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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION

TO

ROMANIA

Bucharest, Romania

9-16 October 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA

Integrated
Regulatory
Review Service

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
FOLLOW-UP REPORT TO
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Mission date:	*9-16 October 2017*
Regulatory body:	*National Commission for Nuclear Activities Control (CNCAN)*
Location:	*Bucharest, Romania*
Organized by:	*IAEA*

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

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EXECUTIVE SUMMARY

At the request of the Government of Romania, an international team of senior safety experts met representatives of the National Commission for Nuclear Activities (CNCAN) from 9 to 16 October 2017 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The mission took place at CNCAN Headquarters in Bucharest. The purpose of the peer review was to review the Romanian regulatory framework for nuclear and radiation safety.

The IRRS team consisted of 8 senior regulatory experts from 7 IAEA Member States, 1 EU observer and 3 IAEA staff members.

The purpose of the IRRS follow-up mission was to review the measures undertaken to address all the recommendations and suggestions made during the 2011 IRRS mission and the lessons learned from the TEPCO Fukushima Daiichi accident. The review compared the Romanian regulatory framework for safety against IAEA safety standards as the international benchmark for safety

The IRRS review addressed the full scope of regulated facilities and activities by CNCAN. Special attention was given to regulatory implications to the Romanian framework for safety in relation to the TEPCO Fukushima Daiichi accident. 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. As part of the peer review process the IRRS team met the General Secretary of the Government of Romania.

CNCAN provided the IRRS team with advance reference material and documentation including the follow-up self-assessment report. The mission included interviews and discussions with CNCAN staff. It was noted that CNCAN made extensive preparation to ensure the effectiveness of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory and technical areas by all parties. In particular, the staff of CNCAN provided full assistance and demonstrated extensive openness and transparency to the expert review team.

The IRRS team noted that the recommendations and suggestions from the 2011 IRRS mission have been considered systematically. Significant progress has been made in many areas. Specifically, 30 out of 34 recommendations and all 18 suggestions were closed. During the follow-up mission, the IRRS team developed 8 new recommendations and 4 new suggestions.

The IRRS team made the following general observations in relation to the progress made by Romania since the 2011 IRRS mission.

The Romanian Government showed a strong commitment to nuclear safety and improvement of regulatory control of the nuclear sector including;

- Approval of the National Strategy on Nuclear Safety and Security (NSNSS);
- Advanced the revision of the national strategy for radioactive waste and nuclear spent fuel management;
- Significant progress in the amendment of the Law 111/1996 to implement the BSS Directive;
- Commitment to ensuring an appropriate level of human resources to CNCAN when the Law 111 has been amended;
- Plans to significantly increase the CNCAN operational budget starting at the 2018 state fiscal year.

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

- Initiated, led or coordinated many initiatives related to the NSNSS;
- Progressed the implementation of the graded approach throughout its programmes;
- Continued to develop regulations and guidance for authorizations, and internal procedures for review, assessment, and inspections;
- Advanced its capabilities to respond to nuclear and radiological emergencies;

- Adequately addressed the TEPCO Fukushima Daiichi response plan.

In spite of all the improvement work carried out by CNCAN, many tasks were not completed due to resource constraints. It is expected that the actions initiated by the Government to increase resources for CNCAN, will support the prompt completion of these tasks.

The IRRS team identified important areas including new findings warranting attention or in need of improvement. The IRRS team believes that consideration of these would enhance the overall performance of the regulatory system.

The Government of Romania should:

- Enable CNCAN to take measures to facilitate retention and attraction of experience staff;
- Expedite implementation of the NSNSS;
- Take measures to implement the regulation of the disposal of radioactive waste.

CNCAN should:

- Continue the establishment of an integrated management system and ensure its sustainable implementation;
- Develop and implement a common national program for the training of emergency response personnel belonging to public authorities.

The IRRS team findings are summarized in Appendices IV and V.

At the end of the mission an IAEA press release was issued.

I. INTRODUCTION

At the request of the Government of Romania, an international team of senior safety experts met representatives of CNCAN, the Romanian Regulatory Body, from 9 to 16 October 2017 to conduct an IRRS follow-up mission. The purpose of the peer review was to review the Romanian regulatory framework for nuclear and radiation safety. The follow-up mission was formally requested by the Government of Romanian in 22 January 2016. A preparatory meeting was conducted on 11-12 April 2017 at CNCAN Headquarters in Bucharest to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by CNCAN and selected safety aspects.

The IRRS review team consisted of 8 senior regulatory experts from 7 IAEA Member States, 1 observer and 3 IAEA staff members. The IRRS review team carried out the review in the areas covered by the main mission in 2011. The IRRS review addressed the full scope of regulated facilities and activities. Special attention was given to regulatory implications to the Romanian framework for safety in relation to the lessons learned from the TEPCO Fukushima Daiichi accident. The IRRS mission included discussions on policy issues regarding: Effective independence of the regulatory body.

CNCAN prepared a national follow-up report addressing the findings of the main mission. The results of Romania's follow-up report and supporting documentation were provided to the team as advance reference material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from CNCAN. The IRRS team met the General Secretary of the Government.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the Romanian radiation and nuclear safety regulatory framework and activities. The IRRS team reviewed the measures undertaken to address the recommendations and suggestions made during the 2011 IRRS mission and the lessons learned from the TEPCO Fukushima Daiichi accident. As for the 2011 initial mission, the follow-up IRRS review scope included all facilities and activities regulated by CNCAN.

The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Romania and other Member States from the knowledge gained and experiences shared between CNCAN and IRRS reviewers and through the evaluation of the effectiveness of the Romanian regulatory framework for nuclear and radiation safety and its good practices.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Romania, a preparatory meeting for the IRRS follow-up mission was conducted from 11 to 12 of April of 2017. The preparatory meeting was carried out by the appointed Team Leader Mr Miguel Santini, Deputy Team Leader Mr Jarlath Duffy and the IRRS IAEA team coordinators, Ms Olga Makarovska and Mr Jean-René Jubin.

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, Director of the Nuclear Fuel Cycle Division and Liaison Officer, and other senior managers and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Nuclear power plants;
- Research reactors;
- Fuel cycle facilities;
- Medical, industrial and research facilities and activities;
- Waste management facilities;
- Emergency preparedness and response;
- Interface between safety and security.

Comparison of existing regulatory arrangements was done against the IAEA safety standards, Code of Conduct on Safety and Security of Radioactive Sources and Code of Conduct on the Safety of Research Reactors. Mr Cantemir Ciurea-Ercau and Ms Madalina Tronea made presentations on the national context, the current status of CNCAN and the progress made by CNCAN since the original mission of 2011.

IAEA staff presented the IRRS principles, process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Romania in October 2017.

The proposed IRRS review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS review team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer assignment confirmation, lodging and transport arrangements were also addressed.

CNCAN provided the IAEA and the IRRS team with the advance reference material (ARM) for the review in August 2017. In preparation for the mission, the IAEA team members conducted a review of the ARM and provided their initial review comments to the IAEA Team Coordinator prior to the follow-up mission.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards, the Code of Conduct on the Safety of Research Reactors and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. A more complete list of IAEA publications used as the reference for this mission is given in Appendix VII.

C) CONDUCT OF THE REVIEW

An initial IRRS review team meeting was conducted on 09 October 2017, in Bucharest by the IRRS team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the follow-up IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

The Liaison Officer was present at the initial IRRS review team meeting on 09 October 2017, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers reported their first impressions based on the preliminary review of the ARM.

The IRRS entrance meeting was held on the 10th of October, with the participation of CNCAN senior management and staff. Opening remarks were made by Mr Rodin Traicu, CNCAN President, and Mr Miguel Santini, IRRS Team Leader, who presented the expectations of the mission and initial impressions on the ARM.

During the mission, a review was conducted for all review areas with the objective of reviewing the Government and CNCAN's response to the recommendations and suggestions identified during the original mission as well as to the lessons learned from the TEPCO Fukushima Daiichi accident. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

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

The IRRS exit meeting was held on the 16 of October 2017. Mr Rodin Traicu, CNCAN President, opened the meeting and delivered his opening remarks. Then the IRRS Team Leader, Mr Miguel Santini, presented the results of the follow-up mission highlighting the main findings. Closing remarks were made by IAEA Team Coordinator, Mr Jean-Rene Jubin.

IAEA and CNCAN press releases were issued after the exit meeting.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R1	**Recommendation:** The Government of Romania should issue the national policy and the strategy for safety, and implement them in accordance with a graded approach

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S1	**Suggestion:** The government should consider all fundamental safety objectives and principles, established in the IAEA Fundamental Safety Principles document, when finalizing the national policy and strategy.

Changes since the initial IRRS mission

Recommendation 1: The Romanian Government issued Decision No 600/2014, approving the National Strategy on Nuclear Safety and Security (NSNSS), which became effective on 30 July 2014.

The Strategy establishes a general framework for the nuclear sector and all governmental departments with a jurisdictional mandate on the nuclear sector. The scope of the Strategy encompasses all activities regulated by CNCAN. Article 12 establishes clear and strong strategic and enabling objectives. The Government committed to revise and update the Strategy every 5 years or as necessary.

The Strategy is supported by an Action Plan, with clear activities, tasks, milestones and implementation responsibilities distributed across Government organizations, including CNCAN, according to their mandate. The Action Plan was designed so that most of the actions should be either implemented on or before December 2017, or be declared as permanent, i.e., to be implemented on a continuous basis. CNCAN is required to consolidate and report the status of the implementation of the Strategy Action Plan on an annual basis every year.

Both the 2015 and 2016 status reports show gradually increasing delays in the completion of many deliverables in the Action Plan.

In both cases, the implementation delays were documented and attributed to the lack of resources of the contributors, particularly CNCAN. The resource constraints issues are being discussed under Recommendation 3 of this report. The 2017 status report is yet to be released.

The level of development of the Action Plan deliverables by CNCAN is late but quite advanced. However, the status of the deliverables by several other government institutions is considerably behind with respect to the commitments made in the Strategy.

Suggestion 1: Chapter III, Art.9, Guiding Principles of the National Strategy for Nuclear Safety and Security (NSNSS) describes the twelve Guiding Principles of the National Strategy. These principles mirror the IAEA Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1)

The NSNSS adds principle b) to commit the Government to use nuclear energy for peaceful purposes exclusively. Principle f) emphasizes the priority of nuclear safety and security over other factors.

Status of the finding in the initial mission

Recommendation 1 is closed as it is superseded by Recommendation RF1. The national policy was issued and approved but the implementation is behind schedule.

Suggestion 1 is closed as the mapping of the SF-1 principles is done in Article 9 of the NSNSS.

New findings from the follow-up mission

The Strategy document (NSNSS), once implemented and maintained, will be a powerful instrument to maintain the Government focus on Nuclear Safety and Security in the years to come.

Whereas CNCAN has made significant progress on the implementation of the strategy most deliverables in the Action Plan are lagging behind what was originally proposed. This is especially significant for the other contributors to the Strategy, some of whom are waiting for CNCAN coordination activities.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The implementation of the Strategy is signifficantly delayed with respect to the proposed dates in the Action Plan . The National Strategy has been approved but the implementation has been delayed.	
(1)	**BASIS: GSR Part 1, Requirement 1 (Rev 1)**, states that *"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".*
RF1	**Recommendation: The Romanian Government should expedite the implementation of the National Strategy on Nuclear Safety and Security, which came into force in July 2014, in accordance with a graded approach.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R2	**Recommendation: The Government should ensure that there is no duplication in responsibilities between CNCAN and other government organizations for establishing safety principles, criteria, and regulations for nuclear safety and radiological protection**

Changes since the initial IRRS mission

Recommendation 2: The NSNSS Art. 28 states that legislative initiatives to amend and / or supplement the normative acts of higher level should be undertaken. It also instructs the ministries to include the new requirements and opportunities arising from the strategy in their annual legislative plans.

In 2011 the IRRS team highlighted some potential overlapping of jurisdiction in the legislation between CNCAN and the Ministry of Health (MoH). CNCAN stated that there have been only isolated cases in which there was confusion over some regulatory responsibilities. They state that there are no actual duplications, but the interpretations have generated confusions.

The follow-up review did not find changes to the legislations to prevent potential conflicts and wrong interpretations.

However, the same review did not uncover any radiation safety regulations that show any conflicting safety requirements between CNCAN and MoH, as both authorities follow a procedure of consultation and concurrence of the draft regulations.

During this follow-up period a MoH regulation was issued in the area of medical exposure optimization while CNCAN covered the issuance of general and practice for specific radiation safety standards. CNCAN and MoH have the practice of issuing jointly approved regulations when it is reasonable to cover with one regulation areas of responsibilities of both authorities. Drafted

amendments to the Law 111/1996 propose additional responsibilities for MoH that do not duplicate or conflict with CNCAN responsibilities.

Status of the finding in the initial mission

Recommendation 2 is closed on the basis of progress made and confidence in the effective completion as any potential duplication is minimized through proactive cooperation between CNCAN and other relevant Governmental authorities with responsibilities for safety.

1.3. ESTABLISHMENT OF A REGULATORY BODY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R3	**<u>Recommendation</u>: The Government should provide CNCAN with the financial and human resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.**

Changes since the initial IRRS mission

Recommendation 3: CNCAN workforce numbers decreased in the period 2011 – 2015. CNCAN was authorized by the Government to start hiring in 2015, but in most cases the new hires was to complement attrition of experienced technical staff. In 2016-17, after the hiring of new staff the numbers are comparable to the 2011 level.

The lack of adequate human and financial resources in CNCAN since the 2009 drastic reduction of its staff complement and budget has caused the delay of multiple initiatives started in response of international peer review missions such as IRRS or EPREV and other initiatives. The lacks of human resources result on expertise gaps in many of the areas documented in the National System of Competencies in Nuclear Safety Model and Guidelines for CNCAN.

This was compounded by the demands caused by the priority work launched in response to the TEPCO Fukushima Daiichi accident. The following table is only a sample of the activities that had to be delayed, put on hold or suspended due to the lack of resources in CNCAN:

1. Implementation of the NSNSS (see R1, R7)
2. Implementation of the National Strategy for radioactive waste and spent nuclear fuel management (see R6)
3. Independent analysis of events, identification of lessons learned (see R8)
4. Completion of the IMS documentation and its implementation (see R11)
5. Secure sufficient number of technical specialists and necessary analytical tools to support nuclear safety assessment and emergency preparedness (see R18)
6. Updating of the legal and regulatory framework (see R28, R29, R30)
7. CNCAN implementation of the Governmental Decision 557/2016 (see RF7)
8. Need to maintain and improve CNCAN-ERC facility and equipment (see S13)
9. Develop and implement a common national program for the training of emergency response personnel (see R33)
10. Review licence applications including safety assessments for waste management facilities including disposal facilities (see R15)
11. Implement the standard review plan and review procedure for waste disposal facility (see S11)

The Government undertook the amendment of the Law 111/1996 to comply with the Council Directive 2013/59/EURATOM known as BSS Directive and Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations and its amendment, Directive 2014/87/EURATOM known as NS (Nuclear Safety) directive. Amongst the changes proposed to the law, Art 4 on resources was changed to define an explicit number (170) as the minimum number of staff to be assigned to CNCAN. Other changes, mandated by the BSS directive, add new legal responsibilities to CNCAN under the revised law, such as to coordinate the National Approach to Radon gas risks.

The law is at the stage where it should be tabled to parliament as soon as mid-October 2017 through an emergency ordinance which should expedite its sanction.

In addition to the potential increase of staff resources, the IRRS team members were informed by the Government that CNCAN should have a considerable increase on the annual budget for 2018. If these human and financial resources increases materialize, CNCAN could recover the level of staffing as the 2004 levels, which is more suitable for the mandate assigned to the organization through the legislation.

Status of the finding in the initial mission

Recommendation 3 remains open as the Government has not yet provided CNCAN with the financial and human resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.

New findings from the follow-up mission

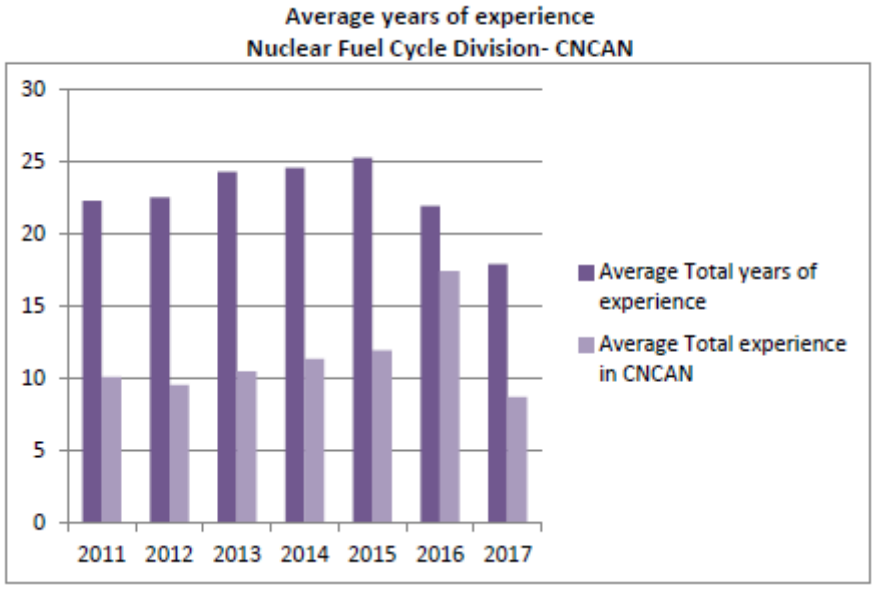
CNCAN had a significant turnover since 2011 due to attrition. Although the newly hired staff was selected based on their strong and adequate education background (e.g. nuclear engineering, physics), their work experience is very limited to non-existent.

The net loss of cumulative experience of the staff may impact the level of competency of CNCAN to carry out its oversight regulatory activity of the nuclear sector. The main cause of this reduction of average years of experience is due in part to attrition by retirement, and the difficulties of the Nuclear Fuel Cycle Division (NFCD) to refill the positions with experienced technical staff.

CNCAN has a sound training (including on-the job training) programme for new staff which may compensate partially the experience loss seen in the last few years.

As an example, a quick comparison of salary level between equally experienced staff in the Cernavoda utility or Nuclearelectrica (Cernavoda's shareholder) and CNCAN nuclear safety experts shows that the technical job salaries at CNCAN are significantly less competitive. In fact, the salary levels in the industry range from double, for recently graduated employees, to quadruple for an upper management position with more than fifteen years of experience.

This salary gap has caused the lack of interest of experienced staff to join CNCAN and the vacancies need to be filled with recently graduated professionals. As a consequence and as example, more than a third of the nuclear safety staff in the NFC Division has less than 5 years of experience, and 8 out of 10 of these, have less than 2 years of experience. The following graph illustrates how the average years of experience in the NFCD organization has experienced a significant reduction in the last 2 years, when the expected trend should have been the opposite.



There is a sustainability issue for CNCAN due to its limitations to retain its qualified workforce on nuclear safety assessment or to attract qualified staff through their staffing process.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CNCAN is challenged to attract and retain experienced technical staff.	
(1)	**BASIS: GSR Part 1 (Rev 1), Requirement** 3 states that "*The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities*".
(2)	**BASIS: GSR Part 1 (Rev 1), Requirement 18** states that "*The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities*".
RF2	**Recommendation: The Government should enable CNCAN to take measures to augment its retention or attraction capabilities of experienced safety experts, before the attrition is extended to the new staff that are presently acquiring the competence.**

1.4. INDEPENDENCE OF THE REGULATORY BODY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R4	**Recommendation: The Government should provide CNCAN with adequate financial and human resources, and authority in the management of its organizational structure.**

Changes since the initial IRRS mission

Recommendation 4: The issues of financial and human resources have been discussed under R3. The issue of the CNCAN's capability/authority to manage its own organization structure was not been discussed in the ARM.

Further probing revealed that, although changes to organizational structure must be approved by the General Secretary of the Government, these approvals are based on CNCAN's proposals on their own organization structure changes. This approval is a government driven process that has no inference on the design of the internal CNCAN structure itself.

The IRRS team observed that CNCAN needs to complete Action DSA 12.3 in the NSNSS Action Plan to establish principles and policies regarding its own Organization changes. This task is captured under follow-up Recommendation RF1 (in Chapter 1).

Status of the finding in the initial mission

Recommendation 4 is closed as it is no longer relevant given the current practice of approval of organizational changes and as Recommendation 3 remains open.

1.5. PRIME RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

1.6. COMPLIANCE AND REGULATIONS AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

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

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R5	**Recommendation: The Government should make provisions for effective coordination of regulatory functions between CNCAN and other authorities.**

Changes since the initial IRRS mission

Recommendation 5: The preparatory work for the development of the NSNSS addressed many of the deficiencies pointed out during the 2011 IRRS mission. Work is continuing through the implementation of the strategy, identifying the coordinating institution for each one of the tasks.

Article 29 of the NSNSS mandates all the responsible organizations to work in a coordinated fashion to implement the strategy:

- identifying opportunities for improvement in each organization responsible, and developing action plans and programs relating to implementation of this strategy;
- provide a legal framework for delegation, coordination, control and specific responsibilities for implementation of this strategy.

CNCAN has signed several ad-hoc agreements (Memoranda of Understanding) with other organizations with jurisdictional mandate on the nuclear sector. Specifically, on the area of transport, CNCAN has agreements on the transportation of hazardous goods with the Ministry of Transport (MT), the State Inspectorate for Control on Road (ISCTR) and the Romanian Road Authority (ARR).

A number of new additional agreements have also been signed in relation to emergency preparedness and response between CNCAN and other authorities and organizations.

- National Environmental Protection Agency to Strengthening cooperation between the Parties to increase the efficiency of emergency and emergency response for radiological emergencies (2012);
- Piteşti Nuclear Research Institute for support on the surveillance of the environment around nuclear installation and to support CNCAN during the emergency response (2014);
- National Administration for Meteorology for the provision of online weather prediction data for 36 hours to the CNCAN Emergency Operation Centre (2015).

The issues identified in 2011 on the jurisdictional overlapping between CNCAN and the Ministry of Health, in spite of existing agreements, are addressed under Recommendation 2.

It is clear that CNCAN has a very proactive approach to work collaboratively with all organizations having jurisdiction or activities on the nuclear sector.

Recommendation 5 is closed as the Government has made adequate provisions for effective coordination among the relevant governmental authorities.

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

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R6	**Recommendation: The Government should issue and implement a revised national strategy for radioactive waste and nuclear spent fuel management as part of the overall Nuclear Strategy for the Development of Nuclear Sector.**

Changes since the initial IRRS mission

Recommendation 6: The IRRS team found progress in the updating of National Strategy. ANDR (Nuclear Agency for Radioactive Waste) is responsible for developing the national strategy on the management of radioactive waste as Council Directive 2011/70/EURATOM requires. The National Strategy includes the National Programme for management of radioactive waste. The national strategy has been issued and now it shall follow SEA (Strategic Environment Assessment) procedure. The national strategy which includes the national programme for management of radioactive waste has been developed by a joint technical group of representatives of various organisation having duties in management of radioactive waste: Ministry of Economy, Ministry of Energy, CNCAN, Nuclearelectrica National Company, Cernavoda Nuclear Power Plant, National Institute for Physics and Nuclear Engineering-Horia Hulubei, Technologies for Nuclear Energy State Owned Company (RATEN) and others.

Status of the finding in the initial mission

Recommendation 6 is closed as it is superseded by Recommendation RF3.

New findings from the follow-up mission

A comprehensive draft for a national policy and strategy has been developed. However the necessary measures for its implementation have not been taken. The document states that the costs for disposal and decommissioning are covered by a designated fund. In practice this does not cover the regulatory costs and sufficient funding of the regulatory body is not secured. In the past a minor part of these costs was covered by license fees which no longer are available to the regulator. No regulations for covering the regulatory work from the dedicated funds or other sources exist. The system of financing regulatory work via fees does not seem to be flexible enough to cover all regulatory costs – especially for bigger projects like decommissioning projects or disposal facilities. The regulator should be enabled to be financed according the real work that is necessary.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: No measures are implemented as laid down in the national policy and strategy to cover the regulatory costs.	
(1)	**BASIS: GSR Part 1 (Rev 1), Requirement 10, paragraph 2.28**. states that *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of*

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility between successive authorized parties".
(2)	**BASIS: GSR Part 1 (Rev 1), Requirement 4**, paragraph 2.8. states that *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;"*
RF3	**Recommendation**: **The Government should take measures to implement the financing arrangements of regulatory costs for radioactive waste and nuclear spent fuel management as it is laid down in the Nuclear Strategy for the Development of Nuclear Sector.**

1.9. COMPETENCE FOR SAFETY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R7	**Recommendation:** The Government should establish a national policy and strategy to develop and implement the necessary training program for maintaining and enhancing the competence of a sufficient number of suitably qualified and experienced staff employed in the nuclear sector.

Changes since the initial IRRS mission

Recommendation 7: NSNSS strategic objectives related to national training programmes are geared to maintaining and improving the number and level of competence of the qualified staff in the nuclear sector. The training is supplemented by support of research and international cooperation to advance the knowledge on nuclear science and nuclear safety.

For example, in the area of nuclear installations and for all phases and stages of the facilities, the CNCAN developed the National System of Competencies in Nuclear Safety Model and guidelines applying the four quadrant SARCON methodology for each relevant combination of General Area of Competence / Nuclear Installation and Activity / Functions. The document covers from Competences related to CNCAN and licensees' processes and practices.

The competency development methodology for other government institutions with jurisdiction on the nuclear sector has not yet been issued by CNCAN for consultation with the stakeholders due to resources constraints. This delay, perhaps combined with internal constraints within the rest of the institutions, has caused their inability to deliver on this task, part of DSA 9.4 to 9.8 in the NSNSS action plan.

The strategy to develop and implement the necessary training programmes required under this is a subset of the NSNSS.

For nuclear installations and all activities authorized by CNCAN, training of workers is mandated by CNCAN through a suite of regulations to ensure that licensees' staff are adequately sufficient and competent. The IRRS team confirmed the adequacy of the suite regulations and requirements for this purpose.

Status of the finding in the initial mission

Recommendation 7 is closed as it is superseded by RF1 for the implementation of the National Strategy for Nuclear Safety and Security.

1.10. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the initial IRRS mission.

1.11. POLICY DISCUSSION "EFFECTIVE INDEPENDENCE OF THE REGULATORY BODY"

CNCAN and the IRRS team held a policy discussion on: Effective independence of the regulatory body as required by IAEA Safety Standard GSR Part 1 (rev.1), Requirement 4, which states that "The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."

As introduction to the discussion, CNCAN highlighted the following relevant background information concerning its independence:

CNCAN is separated and independent from organizations promoting the use of Nuclear Energy;

- CNCAN is independent from the Ministry and other public authorities and directly reports to the Prime Minister;
- The President of CNCAN organizes the structure of CNCAN which then is approved by the Government;
- CNCAN currently is financed through state budget. Before November 2009 it was financed by fees which after then became direct revenue to the state budget;
- CNCAN had at that time of the mission 65 technical positions;
- CNCAN has tried to increase its staff position without success so far;
- CNCAN may hire external consultants where necessary;
- CNCAN significantly benefits from external experts provided through international cooperation projects.

Several IRRS team members from various countries provided insights on their national provisions to establish and maintain an effective independent regulatory body. Though the details varied between countries, the Romanian structure was not considered to be unusual and was acknowledged as enabling an independent regulatory body.

The IRRS team noted that having clear legal framework that enable the regulatory body to have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities, including the ability to charge and receive appropriate fees, having access to relevant funds, or being able to refinance its actions, are very important aspects of effective independence.

Lastly, the IRRS team shared the view that having competent staff in sufficient numbers as well as having access to external experts are essential features of an effectively independent regulatory body. It was noted that if CNCAN could grow as an organization then there was a limited pool of nuclear specialist resources within Romania.

Training and procedural mechanisms will then be important to ensure that new staff become competent quickly and, from an outside perspective, are also seen to be independent of previous affiliations, minimizing any potential conflicts of interest.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

There were no findings in this area in the initial IRRS mission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R8	**Recommendation:** CNCAN should make arrangements for independent analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community.

Changes since the initial IRRS mission

Recommendation 8: In 2017, CNCAN issued a new regulation, NSN 18 "Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations". This regulation is comprehensive and is an adequate regulatory framework for providing CNCAN with appropriate inputs for being able to address the recommendation.

Regarding radiation sources, requirements are directly set in license conditions.

CNCAN also issued in September 2017 an internal procedure for the independent analysis and investigation of events occurred at nuclear installations.

In the nuclear fuel cycle division, new staff were trained in internal event analysis, and they were initially tasked with reviewing past events as complementary on-the-job training. The IRRS team finds the work carried out to date is satisfactory. However, these efforts could be compromised if this division remains understaffed.

The radiological installations and sources inspection division is capable of performing some independent analysis of events and can also acquire independent expertise from two national institutes. However, due to the lack of resources, activities related to events can be limited to reactive inspections and documentation review. The division records the results of these reviews internally, through the database system. Consequently, this division is less involved in the international community activities.

Status of the finding in the initial mission

Recommendation 8 is closed as it is superseded by recommendation RF4.

New findings from the follow-up mission

CNCAN just issued an internal procedure for making arrangements for independent analysis of events, identification of lessons learned and dissemination of related information. Junior staff is completing its specific training.

The IRRS team noted that CNCAN has started to set an organisation for analysing events to identify lessons. However, the IRRS team concluded that CNCAN has to reinforce its arrangements for ensuring effective identification of lessons and dissemination of feedback experience to other relevant authorities.

In addition, CNCNA has now to focus its efforts for a sustainable implementation of this competence.

Lastly, efforts provided by CNCAN could be jeopardized at short term by the lack of competent human resources in CNCAN technical divisions (see R3).

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CNCAN has to reinforce its arrangements for ensuring effective identification of lessons and dissemination of feedback experience to other relevant authorities. In addition, these new arrangements could be jeopardized at short term by the lack of competent human resources in CNCAN operation divisions.	
(1)	**BASIS: GSR-Part 1, Requirement 15** states that "*The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.*"
RF4	**Recommendation**: **CNCAN should expedite the effective and sustainable implementation of arrangements for analyzing events and identifying lessons in order to facilitate an effective exchange and use of operating and regulatory experience with the international community.**

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R9	**Recommendation:** CNCAN should implement measures for managing available resources in a manner commensurate with the radiation risks associated with facilities and activities.

Changes since the initial IRRS mission

Recommendation 9: The management system manual of CNCAN (MSM-CNCAN) issued in 2017 establishes general considerations to be used as a basis to deploy appropriate resource among regulatory activities according to a graded approach. The graded approach consideration has been completed by additional provisions in CNCAN core process procedures in place or under development. Most of them still need to be further detailed for ensuring practical implementation of graded approach, e.g., CP3 Review and Assessment.

Law 111/1996 article 24 on the safe deployment, regulation, authorisation and control of nuclear activities provides that the quality management system (QMS) of suppliers of products and services to be used in nuclear installations and classified as important for nuclear safety is subject to licence. Order No 236 issued in December 2014 provides provisions to remove suppliers of spare parts which have been already licensed once by CNCAN from the list of suppliers which have to be licensed periodically. On the other hand, the licensees of nuclear installation are required to oversee the QMS of this category of suppliers and to keep CNCAN informed. Considering the validity period of two years for a licence, CNCAN expected to observe a reduction of the number of licence in 2017.

The draft regulation for the transposition of the Council directive 2013/59/EURATOM clarifies activities and facilities which will be subject to either registration or licensing. When in force, the number of registration will increase leading to decrease the number of license application.

The revision of regulation NSR-03 – Norms for the Radiation Safety Authorization Procedure will introduce also simplification in licensing process considering in a better way a graded approach. Thus:

- Certain modifications previously submitted to licence application will be subject to notification henceforth, e.g., a source replacement in radiography;
- Similar practices at one site may be authorized by only one license, e.g., 3 accelerators in a teletherapy department will be authorized by one single license not three;

There is on-going discussion about the requalification permits for radiation protection officers for low-risk practice to be replaced by a notification when retraining is performed in the training centres certified by CNCAN.

The full licensing process for radiation facilities comprises five steps: siting, construction, commissioning, operation and decommissioning. Only five medical high-risk facilities are required to get licence at each licensing step. For the other lower-risk facilities licensing steps are combined and required to get between 1 to 3 licences during the lifetime of a facility. The maximum validity period for a licence or registration is 5 or 10 years with the exception of licences for the temporary storage of the disused sources and generators not in use which are delivered for 2 years.

However, currently the annual number of permits and authorisations still remains at the level of 4000-4500 for about 2000 licensees. The IRRS team was informed that the important number of licence renewals and applications to authorize modifications generates a significant work load for the CNCAN inspectors who perform systematically pre-licensing inspections.

Status of the finding in the initial mission

Recommendation 9 is open as provisions planned by CNCAN to further consider a graded approach have yet to be fully implemented.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

There were no findings in this area in the initial IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

There were no findings in this area in the initial IRRS mission.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the initial IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R10	**Recommendation:** CNCAN should identify and, if necessary, issue and implement a comprehensive set of procedures for the regulatory processes and provide applicants/licensees with the comprehensive set of guidance for the format and content of the documents to be submitted by the applicant in support of an application.

Changes since the initial IRRS mission

Recommendation 10: A series of regulations and regulatory guides have been published for specifying or providing guidance on the format and content of the documents to be submitted by an applicant or licensee in support of an application related to nuclear installations, transport, decommissioning, predisposal of radioactive waste, spent sealed radioactive sources and spent nuclear fuel, disposal of Radioactive Waste, and the use of ionizing radiation for medical and industrial purposes. Only few regulatory provisions needed to be finalized to complete the set of provisions on the format and content of application for activities and facilities regulated by CNCAN.

Specifically, for radiation facilities and activities, CNCAN published in 2016 on its website lists of the documents to be submitted by the applicant. These lists are supported by the regulation NSR-03 – *Norms for the Radiation Safety Authorization Procedure* on the content of the documents to be provided for a licence application.

As part of the documentation of its management system, CNCAN started the establishment of a comprehensive set of procedures to cover all its regulatory core functions. In that respect, the following processes were already documented:

- *CP2: Licensing;*
- *CP3: Review and Assessment;*
- *CP4: Inspection;*
- *CP6: Emergency Planning and Preparedness.*

The procedure for the process *CP5: Enforcement* was under preparation whereas the development of procedures to document *CP1: Regulations* process (to replace the current procedure P0-CP1-01 issued in 2012) and *CP7: Control of nuclear materials* process was planned by CNCAN although no

schedule was established. In the area of radiation safety, CNCAN had fourteen procedures for managing the authorization and inspection process related to the use of radiation sources.

Status of the finding in the initial mission

Recommendation 10 is closed on the basis of progress made and confidence in the effective completion of the set of internal procedures for the regulatory processes and as the regulatory provisions on content and format of licence applications have been established or will be established soon for all types of facilities and activities regulated by CNCAN.

3.7. SAFETY RELATED RECORDS

There were no findings in this area in the initial IRRS mission.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There were no findings in this area in the initial IRRS mission.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R11	**Recommendation:** CNCAN should develop and implement an Integrated Management System satisfying the requirements set out in GS-R-3.

Changes since the initial IRRS mission

Recommendation 11: The development of the new integrated management system of CNCAN was undertaken under an extra-budgetary project funded by Norway with the support of international experts. CNCAN developed a management system manual (MSM-CNCAN, rev. 5 2017). This manual was endorsed by the CNCAN Chairman two weeks before the IRRS Follow-up mission. The review of this document manual showed that most of GS-R-3 and GSR Part 2 requirements were systematically addressed for covering the following aspects:

1. Management Responsibility;
2. Resource Management;
3. Process Implementation;
4. Measurement, Assessment and Improvement.

The IRRS team noted that the development of a management system was initiated without establishing clear responsibilities, including the identification of the process owner and the management system manager, and without any action plan to ensure a sustainable development, maintenance and improvement. Over time CNCAN developed about 200 procedures and other documents for managing its activities and processes. The revision of these documents necessitates to be organized with clearly assigned responsibilities for delivering this important amount of work, and under the single accountability of the process owner. Further, the significant number of documents developed 'under' the management system appears to be segmented; this could lead to inconsistencies.

The IRRS team found that, contrary to IAEA Safety Requirement related to the integration of the management system which provides among others that regulatory requirements shall be reflected in the management system, the 'managerial' requirements applicable to all governmental organizations, therefore to CNCAN, established by the Governmental Order SGG/400/2015, are not covered by the management system manual. These requirements are subject to a dedicated commission composed by the CNCAN divisions and unit heads.

Still under development, the management system needs to be fully implemented, including the process MP7: Measurement, Assessment and Improvement. The IRRS team was informed that no senior management review had been conducted at the time of the mission even if such reviews are considered in the procedure for conducting management system reviews, approved by senior management in early October 2017.

Status of the finding in the initial mission

Recommendation 11 is open as CNCAN management system is partially established, is not fully integrated and it is at an early stage of implementation. CNCAN has neither established a work plan nor assigned clear responsibilities regarding the establishment and maintenance of the management system.

5. AUTHORIZATION

5.1. GENERAL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R12	**Recommendation:** CNCAN should revise its system for authorization in accordance with a graded approach

Changes since the initial IRRS mission

Recommendation 12: CNCAN has revised and updated the authorization and licensing process procedure to include provisions and principles for the application of graded approach. This procedure was developed under the auspices of the Norway Project, "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania", and is currently undergoing internal review in accordance with CNCAN's Management System and internal processes.

The application of the graded approach in authorization and licensing was demonstrated in three applications, as the bases of the recommendation have been identified in 2011 IRRS Report:

1. ***Radiation Sources Practices and Waste Management:*** since the initial IRRS mission, CNCAN has made progress in the transposition and implementation of the BSS Directive to introduce the concept of Notification as a system for authorization according to a graded approach. Notifications are to be applied for all practices involving very low risk and are exempted from either registration or licensing, as deemed adequate by CNCAN; or sources with very low risk are exempted from authorization and only require registration. In addition, some regulatory documents have been revised to explicitly specify the application of a graded approach; for instance, in regulation NDR-01, Art. 54, b) for *"Fundamental Norms on Safe Radioactive Waste Management and Spent Nuclear Fuel (2014)"*.
2. ***Quality Management System (QMS):*** Regulatory requirements for CNCAN's Quality Management System Norms (NMC-01 to NMC-13) are currently being applied in a graded approach for all nuclear facilities such as NPP, research reactor, fuel manufacturing facility and suppliers of products and services. As an example of a graded approach applied to QMS, regulatory requirements NMC-01 was revised, as per CNCAN order 236/2014 for the modification of NMC-01, to introduce the following modification:
    - Personnel having responsibility in developing, implementing and assessment of QMS of the suppliers must only demonstrate their qualification, as opposed to being fully licensed by CNCAN, as is the case for nuclear installations.
3. ***Operating/Management Personnel Licensing:*** The graded approach for licensing of personnel was implemented, in 2014, through harmonizing of CNCAN requirements with international practices. For example, the requirement for relicensing and examination NPP operators was extended from two (2) years to five (5) years.

Progress in the implementation of the graded approach in authorization of radiation sources is described in Section 3 (see R9).

Status of the finding in the initial mission

Recommendation 12 is closed on the basis of progress made and confidence in effective completion as Recommendation 9 is open and the application of the graded approach to authorization is undergoing internal reviews in accordance with CNCAN's Management System and internal processes.

5.2. NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

5.3. RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

5.4. FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

5.5. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R13	**Recommendation:** CNCAN should ensure that its implementation of authorization processes of radiological facilities and activities is consistently in accordance with the provision of the law, regulations and procedures.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R14	**Recommendation:** CNCAN should establish procedures for the import and export of radioactive sources in accordance with the provisions of the Guidance on the Import and Export of Radioactive Sources

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S2	**Suggestion:** CNCAN should consider establishing mechanisms for assessing all relevant information received from different sources to ensure its consistency.

Changes since the initial IRRS mission

Recommendation 13: Twelve new practice specific authorization procedures were issued in 2016 and the regulatory staff have been trained in their application in accordance with the management system. Expectations regarding the strict observance of the provisions of the Law, regulations and procedures have been reinforced. For each authorization an evaluation check-list is completed by the reviewer and this together with the draft license is checked and approved by the supervisor. The activities of this process have been audited to verify the consistency of the implementation of the authorization procedures. A new operational procedure PO-MP4.1-01 regarding the coordination of the authorization and inspection divisions (DAURI and DSURI) has been developed. This procedure includes guidance on the holding points of the authorization process that help to keep the reviewer within a specified timeframe. The management information system / database also supports the staff with the regulatory processes.

Recommendation 14: The law 111/1996 regulates the import, export and intracommunity transfer of radiation sources, radioactive waste and nuclear materials under safeguards control (art.7). The import and export of radioactive sources means import to and export from European Union. These are licensed by CNCAN. The intracommunity transfer means the movement of radioactive sources to/from Member States of European Union and this is based on the consent on the country of destination. This movement is based on Council Regulation 1493/93 on shipment of radioactive sources between Member States. The import and export to/from Romania of radioactive sources is licensed by CNCAN. At the time of the follow up mission it was noted that there were no sources imported from outside the European Union or exported out of the European Union.

The import, export and intracommunity transfer of radioactive waste and spent nuclear fuel is based on Council Directive 2007/117/EURATOM and consists of an application sent by consignee to the competent authority of origin country, submission of this application to transit and destination countries, acknowledgment of receipt of duly completed application, consent or refusal of transit and destination countries and finally authorisation by the country of origin. The import, export and intracommunity transfer of nuclear material under safeguards control is licenced by CNCAN.

There is a Government Ordnance 119/2010 Article 4 on import / export controls which is implemented by ANCEX (the national authority for import / export control for non-proliferation purposes (strategic products with dual use capability). ANCEX is a section of the Department of Foreign Affairs. A Protocol is in place regarding the exchange of information between CNCAN and ANCEX (Law No 35 of 2013). CNCAN sit on the Inter-Ministerial Council to discuss export licenses for dual use items. The procedures for import and export are part of the CNCAN licensing process. For the export of a nuclear material outside of the EU the licensee must have an export licence issued by CNCAN and ANCEX. The Team were informed that the practice of import and export of radioactive sources is in accordance with the provisions of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the associated Guidance.

Suggestion 2: The current database used by the Division in charge of the authorization of ionizing radiation sources ensures that all the relevant information (including matters relating to import/export controls) is available to relevant personnel, including the inspectors (headquarters and regional). The inspectors upload their inspection reports, letters and other relevant documentation to the system, making them available to those in charge of review and assessment and licensing. As part of import controls, CNCAN use the suppliers' reports to check the import of radioactive sources to authorized users. A 30 day deadline is used. If the dead line is not followed, an inspection is undertaken and enforcement actions are taken as appropriate. An example of low-risk radiation generator import follow-up case was seen, where the end user had not applied for a license. There were no cases where a radioactive source was supplied to the end user without the appropriate authorization or application for the authorization being in place in advance.

Status of the finding in the initial mission

Recommendation 13 is closed as CNCAN has ensured the implementation of authorization processes of radiological facilities and activities in accordance with the provision of the law, regulations and procedures.

Recommendation 14 is closed as the import / export of radioactive sources is part of the authorisation process (*CP2: Licensing*). There is also a system in place between CNCAN and ANCEX regarding the import / export controls for non-proliferation purposes (strategic products with dual use capability).

Suggestion 2 is closed as CNCAN has established and implemented mechanisms for assessing all relevant information about the import of radioactive sources received from suppliers and end-users to ensure its consistency.

5.6. WASTE FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R15	**Recommendation:** CNCAN should establish and implement authorization processes and procedures for all radioactive waste management and decommissioning activities.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R16	**Recommendation:** The regulator should change the requirements in a way that attention should be given to changes in the barrier design.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R17	**Recommendation:** CNCAN should develop regulations for dealing with legacy waste, abandoned radioactive material, source, sites or facilities.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S3	**Suggestion:** The regulatory authority should consider to eliminate or extend the time limit of 6 month for the licensing of disposal facilities.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S4	**Suggestion:** The regulatory body should consider taking steps to adjust the waste classification at Cernavoda NPP to be in line with the national waste classification system.

Changes since the initial IRRS mission

Recommendation 15: Since the IRRS mission in 2011, CNCAN has developed or is in progress of developing:

- The Regulation on the Safety Requirements for Predisposal Management of Radioactive Waste, Spent Sealed Radioactive Sources and Spent Nuclear Fuel. The regulation was approved and published in Official Bulletin of Romania. The regulation of safety of predisposal of radioactive waste, spent sealed radioactive sources and spent nuclear fuel has been approved by CNCAN order 148/2017 and published in Official Bulletin of Romania no.629/2017.
- The regulation details the authorisation practices for predisposal management of radioactive waste activities
- The regulation on the Safety Requirements for Disposal Management of Radioactive Waste. The regulation details the authorisation practices for disposal management of radioactive waste activities. The regulation is submitted to Member Stated for comments.
- The regulation on the Safety Requirements for Decommissioning of Nuclear and Radiological Facilities. The specific regulation on the safety of decommissioning of nuclear and radiological facilities was approved by order of CNCAN no 115/2017 and published in Official Bulletin of Romania no. 446/2017. The regulation details the authorisation practices for decommissioning.
- The regulation on the Safety Requirements for Natural Sources. This covers also abandoned sites and installations. The requirements will be also developing din the transposition of council Directive 2013/59/EURATOM (in progress).

Recommendation 16: CNCAN has developed a regulation on the safety requirements for disposal management of radioactive waste. The regulation considers this aspect.

Recommendation 17: CNCAN has developed a regulation on the safety requirements for existing exposure situation. This covers also abandoned sites and installations. Requirements on existing exposure situations will be addressed during the transposition of Council Directive 2013/59/EURATOM.

Suggestion 3: CNCAN has developed a regulation on the safety requirements for disposal management of radioactive waste. The regulation considers this aspect and eliminated the time period of 6 month needed for review and assessment.

Suggestion 4: The classification of radioactive waste has been modified in order to be in line with national radioactive waste classification. Currently, the reporting of radioactive waste quantities is done in terms of new classification. For operating purposes, Cernavoda NPP licensee continues to use the old classification of radioactive waste with respect to doses on surface of packages.

Status of the finding in the initial mission

Recommendation 15 remains open as the necessary steps for implementation cannot be taken.

Romania successfully developed authorization processes and procedures for all radioactive waste management and decommissioning activities. The *regulations for predisposal management of radioactive Waste, Spent Sealed Sources and Spent nuclear fuel* as well as Specific *Regulation on Safety requirements for Decommissioning of Nuclear and radiological Facilities* have been published in 2017. Regulations for disposal are developed and are expected to be approved and published soon.

However, the necessary fields of expertise cannot be covered. The experts in charge due to a lack of financial and human resources do not have the necessary tools (including the possibility to hire external services) and cannot cover all important fields of expertise in order to review licence applications including safety assessments. **The issue of human and financial resources is addressed in Recommendation 3.**

Recommendation 16 is closed on the basis of progress made and confidence in effective completion as the regulations on disposal are expected to be published soon.

Recommendation 17 is closed on the basis of progress made and confidence in effective completion as the regulations on disposal are expected to be published soon.

Suggestion 3 is closed as the new developed and approved regulations eliminated the time limit of 6 months for the licensing of disposal facilities.

Suggestion 4 is closed as the waste classification at Cernavoda NPP is in line with the national waste classification system.

6. REVIEW AND ASSESSMENT

6.1. GENERAL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R18	**Recommendation:** CNCAN should include in its request to the government that adequate financial resources are allocated and provided in CNCAN's budget in order to allow acquiring sufficient resources and necessary analytical tools supporting nuclear safety assessment and emergency preparedness, as well as for securing sufficient numbers of staff specialized in safety assessment.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R19	**Recommendation:** The regulatory body should formalize the graded approach for review and assessment.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R20	**Recommendation:** CNCAN should establish requirements for the operating organizations to carry out an independent verification of safety assessments, in accordance with the graded approach before it is used by the operating organization or submitted to the regulatory body.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S5	**Suggestion:** CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment for all nuclear facilities.

Changes since the initial IRRS mission

Recommendation 18: The National Strategy for Nuclear Safety and Security, issued in 2014, has included a provision for sufficient resources of qualified personnel to perform reviews and safety assessments. However, no significant progress in implementation has been made since the issuance of the National Strategy.

CNCAN performed an analysis of the necessary resources, mainly for activities of review and assessments and emergency preparedness. In the last two years, a number of new university graduates have been employed in this area of safety assessment, to recover the personnel that left the organization between 2011-2014. In addition, progress in acquiring necessary analytical tools supporting nuclear safety assessment and emergency preparedness has been made under the Norway Project "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania". New computer codes have been purchased or made available by the licensees; e.g., ANSYS-CFX and MAAP4-CANDU, and training on their use was organized by CNCAN.

Nonetheless, the acquisition of and accessibility to resources specialized in safety assessment and necessary analytical tools and necessary hardware to support nuclear safety assessment and

emergency preparedness remain insufficient due to the lack of financial support from the government – see also open recommendation R3.

Recommendation 19: The principle of the graded approach has been formalized in CNCAN's core process, PO-CP3-00 "*Review and Assessment*", issued in September 2017. For instance, guides that specify the content of the Final Safety Analysis Report (FSAR) in consideration of a graded approach, is developed for nuclear power plants, research reactors and nuclear fuel fabrication:

- Guide regarding the structure and the content of the Final Safety Analysis Report for Nuclear Power Plants (GSN04), published in the Official Gazette, Part I no. 752/ 08 October 2015.
- Guide regarding the structure and the content of the Final Safety Analysis Report for Research Reactors (GSN05), published in the Official Gazette, Part I no.561 / 14 July 2017.
- Guide regarding the structure and the content of the Final Safety Analysis Report for Nuclear Fuel Fabrication (GSN06), published in the Official Gazette, Part I no. 565/17 July 2017.

These aforementioned documents provide guidance on the breadth and depth of analyses commensurate with the risk associated with the nuclear facility.

Furthermore, the requirement for the application of graded approach was formalized in Norms on nuclear safety fundamentals for nuclear installations (*NSN-21: Fundamental Nuclear Safety Requirements for Nuclear Installations*), published in the Official Gazette, Part I, no. 441 / 14 June 2017, and reads as follows (text translated):

> *Art. 10. - (1) of NSN-21 "For any stage of the licensing of a nuclear installation, the licensee or applicant shall perform, document and submit to CNCAN an assessment of the nuclear safety. The scope and level of details of this assessment shall be commensurate with the potential magnitude and the nature of the risk associated with the nuclear installation and its site."*

Recommendation 20: CNCAN has incorporated in some of its existing regulatory documents requirements for the operating organizations to carry out an independent verification of safety assessments, in accordance with the graded approach, before it is used by the operating organization or submitted to the regulatory body.

This requirement has been explicitly stated in NSN-21 "*Fundamental nuclear safety requirements for nuclear installations*", Art. 11 (2), issued in June 2017, and reads as follows (text translated):

> *"Nuclear safety analyses and assessments performed by external organizations for the licensee or the applicant shall be independently verified in order to ensure that all applicable regulatory requirements and recommendations are fulfilled, in accordance with the CNCAN current norms, guides, standards and best practices recognized at the international level"*

For instance, requirements for independent verification of safety assessments of Operating Limits and Conditions (OLCs) for nuclear installations currently form part of the revised regulatory requirements in NSN-05 "*Nuclear Safety Norms regarding Operating Limits and Conditions for nuclear installations*" (Art. 16 (5), Art. 17 (4), issued in October 2015).

Furthermore, in September 2015 CNCAN issued GSN-02 "*Guidance regarding independent verification of the nuclear safety analyses and assessments performed for nuclear installations*", containing regulatory recommendations and clarifications of conditions necessary for performing independent verification of safety analyses and assessments.

Suggestion 5: Since the IRRS mission in 2011, CNCAN has developed new nuclear safety review procedures, guides and checklists applicable to several nuclear installations and safety related activities. This development of review procedures was partially supported by the Norway project: "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania", with financial support from the Government of Norway.

Examples of internal procedures and guides developed for regulatory reviews are as follows:

- Guide for the regulatory review of proposals for plant design modifications for nuclear installations;

- Guidelines for the regulatory review of Emergency Operating Procedures (EOPs) and Severe Accident Management Guides (SAMGs) for NPPs and Research Reactors;
- Guidelines for the regulatory review of Deterministic Safety Analysis;
- Guidelines for regulatory review of Severe Accident Analyses;
- Review Guide for the review of Seismic Margin Assessment, … etc.

Other review procedures include the areas of:

- Predisposal, disposal, decommissioning and NORM (Naturally Occurring Radioactive Material);
- Transport, shipment activities as well as for package design and testing of transport packages.

Plans to review and update some of existing review procedures are underway (e.g., review of Probabilistic Safety Assessment). While some of these review guides are pending translations and integration into CNCAN's Management System, the IRRS team observed a good progress to warrant closure of this suggestion.

Status of the finding in the initial mission

Recommendation 18 is closed as CNCAN has requested the Government to provide adequate financial resources to procure sufficient resources and necessary analytical tools and hardware in support of nuclear safety assessment and emergency preparedness, and as R3 remains open.

Recommendation 19 is closed on the basis of progress made and confidence in effective completion as CNCAN has formalized the application of graded approach in review and assessment of its regulatory framework. Recommendation 9 remains open to address the implementation.

Recommendation 20 is closed as explicit requirements have been incorporated in NSN-21 "*Fundamental nuclear safety requirements for nuclear installations"*, Art. 11(2), and supported with guidance GSN-02 *"Guidance regarding independent verification of the nuclear safety analyses and assessments performed for nuclear installations"*.

Suggestion 5 is closed on the basis of progress made and confidence in effective completion. CNCAN has developed several internal procedures and guidance for the review and assessment of nuclear facilities and some are awaiting integration into CNCAN's Management System.

6.2. NUCLEAR POWER PLANTS AND RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

6.3. FUEL CYCLE FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R21	**Recommendation:** CNCAN should perform review and assessment of all stages of lifetime of fuel cycle facilities including commissioning.

Changes since the initial IRRS mission

Recommendation 21: All new nuclear safety regulations have been issued to be applicable for all nuclear installations. A requirement has been included in the "Fundamental nuclear safety requirements for nuclear installations", which has been published in June 2017, clearly stating that safety analysis / evaluation is part of the licensing basis of a nuclear installation, in all stages of its lifetime (which coincide with the licensing phases) (Article 10 (1) and (5) of NSN-21).

New regulatory guides with the format and content of the safety analysis reports for research reactors (GSN-05) and nuclear fuel fabrication plants (GCN-06) have been published in July 2017. These are in addition to GSN-04 on the format and content of the safety analysis reports for NPP's.

The regulatory review and assessment process procedure has been developed to cover all nuclear installations and all stages of their lifetime. The procedure that describes the process for review and assessment, issued in September 2017 is applicable for all installations, facilities, sources, materials and activities that are licensed by CNCAN according to the requirements for licensing from the NSN-21 regulation.

Status of the finding in the initial mission

Recommendation 21 is closed as the regulatory review and assessment process procedure has been developed to cover all nuclear installations licensed according to the NSN-21 "Fundamental nuclear safety requirements for nuclear installations", for all stages of their lifetime.

6.4. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S6	**Suggestion:** CNCAN should consider improving its procedures for review and assessment by including provisions for periodic review and assessment and identifying situations that trigger review and assessment process.

Changes since the initial IRRS mission

Suggestion 6: In accordance with the CNCAN "Core Process CP3: Review and assessment" the review process starts with application. This application can be made by the applicant or the inspector may require the applicant to do this. If an inspector discovers modifications of the facility or practice with the radiation sources or other changes that need a new review and assessment - a request to the licensee for a license amendment is made in the inspection report. In accordance with the operational procedure PO-MP4.1-01 regarding any correlation between divisions that are in charge of authorization and inspection reports' copies are sent to the division that is in charge of authorization. Periodic review and assessment is undertaken when the license is renewed: once every 5 years for practices that are subject to licensing and once every 10 years for the practices that are subject to registration. Examples were provided when an inspector made a request to modify the license: 1) when the Radiation Protection Officer had changed; 2) the new radiation installation was put into operation. This triggered the review and assessment process.

Status of the finding in the initial mission

Suggestion 6 is closed as the review and assessment process for facilities and activities has been updated to include situations that trigger the process.

6.5. WASTE FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R22	**Recommendation:** CNCAN should improve its procedures for review and assessment, including provisions for periodic verifications, and whether radiation risks are as low as reasonably achievable.

Changes since the initial IRRS mission

Recommendation 22: The new process procedure for review and assessment addressed this recommendation. All specific technical review and assessment procedures will include such provisions.

In the field of predisposal and disposal of radioactive waste, CNCAN developed regulations that require the licensee to perform periodic safety verifications. For decommissioning of nuclear and radiological facilities, periodic verifications of safety of facility are also regulatory requires.

CNCAN developed regulatory review procedures for predisposal activities, code PO-CP3- DR-01 and for disposal activities, code PO-CP3- DR-02; as well as, for decommissioning, code PO-CP3- DEZ-01. In addition, CNCAN developed regulatory review procedures for natural sources, under code PO-CP3- DR-03.

Status of the finding in the initial mission

Recommendation 22 is closed as CNCAN has developed and approved a comprehensive set of procedures.

New findings from the follow-up mission

Following Recommendation 22 a comprehensive set of procedures has been developed. However in the periodic safety reviews to be carried out by the operators the necessary field of expertise cannot be covered by the regulatory body. It is recommended that the necessary resources are made available to the regulatory body.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory body does not have the resources to cover the necessary fields of expertise and to implement the Recommendation 22.	
(1)	**BASIS: GSR Part 1 (rev 1), Paragraph 4.43** states that "*The regulatory body shall assess the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.*"
RF5	**Recommendation: CNCAN should implement the procedures for review and assessment, including provisions for periodic verifications.**

7. INSPECTION

7.1. GENERAL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R23	**Recommendation:** CNCAN should establish a consistent and comprehensive inspector training programme and qualification process.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R24	**Recommendation:** CNCAN should establish a systematic and comprehensive inspection programme based on a graded safety approach and formally describe its processes in procedures for consistency of regulatory practices.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S7	**Suggestion:** CNCAN should consider including in its procedures a programme to monitor, share and follow-up inspection findings.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S8	**Suggestion:** CNCAN should consider the development of adequate internal procedures and guidance for the review and assessment and for inspection for all nuclear facilities.

Changes since the initial IRRS mission

Recommendation 23: With assistance from IAEA, CNSC and US NRC inspectors, in the framework of the "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania", CNCAN issued the process procedure "Training, qualification and certification of CNCAN inspectors" (PS1–01–00).

This procedure covers all the field of competence of CNCAN inspectors. In particular, it addresses the assessment of the qualification, competences and training needs for the inspectors-in-training, the development of individual training and qualification plans for the inspectors-in-training, the implementation of adequate training and the evaluation of the competences acquired by the inspectors-in-training. Furthermore, this procedure provides guidance for inspector certification.

The nuclear fuel cycle division implemented part of this procedure for the newcomer training. It identified the necessary technical trainings (provided by CNCAN, Romanian organizations or foreign organizations such as US NRC, CNSC or IAEA) and on-the-job activities. As currently set, trainings could have a 2 years/2 and half years duration. Training logs based on the procedure are set and used. The division already gathered some experience for adapting and optimize these trainings.

In 2013, there were training courses for inspectors of DSURI in the frame of AMEC NUCLEAR RO contract 23/16.05.2013 - Strengthening the CNCAN technical capabilities in developing practices for radiological protection – for all the practices inspected by the inspectors from DSURI. The training course also provided the possibility to develop the draft version of detailed procedures and guides. The inspectors were provided with training on CNCAN's newly developed authorization and inspection procedures on 12 practices regarding ionizing radiation and national and international

requirements. In 2015 January, more than 30 CNCAN inspectors were provided with training on CNCAN's newly developed "Training on Inspection and Enforcement Process" The training included presentations and practical exercises in group work for both general and practical aspects of every practice The duration of training was one week and the training materials that were developed during the Norway project are available for further CNCAN use. The IRRS team was informed that CNCAN plan to use the training materials in the initial training of new staff. The training, qualification and certification of CNCAN staff are supported by PS-01-00 procedure.

Refresher and continuing training program has not been implemented yet in a systematic and documented manner as required by the procedure. However, the IRRS team was informed about the CNCAN plans to address refresher training in the coming years. The priority was to train the newcomers.

Recommendation 24: With assistance from IAEA, CNSC and US NRC inspectors, in the framework of the "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania", CNCAN issued in 2015 the process procedure "PO-CP4-00 – Inspection process".

The principle of graded approach was considered for the definition of the number, the scope and the nature of the facilities/sources inspected. This procedure details inspections to be carried out by domains covered by the divisions in charge of inspection.

Nuclear fuel cycle division has started considering this procedure in the definition of the annual inspection programme. The IRRS team was informed that the division also plans to extend the inspection programme by up to 5 years for covering one recurrence cycle. Furthermore, the division started developing specific inspection procedures, instructions and checklists for all inspected areas for improving consistency in regulatory practices. Inspections programmes are built according to proposal from site inspectors for walk downs and system inspections, and are supplemented by the proposal from the division.

CNCAN also received first feedback from counterparts on the implementation of the procedure to be considered at short term in a new version of the procedure.

The radiological installation and sources inspection division has an operational procedure MC-PO-DSURI-01, which considers the graded approach for defining their frequency based on several criteria: safety significance, radiological risk, available resources. Inspection programmes are prepared by each inspector each year and submitted to division head.

All reports issued by divisions are based on a similar template and stored in the CNCAN centralised database. All inspectors have access to the database, including staff also involved in authorisation/review/licensing processes.

Suggestion 7: The new process procedure "PO-CP4-00 – Inspection process" has provisions for monitoring, sharing and following-up the inspection findings.

The centralised database is the main tool for ensuring these missions within CNCAN. Inspectors can store any document issued by CNCAN and track follow-up actions requested from the licensees in these documents. Any document sent by the licensee is also stored in the appropriate licensee folder and the inspector has to record the status of inspection findings. All inspectors have access to the database, as well as staff involved in authorisation/review/licensing processes.

However, due to current lack of resources, CNCAN has not yet used this useful information for sharing and cross-checking inspection findings and issuing periodic reviews on specific areas inspected.

Suggestion 8: The process procedure "PO-CP4-00 – Inspection process" has provisions for defining inspection checklists for all domains inspected by CNCAN.

The nuclear fuel cycle division has developed 15 new inspection checklists for safety related areas. Moreover, the IRRS team was informed about the development of new checklist procedures:

- CNCAN identified at least 15 new inspection checklists to be developed for Cernavoda NPP;
- For research reactors up to ten checklists are planned to be developed.

The radiological sources and facilities inspection division issued 12 operational procedures for inspection, including checklist and the IRRS team was informed about the need for developing procedures for veterinary applications and companies that provide service and maintenance for quality control purposes. Checklists are part the quality systems and will be updated according to the system dispositions.

The different documents developed for addressing recommendations 23 and 24 and suggestions 8 and 9 constitute a detailed and appropriate framework for the inspection. However, their effective and sustainable implementation could be compromised due to (1) an inadequate implementation of the management system (see R11) and (2) the lack of available competent persons within CNCAN (see R3).

Status of the finding in the initial mission

Recommendation 23 is closed as CNCAN succeeded in defining and issuing a comprehensive procedure for inspector training and qualification.

Recommendation 24 is closed as CNCAN established a systematic and comprehensive inspection programme based on a graded approach.

Suggestion 7 is closed on the basis of progress made and confidence in effective completion as CNCAN has developed an operational database for storing documents related to inspection activities. Due to the lack of resources, there has been no opportunity to analyse the inspection findings.

Suggestion 8 is closed on the basis of progress made and confidence in effective completion. CNCAN started drafting, issuing and using inspection checklists for nuclear facilities. CNCAN will continue to work on the development of new inspection checklists for covering all areas inspected by CNCAN for nuclear facilities.

7.2. NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

7.3. RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

7.4. FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

7.5. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R25	**Recommendation:** CNCAN should improve its inspection system as to ensure that the inspections are done in full compliance with the regulations and procedures and that subjective judgment is avoided.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S9	**Suggestion:** CNCAN should consider enhancing its procedures to support its regional inspectors undertaking their inspection duties to ensure proper preparation of initial inspections.

Changes since the initial IRRS mission

Recommendation 25: This recommendation is being addressed for all CNCAN inspectors through the training and qualification process and through the implementation of the new inspection procedures.

New inspection procedures and training

These include 14 new operational procedures issued by CNCAN that are used by inspectors: the operational procedure MC-PO-DSURI 01 regarding control of radiation sources, the operational procedure PO-MP4.1-01 regarding coordination of authorization and inspection activities, 12 practice specific authorization and inspection procedures PO-CP2.3-01 to PO-CP2.3-12. All HQ's and regional inspectors are trained in these procedures. Inspectors' reports are reviewed by the supervisors and any feedback is discussed with inspectors. An internal audit of inspection processes was undertaken in 2016.

Other improvements in the inspection system

The frequency of the inspections for radiological installations and for the use of ionizing radiation sources is stated in the operational procedure MC-PO-DSURI 01 considering the radiological risk of the practice and the safety requirements.

There are also inaugural inspections and inspections for the renewal of the authorizations in accordance with the operational procedure PO-MP4.1-01 regarding correlation between DAURI and DSURI activity. The frequency of the inspections is based on the graded approach: registration and authorization. The inspection frequency is decreased for low risk radiation sources (once per 2 years and for the lowest risk radiation sources – twice during the period of validity of the license) and is increased for high risk activities (twice per year). The inspectors' opinion is that these frequencies may be further reduced after the experience of the implementation is gained in practice. At present, the inspection program is designed based on the established frequencies. Inspectors informed the Team that it may happen that not all planned inspections comply with the established frequencies as the priority is given to the pre-licensing inspections and others connected to the authorization process (about 1000 inspections per year that consist 80% of the whole number of inspections). These inspections are requested by the authorization division and cannot be planned in a full scope as they are initiated by user applications.

The regional inspectors have access to CNCAN's database to consult the file for authorization for initial inspections. The inspectors have access to qualified experts who oversee the file for authorization. The applicants must have a registered copy of the file submitted to CNCAN.

The operational procedure MC-PO-DSURI 01 also describes how to apply sanctions: fines or criminal offences taking into account the graded approach.

Existing inspection procedures require the inspectors to consult the file for authorization for the preparation of initial pre-licensing inspection. To support regional inspectors in this task they are provided access to the CNCAN's radiation sources information system/data base (see text for the S9). Interviewed regional inspectors confirmed this information. A new suggestion SF2 has been developed in this area to support further improvement.

Suggestion 9: The new operational procedures issued by CNCAN that are used by inspectors, include: the operational procedure MC-PO-DSURI 01 regarding control of radiation sources, the operational procedure PO-MP4.1-01 regarding coordination of authorization and inspection activities, the 12 practice specific authorization and inspection procedures PO-CP2.3-01 to PO-CP2.3-12. In 2013 and 2014 each regional inspector had one month's training in using the draft procedures that were finally approved in 2016 in accordance with PS1-01. Inspectors have access to the database information, in particular with respect to: assessment of the application file submitted to the authorization division and other notifications, addresses, records, reports; CNCAN's authorizations issued for the applicant; limits and conditions from all CNCAN licensees; required applicant actions' deadlines; technical data about radiological installations, Radiation Protection Officer etc.; findings from previous inspections and outcomes. As the information system/database was not upgraded since 2010 applicant documents (as part of the licensing file) are still not available in the database and for

regional inspectors that are not Bucharest residents. Regional inspectors continue to use copies held by the radiation protection qualified expert and by the representatives of the applicant.

Status of the finding in the initial mission

Recommendation 25 is closed as CNCAN improved its inspection system for radiation sources and ensures that the inspections are undertaken in compliance with the procedures Core Process Document CP4 and subjective judgment is minimized.

Suggestion 9 is closed as new enhanced practice specific inspection procedures have been implemented relating to the industrial, medical and research facilities. The CNCAN Inspection Process is now clearly outlined in the Core Process Document CP4. Additionally, evaluations of the effectiveness of the inspection process are undertaken by independent audits and external reviews. A comprehensive training, qualification and certification system for CNCAN inspectors is now in place (PS1-01).

A new suggestion for upgrading the information system/database for radiation sources has been made.

New findings from the follow-up mission

The information system/database for radiation sources was not upgraded since 2010. Applicants' documents that are part of the licensing file are not available in the database for regional inspectors that are not Bucharest residents. CNCAN staff have gained significant experience in the operation of the database and collated feedback on how to improve the existing information system.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Applicants' documents that are part of the licensing file are not available in the database and for regional inspectors that are not Bucharest residents. The IRRS team was informed that the database also requires improvements following operational experience since 2010.	
(1)	**BASIS: Requirement 4.14 of GS-G-1.3 states that** *"Before an inspection is carried out, the inspection personnel should be thoroughly prepared for the task…"*
SF1	**Suggestion: CNCAN should consider upgrading the information system/database for radiation sources based on the feedback of its operation. In particular, CNCAN should consider including the applicants' documents that are part of the licensing file, extending the database with additional modules and having it maintained by a specialized service provider.**

7.6. WASTE FACILITIES

There were no findings in this area in the initial IRRS mission.

8. ENFORCEMENT

8.1. GENERAL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R26	**Recommendation:** CNCAN should develop and implement administrative procedures and guidelines to clarify its enforcement policy. The enforcement procedures should ensure that: (1) enforcement measures are consistently applied in accordance with a graded approach; (2) subjective decision making with respect to enforcement is avoided; (3) all non-compliances are properly addressed in the enforcement process; (4) all enforcement actions are clearly based on regulatory requirements.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R27	**Recommendation:** The government should ensure full provisions are provided for appeal of all decisions by CNCAN.

Changes since the initial IRRS mission

Recommendation 26: Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania, supported by the Norway Grants 2009-2014, includes tasks on regulation and guides. Two significant activities of the Project relate to the development and updating of the Romanian regulations in line with the EU and IAEA standards and guidelines and improving the training of CNCAN staff in relation to effective knowledge transfer methods that will ensure sustainability of organisational competence.

In the frame of Norway Grant project, a general procedure for the CNCAN Enforcement Process (PO-CP6-00) was developed and is planned for approval at the end of 2017. The procedure defines the application of enforcement measures based on regulatory requirements and the graded approach. The final assessment has 4 types of sanctions: very serious, serious, penalties, acceptable. The type of non-conformity is associated with a score and finally with the provisions from the law 111/1996 revised (art. 48). The procedure gives a common base for inspector decisions that is designed to avoid subjectivity. The procedure clearly defines the responsibility, the task, the output documents and its relation to other core processes. This procedure is comprehensive and well detailed. However, it could be considered as being complex to implement due to the level of detail and the current lack of resources of CNCAN. The issue of human and financial resources is addressed in Recommendation R3.

The Radiation Source Division's approved procedure for performing inspections (MC-PO-DSURI-01) was found by the IRRS team to be generally used by the inspectors in this division. This procedure also includes detailed checklists and formalized documents relating to enforcement actions. The connected internal guide for sanctions determines the scoring of non-conformities with graded approach. The IRRS team remarked that this procedure should be revised, once the general Enforcement Process procedure (PO-CP6-00) is approved.

The information related to inspector training is addressed in Chapter 7.

Recommendation 27: The Article 54 of Law 111/1996 stipulates the right to appeal to any natural or legal person in the case of abuse made by the Commission or another body provided under this Law within thirty days with the contentious business falling within the competence of the administrative

courts. The CNCAN legal advisor informed the IRRS team that appeal measures are within the general legal framework of Romania and stipulated in the law of administrative litigation 554/2004.

Furthermore, article 51 of Law 111/1996 refers to the Government Ordinance No. 2/2001 on the legal status of infringements. If contravention measures are imposed during inspections, an appeal to the court of justice can be initiated within 15 days from the date of communication or delivery. Point 7 of Article 16 of Government Ordinance No. 2/2001 stipulates that the inspector must inform the infringer about their appeal rights at the time of communication of the contravention. The IRRS team was informed that this is carried out and was shown templates for recording the finding of contraventions and the inclusion of appeal information.

Status of the finding in the initial mission

Recommendation 26 is closed on the basis of progress made and confidence in effective completion as CNCAN has developed the procedure and commenced associated training of staff but has yet to be approved.

Recommendation 27 is closed as full provisions for appeal of CNCAN enforcement decisions are available.

8.2. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

There were no findings in this area in the initial IRRS mission.

9. REGULATIONS AND GUIDES

9.1. GENERAL

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R28	**Recommendation:** CNCAN should identify, complete and issue those regulations for safety upon which regulatory judgements and actions are based.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R29	**Recommendation:** CNCAN should review and revise as necessary, its regulations and guides for completeness and consistency.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R30	**Recommendation:** CNCAN should ensure that all provisions related to authorization are consistent across the entire set of regulations and procedures.

Changes since the initial IRRS mission

As discussed in relation to Recommendation R26, two significant activities of the Norway Grant project were the development and updating of the Romanian regulations in line with the EU and IAEA standards and guidelines and improving the training of CNCAN staff in relation to effective knowledge transfer methods that will ensure sustainability of organisational competence.

The IRRS team concluded that these activities have enhanced CNCAN's regulatory capabilities in the areas of safety analysis, integrated management systems and knowledge management, inspections, safety and security of transport and transit of radioactive and nuclear materials, emergency preparedness and response, ionizing radiation sources control, radioactive waste and spent nuclear fuel management and safeguards control.

The Quality Management System of CNCAN includes a procedure for drafting regulations. The internal procedure to develop regulation and guides (PC-CP1-01) was issued in 2005 and the first revision was in 2012. Proposals for new and revised regulations are published in draft on the CNCAN website and are sent for external consultation to all interested organisations to receive feedback. The comments and suggestions received are analysed and discussed in stakeholder meetings. Subsequently, the final revision of a regulation is approved by the President of CNCAN and then submitted for publication in the Official Gazette of Romania. The process described in the procedure is in accordance with Law No. 24/2000 on the legislative technique norms for drawing up regulatory acts. CNCAN publishes the regulations on its website.

Several new regulations have been issued in the period 2011– 2017 and several regulations are being currently being finalized for publication.

The list provided below presents the regulations and regulatory guides that have already been published and have recently come into force:

1. NSN-05 - Nuclear safety requirements on the operational limits and conditions for nuclear installations (2015)
2. NSN-06 - Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin (2015)
3. NSN-07 - Nuclear Safety Requirements on the response to transients, accident management and on-site emergency preparedness and response for NPPs (2014)

4. 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 (revised and republished in 2014)
5. NSN-17 - Nuclear safety requirements on ageing management for nuclear installations (2016)
6. NSN-18 - Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations (2017)
7. NSN-20 - Regulation on the nuclear safety policy and independent nuclear safety oversight for nuclear installations (2015)
8. NSN-21 - Fundamental Nuclear Safety Requirements for Nuclear Installations (2017)
9. NSN-23 - Training, qualification and authorization of nuclear installations personnel with nuclear safety related jobs (2017)
10. GSN-01 - Guide on the industrial codes and standards for nuclear power plants (2015)
11. GSN-02 - Guide on the independent verification of nuclear safety analyses and evaluations (2015)
12. GSN-04 - Guide on the format and content of the Final Safety Analysis Report for nuclear power plants (2015)
13. GSN-05 - Guide on the format and content of the Final Safety Analysis Report for research reactors (2017)
14. GSN-06 - Guide on the format and content of the Final Safety Analysis Report for nuclear fuel fabrication plants (2017)
15. Modifications and completions to the Regulations on the authorization of the quality management systems applied to the construction, operation and decommissioning of nuclear installations (NMC-02) and to the Specific requirements for the quality management systems applied to procurement activities for nuclear installations (NMC-06) (2014)
16. NSC-01 – Regulation on the protection of nuclear installations against cyber threats (2014)
17. NUR – Requirements on the planning and preparedness of the license holders for the intervention in nuclear or radiological emergency (2014)
18. NDR-01 rev.1 - Regulation on the safe management of radioactive waste and spent nuclear fuel approved (revised and republished in 2014)
19. NDR-07 Regulation for safety requirement on decommissioning of nuclear and radiological facilities (2017)
20. NDR-08 Regulation for safety requirement on predisposal of radioactive waste, spent sealed sources and spent nuclear fuel (2017)
21. Authorization requirements on the practice of maintenance / service of radiological installations (2015)
22. Modifications and completions to the Regulations on individual dosimetry (2013)

According to the procedure for drafting regulations, CNCAN's annual plan for reviewing regulations and guides is the responsibility of the CNCAN coordinator and the annual plan is approved by the CNCAN President. The current annual plan is for the period 2016-2018 and is a strategic document and describes the systematic method of identifying gaps aspects to be considered. Regulations are issued and revised taking account of the regulatory experience, changes in international standards and the actual licensing needs. The annual plan contains 13 new regulations and guides to be developed and 6 to be revised. However, the IRRS team noticed that some elements of the plan are delayed due to the current lack of resources within CNCAN.

The IRRS team was informed that the procedure for drafting regulations is to be revised in order to amend the requirement to a long-term 5-year plan. Before 2014 no guides were issued. In the process of developing regulation and guides the graded approach, based on expert judgement, is used to determination the priority of work.

The Quality Management System of CNCAN includes guidance procedure for the Generation of Regulatory Guidance (PS-MP2.2-01), which was developed in 2012 and revised in 2017. The

procedure contains the responsibilities and process description for developing and reviewing internal procedures.

During the last two years few young experts of CNCAN staff have attended the IAEA training course on drafting regulations.

Recommendation 28: Regulations are issued and revised by CNCAN taking account of the regulatory experience, change in international standards and the actual licensing needs. Improvements to the regulatory framework are a continuous process. However, the limited resources available to CNCAN in recent years have had a negative impact on the process of updating this framework. The issue of human and financial resources is addressed in Recommendation R3.

Recommendation 29: Annual plans for issuing and revising regulations and guides are in place. The regulations and guides are issued and revised taking account of the regulatory experience, change in international standards and the actual licensing needs. Improvement of the regulatory framework requires continuous work. However, the limited resources available to CNCAN in recent years have had a negative impact on the process of updating this framework. The issue of human and financial resources is addressed in Recommendation R3.

Recommendation 30: This recommendation is being implemented gradually in the revision of the regulations and provisions related to authorization in order to ensure that they are consistent. However, the limited resources available to CNCAN in recent years have had a negative impact on the process of updating this framework. The issue of human and financial resources is addressed in Recommendation R3.

Status of the finding in the initial mission

Recommendation 28 is closed as new regulations have been issued.

Recommendation 29 is closed as regulations and guides have been reviewed and revised as necessary for completeness and consistency.

Recommendation 30 is closed as CNCAN has ensured that regulations and provisions related to authorization are consistent.

9.2. NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

9.3. RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

9.4. FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

9.5. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S10	**Suggestion:** CNCAN should consider amending the regulations to include the categorization of sources in accordance with the associated radiation risks.

Changes since the initial IRRS mission

Suggestion 10: This is being implemented in the process of transposing the revised BSS Directive. The Norms on High Activity Sealed Sources have been revised and are to be implemented in 2018. Annex 13 and 14 of the draft legislation clearly specify the requirements for high activity sealed

sources (Annex 13, Articles 182 – 198)) and Annex 14, Categorization of sources (1-5), in accordance with the IAEA categorization system.

Status of the finding in the initial mission

Suggestion 10 is closed based on progress made and confidence in effective completion as the transposition of the BSS Directive includes categorization of radioactive sources. The draft Regulation is currently in the process of being approved by the Government.

9.6. WASTE FACILITIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S11	**Suggestion:** The regulatory body should consider developing the standard review plan that describes the detailed criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility.

Changes since the initial IRRS mission

Suggestion 11: This aspect has been addressed as part of the NOR-ROM EBP started in 2014. A regulatory methodology addressing criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility has been developed. CNCAN developed the Regulation on Safety Requirements for Disposal Management of Radioactive Waste. The regulation is submitted to Member States for comments. Based on this regulation CNCAN developed regulatory review procedures for disposal activities, code PO-CP3-DR-02. The procedure includes aspects on final siting and design of disposal facilities.

Status of the finding in the initial mission

Suggestion 11 is closed as a comprehensive review plan has been developed.

New findings from the follow-up mission

A comprehensive standard review plan was developed. However, there are no means to implement it. The available staff have no means to cover the required areas of competence. The review of a license for a disposal quality requires covering a very wide range of expertise and extensive work. At the current stage the available staff would not be able to cover the needed areas of expertise and to implement that knowledge in the review process.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The available staff have no means to cover the required areas of competence to review a license for a disposal facility	
(1)	**BASIS: GSR Part 5, Requirement 11**, states that *"Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment."*
SF2	**Suggestion: CNCAN should consider implementing the standard review plan that describes the detailed criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility.**

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. BASIC RESPONSIBILITIES

10.1.1. BASIC RESPONSIBILITIES

There were no findings in this area in the initial IRRS mission.

10.1.2. ASSESSMENT OF THREATS

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R31	**Recommendation:** The government should finalize the radiation threat assessment at the national level for all postulated nuclear and radiological emergencies for all nuclear facilities and activities.

Changes since the initial IRRS mission

Recommendation 31: CNCAN's self-assessment describes specific changes since the initial mission and explains that a new Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) has passed through the public consultation process and is undergoing final approval process. The legal and regulatory framework in this Order, when applied during the licensing process to nuclear/radiological facilities and activities, adopts the five emergency preparedness threat categories in IAEA GS-R-2 (2002); which are unchanged in the updated version IAEA GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency (2015). Although the structure of the current draft Order is different, the IRRS team was provided with the latest draft that is available in English and assured that the threat categorisation requirements remain unchanged. CNCAN are developing a process for implementing the categorisation requirements during the licensing and review of licences processes and intend to amend their licensing database in order to record the outcome.

CNCAN has also drafted two regulations that complement the threat categorisation within the Order and contain detailed requirements for emergency planning. The first is a revision of regulation 69/18.04.2014 (Regulations and Requirements on Planning and Preparedness for Intervention to Nuclear or Radiological Emergencies), Specific Requirements for Licensees in EPC I, II, and III. The second is a new regulation, Emergency Preparedness and Response Requirements for Legal Activities in EPC IV. CNCAN provided the IRRS team with the latest drafts available in English. Both are under consultation until November 2017 and CNCAN intend to publish them in early 2018.

In addition to implementing the IAEA threat categories, this Order also updates Romania's emergency preparedness legislation in relation to the European Basic Safety Standards Directive (2013/59/EURATOM) (2013) and IAEA GSR Part 7 (2015). However, in order for the Order to be published, the revised overarching Law no. 111/1996 (on the safe deployment, regulation, licensing and control of nuclear activities) must first be published.

CNCAN expect the Law, Order and Regulation to be published by the end of 2017.

Status of the finding in the initial mission

Recommendation 31 is closed on the basis of progress made and confidence in the effective completion as publication of the Law, Order and Regulations and development of internal implementation processes and a recording mechanism are expected in late 2017/ early 2018.

10.1.3. ESTABLISHING EMERGENCY MANAGEMENT AND OPERATIONS

There were no findings in this area in the initial IRRS mission.

10.1.4. IDENTIFYING, NOTIFYING AND ACTIVATING

There were no findings in this area in the initial IRRS mission.

10.1.5. MITIGATORY ACTION

There were no findings in this area in the initial IRRS mission.

10.1.6. TAKING URGENT PROTECTIVE ACTION

There were no findings in this area in the initial IRRS mission.

10.1.7. PROTECTING EMERGENCY WORKERS

There were no findings in this area in the initial IRRS mission.

10.1.8. ASSESSING THE INITIAL PHASE

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R32	**Recommendation:** CNCAN should update ministerial order No.242/1993 and implement it in accordance with the requirements of GS-R-2.

Changes since the initial IRRS mission

Recommendation 32: CNCAN's self-assessment describes specific changes since the initial mission and explains that the latest regulatory mechanisms that clearly allocate the responsibilities for preparedness and response for a nuclear or radiological emergency are:

- The updated Governmental Decision 557/2016 regarding to management of 22 types of risks and defines the responsibilities for preparedness and response for a nuclear or radiological emergency requires to be with CNCAN.
- A new Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) – see Recommendation 31 – which is expected to be published by the end of 2017.

In addition to the ARM information, CNCAN identified to the IRRS team during the mission the document GO 21/2004 (The National System for the management of the Emergencies) describes the components of the national emergency response system which assigns responsibilities in all types of emergencies. It requires relevant Ministries to make recommendations on protective actions to identified decision makers. For local emergencies this is the Mayor, for county level it is the Prefect, and national level the Prime Minister.

In particular, as noted as a failing in the IRRS 2011 report, the new Order (Article 28 in the latest draft that is available in English) now requires the licensee to propose Operational Intervention Levels (OILs) for EPC I and II facilities, CNCAN to propose them for EPC IV and V situations, and all OILS to be approved by CNCAN or MoI (as appropriate).

To aid licensees identify and propose on-site OILs for CANDU reactors in their license applications/ 3 yearly reviews, CNCAN held two workshops in 2016 with IAEA experts and produced a report. CNCAN also developed a procedure in 2016 for specifying off-site OILs.

For category IV facilities, CNCAN specified action levels in the new regulation, Emergency Preparedness and Response Requirements for Legal Activities in EPC IV, which they intend to publish in early 2018.

Status of the finding in the initial mission

Recommendation 32 is closed on the basis of progress made and confidence in the effective completion as the publication of Governmental Decision 557/2016, document GO 21/2004 (The National System for the management of the Emergencies) and the Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) are expected in late 2017.

10.1.9. KEEPING THE PUBLIC INFORMED

There were no findings in this area in the initial IRRS mission.

10.1.10.TAKING LONG TERM PROTECTIVE ACTIONS

There were no findings in this area in the initial IRRS mission.

10.1.11.CONDUCTING RECOVERY OPERATIONS

There were no findings in this area in the initial IRRS mission.

10.1.12.ORGANIZATION

There were no findings in this area in the initial IRRS mission.

10.1.13.PLANS AND PROCEDURES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S12	**Suggestion:** CNCAN should consider the finalization of the implementation of common software platform for data and information exchange during emergencies (ELAN system) and maintain the system operational in CNCAN–ERC.

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S13	**Suggestion:** CNCAN should consider the completion of the development of the software application for data transmission from Cernavoda NPP to the CNCAN-ERC and maintain it in proper conditions to be used in exercises and real situations.

Changes since the initial IRRS mission

Suggestion 12: The initial IRRS report (2011) described software under development, with contributions by BMU and BfS Germany, for the management of all information received / sent inside the National System in the case of a radiation emergency - ELAN - E for Romania ("Electronic Situation Display for Radiation Emergencies"). The IRRS team noted that in the IRRS report 2011 that CNCAN's involvement in the development of this common software platform for data and information exchange during emergencies was identified as a Good Practice (GP1).

CNCAN's self-assessment states that the ELAN platform ("software dedicated to exchange information during the emergency") was installed onto the CNCAN-EOC computer server in 2010 and is used (password protected) by all national and local organisations (approximately 100) involved in emergency response. The software has been updated to version 2.5 in the intervening period and the IRRS team was informed that a new update is likely to be available shortly. CNCAN hold annual meeting with the software suppliers. CNCAN have a specific training module for their users and the common software platform was used in the national exercise Valahia 2016. The IRRS team observed

use of the ELAN software in the CNCAN-EOC during this mission and its application during exercise Valahia in 2016 was described by EOC management.

Suggestion 13: CNCAN's self-assessment states that the software application "EPTAR" for on-line transmission data from Cernavoda NPP to the CNCAN-ERC has been fully functional since the end of 2011.

The IRRS team observed use of the EPTAR software (version 3) in the CNCAN-EOC during this mission. Since 2011, the software and the data transmitted from the NPP have been significantly improved to contain the majority of parameters available to the operators in the NPP main control room. Back-up arrangements are also in place for transmission of this data to CNCAN in the event of network failure. The NPP are responsible for provision of the data and thereby ensure the corresponding software support.

Availability of this real-time information is particularly beneficial to CNCAN's Nuclear Safety Assessment Group and the Radiological Consequences Group during an emergency.

EOC management described how, according with the terms of the protocol, every year, the Parties shall discuss, review and revise EPTAR, in the light of the lessons learned for experience and emergency exercises.

Status of the finding in the initial mission

Suggestion 12 is closed as CNCAN has finalised, implemented and maintained the ELAN software in the CNCAN-ERC.

Suggestion 13 is closed as CNCAN has developed, maintained and is using the EPTAR software in the CNCAN-ERC.

New findings from the follow-up mission

During review of the CNCAN–ERC facilities in relation to the above suggestions and the level 1 lessons from the Valahia national emergency exercise in 2016 it became evident to the IRRS team that a quality assurance programme for the CNCAN-ERC is incomplete and should be part of the integrated management system of CNCAN.

It was noted by the IRRS team that the draft Common Order below requires corresponding QA programmes for Operator's Emergency Centres at NPPs.

- New Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) – to be published in late 2017:
    - Section 4. Quality management programme

      Art.105 The Regulatory Authority shall ensure that a quality management programme is established to ensure availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary for effective emergency response.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation*:* The quality management programme in place for the CNCAN-ERC is incomplete.	
(1)	**BASIS: IAEA GSR Part 7, Requirement 26** states that "*Quality management programme for emergency preparedness and response.* *The government shall ensure that a 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".*
RF6	**Recommendation: CNCAN should extend its management system to complete the quality management programme for the CNCAN-ERC to ensure the high degree**

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	of availability and reliability of all the supplies, equipment, communication systems and facilities, plans and procedures necessary to perform the assigned response functions.

10.1.14.LOGISTICAL SUPPORT AND FACILITIES

There were no findings in this area in the initial IRRS mission.

10.1.15.TRAINING, DRILLS AND EXERCISES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R33	**Recommendation:** CNCAN should develop and implement internal training and exercise program for the personnel with assigned responsibilities in the emergency organization.

Changes since the initial IRRS mission

Recommendation 33: Historically the training of emergency response staff at CNCAN has been repeatedly recommended since IRRT 2002, RaSSIA 2002, IRRS 2006, IRRS 2011 and the CNCAN improvement Plan 2014. The new "CNCAN Training Program for Emergency Response Team" (CNCAN Procedure PO-CP05.02-01, Rev 0, dated 27/2/2013) was implemented for all CNCAN staff nominated into the CNCAN emergency response team.

The training program was reviewed in 2016 during the Project "Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania", Sub-Project CNCAN 5 Emergency Preparedness and Response, by CNCAN, and experts from the Norwegian Radiation Protection Authority and IAEA. Improvements were identified and incorporated.

The review recognised that CNCAN is well supported by upper management in regards to the training of its Emergency Response Program, that the Emergency Response Training Program has a good base of working instructions and baseline training materials, and that it contains a comprehensive training and exercise schedule.

Improvements in the areas of identification of the training requirements for CNCAN Emergency Response staff, a training matrix outlining the baseline competence and training requirements for each emergency response position was developed and six training modules produced. During the mission the IRRS team examined the training programme, the knowledge requirement matrix, procedures for each position in the CNCAN ERC, and the content of the six modules (which have delivery times ranging from 30 minutes to 5 days and contain attendee evaluations in the forms of quizzes and written examinations). The IRRS team recognized that significant progress in this area has been made since the initial mission.

The revised training programme (CNCAN Procedure PO-CP05.02-01, Rev 1, 2017) has yet to be approved by the CNCAN president.

The IRRS team observed during the mission that the resources available in the CNCAN Emergency Planning Team are very limited and unlikely to be able to support the delivery of the revised programme. For example, only the Acting Head of Section for Radiation Emergencies is currently delivering the six training modules and the spreading of training delivery responsibilities around the whole organisation would aid resourcing the program, improve and vary delivery of it, and spread and improve learning form it.

Status of the finding in the initial mission

Recommendation 33 is closed as the plan was developed and implemented in 2013.

New findings from the follow-up mission

The revised CNCAN Training Program for Emergency Response Team (2017) has not yet received CNCAN presidential approval and does not have an associated resourcing and delivery plan for its implementation. The issue of human and financial resources is addressed in Recommendation 3.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The revised CNCAN Training Program for internal training of personnel with assigned responsibilities in the emergency organization has not been officially approved and does not have an associated resourcing and delivery plan for its implementation.	
(1)	**BASIS: GSR Part 7, Requirement 25** states that "*The government shall ensure that personnel relevant for emergency response shall take part in regular training, drills and exercises to ensure that they are able to perform their assigned response functions effectively in a nuclear or radiological emergency".* *"6.28. The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training".*
RF7	**Recommendation: CNCAN should adopt the revised (2017) training plan and produce a plan for delivering its components in an effective and sustainable manner.**

10.1.16.QUALITY ASSURANCE PROGRAMME

There were no findings in this area in the initial IRRS mission.

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

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S14	**Suggestion:** CNCAN should consider finalizing the regulation on radiological safety of working activities involving enhanced natural radioactive material.

Changes since the initial IRRS mission

Suggestion 14: CNCAN has developed the Regulation on Safety Requirements for Natural Sources which covers working activities involving enhanced natural radioactive materials. The industrial sectors involving enhanced natural radioactive materials are listed in the regulation. The regulation contains criteria for practices, criteria for licensing of working activities involving enhanced natural radioactive materials. The requirements for development of a dose assessment or measures for activity concentration are included in the regulation.

The Regulation is in the final stage of review in order to implement the comments received from the consolation with the EU Member States and will be soon published in the Official Gazette.

Regarding emergency planning requirements, these are not specified in the Regulation but are included in the new Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) – see Recommendation 31 – expected to be published by the end of 2017. This identifies an emergency preparedness Category VI, that includes practices involving radioactive materials (including natural materials), that meet the criteria relating to very low activity concentration materials. In the new Regulation (Emergency Preparedness and Response Requirements for Legal Activities in EPC IV, which they intend to publish in early 2018, article 4(2) and (3)) emergency response plans or procedures are required for materials above and below this criteria respectively.

Status of the finding in the initial mission

Suggestion 14 is closed on the basis of progress made and confidence in the effective completion as the publication of the Order and Regulations is expected in late 2017/ early 2018.

New findings from the follow-up mission

The IRRS team noted during the mission that, with the exception of significant interaction with the Norwegian Radiation Protection Authority (NRPA) and the IAEA (2010-14) in regional excellence project, CNCAN do not significantly participate in international cooperation on emergency preparedness for nuclear and radiological accidents in order to exchange experiences and improve national capabilities with a focus on cooperation with neighbouring and European countries.

This improvement opportunity is identified in the following National Security and Safety Strategy but has not generally been addressed.

- Government of Romania - Decision no. 600/2014 of 23 July 2014

  Decision no. 600/2014 on the approval of the National Security and Safety Strategy
  CNCAN has responsibility for…..*19(f) DSA 6.6: Enhancing participation in technical assistance projects and international cooperation on emergency response preparedness radiological or nuclear accident, to exchange experiences and improve national capabilities with a focus on cooperation with neighbouring countries;*

The IRRS team also noted that the IRRS Bulgaria follow-up mission in 2013 recommended reviewed the previous recommendation R12: The Government should take steps for the harmonization of emergency preparedness and response arrangements with Romania in order to implement decisions on urgent protective actions across its national borders. The IRRS team at that time closed the recommendation on the basis of progress and confidence in completion as a formal agreement between BNRA and CNCAN provides a crucial step for harmonization between both countries. The IRRS team was informed that although this agreement was put in place, and updated in 2016, little progress has been made towards its useful implementation.

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation*:* CNCAN does not efficiently maximise benefits from, and opportunities for, the international cooperation on emergency preparedness for nuclear and radiological accidents in order to exchange experiences and improve national capabilities.	
(1)	**BASIS: GSR Part 7, Requirement 22** on the Coordination of emergency preparedness and response states that: *"The government shall ensure that arrangements are in place for the coordination of preparedness and response for a nuclear or radiological emergency between the operating organization and authorities at the local, regional and national levels, and, where appropriate, at the international level".*
SF3	**Suggestion: CNCAN should consider enhancing participation in international cooperation on emergency preparedness for nuclear and radiological accidents in**

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	order to exchange experiences and improve national capabilities with a focus on cooperation with neighbouring and European countries.

The updated Governmental Decision 557/2016 regarding the management of 22 types of risks defines the responsibilities for preparedness and response for a nuclear or radiological emergency to be with CNCAN. CNCAN had previously identified the improvement opportunity in the National Security and Safety Strategy (Decision no. 600/2014, Article 19(h) DSA 6.8) to *develop and implement a common national program for training of personnel management and intervention in case of nuclear accident or radiological emergency by category for all authorities and institutions SNMSU components.* However, no progress has been made to date.

The IRRS team also identified requirements for CNCAN to develop and implement a common national program for the training of emergency response personnel belonging to public authorities in the new Common Order of CNCAN and Ministry of Interior (General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency) – to be published in late 2017:

- *Art.30 (1) In addition to the duties mentioned in chapter (2), as Regulatory Authority, the CNCAN has the following specific responsibilities as it pertain to emergency preparedness and response:*
    - *k) to ensure the on-going training, testing and exercising of emergency response arrangements and capabilities at all levels of response.*
- *Article 34. The Public Authority shall:*
    - *d) lead and participate in drills, exercises, and training to verify that the response capabilities are operational, relevant, inter-operable and up-to-date;*

Follow-Up Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CNCAN has yet to develop a common national program for the training of emergency response personnel belonging to public authorities envisaged by the national Security and Safety Strategy.	
(1)	**BASIS: IAEA GSR Part 7, Requirement 2** states that "*The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned.* *4.10. The government shall establish a national coordinating mechanism to be functional at the preparedness stage, consistent with its emergency management system, with the following functions:* *(h) To ensure that appropriate and coordinated programmes of training and exercises are in place and implemented, and that training and exercises are systematically evaluated".*
RF8	**Recommendation: CNCAN should develop and implement a common national program for the training of emergency response personnel belonging to public authorities.**

11. TRANSPORT OF RADIOACTIVE MATERIAL

11.1. INTRODUCTION AND BACKGROUND

There were no findings in this area in the initial IRRS mission.

11.2. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES IN TRANSPORT

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
R34	**Recommendation:** CNCAN should enhance and rejuvenate co-operation with the Ministry of Transport and Infrastructure at the highest level.

Changes since the initial IRRS mission

Recommendation 34: CNCAN has signed cooperation agreements with two organisations with responsibilities in transport:

- The State Inspectorate for Control of Road Transport (ISCTR) signed 2015
- The Romanian Road Authority (ARR) updated in September 2016.

These organisations are part of the Ministry of Transport and Infrastructure. The development of an agreement with Civil Aeronautical Authority is underway.

The cooperation agreement with ISCTR stipulates support for each other in inspection activities, relating to transport of radioactive materials. The exchange of information and participation in regular meetings are also provided.

The cooperation agreement with ARR provides support of each other in regulation and licensing with respect to transport of radioactive materials. The exchange of information and participation in regular meetings are also provided for. The agreement was enhanced in 2016 to allow CNCAN staff to be part of the examination team for safety advisors and drivers.

Status of the finding in the initial mission

Recommendation 34 is closed as the practical implementation of the cooperation agreements is in place between CNCAN, the State Inspectorate for Control of Road Transport (ISCTR) and the Romanian Road Authority (ARR).

11.3. REGULATORY BODY RESPONSIBILITIES AND FUNCTIONS

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S15	**Suggestion:** CNCAN should consider adopting international best practice safety guidance relating to the transport of radioactive material.

Changes since the initial IRRS mission

Suggestion 15: CNCAN developed the Regulation on transport of radioactive material which requires that all applicable requirements in international agreements for transport of dangerous goods to be applied (ADR, RID, AND, ICAO-TI). The regulation contains also licensing requirements.

CNCAN issued a regulation which contains requirements on the development and implementation of the radiation protection program in transport of radioactive materials (222/2017). This Regulation on Requirements for Development and Implementation of the Radiation Protection Program in transport also outlines the management system which must be implemented by the licensee. These are based on the IAEA Safety Guides. Regulation on the package design safety report has also been developed by CNCAN (223/2017). This regulation is primarily based on the European Package Design Safety Report developed under the framework of the European Association of Competent Authorities for the

Safe Transport of Radioactive Material (EACA). The procedure for inspection of transport activities, approved by Order 147/2017 is primarily based on the Inspection or Compliance Guide prepared by EACA. Additionally, procedures for regulatory review of package testing facilities, Order 202/2017 and procedures for the inspection of testing facilities approved by Order 200/2017 are available.

Status of the finding in the initial mission

Suggestion 15 is closed as CNCAN has adopted the IAEA Safety Guides and relevant EACA documents.

11.4. ORGANIZATION OF THE REGULATORY BODY

There were no findings in this area in the initial IRRS mission.

11.5. AUTHORIZATION PROCESS, REVIEW AND ASSESSMENT

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S16	**Suggestion:** CNCAN should consider performing a periodic assessment of the radiation doses received by persons involved in the transport of radioactive material, to ensure that the system of protection and safety complies with the provisions within the Fundamental Norms on Radiological Safety and of the applicable relevant norms on nuclear safety as well as the IAEA TS-R-1.

Changes since the initial IRRS mission

Suggestion 16: In accordance with current legislation, transport of radioactive material is a practice, where all radiological safety requirements must be applied. As in all practices, the dose assessment must be included.

CNCAN has prepared a Regulation on the Requirements for Development and Implementation of a Radiation Protection Program for the transport of radioactive material (222/2017). The requirement to have Radiation Protection Program is also part of the current ADR (2017) which gives effect to requirements of IAEA SSR-6 (the current Safety Requirements for the Safe Transport of Radioactive Material.

The assessment of the doses to staff involved in transport of radioactive material is undertaken as part of the authorization process, and periodically checked during routine inspections. Doses to transport workers may also be analysed by CNCAN from the data in the National Dose Register.

Status of the finding in the initial mission

Suggestion 16 is closed as CNCAN performs periodic dose assessments which are consistent with the requirements of IAEA SSR-6 and the current ADR 2017.

11.6. INSPECTION AND ENFORCEMENT

There were no findings in this area in the initial IRRS mission.

11.7. DEVELOPMENT OF REGULATIONS AND GUIDES

There were no findings in this area in the initial IRRS mission.

11.8. EMERGENCY PREPAREDNESS FOR TRANSPORT

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S17	**Suggestion:** CNACN should consider establishing in consultation with relevant

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
	licensees a systematic method for conducting transport emergency drills or exercises periodically.

Changes since the initial IRRS mission

Suggestion 17: Several emergency exercises and drills involving transport have been conducted. Plans are in place to expand the scope of transport emergency drills and exercises. One specific exercise is planned as part of the IAEA-TC project with CNCAN and it is scheduled to be undertaken in 2018. The scope of the 3-day proposed exercise involving CNCAN, emergency response personnel, licensees, and Border Police was provided to the IRRS team.

Status of the finding in the initial mission

Suggestion 17 is closed on the basis of progress made and confidence in effective completion as CNCAN has planned an exercise with the support of the IAEA to be held in 2018.

11.9. MANAGEMENT SYSTEMS FOR REGULATORY BODIES

2011 MISSION RECOMMENDATIONS, SUGGESTIONS	
S18	**Suggestion:** The revision of the current management system should also take into account the topics set out in the current IAEA Safety Guide on the Management System for the Safe Transport of Radioactive Material (IAEA No TS-G-1.4) and the current IAEA Safety Guide on Compliance Assurance for the Safe Transport of Radioactive Material (IAEA No TS-G-1.5).

Changes since the initial IRRS mission

Suggestion 18: A procedure for inspection of transport activities was developed and approved in CNCAN. It is based on an Inspection guide developed by EACA-European Association of Competent Authorities. The implementation of the management system at the licensee is audited by CNCAN.

The scope of Procedure on Inspection of Transport Activities, code PO-CP4-TRAN-01 details the steps of the inspection process associated with different activities: design, manufacturing, repairing and maintenance of the transport packaging, fabrication, loading, unloading of transport packages, transport and shipment of transport packages and investigation of transport events.

In the field of transport of radioactive waste CNCAN developed a regulatory review process for transport activities, code PO-CP3- TRAN- 01. The review and assessment of the transport packages is made in accordance with the procedure code PO-CP3- TRAN-02, while the review and assessment of package testing facilities code PO-CP3- TRAN-03.

The revised regulation on transport of radioactive material requires that all applicable requirements in international agreements for transport of dangerous goods to be applied (ADR, RID, AND, ICAO-TI). The regulation contains licensing requirements.

CNCAN issued a regulation which contains requirements on the development and implementation of a radiation protection program in transport of radioactive materials (Order 222/2017). This regulation also provides details of the management system which must be implemented by licensee. The requirements of a management system are in line with IAEA No TS-G-1.4 and IAEA No TS-G-1.5.

Regulation on the development of a package design safety report has been produced by CNCAN (Order 223/2017). This regulation is based on European Package Design Safety Report developed within the framework of EACA.

The new regulations are finalized and are to be published in Official Bulletin of Romania.

Status of the finding in the initial mission

Suggestion 18 is closed as guides and documents were developed as part of the management system.

12. INTERFACE BETWEEN SAFETY AND SECURITY

There were no findings in this area in the initial IRRS mission.

13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAIICHI ACCIDENT

13.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

The IRRS team was informed that CNCAN Emergency Response Centre (CNCAN-ERC) was activated during the TEPCO Fukushima Daiichi accident as an immediate action. The main purpose of the activities for the period of the accident was to inform the Romanian Government, media and the general public about the accident situation and potential radiological consequences on Romanian territory, as well as to provide advice and recommendations to the Government about the actions, if deemed necessary, for the protection of Romanian citizens from Romania and Japan involving the Ministry of External Affairs.

The IRRS team was also informed that CNCAN-ERC is activated in accordance with the activation procedure. The number of staff that have to be involved in the Centre's activities depends on the type of the installation where the accident occurred, the level of emergency that have been declared by the licensee (e.g site emergency, general emergency, unit emergency, etc.) and, for accidents outside Romania, on the distance to Romania from the epicenter of the accident. The level of activation of CNCAN-ERC could be total, partial or stand-by (only the duty officer, the press-communication officer and the President of CNCAN are involved).

In the case of the TEPCO Fukushima Daiichi accident, the CNCAN-ERC was appropriately activated and functioned until the stable condition was declared. Following declaration of stable conditions, the duty officer monitored daily progress of the accident and was responsible for periodically informing the CNCAN President.

The IRRS team noted that CNCAN analyzed the situation based on the official sources of information ex. USIE, TEPCO as well as using information provided by Romanian Embassy in Japan received through the Ministry of External Affairs. Engineering judgments were done with the purpose of understanding the accident progress, based on the technical information provided through official channels.

In the aftermath of the TEPCO Fukushima Daiichi accident CNCAN required SNN, the licensee for Cernavoda NPP, to perform safety reviews in accordance with the EU "stress tests" specifications. By the time the requirement was addressed SNN had already started to perform its own reviews based on the Significant Operating Experience Report issued by the World Association of Nuclear Operators (WANO) SOER 2011-02 (Fukushima Daiichi Nuclear Station Fuel Damage Caused by Earthquake and Tsunami).

The "stress tests" review required by the European Council for all the European nuclear power plants was conducted in compliance with the specifications and criteria issued by the European Commission, based on the work done by the European Nuclear Safety Regulators' Group (ENSREG) and the Western European Nuclear Regulators' Association (WENRA).

When performing its regulatory review on the implementation of the "stress tests", CNCAN focused on verification of the completeness and validity of the reports submitted by SNN. To conduct this verification, CNCAN carried out also a number of on-site inspections to check the progresses made for implementing the improvement actions resulting from the 'stress tests' safety review. The design changes associated with the improvements initiated by SNN have been subject to CNCAN review and approval.

The "stress tests" results have been extensively presented in the National Report of Romania for the 2nd Extraordinary Meeting under the Convention on Nuclear Safety (May 2012) and made publicly available on the CNCAN website. The results were also presented to the general public by the CNCAN President during a press-conference.

The detailed results of the post-TEPCO Fukushima Daiichi accident safety reviews have been subject to several public reports, including:

- National Report of Romania for the 2nd Extraordinary Meeting under the Convention on Nuclear Safety (May 2012);
- Report on the implementation of the European 'stress tests' by Romania (December 2011);

- National Report of Romania under the Convention on Nuclear Safety, 7th edition (August 2016).

Taking into account the insights from the TEPCO Fukushima Daiichi accident, new regulations have been issued to reflect necessity of the concept of design extension conditions, qualification of external events, and improving emergency operating procedures and severe accident management guidelines.

CNCAN is permanently monitoring SNN's progress in the implementation of the planned improvements and continues to perform safety reviews and inspections to ensure that all the opportunities for improvement are properly addressed taking account of the lessons learned from the TEPCO Fukushima Daiichi accident. SNN regularly provides CNCAN with a report on the progresses made in implementing the improvements planned as a result of the SNN' own safety reassessments. CNCAN performs reviews and assessments of such reports and conducts an annual targeted inspection focused on the post-Fukushima issues.

The role of CNCAN in the National System for the Management of Emergencies was reconsidered to improve its communication with other involved governmental agencies and the public. Governmental Decision no. 557/2016 specifies all the national and local organizations involved in the response of the nuclear or radiological emergency, as well as the main functions and the support functions for emergency response for each involved authority, including CNCAN. According to this Governmental Decision, CNCAN has the responsibility to coordinate the planning and preparedness of the nuclear and radiological emergencies in cooperation with Ministry of Internal Affairs and other relevant national authorities. The on-site emergency response plan is developed by the licensee and has to be approved by all involved authorities, including CNCAN. CNCAN is also responsible for periodically reviewing the plans and evaluating their consistency.

13.2. TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT

At the 2nd Extraordinary Meeting organised under the Convention on Nuclear Safety (May 2012), CNCAN presented the National Report of Romania. This focused on the results of safety reassessments ("stress-tests") performed by SNN, reviews and assessments performed by CNCAN, and included:

- review of the safety margins for extreme external events;
- analysis of loss of electrical power and loss of ultimate heat sink accident scenarios;
- severe accident analyses;
- emergency preparedness and response.

"Stress tests" results and peer-review of "stress-tests"

The peer-review of the "stress test" conducted by Romania acknowledged the comprehensive studies and work performed to increase protection of the Cernavoda NPP against seismic events and the substantial and recent studies for the assessment of flooding hazards. The "stress test" report of Romania was noted to fully comply with the ENSREG stress tests specifications. However, the peer reviewers concluded that margins to cliff edge effects for earthquakes and extreme external events were not adequately addressed in depth.

Regarding the protection against earthquakes at Cernavoda NPP, SNN's assessments demonstrated that the safety functions for the success paths for seismic events are fulfilled with a minimal margin of 0.4g. This corresponds to an event with a frequency of occurrence of less than 1 every 20000 years. In addition, based on deterministic studies performed by the national competent institutes for earth physics, seismic events yielding a Peak Ground Acceleration (PGA) > 0.2g are considered not physically possible and there are no cliff-edge effects occurring for PGA $\leq$ 0.4g. Therefore, assessments of plant behaviour for PGA values greater than 0.4g was found to be unnecessary, meaning that any additional seismic capacity above this value has not been quantified by SNN. Further analyses and assessment are planned once an agreed methodology is in place for the performance of assessments focused on cliff-edge effects rather than of seismic margins expressed in High Confidence, Low Probability of Failure (HCLPF) values.

The licensee's re-assessment of the protection against external flooding has not identified the need for any further protection measures, since the margins for such events were judged as sufficient. Based on the analysis results obtained by making use of the latest deterministic tools, and complemented by probabilistic approach, it was concluded that the Cernavoda NPP design intent in relation to flooding hazards provides sufficient margins, and therefore no further protection measures were envisaged in this area.

The European "stress test" peer-review team suggested that CNCAN and SNN consider improving the volumetric protection of the buildings containing safety related equipment located in rooms below plant platform level so that protection does not rely solely on the elevation of the platforms. This was accepted as a generic improvement and actions for implementation are in progress.

SNN's reassessment of protection against extreme weather events has been less systematic than the reassessment of protection against seismic and flooding events. This was due to the shorter time available for the review, since the initial specifications for the "stress test" did not explicitly include requirements for the assessment of extreme weather events. Therefore, the "stress test" peer-review concluded that the information presented is limited and the safety margins to cliff-edge effects are not sufficiently quantified. However, no recommendations have been made in this area. Finally for extreme external events, the reassessments by SNN concluded that the worst-case scenarios that could be initiated are bound by Station Black-Out (SBO), Loss of Ultimate Heat Sink (LOUHS) and combined SBO - LOUHS.

CNCAN reviewed the above mentioned results and concluded the conclusions are justified.

Based on the results of the Cernavoda NPP safety reassessment SNN implemented safety upgrades at Cernavoda NPP to improve protection against severe accidents. The safety upgrades included measures and means against extreme external events, such as those causing LOOP, LOUHS, and for severe accident management, namely:

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

Taking into account the lessons learned from the TEPCO Fukushima Daiichi accident, CNCAN have issued the following related new regulations:

- NSN-05 – Nuclear safety requirements on the operational limits and conditions for nuclear installations, (2015);
- NSN-06 – Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin, (2015);
- NSN-07 – Nuclear Safety Requirements on the response to transients, accident management and on-site emergency preparedness and response for NPPs, (2014);
- NSN-18 – Nuclear safety requirements on event reporting and analysis and on the use of operating experience feedback for nuclear installations, (2017);
- NSN-20 – Regulation on the nuclear safety policy and independent nuclear safety oversight for nuclear installations, (2015);
- NSN-21 – Fundamental Nuclear Safety Requirements for Nuclear Installations, (2017);
- NSN-23 – Training, qualification and authorization of nuclear installations personnel with nuclear safety related jobs, (2017);
- NUR – Requirements on the planning and preparedness of the license holders for the intervention in nuclear or radiological emergency, (2014).

The concept of design extension conditions (DEC) has been adopted in Romania. CNCAN has issued a number of regulatory guides covering issues such as seismic margins assessment, development of

the deterministic safety analyses, reviewing severe accident analyses for NPPs, and reviewing Emergency Operation Procedures (EOPs) and Severe Accident Management Guidelines (SAMGs) at NPPs. IRRS team noted that concept of the design extension conditions has not been formally introduced into the regulatory requirements. However, as it has been implemented in practice, CNCAN is committed to introduce it into the regulations during their next periodical revision.

Follow-up actions by the regulatory body

Based on the results of the "stress tests" safety reassessment, the Romanian National Action Plan on post-Fukushima actions has been developed and contains 43 actions. At the time of this follow-up IRRS mission, the majority of the actions planned have been implemented, two actions are found in the process of implementation (discussed in the next section of the present Chapter), and two actions require continuous activities.

CONCLUSION [1]
The IRRS team considers that the TEPCO Fukushima Daiichi accident implications were adequately addressed in the regulatory activity of CNCAN. Romania has implemented the European "stress-tests" safety reassessment to the full extent, presented its results to the international community and made it publicly available. A set of actions for safety improvement were identified, planned and implemented. Additional continuous activities are addressed both by the regulatory authority and the licensee.

13.3. PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT

Actions by the licensee

The Romanian National Action Plan on post-Fukushima (AP) actions includes 30 actions to be implemented by the licensee (SSN) and 5 actions to be jointly implemented by the licensee and CNCAN. Both the regulatory body and the licensee regarded post-Fukushima issues as of a high priority and have concentrated as much available resources as possible to address them.

At the time of this mission the IRRS team was informed that most of the planned actions have been completed.

The IRRS team noted that the initial target dates for implementation of the two actions by SNN have been extended several times and approved by CNCAN. These actions are still to be completed.

Action No. 5 is devoted to design modifications to replace selected doors with flood resistant doors and penetrations sealing (for improving the volumetric protection of the buildings containing safety related equipment located in rooms below plant platform level) at Cernavoda NPP. The SNN's AP implementation report of August 2017 submitted to CNCAN requests extending the completion deadline to June 2018 due to the application of legal procurement procedures.

The similar request and the corresponding justifications are addressed for Action No. 31, which is devoted to establishing a new seismically qualified location for the on-site emergency control centre and fire fighters. Such a location is intended to include important intervention equipment (mobile diesel generators, mobile diesel engine pumps, fire-fighter engines, radiological emergency vehicles, heavy equipment to unblock roads, etc.) and to be protected against all external hazards.

Within the regulatory oversight framework, CNCAN assesses SNN's AP implementation reports provided twice a year and conducts evaluation on the adequacy of implementation of the actions, the addressed requests and their justification in order to make appropriate regulatory decisions.

Identified continuous activities continue to be implemented jointly by both licensee and regulatory body.

Action No. 43 of the AP devoted to the participation in international activities for sharing experience on lessons learned from the Fukushima accident and on actions taken to improve safety. This is being jointly implemented by SNN and CNCAN on a continuous basis.

Action No. 10 of the AP requests that CNCAN perform further work for developing approaches to assessment of the margins to cliff-edge effects due to external events and vulnerability in the design. The action is marked as "planned" with no specific target dates or timeline. The justification provided by CNCAN states that the implementation of this action depends on the development of a common methodology at EU-level for assessing margins to cliff-edge effects due to external events.

At the time of this IRRS mission, the requirement of performing the assessment of cliff-edge effects due to external events of natural origin, included in regulation NSN-06 – "Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin" (2015), was not yet implemented. The IRRS team was informed that plans to implement Action No.10 of the AP depend on the development of a common methodology at the EU-level for assessing margins to cliff-edge effects due to external events.

The IRRS team acknowledged that a seismic margin assessment was performed for Cernavoda NPP, with a review level earthquake (RLE) established at a reasonably high level seismic ground motion, based on site seismicity and plant specific design features. The seismic margin assessment shows that in comparison with the original design basis earthquake of 0.2g, which has a frequency of 10^{-3} events/year, all Structures, Systems and Components (SSCs) that relate the safe shutdown path after an earthquake would continue to perform their safety function up to 0.4g.This has an estimated frequency of 5×10-5 events/year. This margin is considered adequate as it meets the safety goals applied internationally for new NPPs.

Based on deterministic studies performed by national institutes (presented in the National Report of Romania for the 2nd Extraordinary Meeting under the Convention on Nuclear Safety) and the seismic margin assessment performed, there are no cliff-edge effects occurring for PGA ≤ 0.4g. CNCAN recognizes that additional margins may exist beyond the value of 0.4g but that they have not been quantified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Practical implementation of the requirement devoted to assessment of the margins to cliff-edge effects due to external events included in the regulation NSN-06 – "Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin", (2015), has not been carried out because they have not identified a methodology of performing such an assessment.	
(1)	**BASIS: SSR-2/1 (Rev. 1) Requirement 42**, para. 5.73 states that *"The safety analysis shall provide assurance that uncertainties have been given adequate consideration in the design of the plant and in particular that adequate margins are available to avoid cliff edge effects and early radioactive releases or large radioactive releases."*
(2)	**BASIS: SSR-2/1 (Rev. 1) Requirement 42**, para. 5.76 states that *"The design shall take due account of the probabilistic safety analysis of the plant for all modes of operation and for all plant states, including shutdown, with particular reference to:* …….. *(b) Providing assurance that situations in which small deviations in plant parameters could give rise to large variations in plant conditions (cliff edge effects) will be prevented;* ……
SF4	**Suggestion: CNCAN should consider ensuring that the Cernavoda NPP licensee effectively implements the regulatory requirements for assessment of margins to cliff-edge effects due to external events and use existing best international practices to ensure that the safety analyses provides adequate margins to avoid cliff edge effects.**

Actions by the Regulatory Body

Two out of the eight AP actions by CNCAN were in progress at the time of the mission:

- implementation of recommendations from the initial 2011 IRRS mission; and
- review of the national regulatory framework for nuclear safety to identify and implement actions for improvement, which is a continuous activity performed on the regular basis.

Planned changes in the legal background, regulations and guides

CNCAN is now implementing their plan for the development safety regulations and guides for the period 2016 – 2017. The most significant developments regarding the Fukushima issues are:

- safety rules for commissioning of nuclear installations;
- safety rules for operation of nuclear installations;
- safety rules for monitoring, maintenance, testing and inspections of equipment during operation of nuclear installations;
- rules nuclear installations configuration management;
- fundamental nuclear safety standards;
- rules of nuclear installations authorization.

Additionally, new regulations on emergency preparedness and response are being developed by CNCAN. The draft General Regulation for Preparedness and Response to a Nuclear or Radiological Emergency was passed through the public consultation process and are undergoing final approval. The revision of the Regulations and Requirements on Planning and Preparedness for Intervention to Nuclear or Radiological Emergencies, Specific Requirement for Licensees on EPC I, II and III have also been drafted, and new Emergency Preparedness and Response Requirements for Legal Activities in EPC IV have been drafted.

CONCLUSION [2]
The IRRS team concluded that the Romanian National Action Plan on post-Fukushima actions covering the topics considered important from the point of view of protection against extreme and low probability beyond design basis events similar to those occuring in the TEPCO Fukushima Daiichi accident have been sucessfully implemented. CNCAN have issued a number of new regulations taking into accout Fukushima lessions learned and is in the process of reviewing and updating other safety requirements. CNCAN is also reviewing its assessment and inspectioning activities for Cernavoda NPP.

13.4. CONCLUSIONS BY REVIEWED AREAS

Note: ***The significance of Fukushima implications was considered as part of the review of the progress for each IRRS Chapter. The review conclusions below and the plans presented by Romania to further address issues associated with the TEPCO Fukushima Daiichi accident in the coming years should be regarded along with assessment of the progress in fulfilling the recommendation and suggestios raised during the initial IRRS mission in 2011.***

Chapter 1: Responsibilities and Functions of the Government

All aspects of regulatory independency are adequately considered by the legal powers mandated through the law 111/96, which ensures independency to the Regulator from government interference. CNCAN has the adequate levels of competency necessary to respond to radiological emergencies, albeit a bit understaffed to deal with major nuclear emergencies (this aspect is covered under Recommendation 3 of the report).

The licensee's duty to inform the public during normal or emergency situations is properly legislated and implemented. Aspects of international cooperation are addressed by CNCAN by multiple bilateral agreements and agreements with the IAEA.

While the personal dosimetry service during nuclear emergencies is provided by the licensee for on-site responders, for off-site responders each participating organization dosimetry service and personnel protection must be provided by each participating organization.

CONCLUSION [3]
The IRRS team concludes that no concerns needed to be raised. Several legal instruments appropriately assign responsibilities and functions for ER for nuclear and radiological emergencies: Law 15/2005, GD 94/2014, GD 1491/2004 and 1492/2004, GD 557/2016. The role of the licensees, including their duty to inform the public during normal or emergency situations is properly legislated and implemented.

Chapter 2: Global Nuclear Safety Regime

According to Art. 35 of the Law no. 111/1996 on the safe deployment, regulation, licensing and control of nuclear activities, one of the main responsibilities of CNCAN is to control the implementation of the provisions of international treaties and bilateral agreements on the intervention in case of nuclear accident, such as:

- IAEA Convention on Early Notification of a Nuclear Accident;
- IAEA Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Convention Regarding the Liability for Nuclear Damages;
- Bilateral Agreements on Early Notification of Nuclear Accidents and Exchange of Information on Nuclear Installations with Bulgaria, Greece, Hungary, Slovakia, Russian Federation and Ukraine.

CNCAN is the national contact point for IAEA Conventions for Early Notification and Assistance.

As member of the European Union, Romania uses the European Community Urgent Radiological Information Exchange (ECURIE) system and the automatic European Radiological Data Exchange Platform (EURDEP). ECURIE is the official notification system of the European Commission through which EU member states are obliged to notify and send relevant information in case of radiological/nuclear accident.

The IRRS team was informed that Romania will participate in the European topical peer reviews focused on the ageing management of nuclear power plants. These peer reviews are based on a consistent process to enable participating countries to benchmark their ageing management programmes against international good practices.

CONCLUSION [4]
The IRRS team concludes that Romania has adequate provisions in place for the implementation of the Convention on early Notification of a Nuclear Accident and the Convention on Assistance in Case of a Nuclear Accident. Romania also has appropriate provisions in place for the implementation of these conventions. **Romania also fulfill its obligations and responsibilities towards the Convention on Nuclear Safety. It allocates appropriate human resources in the preparation of the review meetings and releases publicly the national reports.** **Government of Romania supports and remains involved in international peer review missions, including European peer reviews.**

Chapter 3: Responsibilities and Functions of the Regulatory Body

CNCAN is an independent regulatory authority on nuclear and radiation safety reporting to the Prime Minister.

CNCNA is still struggling with the lack of resources affecting the effective discharge of some regulatory functions. This issue was even more acute in the aftermath of TEPCO Fukushima Daiichi accident when CNCAN had to refocus its resources to follow up the implications of this accident including the follow-up of the safety reviews post-Fukushima and the improvement of the safety regulations.

The initial IRRS mission in 2011 did not raise any particular issue related to communication with interested parties, including the public as well as licensees, either in normal situations or during a possible nuclear or radiological emergency. In June 2017, as part of the transposition of an EU directive, NSN-21 – Fundamental Nuclear Safety Requirements for Nuclear Installations regulation was issued. NSN-21 specifies, under Section Transparency, regulatory obligations placed on licensee to inform the interested parties, especially those living in the vicinity of nuclear installations and workers, including about the normal operating conditions and about incidents and accidents. This new provisions are in line with Reg. 36 of GSR Part 1 (Rev.1).

CONCLUSION [5]
The IRRS team considers that appropriate actions have been taken. The TEPCO Fukushima Daiichi accident had significant impact on the regulatory activities as CNCAN had to refocus its resources to follow up the implications of this accident.

Chapter 4: Management System of the Regulatory Body

The development of the management system was slowed down due to the available resources being focused on the implications of the TEPCO Fukushima Daiichi accident. At the time of the mission CNCAN management system was at an early stage of development and implementation. Significant efforts are still necessary to establish an effective and integrated management system.

The management system manual was finalized and endorsed by the Chairman of the CNCAN but most of the other documents needed to be either revised or developed and finalized. However, no formal plan to prioritize the tasks and assign relevant responsibilities, including identification of the process owner and the management system manager, has been developed to manage efficiently the development of the system.

In CNCAN Chairman's Commitment, it is clearly stated that safety is as a first priority and the importance of a sound safety culture is acknowledged, when further enhancing the quality and effectiveness of CNCNA work and continuously improving the professional competence of CNCAN staff. In their statement, the CNCAN senior managers commit to provide sufficient resources and competence and promote a culture for safety. As regards this latter, only few activities have been conducted for strengthening safety culture within the organization, including a limited exercise for a safety climate survey and several training activities for staff in this.

All processes are identified under the management system manual including the process for measurement, assessment and improvement of the management system and overall the performance of CNCAN. But this process has not been implemented yet.

CONCLUSION [6]
The IRRS team considers that further actions are needed to develop and implemented an integrated management system.

Chapter 5: Authorization

The IRRS team concludes that based on the self-assessment carried out using the questionnaire provided by the IAEA, there is a need to introduce the concept of design extension conditions (DEC) in CNCAN's nuclear safety regulations. The concept of design extension conditions has already been used in regulations only for the case of external events, in the regulation NSN-06 – Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin (2015).

Nevertheless, in practice, the concept of design extension conditions has been applied both in safety analyses and in the implementation of design upgrades.

The IRRS team was informed that CNCAN is going to issue new regulatory requirement and guidance that will cover the concept of design extension conditions, planned for by the end of 2018.

While incorporation of the DEC concept has been self-identified as a shortcoming by CNCAN, the IRRS team considers it of no major concern, and finds that CNCAN's planned process to introduce design extension conditions for regulatory reassessment acceptable.

CONCLUSION [7]
The IRRS team considers that CNCAN is committed to act in light of the implementation of the DEC concept in its authorization process based on the necessary updates of the regulatory requirements that will be implemented during the review of the existing regulations on the regular basis or issuance of the new ones.

Chapter 6: Review and Assessment

Having outstandingly updated the Romanian licensing basis with the focus on the post-Fukushima implications, CNCAN follows the systematic approaches to review and assessment of the Cernavoda NPP safety evaluations, including periodic safety assessment, with the respective use of deterministic and probabilistic safety analysis, identification of internal and external hazards and considering the possible combinations of initiating events. Special attention is paid to the worst-case scenarios that could be initiated by SBO, LOUHS and combined SBO + LOUHS.

CONCLUSION [8]
The IRRS team concurs with that the existing status of the review and assessment process in the light of the TEPCO Fukushima Daiichi accident is appropriate, no gaps and no actions for improvement have been identified.

Chapter 7: Inspection

On the basis of the information derived from the European Union "stress tests" comprehensive exercise and of the different on-going reviews and assessments, CNCAN considered several actions in its inspection activities: in the first years following the conclusions of the stress tests, CNCAN injected reactive inspections in its inspection program for checking the adequate implementation of the modifications considered. Post-Fukushima actions are now subject to targeted inspections, included in the inspection program at least once a year. CNCAN focuses these inspections on the maintenance and testing of post-Fukushima equipment and the associated adequate initial and refreshing training of staff.

CONCLUSION [9]
The IRRS team concludes that, in the framework of EU stress tests CNCAN carried out appropriate inspection activities for being able to confirm the outcomes of the reviews conducted.

Chapter 8: Enforcement

CNCAN has all the necessary authority to require an analysis of the risk involved by the unforeseen situations and to demand corrective actions which can include suspension of operation until the issues are solved. CNCAN will use the normal enforcement process, because the legal basis exists and can be used.

CONCLUSION [10]
The IRRS team concludes that the existing status is appropriate. The regulatory body is in the position to exercise a graded enforcement policy whenever necessary and in particular in a situation similar to the Fukushima accident.

Chapter 9: Regulations and Guides

23 new regulations and guides issued since 2011, all incorporate lessons learned from the Fukushima accident and from the safety reviews and inspections performed and reflect the best available knowledge, including the implications of the Fukushima accident. Efforts for further developing / expanding the regulatory framework are continuing. The actual annual plan for developing regulations and guides addresses the implications of the Fukushima accident as lessons learned. The internal procedure for developing regulations and guides (PC-CP1-01) issued in 2005, was revised in 2012. The actual version has not addressed the implications of the Fukushima accident. The IRRS team was informed that it will be taken into account in the next revision.

CONCLUSION [11]
The IRRS team concludes that the existing status is appropriate and necessary further actions have been initiated.

Chapter 10: Emergency Preparedness and Response

The IRRS team noted that regulatory requirements on the inclusion of beyond design basis accidents and multi-unit events in the emergency preparedness and response plans are provided in a number of newly enacted and drafted regulations. For the NPP beyond design basis accidents and multi-unit events have been included in the licensee's emergency preparedness and response plans and procedures. CNCAN has performed assessments and inspections on these aspects, both in the framework of the post-Fukushima stress tests and as part of the routine inspection activities for verifying compliance with the regulations.

CONCLUSION [12]
The IRRS team concludes that the necessary further actions have been initiated.

APPENDIX I: LIST OF PARTICIPANTS

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APPENDIX II: FOLLOW-UP MISSION PROGRAMME

<table>
<tr><th>Time</th><th>MON – 09 October</th><th>TUE – 10 October</th><th>WED – 11 October</th><th>THU – 12 October</th><th>FRI – 13 October</th><th>SAT - 14October</th><th>SUN – 15 October</th><th>MON – 16 October</th></tr>
<tr><td>9:00-10:00</td><td rowspan="6">Arrival of Team Members</td><td rowspan="2">Entrance Meeting (hotel)
Group photo</td><td rowspan="3">Interviews</td><td>TM write Report

TL and DTL review introductory parts</td><td rowspan="2">Discussion Counterpart/Expert

Secretariat finalizes the report</td><td>Written comments by the Host to the team</td><td rowspan="11">Social Event</td><td rowspan="2">Exit Meeting (hotel)</td></tr>
<tr><td>10:00-11:00</td><td>Comments discussed by the Team</td></tr>
<tr><td>11:00-12:00</td><td rowspan="2">Interviews</td><td rowspan="2">Cross-reading</td><td rowspan="2">Comments discussed with the host</td><td rowspan="2">Farewell</td></tr>
<tr><td>12:00-12:30</td></tr>
<tr><td>12:30-13:30</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td colspan="2">Lunch</td><td>Lunch</td><td rowspan="9">Departure of Team Members</td></tr>
<tr><td>13:30-14:30</td><td rowspan="4">Interviews</td><td>Policy discussion on the Independence of RB</td><td>Meeting with General Secretary</td><td colspan="2">Submission of the Draft to the Host</td><td rowspan="3">Preparation of the Draft Report</td></tr>
<tr><td>14:30-15:00</td><td rowspan="3">Interviews</td><td>Secretariat edits the report.
Preliminary draft report ready</td><td rowspan="3">Host reads Draft and prepares written comments</td><td rowspan="3">TL finalises the presentation</td><td rowspan="3">TC drafts the Press Release</td></tr>
<tr><td>15:00-16:00</td><td rowspan="3">Initial Team Meeting (Attended by the LO):
• Admin and logistical issues (LO)
• IRRS objectives, process
• Report writing
• Schedule
• First observations
• PI evaluations

- At the Hotel -</td><td rowspan="3">Team discussion of the draft report
- At the Hotel -</td></tr>
<tr><td>16:00-17:00</td><td>Preliminary findings delivered</td><td rowspan="2">Discussion of Executive Summary</td><td rowspan="2">Presenting Draft Report to the Host

Finalisation of the Report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting
- At the Hotel -</td><td>Daily Team Meeting:
Discussion of findings
- At the Hotel -</td></tr>
<tr><td>18:00-19:00</td><td rowspan="2">Team Building Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Official Dinner</td></tr>
<tr><td>19:00-20:00</td></tr>
</table>

APPENDIX III: LIST OF MISSION COUNTERPARTS

Overall coordinator

Mr Cantemir Ciurea-Ercau, CNCAN Liaison Officer

Chapters 1 and 2

Ms MadalinaTronea, Coordinator, Nuclear Regulations and Standards Unit, Nuclear Fuel Cycle Division

Chapter 3

Ms MadalinaTronea, Coordinator, Nuclear Regulations and Standards Unit, Nuclear Fuel Cycle Division

Chapter 4

Ms Maria Oprisescu, Coordinator, Management System Oversight Unit, Nuclear Fuel Cycle Division

Chapters 5 and 6

Ms Daniela Casaru, Director, Licensing the Use of Ionising Radiation Division

Ms Elena Dinca, Coordinator, Nuclear Safety Assessment Unit

Ms Daniela Dogaru, Coordinator, Radiation Protection, Radioactive Waste Management and Transport Unit, Nuclear Fuel Cycle Division

Chapters 7 and 8

Ms MadalinaTronea, Coordinator, Nuclear Regulations and Standards Unit, Nuclear Fuel Cycle Division

Mr Alexandru Eremia, Director, Surveillance the Use of Ionising Radiation Division

Chapter 9

Ms Madalina Tronea, Coordinator, Nuclear Regulations and Standards Unit, Nuclear Fuel Cycle Division

Ms Daniela Casaru, Director, Licensing the Use of Ionising Radiation Division

Chapter 10

Mr Petre Min, coordinator, Radiological Emergency Unit, Nuclear Fuel Cycle Division

Chapter 11

Ms Daniela Dogaru, Coordinator, Radiation Protection, Radioactive Waste Management and Transport Unit, Nuclear Fuel Cycle Division

Chapter 12

n/a

Chapter 13

Mr Cantemir Ciurea-Ercau, Director, Nuclear Fuel Cycle Division

APPENDIX IV: RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE 2011 IRRS MISSION THAT REMAIN OPEN

Section	Chapter	R/S	Recommendations/Suggestions
1.3.	Responsibilities and Functions of the Government	R3	The Government should provide CNCAN with the financial and human resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.
3.1.	Responsibilities and Functions of the Regulatory Body	R9	CNCAN should implement measures for managing available resources in a manner commensurate with the radiation risks associated with facilities and activities.
4.	Management System of the regulatory Body	R11	CNCAN should develop and implement an Integrated Management System satisfying the requirements set out in GS-R-3.
5.6.	Authorization	R15	CNCAN should establish and implement authorization processes and procedures for all radioactive waste management and decommissioning activities.

APPENDIX V: RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2017 IRRS FOLLOW-UP MISSION

Section	Chapter	RF/SF/ GPF	Recommendations, Suggestions or Good Practices
1.1.	Responsibilities and Functions of the Government	RF1	The Romanian Government should expedite the implementation of the National Strategy on Nuclear Safety and Security, which came into force in July 2014, in accordance with a graded approach.
1.3.	Responsibilities and Functions of the Government	RF2	The Government should enable CNCAN to take measures to augment its retention or attraction capabilities of experienced safety experts, before the attrition is extended to the new staff that are presently acquiring the competence.
1.8.	Responsibilities and Functions of the Government	RF3	The Government should take measures to implement the financing arrangements of regulatory costs as it is laid down in the Nuclear Strategy for the Development of Nuclear Sector.
2.2.	Global Nuclear Safety Regime	RF4	CNCAN should expedite the effective and sustainable implementation of arrangements for analyzing events and identifying lessons in order to facilitate an effective exchange and use of operating and regulatory experience with the international community.
6.5.	Review and Assessment	RF5	CNCAN should implement the procedures for review and assessment, including provisions for periodic verifications.
7.5.	Inspection	SF1	CNCAN should consider upgrading the information system/database for radiation sources based on the feedback of its operation. In particular, CNCAN should consider including the applicants' documents that are part of the licensing file, extending the database with additional modules and having it maintained by a specialized service provider.
9.6.	Regulations and Guides	SF2	CNCAN should consider implementing the standard review plan that describes the detailed criteria and review procedure for the application of the radioactive waste disposal facility prior to the final siting license and design of the disposal facility.
10.1.13.	Emergency Preparedness and Response	RF6	CNCAN should establish a quality management programme to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities, plans and procedures necessary to perform the

Section	Chapter	RF/SF/ GPF	Recommendations, Suggestions or Good Practices
			assigned response functions, namely at the CNCAN-ERC.
10.1.15	Emergency Preparedness and Response	RF7	CNCAN should adopt the revised (2017) training plan and produce a plan for delivering its components in an effective and sustainable manner.
10.2.	Emergency Preparedness and Response	SF3	CNCAN should consider enhancing participation in international cooperation on emergency preparedness for nuclear and radiological accidents in order to exchange experiences and improve national capabilities with a focus on cooperation with neighbouring and European countries.
10.2.	Emergency Preparedness and Response	RF8	CNCAN should develop and implement a common national program for the training of emergency response personnel belonging to public authorities.
13.3.	Regulatory Implications of the TEPCO Fukushima Daiichi Accident	SF4	CNCAN should consider ensuring that the Cernavoda NPP licensee effectively implements the regulatory requirements for assessment of margins to cliff-edge effects due to external events and use existing best international practices to ensure that the safety analyses provides adequate margins to avoid cliff edge effects.

APPENDIX VI: REFERENCE MATERIAL PROVIDED BY CNCAN

1. IRRS Follow-up mission to Romania, *Advance Reference Materials, Self-assessment report, rev. 1*
2. IRRS Follow-up mission to Romania, *Advance Reference Materials, Self-assessment report, rev. 0*
3. Law no. 111/1996 on the safe deployment, regulation, authorisation and control of nuclear activities, republished
4. National Strategy on nuclear safety and security, approved through Governmental Decision no.600/2014, published in the Romanian Official Bulletin, Part I, no. 564/30.07.2014
5. CNCAN Core Process CP2: Licensing - Process Description
6. CNCAN Core Process CP3: Review and Assessment - process description
7. CNCAN Core Process CP4: Inspection - Process Description
8. CNCAN Core Process CP6: Enforcement - Process Description
9. CNCAN Management Process: MP 7 Measurement, Assessment and Improvement - Process Description
10. CNCAN Management Sub-Process MP 7.1: MS Performance Monitoring and Measuring - Sub-Process Description
11. CNCAN Management Sub-Process MP 7.2: Self-Assessment - Process Description
12. CNCAN Management Sub-Process MP 7.4: Experience Feedback - Process Description
13. CNCAN Management Sub-Process MP 7.5: Management System Review - Process Description
14. CNCAN Management Sub-Process MP 7.6: Management of non-conformances, corrective and preventive actions - Sub-Process Description
15. CNCAN Management Sub-Process MP 7.7: Improvement - Process Description
16. CNCAN Management System Manual, rev 5
17. Procedure for inspection of activities for nuclear materials transport (Romanian version), code PO-CP4-TR-01
18. Procedure for training, qualification and certification of CNCAN inspectors, code PS1 - 01-00
19. Guidelines for regulatory review of EOPs and SAMGs
20. Guidelines for regulatory review Of EOPS and SAMGS for research reactors
21. Procedure for regulatory review of predisposal activities and facilities, code PO-CP3-DR-01
22. Draft regulation on basic radiation safety (version on Nov 2016)
23. General regulation for preparedness and response to a nuclear or radiological emergency
24. Guidelines for the performance of deterministic safety analysis for Nuclear Power Plants
25. Guidelines for review the National Strategy for the management of nuclear spent fuel and radioactive waste (Romanian version)
26. NSR 10 - Norms on operational radiation protection for the development of the Non-Destructive Testing practice with the ionizing radiation
27. NSR 04 - Norms on the radiation protection of individuals in case of medical exposure to ionizing radiation
28. NSR 07 - Norms regarding the issue of exertion licences for nuclear activities and appointment of accredited experts in radiological protection
29. Regulation on specific requirements for decommissioning of nuclear and radiological facilities
30. Regulation on the safety requirements for the predisposal activities of radioactive waste, disused radioactive sources and spent nuclear fuel
31. Norms regarding the licensing requirements of the activities for nuclear materials transport (Romanian version)
32. Protocol for cooperation between the National Commission for Nuclear Activities Control and the Meteorological National Administration
33. Protocol for cooperation between the National Commission for Nuclear Activities Control and the National Agency for Environmental Protection
34. Protocol for cooperation between the National Commission for Nuclear Activities Control and the National Company “Nuclearelectrica” S.A.
35. Areas requesting appropriate attention in the light of the Fukushima accident for each Chapter of the IRRS follow-up mission

- Chapter 1: Responsibilities and Functions of the Government
- Chapter 2: Global Nuclear Safety Regime
- Chapter 3: Responsibilities and functions of the regulatory body
- Chapter 4: Management system of the regulatory body
- Chapter 5: Authorization
- Chapter 6: Review and Assessment
- Chapter 7: Inspection
- Chapter 8: Enforcement
- Chapter 9: Regulations and guides
- Chapter 10: Emergency preparedness and response

APPENDIX VII: IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010).
3.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
4.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
5.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
6.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009).
8.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014).
9.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012).
10.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011).
11.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003).
12.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Safety Requirement Series No. NS-R-4, IAEA, Vienna (2005).
13.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Safety Requirement Series No. NS-R-5, IAEA, Vienna (2014)
14.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
15.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012)
16.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002).
17.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002).
18.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).
19.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002).

20.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
21.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
22.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
23.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. SSG-25, IAEA, Vienna (2013)
24.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
25.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999)
26.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
27.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
28.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiological Protection for Medical Exposure to Ionizing Radiation, Safety Guide Series No. RS-G-1.5, IAEA, Vienna (2002)
29.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
30.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2006)
31.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
32.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
33.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
34.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
35.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)
36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
37.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)

39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel Specific Safety Guide Series No. SSG-15, IAEA, Vienna (2012)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
42.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
43.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
44.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
45.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - 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)
46.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
47.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Regulatory Control of Radiation Sources, General Safety Guide No. GS-G-1.5, IAEA, Vienna (2004)
48.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999)
49.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Medical, Industrial and Research Facilities (1999) Safety Guide Series No.WS-G-2.2, IAEA, Vienna (1999)
50.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No.WS-G-2.3, IAEA, Vienna (2000)
51.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No.WS-G-2.4, IAEA, Vienna (2001)
52.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No.WS-G-2.5, IAEA, Vienna (2003)
53.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003)
54.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Management of Waste from the Use of Radioactive Materials in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No.WS-G-2.7, IAEA, Vienna (2005)
55.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
56.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
57.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII: CNCAN ORGANIZATIONAL CHART

No of positions: 103