions or recommendations arising from this section have been incorporated into section 9.1.

#### 11.8. EMERGENCY PREPAREDNESS FOR TRANSPORT

For detailed background information on emergency preparedness refer to section 10.1. The Ministry of Transport and infrastructure has issued an emergency guide through the Romanian Road Authority regarding the intervention in case of a transport accident involving dangerous goods. This guide considers all nine classes of dangerous goods including radioactive material, i.e. Class 7. The guide covers the first measures after an accident. Accidents/incidents have to be reported to the Emergency Center.

It is also noted in Article 10 of NTR-01 that a radiation protection programme (including and intervention plan) applicable to the transport activity must be submitted as part of the technical documentation associated with the authorization. This requirement is also included in shipment certificates.

In the event of accidents or incidents during the transport of radioactive material, emergency provisions are in place to protect persons, property and the environment in accordance with the provisions of NTR-01, Articles 308-310. Adequate preparations have been established and maintained at a local and national level to respond to emergencies relating to the transport of radioactive material.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** TS-R-1(2009), 305 states that “*Emergency procedures shall take into account the formation of other dangerous substances that may result from the reaction between the*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

*contents of a consignment and the environment in the event of an accident.”*

- S17 **Suggestion:** CNACN should consider establishing in consultation with relevant licensees a systematic method for conducting transport emergency drills or exercises periodically.

### 11.9. MANAGEMENT SYSTEMS FOR REGULATORY BODIES

CNCAN has established and implemented a Management System in accordance with the EN ISO 9001:2008 requirements and is currently revising it in order to implement the requirements in the IAEA GS-R-3 standard. The Management Manual of CNCAN describes the policies with regard to the regulation, licensing and control activities, the strategic objectives and plans, the interfaces at national and international level, the responsibilities of the organisational units of CNCAN, the mechanisms for measuring, evaluating and improving the effectiveness and efficiency of the regulatory activities, etc. It also provides a set of general requirements applicable to the performance of activities within all organisational units and the specific requirements applicable to the assessment and inspection activities performed by the technical divisions. The more detailed requirements and criteria are set in the procedures defining the various regulatory processes. In order to ensure the adequate implementation and improvement of the management system, the relevant procedures are sent for review and approval to all the divisions and departments. The Management Manual and all the internal procedures are available in electronic format on the local area network.

The management system manual of CNCAN is currently being reviewed and revised with external support from experts contracted under the IAEA Extra Budgetary Programme funded by CNCAN and NRPA (the regulatory body of Norway) in order to provide for alignment with the requirements in the IAEA GS-R-3 safety standard.

While for the most part a compliance assurance programme based on international, national or other standards acceptable to the competent authority has been established and implemented for Type A, Industrial, Type B(U) and fissile packages to ensure compliance with the relevant provisions of the regulations, there are no such programmes in place for the testing, inspection and documentation in respect of all special form radioactive material, low dispersible radioactive material and packages; use, maintenance and inspection of all packages; transport and temporary storage operations;

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GSR Part 1, Requirement 19 states that *“The regulatory body shall establish, implement and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”*

- S18 **Suggestion:** The revision of the current management system should also take into account the topics set out in the current IAEA Safety Guide on the Management System for the Safe Transport of Radioactive Material (IAEA No TS-G-1.4) and the current IAEA Safety Guide on Compliance Assurance for the Safe Transport of Radioactive Material (IAEA No TS-G-1.5).

## 12. INTERFACE BETWEEN SAFETY AND SECURITY

### Background

CNCAN's involvement with nuclear security related matters began in the mid 1970s with support and advice from the US (NRC) leading to the fuelling and operation of the TRIGA research reactor at Pitesti. CNCAN's approach has continued to be informed by its ongoing co-operation, collaboration and liaison with the US starting with the NRC physical protection requirements for the TRIGA installation evolving through time to inputs post 9/11 2001 to the development of appropriate Design Basis Threat(s) (DBT) for facilities and activities regulated by CNCAN. As the IAEA's involvement and remit has extended to security related matters CNCAN's approach has been reviewed to ensure that the IAEA requirements and provisions are addressed.

### Findings

Through Article 5 of the Romanian Nuclear Law CNCAN has been established by the Government as the competent authority for nuclear safety and security regulation in Romania. CNCAN is therefore empowered to issue regulations regarding requirements for nuclear, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials and safe and secure management of radioactive waste and spent fuel as part of the National Strategy for the development of the nuclear sector.

The current requirements and responsibilities for 'physical protection' are set out in the "Norms on physical protection in the nuclear field" CNCAN nr. 382/24.10.2001 published 30.11.2001

CNCAN is a member of the National system to prevent and combat terrorism, and has a protocol with a number of other authorities who also have responsibilities in this area including

- Romanian Intelligence Service
- Romanian Gendarmerie
- General Inspectorate of Romanian Police
- Romanian Border Police

CNCAN's approach and current provisions are based on a Design Basis Threat (DBT) (issued in 2002) which informs specific facility / site / activity security plans which are approved by CNCAN.

Through the approved 'Security Plan(s)' it is clear that the management of the operating organisation takes the prime responsibility for safety and security.

Emergency preparedness and response plans in the field of safety and security are co-ordinated between all relevant parties with joint exercises conducted on a regular basis. National and bi-lateral exercises are also undertaken and a joint safety / security exercise with Bulgaria is planned for April 2011.

CNCAN's approach to safety and security is integrated. However because of the 'need to know principle' the number of staff providing safety assessment input is limited. Because of knowledge and experience a single senior manager provides oversight of detailed safety and security integration.

The staff operating in this area is aware and understand the security requirements and the inter-relationship and potential conflicts with safety requirements of the facilities/sites and activities which they are regulating.

Although the staff is conversant and effective in fulfilling their responsibilities little of their methods and approach is formally documented within CNCAN's Integrated Management System. (See also Section 4 – Management System of the Regulatory Body)

## **Conclusion**

The staff of CNCAN were able to effectively demonstrate their knowledge, awareness and application of the key attributes of from GSR Part 1 - Requirement 12 (“ The government shall ensure that, within the government and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system for accounting for, and control of, nuclear material as well as the provisions for Regulatory Bodies in INSAG 24 (The Interface between Safety and Security at Nuclear Power Plants), namely, that they should

- Define the requirements to be satisfied by the operator for both safety and security
- Have an established licensing, inspection and enforcement system
- Have ensured that an adequate emergency response system is in place, including various off-site elements that are not the responsibility of the operator
- Are observing international commitments in both the fields of safety and security
- Have an established protocol with other Government entities for assistance on security matters.





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## APPENDIX II – MISSION PROGRAMME

<b>Sunday, 16 January 2011</b>		<b>VENUE</b>
14:00 - 18:00	Opening Team Meeting	HOTEL
<b>Monday, 17 January 2011</b>		
09:30 - 17:00	Opening Remarks by Romanian officials and IRRS team leader Self-Introductions of the IRRS Review Team IRRS Team Leader presentation on the IRRS Process and Objective Counterpart Presentations: Overview of the Romanian regulatory approach - Introduction of the 12 Modules	HOTEL
17:00 - 18:00	Daily IRRS Review Team Meeting	HOTEL
<b>Tuesday, 18 January 2011</b>		
09:00 – 17:00	Interviews and Discussions with Counterparts (Parallel discussions)	CNCAN OFFICES
17:30 – 18:30	Daily IRRS Review Team Meeting	HOTEL
19:00 –	Group Report Writing	HOTEL
<b>Wednesday, 19 January 2011</b>		
09:00 – 17:00	Interviews and Discussions with Counterparts	CNCAN OFFICES
17:30 – 18:30	Daily IRRS Review Team Meeting	HOTEL
19:00 –	Group Report Writing	HOTEL
<b>Thursday, 20 January 2011</b>		
09:00 – 17:00	Group 3: Site visit to NPP <i>(group 3 to stay overnight in Cernavoda if needed)</i>	Cernavoda
	Group 4: Site visit to RR & fuel cycle facility	Pitesti
	Group 5: Site visit to a medical radiological facility	Bucharest
	Group 6: Site visit to waste management facility	Pitesti
	Other groups: Interviews and Discussions with Counterparts	CNCAN OFFICES
17:30 – 18:30	Daily IRRS Review Team Meeting	HOTEL
19:00 –	Group Report Writing	HOTEL
<b>Friday, 21 January 2011</b>		
09:00 – 17:00	Group 3: Continue site visit to NPP <i>(If not completed on Thu)</i>	Cernavoda
	Group 5: Site visit to an industrial radiological facility	Bucharest
	Other groups: Interviews and Discussions with Counterparts (if required)	CNCAN OFFICES
17:30 – 18:30	Daily IRRS Review Team Meeting	HOTEL
19:00 –	Group Report Writing	HOTEL

<b>Saturday, 22 January 2011</b>		
09:00 – 12:00	Report writing	HOTEL
12:00	Delivery of group drafts to Admin Assistant for compilation	
16:00 – 18:00	Team discussion of draft	
20:00	Admin Assistant to send compiled draft report back to the team	
<b>Sunday, 23 January 2011</b>		
09:00 – 18:00	Sightseeing	TbD
<b>Monday, 24 January 2011</b>		
09:00 – 12:00	Continuation with interviews and discussions with counterparts as needed	CNCAN OFFICES
13:00 – 18:00	Policy Issue discussion	HOTEL
18:00 – 19:00	Daily IRRS Review Team Meeting	HOTEL
19:00 –	Group Report Writing	HOTEL
<b>Tuesday, 25 January 2011</b>		
09:00 – 10:00	Concluding interviews and discussions with counterparts	CNCAN OFFICES
10:00 – 16:00	Finalizing group inputs to the report	CNCAN OFFICES
16:00	Delivery of group inputs to Admin Assistant for compilation	
20:00	Admin Assistant to send the draft report back to the team	
<b>Wednesday, 26 January 2011</b>		
09:00 – 16:00	Review the draft report by the team as a whole to agree on recommendations, suggestions and good practices	CNCAN OFFICES
16:00	Handover of Draft IRRS Mission report to CNCAN for review and comments	
<b>Thursday, 27 January 2011</b>		
09:00 – 13:00	CNCAN review and comments on the draft report	
13:00 – 18:00	Discussion of CNCAN comments (all IRRS review team)	HOTEL
	Preparation for Press Release (IAEA press officer)	HOTEL
<b>Friday, 28 January 2011</b>		
09:00 – 11:00	IRRS Exit Meeting	HOTEL

### **APPENDIX III – SITE VISITS**

<b>1.</b>	<b>Cernavoda NPP and Waste Facility</b>
<b>2.</b>	<b>Pitesti Research Reactor and Waste Facility</b>
<b>3.</b>	<b>Oncology Institute</b>
<b>4.</b>	<b>Laboratory of Radiation Metrology, Testing and Dosimetry of the Horia Hulubei Institute of Physics and Nuclear Engineering</b>

**APPENDIX IV – LIST OF COUNTERPARTS**

	<b>AREAS</b>	<b>IRRS EXPERTS</b>	<b>CNCAN Counterpart</b>	<b>Support Counterpart</b>
<b>1.</b>	<b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>			
		<ul style="list-style-type: none"> <li>➔ Greg Rzentkowski</li> <li>➔ Olga Makarovska</li> <li>➔ Miguel Santini</li> <li>➔ David Graves</li> </ul>	➔ Borbala Vajda	➔ Lucian Biro
<b>2.</b>	<b>GLOBAL NUCLEAR SAFETY RÉGIME</b>			
		<ul style="list-style-type: none"> <li>➔ Greg Rzentkowski</li> <li>➔ Olga Makarovska</li> <li>➔ Miguel Santini</li> <li>➔ David Graves</li> </ul>	➔ Borbala Vajda	<ul style="list-style-type: none"> <li>➔ Lucian Biro</li> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Mihaela Ion</li> </ul>
<b>3.</b>	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>			
		<ul style="list-style-type: none"> <li>➔ Greg Rzentkowski</li> <li>➔ Olga Makarovska</li> <li>➔ Miguel Santini</li> <li>➔ David Graves</li> </ul>	➔ Borbala Vajda	<ul style="list-style-type: none"> <li>➔ Lucian Biro</li> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Angelica Preoteasa</li> <li>➔ Radu Viorel</li> </ul>
<b>4.</b>	<b>MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>			
		<ul style="list-style-type: none"> <li>➔ Robbie Gray</li> <li>➔ Jean Pierre Boogaard</li> </ul>	➔ Borbala Vajda	<ul style="list-style-type: none"> <li>➔ Lucian Biro</li> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Constantin Benescu</li> <li>➔ Daniel Bogdan</li> <li>➔ Madalina Tronea</li> <li>➔ Goicea Lucian</li> </ul>
<b>5.</b>	<b>AUTHORIZATION</b>			
	Nuclear Power Plants	<ul style="list-style-type: none"> <li>➔ Matjaž Podjavoršek</li> <li>➔ Jan Husarcek</li> </ul>	➔ Lucian Biro	➔ Cantemir Ciurea-Ercau
	Research Reactors		➔ Lucian Biro	➔ Cantemir Ciurea-Ercau
	Fuel Cycle Facilities		➔ Nicolae Dumitrescu	➔ Atena Niculescu
	Industrial, Medical and Research Facilities	➔ Maria Helena Marechal	➔ Angelica Preoteasa	➔ Madalina Botgros

	AREAS	IRRS EXPERTS	CNCAN Counterpart	Support Counterpart
		<ul style="list-style-type: none"> <li>➔ Hazem Suman</li> <li>➔ Jarlath Duffy</li> </ul>		<ul style="list-style-type: none"> <li>➔ Virgil Iliescu</li> <li>➔ Mancas Sorin</li> </ul>
	Waste Facilities	<ul style="list-style-type: none"> <li>➔ Seung-Young Jeong</li> <li>➔ Kai Möller</li> </ul>	➔ Oana Velicu	<ul style="list-style-type: none"> <li>➔ Alexandru Rodna</li> <li>➔ <u>Dogaru Daniela</u></li> <li>➔ <u>Cornelia Virtopeanu</u></li> </ul>
<b>6.</b>	<b>REVIEW AND ASSESSMENT</b>			
	Nuclear Power Plants	<ul style="list-style-type: none"> <li>➔ Matjaž Podjavoršek</li> <li>➔ Jan Husarcek</li> </ul>	➔ Cantemir Ciurea-Ercau	<ul style="list-style-type: none"> <li>➔ Elena Dinca</li> <li>➔ Madalina Tronea</li> <li>➔ Oana Velicu</li> <li>➔ Constantin Benescu</li> <li>➔ Daniel Bogdan</li> <li>➔ Iosif Rebleanu</li> <li>➔ Irina Sanda</li> </ul>
	Research Reactors	<ul style="list-style-type: none"> <li>➔ Matjaž Podjavoršek</li> <li>➔ Jan Husarcek</li> </ul>	➔ Cantemir Ciurea-Ercau	<ul style="list-style-type: none"> <li>➔ Elena Dinca</li> <li>➔ Iosif Rebleanu</li> <li>➔ Simina Lungu</li> <li>➔ Oana Velicu</li> <li>➔ Radian Sanda</li> </ul>
	Fuel Cycle Facilities	<ul style="list-style-type: none"> <li>➔ Matjaž Podjavoršek</li> <li>➔ Jan Husarcek</li> </ul>	➔ Nicolae Dumitrescu	<ul style="list-style-type: none"> <li>➔ Atena Niculescu</li> <li>➔ Irine Popovici</li> <li>➔ Lorena Pop</li> </ul>
	Industrial, Medical and Research Facilities	<ul style="list-style-type: none"> <li>➔ Maria Helena Marechal</li> <li>➔ Hazem Suman</li> <li>➔ Mr. J. Duffy</li> </ul>	➔ Angelica Preoteasa	<ul style="list-style-type: none"> <li>➔ Madalina Botgros</li> <li>➔ Virgil Iliescu</li> <li>➔ Mancas Sorin</li> </ul>
	Waste Facilities	<ul style="list-style-type: none"> <li>➔ Seung-Young Jeong</li> <li>➔ Kai Möller</li> </ul>	➔ Alexandru Rodna	<ul style="list-style-type: none"> <li>➔ Oana Velicu</li> <li>➔ Dogaru Daniela</li> <li>➔ Cornelia Virtopeanu</li> </ul>
<b>7.</b>	<b>INSPECTION</b>			
	Nuclear Power Plants	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Cantemir Ciurea-Ercau	<ul style="list-style-type: none"> <li>➔ Lili Heroiu;</li> <li>➔ Sorin Marinescu;</li> <li>➔ Oana Velicu</li> </ul>

	AREAS	IRRS EXPERTS	CNCAN Counterpart	Support Counterpart
				<ul style="list-style-type: none"> <li>➔ Rodna Alexandru</li> <li>➔ Daniel Bogdan</li> <li>➔ Goicea Lucian</li> </ul>
	Research Reactors	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Cantemir Ciurea-Ercau	<ul style="list-style-type: none"> <li>➔ Oana Velicu;</li> <li>➔ Iosif Rebleanu;</li> <li>➔ Irina Sanda</li> </ul>
	Fuel Cycle Facilities	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Sorin Repanovici	<ul style="list-style-type: none"> <li>➔ Atena Niculescu</li> <li>➔ Nicolae Dumitrescu</li> <li>➔ Grigoras Benescu</li> </ul>
	Industrial, Medical and Research Facilities	<ul style="list-style-type: none"> <li>➔ Maria Helena Marechal</li> <li>➔ Hazem Suman</li> <li>➔ Jarlath Duffy</li> </ul>	➔ Viorel Radu	<ul style="list-style-type: none"> <li>➔ Rotaru Cristina</li> <li>➔ Barca Catalin</li> <li>➔ Eremia Alexandru</li> <li>➔ Silvia Serban</li> <li>➔ Craciunoiu Bogdan</li> <li>➔ Ioana Berechet</li> </ul>
	Waste Facilities	<ul style="list-style-type: none"> <li>➔ Seung-Young Jeong</li> <li>➔ Kai Möller</li> </ul>	➔ Oana Velicu	<ul style="list-style-type: none"> <li>➔ Alexandru Rodna</li> <li>➔ Dogaru Daniela</li> <li>➔ Cornelia Virtopeanu</li> </ul>
<b>8.</b>	<b>ENFORCEMENT</b>			
	Nuclear Power Plants	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Lucian Biro	<ul style="list-style-type: none"> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Lili Heroiu;</li> <li>➔ Sorin Marinescu;</li> <li>➔ Grigoras Benescu</li> <li>➔ Goicea Lucian</li> <li>➔ Tronea Madalina</li> </ul>
	Research Reactors	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Lucian Biro	<ul style="list-style-type: none"> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Grigoras Benescu</li> <li>➔ Goicea Lucian</li> <li>➔ Iosif rebleanu</li> <li>➔ Oana Velicu</li> <li>➔ Radu Viorel</li> <li>➔ Dogaru Daniela</li> </ul>

	AREAS	IRRS EXPERTS	CNCAN Counterpart	Support Counterpart
	Fuel Cycle Facilities	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Nicolae Dumitrescu	➔ Atena Niculescu
	Industrial, Medical and Research Facilities	<ul style="list-style-type: none"> <li>➔ Maria Helena Marechal</li> <li>➔ Hazem Suman</li> <li>➔ Jarlath Duffy</li> </ul>	➔ Viorel Radu	<ul style="list-style-type: none"> <li>➔ Rotaru Cristina</li> <li>➔ Barca Catalin</li> <li>➔ Eremia Alexandru</li> <li>➔ Silvia Serban</li> <li>➔ Craciunoiu Bogdan</li> <li>➔ Ioana Berechet</li> </ul>
	Waste Facilities	<ul style="list-style-type: none"> <li>➔ Seung-Young Jeong</li> <li>➔ Kai Möller</li> </ul>	➔ Alexandru Rodna	<ul style="list-style-type: none"> <li>➔ Oana Velicu</li> <li>➔ Dogaru</li> <li>➔ Vartopenau</li> <li>➔ Tite Fierbantu</li> <li>➔ Plavitu</li> </ul>
<b>9.</b>	<b>REGULATIONS AND GUIDES</b>			
	Nuclear Power Plants	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Madalina Tronea	<ul style="list-style-type: none"> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Grigoras Benescu</li> <li>➔ Goicea Lucian</li> <li>➔ Rodna Alexandru</li> <li>➔ Oasna Velicu</li> <li>➔ Dinca Elena</li> </ul>
	Research Reactors	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Madalina Tronea	<ul style="list-style-type: none"> <li>➔ Cantemir Ciurea-Ercau</li> <li>➔ Grigoras Benescu</li> <li>➔ Goicea Lucian</li> <li>➔ Rodna Alexandru</li> <li>➔ Oana Velicu</li> <li>➔ Dinca Elena</li> </ul>
	Fuel Cycle Facilities	<ul style="list-style-type: none"> <li>➔ Ronald Bellamy</li> <li>➔ Adeline Clos</li> </ul>	➔ Nicolae Dumitrescu	<ul style="list-style-type: none"> <li>➔ Atena Niculescu</li> <li>➔ Lorena Pop</li> </ul>
	Industrial, Medical and Research Facilities	<ul style="list-style-type: none"> <li>➔ Maria Helena Marechal</li> <li>➔ Hazem Suman</li> <li>➔ Jarlath Duffy</li> </ul>	➔ Angelica Preoteasa	<ul style="list-style-type: none"> <li>➔ Madalina Botgros</li> <li>➔ Virgil Iliescu</li> <li>➔ Mancas Sorin</li> <li>➔ Garjoaba Olga</li> </ul>



	AREAS	IRRS EXPERTS	CNCAN Counterpart	Support Counterpart
	Waste Facilities	<ul style="list-style-type: none"> <li>➔ Seung-Young Jeong</li> <li>➔ Kai Möller</li> </ul>	<ul style="list-style-type: none"> <li>➔ Dogaru Daniela</li> </ul>	<ul style="list-style-type: none"> <li>➔ Rodna Alexandru</li> <li>➔ Virtopenau Cornelia</li> </ul>
10.	<b>EMERGENCY PREPAREDNESS AND RESPONSE</b>			
		<ul style="list-style-type: none"> <li>➔ Marina Nizamska</li> </ul>	<ul style="list-style-type: none"> <li>➔ Adriana Baci</li> </ul>	<ul style="list-style-type: none"> <li>➔ Lolea Florin</li> <li>➔ Adriana Stoiciu</li> </ul>
11.	<b>TECHNICAL AREAS: TRANSPORT</b>			
		<ul style="list-style-type: none"> <li>➔ Jarlath Duffy</li> </ul>	<ul style="list-style-type: none"> <li>➔ Tite Fierbantu</li> </ul>	<ul style="list-style-type: none"> <li>➔ Alexandru Rodna</li> <li>➔ Oana Velicu</li> <li>➔ Dogaru Daniela</li> </ul>
12.	<b>INTERFACES WITH NUCLEAR SECURITY</b>			
		<ul style="list-style-type: none"> <li>➔ Robbie Gray</li> <li>➔ Jean Pierre Boogaard</li> </ul>	<ul style="list-style-type: none"> <li>➔ Lucian Biro</li> </ul>	<ul style="list-style-type: none"> <li>➔ Sorin Repanovici</li> <li>➔ Atena Niculescu</li> </ul>

## APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
<b>1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>	<b>R 1</b>	<b><u>Recommendation:</u></b> The Government of Romania should issue the national policy and the strategy for safety, and implement them in accordance with a graded approach.
	<b>S 1</b>	<b><u>Suggestion:</u></b> The government should consider all fundamental safety objectives and principles, established in the IAEA Fundamental Safety Principles document, when finalizing the national policy and strategy.
	<b>R 2</b>	<b><u>Recommendation:</u></b> The Government should ensure that there is no duplication in responsibilities between CNCAN and other government organizations for establishing safety principles, criteria, and regulations for nuclear safety and radiological protection.
	<b>R 3</b>	<b><u>Recommendation:</u></b> The Government should provide CNCAN with the financial and human resources necessary to fulfill its statutory obligation for the regulatory control of facilities and activities.
	<b>R 4</b>	<b><u>Recommendation:</u></b> The Government should provide CNCAN with adequate financial and human resources, and authority in the management of its organizational structure.
	<b>R 5</b>	<b><u>Recommendation:</u></b> The Government should make provisions for effective coordination of regulatory functions between CNCAN and other authorities.
	<b>R 6</b>	<b><u>Recommendation:</u></b> The Government should issue and implement a revised national strategy for radioactive waste and nuclear spent fuel management as part of the overall Nuclear Strategy for the Development of Nuclear Sector
	<b>R 7</b>	<b><u>Recommendation:</u></b> The Government should establish a national policy and strategy to develop and implement the necessary training program for

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
		maintaining and enhancing the competence of a sufficient number of suitably qualified and experienced staff employed in the nuclear sector.
<b>2. GLOBAL NUCLEAR SAFETY REGIME</b>	<b>R 8</b>	<b><u>Recommendation:</u></b> CNCAN should make arrangements for independent analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community.
<b>3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	<b>R 9</b>	<b><u>Recommendation:</u></b> CNCAN should implement measures for managing available resources in a manner commensurate with the radiation risks associated with facilities and activities.
	<b>R 10</b>	<b><u>Recommendation:</u></b> CNCAN should identify and, if necessary, issue and implement a comprehensive set of procedures for the regulatory processes and provide applicants/licensees with the comprehensive set of guidance for the format and content of the documents to be submitted by the applicant in support of an application.
<b>4. MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>	<b>R 11</b>	<b><u>Recommendation:</u></b> CNCAN should develop and implement an Integrated Management System satisfying the requirements set out in GS-R-3.
<b>5. AUTHORIZATION</b>	<b>R 12</b>	<b><u>Recommendation:</u></b> CNCAN should revise its system for authorization in accordance with a graded approach
	<b>R 13</b>	<b><u>Recommendation:</u></b> CNCAN should ensure that its implementation of authorization processes of <u>radiological facilities and activities</u> is consistently in accordance with the provision of the law, regulations and procedures.
	<b>R 14</b>	<b><u>Recommendation:</u></b> CNCAN should establish procedures for the import and export of radioactive sources in accordance with the provisions of the Guidance on the Import and Export of Radioactive Sources
	<b>S 2</b>	<b><u>Suggestion:</u></b> CNCAN should consider establishing mechanisms for assessing

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
		all relevant information received from different sources to ensure its consistency.
	R 15	<b><u>Recommendation:</u></b> CNCAN should establish and implement authorization processes and procedures for all radioactive waste management and decommissioning activities.
	R 16	<b><u>Recommendation:</u></b> The regulator should change the requirements in a way that attention should be given to changes in the barrier design.
	R 17	<b><u>Recommendation:</u></b> CNCAN should develop regulations for dealing with legacy waste, abandoned radioactive material, source, sites or facilities.
	S3	<b><u>Suggestion:</u></b> The regulatory authority should consider to eliminate or extend the time limit of 6 month for the licensing of disposal facilities.
	S4	<b><u>Suggestion:</u></b> The regulatory body should consider taking steps to adjust the waste classification at Cernavoda NPP to be in line with the national waste classification system.
6. REVIEW AND ASSESSMENT	R 18	<b><u>Recommendation:</u></b> CNCAN should include in its request to the government that adequate financial resources are allocated and provided in CNCAN's budget in order to allow acquiring sufficient resources and necessary analytical tools supporting nuclear safety assessment and emergency preparedness, as well as for securing sufficient numbers of staff specialized in safety assessment
	R 19	<b><u>Recommendation:</u></b> The regulatory body should formalize the graded approach for review and assessment
	R 20	<b><u>Recommendation:</u></b> CNCAN should establish requirements for the operating organizations to carry out an independent verification of safety assessments, in accordance with the graded approach before it is used by the operating organization or submitted to the regulatory body.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S 5	<b><u>Suggestion:</u></b> CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment for all nuclear facilities.
	R 21	<b><u>Recommendation:</u></b> CNCAN should perform review and assessment of all stages of lifetime of fuel cycle facilities including commissioning.
	S 6	<b><u>Suggestion:</u></b> CNCAN should consider improving its procedures for review and assessment by including provisions for periodic review and assessment and identifying situations that trigger review and assessment process.
	R 22	<b><u>Recommendation:</u></b> CNCAN should improve its procedures for review and assessment, including provisions for periodic verifications, whether radiation risks are as low as reasonably achievable.
7. INSPECTION	R 23	<b><u>Recommendation:</u></b> CNCAN should establish a consistent and comprehensive inspector training programme and qualification process.
	R 24	<b><u>Recommendation:</u></b> CNCAN should establish a systematic and comprehensive inspection programme based on a graded safety approach and formally describe its processes in procedures for consistency of regulatory practices.
	S 7	<b><u>Suggestion:</u></b> CNCAN should consider including in its procedures a programme to monitor, share and follow-up inspection findings.
	S 8	<b><u>Suggestion:</u></b> CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment and for inspection for all nuclear facilities.
	R 25	<b><u>Recommendation:</u></b> CNCAN should improve its inspection system as to ensure that the inspections are done in full compliance with the regulations

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
		and procedures and that subjective judgment is avoided.
	S 9	<b>Suggestion:</b> CNCAN should consider enhancing its procedures to support its regional inspectors undertaking their inspection duties to ensure proper preparation of initial inspections.
8. ENFORCEMENT	R 26	<p><b>Recommendation:</b> CNCAN should develop and implement administrative procedures and guidelines to clarify its enforcement policy. The enforcement procedures should ensure that:</p> <ul style="list-style-type: none"> <li>(1) enforcement measures are consistently applied in accordance with a graded approach</li> <li>(2) subjective decision making with respect to enforcement is avoided</li> <li>(3) all non-compliances are properly addressed in the enforcement process</li> <li>(4) all enforcement actions are clearly based on regulatory requirements</li> </ul>
	R 27	<b>Recommendation:</b> The government should ensure full provisions are provided for appeal of all decisions by CNCAN.
9. REGULATIONS AND GUIDES	R 28	<b>Recommendation:</b> CNCAN should identify, complete and issue those regulations for safety upon which regulatory judgements and actions are based.
	R 29	<b>Recommendation:</b> CNCAN should review and revise as necessary, its regulations and guides for completeness and consistency.
	R 30	<b>Recommendation:</b> CNCAN should ensure that all provisions related to authorization are consistent across the entire set of regulations and procedures

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S 10	<b><u>Suggestion:</u></b> CNCAN should consider amending the regulations to include the categorization of sources in accordance with the associated radiation risks.
	S 11	<b><u>Suggestion:</u></b> The regulatory body should consider developing the standard review plan that describes the detailed criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility.
<b>10. EMERGENCY PREPAREDNESS AND RESPONSE</b>	R 31	<b><u>Recommendation:</u></b> The government should finalize the radiation threat assessment at the national level for all postulated nuclear and radiological emergencies for all nuclear facilities and activities.
	R 32	<b><u>Recommendation:</u></b> CNCAN should update ministerial order No.242/1993 and implement it in accordance with the requirements of GS-R-2.
	S 12	<b><u>Suggestion:</u></b> CNCAN should consider the finalization of the implementation of common software platform for data and information exchange during emergencies (ELAN system) and maintain the system operational in CNCAN-ERC.
	S 13	<b><u>Suggestion:</u></b> CNCAN should consider the completion of the development of the software application for data transmission from Cernavoda NPP to the CNCAN-ERC and maintain it in proper conditions to be used in exercises and real situations.
	GP 1	<b><u>Good Practice:</u></b> CNCAN's involvement in the development of a common software platform for data and information exchange during emergencies.
	R 33	<b><u>Recommendation:</u></b> CNCAN should develop and implement internal training and exercise program for the personnel with assigned responsibilities in the emergency organization.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S 14	<b>Suggestion:</b> CNCAN should consider finalizing the regulation on radiological safety of working activities involving enhanced natural radioactive material.
<b>11. TRANSPORT OF RADIOACTIVE MATERIAL</b>	R 34	<b>Recommendation:</b> CNCAN should enhance and rejuvenate co-operation with the Ministry of Transport and Infrastructure at the highest level.
	S 15	<b>Suggestion:</b> CNCAN should consider adopting international best practice safety guidance relating to the transport of radioactive material.
	S 16	<b>Suggestion:</b> CNCAN should consider performing a periodic assessment of the radiation doses received by persons involved in the transport of radioactive material, to ensure that the system of protection and safety complies with the provisions within the Fundamental Norms on Radiological Safety and of the applicable relevant norms on nuclear safety as well as the IAEA TS-R-1.
	S 17	<b>Suggestion:</b> CNACN should consider establishing in consultation with relevant licensees a systematic method for conducting transport emergency drills or exercises periodically.
	S 18	<b>Suggestion:</b> The revision of the current management system should also take into account the topics set out in the current IAEA Safety Guide on the Management System for the Safe Transport of Radioactive Material (IAEA No TS-G-1.4) and the current IAEA Safety Guide on Compliance Assurance for the Safe Transport of Radioactive Material (IAEA No TS-G-1.5).
<b>12. INTERFACE BETWEEN SAFETY AND SECURITY</b>	-	-



## APPENDIX VI – CNCAN REFERENCE MATERIAL USED FOR THE REVIEW

1. Nuclear Safety Republican Norms - Nuclear Reactors and Nuclear Power Plants (1975);
2. Order no. 40/1990 of the President of State Committee for Nuclear Energy, approving criteria for establishing radiological risk categories for workplaces of units licensed to perform nuclear activities;
3. Normative for granting and utilisation of individual equipment for protection against ionising radiation (2000);
4. Norms on Designation of Notified Bodies for nuclear domain, (2000)
5. Order no 25/15 February 2000 of the President of National Commission for Nuclear Activities Control, modifying the Nuclear Safety Republican Norms - Working Rules with Radiation Sources (1976);
6. Radiological Safety Fundamental Norms (2000);
7. Radiological Safety Norms - Licensing Procedures (2001);
8. Norms on licensing the use of radiation sources in outside protected areas (2002);
9. Norms on Radiological Safety - Operational Radiation Protection in Mining and Milling of Uranium and Thorium Ores (2002);
10. Norms on decommissioning of nuclear research reactors (2002);
11. Norms on Radiological Safety - Management of Radioactive Waste from Mining and Milling of Uranium and Thorium Ores (2002);
12. Norms on issuing of exercising permits of nuclear activities and designation of radiation protection qualified experts (2002);
13. Norms on Transport of Radioactive Materials - Licensing Procedures (2005);
14. Norms on Radiological Safety - Acceptance Procedures for External Units (2003);
15. Norms on authorisation of the quality management systems applied to the commissioning, operation and decommissioning of nuclear installations (2003);
16. General requirements for quality management systems applied to the setting-up, operation and decommissioning of nuclear installations (2003) and set of specific requirements;
17. Norms on Radiological Safety - Operational Radiation Protection in Deployment of Non-destructive Testing with Ionising Radiation (2003);
18. Norms on Radiological Safety on Interventional and Diagnostic Radiology Practices (2003);

19. Norms on Radiological Safety on Decommissioning of Mining and/or Processing of Uranium and Thorium Installations and Ores - Criteria for Release from the Licensing Regime of National Commission for Nuclear Activities Control, for Use for Other Purposes of Buildings, Materials, Installations, Dumps and Lands Contaminated from the Activities of Mining and/or Processing of Uranium and Thorium Ores (2003);
20. Norms on Radiological Safety - Licensing Procedures of Mining and Milling Uranium and Thorium Ores, of Row Nuclear Materials and Fabrication of Nuclear Fuel (2004);
21. Norms on Radiological Safety on Radiotherapy Practice (2004);
22. Norms on Radiological Safety for Nuclear Gauges (2004);
23. Normative for granting and utilisation of individual equipment for protection against ionising radiation (2005);
24. Norms on Procedures for Licensing of Activities Involving Materials, Devices, Equipment and Information Pertinent for Nuclear Weapons and Other Nuclear Explosive Devices Proliferation (2005);
25. Norms on Granting Exercising Permits for Operating, Management and Specific Training Personnel of Nuclear Power Plants, Nuclear Reactors and Other Nuclear Installations (2005);
26. Norms on Radiological Safety on Nuclear Medicine (2005);
27. Norms on Licensing of Personnel Performing Temporary or Permanent Activities in Key Working Points in Nuclear Installations or Have Access to Top Secret Information (2006)
28. Norms on Licensing of Construction of Nuclear Buildings (2006);
29. Norms on Medical Exposures to Ionising Radiations for Medical and/or Biomedical Research (2006);
30. Norms on Radiological Safety for Decommissioning of Uranium and Thorium Mining and Milling Installations (2006);
31. Guide on Technical Requirements for Design, Sitting, Construction, Operation and Decommissioning of Uranium and Thorium Ores Storage Facilities and Waste from Uranium and Thorium Ores Mining and Milling (2006);
32. Norms on Medical Physics Experts (2006). <ul style="list-style-type: none"> <li>• Law no. 111/1996 rev. 2006</li> <li>• Radiological Safety Fundamental Norms/24 January 2000, approved by Order no. 14 on 24 January 2000 of the CNCAN President and published in Official Gazette no. 404 bis on 29 August 2000 (transposition of Council Directive 96/29/EURATOM and in compliance with IAEA Safety Series No. 115);</li> <li>• Radiological Safety Norms - Licensing Procedures, approved by Order no. 366 on 22 September 2001 of the CNCAN President and published in Official Gazette, Part I no. 764 bis on 30 November 2001</li> </ul>

- NSR-11, Specific regulations on diagnostic radiology. (order no. 173/2003)
- NSR-12, Specific regulations on radiotherapy
- Inspection procedures, PCDRIO-01 (2001) rev. 7
- CNCAN Organizational order no. 319 of 8 Nov 2010
- Norm regarding radiological surveillance for recyclable metal material and sources during the entire cycle of collecting, selling and processing (CNCAN order no. 89, 8 April 2010)
- NORM on orphans sources and control of HASS sources (Gazette 1109 (8 Dec 2005))
- Specific regulation on non-destructive testing

## APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1.] **IAEA SAFETY STANDARDS SERIES GS-R-1** - *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
- [2.] **IAEA SAFETY STANDARDS SERIES GS-G-1.1** - *Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- [3.] **IAEA SAFETY STANDARDS SERIES GS-G-1.2** - *Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [4.] **IAEA SAFETY STANDARDS SERIES GS-G-1.3** - *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*
- [5.] **IAEA SAFETY STANDARDS SERIES GS-G-1.4** - *Documentation for use in Regulation of Nuclear Facilities*
- [6.] **IAEA SAFETY STANDARDS SERIES GS-G-1.5** - *Regulatory Control of Radiation Sources*
- [7.] **IAEA SAFETY STANDARDS SERIES GS-R-2** - *Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*
- [8.] **IAEA SAFETY STANDARDS SERIES GS-R-3** - *Management System for Facilities and Activities*
- [9.] **IAEA SAFETY STANDARDS SERIES NS-R-1** - *Safety of Nuclear Power Plants: Design Safety Requirements*
- [10.] **IAEA SAFETY STANDARDS SERIES NS-R-2** - *Safety of Nuclear Power Plants: Operation Safety Requirements*
- [11.] **IAEA SAFETY STANDARDS SERIES NS-R-4** - *Safety of Research Reactors*
- [12.] **IAEA SAFETY STANDARDS SERIES NS-G-4.1** - *Commissioning of Research Reactors*
- [13.] **IAEA SAFETY SERIES No. 115** - *International Basic Safety standards for Protection against ionizing Radiation and for the Safety of Radiation Sources*
- [14.] **IAEA SAFETY STANDARDS SERIES TS-R-1** - *Regulations for the Safe Transport of Radioactive Material*
- [15.] **IAEA SAFETY STANDARDS SERIES WS-G-2.1** - *Decommissioning of Nuclear Power Plants and Research Reactors*
- [16.] **IAEA SAFETY STANDARDS SERIES WS-G-2.2** - *Decommissioning of Medical, Industrial and Research Reactors*
- [17.] **IAEA SAFETY STANDARDS SERIES WS-R-1** - *Near Surface Disposal of Radioactive Waste*
- [18.] **IAEA SAFETY STANDARDS SERIES WS-R-2** - *Predisposal Management of Radioactive Waste including Decommissioning*
- [19.] **IAEA SAFETY STANDARDS SERIES WS-G-2.3** - *Regulatory Control of Radioactive Discharges to the Environment*
- [20.] **IAEA SAFETY STANDARDS SERIES WS-G-2.4** - *Decommission of Nuclear Fuel Cycle Facilities*
- [21.] **IAEA SAFETY STANDARDS SERIES WS-G-2.5** - *Predisposal Management of Low and Intermediate Level Radioactive Waste*
- [22.] **IAEA SAFETY STANDARDS SERIES WS-G-2.6** - *Predisposal Management of High Level Radioactive Waste*

- [23.] **IAEA SAFETY STANDARDS SERIES WS-G-2.7** - *Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*
- [24.] **IAEA SAFETY STANDARDS SERIES WS-R-3** - *Remediation of areas contaminated by past activities and accidents*
- [25.] **IAEA SAFETY STANDARDS SERIES WS-R-5** - *Decommissioning of facilities using Radioactive Material*
- [26.] **IAEA SAFETY STANDARDS SERIES WS-G-6.1** - *Storage of Radioactive Waste*
- [27.] **IAEA SAFETY STANDARDS SERIES RS-G-1.7** - *Application of the Concepts of Exclusion, Exemption and Clearance*
- [28.] **IAEA SAFETY STANDARDS SERIES RS-G-1.8** - *Environmental and Source monitoring for Purpose of Radiation Protection*
- [29.] **IAEA SAFETY STANDARDS SERIES RS-G-1.9** – *Categorization of Radioactive Sources,*
- [30.] **Code of conduct on the Safety of Research Reactors**
- [31.] **Guidance on the Import and Export of Radioactive Sources**
- [32.] **IAEA SAFETY SERIES NO. 111-G-1.1** - *Classification of Radioactive Waste*
- [33.] **IAEA SAFETY SERIES NO. 35 – G2** - *Safety in the Utilization and Modification of Research Reactors*
- [34.] **IAEA TECDOC 1388** - *Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies*
- [35.] **INSAG SERIES NO. 17** - *Independence in Regulatory Decision Making*
- [36.] **INSAG SERIES NO. 20** - *Stakeholder Involvement in Nuclear Issues*
- [37.] **INSAG SERIES NO. 21** - *Strengthening the Global Nuclear Safety Regime*
- [38.] **IAEA LEGAL SERIES NO.14** - *Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency*
- [39.] **IAEA SAFETY STANDARDS SERIES** – *Predisposal Management of Radioactive Waste (Draft Safety Requirements, DS353).*

APPENDIX VIII – CNCAN ORGANIZATIONAL CHART

