

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

Bucharest, Romania

*30 October to 10 November 2023*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated  
Regulatory  
Review Service  
**IRRS**



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Regulatory  
Review Service

IRRS

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





## REPORT OF THE INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO ROMANIA

**Mission dates:** 30 October to 10 November 2023  
**Regulatory body visited:** National Commission for Nuclear Activities Control (CNCAN)  
**Location:** Bucharest, Romania

<b>Regulated facilities, activities, and exposure situations in the mission scope:</b>	<i>nuclear power plants, research reactors, radiation sources applications, fuel cycle facilities, waste management facilities, emergency preparedness and response, transport, decommissioning, occupational exposure, medical exposure, public exposure, interfaces with nuclear security</i>
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<b>Organized by:</b>	IAEA
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**The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. 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 senior safety experts met representatives of the National Commission for Nuclear Activities Control (CNCAN), from 30 October to 10 November 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission as part of its third IRRS cycle as recommended by the IRRS guidelines. The review took place at the headquarters of CNCAN in Bucharest.

The purpose of this peer review was to review the Romanian governmental, legal and regulatory framework for nuclear and radiation safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Romanian counterparts in the areas covered by the IRRS.

The IRRS team consisted of 16 senior regulatory experts from 15 IAEA Member States, three IAEA staff members as well as an observer of the European Commission (EC).

The IRRS team reviewed the following areas: responsibilities and functions of the government; the global 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, and development and content of regulations and guides; emergency preparedness and response; nuclear power plants; nuclear fuel cycle facilities; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; control of medical, occupational and public exposures; interfaces with nuclear security and regulatory implications of pandemic situations. The IRRS mission included discussion of two policy issues: "Human resources and knowledge management" and "Integrating the requirements on management systems from different standards or applicable regulations".

The IRRS team conducted interviews and discussions with the staff of CNCAN, the Ministry of Health, the Institute of Public Health and the Nuclear and Radioactive Waste Agency (ANDR). Members of the IRRS team also observed regulatory activities at Cernavoda NPP, the TRIGA Research Reactor located at the Institute for Nuclear Research (RATEN-ICN) Pitesti, the National Institute for Research and Development in Physics and Nuclear Engineering "Horia Hulubei" (IFIN-HH), the industrial radiography facility Dyomedica CND SRL - NDT laboratory, the clinic MNT Health Care Europe, an industrial facility (NDT-DYOMEDICA) and the IFIN - MNT Neolife Hospital. The visits included also discussions with management and staff of facilities.

A meeting with Mr Lucian Rusu, Deputy General Secretary of the Government, and representatives of the Ministry of Health was also organized.

In preparation for the IRRS mission, CNCAN conducted a self-assessment and prepared a preliminary action plan to address areas that were identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission.

The IRRS team acknowledged the outstanding efforts of CNCAN, to engage in this extensive and full scope international peer review, enabling the IRRS team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety in Romania.

Romania has a comprehensive regulatory framework for nuclear and radiation safety covering all nuclear and radiation facilities and activities regulated by CNCAN. CNCAN is considered a mature regulator, with a highly experienced core staff, and is able to independently fulfil its statutory obligations.

The IRRS team also identified areas of good performance, including:

- The performance, during a CNCAN inspection, of an on-the spot written test for the authorized staff dedicated to radiation safety and emergency preparedness.
- The development of a detailed cooperation protocol between CNCAN and the Romanian customs authority to ensure the safe inspection of radioactive packages.
- The prompt update of the regulation for reactors and installations with multiple modules, after the signature of memorandum of understanding between CNCAN and NuScale Power, to evaluate small modular reactors.
- The systematic and holistic approach of CNCAN to address the interface of safety and security in its regulatory oversight programme for NPPs.

In the spirit of continuous improvement, the IRRS mission report includes a number of recommendations and suggestions to improve the Romanian nuclear regulatory infrastructure and regulatory practices on matters of nuclear and radiation safety.

The IRRS team identified two main challenges in Romania. The first challenge is the implementation of the fundamental principles of radiation protection within the regulation of radiation source facilities and activities. To address this, the government should ensure that the roles and responsibilities of CNCAN and the Ministry of Health are clearly assigned and implemented. Furthermore, there needs to be high-level coordination between CNCAN and the Ministry of Health, as CNCAN has done in other areas of potential overlap of responsibilities.

The second challenge is ensuring the adequate provisions of financial and human resources to CNCAN. This has been a long standing issue that is now becoming urgent in the context of Romania's plans to expand its nuclear power programme. The Government of Romania should ensure CNCAN has adequate resources. CNCAN should assess its organizational structure and develop a comprehensive human resource plan to effectively and efficiently manage the available resources.

In addition, the IRRS team concluded the following issues are representative of those which, if addressed by CNCAN and the Ministry of Health, should further enhance the overall effectiveness of the regulatory system to:

CNCAN:

- develop and implement a systematic training programme including inspector qualification.
- evaluate and monitor the effectiveness of its management system and the performance of its regulatory functions.
- develop and implement an overall, risk-based inspection programme to be used in the planning and conduct of inspections, in accordance with a graded approach.

The Ministry of Health:

- revise and implement the regulatory requirements for justification of practices, including the issuance of evidence-based referral guidelines.
- establish, along with CNCAN, dose constraints for the public exposure which consider all potential exposures and then require optimization.
- revise the regulatory requirements for consumer products to be consistent with GSR Part 3 requirements.

The IRRS team identified several other areas for improvement for CNCAN and the Ministry of Health.

The IRRS team considered the invitation from Romania of a full scope international peer review as part of the third IRRS cycle to be a sign of openness, transparency and commitment to continuous improvement for safety. Romania is acknowledged for including the medical exposure oversight in the scope of this mission for the first time.

The IRRS team received the full support and cooperation of all parties in the regulatory, technical, and policy issue discussions which were conducted in a very open, transparent and frank manner throughout the mission.

The IAEA issued a press release upon conclusion of the mission.

## I. INTRODUCTION

At the request of the Government of Romania, an international team of senior safety experts met representatives of the National Commission for Nuclear Activities Control (CNCAN), from 30 October to 10 November 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. This mission is part of Romania's third IRRS cycle. It is noteworthy that Romania is the first country starting its third IRRS cycle.

The purpose of this peer review was to review the Romanian governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Romania in March 2020. A preparatory mission was conducted the 3rd and 4th May 2023 at CNCAN Headquarters in Bucharest to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Romania and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 16 senior regulatory experts from fifteen IAEA Member States, three IAEA staff members, and one observer from the European Commission (EC). The IRRS team carried out the review in the following areas responsibilities and functions of the government; the global 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, and development and content of regulations and guides; emergency preparedness and response; nuclear power plants; nuclear fuel cycle facilities; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; control of medical, occupational and public exposures; interfaces with nuclear security and regulatory implications of pandemic situations. The IRRS mission to Romania was the first full-scope IRRS mission.

The IRRS mission included discussion of two policy issues: "Human Resources and Knowledge Management"; and "Regulatory body's status in the state administration system from the point of view of integrating the requirements on management systems from different standards or applicable regulations".

CNCAN conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of CNCAN self-assessment and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Romania advance reference material, conduct of interviews with management and staff of CNCAN, the Ministry of Health, the Institute of Public Health and the Nuclear and Radioactive Waste Agency (ANDR).

Members of the IRRS team also observed regulatory activities at Cernavoda NPP, the TRIGA Research Reactor located at the Institute for Nuclear Research (RATEN-ICN) Pitesti, the National Institute for Research and Development in Physics and Nuclear Engineering "Horia Hulubei" (IFIN-HH), the industrial radiography facility Dyomedica CND SRL - NDT laboratory, the clinic MNT Health Care Europe, an industrial facility (NDT-DYOMEDICA) and the IFIN- MNT Neolife Hospital. The visits included also discussions with management and staff of facilities.

A meeting with Mr Lucian Rusu, Deputy General Secretary of the Government, and with the Ministry of Health was also organized.

All through the mission the IRRS team received excellent support and cooperation from CNCAN.

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Romania's radiation and nuclear safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Romania. It is expected that this IRRS mission will facilitate regulatory improvements in Romania and other Member State, utilising the knowledge gained and experiences shared between CNCAN and IRRS reviewers and the evaluation of the Romanian regulatory framework for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

- providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- promoting the sharing of experience and exchange of lessons learned among senior regulators;
- providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;
- providing the host country with recommendations and suggestions for improvement;
- providing other states with information regarding good practices identified in the course of the review;
- providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- contributing to the harmonization of regulatory approaches among states;
- promoting the application of IAEA Safety Requirements;
- providing feedback on the use and application IAEA safety standards;
- providing feedback on the regulatory implications of pandemic situations.

### III. BASIS FOR THE REVIEW

#### A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Romania, a preparatory meeting for the IRRS mission was conducted from 3 to 4 May 2023. The preparatory meeting was carried out by the appointed Team Leader at that time Mr John Burta, Deputy Team Leader Ms Geraldine Pina and the IAEA representatives, Mr Zia Shah, Team Coordinator and Ms Vasiliki Kamenopoulou, Deputy Team coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of CNCAN represented by Mr Cantemir Ciurea-Ercau, President of CNCAN and the national Liaison Officer for the IRRS Mission and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Research reactors,
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal); and
- Selected policy issues.

The IRRS mission to Romania was determined to be a full-scope IRRS mission.

Mr Cantemir Ciurea-Ercau delivered a presentation on the national context, the current status of CNCAN, the self-assessment process and the overall action plan; the main counterparts for the different modules presented the results of the self-assessment to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Romania in October 2023.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Liaison Officer for the IRRS mission was confirmed as Mr Cantemir Ciurea-Ercau; Ms Mihaela Ion and Ms Anca Pop were confirmed as deputy and assistant Liaison Officers respectively. CNCAN provided IAEA with the ARM for the review at the end of August 2023. In preparation for the mission, the IAEA review team members reviewed the Romanian ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

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

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

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

The initial IRRS team meeting took place on Sunday 29 October 2023 in Marshal Garden Hotel, directed by the IRRS Team Leader and the IRRS Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The deputy and assistant Liaison Officers were present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 30 October 2023 with the participation of the CNCAN senior management and staff. Welcome address and introductory remarks were delivered by Mr. Cantemir Ciurea-Ercau, CNCAN President and Mr Lucian Rusu, Deputy General Secretary of the Government, followed by Mr Peter Elder, IRRS Team Leader and Mr Zia H. Shah, IAEA Coordinator. Mr Cantemir Ciurea-Ercau presented briefly the national regulatory framework, the self-assessment results and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Romania, CNCAN and the Ministry of Health with recommendations and suggestions for improvement and where appropriate, identifying good performances. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday 10 November 2023. The opening remarks at the exit meeting were presented by Mr Cantemir Ciurea-Ercau and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Peter Elder. Closing remarks were made by Ms Anna Bradford, Director, Division of Nuclear Installation Safety, IAEA.

An IAEA press release was issued.

## 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

### 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The National Strategy on Nuclear Safety and Security (NSNSS) approved through Governmental Decision, became effective on 30 July 2014. By this approval, the Government expressed its commitment for ensuring the nuclear safety at national level.

The NSNSS is based on the main 10 fundamental safety principles referred in IAEA SF-1 with the objective of continuous improvement of nuclear safety and security, including the protection of occupational exposed personnel, public and environment against the effects of ionising radiation. The NSNSS establishes a general framework for the nuclear sector and all governmental departments with a jurisdictional mandate on the nuclear sector. Its scope encompasses all facilities and activities regulated by the National Commission for Nuclear Activities Control (CNCAN) and other authorities. The NSNSS requires that all organisations have adequate human and financial resources and can implement the related research and development provisions by considering the national social and economic conditions. As part of national strategy (NSNSS), promotion of a safety culture is a general rule for all licence holders and the regulatory body(s). The graded approach is also considered towards the developments of nuclear safety and radiation strategy, the relevant legislation, and their supervision.

The Government committed to revise and update the NSNSS every 5 years or as necessary. The IRRS team was informed that the NSNSS is currently under review by CNCAN to update it to consider the governmental plans to expand the nuclear sector in Romania (to introduce SMRs for energy production needs, to complete construction at unfinished reactors at Cernavodă and to refurbish current operating reactors for their lifecycle extension) and to include recent changes in the Romanian regulatory environment. In addition to several clarifications and modernization, the update will include implementation of an integrated management system and the concept of the intelligent customer. The draft NSNSS highlighted the importance of the systematic update of national competence in nuclear safety. CNCAN plans to send the draft NSNSS to the other government institutions for consultation and then to the Government for approval in the first quarter of 2024.

The NSNSS is supported by a Strategic Action Plan, with clear activities, tasks, milestones, and implementation responsibilities distributed across Government organizations, including CNCAN, according to their mandate. The Strategic Action Plan was designed so that most of the actions should be either completed on or before December 2017, or be declared as ongoing actions. CNCAN is required to consolidate and report the status of the implementation of the Strategic Action Plan on an annual basis. Review during the mission revealed that 2015 and 2016 status reports show gradually increasing delays in the completion of many deliverables. These implementation delays have been documented by CNCAN were attributed to the lack of resources of the contributors, particularly that of CNCAN. After 2016 no further progress reports have been prepared. The IRRS team noted that several deliverables are considerably behind the target dates made in the NSNSS. The recent review of NSNSS which is ongoing addresses the Action Plan, timescale, and resources. The recent ongoing review of NSNSS includes an updated Action Plan with new deadlines and includes resources requirements. CNCAN is encouraged to report on the progress of the Action Plan to the Government on a regular basis.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The National Strategy for Nuclear Safety and Security was approved by the Governmental Decision in 2014, which requires its review every 5 years. The first review is planned to be completed in Q1-2024.*

(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 2.2 states that</b> <i>“The government establishes national policy for safety by means of different instruments, statutes and laws. Typically, the regulatory body, as designated by the government, is charged with the implementation of policies by means of a regulatory programme and a strategy set forth in its regulations or in national standards. The government determines the specific functions of the regulatory body and the</i>
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	<i>allocation of responsibilities. For example, the government establishes laws and adopts policies pertaining to safety, whereas the regulatory body develops strategies and promulgates regulations in implementation of such laws and policies. ...”.</i>
(2)	<b>BASIS: GSR Part 1 (Rev. 1) Requirement 1 states that</b> <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>
S1	<b>Suggestion: CNCAN should consider finalizing the review of National Strategy for Nuclear Safety and Security and submitting it to the Government for approval.</b>

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Law 111/1996 on the safe deployment, regulation, licensing, and control of nuclear activities, republished, with subsequent modifications and completions provides the legislative framework governing the safety of nuclear installations. This law sets the basic rules on the functioning of the nuclear regulatory authority and the conditions for licensing nuclear activities, including radiation protection, radiation exposure, environmental protection, safety of the public, workers, and patients, transportation, emergency preparedness, safeguards, and security. The provisions are detailed in specific regulations, issued by CNCAN in the field of competence.

This law empowers the national nuclear regulatory authority, CNCAN, which is the national nuclear regulatory authority, to: issue mandatory regulations; issue licenses for nuclear installations and activities; perform assessments and inspections; verify compliance with the nuclear safety requirements and to take any necessary enforcement actions. This law also designates the competent authorities for these areas and their main roles and responsibilities.

The Ministry of Environment, Waters and Forests performs the monitoring of the environmental radioactivity through its dedicated network. In addition to CNCAN, the Ministry of Internal Affairs, through its dedicated structures, has a significant role in the development, implementation and maintaining the process of prevention, preparedness, response, and assessment of nuclear and radiological emergency situations.

Authorization and inspection of radiation protection of radiation sources facilities and activities is in the mandate of the CNCAN as well as the Ministry of Health. Some of the provisions in the Law 111/1996 and the Order no. 381/2004 of the Minister of Health approving the Basis Sanitary Norm for safe deployment of nuclear activities are overlapping. The IRRS team identified many areas of authorization and inspection that are addressed by both authorities without coordination. This emphasizes the need for a clear delegation of responsibilities among these authorities. Where responsibilities and functions overlap, this could create conflicts between different authorities and lead to different, potentially conflicting requirements being placed on authorized parties or on applicants. This, in turn, could also undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>The regulatory responsibility for radiation protection is in the mandate of the CNCAN as well as Ministry of Health, in some areas. The two systems (e.g. separate laws, authorization and inspection) are operating separately, without any coordination resulting in a radiation protection framework which is incomplete and has duplication and inconsistencies.</i>
(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 2.6 states that</b> <i>“Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>the governmental, legal and regulatory framework for safety."</i>
(2)	<b>BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that</b> <i>“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.”</i>
R1	<b>Recommendation: The Government should ensure that the roles and responsibilities of CNCAN and the Ministry of Health are clearly assigned to avoid conflicting requirements. The Government should ensure that the radiation protection framework is complete to ensure the protection of people and the environment.</b>

### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The nuclear regulatory authority is established and organised in accordance with the legal provisions included in the Law no. 111/1996.

The law stipulates the role and responsibility of CNCAN, as well as its mandate, as follows, CNCAN:

1. is the national competent authority for regulation, licensing, and control in the nuclear field, for all activities and installations under the scope of the Law 111/1996;
2. applies regulations, licensing, and control in the nuclear field, for all activities and installations under the Law;
3. sets the policy and the strategy for regulation, licensing and control for nuclear safety, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials, transportation of radioactive materials and safe management of radioactive waste and spent fuel;
4. ensures, 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;
5. amends the regulations, when necessary, for 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.

CNCAN is under the subordination of the Prime Minister, through the General Secretariat of the Government. CNCAN is completely separated and independent from all the organizations concerned with the promotion or utilization of nuclear energy. CNCAN exercises its functions independently from the ministries and other authorities of the central public administration, subordinated to the Government.

The companies and organizations that operate or own the main nuclear and radiological installations are subordinated to the Ministry of Energy, to the Ministry of Economy, Entrepreneurship and Tourism, or to the Ministry of National Education, and the Ministry of Health.

CNCAN is funded through the state budget. With respect to human resources, in accordance with the legal provisions, CNCAN has been allocated 170 positions (excluding the president and the president’s cabinet), out of which 127 positions are technical and 43 are non-technical. From the 170 positions, 98 positions are occupied. CNCAN has raised this issue with the Government. In response, the Government enacted Law 234/2023 amending Law 111/1996. It provides legal basis to increase the number of positions up to 200 and provisions to increase the level of salaries. Another major change in the new Law allows CNCAN to return to the earlier self-financing provision as of before 2009. The issuance of Law 234/2023 aimed at ensuring the appropriate financial resources to CNCAN with the view to fulfil the nuclear regulatory authority attributions and responsibilities in line with the new national trend in

the nuclear field. However, Law 296/2023 on fiscal and budgetary measures introduced restrictions for the governmental sector staffing that could impact the full implementation of Law 234/2023. CNCAN will need to work with the Government to ensure these do not undermine the intent of Law 234/2023 with regard to adequate financing of the regulatory body.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *In 2023, the Government passed the Law 234/2023 allowing an increase in the number of positions and the level of salaries at CNCAN, as well as changing the manner in which CNCAN is financed. However, the more recent Law 296/2023 introduced restrictions for governmental sector staffing that could impact the full implementation of the law on availability of human and financial resources for CNCAN.*

(1)	<p><b>BASIS: GSR Part 1 (Rev. 1) para. 2.5 states that</b> <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></p> <p><i>(4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;</i></p> <p><i>(5) Provision for the involvement of interested parties and for their input to decision making;</i></p> <p><i>(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;</i></p> <p><i>( )The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation; ...”</i></p>
(2)	<p><b>BASIS: GSG 12 para. 2.11 states that</b> <i>“Adequate and stable financing for all regulatory activities is fundamental to independence. The financing mechanism should be clearly defined in the legal framework”.</i></p>
R2	<p><b>Recommendation:</b> <b>The Government should ensure the timely implementation of the provisions of Law 234/2023 to allow the provision of sufficient human and financial resources to CNCAN.</b></p>

The IRRS team met with the Deputy Secretary-General of the Government, Mr Lucian Rusu. The Deputy Secretary-General stated that Romanian Government is committed to nuclear safety and maintaining high regulatory competence. During this meeting, the IRRS team informed the Deputy Secretary-General of possible conflict due to overlapping function between CNCAN and Ministry of Health in radiation safety. The Deputy Secretary-General organized a high-level meeting with the Ministry of Health to discuss this issue. The Deputy Secretary-General also expressed the support of the Government for addressing the CNCAN resourcing shortfall.

With respect to independence of decision making, CNCAN has the necessary legal authority and procedures to prevent pressure associated with political circumstances, government departments, or licensees. As well, Order 210/2021 provides a Code of ethics and professional conduct for CNCAN staff which regulates conflict of interest. The Code also contains provisions that forbid the rotation of personnel between the regulator and the licence holder.

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

Law 111/1996 clearly stipulates that the prime responsibility for the safety of facilities and/or activities rests with the license holder and the responsibility for the safety of facilities and/or activities cannot be delegated. There is a clear responsibility of licences holder for nuclear damage caused by accidents or problems generated by third parties, such a service provider or supplier to the facility. The clear definition of legal obligations ensures that the licensee’s responsibility for safety cannot be diminished or shifted to the regulatory authority.

As required by the law, a license is needed for each stage of life of a nuclear installation. In addition, Law 111/1996 grants the regulatory body the authority to require the authorized parties to comply with stipulated regulatory requirements, as well as to demonstrate compliance. The Law 111/1996 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, from the obligations stipulated in the law, the conditions stipulated in the licence, or the nuclear or radiological materials and installations covered by that licence.

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

The licensing system administered by CNCAN is in cooperation with other governmental authorities (ministries and agencies) in areas such as environment, health, transport, industrial safety, security, etc. Any issues raised by these authorities are considered before licenses are issued by CNCAN, providing that there is no conflict with the provisions of the Law 111/1996 or CNCAN regulations. Any other licenses required by other governmental authorities for that process are prerequisites to issuance of the CNCAN license. The exception to this is the environmental authorization issued by the Ministry of Environment which is issued after the operation license by CNCAN. The Environmental Agreement, issued by the same ministry is a prerequisite to the siting license issued by CNCAN.

Law 111/1996 assigns authorities having responsibilities in the control of various aspects of nuclear activities. Although their respective responsibilities are established by the legislation in force, CNCAN has a Memoranda of Understanding with each of these organizations, to prevent potential gaps and overlaps in the implementation of their respective duties and responsibilities. The responsibilities of the other authorities empowered by the Law 111/1996 to control specific activities in the nuclear field have not been changed in the last 10 years. To ensure transparency of its activities and decision-making processes, CNCAN consults with, and provides information to all the organizations that have an interest in its regulatory activities, including licensees and other nuclear industry representatives, governmental, local, and municipal authorities, as well as interest groups and individual members of the public. In addition, CNCAN provides information to the media.

The IRRS team identified areas of overlapping responsibility and activities for different authorities. This issue is addressed in the Recommendation R1 in Section 1.2. CNCAN does not have a formal Cooperation Protocol with the Ministry of Health 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.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *There are some areas of authorization and inspection that are overlapping between the Ministry of Health and CNCAN and there is no Cooperation Protocol between the two authorities.*

(1)	<b>BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that</b> <i>“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.”</i>
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R3	<b>Recommendation:</b> <b>The Government should make provisions for effective coordination of regulatory functions between CNCAN and the Ministry of Health.</b>
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### 1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

Law 111/1996 authorizes CNCAN to take any measures to protect the people and the environment when an unforeseen event that jeopardises public health occurs, or to avoid risks that could result from the accidental contamination of any places, materials, or products by radioactive substances. The system for protective actions to reduce these risks is in accordance with current legislative provisions and is consistent with the principles of justification and optimization in radiation protection.

The regulatory authority is empowered by law to identify and evaluate existing exposure situations and to establish the strategies which ensure that the risks and efficiency of protective measures are considered in the management of existing exposure situations. With respect to natural sources, the Norms on radiological safety requirements for natural radioactive sources, CNCAN establishes the requirements for protecting workers, the public, and the environment against risks resulting from exposure to natural radioactive sources. The legal framework is completed by provisions related to sources that are not under regulatory control – also called orphan sources. The regulatory authority is empowered by law to order the recovery of orphan sources and to coordinate recovery activities.

Cooperative activities have been developed for regulating radiation monitoring of scrap metal during the reprocessing cycle, and a mechanism is in place to address any sources identified.

The National Response Plan outlines the steps to be undertaken in case unacceptable radiation risk is identified for any situation. Additional provisions are provided in Order 113/2018 related to the management of nuclear / radiologic emergency situations, which was approved by the CNCAN President.

The financial resources and other means to cover the cost of recovery activities of orphan sources and of those linked to scrap metal are established in accordance with Government Ordinance 11/2003.

### **1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL**

In accordance with Law 111/1996, activities of predisposal and disposal of radioactive waste and spent nuclear fuel, including the decommissioning of facilities are regulated, licenced, and controlled by CNCAN. Romania also follows Euratom Directive 2011/70 that requires a National Strategy on safe management of nuclear fuel and radioactive waste. The licensee is required to develop a decommissioning program at the design phase for any facility and update it periodically. The decommissioning program must be submitted to CNCAN for approval. To meet the requirements of Directive 2011/70, CNCAN developed new regulations and revised the existing regulations on predisposal and disposal of radioactive waste, decommissioning of nuclear and radiological facilities as well as natural sources. The safety decommissioning requirements are detailed in Order no. 102/2022. The decommissioning strategies, end state criteria, development of initial decommissioning plan, planning and conducting of the decommissioning are defined in this regulation. Requirements for transition from operation to decommissioning as well as termination of decommissioning and release of the facility and the site from regulatory control are detailed in this regulation. The clearance criteria for materials and buildings are detailed in Order 155/2022. Law 111/1996, CNCAN Order 74/2022, Government Ordinance 11/2003, Government Decision 1080/2007 contain the main legal and regulatory provisions for cost estimation and financing of radioactive waste management and decommissioning activities. According to these laws and regulations, the licence holder is financially responsible for the safe management of radioactive waste and decommissioning, i.e. the “polluter pays principle”.

Government Decision 1080/2007 establishes two funds for securing the financial provisions for the decommissioning of nuclear power plants as well as for the management of radioactive waste and spent nuclear fuel arising from fuel cycle activities. These funds are paid by fees levied on the Cernavodă NPP, which are calculated based on electricity prices. Both funds are managed by the Nuclear and Radioactive Waste Agency (ANDR), which also implements the National Programme for Radioactive Waste and Spent Fuel Management. ANDR will be the licensee for the planned near-surface Low and Intermediate Level short Lived Waste (LILW) disposal facility so called DFDSMA and the deep geological disposal facility for spent nuclear fuel and LILW-LL. In addition, ANDR is responsible for coordinating the implementation of decommissioning of nuclear and radiological installations at the national level.

According to Government Decision 1080/2007 and Government Ordinance 11/2003, the financial provisions for the management of institutional radioactive waste, including disused radioactive sources,

and the decommissioning of medical, industrial and research facilities, radiological facilities, are to be provided by the generators of radioactive waste and from the budget assigned to ANDR. However, there is not yet a robust mechanism in place that would secure the financial contributions by the licensees of radiological facilities for decommissioning, or by the generators of institutional radioactive waste for predisposal and disposal activities.

The current situation is based on commercial contracts. The National Institute for Research and Development in Physics and Nuclear Engineering-Horia Hulubei (IFIN-HH) collects the institutional radioactive waste from the generators and carries out the necessary predisposal and disposal activities at the Radioactive Waste Treatment Plant at Măgurele and at the LILW disposal facility ANDR at Baita Bihor, respectively. The institutional waste is collected, and the fees for covering the costs of the predisposal and disposal activities are paid on demand by the waste generators. CNCAN verifies that radiological facility licensees maintain adequate financial conditions throughout the operating phase of facilities. Until a robust mechanism is established to implement the provisions in Government Decision 1080/2007 and Government Ordinance 11/2003, financial resources for the safe decommissioning of radiological facilities and management of institutional radioactive waste, including disused radioactive sources, may not be available when needed.

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**Observation:** *There is no robust mechanism in place to ensure that adequate financial resources are available when necessary for safe decommissioning of radiological facilities and for the management of institutional radioactive waste, including disused sources.*

(1)	<p><b>BASIS: GSR Part 5 Requirement 1 states that</b> <i>“The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions...”</i></p>
(2)	<p><b>BASIS: SSR 5 Requirement 1 states that</b> <i>“The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility.</i></p> <p><i>3.7. Matters that have to be considered include: ...</i></p> <p><i>(b) Setting clearly defined legal, technical and financial responsibilities for organizations that are to be involved in the development of facilities for radioactive waste management, including disposal facilities of all types;</i></p> <p><i>(c) Ensuring the adequacy and security of financial provisions for each disposal facility;”</i></p>
(3)	<p><b>BASIS: GSR Part 6 para. 3.2 states that</b> <i>“The responsibilities of the government shall include: ...</i></p> <p><i>- Establishing a mechanism to ensure that adequate financial resources are available when necessary for safe decommissioning and for the management of the resulting radioactive waste....”</i></p>
(4)	<p><b>BASIS: GSR Part 1 Requirement 10 states that</b> <i>“The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.”</i></p>
S2	<p><b>Suggestion:</b> <b>The Government should consider ensuring that ANDR improves the mechanism to secure appropriate financial provisions for the predisposal management</b></p>

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**and disposal of institutional radioactive waste (including disused radioactive sources), and for the decommissioning of radiological facilities.**

A similar finding was made by the 2022 ARTEMIS mission to Romania.

### 1.8. COMPETENCE FOR SAFETY

The Government of Romania continues to emphasize the need for developing and sustaining competences in the nuclear field. The NSNSS contains measures for fostering and maintaining competence for safety for all organizations in the nuclear field and provisions meant to cover the necessary human and financial resources. The ongoing review of NSNSS will be updated in accordance with the governmental plans to expand the nuclear sector in Romania (to introduce SMRs for energy production needs, to reopen constructions at unfinished conserved reactors and to refurbish operating reactors for their lifecycle extension) and to ensure the availability of necessary human and financial resources.

Through the Law 111/1996, regulations and license conditions, the licensees are obligated to ensure adequate financial and human resources. CNCAN reviews and inspects licensees' resources and takes enforcement actions, when necessary, to ensure that long-term staffing plans exist for nuclear-safety related jobs at nuclear installations. Law 111/1996 also provides for selection, training, qualification, and authorization of personnel in organizations responsible for the design, location, construction and assembly, commissioning, operation, and decommissioning of nuclear installations. It further includes provisions for the continuous development and maintenance of competences with a systematic approach to training and competence management. The necessary competences and training for the staff involved in the transport of radioactive materials are mentioned in international agreements ratified by Romania on transport of dangerous goods. In addition, training certificates required by dangerous goods regulations as well as radiation working permits are necessary for those working in transport of radioactive materials.

As regards the regulatory staff, a yearly training programme is established for CNCAN staff on specific regulatory topics. This programme is approved by the CNCAN President and is implemented using CNCAN's own budget which is annually approved by the General Secretariat of the Government. However, until the enactment of Law no 234/2023, the amount allocated financial resources are not sufficient. This is further discussed in Module 3.

International technical cooperation programmes have continued to be used to strengthen the regulatory competence. CNCAN continues to recruit staff for all the available positions with an adequate educational background, experience, and qualifications and to improve staff retention.

CNCAN also receives assistance through the International Regulatory Development Partnership (IRDP), sponsored by the US NRC. Starting in 2014, CNCAN staff received training through numerous activities organized in the framework of the IRDP.

Training received through the IAEA technical cooperation programs and through the US NRC IRDP program are particularly valuable in keeping CNCAN's technical staff up to date with the current international standards and good practices in nuclear safety and regulatory work, as well as with the relevant operating and regulatory experience. However, more resources are needed to be dedicated to staff development, Recommendations R2 in Section 1.3 and R5 in Section 3.3 address this issue.

### 1.9. PROVISION OF TECHNICAL SERVICES

Relevant provisions for technical services relating to safety, such as services for personnel 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 the nuclear field). The authorisation process of these technical services is performed in accordance with the legal

provisions, stipulated in Law 111/1996 and Order 155/2018, which approves the Regulation on the authorisation procedures.

The authorized parties are responsible for ensuring that radiological monitoring equipment is tested and calibrated as needed, with CNCAN verifying compliance. The calibration of personal dosimeters is performed by non-governmental providers. The National Network for Monitoring the Environmental Radioactivity (Order 1978/2010 of the Ministry of Environment and Forests) provides environmental monitoring. The network consists of 37 stations for monitoring the environmental radioactivity (SSRM), 93 automatic stations from the National Environmental Radioactivity Alert/ Alarm Systems (SNAARM) and a National Laboratory for the Reference for Radioactivity.

In Romania, there are no standards for calibration of dosimeters used for patient dosimetry, or accredited laboratory for calibration of survey meters. Recommendation R19 in Section 6.10. addresses this issue.

## **1.10. SUMMARY**

Romania has an established legal framework for radiation protection and nuclear safety and security. The Government's long-term commitment to safety is articulated in the National Strategy. The NSNSS summarizes the commitments of the Government with due consideration given to most elements.

CNCAN constitute the independent regulatory body in Romania. The IRRS team considered that the authorization procedure eliminates undue interference or pressure from governmental authorities.

CNCAN is currently understaffed and under resourced. The IRRS team stressed that the Government need to complete implementation of Law 234/2023 to allow for sufficient human and financial resources to CNCAN.

CNCAN has good coordination with other Government agencies in most areas. However, there are overlapping responsibilities between CNCAN and the Ministry of Health. The Government should clearly define roles and responsibilities and make provisions for effective coordination of regulatory functions between them.



## **2. THE GLOBAL SAFETY REGIME**

### **2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION**

Romania is a contracting party to all relevant international conventions and international agreements for ensuring nuclear safety and security. Romania has made a political commitment to implement the Code of Conduct on the Safety and Security of Radioactive Sources, and Supplementary Guidance on the Management of Disused Radioactive Sources. Romania has also nominated a Point of Contact for the purpose of facilitating the export and/or import of radioactive sources and made available the responses to the Importing and Exporting States Questionnaire. Furthermore, Romania has made a political commitment to the Code of Conduct on the Safety of Research Reactors.

CNCAN contribute to the Romania's effort to fulfil its respective international obligations and agreements, including contribution in international peer reviews, and promote international cooperation and assistance to enhance safety globally. In this regard, CNCAN activities include preparation of country reports and participation in review meetings on the Joint Convention (JC) and the Convention on Nuclear Safety (CNS), and to provide input in the implementation of the other treaties. Romanian institutions cooperate with the IAEA and other international regulatory bodies in the development of codes, standards, and guides. CNCAN participates in the Safety and Security Standards Committees of the IAEA. These fora allow discussion and exchange of information to support in the common understanding of international safety standards.

The Law on the safe deployment, regulation, licensing, and control of nuclear activities empowers CNCAN to issue mandatory regulations on nuclear safety, and clearly establishes an obligation to harmonize these regulations with IAEA safety standards.

CNCAN also takes an active part in the international peer reviews organized by the IAEA for the evaluation of the regulatory infrastructure and nuclear safety of the facilities in several countries. It is important to note that Romania has received several peer review missions organized by IAEA, both for regulatory authority and for the operator (IRRS mission 2006, 2011 and follow up 2017, ARTEMIS 2022, EPREV 2010, IPPAS 2021, SALTO 2020, OSART 2019, SEDO 2015). All these peer review missions addressed the aspects of nuclear safety, identified good practices and performances, and were sources of sharing of experience. CNCAN staff participated as observers in the peer review missions at Cernavodă NPP.

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. Romania has participated in the EU peer review process (Stress Test, Topical Peer Review on ageing management and the recent Topical Peer Review on fire protection).

CNCAN is part of and is participating in Heads of the European Radiological Protection Competent Authorities (HERCA) and European Nuclear Security Regulators Association (ENSRA).

Romania is a member of the Organisation for Economic Cooperation and Development-Nuclear Energy Agency (OECD-NEA), in this regard, CNCAN is participating in the following committees and their related working groups: Committee on Nuclear Regulatory Activities (CNRA), Committee on Safety of Nuclear Installations (CSNI), Nuclear Law Committee (NLC), Committee on Radiological Protection and Public Health (CRPPH). This includes participation in several working groups and in plenary meetings, however due to staffing issues (Recommendation R2 in Section 1.3 addresses this issue)

CNCAN is not able to participate in all relevant meetings. 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. However, there is no written strategy with predefined priorities for which meetings are most important to participate in. CNCAN is encouraged to develop such a strategy and allocate sufficient resources to allow staff to participate more actively in international activities.

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**Observation:** *CNCAN has limited resources to engage and participate in national and international cooperation activities to enhance safety.*

(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 3.2 (e) states that</b> <i>“Regular multilateral and bilateral cooperation between relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections, by means of sharing of knowledge and feedback of experience.”</i>
(2)	<b>BASIS: GSG 12 para. 2.12 states that</b> <i>“Although the overall budget of the regulatory body may be fixed by the government, the regulatory body should have the authority to distribute financial resources to its various regulatory activities for the greatest effectiveness and efficiency”.</i>
S3	<b>Suggestion:</b> <b>CNCAN should consider establishing a strategy for international cooperation that includes priorities to allow for effective use of resources.</b>

With respect to international cooperation and exchange of information, CNCAN maintains cooperation relationships with a various number of nuclear regulatory authorities worldwide, through bilateral arrangements.

CNCAN is acting as the National Contact Point as per IAEA Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (in accordance with the Law 111/1996 and the IAEA letter EPR/CP(0100) from 16/11/2000) with the following functions: National Warning Point, National Competent Authority for a Domestic Accident and National Competent Authority for an Accident Abroad. CNCAN cooperate with the competent authorities in other countries in preparation of protective actions, maintain contacts with all affected countries and coordinates with them exchanges of information and information to the public. In accordance with the legal provisions, primarily the Emergency Governmental Ordinance 21/2004 regarding the National System for the Management Emergency Situations, with further modifications and completions, the National Committee for Emergency Situations is responsible to decide about rendering or accepting foreign assistance. Romania has registered its capabilities to assist in Respond and Assistance Network (RANET) and CNCAN is the national contact point. Romania performs its tasks depending on the available capacity. Most recently safety and radiological protective equipment was offered at the request of Ukraine in 2022.

### 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

CNCAN has made specific arrangements to identify lessons learned from operating experience and regulatory experience, including experience from other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body, and other relevant authorities. Important generic issues of interest at international level, resulting from events, or from new safety analyses and research, are tracked and analysed and licensees’ corrective actions are inspected.

Relevant information and lessons learned from operating and regulatory experience are gained from the participation in the multinational related groups. CNCAN participates in various international activities dedicated to Operating Experience Feedback (OEF) or which address also OEF, including:

- European Clearinghouse on Operating Experience Feedback for Nuclear Power Plants.

- annual meetings of the senior regulators of countries operating CANDU type nuclear power plants.
- review meetings in the framework of the Convention on Nuclear Safety.
- review of reports issued by OECD/NEA Working Group on Operating Experience.
- review of and contribution to operating experience shared through the Incident Reporting System (IRS), Incident Reporting System for Research Reactors (IRSRR) and Fuel Incident Notification and Analysis System (FINAS).

The process of review and assessment of operational events occurring at nuclear facilities is well established. There is a NPP procedure for reporting of events, which is in compliance with the approved CNCAN quality management system manual. CNCAN has also developed an internal guideline for the inspection of recording, reporting, analysis of events and use of operating experience for nuclear installations. Requirements on reporting of operational events are fixed in the operating license of the NPP.

Regulatory requirements on event reporting are provided in the regulation NSN-18 – Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations (issued in 2017, revised and published in 2022). The requirements in regulation NSN-18 include the obligation of the licensees to report significant events to CNCAN, as well as the obligation to use internal and external experience and CNCAN on a yearly basis assesses the use of external experiences.

The results of analyses of domestic events are communicated internationally either through formal channels, such as the NEWS system (for the INES events), the IRS, and IRSRR database or at various international meetings and conferences.

### **2.3. SUMMARY**

Romania through CNCAN fulfils its respective international obligations, participates in the relevant international arrangements, including international peer reviews, and promotes international cooperation and assistance to enhance safety globally.

Furthermore, CNCAN has arrangements to identify lessons learned from operating experience, and regulatory experience, including experience in other states, including the dissemination of the lessons learned and their use by authorized parties, the regulatory body, and other relevant authorities.

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 financial and human resources.

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

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

CNCAN was established as Romania's nuclear regulatory authority by the Law 111/1996. The law establishes CNCAN as the competent authority in the nuclear and radiological field to exercise the regulatory, licensing and control powers provided therein. This mandate includes the attribution and responsibility to issue regulations on the matters under CNCAN's control. CNCAN is led by a President appointed by the Prime Minister, who reports to the Government through the General Secretariat of the Government. In the cases of radiation sources and radiation generating devices used in the medical field, Law 111/1996 assigns overlapping responsibilities for the regulatory oversight (authorization, inspection, development of regulations) with the Ministry of Health. This issue is addressed in Recommendation R1 in Section 1.2.

The IRRS team noted that CNCAN is not autonomous on establishing the structure of the organization, having limited independence in that regard since the organizational chart needs to be approved by a government decision. The current organizational structure of CNCAN was approved by the government decision No 729/2018. Three technical divisions handle the core regulatory functions of the organization for nuclear installations as well as installations and practices involving uses of radiation, allocating about 70% of current staff.

The internal structure of each division, as well as the staff distribution among divisions, is within CNCAN's independent resolve and is exercised by President's decision. CNCAN regularly evaluates its organizational structure and resources, complying with requirements imposed by the government on public institutions. However, these actions remain mainly formal, oriented on non-compliance issues, and few actions are related to organizational improvements (see Section 4.7).

CNCAN is aware of the regulatory challenges that will have to be addressed due to Romania's current and future nuclear projects. Thus, the need for a modification of its organizational structure is recognized in order to maintain and increase its human resources.

CNCAN has been facing a shortage of financial resources for its activities for a long period of time, posing serious challenges to the appropriate functioning of the organization according to its mandate, such as shortage of human resources and under-execution of training activities. A new, recently enacted Law 234/2023 is considered by CNCAN's senior management as a compensatory measure to revert the current state of underfinancing and lack of human resources of the organization. This law assigned CNCAN an increased maximum number of allowed positions of the organization, as well as strengthened budgetary means by allowing CNCAN to be self-financed through the collection of regulatory fees (see Section 3.3).

#### **3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS**

CNCAN is provided by the law with the necessary authority to intervene in all regulatory matters under its control and it exercises this authority without any undue influence. Consistent with this, CNCAN is endowed with its own legal personality, and it is functionally as well as administratively separated from any organization concerned with the promotion or utilization of nuclear energy or ionizing radiations, reflecting its independence. While state owned organizations that operate nuclear or radiological facilities are typically subordinated to a ministry, CNCAN is under the coordination of the Prime Minister through the General Secretariat of the Government. The roles are clearly separated in the legal framework but there is no interface between such organizations and CNCAN except those appropriate between the regulatory body and the authorized parties.

Law 111/1996 empowers CNCAN to perform inspections of all facilities and places where activities under regulatory control might take place. Additionally, CNCAN has the legal power to suspend any

activity under its control, seize sources or close facilities if deemed contravening any legal or regulatory obligation.

CNCAN's Management System describes a commitment from its President to establish a decision-making process that shall not be compromised by considerations of a nature different than the nuclear safety. A series of values are expected and encouraged on CNCAN's staff that refer to an independent performance of their regulatory duties, namely professionalism, competence, integrity, and avoidance of conflict of interests. In order to prevent conflict of interest in relation to staff, positions of responsibility within the organizational structure cannot be occupied by persons who have been engaged in employment for authorized parties within the previous year. This provision is applicable to all levels of managerial positions.

There are certain aspects which might be a source of challenges to CNCAN's independent working. As described in Section 3.1, CNCAN is subject to government approval for modifications of its organizational structure. This requirement has not been identified by CNCAN as a specific concern, since the process for approval from the government is typically swift.

CNCAN's financing is currently provided from within the state budget. In this regard, CNCAN is limited in the management of its overall budget and distribution of financial resources to its various regulatory activities. The IRRS team is aware that provisions of Law 234/2023 provide independent financing to CNCAN, and encourages both the government and CNCAN to finalize full implementation of such arrangements on priority. This issue is addressed in Recommendation R2 in Section 1.3.

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

CNCAN is limited by law on the maximum number of staff positions within the organization. Law 111/1996 established a maximum number of positions of 170. The recent approval of Law 234/2023 increased this number to 200, as an important consideration by the government in recognizing the importance of regulatory activities.

However, the IRRS team was informed that the recent enactment of a Romanian austerity Law 296/2023, applicable also to the regulatory body, could prevent the possibilities of properly staffing the organization by removing all vacant positions from CNCAN's organizational chart, including the recent addition. An exemption of the regulatory body from the provisions of this law is possible and CNCAN has indicated that it will be initiating discussions with the government for such request. The IRRS team noted that CNCAN has not yet been able to implement successful measures for acquiring the competences and the resources necessary to fulfil its statutory obligations.

Even though the number of positions allowed by the government to CNCAN has been until recently 170, only about 55% of those positions are currently filled. The technical positions currently vacant are 61, amounting to about 49% of the technical complement. Vacant support positions are at present 15, amounting to about 34% of the allocation. This situation is attributed by management as largely being due to the external constraints suffered by CNCAN, rendering the regulator an unattractive employer in the present competitive market for both young professionals and experienced specialists. Low wages and an unclear career path have been stated as the most relevant constraints for the difficulties faced by the organization to recruit and retain competent staff. High staff turnover has also been identified as a consequence of the same factors.

The IRRS team noted that CNCAN's staff is competent and dedicated to performing its functions and fulfilling its obligations, often engaging on the responsibilities of vacant positions, absorbing an excessive workload in different matters at a time. Even though this gives the IRRS team confidence that the core regulatory functions are being maintained, fulfilment of those commitments might often come at personal expense for the employees. This dedication could potentially lead to 'burn-out', ultimately contributing to staff leaving the organization. As no regular assessments of the impact of vacant positions on the performance of CNCAN are conducted, the impact of understaffing could potentially be underestimated. Due to the lack of redundancy of qualified staff on some key regulatory areas, the

departure of a relatively small number of professionals could lead to an impairment of core regulatory functions thus threatening the resilience of the regulatory body.

As described in Section 3.1, CNCAN is aware of the regulatory challenges that will have to be addressed due to Romania’s current and future nuclear projects. However, there is no human resource plan detailing the strategy for systematically setting the hiring priorities, according to a graded approach. Competence management is also incomplete, being only done at the level of some units as described in Section 4.4.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN does not have a complete set of competence requirements. Nor has it developed a comprehensive human resources plan establishing the hiring priorities for the strengthening of areas of the structure.*

(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.5 states that</b> <i>“The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach ....”</i>
(2)	<b>BASIS: GSR Part 2 para. 4.23 states that</b> <i>“Senior management shall ensure that competence requirements for individuals at all levels are specified ....”</i>
R5	<b>Recommendation:</b> <b>CNCAN should develop and implement a comprehensive human resource plan setting the competences needed and the hiring priorities, according to a graded approach.</b>

Training of regulatory staff is not systematically considered. Training of new as well as existing staff is conducted annually, according to a training plan. The content of the plan is usually proposed by each division based on their specific competences and qualifications needed for their staff, and is later consolidated by the Human Resources unit. This process is done informally, not following a documented procedure, and there are several instances identified by the IRRS team where training of relevant staff is either insufficient or inadequate (see Section 7.1). The IRRS team was informed that in this regard, a training procedure is being developed. CNCAN recognizes that the execution of the training activities is being affected by the underfinancing of the organization and as a consequence, technical training relies on activities organized by the authorized parties (Nuclearelectrica in the case of NPPs) or events organized by IAEA and other international organizations. Along similar lines, training for staff of support units is limited to self-training activities and free online courses, but these activities are not formalized as part of the training program. Training for newcomers is often primarily focused on CNCAN regulations and the specific legal and regulatory framework, relying extensively on on-the-job training under the mentorship of senior staff for the technical aspects.

Succession planning and transfer of knowledge from retiring staff to younger professionals is considered by CNCAN with limited scope. A mentoring process is initiated whenever possible, but is mainly based on on-the-job training and is not governed by a systematic process, nor registered on the training records of the trainee.

The IRRS team considers that a properly structured and implemented training programme plays a key role for the induction and assimilation into the organization of a potentially large number of new recruits.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *While CNCAN has elements of training in many areas, it does not have an overarching training programme based on a systematic approach. Additionally, CNCAN’s strategy to compensate for the departure of qualified staff is neither systematic nor documented.*

(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.13 states that</b> <i>“A process shall be established to develop</i>
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills ....”</i>
(2)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.12 states that</b> <i>“The human resources plan for the regulatory body [...] shall include a strategy to compensate for the departure of qualified staff.”</i>
R6	<b>Recommendation: CNCAN should further develop and implement a systematic training programme to maintain the necessary competences and skills of its staff, and a strategy for succession planning.</b>

The IRRS team recognizes the impact of budgetary constraints on the effective implementation of a proper human resources plan and encourages both the government and CNCAN to finalize full implementation of those arrangements that will make the organization self-financed. Recommendation R2 in Section 1.3 addresses this issue.

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

The IRRS team took note on the existence of the internal “Council of directors”, established according to the Governmental Decision No 729/2018, composed of members of CNCAN’s upper management. It decides on any necessary matter regarding management of the organization and resources. The council also decides on regulatory matters on particular circumstances. The functions and responsibilities of the “Council of directors” are defined in an “internal rule” document.

CNCAN has no formally established liaison with external advisory bodies or technical support organizations. Some informal links are maintained with RATEN-ICN Pitești, a local research institute subsidiary of Romania’s promotion organization for nuclear energy, with which technical research results are shared.

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

Various interfaces between CNCAN and authorized parties are established within the management system, providing mechanisms for constant, formal and open communication. These interfaces are more developed and mature in the case of communication with Cernavodă NPP or other nuclear facilities, and to a lesser degree in the cases of smaller authorization holders for radiation uses or practices. Adequate venues for hearing the opinion of authorization holders or applicants on regulatory matters concerning them are required by law and are properly established by CNCAN.

In the case of Cernavodă NPP, formal and frequent communication is established through the constant interaction of CNCAN’s resident inspectors and plant management. In addition, regular meetings are conducted between CNCAN and Cernavodă NPP management to discuss current operating and regulatory issues and challenges. Formal correspondence is used when matters require an official notification, response or action.

Similar periodic meetings are used to interact regarding issues pertaining to different projects of other nuclear licensees, such as the National Agency for Radioactive Waste or the National Institute for Physics and Nuclear Engineering. It is worth mentioning that such interaction is not provided with the Ministry of Health and in particular with the Institute of Public Health.

Interaction with applicants and authorized parties of non-nuclear facilities or activities is conducted by other means. Continuous communication with these users is based on electronic mails and through website exchanges. CNCAN maintains a website where all safety issues and legislative framework for radiation safety (including radiation protection) is published. A dedicated platform is put at the disposal of authorized parties for radiological facilities where they can submit documentation related to licensing issues or notifications. The possibility to request an audience with CNCAN is stated by law, and

CNCAN has established adequate means for compliance with this requirement. However, the IRRS team identified that authorized parties of non-nuclear facilities or activities may be confused by the overlapping responsibilities in the areas of authorization and inspection of CNCAN and the Ministry of Health, subjecting them to an enhanced workload to comply with relevant requirements and often inconsistent obligations from both authorities. The conflicting and overlapping roles of CNCAN and the Ministry of Health are discussed in Sections 1.2 and 1.5.

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

CNCAN's responsibilities and attributions are established by Law 111/1996, while the safety objectives, criteria and regulatory requirements imposed on authorization holders are established in an extensive corpus of regulations. Currently, CNCAN has issued 113 regulations enveloping a substantial portion of areas of regulatory control. CNCAN also issues guides in order to provide advice and support on the implementation of requirements. In general, whenever a regulation needs to be drafted or amended, extensive consultation with stakeholders is conducted, including public hearings and the reception of written comments and requests, for which CNCAN is obliged to provide an answer (see Section 3.8).

In order to maintain consistency through its operations, CNCAN resorts to a comprehensive management system that includes policies, management commitments, procedures and instructions for the execution of its activities. Within the management system, a dedicated procedure provides a defined mechanism to produce regulatory decisions, which involves the participation of specialists and the responsible managers.

As mentioned in Section 3.2, in order to avoid conflict of interest, positions with responsibilities for the decision making within CNCAN cannot be occupied by former employees of authorized parties who left the organization within the previous year.

CNCAN's inspectors are empowered by law to apply sanctions to authorized parties as an immediate result of their regulatory activities. The sanctions at the inspector's disposal include economic fines. In such cases, the authorized party might express their disagreements that would be recorded in the inspection report, but if the sanction stands, there is no internal appeal process within the regulatory body and the formal appeal forum left for the authorization holder is the court of law.

### **3.7. SAFETY RELATED RECORDS**

Keeping of records is undertaken simultaneously by both CNCAN and authorized parties. CNCAN verifies that compliance with requirements for existence and conservancy of safety records are met by authorized parties.

Regulations, licenses, and authorizations establish conditions to authorized parties to properly maintain safety records during all stages of the lifetime of the facility or activity. Generally, a definition of which safety records must be kept is given within the license or authorization conditions of the respective facility or activity. However, some requirements for the retention period of records of calibration, dosimetry and quality assurance related to medical exposure are not specified (see Section 6.10).

Requirements are also established for periodic reporting and notification to CNCAN. Compliance with these conditions is verified as part of regular inspections to authorized parties. Additionally, CNCAN's inspectors have unrestricted access granted by law to all records of authorized parties.

CNCAN's obligation for record keeping is set in the law, however the storage and conservation of safety records present inconsistencies. CNCAN has a physical archive, but the capacity has long been exhausted and paper records are regularly maintained at individual offices with no clear responsible person for each record. Types of records kept in this way include CNCAN's own reports produced by reviewers and inspectors and submissions from authorized parties. Even though the official records are the ones on paper, CNCAN additionally stores digital documents in a centralized place, but the IRRS team was informed that records stored in such a way have no clear arrangement for maintaining them, challenging retrievability. Moreover, several instances have been identified where digital documents are



only kept on individual workers computers. Backing up of digital information is not consistent, being made in an ad-hoc basis.

Dose records maintained by CNCAN consist of plain spreadsheets with no proper protection in relation to its integrity nor conservation. CNCAN is responsible for maintenance of official dose records of occupationally exposed workers. The kind of recording described is inadequate to fulfil that obligation.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>CNCAN's provisions for establishing and maintaining safety records are neither systematic nor retrievable. For example, CNCAN keeps the National Dose Register for occupational exposure, however the retrieval or analysis is not practical. In addition, there are no measures in place to ensure the integrity of data.</i>	
<b>(1)</b>	<p><b>BASIS: GSR Part 1 (Rev. 1) para. 4.63 states that</b> <i>“The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:</i></p> <ul style="list-style-type: none"> <li>- <i>Registers of sealed radioactive sources and radiation generators;</i></li> <li>- <i>Records of doses from occupational exposure;</i></li> <li>- <i>Records relating to the safety of facilities and activities;</i></li> <li>- <i>Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;</i></li> <li>- <i>Records of events, including non-routine releases of radioactive material to the environment;</i></li> <li>- <i>Inventories of radioactive waste and of spent fuel.”</i></li> </ul>
<b>(2)</b>	<p><b>BASIS: GSR Part 3 para. 3.73 states that</b> <i>“The regulatory body shall be responsible, as appropriate, for: ....</i></p> <p><i>(d) Review of periodic reports on occupational exposure (including results of monitoring programmes and dose assessments) submitted by employers, registrants and licensees;</i></p> <p><i>(e) Provision for maintaining exposure records and results of the assessment of doses from occupational exposure;</i></p> <p><i>(f) Verification of compliance of an authorized practice with the requirements on the control of occupational exposure.”</i></p>
<b>S4</b>	<p><b>Suggestion:</b> <b>CNCAN should consider making provisions for adequate management of safety related records, including, but not limited to the National Dose Register for occupational exposure.</b></p>

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Law 111/1996 defines CNCAN’s tasks including a mandate to inform interested parties about radiation and nuclear safety matters in an active and objective way. Accordingly, CNCAN has identified its interested parties as the general public, media, the applicants for authorizations and the authorized parties.

CNCAN manages its communication through its International Affairs and Communications division, in charge of all matters related to liaison with the public and interested parties others than authorization holders. The communications policy of CNCAN is part of the communication strategy. The strategy describes a communications plan currently being used by CNCAN for governing its communications based on principles of openness and transparency, as described in CNCAN’s Management System.

CNCAN has a procedure in place to manage interaction with media during times of normal operation. Preferred methods to conduct this are press releases and press conferences. The President is the only spokesperson of CNCAN, and generally no other employee can speak in representation of CNCAN unless specifically delegated by him on case-to-case basis.

Provisions for communication during emergency situations cover the definition of a strict group of press officers responsible of representing CNCAN before the media. There are no provisions taken before hand for electronic communications on emergency situations.

Communication and consultancy with interested parties is achieved by different means. CNCAN implemented a procedure which established the mechanism to guarantee free public access to information, as required by Law 544/2001. Whenever a regulation is in the process of creation or amendment, public hearings are conducted at locations resulting more convenient for the parties interested on the matter, for example near site on matters related to Cernavodă NPP. If the regulation relates to an issue with broader application, for example medical uses of radiation, the public consultancy is better conducted by electronic means, with an obligation on CNCAN to provide answers and explanations to all comments received. In this manner, CNCAN complies with Law 52/2003 on transparency of the decision-making process.

Additionally, CNCAN has issued regulations establishing specific requirements to authorized parties to communicate and consult the public on matters of licensing, keeping transparency as a major goal of the process.

### **Policy Issue Discussion on Human Resources and Knowledge Management**

Romania is in a situation where:

- Site licensing of a small modular reactor will start at short-term;
- The building process of Cernavodă units 3 and 4 will restart at mid-term;
- A refurbishment of Cernavodă unit 1 is scheduled in 2026.

The Romanian Government approved recently an increase of the number of staff positions within CNCAN. This implies for CNCAN significant efforts in terms of recruitment and training and creates challenges regarding the need to retain competent staff and develop new talents in various technical areas to be able to respond to evolving requirements.

Romania expressed therefore its interest in having focused discussions on human resources and knowledge management and to gain insights from IRRS team members' national good practices on issues such as, attracting and retaining competent staff; training programmes; synergy with universities for developing nuclear courses; and optimizing the available experts and competences.

The IRRS team members who participated in the discussions shared the same challenges for competence management and capacity building in a context of nuclear experts shortage, and in particular: achieving and maintaining sufficient attractiveness for new talents; securing, on the medium and long term; and keeping competent staff.

The policy discussion highlighted the following key items and messages for the regulatory body:

- Develop a competency matrix allowing a clear view of occupied positions and the needed competences to be filled in. This allows to have a clear view on the profiles to be recruited and the tasks to be assigned as well as the training sessions to be provided;
- The SARCoN tool is a relevant competence management tool supporting the development in both nuclear safety and radiation protection;
- Consider discussions with the licensees, the research facilities and the universities for collaboration on (under)graduate and/or post-graduate programs;
- Promote nuclear careers within engineering courses;
- Hire students for summer work related to short projects;
- Consider to pay for education abroad according to the needs;

- Consider the funding of education fees by CNCAN to be reimbursed on staff salary during several years;
- A retention period could be considered during which a repay of training costs could be reclaimed to the staff member in case of a departure before a specific timeframe;
- Establish rotational opportunities or temporary assignments within the organization as part of the staff development and training;
- Large training program could be designed even with limited budget, taking benefit of internal expertise for providing training to younger staff;
- Take benefit of the IAEA young professional program as well as training courses (e.g. Inspection training courses) or post graduate training programme on radiation protection;
- Establish a knowledge management process aiming at developing and transferring knowledge within the organization;
- Consider that a large staff increase implies the emergence of a new organisational culture;
- Consider other IRRS mission reports for good practices identification in the area of competence management.

### **3.9. SUMMARY**

The Romanian legal framework establishes CNCAN as the nuclear regulatory body and ensures its independence in the performance of its regulatory functions. For non-nuclear activities, significant overlapping was identified between CNCAN and the Ministry of Health.

CNCAN has experienced a significant understaffing for several years and for the time being is impeded by the provisions of the law from hiring staff to cover all current vacancies. A formal assessment of the organizational structure and the changes that it might need has also not been done. While the staff of CNCAN is generally qualified and competent, there is a lack of redundancy of staff in some key functional areas that impacts the resilience of the organization. Training is not systematically formalized and elements like competence management, succession planning or on-the-job-training are being informally carried out and on a limited scale.

CNCAN has an internal advisory body which deals with both administrative and regulatory matters. The functions and responsibilities of this “Council of directors” are formally described. There is no other internal or external advisory body or Technical Support Organization being considered by CNCAN.

The relationship between CNCAN and its authorized parties is well established with formal and informal channels of communication and is conducted in a generally open and transparent manner. Site inspectors maintain a permanent communications channel with the licensee at Cernavodă NPP and digital channels are well established for interaction with other users of radiation.

CNCAN’s stability and consistency of its regulatory process is sustained by a comprehensive corpus of regulations covering a substantial portion of areas of its control. A formal process for decision-making involves several levels of responsibility. CNCAN’s inspectors are empowered by the law to apply sanctions, including financial penalties directly.

Provisions for keeping safety records are imposed by CNCAN on authorized parties and are regularly checked during inspections. Nonetheless, CNCAN’s own practices for storage and conservancy of the information produced by the organization, as well as the records submitted by the authorized parties, do not provide proper assurances in relation to its integrity, retrievability nor conservancy.

CNCAN’s communication strategy, although not yet formally documented, provides adequate links between the regulator and the interested parties, and proper channels for consultation have been established by CNCAN, in compliance with provisions established by law.

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## 4. MANAGEMENT OF THE REGULATORY BODY

### 4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The senior management of CNCAN demonstrates leadership for safety through the establishment and implementation of objectives specified on the Law 111/1996 and the “National Strategy for Nuclear Safety and Security”. There are currently 35 formalised “Derived Strategic Objectives” (DSO) which are used by Division Heads for defining operational objectives. These objectives are approved by CNCAN’s President and are monitored through Key Performance Indicators (KPI) and reviewed twice a year during a coordination meeting between Division Heads. However, these indicators are not considered as targets to be reached.

According to the Management System Manual (MSM), the DSOs are meant to be integrated in the CNCAN strategic plan covering a 5-year period. The IRRS team was informed that CNCAN has yet no such plan.

The function of departments/services as well as roles and responsibilities of the senior management are described within CNCAN Order 177/2021. CNCAN is committed to the values of: Priority given to nuclear safety and radiological protection, Competence, Integrity, Transparency, Responsibility, Cooperation. Additionally, CNCAN staff members have to follow ethical standards on the basis of the “Code of Ethics and Professional Conduct” (President Order 210/2021). This document also includes a policy dedicated to conflict of interest.

All managers conduct yearly performance appraisals with staff members. Nevertheless, the expectations are in some areas similar for both managers and staff without major distinction of the specific role and responsibility levels within the organisation. The general criteria for evaluating the individual professional performance of executive and management personnel are established by Law 153/2017 and are used in annual appraisals conducted yearly.

The CNCAN Management System Manual highlights some general expectations with regards to the leadership and management for safety. However, CNCAN has no policy document setting detailed expectations in that matter. In addition, there is no specific training on leadership and management for safety within CNCAN.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN has no policy defining leadership for safety expectations or a systematic training programme for leaders.

(1) **BASIS:** GSR Part 2 para. 4.24 states that “Competences to be sustained in-house by the organization shall include: competences for leadership at all management levels; competences for fostering and sustaining a strong safety culture; and expertise to understand technical, human and organizational aspects relating to the facility or the activity in order to ensure safety.”

S5 **Suggestion:** CNCAN should consider developing a policy defining the leadership for safety expectations and a training programme for leaders.

### 4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The President of CNCAN is responsible for the development, the coherent implementation and the continuous improvement of the management system. The overall responsibility for implementation and monitoring of the effectiveness of the management system is assigned to the Secretary of the Commission on managerial control, as an internal CNCAN group. The responsibility for the development and improvement of processes are assigned to process owners. The list of process owners is available on the CNCAN server for the staff members and the role of process owner is defined in the MSM. The process owners are mostly the Division Heads. There is nevertheless no dedicated training

(initial or refreshment) for process owners. The IRRS team observed that several process owners are appointed for the same process, e.g. for the inspection process or the review and assessment process. In addition, the IRRS team observed examples, e.g. regarding the inspection practices (see section 7.2), of a lack of an integrated view on regulatory processes.

A yearly evaluation is performed by the Division Heads for their respective Division. A self-assessment is also conducted annually on the basis of a predefined questionnaire. The results of the self-assessments are discussed within the CNCAN Monitoring Committee and a report is sent to the Secretary of the Government. However, the IRRS team was informed that CNCAN process owners do not perform evaluations of their respective processes.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN does not regularly evaluate the effectiveness of its processes. Further there are several process owners for the same process, as a result, there is no clear responsibility for evaluation of processes nor an individual with an overall view of the process performance.*

(1)	<b>BASIS: GSR Part 2 para. 6.2 states that</b> <i>“All processes shall be regularly evaluated for their effectiveness and for their ability to ensure safety.”</i>
(2)	<b>BASIS: GSG 12 para. 5.14 states that</b> <i>“The process owner is responsible for the management of the assigned process and should be made accountable for ensuring that the process is clearly identified, documented, reviewed, maintained and improved. Usually, this is a manager with a direct interest in the outcome of the process or who has the most resources involved.”</i>
S6	<b>Suggestion: CNCAN should consider regularly evaluating its processes as a central input for continuous improvement.</b>
S7	<b>Suggestion: CNCAN should consider designating only one owner per process to ensure a consolidated view on process performance and to enhance accountability.</b>

### 4.3. THE MANAGEMENT SYSTEM

The management system of CNCAN describes the organisational structure as well as the core, support and management processes according to the principles of the ISO 9001:2015, GSR Part 2 as well as GSG-13. The organisational structure is established by Governmental Decision and the process map is described in the Management System Manual. Organisational changes related to the structure of divisions are under the responsibility of the Government. The organisational design of the unit level is under the responsibility of CNCAN for which there is a dedicated procedure “Organisational change management” to be used in the case of a modification of the organisation scheme.

CNCAN’s management system consists of 25 processes. CNCAN’s documentation system is structured on the basis of a three-level model: policies and strategies, processes and operational procedures, work instructions. Processes and operational procedures should be approved by CNCAN President, work instructions are only approved at the level of the Division Head. Master copies of these procedures are managed by the legal department. These documents are available to all staff members on a directory of the CNCAN server (NASZAL).

CNCAN’s management system covers all regulatory functions. Some of the procedures linked to the functions, e.g. regarding Knowledge Management are still in a draft version. In addition, with regard to the specific area of safe transport of radioactive material, specific procedures for reviewing and assessing the technical documents accompanying applications for licenses and approvals have not been fully implemented by CNCAN.

CNCAN has not developed a dedicated procedure for each subprocess. The technical documentation (e.g. drawings) is not fully integrated within an electronic database but remain stored as paper documents.

The principle of the graded approach is described in the MSM and implemented in different procedures. For instance, the procedure related to the emergency response identifies different levels of plan activation according to the specific situation.

The IRRS team also noted a lack of systematic implementation of the graded approach leading to decisions grounded on an ad hoc, informal or individual perspective. The IRRS team identified the need to further implement a graded approach with regard to authorization (see Section 5.6), review and assessment (see Sections 6.1, 6.5, 6.7), inspection (see Section 7.1) and to the development of regulations and guides (see Section 9.1).

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN does not fully implement a graded approach in the application of its management system related to core regulatory functions.*

(1)	<p><b>BASIS: GSG-12 para. 5.26 states that</b> <i>“A graded approach is required to be applied throughout the integrated management system so that appropriate resources, time and attention are devoted to those processes, activities and decisions that have significant impact on regulatory effectiveness and efficiency [10]. This should take into account the nature and complexity of the processes, the impact of the performance (or non-performance) of regulatory activities, and the safety related risks and other risks that may arise (e.g. business risks, cost risks, environmental risks, legal risks, political risks, and risks associated with public perception and credibility of the regulatory body). The nature of the regulatory approach (e.g. prescriptive or performance-based) should also be considered in developing the core processes”.</i></p>
(2)	<p><b>BASIS: GSR Part 2 para. 4.15 states that</b> <i>“The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:</i></p> <ul style="list-style-type: none"> <li><i>(a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;</i></li> <li><i>(b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity;</i></li> <li><i>(c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.”</i></li> </ul>
S8	<p><b>Suggestion:</b> <b>CNCAN should consider further implementing a graded approach in the application of its management system related to core regulatory functions.</b></p>

#### 4.4. MANAGEMENT OF RESOURCES

Direct line managers (as e.g. Head of Divisions or Head of units) are responsible for defining the required individual level of competences through job descriptions. Competence evaluation is also considered in the frame of the yearly personnel performance evaluation. In addition, the IRRS team was informed that CNCAN started to develop a competence matrix at the level of some units using the IAEA SARCoN methodology.

The training needs are identified at the level of each employee in the frame of the annual performance evaluation. Through performance appraisals, CNCAN managers systematically follow up staff competences to ensure that staff members have the needed knowledge and skills to carry out their duties. The HR department compiles the training needs and prepares a training plan for the next year. In 2023, the training plan has been reduced due to budget cuts. A prioritization of training needs has been done at the level of each division on the basis of criteria depending on the specific situation of the respective divisions. CNCAN takes also benefit of participation in relevant IAEA training activities.

CNCAN provides internal training (i.e. mainly initial trainings for newcomers) and On-the-Job trainings in order to achieve and maintain the required level of competence. Nevertheless, no procedure describing the training process is available. Recommendations in this regard are made in section 3.3.

A qualification process for inspector exists since 2015 but has not been fully implemented due to the successive departures of inspectors. In addition, experienced staff reaching the retirement age are allowed to stay 3 additional years within CNCAN to ensure the knowledge transfer and mentoring of younger staff.

CNCAN is facing a lot of departures of newcomers, reducing drastically its workforce. The decision to increase the salary level within CNCAN has been recently considered by the Government and should enter into force by January 2024. In addition, the IRRS team noted that the HR department is currently changing its recruitment strategy favouring experienced experts instead of young professionals.

#### **4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES**

The CNCAN Management system is process oriented. The procedures linked to a process contain in appendix a flow chart identifying the responsibilities, the activities to be performed and the expected outputs. Inputs and interfaces with other processes are explicitly considered in a generic section of each process procedures.

The CNCAN President approved the new processes to be designed on the basis of a documented justification. Any new process within CNCAN has to be grounded on a legal basis. More largely, within CNCAN, low level initiatives have also to be approved by the President.

There is no mandatory timeframe for systematically revising the procedures. There is a yearly follow-up of the procedures revised. The IRRS team was informed that there are less than 10 procedures to be modified per year. According to the needs, modifications are more common regarding the work instructions and are performed at the level of the unit with the approval of the respective Division Head.

A decision-making group, the “Council of directors”, is systematically organised for the decision regarding the management of the organisation – including the planning of activities, the management of resources or interface issues – and, if needed, regarding major impact on nuclear safety (e.g. the licensing of a large nuclear installation). The “Council of directors” is established according to the Governmental Decision and its operational functioning is described within a CNCAN “internal rule” document.

CNCAN has developed a management process for the control of external interfaces that identifies the interested parties.

CNCAN does not sign contracts with external experts.

#### **4.6. CULTURE FOR SAFETY**

In general terms, the IRRS team has not identified indications of a lack of safety culture within CNCAN. The CNCAN Management System Manual provides an overall conceptual view on how the safety culture is defined but neither a safety culture policy has been designed (a related suggestion in this regard is made in section 4.1) or an assessment has been recently performed. The first safety culture survey was administered approximatively 5 years ago but with no subsequent action plan. Although the expertise on that matter is available according to CNCAN, there is no systematic training on regulatory body safety culture and no recent assessment initiative. CNCAN has identified this last issue as an improvement action in the self-assessment report submitted in the ARM. The IRRS team supports CNCAN’s observation and encourages CNCAN to develop a safety culture assessment process (attributes, scope, frequency, action plan...) to be applied in the frame of the assessment of leadership for safety and safety culture.



#### 4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

CNCAN has developed a process dedicated to measurement, evaluation and improvement, and a procedure for the yearly management review is in place. Management reviews consider the results of the yearly self-assessments performed by the Division Heads, a risk analysis on the basis of established risks, and the performance indicators related to the DSO. Management reviews lead to the identification of actions to be approved by the Head of Divisions and the CNCAN President.

The IRRS team noted that the management reviews do not consider explicitly information sources as interviews with staff, customer satisfaction, stakeholder surveys, external audits, benchmarking regulatory bodies or results of international missions. These sources of information would be useful in order to diversify the data to be addressed in the frame of a management review.

In addition, there is no effectiveness evaluation of the processes. Suggestion S6 in Section 4.2 addresses this issue.

The IRRS team observed that the actions identified are limited to non-compliance issues and mainly related to procedure modifications. In contrast, there are few actions related to organisational improvements responding to potential effectiveness issues.

CNCAN is audited by external parties, such as the Secretary of the Government or the Audit Court, including aspects of the management system. The IRRS team was informed that internal audits are not performed by CNCAN due to the absence of internal auditors. CNCAN identified this issue as an improvement action in the self-assessment report submitted in the ARM. The IRRS team supports CNCAN’s observation and encourages CNCAN to implement an internal audit programme.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN has developed a process dedicated to measurement, evaluation and improvement of its performance but not all elements required for evaluation and monitoring of CNCAN’s effectiveness have been used.

(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.16 states that</b> <i>“The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost effective manner so as to build confidence.”</i>
(2)	<b>BASIS: GSR Part 2 para. 6.1 states that</b> <i>“The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended and to identify opportunities for improvement of the management system.”</i>
S9	<b>Suggestion:</b> CNCAN should consider making use of all elements required for evaluation of its management system, including the inputs from the internal audit activities.

#### Policy Issue Discussion on Integrating the Requirements on Management Systems from Different Standards or Applicable Regulations

CNCAN as a part of a state administration is challenged by some requirements posed to it as its management system is “process based” and integration of some requirements of the state administration system might require significant changes in the CNCAN’s management system. In addition, their implementation might need substantial human resources. Additional challenges might be the regular reporting of performance indicators (PI) and the external audits conducted at CNCAN that might not always reflect a graded approach.

IRRS team members shared their experiences:

- In Canada two types of PI were developed, i.e. one to be sent to the government and another to be used by the regulatory body. An analysis of PI has been conducted in order to avoid any

duplication. Regarding the integration of different requirements on the management system a graded approach has been applied, namely, only the high level processes are fully integrated. Cooperation with external audits including an audit on financial aspects requires an efficient communication. The regulatory body provides sufficient explanation to auditors to assure that mutual understanding is achieved, as nuclear and radiation safety area have some particularities, e.g. the assessment of appropriate number of nuclear inspectors might be challenging. When recruiting the staff, the regulatory body also pays attention to recruit candidates already knowledgeable on the functioning of the state administration.

- In France, the regulatory body is an independent administration, not subjected to the state administration requirements. However, a number of PIs relevant to external auditors exist which enable mid-term and long-term tracking.
- In Belgium, a dashboard is used to identify any duplication of PI.
- In Slovenia and USA the PI to be reported externally or used internally in the regulatory processes are a part of the IT systems of their regulatory bodies. The IT systems enable efficient collection, analysis and reporting of PI as needed and substantially decrease a workload of the regulatory staff.
- In UK, the authority in Scotland prepares three types of annual reports, each with specific set of PI, e.g. reports to be sent to the Scottish Government, UK Government and reports to be sent to another interested parties.
- In Türkiye, selected PIs are available online in order to ensure transparency of regulatory control of nuclear and radiation safety.

#### **4.8. SUMMARY**

The CNCAN management system was established and documented in line with IAEA requirements. The management system, however, could be improved using a more comprehensive evaluation and monitoring process of CNCAN regulatory processes effectiveness, both at the level of the process owners and at the level of the whole organisation performance.

The IRRS team also identified an area for improvement in CNCAN's management system related to the lack of description of leadership expectations and a systematic training program for leaders.

## **5. AUTHORIZATION**

### **5.1. GENERIC ISSUES**

The Romanian nuclear regulatory framework for activities using nuclear or radioactive material is primarily defined in Law No 111/1996 on the safe conduct, regulation, licensing and control of nuclear activities. CNCAN's regulatory programs consist of: registration, issuance of authorizations and permits. CNCAN regulations establish limits and exemption criteria consistent with international standards.

The authorization process is one of the core processes of the CNCAN Management System. Depending on the type of authorization and its associated complexity, the responsible CNCAN department plans the authorization review process in a graded manner. The general description and detailed information on the authorization process is described in CNCAN internal procedure PO-CP2-00 – "Authorization Process within CNCAN".

CNCAN regulations establish requirements and information to be provided with the notification, application for registration, authorization and issuance of practice permits by applicants or authorization holders. The detailed authorization requirements for different types of installations and activities subject to CNCAN control are defined in the specific regulations issued by CNCAN and are supplemented, as appropriate, by CNCAN requirements issued through regulatory letters, meeting minutes, or actions recorded in meeting minutes.

Provisions for appealing CNCAN's decisions are provided in the Law 111/1996, article 54 and Law 554/2004 on administrative litigation that include specific provisions on how to apply to the High Court of Cassation and Justice.

All of the regulatory decisions taken by CNCAN, either in the licensing decisions (i.e., to grant a license or reject a licensing submission), or enforcement decisions (i.e., to direct compliance, apply penalties, amend, suspend or revoke licenses), are based on the requirements stipulated in the Law and in the nuclear regulations in force.

### **5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS**

The authorization process for Cernavodă NPP is based on the provisions of Law 111/1996 and regulations issued by CNCAN. Law 111/1996 clearly assigns the primary responsibility for the safety of a nuclear power plant to the license holder. Regulation NSN-22, approved by CNCAN 336/2018 and amended by CNCAN order 53/2023, describes the requirements for the licensing process and specific phases of the life cycle (such as design, siting, construction and/or installation, commissioning and operation) of nuclear installations. Authorization for decommissioning nuclear installations is addressed in the Rule on safety requirements for the decommissioning of nuclear and radiological installations, detailed in CNCAN Order 102/2022.

The main document for licensing submissions is a safety analysis report prepared in accordance with the specifications established by CNCAN for the particular stage of the licensing process. Other documents are also required to fulfil all legislative and regulatory requirements. CNCAN reviews the documents submitted by the applicant and if the review concludes that all the requirements have been satisfied by the applicant, a license can be issued by CNCAN. Licenses are issued for a specified period as per regulation NSN-22 and contain any specific conditions for that license.

Training requirements are established for personnel who operate and manage nuclear installations including nuclear power plants, research reactors and other nuclear installations (NSN-14 rev.1).

The IRRS team noted that CNCAN regulation NSN-14, art. 65 allows the NPP licensees to have either 8 or 12 hour operating shifts. Cernavodă NPP currently uses a 12 hour operating shift. CNCAN analysed the impact of human performance factors with respect to personnel effectiveness and fitness for duty in 2011. However, CNCAN should determine if there is a need to re-analyse human performance factors

with respect to effectiveness and fitness of personnel to undertake their duties based on operational experience.

As a prerequisite to the issuance of a CNCAN nuclear installation license, the operator must demonstrate to CNCAN that all other required authorizations have been obtained. For example, before CNCAN issues a license the applicant must obtain the environmental agreement, issued by the Ministry of Environment, Waters and Forests. Any issues and conditions raised by the other national authorities are addressed by CNCAN before licenses are granted, provided that there is no conflict with the provisions of the Law or the applicable CNCAN regulations.

CNCAN issued NSN-25 in 2019, which details the requirements for decisional transparency in the licensing process for nuclear installations. NSN-25 increased the opportunity for public participation in the decision-making process for licensing nuclear installations, particularly in nuclear safety.

### **5.3. AUTHORIZATION OF RESEARCH REACTORS**

Romania has one dual core pool type TRIGA Mark II Research Reactor in Pitești which has been in operation since 1979 and is primarily used for materials testing.

The authorization for research reactors in Romania is based on the Law 111/1996 and the regulations issued by CNCAN, which stipulate that the primary responsibility for safety rests with the license holder. A license is needed for each stage of life of a nuclear installation. The licensing requirements and licensing process are established in the regulation on the licensing of the nuclear installations (NSN-22). The licensing stages for a research reactor include design, siting, construction, commissioning, operation, and decommissioning.

NSN-22 establishes that the operating authorization issued by CNCAN is valid for the period requested by the applicant following review, assessment and agreement of CNCAN. NSN-22 also requires periodic safety reviews and assessment for nuclear installations every 10 years. The current authorization for the TRIGA Research Reactor in Pitești is for 5 years, expiring in 2024, and a PSR has already been requested from the licensee for a new operating license.

Guidance on the format and content of safety analysis reports for the authorization of research reactors is available in GSN-05.

### **5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES**

Nuclear fuel cycle facilities in Romania comprise uranium mining and processing facilities (currently in decommissioning), a uranium concentrate processing plant, and a fuel fabrication facility. All these facilities within the Nuclear Fuel Cycle are authorized by CNCAN.

The fuel fabrication facility is in the process of licensing under NSN-22, which applies to all nuclear installations and establishes the licensing process and requirements. NMR-04 details the information CNCAN requires to consider applications for each phase of operation for uranium and thorium mining and processing facilities, processing of nuclear raw materials and production of nuclear fuel. The requirements of NMR-04 are not consistent with the IAEA Safety Standards, therefore CNCAN should consider amending the existing NMR regulations or develop new licensing regulations for mining and processing facilities for uranium and thorium ores consistent with NSN-22.

### **5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES**

Law 111/1996 requires predisposal and disposal activities and facilities to be authorized in a series of steps; design, siting, construction, commissioning, operation, decommissioning and, in case of disposal facilities, closure and institutional control. The safety and licensing requirements specific to predisposal and disposal facilities are included in CNCAN Order 103/2022 and CNCAN Order 11/2019, respectively. These regulations are consistent with IAEA safety standards.

The IRRS team was informed that operational waste from Cernavodă NPP is conditioned according to the radioactive waste acceptance criteria established for storage on site and does not consider ANDR’s preliminary waste acceptance criteria for disposal at the planned near surface disposal facility DFDSMA. The final waste acceptance criteria for disposal at DFDSMA will be based on the safety case for the facility. The IRRS team was informed that the existing cavern-type facility DNDR for institutional LILW-SL (and small quantities of LILW-LL) disposal situated at Baita Bihor in a previous uranium mine is licensed as a radiological facility and is expected to be in operation until 2040. The planned near-surface disposal facility DFDSMA will be licensed as a nuclear facility for disposal of LILW-SL (and small quantities of LILW-LL) from the Cernavodă NPP, and for institutional LILW from 2040 onwards. As a consequence, a different set of regulatory requirements will apply to the two disposal facilities, although both are intended for the same type of radioactive waste involving comparable radiation risks. This also applies to the storage of LILW at the Cernavodă site, licensed as a nuclear facility, and the predisposal facility (STDR) for processing and storage of institutional radioactive waste IFIN-HH. CNCAN is encouraged to review and, as necessary, revise the regulatory requirements for radioactive waste management facilities for the sake of consistency in regulatory control.

The latest updates to CNCAN Order 103/2022 and CNCAN Order 11/2019 made provisions for managing the ageing of systems, structures and components (SSC) important to safety at predisposal and disposal facilities for radioactive waste and spent nuclear fuel, to ensure their capability to perform their safety functions throughout their design life. The IRRS team was informed that SSCs of the predisposal facilities (STDR) for processing and storage of radioactive waste at RATEN-ICN and IFIN-HH, as well as the LILW disposal facility DNDR at Baita Bihor are tested periodically and are maintained as required. In addition, major refurbishments have been undertaken at the STDR at RATEN-ICN in 2013-2014, the STDR at IFIN-HH and at the DNDR disposal facility in 2011-2015. For the DICA dry storage facility for SNF located at the Cernavodă NPP site, the authorized party performs regular measurements to verify containment of radioactive material. Additionally, the authorized party performs analyses in preparation for long-term storage (> 50 years).

Ageing management, including technological obsolescence, is not addressed systematically for all SSCs important to safety as per applicable regulatory requirements. The importance of the ageing management programmes is increased in the absence of PSRs for the radioactive waste management facilities.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *There are no ageing management programmes established at the DICA dry storage facility for SNF, the predisposal facilities for processing and storage of institutional radioactive waste at RATEN-ICN and IFIN-HH, as well as for the LILW disposal facility DNDR at Baita Bihor, to ensure the capability of items important to safety to perform their necessary safety functions throughout their design life.*

(1)	<b>BASIS: SSR-4 Requirement 60 states that</b> <i>“The operating organization shall ensure that an effective ageing management programme is implemented to manage the ageing of items important to safety so that the required safety functions are fulfilled over the entire operating lifetime of the nuclear fuel cycle facility.”</i>
(2)	<b>BASIS: GSR Part 5 para. 4.22 states that</b> <i>“Provision has to be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity...”</i>
(3)	<b>BASIS: SSG-29 para. 5.54 states that</b> <i>“As a near surface disposal facility will operate for long periods before its final closure, a programme to manage ageing (e.g. a programme of preventing maintenance) should be put in place for both active and passive systems ...”</i>
R7	<b>Recommendation:</b> <b>CNCAN should ensure the timely development and implementation of ageing management programmes for all waste management facilities.</b>

## **5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES**

CNCAN is responsible for granting authorization of facilities and activities with radiation sources as stated in the Law. However, the IRRS team noted the Laboratory for Ionizing Radiation Hygiene which reports to the Public District Health Inspectorate under the Ministry of Health, is also responsible for granting authorization. Overlaps in those authorizations could create conflicts between the two different authorities and lead to conflicting requirements, causing confusion on the part of the authorized party or the applicant. The issue is addressed in Recommendation 1 in Section 1.2.

CNCAN authorizes import and export of radiation generators and radioactive sources. According to the regulations two types of authorization exist using a graded approach; registration and licensing. A registration issued by CNCAN is valid for 10 years and a licence for 5 years. Notifications are also a part of the regulatory regime.

CNCAN regulations also include authorization of persons. CNCAN can issue “permit certificates” at graded levels; Level 1, 2 and 3, for workers, radiation protection officers and qualified experts respectively. Permit certificates for qualified experts are valid for five years. The IRRS team was informed that at present about 110 persons are certified in the country. CNCAN also issues certificates for radiation protection officers and workers in specific practices that are also certified in radiation protection matters such as interventional radiology. The IRRS team was informed that about 2000 permit certifications are issued each year by CNCAN. This number also includes certification of personnel for which legislation does not require certification but which the employer requires.

CNCAN also authorizes so-called “notified laboratories for the nuclear field”, technical services providing field radiation measurements. The IRRS team was informed that according to regulations, CNCAN authorizes laboratories at the Ministry of Health to conduct such measurements. One prerequisite for such authorization is ISO/IEC 17025 accreditation. An authorization is valid for 5 years.

All phases of a facility’s or activity’s lifecycle are authorized by CNCAN. Modifications are also subject to authorization. The regulatory framework includes exemptions and clearance levels, authorization of discharges and requirements related to consumer products as well as provisions for renewal, suspension, revocation, and termination. The framework includes provisions for appeals against regulatory decisions.

CNCAN uses an internal procedure to review applications for authorization. The procedure is described on a flowchart which includes CNCAN activities related to the specific action. Pre-authorization inspections can form part of the authorization process, if appropriate. The IRRS team was informed that pre-authorization inspections are not conducted prior to issuing the authorization for low-risk facilities but six months after.

In 2022 around 2800 authorizations were issued, including around 60 authorizations for import and 20 authorization for export of radiation sources. The authorizations process is conducted by CNCAN staff organized in the Licensing the Use of Radiation Sources Division (DAURI) with 16 current staff, about half of whom have joined CNCAN in the last five years. CNCAN does not involve a TSO in the authorization process. Internal and external training is planned for CNCAN staff involved in authorization. Competence of the staff is addressed in Recommendations R5 and R6 in Section 3.4. The applications for authorization should be sent to CNCAN through an information system where a list of all required documents and data are given. The system leads an applicant to submit all required documents.

The legal framework includes justification as one of the main principles in radiation protection and an applicant is required to address justification in the authorization process. The IRRS team noted that CNCAN regulations do not fully address the requirements for justification and there is no internal CNCAN process on justification. A procedure for justification has been developed only for medical exposures. Additionally, a procedure to review justifications does not exist.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN has not developed justification procedures for all practices (not involving medical exposure). Furthermore, a procedure for reviewing the justification does not exist for all practices, as necessary.

(1)	<b>BASIS: GSR Part 3 para. 3.16 states that</b> “The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized.
R8	<b>Recommendation:</b> CNCAN should develop procedures to assess justification of any type of practice and to review the justification, as necessary.

An applicant for authorization is required to provide documentation to CNCAN to demonstrate compliance with safety requirements, including technical specifications of a facility and sources, measurements conducted by the authorized personnel and an emergency plan. The IRRS team noted that there are no requirements for providing documented safety assessment, either specific or generic. Independent review of safety assessment is also not required, where appropriate.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN does not require from an applicant for authorization of facility or activity with radiation sources to submit a documented safety assessment, either generic or specific, as appropriate. An independent review of safety assessment is also not required for higher risk activities.

(1)	<b>BASIS: GSR Part 3 para. 3.29 states that</b> “The regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. Prior to the granting of an authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.”
(2)	<b>BASIS: GSR Part 3 para. 3.34 states that</b> “Registrants and licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.”
(3)	<b>BASIS: GSR Part 4 (Rev. 1) Requirement 2 states that</b> “A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.”
(4)	<b>BASIS: GSR Part 4 (Rev. 1) Requirement 21 states that</b> “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.”
R9	<b>Recommendation:</b> CNCAN should require the applicant for authorization of radiation sources facilities and activities to submit a documented safety assessment, including, where appropriate, an independent review.

The applicant for an authorization submits several types of documents on occupational exposure to CNCAN. The required documents do not include a full scope of the Radiation Protection Programme. The IRRS team noted that there is no guidance on form and content of an authorization application, such as the need for authorizations of other competent authorities and documents on worker training or radiation protection officer training.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN regulations do not address for all practices a complete scope of a Radiation Protection Programme to be submitted by an applicant for authorization or to be implemented by a registrant or a licensee as appropriate. Furthermore, CNCAN did not develop a complete guidance on the format and content of the documents to be submitted by an applicant in support of an application for an authorization.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS: GSR Part 3 para. 4.34 states that</b> <i>“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 applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process.”</i>
(2)	<b>BASIS: GSR Part 3 Requirement 24 states that</b> <i>“Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure.”</i>
(3)	<b>BASIS: GSG 13 para. 3.60 states that</b> <i>“The radiation protection programme should document the following, with an appropriate level of detail: (a) The assignment of responsibilities for protection and safety for workers to different management levels, including corresponding organizational arrangements and, if applicable (e.g. in the case of itinerant workers), the allocation of the respective responsibilities between employers and the registrant or licensee; (n) The requirements for the assurance of quality and process improvement.”</i>
<b>R10</b>	<b>Recommendation:</b> CNCAN should develop guidance on the format and content of documents to be submitted by the applicant in support of an application for an authorization, including a complete scope Radiation Protection Programme with the appropriate level of detail.

Although the authorization process is based on a graded approach, a graded approach is not fully implemented, e.g. for dental practices the competence of medical doctors is checked every five years. The issue is addressed in Suggestion S8 in Section 4.3.

The Ministry of Health is responsible for the regulatory control of consumer products under Law 527/2004. The legislation does not contain all requirements for the design, manufacture, maintenance, or disposal as required in GSR Part 3. The IRRS team was informed that the Ministry of Health has recently drafted an update to the law addressing these requirements. However, the document has not been published yet. The IRRS team was also informed that the Ministry of Health is planning to conduct a study on the use of consumer products in Romania.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>Legislation on consumer products published in 2004 is not in line with IAEA GSR Part 3.</i>	
(1)	<b>BASIS: GSR Part 3 Requirement 33 states that</b> <i>“Providers of consumer products shall ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized.”</i>
(2)	<b>BASIS: GSR Part 3 para. 3.140 states that</b> <i>“Providers of consumer products: (a) Shall comply with the conditions of the authorization to provide consumer products to the public; (b) Shall ensure that consumer products comply with the requirements of these Standards; (c) Shall plan for appropriate arrangements for the servicing, maintenance, recycling or disposal of consumer products.”</i>
<b>R11</b>	<b>Recommendation:</b> The Ministry of Health should revise the legal requirements for consumer products to be consistent with GSR Part 3 requirements.



CNCAN operates the National Registry of Radiation Sources to track all sources. The IRRS team was informed that a part of the Registry is not operational, therefore a registrant or licensee cannot access or update technical data on sources. The issue is addressed in Suggestion S4 in Section 3.7.

As a general rule, disused sources are sent back to a supplier. Other options for management of disused sources also exist. There are no financial provisions to ensure the safe management of disused sources. The IRRS team found that current provisions for on-site short-term storage for sources not in use can be in place for several years. The issue related to financial provisions for decommissioning and radioactive waste management is addressed in Suggestion S2 in Section 1.7. CNCAN issues an authorization for such on-site storage with a time limit, which can be renewed or extended. Only when a source is declared as “disused” by its owner or user, it is managed as a disused source, and its temporary storage is then limited to six months. The IRRS team observed that this arrangement might lead to long-term storage of disused sources on-site.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *Sources, for which there is no further intended purpose, can be in temporary storage for long term periods rather than being declared disused sources.*

(1)	<p><b>BASIS: Guidance on the Management of Disused Radioactive Sources para. 17 states that</b> <i>“Each State should ensure that the regulatory body:</i></p> <p><i>g. Specifies the safety and security requirements for short-term storage, for example by a user on its premises prior to further management option, including the time limit for such short-term storage;”</i></p>
(2)	<p><b>BASIS: Guidance on the Management of Disused Radioactive Sources states that</b> <i>“However, storage in short term conditions of a disused source for protracted periods running into many years, particularly at most user’s site, is not generally appropriate as it may increase the safety and security risks, and to complicate its further management.”</i></p>
S10	<p><b>Suggestion:</b> <b>CNCAN should consider developing provisions assuring that short-term storage is not used for a long period and that sources are declared as disused in a timely manner.</b></p>

### 5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

In Law 111/1996, decommissioning is recognised as a distinct step in the lifetime of nuclear and radiological facilities and must be specifically licensed by CNCAN. Authorization of decommissioning activities are based on the provisions in CNCAN Order 102/2022.

The VVR-S research reactor at IFIN-HH at Măgurele, was shut down in 1997 after 40 years of operation. The decommissioning took place in three stages, which required a decommissioning plan including the supporting safety assessment to be developed by the authorized party and approved by CNCAN. The facility was released from regulatory control in 2020. The entire inventory of spent nuclear fuel (type C-36 and EK10) was shipped back to the Russian Federation (the country of origin) under the initial agreement.

There are no ongoing decommissioning activities in Romania. However, the final decommissioning plan for the cyclotron at IFIN-HH at Măgurele has recently been reviewed and approved by CNCAN and decommissioning will begin soon.

Authorized parties of nuclear and radiological facilities are required to update their initial decommissioning plans every 5 years and submit these to CNCAN for approval. CNCAN must approve a final decommissioning plan before an authorization for decommissioning can be issued. CNCAN requires an independently verified final characterisation survey and a final decommissioning report providing evidence that the desired end state has been reached before releasing a site from regulatory control.

The IRRS team was informed that CNCAN does not have adequate capabilities to carry out complementary measurements to verify that the desired end state has been met because of a lack of trained staff and limited financial resources. This issue is addressed in Recommendations R5 and R6 in Section 3.3, as well as in Recommendation R20 in Section 7.1.

## **5.8. AUTHORIZATION OF TRANSPORT**

Radioactive material in Romania is transported by air, road, rail, and inland waterways.

Industrial and Type A packages for the transport and storage of radioactive waste are manufactured in the country. Testing facilities (authorized by CNCAN) exist in Romania for the qualification of transport packages.

Based on available data, about 60 shipments (imports) were made in 2022, mainly using type A and B(U) packages (80% by road and 20% by air).

CNCAN is the regulatory authority for the safe transport of radioactive materials in accordance with the provisions of Law 111/1996 and issues authorizations in accordance with the Regulation on the Requirements for the Authorization of the Activity of Transport of Radioactive Materials, (hereinafter referred to as CNCAN Order 221/2017) for transportation and storage in transit of radioactive materials. The first condition for the issuance of those licenses is that the applicant must have at least one person certified as an expert in radiation protection in accordance with CNCAN Order 202/15.10.2002.

The transport license is issued to the carrier (for each mode of transport), while the storage in transit license is issued to the operator of the facility where storage takes place and allows the operator to temporarily store and handle the package.

The licensing is handled by CNCAN, in cooperation with other government authorities. For example, training certifications issued by the Ministry of Transport in accordance with the requirements of the applicable modal regulations are prerequisites for CNCAN to issue a license.

The carrier licensing process includes the additional requirements set forth for each mode by SSR-6 (Rev. 1), and specific conditions are provided as part of the license.

The provisions for authorizing carriers are consistent with the graded approach. CNCAN includes specific UN numbers and shipping name of the radioactive material the applicant is authorized to transport.

To date there are about 70 licensed carriers in Romania for all modes of transport.

The IRRS Team observed that transit storage authorization is also issued to airport ground handlers. This, with particular reference to air transport, allows CNCAN to certify the effectiveness of the procedures of all operators involved in the transport chain. This is a commendable approach as ground handling operators are usually certified by air transport authorities generically covering exclusively dangerous goods transport issues.

In accordance with Order 221/2017, CNCAN is also responsible for issuing (to the manufacturer, carrier, consignor or consignee) approvals and validations required by SSR-6 (2012 edition).

The IRRS Team also noted, as a state variation, that Type A packages are approved by CNCAN in accordance with the provisions of Article 23 of Law 111/1996.

Finally, CNCAN Order 221/2017 defines the requirements for:

- notification to CNCAN within 72 hours of any international shipment of radioactive material;
- reporting of transport events.

CNCAN is encouraged to improve records management for transport safety related to:

- approved package designs;
- approved shipments;

- validated package designs;
- authorized carriers for the transport of radioactive material;
- authorized operators for in-transit storage.

This issue of the management of safety related records is addressed at the Suggestion S4 in Section 3.7.

The "Transport Activities" sub-process has been formally established in the general authorization process, but the CP2.6 operating procedure mentioned in Chapter 6 of OP-CP2-00 has not been developed.

## **5.9. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE**

Requirements for occupational exposure in planned exposure situations are established for employers, registrants, and licensees. In the licensing process, the applicant demonstrates the design criteria and design features for worker exposure and potential exposure in all operational states and in potential exposures conditions, and the design criteria and design features for occupational exposure monitoring. In the authorization process the applicant/authorised party also demonstrates that the personal protective equipment and personnel protection procedure meets requirements.

Radiation protection programme for occupational exposure needs to be required in accordance with defined format and content which is addressed in Recommendation R10 in Section 5.6.

The issue of justification of practices involving occupational exposure is addressed in Recommendation R8 in Section 5.6.

Assessment of occupational exposure and record keeping is required. Worker training on occupational exposure is also required.

The designation of service providers for individual dose monitoring services as notified bodies in the country is performed according to the law. The authorised parties have the primary responsibility for maintaining occupational exposure records for each worker for whom an occupational exposure assessment is required. The requirements for maintaining dose records may be carried out on behalf of the authorised parties according to legislation by an approved individual dose monitoring service.

The National Dose Register for both external and internal worker exposure is kept by CNCAN in accordance with the regulations. The National Dose Register contains the identification information for each worker. The retrieval of previous doses, or any analysis of the data included is not currently possible. This also prevents CNCAN from reporting, analysing and evaluating doses. This issue is addressed in Suggestion S4 in Section 3.7.

## **5.10. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE**

Safety requirements for medical exposures are stipulated in the 'Rules for Basic Radiation Safety Requirements, 2018'. The CNCAN Norms on radiological safety address specific requirements for authorization for diagnostic radiology and interventional radiology practices, nuclear medicine practice and radiotherapy practice.

CNCAN issues registrations to low hazard potential X-ray facilities (excluding CT and interventional radiology) in accordance with the Norms on Authorization while all other medical facilities require authorization, following a graded approach. The submissions reviewed include performance test reports, quality management programme, emergency preparedness plan and radiation protection programme. License terms and conditions also include reporting requirements and compliance with basis documents. Every registration or authorization requires inspection by CNCAN, either at the pre-authorization stage or within 6 months of issuance of the registration. The generic format and content of the application for authorization is provided in the authorization procedure, but there are no specific formats for individual practices. This issue is addressed in Recommendation R10 in Section 5.6.

CNCAN specifies requirements for education, training and competence in the relevant specialty and authorizes the training programs on radiation safety and protection and issues practice specific individual permits to personnel involved in medical exposure.

The applicant or authorised party currently submits the same set of documents to both CNCAN and the Ministry of Health; one for issuance of authorization for use by CNCAN, and another for issuance of ‘sanitary authorization’ by the MoH, issued under the Basic Health Norms for the Safe Conduct of Nuclear Activities as mandated by the Ministry of Health, vide Order 381/2004. The IRRS team noted that the sanitary authorization duplicates the authorization issued by CNCAN. Further, for a nuclear medicine facility, the IRRS team also observed inconsistencies in these two authorizations with regard to the maximum permitted radioactivity. This issue is addressed in Recommendation R1 in Section 1.2.

The Ministry of Health has established DRLs for typical procedures in diagnostic radiology and nuclear medicine practices. The IRRS team observed that there is a conflict between the Order enabling the DRLs to be established and the Basic Radiological Safety Norms 2018 regarding requirements for investigations by licensees when local DRLs fall substantially below the established limits. Duplication and inconsistency in regulatory framework is addressed in Recommendation R1 in Section 1.2. The Ministry of Health has established dose constraints for carers and comforters in medical exposures and for volunteers in biomedical research. Criteria for release of patients treated with radionuclides is stipulated in the practice specific requirements of CNCAN.

Regulations place the obligation to justify medical exposure on the referring medical practitioner. However, there are no referral guidelines (appropriateness criteria) available to the referring medical practitioner to prepare the justification for a radiological procedure to an individual patient.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *There are no referral guidelines to be used by referring medical practitioners supporting them in the justification of the medical exposure of an individual patient in a radiological procedure.*

(1)	<b>BASIS: GSR Part 3 para. 3.158 states that</b> <i>“Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure”.</i>
(2)	<b>BASIS: GSR Part 3 para. 3.155 states that</b> <i>“Medical exposures shall be justified by weighting diagnostic...benefits...against the radiation detriment that they might cause, with account taken of benefits and the risks of alternative techniques.”</i>
(3)	<b>BASIS: SSG 46 para. 2.59 states that</b> <i>“National or international referral guidelines should be used as an important tool in the application of the process of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing evidence based referral guidelines. “</i>
R12	<b>Recommendation:</b> <b>The Ministry of Health should, in consultation with the relevant professional bodies, provide for evidence-based referral guidelines for use by the referring medical practitioners.</b>

Requirements on radiation protection of pregnant and breast-feeding patients, quality assurance, patient dosimetry and calibration of measuring & monitoring instruments are specified in the regulations.

### 5.11. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The rules on basic radiation safety requirements, 2018, address public exposure and introduce dose limits. CNCAN procedure PO-CP2-00 describes the authorization process and includes the need to review the effectiveness of the process. Annex Order 336/2018, provides rules on licencing nuclear installations does not include requirements for the consideration of public exposure. However, Annex Order 102/2018 addresses public exposure, although it is limited in scope to nuclear activity necessitates that the radiation protection officer has the obligation to prevent over exposure of the public and the

radiation protection expert has duties in regard to public dose limits and dose constraints. CNCAN Order 154 requires the use of optimization and dose constraints to protect the public from ionising radiation. This order specifies a dose constraint of 1 mSv making optimisation not applicable. Neither Ministry of Health nor CNCAN independently assess the potential impact on the representative person. Nor does Ministry of Health or CNCAN make any provision for assessing discharges from two sources to the same receptor, thus the total dose to the representative person exposed to multiple sources may be underestimated. It is possible for multiple releases to impact the same representative person, exceeding the dose limit.

CNCAN reviews the input data used to assess the potential dose for applications for discharging radioactive waste, however, neither Ministry of Health nor CNCAN undertakes any independent review of the model’s output.

If the dose assessment provided by the operator is below the 1 mSv constraint/limit CNCAN does not require optimization of discharges in respect of public dose. If it is above that limit, the application is not approved. Hence despite Order 154 being in place, CNCAN does not apply optimization to public dose in practice.

The Ministry of Health reviews information relating to the potential impact of the use of radioactive material on the public as part of its approval process. However, consistent with the approach taken by CNCAN, optimization of public doses is not applied by the Ministry of Health in assessing the application.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *Public dose constraints do not consider contributions from other authorized practices. Optimization of public exposure has not been applied, as the dose constraint value is the same as the dose limit.*

(1)	<b>BASIS: GSR Part 3 para. 3.120 states that</b> <i>“The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public. When establishing or approving constraints in respect of a source within a practice, the government or the regulatory body shall take into account..... (c) Dose contributions from other authorized practices or from possible future authorized practices, estimated at the design and planning stage, so that the total dose to members of the public is not expected to exceed the dose limit at any time after the start of operation of the source.”</i>
(2)	<b>BASIS: Safety Fundamentals Principle 5 para. 3 states that</b> <i>“The optimization of protection requires judgements to be made about the relative significance of various factors, including: The number of people (workers and the public) who may be exposed to radiation;”</i>
(3)	<b>BASIS: GSR Part 3 para. 3.24 states that</b> <i>“For occupational exposure and public exposure, registrants and licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety.</i>
(4)	<b>BASIS: GSR Part 3 para. 3.122 states that</b> <i>“Before authorization of a new or modified practice, the regulatory body shall require the submission of, and shall review, the safety assessments ... that address the optimization of protection and safety...”</i>
<b>R13</b>	<b>Recommendation:</b> <b>CNCAN and the Ministry of Health should establish dose constraints for the public exposure which consider all potential exposures and then require optimization.</b>

There is no evidence in the authorization process that the either Ministry of Health nor CNCAN undertakes its own assessment of potential doses to the public.

Order 102/2022 approving the Regulation on specific requirements for decommissioning of nuclear and radiological facilities includes an annual reporting requirement for facilities to provide monitoring results and public doses to CNCAN. Order 103/2022 approving Regulation on the safety requirements

for the predisposal activities of radioactive waste, disused radioactive sources and spent nuclear fuel contains the same reporting requirement.

The Ministry of Health issues a sanitary authorization for medical facilities to possess and use radioactive sources. A sanitary license is not dependent on the existence of a CNCAN authorization; the sanitary authorization requires annual reporting of areas including sending a copy of the CNCAN licence. Clarity on the roles and responsibilities of both Ministry of Health and CNCAN in the permitting process would aid effectiveness of the regulatory process and efficiency of the operator. This issue is addressed in Recommendation R1 in Section 1.2.

Neither CNCAN nor the Ministry of Health undertake an independent monitoring programme to verify the dose to the public from planned exposures has not exceeded the dose limit. Nor do they verify the monitoring programme undertaken by the operator. The Ministry of Health has an extensive monitoring programme across Romania which includes drinking water, environmental samples and commodities. This programme currently reports concentration values but could be adapted to verify the operators' environmental monitoring programme, discharges and assess public dose. The Ministry of Health could use this programme to assure itself and CNCAN that the annual dose limit to the public has not been exceeded.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *Neither CNCAN nor the Ministry of Health independently assess the dose to the public.*

(1)	<b>BASIS: GSR Part 3 para. 3.135 states that</b> <i>“The regulatory body shall be responsible, as appropriate, for: (a) (ii) Assessing doses from public exposure; (c) making provision for an independent monitoring programme; (d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of the monitoring data provided by the registrants and licensees and with the use of independent monitoring and assessments; (f) verification of compliance of an authorized practice with the requirements of these standards for the control of public exposure.”</i>
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R14	<b>Recommendation:</b> <b>The Ministry of Health and/or CNCAN should develop an independent monitoring programme and a framework to assess the dose to the public and demonstration of compliance with the dose limits.</b>
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Exemption from the requirements of authorisation is detailed in Annex No 2 of the standards. Release from licencing regimes is detailed in Article 39 and requires compliance with the dose criteria. Article 50 requires CNCAN to determine the dose constraint to the representative person whenever appropriate. The operator is required to establish derived emission limits for radioactive effluents (exempted, cleared and authorized) which are then approved by CNCAN. For nuclear sites, the operator applies for clearance by submitting a procedure for exemption and clearance for any waste stream. CNCAN undertakes an inspection of the laboratory to ensure that compliance will be achieved when reviewing an application. Facilities report an inventory of cleared material to CNCAN annually.

Basic requirements on radiological safety (jointly issued by CNCAN, the Ministry of Education and the Ministry of Health) 2018 prohibit the sale or public availability of consumer products if their intended use is not justified or if their use does not meet the criteria for exemption. These regulations (in respect of public exposure) largely relate to CNCAN responsibilities. However, the basic health standards of 2004 for the safe conduct of nuclear activities place additional requirements on operators and responsibilities on the Ministry of Health. For example, Ministry of Health approval is required for products containing radioactive materials. Further, the introduction of radioactivity above natural levels into construction materials requires approval from the Ministry of Health. Recommendation R1 in Section 1.2 addresses the role of both CNCAN and Ministry of Health in radiation protection.

Existing exposure situations in Romania include natural, end of emergency and past practices, with the latter using a reference level range of 1-20 mSv yr<sup>-1</sup> and a legal liability value of 1 mSv yr<sup>-1</sup>. Some existing exposure situations have been identified in Romania including a phosphogypsum site and a

NORM contaminated site; both sites had assessed doses of below 1 mSv yr<sup>-1</sup>. Formal consideration of intervention is required if the dose exceeds 6 mSv yr<sup>-1</sup> with the objective of reducing dose to below 1 mSv yr<sup>-1</sup>, although this objective is site specific.

The Ministry of Health is responsible for radon. A radon action plan has been established although some of the planned actions such as a radon map have yet to be developed. The radon action plan sets the action level at 300Bq m<sup>3</sup>. This is addressed in Suggestion S20 in Section 9.9.

## **5.12. SUMMARY**

The Romanian regulatory framework is defined primarily in Law 111/1996 on the safe conduct, regulation, licensing and control of nuclear activities. CNCAN's regulatory approvals consist of registration, issuance of authorizations and practice permits. CNCAN regulations establish limits and exemption criteria. The system of authorization for nuclear power plants, research reactors, and fuel cycle facilities is well established but further improvements could be made.

CNCAN should develop procedures to assess justifications. In addition, it should require the applicant to submit a documented safety assessment, including an independent review and a complete scope of Radiation Protection Programme with the appropriate level of detail. CNCAN should also consider developing provisions assuring that short-term storage is not used for a long period and that sources are declared as disused in a timely manner.

CNCAN issues authorizations to medical facilities in accordance with established regulatory requirements, while the Ministry of Health is also issuing 'sanitary authorization' for these facilities. There is a need for coordination between CNCAN and MoH to ensure consistency and avoid duplication in their authorization processes. The IRRS noted areas for improvement in justification for medical exposures for individual patients and the need for consistency in the requirements for review of Diagnostic Reference Levels (DRLs) by the authorized parties.

## **6. REVIEW AND ASSESSMENT**

### **6.1. GENERIC ISSUES**

#### **6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT**

Law no. 111/1996 gives CNCAN responsibilities for the authorization of the facilities and activities, based on technical review and assessment and on the findings of inspection. The review and assessment (CP3) is one of the core processes of CNCAN and detailed CNCAN management system manual. CNCAN has developed internal processes and procedures (PO-CP3-00) for review and assessment of facilities and activities. These internal processes allocate responsibilities for the review and assessment of the technical documentation submitted by the licensees or applicants to different technical units within CNCAN. The process for review and assessment of safety documentation submitted by the license holder or applicant aims at assessing compliance with Law no. 111/1996. The authorization for any activity or installation can only be issued if compliance has been demonstrated with all applicable legal and regulatory requirements. The review and assessment activities are performed with the objectives of determining that: the applicable safety objectives and requirements for each aspect or topic have been met; the safety analyses cover both normal and accident conditions and; the safety submissions provided are sufficiently complete, detailed and accurate.

Documentation submitted by the licensees for regulatory review and assessment include but is not limited to: safety analysis reports; periodic safety review documentation; aging management programs; periodic inspection reports; design modifications (permanent or temporary); life extension basis documents; together with other technical documentation and procedures.

CNCAN's review and assessment reports are documented in manner which follows the format detailed in annex-3 of procedure PO-CP3-00. The evaluation report includes reference number, date, CNCAN code, revision etc., which allows clear traceability. The electronic file is maintained by CNCAN.

Formal observations, dispositions or other actions resulting from the review and assessment of the submitted documentation by CNCAN are addressed to the authorization applicant through official letters. Actions resulting from the review and assessment of a licensing submission can include limits and conditions in the authorization.

#### **6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT**

In its review and assessment activities CNCAN uses its own personnel and does not rely on external TSO's, advisory bodies or committees. However, in limited cases, external consultants can be employed to assist CNCAN staff only once any potential conflict of interest has been addressed. Where needed, CNCAN can also draw on external expertise, through IAEA technical co-operation projects and bilateral agreements with regulatory authorities from other countries. CNCAN can, in accordance with the provisions in the regulations also request for independent, third-party review of documents submitted.

CNCAN has plans to increase the complement of its technical staff allowing it to develop a structured approach for review and assessment activities for complex cases, such as new-build projects or SMRs. CNCAN believe that this approach will improve the regulatory framework and processes. In this regard, CNCAN has officially requested the Government to allow it to increase staff numbers based on current and anticipated workload. However, any increase in staff will require an associated training programme to ensure competence and maintenance of such competence for all staff. This issue has been identified in the action plan.

The requirement for periodic safety reviews (PSR) for all nuclear installations is included in CNCAN's regulation NSN-21. In addition, CNCAN issued a specific regulation on PSRs of NPPs (i.e. NSN-10), which details the scope and the required content of the PSR, including establishing the expected safety factors to be assessed by the licensee. Although the regulation is specific for nuclear power plants, its provisions were recommended as guidance for other nuclear installations, including research reactors. According to CNCAN Order 103/2022 and CNCAN Order 11/2019, PSRs are required for all



predisposal waste management facilities and disposal facilities. However, to date, PSRs have yet to be carried out for: the TRIGA research reactor; the DICA spent fuel storage; the predisposal waste management facilities at IFIN-HH and RATEN-ICN; together with the LILW disposal facility DNDR at Baita Bihor.

The IRRS team note that there remains an absence of specific guidance on the conduct of PSRs for all nuclear and radiological facilities. This was identified in CNCAN’s action plan.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *There is no specific guidance on periodic safety reviews to cover research reactors, spent fuel storage, and fuel cycle facilities. Periodic safety reviews have not yet been completed for the afore mentioned installations in accordance with regulatory requirements.*

(1)	<b>BASIS: GSR Part 4 para. 4.8 states that</b> <i>“The frequency at which the safety assessment shall be updated is related to the radiation risks associated with the facility or activity, and the extent to which changes are made to the facility or activity. As a minimum, the safety assessment shall be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements.”</i>
(2)	<b>BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that</b> <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>
R15	<b>Recommendation:</b> <b>CNCAN should ensure that licensees carry out periodic safety reviews for research reactors, spent fuel storage, and fuel cycle facilities, in accordance with regulatory requirements, and provide the necessary guidance for the conduct of such reviews.</b>

### 6.1.3. BASES FOR REVIEW AND ASSESSMENT

CNCAN periodically assesses reports, programmes and procedures, submitted by the licensees including, but not limited to: safety analysis report; operating license renewal documents, including updates to the FSARs; new or updated safety analyses performed by the licensee; results of periodic safety reviews (PSR or other more frequent routine reviews); significant events reported by the licensee; modifications to procedures and processes; aging management programs; periodic inspection programs; design changes; quality assurance programs. The submission of this information is specified in the regulations (for example in NSN-22) and the regulatory guides, or in the authorization conditions. Some submissions by the licensee do not require approval by the regulatory body, however, such submissions are reviewed by and their conformity with the applicable requirements assessed by CNCAN. Dependent on the potential impact to safety or on the authorization conditions, the relevant information resulted from the review is documented in internal evaluation reports prepared by CNCAN as explained in section 6.1.1.

The licensee is required to submit an annual report on the activity performed, which is reviewed and assessed by CNCAN. In accordance with the requirements in the regulations and in the license conditions, any modifications of the licensing basis documentation or documentation that could impact the safety of a nuclear installation must be submitted for approval of CNCAN.

### 6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

For major reviews, such as those performed by CNCAN prior to granting a license or an approval for a licensing milestone, interdisciplinary teams are established, which include experienced staff from all the technical units involved in the licensing of NPPs, with the necessary expertise for covering all the areas of review. All safety significant issues identified in the review are brought to the attention of the senior management in a timely manner.

Observations, recommendations, dispositions or other actions that result from the review and assessment by CNCAN are addressed to the authorization applicant / holder through official letters issued by CNCAN. For each observation/finding, the impact is highlighted and the designated person in charge is required to resolve the respective observation and report the stage of its fulfilment. In response to any safety improvements or measures identified by CNCAN, the licensee develops an action plan, the implementation of which is monitored by CNCAN.

During review and assessment, inspections are performed to verify and validate assumptions made in the safety analyses and evaluations. As needed, these inspection findings can be used for additional reviews and assessments.

Findings of individual inspections are addressed by the licensee. In order to build a comprehensive regulatory view of the overall safety status of operating facilities, an integrated safety assessment (ISA) is considered a valuable tool. The ISA is a structured and systematic safety evaluation that considers the overall safety of operating facilities in order to ensure continuous safe operation. The IRRS team noted that CNCAN does not identify, in systematic and integrated way, the trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of their activities, as a result CNCAN is not performing ISA's in a systematic manner.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>CNCAN does not systematically document integrated safety assessments for operating facilities.</i>	
(1)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.46 states that</b> <i>“For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach”.</i>
S11	<b>Suggestion:</b> <b>CNCAN should consider documenting the integrated safety assessments of operating facilities.</b>

## 6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

In accordance with the provisions of the Law and the regulations, CNCAN is empowered to request from the licensees, or from the applicants, all the documentation needed for the regulatory decision-making process on safety related matters. The documentation to be submitted to CNCAN for review and approval is specified in the regulations and regulatory guides. According to the CNCAN regulatory requirements, the safety review and assessment is mandatory for all nuclear power plants. Relevant requirements for the assessment and verification of safety, for the different phases of a nuclear installation, are also included in the set of regulations on quality management systems for nuclear installations (NMC series) which contain provisions related to the quality assurance and safety of operation, maintenance, in-service inspection, testing, modifications, etc.

The assessment criteria are specified in regulations, regulatory guides and in the internal procedures of CNCAN. Additional regulatory requirements and criteria are also established as necessary based on applicable international standards, codes and guides. The regulatory requirements established in regulations also specify the criteria for validation of analyses and computer codes. Tools and methodologies used in the safety report have to be consistent with national and international practices, and are also validated against relevant test data and benchmarks.

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

Evaluation of the safety documentation includes the review of deterministic analyses, probabilistic analyses, reliability analyses, hazard analyses, habitability analyses, human and organizational factors etc. The review and assessment performed by CNCAN as part of the licensing process and as part of the continuous regulatory oversight focuses on:

- Operating license renewal documents, including updates to the FSARs;
- New or updated safety analyses performed by the licensee;
- Resulting of periodic safety reviews (PSR or other more frequent routine reviews);
- Station safety performance;
- Significant events reported by the licensee;
- Temporary configuration changes;
- Plant modifications.

Major modifications of a plant that have an impact on nuclear safety are submitted to CNCAN for review and approval. CNCAN monitors the licensee's progress in the implementation of the planned improvements and continues to perform safety reviews and inspections to ensure that all opportunities for improvement are properly addressed taking account of the lessons learned from major events, e.g., from the Fukushima accident. Other design improvements are identified and reviewed taking into account the latest standards, new regulatory requirements, available operational experience feedback and the results of research and development activities. CNCAN has issued specific regulatory requirements and guidance for the ageing management of nuclear installations and verifies compliance through the routine regulatory processes of review and assessment and inspection.

CNCAN also performs reviews and assessments of the licensees' programmes for training, qualification and authorization of personnel with jobs important to nuclear safety. CNCAN evaluates the technical knowledge, skills, attitudes and capabilities of the licensed personnel in their assigned areas of responsibility. The implementation of the training programs for all personnel with duties important to safety and the observance of the station training policy are also extensively reviewed and assessed by CNCAN through periodic reviews, inspections and audits.

### **6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS**

CNCAN follows the same process for the review and assessment of research reactors as for nuclear power plants. Procedure PO-CP3-00 specifies the review and assessment process for all installations regulated by CNCAN. GSN-05 provides guidance for review and assessment of final safety analysis reports of research reactors.

For research reactors, CNCAN has yet to develop specific checklists or guides for review and assessment. In the absence of these CNCAN staff base their practice on international guidance and the documents developed for NPPs. In its action plan, CNCAN addresses this issue.

### **6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES**

In the review and assessment of Fuel Fabrication Plants, CNCAN staff uses regulatory guide GSN-06, which specifies the requirements for periodic update of the safety analysis report (SAR) and information to be included in each chapter of the SAR.

For mining facilities, CNCAN has issued a work instruction on the review and assessment of authorization documentation (IL-CP3.8-01), this takes into account the national regulations and requirements for each activity necessitating authorization.

## **6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES**

CNCAN's review and assessment process for radioactive waste management facilities is based on the regulatory provisions in CNCAN Order 74/2022, CNCAN Order 103/2022 and CNCAN Order 11/2019. These orders include requirements and guidance on the stepwise development of safety case and supporting safety assessment, such safety assessments are required to be verified by an independent organisation. CNCAN's review and assessment of radioactive waste management facilities and activities is carried out according to internal processes, procedures, checklists and work instructions.

The IRRS team was informed that the prioritisation of review and assessment areas and the efforts and resources used for review and assessment of the different parts of the safety cases and safety assessments are based on expert judgement of individual CNCAN staff. This implies that there is not a formalised, systematic and consistent approach in applying the graded approach in the review and assessment of safety cases and the assessment of radioactive waste management facilities. This issue is addressed in Suggestion S8 in Section 4.3.

According to CNCAN Order 103/2022 and CNCAN Order 11/2019, PSR of predisposal and disposal facilities, respectively, are required to be carried out at least every 10 years. However, no PSR for these types of facilities have yet been carried out. This will be done at the next licence renewal. This issue is addressed by Recommendation R15 in Section 6.1.2.

## **6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES**

Review and assessment of applications for licensing / authorization except authorizations related to discharges is conducted by CNCAN division DAURI which has three units, namely: Unit for authorization of industrial and medical practices;; Unit for National Register of Occupational Doses and Registry of Radiation Sources. DAURI has 16 staff members dedicated to authorization and review and assessment. Limitations on the number of CNCAN staff and their competences are addressed in Recommendations R5 and R6 in Section 3.3.

When an application for authorization is submitted, the Head of the licencing division distributes the task for review and assessment of documentation, to the units, this review can be supplemented by a pre-authorization inspection as needed. Requests for the pre-authorization are managed within an information system. All steps for performing the review and assessment are documented including any requests from CNCAN for any additional information. The evaluation report is checked by the Head of the DAURI and is part of the supporting documents for the approval of the president of CNCAN.

Authorizations issued by CNCAN are time limited. For reauthorization of activities review and assessment is conducted, this requires the registrant or licensee to send specific reports, e.g. on incidents or modifications to the activity. Inspections reports can also be used in the review process to provide the oversight of the compliance of registrants and licensee to requirements. Inspection findings are used as a feedback to the authorization process.

The IRRS team was informed that Public District Health Inspectorates under the Ministry of Health also perform control of registrants and licenses in the use of radioactive material, through authorization. The Ministry of Health undertake annual measurements of radiation fields and issues a document to the registrants and licensees with their results without any liaison with CNCAN about the results. The IRRS team did not review the performance of the Public District Health Inspectorates regarding review and assessment. The lack of cooperation among competent authorities is addressed in Recommendation R1 in Section 1.2.

## **6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES**

There are no ongoing decommissioning activities in Romania. However, the final decommissioning plan for the cyclotron at IFIN-HH at Măgurele has recently been reviewed and approved by CNCAN and decommissioning will begin soon. CNCAN's review and assessment of decommissioning activities by

CNCAN is based on the regulatory provisions in CNCAN Order 102/2022 and carried in accordance with internal processes, procedures, checklists and work instructions. Requirements on using the graded approach during the development of decommissioning plan are clearly stated in CNCAN Order 102/2022. Examples on the manner of implementing this requirement are in the specific decommissioning plans for NPP, RR and Cyclotron facilities. The review and assessment activities for the decommissioning plans are implicitly based on a graded approach and are harmonized with the requirements from CNCAN regulations. However, the IRRS team was informed that the graded approach is not applied by CNCAN to its internal process for review and assessment of decommissioning plans in a formalised, systematic and consistent manner. This issue is addressed in Suggestion S8 in Section 4.3.

## 6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

CNCAN has implemented a general procedure for reviewing and assessing technical documentation attached to license applications.

For transport and storage in transit authorizations the main document in support of the licence application is the radiation protection programme. Systematic provisions aimed at taking radiation protection measures into adequate consideration and constituting the main body of the radiation protection program are included in CNCAN Order No. 104/2022.

With regard to authorised parties and the performance of the authorized activities, by law, CNCAN receives annually, by the end of March, a list of shipments made in the previous year by each licensed carrier. These reports are not used for the purpose of preparing any periodic assessments to evaluate radiation doses to workers and the public from the transport of radioactive material.

For the issuance of type-approval certificates of package designs produced in Romania, CNCAN requires that a design safety assessment report be submitted. In this context, CNCAN staff review the results of tests and calculations.

Specific procedures for review and assessment of the technical documentation attached to applications for authorization and approval for transport is only partially in place and are outdated. CNCAN is encouraged to complete the set of procedures for the review and assessment for the authorization process in the field of transport of radioactive material.

It was noted during interviews and site visits that CNCAN does not undertake any review or assessment of the procedures implemented by shippers for the classification of radioactive material to be shipped, in accordance with SSR-6 (Rev. 1) requirements. At present CNCAN accepts the consignor's proposed classification as being appropriate.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN does not review and assess the procedures implemented by consignors for the proper classification of the radioactive material to be shipped, in accordance with SSR-6 (Rev. 1) requirements.

(1)	<b>BASIS: SSG-78 para. 4.6 states that</b> “Compliance assurance programmes may be relatively simple and straightforward or may be complex and wide ranging, commensurate with the size and variety of the transport industry for which the competent authority has responsibility. At a minimum, for a simple compliance assurance programme in a State that performs a limited number of shipments including only a few types of radioactive material, account should be taken of the following: (a) Radioactive material classification ...”.
(2)	<b>BASIS: SSR-6 (Rev.1) para. 401 states that</b> “Radioactive material shall be assigned one of the United Nations (UN) numbers specified in Table 1 in accordance with paras 408–434.”.
S12	<b>Suggestion:</b> CNCAN should consider reviewing and assessing the procedures implemented by consignors for the proper classification of the radioactive material to be shipped, in accordance with SSR-6 (Rev. 1) requirements.

The number of staff involved in conducting review and assessment of technical documents submitted in support of applications for authorizations and issuance of approvals for transport activities is considered not sufficient to allow CNCAN to fulfil all its duties relating to transport (currently 3 people). This issue is addressed by Recommendations R5 and R6 in Section 3.3.

In accordance with Law No. 111/1996, CNCAN must develop and implement training programs for its staff relating to the regulation, licensing, and control of nuclear activities. CNCAN staff involved in review and assessment activities have not received any specific training on transport of radioactive material matters. This issue is addressed by Recommendation R6 in Section 3.3. To aid training and development CNCAN is encouraged in considering allocating resources to allow staff working on authorization processes related to the transport of radioactive material to have the opportunity to join relevant international forums. This issue is addressed by Suggestion S3 in Section 2.1.

#### **6.9. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE**

CNCAN conducts review and assessment of all documents supporting measures related to occupation exposure including optimization, monitoring programme and classification of areas. If occupational dose reports can be retrieved (the issue is addressed in Suggestion S4 in Section 3.7) occupational exposure reports are reviewed by CNCAN as part of the assessment process. As the complete radiation protection programme is not submitted by the applicant for all practices, review and assessment is not comprehensive. The issue is addressed in Recommendation R10 in Section 5.6.

Dosimetry services are obliged to send to CNCAN the data on occupational doses every month or every three months as appropriate. CNCAN assess the results and act when needed.

#### **6.10. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE**

CNCAN has internal guidance procedures for issuance of the registration/authorization to medical facilities. The practice specific regulations (i.e. 'Norms' for Radiotherapy, Nuclear Medicine and Diagnostic & interventional radiology) require the authorized party to establish a quality management program for ensuring compliance with regulatory and safety requirements. This programme is reviewed by CNCAN for issuance of authorization for use of medical equipment/sources. However, the submission to CNCAN does not include a comprehensive safety assessment report. As part of its review process, CNCAN requires independent verification of the calibration of radiotherapy equipment prior to clinical use.

Only the radioactive sources and radiotherapy equipment that possess a Registration Certificate of the Medical Device, or a Registration Certificate for the Medical Device, in the operating place, issued by The National Agency for Medicines and Medical Devices (ANMDM) of Romania, under the MoH, are allowed for clinical use.

CNCAN issues radiation safety authorization (ASR) for new equipment models after the review of technical documents.

The IRRS team observed that the Ministry of Health and CNCAN are acting in an independent manner with regard to their domains. Issues concerning the lack of interaction and coordination between these authorities are addressed in Recommendation R1 in Section 1.2.

CNCAN is empowered to issue authorizations to agencies for installation, servicing and maintenance of medical devices according to Law No. 111/1996 and issues permits to personnel involved in such activities. The IRRS team was informed that ANMDM has recently commenced issuance of authorization to such agencies involved in the supply of pre-owned equipment, but the criteria for issuance of such authorization has not been provided to CNCAN.

Dose constraints for carers and comforters, and volunteers in biomedical research are established by Order of the Ministry of Health. The IRRS team was informed that the implementation of justification and dose constraints are under the jurisdiction of the Ministry of Health, though CNCAN during its review and inspection has recently started addressing these aspects. As per Law 111/1996 there are

several responsibilities placed on the Ministry of Health, including justification, dose constraints, conduct of clinical audits etc. Although the Ministry of Health has specified the requirements in this regard for the authorized parties, their implementation is not assessed.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The Ministry of Health is not reviewing the procedures for justification, implementation of dose constraints for carers and comforters in medical exposures, conduct of clinical audits or periodic radiological reviews, nor is it verifying implementation.*

(1)	<b>BASIS: GSR Part 3 para. 3.173 states that</b> <i>“Registrants and licensees shall ensure that relevant dose constraints are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter”.</i>
(2)	<b>BASIS: GSR Part 3 para. 3.157 states that</b> <i>“The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric of ....”</i>
(3)	<b>BASIS: GSR Part 3 para. 3.182 states that</b> <i>“Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility..... investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.”</i>
<b>R16</b>	<b>Recommendation:</b> <b>The Ministry of Health should review the authorized parties’ procedures for justification, periodic radiological reviews and audits, conformance to dose constraints and verify their implementation.</b>

Both CNCAN and the Ministry of Health have established the requirements for reporting of events of unintended or accidental medical exposures. However, the IRRS team was informed that only one event has been reported to CNCAN and none to the Ministry of Health over the last several years. Clear guidance on which reports need to be submitted to which authority, and a mechanism for dealing with incidents related to design flaws has not been established. The number of reported events reflects a need to strengthen the efficiency of the reporting system and provide operational feedback experience. Further, there was no dissemination of lessons learnt from incidents reported.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The small number of events of unintended or accidental medical exposures reported to CNCAN and the Ministry of Health till date challenges the robustness and the efficiency of the reporting system. Also, absence of procedure at CNCAN for prompt dissemination lessons learnt from reported significant events restricts the CNCAN, the licensees and other interested parties from benefitting from an efficient feedback experience.*

(1)	<b>BASIS: GSR Part 3 para. 3.15 states that</b> <i>“Registrants and licensees .... (g) Shall establish procedures for reporting on and learning from accidents and other incidents;”</i>
(2)	<b>BASIS: GSG 46 para. 5.274 states that</b> <i>“Another approach, independent from any legal requirement for reporting to the regulatory body, is to participate in voluntary international or national databases designed as educative tools.... Facilities performing radiation therapy should be active participants and users of SAFRON, ROSEIS or similar international databases or equivalent national ones”.</i>
(3)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 15 states that</b> <i>“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.”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(4)	<b>BASIS:</b> SSG-46 para. 5.274 states that “ ... <i>The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events</i> ”
S13	<b>Suggestion:</b> CNCAN and the Ministry of Health should consider reviewing the incident reporting system of authorized parties, so as to encourage reporting to CNCAN and/or the Ministry of Health, and to participate and use relevant international databases.
R17	<b>Recommendation:</b> CNCAN and the Ministry of Health should enhance the reporting system of significant events in medical exposures, encourage sharing of such events and disseminate the lessons learnt to the interested parties.

Review and assessment of the quality assurance programme is carried out for the issuance of an authorization. However, the period of retention of records pertaining to patient dosimetry, calibration etc are not stipulated by CNCAN or the Ministry of Health. Responsibilities of CNCAN and the Ministry of Health with regard to stipulating the record keeping requirements is not clearly assigned.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>The retention period of authorized parties’ records of calibration, dosimetry, quality assurance, and records of medical exposure are not specified in the regulations.</i>	
(1)	<b>BASIS:</b> GSR Part 3 para. 3.184 states that “ <i>Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance....</i> ”
(2)	<b>BASIS:</b> GSR Part 3 para. 3.185 states that “ <i>Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure: (a) For diagnostic radiology, information necessary for retrospective assessment of doses,..... (d) For external beam radiation therapy or brachytherapy, a description of the planning target volume... (f) Reports on investigations of unintended and accidental medical exposures</i> ”
R18	<b>Recommendation:</b> CNCAN and the Ministry of Health should specify the retention period for records related to medical exposure.

In Romania, there is no standards laboratory for calibration of dosimeters used for patient dosimetry. Radiotherapy centres have the equipment calibrated abroad or by manufacturers. CNCAN has not included verification of traceability of such instruments to standards dosimetry laboratory as a part of its review process.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>The traceability of calibration of dosimeters used for patient dosimetry to a standards dosimetry laboratory is not verified by CNCAN.</i>	
(1)	<b>BASIS:</b> GSR Part 3 para. 3.167 states that “... <i>d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.</i> ”
R19	<b>Recommendation:</b> CNCAN should verify that the calibration of dosimeters used for patient dosimetry is traceable to a standards dosimetry laboratory.

### 6.11. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Discharge limits are proposed by the licensee to CNCAN as part of the application process. CNCAN reviews the input data to these limits to ensure that the dose to the representative person is below the 1



mSv constraint. If this dose is below 1 mSv further optimization is not considered by CNCAN. This issue has been addressed in Recommendation R13 in Section 5.11. Medical facilities also require a sanitary permit issued by the Ministry of Health to operate, although this approval process makes no additional assessment of the impact on public health but could include different conditions.

The licensee is required to ensure optimization of protection and safety of the occupationally exposed workers in emergency situations and the public through the use of dose constraints value established by CNCAN (0.8 -1 mSv yr<sup>-1</sup> for public).

CNCAN Order 11/2019 requires measures to be taken for ensuring the protection of people who are exposed as a result of disposal activities for radioactive waste to be optimized with due regard to the dose constraint established by CNCAN during the development phases of disposal facilities. The use of a dose constraint (0.3 mSv) has been adopted for a disposal facility, with a value of 1 mSv used for inadvertent intrusion post closure. Article 118 requires the authorised party to provide assurance through the safety case that members of the public and the environment are, and will remain, adequately protected against the hazards associated with the waste being disposed.

No information was provided to the IRRS team on how CNCAN verifies the dose calculation to the public or discharges to the environment. This issue is addressed in Recommendation R14 in Section 5.11.

## **6.12. SUMMARY**

Under the Romanian regulatory framework, CNCAN is responsible for the authorization of facilities and activities, following technical review and assessment and, where needed, inspection. The IRRS team noted that there is no guidance for all types of facilities for periodic safety reviews, nor have periodic safety reviews been carried out for all nuclear installations. To harmonize the process as per regulation NSN-22, CNCAN should ensure that licensees carry out periodic safety reviews for all facilities and provide the necessary guidance for the conduct of such reviews.

The IRRS team noted that CNCAN has no formal documented process or guidance on how to perform the safety assessment of operating facilities in an integrated and systematic manner which would allow CNCAN to evaluate such facilities to support continuous safe operation. For enhancing the effectiveness of CNCAN, CNCAN should consider develop such a process and then performing and documenting the integrated safety assessments of operating facilities.

The CNCAN has limited number of experienced staff to perform comprehensive review and assessment related to radiation facilities and activities. The IRRS team noted that there are overlapping responsibilities regarding review and assessment of radiation sources facilities and activities between CNCAN and Laboratories for Ionizing Radiation Hygiene. The IRRS team was not able to assess the review and assessment process conducted by the aforementioned laboratories.

CNCAN conducts review and assessment of medical facilities based on internal guidance procedures. As per Law 111/1996, the IRRS team noted that responsibilities placed on the Ministry of Health relating to justification, periodic radiological reviews and audits, conformance to dose constraints should be addressed. The IRRS team also identified areas of improvement with regard to establishing requirements for retention of records relevant to calibration, quality assurance, dosimetry and strengthening the reporting mechanism for significant events by both CNCAN and MoH.

## 7. INSPECTION

### 7.1. GENERIC ISSUES

CNCAN empowers inspectors to conduct inspections under Chapter IV of Law 111/1996. A variety of inspection types are described in CNCAN's general inspection process, including announced and unannounced inspections. CNCAN conducts a variety of inspections to verify compliance with the regulatory requirements and with the conditions specified in the authorization. Inspections of facilities and activities authorized by CNCAN are conducted by inspectors organized in the technical divisions/units, or jointly with other headquarters staff, with the occasion of the major authorization milestones. CNCAN has resident inspectors at the Cernavodă NPP and regional inspectors for the use of ionising radiation sources within the territory of Romania. CNCAN prioritizes preauthorization inspections, which has put pressure on the limited inspector resources in the radiation source area.

There is not an overall risk-based inspection programme from which to base the planning of inspections. Inspection areas are defined under the mentioned general inspection procedure, CNCAN Inspection Process Description, PO-CP4-00, but the coverage of inspection areas, including types, timing, and frequency, is not defined. There is no defined alignment between the inspection areas in the inspection process and coverage provided by the inspection checklists. CNCAN staff prepare an annual inspection plan for the NPP, which is updated quarterly, however, the production of this list is based on expert knowledge, rather than a defined inspection programme. Recommended frequencies of inspections are identified in some specific NPP inspection checklists, but this information is not complete, and has not been collected and reviewed to ensure the choice of topics and the thoroughness of activities is applied in a graded approach based on radiation risks involved.

Records of completion of the annual inspection plans indicate that insufficient resources are assigned to inspection, with some inspections being deferred. Without a well-defined inspection programme, which identifies necessary inspections including defined frequencies, it is not known what the impact of the inspection deferrals is. A minimum set of inspections, with defined frequencies and topic areas, outlined in an inspection programme could inform the quantification of resources necessary to implement the inspection programme. As the necessary inspections have not been identified, it is not clear to what extent the lack of completion of the inspection programme impacts CNCAN's confidence in overall compliance of operators.

The IRRS team was informed the frequency of planned inspections of predisposal and disposal facilities is the same for all, regardless of hazard level. The inspection programme is based on experience from the inspection practices for predisposal and disposal facilities and the status of the Romanian Nuclear Programme. In addition, the prioritization of inspection topics and the thoroughness of inspection activities related to the different inspection topics is based on expert judgement of individual CNCAN staff.

An inspection programme has been developed for radiation sources facilities and activities. The inspection programme applicable for the fuel cycle facilities and activities does not establish in detail the frequencies of inspections for all areas. A holistic inspection programme allows more accurate identification and allocation of resources and assists in providing reasonable assurance that coverage of applicable inspection areas is commensurate with radiation risk. This information would be useful as an input into the planning of the allocation of new positions in CNCAN.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN's inspection programme does not explicitly define the frequencies and risk-based criteria, nor does it explicitly confirm there is reasonable assurance of complete coverage of inspection areas.*

(1)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 29 states that</b> <i>“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS: GSR Part 1 (Rev.1) para. 4.50 states that</b> <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.”</i>
(3)	<b>BASIS: GSR Part 1 (Rev. 1) para. 4.52 states that</b> <i>“Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections... The manner, extent and frequency of inspections shall be in accordance with a graded approach”.</i>
(4)	<b>BASIS: GSR Part 2 para. 4.21 states that</b> <i>“Senior management shall make arrangements to ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency response.”</i>
S14	<b>Suggestion: CNCAN should consider further improving their inspection programme to explicitly define the frequencies and risk-based criteria, and to explicitly confirm there is reasonable assurance of complete coverage of inspection areas.</b>

The implementation of a sound inspection programme relies on the competency of the staff in executing their inspection and enforcement function. There are several challenges to the execution of the inspection programme noted by the IRRS team. For example: CNCAN has limited resources to provide on-the-job training (OJT) for NPP resident inspectors; not all transport inspectors are fully trained; and CNCAN has been challenged to perform all necessary inspections of decommissioning activities due to limited staff numbers as well as limited financial resources for measuring equipment.

CNCAN has a plan to train, qualify and certify, inspectors, including the provision of refresher and continuing training, which has not been implemented. CNCAN has identified this issue as an improvement action in its self-assessment. The IRRS team supports CNCAN’s observation and encourages CNCAN to implement this plan. For each inspector, an annual training plan is prepared, but due to the lack of funds, it is not always accomplished.

The functions of CNCAN staff in the inspection process are described in CNCAN procedure PO-CP4-00. Technical staff from CNCAN headquarters support and perform some inspection functions. These staff with functions related to inspection, such as “Nuclear Safety Advisors”, in addition to inspectors, are issued certificates which permit them to conduct inspections. The certificate, issued to new staff shortly after being hired, identifies the role of the certificate holder, such as “Advisor”, and specifies that it grants inspection powers under Chapter IV of Law 111/1996. The IRRS team was informed that the issuance of these certificates is only to the personnel that have inspection activities according to the law. The IRRS team was also informed that the certificates are issued based on the individual work contract and job description and are not intended to identify inspectors. The CNCAN enforcement process identifies that it is inspectors who hold enforcement authorities, which are also granted by Chapter V of Law 111/1996. Despite the distinction in some documentation, without the implementation of a systematic, documented inspector training and qualification, the roles, and responsibilities of CNCAN staff with respect to inspection and resulting enforcement may not be clear neither to inspected operators or to CNCAN staff. This should be considered by CNCAN in addressing Recommendation R5 in Section 3.3 regarding competence requirements.

The expansion of the nuclear programme in Romania, including the refurbishment of Cernavodă Unit 1, resumption of construction on Cernavodă Units 3 and 4, and addition of SMR technology will increase the volume of inspection activities, including preauthorization inspections, and add new technologies to

the scope of inspections. In addition, the rapid growth of the number of uses of ionizing radiation in the medical field and new techniques in this area are foreseen, e.g. proton radiotherapy. Implementation of a sustainable, appropriately resourced, training programme for new and existing inspectors will be essential to CNCAN’s delivery of their inspection programme.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN has not implemented, in a systematic and documented manner, its training and qualification programme for inspectors.

(1)	<b>BASIS: GSR Part 1 (Rev.1) para. 4.13 states that</b> “A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills....”
(2)	<b>BASIS: GSG-12 para. 4.57 states that</b> “The regulatory body should ensure that the responsibilities assigned to different parts of its Organization are clearly defined.”
<b>R20</b>	<b>Recommendation:</b> CNCAN should implement its training and qualification programme with focus on recently hired inspectors and new technologies.

### 7.2. INSPECTION OF NUCLEAR POWER PLANTS

There is one NPP in Romania, which currently has two operating CANDU units. There are three resident inspectors, who are responsible for daily routine inspection of the condition of the plant and the main control room, as well as inspections of systems. They also participate in inspections of programs and audits.

The annual inspection plan includes system inspections, which prioritize systems important to safety, process inspections supported by CNCAN headquarters staff and may periodically include management system audits also supported by CNCAN headquarters staff. Inspections of systems and processes are typically announced. However, follow up inspections related to abnormal condition reports and reactive inspections following incidents may be unannounced. CNCAN resident inspectors have free access to the Cernavodă NPP, at any time, and perform inspections outside of normal working hours periodically. Access to areas of the plant is facilitated by qualification of inspectors to appropriate levels of facility-specific radiation protection.

#### Site visit to Cernavodă NPP

On November 1, 2023, the IRRS team observed the three resident inspectors performing routine inspection activities in the main control room and in Unit 2. All CNCAN inspectors were very knowledgeable, professional, and competent. Their dedication to their jobs, including ensuring that the most significant inspection tasks were completed, as efficiently as possible, despite limited resources is commendable.

Interaction of CNCAN inspectors with Cernavodă NPP staff in the main control room as part of a daily inspection demonstrated an open, transparent, and respectful relationship. The resident inspectors prioritize highest risk activities and maintain a high degree of awareness of plant conditions. Daily activities include review of licensee abnormal conditions reports, review of station logs and plant status, observation of licensee meetings, and follow up on concerns.

Sample inspection reports, which are prepared following inspections and submitted to the licensee, were reviewed by the IRRS Team. Timelines for correction of non-compliant observations, based on a risk-based ranking, are tracked in a database maintained at headquarters. The licensee is expected to sign for receipt of the inspection report; however, CNCAN staff indicated that this has at times been misunderstood to be a signature to represent acceptance of the content, rather than acknowledgment of receipt of the findings.

CNCAN staff indicated that the licensee is generally quite responsive to proposed corrective actions, and more formal enforcement actions, as described in the enforcement process, is very rarely needed. During the site visit CNCAN resident inspectors and Cernavodă NPP management confirmed clear understanding that prime responsibility remains with the authorized party.

CNCAN uses the results of inspections as feedback information for regulatory processes. The IRRS Team was informed that an inspection related to procurement performed in 2020 led to the identification of a need for the development of regulation in that area, which was completed in 2022.

CNCAN identifies integrity as an assumed value under the management system manual. This enables objective regulatory decisions without conflicts of interest. While there are specific provisions to avoid conflict of interest with management staff, no such provisions exist for resident inspectors. There is no rotation policy and the 3 current resident inspectors can remain at the site indefinitely.

Objectivity is noted as a measurement of effectiveness of the inspection process; however, no documented policies are in place to assure the regulatory independence or objectivity of resident inspectors. Some informal practices are in place, such as the use of headquarter staff in the execution of inspection of processes. CNCAN resident inspectors have also proposed practices such as periodic independent verification of system inspection results by CNCAN headquarters staff, however resources have not been made available for this type of activity.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN does not have a documented or implemented process for ensuring the regulatory independence and objectivity of CNCAN resident inspectors at Cernavodă NPP.

(1)	<b>BASIS: GSG-12 para. 6.10 states that</b> “...Staff assignments should be regularly reviewed to ensure that regulatory independence and objectivity are maintained in dealings with authorized parties.”
S15	<b>Suggestion:</b> CNCAN should consider documenting and implementing a formal process to ensure the comprehensive, regular review of the regulatory independence and objectivity of resident inspectors at NPPs.

There is a general procedure for execution of inspections, and many checklists detailing specific coverage of inspection areas, but some checklists are yet to be developed. CNCAN has a strategy in place to produce or update a large number of work instructions for the conduct of nuclear power plant inspections by 2025. Prioritization and resource allocation should be considered for those inspections that are required to ensure sufficient coverage of inspection areas which don’t already have adequate guidelines in place. Without a clearly defined, comprehensive inspection programme for NPPs, the availability of sufficiently detailed inspection guidelines to ensure coverage of applicable inspection areas checklists cannot be assured.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN does not have detailed guidelines for all areas of NPP inspections to conduct necessary inspections of each applicable inspection area to a consistent standard, based on a graded approach.

(1)	<b>BASIS: GSG-13 para. 3.26 (c) states that</b> “Inspection of facilities and activities; the regulatory body should provide its inspectors with written guidelines in sufficient detail to ensure that facilities and activities are inspected to a common standard, based on a graded approach, and that there is a consistent level of safety.”
(2)	<b>BASIS: GSG-13 para. 3.281 states that</b> “Inspections should be conducted in accordance with an approved inspection programme, plan, guidelines, procedures and checklists.”
S16	<b>Suggestion:</b> CNCAN should consider further developing detailed NPP inspection guidelines required for each applicable inspection area to ensure consistent and adequate

coverage, based on a graded approach.

### **7.3. INSPECTION OF RESEARCH REACTORS**

For the research reactors, inspection plans are elaborated annually, by the CNCAN Units involved in the regulation of these installations. The Inspection Plans cover all areas given in the Operating Licence for the Research Reactor. All areas from the licence are covered with a frequency of 2–3 years, which is stated in the Plan. The inspection methods are covered in the procedure for inspection at nuclear installations. The inspection plan specifies the theme of the inspections, date, days required for the inspection, number of participants, type (reactive, planned, unplanned).

The training, qualification and certification of personnel designated by CNCAN to perform inspection/control activities at research reactors follows the internal procedure PS1-01-00.

#### Site visit to TRIGA Research Reactor located at the Institute for Nuclear Research (ICN Pitești)

A site visit to the TRIGA Mark II Research Reactor located at the Institute for Nuclear Research (ICN Pitești) was conducted on November 1st, 2023, when one member of the IRRS team observed a planned inspection conducted by two CNCAN inspectors. The reactor was in shutdown state, defueled for maintenance and tests. Several safety features of the technical limits and conditions of the reactor were inspected, but it was noticeable that the inspection did not address some aspects of occupational exposure and industrial safety. Radiation protection was out of the scope of the inspection observed by the IRRS team. The IRRS team was informed that CNCAN conducts separate inspections on radiation protection.

The visit also showed that there is mutual trust between the licensee and the CNCAN inspectors and that the licensee understands well the role and the importance of the regulatory oversight conducted by CNCAN. The visit confirmed that the operator has a significant shortage of manpower due to the recent retirement of a significant proportion of its employees. This is affecting the ability of the licensee to meet the requirement for a periodic safety review.

### **7.4. INSPECTION OF FUEL CYCLE FACILITIES**

Inspection of fuel cycle facilities is carried out in accordance with the general inspection procedure PO-CP4-00 and the procedure PC-DMS-02.

The areas of inspections are radiation protection, physical protection, safeguards, training and qualification of personnel, emergency preparedness and response, and management systems.

The training, qualification and certification of personnel designated by CNCAN to perform inspection/control activities at fuel cycle facilities follow the internal procedure PS1-01-00.

### **7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES**

CNCAN carries out inspections of predisposal and disposal facilities in accordance with inspection plans and checklists based on the provisions of the applicable regulations, the license's limits and conditions, dispositions from previous inspections, and reports of the authorized party. Inspections reports are finalised at the end of each inspection and signed by CNCAN's inspectors and the authorized parties. The inspection reports report contains the findings and, in case of noncompliance, dispositions with deadlines for reporting on the fulfilment of the dispositions to CNCAN.

As described in Section 7.1, CNCAN does not apply the graded approach to the inspections of radioactive waste management facilities in a formalised, systematic and consistent manner. This issue is addressed in Suggestion S14 in Section 7.1.

#### Site visit to the National Institute of Physics and Nuclear Engineering “Horia Hulubei” (IFIN-HH) at Măgurele

On 1 November 2023 the IRRS team observed an inspection of the predisposal waste management facility (STDR) at IFIN-HH Măgurele conducted by five CNCAN inspectors, two for transport and three for waste. The inspection topics were communicated to the authorized party in advance.

IFIN-HH operates a predisposal waste management facility for processing and storage of institutional radioactive waste as well as the LILW disposal facility DNDR at Baita Bihor. The STDR has been in operation since 1975 and disposal operations at DNDR began in 1985.

After the introductory meeting, the inspection team performed a site walk-down. The IRRS team members noted that CNCAN inspectors did not note several shortfalls:

- In a storage facility neutron sources are stored but no type of neutron detection was available;
- IFIN-HH did not follow its procedure regarding ventilation of a storage facility. As a consequence, the alarm connected to the dosimeter of an IFIN-HH staff went off due to too high radiation field shortly after entering the facility and the inspection team including the IRRS team left the building immediately.
- There was no clear delineation of contamination areas. There was no contamination monitoring at the exit of each building on the site.
- The operator did not establish monitoring points to enable assessment of consistent values of background. The inspector did not verify that the operator has sufficient monitoring instruments to verify the radiation hazard.

These observations point to the need for CNCAN to improve inspection training as noted in Recommendation R20 in Section 7.1.

After the site walk-down, the group of inspectors split into two, one inspected predisposal waste management activities, while the second one carried out an inspection relating to the transport of radioactive materials.

The inspection of transport vehicles included the availability of required documentation and ADR equipment on board, a visual check of the adequacy of fastenings arrangements for packages, and a measurement by IFIN-HH of non-fixed surface contamination.

Both inspections included interviews based on checklists. The presence of the required documents and formal compliance with the authorization provisions were checked. No independent measurements or functional tests were carried out by CNCAN inspectors during the inspection. At the end of the inspection CNCAN staff drafted the inspection report with IFIN-HH staff present and presented the findings to the operator. The operator signed and stamped a copy of the report to acknowledge receipt.

The operator was asked by the IRRS team on the relationship between CNCAN and themselves. IFIN-HH staff noted that they had a good relationship with CNCAN and there was clear understanding of the role of CNCAN and responsibilities. Actions following inspections are time limited and on occasion challenging. In such situations the operator could approach CNCAN to review such actions.

IFIN-HH stated that it is typically inspected once a year. Regarding changes to requirements, IFIN-HH staff said that they were consulted by CNCAN on any draft changes, and they considered that their views were taken into account before any changes were enacted.

## **7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES**

The IRRS team was informed that in 2022 CNCAN conducted 2045 inspections related to radiation facilities and activities, approximately half of them related to authorization process. As already mentioned, CNCAN conducts pre-authorization inspection for medium and high-risk practices while for low-risk practices inspections are conducted at latest 6 months after issuing an authorization. About 70% of the inspections are announced. CNCAN has overarching inspection procedure PO-CP4-00 and specific procedure MC-PO-DSURI-01 focusing on inspections of facilities and activities with radiation sources. CNCAN is also developing specific check lists to be used by inspectors during preparation and

on-site inspections activities regarding specific facilities and activities. The IRRS team acknowledged that there are not issued check lists for all types of facilities or activities. This was noted in the CNCAN Action plan regarding check lists for well logging and non-medical exposures. The IRRS team encourages CNCAN to complete the check lists.

The inspectors have a full access to facilities and the power to stop activities on the spot when needed. The IRRS team was informed that CNCAN has recently reviewed the procedure to address a preparation of the Annual plan for inspections in order to fully implement a graded approach, e.g. inspections of industrial radiography facilities should be conducted every year, while dental practices once per 10 years. The IRRS is encouraging CNCAN to further implement a graded approach in inspections, as noted in Suggestion S14 in Section 7.1. The inspection reports, which are signed by inspectors as well as by a representative of the inspected entity, typically contain required corrective actions as well as deadlines to implement them. The follow up of corrective actions is done. The feedback from the inspections is incorporated in other regulatory processes.

The DSURI Division of CNCAN has four inspection services, namely, the East Surveillance Service, the West Surveillance Service, the South Surveillance Service, and the Bucharest Service with a total of 20 inspectors. On average every inspector conducts about 12 inspections per month and as a rule, 2 to 3 inspectors are involved in one inspection. The training programme for newcomers is foreseen as well as retraining but not currently in place. As noted in the Action plan, training of inspectors is not consistently done. The issue is addressed in Recommendation R20 in Section 7.1. The IRRS team also noted that there is a lack of calibrated equipment to be used by the CNCAN inspectors, see Recommendation R19 in Section 6.10.

Inspectors are also involved in management of orphan sources, when appropriate. Orphan sources are taken by Institute for Nuclear Physics or by RATEN – ICN Pitești, in cooperation with CNCAN, and are stored in a licensed interim storage.

#### Site visit at S.C. Dyomedica CND. S.R.L. at Ploiești

The IRRS team observed an inspection conducted by two CNCAN inspectors. The company performs industrial radiography with gamma sources and radiation generators as well as supply and maintenance of industrial and medical equipment with and without radiation sources including supply of radioactive sources for industrial radiography. The entrance meeting was dedicated to a short introduction of the inspection scope. The inspection was dedicated to reviewing safety systems related to the irradiation room, transport of radioactive sources, and maintenance of an exposure device of a client including source replacement.

The majority of the inspector activities were related to observations of work along with the review of selected documentation. The inspectors used a check list prepared for that specific inspection from a general check list of industrial radiography inspection. Inspectors communicated with both radiation protection officers (RPO) and with selected workers on a site. As a part of an inspection one of the RPO was obliged to write, on the spot, a written test dedicated to knowledge and awareness of radiation safety and emergency preparedness. Such an approach is considered by the IRRS team to be a good performance.

The inspection report was signed by the operator and inspectors at the end of the inspection. It contained clear requirements to implement a corrective action with a time period to implement each action.

In the discussion with the operator, it was noted that there was good cooperation between CNCAN and the operator. The operator used CNCAN's online system to apply for licenses. However, the operator believed that the large number of licenses needed did not contribute to safety. Altogether, it had 10 different licenses from CNCAN and about 5 from the Public District Health Inspectorate.

The IRRS team observed the lack of risk-based approach to the inspection in particular regarding the control of contamination and shielding related to different types of equipment.



## **7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES**

There are no ongoing decommissioning activities and hence, no inspection activities in this area. However, the final decommissioning plan for the cyclotron at IFIN-HH at Măgurele has recently been approved by CNCAN and decommissioning will begin soon.

The IRRS team was informed that during the staged decommissioning of the VVR-S research reactor of IFIN-HH, CNCAN performed inspections regarding clearance of radioactive waste. However, the limited number of staff and limited measuring equipment hindered CNCAN from performing complete inspections. As such, there was no verification that the desired end state was met. This issue is addressed in Recommendation R20 in Section 7.1.

## **7.8. INSPECTION OF TRANSPORT**

Although transport inspections are typically performed at consignors and consignees, CNCAN inspectors have powers to perform inspection to land, air and inland waterways transport operators and have unlimited access to each mode authorized facilities in accordance with Law 111/1996. CNCAN inspectors are also authorized to stop the vehicles on the road with support of the State Inspectorate for Road Transport Control (ISCTR). A specific procedure for inspection of the transport of radioactive material (PO-CP4-TR-01) has been developed. The IRRS team observed that CNCAN inspection process for transport was extensive. In particular, the documentary check during an inspection included the radiation protection programme, the arrangements for preparedness and response, the management system and the training records for persons engaged in the transport of radioactive material.

Three staff members are in charge in inspecting the transport of radioactive material. It is considered that more staff could be needed to fulfil the statutory obligations of CNCAN in this respect. This issue is addressed by Recommendation R5 in Section 3.3.

Only one of the three staff members (in the transport division) received specific training in transport. CNCAN should ensure that its staff have access to expertise in many different fields related to the safe transport of radioactive material. This issue is addressed by Recommendation R6 in Section 3.3.

In order to avoid conflicts with other organizations having responsibility over different aspects of the transport Regulations, CNCAN established formal agreements with agencies whose purview may have an interface with the transport of radioactive material. In particular, CNCAN signed cooperation protocols with the Romanian Road Authority (ARR), the State Inspectorate for Road Transport Control (ISCTR) and the Romanian customs authority.

In particular, the cooperation protocol with the Romanian customs authority was signed in order to ensure that customs operations involving the inspection of the radioactive content of packages are carried out only in places where adequate means of controlling radiation exposure are provided and in the presence of qualified persons. This is considered a good performance.

## **7.9. INSPECTION OF OCCUPATIONAL EXPOSURE**

CNCAN uses comprehensive inspection check lists for radiation sources. The check lists address occupational exposure and compliance with authorization documentation and limits and conditions given in authorization. However, the IRRS team noted that checklists are not available for all types of facilities or activities. It was noted that the CNCAN inspection process strongly relies on cooperation with the radiation safety officers. According to CNCAN procedure for inspection, the inspection of occupational exposure is part of every routine inspection for planned exposures for radiation sources facilities and activities. Design of facilities, including shielding, and classification of areas are regularly inspected.

According to the CNCAN procedure the review and assessment of the protection of workers on site is undertaken routinely during inspections.

At the site visit to S.C. Dyomedica, the IRRS team noted that the inspection did not address occupational exposure although the inspection was dedicated to a high-risk activity conducted in controlled areas. For example, the adequate use of personal protective equipment and the calibration of the measurement equipment was not inspected. Detailed information of the site visit is given in Section 7.6.

At the site visit to TRIGA Research Reactor located at the Institute for Nuclear Research (ICN Pitești) the IRRS team noted the same lack of addressing the occupational exposure during the inspection. Detailed information of the site visit is given in Section 7.3.

This points to a general issue with the formal training of inspectors. The training of the inspectors is addressed in Recommendation R20 in Section 7.1.

## **7.10. INSPECTION OF MEDICAL EXPOSURE**

During the year 2022, CNCAN has conducted inspections of 1448 medical (equipment/ installation) with around 1000 of these being X-ray and dental facilities.

CNCAN has developed specific inspection checklists for all medical practices for use during pre-authorization inspections, and the elements of the same checklists are used during periodic inspections. The IRRS noted there are limited number of experienced inspectors for radiotherapy and nuclear medicine inspections. Training of newcomers is mainly on-the-job training during site visits with senior inspectors. CNCAN would benefit in establishing a systematic inspector training and certification programme. This issue is addressed in Recommendation R20 in Section 7.1.

### A site visit at MNT Health Care Europe, Bucharest

The IRRS team observed an inspection at a nuclear medicine facility which possesses one SPECT and a PET-CT equipment. The inspection started with an initial meeting with licensee, and a walkthrough of the facility. Verification of related documents for availability of trained manpower, personnel dose records, equipment calibration records, compliance to previous inspection findings as well as arrangements for effluents management in a context recent increased activity for nuclear medicine procedures was conducted. The inspectors were meticulous and observant during the inspection. However, the IRRS team noted that the inspector did not carry a contamination monitor. The CNCAN instruments were not available since the calibration validity had expired.

The inspection findings were formally communicated to the authorised party at the exit meeting and the inspection report was issued, along with requirements on the time period for resolution of the non-compliances.

The IRRS team asked the authorised party about the relationship with CNCAN. The authorised party expressed that they are highly satisfied with the relationship and that it was professional. The IRRS team was informed that CNCAN inspectors were approachable and ready to provide any additional guidance through informal communication. The authorised party noted that reduction of the time needed (4-5 months) for the authorisation of the new medical facilities from CNCAN and the Ministry of Health would be beneficial.

## **7.11. INSPECTION OF PUBLIC EXPOSURE**

Inspections conducted by CNCAN can be thematically based and include public exposure. Inspections by CNCAN can include verifying the monitoring data collected by the operators and discharges, although this does not extend to verifying the assessment of dose to the public. This issue is addressed in Recommendation 14 in Section 5.11.

Compliance with the requirements of consumer products and drinking water are inspected by the Ministry of Health using 18 laboratories across Romania supporting the “Radioactive Hygiene Laboratory Network” with three further national laboratories also supporting this programme.

Inspections on public exposure are performed by CNCAN either announced or unannounced. Inspections can be undertaken to consider public exposures which include on and off the site exposure

pathways. The inspection verifies compliance (or otherwise) with discharge limits (See Section 8), which have been calculated by the operator together with the operators monitoring programme.

In the workplaces where radon concentration exceeds the reference level, CNCAN verifies the implementation of monitoring and protective actions derived from remediation program. In the industries working with natural sources, the implementation of protective actions and remediation action are inspected.

Order 2195 details that the training programme for nuclear medicine specialists needs to consider public dose. CNCAN Order 103/2022 approving Regulation on the safety requirements for the predisposal activities of radioactive waste, disused radioactive sources and spent nuclear fuel requires an annual report to be submitted to CNCAN on exposure to the public and discharges. However, CNCAN does not independently verify this report. This issue is addressed in Recommendation R14 in Section 5.11.

## **7.12. SUMMARY**

CNCAN conducts, documents, and follows up on inspections following an established inspection procedure. There is inspection guidance available as well. The IRRS team found that inspectors did consistently follow the check list while performing inspections. The IRRS team did identify some areas for improvement. There is no overall inspection programme, with defined frequencies, to support the planning and resourcing of inspections, and to provide assurance of appropriate coverage of inspection areas. In addition, there is a lack of detailed checklists to support the conduct of inspections of NPPs across all inspection areas. Once an inspection programme has been defined for NPPs, it will be more apparent which checklists should be prioritized for completion.

There is a documented, formal inspector training program. However, CNCAN has not been able to fully implement it due to a lack of resources. The impact of the lack of systematic training was noted during some of the inspections that the IRRS team observed.

CNCAN performs regulatory oversight for only one NPP, and as such, does not rotate the resident inspectors. CNCAN should consider other mechanisms to support the regulatory independence and objectivity of the resident inspectors.

## 8. ENFORCEMENT

### 8.1. ENFORCEMENT POLICY AND PROCESS

CNCAN is empowered by Law 111/1996 to enforce regulatory requirements and conditions of authorizations. Application of sanctions, or enforcement, is identified in the CNCAN management system as a core process. The framework for enforcement applies a graded approach, based on risk-significance, to corrective actions required by authorized parties in situations of non-compliances. There is an internal procedure, PO-CP5-00, to guide CNCAN staff on applying the enforcement policy. The timeframe of responses to non-compliances is set according to the safety significance of the non-compliances.

CNCAN's enforcement programme includes a suite of possible enforcement actions to be applied in a graded approach, which ranges from regulatory letters to fines, prosecution, and revocation of authorization. Interactions with other authorities, such as the General Inspectorate of the Romanian Police, in the case of criminal prosecution is included in the procedures. If non-compliances are criminal in nature, the police are contacted by CNCAN.

The IRRS team was informed that CNCAN does use its enforcement powers. For example, a RPO suspended following the breach of authorization conditions of a CNCAN permit.

Enforcement action can be undertaken by CNCAN in relation to breaches of authorization conditions which have an impact on public exposure. However, as CNCAN does not assess the impact on the dose to the public, determination of a breach of the law would not be possible in this area. See Recommendation R14 in Section 5.11.

The IRRS team identified that there are requirements that neither CNCAN nor the Ministry of Health are enforcing. Some of these are regulatory requirements that have been in place for several years that operators have not yet implemented like ageing management for radioactive waste management facilities, and periodic safety reviews for radioactive waste management facilities and research reactors. These are discussed further in Recommendations R7 in Section 5.5 and R15 in Section 6.1.

In addition, the Ministry of Health is responsible for the implementation of several requirements with respect to medical exposures, such as justification, dose constraints for carers and comforters, periodic radiological reviews, etc. Although the Ministry of Health has specified the requirements for the authorized parties, their implementation is not verified by the Ministry of Health.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *There are many requirements and regulations that have not been implemented by authorized parties. Corresponding enforcement action has not been taken by the Ministry of Health or CNCAN.*

(1) **BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that** *“The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”*

(2) **BASIS: GSR Part 1 (Rev. 1) Requirement 31 states that** *“In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.”*

**R21 Recommendation: The Ministry of Health and CNCAN should fulfil their statutory duties for enforcement.**

### 8.2. ENFORCEMENT IMPLEMENTATIONS

CNCAN resident inspectors at the Cernavodă NPP confirmed to the IRRS team that they were aware of their power to enforce the cessation of activities in situations of imminent likelihood of safety significant events under the Law 111/1996. Internal processes would suggest consultation with senior CNCAN

headquarters staff would be expected prior to shutting down of a nuclear power plant but this consultation is not mandatory.

Enforcement actions issued to authorized parties are tracked by CNCAN staff. Confirmation of acceptability and implementation of corrective actions is performed by CNCAN staff, and the acceptance of corrective actions is formally documented and communicated to the authorized party.

CNCAN conducts inspections to identify instances of noncompliance that may require corrective action by the transport operator. Guidance material from SSG-26 (Rev.1) on how to correct certain non-compliances, as applicable, to meet specific regulatory requirements of IAEA Regulation SSR-6 (Rev. 1) has not been made available to operators. CNCAN is encouraged to provide guidance to operators on how to meet certain regulatory requirements for various transport activities.

Written inspection reports and regulatory letters identify the specifics of the non-compliance, the expected action, and a time period for correction. In 2022 CNCAN issued the procedure PO-CP5-00 addressing the application of the enforcement process. The process includes instruction for inspectors to record and communicate the non-compliances and the relevant legal provisions, and to inform the licensee of its rights including appeal.

One of the potential enforcement activities CNCAN inspectors may need to conduct is sealing of a radiation generator. The IRRS team was informed that the process for sealing a radiation generator is not included in the enforcement procedure. Furthermore, the training of inspectors to perform sealing has not been conducted. The issue has been noted in CNCAN’s Action plan.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> <i>The CNCAN procedure to conduct enforcement does not include the sealing of radiation generators, if required. Inspectors have not been trained on the sealing of radiation generators.</i>	
(1)	<b>BASIS:</b> <i>GSR Part 2 Requirement 10 states that “Processes and activities shall be developed and shall be effectively managed to achieve the organisation’s goals without compromising safety”.</i>
(2)	<b>BASIS:</b> <i>GSR Part 1 (Rev. 1) para. 4.13 states that “A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.”</i>
S17	<b>Suggestion:</b> <b>CNCAN should consider updating the procedure on enforcement to be used in the enforcement process so that all enforcement activities are taken into account including sealing of unauthorized radiation generators. CNCAN then should update the Inspector training to include all enforcement activities.</b>

### 8.3. SUMMARY

CNCAN has established, and implements a well-defined, risk-informed enforcement process supported by several enforcement tools, including fines which may be delivered by inspectors.

The enforcement process is generally applied in a manner that considers the risk of the non-conformities, the willingness of the authorized party to comply, and the compliance history of the authorized party. There are some instances where regulatory requirements are not being complied with by authorized parties, and neither CNCAN nor the Ministry of Health are performing their statutory duties to take corresponding enforcement actions.

CNCAN's enforcement procedure is lacking specific instruction related to sealing unauthorized radiation generators, and training for inspectors on that activity will be required once the procedure is updated.

## 9. REGULATIONS AND GUIDES

### 9.1. GENERIC ISSUES

The Romanian regulatory framework for nuclear and radiation safety includes law, regulations, norms, standards and codes, regulatory guides, instructions, formal letters and CNCAN dispositions and actions stated in the inspection reports.

CNCAN is empowered by Law 111/1996 on the Safe Conduct, Regulation, Licensing and Control of Nuclear Activities. The law defines the basic rules on the functioning of the nuclear regulatory authority and the conditions for licensing the nuclear activities, radiation protection including exposure situations, environmental protection, safety of the public, workers, and patients, transport, emergency preparedness, safeguards and security. The law also empowers CNCAN to develop and update mandatory and enforceable regulations in order to detail the general legal requirements, as well as any other regulations necessary to support the licensing and control of nuclear activities.

The drafting and updating of the regulatory framework mainly takes into account the experience of the regulatory body, recommendations, requirements and mission findings of international organizations such as IAEA, WENRA, HERCA, etc., international standards, amendments in European legislation, stakeholder proposals and the results of research and development. The procedure PO-CP1-01 Elaboration of normative acts specific to CNCAN's field of activity which was updated in 2018 establishes the conduct of activities for the elaboration, analysis and approval of draft laws, regulations, guides and instructions issued by CNCAN. The procedure which is within the scope of IMS also defines the responsibilities and interfaces for drafting of those documents. The technical departments issue the drafts taking into consideration the advice of the legal expert of CNCAN. Comments of the relevant authorities and public are taken into consideration during preparation of the drafts.

The IRRS Team was informed that the legal department of CNCAN is staffed with only one expert who is responsible, along with technical staff, for the regulatory framework. The IRRS team noted that CNCAN should consider assessing the structure and staffing needs of its legal department to perform its regulatory and legislative functions. The issue of developing and implementing a comprehensive human resources plan is addressed in Recommendation R5 in Section 3.3.

Law 111/1996 is supported by 113 regulations in force. The regulations and guides come into force after being published in the Official Gazette of Romania. All regulations and guides in force are available on CNCAN's website. In order to support its authorization and control activities of nuclear installations and applications, CNCAN issued regulations in the following areas which are identified by different codes:

- Radiological safety regulations (NSR)
- Nuclear safety regulations and regulatory guides (NSN, GSN)
- Nuclear safeguards regulations (NGN)
- Physical protection regulations in the nuclear field (NPF)
- Radioactive mining regulations (NMR)
- Radioactive material transport regulations (NTR)
- Radioactive waste management regulations (NDR)
- Quality management regulations in the nuclear field (NMC)
- Regulations on emergency preparedness and response (NUR)
- Regulations on natural radiation sources (NRNs)
- Regulations on the preparation and certification of nuclear personnel (NPP)

- Nuclear construction regulations (NCN)
- Nuclear Cyber Security regulations (NSC)

In accordance with the procedure PO-CP1-01, the regulatory framework is reviewed every five years. If no update is needed as the result of the review, a reconfirmation notice, which states the validity of the document is issued. As part of preparation of regulations, the drafts are issued on CNCAN’s website for comments from the interested parties, however, there is no formal decision-making process describing the roles and responsibilities of drafting, incorporating comments, formal communication with licensees for seeking their comments etc. applicable for issuance and revision of regulations.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The CNCAN procedure for developing or updating regulations and guides does not include a formal decision process taking place before the drafting of regulations and guides commences.*

(1)	<b>BASIS: GSR Part 2 Requirement 10 states that</b> <i>“Processes and activities shall be developed and shall be effectively managed to achieve the organisation’s goals without compromising safety”.</i>
(2)	<b>BASIS: GSR Part 2 para. 4.28 states that</b> <i>“Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation.”</i>
S18	<b>Suggestion: CNCAN should consider revising the procedure for developing or updating regulations and guides to include a formal decision process.</b>

The IRRS team noted that most of CNCAN’s regulations are newly issued or revised as a result of internal review.

The IRRS team was informed that CNCAN’s regulation NSN-22 on licensing of nuclear installations came into force in 2019. In 2021, Nuclearelectrica S.A (the company that owns Cernavodă NPP) and the US company NuScale signed a teaming agreement to advance the deployment of NuScale’s SMR technology in Romania. After the signature of this agreement, CNCAN revised the regulatory framework in order to evaluate the development, licensing and construction of small modular reactors (SMRs). The prompt update of the regulation for reactors and facilities with multiple modules is considered a good performance.

CNCAN conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. In the action plan CNCAN stated that specific regulations on nuclear fuel cycle facilities and research reactors, addressing all the particular aspects relevant to their entire life cycle including periodic safety review, human factor engineering and design should be developed and issued. CNCAN also stated that a regulatory framework should be completed for authorization of radiation sources and activities.

### 9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

CNCAN has a set of safety requirements specific to nuclear power plants. There also exists some requirements specific for CANDU type designs. There are a total of 25 regulations covering authorisation, siting, design, construction, operational limits and conditions, emergency response, periodic safety review, probabilistic safety assessment, specific systems for CANDU NPPs, ageing management, independent oversight, personnel authorisation, safety analysis, cyber threats, and interfaces between safety and security in regulation of NPPs. Regulations are supported by 10 guides which are applicable to NPPs.

The IRRS team was informed that NSN-02 related to design and construction of NPPs is planned to be revised during the next year. Also, CNCAN is planning to draft two new regulations for supporting its regulatory infrastructure. These are:



- Nuclear Safety Requirements for Electrical Systems for NPPs
- Nuclear Safety Requirements for Instrumentation and Control Systems for NPPs

The IRRS Team observed that most of the regulations applicable to NPPs were recently updated.

In 2020, CNCAN issued a Regulation on the use of standards for the assessment and continuous improvement of nuclear safety for nuclear power plants (NSN-27) and revised it and updated it in 2021. Among other requirements, this regulation imposes that the licensees and license applicants for nuclear installations, for all phases of development:

- systematically use the relevant and applicable IAEA Safety Standards (listed, by categories, in an annex to the regulation and including the standards relevant for fire protection),
- produce self-assessments of the conformance with these standards and
- include them in the licensing basis documentation, in PSR (Periodic Safety Review) evaluations and also
- take into account any new edition of these standards.

Starting with 2023, compliance with the applicable WENRA Reference Levels and the applicable IAEA Safety Standards is required, for all nuclear installations, by the provisions of NSN-22 - Regulation on the licensing of the nuclear installations (the regulation was initially issued 2019 and was supplemented in 2023).

### **9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS**

Most of the regulations on nuclear installations also apply to research reactors and all the essential requirements are included. As a result of self-assessment, CNCAN has identified a need for development of a specific regulation on research reactors, to systematically address the particular aspects related to research reactors for their entire lifecycle which is part of its Action Plan. This regulation will reference the existing regulations on nuclear installations that are applicable to research reactors. The IRRS team observed this initiative as an example of consideration of graded approach in development of regulations.

Deterministic Safety Analyses (DSA) are required by regulation NSN-24 for all nuclear installations. However, CNCAN does not have regulatory guides for the application of DSA for the authorization of research reactors following the graded approach. CNCAN should consider reviewing the current regulation or issuing a specific regulation on the application of DSA for research reactors using the graded approach.

Although required by regulations NSN-21 and NSN-22 for nuclear installations, CNCAN has no guidance specifically on the application of these requirements for the Periodic Safety Review (PSR) of research reactors. The current CNCAN guideline recommended the research operator to use IAEA's Safety Report Series 99 (Periodic Safety Review for Research Reactors). However, this IAEA publication is not a Safety Standard and the IRRS team found that CNCAN should develop specific guidance on the PSR of research reactors (see Recommendation R15 in Section 6.1.2).

### **9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES**

Most of the regulations on nuclear installations also apply to fuel cycle facilities and all the essential requirements are included in them. In its Action Plan, CNCAN plans to issue a specific regulation on fuel cycle facilities, to systematically address the particular aspects related to fuel cycle facilities for their entire lifecycle. This regulation will reference the existing regulations on nuclear installations that are applicable to research reactors. The IRRS team finds that this initiative will help apply the graded approach to regulating fuel cycle facilities.

Deterministic Safety Analyses (DSA) are required by regulation NSN-24 for all nuclear installations. However, CNCAN does not have regulatory guides for the application of DSA for the authorization of

fuel cycle facilities following the graded approach. CNCAN should consider developing a specific regulation or a regulatory guide on the application of DSA for fuel cycle facilities using the graded approach.

Although required by the regulations for nuclear installations, there is no guidance on the application of the graded approach for the PSR of fuel cycle facilities. CNCAN should develop guidance on the PSR of fuel cycle facilities (see Recommendation R15 in Section 6.1.2).

### 9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

CNCAN developed regulations (CNCAN Order 74/2022, CNCAN Order 156/2005, CNCAN Order 155/2022, CNCAN Order 103/2022 and CNCAN Order 11/2019) for waste management, waste classification, clearance, predisposal and disposal facilities, which are consistent with IAEA safety standards. Additional regulations apply to predisposal facilities for processing and storage of radioactive waste and spent fuel at the Cernavodă NPP site, since these are licensed as nuclear installations. However, the implementation of all the requirements by the authorized parties are still pending. An example is the conduct of PSRs of predisposal and disposal facilities. This issue is addressed in Recommendation R15 in Section 6.1.2.

### 9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The regulations and guides developed for facilities and activities with radiation sources contain general requirements as well as specific ones for addressing specific facilities or activities with radiation sources are listed below:

- Regulations regarding basic requirements for radiological safety;
- Regulations for control of radioactive sources and the safe management of orphan sources;
- Regulation regarding authorization procedures;
- Regulations regarding the designation of notified laboratories for the nuclear field;
- Regulations for issuing permits for working in nuclear field;
- Regulations regarding individual dosimetry and radon;
- Regulation regarding requirements for radiological safety in practices of non-destructive testing;
- Regulation regarding requirements for radiological safety in practices involving level gauges;

Due to the recent amendment of the Law 111/1996, several regulations and guides have been either drafted for the first time or revised. The list of regulations and guides developed by CNCAN and applicable to all types of radiation sources facilities and activities in Romania is not complete, e.g. as noted in the Action plan there are no regulations and guides for well logging and non-medical exposures, but these are currently in development.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The regulations and guides issued by CNCAN do not form a comprehensive and complete set of needed regulations and guides for all types of radiation sources facilities and activities.*

(1)

**BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that** *“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.”*

R22

**Recommendation:** CNCAN should systematically develop a complete and comprehensive set of regulations and guides demonstrating a graded approach.

Each year, CNCAN sends the annual plan to the Government containing a list of foreseen regulations and guides to be developed or revised. The current annual plan is to develop ten regulations and guides related to facilities and activities with radiation sources.

### 9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

CNCAN established a regulation, CNCAN Order 102/2022, specific to the decommissioning of nuclear and radiological installation, which is in line with IAEA safety standards. No issues in this area have been identified by the IRRS team.

### 9.8. REGULATIONS AND GUIDES FOR TRANSPORT

International modal regulations have been adopted as the basis for regulation of the carriage of dangerous goods by road, rail, inland waterways and air within the territory of Romania and have been ratified by in the national framework, as follows:

- European Agreement on the International Transport of Dangerous Goods by Road (A.D.R.): Law 31/1994, published in the Official Gazette of Romania, Part I, 136 of May 31, 1994, with subsequent amendments and completions;
- Regulation on the International Transport of Dangerous Goods by Rail (RID), in Annex C to the Convention on International Transport by Rail (COTIF): Government Ordinance no. 69/2001, published in the Official Gazette of Romania, Part I, no. 538 of 1 September 2001, approved by Law 53/2002, published in the Official Gazette of Romania, Part I, no. 45 of 22 January 2002;
- European Agreement on the International Transport of Dangerous Goods by inland waterways (ADN): Law 159/2008, published in the Official Gazette of Romania, Part I, no. 675 of October 1, 2008;
- Technical instructions published by the International Civil Aviation Organization in Montreal, for the safety of the transport of dangerous goods by air, in addition to Annex 18 of the Chicago Convention on International Civil Aviation: Decree of the Council of State no. 194, published in the Official Gazette of Romania, no. 14 of 24 April 1965.

The Regulation on the requirements for the authorization of the activity of the transport of radioactive materials hereinafter referred to as CNCAN Order 221/2017 is the only guidance available for transport operators, was issued in 2017 and is based on the IAEA SSR-6 (2012). The IRRS team noted misalignments between CNCAN Order 221/2017 and the current version of the IAEA Transport Regulations.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The Regulation on the requirements for the authorization of the activity of the transport of radioactive materials was issued in 2017 and it is based on the IAEA safety requirements SSR-6, so is not in line with SSR-6 (Rev. 1).*

(1)	<b>BASIS: SSR-6 (Rev. 1) para. 307 states that</b> <i>“The competent authority shall assure compliance with these Regulations”.</i>
(2)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 32 states that</b> <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>
<b>R23</b>	<b>Recommendation:</b> <b>CNCAN should update its requirements for transport of radioactive material to be consistent with up to date requirements of international regulations.</b>

CNCAN published guides (available on its website) for:

- the development of a radiation protection programme for transport; and

- the contents of a package design safety report.

Romania manufactures industrial and Type A packaging for the transport and storage of radioactive waste, but CNCAN has not developed guidelines for establishing and operating test facilities for radioactive material transport packages.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** CNCAN has not developed guidelines for establishing and operating test facilities for radioactive material transport packages.

(1)

**BASIS: SSG-78 para. 4.33 (d) states that** “It should be clearly established that the test facilities comply with the regulatory requirements, particularly in the case of the targets used for drop and penetration tests, where the weight of the test specimen should not exceed the capacity of the test facility”.

S19

**Suggestion:** CNCAN should consider developing and issuing guidelines for facilities performing testing of radioactive material transport packages.

### 9.9. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

CNCAN has published a number of regulations and guides which include general requirements and specific practices concerning occupational exposure. CNCAN has established and enforced general requirements to ensure that protection and safety is optimized for occupational exposure. Requirements for the qualifications and work experience of occupationally exposed workers are included.

Requirements and responsibilities for the protection of workers in planned and existing exposure situations include cooperation of employers and authorised parties and outside workers; designation of areas; and monitoring of workplaces.

Requirements on dose limits and dose constraints are established, as are the general requirement for optimization. There are specific requirements for the protection of female workers and foetuses in the regulations.

Specific practices are lacking guides and regulations. Therefore, all occupational exposures are not fully addressed in regulations and guides. This issue is addressed in Recommendation R22 in Section 9.6.

There is no requirement in the regulations for all the practices addressing the need of employers, registrants and licensees to ensure that persons under the age of 18 are allowed to access to a controlled area only under supervision. Access should always be justified. The requirement is important as it implies that for this group of persons access is only justified if it is related to training or studies which is of benefit to them. This issue is addressed in Recommendation R22 in Section 9.6 concerning the guides and regulations that are recommended to be developed.

Regulations include requirements for the airlines in the case where the effective dose of the aircrew may exceed 1 mSv per year. The IAEA team was informed that CNCAN asked the Romanian airline to perform monitoring for the aircrew for a period of two years (2002-2004) and the mean dose was found to be lower than 1 mSv. CNCAN is encouraged to consider whether assessment of the exposure of aircrew due to cosmic radiation is warranted and then establish a framework which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation.

Provisions for the establishment of the dose constraint are included in the regulations, however investigation levels for the optimization of protection of workers during normal working conditions have not been established. Therefore, timely actions for the investigation cannot be implemented. Introducing investigation levels will further enhance optimization of protection and safety to workers.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *With the exception of the medical area, there are no investigation levels for occupational exposures during normal working conditions.*

(1)	<b>BASIS: GSR Part 3 Requirement 16 states that</b> <i>“Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant for protection and safety”.</i>
(2)	<b>BASIS: GSR Part 3 para. 3.46 states that</b> <i>“Registrants and licensees shall conduct an investigation as specified by the regulatory body in the event that:(a) A quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions;...”</i>
<b>R24</b>	<b>Recommendation: CNCAN should have a regulatory requirement enabling investigation levels to be established.</b>

The radon action plan has been prepared and CNCAN is responsible for coordination of actions foreseen in the Action plan. The IRRS team noted that deadlines for these particular actions given in the Action plan are expired.

As identified in the Action plan, CNCAN does not have a procedure to inspect exposure due to radon in workplaces. CNCAN is encouraged to revise its inspection manual accordingly. The quality manual should be revised when there is enough information whether there are workplaces in Romania that would be considered as a planned exposure situation because of the radon concentration.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The action plan for addressing radon is not fully implemented.*

(1)	<b>BASIS: GSR Part 3 Requirement 50 states that</b> <i>“The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors...”</i>
(2)	<b>BASIS: GSR Part 3 Requirement 52 states that</b> <i>“Exposure in workplaces. The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations.”</i>
<b>S20</b>	<b>Suggestion: The Ministry of Health and CNCAN should consider fully implementing and maintaining the action plan for radon, in cooperation with other institutions and authorities.</b>

### 9.10. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The safety requirements for medical exposures are provided in the Law 111/1996 and Norms on basic radiological safety requirements, 2018. CNCAN has published the following practice specific ‘Norms’ on:

- Radiological safety in diagnostic radiology and interventional radiology practices, 2022
- Radiological safety in nuclear medicine practice, 2004
- Radiological safety in radiotherapy practice, 2004

The above set of documents and additional Orders issued from time to time by the president of CNCAN cover most of the safety requirements for medical exposures in line with the IAEA Safety Standards. In addition, the Ministry of Health has also specified requirements for medical exposures through several Orders. The authorised parties do not have a readily available consistent and comprehensive set of all

applicable requirements for a specific practice. This issue is addressed in Recommendation R22 in Section 9.6.

### **9.11. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE**

Public exposure is addressed in nuclear law and the authorisation process (see Section 5). There are several orders detailed in Section 5.11 which relate to the requirements for public exposure. However, there are no guides on how exposures are to be assessed or verified by either CNCAN or the Ministry of Health for planned or existing exposure situations except for radon which has specific concentration requirements. Order 153/2023 details that a radon map and results are to be published each year, however such a map is yet to be developed. The overall radon action plan is available on the CNCAN website and includes some actions which are yet to be completed by both CNCAN and other parties. Suggestion S20 in Section 9.9 addresses this issue.

### **9.12. SUMMARY**

The basis for requirements for nuclear safety and radiation safety are regulated in Law 111/1996. More detailed provisions are included in the legally binding regulations of CNCAN. There are also a number of guides on CNCAN's field of activity.

CNCAN's regulations and guides are prepared and revised according to the provisions of the internal procedure on "Elaboration of Normative Acts Specific to CNCAN's Field of Activity". The IRRS team identified areas for improvement in CNCAN's set of regulations and guides in regard to comprehensiveness and completeness for all facilities and activities regulated with defined process.

## **10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**

### **10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS**

CNCAN is the authority for regulation of emergency preparedness and response (EPR) and the lead authority for nuclear and radiological issues during an emergency in Romania according to Law 111/1996. According to Article 5, Paragraph 1 of Law 111/1996, CNCAN is the sole regulatory authority for operating organizations for planning, preparedness and response in nuclear or radiological emergency situations. In carrying out its EPR responsibilities under this law, CNCAN has developed a National Nuclear Response Plan (NNRP) and implementing procedures to address nuclear and radiological emergencies within Romania. CNCAN's implementation uses a graded approach that uses specific requirements for each Emergency Preparedness Category. The NNRP was developed to implement the Common Order between CNCAN and Ministry of Interior 61/113/2018.

In accordance with GD 557/2016, CNCAN is the primary authority for prevention, preparedness, investigation, and recovery during an incident involving nuclear or radioactive material. CNCAN developed the implementing requirements in consultation with the Ministry of Internal Affairs (MOI) to ensure a comprehensive, all-hazards approach. The CNCAN management system documents the basis, organization, and goals of CNCAN's nuclear and radiological response program.

The IRRS team was informed that MOI has an all-hazards emergency response plan and the NNRP is implemented as a coordinating part of the overall national plan. In the NNRP, the CNCAN Emergency Committee leads for radiological or nuclear issues while supporting the larger Romanian government response. CNCAN also developed a plan for consistent and prompt public messaging throughout an emergency as part of the NNRP. This approach ensures an overall coordinated approach that supports decision making and enhance public trust. The plan also includes provisions for early notification of neighbouring countries and the IAEA. While most of CNCAN's emergency response procedures are complete and in effect, the procedures relating to the new Emergency Operation Centre are under development.

### **10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS**

CNCAN EPR requirements are consistent with the EPR European Directives and IAEA international standards (i.e. GSR Part 7), and also consider lessons learned and good practices.

The common Order between CNCAN and Ministry of Interior 61/113/2018 requires the operating organization to prepare and implement an emergency response program prior to startup of the nuclear facility. In addition, an emergency exercise is required prior to facility startup to validate the program. The IRRS team was informed that these exercises are inspected by CNCAN, and a report on the findings from exercises by the operating organization must be provided to CNCAN. Operating organizations must also harmonize site plans with any changes in Romanian laws, directives, and CNCAN EPR program changes. These changes are inspected by CNCAN. The law also requires an annual exercise by the operating organization which is observed and inspected by CNCAN.

According to the CO between CNCAN and MOI 61/113/2018 art. 21, the operating organization's EPR plan should include on-site response, arrangements for notifications, prompt evaluation of the event, mitigating and protective actions, offsite support, training and exercises, and arrangements for financial resources to cover damages. The IRRS team was informed that CNCAN EPR staff review and approve all licensee response plans, which must meet requirements of CO between CNCAN and MOI 61/113/2018, CNCAN order 149/2018, and CNCAN order 147/2018, including staffing, training, exercises, mitigating equipment, severe accident scenarios, and postulated accident scenarios.

The IRRS team observed that CNCAN's regulatory framework maintains the appropriate regulatory independence in the oversight of the operating bodies' emergency response plan.

### **10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS**

Law 111/1996 Art. 35, point (c), states that the regulatory body "approves, in the authorization process and throughout the period of operation, the radiological and nuclear emergency response plans of the licensee". The CO between CNCAN and MOI 61/113/2018, art. 23 states that the operating organization shall demonstrate emergency preparedness, prior startup or other activity involving use of radiological material, including fresh nuclear fuel. This demonstration includes a full scale exercise. CNCAN Order 146/2018 art. 52 requires any operating organization to conduct an evaluated exercise to identify areas for improvements and address corrective actions.

CNCAN also requires that the license harmonize its emergency response plans with other on-site plans (i.e. security plans) and all off-site plans. CNCAN Order 146/2018 contains more detail regarding requirements for operating organization emergency response plans. For example, art. 4n requires the on-site emergency response plan to be endorsed by the MoI; art. 5 requires the on-site emergency plan to be based on hazard assessment results; art. 9 requires the operating body to include provisions for on site and off site information; and art. 7 and 11 require the hazard assessment to include accident scenarios with the Design Basis Accident, the Beyond Design Basis Accident, very, very low probability events, loss of nuclear safety functions, and extreme external hazards (e.g. extreme weather events, earthquakes).

The IRRS team was informed that CNCAN observes and assesses the operating organization's plans and performance in exercises. Most recently, CNCAN and Cernavodă planned and conducted a full-scale international exercise, Valahia 2023, to test and further improve their response plans. The exercise tested Cernavodă's response and communication capabilities and was observed by CNCAN staff and included exercise play by representative stakeholders from CNCAN and other Romanian government and non-government organizations.

CNCAN emergency response staff also participated in the exercise which provided an opportunity for CNCAN to use its response procedures including those for the coordination of response with other Romanian authorities (National and local), public communications, international notification treaties and coordination of international aid during an emergency. CNCAN is currently preparing a report which will capture lessons learned (gaps and best practices) from this exercise with the intention that these observations will be used in support of CNCAN's continuous improvement.

### **10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY**

The Romanian National System consists of a network of bodies and structures competent in emergency management. The governing regulations include OUG 21/2004, which establishes infrastructure and tasks, and subsequent acts including GD 557/2016, management of types of risks, GC 1491/2004 (organization of the committees), and Joint Order of CNCAN and MOI 113/2018.

CNCAN has implemented significant changes to its emergency response program in the last few years to address findings in previous audits, IRRS missions and self-assessments. Progress has been made in establishing comprehensive regulations, developing and testing response plans and procedures (CNCAN internal and national level), international cooperation, emergency communications to the public, and planning for a response. Response plans are well-considered and reflect a whole-of-government approach, efficiently coordinating functions across the government in response to an emergency rather than creating duplicative capabilities in multiple organizations. Response plans also include a provision for investigation, enforcement, and prosecution in cases where it is necessary (e.g. smuggling, theft, terrorist actions). The IRRS team noted that CNCAN plans include provisions for consistent public messaging before, during, and following an emergency, as well as provisions for using and monitoring social media to effectively communicate with the public.

The IRRS team was informed that currently, only one CNCAN staff member is appointed for initial screening and notification of events. The IRRS team was also informed that there are not sufficient



CNCAN technical staff available to train in responding to an actual event and insufficient staff to give this training.

CNCAN staff are active in international EPR activities, including the IAEA’s Emergency Preparedness and Response Standard Committee and collaborating with IAEA in planning and conducting ConvEx 2c (Valahia 2023). The IRRS team was informed that the exercise provided the impetus for the development of many procedures for coordination with other government departments and public communication. The IRRS team was informed that CNCAN participants in Valahia 2023 did not practice shift turnovers, and that CNCAN does not have sufficient staff for a full-time (around the clock) emergency response for more than a few days, which is likely to be required for an extended response. CNCAN is encouraged to continue to participate in international exercises.

CNCAN is encouraged to organize periodic exercises with all Romanian government counterparts to ensure each counterpart is prepared to fully implement its role in a national level. Tabletop exercises can achieve this goal while avoiding undue expense. Players should include the decision-making level (those who can commit their department’s resources) for each organization.

CNCAN’s EPR training program is designed to provide training for CNCAN staff as well as staff from cooperating Romanian government organizations, first responders, and media. The training plans are well developed and detailed, however, CNCAN lacks the staff to implement the training program.

It is suggested that CNCAN ensure sufficient competent staff and resources are available for an emergency response, CNCAN needs to appropriately resource this area.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN does not have sufficient resources to conduct response training for qualification and periodical requalification for all staff with response duties.*

(1)	<b>BASIS: GSR Part 7 Requirement 21 states that</b> “ <i>Personnel who are assigned to positions in all operating organizations and response organizations to perform the functions necessary to meet the requirements established in Section 5 shall be qualified and shall be assessed for their initial fitness and continuing fitness for their intended duties.</i> ”
(2)	<b>BASIS: GSR Part 7 para. 3.1 states that</b> “ <i>...This capability relates to an integrated set of infrastructural elements that include, but are not limited to: authority and responsibilities; organization and staffing; coordination; plans and procedures, tools, equipment and facilities, training, drills and exercises; and a management system.</i> ”
R25	<b>Recommendation:</b> <b>CNCAN should ensure sufficient resources are available to conduct response training for qualification and periodical requalification for all staff with response duties.</b>

Under the NNRP and CNCAN procedure PO-CP6-01, CNCAN monitoring teams will be trained and equipped to perform some monitoring. These monitoring teams will be augmented by teams from other Romanian government organizations. Staffing and resource challenges within CNCAN has resulted in CNCAN’s monitoring teams not being fully staffed at present.

As noted above, CNCAN has the responsibility and authority to lead the Romanian national response in a nuclear or radiological event. CNCAN is currently constructing a training and response centre to facilitate that role. The IRRS team visited the construction site for the new EOC. To fulfil its national responsibilities, CNCAN is encouraged to ensure that adequate resources remain available to complete construction of and fully equip the new facility in a timely manner.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *CNCAN’s Emergency Operations Centre is currently under construction.*

(1)	<b>BASIS: GSR Part 7 Requirement 26 states that</b> “ <i>The government shall ensure that a</i>
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>programme is established within an integrated management system to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary for effective response in a nuclear or radiological emergency.”</i>
<b>S21</b>	<b>Suggestion: CNCAN should consider completing the construction and implementing existing plans to equip the Emergency Operations Training and Information Centre and fully implement its emergency response strategy.</b>

The IRRS team noted that CNCAN has an especially comprehensive response termination plan that considers all conditions, radiological, non-radiological, social, etc. needed to terminate a declared emergency. The plans incorporate all relevant Romanian government entities and local authorities and provide for rapid and coordinated public communication, with a focus on communications issued by public trust authorities for each area of public interest. CNCAN’s comprehensive emergency termination plan will allow the efficient return to normal operations while ensuring public safety in affected locations. Considerations for radiological, non-radiological, and social concerns are evaluated by CNCAN emergency committee and decided on by the National Committee for Emergency Situation.

### 10.5. SUMMARY

CNCAN is the national regulator for both normal and emergency conditions. CNCAN has developed a comprehensive emergency response program including training for CNCAN staff and staff from cooperating departments from the Romanian government and begun construction for a new CNCAN Emergency Operations Training and Information Centre. CNCAN should continue to follow through on the actions identified in the Strategy for Implementation of CNCAN procedure CP6. Important issues highlighted in this module include availability of adequate resources, training of staff, and timely completion of the new Emergency Operations Centre.

## **11. INTERFACE WITH NUCLEAR SECURITY**

### **11.1. LEGAL BASIS**

CNCAN is the national regulatory authority responsible for nuclear safety, nuclear security, and nuclear safeguards. In accordance with the Law no. 111/1996 on the safe deployment, regulation, licensing, and control of nuclear activities, CNCAN is the national authority responsible for the regulation, licensing, and control in the nuclear field, for all the activities and installations under the scope of the Law. CNCAN has all the necessary legal powers to issue mandatory regulations, to issue licenses for nuclear facilities and activities and to perform evaluations, inspections, and enforcement. CNCAN issues regulations on nuclear safety, radiological protection, physical protection, nuclear safeguards, cyber security for nuclear installations, radioactive waste management, transport of radioactive material, emergency planning and preparedness, etc. CNCAN regulates nuclear safety, security, and safeguards in an integrated manner. Although the current legal basis was sufficient for an effective regulatory oversight, in an effort for continuous improvement, CNCAN developed in 2019 a new regulation to further expand these requirements. Accordingly, NSN-26 - Regulation on the interfaces between nuclear safety, radiological safety, physical protection, protection against cyber threats, and the control of nuclear safeguards was issued.

The National Strategy for Nuclear Safety and Security is currently under revision. The fundamental objective of the Strategy is the continuous improvement of nuclear safety and security, for the protection of the workers, public and environment against the harmful effects of ionizing radiation. In the context of this strategy, nuclear safety, when referred to in a generic manner, includes radiological protection, while nuclear security includes physical protection, protection against cyber threats and safeguards.

### **11.2. REGULATORY OVERSIGHT ACTIVITIES**

The compliance assessments and inspections for the specific requirements on the nuclear safety and security interface are performed as part of the regulatory oversight process. This process includes regulatory reviews (for example, the review and assessment of technical and organizational changes that the licensees have the obligation to submit to CNCAN for approval prior to implementation) and inspection activities in accordance with CNCAN internal working instruction IL-CP4-1.59 - Inspection of interfaces between nuclear safety, radiological safety, physical protection, protection against cyber threats and control of safeguards. Some of the CNCAN regulatory oversight activities relevant for the interfaces between nuclear safety and security include the following:

- Verification of establishment and revision of vital areas based on the latest safety analyses and risk assessments;
- Review of temporary and permanent design modifications to ensure there is no adverse impact on either nuclear safety or nuclear security;
- Review of updated deterministic and probabilistic safety analyses to identify any scenarios that need to be further considered in the enhancement of the physical protection system;
- Inspections on site, in the nuclear installations, to check the operation of the nuclear safety related systems, the functioning of the physical protection systems and the provisions for nuclear security, including cyber security;
- Verification of personnel training and qualification to determine if they understand interface issues and are able to report potential problems;
- Participation in the emergency exercises, to observe and identify any practical aspects of interface between safety and security relevant for emergency exercises.

In accordance with the National Strategy for Nuclear Safety and Security, nuclear security and nuclear safety have a common objective, namely protection of people, society and the environment against exposure to ionizing radiation or radioactive contamination above the limits allowed by the legislation

in force. The integrated approach is justified from the point of view of the similarities between the two fields, as well as through the need to ensure that nuclear safety and security measures are implemented in a coherent manner and in coordination. The integrated approach to nuclear safety and security aims to control and maintain the specific risks associated with the installations, materials and activities in the nuclear field at the lowest reasonably possible level.

CNCAN established the requirements in regulation, NSN-21 - Fundamental nuclear safety requirements for nuclear installations, that the licensee shall identify and evaluate all the interfaces between the nuclear safety measures, the physical protection measures and the measures related to the control of nuclear safeguards. NSN-26 determines that the licensee shall establish the necessary measures, as part of the configuration management process, to ensure that any design modification, temporary or permanent, is assessed, before the implementation, in an integrated way. The licensee shall also ensure that any organizational change is assessed in an integrated manner before implementation, in terms of the impact on the processes, activities and resources in the areas of nuclear safety, radiation safety, physical protection, nuclear safeguards and protection against cyber threats.

In accordance with the existing legal and regulatory provisions and with the conditions in the licenses for nuclear installations, the licensees have to submit to CNCAN for review and approval, prior to implementation, all the technical and organizational modifications / changes that may have an impact on nuclear safety or nuclear security.

The CNCAN inspection plan provides for targeted inspection on the interface between safety and security.

The IRRS team noted, that CNCAN reviewed and assessed in a comprehensive manner the interfaces between nuclear safety, radiological safety, physical protection, protection against cyber threats, and the control of nuclear safeguards. Starting with the development of the legal basis to extend the regulatory oversight program to interfaces between safety and security oversight as a special field is considered as area of good performance.

### **11.3. INTERFACE AMONG AUTHORITIES**

The Law 111/1996 provides a list of authorities having responsibilities in controlling various aspects related to nuclear activities. CNCAN has also signed formal Memoranda of Understanding or protocols with each of these organizations, for ensuring the prevention of potential gaps and overlaps in the implementation of their respective duties and responsibilities and for a better collaboration within the organizations. For ensuring transparency of its activities and decision-making process, CNCAN routinely consults with all organisations that have an interest in its regulatory activities and also for ensuring the prompt response to emergency situations, 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. For the licensees there are specific requirements established in CNCAN regulation, NSN-26 regarding the integration of emergency response arrangements for both safety related and nuclear security related incidents. Emergency preparedness and response in Romania is organized in accordance with the Law 15/2005 for the approval of the Governmental Ordinance no. 21/2004, regarding the National System for the Management of Emergencies, with subsequent modifications and completions. The co-ordination of the intervention preparations in case of nuclear accident shall be ensured by the National Committee for Special Emergency Situations (CNSSU) within the Ministry of Internal Affairs (MAI), in co-operation with all specialized bodies of the central and local public administration. The intervention plan in case of nuclear accident for the site of nuclear installations shall be developed by the licensee, together with all the responsible central and local public authorities and specialized organizations. The on-site intervention plans shall be approved by CNCAN, which has also the responsibility to evaluate periodically and control the applicability of the plan.

The intervention plans are elaborated and implemented in accordance with the legislation and the regulatory requirements issued by CNCAN, which include specific provisions for nuclear safety,

security, and safeguards. CNCAN has also responsibility to evaluate periodically and control the applicability of the plan.

#### **11.4. SUMMARY**

Romania has put in place a legal framework for the interfaces of safety with nuclear security. CNCAN has an internal working instruction that provides guidance and expectations on how to address interfaces of safety and security. There are also measures in place ensuring that safety and security are effectively integrated, and do not compromise each other. The CNCAN inspection plan contain targeted inspections for safety security interface at an NPP. In this regard, the oversight of interfaces between safety and security at NPPs is an area of good performance.

## **12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS**

This section presents relevant feedback and main conclusions drawn by the IRRS team from the discussions and evaluations made during the mission, with the objective to identify ways to strengthen governmental, legal and regulatory frameworks for safety.

### **12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY**

Upon the outbreak of the COVID-19 pandemic, the Government issued a Decree regarding the establishment of the state of emergency on the territory of Romania, which stipulates that:

“Public authorities and institutions establish the necessary measures to ensure the optimal conduct of activities, while respecting the health discipline rules established by the authorities with competence in the field, including through the decisions of the National Committee for Special Emergency Situations, with a primary focus on ensuring prevention and reducing the risk of infection.”

Hence, CNCAN had the legal basis for maintaining its regulatory duties with additional measures.

### **12.2 REGULATORY FRAMEWORK**

In March 2020, CNCAN adopted a business continuity plan aiming to:

- maintain essential activities;
- ensure the basic needs for the continuation of activities;
- maintain the nuclear activities control;
- continuously monitor the hazards and risks allocated in the emergency situations field;
- continuously support the decision-making process in emergency situations;
- ensuring the decision-making process at the governmental level.
- ensuring prevention and reducing the risk of infection of CNCAN staff.

The following functions were continuously assured within CNCAN:

- CNCAN President's office;
- CNCAN's Committee for Emergency Situations;
- On duty officer;
- Emergency Response Team;
- Mobile intervention Team.

Work from home has been adopted for a limited number of staff, depending on the evolution of the sanitary crisis and the specific measures needed to be implemented in order to limit the number of infections, provided that the regulatory activities were not severely impaired. A team rotation in CNCAN offices was established in order not to mix staff and therefore limit the risk of contamination. Despite the remote working arrangements, most of the time CNCAN staff worked at the offices.

### **12.3 REGULATORY FUNCTIONS**

In 2020 CNCAN revised and published the regulation (initially issued in 2014): “NSN-07 (rev.1) - Nuclear safety requirements on the response to transients, accident management and on-site emergency preparedness and response for NPPs”. The modifications made concern more detailed requirements on the verification and validation of emergency operating procedures, specific requirements to ensure that all the necessary resources and measures for responding to transients, accidents and emergency situations are available and feasible also in case of epidemic / pandemic. Also, generic requirements have been introduced on the preparedness for epidemic / pandemic situations.

One of the measures that CNCAN implemented to manage the impact of COVID-19 pandemic on the regulatory work included the automatic extension of existing authorizations during the period of the pandemic. This resulted in a smaller number of applications to be processed by CNCAN. This effect was increased by the fact that also the licensees reduced the scope of operations, e.g., treatment and transport of radioactive waste, during the pandemic.

Interaction with authorized parties on matters related to licensing, some of regulatory inspections and audits was performed on-line. The resident site-inspectors at Cernavodă NPP site were continuously available during pandemic, but with limited inspection duties and interaction with NPP staff.

The frequency and duration of inspections in nuclear facilities and the physical participation in meetings were reduced. Instead on-line meetings were promoted.

All inspections in the areas of radioactive waste management and decommissioning were deferred. Instead, CNCAN requested weekly reports from the licensees.

When the restrictions due to the pandemic were lifted, CNCAN phased a period of intense regulatory control in terms of renewal of authorizations and inspections.

#### **12.4 EMERGENCY PREPAREDNESS AND RESPONSE**

CNCAN has activated its existing “Emergency Committee” composed of the Head of Division and the Head of the EPR unit. New instructions have been set up with regards e.g. to the need of establishing weekly continuity plans.

In general, during the pandemic period, the CNCAN activities and the availability of staff were organized in such a way that the emergency related functions were continuously assured (see Section 12.2).

For CNCAN’s activities as a regulator, emergency preparedness staff developed a plan detailing which CNCAN positions that were required to be staffed under all conditions and positions that could be suspended or performed from locations other than the office. For the positions that were required to be in the office, CNCAN staggered hours to decrease in person staff interactions. CNCAN established requirements for operating organizations to minimize the risk of insufficient staffing because of the pandemic. The operating organization for Cernavodă developed and implemented a scheme, consistent with guidance developed by CNCAN, of onsite work and residence to minimize the risk, as much as reasonable, of a pandemic outbreak among operating staff.

## APPENDIX I – LIST OF PARTICIPANTS

<b>INTERNATIONAL EXPERTS:</b>		
<b>ELDER</b> Peter	Canadian Nuclear Safety Commission (CNSC)	peter.elder@cnscccsn.gc.ca
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<b>OBSERVER</b>		
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<b>IAEA STAFF</b>		
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**LIAISON OFFICER**

**CIUREA-ERCAU** Cantemir

National Commission for Nuclear Activities  
Control (CNCAN)

**GROUP PHOTO**



## APPENDIX II – MISSION PROGRAMME

FIRST WEEK											
Time	SAT	SUN	MON	TUE	WED	THU	FRI	SAT	SUN	Time	
08:00-09:00	Arrival of IRRS Team members									08:00-09:00	
09:00-12:00			Entrance Meeting	Interviews	Interviews	Site Visits	Follow-up interviews	FU Interviews and report preparation DTC writes introductory parts	IRRS Team members draft the report. Finalization of recommendations, suggestions and good practices	IRRS Team rest day	09:00-12:00
12:00-13:00			Standing lunch	Standing lunch	Standing lunch	Standing lunch	Standing lunch	Standing lunch		12:00-13:00	
13:00-14:00		Initial Team Meeting • TL Opening remarks • IAEA Introduction • Self-introduction of all attendees • IRRS Process, IAEA • Schedule (TL, IAEA) • Presentations of the first impressions • Administrative arrangements: Liaison Officer, IAEA	Interviews (parallel discussions)	Interviews	TBD, Visit Ministry: TL DTL, TC, M1, 2, 3 IRRS Reviewers	Writing first draft of preliminary findings R/S/GP  Site Visit	Report preparation	Policy issues discussion		IRRS Team members draft the report. Finalization of recommendations, suggestions and good practices	13:00-14:00
14:00-15:00											14:00-15:00
15:00-16:00											15:00-16:00
16:00-17:00											16:00-17:00
17:00-18:00											17:00-18:00
18:00-20:00		Dinner	Dinner (D)	D	D	D	D	D		D	18:00-19:00
20:00-24:00				Report Writing (RW)	R W	NPP group departs to NPP site	RW	RW		RW	TL, DTL, TC edit the report

SECOND WEEK													
Time	MON	TUE	WED	THU	FRI	Time							
08:00-09:00		Finalization of the draft Report				08:00-09:00							
09:00-10:00	Individual discussions of report sections with counterparts	Report writing	Submission of the Draft Report to the Host	Hosts review the Report Draft	TL, DTL, TC finalize Executive Summary	09:00-10:00							
10:00-11:00							TL, DTL, TC draft Executive Summary	Hosts reviews the Report Draft	Written Host's comments are submitted to the Team	TL finalises exit presentation	Discussion with Host on findings	Exit Meeting	10:00-11:00
11:00-12:00													11:00-12:00
12:00-13:00	Standing lunch	Standing lunch			Standing Lunch	Lunch	12:00-13:00						
13:00-15:00	Draft Report cross-reading			IRRS Team members	Team meeting for finalisation of the Report	Submission of the Final Draft Report to the Hosts	13:00-15:00						
15:00-17:00								TL, DTL, TC prepare exit presentation	Host reviews the Report Draft	Host's comments	Briefing of the IAEA official	IRRS Team Members Departure	15:00-17:00
17:00-18:00	TL, DTL, TC and DTC finalise the report text				Finalisation of the press release		17:00-18:00						
18:00-20:00	Dinner	Dinner					18:00-20:00						
20:00-24:00	TL, DTL, TC and DTC finalise the report text	TL, DTL, TC and „editors“ finalise the report text					20:00-24:00						

### **APPENDIX III – SITE VISITS**

1. 31 October 2023 - DYOMEDICA CND
2. 1 November 2023 – SN Nuclearelectrica SA (SNN) - Cernavodă Nuclear Power Plant
3. 1 November 2023 - The Technologies for Nuclear Energy State Owned Company (RATEN) – Institute for Nuclear Research (ICN) Pitești
4. 1 November 2023 - “Horia Hulubei” National Institute for R&D in Physics and Nuclear Engineering (IFIN HH)
5. 1 November 2023 - MNT HEALTHCARE EUROPE– NEOLIFE BUCURESTI

## APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	<b>LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES</b>		
	Ms. Eszter RETFALVI	Ms. Camelia LIUTIEV	Mr. Cantemir CIUREA-ERCAU Ms. Mihaela ION
2.	<b>GLOBAL NUCLEAR SAFETY REGIME</b>		
	Ms. Eszter RETFALVI	Ms. Camelia LIUTIEV	Mr. Cantemir CIUREA-ERCAU Ms. Mihaela ION
3.	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>		
	Mr. Geronimo POLETTO ANTONACCI	Ms. Mihaela ION	Mr. Cantemir CIUREA-ERCAU Ms. Petruta GHINEA Mr. Florin TATAR
4.	<b>MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>		
	Mr. Benoit BERNARD	Ms. Maria OPRISESCU	Mr. Cantemir CIUREA-ERCAU
5.	<b>AUTHORIZATION</b>		
	Ms. Kimberly HAZELTON Mr. Shahid RASHID Mr. Eduardo FIGUEIRA DA SILVA Mr. Heidar HÜTTMANN Mr. Paolo ALVANO Ms. Helena JANZEKOVIC Ms. Siiri-Maria AALLOS-STÄHL Ms. Sivaramkrishnan MAHALAKSHMI Mr. Paul DALE	Ms. Madalina IONITA Ms. Iulia JIANU Ms. Daniela DOGARU Ms. Ruxandra POPESCU	Mr. Daniel BOGDAN Mr. Constantin SUMANARIU Mr. Octavian DIRTU Ms. Cornelia VIRTOPEANU Ms. Alexandra ALEXOIU Mr. Nicolae DUMITRESCU Ms. Atena NICULESCU Ms. Stefania PREDA Ms. Maria NAE Ms. Maura PETCU Ms. Alina DUMITRESU (INSP) Ms Henrieta BIRCA
6.	<b>REVIEW AND ASSESSMENT</b>		
	Ms. Kimberly HAZELTON Mr. Shahid RASHID Mr. Eduardo FIGUEIRA DA SILVA	Ms. Madalina IONITA Ms. Iulia JIANU Ms. Daniela DOGARU	Mr. Daniel BOGDAN Mr. Constantin SUMANARIU Mr. Octavian DIRTU

	<b>IRRS EXPERTS</b>	<b>Lead Counterpart</b>	<b>Support Staff</b>
	Mr. Heidar HÜTTMANN Mr. Paolo ALVANO Ms. Helena JANZEKOVIC Ms. Siiri-Maria AALLOS-STÄHL Ms. Sivaramakrishnan MAHALAKSHMI Mr. Paul DALE	Ms. Ruxandra POPESCU	Ms. Cornelia VIRTOPEANU Ms. Alexandra ALEXOIU Mr. Nicolae DUMITRESCU Ms. Stefania PREDA Ms. Maria NAE Ms. Alina DUMITRESU (INSP) Ms Henrieta BIRCA
<b>7.</b>	<b>INSPECTION</b>		
	Ms. Kimberly HAZELTON Mr. Shahid RASHID Mr. Eduardo FIGUEIRA DA SILVA Mr. Heidar HÜTTMANN Mr. Paolo ALVANO Ms. Helena JANZEKOVIC Ms. Siiri-Maria AALLOS-STÄHL Ms. Sivaramakrishnan MAHALAKSHMI Mr. Paul DALE	Ms. Madalina IONITA Ms. Daniela DOGARU Mr. Daniel BOGDAN Ms. Maura PETCU	Ms. Madalina COCA Mr. Sorin MARINESCU Ms. Cornelia VIRTOPEANU Ms. Alexandra ALEXOIU Mr. Dan MANEA Mr. Dorin BALAN Mr. Alexandru EREMIA Ms. Andreea MIHAILESCU Mr. Catalin BIRCA Mr. Gelu MOCANU
<b>8.</b>	<b>ENFORCEMENT</b>		
	Ms. Kimberly HAZELTON Mr. Shahid RASHID Mr. Eduardo FIGUEIRA DA SILVA Mr. Heidar HÜTTMANN Mr. Paolo ALVANO Ms. Helena JANZEKOVIC Ms. Siiri-Maria AALLOS-STÄHL Ms. Sivaramakrishnan MAHALAKSHMI Mr. Paul DALE	Ms. Madalina IONITA Ms. Daniela DOGARU Mr. Daniel BOGDAN Ms. Maura PETCU	Ms. Madalina COCA Mr. Sorin MARINESCU Ms. Cornelia VIRTOPEANU Ms. Alexandra ALEXOIU Mr. Dan MANEA Mr. Dorin BALAN Mr. Alexandru EREMIA Ms. Andreea MIHAILESCU Mr. Catalin BIRCA Mr. Gelu MOCANU
<b>9.</b>	<b>REGULATIONS AND GUIDES</b>		
	Ms. Oya ÖZDERE GÜLOL Ms. Kimberly HAZELTON Mr. Shahid RASHID Mr. Eduardo FIGUEIRA DA SILVA	Ms. Madalina IONITA	Ms. Ruxandra POPESCU Ms. Daniela DOGARU Ms. Cornelia VIRTOPEANU Ms. Alexandra ALEXOIU

	<b>IRRS EXPERTS</b>	<b>Lead Counterpart</b>	<b>Support Staff</b>
	Mr. Heidar HÜTTMANN Mr. Paolo ALVANO Ms. Helena JANZEKOVIC Ms. Siiri-Maria AALLOS-STÄHL Ms. Sivaramakrishnan MAHALAKSHMI Mr. Paul DALE		Ms. Mirela GODEANU Ms. Liliana CENUSA
10.	<b>EMERGENCY PREPAREDNESS AND RESPONSE</b>		
	Ms. Jane MARSHALL	Mr. Petre MIN	
11.	<b>INTERFACE WITH NUCLEAR SECURITY</b>		
	Ms. Eszter RETFALVI	Ms. Madalina IONITA	Ms. Camelia LIUTIEV Ms. Madalina COCA
12.	<b>REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS</b>		
	Mr. Benoit BERNARD	Ms. Mihaela ION	Mr. Cantemir CIUREA-ERCAU



**APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
<b>1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES</b>	<a href="#"><u>S1</u></a>	CNCAN should consider finalizing the review of National Strategy for Nuclear Safety and Security and submitting it to the Government for approval.
	<a href="#"><u>R1</u></a>	The Government should ensure that the roles and responsibilities of CNCAN and the Ministry of Health are clearly assigned to avoid conflicting requirements. The Government should ensure that the radiation protection framework is complete to ensure the protection of people and the environment.
	<a href="#"><u>R2</u></a>	The Government should ensure the timely implementation of the provisions of Law 234/2023 to allow the provision of sufficient human and financial resources to CNCAN.
	<a href="#"><u>R3</u></a>	The Government should make provisions for effective coordination of regulatory functions between CNCAN and the Ministry of Health.
	<a href="#"><u>S2</u></a>	The Government should consider ensuring that ANDR improves the mechanism to secure appropriate financial provisions for the predisposal management and disposal of institutional radioactive waste (including disused radioactive sources), and for the decommissioning of radiological facilities.
<b>2. THE GLOBAL SAFETY REGIME</b>	<a href="#"><u>S3</u></a>	CNCAN should consider establishing a strategy for international cooperation that includes priorities to allow for effective use of resources.
<b>3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	<a href="#"><u>R5</u></a>	CNCAN should develop and implement a comprehensive human resource plan setting the competences needed and the hiring priorities, according to a graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>R6</u>	CNCAN should further develop and implement a systematic training programme to maintain the necessary competences and skills of its staff, and a strategy for succession planning.
	<u>S4</u>	CNCAN should consider making provisions for adequate management of safety related records, including, but not limited to the National Dose Register for occupational exposure.
<b>4. MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>	<u>S5</u>	CNCAN should consider developing a policy defining the leadership for safety expectations and a training programme for leaders.
	<u>S6</u>	CNCAN should consider regularly evaluating its processes as a central input for continuous improvement.
	<u>S7</u>	CNCAN should consider designating only one owner per process to ensure a consolidated view on process performance and to enhance accountability.
	<u>S8</u>	CNCAN should consider further implementing a graded approach in the application of its management system related to core regulatory functions.
	<u>S9</u>	CNCAN should consider making use of all elements required for evaluation of its management system, including the inputs from the internal audit activities.
<b>5. AUTHORIZATION</b>	<u>R7</u>	CNCAN should ensure the timely development and implementation of ageing management programmes for all waste management facilities.
	<u>R8</u>	CNCAN should develop procedures to assess justification of any type of practice and to review the justification, as necessary.
	<u>R9</u>	CNCAN should require the applicant for authorization of radiation sources facilities and activities to submit a documented safety assessment, including, where appropriate, an independent review.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<a href="#"><u>R10</u></a>	CNCAN should develop guidance on the format and content of documents to be submitted by the applicant in support of an application for an authorization, including a complete scope Radiation Protection Programme with the appropriate level of detail.
	<a href="#"><u>R11</u></a>	The Ministry of Health should revise the legal requirements for consumer products to be consistent with GSR Part 3 requirements.
	<a href="#"><u>S10</u></a>	CNCAN should consider developing provisions assuring that short-term storage is not used for a long period and that sources are declared as disused in a timely manner.
	<a href="#"><u>R12</u></a>	The Ministry of Health should, in consultation with the relevant professional bodies, provide for evidence-based referral guidelines for use by the referring medical practitioners.
	<a href="#"><u>R13</u></a>	CNCAN and the Ministry of Health should establish dose constraints for the public exposure which consider all potential exposures and then require optimization.
	<a href="#"><u>R14</u></a>	The Ministry of Health and/or CNCAN should develop an independent monitoring programme and a framework to assess the dose to the public and demonstration of compliance with the dose limits.
<b>6. REVIEW AND ASSESSMENT</b>	<a href="#"><u>R15</u></a>	CNCAN should ensure that licensees carry out periodic safety reviews for research reactors, spent fuel storage, and fuel cycle facilities, in accordance with regulatory requirements, and provide the necessary guidance for the conduct of such reviews.
	<a href="#"><u>S11</u></a>	CNCAN should consider documenting the integrated safety assessments of operating facilities.
	<a href="#"><u>S12</u></a>	CNCAN should consider reviewing and assessing the procedures implemented by consignors for the proper classification of the radioactive material to be shipped, in accordance with SSR-6 (Rev. 1) requirements.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<a href="#"><u>R16</u></a>	The Ministry of Health should review the authorized parties' procedures for justification, periodic radiological reviews and audits, conformance to dose constraints and verify their implementation.
	<a href="#"><u>S13</u></a>	CNCAN and the Ministry of Health should consider reviewing the incident reporting system of authorized parties, so as to encourage reporting to CNCAN and/or the Ministry of Health, and to participate and use relevant international databases.
	<a href="#"><u>R17</u></a>	CNCAN and the Ministry of Health should enhance the reporting system of significant events in medical exposures, encourage sharing of such events and disseminate the lessons learnt to the interested parties.
	<a href="#"><u>R18</u></a>	CNCAN and the Ministry of Health should specify the retention period for records related to medical exposure.
	<a href="#"><u>R19</u></a>	CNCAN should verify that the calibration of dosimeters used for patient dosimetry is traceable to a standards dosimetry laboratory.
<b>7. INSPECTION</b>	<a href="#"><u>S14</u></a>	CNCAN should consider further improving their inspection programme to explicitly define the frequencies and risk-based criteria, and to explicitly confirm there is reasonable assurance of complete coverage of inspection areas.
	<a href="#"><u>R20</u></a>	CNCAN should implement its training and qualification programme with focus on recently hired inspectors and new technologies.
	<a href="#"><u>S15</u></a>	CNCAN should consider documenting and implementing a formal process to ensure the comprehensive, regular review of the regulatory independence and objectivity of resident inspectors at NPPs.
	<a href="#"><u>S16</u></a>	CNCAN should consider further developing detailed NPP inspection guidelines required for each applicable inspection area to ensure consistent and adequate coverage, based on a graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
<b>8. ENFORCEMENT</b>	<a href="#"><u>R21</u></a>	The Ministry of Health and CNCAN should fulfil their statutory duties for enforcement.
	<a href="#"><u>S17</u></a>	CNCAN should consider updating the procedure on enforcement to be used in the enforcement process so that all enforcement activities are taken into account including sealing of unauthorized radiation generators. CNCAN then should update the Inspector training to include all enforcement activities.
<b>9. REGULATIONS AND GUIDES</b>	<a href="#"><u>S18</u></a>	CNCAN should consider revising the procedure for developing or updating regulations and guides to include a formal decision process.
	<a href="#"><u>R22</u></a>	CNCAN should systematically develop a complete and comprehensive set of regulations and guides demonstrating a graded approach.
	<a href="#"><u>R23</u></a>	CNCAN should update its requirements for transport of radioactive material to be consistent with up to date requirements of international regulations.
	<a href="#"><u>S19</u></a>	CNCAN should consider developing and issuing guidelines for facilities performing testing of radioactive material transport packages.
	<a href="#"><u>R24</u></a>	CNCAN should have a regulatory requirement enabling investigation levels to be established.
	<a href="#"><u>S20</u></a>	The Ministry of Health and CNCAN should consider fully implementing and maintaining the action plan for radon, in cooperation with other institutions and authorities.
<b>10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS</b>	<a href="#"><u>R25</u></a>	CNCAN should ensure sufficient resources are available to conduct response training for qualification and periodical requalification for all staff with response duties.
	<a href="#"><u>S21</u></a>	CNCAN should consider completing the construction and implementing existing plans to equip the Emergency Operations Training and Information Centre and fully implement its emergency response strategy.

## APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

1. Law no. 111/1996 on the Safe Deployment, Regulation, Licensing and Control of Nuclear Activities, republished, with subsequent modifications and completions
2. Law 234/2023 on amending and supplementing of Law 111/1996, on the safe deployment, regulation, licensing and control of nuclear activities and for the amendment of Law No. 329/2009 on the reorganization of certain public authorities and institutions, rationalization of public expenditure, support for the environment business and compliance with framework agreements with the Commission and the International Monetary Fund
3. National Strategy on Nuclear Safety and Security, approved by Government Decision no. 600/2014
4. Organization and functioning of National Commission for Nuclear Activities Control approved by Government Decision no. 729/2018
5. The 1<sup>st</sup> revision of the roles and responsibilities of the CNCAN structures, approved by CNCAN Order no 177/2021
6. Code of ethics and professional conduct for CNCAN staff , approved by CNCAN Order no 210/2021
  
7. NSN-10 - Nuclear safety requirements on Periodic Safety Review for NPPs (2006);
8. NSN-14 (rev.1) – Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations (2014);
9. NSN-17 (rev. 1) - Nuclear safety requirements on ageing management for nuclear installations (2021);
10. NSN-18 – Regulation on the recording, reporting, analysis of events and on the use of operational experience for nuclear installations (2017);
11. NSN-21 (rev. 1) – Fundamental Nuclear Safety Regulations for Nuclear Installations (2020);
12. NSN-22 (rev. 1) – Regulation on the licensing of the nuclear installations (2023);
13. NSN-24 – Regulation on the deterministic nuclear safety analyses for nuclear installations (2019);
14. NSN-25 – Requirements on the decisional transparency in licensing process for nuclear facilities (2019);
15. NSN-26 – Regulation on interfaces between nuclear safety, radiological safety, physical protection, protection against cyber threats, and the control of nuclear safeguards (2019);
16. NMR-04 – Requirements on the licensing procedures for uranium and thorium mining and milling, processing of nuclear raw materials and production of nuclear fuel
17. Fundamental regulation on radioactive waste and spent nuclear fuel approved by CNCAN Order no 74/2022;
18. Disposal regulation approved by CNCAN Order no 11/2019;
19. Regulation on classification of radioactive waste approved by CNCAN Order no 156/2005;
20. Regulation on the clearance approved by CNCAN Order no 155/2022;
21. Regulations on safety requirements for decommissioning of nuclear and radiological installations approved by the CNCAN Order no. 102/2022;
22. Requirements on licensing of transport activities in the regulation approved by CNCAN Order no 221/2017;
23. Radiological safety norms regarding the implementation of practices for controlling the process parameters with ionizing radiation, approved by CNCAN Order no. 154/2023
24. GSN-05 – Guide on the format and content of the Final Safety Analysis Report for research reactors

25. GSN-06 – Guide on the format and content of the Final Safety Analysis Report for nuclear fuel fabrication plants
26. Regulation on the management of nuclear / radiologic emergency situations specific to nuclear or radiological hazards approved by the Joint Order of Ministry of Interior and CNCAN no. 113/2018 for the approval of the
27. Government Ordinance no 11/2003 on the safe management of radioactive waste and spent nuclear fuel
28. Government Decision no 1080/2007 on the establishment and management of financial resources for the safe management of radioactive waste and the decommissioning of nuclear and radiological facilities
29. Government Decision no 557/2016 on the management of risk types
30. Regulations on using the graded approach during the development of decommissioning plan approved by CNCAN Order no 103/2022
31. Radiation protection measures into adequate consideration and constituting the main body of the radiation protection program approved by CNCAN Order no. 104/2022
32. Regulations on the authorization procedures approved by CNCAN Order no 155/2018
33. Requirements on prevention, preparedness and response in case of emergency situations category IV and VI approved by CNCAN Order no 147/2018
34. Requirements on prevention, preparedness and response in case of emergency situations category I, II and III approved by CNCAN Order no 146/2018
  
35. Law 544/2001 on free public access to public information
36. Law 52/2003 on transparency of the decision-making process in public administration.
37. Law 153/2017 on general criteria for evaluating the individual professional performance of executive and management personnel
38. Law 554/2004 on administrative litigation that include specific provisions on how to apply to the High Court of Cassation and Justice

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

1. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> – Leadership and Management for Safety, General Safety Requirements Part 2, No GSR Part 2, IAEA, Vienna (2016)
4. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No GSR Part 3, IAEA, Vienna (2014).
5. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety assessment for facilities and activities, General Safety Requirements Part 4, No GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Predisposal Management of Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
7. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
8. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
9. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Site Evaluation for Nuclear Installations, Specific Safety Requirements No SSR-1, IAEA, Vienna (2003)
10. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Nuclear Power Plants: Design, Specific Safety Requirements No SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements No SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Research Reactors, Specific Safety Requirements No SSR-3, IAEA, Vienna (2016)
13. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements No SSR-4, IAEA, Vienna (2017)
14. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Disposal of Radioactive Waste, Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
15. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018)
16. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Classification of Radioactive Waste, General Safety Guide No GSG-1, IAEA, Vienna (2009)
17. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide No GSG-2, IAEA, Vienna 2011)
18. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide No GSG-6, IAEA, Vienna (2017)
19. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Occupational Radiation Protection, Safety Guide No GSG-7, IAEA, Vienna (2018)
20. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide No GSG-9, IAEA, Vienna (2018)
21. <b>INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide No GSG-12, IAEA, Vienna (2018)



<b>22. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Functions and Processes of the Regulatory Body for Safety, General Safety Guide No GSG-13, IAEA, Vienna (2018)
<b>23. INTERNATIONAL ATOMIC ENERGY AGENCY</b> Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide No GSG-16, IAEA, Vienna (2022)
<b>24. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide No GS-G-2.1, IAEA, Vienna (2007)
<b>25. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Modifications to Nuclear Power Plants, Safety Guide No SSG-71, IAEA, Vienna (2022)
<b>26. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide No NS-G-2.8, IAEA, Vienna (2002)
<b>27. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide No RS-G-1.8, IAEA, Vienna (2005)
<b>28. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide No RS-G-1.10, IAEA, Vienna (2008)
<b>29. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Borehole Disposal Facilities for Radioactive Waste, Safety Guide No SSG-1, IAEA, Vienna (2009)
<b>30. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides No SSG-2, IAEA, Vienna (2010)
<b>31. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-3, IAEA, Vienna (2010)
<b>32. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-4, IAEA, Vienna (2010)
<b>33. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide No SSG-5, IAEA, Vienna (2010)
<b>34. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide No SSG-6, IAEA, Vienna (2010)
<b>35. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide No SSG-7, IAEA, Vienna (2010)
<b>36. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Licensing Process for Nuclear Installations, Specific Safety Guide No SSG-12, IAEA, Vienna (2010)
<b>37. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide No SSG-14, IAEA, Vienna (2011)
<b>38. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Storage of Spent Nuclear Fuel, Safety Guide No SSG-15 (Rev. 1), IAEA, Vienna (2020)
<b>39. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Periodic Safety Review for Nuclear Power Plants, Safety Guide No SSG-25, IAEA, Vienna (2013)
<b>40. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26 (Rev. 1), IAEA, Vienna (2018)
<b>41. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Commissioning for Nuclear Power Plants, Safety Guide No SSG-28, IAEA, Vienna (2014)
<b>42. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide No SSG-40, IAEA, Vienna (2016)
<b>43. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide No SSG-41, IAEA, Vienna (2016)

<b>44. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide No SSG-45, IAEA, Vienna (2019)
<b>45. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide No SSG-46, IAEA, Vienna (2018)
<b>46. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide No SSG-47, IAEA, Vienna (2018)
<b>47. INTERNATIONAL ATOMIC ENERGY AGENCY</b> – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide No SSG-48, IAEA, Vienna (2018)
<b>48. INTERNATIONAL ATOMIC ENERGY AGENCY</b> –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide No SSG-49, IAEA, Vienna (2019)
<b>49. INTERNATIONAL ATOMIC ENERGY AGENCY</b> – Operating Experience Feedback for Nuclear Installations, Safety Guide No SSG-50, IAEA, Vienna (2018)
<b>50. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Accident Management Programmes for Nuclear Power Plants, Safety Guide No SSG-54, IAEA, Vienna (2019)
<b>51. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material, Safety Guide No SSG-65, IAEA, Vienna (2022)
<b>52. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
<b>53. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna (2008)
<b>54. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No. SSG-78, IAEA, Vienna (2023)
<b>55. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna (2014)
<b>56. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Storage of Radioactive Waste, Safety Guide No WS-G-6.1, IAEA, Vienna (2006)
<b>57. INTERNATIONAL ATOMIC ENERGY AGENCY</b> - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide NoWS-G-5.2, IAEA, Vienna (2009)

# APPENDIX VIII – ORGANIZATIONAL CHART

## CNCAN

