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INTERNATIONAL ATOMIC ENERGY AGENCY

**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)**

FOLLOW-UP MISSION OF IRRT AND RaSIA

TO

Romania

Bucharest

16 – 26 January 2006

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

conducted under IAEA Technical Co-operation Project ROM/9/026

DEPARTMENT OF TECHNICAL CO-
OPERATION
Division for Europe, Latin America and
West Asia

DEPARTMENT OF NUCLEAR SAFETY
AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICES

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish standards of safety for protection of health and minimization of danger to life and property in the civil development and application of nuclear energy and to provide for the application of these standards to peaceful activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. The Agency also provides Safety Services, at the request of Member States, which are directly based on the IAEA Safety Standards and Security Guidance.

In the thematic area of Legal and Governmental Infrastructure (LGI) the Agency offers several peer review services:

- ✓ The ***International Regulatory Review Team (IRRT)*** programme provides advice and assistance to Member States to strengthen and enhance the effectiveness of the legal and governmental infrastructure for nuclear safety;
- ✓ The ***Radiation Safety and Security Infrastructure Appraisal (RaSSIA)*** assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources.
- ✓ The ***Transport Safety Appraisal Service (TranSAS)*** has for objective to assess the implementation of the Agency's Transport Regulations;
- ✓ The ***International Nuclear Security Advisory Service (INSServ)*** assists Member States in the identification of the best means by which to strengthen their nuclear security;
- ✓ The ***Emergency Preparedness REView (EPREV)*** is conducted to review both the preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

In addition, to ensure and enhance the safety of operating research reactors, the *INternational Safety Assessment of Research Reactors (INSARR)* is being offered to Member States. In this area, in the context of LGI, another instrument that needs to be considered is the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in March 2004.

The importance of peer review and enhancing the regulatory body self-assessment capabilities to identify strengths and weaknesses as well as indicate areas for improvement of the necessary legislative and regulatory frameworks had been underlined during the 3rd Review Meeting of the contracting parties to the International Convention on Nuclear Safety (CNS) in April 2005. Peer reviews are now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. They are neither an inspection nor an audit but are a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, and that contributes to ensuring a strong nuclear safety.

Moreover, considering that the five peer reviews listed above have areas in common, the IAEA Department of Safety and Security has initiated the development of an integrated approach to review missions on Legal and Governmental Infrastructure. The new service is

structured in modules, which cover general requirements, regulatory activities and management systems for Nuclear Installation Safety (Nuclear Power Plants, Fuel Cycle Facilities, and Research Reactors), Radiation Safety, Waste Safety, Transport Safety, Emergency Preparedness and Response and Security. The objectives are to make the IAEA services related to LGI more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of IAEA Safety Standards. The modular structure also enables tailoring the service to meet the need and priority of the Member State.

The missions will also be used as the most effective feedback for the improvement of existing standards and guidance, the development of new ones, and to establish a knowledge base in the context of an integrated safety approach.

Global Nuclear Safety and Security Regimes have emerged over the last ten years, with international legal instruments such as Conventions and Code of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA Safety Standards and Security Guidance. The IAEA will continue to support the promotion of the Conventions and Codes of Conduct, as well as the application of the IAEA Safety Standards and Security Guidance in order to prevent serious accidents and continuously improve the global levels of safety and security. Through its Integrated Regulatory Review Service (IRRS), the IAEA assist Member States in strengthening their national safety and security infrastructure. This would contribute towards achieving a strong and sustainable global safety and security regime.

REPORT

INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION OF IRRT AND RaSIA

**REPORT TO
THE GOVERNMENT OF ROMANIA**

Bucharest, Romania
16 – 26 January 2006



INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION OF IRRS AND RaSIA

Bucharest, Romania

16 – 26 January 2006

Mission date: 16 January – 26 January 2006

Regulatory Body: CNCAN (Comisia Națională pentru Controlul Activităților Nucleare)

Location: CNCAN, Bucharest, Romania

Regulated Facilities/Applications: Nuclear Power Plants, Research Reactors and Radiation Sources

Organized by: IAEA

Technical Co-operation Project: ROM/9/026

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IRRT

FOREWORD

by the

Director General

The IAEA International Regulatory Review Team (IRRT) programme assists Member States to enhance the organization and performance of their nuclear safety regulatory body. Such a regulatory body must work within the framework of its national legal system, which in turn should ensure both the independence and the legal powers available to the regulatory body. Additionally the national administrative and legislative system should ensure that the regulatory body has sufficient funding and resources to carry out its functions of reviewing and assessing safety submissions; licensing or authorizing nuclear safety activities, establishing regulations and criteria; inspecting nuclear facilities and enforcing national legislation. The regulatory body should be resourced and staffed by capable and experienced people to a level commensurate with the national nuclear programme. IRRT missions focus on all these aspects in assessing the regulatory body's safety effectiveness. Comparisons with successful practices in other countries are made and ideas for improving safety are exchanged at the working level.

An IRRT mission is made only at the request of a Member State. It is not an inspection to determine compliance with national legislation, rather an objective review of nuclear regulatory practices with respect to international guidelines. The evaluation can complement national efforts by providing an independent, international assessment of work processes that may identify areas for improvement. Through the IRRT programme, the IAEA facilitates the exchange of knowledge and experience between international experts and regulatory body personnel. Such advice and assistance will enhance nuclear safety in all nuclear countries. An IRRT mission is also a good training ground for observers from newly formed regulatory bodies in developing countries who follow the evaluation process. This approach, based on voluntary co-operation, contributes to the attainment of international standards of excellence in nuclear safety at the regulatory body level.

Essential features of the work of the IRRT experts and their regulatory body counterparts are the comparisons of regulatory practices with international guidelines and best practices, and a joint search for areas where practices can be enhanced. The implementation of any recommendations or suggestions, after consideration by the regulatory body, is entirely voluntary.

RaSIA

FOREWORD

Many States have engaged in an extensive programme to enact laws¹ and establish a regulatory infrastructure to implement the requirements of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources (the BSS), published as Safety Series No. 115 in 1996 and the requirements of the IAEA Safety Standard GS-R-1 on Legal & Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (GS-R.1). In support of this programme, the IAEA introduced a technical cooperation programme (Model Project on Upgrading Radiation Protection Infrastructure) to improve the infrastructure for radiation protection and safety of radioactive sources. A first priority was assistance for strengthening their regulatory programmes for radiation safety. Subsequently, on 25 September 1998, the IAEA's General Conference adopted resolution (GC(42)/RES/12), which encouraged all governments to; "*take steps to ensure the existence within their territories of effective national systems of control for ensuring the safety of radioactive sources and the security of radioactive materials*". More than 100 States have received technical cooperation assistance through national and regional TC projects, regional agreements, regular and extra-budgetary programmes.

Appraisal of the effectiveness of a regulatory programme for radiation safety is an important part of quality assurance, both with regard to implementation of the International Standards (BSS and GS-R.1), *the Code of Conduct on the Safety and Security of Radioactive Sources* and meeting the objectives of the General Conference resolution of 25 September 1998. Consequently, a document (IAEA-TECDOC-1217) was developed to provide a methodology by which the status of the infrastructure for a regulatory programme for radiation safety could be assessed. Appraisal also identifies areas where improvements are necessary or useful. Initially, appraisals were provided through IAEA 'Radiation Safety Regulatory Infrastructure' (RSRI) missions. By the end of 2002 some 56 appraisals (peer reviews), based on TECDOC-1217 methodology, had been completed and experience gained has been invaluable in developing this present document.

¹ There is some variation in the terminology used by States. However, in the context of this document "*law*" is taken to mean the primary *legislation* (Act, Statute, Decree, etc) which establishes both the regulatory body and the principles by which workers, the public and the environment are to be protected against the hazards of ionizing radiation, as well as the *regulations*. For the purposes of the RaSIA, legislation and regulations are appraised separately.

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 IRRT/RaSIA reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

Upon the request of the Romanian Authorities, an IAEA team of ten experts visited the National Commission for Nuclear Activities Control (Comisia Națională pentru Controlul Activităților Nucleare – CNCAN) from 16 to 26 January, 2006 to conduct an Integrated Regulatory Review Service (IRRS) (follow-up mission of IRRT and RaSIA).

The purpose of the mission was to review the effectiveness of the regulatory body of Romania and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety. The mission had two particular objectives: the first one related to the review of the progress in implementing recommendations or suggestions resulting from previous missions: International Regulatory Review Team - IRRT (May, 2002) and Radiation Safety Infrastructure Appraisal – RaSIA (May, 2004) and the second one was to provide further reviews in areas where significant changes have been reported since the previous missions.

This mission was the first follow-up mission integrating both IRRT and RaSIA content using the IRRS concept. It has demonstrated full compliance with the IRRT and RaSIA content and provided a more comprehensive review of the national regulatory infrastructure for nuclear, radiation, radioactive waste and transport safety.

The team reviewed the response to the recommendations and suggestions from the previous missions in a systematic manner. During the review the team recognized that CNCAN has taken a number of initiatives to improve its effectiveness and efficiency and that it faces a number of new challenges. In the opinion of the team these initiatives have resulted in significant improvements.

The team considers that it is important to mention that the number of new recommendations reflects the detailed evaluation carried out by each reviewer and the number of such recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Therefore comparisons of such numbers between IRRT/RaSIA reports from different countries should not be attempted.

The team considers it important to highlight the proactive role of CNCAN regarding the international arrangements as well as its involvement in the International Conventions. In particular with the IAEA and other regulatory forums in order to receive assistance/advice and to exchange safety related information to continuously improve its effectiveness and efficiency.

In the opinion of the team, many recommendations and suggestions from the previous missions have been successfully addressed, particularly those which CNCAN had the full responsibility for implementation. Some of them are in preparation status at the level of preparation plan and only few of the remaining recommendations need additional efforts in order to be implemented.

Progress has been identified in particular in:

- New Ordinances and Laws
- Issuing new regulations
- Improved Organization of the Regulatory Body
- Consistent authorization process
- Well planned and implemented of on-site inspections and written procedures

- Well established CNCAN Quality Management System
- Consistent Nuclear Safety strategy for next 5 years
- Well established authorization process for waste management facilities
- Encouraging the ALARA Committee on the NPP
- Developments of Procedures and Check-list for Authorization Process

The report however includes new recommendations or suggestions where improvements are necessary or desirable to further strengthen the legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety.

The team believes that the following items should be given high priority because they were identified in several review areas or because the experts consider that they will significantly contribute to the enhancement of the overall performance of the regulatory system:

- Nuclear Agency overlap and conflict
- Regulations containing licensing requirements for nuclear installations to met IAEA Safety Standards
- Insufficient staffing in different Areas considering the regulated installations
- Insufficient skills on radiation protection area
- Improvements on safety analysis independent capability
- Enhancing Probabilistic Safety Assessment capabilities
- Enhancing conduct of inspections on industrial and medical facilities
- Improve arrangements among authorization, regulation, inspection for waste management activities

The report also includes a number of new suggestions to further strengthen the regulatory body in Romania and to support the observed continuous improvement. In addition, the reviewers also identified a number of new good practices and these have been recorded for the benefit of other Nuclear Regulatory Bodies.

The Mission Findings are summarized in Appendix V.

CNCAN staff put a significant effort into the preparation of the mission. During the review the administrative and logistic support was excellent and the team extended full co-operation during technical discussions with CNCAN personnel. CNCAN counterparts were enthusiastic and interested in obtaining further advice on the way they conduct their work and on their plans for further development.

I. INTRODUCTION

BACKGROUND

At the request of the Romanian authorities, an IAEA team of ten experts visited the National Commission for Nuclear Activities Control (Comisia Națională pentru Controlul Activităților Nucleare – CNCAN) in May 2002 to conduct a full scope International Regulatory Review Team (IRRT) mission. Following an Agency's proposal and its acceptance by the Romanian Competent Authority, National Commission for Nuclear Activities Control (CNCAN), a Radiation Safety Infrastructure Appraisal (RaSIA), took place in May 2004 in Romania conducted by IAEA team of six experts.

On August, 2005 the Romanian authorities requested an Integrated Regulatory Review Service (IRRS) follow-up mission, based on both to review the measures undertaken following the recommendations and on the suggestions presented in the IRRT/RaSIA reports (see Appendix IV). This review was conducted from 16 to 26 January 2006 by an IAEA team of ten experts. Before taking part in the mission the experts reviewed the Advanced Reference Material provided by CNCAN. It included descriptive material, reports showing CNCAN changes from last reviews and a table summarizing the response from CNCAN to the set of recommendations and suggestions presented in the reports of the previous missions.

The team reviewed the response to the recommendations and suggestions from the previous mission in a systematic manner. During the review the team recognized that CNCAN has taken a number of initiatives to improve its effectiveness and efficiency and that CNCAN faces several new challenges. These include additional responsibilities in the regulation of nuclear facilities and the use of radiation sources and those resulting from the regulatory aspects coming from the construction of a nuclear power plant unit Cernavoda II.

The IRRS activities took place at the CNCAN offices in Bucharest and direct observations in different Romanian installations and facilities were carried out according to the Mission Programme established in Appendix II. At the invitation of CNCAN, representatives of the Prime Ministers Office were also interviewed.

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS Follow-up to review the effectiveness of the regulatory body of Romania and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety.

Specifically, the mission had two particular objectives: the first one related to the review of the progress in implementing improvements resulting from previous IRRT/RaSIA missions (recommendations or suggestions); and the second one to provide further reviews in areas where significant changes have been reported since the previous missions.

Particularly, the objective of the specific missions was the following:

IRRT missions are tailored to address the specific needs or activities of the regulatory body, or to review a situation where the scope of regulatory responsibility is changing.

The key objectives of an IRRT mission are to enhance nuclear safety by:

- Providing the host country (regulatory body and governmental authorities) with an objective peer review of their nuclear regulatory practices with respect to international safety standards;
- Providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance falls short of internationally accepted standards;
- Providing key staff at the host regulatory body with an opportunity to discuss their practices with experts who have experience of other practices in the same field;
- Providing all Member States with information regarding good practices identified in the course of the review; and
- Providing experts from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.

In addition in preparing for the mission the IRRT:

- Provides the host country (regulatory body and governmental authorities) through completion of the IRRT questionnaire with an opportunity for self-assessment of its activities against International Standards

RaSIA is designed to provide the IAEA and the State in question with a means for evaluating progress in establishing and/or implementing a national regulatory infrastructure for radiation safety. The report therefore, encompasses many separate areas of IAEA expertise.

The aim of any RaSIA mission is to assist the requesting State in assessing and, if needed, improving its regulatory infrastructure for radiation safety and the security of radioactive sources by:

- Conducting an appraisal of the current status of the national regulatory infrastructure for radiation safety and security of radioactive sources with regard to international standards, the *Code of Conduct for the Safety and Security of Radioactive Sources* and other IAEA publications;

- Recommending actions and improvements in areas where shortcomings and deficiencies (against relevant international standards and the Code of Conduct) have been identified;
- Providing an action plan for improving the national regulatory infrastructure in accordance with standards and the *Code of Conduct*; and
- Identifying and sharing good practice.

The primary objectives of RaSIA are to:

- Determine the detailed status of development of each element of the regulatory regime; and,
- Provide advice and recommendations with regard to any identified needs for improvement.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work was carried out by G. Caruso, NSNI/ IAEA staff member, acting as the Team Leader of the mission and by S. Evans NSRW/IAEA staff member, acting as Deputy Team Leader. In accordance with the request from CNCAN, and taking into account the scope as above indicated, it was agreed that the IAEA review team was comprised of 5 external experts: Mr. West, Bill (United Kingdom), Mr. Misak, Jozef (Slovak Republic), Mr. Lecomte, Thierry (France), Mr. Mallick, Shahid (Pakistan), Mr. Van Aarle, Jan (Switzerland) and one external expert as Observer Mr. JUBIN, Jean-Rene (France). The IAEA staff experts were Mr. Jova Sed, Luis (IAEA/NSRW) and Mr. Guo, Lingquan (IAEA/NSNI).

The working areas and the Romanian counterparts were distributed according to Appendix III.

During the preparatory period the electronic file of the documents were sent by CNCAN and distributed to the experts. All details and organizational aspects were defined with the nominated CNCAN Counterpart, acting as Liaison Officer Mr. Lucian Biro, Director of the Nuclear Reactors Division.

B) REFERENCES FOR THE REVIEW

The main reference documents provided by CNCAN for the review mission are indicated in Appendix VI part A. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VI part B.

C) CONDUCT OF THE REVIEW

During the mission, a systematic review for both the measures implemented and the progress made was completed. The review was conducted through meetings and visits to the different areas and buildings of the CNCAN and regulated facilities reviewing the written material, interviewing the CNCAN personnel and through direct observations regarding the national practices and activities.

The team performed its activities based on the Mission Programme stated in Appendix II. Additionally, specific topics were reviewed considering the changes since the last missions.

The Exit meeting was held on Thursday, morning with the CNCAN authorities, Mr. V. Zsombori, President of CNCAN, Mr. L. Biro, Director of the Nuclear Reactors Division, Managers, Section Heads and Technical staff. The draft mission report was handed over to CNCAN at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

The principal documents of the Romanian legislation are listed below:

- (1) Law No. 111 / 10 October 1996, on the Safe Deployment of Nuclear Activities republished with subsequent modifications and completions (hereafter referred to as Law No. 111/1996);
- (2) Governmental Ordinance No. 2 / 4 January 2001 on the distribution of responsibilities among ministries of the Government of Romania;
- (3) Law No. 703 / 3 December 2001, on the Civil Liability for Nuclear Damage with subsequent modifications and completions;
- (4) Law No. 24 / 27 March 2000, on Legislative Technique Norms for Elaboration of Normative Acts republished;
- (5) Governmental Ordinance No. 14 / 13 March 2000, on establishment of the civil protection formations for emergency intervention in case of disasters approved by Law 448/2001;
- (6) Law No. 197 / 4 November 1998, on the approval of Governmental Ordinance no. 19/1997 on transports.

In the period since the IRRT mission in 2002 and the RaSSIA mission in 2004 there have been a number of changes relating to legislative and governmental responsibilities.

In addition to the legislation above, the following new legislations have been approved:

- 1.1.1. Law No. 321/2003 approving the Governmental Ordinance No. 7/2003 on the use of nuclear energy exclusively for peaceful purposes
- 1.1.2. Law No. 320/2003 approving the Governmental Ordinance No. 11/2003 on the management of spent nuclear fuel and radioactive waste, including final disposal
- 1.1.3. Government Ordinance No. 64/ 26 June 2003 for establishing some measures on setting-up organisation, reorganisation or functioning of some structures within the Government, of ministries and other specialized organisations of central public administration and of public institutions, approved by Law 191/2004
- 1.1.4. Ordinance No. 11 / 2003, dated 30 January 2003 published in official Law Bulletin, Part 1, No. 61 from 01/02/2003 on *Management of Spent Nuclear Fuel and Radioactive Waste, including Final Disposal*".
- 1.1.5. Government Decision No 1627 / 2003 'Rule for Organising and Functioning of CNCAN' (Decision 1627), published in Official Gazette 27.01.04.
- 1.1.6. Government Decision No 750 of 14.05.04 of 14.05.04 (Amendment 750).
- 1.1.7. Law 194/2004 dated 25/05/2004 published in official Bulletin, part 1 no. 486 dated 31/05/2004 on approval of Ordinance No. 64/2003
- 1.1.8. Governmental Decision No. 1627/2003 approving the National Commission for Nuclear Activities Control internal rules with subsequent modifications;

- 1.1.9. Governmental Decision 894/2003 on approving the norms for application the provisions of the Law 703 / 3 December 2001, on the Civil Liability for Nuclear Damage;
- 1.1.10. Law no.481/2004 on civil protection;
- 1.1.11. Governmental Decision No.1489/2004 approving the National Committee for Emergency Situations internal rules;
- 1.1.12. Governmental Decision No.1490/2004 approving the General Inspectorate for Emergency Situations internal rules and organisational chart;
- 1.1.13. Governmental Decision No.1491/2004 approving the Framework regulation for organizational structure, attribution, functioning and endowment of emergency committees and operatives centers;
- 1.1.14. Governmental Decision No.1492/2004 on the organizational principles, functioning and attributions of professional emergency services;

The previous IRRT mission was informed that according to Article 55 of Law 111/1996, a further law would be introduced on the fund for radioactive waste and decommissioning. At the time of the previous mission, the draft law was awaiting approval by the relevant Ministers before presentation to Parliament for adoption and publication. However, this draft law was never promulgated. It should be noted that Article 55 has since been repealed under Amendment 193 / 2003. It is understood that the repeal of Article 55 was made because a separate authority called the National Agency for Radioactive Waste Management (ANDRAD) was created in 2002 under Ordinance No 11 / 2003 promulgated through Law no. 320/2003. This Agency is accountable to the Ministry of Economy and Commerce. However the IRRS Team was informed that the draft proposal for contribution to the fund for managing radioactive waste and decommissioning is still under discussion. This draft is likely to be incorporated in an amendment to Ordinance 11 / 2003 which resulted in the formation of ANDRAD.

The Law on Civil Liability which had not entered into force at the time of the last IRRT mission has now entered into force.

According to Article 12 of Ordinance No 11 / 2003 dated 30.01.2003 on “*Management of Spent Nuclear Fuel and Radioactive Waste, including Final Disposal*”, promulgated through Law No 320 and published in Official Gazette on 22.07.2003 the national competent authority of coordination at national level of safe management of spent nuclear fuel and radioactive waste, including final disposal is the National Agency for Radioactive Waste – ANDRAD.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

A number of ordinances and laws have been issued since the 2002 IRRT as mentioned above. Some of these have implications on the effective independence of CNCAN especially law no. 320/2003 and 321/2003 (See section 1.2 on “Position of CNCAN” for detail of these

implications).

1.1.1. Findings of the 2006 follow-up IRRS mission

No new findings were identified for this section.

1.1.1.1. Recommendations, Suggestions and Good Practices

There were no recommendations or suggestions for this section

1.2 POSITION AND RESOURCES OF THE REGULATORY BODY

1.2.1 Position of CNCAN

According to Article 4 (1) of Law 111 / 1996 as amended by Law 193 / 2003), CNCAN is “*The competent national authority in the nuclear field...and coordinated by the Ministry of Water and Environment*”. However, subsequent to promulgation of Ordinance No 64 / 2003 dated 26.06.2003 titled: “*Establishing, Organising, Re-organising or Functioning of Some Structures of Work, Apparatus of the Government, Ministries, of Speciality Bodies, of Central Public Administration and of some Public Institutions*”, through Law No 194 / 2004 dated 25.05.2004 on “*Approval Of Ordinance No 64 / 2003*” moves responsibility for coordination of CNCAN from the Ministry of Water and Environment to the Office of the Prime Minister. With such a modification CNCAN link at the highest level of Government is further enhanced.

However, according to Ordinance No 7 / 2003 (r1) and subsequent law 321/2003 on “*Use of Nuclear Energy for Peaceful Purposes*” republished in the Official Gazette No 59 on 01.02.2003 this is a promotional Ordinance, and Article 7 of this law establishes a Nuclear Agency which is under the Ministry of Research and Education. However Article 3 of this law is in conflict with the requirement for establishing a regulatory body that shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. Article 3 of Ordinance No 7/2003 (r1) defines the activities of Nuclear Agency as responsible for physical protection of nuclear and radiological facilities; quality management, nuclear safety, radiation protection and preparing regulations at national level in nuclear field. This ordinance was promulgated through the law 321/2003. Similarly Article 3 of Government Rule on Organising and functioning of Nuclear Agency dated 17/12/2003 reiterates the definition of activities of Nuclear Agency as the state authority, which ensures an approval from nuclear safety point of view of the feasibility studies and investment projects in nuclear field.

Again Article 17(g) of Ordinance 7/2003 (r1) states “*the Agency is responsible for analyzing periodical information presented by CNCAN regarding safety of nuclear and radiological installations*”. Although this Ordinance under Article 13 explicitly states that the regulatory control in the nuclear domain remains in the purview of CNCAN. However, from article 3 and 17 of Ordinance no. 7/2003 and article 3 of the govt rule dated 17/12/2003 there seems to be significant overlap in responsibilities of CNCAN and Nuclear Agency (AN) which has implications for the effective independence of CNCAN especially in view that AN is by definition a promotional body.

According to Article 9 (1) of Ordinance No 11 / 2003 dated 30.01.2003 on “*Management of Spent Nuclear Fuel and Radioactive Waste, including Final Disposal*”, promulgated through Law No 320 and published in Official Gazette, part 1 no. 527 on 22.07.2003 the national competent authority of coordination at national level of safe management of spent nuclear fuel and radioactive waste, including final disposal is the National Agency for Radioactive Waste – ANDRAD. Article 15 of the law 320/2003 defines the responsibility of ANDRAD as body that elaborate specific technical norms and procedures for all stages of spent nuclear fuel. The related government decision no. 1601/2003 and rules on organising and functioning of ANDRAD further reiterates the responsibility of ANDRAD among others as the authority to elaborate specific technical norms and procedures for all stages of management of spent fuel and radioactive waste, including final waste disposal and decommissioning of nuclear and radiological installations. The article 15 of law 320/2003 is in conflict with Article 5 (1) of law 111/1996 and its subsequent amendment through law 193/2003 which states “*The Commission is empowered to issue regulations.....for management of radioactive waste and spent nuclear fuel... as well as any other regulations necessary for authorization and control activity in nuclear field*”.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

Significant changes were made since 2002 IRRT because of promulgation of Law 320/2003 and Law no 321/ 2003 and both these laws have implications on position and independence of CNCAN.

1.2.1. Findings of the 2006 follow-up IRRS mission

Article 3 and 17 of Ordinance no. 7/2003 and article 3 of the govt rule dated 17/12/2003 shows significant overlap in responsibilities of CNCAN and Nuclear Agency which has implications for the effective independence of CNCAN especially in view that Nuclear Agency is by definition a promotional body.

The article 15 of law 320/2003 is in conflict with Article 5 (1) of law 111/1996 and its subsequent amendment through law 193/2003, which states, “*The Commission is empowered to issue regulations for management of radioactive waste and spent nuclear fuel... as well as any other regulations necessary for authorization and control activity in nuclear field*”.

1.2.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA Safety Standards Series (SSS) document GS-R-1 Requirements: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (LGI) requires in §2.2(2) that “*A regulatory body shall be established and*

maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgments can be made and enforcement actions taken, without pressure from interests that may conflict with safety”.

- R1) **Recommendations:** *The Government of Romania should consider revision of conflicting sections of Articles 3 and 17 of law 321/2003 and related government decisions and rules so that the regulatory body remains effectively independent and judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.*
- 2) **BASIS:** IAEA Safety Standards Series (SSS) document GS-R-1 Requirements: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (LGI) requires in §2.2(3) that “*Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides*”.
- R2) **Recommendations:** *The Government of Romania should consider repeal of overlapping sections of Articles 9 of law 320/2003 and related government decisions and rules so that clear responsibility could be assigned to the regulatory body for establishing safety principles, criteria, and regulations for safe management of spent nuclear fuel and radioactive waste.*

1.2.3. Resources assigned to the Regulatory Body

In accordance with the recommendation made by the previous IRRT mission Law 111 / 1996 Article 4 has been amended to make provision for an income regime for regulatory body staff consistent with the incomes offered to equivalent staff in the nuclear power plant.

The amended Article 4 (3) states that “*The commission finances shall be fully provided from extra-budgetary revenues obtained out of charges for the authorisation and control of the nuclear activities stipulated under Article 2, and contributions from International institutions or traders*”. The provision of contributions from international institutions or traders could impact on the effective independence of the regulatory body. It was further noted that there is a draft proposal for revision of this same Article approved by the Senate, which further aggravates the situation allowing contributions from “*other sources*” also.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- “*The new legislative framework should effectively provide for an income regime for the staff of the Regulatory Body consistent with the incomes offered to staff of equivalent level in NPP*”.

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

In accordance with the recommendation made by the previous IRRT mission Law 111 / 1996 Article 4 has been amended to make provision for an income regime for regulatory body staff consistent with the incomes offered to equivalent staff in the nuclear power plant.

1.2.3.1. Findings of the 2006 follow-up IRRS mission

The provision of contributions from international institutions or traders could impact on the effective independence of the regulatory body. It was further noted that there is a draft proposal for revision of this same Article, which further aggravates the situation allowing contributions from “*other sources*” also.

1.2.3.2. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA Safety Standards Series (SSS) document GS-R-1 Requirements: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (LGI) requires in §2.2(2) that “*A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgments can be made and enforcement actions taken, without pressure from interests that may conflict with safety*”, IAEA Safety Standards Series (SSS) document GS-R-1 Requirements: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (LGI) requires in §2.2(4) that “*The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities*”.
- R3) **Recommendation:** *The Government of Romania should consider amending Article 4 of the Law 111 / 1996 to ensure the regulatory body may not be unduly influenced.*

2. AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

2.1 GENERAL SITUATION

As reported by the previous IRRT and RaSIA missions CNCAN has broad responsibilities and functions with clear authority in the related fields. Under Law 111 / 1996 and its subsequent amendment to develop safety principles and criteria, establish legally binding regulations (Article 5 Law 111 / 1996) and issue guidance. Article 31 (1) (e and f) explicitly requires the operator to provide any necessary information including that from its suppliers even if this information is proprietary. CNCAN has robust mechanisms for confidentiality of proprietary information in accordance with the requirements of Romanian general law.

Chapter IV “Control Rules” of Law 111 / 1996 provides details of the authority on how to issue, amend, suspend or revoke authorisation and set conditions. Article 31 (1) gives authority to enter a site or facility at any time to carry out inspections and enforce regulatory requirements.

Decision 1627 / 2003 ‘*Rule for Organising and Functioning of CNCAN*’ provides a clear and direct line of communication between the President of CNCAN and the Office of the Prime Minister. 1627 / 2003 and its subsequent amendments also establish authority to communicate independently its regulatory decisions, opinions and their basis to the public.

Article 1 paragraph 2 of 1627 / 2003 states that CNCAN is a legal entity and institution of national interest funded entirely from its own income being in coordination with the Office of the Prime Minister.

Article 9 Paragraph 1 of 1627 / 2003 sets out the organisational structure of CNCAN which is attached as Annex 1 of this document. Article 9 Paragraph 2 as amended states that the President of CNCAN, with the advice of the PM’s Office, organises the subsidiary structures of the Divisions of CNCAN depending on actual need and conditions of the activities of CNCAN.

Amended Article 9 Paragraph 3 gives the maximum number of staff of CNCAN as 171 excluding the President.

Article 9 Paragraph 4 states the number of staff necessary per section and/or branch is established by order of the CNCAN President in compliance with legal provisions (these legal provisions are defined in Article 17 Paragraph 2 and are of an internal nature).

Article 9 Paragraph 5 states CNCAN posts and their hierarchy are decided by the CNCAN President in accordance with the advice of the PM’s Office.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions for this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions for this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

No significant changes apart from those already discussed in previous chapter regarding some overlapping and conflicting of authority and responsibilities between CNCAN and Nuclear Agency as well as CNCAN vs ANDRAD under law no. 321/2003 and law no. 320/2003

2.1.1. Findings of the 2006 follow-up IRRS mission

Overlapping and conflicting of authority and responsibilities were found between CNCAN and Nuclear Agency as well as CNCAN vs ANDRAD under law no. 321/2003 and Law no. 320/2003. These findings and subsequent recommendations have been addressed in chapter 1.

2.1.2. Recommendations, Suggestions and Good Practices

See related recommendations in section 1.2.1.1

2.2. COORDINATION WITH OTHER BODIES

In addition to Appendix 3 of Law 111 / 1996 which lists all the bodies involved in the control of nuclear activities, CNCAN has established formal Memorandums of Understanding with the following national organisations:

- The Ministry of Health 03.93;
- The General Inspectorate of Police 03.93;
- The Legal Metrology Bureau 07.97;
- The National Agency for Exports Control 06.01;
- The Romanian Intelligence Service 04.04;
- Customs National Authority 09.05.

Although Article 34 (1) of Law No. 111/1996 assigns clear authority to CNCAN for co-ordination with all such bodies, these Memorandums of Understanding help to prevent potential gaps and overlaps in the implementation of the respective duties and responsibilities of all such bodies.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions for this section*

RaSIA 2004 Recommendations:

- *CNCAN should extend its policy with regard to the establishment of Memorandums of Understanding to include all relevant national agencies involved in the regulatory process.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Since the IRRT 2002 and RaSIA 2004 report two additional Memorandums of Understanding have

been made and this reflects the recommendation of the RaSIA mission.

2.4.1. Findings of the 2006 follow-up IRRS mission

There are no findings in this section

2.4.1.1. Recommendations, Suggestions and Good Practices

G1) **Good Practices:** *Although the Law 111/1996 provides clear direction for CNCAN to coordinate the activities of bodies given in Appendix 3 of Law 111/1996 engaged in the control of nuclear activities, having several Memorandums of Understanding clearly helps at the implementation level.*

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

The primary role of CNCAN continues to be the regulation of the safety of nuclear installations and activities involving the use of ionising radiation in Romania. As reported in the 2002 IRRT report and the RaSIA report of 2004, the responsibilities and authority of CNCAN were established in the Romanian Government Decision No. 287 / 27 May 1998.

The current structure of CNCAN has a staffing complement that has increased since the 2002 IRRT mission from 80 to 133 (of an approved establishment of 171).

The approval of the organisational structure of CNCAN is a two-step process: Article 9 Paragraph 2 of Governmental Decision 1627 / 2003 as amended (Decision No 750) states that the President of CNCAN with the advice of the Prime Minister Office (PMO), may organise the subsidiary structures of the Divisions of CNCAN depending on needs and the activities of CNCAN. The more senior tiers however, are appointed in consultation with the PMO. By implication, CNCAN Divisions and higher levels of its hierarchy are decided only with the agreement of the PMO. This mechanism has implications for the responsiveness and adaptability of the regulatory body over the course of time.

The CNCAN organisational structure and its position in governmental structure are shown in Appendix I and Appendix II (Figure 1 and Figure 2). Since the earlier missions, the number of Divisions has increased from five to eight and some Divisions have been renamed. The current eight Divisions are:

- The Nuclear Reactors Division;
- The Quality Control Division;
- The Ionising Radiation Division;
- The Radiation Protection and Radioactive Waste Division;
- The Special Materials Division;
- The Economic Division.
- The International Affairs Division;
- The Public Relations Division.

The latter two are relatively new additions to the Divisional structure. Each Division comprises two or three sections.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions for this section*

RaSIA 2004 Recommendations:

- *CNCAN should consider organizational realignment such that inspections are carried out by one group/section, instead of by both the authorization and inspection sections.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Since the earlier missions the number of Divisions has increased from five to eight and some Divisions have been renamed. The current structure of CNCAN has a staffing complement that has increased since the 2002 IRRT mission from 80 to 133 (of an approved establishment of 171).

The senior tiers in CNCAN are appointed in consultation with the PMO. By implication, CNCAN Divisions and higher levels of its hierarchy are decided only with the agreement of the PMO. This mechanism has implications for the responsiveness and adaptability of the regulatory body over the course of time.

3.1.1. Findings of the 2006 follow-up IRRS mission

The approval mechanism of the organization structure indicates certain rigidity, which has implications for responsiveness and adaptability of the regulatory body.

3.1.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS Report No. GS-R-1 “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety” states in §4.1 that “*The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently*” and in addition IAEA SSS Report No. GS-G-1.1 “Organisation and Staffing of the Regulatory Body for Nuclear Facilities” recommends in §3.2 that “*the structure and composition of the regulatory body should be adapted in the course of time for it to be able to act effectively and to address key issues ...*”
- R4) **Recommendations:** *The Government of Romania should consider a review of Governmental Decision 1627 / 2003 in order to provide CNCAN with greater flexibility in the management of its organisational structure.*

3.2 QUALITY MANAGEMENT SYSTEM

CNCAN has revised the Quality Manual (MMC - CNCAN Rev. 3) first introduced in 2002.

Good progress has been achieved in the dissemination of the Manual (as recommended by the 2002 IRRT) and in December 2005 an elaborate internal audit which included both technical and administrative aspects of the Quality Management System (QMS) was performed as per the suggestion of the IRRT 2002 team.

The audit involved each Division and yielded a total of five findings. In addition, a number of recommended improvements affecting every Division were also made by the audit team. For instance, in the Economic Division two recommendations and one finding were reported. The finding states that internal procedures regarding management activities in the Economic Division shall be made known to the personnel of the Division through a programme of internal training and active involvement in the consultation process. Similarly, the Ionising Radiation Division received two recommendations related to prioritising the issuance of regulations. For the Radiation Protection and Radioactive Waste Division two recommendations and two findings were reported.

One of the the findings related to the need to develop a procedure for the conduct of control activities. It was also found that relevant QMS documents and procedures were not available in the Emergency Response Centre. Only one finding was reported in Nuclear Reactors Division and that related to the need for planning and optimizing the workload arising from licensee applications as there was a concern that the workload on staff members might have negative impact on effectiveness.

Under a PHARE project the CNCAN quality management system was reviewed in February 2005 and advice was given regarding better management of the system and in particular improvements to the quality manual.

In order to raise understanding of QMS, all relevant procedures are sent for review and approval to all the divisions and departments. The quality manual is also distributed to each division for use and for periodic training. The manual and all relevant procedures are available in electronic format on local area network.

CNCAN as per the suggestion of the IAEA 2002 IRRT mission has published annual reports on its activities to be disseminated amongst its stakeholders and staff. Progress has also been made on the suggestion of the 2002 IRRT mission for the creation of a staff-experience matrix which provides a detailed profile of each staff member including qualifications, experience, training and job description.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Recommendation: Some formal arrangements exist to ensure that staff are aware of the contents of the Quality Manual in relation to the function that they perform. These arrangements should be extended to all Directorates.*
- *Suggestion: CNCAN should consider publishing reports on its activities that include disseminating to its stakeholders the objectives of the organisation. Such dissemination would also serve to enhance the awareness of CNCAN staff on the policies of the organisation.*
- *Suggestion: The audit of the CNCAN working arrangements against the requirements of the Quality Manual planned for 2002 should include both the technical and administrative aspects of the arrangements.*
- *Suggestion: CNCAN should consider the creation of a staff/experience matrix which could identify the individuals suitable for specific work.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions for this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Since the previous missions, CNCAN has developed effective mechanism for the dissemination of the Quality Manual, which includes sending relevant procedures for review and approval to all the divisions and departments. The availability of the manual and all relevant procedures in electronic format on local area network helps in its dissemination within all divisions/departments within CNCAN.

CNCAN has published annual report on its activities for dissemination amongst its stakeholder and staff.

3.2.1 Findings of the 2006 follow-up IRRS mission

No findings were identified for this section.

3.2.1.1 Recommendations, Suggestions and Good Practices

There were no recommendations or suggestions for this section

3.3. STAFFING AND TRAINING

The CNCAN approved structure currently has 171 staff positions, (108 are regulatory, having advanced degrees and 25 administrative). As mentioned above the numbers of staff and Divisions have considerably increased to take account the construction and commissioning of Cernavoda Unit 2 and decommissioning of the Magurele research reactor. Three new Divisions have been introduced. The regulatory staff distribution amongst the Divisions and Sections is as follows:

- There are now 15 filled positions (from the total of 29) as against 9 filled positions in the Nuclear Reactors Division reported by the previous IRRT, of these 29, only 3 have reported to be designated as full-time inspectors. There are 14 positions vacancies in this division.
- There are 13 filled positions (from the total of 18) in the Division of Radiation Protection and Radioactive Waste out of which 4 are designated as inspectors. 5 positions are still vacant.
- There are 14 filled positions (from the total of 18) in the Division of Quality Control, of which 12 are designated as inspectors. 4 positions are still vacant.
- The Division of Special Materials has 13 filled positions (from the total of 14) and 1 vacancy.
- The Ionising Radiation Division has the largest number of positions. This division has 37 filled positions (from the total of 42) and 5 vacancies.
- International Affairs, Economic and Public Relations Divisions have collectively, 31 filled positions (from the total of 38) and 7 vacancies.

Not much evidence was found of qualification and experience requirement for a designated inspector for nuclear and radiological facilities. It seems that this designation is made during the time of recruitment and written in job description. Of the current staffing of 133, more than 90 have over 10 years pertinent experience. However, about 34 staff is considerably less experienced. In spite of this recent large recruitment of new staff there remain 38 posts to be filled. The recent introduction of a large number of relatively inexperienced staff has implications for the assimilation of such a large group into a small organisation and for the training policy and programme. CNCAN is aware of these implications and has formulated a good policy for training.

The policy recognises the need for systematic approach to training. A systematic training need assessment has been performed using IAEA guidelines (TECDOC 1254) for only the Nuclear Reactors Division to date. In view of the large number of new inexperienced people a systematic approach to training needs assessment is required across all the technical divisions. A procedure was elaborated (MC-PC-06) “Assesment of Training Needs and Training Planning” for systematic assessment of the training needs of CNCAN staff.

The training programme for the Nuclear Reactors Division is extensive and appropriate for people working in regulation of research reactors and nuclear power plants. However, it was noted that there is little awareness of the earlier CNCAN training programme initiated in collaboration of the AECB (now the CNSC) of Canada in 1990. Twelve CNCAN staff received, through the AECB programme, an extensive three months tailor-made training on the regulatory control of CANDU but unfortunately only 4 to 5 of these individuals remain at CNCAN.

Little evidence was found to confirm the effectiveness of the training programme in other Divisions, although staffs do have a programme mapped out for them, it does not appear to be based on a systematic training needs assessment and there is no formal evidence of its implementation or effectiveness.

Only 1% of the total CNCAN budget is formally dedicated to training (approximately 38,000 euros).

IRRT 2002 reported that CNCAN had suffered the loss of a number of experienced members of staff. This tendency is continuing to date. These problems are attributed by CNCAN to the low level of salaries available (although it should be noted that over the last three years, through the efforts of CNCAN and the 2003 amendment to Law 111 / 1996 allowing CNCAN to use licensing fees directly) salaries have been almost doubled. Despite the rise in salaries, it is understood there remains a significant differential between regulatory staff and the employees of the licensees and operators.

In direct contradiction with international standards, CNCAN continues to include a compensatory element in the salaries of staff that may be at risk of occupational radiation exposure. This was stated to be a matter of concern in the RaSIA of 2004.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2004 Recommendations:

- *Recommendation: CNCAN should take all necessary steps to ensure that the 11 vacant positions should be filled by suitably qualified and experienced persons as soon as possible.*
- *Recommendation: To complement the policies already implemented by the Directorates, CNCAN should produce a written general policy on training and staff development.*

RaSIA 2004 Recommendations:

- *CNCAN should consider the recruitment of additional staff in order to perform effectively its regulatory activity, in particular, at the regional offices.*
- *CNCAN should prepare and implement a structured training and qualification program for its staff, including the qualifications required to complete independent inspections of various license types.*
- *CNCAN should review the appropriateness of providing compensation to CNCAN staff on the basis of their status as radiation workers.*

Changes since the 2002 IRRT / 2004 RaSIA missions

The number of divisions has increased to eight similarly the number of staff has gone up to 133 with an approved establishment of 171. A systematic training need assessment has been performed using IAEA guidelines (TECDOC 1254) for only the Nuclear Reactors Division to date. In addition, CNCAN has developed a good policy on training of its staff.

3.3.1. Findings of the 2006 follow-up IRRS mission

In spite of this recent large recruitment of new staff there remain 38 posts to be filled. A systematic training need assessment has been performed using IAEA guidelines (TECDOC 1254) for only one of the divisions. For other divisions although staffs do have a programme mapped out for them, it does not appear to be based on a systematic training needs assessment and there is no formal evidence of its implementation or effectiveness.

It was also found that salaries package includes an explicit element of remuneration in compensation for the potential risk of occupational exposure in direct contradiction with International Standards.

3.3.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - According to §4.6 of IAEA SSS document GS-R-1 *“The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities.”*
- R5) **Recommendation:** *CNCAN should take all necessary steps to ensure that the vacant positions are filled by suitably qualified and experienced persons.*
- 2) **BASIS:** BSS 115 states in §I.15 that *“the conditions of service of workers shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of the Standards”.*
- R6) **Recommendation:** *The conditions of CNCAN staff shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of the Standards.*

- 3) **BASIS** - IAEA SSS document GS-R-1 states in §4.7 that “*In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes.*”
- S1) **Suggestions:** *One of the prerequisites of a well-defined training programme is to perform systematic training needs assessment. CNCAN should consider performing a systematic training needs assessment of all its Divisions, using the same model as that applied to the Nuclear Reactors Division, from which a formal training programme can be developed.*
- S2) **Suggestion:** *CNCAN should consider establishing a dedicated training unit for implementing the CNCAN training programme and an in-house training programme across all Divisions in a systematic and consistent manner in accordance with the needs of the regulatory programme.*

3.4. INTERNATIONAL CO-OPERATION

The CNCAN responsibilities in the field are stated mainly in Art. 35 (f, g, h) of the Law no. 111/1996 on safe deployment for nuclear activities republished with subsequent modification and completions. According to this provisions CNCAN is empowered to cooperate with the International Atomic Energy Agency (IAEA) in areas such as safety of nuclear installations, safeguards, physical protection of nuclear installations, waste management, transport of radioactive waste and nuclear materials, radiation protection and combating illicit trafficking of nuclear materials. Up to 2005, CNCAN was liaison office for the technical cooperation programme with the IAEA.

Also CNCAN is point of contact for early notification of nuclear accidents to IAEA, for safeguards and illicit trafficking as well as for INES scale events.

CNCAN fully participates in dedicated working groups of nuclear regulators such as: Western European Nuclear Regulators Association (WENRA), CANDU senior regulators working group and Central European Nuclear Safety (CENS).

CNCAN cooperates with nuclear regulatory authorities from Europe United States and Canada based on specific agreements concluded for this purpose. In order to apply the Convention on early notification of nuclear accident CNCAN is the competent authority for a number of agreements on early notification of nuclear accident concluded between the Government of Romanian and the Governments of neighbouring countries.

In accordance with Romania’s policy to accede to the European Union CNCAN was involved in the negotiation process of Chapter 14-Energy, subchapter “Nuclear sector” and Chapter 22-Environmental protection, subchapter “Nuclear safety and radiation protection”, being appointed as coordinator for the working groups under these subchapters.

Supplementary to these responsibilities CNCAN is national authority as provided by the Comprehensive Nuclear Test Ban Treaty according to the Art. 3 of the Law No. 152/1999.

3.4.1.1 Findings of the 2006 follow-up IRRS mission

There were no findings for this section

3.4.1.2. Recommendations, Suggestions and Good Practices

- G2) **Good Practice:** *The team considers it important to highlight the proactive role of CNCAN regarding the international arrangements as well as its involvement in the International Convention, in particular with the IAEA and other regulatory forums in order to receive assistance/advice and peer reviews in order to exchange safety related information and continuously improve its effectiveness and efficiency.*

4. AUTHORISATION

4.1. TYPES AND STAGES OF AUTHORISATION

According to Law No. 111/1996 three types of authorizations are granted by CNCAN:

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

The fulfilment of regulatory body conditions for authorization is confirmed both through:

- safety documents submitted by the operator;
- management system authorizations;
- specific authorization inspection programme performed by CNCAN prior to the authorization issuance.

The purpose of the authorization inspection programme is:

- verification of the plant modifications implementation status;
- verification of the fulfilment of CNCAN dispositions provided during previous inspections and assessment of operating activities;
- verification of the implementation of corrective action plans resulted from assessment of event reports;
- compliance with additional requirements for installation.

The completeness of safety documentation is independently assessed by CNCAN in order to satisfy itself that necessary documents submitted by the utility are in compliance with:

- nuclear law;
- nuclear safety regulations and quality management regulations;
- safety design guides;
- CNCAN dispositions;
- international methodologies applicable for that specific field.

The licences issued by CNCAN are time limited in accordance with the requirements specified in the regulations. Usually the authorization is limited to two years (for the QMS licenses the validity is two years, for the construction activities maximum three years). The application for the renewal of a license is mandatory within 30 days before the ending of the previous authorization.

Some authorizations are issued in cooperation with other authorities. In such cases approval by other authorities serves as necessary precondition for final approval by CNCAN.

Further in this chapter, the authorization process relevant to nuclear facilities and radiation sources is covered. The authorization process for waste management and transport of radioactive materials is addressed in the corresponding chapters of the report.

4.1.1. Authorisation for Nuclear Facilities and Activities

Among main nuclear installations under CNCAN supervision, there are units of Cernavoda NPP, fuel fabrication factory, 2 research reactors (one of them under decommissioning), and dry spent fuel storage from CANDU reactors. General conditions for authorization are provided in the Law

no. 111/1996 and its amendments, Chapter II, Section 2, art.18 - "Authorization conditions". Taking into account that each authorization is issued for one specific purpose and site, the content of the licence issued by CNCAN is adapted for each type of nuclear installation in order to specify clearly the authorization conditions.

Regarding Cernavoda NPP, its current state is reflected in the FSAR, which is updated every two years. In addition, the status of the design change implementation is made available to CNCAN by means of NPPs permanent surveillance activities.

CNCAN issues licence for deployment of the nuclear activities in different stages of a nuclear installation (multi-stage authorization process). For complex facilities such as a new construction (Cernavoda Unit 2) the licenses are issued depending on the main stages of the project. In accordance with la Law 111/1996, republished Art. 8 (6), the authorization phases of the nuclear facilities and plants shall, as applicable, be the following:

- designing;
- siting;
- production;
- construction and installation;
- commissioning;
- test operation;
- operation and maintenance;
- repair or modification;
- conservation;
- decommissioning.

The authorization process applied to the research reactors and fuel production facility is similar to the one followed for the NPP.

The conditions for issuing authorizations at each stage of nuclear installation are established in nuclear safety regulations and QMS regulations. As a prerequisite for the issuance of the construction / commissioning / operation / decommissioning licence, the Quality Management Authorization licence must be issued.

There is a given timeframe established for response by the regulatory body to any request of the licensee or of any applicant. The time limit is 30 days for granting the license or sending a written official reply. In case of the NPP, taking into account the amount of safety documentation volume that must be reviewed and assessed, this time limit is very short. Therefore in order to issue the licence for construction, commissioning and operation in time, CNCAN agrees with the operator for submission of the documents well in advance to the time of licensing application. In addition, since CNCAN receives quarterly plant reports and there are monthly licensing meetings, CNCAN maintains effective means for communicating to the applicant the findings arisen from the evaluation of the documents submitted and for receiving feedback. It seems that no real problems appeared till now from this time limit.

4.1.2. Authorisation of practices and activities using Radioactive Sources

As defined by the Order of CNCAN President No.40 / 1990 CNCAN radioactive sources are categorized taking into account a combination of the type of source, the activity and the practice. Using this approach, Annexes 1 to 5 of Order No. 40 define workplaces by radiological risk and from this the workplace category is defined in 5 levels ranging from 'Insignificant' to Category IV (this being the highest risk category).

However, the categorization system used is not fully compatible with the IAEA-TECDOC-1344.

Currently, sources with a ‘short half-life’ (such as Iridium 192) (CNCAN defines these informally as sources which are normally changed within approximately three months) are not included in the national inventory of sources because the limits of the CNCAN licence for such sources do not include the source identification number. Instead, for such short-life sources, the maximum activity of the source is stated in the licence. As a consequence, these sources do not currently appear in the national sources inventory (although records of the source are kept of the import and also with the file for the facility). There are plans to upgrade the CNCAN current database for the national inventory of radioactive sources in order to address this issue and also to ensure that the inventory will comply with international standards.

4.1.3. Authorisation of Licensees Quality Management Systems

Legal basis for the control of QMS of Nuclear Installations is the Law No. 111/1996, revised as the law No. 1993/2003. According to the law, all organizations that deploy nuclear activities in Romania must be authorized by CNCAN, i.e. authorization (license) by CNCAN of the QMS is a precondition for deployment of activities in the nuclear field. This is true not only for owners and operators of nuclear installations, but it is mandatory also for all their subcontractors. The capability of the applicant/licensee to understand the requirements placed on it and to produce required documentation is assessed by CNCAN during the QMS licensing stage. As a part of QMS authorization, CNCAN also authorizes minimum 2 persons responsible for development and auditing of the QMS. The requirements regarding the content of the QMS documentation are clearly defined in CNCAN regulations. Records regarding the licensees, inspections performed, etc. are stored in a CNCAN database.

In the years 2003, 2004, 2005 number of QMS licenses issued was 76, 77 and 78, respectively. At present, 99 organizations have the licenses; total number of licenses is 207. Every two years, CNCAN shall perform an audit and a number of inspections of every licensed organization. QMS is also subject of inspections. E.g. during 2005 outage at Cernavoda NPP, there were 42 relevant inspections, and 63 inspections in 2005 were on services of suppliers.

4.1.4. Authorisation of Selected Licensee Personnel

In addition to the Article 9 (1) of Law No. 111/1996, the general procedures and conditions for issuing a “practise permit” are further detailed in the newly issued (in 2005) regulation “Norms Relating Issuance of the Practice Permit for Operating Personnel, Management Personnel and Specific Training Personnel from Nuclear Installations”. This regulation defines the conditions relating the issuance of the practise permit for operating personnel, management personnel and specific training trainers / instructors, who carry on any specific nuclear activities in a NPP, research reactor or in another nuclear installation.

The regulation establishes:

- a) The qualification requirements for the operating personnel of the main control room, starting from commissioning phase of the nuclear installation up to complete removal of the nuclear fuel from the core, of the management personnel and the specific training trainers/instructors;
- b) The steps of the licensing process for each category;
- c) The issuance methodology of the practice permits for the above mentioned personnel and covers:
 - Objectives of candidate’s assessment,
 - Content and phases of evaluation,
 - Methodology of examinations,

- Criteria and performance indicators.

The CNCAN President appoints two examining commissions (one for NPP staff and one for research reactor staff, respectively) to conduct the examinations needed for the authorization of the selected licensee personnel. In the case of a positive result of the examination, CNCAN issues a “practise permit” with a validity of two years. Approx. 20 licenses are issued per year; currently 80-100 people have the license.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Suggestion: To further improve its effectiveness and efficiency and to ensure its effective independence, the CNCAN is advised to consider, whether it is appropriate, in future to modify Romanian legislation so as to release CNCAN from the responsibility for issuing quality assurance authorizations for nuclear facilities component suppliers and subcontractors.*
- *Suggestion: In order to make optimal use of the CNCAN staff resources, it might be useful to consider the assignment of QA authorization to the TSO once established.*
- *Suggestion: The CNCAN should consider involving experts from external relevant organizations in the work of the State Examination Commissions. CNCAN should consider appointing some of CNCAN Consultative Council members as members of these Commissions as well.*

RaSIA 2004 Recommendations

- *CNCAN should review their existing frequencies for routine inspections, as well as authorization renewals, to determine any inconsistencies with IAEA recommendations, and make adjustments as necessary, according to the categorization of radioactive sources.*
- *CNCAN should further expand its national inventory to include all Category 1 and 2 radiation sources and facilities (i.e., to include iridium-192).*
- *CNCAN should develop and implement a written procedure and checklist for the review of all authorization actions to ensure the consistency and accuracy among CNCAN staff performing these reviews.*

Changes since the 2002 IRRT / 2004 RaSIA missions

In the Law 193/2003, Art. 35o) CNCAN is empowered, in addition to previous authorizations, to authorize the carrying out of nuclear related constructions and to perform the state control over the quality of constructions within nuclear installations (e.g. for spent fuel storage). According to the same law, there is also the possibility to set-up a technical support organization for CNCAN.

Thirteen new regulations concerning QMS were elaborated and issued by CNCAN since last IRRT mission. The regulations are being improved using feedback from stakeholders, with the help of Consultative Committee for the Drafting and Revising the Quality Assurance Norms in Nuclear Field in order to achieve full compliance with the IAEA Safety Standards and EU Directives. Several workshops were held in order to familiarize stakeholders with newly issued regulations and a number of training materials were developed. In 2004, number of quality control personnel in CNCAN was increased from 7 to 14.

The new regulation “Norms Relating Issuance of the Practice Permit for Operating Personnel, Management Personnel and Specific Training Personnel from Nuclear Installations” has been issued in 2005. State Examining Commission now has two external experts out of 7 for NPP

commission, hired on contractual basis. For research reactors, there are 5 members of the commission.

4.1.5. Findings of the 2006 follow-up IRRS mission

Similarly as in 2002, the IRRS 2006 mission concluded that the authorization process for all of the nuclear facilities and related activities is consistent, systematic and well structured. No further recommendations are needed on the authorization process. However the following IRRS observation should be noted:

The IRRS team attended an inspection at the Nuclear Medicine facility of the Oncology Institute in Bucharest. Although this was a demonstration inspection, the Review Team made a significant observation relating to the authorisation process:

The facility was licensed in November 2005. At that time ‘*Norms of Radiological Safety on Nuclear Medicine*’ (NSR-14), was already approved and published in the Official Gazette Part I no. 139/ 15.02.2005. Thus the main requirements for the practice of nuclear medicine had come into force at least one year before a license was granted to the Oncology Institute.

Although the inspection did not assess compliance with medical exposure requirements and focused mainly on occupational exposure and other organizational aspects, nevertheless 12 instances of non-compliance with the established regulations were identified.

In the opinion of the Review Team this indicates that the authorization process and the pre-authorisation inspection did not adequately apply the established Regulation (NSR-14), with the consequence that an unconditional authorisation had been granted to a user not yet able to comply with regulatory requirements.

The process for selection, training and examination of personnel is well established by the norm and no further recommendation is needed in this area.

In general, authorization of the QMS of all organizations that deploy nuclear activities in Romania is very well established.

CNCAN management is of opinion that given the circumstances existing in the country it is justified that all organizations participating at projects in nuclear field, including subcontractors are certified by CNCAN. Since manpower of the Quality Control Division, within CNCAN was increased, according to the CNCAN management there is no need to transfer this activity to another organization. It is envisaged that authorization of subcontractors will be terminated after Romania joining EU.

However the IRRT experts consider, while recognizing that this type of authorization is a specific and legitimate part of CNCAN’s responsibilities, that according to the international practice the operating organizations/licensees are fully responsible for control of the implementation of QA procedures by their suppliers and subcontractors. In addition, the transfer of this work to the owners/operators would allow the workload placed on some of the CNCAN staff members to be reduced, to free resources to be used for other regulatory activities.

CNCAN has not yet adopted categorization of radiation sources in accordance with International Standards. Also the national register of radiation sources does not include sources considered to have a short half-life (considered by CNCAN to be sources which are replaced within three months).

4.1.5.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS GS-R-1 (LGI) requires in §5.3. that: “Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures”. IAEA SSS GS-R-1 (LGI) requires in §5.4. that: “The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.” IAEA SSS GS-R-1 (LGI) requires in §5.5. that: “The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either: (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator’s subsequent activities; or (2) the refusal of such an authorization. The regulatory body shall formally record the basis for these decisions.” IAEA SSS GS-R-1 (LGI) requires in §5.9. that: “A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that: (1) the available information demonstrates the safety of the facility or proposed activity; (2) the information contained in the operator’s submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements” ...
- R7) **Recommendation:** CNCAN should revise regulations on safety requirements for authorization of practices and facilities to include requirements for the documentation to be presented in support to the authorization request to ensure compliance with new IAEA Safety Standards and other international requirements, taking into account the current authorization needs.
- R8) **Recommendation:** CNCAN should review and as appropriate, revise or develop new procedures to review and assess applications for authorization (other than nuclear installations). These procedures should address the requirements of the approved regulation on the given practice, indicating the main safety criteria to be taken into account in the review process.
- R9) **Recommendation:** CNCAN should consider in the quality management system, the implementation of a routine second review of submitted documentation in support of the request for authorization in combination with the findings of a pre-inspection before authorisation is granted.

- 2) **BASIS:** The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in § 2.2 (2): *“A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgments can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.”* In addition, § 3.5 states: *“The regulatory body may also have additional functions. When such functions are undertaken, care shall be taken by the regulatory body to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished.”*
- R10) **Recommendation:** *In order to place prime responsibility on the operator for ensuring quality assurance of component suppliers and subcontractors, the present Romanian Legislation should be modified at the earliest opportunity so that CNCAN is released from its obligation to issue quality assurance authorizations for component suppliers and subcontractors.*
- 3) **BASIS:** Code of Conduct 2004 III, 11 – *“Every State should establish a national register of radioactive sources. This register should, as a minimum, include Category 1 and 2 radioactive sources as described in Annex 1 to this Code. The information contained in that register should be appropriately protected. For the purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavour to harmonise the formats of their registers”*
- R11) **Recommendation:** *CNCAN should adopt a system of categorization of radioactive sources in accordance with IAEA Standards.*
- R12) **Recommendation:** *CNCAN should upgrade its national inventory to include all Category 1 and 2 radiation sources (including those defined by CNCAN as ‘sources with a short half-life’).*

4.2 DOCUMENTATION PRODUCED BY THE REGULATOR

Control of licensing submissions is described in the internal CNCAN QA manual. The licensing process is documented according to CNCAN internal procedure. The bases for either granting or refusing an authorization application are substantiated in assessment/review reports and are recorded as part of authorization documents. The reports, especially the assessment reports and all other technical reports are kept as permanent records. Currently circulation of documents associated with any submission is recorded in a paper document, but there is a plan later on to use a computerized system.

The review and assessment by the regulatory body is according to the the Law 111/1996 documented by one of the following means:

- evaluation report;
- CNCAN official letters;
- reports on the CNCAN findings and dispositions issued after relevant regulatory inspections;
- written minutes as result of the license meetings..

The main document produced by the regulatory body is a license, or in case of authorization of personnel, a practice permitting document. All the limits and conditions derived for each specific case are clearly stated in the license. In the license there are sections devoted to QMS, emergency preparedness, radiation protection, reporting requirements, licensing basis documents, the hierarchy of documents of the licensee, etc.

General format and content of the licence has been established by CNCAN President Order and refers to:

- facility and activities covered by the authorization;
- period of validity;
- general conditions specifying the documents on which the authorization is based on;
- specific conditions on the facility organization and personnel;
- specific conditions for the operation (limits and conditions);
- specific conditions related to personnel, public and environment protection to radiation;
- specific conditions regarding approvals for design changes and changes in the operating conditions;
- specific conditions for the records management;
- specific conditions governing the procurement, possession, the use, transfer, and storage of the nuclear fuel, of the nuclear material, of radioactive material, and of radioactive sources;
- specific conditions regarding safeguards;
- specific conditions regarding physical protection;
- specific conditions regarding quality assurance;
- reporting requirements (incident reporting, quarterly and annual reports);
- specific conditions regarding periodic safety review;
- status of emergency preparedness arrangements (described in quarterly reports).

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Suggestion: In the development of the new regulations, which define the scope and type of the safety related documentation required from the licensee, CNCAN should consider the explicit inclusion of requirements for the performance of periodic safety reviews (PSR) in an appropriate document.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

CNCAN is developing a regulation on PSR, which is now in an advanced stage of drafting and it is envisaged that it will be sent for external consultation at the beginning of 2006. The regulation is mainly based on the IAEA Safety Guide on PSR and addresses all the related reference levels produced by WENRA. In the draft regulation, periodicity for the PSR is envisaged as 10 years.

Development of the PSR Programme is a specific condition included in Cernavoda NPP Unit 1 Operating License and according to it the licensee started an overall programme for the Periodic Systematic Review of Nuclear Safety, which covers the period 1997-2007. Activities of the PSR Programme are on-going and the scope of these activities covers all safety factors contained within by IAEA Safety Guide on PSR.

Since license renewal for all nuclear installations is required every 2 years, and the NPP is rather new, implementation of PSR is not considered as urgent task.

4.2.1. Findings of the 2006 follow-up IRRS mission

The operator should present the results of the first Periodic Safety Review for Unit 1 of Cernavoda NPP in 2007, i.e. there is still certain time available. However, since comprehensive evaluation of NPP safety within the framework of PSR is a manpower and time demanding task, CNCAN should finalize the regulation on PSR as soon as possible in order to minimize future efforts to adapt the PSR methodology and the evaluation criteria for compliance with the regulations.

4.2.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 3.3. (10) *“In order to discharge its main responsibilities... ..the regulatory body: (10) shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review.”*
- S3) **Suggestions:** *CNCAN is encouraged to finalize the regulation on Periodic Safety Review as soon as possible in order to minimize future efforts to put the ongoing PSR at Cernavoda NPP into compliance with the regulations.*

4.3 DOCUMENTATION PRODUCED BY THE LICENSEES

Technical documentation submitted by the applicant has to be issued in accordance with the requirements of the specific regulations for authorizations. The applicant has to demonstrate through this technical submission the compliance with the requirements of the safety and quality management principles and criteria. The quality and scope of the documentation to be presented by the operator are established by either nuclear safety and quality management regulations or by CNCAN official letter. General format and content for submission of documents supporting the license application is given in a regulation from 1975, which is valid for any type of nuclear installation and in each new submission it is supplemented by an official letter of CNCAN. Reference to additional specific supporting documents is listed in the license.

The Safety Analysis Report and its amendments form the main part of documentation to be produced by licensees. The report shall also include a section on the preliminary decommissioning plan and the conceptual plans or alternatives which can be used in the decommissioning. By means of the official letter CNCAN also updates scope of the safety documentation in order to reflect the current international requirements in the nuclear safety area.

The operator shall submit any documents required by the regulatory body by the deadlines specified by the regulator. In some specific cases CNCAN agrees with the operator during the monthly authorization meetings that the safety documentation to be submitted as they are developed before the official submission. Usually the submission of the safety documents for commissioning and operation licence starts at least 6 months in advance.

Currently, Final Safety Analysis Report (FSAR) of Cernavoda NPP is reviewed and updated every two years, unless otherwise required in writing by CNCAN by an official letter, typically related to operator's request for NPP modification. The updated FSAR is submitted to CNCAN and includes mainly the following aspects:

- new or updated safety analyses using current best-estimate methods and information;
- design and procedural changes;
- results of self-assessment by the plant;
- changes of plant procedures;
- the status of NPP's nuclear safety programmes regarding to:
 - physical condition of the nuclear power plant;
 - nuclear safety policy;
 - control of modifications;
 - systems surveillance;
 - strategic plan for renewal of nuclear safety analyses;
 - ageing and environmental qualification;
 - radioprotection;
 - environmental impact;
 - organization and administration;
 - shift structure for maintenance and operating personnel;
 - plant personnel training;
 - periodic inspections;
 - systematic revision of spare parts;
 - preventive maintenance;
 - development of the PSR programme;
 - emergency planning;
- PSA results.

Another kind of the document to be produced by the licensee in the future is a periodic Safety Review (PSR) report. Format and content of the report will be prescribed in a specific regulation on the PSR.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There was no recommendation made from this section.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

A number of QMS regulations have been issued by CNCAN, which specify the rules for the process of development of safety documentation.

4.3.1. Findings of the 2006 follow-up IRRS mission

Existing regulation describing regulatory requirements regarding safety documentation has been issued more than 30 years ago. Rather than ad hoc specification of format and content of safety documentation, the regulation “Nuclear Safety Norms - Nuclear Reactors and Nuclear Power Plants (1975)”, which contain provisions concerning licensing basis documentation, site evaluation criteria and design criteria for NPPs should be updated so as to specify the format and content of Safety Analysis Report for various nuclear installations in order to ensure compliance with the recent IAEA Safety Standards and international requirements on nuclear safety.

4.3.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 5.4. *“The regulatory body should issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.”*
Further on, Article 5.26 says *“Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.”*, Article 5.27 *“Guides, of a non-mandatory nature ... may also provide information on documentation to be submitted to the regulatory body by the operator”*, Article 5.28 *“Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards.”* More guidance can be found in IAEA Safety Guides No. GS-G.1.4 and GS-G.4.1.
- R13) **Recommendations:** *The regulation “Nuclear Safety Norms - Nuclear Reactors and Nuclear Power Plants (1975)” should be updated so as to specify the format and content of Safety Analysis Report for various nuclear installations in order to ensure compliance with the recent IAEA Safety Standards and other international requirements on nuclear safety.*

5. REVIEW AND ASSESSMENT

5.1 ESTABLISHMENT AND USE OF REVIEW AND ASSESSMENT CRITERIA

The following standards, guides and other IAEA documents are used to specify licensing requirements, which should be subsequently used as assessment criteria:

- Romanian nuclear safety norms (regulations);
- Canadian regulatory documents and standards for design, construction, testing and inspection of power plants components;
- IAEA safety standards;
- US. NRC Regulatory Guides;
- CNCAN technical procedures;
- Romanian quality management norms;
- Basic technical handbooks and advanced scientific references;
- IAEA TECDOCs.

From sample cases discussed during the IRRS it was seen, that most typically the criteria are set up by CNCAN ad hoc, usually approving criteria from country of origin as proposed by the applicant.

This chapter further on discusses the CNCAN review and assessment activities related to the NPP Cernavoda, the two Romanian research reactors, the fuel production facility in Pitesti and dry spent fuel storage from CANDU reactors. Review and assessment relevant to other facilities and activities, which are under CNCAN regulation, are addressed in the other corresponding chapters.

Recommendations and Suggestions from the 2002 IRRS / 2004 RaSIA reports

IRRS 2002 Recommendations:

- *There was no recommendation made from this section.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRS / 2004 RaSIA missions

CNCAN has started to develop a set of new technical regulations, which will contain specific acceptance criteria for demonstrating safety of nuclear installations.

5.1.1. Findings of the 2006 follow-up IRRS mission

Although present approach with ad hoc specification of acceptance criteria is acceptable, it would be more appropriate to codify such criteria comprehensively in the regulations. In particular, the regulation on safety of nuclear installations, which should replace the Nuclear Safety Norms - Nuclear Reactors and Nuclear Power Plants from 1975, should be developed as soon as possible. This finding is also in compliance with the needs identified through the harmonization study in WENRA countries.

5.1.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 5.8 “...the regulatory body shall define and make available to the operator the principles and criteria on which its judgements and decisions are based.” and in Article 5.26 “The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.”

Suggestions: See relevant suggestion in section 4.3.1.1 of this IRRS report.

5.2 MANAGEMENT OF REVIEW AND ASSESSMENT

The organizational structure of CNCAN is properly arranged in order to cover with specialists all assessment activities required in all phases of a facilities (site selection, design, construction, commissioning, operation and decommissioning). The Nuclear Reactors Division is mainly responsible for the review and assessment activities related to nuclear safety, but is usual practice to involve staff from other divisions and sections as needed. In some specific cases, assistance from external specialists was required to supplement the assessment needs of CNCAN. Review of major submissions is organized as a project, with distribution of tasks among sections and individuals. Review process is recorded in internal documents.

As regards the review and assessment from QMS point of view, CNCAN has issued quality management regulations for each stage of the lifetime of a nuclear power plant. Quality management specialists within CNCAN are monitoring each stage of the process and reviewing and assessing the documentation related, according to the quality management norm. A set of procedures establishing the administrative rules for conducting the review and assessment activities have been issued and they are included in the CNCAN QMS manual.

CNCAN uses external consultants in limited extent to assist CNCAN staff in licensing activities of NPP, research reactors and transport of radioactive materials. Use of external consultants covers a small part of CNCAN activities.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Recommendation: CNCAN management should take urgent actions to fill the position of Director of Directorate of Nuclear Safety with a suitably qualified expert.*
- *Recommendation: CNCAN management should take actions to complete its review and assessment procedures, to establish priorities and prepare its own programme to manage these activities in the most effective way, taking into account the available limited resources.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRR / 2004 RaSIA missions

In the CNCAN organization structure, the Nuclear Reactors Division is managed by Dr. Lucian Biro, as the division director and also as the project manager for Cernavoda NPP.

As a part of increasing CNCAN staff from 80 to 122, 4 more people were added to Nuclear Reactors Division. A set of internal procedures as follows has been issued in order to manage the review and assessment process:

- Assessment of Safety Documentation Attached to Licensing Application;
- Review and Assessment Activities of CNCAN during Commissioning of Cernavoda NPP;
- Renewal of NPP Operating Licence;
- Review of Commissioning Specifications;
- Regulation of Power Plant Commissioning;
- Documents to Be Included with an Application for an Operating Licence and Their Distribution;
- Overall Review of Licensee's Design and Accident Analysis;
- Approval of Reactor Power Ascensions during Phase "B" and Phase "C" Commissioning;
- Preparation of Specialist Assessment Work Requests and Assessment Reports or Comments;
- Fire Protection Programme Evaluation.

5.2.1. Findings of the 2006 follow-up IRRS mission

It can be concluded that review and assessment process in CNCAN is well managed and newly issued internal procedures significantly contributed to quality of this process. Similarly, filling the position of the director of the Nuclear Reactors Division and increasing number of staff are other positive factors. However, internal review procedures mostly deal with the organization and process of the review, flow of the information, completeness of required components of the analysis, and control of steps to be performed. Specific review procedure concentrated on technical details exists only for some areas, e.g. for fire hazard analysis. Complementing existing procedures with a guidance to ensure the technical quality of the review and assessment, will allow CNCAN to further increase its effectiveness and efficiency.

5.2.1.1. Recommendations, Suggestions and Good Practices

1) **BASIS:** The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in § 5.10 that *"The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."*

R14) **Recommendation:** *CNCAN management should take actions to complete its internal review and assessment procedures, concentrating on assessment of compliance with the technical and safety requirements contained in relevant regulations.*

5.3. AREAS OF EXPERTISE AND TECHNICAL SUPPORT ORGANISATIONS

Generally, scope and level of technical expertise of staff in Nuclear Reactors Divisions, as well as in other divisions involved in review and assessment is high. However, independent capability of CNCAN in performing and reviewing in sufficient detail safety analyses seems to be a problem. Rather than establishing a technical support organization, CNCAN management decided to develop this capability internally, as integral part of the CNCAN structure mainly in the Nuclear Safety Section. The section at present has 5 employees, mostly young engineers, while plans are to have 11 people. The problem is time needed for their adequate training. It is estimated that 2-3 years are required for learning how to use a complex code, even more for qualified supervision and independent review of analyses. CNCAN intends to develop in-house capability to analyze thermal-hydraulic, mechanical, I&C, and nuclear physics issues, as well as to perform structural analysis, containment response, radioactivity transport and PSA analysis. Roughly up to 10 different computer codes are envisaged for the use, but no adequate (best-estimate) codes are available at present and the financial resources are limited. Independent computational analyses were performed in 2003 for LLOCA and for TH analysis of stationary flow regime for PHTS (FIREBIRD and NUCIRC). At present no independent computational analysis is performed by CNCAN. In addition, insufficient financial resources do not allow for contracting external organizations. Even with resources available, there would be very limited possibilities to find expertise outside the plant. Limited financial resources have been allocated as co-financing for the supply of several computer codes under Phare projects.

If necessary, additional analyses are requested by CNCAN from the applicant. Operator of Cernavoda NPP is quite strong in performing its own safety analyses. There are two relevant groups at the NPP, the first has 12 people performing deterministic analyses, and in the second group 8 people are providing probabilistic analyses. CNCAN own capabilities in the area of safety analysis are very much needed, in order to become a qualified reviewer. Recent indication to continue with construction of Units 3-5 of Cernavoda NPP underlines the need for urgent development of new requirements and to enhance independent CNCAN capability for review and assessment.

Temporarily, a lack of independent safety analysis capability is addressed by requiring additional analyses from the applicants, and extensive use of external support from the IAEA and PHARE projects, as well as from bilateral cooperation.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Suggestion: CNCAN should, as a long-term objective, support conditions for the effective functioning of an organization (system of organizations) capable of performing typical tasks of a Technical Support Organization.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Instead of establishing a technical support organization for performing independent safety analyses required for review and assessment, CNCAN management decided to develop in-house capability as an integral part of the CNCAN structure. Several steps in order to provide relevant training to new staff (training courses, fellowships) have been already taken.

5.3.1. Findings of the 2006 follow-up IRRS mission

Currently the CNCAN staff has not capacity/capability to perform independent analyses using specific computer codes. The assessment activities are limited to review of the methodologies, verification of hypotheses used by NPP during analyses and conservative hand calculations.

Hiring and training of people is urgently needed, estimation for achieving good level for review of safety analyses is minimum 3 years. Analysis is also needed for preparation of emergency drills.

In addition to training of new staff, present practice with utilization of IAEA and PHARE projects should continue. Availability of resources for contracting foreign organizations should also be investigated, in particular for establishing closer contacts with experts in the country of origin or with other regulatory bodies in countries operating CANDU reactors.

5.3.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 4.8. that *“In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator”* and in Article 4.7 that *“In order to ensure that the proper skills are acquired and that adequate level of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes”*.
- R15) **Recommendation:** *CNCAN should ensure that number of staff involved in safety analyses be increased as planned and receive appropriate training.*
- 2) **BASIS:** The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Art. 4.1 that *“The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities.”* and in addition the IAEA Safety Guide No. GS-G-1.1 “Organization and Staffing of the Regulatory Body for Nuclear Facilities” recommends in Art. 3.14 that *“If sufficient expertise is not available within the regulatory body, part of the review and assessment activities may be contracted out, for example, to a dedicated support organization or a consultant.”*
- R16) **Recommendation:** *CNCAN should ensure that adequate resources are allocated in its budget in order to allow acquiring necessary computational tools and for external support as necessary.*

5.4 REVIEW AND ASSESSMENT OF OPERATIONAL EXPERIENCE FEEDBACK

The process of review and assessment of operational events occurring at nuclear installations is well established. Requirements on reporting of operational events are fixed in the operational license of the NPP. There is a NPP procedure for reporting of events, which is in compliance with the approved by CNCAN QA manual. 34 categories of events are specified for reporting. Over the last three years, there were 10-20 events reported per year, but currently 1 event per year is being reported by CNCAN to IAEA IRS system. No INES 2 event occurred in Cernavoda operation till now. The NPP has a commission for analysis of the events, and CNCAN attends meetings of the commission as considered important.

Similarly as for NPP, licenses for other nuclear installations e.g. research reactors include requirements for reporting of operational events and, in accordance with their QMS, operators of those installations have procedures for reporting.

CNCAN has an internal procedure for assessment of operational events in NPPs no. MC-PA-01 issued in February 2002. Another procedure is available for assessment of emergency situations. A similar procedure as for NPPs exists for assessment of events in research reactors. CNCAN assesses the INES classification, studies direct and root causes, reviews the action plan, and verifies its implementation. Site inspectors receive the list of corrective actions and monitor their implementation. Resident inspectors also collect required information from the plant needed for any review and assessment.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There was no recommendation made from this section.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

New revision of the licensee's procedure for reporting events has been issued and evaluated by CNCAN, with modified reporting criteria.

5.4.1. Findings of the 2006 follow-up IRRS mission

Similarly as stated by IRRT mission in 2002, the IRRS mission concluded that the staff of the Nuclear Reactors Division have good capabilities for performing in depth assessments of NPP Cernavoda events reported to the regulatory body.

5.4.1.1. Recommendations, Suggestions and Good Practices

There were no recommendations or suggestions made for this section.

5.5. PERFORMANCE OF MAJOR REVIEW AND ASSESSMENT TASKS

Typical examples of regulatory actions requiring review and assessment are applications for new licenses, for temporary changes in the plant configuration, assessment of modifications, updating of procedures, reporting of unplanned operating events, analytical support for PSA studies. Major review and assessment tasks performed during the period 2003-2005 (since the previous IRRT mission) are summarized below.

Within the framework of design, construction, manufacturing and installation of Cernavoda NPP Unit 2, the review and assessment activities has been concentrated on the Preliminary Safety Analysis Report, on design implementation, changes to the authorized design, construction activities, construction and commissioning procedures, and assessment of commissioning safety objectives.

Review and assessment activities related to operation of Cernavoda NPP Unit 1 have been concentrated on the review of the safety performance, review of significant events reported by the licensee, review and approval of temporary configuration changes, review of plant modifications, review and assessment of operating license renewal documents (Cernavoda NPP Unit 1 FSAR updates).

In the area of verification of deterministic nuclear safety analyses, efforts were devoted to the assessment of nuclear safety documentation submitted by the utility in support for design changes of Cernavoda NPP Unit 1 and Unit 2, to the verification of methodologies and assumptions used in accident analyses for Cernavoda NPP Unit 2 (PSAR for Cernavoda NPP Unit 2), review of Fire Hazard Analysis Report for Cernavoda NPP Unit 1, review of the Overpressure Protection Report for Primary Circuit and Special Safety Systems, review of the methodology for seismic fragility calculation as support for Cernavoda NPP Unit 1 Seismic PSA, and review of the methodology for Seismic Hazard Analyses for Cernavoda site.

TRIGA safety analysis report was prepared in 2002, concentrating on replacement of a control rod and other modifications. From 2005, new fuel with lower enrichment will be used. Final safety analysis report will be prepared at the end of all modifications and reviewed by CNCAN afterwards.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There was no recommendation made from this section.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Increasing number of submissions related to operation of Cernavoda Unit 1 and construction of Unit 2, in particular in the area of probabilistic safety assessment was observed.

5.5.1 Findings of the 2006 follow-up IRRS mission

Changes and findings as formulated in previous sections of this chapter apply also here. In enhancing capability of CNCAN in the area of review and assessment as well as in developing new regulations, priority should be given to the NPP due to potential magnitude and nature of the hazard.

5.5.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** The IAEA Safety Requirements No. GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 4.8. that “ *Review and assessment shall be performed in accordance with the stage of the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity.*”

Recommendations/suggestions as formulated in sections 4.3.1.1, 5.2.1.1, 5.3.1.1, and 5.6.1.1 apply here.

5.6. USE OF PROBABILISTIC SAFETY ASSESSMENT

Although probabilistic safety criteria are not prescribed quantitatively by CNCAN, deterministic and probabilistic supporting calculations are both used in submissions to demonstrate acceptability of the request. PSA study level 1 is an obligatory part of the safety documentation for NPPs. Several versions of PSA level 1 (internal and external events) for Cernavoda NPP Unit 1 have been already developed. An internal events Level-1 PSA was completed for Cernavoda Unit 1 NPP in 2003. The study was refined and an updated report produced in 2004. In January 2005, a Level-1 PSA for internal fires and floods and seismic events for Unit 1 has been completed and a final report produced. The Unit 1 PSA was used as a technical basis for evaluation of the potential risk impacts from the Unit 2 design changes. Plant-specific PSA for Unit 2 will be prepared and submitted to the regulatory authority within 6 months after achievement of Unit 2 commercial operation. This will most likely be in early 2007.

Up to now, CNCAN made use of external support such as technical assistance provided through IAEA technical cooperation programme and PHARE programs in order to evaluate from regulatory point of view the PSA study level 1 for Cernavoda NPP. In December 2002, the IAEA organized a National Workshop for PSA Specialists and Practitioners on Methodology Approaches for Internal Fires and Floods, Seismic and Other External Events PSA (Bucharest). An International Probabilistic Assessment Review Team (IPSART) mission was held in March 2003 at Cernavoda NPP. In May 2005, an IPSART mission was planned for the Cernavoda Unit 1 Level-1 PSA for internal fires, internal floods, and seismic events for full power operation conditions.

Up to now, no PSA study has been elaborated for nuclear installations other than Cernavoda NPP.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There was no recommendation made from this section.*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section.*

Changes since the 2002 IRRT / 2004 RaSIA missions

PSA evaluations are often a part of the supporting analysis for submissions, not only for licensing of the NPP, but also for its modifications. The plant also intends to develop and use the risk monitor. CNCAN has initiated a new PHARE project n. 2005/017-519.03.01 on Support for

Regulatory Authority Staff to Improve its Capabilities with the View of Probabilistic Safety Assessment. CNCAN expects from the project not only support in review of the PSA studies, but also advice on methodology for the regulatory review, and implications for other regulatory functions, like planning of inspections, etc. The project has been already approved, and it is supposed to start soon in 2006, with duration at least one year. A number of fellowships have been also proposed within the PSA field.

5.6.1. Findings of the 2006 follow-up IRRS mission

There are a lot of needs and interests to enhance use of PSA methods for demonstration and improvements of nuclear installations safety, as well as for regulatory work and CNCAN's own capability in the area. CNCAN plans broader use of risk informed regulations, but the process did not start yet. At present CNCAN manpower and expertise in this area is limited.

5.6.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 4.6. that “ *The regulatory body shall acquire and maintain the competence to judge, on the overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.* ”
- R17) **Recommendation:** *Special attention should be devoted to enhancing of the CNCAN capabilities in the area of probabilistic safety assessment due to its importance not only for evaluating safety of nuclear installations, but also for future implementation of risk informed regulations as intended.*

6. INSPECTION AND ENFORCEMENT

6.1. OBJECTIVES OF INSPECTION AND ENFORCEMENT

The key objective of CNCAN inspection is to monitor compliance with regulatory requirements that relate to nuclear and radiation safety, and to take enforcement action in the event of non-compliance. The legal basis that supports this objective is the same as that in force at the time of the 2002 IRRRT and the 2004 RaSIA and is specified in law 111/1996, Chapter IV: “Control Rules” This describes the authority to inspect, what must be done with the information gathered during inspections, the obligations of those being inspected, and enforcement powers and sanctions. The 2002 IRRRT noted that there is no appeal process described in the law. Although no specific recommendation was made on this issue in 2002, accession to the EU will require Romania to establish appeal processes.

Recommendations and Suggestions from the 2002 IRRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There was no recommendation made from this section*

RaSIA 2004 Recommendations:

- *There was no recommendation made from this section*

Changes since the 2002 IRRRT / 2004 RaSIA missions

No significant changes were noted regarding the objectives of inspection and enforcement

6.1.1. Findings of the 2006 follow-up IRRS mission

No new findings were noted regarding the objectives of inspection and enforcement.

5.6.1.1. Recommendations, Suggestions and Good Practice

There were no recommendation made from this section

6.2. MANAGEMENT AND ORGANISATIONAL STRUCTURE OF INSPECTION

The management structure operates satisfactorily from the point of view of planning, implementing and following-up inspections. However this process relies sometimes on informal co-operation between the Division Directors. One advantage of this is that it facilitates the use of staff from the different divisions to take part in inspection teams. This is very important during a time when many of CNCAN staff are not experienced and need to be accompanied by more experienced staff during an inspection. Such experienced staff may work in different divisions. However, it is suggested that one senior person in CNCAN should formally be in charge of the whole inspection programme. This person would be a focal point of contact with the NPP and would obviate any future difficulties if there should be a change of personnel in the senior positions.

A similar observation was made regarding the inspection of radioactive sources where inspections are carried out by both the authorisation and inspection sections.

Although some progress has been made in enhancing the team at Cernavoda, there is still an urgent need to recruit two more inspectors. This is particularly important because of the impending commissioning and routine operation of Cernavoda Unit 2. Discussion on site with the existing team led to the conclusion that one of the new recruits should be a radiation protection expert.

The three members of the existing Cernavoda Unit 1 site team carry out their functions efficiently and effectively. They have several years experience and have earned the respect of Cernavoda management as competent engineers whose views and opinions are important to safety. Whilst this is a very positive situation, problems may inevitable arise in the future should any of these staff leave. Procedures are in place for the training of new resident inspectors and the current team is documenting the inspection processes. However a good site inspector needs a wide knowledge of the regulatory process. It is recommended therefore that, in addition to recruiting new staff for the site team, there should be a programme to train these recruits in the broader aspects of regulation to enable safety judgments to be made on a sound priority basis.

During the observation of inspections at a number of facilities ranging through hospitals, to factories performing NDT", many of which appear to have common roots:

Inspectors may not be sufficiently conscious of their personal safety or the safety of other persons present. In one instance, CNCAN inspectors invited the IAEA observers (who were unauthorised individuals and did not have personal dosimeters) to join them in the controlled area. In another instance within the workshops of a heavy industrial facility, no protective apparel (such as hard hats) was provided. When this was realised, the inspectors decided it was not necessary to return to the office to collect the hats.

In another case, having visited a controlled area, the CNCAN inspectors did not perform individual monitoring to ensure they were uncontaminated although they were aware they had visited contaminated rooms where during the course of the visit, a person working in the nuclear medicine unit had been found to be contaminated.

In one instance, a device for measuring contamination was used by the inspectors. The experts noticed that inspector's controls were not relevant. For example, several unnecessary checks were undertaken in a room where patients have been administered radiopharmaceuticals and are therefore contaminated.

CNCAN has prepared thorough practice-specific checklists and procedures for inspections. For the preparation of the control at the above mentioned nuclear medicine facility, the inspectors assessed the documentation (the file) at the CNCAN headquarters. However, the checklists were not used during the inspections (except in some cases at the end of the inspection, to aid the completion of the written report). Additionally, it was not clear in every case, whether the inspectors had reviewed the files for the facilities or had immediate access to these files. The topics included in the checklist are very different and the information about them should be received by different person with different responsibilities (such as: responsible for radiological safety, legal representative, etc.). The completed form (electronic format) of the checklist is made up at the end of the inspection and is annexed to the inspection report. It is necessary to mention that in the nuclear medicine case, the checklist should be complemented and updated in accordance with the approved regulations in this field.

It is necessary to mention that in the nuclear medicine case, the checklist should be complemented and updated with the approved regulations in this field.

Given the regular modification of regulations and guidance, together with the potentially changed circumstances at the facility, the use of a checklist and immediate access to the regulatory body's file for the facility throughout the inspection is a good practice that would allow the inspector to carry out the pertinent activities in a logical and comprehensive manner, especially for the first visit of the facility. However, the experts noticed that the inspector used it only during the exit meeting. This did not facilitate the identification of recommendations.

There appeared to be a greater emphasis on evaluation of the operator's documentation and less attention given to the procedural and technical aspects, even where shortcomings were apparent.

These findings lead the experts to consider that CNCAN inspectors need further training on the performance of inspections in order to ensure that they inspect in safe and efficient manner.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *CNCAN should take urgent action to fill the three vacant positions in the Directorate of Cernavoda NPP Surveillance.*

There is one additional staff at the NPP. The recommendation has been partly completed but the staffing of the on-site surveillance department is still a major issue. This is addressed in section 6.2.1 below.

RaSIA 2004 Recommendations:

- *CNCAN should consider organizational realignment such that inspections are carried out by one group/section, instead of by both the authorization and inspection sections.*
- *CNCAN should review their existing frequencies for routine inspections, as well as authorization renewals, to determine any inconsistencies with IAEA recommendations, and made adjustments as necessary, according to the categorization of radioactive sources.*
- *CNCAN should develop and implement a written procedure and checklist for the review of all authorization actions to ensure the consistency and accuracy among CNCAN staff performing these reviews. CNCAN should develop and implement a written procedure and checklist for the review of all authorization actions to ensure the consistency and accuracy among CNCAN staff performing these reviews.*

Changes since the 2002 IRRT / 2004 RaSIA missions

CNCAN has implemented changes in the management structure for NPP surveillance. The Directorate of NPP surveillance has been replaced by NPP Surveillance Section within Nuclear Reactors Division. The responsibilities for NPP inspection is shared between the Nuclear Reactor Division, the Radiation Protection and Radioactive Waste Division, and the Quality Control Division. The team at the Cernavoda Site report to the Director of the Nuclear Reactors Division. There is also a CNCAN site inspector appointed by the Quality Control Division, who is dedicated to the inspection/audit activities with regard to quality assurance program for Cernavoda Unit 2 construction and commissioning.

Since RaSIA 2004 CNCAN has revised its formal procedures for inspection (PC-DRI-01), the current version being revision 6 dated 01.09.2005. In addition, CNCAN has introduced a procedure for the planning and scheduling of inspections (PPLC-DRI-01 Rev 1) dated 10.01.2006.

Article 5.3 of PPLC-DRI-01 sets down inspection criteria in accordance with the:

- type of activity;

- type of radioactive source;
- nature and complexity of the practice;
- the hazard or risk associated with the practice;
- risk to occupationally exposed workers, other persons and to the environment;

Annex A of PPLC-DRI-01 sets out the routine frequency for inspections based on source categorization ranging from twice yearly for Category 1 and 2 sources through annual inspection for sources such as those used diagnostic radiology to every two years for low risk sources. In addition, authorisation by registration only is now used for basic dental radiology devices and some laboratory equipment.

6.2.1. Findings of the 2006 follow-up IRRS mission

The management structure operates satisfactorily from the point of view of planning, implementing and following-up inspections. However this process often relies on informal co-operation between the Division Directors.

Although some progress has been made in enhancing the team at Cernavoda, there is still an urgent need to recruit two more inspectors.

The members of the existing site team carry out their functions efficiently and effectively. They have several years experience and have earned the respect of Cernavoda management as competent engineers whose views and opinions are important to safety.

A site inspector needs a wide knowledge of the regulatory process. Some preparations have been made to ensure that new recruits rapidly obtain this knowledge. However, more formal training is needed.

During the observation of inspections at a number of facilities ranging through hospitals, to factories performing NDT (but not Cernovoda NPP), the experts noted the several issues, many of which appear to have common roots. Some inspectors do not appear to be sufficiently conscious of their personal safety.

CNCAN has prepared thorough practice-specific checklists and procedures for inspections. However, the checklists were not used during the inspections (except in some cases at the end of the inspection, to aid the completion of the written report).

6.2.1.1. Recommendations, Suggestions and Good Practices

1) **BASIS** - IAEA SSS Report No. GS-R-1 “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety” requires in §4.1. that: “*The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The regulatory body shall establish a planned and systematic inspection program.*”

R18) **Recommendations.** CNCAN should take immediate steps to fill the two vacant posts in the NPP surveillance team at Cernavoda. One of these should be a radiation protection expert.

- R19) **Recommendation:** *CNCAN should train new site inspection staff in all aspects of nuclear and radiation safety regulation to enable them to evaluate safety priorities and to ensure that they are fully aware of the inspection criteria.*
- S4) **Suggestion:** *CNCAN should consider formally nominating one senior member of staff to be in charge of inspection programmes for all regulated installations, facilities and sources and to address the organizational realignment identified in the RaSIA 2004 report.*
- 2) **Basis – GS-R-1 5.14** – *“The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity”*
- R20) **Recommendation:** *With respect to radiation sources, CNCAN should review the frequency of routine inspections in accordance with International Standards and Guidance, and make adjustments as necessary having particular regard to the potential magnitude and nature of the hazard associated with the facility or activity.*

6.3 PERFORMANCE OF THE REGULATORY INSPECTIONS

At Cernovoda NPP, there are two main types of inspection: Quality control inspections and Nuclear safety inspections. The Quality control inspections are concerned with the authorisation of suppliers of equipment. Typically there are 75 – 100 such inspections each year carried out by CNCAN Quality control department. Authorisation of suppliers is not a common practice in Western Europe and CNCAN acknowledge that the practice may disappear when Romania becomes part of the European Union. This should release resources for other work. The Quality Control Department also carried out Quality control audits on site. Inspection of hold points and tests at Cernavoda 2 is becoming increasingly demanding.

CNCAN HQ also carries out “supplementary inspections”. These are done every three months by a team of 3-5 inspectors drawn from across CNCAN’s divisions. They are carried out in accordance with the CNCAN inspection plan and cover Cernavoda’s processes – for example maintenance. Other HQ based inspection include inspections during the annual outages. Inspectors will witness tests and clear hold points. Typically there will be about 30 inspections concerning the outage. Staff from the Nuclear Reactor Division will also carry out inspections on site to support their work in reviewing safety submissions from Cernavoda.

Inspectors from HQ also carry out routine inspections at the two research reactors in Romania. The VVRS reactor at Magurele was closed in 1996 but still contains fuel. Inspections relate to the fuel integrity and the vessel integrity. The Triga reactor at Pitesti operates intermittently. It is subject to Quality assurance inspections and periodic inspections by the Radiation Protection Division and the Nuclear Reactor Division.

Members of the IRRRT team visited the Cernavoda Site and spoke with the resident inspectors. The team concluded that the site team carried out their duties effectively. The process of routine inspection and the interface with station staff at their routine morning meetings was noted. The CNCAN resident inspectors carry out routine inspection in 11 areas every 3 months (44 routine inspections per year). In addition they also carry out work in accordance with the annual plan. This includes outage inspections and witnessing the annual site emergency exercise. In addition the site team will respond to events reported to CNCAN by Cernavoda.

The CNCAN site team are responsible for producing the first draft of the annual inspection plan. This is reviewed and supplemented by HQ departments and agreed by HQ. The plan is a “live” document and can be changed to respond to different circumstances.

The IRRT team considered the reporting of inspection was very good. Of particular merit is the process of informing the Licensee of inspection findings and the feedback into the regulatory process. This good practice was also observed by the IRRT team during an inspection at a nuclear medical unit in a hospital in Bucharest by two CNCAN inspectors. The experts noticed that the inspection was overall well structured. The inspection started by an opening meeting during which the inspectors introduced themselves and presented the inspection objectives. After the inspection itself, during a wash-up inspector meeting, the CNCAN’s representatives prepared a report formalising their recommendations in relation with their finding. One copy is given to the hospital head and the other one to the regulatory body.

The IRRT team concluded that the inspection process is comprehensive and well structured. There are however some doubts regarding the CNCAN ability to sustain this level of activity with the imminent commissioning of Cernavoda 2 and the planned construction of Cernavoda 3 and 4. Whilst these are all units of similar design they will inevitably increase the regulatory workload. Pending the recruitment of new staff and their assimilation into the CNCAN organisation, it may be necessary for CNCAN to rationalise its inspection activities. It is recommended therefore that CNCAN should take steps to evaluate the safety significance of all inspection activities and establish a priority order of activities that is based only on safety.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section from the 2002 IRRT*

RaSIA 2004 Recommendations:

- *CNCAN should consider issuing personnel dosimeters to all staff involved in the inspection of licensed facilities.*
- *CNCAN should develop and implement a written procedure and checklist for the review of all authorization actions to ensure the consistency and accuracy among CNCAN staff performing these reviews.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Since the 2002 IRRT, CNCAN has continued to enhance its written procedures regarding the inspection process part of the Quality management system. The number of inspections has increased – mainly due to the activities of the quality control department. As stated in section 6.2.1 above, there is no longer a centralized NPP Surveillance Directorate.

6.3.1. Findings of the 2006 follow-up IRRS mission

There are two main types of inspection: Quality control inspections and nuclear safety inspections. These are carried out by CNCAN HQ and the Cernavoda site team

The IRRT team considered the reporting of inspection was very good. of particular merit is the process of informing the Licensee of inspection findings and the feedback into the regulatory process. Through varieties of inspections (daily, routine, topical inspection), the resident office formulates its findings simultaneously, further investigation of the issues found, if necessary, then drafts the inspection report including the corrective actions, sends it to relevant departments of NPP and Headquarters on time, in order to receive the confirmation and/or explanation on the comments made from the NPP and additional necessary corrective actions from Headerquarters.

The IRRT team concluded that the inspection process is comprehensive and well structured. There are however some doubts regarding the CNCAN ability to sustain this level of activity with the imminent commissioning of Cernavoda 2 and the planned construction of Cernavoda 3 and 4.

6.3.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** According to Safety Guide No. GS-G-1.3 Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body paragraph 3.1 *Inspections by the regulatory body should be concentrated on areas of safety significance.*
- R21) **Recommendation:** *CNCAN should prioritise its inspection plans so as to focus on safety significant issues. This is applicable to all regulated installations, facilities and activities.*
- 2) **BASIS:** BSS 115/I.33 – “*For any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible ...*”
- R22) **Recommendation:** *At the earliest opportunity CNCAN should arrange for all its staff who may work in controlled areas with a personal dosimeter in accordance with the Romanian regulations and ensure that appropriate exposure records are maintained.*
- 3) **BASIS:** the IAEA Safety Requirements N° GS-R-1 on legal and Governmental for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in 5.17 that “*Regulatory inspectors shall to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process*”
- G3) **Good Practice:** *CNCAN has established a sound feedback system for their inspection activities, which requests that inspection reports are prepared, discussed with the licensee at the end of each inspection and then sent back to the regulatory process. The findings are then fed back into the next inspection plan, to ensure that any deficiencies or significant safety issues found on site could be solved on time.*

6.4. REGULATORY ACTION AND ENFORCEMENT

According to Art. 32 (e) of law 111/1996, infringements are possible to either legal or natural (physical) persons. The basis and the sanctions for infringements are given in the Arts. 45 and 47 of the law 111/1996. Several examples of infringement of physical persons were noted. The

examples included smoking in controlled area and non-compliance with internal radiation protection requirements both observed in the National Institute of Research and Development for Physics and Nuclear Engineering - Horia Hulubei, Magurele (ref. 10 July 2003). Another example concerned a non-compliance with a requirement which was given in an earlier inspection report about control of pressure vessels at IT ISCIR (ref. 13 September 2005).

The IRRT mission noted however that CNCAN staff at Cernavoda NPP did not implement the practice of issuing penalties on physical persons. All enforcement matters are referred to HQ.

The possibility to put sanctions to natural persons may contain the potential risk that non-compliances or failures are not reported accordingly and thus, no corrective action may be taken. This may result in a decrease of safety for the transport of radioactive material.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions made for this section*

RaSIA 2004 Recommendations:

- *CNCAN should review the appropriateness of its current policy of allowing inspectors to issue sanctions directly to licensees and licensee employees.*

Changes since the 2002 IRRT / 2004 RaSIA missions

- *There were no changes found for this section*

6.4.1. Findings of the 2006 follow-up IRRS mission

The possibility to put sanctions to natural persons may contain the potential risk that non-compliances or failures are not reported accordingly and thus, no corrective action may be taken.

6.4.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** – Para. 5.13 of IAEA SSS GS-G-1.3 states “... Experience in some States shows that imposing penalties on the organization rather than on individuals is preferable and is more likely to lead to improvements in safety performance.”
- S5) **Suggestion:** *CNCAN should evaluate its policy regarding the possibility to take legal actions to physical persons (Art. 32 of law 111/1996). It is internationally considered to be more effective to take actions to legal persons and not to physical persons to ensure that the licensee performs a thorough investigation and to take all necessary measures about its safety and radiation protection related arrangements to prevent recurrence.*

7. DEVELOPMENT OF REGULATIONS AND GUIDES

7.1. PROCESS FOR DEVELOPMENT OF REGULATIONS AND GUIDES

Law No.111/1996 (which was modified and complemented through Law No.16/1998, Law No 384/2001 and Law No. 193/2003) regulates the use of nuclear energy and empowers CNCAN to issue regulations in fields of its competence. The ordinary Law No.24/2000 on “Legislative technique for elaboration of the normative acts” and Governmental Decision No 555/2001 “Appointing a Regulation regarding procedures for submitting draft normative acts to governmental endorsement” establish the provisions, technical rules and administrative procedures for the development of regulations (normative acts) in Romania. Development of all regulations should fulfil the mandatory steps prescribed in Law no.24/2000. The remarks and comments of the draft regulation are required from the interested bodies within appropriate time scales (maximum 30 days).

In development of regulations large number of CNCAN experts are involved, as well as external and foreign experts. External experts are typically used to review the draft regulations developed by CNCAN staff. There is an internal CNCAN QA procedure on drafting a regulation. According to this procedure, a process is in place to ensure internal consultation among CNCAN departments regarding the regulations in draft. This is usually undertaken prior to the external consultation. The aim of this internal review is to provide an independent assessment of the scope, structure, content and implications of the regulatory documents by persons not directly involved in their production. The correctness with regard to technical and legal aspects is observed. The regulations in draft are sent for external consultation to all interested organizations in order to receive feedback. The comments and suggestions received are analysed and discussed in common meetings. Subsequently, the final draft is approved by CNCAN President and is submitted for publication in Official Gazette. Besides publication in the Official Gazette, in order to provide for broader dissemination, CNCAN publishes its regulations separately in brochures, distinguished for different areas of applicability by cover colour.

In 2001, the Committee for the review and drafting of QMS regulations was created, composed of representatives of industry and research and design national companies.

Although this chapter deals with the issue of development of regulations and guides in general, some specific aspects related to radiation safety, waste safety and transport safety are further addressed in the corresponding chapters of this report.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations

- *Recommendation: CNCAN should establish the priority for development of different regulations taking into account the needs of the current authorization process.*
- *Suggestion: CNCAN should seek further options to optimize the management of internal and external resources, involved in the development of the regulations, in order to ensure the completion of the documents in a timely manner, as appropriate.*
- *Suggestions: CNCAN should develop an internal QA procedure on regulation drafting and reviewing.*

RaSIA 2004 Recommendations:

- *CNCAN should promptly finalize and publish all regulations necessary to ensure consistency with the BSS and GS-R-1.*

Changes since the 2002 IRRRT / 2004 RaSIA missions

Since the previous IRRRT mission, extensive work was performed in the area of development of regulations and guides. Many old regulations were replaced with a new set of regulations and guides. More than 50 regulations were issued in the following areas (see the attachment):

- Nuclear Safety and Radiological Protection System of Regulations for the Nuclear Facilities;
- Licensing of Quality Management System;
- Radiation Safety System of Regulations in the Field of Ionizing radiation Application;
- Planning, Preparedness and Intervention in Nuclear Accidents and Radiological Emergencies;
- Radiation Waste Management System of Regulations;
- Transport of Radioactive Materials System of Regulations;
- Physical Protection System of Regulations in the Nuclear Field;
- Safeguard System of Regulations in the Nuclear Field.

In particular, the regulations pertaining to the QMSs of the nuclear installations in all the phases of existence and the regulations related to the QMSs of the suppliers for the main products and services for nuclear installations were issued in 2003, were amended in 2004 and a supplementary regulation was issued in 2005. The process took into account the needs of the authorization process of the QMSs in the nuclear field in Romania.

Besides the needs arisen from the licensing process, priorities for development of regulations were established as part of the harmonization process in WENRA countries. Since 2003, CNCAN is a member of WENRA and participates in the process of nuclear safety harmonisation. During the harmonisation study national regulations have been benchmarked against the reference levels established by the Reactor Harmonisation Working Group based on the Safety Requirements and Safety Guides of the IAEA Safety Standards Series. Another working group was dealing with the issues related to decommissioning, etc.

Safety issues covered by the benchmark included the following areas:

- A Safety Policy
- B Operating Organisation
- C Quality Management
- D Training and Authorisation of NPP Staff
- E Verification and Improvement of the Design
- F Design Basis Envelope for Existing Reactors
- G Safety Classification of Structures, Systems and Components
- H Operational Limits and Conditions
- I Ageing Management
- J System for Investigation of Events and Operational Experience Feedback
- K Maintenance, In-Service Inspection and Functional Testing
- LM Emergency Operating Procedures and Severe Accident Management Guidelines
- N Contents and Updating of Safety Analysis Report
- O Probabilistic Safety Analysis

- P Periodic Safety Review
- Q Plant Modification
- R On-site Emergency Preparedness
- S Fire Protection against Internal Fire.

7.1.1. Findings of the 2006 follow-up IRRS mission

The IRRS mission concluded that there is a good management commitment to implement a sound and systematic approach towards managing of regulations drafting and ensuring high technical quality.

The proposed system of regulations and guides in Romania seems to be chosen so as to suit the national legal system and the nature and extent of the facilities and activities to be regulated. It was noted, however, that there is not much guidance on how to establish the technical contents of each document. Although the initial drafting has been initiated for many documents, there have been some delays, in particular in those areas, where the in-house capacity expertise is not sufficient.

Appendix 2 “definitions” of law 111/1996 item 24 defines “regulations” and states that these are mandatory. However, this definition includes methodological rules, guide-books (guidance), thus making guidance mandatory also.

7.1.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - The IAEA Safety Requirements No GS-R-1 on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, states in Article 5.26 “*The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.*” And in Article 5.28 “*Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards.*” In addition the IAEA Safety Guide No. GS-G-1.4 “Documentation for Use in Regulating Nuclear Facilities” states in Art. 3.26 (2) that “*The procedure followed by the regulatory body for establishing regulation should include... (2) Setting the priority for development of regulations. The regulatory body should consider the advantages and disadvantages of the proposed regulation, including such matters as: risks associated with the type of facility, the needs for improvements in safety, the number of operators to be affected, and the effect on the efficiency of the authorization process.*”

Suggestions: please see R7

- G4) **Good Practice:** CNCAN devotes significant effort aimed at broad dissemination of its regulations among the stakeholders by publishing the regulations separately in regulatory brochures in addition to publication in the Official Gazette.
- G5) **Good Practice:** CNCAN has developed and implemented a comprehensive and effective system of regulations governing authorization of the QMS of all organizations that deploy nuclear activities in Romania as well as internal QMS manual for all functions of the

regulatory body.

- 2) **BASIS** – GS-R-1, 5.27 – “*Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator*”
- R23) **Recommendation:** *Government of Romania should consider the revision of Appendix 2 “definitions” of Law 111/1996 item 24 to exclude guidance from the definition of mandatory regulations.*

7.2. REVIEW AND REVISION OF REGULATIONS AND GUIDES

The proposed system of regulations to be developed by CNCAN implies great level of prescriptiveness. Prescriptive regulations reduce the time and skills necessary to perform a licensing review or conduct an inspection. They are narrowly applicable to a specific activity or situation, and need to be regularly reviewed and amended, as necessary, to keep pace with technological changes. The CNCAN management is aware of the resources and efforts needed to develop and maintain up-to-date its system of regulations. Possible sources of information relevant for updating the system of regulations and guides are utilized, including international cooperation, comments from the operators and from resident inspectors who have the experience from enforcement of the regulations. Therefore, it is considered to be a good practice to get comments from them for drafting new regulations as necessary. However, the current CNCAN QA manual and internal procedures do not address specifically periodicity for review and update of the CNCAN regulations.

Recommendations and Suggestions from the 2002 IRRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *Recommendation: CNCAN should consider in future the need for periodic review of its regulations and establish an appropriate mechanism and periodicity for updating the regulations*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section.*

Changes since the 2002 IRRRT / 2004 RaSIA missions

The necessity for the review of regulations was taken into account, with input from other government agencies and stakeholders involved in the nuclear field, industry, research institutes and academic staff. The Consultative Committee for the Drafting and Revising the Quality Assurance Norms in Nuclear Field, was established in 2001, composed of representatives of the organizations, coordinated by the CNCAN. CNCAN staff stated that periodicity for reviewing the regulations is also under responsibility of the committee.

Need for review of regulations was reflected by CNCAN in updated legislation. Namely, article 5 (1) of Atomic Law as amended by Law No. 193/2003 states:

“(5) The Commission shall review the regulations whenever it is necessary for these to be consistent with international standards and with ratified international conventions in the domain,

and shall order the measures required for the application thereof.”

Prioritization of development of regulations and mainly identification of any gaps were made partly in the framework of WENRA harmonization process. Examples of gaps to be covered by updated regulations are related to beyond design basis and severe accidents, accident management, EOPs, PSA Lev 2, ageing management. In addition to regulations which are already in advanced stage of preparation, 10 more regulations are to be issued according to the rough estimation.

7.2.1. Findings of the 2006 follow-up IRRS mission

Substantial effort was devoted to the development of QMS regulations, which specify rules for the process, responsibilities, reporting, etc. The set of Norms on Quality Management Systems for nuclear installations (2003) contains provisions related to the quality assurance and safety of operation, maintenance, in-service inspection, testing, modifications, training of personnel, procurement activities, etc. Existing 13 QMS regulations cover main activities related to all phases of life-time of nuclear installations and they are further updated in order to ensure compliance with the IAEA Safety Standards.

However, QMS regulations do not contain technical details, needed for specification of licensing requirements. These details should be contained in different kind of regulations. Some of this kind of norms were developed prior to present Atomic Law and certainly need to be reviewed and updated, namely:

- Nuclear Safety Norms - Nuclear Reactors and Nuclear Power Plants (1975), which contain provisions concerning licensing basis documentation, site evaluation criteria and design criteria for NPPs;
- Norms for prevention and extinction of fires, applicable in the nuclear activities (1976);
- Nuclear Safety Norms on Planning, Preparedness and Intervention in Nuclear Accidents and Radiological Emergencies (1993).

Some of new regulations have been already developed, e.g.:

- Norms on issuing of practice permits for operating, management and specific training personnel of nuclear power plants, research reactors and other nuclear installations (2004), which contain provisions regarding the training and licensing of NPP personnel;
- Norms for Containment Systems for CANDU NPPs (2005);
- Norms for Shutdown Systems for CANDU NPPs (2005).

The following important regulations are in external consultation prior to publishing:

- Norms on Fire Protection in NPPs;
- Norms for Emergency Core Cooling System for CANDU NPPs;
- Requirements for Concrete Structures in Nuclear Installations.

The following regulations are in advanced stage of preparation:

- Norms regarding Periodic Safety Review for NPPs;
- Norms regarding Modifications to NPPs;
- Norms regarding Probabilistic Safety Assessment for NPPs;
- Norms regarding the classification of SSCs important for safety;

- Norms regarding decommissioning of NPPs.

Based on the results obtained in benchmarking, a plan is going to be developed for ensuring that national legislative framework will cover all issues identified. According to the commitments within the WENRA harmonization process, all improvements are to be implemented by 2010. In some cases, licensing requirements are established by ad hoc approving regulations of a foreign country of origin, such as using US regulation for spent fuel storage.

Besides regulations related to NPPs, there are many others related to other types of nuclear installations, activities and radiation sources.

7.2.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA Safety Requirements No. GS-R-1 “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety” requires in Art. 5.28 that *“In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience.”* and IAEA Safety Guide No. GS-G-1.4 “Documentation Used in Regulating Nuclear Facilities” states in Art. 3.28 that *“The regulatory body should ensure that regulations and guides are kept up to date, and procedures should be established for their periodic review.”*
- S6) **Suggestion:** *CNCAN should consider in future the need for periodic review of its regulations and establish an appropriate mechanism and periodicity for updating the regulations.*
- G6) **Good Practice:** *CNCAN efficiently utilizes all possible sources of information relevant for identifying gaps and updating the national legislation of regulations, in such as WENRA harmonization process, comments from the operators and from CNCAN resident inspectors.*

8. EMERGENCY PREPAREDNESS

8.1 Overview of Romanian Emergency Preparedness

There have been major changes in Romanian Emergency Preparedness since the 2002 IRRT. In 2004 a new Government Ordinance and four Government decisions came into force. These are:

- Government Ordinance 21/2004 – National system for the management of emergencies;
- Government decision 1489/2004, 1491/2004, 1492/2004 that relate to the organisation, function and approval of national committees for emergencies and professional emergency services;
- Government Decision 2288/2004 that relates to the functions which ministries, state authorities and non-governmental organisations have to perform.

Ministerial order 242/1993 “Nuclear safety republican regulations on the planning, preparedness and intervention in case of nuclear accidents and radiological emergencies” is still in force. This order is focussed particularly on accidents at NPPs. It will shortly be replaced by an updated order which will address radiological emergencies in addition to NPP accidents.

Other norms for NPP releases, meteorological measurements, monitoring of releases and environmental radioactivity monitoring around nuclear installations, came into force in 2004.

A new comprehensive regulation regarding the specific requirements for emergency preparedness and response at nuclear installations is in the process of being issued by CNCAN.

The new legislative basis (Government Ordinance 21/2004, Civil Protection Law 481/2005) establishes the National System for the Management of Emergencies. The National System for the Management of Emergencies is composed of decision, executive and operational structures:

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

All the decisional executive and operational structures are established on three levels: national, county and local.

As a decision structure, at national level is organized the National Committee for Emergencies and the Ministerial Committees for Emergencies. The National Committee for Emergencies is established under the co-ordination of the Prime Minister and managed by the Minister of Administration and Interior. All the Ministerial, County and Local Committees are subordinated to the National Committee for Emergencies.

The Ministerial Committee for Emergencies of the Ministry of Administration and Interior (MAI) – is responsible for the management of nuclear and radiological emergencies. This Ministerial Committee is the decision-making committee for nuclear and radiological emergencies.

The decision structure is supported by an executive structure and an operational structure also at National, County and local levels. As an executive structure, at national level is established the General Inspectorate for Emergencies (IGSU), a specialized organization in the Ministry of

Administration and Interior. IGSU has the responsibility of permanent co-ordination of the prevention and management of emergency situations, at national level. It is the role of the General Inspectorate at national level to approve the County and Local emergency plans of the public authorities.

The executive structures at county and local levels are the county/local Inspectorates for Emergencies.

CNCAN controls, evaluates and approves the on-site emergency plans of nuclear installations and radiological facilities. It maintains close collaboration with the General Inspectorate.

According to the new legislative framework, CNCAN main functions are:

1. Monitoring of specific hazards and risks, together with their associated negative consequences.
2. Informing, notifying and alerting.

CNCAN is the National Contact Point as per IAEA Conventions for Early Notification and Assistance, with the following functions (as defined in ENATOM, 2000):

- National Warning Point (NMP),
- National Competent Authority for a Domestic Accident (NCAD),
- National Competent Authority for an Accident Abroad (NCAA).

The CNCAN Radiological Emergencies Section is currently a section within the Radiation Protection and Radioactive Waste Division. This is not a prominent position for a significant function that has direct contact with the general public and is the last line of public protection should all other safety measures fail. Because of the major changes in Romanian Emergency Preparedness and the Role of CNCAN to advise the National Committee on Emergencies and the Ministerial Committee on Emergencies. IRRT members considered that the unit should have a more prominent position in the CNCAN structure. IRRT members consider that the emergency preparedness function should be under the direct control of the CNCAN President.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

- *There were no changes in this section*

8.1.1. Findings of the 2006 follow-up IRRS mission

There have been major changes in the infrastructure for managing emergencies in Romania. The emergency preparedness function should have a higher profile in the CNCAN structure.

8.1.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS GS-R-2 “Preparedness and Response for a Nuclear or Radiological Emergency in §5.34 requires that; The emergency arrangements shall include the clear allocation of responsibilities, authorities and arrangements for co-ordination in all phases of the response. These arrangements shall include ensuring that for each response organization a single position has the authority and responsibility to direct its response actions.....”
- R24) **Recommendation:** *That the CNCAN structure should be amended such that the emergency preparedness function reports directly to the CNCAN President.*

8.2 REGULATION OF LICENSEE’S ON- SITE EMERGENCY PREPAREDNESS

Under Ministerial Order No. 242 (under revision) all Nuclear Installations must have an Emergency Plan which is periodically revised. This plan is approved by CNCAN. One feature of the Cernavoda plant is that it addresses the interface with the local municipality’s plan. In fact, the Cernavoda NPP’s on-site emergency plan is harmonised with the municipality’s plan. The new regulations which are to be issued by CNCAN in the next months stipulate that the harmonisation of plans shall be ensured by close co-operation of the authorization holder and local public authority. Therefore CNCAN shall be involved in reviewing and approving the municipality plan as far as it applies to nuclear emergencies.

All other features of the Site plans and CNCAN’s role are similar to that described in the 2002 IRRRT report. Cernavoda still carries out an annual site exercise that is witnessed by CNCAN staff. However Romania now carries out national exercises that test the response of the whole system. One such exercise was held in 2005 which was based on a hypothetical accident at Cernavoda NPP.

Recommendations and Suggestions from the 2002 IRRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *CNCAN should pursue the possibility of formally reviewing/approving the local municipality’s emergency response plan.*

The new emergency arrangements in Romania clearly state that it is the responsibility of the General Inspectorate for Emergencies to approve the municipality plan. The recommendation is not now directly valid. However the CNCAN input to the plan is described in 8.2.1

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRRT / 2004 RaSIA missions

The changes since the 2002 IRRRT regarding the regulation of emergency preparedness arise from the clarification of the responsibilities for approving plans. In addition CNCAN has a new Emergency Response Centre located in a building belonging to the Romanian National

Administration for Meteorology, at about 15 Km from Bucharest City Centre. The operation of this center is described in section 8.4 – 8.6 below.

8.2.1. Findings of the 2006 follow-up IRRS mission

Under Ministerial Order No. 242 (under revision) all Nuclear Installations must have an Emergency Plan which is periodically revised. This plan is approved by CNCAN.

The features of the Site plans and CNCANs's role are similar to that described in the 2002 IRRT report. CNCAN is now in the process of issuing a new comprehensive regulation regarding the specific requirements for emergency preparedness and response at nuclear installations.

Romania now carries out national exercises that test the response of the whole system. One such exercise was held in 2005 which was based on a hypothetical accident at Cernavoda NPP.

8.2.1.1. Recommendations, Suggestions and Good Practices

No specific recommendations regarding the Regulation of Licensees' emergency arrangements

8.3. CNCAN EMERGENCY PREPAREDNESS TRAINING

CNCAN have carried out training of staff since the last IRRT. More training is planned in the near future. This training will be carried out by international organisations. Whilst this is important, the IRRT team considered that it is equally important to carry out training of staff in the Romanian Emergency Response System. This training should address the CNCAN role and also the role of other organisations and individuals in the national plan. Such a training course can only be organised in Romania. The feedback from the National Exercises such as exercise CONVEX in 2005 could be used to develop a course content. The course should specifically identify the role of those CNCAN staff who are not routinely involved in emergency situations/ exercises such as the Nuclear safety and radiation protection specialists who may be required to attend the CNCAN emergency centre.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *CNCAN should ensure that all staff who are involved in, or could be involved in, an emergency role, receive appropriate emergency preparedness training.*

RaSIA 2004 Recommendations:

- The training program of CNCAN in the area of emergency preparedness shall be adjusted to the needs of the emergency response organisation in terms of scope, frequency and focusing on specific tasks, as well as understanding the organisation and establishing communication links.
- The CNCAN staff should have more exercises as players taking part in nuclear power plant

exercises and devise some of their own drills or tests.

These recommendations have been addressed by CNCAN but changes in staff, new staff and the role of CNCAN in the National plan suggests that these recommendations should be an ongoing action. This is addressed in section 8.3.1.

Changes since the 2002 IRRT / 2004 RaSIA missions

The establishment of the CNCAN Emergency Center and CNCAN's role in the National Plan as described in sections 8.4, 8.5 and 8.6 requires comprehensive training of staff

8.3.1. Findings of the 2006 follow-up IRRS mission

Training on emergency arrangements has been carried out and more is planned.

The IRRT team considered that it is important to carry out training of staff specifically on the Romanian Emergency Response System.

8.3.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS GS-R-2 "Preparedness and Response for a Nuclear or Radiological Emergency in §5.31 requires that *"The operator and the response organizations shall make arrangements for selection of personnel and training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, procedures and other arrangements to perform their assigned response functions. The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training"*.
- R25) **Recommendation:** *CNCAN should ensure that all staff who may participate in the CNCAN emergency response organization receive training on their specific roles in the National Emergency Plan and also in relation to the role of other organizations and individuals. This training should be repeated to accommodate new staff and refresher training for existing staff.*

8.4. OFF-SITE EMERGENCY PREPAREDNESS

The impact of nuclear emergencies in neighbouring countries was raised in the RaSIA report 2004, however, this issue is now closed following the establishment of the Romania National Plan. This requires close co-operation with neighbouring countries.

A member of the IRRS team visited the CNCAN Emergency Centre and discussed its operation with CNCAN staff.

CNCAN's main role in the case of an emergency is to provide independent advice and technical expertise to the Ministerial decision-making committee which will, in case of emergency, convene at the National Emergency Centre (not visited by IRRT). CNCAN are represented at a senior level on this committee. In order to facilitate its obligation to provide advice and technical expertise and

to fulfil international reporting obligations CNCAN established a dedicated Emergency Centre in 2005.

The facility is located in a building belonging to the Romanian National Administration for Meteorology. It includes all facilities expected of such a centre. It has dedicated communications rooms with direct phone/fax access to each of the countries with whom Romania has bilateral agreements. Reporting to the IAEA in Vienna is the responsibility of this centre. There is also a laboratory for sample analysis. During normal times (non-emergency) the laboratory is used for the routine analysis of samples taken in the environment. There are two rooms for CNCAN experts to carry out their work on providing technical evaluations. One is for nuclear safety experts and a second is for radiological protection experts who will provide advice on the radiological consequences of an accident. There is an ongoing PHARE Project for the future development and endowment of CNCAN Emergency Centre. The Phare Project RO 5812.06.01 “Technical Assistance for the Romanian Regulatory Emergency Centre” includes two components: one to develop the overall architecture of the emergency centre, including the equipment needed to perform the tasks in emergency situations, and another one to supply the equipment identified to be necessary at the emergency centre. This project together with the CNCAN’s own development of the Emergency Center, will ensure that all the documentation needed for assessments and technical evaluations will be in place. Pending completion of this work, CNCAN should identify the documentation necessary for their experts to carry out their work.

In routine situations the Centre is staffed by 5 people – two of whom are chemists and two are recent recruits to CNCAN. They are organised as the Radioprotection and Radiological Emergencies Section of CNCAN.

The centre took part in exercise Convex in 2005. The feedback from this exercise indicated that the main deficiencies in the National Plan concerned communication between emergency centres (site, local, county, national and CNCAN centre). The CNCAN international notifications worked well. IRRS experts recommended that after each major national exercise CNCAN should review and amend its procedures associated with emergency arrangements.

IRRS members concluded that the establishment of the CNCAN Emergency Centre is a positive step forward. It will facilitate implementation of international obligations and help CNCAN fulfil its role in the National plan.

During the visit to the CNCAN Emergency Centre discussions were also held with staff from the General Inspectorate for Emergencies. The General Inspectorate is part of the Ministry of Administration and Interior. It was established under the civil protection act 2005. It has approximately 300 staff at national level. General Inspectorate staff explained the structure and operation of the national emergency centre. They also described their role as part of the general emergency response at with particular reference to the interface with CNCAN and the Nuclear Installations. Issues such as evacuation, sheltering and distribution of stable iodine were discussed. No specific issues were identified.

The General Inspectorate staff explained their own role in environmental monitoring during an emergency. The operation of their mobile monitoring laboratory was demonstrated. This was well equipped and would carry sufficient supplies and equipment to be in the field for 2 weeks. Although there is only one vehicle there is an arrangement with neighbouring countries to give support within 36 hours. Similarly, Romania will give support to other countries.

During discussions with CNCAN and the General Inspectorate IRRS member was informed that fixed environmental radioactivity monitoring points are in place around all nuclear sites (including Bechet near Kozloduy). The Ministry for Environment and Water Management manages this

system. Up to the present the Ministry for Environment and Water Management has been unwilling to share the data from these monitoring networks with other responsible organisations, as CNCAN and the General Inspectorate. It appears that (due to changes in the organizational structure) this may soon change, therefore IRRS makes no specific recommendation on this issue.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section from the 2002 IRRT*

RaSIA 2004 Recommendations:

- *The nuclear emergencies in neighbouring countries having potential direct impact on Romania should be addressed in national emergency plan.*

Changes since the 2002 IRRT / 2004 RaSIA missions

Roles and responsibilities of participating organizations have been redefined.

8.4.1. Findings of the 2006 follow-up IRRS mission

IRRS members concluded that the establishment of the CNCAN Emergency Centre is a positive step forward. It will facilitate implementation of international obligations and help CNCAN fulfil its role in the National plan.

CNCAN's principle role in the case of an emergency is to provide independent advice and technical expertise to the Ministerial Decision making committee which will, in case of emergency, convene at the National Emergency Centre.

The CNCAN emergency centre is located in a building belonging to the Romanian National Administration for Meteorology. It includes all facilities expected to be found in such a centre.

CNCAN participated in a major international exercise in 2005. Such exercises inevitable generate changes to plans. Feedback from exercises should be used to update and amend CNCAN's procedures that relate to emergency preparedness.

Under international support (Phare Project 5812.06.01 "Technical Assistance for the Romanian Regulatory Emergency Centre") CNCAN is developing the overall architecture and is establishing the endowment for the Emergency Centre, in accordance with the responsibilities and tasks to be performed in emergencies.

The General Inspectorate for Emergencies and CNCAN co-operate well.

Fixed environmental radioactivity monitoring points are in place around all nuclear sites (including Bechet near Kozloduy). These are managed by the Environment Ministry. Up to the present the Ministry for Environment and Water Management has been unwilling the share the data from this monitoring network with other responsible organisations, such as CNCAN and the General Inspectorate.

8.4.1.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** – IAEA safety Standards series No. GS-R-2 Paragraph 5.3 states: *All operating organisations and local and National Authorities involved in Emergency preparedness should document their own roles, functions, authorities and procedures*
- R26) **Recommendations:** *That CNCAN reviews, and amends as necessary, its procedures relevant to its emergency preparedness after each major national exercise according to lessons learned.*
- R27) **Recommendation:** *Pending the completion of the PHARE Project that will provide a data link with Cernavoda, CNCAN should determine which documents and equipment should be in place at the CNCAN Emergency Centre to enable the CNCAN experts to carry out their work during an emergency.*

8.5. FIELD MONITORING IN EMERGENCY SITUATIONS

Initial monitoring in the immediate vicinity of Cernavoda is carried out by Site staff. This information is supplied to the Local Authority Centre to assist with their decision making. The General Inspectorate carry out monitoring during the later stages of an emergency using the mobile laboratory described in 8.4 above. The General Inspectorate also has an arrangement with Nuclear Police for use of their laboratories.

In addition to the Convex Exercise, the General Inspectorate (with mobile laboratory) and CNCAN took part in an exercise on Terrorist Radiological Dispersion Device Emergency (Romania – NATO organisation) in October 2003. CNCAN staff also participated in training courses on field measurements, and radioactive sources search and identification. CNCAN intervention team has specific portable equipment for field measurements.

In the case of nuclear accidents, CNCAN participate in post-accident actions with the mobile intervention unit. In the case of radiological emergencies, CNCAN participate at the intervention, with the mobile intervention unit. CNCAN mobile intervention carries out field radiation measurements and takes samples for laboratory analysis. The samples are analysed in the CNCAN Emergency Centre laboratory

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section from the 2002 IRRT*

RaSIA 2004 Recommendations:

- *The training program of CNCAN in the area of emergency preparedness shall be adjusted to the needs of the emergency response organisation in terms of scope, frequency and focusing on specific tasks, as well as understanding the organisation and establishing communication links.*
- *CNCAN staff should have more exercises as players taking part in nuclear power plant*

exercises and devise some of their own drills or tests.

- *The operational intervention levels should be developed considering the release from the CANDU plant and the generic intervention levels should be updated.*

Changes since the 2002 IRRT / 2004 RaSIA missions

The General inspectorate for emergencies now carries out Field Monitoring during Accidents at Nuclear Installations and during source accidents.

8.5.1. Findings of the 2006 follow-up IRRS mission

In addition to the Convex Exercise, the General Inspectorate (with mobile laboratory) and CNCAN took part in other exercises and participated in several training courses on field measurement.

8.5.1.1. Recommendations, Suggestions and Good Practice

There were no recommendations or suggestions for this section.

8.6. INTERFACE WITH THE MEDIA AND THE PUBLIC

IRRT expert discussed the role of the National Emergency centre concerning public information with members of the General Inspectorate for Emergencies. The performance of this aspect at the recent CONVEX exercise was discussed with CNCAN.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section from the 2002 IRRT*

RaSIA 2004 Recommendations:

- *The provision of the affected public with the information on protective actions should be evaluated for its effectiveness and, government officials and mass media needs should be analysed and measures to supply this information should be established.*

Changes since the 2002 IRRT / 2004 RaSIA missions

During an emergency the National Centre will take responsibility for the authorizing press statements. CNCAN has a representative at this centre.

8.6.1. Findings of the 2006 follow-up IRRS mission

Information to the Public in the vicinity of a nuclear installation is provided by the local municipality using pre-installed alarm systems and local media. This will advise on sheltering, and evacuation.

Exercise CONVEX in 2005 identified several areas for improvement regarding the issue of press releases. Despite the defined responsibilities in the various plans, press releases were not well coordinated.

CONVEX also identified the need for specially designated areas for the press at the local/county level.

8.6.1.1. Recommendations, Suggestions and Good Practices

There were no recommendations or suggestions for this section.

9. WASTE MANAGEMENT AND DECOMMISSIONING

9.1 LEGAL FRAMEWORK

CNCAN has the responsibility to exercise regulatory control over a broad range of radioactive waste management facilities and activities including those associated with the small scale use of radioactive sources, mining and minerals processing waste, low and intermediate level waste from nuclear fuel cycle facilities and spent nuclear fuel. It is also responsible for regulating all radioactive waste management stages; predisposal, including discharge control and removal of materials from regulatory control, storage, disposal and decommissioning. IAEA Safety Standards for radioactive waste management have been developed during the past few years and some are still under development. These have been used as a basis for the review. CNCAN has identified and adapted some of these IAEA Standards within the regulatory process but a number of areas have been identified where particular aspects should be still addressed. These particularly include the predisposal management and disposal of radioactive waste and the application of safety assessment methodology to both predisposal and disposal facilities as well as to decommissioning. The responsibility for waste safety activities is focused within one section of CNCAN, but there are also related responsibilities in the Divisions and Sections dealing with the licensing of particular facilities and activities such as the use of radiation sources, mining and minerals processing and power reactors. In this respect a careful interaction is needed which was recommended in the 2002 IRRT Mission to ensure consistency and whilst the experts involved expend considerable effort to achieve this objective, the number of specialist personnel available is limited.

9.1.1. General

Romania has ratified by the Law No. 105 / 1999 the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. By the provisions of Law No. 111/1996 on Safe Deployment of Nuclear Activities, with subsequent modifications and completions, CNCAN is the competent authority exercising the regulation, authorization and control in nuclear field. CNCAN is in the process of establishing the new set of regulations related to spent fuel and radioactive waste management. In order to fulfill its obligations under the Joint Convention, Romanian Government issued the Governmental Ordinance No.11/2003 on the Management of Spent Nuclear Fuel and Radioactive Waste, including final disposal. The ordinance was approved with modifications by the Law No. 320/2003.

Ratifying the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management, Romania has shown its willingness to undertake all the necessary steps for achieving the required level in the safe managing of the spent fuel and radioactive waste.

The national strategy for radioactive waste established by ANDRAD shall be approved by Nuclear Agency, which, according to the Governmental Ordinance No.7 approved by the Law No 321/2003, is responsible for elaboration of the Strategy for Developing the Nuclear Field, of Action Plan and of National Nuclear Plan. According to the Law 320/2003 for approving of Ordinance No. 11/2003 on the management of radioactive waste including disposal of nuclear spent fuel, ANDRAD is responsible for elaboration of the national strategy on the safe management of nuclear spent fuel and radioactive waste.

The National Strategy on Medium and Long Term regarding the Management of Spent Nuclear Fuel and Radioactive Waste, including their Disposal and Decommissioning of Nuclear and Radiological Facilities, hereafter called NSRW (National Strategy for Radioactive Waste), was

approved by Order No. 844 / 2004 and published in the Official Monitor of Romania no. 818/6 September 2004.

9.1.1.1. Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There are no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *ANDRAD should finalise the national radioactive waste management strategy, which should address the waste management route for decommissioning as well, without undue delay to assure proper and timely implementation of activities, which are waiting for the implementation.*

9.1.1.2. Findings of the 2006 follow-up IRRS mission

CNCAN has issued The Fundamental Norms on the Safe Management of Radioactive Waste (NDR-01) by Order of CNCAN President No. 56/25.03.2004. The Norms establish requirements to comply with the IAEA Principles of Radioactive Waste Management that are the basis for The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

CNCAN surveys the implementation of the strategies in order to be sure whether the safety requirements are met. In the opinion of the IRRS Mission CNCAN has responsibility with the elaboration and implementation of the National Policy and Strategy considering that this should be elaborated on the basis of the IAEA Principles of Radioactive Waste Management.

The National Strategy was issued by the Order No 844/2004 of the President of the Nuclear Agency as part of the National Strategy in Nuclear Field approved by the Government throughout the Government Decision No 1259/ 2002. Presently this National Strategy on Safe Radioactive Waste Management is under review to take into account recommendations given by CNCAN.

9.1.1.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 (LGI) requires in §3.4.(4) “*The regulatory body shall cooperate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary: (4) radioactive waste management (including determination of national policy)*”; The Joint Convention requires in §32 (1). In accordance with the provisions of Article 30, each *Contracting Party shall submit a national report to each review meeting of Contracting Parties. This report shall address the measures taken to implement each of the obligations of the Convention. For each Contracting Party the report shall also address its: (i) spent fuel management policy; (ii) spent fuel management practices; (iii) radioactive waste management policy;*
- R28) **Recommendation:** *CNCAN should have an active role in the review and approval of the existing National Strategy on Radioactive Waste Management according to its responsibilities and presented recommendations.*

G7) ***Good Practice:*** *The approach to develop a regulation complementing and expanding the IAEA Principles of Radioactive Waste Management that are the basis for The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management is considered to be a good approach.*

9.1.2. Defining of Radioactive Waste and Removal of Materials from Regulatory Control

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 recommendations:

- *R12. Recommendation: CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and Th-nat as applied to waste materials containing natural radionuclides.*
- *R13. Recommendation: CNCAN should develop and issue guidance on removing materials, containing elevated levels of natural radionuclides from regulatory control. This is linked to the recommendation on application of the exception levels to such materials.*
- *R14. Recommendation: Further consideration needs to be given by CNCAN to application of intervention principles, which result in materials being removed from regulatory control with levels of radioactive content, or contamination above both exception and exclusion levels.*
- *R15. Recommendation: CNCAN should establish a set of generic clearance levels for normal operations, together with guidelines for their application, which can be generally adopted by all licensed facilities including nuclear installations, mining and minerals processing facilities and facilities using radiation sources.*

RaSIA 2004 recommendations:

- *The CNCAN should request the operators to develop procedures to release the waste from regulatory control, if appropriate, in accordance with regulations*
- *Finalise the regulations which address predisposal and disposal of radioactive waste in due time.*

9.1.2.1. Changes since the 2002 IRRT / 2004 RaSIA missions

The legal framework makes provision for defining radioactive waste. Law No. 111/1996 and the Radiation Safety Fundamental Norm (RSFN) make it clear that radioactive waste is material for which there is no further use and which is contaminated with radionuclides above “exclusion limits”. The latter is a concept that has been adopted within Romania, and the values are set at a fraction of the exemption levels, which correspond to those in the BSS. This definition is consistent with the IAEA Safety Series SS No. 111-F Safety Fundamentals the Principles of Radioactive Waste Management, and with the Joint Convention.

CNCAN has issued The Norms (NDR-02) on Releasing under License Regime of the Materials Resulted from Authorized Practices by Order of CNCAN President No. 62/2004. According to the norms, the unconditional clearance levels are those provided for exclusion in the Fundamental Norms for Radiological Safety issued in 2000. Higher levels can be accepted for unconditional clearance if the amount of ingestion and inhalation is limited due to the low quantity of contaminated material and/or its physical and chemical form. Conditional clearance can be granted

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

9.1.2.2. Findings of the 2006 follow-up IRRS mission

CNCAN had developed and issued guidance on removing materials, containing elevated levels of natural radionuclides from regulatory control. This is linked to the recommendation on application of the exception levels to such materials.

The Review Mission was informed that for users of radiation sources the clearance of radioactive material from the regulatory control is authorized in the license issued to the operator and the control of this condition is mainly relying on the operator taking into account the activity concentration, the total activity of the sources authorized and the safety culture. There is in place a wide use of the rule of waiting ten half-life period of the radionuclide to clear the radioactive material from the regulatory control and its discharge. The Review Mission explained how this rule is not universal and could not be applied in all the cases. During the inspection organized to the Oncology Institute it was noticed that the considered premises to rely on the operator for clearance and discharge radioactive material are not always in place and there is a need for a clear procedure on how to proceed with clearance, discharge and its control and record keeping.

The NMR-03 regulation has been issued on the application of the release criteria, in the Radiological Safety Norms on Decommissioning of Uranium and Thorium Ores Mining and Milling Facilities. Two main values appears in this Norm for “unrestricted” release of soils: 0,2 Bq/g for release to be used for other industrial activities, agricultural or forest zones or for parks construction, and 1 Bq/g to be used for forest zone or agriculture areas with the exclusion of food production. The Appendix 8 of this regulation stipulates the content of the authorisation granted, with provisions for: requirements for the site uses, and the long-term institutional control. If this is the case, this guidance should not use the word “unrestricted” as a concept due to the established requirement in this regulation on remaining of some conditions on the site e.g. a long term institutional control for the release from regulatory control.

9.1.2.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA Safety Series 115 “International Basis Safety Standards for Protection against Ionizing radiation and the Safety of radiation Sources” (BSS) recommends in §2.19 footnote (8) “*Clearance of bulk amounts of materials with activity concentrations lower than exemption levels specified in Table I-I if Schedule 1 may require further consideration by the Regulatory Authority*” and in §2.5 footnote (3) “*...the exposure to other natural sources being expected to be dealt with by exclusion or exemption of the sources or otherwise at the discretion of the Regulatory Authority.*”
- R29) **Recommendations:** CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and Th-nat as applied to waste materials containing natural radionuclides.

- 2) **BASIS:** IAEA SSS WS-R-2 in §5.8 requires that: *“Authorized discharge, authorized use and clearance of materials from regulatory control, if necessary after an appropriate treatment and/or a sufficiently long storage period, can be effective in reducing the volume and amount of radioactive material that requires further processing. However, it shall be ensured that these management options, if implemented, are in compliance with the conditions and criteria established by the national regulatory body. In the application of such options, the regulatory body shall ensure that due account is given to non-radiological hazards”*.
- R30) **Recommendations:** *CNCAN should develop and issue practical guidelines for the practical application of the concept of clearance of radioactive material from regulatory control, control and record keeping of radioactive materials discharges which can be generally adopted by all facilities using radiation sources and radioactive materials other than nuclear installations, e.g. nuclear medicine and research facilities.*
- 3) **BASIS:** IAEA SSS Report No. GS-R-1 “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety” states in §2.2(1): *“A legislative and statutory framework consistent with international standards shall be established to regulate the safety of facilities and activities”*. IAEA Safety Series No. 115 “International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources” states in §2.5 *“Exposure to natural sources shall be considered as a chronic exposure situation, ..., except that , (b) occupational exposure of workers to natural sources shall be subject to the requirements for practices... if these sources lead to (iii) exposure specified by the Regulatory Authority to be subject to such requirements”*.
- S7) **Suggestion:** *The NMR-03 regulation on Decommissioning of Uranium and Thorium Ores Mining and Milling Facilities should not use the word “unrestricted” as a concept due to the established requirement in this regulation on remaining of some safety requirements on the site e.g. a long term institutional control after the release from regulatory control.*

9.1.3. Orphan Sources and Abandoned Wastes, Sites or Facilities

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *R16 Recommendation: Legal provision for dealing with orphan radiation sources and abandoned sites or facilities should be adopted as soon as possible. In this regard the specific roles and responsibilities of CNCAN should be addressed.*

RaSIA 2004 Recommendations

- *There were no recommendations or suggestions*

9.1.3.1. Changes since the 2002 IRRT / 2004 RaSIA missions

In 2002 there were no particular provisions in the legislation for orphan sources, or abandoned sites, or facilities. According to the Law No 111/1996 art. 35, letter n), CNCAN disposes and coordinates the recovery of orphan sources. In the event of a site or facility being abandoned, or a

situation arising of an area becoming contaminated from an orphan source, no identified operator is available to carry out the required actions. In such an event, it would be reasonable to expect the government to assume responsibility.

Regulations (NSR-16) on Orphan Sources and Control of High Activity Sealed Sources issued by CNCAN President Order no. 356/2005 transpose the DIRECTIVE 2003/122/EURATOM. In the Chapter IX on orphan sources, CNCAN has responsibilities related with the preparation of the recovery plan. In case of accident CNCAN shall give technical assistance to the public. CNCAN shall also prepare a preventive plan to detect the orphan sources from old practices.

9.1.3.2. Findings of the 2006 follow-up IRRS mission

Legal provision for dealing with past practices, abandoned sites or facilities still remain unsolved, this is the reason why Recommendation 16 of the IRRT 2002 is still open

9.1.3.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 in §6.10 requires that “*Government shall ensure that adequate arrangements are made for the safe storage and disposal of radioactive waste. Responsibilities shall be delineated and assigned to ensure that any transfer of responsibility for waste is adequately managed.*” IAEA Code of Conduct on the Safety and Security of Radioactive Sources in §22 (o) requires that: “*Every State should ensure that its regulatory body: is prepared, or has established provisions, to recover and restore appropriate control over orphan sources, and to deal with radiological emergencies and has established appropriate response plans and measures;*”
- R31) **Recommendation:** *Legal provision for dealing with past practices, abandoned radioactive materials, sources, sites or facilities should be adopted as soon as possible. Further implementation of the Directive and Romanian Regulation NSR-16 is necessary. In this regard the specific roles, responsibilities, and procedures for recovery by CNCAN should be addressed.*

9.1.4. Classification of Radioactive Waste

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *R17 Recommendation: CNCAN should develop guidelines on the classification of radioactive waste on a national basis with a view to clarifying what types of waste can be disposed of in identified disposal facilities, particularly identifying waste which is not acceptable in near surface disposal facilities and also where waste containing naturally occurring radionuclides can be disposed.*

RaSIA 2004 recommendations:

- *Finalise the regulations which address predisposal and disposal of radioactive waste in due time.*

9.1.4.1. Changes since the 2002 IRRT / 2004 RaSIA missions

CNCAN has issued the Norms (NDR– 03) on Classification of Radioactive Waste by the Order of President No. 156/2005. This regulation is mainly disposal oriented but it establishes that the predisposal management facilities should establish the operational classification needed for their proper operation.

9.1.5. Responsibilities

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *R18 Recommendation: CNCAN should give consideration to establishing requirements on the qualifications and experience necessary for personnel with defined responsibilities in waste safety.*
- *S11 Suggestion: Mechanisms, such as professional registration, to assist in demonstrating compliance with such requirements should be investigated by CNCAN together with the provision of appropriate training and staff development programmes.*
- *R19 Recommendation: The responsibility for institutional control over waste disposal facilities in the longer term should be addressed in legislation.*

RaSIA 2004 recommendations:

- *The CNCAN personnel should receive adequate training in the review of safety assessments for radioactive waste disposal facilities.*

9.1.5.1. Changes since the 2002 IRRT / 2004 RaSIA missions

The responsibilities of various parties in respect of the safety of radioactive waste management are addressed in legislation. This includes waste generators/operators, the regulatory body and other organs of government. There is an involvement of other government bodies in the control over waste management activities, relating to broader environmental impact from other than radiological effects and from industrial safety and hygiene considerations. There appears to be effective collaboration – no conflicts were identified.

The Norm (NSR-07) on Issuing of Exercising Permits for Nuclear Activities and Designation of Qualified Experts issued by order of CNCAN President No. 202/2002 includes provision for training and certification for the radioactive waste management specialists. The draft regulation under development on the disposal of radioactive waste has in chapter 9 “Operation” requirements on personnel qualifications. Further approval of the draft regulation and development of procedures for implementation is necessary. Similar is the situation for the personal involved in predisposal radioactive waste management activities and decommissioning.

9.1.5.2. Findings of the 2006 follow-up IRRS mission

The issue of competent staffing by the operator is still an issue. Licensees are required, inter alias, to demonstrate that staff have the necessary professional qualifications and level of knowledge to ensure the safety of facilities. CNCAN must make a judgment if the qualifications and experience of staff are in fact adequate and in order to do these criteria need to be in place.

The requirements on personnel qualifications could be included in the draft regulation under development in this moment. For the CNCAN personnel, the training programme is elaborated according to the internal procedure.

The issue of exercising institutional control over waste disposal facilities or facilities for the extended storage of radioactive waste are not explicitly addressed in the legislation. The draft regulations on the disposal of radioactive waste presently under development define the institutional control as well as the requirements for its implementation. At present, for the existing disposal facility, the operator has been proposed the period of institutional control in the authorization process which should be approved by CNCAN.

The recommendations given in this regards (R18 and R19) as well as the suggestion continues to be unsolved.

9.1.5.3.. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS NS-R-1 Requirements “Safety of Nuclear Power Plants: Operation” in §3.1. requires that *“The operating organization shall define the qualifications and experience necessary for personnel performing duties that may affect safety. These qualifications and experience shall be approved by the regulatory body if so required. Suitably qualified personnel shall be selected and given the necessary training and instruction to enable them to perform their duties correctly for the different operational states of the plant and in the event of an accident, in accordance with the appropriate operating or emergency procedures. Persons performing certain functions important to safety shall be required to hold a formal authorization; this may be issued or acknowledged by the regulatory body in accordance with national requirements.”* and in addition IAEA SSS WS-R-2 Requirements in §3.12 requires *“In order to provide an adequate level of safety, the operator shall...ensure that staff are trained, qualified and competent...”*
- R32) **Recommendation:** CNCAN should establish the detailed requirements on the qualification and experience of personnel involved in predisposal, disposal and decommissioning activities and thereafter continue improving the qualifications of personnel in the area of radiation protection and waste safety. The training programme of staff involved in the safety radioactive waste and decommissioning is strongly recommended.
- S8) **Suggestion:** Mechanisms, such as professional registration, to assist in demonstrating compliance with such requirements should be assessed by CNCAN together with the provision of appropriate training and staff development programmes.

- 2) **BASIS:** IAEA SSS GS-R-1 (LGI) in §6.12 requires that “*If institutional control after closure of a repository is deemed necessary, responsibility for carrying out institutional control shall be clearly assigned.*”
- R33) **Recommendation:** *The responsibility for institutional control over waste disposal facilities in the longer term should be addressed in the regulation.*

9.1.6. Decommissioning

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *R20 Recommendation: The quantum of funding to be paid into the Decommissioning Fund by different installations should be clearly identified in the legislation. This should be linked to an agreed liabilities assessment methodology.*
- *R21 Recommendation: The role of CNCAN in the determination of the amount of funds to be paid to the decommissioning fund needs to be set down and the periodicity of review of the adequacy of the amount.*
- *R22 Recommendation: CNCAN should established standard for the removal of sites and facilities from regulatory control under normal circumstances. CNCAN should also develop guidance on demonstrating compliance with such standards.*

RaSIA 2004 Recommendations

- *There were no recommendations or suggestions*

9.1.6.1. Changes since the 2002 IRRT / 2004 RaSIA missions

There is provision for decommissioning in the legislation, it is identified as a stage in the licensing process and the legislation requires provision to be made for financial arrangements to be in place and there is a requirement for adequate and competent operators to be available. Whilst the law makes provision for contributions to be made to a decommissioning fund, a number of aspects related to this fund still need to be addressed. Article 26 of Law No. 111/1996 requires “*For the deployment of a nuclear activity generating or having generated radioactive waste, the authorization holder shall compulsorily... c) pay the legal contribution to the Fund for the management of waste and decommissioning*”. The establishing of contributions of the operators is envisaged by modification of the Government Ordinance no. 11/2003 approved by law 320/2003. At this stage such a fund has not been established.

CNCAN shall assess the proposals for the contributions for radioactive waste and decommissioning and shall give advice to the Government for the establishing of the amounts paid by the waste producers. The amounts shall be included in the future Government Decision on the financial contribution for radioactive waste management and decommissioning.

Norm (NSN-15) on the Decommissioning on Nuclear Installations other than nuclear power plants was issued. Nevertheless criteria for the removal of sites from regulatory control have not been

explicitly addressed in this regulation. The dose constraint for the public is established by CNCAN in the decommissioning authorization process. For demonstration of compliance with the constraints, CNCAN requires that the licensee uses American guidance: Multi-Agency Radiation Survey and Site Investigation Manual (MARSIM), NUREG -1575/2002.

9.1.6.2. Findings of the 2006 follow-up IRRS mission

As already was mentioned in 2002 CNCAN issued a Norm (NSN-15) on Decommissioning of Nuclear Installations other than Nuclear Power Plants. The regulation for decommissioning of NPPs was not yet elaborated. The regulation in force on Decommissioning on Nuclear Installations other Than Nuclear Power Plants is missing as well the safety requirement concerning the safety assessment of the decommissioning phase of the nuclear facilities.

The law on radioactive waste and decommissioning fund has not been issued. After the modification of the Government Ordinance no. 11/2003, the government shall issue a Government Decision on the financial contribution for radioactive waste management and decommissioning. There are a number of issues related to such arrangements that need to be addressed. These include the amount of funds to be paid, allocation of the responsibility to determine the amount and the periodic review of its adequacy. The latter are safety related issues and CNCAN still has a role to play in this regard.

At present there are a number of facilities under decommissioning consideration at the Magurele site, including a VVR-S type research reactor and associated facilities. The preliminary decommissioning plan of the nuclear power plant at Cernavoda is under development and was rejected by the CNCAN several times for different reasons, including financial aspects.

The recommendations (R20, R21, R22) given on decommissioning still need to be solved.

9.1.6.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 (LGI) in §2.4 (13) requires that the legislation “*shall set out the responsibilities and obligations in respect of financial provision for radioactive waste management and decommissioning*”;
- R34) **Recommendation:** *Government should implement the law establishing the Fund for management of radioactive waste and decommissioning as stipulated by Law 111 and adjust the levy accordingly to the delay in accumulation of funds since 1996.*
- R35) **Recommendation:** *The quantum of funding to be paid into the Decommissioning Fund by different installations should be clearly identified in the legislation. This should be linked to an agreed liabilities assessment methodology.*
- R36) **Recommendation:** *The role of CNCAN in the determination of the amount of funds to be paid to the decommissioning fund needs to be set down and the periodicity of review of the adequacy of the amount.*

- 2) **BASIS:** IAEA SSS WS-R-2 in §3.7 requires that *“The regulatory body shall establish safety criteria for decommissioning of nuclear facilities, including conditions on the end points of decommissioning.”*
- R37) **Recommendation:** *CNCAN should establish regulations which include safety criteria for decommissioning of nuclear facilities, including conditions on the end points of decommissioning under normal circumstances. CNCAN should also develop guidance on demonstrating compliance with such regulations.*
- 3) **BASIS:** IAEA SSS WS-R-2 in §3.7 requires that *“The regulatory body shall establish safety criteria for decommissioning of nuclear facilities, including conditions on the end points of decommissioning.”* and IAEA SSS WS-G-2.1 “Decommissioning of Nuclear Power Plants and Research Reactors” in §2.8 recommends that the *“National regulatory authorities should provide guidance on radiological criteria for the removal of regulatory controls over the decommissioned installations and sites and should ensure that an adequate system is in place for properly managing the removal of controls.”*
- G8) **Good Practice:** *The approach to develop and issue a Norm (NSN-15) on the Decommissioning on Nuclear Installations (other than NPP) and applying the experience in applying regulatory control to the decommissioning of the research reactor at Magurele before developing requirements for the power reactor is considered to be a good approach, particularly with the limited staff resources available within CNCAN.*
- 4) **BASIS:** IAEA SSS WS-R-2 in §3.7 requires that *“The regulatory body shall establish safety criteria for decommissioning of nuclear facilities, including conditions on the end points of decommissioning.”*
- R38) **Recommendation:** *CNCAN should elaborate and establish regulations for the safety assessment on the decommissioning of NPPs, including the safety requirements and safety criteria.*
- 5) **BASIS:** IAEA SSS WS-R-2 in §7.2 requires that: *“Facilities and activities for predisposal management of radioactive waste, including decommissioning activities, shall be subject to safety and environmental impact assessments in order to demonstrate that they are adequately safe and, more specifically, that they will be in compliance with safety requirements established by the regulatory body”*. IAEA SSS WS-R-2 in §7.3 requires that: *“These safety and environmental impact assessments shall address the facility’s structures, systems and components, the waste to be processed and all associated operational work activities, and shall encompass both normal operation and anticipated incidents and accidents. In the latter case, the safety and environmental impact assessments shall demonstrate that appropriate measures have been taken to prevent incidents or accidents and that consequences would be mitigated should an incident or accident occur.”*
- R39) **Recommendation:** *CNCAN should consider the revision of existing regulations on the decommissioning facilities other than NPP to include safety assessment for decommissioning.*

9.1.7. Public Involvement

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

R23 Recommendation: CNCAN should investigate mechanisms for a broader stakeholder access to and involvement in the licensing of waste management facilities in particular waste disposal facilities.

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions*

9.1.7.1. Changes since the 2002 IRRT / 2004 RaSIA missions

The public has involvement in the environmental licensing process in terms of Law No 137/2000. This legislation does not belong to the responsibility of CNCAN, who in terms of licensing legislation are not obliged to involve the public in the licensing process. Nevertheless, presently the involvement of public and other stakeholders is assured in the process of public consultancy required in the process of environmental impact assessment and procedures for getting the environmental agreement.

9.1.8. Effluent Discharges

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

R24 Recommendation: CNCAN should establish prescriptive requirements for small-scale users of radioactive material for the control of effluent discharges to the environment.

S12 Suggestion: The guidance provided in Safety Guide WS-G-2.3 Regulatory Control of Radioactive Waste Discharges to the Environment should be adopted.

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions*

9.1.8.1. Changes since the 2002 IRRT / 2004 RaSIA missions

The authorization process makes provision for the control of effluent discharge from regulated facilities. The process adopted involves the operator establishing derived criteria for release of effluents, which are approved by CNCAN. CNCAN has issued by the Order of President No. 221/2005 the Norms (NDR – 04) on Emission of Radioactive Effluents in the Environment. The norms establish limits for effluents releases both for nuclear installations and for small radioactive waste producers. The norms observe the guidance provided in WS-G-2.3. Beforehand the Norms (NSR-14) on Radiological Safety on Nuclear Medicine approved by the President Order No. 358/2004 established the criteria for release of effluent from medical facilities. The criteria established in these two regulations are in accordance.

9.1.8.2. Findings of the 2006 follow-up IRRS mission

In the 2002 IRRT Mission, it was noticed that whilst for larger licensees such as the Cernavoda NPP and the Magurele and Pitesti Research Facilities, it would be reasonable to expect that they would have the necessary expertise available to carry out impact assessments and derive appropriate criteria for discharge control, this is unlikely to be the case for smaller users of radioactive material, such as in nuclear medicine departments in hospitals.

During the inspection organized to the Oncology Institute it was noticed by the Review Team that there is not an appropriate control and record keeping of the discharges of radioactive material that are systematic done in the Nuclear Medicine Department of this Hospital. There is a system in operation for the collection and release of the discharges containing I-131. Nor the operator nor the regulatory body controlled the proper operation of this system. During the inspection to the Oncology Hospital, the inspectors controlled only the registers of radioactive sources and radioactive waste. The proper operation of the system could not be done because the retention tanks were inundated for a couple of days.

The recommendation R24 given in the previous IRRT 2002 Mission is still to be solved.

9.1.8.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 (LGI) in §5.8 requires that: *“Authorized discharge, authorized use and clearance of materials from regulatory control, if necessary after an appropriate treatment and/or a sufficiently long storage period, can be effective in reducing the volume and amount of radioactive material that requires further processing. However, it shall be ensured that these management options, if implemented, are in compliance with the conditions and criteria established by the national regulatory body. In the application of such options, the regulatory body shall ensure that due account is given to non-radiological hazards”.*
- R40) **Recommendation:** *CNCAN should establish prescriptive requirements for small-scale users of radioactive material (unsealed sources) for the control of effluent discharges to the environment.*

9.1.9. Waste Acceptance Criteria

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *R25 Recommendation: The safety assessment for the Baita Bihor disposal facility should be finalized and independently evaluated by CNCAN. The conditions of authorization revised to reflect operational controls, including waste acceptance criteria, derived on the basis of the assessment.*
- *R26 Recommendation: The safety assessment for the proposed disposal facility for Cernavoda low and intermediate level waste should be progressed without further delay.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions*

9.1.9.1. Changes since the 2002 IRRT / 2004 RaSIA missions

In 2002 waste acceptance criteria have been established for the Baita Bihor near surface waste disposal facility on the basis of generic considerations, but work was in hand on a site specific safety assessment with assistance from the EU including both the carrying out of a safety assessment and development of expertise. The Preliminary Safety Assessment for Baita-Bihor repository is performed under a PHARE project. The draft report was submitted to CNCAN for comments on 7-th December 2005. The completed report shall be submitted to CNCAN in June 2006.

Consideration is being given to the development of a near surface repository for low and intermediate level waste arising from the Cernavoda NPP. Work has commenced on this project and a performance assessment has been compiled by the operator. The operator of NPP submitted to CNCAN in 2001 as technical documentation for the siting authorization the Initial Safety Assessment Report for the low and intermediate disposal facility to be located in Saligny near the Cernavoda NPP site. CNCAN reviewed the documentation and requested clarifications. In the mean time the operator has given up to the application. At present, there is no application for the siting of any other disposal facility.

9.1.9.2. Findings of the 2006 follow-up IRRS mission

The Recommendation R26 on the safety assessment for the proposed disposal facility for Cernavoda low and intermediate level waste is still unsolved due to the fact that the safety assessment for Baita Bihor near surface waste disposal facility has not been presented yet. This safety assessment is still working at present.

CNCAN has given special attention to the determination of waste acceptance criteria for the existing Baita Bihor near surface waste disposal facility. Nevertheless, there is not the same situation for the determination or approval by the regulatory body of the waste acceptance criteria for the radioactive waste generated in other authorized users of radiation sources and material. CNCAN is not aware and did not approve the requirements established by the treatment plant (if there are some) to collect the radioactive waste from the users.

9.1.9.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS WS-R-1 in §3.1 requires that *“Before construction of any repository, the operator shall perform a comprehensive and systematic assessment of the safety of the planned repository throughout its operating lifetime and the period following closure. This safety assessment shall be reviewed by the regulatory body. The regulatory body shall not authorize operation of a near surface repository until it is satisfied, on the basis of the safety assessment and other information, that the operator has demonstrated with reasonable assurance that the safety criteria will be met”*.

- R41) ***Recommendation:*** *CNCAN should follow up closely to the elaboration by the operator of the design and safety assessment for the proposed disposal facility for Cernavoda low and intermediate level waste. At the same time, be prepared to do the proper review of the authorization request and to take the final decision.*
- 2) ***BASIS:*** *IAEA SSS WS-R-2 in §5.4 requires that: “At various stages in the process of predisposal management of radioactive waste, the radioactive waste shall be characterized in terms of its physical, chemical, radiological and biological properties. Such characterization shall serve to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for storage, transport and disposal. Provisions shall be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria. Appropriate collection or segregation may expedite the achievements of such goals”.*
- R42) ***Recommendation:*** *CNCAN should approve and control the waste acceptance criteria established by the treatment plant to collect the radioactive waste and disused radiation sources from users other than nuclear installations.*

9.1.10. Records and Reporting

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *R27 Recommendation: CNCAN should establish, in line with international standards, requirements for the duration for which records should be kept for activities at waste management facilities.*
- *R28 Recommendation: CNCAN should extend the existing waste management facility specific reporting requirements to include, not only reporting of licence or regulation violations, but also occurrences of a lesser nature which could be indicators of precursors to more incidents or of degraded performance.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions for this section*

9.1.10.1. Changes since the 2002 IRRT / 2004 RaSIA missions

Requirements are in place for records to be maintained regarding radioactive waste management activities. Time periods for retention of specific information are not specified and it was indicated that provision in this regard would be made in specific regulations. At present the records are kept indefinitely. The future regulations on radioactive waste management shall include the duration of records keeping. This is the reason why the Recommendation R27 of the IRRT 2002 Mission is still open.

Occurrence reporting arrangements are limited to exceeding certain prescriptions in the regulations and law. Nevertheless the authorization for each radioactive waste management facility requires that the operator notifies any event to CNCAN. In each authorization CNCAN requests to the

operator to submit to the regulatory body an annual report on the operation. The reports shall contain data on the inventory, activities performed, non-conformities etc.

9.1.10.2. Findings of the 2006 follow-up IRRS mission

In the inspection visit organized to the NPP Cernavoda and the Oncology Hospital the Review Mission noticed different levels of knowledge, and quality of the record keeping practice. In the Oncology Institute there exist a level of records on radioactive waste management that permit to have an idea of the radioactive waste management situation but do not allow having a permanent traceability of the radioactive material. For example the Hospital waits for the treatment plant to send to them the record of the collected radioactive waste by the treatment plant. In some instances, it takes some months for this reception, mean while there is no record at the hospital.

9.1.10.3. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 (LGI) requires in §3.2.(3) (ix) that in fulfilling its statutory obligations the regulatory body “*shall specify... (ix) the records that the operator is required to retain and the time periods for which they must be retained;*” IAEA SSS GS-R-1 (LGI) requires in §3.3.(8). “*In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: (8) shall ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable*”;
- R43) **Recommendation:** *CNCAN should establish in line with IAEA Safety Standards, requirements on records keeping including their content and format as well as the time period to be kept. The specific requirements on predisposal, disposal and decommissioning under development should cover waste generators and operators.*

9.1.11. Storage

According to the provisions of the Governmental Ordinance No.11/2003 any producer of radioactive waste is responsible for the management of that waste and for the decommissioning of its facility; the producer shall bear the expenses related the collection, handling, transport, treatment, conditioning, temporary storage and disposal of the waste produced, and shall pay the legal contribution to the above mentioned fund.

By conditions set in the operating authorization, and by regulatory dispositions, the holder of authorization is requested to send the radioactive waste (including the spent sources) for treatment and disposal or long term storage at dedicated facilities. The holder of authorization shall bear the expenses related to the collection, handling, transport, treatment, conditioning, temporary storage and disposal of the waste produced in its activity; It has to be mentioned that the operating authorization is granted by CNCAN only for an established period of time (max. 3 years for spent fuel storage, maximum 5 years for radioactive waste management facilities). After this period the authorization shall be renewed. Periodically (generally at 10 years), the Final Safety Assessment Report has to be revised.

The transitional radioactive waste is waste having activity concentration above clearance levels, but which decays below clearance levels within a reasonable storage period (not more than 5 years).

In the Safety Criteria for Nuclear Reactors and NPPs, Norms for Nuclear Safety-1975, there are established conditions for the management, storage and surveillance for spent fuel storage (Art.72, 73, 74).

9.1.11.1. Findings of the 2006 follow-up IRRS mission

The Review Mission was informed that the safety requirements for the long term storage of the spent fuel and radioactive waste storage are not clearly defined. The Law 111/1996 stipulates only that the operator is responsible for the safe storage of spent fuel and radioactive waste. In other hand there are not established time limits in the regulations. The time limits are established in a case by case basis by CNCAN.

The regulation in force does not ensure that over a pre-determined time scale nuclear activities can not start without sufficient storage capacity pending disposal. In the assessment of justification of the practices, CNCAN may close a practice if it has no sufficient storage capacity. (NSR-01 art. 12, 13).

During the visit done to the radioactive waste storage facility of the Cernavoda NPP it was noticed that some of the IAEA Safety Requirements on safe radioactive storage are not in place. Something similar occurred during the visit to the Oncology Institute. The Review Mission was informed that such requirements will be considered in the regulation under development on predisposal radioactive waste management.

9.1.11.2. Recommendations, Suggestions and Good Practice

- 1) **BASIS:** IAEA SSS WS-R-2 requires in §5.23 that: *“The radioactive waste storage facility shall be designed on the basis of the assumed conditions for its normal operation and assumed incidents or accidents. It shall be designed and constructed for the likely period of storage, preferably with passive safety features, with the potential for degradation taken into account. Provisions shall be made for regular monitoring, inspection and maintenance of the waste and the storage facility to ensure continued integrity. The adequacy of the storage capacity should be periodically reviewed, with account taken of the predicted waste arising and the expected life of the storage facility”.*
- R44) **Recommendation:** *CNCAN should establish in line with international standards, requirements on storage of radioactive waste, paying special attention to requirements for long term storage. The specific requirements on predisposal, and decommissioning under development should cover storage requirements for waste generators and operators, including long term storage.*

9.1.12. Disposal facilities and activities

By conditions set in the operating authorization, and by regulatory dispositions, the holder of authorization is requested to send the radioactive waste (including the disused radioactive sources) for treatment and disposal or long term storage at dedicated facilities.

Final disposal is carried out at the National Repository for Radioactive Wastes (DNDR) at Baita-Bihor. The radioactive wastes, treated and conditioned in long-lasting matrices are disposed of at the National Repository for Radioactive Wastes (DNDR) Baita Bihor provided that they are satisfying the maximum concentration of activity allowed for disposal in that facility. Radioactive wastes, containing short lived radionuclides, including disused sealed sources are collected, treated and conditioned at IFIN – HH before final disposal, provided that they are satisfying the maximum concentration of activity allowed for disposal at Baita Bihor repository. The long lived radioactive wastes including disused sources are stored on site at STDR Magurele.

The deep geological disposal is considered in the National Strategy for Radioactive Waste Management that has to be operational after maximum 45 years from now. The management of the non-fuel cycle radioactive wastes from all over Romania is centralized at IFIN – HH in the Radioactive Waste Treatment Plant (STDR).

9.1.12.1. Findings of the 2006 follow-up IRRS mission

The Review Mission was informed that CNCAN recently developed regulations for near surface disposal facilities. The Norm on Near Surface Disposal of Radioactive Waste was approved by the President of CNCAN by the Order No 400/2005 and should be published and entry in force in a short time period. This Norm includes general requirements for near surface disposal facilities, authorization procedures and guidance, content and format of the safety assessment to be developed demonstrating safety of the facility.

9.1.12.2. Recommendations, Suggestions and Good Practice

In this context should be taken in consideration the recommendations given in the following sections: 9.1.5.; 9.1.9.; and 9.1.10.

9.2. ORGANIZATION OF THE REGULATORY AUTHORITY

CNCAN has a broad range of activities for which it is responsible as a regulatory body in terms of radioactive waste safety. This ranges from predisposal management of small amounts of waste from users of radioisotopes on a small scale to the management and disposal of high level waste and spent nuclear fuel. The facilities under its control cover uranium mining and processing, mining and processing of other radioactive minerals, use of radioisotopes, manufacture of nuclear fuel, reactor operation, decommissioning and the predisposal management of radioactive waste and disposal. It must also give consideration to facilities designed to previous standards with a view to their upgrading. The organization is responsible for establishment of regulations, evaluation of licensee submissions including safety assessments, setting of conditions of authorization and inspection and enforcement of compliance.

With regard to radioactive waste management activities, the prime responsibility falls upon the Radiation Protection and Radioactive Waste Division. A number of the other Divisions and Sections have some responsibilities for waste safety including the Special Materials Division (mining and minerals processing waste), Nuclear Reactors Division (NPP and research reactors spent fuel management), Division of Ionizing Radiation (waste from radioisotopes use).

9.2.1. Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions made for this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions made for this section*

9.2.2. Changes since the 2002 IRRT / 2004 RaSIA missions

The regulation of the safety of radioactive waste and decommissioning is performed by the Radioactive Waste and Decommissioning Section which runs under the Radiation Protection and Radioactive Waste Division. The section includes 5 positions. There is only one vacancy. The present staff within the section dealing with these responsibilities are four experts; two of them being junior experts. The number of dedicated personnel is small for such a broad range of facilities and activities. In addition, two of the experts are junior with limited experience in the field of radiation protection and radioactive waste safety. This is still an area of concern. The position of the head of Radioactive Waste and Decommissioning Section is not filled. In this moment the management of this department is done directly by the director.

9.2.3. Findings of the 2006 follow-up IRRS mission

In reviewing the presented documents, interviewing CNCAN staff and participating in organized inspections, the review mission noticed that there exists a lack of coordination between different areas regulating and controlling radioactive waste management and decommissioning of different facilities. This is the case for example with waste acceptance criteria, record keeping and decommissioning. Recommendation R29 of the IRRT 2002 Mission is not closed.

CNCAN considers that in the field of radioactive waste management and decommissioning they are still not sufficient and it should use external technical support organizations (TSO) or qualified experts. Due to this reason there was noticed that for some activities or safety assessment review the CNCAN needs to rely on the operator's assessments and results.

9.2.4. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS GS-R-1 (LGI) requires in §4.1 that the *“The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities...”*

- R45) ***Recommendation:*** *The number of specialist staff in the area of waste safety and decommissioning as well as the matrix management arrangements for waste safety activities should be reviewed and upgraded accordingly.*
- R46) ***Recommendation:*** *A systematic and consistent process should be established in CNCAN for regulating, authorizing, inspecting and recording all the various different types of radioactive waste management related activities and facilities, including decommissioning.*
- R47) ***Recommendation:*** *CNCAN should identify the fields where it will need technical support to review the safety assessment and support documentation presented by the operators in support of their authorization requests. In the identified fields CNCAN should develop an action plan to find the qualified institutions or qualified experts that could support its review.*

9.3. AUTHORIZATION PROCESS

In some areas of the radioactive waste management various levels of guidance and requirements have been developed on the information to be submitted in support of licence application. One area in need of such guidance since 2002 is long-term storage and disposal. Requirements in the area of decommissioning are further developed for nuclear installations other than NPP. In view of some of the significant projects that are presently under consideration such as safety assessment for disposal facilities and long terms storage of spent fuel a consistent and harmonized approach to the licensing process is important. Additionally, consideration should be given to the control to be exercised over activities involving materials containing elevated levels of naturally occurring radionuclides.

9.3.1. Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *R 30 Recommendation: CNCAN should further develop its existing guidance and requirements so that a systematic and consistent process is established for authorizing all the various different types of waste management related activities.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions made for this section*

9.3.2. Changes since the 2002 IRRT / 2004 RaSIA missions

Since the previous missions, CNCAN issued some authorizations for radioactive waste management activities and facilities such as:

- the Radioactive Waste Treatment Plants of the Nuclear Research Institute from Pitesti,
- the National Institute of Research and Development for Physics and Nuclear Engineering Horia Hulubei;
- the Dry Storage Facility for spent nuclear fuel from NPP Cernavoda (DICA); and
- the wet storage facility for WWR-S research reactor from Magurele.

9.3.3. Findings of the 2006 follow-up IRRS mission

At present two main important regulations are in drafting: - regulations on general requirements for surface disposal of radioactive waste; and - regulations on requirements for predisposal management of radioactive waste in nuclear installations and major radiological installations. These regulations shall be issued in the first semester of 2006. The Review Mission was informed that these two draft regulations will include the scope and content of the documentation to be presented in support of the operator's authorization request. The issue of the above mentioned regulations will contribute to solve the Recommendation R30 that is still not closed.

9.3.4. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS GS-R-1 (LGI) requires in §5.4. that *“The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.”*
- R48) **Recommendations:** *CNCAN should complete the set of regulations to detail the safety requirements for authorization of predisposal, disposal and decommissioning activities and facilities, including the requirements for the documentation to be presented in support to the authorization request. The requirements should cover both small and large facilities.*

9.4. REVIEW AND ASSESSMENT

Since 2002 information was provided that safety assessments were performed for all pre-disposal radioactive waste management activities. However it was also indicated that these assessments would be reviewed in accordance with recent international requirements. It was also indicated that there are no formal guidelines or requirements for such assessments. This situation still remained. This is an area where there is a lack of international harmonization, but an area where good assessment is indicated to be necessary because of the extended storage periods that are being experienced and with view to ensuring that arrangements are adequate and that appropriate conditions of authorization are set down on the basis of the assessments and that regulatory inspection and enforcement actions are appropriately focused.

With regard to disposal facilities, a certain amount of work has been carried out and expertise is being developed in Romania. Requirements should continue to be developed and IAEA Safety Standards should be used as a basis in this process.

CNCAN's personal is not participating in IAEA co-ordinated research programme on application of safety assessment methodologies to near surface radioactive waste disposal facilities (ASAM) and safety assessment of predisposal activities and facilities (SAWDRMS).

9.4.1. Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *R 31 Recommendation: CNCAN should develop and adopt standards for safety assessment of waste management facilities, both predisposal and disposal taking into consideration relevant IAEA safety standards in this area i.e. DS 284 Draft Safety Guide “Safety Assessment for Predisposal Waste Management Facilities” and WS-R-1 “Safety Requirements for near Surface Disposal of Radioactive Waste”.*

IRRT 2002 Suggestions:

- *S13 Suggestion: CNCAN should actively participate in the IAEA co-ordinated research programme on application of safety assessment methodology to near surface radioactive waste disposal facilities and share the experience developed to date.*

9.4.2. Changes since the 2002 IRRT / 2004 RaSIA missions

Two new regulations are planned both on general requirements for surface disposal of radioactive waste and requirements for predisposal management of radioactive waste in nuclear installations and major radiological installations. The Review Mission was informed that both drafts will consider the IAEA safety requirements and guidance on safety assessment of predisposal activities and facilities as well as near surface disposal facilities.

9.4.3. Findings of the 2006 follow-up IRRS mission

The Review Mission was informed that in some instances CNCAN relies on the safety documentation presented by the operator safety documentation due to its high qualification and in some instance due to the lack of qualified personnel in CNCAN to perform the safety assessment review. The Review Mission had the opportunity to review some records of the safety review done by CNCAN’s personnel. Nevertheless it was informed that this is not a systematic practice.

Recommendation R31 and Suggestion S13 are not solved yet.

9.4.4. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA Safety Series 111-F “The Principles of Radioactive Waste Management” states in Principle 9 that “*The safety of facilities for radioactive waste management shall be appropriately assured during their lifetime.*” IAEA SSS WS-R-1 in §3.1. requires that “*Before construction of any repository, the operator shall perform a comprehensive and systematic assessment of the safety of the planned repository throughout its operating lifetime and the period following closure. This safety assessment shall be reviewed by the regulatory body. The regulatory body shall not authorize operation of a near surface repository until it is satisfied, on the basis of the safety assessment and other information, that the operator has demonstrated with reasonable assurance that the safety criteria will be met*”. IAEA SSS WS-R-1 in §7.2. requires that “*Facilities and activities for predisposal management of radioactive waste, including decommissioning activities, shall be subject to safety and environmental impact assessments in order to demonstrate that they are adequately safe and, more specifically, that they will be in compliance with safety requirements*

established by the regulatory body”.

- R49) **Recommendations:** *CNCAN should develop and adopt standards for safety assessment of waste management facilities, both predisposal and disposal taking into consideration relevant IAEA Safety Standards in this area i.e. DS 284 Draft Safety Guide “Safety Assessment for Predisposal Waste Management Facilities” and WS-R-1 “Safety Requirements for near Surface Disposal of Radioactive Waste”.*
- S9) **Suggestion:** *CNCAN should actively participate in the IAEA co-ordinated research programme on application of safety assessment methodologies to near surface radioactive waste disposal facilities (ASAM) and predisposal activities and facilities (SAWDRMS) and share the experience developed to date.*
- 2) **BASIS** - IAEA SSS WS-R-1 in §3.3. (10) requires that: *“In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: (10) shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review”*
- R50) **Recommendations:** *CNCAN should include in the standards under development for the safety of the predisposal activities and facilities as well as for the safety of disposal facilities the systematic safety reassessment or periodic safety review taking into consideration relevant IAEA Safety Standards in this area.*
- 3) **BASIS** - IAEA SSS WS-R-1 in §5.5. requires that: *“The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either: (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator’s subsequent activities; or (2) the refusal of such an authorization. The regulatory body shall formally record the basis for these decisions”.*
- R51) **Recommendations:** *CNCAN should systematise the practice of formally recording the review process and the basis for its decisions.*

9.5. INSPECTION AND ENFORCEMENT

Inspection and enforcement actions for radioactive waste management activities are performed by the technical staff of the Radiation Protection and Radioactive Waste Management Division. During the course of the IRRS, visits were made to the Cernavoda site (waste drumming area and treated waste storage facility), and the Oncology Institute in Bucharest. In all these visits there was evidence of an awareness of regulatory requirements related to waste management. There was also evidence of a good level of dialogue between the personnel of CNCAN and the operator and there was general evidence of compliance with regulatory requirements.

9.5.1. Findings of the 2006 follow-up IRRS mission

Consideration was given to the overall programme of inspections in the area of radioactive waste management. CNCAN has an inspection programme, which considers a frequency of one inspection every three months for the most important waste management facilities. The Review Mission was informed also about the existence of a data base for recording the inspections finding and its systematic review.

There exists an inspection check list for doing the inspections in the main waste management facilities based on the check list prepared by the IAEA for inspecting practices with unsealed sealed sources (IAEA TECDOC-1113 “Safety Assessment Plans for Authorization and Inspection of Radiation Sources”). Nevertheless it was noticed that this check list should be reviewed and updated in accordance with the waste safety regulations in force.

9.5.2. Recommendations, Suggestions and Good Practices

- 1) **BASIS** - IAEA SSS GS-R-1 (LGI) requires in §5.12. that: “Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations”...
- R52) **Recommendations:** CNCAN should review and update the inspection checklists in use for waste management facilities according to the regulations in force in this field.
- 2) **BASIS** - IAEA SSS GS-R-1 (LGI) requires in §5.14. that: “The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.” IAEA SSS GS-R-1 (LGI) requires in §5.17. that: “Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process.”
- G9) **Good Practices:** The approach to design and maintain updated a data base for the control of the compliance of the instructions given during the inspections is considered a good practice.

10. RADIATION PROTECTION

10.1. LEGISLATIVE FRAMEWORK AND ORGANIZATION

The legal framework for radiation protection in Romania is established under the modified Law No. 111/1996 (hereafter “the Law”).

The Law (art.4) establishes CNCAN as the regulatory authority. Three different divisions of CNCAN have responsibilities for radiation protection: Ionising Radiation Division (uses of radioactive sources), Special Materials Division (Mining and fuel cycle facilities) and Radiation Protection and Radwaste Division (for nuclear reactors).

CNCAN is empowered by Article 5 of the Law to issue regulations of the general requirements for protection against ionizing radiation. Further, each division is responsible for the development of general or specific radiation protection regulations, as far as they are concerned.

The Radiological Safety Fundamental Norm (RSFN), issued in 2000 addresses radiological safety for all sources, including NPP and reactors, and also TENORM.

For medical exposure, there is a separate Norm (Ministry of Health and Family and CNCAN common order no. 285/79/2002), which was jointly published in June 2002. This Norm is a transposition of the European Directive 97/43/EURATOM of 30 June 1997. More specific regulations related to medical exposures for each type of medical practice were developed in close collaboration with the Ministry of Health and Family, and the professional colleges e.g. Medical Physics, Radiation Oncology, Nuclear Medicine Physicians, and Radiologists.

Article 38 of the Law gives the authority to the Ministry of Health to regulate the following areas:

- To authorise the introduction of products for utilisation or consumption by the population that contain radioactive materials or have been subject to irradiation (Norm on food and food ingredients treated with ionising radiation approved by CNCAN President by Order 90/2002) ;
- To authorise the introduction into the medical field for medical treatment or diagnosis purposes of radiation sources, from the health system point of view. Such as ionising radiation generating devices, pharmaceutical products containing radionuclides and open and sealed radiation sources.

Article 39 of the Law requires that the Ministry of Health organise a monitoring network for the contamination of food, including drinking water, with radioactive materials, and the radiation monitoring of other goods and products destined to be used in Romania. Around 40 counties Divisions depending on the Public Health Divison of the Ministry of Health, with special dedicated laboratories, are in charge of analysing samples collected in water or food. These laboratories are under the control of CNCAN that issues a certificate for those complying the appropriate QA standard (ISO 17025).

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and natural Th, as applied to materials containing natural radionuclides.*
- *CNCAN should develop a set of generic clearance levels for normal operations, together with guidelines for their application, which can be used by licensed facilities.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSSIA missions

Regarding the radiation protection, new regulations have been issued by CNCAN.

In the scope of Radiation Protection and Radwaste:

- Norms regarding the calculation of the dispersion of radioactive effluents released in the environment at nuclear installations, approved by the Order of CNCAN President n° 360/2004 ;
- Norms regarding the meteorological and hydrological measurements at nuclear installations, approved by the Order of CNCAN president n° 361/2004;
- Norms on monitoring of radioactive emissions from nuclear and radiological installations, approved by the Order of CNCAN president n° 276/2005
- Norms on monitoring of radioactivity of the environment in the vicinity of a nuclear or radiological installation, approved by the Order of CNCAN president n° 275/2005
- Norms on limitation of radioactive releases in the environment, approved by the Order of CNCAN President n° 221/2005
- Norms on clearance from the authorisation regime of the materials resulted from authorized practices in nuclear field, approved by the Order of CNCAN president n° 62/2004

In the scope of Special Materials:

- Radiological Safety Norms on Operational Radiation Protection in Mining and Milling of Uranium and Thorium Ores approved by CNCAN President Order 127/27.05.2002 and published in MO Part. I, No 677/12.09.2002
- Radiological Safety Norms on the Management of the Radioactive Waste Resulted from Mining and Milling of Uranium and Thorium Ores approved by CNCAN President Order 192/26.09.2002 and published in MO No 867 bis from December, 02,2002
- Radiological Safety Norms on Decommissioning of Uranium and Thorium Ores Mining and Milling Facilities approved by CNCAN President Order 207/24.11.2003 and published in MO, Part I, No 933/24.12.2003
- Radiological Safety Norms – Authorization Procedures for Uranium and Thorium Mining and Milling, Nuclear Row Materials Processing and Nuclear Fuel Production Activities approved by CNCAN President Order no 171/24.11.2003 and follow up to be published in the official law bulletin

In the scope of Ionising Radiation – since the last RaSIA:

- Radiological safety on radiotherapy practice approved by the Order of CNCAN president n° 94/2004;
- Radiological safety on nuclear medicine approved by the Order of CNCAN president n° 358/2004;
- Radiological Safety for Nuclear Gauges approved by Order of CNCAN president n° 144/2004;
- Normative of granting and utilisation of ionising radiation protection individual equipment approved by Order of CNCAN president n° 421/2004 ;
- List of dsimetric accredited bodies, designed by CNCAN approved by Order of CNCAN president n° 302/2004;
- Prohibition of the use of medical fluoroscopic radiological installations without image intensification approved by Order of CNCAN president;

Regarding the organisational issues, the two Government decisions n° 750/2004 and 1627/2003 changed with an increased number of competent staffs:

The Radiation Protection and Radwaste Section into a Division, which is composed of three major sections or branches:

- Radiation Protection and Radiological Emergencies Section ;
- Radwaste Management and Decommissioning Branch ;
- Radioactive Materials Transport Branch

The Safeguards, Physical, Protection & Fuel Cycle Office into a new Division: Special Material Division which is composed of two sections:

- Safeguards and Physical Protection Section;
- Licencing and Radioactive Mining Bureau, in charge of Radiation Protection in the field of the nuclear fuel cycle facilities;

The main change for the staff training is that CNCAN has established training programme policy and procedures in the Management Manual of CNCAN: “Staff Training Programme”, MC-PC-03 and “Training Requirements Assessment”, MC-PC-06, CNCAN Personnel Training Program Development, MC-PC-03, Project Team Development, MC- PC-04.

10.1.1. Findings of the 2006 follow-up IRRS mission

Article 31 of the Law states that “The CNCAN personnel who, by the nature of their activity, are exposed to the action of ionizing radiation shall be deemed as occupationally exposed personnel and shall benefit from the wage additions granted for such work conditions under the provisions of the Law”, which is in contradiction with AIEA standards.

There is no new guidance on exclusion level of natural radioactive materials. A special norm about TENORM is planned to be written and published in 2007. All the recommendations and suggestions related to these issues are addressed in chapters 9.1.2.2 and 9.1.2.3.

Each Division is entrusted with training its own staff on a case by case basis. An annual programme is elaborated by each Division according to the specific needs estimated by the head of Division, after an evaluation meeting with each staff. There’s no training requirement predefined for each position nor qualification process established to allow CNCAN staff to perform its mandatory function, at least for some key position. According to the 1996 Law (article 31.3), “the CNCAN staff who, by nature of their activity, are exposed to the action of ionising radiation shall be deemed as occupationally exposed personnel” and should thus be informed and trained on radiological hazards, with a refreshment each 5 years (articles 49 and 50 of the RSFM).

Only twelve CNCAN staffs are officially professionally exposed, according to a list approved by CNCAN Order signed in 2004. This list doesn’t include all CNCAN staff who has to perform mandatory activities in controlled area and should therefore be modified to include them.

10 vacancies still need to be filled for the two of the Divisions to satisfy their jobs. The outstanding lack of competent staffs is in the Radiation Protection and Radioactive Waste Division at present time; only two staffs (including director) are responsible for the inspection and assessment for radiation protection at nuclear installations.

10.1.1.1 Recommendations, Suggestions and Good Practices

1) **BASIS:** *According to §4.6 of IAEA SSS document GS-R-1 “The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise”.*

R53) **Recommendation:** *CNCAN should define the required competencies in radiation protection for all staff, especially for the key positions, and ensure its adequate training and periodical refreshment on this topic to fulfil its mandatory function.*

See recommendation R5

2) **BASIS:** *According to § I-32 off BSS115 “Employer of any worker, as well as self-employed individuals, and the registrants and licensees shall be responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements be made with appropriate dosimetry services under an adequate quality assurance programme.” According to §2.8 of IAEA Safety Guide GS-G-1.3*

*“Regulatory Inspection of Nuclear Facility and Enforcement by the regulatory body”;
“The regulatory body shall have the authority and powers necessary to carry out its inspections. The operator shall give inspection personnel free and prompt access to any area of the facility and its site for the purposes of regulatory inspection. The only necessary limitation to this requirement may arise when the operator can demonstrate that such access would give rise to a hazard.”*

- R54) **Recommendation:** *CNCAN should modify its own list of exposed staff so that to ensure that all staff working regularly or occasionally in controlled area in the plants or facilities is included (see also recommendation in 6.3.1.1).*
- 3) **BASIS:** *IAEA SSS document GS-R-1 states in §4.7 that “In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes.”*
- G10) **Good Practice:** *Regarding training and staff development. CNCAN has established an individual evaluation in its training approach so that it could identify clearly the individual needs and the training programme for the following year.*
- G11) **Good Practice:** *Every staff member to go to a facility or a plant for inspection has been equipped with a Personal Alarm Dosimeter.*

10.2. SYSTEM OF NOTIFICATION, AUTHORIZATION, INSPECTION AND ENFORCEMENT

The Ionizing Radiation Division has developed a comprehensive centralized database for the radiation source inventory in Romania.

The register includes information about the owner of the source (licensee or registered owner), radiation source used, the practice, the results of the authorization process, the inspections outcomes and the enforcement notices issued to licensees/registered owners.

Licensees are required to notify CNCAN immediately in case of: effluent release above the legal discharge limit specified in the licence and a loss or theft of radiation source (Article 134 of RSFN). If the licensee investigation report about an incident or accident is not clear, then CNCAN will conduct its own investigation.

The dosimetry service providers have to submit reports to CNCAN for each worker overexposure.

CNCAN has approved an investigation level of 1 mSv per month for NPP worker occupational exposure spread out later for other practices.

As required by RSFN, there is five dosimetry service providers accredited by CNCAN every 3 years.

The workers involved in nuclear and radiological activities defined in the Law must have a “practice permit” (article 9). There are three levels of “practice permits” issued either by CNCAN or the licence holder (level 1 and part of level 2), according to the NSR-07 Norm. For record:

- level 3 is for a qualified expert;
- level 2 is for a radiation protection officer and;
- level 1 for a person responsible for a low associated risk practice.
-

The applicants must have attended a training course of one of the 5 centres accredited by the CNCAN, prior to the permit issuance.

The three CNCAN Divisions involved in radiation protection issue the practice permit for the workers of the facilities they are regulating. In the case of the NPP workers, there is 4 categories defined by colours and approved by CNCAN: red colour for unqualified in radiation protection, orange for level 1, and yellow and green for level 2. Supplementary, there are three qualified experts (level 3) at the NPP.

Moreover, these three Division regulate their installations: Cernavoda NPP, TRIGA reactor and the 3 laboratories located in the Pitesti Research Centre for the Radiation Protection and Radwaste Division: mining, milling and nuclear fuel cycle facilities for the Special Materials Division and small scale radioactive sources users for the Ionising Radiation Division. This includes inspections and authorisation process.

Recommendations and Suggestions from the 2002 IRRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *CNCAN should proceed with completing a national registry of occupational exposure records.*
- *CNCAN should continue to develop material, and methods of communication (conferences, newsletters, website), on improving safety culture for users of radiation sources.*
- **S.14.** *Based on analyses of data in an occupational exposure registry, CNCAN should give consideration to extending the current investigation levels for occupational exposure at NPPs to other facilities and activities. The investigation levels could be set at different levels for different occupational categories.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRRT / 2004 RaSSIA missions

Doses for mining workers have decreased a lot due to the closure of 3 mines which were very deep and were generating high levels of internal doses. The maximum doses received now by mining workers are under the annual value of 10 mSv.

The concept of investigation levels has been set in specific regulations like the nuclear medicine (example of 0,5 mSv/month for the whole body or 12 mSv/month for fingers), diagnostic and interventional radiology (0,5 mSv/month for the whole body or 12 mSv/month for fingers). The licensee should investigate each monthly dose above these levels. These specific regulations include also an action level of 10 mSv/year, above which a qualified expert is required to make a complete evaluation of the radiation protection system.

The national registry containing information about sources and applicants contains now some workers exposure records.

CNCAN has developed materials and methods of communication since 2002: a new Website in 2004, the participation to congress with specialists in the medical field, the edition of a technical guidance on gauges. In the near future, CNCAN has planned to write and send a newsletter with juridical information and is already using its Website to collect comments on its draft of regulations. It should continue in that way so that to develop technical materials and methods of communication, like the technical guidance on gauges but extended to the other practices, with the aim of underlining and explaining the key points of the regulation.

Findings of the 2006 follow-up IRRS mission

Two dosimetry services providers have been approved by CNCAN for internal dosimetry evaluation. In the case of the mining workers, only the workers who have been working for more than 10 years are undergoing the whole body counter examination in Magurele. The whole staff of nuclear fuel cycle facilities exposed to internal contamination should undergo this examination.

The national registry system for occupational exposure records contains statistical data from workers in all the practices handled in Romania. The individual data are supposed to be sent annually by each dosimetry laboratory and each licensee according to article 68 of RSN. The individual data in the database are from 2004 and cover just about 1500 workers out of the 14 000 having been monitored during this year. Moreover CNCAN staff has to enter manually each individual data in the database.

According to article 7 of the RSN, “The content, conditions and stages of authorisation process of practices are established by the specific regulations issued by CNCAN.” The Norm “Radiation Safety Norm – Authorisation procedures” from 22th of September 2001 specifies more in more detail the content of the technical documentation required for granting an authorisation to users (other than nuclear installations) (article 58 and followings), especially from the radiation protection point of view. However, for Cernavoda NPP, the content of radiation protection related documentation to be submitted by Cernavoda NPP to CNCAN within the licensing process is not clearly defined in any updated regulation or guidance.

In the case of the Cernavoda NPP, the detailed criteria for incident notification are described in an internal procedure of the plant, approved by CNCAN. For the other nuclear facilities (TRIGA reactor and three other laboratories and nuclear fuel cycle facilities), there are no such detailed criteria approved or issued by the CNCAN.

Regarding the resident inspection in the NPP, now there are only three resident inspectors on site, they conduct all inspection activities which cover all the technical issues of plant on behalf of CNCAN, sometime they do the analysis job like radiation safety evaluation for small work programs. Two additional inspectors are under consideration to be recruited to meet the need of site inspection for Cernavoda Unit 1 and Unit 2.

Through varieties of inspections (daily, routine, topical inspection), the resident office formulates its findings simultaneously, further investigation of the issues found, if necessary, then drafts the inspection report including the corrective actions, sends it to relevant departments of NPP and Headquarters on time, in order to receive the confirmation and/or explanation on the comments made from the NPP and additional necessary corrective actions from Headquarters.

10.2.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS:** IAEA SSS Report No. GS-R-1 “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety” states in §4.1 that “... *the regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently ...*” and in §3.3(8) that in order to discharge its main responsibilities the regulatory body “*shall ensure that appropriate records to the safety of facilities and activities are retained and retrievable*”. The IAEA Safety Series No. 115 “International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources” states in §IV.18: “*Registrants and licensees shall conduct formal investigations as specified by the Regulatory Authority if: (a) a quantity or operating parameter related to protection or safety exceeds an investigation level ...*”.
- R55) **Recommendations:** CNCAN should complete its national registry system for occupational exposure records in order to include all exposed workers. CNCAN should improve its arrangements to use this system in an effective and efficient manner, updating continuously the data, especially to facilitate checking and tracking the records.
- 2) **BASIS :** IAEA BSS 115 document states in § I-35 that “*nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.* » and in § I-4 (f) that “*Employers, registrants and licensees shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that: (f) necessary health surveillance and health services be provided;*”
- R56) **Recommendation:** CNCAN should request the licensees of nuclear fuel cycle facilities to implement arrangements to ensure that all occupationally exposed staff undergoes a periodical whole body counter measurement.
- 3) **BASIS:** IAEA SSS document GS-R-1 states in §5.4 that “*The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested.*”
- R57) **Recommendation:** CNCAN should issue guidance on the format and content of radiation protection related documents to be submitted by Cernavoda NPP to CNCAN within the licensing process (see also the suggestion in chapter 4.3.1.1).

- 4) **BASIS:** IAEA SSS document GS-R-1 states in §3.1 that “ *In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.* » and then in §3.2 that “*In fulfilling its statutory obligations, the regulatory body shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified): (vii) the requirements for incident reporting;*”
- R58) **Recommendation:** *CNCAN should define more detailed criteria on the radiation protection incidents to be reported, clear and unambiguous, for all type of nuclear facilities (except for Cernavoda NPP where these criteria are already adequately defined).*
- 6) **BASIS:** IAEA SSS document GS-G-1.1(Organization and Staffing of the Regulatory Body for Nuclear Facilities) states in §4.1 that “*The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.*”
- S10) **Suggestion:** *CNCAN should consider recruiting new resident inspectors with radiation protection background. (see also recommendation in 6.2.1.1)*
- G12) **Good Practice:** *Three inspections for radiation protection have been carried out on NPP site in 2005, and 7 are planned for 2006. These inspections are performed by the staff of the Radiation Protection and Radwaste Division along with the resident inspectors. These team inspections including resident inspectors and headquarters staff allow exchanges of technical and operational experiences.*

10.3. REVIEW AND ASSESSMENT

The three CNCAN Divisions involved in radiation protection are in charge of the review and assessment of their installations.

For the Cernavoda NPP, the Radiation Protection and Radioactive Waste Division reviews and assess each 2, and soon 3, years the part of the documentation related to radiation protection. The documentation is composed of the chapter 12 of the Final Safety Analysis Report, and of a so-called “Reference-Documents” composed of several procedures and documents: ALARA and release evaluation, dosymetry, emergency, radiation protection internal regulation, as well as the personal training. The CNCAN has encouraged the NPP to create an ALARA Committee in charge of assessing all types of works leading to a collective dose above 20 men.mSv.

A document explaining the organisation of this future Committee is in draft at the plant level and will have to be sent to CNCAN for approval or replacement of the Reference Documents.

Before each work, including yearly outage, involving dose above 10 men.mSv, the plant prepares a “safety work plan” which includes an ALARA evaluation with a target collective dose.

The Radiation Protection and Radioactive Waste Division is also in charge of reviewing and assessing the radiation protection part of the documentation of the TRIGA reactor (renewal each 2 years), of the 3 laboratories located in the Pitesti Research Centre (renewal each 5 years), of the VVR research reactor and currently, of a new pilot plant which will be dedicated to the reprocessing of heavy water from the Cernavoda NPP. Only 2 staffs, including the head of Division, are in charge of these tasks, but also of the inspections, which appears clearly to be no sufficient.

The Special Materials Division / Licensing and Radioactive Mining bureau (3 staffs) is in charge of reviewing and assessing the radiation protection part of the documentation of the mining, milling and nuclear fuel cycle facilities: a 2 years renewal for the facilities in operation (2 Uranium Mines, a “U3O8” plant, a “UO2 Powder” plant and a “nuclear fuel plant”) and a 5 years renewal for the installations under decommissioning (3 uranium mines).

The Ionising Radiation Division / Assessment and Evidence Section (11 staffs) is in charge of reviewing and assessing the documentation of the small-scale radioactive sources users.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Findings of the 2006 follow-up IRRS mission

The review and assessment process, from the radiation protection point of view, is not addressed in any internal CNCAN procedure.

The 2005 ALARA evaluation made by the NPP for the outage was based on a target collective dose taking only into account the external exposure.

Moreover, the ALARA evaluation is not sent to the CNCAN before the outage but evaluated on site, with the members of the Radiation Protection and Radioactive Waste Division, without the resident inspectors, during a previous meeting.

The individual annual Dose constraint accepted by the CNCAN for the NPP is 18 mSv, when the more exposed worker receives yearly no more than 10-11 mSv.

10.3.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** : IAEA SSS document GS-R-1 states in §4.5 that “The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken. »

- R59) **Recommendation:** *CNCAN should develop guidance for the systematic review and assessment of the radiation protection aspects of the documentation submitted by the applicant*
- 2) **BASIS:** *IAEA SSS document GS-R-1 states in §5.4 that “The regulatory body shall review and assess submissions on safety from the operators both prior and periodically during operation as required” and in § 5.9 that “ A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria.” According to § 2.24 and 2.25 off BSS115 “ In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimized in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the doses to individuals delivered by the source be subject to dose constraints. The process of optimization of protection and safety measures may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques, but shall be sufficient to take all relevant factors into account in a coherent way so as to contribute to achieving the following objectives: (a) to determine optimized protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and (b) to establish criteria, on the basis of the results of the optimization, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.”*
- R60) **Recommendations :** *CNCAN should ensure that the ALARA evaluation takes into account all activities during the outages at the NPP including internal exposure and that the review and assessment of the ALARA evaluation is forwarded to CNCAN before outage.*
- 3) **BASIS :** *AIEA BSS115 document states in § 2.26 that “ Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints which: (a) do not exceed either the appropriate values established or agreed to by the Regulatory Authority for such a source or values which can cause the dose limits to be exceeded ». According to article 4.11 of the IAEA safety guide RSG1-1 « Occupational radiation exposure », « Optimization of protection should be a regulatory requirement. Regulatory authorities should be committed to optimization of radiation protection and should encourage its application. Where necessary, they should undertake all relevant actions to enforce regulatory requirements on management to apply this principle. » According to 4.20 of the same AIEA safety guide, Dose constraints may be set by management, in consultation with those involved in the exposure situation. Regulatory authorities may use them in a generic way — for categories of similar sources, practices or tasks — or specifically, in licensing individual sources, practices or tasks. The establishment of constraints may be the result of interaction between the regulatory authority, the affected operators and, where appropriate, workers’ representatives.*
- S11) **Suggestion:** *CNCAN should encourage the NPP to review its dose constraint, given the experience feedback of the workers occupational exposure.*

10.4 MEDICAL EXPOSURE

The regulatory body in charge of controlling medical exposure is CNCAN, but the regulations are issued by Ministry of Health, after consultation with CNCAN.

The specific regulations published for the medical practices encompass the medical exposure.

The Ionising Radiation Division is in charge of controlling the medical exposures through its mandatory functions (inspection, authorization, review and assessment).

This regulatory activity is performed in close collaboration with the Ministry of Health and Family, and the professional colleges e.g. Medical Physics, Radiation Oncology, Nuclear Medicine Physicians, and Radiologists.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section from the 2002 IRRT*
- CNCAN should review resource allocation to ensure that the nuclear medicine norm is completed and published as a matter of priority
- All new norms should be subject to QA/QC to ensure self consistency where appropriate regarding responsibilities eg requirement for written prescriptions
- CNCAN should set out guidance on the relationship between the licensee and suppliers of equipment, sources and services regarding regulatory responsibilities
- CNCAN should review its training programme to ensure that all inspectors are fully aware of the criteria for inspection.

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section from the 2004 RaSIA*

Changes since the 2002 IRRT / 2004 RaSSIA missions

The nuclear medicine norm has been completed and published the 15/02/2005 (NSR-14). Another specific regulation was published for radiotherapy practice (published the 24/12/2004). The new specific regulations describe in detail the regulatory responsibilities of licensees and suppliers of equipment, sources and services.

New regulations on diagnostic and interventional diagnostic and radiotherapy have been written and are supposed to be approved by CNCAN President and published in the national Gazette as soon as the new modification of the law enters into force. They take into account the requirements for written prescription.

Findings of the 2006 follow-up IRRS mission

No new findings

10.4.1. Recommendations, Suggestions and Good Practices

- 1) **BASIS** – According to §4.7 of the IAEA SSS GS-R1, “*In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts.*”
- R61) **Recommendations:** *CNCAN should review its training programme to ensure that all inspectors are fully aware of the criteria for inspection. (“against regulatory requirements and not against expected standards” according the 2004 Russia report).*

11. TRANSPORT OF RADIOACTIVE MATERIAL

11.1. TRANSPORT SAFETY INFRASTRUCTURE IN ROMANIA

Transport of radioactive material in Romania involves material related to different applications:

- Nuclear power generation
- Research
- Medical and technical applications

These applications include the shipment of fissile material, i.e. for power generation and research, and non-fissile material, i.e. for research, medical, and technical applications. The activity of radioactive sources ranges from very low quantities to large quantities which are shipped by all modes of transport, i.e. road, rail, air, and inland waterways (Danube River). There has been no transport by sea and none is scheduled in the near future.

Radioactive material is shipped in excepted packages, industrial packages, Type A packages and Type B packages which are of Romanian or foreign origin. According to Ordinance No. 357, published in the Official Bulletin of Romania No. 1152bis of 20 December 2005 (NTR-01), expedition of radioactive material by national post is allowed up to one tenth of the activity limits given in Para. 410 of IAEA Safety Standards Series (SSS) No. TS-R-1 "*Regulations for the Safe Transport of Radioactive Material*", Edition 1996 (As amended 2003).

Major installations in Romania with respect to transport of radioactive material are:

- the Nuclear Power Plant (NPP) at Cernavoda.(one CANDU type reactor in operation). Transport to and from this facility includes shipment of fresh fuel elements from the production plant in Pitesti to Cernavoda by road. Spent fuel is not transported as there is a long-term intermediate storage facility on site;
- the mining areas at Tulges and Crucea. Uranium ores of 0.1 % natural uranium are mined and transported by road and rail to the fuel fabrication plant at Pitesti;
- the research reactor TRIGA at Pitesti which is in operation since 1979. It is operated partly with HEU type elements;
- the VVR-S research reactor at Magurele which is under conservation and is going to be decommissioned;
- radioactive waste including spent sealed sources from users to IFIN-HH and SCN Pitesti;
- conditioned radioactive waste from IFIN-HH to the waste repository at Baita Bihor;
- several facilities manufacturing NDT sources; and
- producers, suppliers, and users of radiopharmaceuticals.

In addition, transit of fresh and spent fuel is carried out between the Russian Federation and the Kozloduy NPP, Bulgaria, sited on the river Danube near the border between Romania and Bulgaria. It consists of four VVER-440 units and two VVER-1000 units. The corresponding transports go on special Bulgarian dedicated barges and seagoing vessels on the Danube, which becomes a Romanian inland waterway before it reaches the Black Sea.

In this section, the term “*radioactive material*” is used in a manner consistent with the definition provided in the IAEA SSS TS-R-1 and the term “*fissile material*” is a sub-category of radioactive material as defined in Para. 222 of TS-R-1. The review undertaken for transport safety as part of this IRRS mission was based upon the draft questionnaire developed by the IAEA to support IAEA Transport Safety Appraisal Service (TranSAS) missions. However, the evaluation undertaken as part of this IRRT mission was not as comprehensive as a full-scope TranSAS mission appraisal would have been.

11.2 LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES IN TRANSPORT

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

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

- Law No. 111/1996 which is the fundamental law regarding the safe deployment of nuclear activities; and
- Ordinance No. 357 published in the Official Bulletin of Romania No. 1152bis of 20 December 2005 (NTR-01) which is a direct translation of the IAEA Safety Standards Series No TS-R-1, Edition 1996 (As amended 2003)

According to Law No. 111/1996 (Art. 4) and Art. 101 of NTR-01, CNCAN is the competent authority in the nuclear field, with duties in regulation, authorization, and control. This includes also the transport of radioactive material by all modes (road, rail, air, inland waterways). CNCAN is also empowered to issue regulations in accordance with Law No. 111/1996 (Art. 5).

Romania has legally adopted the various conventions and thereby the corresponding modal agreements for the safe transport of dangerous goods (ADR, RID, ICAO-TI, and IMDG-Code).

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

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IRRT 2002 Recommendations:

- *Recommendation: CNCAN should give consideration to the legal status and the interdependence of Law No. 111/1996 and the international agreements (ADR, RID, ICAO-TI, IMDG-Code) which were adopted by Romania, because there are conflicting requirements. A closer cooperation with the Ministry of Transport should be implemented.*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions for this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

The norms on transport of radioactive materials (NTR-01) were revised in 2004 to solve the conflicts with the modal regulations. A close cooperation with the Ministry of Transport, Buildings, and Tourism has been implemented, regarding the revision of regulations for the transport of dangerous goods. In addition, CNCAN has a representative in the inter-ministerial committee for rail transport.

11.2.1 Findings of the 2006 follow-up IRRS mission

CNCAN has no formal agreement with the Ministry of Transport, Buildings, and Tourism concerning road, air and inland waterway transport therefore, part of the recommendation is not closed.

11.2.2 Recommendations, Suggestions and Good Practices

- 1) **BASIS:** In Para.103 the IAEA SSS TS-R-1 states that *“In certain parts of these Regulations, a particular action is prescribed, but the responsibility for carrying out the action is not specifically assigned to any particular legal person. Such responsibilities may vary in accordance with the laws and the customs of the different countries and international conventions into which these countries have entered”*. Para. 4.2 of IAEA SSS GS-R-1 states (in part) that *“If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and coordinated, in order to avoid any omissions or unnecessary and to prevent conflicting requirements being placed on the operator. In addition the authorities... shall be effectively coordinated”*.
- R62) **Recommendation:** CNCAN should give consideration to the legal status and the interdependence of Law No. 111/1996 and the international agreements (ADR, RID, ICAO-TI, IMDG-Code) which were adopted by Romania. The cooperation with the Ministry of Transport, Buildings, and Tourism should be enhanced and formalized.

11.3 AUTHORITY RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

This area was not considered.

11.4 ORGANIZATION OF THE REGULATORY BODY

CNCAN has all of the regulatory authorities and responsibilities commonly assumed by competent authorities, including those related to reviewing package designs, issuing competent authority approvals, and many general responsibilities that are associated with competent authority. These latter responsibilities include inspecting, enforcing, training, communicating, being available to respond to emergency situations, and providing information to the public and media (e.g., see Section III of IAEA SSS TS-R-1 and IAEA Safety Series (SS) 112 (*“Compliance Assurance for the Safe Transport of Radioactive Material”*, 1994 Edition).

CNCAN consists of eight divisions and 24 sub-divisions (branches). An organizational chart is given in Appendix VI B) (page 142). One branch, the Radioactive Material Transport Branch, is dedicated to the transport of radioactive material. CNCAN considers five staff members to be necessary in this branch. However, to date only one staff member is working in this branch. His main responsibilities consider the approval of packages and the performance of inspections concerning the transport of fissile material, i.e. fresh and spent nuclear fuel.

The transport of non-fissile material or radioactive waste is supervised by about three additional staff members from two different divisions within CNCAN. They are in charge of performing inspections and issuing transport authorizations and approvals according to Para. 820 of IAEA SSS TS-R-1.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *See section Staffing and Training (3) from previous report*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

See section Staffing and Training (3)

11.4.1 Findings of the 2006 follow-up IRRS mission

Although there are about four staff members responsible for the transport of radioactive material, the person-equivalent is divided into several branches within CNCAN. It should be taken into account that the regulations for the safe transport of radioactive material are complicated and need very specialized knowledge. It would be advantageous to have one branch specializing on that subject. CNCAN, as the competent authority, is the primary source of information for Romanian companies being engaged in the area of transport of radioactive material. International transports frequently need co-operation between the relevant competent authorities.

11.4.2 Recommendations, Suggestions and Good Practices

- 1) **BASIS** – The IAEA Safety Standards Series GS-R-1 “*Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*” requires in paragraph 2.2 (4) that “*the regulatory body shall have adequate staffing and financial resources to discharge its assigned responsibilities*”. In addition, the IAEA Safety Standards Series draft Safety Guide DS247 “*Organization and Staffing of the Regulatory Body for Nuclear Facilities*” provides guidance on the appropriate organization and staffing of regulatory bodies (and this guidance can apply to transport as well as facility regulation).
- R63) **Recommendation:** *CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team.*

11.5 AUTHORIZATION PROCESS

The general procedure to obtain an authorization or approval for the transport of radioactive material is given in chapter 8 and is detailed in Annex 2 of NTR-01. The applicant has to provide appropriate documents according to NTR-01.

A general transport authorization issued by the Ministry of Transport, Buildings, and Tourism is necessary for each carrier to apply for an authorization for the transport of radioactive material as a practice. Art. 53 of NTR-01 allows applicants to appeal decisions should they disagree with decisions made by CNCAN within 30 days.

CNCAN provides in depth review of applications for package designs, and ensures complete and archived documentation associated with these reviews. The reviews include applications for designs originating in Romania, and for endorsement of designs originating outside Romania.

CNCAN requires approvals for all radioactive material shipments, not just those specified in Paras. 820 to 823 of IAEA SSS TS-R-1. This increases the workload on the regulator, but is consistent with the conservative approach noted in IAEA SSS GS-R-1. Para. 5.6 indicates that “*amendments, renewals, suspensions or revocations of authorizations shall be undertaken in accordance with a clearly defined and established procedure*”. Issuing of these approvals requires actions on the part of the competent authority to define for applicants the procedures to be followed. It results in the requirement for the performance of reviews and assessments of applications submitted. Paras. 501 through 518 of the IAEA SS 112 elaborates on responsibilities of competent authorities in reviewing applications for approvals. This review in the transport safety area demonstrated that CNCAN operates to this requirement for packages that require competent authority approval both Type B packages and packages for the transport of fissile material, respectively.

Romania also entered the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste management (European Directive 92/3). The requirements regarding transboundary movements of radioactive waste according to Art. 27 of the Joint Convention are implemented into Romanian law through the Fundamental Norms for the Safe Management of Radioactive Waste (NDR-01, 2004).

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

IRRT 2002 Recommendations:

- *There were no changes in this section since the 2002 IRRT*

RaSIA 2004 Recommendations:

- *There were no changes in this section since the 2004 RaSIA*

11.5.1 Findings of the 2006 follow-up IRRS mission

The emphasis of the transport safety regulatory efforts at CNCAN is focused almost entirely upon the transport of nuclear fuel cycle material in certified packages. There does not appear to be any guides for package requirements for non-certified packages (i.e., for excepted packages, industrial packages and Type A - non-fissile - packages). CNCAN has not inspected the documentation for non-certified packages used by consignors in Romania nor do they monitor in any way that the packaging being used has been manufactured to the applicable design specifications. The only compliance actions taken relative to these packages have focused on the identification and correction of improper shipping documents and labels

The written procedure regarding the rejection of applications, i.e. Art. 6 (2) in Annex 2 of NTR-01, seems to be too restrictive, since it does not allow the applicant to use rejected files or parts of them for other applications for authorization.

CNCAN accepts application for multilateral approval of packages to be sent in either from the owner of the certificate of approval or by the consignor of a shipment. The responsibilities regarding the quality assurance of packages are usually assigned to the owner of the original certificate of approval. Thus, in order to ensure that appropriate quality assurance procedures are followed, CNCAN should receive a written confirmation from the owner of the certificate of approval in the case that the applicant is not the owner of the package approval.

11.5.2 Recommendations, Suggestions and Good Practices

- 1) **BASIS** – Para. 310 of IAEA SSS TS-R-1 specifies that “*The competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, and the preparation, documentation, handling and stowage of packages by consignors and carriers respectively, to provide evident that the provisions of these Regulations are being met in practice.*”
- 2) **BASIS** – Para. 801 of TS-R-1 requires “*For package designs where it is not required that a competent authority issue an approval certificate the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements.*”
- R64) **Recommendation:** *CNCAN should expand its regulatory inspection and enforcement efforts to include the design, manufacture and use of non-certified packages, with a focus on design documentation, as-fabricated conditions, preparation of packages for shipment by consignors, stowage by carriers, and – for any reusable packages – application of specified maintenance procedures.*
- 3) **BASIS** – Para. 802 of TS-R-1 states “*Competent authority approval shall be required for the following:*
(a) *designs for*

- (i) *special form radioactive material (see paras 803, 804 and 818);*
- (ii) *low dispersible radioactive material (see paras 803 and 804);*
- (iii) *packages containing 0.1 kg or more of uranium hexafluoride (see para. 805);*
- (iv) *all packages containing fissile material unless excepted by para. 672 (see paras 812–814, 816 and 817);*
- (v) *Type B(U) packages and Type B(M) packages (see paras 806–811, 816 and 817);*
- (vi) *Type C packages (see paras 806–808);*
- (b) *special arrangements (see paras 824–826);*
- (c) *certain shipments (see paras 820–823);*
- (d) *radiation protection programme for special use vessels (see para. 575(a));*
- and
- (e) *calculation of radionuclide values that are not listed in Table I (see para. 402).”*

S12) **Suggestion:** *Art. 6 (2) in Annex 2 of NTR-01 should be revised in order to be in line with the International Standards.*

4) **BASIS** – Para. 802 of TS-R-1 says that “*Quality assurance programmes based on international, national or other standards acceptable to the competent authority shall be established and implemented for the design, manufacture, testing, documentation, use, maintenance and inspection of all special form radioactive material, low dispersible radioactive material and packages and for transport and in-transit storage operations to ensure compliance with the relevant provisions of these Regulations. Certification that the design specification has been fully implemented shall be available to the competent authority. The manufacturer, consignor or user shall be prepared to provide facilities for competent authority inspection during manufacture and use and to demonstrate to any cognizant competent authority that:*

- (a) *the manufacturing methods and materials used are in accordance with the approved design specifications; and*
- (b) *all packagings are periodically inspected and, as necessary, repaired and maintained in good condition so that they continue to comply with all relevant requirements and specifications, even after repeated use.*

Where competent authority approval is required, such approval shall take into account and be contingent upon the adequacy of the quality assurance programme.”

S13) **Suggestion:** *In order to ensure that appropriate quality assurance procedures are followed, CNCAN should receive a written confirmation by the owner of the package approval certificate together with the application.*

G13) **Good Practice:** *The implementation of Art. 27 of the Joint Convention into Romanian law through the Fundamental Norms for the Safe Management of Radioactive Waste (NDR-01, 2004) is considered as a good practice.*

11.6 REVIEW AND ASSESSMENT

This area was not considered.

11.7 INSPECTION AND ENFORCEMENT

According to Art. 30 of Law 111/1996, controls shall be performed to be preventive, prompt, current as well as subsequent.

There is no general inspection plan concerning the transport of radioactive material. The inspections carried out by CNCAN staff members are mostly reactive to the kind of transport being carried out or the kind of authorization/approval that is applied for. The transports of fissile material concerning both the Kozloduy NPP and the Pitesti Research Reactor, respectively are inspected to the extent of 100 %. Other transport activities are not systematically inspected.

For Type B packages and packages for fissile material the inspections cover the areas given in Para. 311 of IAEA SSS TS-R-1. For packages not requiring competent authority approval (excepted packages, industrial packages, Type A packages – non fissile), inspections cover only the user statement that these packages comply with the regulations.

In preparation for an inspection, checklists are prepared but no general guidance is given to the inspectors about how inspections have to be carried out.

There is a standardized form of inspection report. The report has the status of a decree and states the required actions. It is agreed upon by the inspector and a representative of the inspected unit and signed by both representatives. Findings are followed up by their termination. However, CNCAN has no systematical review procedure in place to assess the findings in order to derive “lessons learned”. The implementation of a data base for the up-take of findings and possible assessment is planned for 2006.

According to Art. 32 (e) of law 111/1996, imposing of penalties are possible on either legal or natural (physical) persons. The basis and the penalties for infringements are given in the Arts. 45 and 47 of the Law 111/1996. Examples where physical persons were fined included smoking in controlled area and non-compliance with internal radiation protection requirements both observed in the National Institute of Research and Development for Physics and Nuclear Engineering - Horia Hulubei, Magurele (ref. 10 July 2003). One example in which a legal person was fined concerned a non-compliance with a requirement which was given in an earlier inspection report about control of pressure vessels at IT ISCIR (ref. 13 September 2005).

During a visit to the National Institute of Research and Development for Physics and Nuclear Engineering - Horia Hulubei, Radioactive Waste Department at Magurele, it could be observed that the inspectors keep to the general inspection process. However, it has also been observed that adequate training be needed for the inspectors concerning radiation protection principles.

Recommendations and Suggestions from the 2002 IRRT / 2004 RaSIA reports

IRRT 2002 Recommendations:

- *There were no recommendations or suggestions in this section*

RaSIA 2004 Recommendations:

- *There were no recommendations or suggestions in this section*

Changes since the 2002 IRRT / 2004 RaSIA missions

IRRT 2002 Recommendations:

- *There were no changes in this section since the 2002 IRRT*

RaSIA 2004 Recommendations:

- *There were no changes in this section since the 2004 RaSIA*

11.7.1 Findings of the 2006 follow-up IRRS mission

There is no general planning of inspections concerning the transport of radioactive material. Annual planning of inspections with respect to transport could help CNCAN to fulfil its duties according to Para. 311 of IAEA SSS TS-R-1. Additional guidance is given in the IAEA SS 112 concerning the inspection of packages not requiring competent authority approval.

No assessment of inspections findings is carried out by CNCAN with regard to “lessons learned” and no general guidance is given to the inspectors about how inspections have to be carried out. However, incidents/accident reports in the transport area are analyzed taking into account the INES scale for the transport of radioactive material proposed by IAEA (Ref “*Rating of Transport and Radiation Source Events - Draft Additional Guidance for the INES National Officers for Pilot use and feedback, Revision 26 May 2004, edited by IAEA, INES WM 01/2004*”).

The possibility to impose penalties on natural persons may contain the potential risk that non-compliances or failures are not reported accordingly and thus, no corrective action may be taken by the licensee. This may result in a decrease of safety for the transport of radioactive material. However, regarding the enforcement, there has been sufficient training for the inspectors by a CNCAN lawyer.

Adequate training is needed for the inspectors of CNCAN concerning radiation protection principles (see section Radiation Protection (10) for recommendations).

11.7.2 Recommendations, Suggestions and Good Practices

- 1) **BASIS** - Para. 5.14 of IAEA SSS GS-G-1.3 requires that “*the regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity*”.

- R65) **Recommendation:** *CNCAN should develop and implement a systematic inspection plan for the transport, in order to assure compliance with the relevant transport regulations.*
- 2) **BASIS** – Para 5.17 of IAEA SSS GS-R-1 states that “*Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process.*”
- R66) **Recommendation:** *CNCAN should consider implementing a systematic assessment of findings with regards to “lessons learned” in order to assure the feedback process and compliance with the regulations. In addition, general guidance should be developed by CNCAN on how to perform inspections.*
- 3) **BASIS** – Para. 5.13 of IAEA SSS GS-G-1.3 states “... *Experience in some States shows that imposing penalties on the organization rather than on individuals is preferable and is more likely to lead to improvements in safety performance.*”
- S14) **Suggestion:** *CNCAN should evaluate its policy regarding the possibility to take legal actions to physical persons (Art. 32 of law 111/1996). It is considered more appropriate to take actions to legal persons and not to physical persons to ensure that the licensee performs a thorough investigation and to take all necessary measures about its safety and radiation protection related arrangements to prevent recurrence.*

11.8 DEVELOPMENT OF REGULATIONS AND GUIDES

This area was not considered.

11.9 EMERGENCY PREPAREDNESS FOR TRANSPORT

The Ministry of Transport, Buildings, and Tourism issued an emergency guide through the Romanian Road Authority regarding the intervention in case of a transport accident involving dangerous goods. This guide considers all nine classes of dangerous goods including radioactive material, i.e. Class 7. The guide covers the first measures after an accident. Accidents/incidents have to be reported to the Emergency Center, AFUMATI Laboratory, which is part of CNCAN.

CNCAN approves intervention plans issued by carriers according to Paras. 308 and 309 to IAEA SSS TS-R-1

APPENDIX I – LIST OF PARTICIPANTS

COMPOSITION OF THE IAEA REVIEW TEAM

IAEA EXTERNAL EXPERTS:

- | | | |
|--------------------------------|---|--|
| 1. Thierry LECOMTE | Autorite de Surete
Nucleaire (DGSNR) | thierry.lecomte@asn.minefi.gouv.fr |
| 2. Jan VAN AARLE | Swiss Federal Nuclear
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| 3. Bill WEST | Health and Safety
Executive
Nuclear Safety Division | bill.west@hse.gsi.gov.uk |
| 4. Shahid A.
MALLICK | Pakistan nuclear
regulatory authority | shahid.mallick@ins.pnra.org |
| 5. Josef MISAK | Nuclear Research
Institute Rez plc | mis@ujv.cz |
| 6. Jean-Rene JUBIN | Autorite de Surete
Nucleaire (Observer) | Jean-rene.jubin@asn.minefi.gouv.fr |

IAEA STAFF MEMBER:

- | | | |
|--------------------------|-----------|--|
| 1. Gustavo CARUSO | IAEA/NSNI | G.Caruso@iaea.org |
| 2. Steve EVANS | IAEA/NSRW | S.Evans@iaea.org |
| 3. Luis JOVA SED | IAEA/NSRW | L.Jova-Sed@iaea.org |
| 4. Lingquan GUO | IAEA/NSNI | L.Guo@iaea.org |

OFFICIAL ROMANIAN LIAISON OFFICER:

CNCAN – COMISIA NAȚIONALĂ PENTRU CONTROLUL ACTIVITĂȚILOR NUCLEARE

- | | | |
|-----------------------|---|--|
| 1. Lucian BIRO | Comisia Națională pentru
Controlul Activităților
Nucleare – CNCAN | lucian.biro@cncan.ro |
|-----------------------|---|--|

APPENDIX II – MISSION PROGRAMME

Sunday, 15 January 2006

19:00 – 21:00 **Team Meeting at Hotel**

-Self Introduction of Experts with curriculum vitae: 1 – 2 minutes each

-Briefing by the Team Leader

◆ Whole IRRS Mission and IRRT follow-up by Mr. CARUSO Gustavo

◆ RaSIA Mission Follow-up by Mr. EVANS, Stephen Anthony;

◆ Structure and Reporting of the Final Report by Mr. GUO Lingquan

-Brief Statement of their initial impressions following a review of the ARM: 5 – 10 minutes each

Monday, 16 January 2006

Entrance Meeting between CNCAN and Mission Members

09:00 – 10:00 Welcome

10:00 – 11:00 Brief Self Introduction

Presentation of IRRS

Presentation of RaSIA as component of IRRS

12:00 – 13:30 Presentation of the CNCAN progress against IRRT 2002 / RaSIA 2004 outcomes

13:30 – 14:30 Lunch

14:30 – 17:00 Continue Presentation of the CNCAN progress against IRRT 2002 / RaSIA 2004 outcomes

Each Participant

G. CARUSO

S. EVANS

Tuesday, 17 January 2006

Interviews

Wednesday, 18 January 2006

Interviews

Thursday, 19 January 2006

Direct Observation at:

A. Cernavoda NPP Unit 1

B.1. Inspection to industrial facilities: (Mr. Evans)

1.3. FAUR Bucuresti – GRIRO Industrial radiography – X and gamma.

B.2. Transportation of Radioactive Waste

2.1. National Institute of Research and Development, Radioactive Waste Department at Magurele

Friday, 20 January 2006

Interviews and Direct Inspections:

A. Inspection to hospitals:

1. Nuclear Medicine;

1.1. Oncologica Institute Fundeni –

2. CNCAN Emergency Response Center

Saturday, 21 January 2006:

Report drafting

Sunday, 22 January 2006

Social Activities

Monday, 23 January 2006:

Final Interviews
Report Drafting

Tuesday, 24 January 2006:

Report Drafting and Team meeting in order to get the consensus of all findings.
Report Submission to CNCAN
Visit to Ministry to present the IRRS results

Wednesday, 25 January 2006:

Discussions of findings taking into account the CNCAN comments
Final drafting of Report

Thursday, 26 January 2006:

Exit meeting
Press Conference
Visit to the Ministers Office

APPENDIX III MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	CNCAN Counterparts	Rooms
A	Legislative and governmental responsibilities	<ul style="list-style-type: none"> • Mr. Shahid Mallick (IRRT), • Mr.EVANS, Stephen (RaSIA) 	<ul style="list-style-type: none"> • Mr. ZSOMBORI, Vilmos (IRRT, RaSIA) • Dr. BIRO, Lucian (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	
B	Authority, responsibilities and functions of the regulatory body	<ul style="list-style-type: none"> • Mr. Shahid Mallick (IRRT), • Mr.EVANS, Stephen (RaSIA) 	<ul style="list-style-type: none"> • Mr. ZSOMBORI, Vilmos (IRRT, RaSIA) • Dr. BIRO, Lucian (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	
C	Organization of the regulatory body	<ul style="list-style-type: none"> • Mr. Shahid Mallick (IRRT), • Mr.EVANS, Stephen (RaSIA) 	<ul style="list-style-type: none"> • Mr. ZSOMBORI, Vilmos (IRRT, RaSIA) • Dr. BIRO, Lucian (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	
D	Authorization process	<ul style="list-style-type: none"> • Mr.Jozef Misak (IRRT), • Mr. T. Lecomte (RaSIA) • Mr.GUO .L 	<ul style="list-style-type: none"> • Dr. BIRO, Lucian (IRRT) • Mr. GOICEA, Lucian (IRRT) • Dr. COROIANU, Anton (RaSIA) 	
E	Review and assessment	<ul style="list-style-type: none"> • Mr.Jozef Misak (IRRT), • Mr. T. Lecomte (RaSIA) • Mr.GUO .L 	<ul style="list-style-type: none"> • Mr. CIUREA, Cantemir (IRRT) • Mrs. TRONEA, Madalina(IRRT) • Mrs. ROSCA, Gabriela (RaSIA) 	
F	Inspection and enforcement	<ul style="list-style-type: none"> • Mr. Bill West (IRRT), • Mr. T. Lecomte (RaSIA) • Mr.GUO .L 	<ul style="list-style-type: none"> • Mr. GOICEA, Lucian (IRRT) • Mrs. MURESANU, Daniela (IRRT) • Mr. POP, Silviu (IRRT) • Mrs. SERBAN, Silvia (RaSIA) 	
G	Development of regulations and guides	<ul style="list-style-type: none"> • Mr.Jozef Misak (IRRT), • Mr. T. Lecomte (RaSIA) • Mr.GUO .L 	<ul style="list-style-type: none"> • Mr. GOICEA, Lucian (IRRT) • Mrs. TRONEA, Madalina (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	
H	Emergency preparedness	<ul style="list-style-type: none"> • Mr. Bill West (IRRT), • Mr. T. Lecomte (RaSIA) • Mr.EVANS,Stephen (RaSIA) 	<ul style="list-style-type: none"> • Mrs. BACIU, Adina (IRRT) • Mr. RODNA, Alexandru (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	
I	Waste management and decommissioning	<ul style="list-style-type: none"> • Mr.JOVA SED, Luis (IRRT, RaSIA) 	<ul style="list-style-type: none"> • Mrs. DOGARU, Daniela (IRRT) • Ms. PREOTEASA, Angelica (RaSIA) 	

J	Radiation protection	<ul style="list-style-type: none"> • Mr.EVANS, Stephen, (IRRT, RaSIA) • Mr.T. Lecomte (IRRT, RaSIA) 	<ul style="list-style-type: none"> • Mr. RODNA, Alexandru (IRRT) • Mrs. ROSCA, Gabriela (RaSIA) 	
K	Transport of radioactive material	<ul style="list-style-type: none"> • Mr.Jan van Aarle 	<ul style="list-style-type: none"> • Mr. RODNA, Alexandru • Mr. ILIESCU, Virgil 	

APPENDIX IV A – RECOMMENDATIONS/SUGGESTIONS FROM PREVIOUS MISSIONS IRRT

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status
A.	Legislative and Governmental Responsibilities	R1.	The new legislative framework should effectively provide for an income regime for the staff of the Regulatory Body consistent with the incomes offered to staff of equivalent level in the NPP.	open
B.	Authority, Responsibilities and functions of the Regulatory Body	G1.	Requesting regular information on financial situation and resources of the operating organization provides valuable information on one of the prerequisites for a sound safety situation of plants and facilities.	
C.	Organization of the Regulatory Body	R1.	Some formal arrangements exist to ensure that staff are aware the contents of the Quality Manual in relation to the function that they perform. These arrangements should be extended to all Directorates.	closed
		R2.	CNCAN should take all necessary steps to ensure that the 11 vacant positions should be filled by suitably qualified and experienced persons as soon as possible.	closed
		R3.	To complement the policies already implemented by the Directorates, CNCAN should produce a written general policy on training and staff development.	closed
		S1	CNCAN should consider publishing reports on its activities that include disseminating to its stakeholders the objectives of the organisation. Such a dissemination would also serve to enhance the awareness of CNCAN staff on the policies of the organisation.	closed
		S2	The audit of the CNCAN working arrangements against the requirements of the Quality Manual planned for 2002 should include both the technical and administrative aspects of the arrangements.	closed

		S3.	CNCAN should consider the creation of a staff/experience matrix which could identify the individuals suitable for specific work.	open
		G1.	CNCAN has taken the initiative to commission an external independent review of their Quality Manual. The output of the review will be used to augment the further development of the Manual, which amongst other things will reflect the restructuring of the organisation with the formation of the Technical Support Organisation.	
D.	Authorization Process	S1.	The CNCAN should consider involving experts from external relevant organizations in the work of the State Examination Commissions. CNCAN should consider appointing some of CNCAN Consultative Council members as members of these Commissions as well.	closed
		S2.	To further improve its effectiveness and efficiency and to ensure its effective independence, the CNCAN is advised to consider, whether it is appropriate, in future to modify Romanian legislation so as to release CNCAN from the responsibility for issuing quality assurance authorizations for nuclear facilities component suppliers and subcontractors.	open
		S3.	In order to make optimal use of the CNCAN staff resources, it might be useful to consider the assignment of QA authorization to the TSO once established.	closed
		S4.	In the development of the new regulations, which define the scope and type of the safety related documentation required from the licensee, CNCAN should consider the explicit inclusion of requirements for the performance of periodic safety reviews (PSR) in an appropriate document.	open
		G1.	Complementing written and oral examinations with a practical “on the simulator” examination for licensing of NPP operational staff is considered a good practice.	

E.	Review and Assessment	R1.	CNCAN management should take urgent actions to fill the position of Director of Directorate of Nuclear Safety with a suitably qualified expert	closed
		R2.	CNCAN management should take actions to complete its review and assessment procedures, to establish priorities and prepare its own programme to manage these activities in the most effective way, taking into account the available limited resources.	closed
		S1.	CNCAN should, as a long-term objective, support conditions for the effective functioning of an organization (system of organizations) capable of performing typical tasks of a Technical Support Organization.	closed
		G1.	CNCAN has established an effective practice for in-depth assessment of the NPP events reported to the regulatory body. Taking into systematic considerations the recent operational experience feedback in the preparation of each State examination of the selected plant personnel is considered a good practice.	
F.	Inspection and Enforcement	R1	See also recommendation in section 3.3.1. CNCAN should take urgent action to fill the three vacant positions in the Directorate of Cernavoda NPP Surveillance.	closed
		G1.	CNCAN's inspection programme for NPP's is well documented, and allows expertise from other departments in the organization to contribute to NPP inspection.	
G.	Development of Regulations and Guides	R1.	CNCAN should establish the priority for development of different regulations taking into account the needs of the current authorization process.	closed
		R2.	CNCAN should consider in future the need for periodic review of its regulations and establish an appropriate mechanism and periodicity for updating the regulations.	closed

		S1.	CNCAN should seek further options to optimize the management of internal and external resources, involved in the development of the regulations, in order to ensure the completion of the documents in a timely manner, as appropriate.	open
		S2.	CNCAN should develop an internal QA procedure on regulation drafting and reviewing.	closed
H.	Emergency Preparedness	R1.	CNCAN should pursue the possibility of formally reviewing / approving the local municipality's emergency response plan.	closed
		R2.	CNCAN should ensure that all staff who are involved in, or could be involved in, an emergency role, receive appropriate emergency preparedness training.	closed
I.	Waste Management and Decommissioning	R1.	CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and Th-nat as applied to waste materials containing natural radionuclides.	closed
		R2.	CNCAN should develop and issue guidance on removing materials, containing elevated levels of natural radionuclides from regulatory control. This is linked to the recommendation on application of the exception levels to such materials.	open
	Waste Management and Decommissioning	R3.	Further consideration needs to be given by CNCAN to application of intervention principles, which result in materials being removed from regulatory control with levels of radioactive content, or contamination above both exception and exclusion levels.	open
		R4.	CNCAN should establish a set of generic clearance levels for normal operations, together with guidelines for their application, which can be generally adopted by all licensed facilities including nuclear installations, mining and minerals processing facilities and facilities using radiation sources.	closed

		R5.	Legal provision for dealing with orphan radiation sources and abandoned sites or facilities should be adopted as soon as possible. In this regard the specific roles and responsibilities of CNCAN should be addressed.	open
		R6.	CNCAN should develop guidelines on the classification of radioactive waste on a national basis with a view to clarifying what types of waste can be disposed of in identified disposal facilities, particularly identifying waste which is not acceptable in near surface disposal facilities and also where waste containing naturally occurring radionuclides can be disposed.	closed
		R7.	CNCAN should give consideration to establishing requirements on the qualifications and experience necessary for personnel with defined responsibilities in waste safety.	open
		S1.	Mechanisms, such as professional registration, to assist in demonstrating compliance with such requirements should be investigated by CNCAN together with the provision of appropriate training and staff development programmes.	closed
	Waste Management and Decommissioning	R8.	The responsibility for institutional control over waste disposal facilities in the longer term should be addressed in legislation	open
		R9.	The quantum of funding to be paid into the Decommissioning Fund by different installations should be clearly identified in the legislation. This should be linked to an agreed liabilities assessment methodology.	open
		R10.	The role of CNCAN in the determination of the amount of funds to be paid to the decommissioning fund needs to be set down and the periodicity of review of the adequacy of the amount.	open

		R11.	CNCAN should established standard for the removal of sites and facilities from regulatory control under normal circumstances. CNCAN should also develop guidance on demonstrating compliance with such standards.	closed
		R12.	CNCAN should investigate mechanisms for a broader stakeholder access to and involvement in the licensing of waste management facilities in particular waste disposal facilities.	closed
		R13.	CNCAN should establish prescriptive requirements for small-scale users of radioactive material for the control of effluent discharges to the environment.	closed
		R14.	The safety assessment for the Baita Bihor disposal facility should be finalized and independently evaluated by CNCAN. The conditions of authorization revised to reflect operational controls, including waste acceptance criteria, derived on the basis of the assessment.	closed
	Waste Management and Decommissioning	R15	The safety assessment for the proposed disposal facility for Cernavoda low and intermediate level waste should be progressed without further delay.	open
		R16.	CNCAN should establish, in line with international standards, requirements for the duration for which records should be kept for activities at waste management facilities	open
		R17.	CNCAN should extend the existing waste management facility specific reporting requirements to include, not only reporting of licence or regulation violations, but also occurrences of a lesser nature which could be indicators of precursors to more incidents or of degraded performance.	closed
		R18.	See recommendation in section 3.3.1 The number of specialist staff in the area of waste safety and the matrix management arrangements for waste safety activities should be reviewed and upgraded accordingly.	open

		R19.	CNCAN should further develop its existing guidance and requirements so that a systematic and consistent process is established for authorizing all the various different types of waste management related activities.	open
		R20.	CNCAN should develop and adopt standards for safety assessment of waste management facilities, both predisposal and disposal taking into consideration relevant IAEA safety standards in this area i.e. DS 284 Draft Safety Guide “Safety Assessment for Predisposal Waste Management Facilities” and WS-R-1 “Safety Requirements for near Surface Disposal of Radioactive Waste”.	open
		S2.	The guidance provided in Safety Guide WS-G-2.3 Regulatory Control of Radioactive Waste Discharges to the Environment should be adopted.	closed
	Waste Management and Decommissioning	S3.	CNCAN should actively participate in the IAEA co-ordinated research programme on application of safety assessment methodology to near surface radioactive waste disposal facilities and share the experience developed to date.	open
		G1.	The approach to develop experience in applying regulatory control to the decommissioning of the research reactor at Magurele before developing requirements for the power reactor is considered to be a good approach, particularly with the limited staff resources available within CNCAN.	
K.	Radiation Protection	R1.	See recommendation in 9.1.1.1 (1) (a). CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and natural Th, as applied to materials containing natural radionuclides.	Closed
		R2.	See recommendation in 9.1.1.1 (2) (a). CNCAN should develop a set of generic clearance levels for normal operations, together with guidelines for their application, which can be used by licensed facilities.	Closed
		R3.	CNCAN should proceed with completing a national registry of occupational exposure records.	Closed

		R4.	CNCAN should continue to develop material, and methods of communication (conferences, newsletters, website), on improving safety culture for users of radiation sources.	Closed
		S1.	Based on analyses of data in an occupational exposure registry, CNCAN should give consideration to extending the current investigation levels for occupational exposure at NPPs to other facilities and activities. The investigation levels could be set at different levels for different occupational categories.	closed
	Radiation Protection	G1.	During the development of Law/Regulations/Norms, CNCAN is appropriately considering and using the current international standards for radiation safety, as well as safety related publications published by the IAEA.	
		G2.	CNCAN and the Ministry of Health and Family have well defined roles regarding protection of patients, as set out in the Law and RSFN. CNCAN is responsible for authorizing, inspecting and enforcing radiation protection in the medical use of ionizing radiation, while laboratories under the responsibility of the Ministry of Health are responsible for radiation related measurements in hospitals to confirm that appropriate shielding has been used in the design of medical rooms containing radiation sources and clinical dose related measurements in diagnostic radiology, nuclear medicine and radiotherapy.	

		G3.	CNCAN has developed a comprehensive central register for the inventory of radiation sources in Romania. It will provide CNCAN with an effective tool for the identification of all radiation sources in Romania, for tracking the authorization process of new applications and of information received from licensees and registered owners, for the planning of inspections and follow-up inspections, and for recording enforcement notices issued to users. [NOTE: At present, more than 70% of authorization records have been entered into the database, and it is expected that this task will be completed in late 2002].	
		G4.	CNCAN has a planned and systematic inspection programme for radiation sources.	
	Radiation Protection	G5.	CNCAN provides examples of incidents and accidents, and copies new regulations and discusses their contents, in the training materials for all persons preparing for examinations for work permits (renewed every 5 years).	
	Transport of Radioactive Material	R1.	CNCAN should give consideration to the legal status and the interdependence of Law No. 111/1996 and the international agreements (ADR, RID, ICAO-TI, IMDG-Code) which were adopted by Romania, because there are conflicting requirements. A closer cooperation with the Ministry of Transport should be implemented.	closed
		G1.	To take the IAEA document TS-R-1 as the rule for the safe transport of radioactive material on the Danube is advisable as long as there is no other modern international agreement including radioactive material available. A close and well-established cooperation between Romania and Bulgaria was reached by bilateral agreement.	

		G2.	It is a very good procedure to have the translation of TS-R-1 available as a working document, especially as modal regulations sometimes refer to it. IAEA advisory documents which are directly related to TS-R-1 give often detailed advice.	
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APPENDIX IV B - RECOMMENDATIONS/SUGGESTIONS FROM PREVIOUS MISSIONS (RASIA)

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices	Status
.	Legislative and statutory framework a	R1.	CNCAN should promptly finalize and publish all regulations necessary to ensure consistency with the BSS and GS-R-1.	closed
		R2.	CNCAN should review the appropriateness of its current policy of allowing inspectors to issue sanctions directly to licensees and licensee employees.	open
		R3.	CNCAN should review the appropriateness of providing compensation to CNCAN staff on the basis of their status as radiation workers.	open
		R4.	CNCAN should consider organizational realignment such that inspections are carried out by one group/section, instead of by both the authorization and inspection sections.	open
		R5.	CNCAN should extend its policy with regard to the establishment of Memorandum of Understandings to include all relevant national agencies involved in the regulatory process.	closed
B.	Activities of the Regulatory Body	R1.	CNCAN should review their existing frequencies for routine inspections, as well as authorization renewals, to determine any inconsistencies with IAEA recommendations, and make adjustments as necessary, according to the categorization of radioactive sources.	open
		R2.	CNCAN should further expand its national inventory to include all Category 1 and 2 radiation sources and facilities (i.e., to include iridium-192).	closed

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices	Status
	Activities of the Regulatory Body	R3.	CNCAN should develop and implement a written procedure and checklist for the review of all authorization actions to ensure the consistency and accuracy among CNCAN staff performing these reviews.	closed
		R4.	CNCAN should prepare and implement a structured training and qualification programme for its staff, including the qualifications required to complete independent inspections of various license types.	closed
		R5.	CNCAN should consider issuing personnel dosimeters to all staff involved in the inspection of licensed facilities.	closed
		R6.	CNCAN should consider the recruitment of additional staff in order to perform effectively its regulatory activity, in particular, at the regional offices	partially closed
C.	Occupational Exposure	R1.	All new norms should be subject to QA/QC to ensure self consistency regarding occupational exposure control	partially closed
		R2.	CNCAN should set out its technical requirements for workplace monitoring	partially closed
		R3.	CNCAN should set out its technical requirements for keeping of dose records consistent with the ALARA principle	partially closed
		R4.	CNCAN should ensure that approved services are available for internal dose monitoring and in particular for radon monitoring	partially closed
D.	Medical Exposure	R1	CNCAN should review resource allocation to ensure that the nuclear medicine norm is completed and published as a matter of priority	closed

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices	Status
	Medical Exposure	R2.	All new norms should be subject to QA/QC to ensure self consistency where appropriate regarding responsibilities eg requirement for written prescriptions	open
		R3.	CNCAN should set out guidance on the relationship between the licensee and suppliers of equipment, sources and services regarding regulatory responsibilities	open
		R4.	CNCAN should review its training programme to ensure that all inspectors are fully aware of the criteria for inspection.	partially closed
E.	Public Exposure	R1.	ANDRAD should finalise the national radioactive waste management strategy, which should address the waste management route for decommissioning as well, without undue delay to assure proper and timely implementation of activities, which are waiting for the implementation.	open
		R2.	Government should adopt the law establishing the Fund for management of radioactive waste and decommissioning as stipulated by Law 111 and adjust the levy accordingly to the delay in accumulation of funds since 1996.	open
		R3.	The national inventory of radioactive waste should be finalised by ANDRAD as soon as possible.	open
		R4.	The adequate provisions to limit public exposure in other nuclear and radiation installations except the Cernavoda NPP should be established.	closed
		R5.	Finalise the regulations which address predisposal and disposal of radioactive waste in due time.	closed
		R6.	The CNCAN should request the operators to develop procedures to release the waste from regulatory control, if appropriate, in accordance with regulations.	closed

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices	Status
	Public Exposure	R7.	The CNCAN personnel should receive adequate training in the review of safety assessments for radioactive waste disposal facilities.	open
H.	Emergency Preparedness	R1.	The CNCAN, together with CCANCOC, should seriously reconsider its concept of operations during a nuclear emergency in terms of the authority it has, as well as maximising the use of their knowledgeable staff establishing competent round-a-clock emergency organisation and devise procedures addressing the nuclear emergency with priority, which should be assigned to such an emergency, which might have national or transnational impact.	closed
		R2.	The nuclear emergencies in neighbouring countries having potential direct impact on Romania should be addressed in national emergency plan.	closed
		R3.	Consideration should be given to the fact, if it is really needed that the operator or its owner staff plays such an important role, i.e. co-ordinators, in the public institutions. And, the information flow from the operator should be enhanced by technical and radiological information.	closed
		R4.	The provision of the affected public with the information on protective actions should be evaluated for its effectiveness and, government officials and mass media needs should be analysed and measures to supply this information should be established.	partially closed

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices	Status
	Emergency Preparedness	R5.	The training programme of CNCAN in the area of emergency preparedness shall be adjusted to the needs of the emergency response organisation in terms of scope, frequency and focusing on specific tasks, as well as understanding the organisation and establishing communication links.	partially closed
R6.		The CNCAN staff should have more exercises as players taking part in nuclear power plant exercises and devise some of their own drills or tests.	Closed	
R7.		The operational intervention levels should be developed considering the release from the CANDU plant and the generic intervention levels should be updated.	open	
R8.		The reference levels for emergency workers need to be established.	open	
R9.		Romanian government should consider about inviting the EPREV (Emergency Preparedness REView) to Romania to provide in depth insight and analysis of the emergency preparedness and response organisation.	open	

APPENDIX V RECOMMENDATIONS/SUGGESTIONS FROM THE IRRS MISSION

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
A	Legislative and governmental responsibilities	R1	The Government of Romania should consider revision of conflicting sections of Articles 3 and 17 of law 321/2003 and related government decisions and rules so that the regulatory body remains effectively independent and judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.
		R2	The Government of Romania should consider repeal of overlapping sections of Articles 9 of law 320/2003 and related government decisions and rules so that clear responsibility could be assigned to the regulatory body for establishing safety principles, criteria, and regulations for safe management of spent nuclear fuel and radioactive waste.
		R3	The Government of Romania should consider amending Article 4 of Law 111/1996 to ensure the regulatory body may not be unduly influenced.
B	Authority, responsibilities and functions of the regulatory body	G1	Although the Law 111/1996 provides clear direction for CNCAN to coordinate the activities of Appendix 3 bodies engaged in the control of nuclear activities, having several Memorandums of Understanding clearly helps at the implementation level
C	Organization of the regulatory body	R4	The Government of Romania should consider a review of Governmental Decision 1627 / 2003 in order to provide CNCAN with greater flexibility in the management of its organisational structure.

	R5	CNCAN should take all necessary steps to ensure that the vacant positions are filled by suitably qualified and experienced persons.
	R6	The conditions of CNCAN staff shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of the standards.
	S1	One of the prerequisites of a well-defined training programme is to perform systematic training needs assessment. CNCAN should consider performing a systematic training needs assessment of all its Divisions, using the same model as that applied to the Division of Reactors Safety, from which a formal training programme can be developed
	S2	CNCAN should consider establishing a dedicated training unit for implementing the CNCAN training programme and an in-house training programme across all Divisions in a systematic and consistent manner in accordance with the needs of the regulatory programme.
	G2	The team considers it important to highlight the proactive role of CNCAN regarding the international arrangements as well as its involvement in the International Conventions. In particular with the IAEA and other regulatory forums in order to receive assistance/advice and peer reviews in order to exchange safety related information and continuously improve its effectiveness and efficiency.

D	Authorization process	R7	CNCAN should revise regulations on safety requirements for authorization of practices and facilities to include requirements for the documentation to be presented in support to the authorization request to ensure compliance with the new IAEA Safety Standards and other international requirements taking into account the current authorization needs.(Note: the recommendation is not directly related to the mission findings and needs some explanation).
		R8	CNCAN should review and as appropriate, revise or develop new procedures to review and assess applications for authorization (other than nuclear installations). These procedures should address the requirements of the approved regulation on the given practice, indicating the main safety criteria to be taken into account in the review process.
		R9	CNCAN should consider in the quality management system, the implementation of a routine second review of submitted documentation in support of the request for authorization in combination with the findings of a pre-inspection before authorisation is granted.
		R10	In order to place prime responsibility on the operator for ensuring quality assurance of component suppliers and subcontractors, the present Romanian Legislation should be modified at the earliest opportunity so that CNCAN is released from its obligation to issue quality assurance authorizations for component suppliers and subcontractors.
		R11	CNCAN should adopt a system of categorization of radioactive sources in accordance with IAEA Standards.
		R12	CNCAN should upgrade its national inventory to include all Category 1 and 2 radiation sources (including those defined by CNCAN as ‘sources with a short half-life’).

		R13	The regulation “Nuclear Safety Norms - Nuclear Reactors and Nuclear Power Plants (1975)” should be updated so as to specify the format and content of Safety Analysis Report for various nuclear installations in order to ensure compliance with the recent IAEA Safety Standards and other international requirements on nuclear safety.
		S3	CNCAN is encouraged to finalize the regulation on Periodic Safety Review as soon as possible in order to minimize future efforts to put the ongoing PSR at Cernavoda NPP into compliance with the regulations.
E	Review and assessment	R14	CNCAN management should take actions to complete its internal review and assessment procedures, concentrating on assessment of compliance with the technical and safety requirements contained in relevant regulations.
		R15	CNCAN should ensure that number of staff involved in safety analyses be increased as planned and receive appropriate training.
		R16	CNCAN should ensure that adequate resources are allocated in its budget in order to allow acquiring necessary computational tools and for external support as necessary.
		R17	Special attention should be devoted to enhancing of the CNCAN capabilities in the area of probabilistic safety assessment due to its importance not only for evaluating safety of nuclear installations, but also for future implementation of risk informed regulations as intended.
F	Inspection and enforcement	R18	CNCAN should take immediate steps to fill the two vacant posts in the NPP surveillance team at Cernavoda. One of these should be a radiation protection expert.
		R19	CNCAN should train new site inspection staff in all aspects of nuclear and radiation safety regulation to enable them to evaluate safety priorities and to ensure that they are fully aware of the inspection criteria.

		S4	CNCAN should consider formally nominating one senior member of staff to be in charge of inspection programmes for all regulated installations, facilities and sources and to address the organizational realignment identified in the RaSIA 2004 report.
		R20	With respect to radiation sources, CNCAN should review the frequency of routine inspections in accordance with International Standards and Guidance, and make adjustments as necessary having particular regard to the potential magnitude and nature of the hazard associated with the facility or activity.
		R21	CNCAN should prioritise its inspection plans so as to focus on safety significant issues. This is applicable to all regulated installations, facilities and activities.
		R22	At the earliest opportunity CNCAN should arrange for all its staff who may work in a controlled areas with a personal dosimeter in accordance with the Romanian regulations and ensure that appropriate exposure records are maintained.
		S5	CNCAN should evaluate its policy regarding the possibility to take legal actions to physical persons (Art. 32 of law 111/1996). It is internationally considered to be more effective to take actions to legal persons and not to physical persons to ensure that the licensee performs a thorough investigation and to take all necessary measures about its safety and radiation protection related arrangements to prevent recurrence.
		G3	CNCAN has established a sound feedback system for their inspection activities, which requests that inspection reports are prepared, discussed with the licensee at the end of each inspection and then sent back to the regulatory process. The findings are then fed back into the next inspection plan, to ensure that any deficiencies or significant safety issues found on site could be solved on time.

G	Development of regulations and guides	R23	Government of Romania should consider the revision of Appendix 2 “definitions” of Law 111/1996 item 24 to exclude guidance from the definition of mandatory regulations.
		S6	CNCAN should consider in future the need for periodic review of its regulations and establish an appropriate mechanism and periodicity for updating the regulations.
		G4	CNCAN devotes significant effort aimed at broad dissemination of its regulations among the stakeholders by publishing the regulations separately in regulatory brochures in addition to publication in the Official Gazette.
		G5	CNCAN has developed and implemented a comprehensive and effective system of regulations governing authorization of the QMS of all organizations that deploy nuclear activities in Romania as well as internal QMS manual for all functions of the regulatory body.
		G6	CNCAN efficiently utilizes all possible sources of information relevant for identifying gaps and updating the national legislation of regulations, in such as WENRA harmonization process, comments from the operators and from CNCAN resident inspectors.
H	Emergency preparedness	R24	That the CNCAN structure should be amended such that the emergency preparedness function reports directly to the CNCAN President.
		R25	CNCAN should ensure that all staff who may participate in the CNCAN emergency response organization receive training on their specific roles in the National Emergency Plan and also in relation to the role of other organizations and individuals. This training should be repeated to accommodate new staff and refresher training for existing staff.
		R26	That CNCAN reviews, and amends as necessary, its procedures relevant to its emergency preparedness after each major national exercise according to lessons learned.

		R27	Pending the completion of the PHARE Project that will provide a data link with Cernovoda, CNCAN should determine which documents and equipment is should be in place at the CNCAN emergency centre to enable the CNCAN experts to carry out their work during an emergency
I	Waste management and decommissioning	R28	CNCAN should have an active role in the review and approval of the existing National Strategy on Radioactive Waste Management according to its responsibilities and presented recommendations.
		R29	CNCAN should develop guidance on the application of the exclusion levels, particularly for Ra-226 and Th-nat as applied to waste materials containing natural radionuclides.
		R30	CNCAN should develop and issue practical guidelines for the practical application of the concept of clearance of radioactive material from regulatory control, control and record keeping of radioactive materials discharges which can be generally adopted by all facilities using radiation sources and radioactive materials other than nuclear installations e.g. nuclear medicine and research facilities.
		R31	Legal provision for dealing with past practices; abandoned radioactive material, source, sites or facilities should be adopted as soon as possible. Further implementation of the Directive and Romanian Regulation NSR-16 is necessary. In this regard the specific roles, responsibilities, and procedures for recovery by CNCAN should be addressed.
		R32	CNCAN should establish the detailed requirements on the qualification and experience of personnel involve in predisposal, disposal and decommissioning activities and thereafter continue improving the qualifications of personnel in the area of radiation protection and waste safety. The training programme of staff involved in the safety radioactive waste and decommissioning is strongly recommended.

		R33	The responsibility for institutional control over waste disposal facilities in the longer term should be addressed in the regulation.
		R34	Government should adopt the law establishing the Fund for management of radioactive waste and decommissioning as stipulated by Law 111 and adjust the levy accordingly to the delay in accumulation of funds since 1996.
		R35	The quantum of funding to be paid into the Decommissioning Fund by different installations should be clearly identified in the legislation. This should be linked to an agreed liabilities assessment methodology.
		R36	The role of CNCAN in the determination of the amount of funds to be paid to the decommissioning fund needs to be set down and the periodicity of review of the adequacy of the amount.
		R37	CNCAN should establish regulations, which should include safety criteria for decommissioning of nuclear facilities, including conditions on the end points of decommissioning under normal circumstances. CNCAN should also develop guidance on demonstrating compliance with such regulations.
		R38	CNCAN should elaborate and establish regulations for the safety assessment on decommissioning of nuclear power plants, including safety requirements and safety criteria.
		R39	CNCAN should consider the revision of existing regulations on the decommissioning facilities other than NPP to include safety assessment for decommissioning.
		R40	CNCAN should establish prescriptive requirements for small-scale users of radioactive material (unsealed sources) for the control of effluent discharges to the environment.

		R41	CNCAN should closely follow up to the elaboration by the operator of the design and safety assessment for the proposed disposal facility for Cernavoda low and intermediate level waste. At the same time, be prepared to do the proper review of the authorization request and to take the final decision.
		R42	CNCAN should approve and control the waste acceptance criteria established by the treatment plant to collect the radioactive waste and disused radiation sources from users other than nuclear installations.
		R43	CNCAN should establish in line with international standards, requirements on records keeping including its content and format as well as the time period to be kept. The specific requirements on predisposal, disposal and decommissioning under development should cover waste generators and operators.
		R44	CNCAN should establish in line with international standards, requirements on storage of radioactive waste. The specific requirements on predisposal, and decommissioning under development should cover storage requirements for waste generators and operators, including long term storage.
		R45	The number of specialist staff in the area of waste safety and decommissioning as well as the matrix management arrangements for waste safety activities should be reviewed and upgraded accordingly.
		R46	A systematic and consistent process should be established in CNCAN for regulating, authorizing, inspecting and recording all the various different types of radioactive waste management related activities and facilities, including decommissioning

		R47	CNCAN should identify the fields where it will need technical support to review the safety assessment and support documentation presented by the operators in support of their authorization requests. In the identified fields CNCAN should develop and action plan to find the qualified institutions or qualified experts that could support its review.
		R48	CNCAN should complete the set of regulations to detail the safety requirements for authorization of predisposal, disposal and decommissioning activities and facilities, including the requirements for the documentation to be presented in support to the authorization request. The requirements should cover both small and large facilities.
		R49	CNCAN should develop and adopt standards for safety assessment of waste management facilities, both predisposal and disposal taking into consideration relevant IAEA safety standards in this area i.e. DS 284 Draft Safety Guide “Safety Assessment for Predisposal Waste Management Facilities” and WS-R-1 “Safety Requirements for Near Surface Disposal of Radioactive Waste”.
		R50	CNCAN should include in the standards under development for the safety of the predisposal activities and facilities as well as for the safety of disposal facilities the systematic safety reassessment or periodic safety review taking into consideration relevant IAEA safety standards in this area.
		R51	CNCAN should systematise the practice of formally recording the review process and the basis for its decisions.
		R52	CNCAN should review and update the inspection checklists in use for waste management facilities according to the regulations in force in this field.

		S7	The NMR-03 regulation on Decommissioning of Uranium and Thorium Ores Mining and Milling Facilities should not use the word “unrestricted” as a concept due to the established requirement in this regulation on remaining of some safety requirements on the site e.g. a long term institutional control after the release from regulatory control.
		S8	Mechanisms, such as professional registration, to assist in demonstrating compliance with such requirements should be assessed by CNCAN together with the provision of appropriate training and staff development programmes.
		S9	CNCAN should actively participate in the IAEA co-ordinated research programme on application of safety assessment methodologies to near surface radioactive waste disposal facilities (ASAM) and predisposal activities and facilities (SAWDRMS) and share the experience developed to date.
		G7	The approach to develop a regulation complementing and expanding the IAEA Principles of Radioactive Waste Management that are the basis for The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management is considered to be a good approach.
		G8	The approach to develop and issue a Norm (NSN-15) on the Decommissioning on Nuclear Installations (other than NPP) and applying the experience in applying regulatory control to the decommissioning of the research reactor at Magurele before developing requirements for the power reactor is considered to be a good approach, particularly with the limited staff resources available within CNCAN.
		G9	The approach to design and maintain updated a database for the control of the compliance of the instructions given during the inspections is considered as a good practice.

J	R53	CNCAN should define the required competencies in radiation protection for all staff, especially for the key positions, and ensure its adequate training and periodical refreshment on this topic to fulfil its mandatory function.
	R54	CNCAN should modify its own list of exposed staff so that to ensure that all staff working regularly or occasionally in controlled area in the plants or facilities is included (see also recommendation in 6.3.1.1).
	R55	CNCAN should complete its national registry system for occupational exposure records in order to include all exposed workers. CNCAN should improve its arrangements to use this system in an effective and efficient manner, updating continuously the data especially to facilitate checking and tracking the records.
	R56	CNCAN should request the licensees of nuclear fuel cycle facilities to implement arrangements to ensure that all occupationally exposed staff undergo a periodical whole body counter measurement.
	R57	CNCAN should issue guidance on the format and content of radiation protection related documents to be submitted by Cernavoda NPP to CNCAN within the licensing process (see also the suggestion in chapter 4.3.1.1).
	R58	CNCAN should define more detailed criteria on the radiation protection incidents to be reported, clear and unambiguous, for all type of nuclear facilities (except at Cernavoda NPP where these criteria are already adequately defined).
	R59	CNCAN should develop guidance for the systematic review and assessment of the radiation protection aspects of the document submitted by the applicant

		R60	CNCAN should ensure that the ALARA evaluation takes into account all activities during the outages at the NPP including internal exposure and the review and assessment of the ALARA evaluation is forwarded to CNCAN before outage.
		R61	CNCAN should review its training programme to ensure that all inspectors are fully aware of the criteria for inspection. (“against regulatory requirements and not against expected standards” according the 2004 RaSIA Report).
		S10	CNCAN should consider recruiting new resident inspectors with radiation protection background. (see also recommendation in 6.2.1.1)
		S11	CNCAN should encourage the NPP to review its dose constraint, given the experience feedback of the workers occupational exposure.
		G10	Regarding training and staff development. CNCAN has established an individual evaluation in its training approach so that it could identify clearly the individual needs and the training programm for the following year.
		G11	Every staff member to go to a facility or a plant for inspection has been equipped with a Personal Alarm Dosimeter.
		G12	Three inspections for radiation protection have been carried out on NPP site, in 2005, and 7 are planned for 2006. These inspections are performed by the staff of the Radiation Protection and Radwaste Division along with the resident inspectors. These team inspections including resident inspectors and headquarters staff allows exchanges of technical and operational experiences.
K	Transport of radioactive material	R62	CNCAN should give consideration to the legal status and the independence of Law No.111/1996 and the international agreements (ADR, RID, ICAO-TI, IMDG-Code) which were adopted by Romania. The cooperation with the Ministry of Transport, Buildings, and Tourism should be enhanced and formalized.

		R63	CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team.
		R64	CNCAN should expand its regulatory inspection and enforcement efforts to include the design, manufacture and use of non-certified packages, with a focus on design documentation, as-fabricated conditions, preparation of packages for shipment by consignors, stowage by carriers, and for any reusable packages application of specified maintenance procedures.
		R65	CNCAN should develop and implement a systematic inspection plan for the transport, in order to assure compliance with the relevant transport regulations.
		R66	CNCAN should consider implementing a systematic assessment of findings with regards to “lessons learned” in order to assure the feedback process and compliance with the regulations. In addition, general guidance should be developed by CNCAN on how to perform inspections.
		S12	Art. 6 (2) in Annex 2 of NTR-01 should be revised in order to be in line with the International Standards.
		S13	In order to ensure that appropriate quality assurance procedures are followed, CNCAN should receive a written confirmation by the owner of the package approval certificate together with the application.
		S14	CNCAN should evaluate its policy regarding the possibility to take legal actions to physical persons (Art. 32 of law 111/1996). It is considered more appropriate to take actions to legal persons and not to physical persons to ensure that the licensee performs a thorough investigation and to take all necessary measures about its safety and radiation protection related arrangements to prevent recurrence.

		G13	The implementation of Art. 27 of the Joint Convention into Romanian law through the Fundamental Norms for the Safe Management of Radioactive Waste (NDR-01, 2004) is considered as a good practice.
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APPENDIX VI A.- REFERENCE MATERIAL PROVIDED BY CNCAN

- [1] *Status of recommendations and suggestions implementation By December 2005 CNCAN, IRR- 2002 Mission:*
- [2] *Annual Report, November 2004 - October 2005, National Commission for Nuclear Activities Control (CNCAN),*
- [3] *CNCAN Approach, To Proactive Management of Operational Safety Assessment, 20-24 June 2005*
- [4] *Romanian TRIGA Reactor Conversion Process - Technical & Safety Approach for Fuel Licensing*
- [5] *CNCAN Regulations*
- [6] *Convention on Nuclear Safety, The 3rd Review Meeting, Country Group 4, Romania's Presentation, Vienna, 11 - 22 April 2005*
- [7] *International Licensing Requirements, Romania's Presentation, RRRFR Transport Options Workshop, Bulgaria, Varna, 20 - 23 September 2005*
- [8] *Blocked Control Rod in 14 MW TRIGA Research Reactor, Event Report, The 4th Co-ordinators Meeting, Incidents Reporting System for Research Reactors, Republic of Korea, Daejon, 16-20 May 2005*
- [9] *CNCAN QMM, Chapter 9 + Annexes, - Example - Senior Management Workshop, October 2005*
- [10] *Probabilistic Safety Assessment - Highlights - Meeting of Senior Regulators of Countries Operating CANDU-Type Reactors, Mumbai, India, 14 - 18 November 2005*
- [11] *Romanian Nuclear Regulatory Authority Experience on Quality Management System,*
- [12] *Regulatory Effectiveness - Highlights - Meeting of Senior Regulators of Countries Operating CANDU-Type Reactors, Mumbai, India, 14 - 18 November 2005*
- [13] *Feedback from the 3rd CNS Meeting - Highlights - Meeting of Senior Regulators of Countries Operating CANDU-Type Reactors, Mumbai, India, 14 - 18 November 2005*
- [14] *NPP Licensing Process - Regulatory Perspectives – October 2005*
- [15] *Assessment of the Licensees' Safety Level, Processes, and Activities, October 2005*
- [16] *CNCAN Quality Management System, Presentation for IAEA IRR Mission, CNCAN, Romania, January 2005*
- [17] *Quality Assurance Requirements for Quality Plan during Fabrication in Suppliers Factory (those article belong to CNCAN quality norms for fabrication of nuclear equipment, including instrumentation – 26 October 2005)*
- [18] *Updates on CNCAN activities, 2 September 2005*
- [19] *National Romanian Regulations, Technical Evaluation Working Group (TEWG) for the modernization of the 14 MW TRIGA RR at Pitesti (ROM/4/024), Vienna, IAEA Headquarters, 20-24.06.2005*

- [20] *Radiation Safety Norm – Authorization procedures, Published in the Official Journal, Part I, No.764 bis from 30th of November 2001*
- [21] *Regulations for the Transport of Radioactive Materials – Authorisation Process*
- [22] *Convention on Nuclear Safety, Questions Posted To Romania in 2005*
- [23] *Convention on Nuclear Safety, Romanian National report, August 2004*
- [24] *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, First National Report, March 2003*
- [25] *Joint Convention on the Safety of Spent Fuel Management, and on the Safety of Radioactive Waste Management, Romania's Response to Questions posed on its National Report Confidential under Article 36 of the JC, Vienna, 03-14 November 2003*
- [26] *The Romanian National Report - Highlights - Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management The First Peer Review Conference Vienna, 03-14 November 2003*
- [27] *Norms regarding the authorization of Quality Management systems applied to the construction, operation and decommissioning of nuclear objectives.
Attachment to CNCAN Order no. 65/30.05.2003*
- [28] *Norms regarding general requirements for quality management systems applied to the construction, operation and decommissioning of nuclear objectives
Attachment to CNCAN Order no. 66/30.05.2003*
- [29] *Norms regarding the authorization of quality management systems applied to the activities of assessment and selection of nuclear objectives location
Attachment to CNCAN Order no. 67/30.05.2003*
- [30] *Norms regarding specific requirements for the quality management systems applied to the research-development activities in the nuclear field
Attachment to CNCAN Order no. 68/30.05.2003*
- [31] *Norms regarding specific requirements for the quality management systems applied to design activities for nuclear objectives
Attachment to CNCAN Order no. 69/30.05.2003*
- [32] *Norms regarding specific requirements for the quality management systems applied to procurement activities for nuclear objectives
Attachment to CNCAN Order no. 70/30.05.2003*
- [33] *Norms regarding specific requirements for the quality management systems applied to the fabrication of products and supply of services for nuclear objectives
Attachment to CNCAN Order no. 71/30.05.2003*
- [34] *Norms regarding specific requirements for the quality management systems applied to construction-installation activities for nuclear objectives
Attachment to CNCAN Order no. 72/30.05.2003*
- [35] *Norms regarding specific requirements for the quality management systems applied to the commissioning activities of nuclear objectives
Appendix to CNCAN Order no. 73/30.05.2003*

- [36] *Norms regarding specific requirements for the quality management systems applied to the operation of nuclear objectives*
Appendix to CNCAN Order no. 74/30.05.2003
- [37] *Norms regarding specific requirements for the quality management systems applied to the decommissioning activities of nuclear objectives*
Appendix to CNCAN Order no. 75/30.05.2003
- [38] *Norms regarding specific requirements for the quality management systems applied to the activities of producing and using software for research, design, analysis and calculation for nuclear objectives*
Attachment to CNCAN Order no. 76/30.05.2003
- [39] *Law on the safe deployment of nuclear activities*
Law No.: 111 (1996)

APPENDIX VI B - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1] *No. RS-G-1.1 - Occupational Radiation Protection*
- [2] *No. RS-G-1.2 - Assessment of Occupational Exposure Due to Intakes of Radionuclides*
- [3] *No. RS-G-1.3 - Assessment of Occupational Exposure Due to External Sources of Radiation*
- [4] *No. RS-G-1.4 - Building Competence in Radiation Protection and the Safe Use of Radiation Sources*
- [5] *No. RS-G-1.5 - Radiological Protection for Medical Exposure to Ionizing Radiation*
- [6] *No. WS-R-1 - Near Surface Disposal of Radioactive Waste*
- [7] *No. WS-R-2 - Predisposal Management of Radioactive Waste, Including Decommissioning*
- [8] *No. WS-G-1.1 - Safety Assessment for Near Surface Disposal of Radioactive Waste*
- [9] *No. WS-G-1.2 - Management of Radioactive Waste from the Mining and Milling of Ores*
- [10] *No. WS-G-2.1 - Decommissioning of Nuclear Power Plants and Research Reactors*
- [11] *No. WS-G-2.2 - Decommissioning of Medical, Industrial and Research Facilities*
- [12] *No. WS-G-2.3 – Regulatory Control of Radioactive Discharges to the Environment*
- [13] *No. WS-G-2.4 - Decommissioning of Nuclear Fuel Cycle Facilities*
- [14] *No. WS-G-2.5 - Predisposal Management of Low and Intermediate Level Radioactive Waste*
- [15] *No. WS-G-2.6 - Predisposal Management of High Level Radioactive Waste*
- [16] *Safety Report Series No. 110 – The Safety of Nuclear Installations*
- [17] *Safety Report Series No. 111 – The Principle of Radioactive Waste Management*
- [18] *Safety Report Series No. 115 – International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*
- [19] *Safety Report Series No. 120 – Radiation Protection and the Safety of Radiation Sources*
- [20] *Convention on Nuclear Safety*
- [21] *No. GS-G-1.4 - Documentation for Use in Regulating Nuclear Facilities*
- [22] *No. GS-R-2 - Preparedness and Response for a Nuclear or Radiological Emergency*

APPENDIX VII - LIST OF CNCAN STAFF MEMBERS INTERVIEWED DURING THE IRRS MISSION

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|-----|---------------------------|--|
| 1. | Lucian BIRO | <i>Director of Nuclear Reactors Division</i> |
| 2. | Alexandru RODNA | <i>Director of Radiation Protection and Radioactive Waste Division</i> |
| 3. | Anton COROIANU | <i>Director of Ionizing Radiation Division</i> |
| 4. | Lucian GOICEA | <i>Director of Quality Control Division</i> |
| 5. | Viviana GRAMA | <i>Director of Special Materials Division</i> |
| 6. | Daniela CĂȘARU | <i>Director of International Affairs Division</i> |
| 7. | Lucia CEUCA | <i>Director of Public Relations Division</i> |
| 8. | Anca VELCEA | <i>Director of Economic Division</i> |
| 9. | Cantemir CIUREA | <i>Head of Nuclear Safety Department, Nuclear Reactors Division</i> |
| 10. | Marinel IOANA | <i>Head of Research Reactors Surveillance Department, Nuclear Reactors Division</i> |
| 11. | Aurelia SIMION | <i>Head of Nuclear Operators Licensing Department, Nuclear Reactors Division</i> |
| 12. | Daniela MUREȘANU | <i>Head of Cernavoda NPP Surveillance Department, Nuclear Reactors Division</i> |
| 13. | Grigoraș BENESCU | <i>Head of Department for Suppliers Quality Control Quality Assurance Division</i> |
| 14. | Adina BACIU | <i>Head of Radiation Protection and Emergency Preparedness Department, Radiation Protection and Radioactive Waste Division</i> |
| 15. | Nicolae DUMITRESCU | <i>Head of Section, Special Materials Division</i> |
| 16. | Gabriela ROȘCA | <i>Head of Assessment and Authorization Department, Ionizing Radiation Division</i> |
| 17. | Silvia ȘERBAN | <i>Head of Ionizing Radiation Surveillance Department, Ionizing Radiation Division</i> |
| 18. | Sorin MANCAȘ | <i>Head of the National Registry of Doses and Radiation Sources Department, Ionizing Radiation Division</i> |
| 19. | Constantin SOROP | <i>Head of Human Resources Section</i> |
| 20. | Angelica PREOTEASA | <i>Counselor, Assessment and Authorization Department, Ionizing Radiation Division</i> |
| 21. | Stefan TOBA | <i>Counsellor, Ionizing Radiation Division</i> |
| 22. | Virgil ILIESCU | <i>Counsellor, Ionizing Radiation Division</i> |
| 23. | Carmen RĂDAN | <i>Counselor, Nuclear Safety Department, Nuclear Reactors Division</i> |

24. Camelia **LIUTIEV** *Counsellor, International Affairs Division*
25. Silviu **POP** *Inspector, Cernavoda NPP Surveillance Department, Nuclear Reactors Division*
26. Angelica **PREOTEASA** *Counselor, Assessment and Authorization Department, Ionizing Radiation Division*
27. Daniela **DOGARU** *Coordinator of Radioactive Waste and Decommissioning Department, Radiation Protection and Radioactive Waste Division*
28. Mădălina **TRONEA** *Nuclear Safety Department, Nuclear Reactors Division*
29. Tite, **FIERBANTU** *Radiation Protection and Radioactive Waste Division*

**NATIONAL COMMISSION FOR NUCLEAR ACTIVITIES CONTROL
(CNCAN)**



