INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

TO THE

REPUBLIC OF BULGARIA

Sofia, Republic of Bulgaria

17 – 29 November 2024

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

АГЕНЦИЯ ЗА ЯДРЕНО РЕГУЛИРАНЕ
BULGARIAN NUCLEAR REGULATORY AGENCY

Integrated
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Review Service

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Mission dates:	*17 to 29 November 2024*
Regulatory body visited:	*Bulgarian Nuclear Regulatory Agency (BNRA)*
Location:	*69 Shipchenski prokhod Blvd. 1574 Sofia, Bulgaria*
Regulated facilities, activities, and exposure situations in the mission scope:	*Nuclear Power Plants, Fuel Cycle Facilities, Radioactive waste management facilities, radiation sources in industrial and medical facilities, emergency preparedness and response, transport, decommissioning, Medical Exposure, Occupational Exposure, Public and Existing Exposure.*
Organized by:	*International Atomic Energy Agency (IAEA)*

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IAEA-2024

The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Bulgaria, an international team of senior safety experts met representatives of the Bulgarian Nuclear Regulatory Agency (BNRA) and the Ministry of Health (MoH) at BNRA's headquarters, from 17 to 29 November 2024, to conduct an Integrated Regulatory Review Service (IRRS) mission. This was the second full scope IRRS mission that Bulgaria has hosted since the IRRS programme began in 2006.

The purpose of this IRRS mission was to review Bulgaria's national regulatory framework for nuclear, radiation, radioactive waste, and transport safety against IAEA safety standards. The mission was also used to exchange information and experience between the IRRS team members and the Bulgarian counterparts in the areas covered by the IRRS.

The IRRS team consisted of 16 senior regulatory experts from 15 IAEA Member States, three IAEA staff members, and two observers. The Bulgarian counterparts for the mission were from BNRA and MoH.

The review covered the IRRS core modules 1 to 10: the responsibilities and functions of the government, the global safety regime, the responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, development of regulations and guides, emergency preparedness and response. Facilities reviewed included nuclear power plants, radiation sources, fuel cycle facilities, waste management facilities. Activities and exposure situations reviewed included transport, occupational exposure, medical exposure, and public exposure. The review did not include the optional module 11 on safety and security interface.

At the request of BNRA, the IRRS mission included discussions during which members of the IRRS team and senior staff of BNRA shared views and regulatory experiences regarding one policy issue on capacity building and sustainability.

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

The review mission included a series of interviews and discussions with BNRA staff and representatives of MoH.

The IRRS team was extended full cooperation in the regulatory, technical discussions with the management and staff of BNRA and MoH, in a very open and transparent manner. Policy discussions were held with BNRA. This enabled the IRRS team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety in Bulgaria.

The IRRS team conducted visits at various facilities incl.: Kozloduy NPP, Kozloduy State Enterprise Radioactive Waste Management (SE RAW), Controltest Ltd., Theta Consult Ltd. and Acibadem City Clinic. The IRRS team members reported on the professionalism of BNRA staff in the preparation and conduct of their regulatory inspections. During the site visits, open discussions took place with the management of the authorized parties, who indicated that BNRA and MoH provide valuable feedback on the safety of facilities.

The IRRS team concluded that Bulgaria has a comprehensive and robust regulatory framework for nuclear and radiation safety covering all facilities and activities. BNRA has a culture of continuous improvement and is a very mature and competent regulator which fulfils its statutory obligations without undue influence.

The IRRS team identified several areas of good performance including:

- The BNRA through its Communication Policy proactively engages key stakeholders by using its website, social media and dedicated regular press conferences to provide updated information on nuclear and radiation safety in Bulgaria.
- Daily communications between site inspectors and BNRA headquarters staff ensure that BNRA is consistently updated on the safety status of nuclear installations, enabling timely regulatory responses when necessary.
- The BNRA maintains a comprehensive registry and database for radiation sources which allows the licensee for direct input enabling BNRA to systematically check the status of radiation sources in facilities and to track the import and export of those sources in real time.
- The Regulation on Protection during Medical Exposure outlines the provisions for justification of medical exposure involving both the prescribing physician and the radiological medical practitioner, especially in the case of foetuses, children, and asymptomatic individuals.

In the spirit of continuous improvement, the IRRS report includes several recommendations and suggestions, which, if addressed by the Government of Bulgaria, BNRA and MoH should further enhance the overall performance of the regulatory system.

The Government should:

- adopt the national policy and strategy for safety addressing all elements in line with IAEA safety fundamentals.
- adequately increase BNRA's budget to cater for regulatory activities associated with the planned expansion of their nuclear power programme.
- ensure that there is a comprehensive long-term strategy for human resource development for BNRA and MoH, also considering adequate remuneration of regulatory staff in comparison with other national nuclear organizations.
- finalize the revision of Strategy for Spent Fuel and Radioactive Waste Management.

BNRA should:

- plan for and continue its efforts to fill current and future vacancies and update the "Strategy for Building Professional Capacity in the BNRA 2023 - 2032".
- finalize and implement a comprehensive Procedure for Knowledge Management with emphasis on the implementation of key aspects of the competency management process.
- conduct self and independent assessment of leadership for safety and safety culture throughout the organization.
- consider implementing processes of review and revision of regulation and guides in a systematic and timely manner.
- further improve regulations on EPR and develop a comprehensive EPR process in its management system.

MoH should:

- develop guidance for registrants and licensees to ensure timely investigation of unintended or accidental medical exposures and the implementation of corrective actions as appropriate.
- consider developing guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources.
- consider establishing guidance for the protection and safety of medical exposures.

To conclude, in inviting the IAEA to conduct this IRRS mission and providing a transparent and comprehensive self-assessment, the Government of Bulgaria, BNRA and MoH have demonstrated their commitment to continuous improvement, a basic principle for excellence in nuclear and radiation safety. This report, in particular its recommendations and suggestions, should be viewed in that context.

The IRRS team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the IRRS mission.

I. INTRODUCTION

At the request of the Government of Bulgaria, an international team of senior safety experts met representatives of the Bulgarian Nuclear Regulatory Agency (BNRA) at its headquarters, from 17 to 29 November 2024, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Bulgaria governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Bulgaria in September 2021. A preparatory meeting was conducted 19 – 20 March 2024 at BNRA Headquarters in Sofia to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Bulgaria and their related safety aspects and to agree the scope of the IRRS mission. Where specific facilities and / or activities would not be included in the scope of the IRRS mission, Bulgaria provided an explanation for the exclusion.

The IRRS team consisted of 16 senior regulatory experts from 15 IAEA Member States, and 3 IAEA staff members and 2 observers. The IRRS team carried out the review in the following areas: the responsibilities and functions of the government, the global safety regime, the responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, development of regulations and guides, and emergency preparedness and response. Facilities reviewed included nuclear power plants, radiation sources, fuel cycle facilities, and waste management facilities. Activities and exposure situations reviewed included transport, occupational exposure, medical exposure, and public exposure. In addition, policy issues were discussed, in particular Capacity Building and Sustainability.

BNRA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the BNRA self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the Bulgaria advance reference material, conduct of interviews with management and staff from BNRA and direct observation of BNRA regulatory activities at regulated facilities.

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

II. OBJECTIVE AND SCOPE

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

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Bulgaria, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 19 to 20 March 2024. The preparatory meeting was carried out by the appointed Team Leader Mr Zia H. Shah, Deputy Team Leader Ms Rosa Sardella and the IRRS IAEA Team representatives, Mr Gabriel Soare and Ms Merinda Volia.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of BNRA represented by Mr Tsanko Bachiyski, Chairperson, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

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

Mr Atanas Dobrev made presentations on the national context, the current status of BNRA and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Bulgaria in November 2024.

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

BNRA Liaison Officer for the IRRS mission was confirmed as Mr Atanas Dobrev and Ms Elizabeth Tsvetanova was confirmed as a Deputy Liaison Officer.

BNRA provided IAEA with the advance reference material (ARM) for the review at the beginning of September 2024. In preparation for the mission, the IAEA review team members reviewed the Bulgarian advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 17 November, 2024 in Sofia, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 18 November 2024, with the participation of BNRA senior management and staff. Opening remarks were made by Mr Tsanko Bachiyski, BNRA Chairperson, Ms Dobromira Kareva, Deputy Minister of Health and Mr Zia H. Shah, IRRS Team Leader. Mr Atanas Dobrev gave an overview of the Bulgaria context, BNRA activities and the action plan prepared as a result of the pre-mission self-assessment.

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

In addition to the review, discussions were held to share views, experience and lessons learned between Bulgaria and the IRRS team on selected policy issues.

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

The IRRS exit meeting was held on Friday, 29 November 2024. The opening remarks at the exit meeting were presented by Mr Atanas Dobrev and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Zia H. Shah. Remarks were made by Mr Tsanko Bachiyski, Chairperson of BNRA in response of the mission findings. Closing remarks were made by Ms Kirsi Alm-Lytz, Section Head of the Regulatory Activities Section, IAEA.

An IAEA press release was issued.

Bulgaria is encouraged to report to the next review meeting of the Convention on Nuclear Safety, the results of the missions as well as the progress made against the recommendations and suggestions identified in this report.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Bulgaria is a country with a long-standing and mature radiation and nuclear safety legal system. The elements of policy and strategy for safety are mentioned mainly in the Act on the Safe Use of Nuclear Energy (ASUNE) and other legal documents. The ASUNE adopted by the Parliament regulates the safe use of nuclear energy and ionising radiation and with the safety of radioactive waste management and spent fuel management, as well as the rights and duties of licensees to ensure nuclear safety, radiation protection and physical protection. In aligning with IAEA fundamental safety principles, the governmental, legal and regulatory framework for nuclear safety, security and safeguards as well as for radiation protection are established and applied.

The general regulatory concept defined by the ASUNE is based on the level of risk associated with facilities and activities. Depending on the degree of radiation risk and the type of activity, the Chairperson of BNRA can issue licences, permits, or certificates of registration. Some activities that carry insignificant risk require only notification and are not subject to licensing or permitting. The principle of a graded approach is further developed in the Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy. Depending on the risk, different sets of documents with varying levels of justification are required. Regarding the control exercised by BNRA, the principle of a graded approach is explicitly mentioned in the ASUNE and is further applied in the internal procedures.

Violations of the law and secondary legislation are punishable by enforcement measures and administrative sanctions. Enforcement measures may be imposed to prevent possible noncompliance with the obligations required by the law and the regulations. Regarding the imposition of enforcement measures and administrative penalties, the ASUNE specifies various sanctions for licensees, considering the potential consequences and the level of risk.

Provisions for safety management and safety culture for the licence are included in the ASUNE. The promulgation for safety and safety culture management for the regulatory body are only in the management system documents of BNRA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The elements of policy and strategy for safety are mentioned in the Act on the Safe Use of Nuclear Energy and other legal documents. However, there is no separate document specifying basic principles of safety as long-term commitment of the government.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 1 states that** *"The government shall establish a national policy and strategy for safety…to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals".*
(2)	**BASIS: GSR Part 1 (Rev. 1), Requirement 1, para. 2.3 states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;* *(b) Binding international legal instruments, such as conventions and other relevant international instruments;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(c) The specification of the scope of the governmental, legal and regulatory framework for safety. *(d) The need and provision for human and financial resources.* *(e) The provision and framework for research and development.* *(f) Adequate mechanisms for taking account of social and economic developments.* *(g) The promotion of leadership and management for safety, including safety Culture…"*
R1	**Recommendation: The Government should adopt the national policy and strategy for safety addressing all elements as a statement in line with IAEA safety fundamentals.**
S1	**Suggestion: BNRA should consider initiating the development of a comprehensive national policy and strategy for safety to be adopted by the government.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Bulgarian legal infrastructure has several instruments to establish the regulatory requirements on nuclear safety, nuclear security and radiation protection (Figure 1). As a European Member State, Bulgaria has a legal and regulatory framework implementing the European Directives issued in the framework provided by the EURATOM treaty: the 2009/71/EURATOM Nuclear Safety Directive as amended by the Directive 2014/87/EURATOM, the 2011/70/EURATOM Waste Directive and the 2013/59/EURATOM Basic Safety Standards Directive.

Figure 1. Legislative framework of Bulgaria

The ASUNE establishes the fundamental principles for safety, as well as measures for the protection of the population and the environment from radiation risks. The regulatory framework for activities involving the use of nuclear energy and ionising radiation, as delineated in the ASUNE and the secondary legislation, constitute one of the primary instruments for ensuring such protection. The law imposes numerous obligations on entities engaged in the aforementioned activities. The oversight of compliance with these obligations is precisely aimed at ensuring safety of workers, public and environment.

The safety framework covers all types of nuclear facilities and their related activities (units in operation, units in decommissioning, spent fuel storages, radioactive waste (RAW) management facilities), and the activities with sources of ionising radiation.

Bulgaria has established an institutional framework of duties and responsibilities for the ministries and other state bodies as stipulated in the ASUNE. BNRA serves as the national nuclear regulatory authority and performs state regulation of the safe use of nuclear energy and ionising radiation, and the safe management of radioactive waste and spent nuclear fuel. BNRA establishes regulatory requirements on nuclear safety and radiation protection, issues licence and permits, carries out regulatory control and imposes enforcement measures to ensure compliance with the regulatory requirements; The Ministry of Energy (MoE) carries out the state policy on energy development and implementation of the national energy policy. MoE proposes and implements the national strategy for energy development and the national strategy for spent nuclear fuel management and radioactive waste management. The Ministry of Health (MoH) develops and implements the state policy aimed at protecting the health of the public by establishing mandatory health standards, requirements and rules for radiation protection. MoH carries out specialised functions in the field of health protection in the use of nuclear energy and ionising radiation through its bodies - the National Centre for Radiobiology and Radiation Protection (NCRRP) and the Regional Health Inspectorates (RHI) with Radiation Control departments. The Ministry of Environment and Water (MoEW) manages, coordinates and supervises the development and implementation of the state policy in the field of environmental protection, conservation and use of water and the earth's interior subsurface. MoEW is in charge of the National System for Environmental Monitoring and is the competent decision-making authority in respect of any environmental impact assessment performed. The Ministry of Interior (MoI), through the Fire Safety and Civil Protection General Directorate, coordinates the activities on the protection of the public and the national economy in case of disasters and emergencies, including conducting risk assessment, preventive measures, rescue and urgent remedial works and providing international assistance.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As stated in the ASUNE, BNRA is an independent regulatory authority. While fully independent in its safety related decision making, BNRA's Chairperson and Deputy Chairpersons are designated by the Government. The Chairperson has a direct line of communication with the Government through a designated deputy prime minister. To guarantee political independence of BNRA management, the law established a 5 year term for office of the Chairperson which can be renewed once, while the Governmental term of office is 4 years. There are also specific eligibility requirements for the Chairperson and Deputy Chairpersons e.g. 10 years experience in the nuclear field in addition to a technical high education. BNRA has no promotional functions or other tasks which contradict its control for safety.

BNRA as part of the executive power shall comply with all legal requirements relevant to the state administration including Governmental budgetary procedure. BNRA proposes its own budget in direct communication with the Ministry of Finance (MoF). According to the ASUNE, the agency's activity is financed from the state budget and from the fee revenues collected under this law. Pursuant to the ASUNE, funds from the agency's budget are spent as a priority for financing the performance of studies, analyses and expertise related to the assessment of nuclear safety and radiation protection and the activity of regulating nuclear safety and radiation protection under this law.

BNRA's allocated budget is insufficient as regards the staff expenditures and the remuneration of BNRA's employees, making it very challenging to attract and retain qualified staff, with specific expert knowledge and competences in particular. Based on the analysis performed, salaries of BNRA staff were approximately 50% less than the salary for a corresponding professional-technical position in the nuclear sector, however the IRRS team was informed of a very recent 30% BNRA salary increase. Despite the efforts made in the past period, the budget allocated by BNRA is not sufficient to remunerate BNRA employees to a level that is sufficiently attractive compared to the industrial sector. In view of the government planning of expansion of the nuclear power programme with construction of two large nuclear power units and SMRs, BNRA's human resources will have to be enhanced proportionately to adequately discharge its regulatory oversight

activities for the nuclear power programme. It should also be noted that building the necessary human capacity for BNRA requires immediate effort with long term commitment, addressing the need for readiness for regulatory oversight activities before the actual licensing of new NPPs starts. The issue was already identified by BNRA as part of its self-assessment and included in the action plan submitted as advance reference material for the mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current national human resources strategy does not account for the planned expansion of Bulgaria's nuclear power plant programme and there is no consideration for retention of existing human resources of BNRA.*	
(1)	**BASIS: GSR Part 1 (Rev.1), Requirement 3 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 (Rev. 1), Requirement 2 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities"*
R2	**Recommendation: The government should adequately increase BNRA's budget to cater for regulatory activities associated with the planned expansion of their nuclear power programme.**
R3	**Recommendation: The government should ensure that there is a comprehensive long-term strategy for human resource development and retention by considering adequate remuneration of regulatory staff in comparison with other national nuclear organizations.**

The number of employees is stipulated in the BNRA Rules of Procedure which define its departments, including the allocation of the number of employees per department. BNRA has 114 full-time positions, and the actual number of staff employed, as of July 2024, is 103. Recent analyses of BNRA's human resources and staff competency indicated that currently there is sufficient number of staff with the necessary competency and experience to carry out all the work involved in regulating existing nuclear facilities and activities. However, some aspects are of concern. The average age of the staff is more than 50 years, with only very few people under 40. From the point of view of the age profile of staff the present situation is challenging in terms of long-term planning and sustainability. To solve this problem BNRA is initiating systematic efforts, by implementing its internal strategy to strengthen professional capacity. In parallel, BNRA advertised the vacant positions but achieved only limited success. For highly educated professionals, the working environment is not competitive enough compared to similar positions in the nuclear or industrial sector. It is a legal limitation for determining the individual salaries of employees and to the newly appointed young specialists equal to the employees in the state administration, however, BNRA must make allowances for other working conditions, such as remote working. BNRA has already communicated the need for a change in the ordinance of the government concerning the position in the field of nuclear safety

and radiation protection equivalent to the position in the field of information technology and aviation technology.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The ASUNE clearly assigns responsibility for safety to the licensee, and it may not be delegated to other persons. This responsibility extends throughout the entire lifecycle of the facility. According to the ASUNE every person performing activities regulated by the act, with or without licence or permission, bears responsibility for safety and thus is subject to regulatory control. The primary safety responsibilities include the following obligations - to provide for all measures and actions associated with the safe storage of nuclear material, radioactive substances, spent nuclear fuel, as well as of the radioactive waste generated by the activity thereof, until delivery for management to a person licenced to operate a radioactive waste management facility and also to measure, record and control parameters characterising the nuclear material, the radioactive substances and the other sources of ionising radiation, and to maintain systems for the accounting for and control of the said sources.

The ASUNE assigns BNRA the responsibility to monitor and verify the compliance of individuals and organizations responsible for safety with the requirements of the ASUNE and other relevant legislation. BNRA is authorised to require that individuals or organizations primarily responsible for the safety of facilities and activities comply with regulatory requirements and demonstrate compliance through the authorization, inspection, review and assessment and enforcement mechanism.

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

The Bulgarian legal framework clearly defines the responsibilities and powers of different authorities. According to the legal framework, BNRA is the regulatory body for the safe use of nuclear energy and ionising radiation, as well as for the safe management of radioactive waste and spent fuel. Coordination between BNRA and other government bodies is ensured through several mechanisms: the ASUNE delineates the role of BNRA and its interaction with other institutions. Joint inspections and audits can be conducted by BNRA and other competent authorities (such as MoH) to provide a comprehensive assessment of nuclear safety and radiation protection.

According to the provisions in the Rules of Procedure of the Council of Ministers and its administration, any draft act that needs to be adopted by the Council of Ministers must be consulted with other state bodies on matters related to or affecting their activities. This mechanism prevents duplication or conflicting requirements including these which delineate functions and responsibilities. In collaboration with other state authorities the Chairperson of BNRA develops and proposes the regulations in the areas of nuclear safety of facilities, radiation protection, transportation of nuclear material, radioactive waste, emergency preparedness, and physical protection of nuclear facilities. Specialised committees and councils may be established, including representatives from various ministries and agencies, to ensure coordination and cooperation on issues related to nuclear safety and radiation protection. A memorandum of understanding between BNRA and MoH was signed in 2016. Meetings are organised with different state bodies to ensure a unified level of competency and understanding of regulatory requirements and procedures. Although the MoU and associated agreement are in place, there is a need for further improvement of the coordination between BNRA and MoH. The issue is further elaborated in Section 3.1 of this report.

Through these mechanisms, the Bulgarian government ensures coordination of the regulatory functions of BNRA, and various bodies involved in nuclear safety and radiation protection, thereby guaranteeing high standards of safety and protection of public health and the environment.

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The Regulation on Radiation Protection (RRP) authorises the regulatory body to take any measures to protect the people and the environment when an unforeseen event that jeopardises public health occurs, or to avoid risks that could result from the accidental contamination of any places, materials or products by radioactive substances. The RRP regulates different types of existing exposure situations including exposure from the contaminated areas from past activities and emergency situations, as well the exposure from natural radiation sources, including radon and thoron, or natural material, and exposure from commodities.

According to the RRP, for existing exposure situations, MoH shall establish reference levels for members of the public and via the state health control authorities shall give directions and supervise their implementation. For such situations, the optimisation of protection shall give priority to exposures above the reference level and the optimisation process shall continue to be implemented including where the levels of exposure are below the reference level. On a proposal by the authorities concerned, the Council of Ministers shall adopt strategies, programmes and plans for management of existing exposure situations. Those documents shall determine, as applicable and appropriate, the following: the responsibilities of the interested state bodies connected with management of the identified existing exposure situations, short-term and long-term goals and the respective reference levels, taking into account the annual effective dose from all possible exposure pathways in the range of 1- 20 mSv, identification of the boundaries of the affected areas and affected members of the public from radiation protection point of view, protective measures and the scale of the measures to be applied to a specific existing exposure situation, measures for prevention and control of the access to the affected areas and for imposition of restrictions in respect of living conditions, assessment of the exposure of different groups in the population and the resources necessary for monitoring the exposure of the affected individuals.

The National Strategy for Reducing the Risk of Radon Radiation 2018-2027 focuses on the reduction of radon exposure and the National Radon Action Plan defines the responsibilities, implementing communication strategies, and measurement of radon levels in homes and public buildings. The results are presented on the Radon Action Plan website. To coordinate the functions of reducing the risk of radon exposure, a National Coordinating Council (NCC) was formed with participation from various departments. This NCC oversees the implementation of the National Action Plan. At the regional level, there are 28 regional coordination councils involving regional and municipal administrations, the Executive Agency for the Environment, the Chamber of Engineers, labour and health inspection experts. This is considered as an area of good performance for controlling public exposure due to indoor radon.

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

Decommissioning of nuclear facilities is done only after the issuance of a licence by BNRA. The Procedures for issuing this licence for decommissioning and requirements for the licensing documents, including requirements for the structure and content of the plan for decommissioning and safety assessment reports, are established in the legislation.

A Strategy for Spent Fuel and Radioactive Waste Management was approved by the Council of Ministers in January 2011 and extends to 2030, in pursuance to the ASUNE. The present Strategy for Spent Fuel and Radioactive Waste Management is a strategic plan for achievement of the objectives, tasks, and measures in the management of radioactive waste and spent nuclear fuel and even if the strategy is defined at a general level regarding the main endpoints for all RAW and SF management routes, the current situation of management of radioactive waste and spent fuel in Bulgaria is not included in the strategy from 2011. The strategy has been under revision for a number of years with important steps in the process finalised

(environmental impact assessment, communication with the different Ministers and communication with the neighbouring countries) and awaiting the formal acceptance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Strategy for Spent Fuel and Radioactive Waste Management does not reflect the current situation for management of radioactive waste and spent fuel in Bulgaria.*	
(1)	**BASIS: GSR Part 1 (Rev.1), Requirement 10, para. 2.28 states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organisations concerned and the long timescales that may be involved."*
(2)	**BASIS: GSR Part 5 Requirement 2 states that** *"The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
R4	**Recommendation: The Government should finalise the revision of Strategy for Spent Fuel and Radioactive Waste Management.**

The ASUNE allows for the provision of the financing of Radioactive Waste Management. Anyone generating radioactive waste shall meet all expenses incurred in connection with management of radioactive waste from waste generation to disposal, including monitoring of repositories after closure by contributing to the Radioactive Waste Fund established by the ASUNE. Financing of radioactive waste management during the operation of a nuclear power plant is done by the operator and after all responsibility has moved to the State Enterprise for Radioactive Waste (SE RAW) – by the Radioactive Waste Fund. The financial resources of the Fund are expended solely for the purpose of financing of: the operation and maintenance of the SE RAW; other activities comprehended in radioactive waste management outside the activities of the specialised state-owned enterprise, including research and scientific developments, and decommissioning of radioactive waste management facilities. To finance the decommissioning activities of nuclear facilities, a fund titled the Decommissioning of Nuclear Facilities is established under the MoE. Availability of adequate financial resources for decommissioning is a legal requirement in accordance with the ASUNE. The base for resource planning is assessment of the expenses for the decommissioning. On the base of this assessment, BNRA shall receive evidence that provisions for financial resources are sufficient for the execution of decommissioning plans.

1.8. COMPETENCE FOR SAFETY

The Government has established requirements for the necessary competences for the operation and the regulation of facilities and activities. It also supports and finances the educational system and organises administrative training. The Regulation on Qualification specifies requirements for the system of selection and qualification of personnel. All licensees and individuals are required to maintain and enhance their knowledge and improve their skills. The Regulation on Licensing specifies that to obtain an authorization, applicants have to prove that they possess the required number of staff with the necessary competence and skills to ensure the safety of the facility or activity. This is verified during the authorization process.

In order to maintain the nuclear competence of Bulgaria and in response to the challenges affecting the whole nuclear sector in recent years, the Government adopted a National Strategy for the Development of Human Resources in the Nuclear Sector 2022-2032. The national strategy is carried out in accordance with the requirements and principles of nuclear safety and radiation protection. An essential element necessary to provide and maintain nuclear safety and radiation protection at the highest level, is the availability of personnel with the necessary qualifications in all organizations, carrying out activities in the nuclear sphere. The Strategy is based on an analysis of the needs for development of human resources in the nuclear field. The development is based on active consultations with the interested parties – state bodies, educational institutions and organizations, potential employers, part of which are also included in the Interdepartmental Task Force (ITG) for the development of the Strategy Actions which should result in the development of human resources that would lead to the improvement of the managerial, technical, professional and economic aspects in the nuclear sector. The strategy outlines what needs to be done to address the accumulated challenges in the field of human resource development in the nuclear field, as well as the need for interaction between the interested parties. Based on the National Strategy, a three-year action plan was developed. The implementation of the Strategy also includes a system of monitoring and evaluation, implementation time frame, and identification of responsible entity and the source of funding. This is considered as an area of good performance. BNRA has its own action plan for this period. The implementation of the plan is continuously ongoing.

1.9. PROVISION OF TECHNICAL SERVICES

In accordance with the Regulation on Radiation Protection for all occupationally exposed persons in category A, individual monitoring shall be done systematically. The licensee shall develop and maintain an individual dosimetric control (IDC) programme and shall send the dosimeters to an accredited laboratory. Accredited persons for performance of individual monitoring are obligated to send to MoH current data about the enterprise, numbers of workers, periodicity of monitoring, and used measuring instruments. In accordance with the Regulation on Radiation Protection, the technical means, which are used for radiation control at the facility with sources of ionising radiation, shall be under metrological control within the meaning of the Act on Measurements. Each person who received a licence and/or permit for an activity with Sources of Ionising Radiation (SIR), is obliged to ensure technical support for the systems and equipment which are providing radiological protection.

The Act on Measurements determines requirements for ensuring traceability, accuracy and authenticity of measurements. The traceability of measurements is ensured by establishing national standards and national system for certified comparative materials. Accuracy and authenticity of health measurements, measurements related to public safety and environmental protection are ensured by performance of metrological control and expert opinion.

The IRRS team concluded that the technical services related to nuclear and radiation safety, such as services for personal dosimetry, environmental monitoring and the calibration and testing of equipment, are adequately available.

1.10. SUMMARY

The Bulgarian legal framework covers all types of nuclear and radiation facilities and activities and exposure situations. It covers all phases of nuclear facilities and lifetime of sources. The Bulgarian regulatory framework is composed of several organizations.

The elements of policy and strategy for safety are mentioned in the Act on the Safe Use of Nuclear Energy and other legal documents however, there is no separate document specifying basic principles of safety as long-term commitment of the government.

BNRA operates as an independent regulatory body, however, the current human resources strategy does not account for the planned expansion of Bulgaria's nuclear power programme and there is no systematic consideration for retention of existing human resources. It is recommended that the government should consider making the necessary provision for maintaining the competence of BNRA for effective oversight of existing and future nuclear power programme.

The present Strategy for Spent Fuel and Radioactive Waste Management does not reflect the current situation for management of radioactive waste and spent fuel in Bulgaria with defined timeframe. The Government should finalise the revision of the Strategy for Spent Fuel and Radioactive Waste Management.

The National Strategy for the Development of Human Resources in the Nuclear Sector 2022-2032 is recognised as a good effort towards maintaining and growing human resource capacities in the nuclear sector.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Bulgaria is a founding member of IAEA, member of European Union (EU) and EURATOM Treaty - since 2007, and member of the Nuclear Energy Agency (NEA/OECD) since 2021. The country is also a member of other international fora in the nuclear field such as ENSREG, WENRA, HERCA, WWER Forum, WANO, etc. and takes part in a number of their working bodies (managing bodies, committees, and working groups).

Bulgaria uses the IAEA safety fundamentals, requirements and guides as a basis for developing and maintaining the safety-related regulations. Representatives of BNRA participate in the development of IAEA Safety Standards: BNRA is member of the Nuclear Safety Standards Committee (NUSSC), Radiation Safety Standards Committee (RASSC), Transport Safety Standards Committee (TRANSSC) and Waste Safety Standards Committee (WASSC).

Bulgaria contributes to the relevant global nuclear and radiation safety regime to enhance safety globally and fulfils its respective obligations. Bulgaria actively participates in coordinated international activities aimed at ensuring global nuclear safety and building an effective international emergency response system. Bulgaria is a contracting party to the relevant international treaties and conventions, which establish obligations and mechanisms for ensuring safety in the use of nuclear energy and ionising radiation for peaceful purposes and which provide for an effective coordinated international response to a nuclear or radiological emergency. Bulgaria has adhered to all key conventions, as well as to other fundamental internationally established instruments. According to the ASUNE, the BNRA Chairperson is the contact point for these conventions.

Since the initial IRRS mission in 2013 and follow-up mission in 2016, Bulgaria has hosted a series of peer reviews and missions aimed at enhancing nuclear safety. These include an ARTEMIS mission to review spent nuclear fuel and radioactive waste management policies, and the two ENSREG Topical Peer Reviews under the EU's Safety Directive on Issues of Strategic Importance from the Point of View of their Safety. In 2021, an expert evaluation mission of the IAEA was held with the main emphasis on "the activities of the Nuclear Regulatory Agency in building professional capacity in the field of nuclear safety and security".

In addition, a number of missions have been hosted by the licensee (Kozloduy NPP) to support a high level of operational safety through SALTO missions at Kozloduy NPP units to assess safety, thematic peer reviews on ageing management and probabilistic safety analysis, and WANO technical support missions focusing on operational practices, trend analysis, and training approaches.

BNRA experts are regularly involved in international peer review missions organised by the IAEA and EU, providing assistance to foreign regulators and operators. BNRA's specialists participated as team members and leaders in various international peer review missions such as IRRS, IPPAS and EPREV. Experts from the nuclear operator Kozloduy NPP participated in OSART missions to foreign operators.

Bulgaria has numerous agreements with other countries to foster cooperation in the field of nuclear energy and radiation safety. Bulgaria has intergovernmental agreements with neighbouring and another countries (Greece, Romania, Türkiye, Serbia, Ukraine) to facilitate early notification in the event of a nuclear accident and to exchange information on nuclear facilities. Additionally, BNRA has engaged in arrangements and memorandums of understanding with regulatory authorities from the United States, Russia, Greece, Romania, North Macedonia, Slovakia, Türkiye, Cyprus and Hungary, emphasising cooperation in nuclear safety, radiation protection, and exchange of technical information.

BNRA is acting as the National Contact Point as per IAEA Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

Bulgaria has registered capabilities to provide assistance in the RANET network and BNRA is the national contact point.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

BNRA made specific arrangements to identify lessons learned from operating experience and regulatory experience, including experience from other States, and for the dissemination of the lessons learned and for their use by authorised parties, the regulatory body, and other relevant authorities. Relevant information and lessons learned from operating and regulatory experience are gained from the participation in the multinational related groups and activities. BNRA has limitations due to the lack of human resources to participate more actively in all international fora. The prioritisation of international activities is not established. The decision on participation in international activities is made on a case-by-case basis and no comprehensive plan was developed. The experience obtained from the international event is used for improving the regulatory activities and the regulations, and the Chairperson decides on the implementation of the individual proposals. The follow up of the accepted proposals is not performed systematically.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA's participation in international forums is not based on a formalised predetermined priority. Further, the use of experiences from international activities is not sufficiently documented and followed.*	
(1)	**BASIS: GSG 12 para 6.84 states that** *"An important method for acquiring knowledge and developing competence is the participation in knowledge networks. The IAEA and other international organizations, and professional bodies and associations, facilitate networking, exchange of information and mutual learning based on good practices and experience from different States."*
(2)	**BASIS: GSG 12 para 6.85 states that** *"The regulatory body can benefit from participation in knowledge networks at the national, regional or international level.".*
(3)	**BASIS: GSG 12 para II.8 states that** *"The products of the regulatory body can be regarded as the outputs of regulatory activities. Typically, for a regulatory body, products include documents that relate to the discharge of core functions and supporting functions and their related processes, for example:* *…* *— Plans (e.g. plans for strategic regulatory activities and training);* *— Communications with interested parties (e.g. annual reports, financial reports, seminars, decision letters, requests for information, research and development reports, and contributions to international and national cooperation);* .. *— Results of analyses of operating experience and external events"*
S2	**Suggestion: BNRA should consider further developing the process for participation in international activities, to more effectively benefit from international experience.**

BNRA has established a comprehensive process for analysing operational events at the Kozloduy NPP and incorporating feedback into regulatory activities. The process involves a dedicated team - NPP Event

Analysis Group (EAG), comprising of experts from various BNRA departments. The EAG independently analyses operational events, assesses them according to INES, and identifies reportable events for publication in international databases. Additionally, the EAG reviews corrective actions taken by the KNPP and provides feedback to the IAEA's IRS system. Bulgaria reported incidents to IRS, with the last one in 2014. However, the mechanism for reporting operating and regulatory experience is not updated the 2022 IAEA-IRS Guidelines. The issue was identified by BNRA as part of its self-assessment and included in the action plan submitted as advance reference material for the mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The mechanism for reporting operating and regulatory experience is not revised against the 2022 IAEA-IRS Guidelines.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), para. 3.5A states that** *"Relevant information and lessons learned from operating experience and regulatory experience shall be reported in a timely manner to international knowledge and reporting networks. "*
S3	**Suggestion: BNRA should consider to further improve the mechanism for more effective participation in the International Reporting System for Operating Experience.**

Feedback from operational experiences is integrated into the licensing process and regulatory requirements for nuclear facilities, stressing the importance of continuous improvement in nuclear safety and radiation protection. BNRA conducts inspections to ensure the effectiveness of feedback systems and supervises corrective actions by the licensees, employing enforcement mechanisms when necessary. BNRA utilises feedback from operational experiences, regulatory activities and information exchange to enhance the review. Additionally, BNRA may propose amendments to national legislation to address gaps in the legislation, which were identified from lessons learned, international best practices, and advancements in science and technology. Additionally, BNRA may propose amendments to national legislation to address gaps in the legislation identified through operational experiences and safety analyses.

2.3. SUMMARY

Bulgaria participates in the relevant international arrangements to enhance safety globally and fulfils its respective obligations accordingly. BNRA contributes to the Bulgarian effort to fulfil its respective international obligations in the relevant international arrangements.

BNRA has constraints to systematically benefit from international regulatory experience feedback due to the lack of human resources limiting its participation in international activities, which needs further improvement.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

According to the ASUNE, issued in 2002, BNRA is the regulatory body for radiation and nuclear safety in Bulgaria for nuclear facilities and radiation sources. Both BNRA and MoH have responsibilities for radiation safety in the radiation protection area as it pertains to occupational, medical and public exposure, while MoH has the sole responsibility for supervision in the area of medical exposure of patients.

The BNRA budget is part of the State budget and is determined annually by the Law on the State Budget of the Republic of Bulgaria for the current year. BNRA proposes its own budget in direct communication with MoF. Once granted, BNRA is not restricted in the use of the budget which allows spending according to the regulatory needs. According to the ASUNE, BNRA's budget is (partially) financed from the revenues from the fees collected under this law. It should be noted, however, that the fees are not direct BNRA budget revenue (upon their receipt they are transferred to the state budget). With regard to the remuneration of the employees, the allocated budget is insufficient, making it challenging to retain qualified staff and attract new employees with the necessary competence. This has been recognised in the ARM. The IRRS team was informed of a very recent 30% BNRA salary increase. Salary adequacy compared to the private sector needs to be sustained, however, in the long term.

The overall number of BNRA employees and their allocation across departments (the highest organizational units) are defined in BNRA Rules of Procedure, which is approved by the Council of Ministers. These Rules also outline the roles and responsibilities of BNRA's departments. Any changes to staff numbers or the creation or dissolution of departments require amendments to the Rules of Procedure, following established legal procedures. Within this framework, BNRA independently defines its internal structure and allocates entrusted resources to it to fulfil its responsibilities, prioritising regulatory activities based on the risks associated with specific facilities and activities. The distribution of staff within each department's divisions is determined by the Chairperson, who issues an order based on the functions and needs of the departments. This staffing allocation considers recommendations from the Executive Secretary and Directors and is finalised in the approved staffing table.

It should be noted that the competences of BNRA and MoH overlap, e.g. in the area of core regulatory functions such as inspection and enforcement, which creates a need for a very clear definition of competences, ensuring adequate information exchange and strong cooperation. A Memorandum of Understanding and an Agreement between BNRA and MoH regarding inspections in facilities with Sources of Ionising Radiation (SIR) have been signed, but unfortunately, they are very general and do not describe with the necessary level of detail the mutual cooperation in the areas of medical, occupational and public exposure. The IRRS team was informed of effective cooperation between BNRA and MoH in the case of an event related to radiation protection and occupational exposure. But the IRRS team noted that there is no document formalising how they should cooperate in such cases. The IRRS team was also informed by MoH and BNRA that not all non-compliances identified by MoH regarding medical exposures are reported to BNRA. This could potentially undermine the supervision of the necessary actions for correction of the non-compliances. Although a MoU and the Agreement are in place, the absence of detailed protocols or procedures to outline their cooperation creates ambiguity. This can result in potential gaps, overlaps, or conflicting requirements in the execution of their respective regulatory functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no detailed procedure for coordination and cooperation between BNRA and MoH.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorised parties."*
(2)	**BASIS: GSG 12, para 4.46**: *"Where the responsibilities of the regulatory body and other organizations interact or have an interface, liaison between these bodies should be established by means of a formal agreement specifying each body's responsibilities, the areas of interface and the means for resolving any conflicts between different requirements. It should be ensured that no conflicting requirements are placed upon an authorized party."*
S4	**Suggestion: BNRA should consider further strengthening and detailing the mechanism of the coordination and cooperation with MoH.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

According to the ASUNE, BNRA is an independent authority competent to implement the state regulation in the area of the safe use of nuclear energy and ionising radiation (administrative authority). It has no promotional functions. In executing its executive power, BNRA shall comply with all legal requirements relevant to the state administration including budgetary procedure, while being fully independent in its (safety related) decision making at the same time.

To assist the BNRA Chairperson in the decision-making and to provide independent expert opinion, two permanent advisory bodies are established – Advisory Council on Nuclear Safety and Advisory Council on Radiation Protection with eminent scientists and experts with recognised professional expertise as members. The Chairperson may seek their advice on scientific aspects of nuclear safety and radiation protection; however, the final decision rests with the Chairperson.

Training of incoming staff is a key element for maintaining competence in BNRA. For each newly recruited staff an Individual Training Plan is prepared. Elements of the individual training plan are mandatory for the new entrants who were former licensee employees. The training covers "Conflict of Interest in Public Administration, Concept and Practices" and unacceptable behaviour during inspections. All BNRA employees are required to make a declaration of absence of conflicts of interests and to abide by BNRA's Employee Code of Ethics. Conflicts of interest are addressed in accordance with the Counter-Corruption Act. BNRA is currently updating the course on conflicts of interest for new employees to put more emphasis on the inspector independence.

Regulatory control is exercised by designated officials - inspectors. There are 6 BNRA resident inspectors at the Kozloduy NPP site, who report daily and weekly on the safety status of NPPs. There are also 3 NCRRP resident inspectors supervising radiation protection aspects within MoH's competency (occupational and public exposure). Rights and responsibilities of the inspectors entail, among other things, unhindered access to licensees and facilities; access to any relevant information; issuing mandatory written instructions; issuing statements for administrative violations; and proposing coercive measures (including a revocation of authorization). NPP resident inspectors are not rotated systematically but stay on-site for a

long period of time. BNRA routinely hires former nuclear industry employees, who have an established level of familiarity with licensee staff, as inspectors. This practice can pose additional challenges in terms of inspector attitude and independence. This issue is further addressed in Suggestion **S16** in Chapter 7.2.

BNRA has an enforcement policy, which takes into account the graded approach. The ASUNE and the ACT on Administrative penalties outlines the enforcement powers of the regulatory body, including, the Chairperson and the inspectors. Coercive enforcement measures include the ability to stop work, limit an activity, revoke an authorization etc.

There is provision of internal audit for the verification of BNRA activities and their effectiveness and efficiency. The internal auditor reports to the Chairperson. On a yearly basis, external financial assessment is conducted by the Bulgarian National Audit Office and other state control authorities. It focuses on financial audit of BNRA's Annual financial report. Results are documented in an audit report.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

BNRA independently defines its organizational structure and allocates entrusted resources to it to fulfil its responsibilities, prioritising regulatory activities based on the risks associated with specific facilities and activities. Currently, BNRA has 114 full-time positions, of which 10 remain vacant, representing 9% of the workforce. The overall number of employees has not increased since 2007, while the average staff age is 54, and 33% of employees are at or near retirement age. More than 95% of the staff hold university degrees, with some having PhDs, and many possess long professional experience. Despite this, persistent difficulties in recruiting technical experts for civil servant positions pose ongoing challenges. These issues are particularly concerning given the steadily increasing workload, which risks negatively impacting certain regulatory activities if the situation persists. BNRA's allocated budget is insufficient with regard to the remuneration of BNRA's employees, making it very challenging to attract and retain qualified staff, with specific expert knowledge and competences. Based on the analysis performed, salaries were approximately 50% of the salary for a corresponding professional-technical position in the private sector, however, the IRRS team was informed of a very recent 30% BNRA staff salary increase, this needs to be further enhanced and sustained in the long term.

A National Strategy for the Development of Human Resources in the Nuclear Sector (2022–2032) has been adopted to address workforce challenges in the nuclear sector. In line with this, BNRA developed its own Strategy for Building Professional Capacity 2023–2032, which includes measures to improve human resource management. The longstanding vacancy issue, combined with an aging workforce, highlights the need for a focused sustained action to maintain sufficient and competent staff, especially for core regulatory functions. BNRA should continue its efforts to fill vacancies and attract new employees, including young professionals, inter alia, by updating and enhancing its strategy for building professional capacity. The efforts to attract new workforce should also take into account the needs of the expanding nuclear power programme. While job characteristics and hiring criteria are well-defined and based on a map of competencies, uncompetitive financial conditions compared to the private sector hinder recruitment efforts.

The IRRS team was informed of the Government's December 2023 decision mandating the Council of Ministers to initiate measures for the construction of new nuclear units. This will require a significant increase in staff for licensing and regulatory oversight presenting a substantial challenge to recruit and train personnel in a timely manner. To address this, a detailed recruitment and training plan should be developed to ensure new employees are hired and trained well in advance of the implementation of new nuclear projects. In view of the planned construction of new units, BNRA's human capacity will have to be adequately enhanced to appropriately reflect the increase in regulatory activities. It should be noted that building the necessary human capacity requires long term efforts, given the need for readiness for regulatory activities well before the actual licensing starts.

BNRA Rules of Procedure and job descriptions establish the qualifications and professional experience required for BNRA staff. Individual training programmes are developed to address specific training needs, including those of newly recruited staff. An annual training plan is prepared, based on an analysis of factors such as previous training activities, future needs and feedback from training performed. However, training needs will grow as additional personnel are hired to fill in the vacancies and meet the demands of the nuclear programme expansion.

To address capacity-building challenges, BNRA has actively enhanced the outreach to recruit new professionals. These efforts include participation at job and university fairs, organizing initiatives like a nuclear regulation summer school, and introducing paid internships in addition to the existing unpaid governmental internships. These steps reflect a proactive approach to fostering interest among future young professionals.

While there is sufficient competence to regulate existing nuclear facilities and activities, the increasing workload and upcoming demands (number of sources of ionizing radiation and planned new builds) underscore the urgency of expanding capacity and ensuring sufficient staffing. BNRA should plan for and continue with its efforts and explore new practical approaches to fill existing and future vacancies, particularly in view of the high number of employees in retirement and pre-retirement age, to ensure there is sufficient competent staff with a special attention to the core regulatory functions. The managers of companies visited by the IRRS team expressed their concerns about the fact that many BNRA inspectors are approaching retirement and that they do not see any new inspectors arriving. A detailed plan and strategy to recruit and train a significant number of employees should be in place to cater for an increase in staff numbers in relation to the expansion of the nuclear power programme. This entails a review and an update of the Strategy for Building Professional Capacity in BNRA 2023 - 2032 in order to strengthen the efforts to attract new employees, including young professionals. This issue was identified in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA does not have a sustainable long-term human resources development plan.*	
(1)	**BASIS: GSR part 1 (Rev. 1), Requirement 18, para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(2)	**BASIS: GSR part 1 (Rev. 1), Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
R5	**Recommendation: BNRA should plan for and continue its efforts to fill current and future vacancies and update the "Strategy for Building Professional Capacity in BNRA 2023 - 2032".**

The IRRS team was informed that the number of employees responsible for supervision in the radiation protection area (medical, occupational and public exposure) at MoH has remained the same over the last decades while the number of supervised activities has increased significantly (e.g. the number of sources of ionising radiation has approximately tripled over this period). Financial and human resources should reflect the increasing workload in the area of radiation protection to ensure effective oversight.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The number of employees at MoH responsible for the supervision in the radiation protection area has remained the same over the last decades while the number of supervised activities has increased significantly.*	
(1)	**BASIS: GSR part 1 (Rev. 1.), Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
R6	**Recommendation: MoH should ensure that there are sufficient human resources available in line with increasing workload in the area of radiation protection.**

In 2024, BNRA intensified its efforts to develop a comprehensive knowledge management system, including the creation of a dedicated knowledge management portal to capture and preserve institutional knowledge. These steps were underpinned by the adoption of a knowledge management policy by the chairperson. BNRA has also made progress in developing a comprehensive knowledge management system, including a knowledge management portal and a draft Procedure for Knowledge Management, which is expected to be finalised by the end of 2024. The procedure will address risks related to the loss of critical knowledge due to staff turnover or retirement and will include a succession strategy based on competency mapping and entails detailing professional competencies (knowledge, skills and attitudes) according to the relevant position, following the SARCoN methodology and the IAEA four quadrant model of competencies. However, the prepared draft is yet to be finalised, adopted and implemented. Until this procedure is finalised and implemented, there remains a gap in ensuring the continuity of institutional knowledge. Finalising, adopting, and implementing the Procedure for Knowledge Management should be prioritised, with an emphasis on the competence management elements so as to ensure the regulatory functions are performed in an efficient manner also in the future. The issue was identified by BNRA as part of its self-assessment and included in the action plan submitted as advance reference material for the mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no comprehensive procedure for knowledge management reflecting the risk of loss of critical knowledge due to retirement and turnover.*	
(1)	**BASIS: GSR part 1 (Rev. 1.), Requirement 18, para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management."*
(2)	**BASIS: GSG 12, para. 6.15 states that** *"The regulatory body should, through its competence management, ensure that its organisation is sufficiently robust and flexible to deal with staff departures, retirements or other events, including unexpected staff changes. Succession planning should be included as part of competence management."*
R7	**Recommendation: BNRA should finalise and implement a comprehensive Procedure for Knowledge Management with emphasis on the implementation of key aspects of the competency management process.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

BNRA does not have its own technical support organization (TSO) for use in the review process. As the internal staff cannot cover all required technical competencies, TSOs are contracted to perform independent reviews and/or verification analyses on specific issues. BNRA seeks both national and international TSO support.

The assessment of technical support outputs and the final decision (regarding expert opinion) belongs to the regulatory authority. The results of the TSO assessments (presented in technical reports) are taken into account in the final decision. After review by the responsible BNRA expert, they are included in the final expert position (expert statement/opinion that is a basis for the Chairperson's final decision). In this sense, BNRA's final position contains two integral parts - the results of BNRA's internal review and the accepted results of external expert support.

In addition, to assist the Chairperson in the decision-making, two permanent advisory bodies are established – the Advisory Council on Nuclear Safety and the Advisory Council on Radiation Protection. BNRA may also seek advice from other governmental bodies. In these cases, the practice is to form intergovernmental working groups involving relevant experts.

When areas requiring external expert support are identified in the review and assessment process, BNRA develops technical specifications and procures them in accordance with the Public Procurement Act and the internal Procurement Instruction. A contract is concluded with a TSO organization that has demonstrated appropriate competences and has no conflict of interest. A committee oversees supplier selection, assessing qualifications, other indicators, and potential conflicts of interest using a standardized format. Further details are stipulated in the TSO contracts. BNRA relies on these generic rules applicable to all public procurement processes. However, a detailed mechanism for evaluating the outcomes of TSO support is lacking and could be enhanced. The areas in which BNRA needs external expertise are defined within the process of review and assessment of the design and operational documentation.

As a part of competence management, regular analysis of the possibility of future gaps is essential as well as measures that would place sufficient emphasis on retaining key expert technical knowledge (and ability to be an intelligent customer). This would ensure external expert support is effectively integrated into the decision-making process and that BNRA maintains its role as an "intelligent customer" being able to determine whether it is appropriate to seek assistance from an external expert support organization, to manage and supervise the external expert support and to understand, evaluate and use any relevant advice from external organizations or experts. This issue is further addressed in Suggestion **S12** in Chapter 6.2.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORISED PARTIES

BNRA maintains a professional liaison with authorised parties through both formal and informal mechanisms. The primary methods of communication include official correspondence and inspections. Another key feature of this relationship are meetings, organised either by BNRA or at the request of authorised parties and mainly serve to clarify regulatory requirements. Outcomes of these meetings, including decisions and positions, are documented in formal records, which serve as references in subsequent communications.

BNRA's Deputy Chairperson receives daily briefings from the Kozloduy NPP Safety Manager regarding the status of safety-critical systems, as mandated by the operating licence. Additionally, daily conference calls with on-site inspectors provide updates to BNRA's management, enabling timely clarification of issues and requests for further information when necessary. Open formal and informal (at a working level) dialogue with licensees to address safety-related issues effectively is in place.

Regulatory decisions are justified and transparently communicated. Before the decisions are taken, the applicant is provided; through less formal engagement at the working level, throughout ongoing

administrative procedure – with the expert basis for the Chairperson's final decision (BNRA expert opinion). Should additional information be required, the applicant is formally invited to provide it within a certain deadline. In accordance with the legislation, decisions to grant or deny authorizations must be supported by clear grounds. Positive decisions specify the reasons for granting authorization (fulfilment of requirements), while refusals include more detailed explanations for the negative decision. This approach ensures that authorised parties understand the rationale behind each regulatory decision and can address any concerns effectively. Additionally, BNRA uses its website and letters to provide further guidance in specific areas of safety and radiation protection issues.

While BNRA has well-established mechanisms to ensure ongoing communication and provide clarity in decision-making, certain aspects could be improved. This includes the possibility of sending the applicant's view to the Chairperson to ensure that specific technical concerns raised are assessed by a regulatory body with sufficient expertise.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Stability and consistency of regulatory control are ensured through a legal framework, internal rules, and formalised processes. Regulatory activities are conducted in accordance with the legislative requirements in the field of public administration and detailed through the IMS. This framework provides policies, principles and procedures that guide decision-making, inspections, licensing, and enforcement ensuring objectivity, transparency, and consistency in all regulatory actions.

Regulatory requirements and decisions are informed by safety priorities, as emphasised in the policy statement and the ASUNE. Key processes within the IMS include licensing, inspections, emergency preparedness, and stakeholder communication, among others. The allocation of responsibilities, adherence to detailed internal procedures, and the collective involvement of experts in decision-making, prevent subjectivity and ensure impartiality. All BNRA's employees are, as civil servants, bound by the principles of lawfulness, accountability, and continuous quality improvement, are selected through formal competitive procedures, further reinforcing objectivity and the credibility of regulatory decisions.

The basis for the Chairperson's decisions is a collectively prepared document; an expert statement/opinion. In the event of disagreement by some of the stakeholders involved in the process, a dissenting opinion may be added to the signature of the predefined persons involved in the assessment and preparation of this expert opinion to ensure objectivity. In matters of more fundamental importance, the Chairperson can also request the opinion of the two permanent advisory councils, which can provide unbiased advice on scientific aspects of nuclear safety and radiation protection.

BNRA is empowered to develop new regulatory requirements or amend existing ones, alone or in collaboration with representatives of other government bodies. The Chairperson prepares and submits to the Council of Ministers regulations and their amendments. Stakeholders are consulted on new or amended regulations through public consultations, where all interested parties may participate and with an impact assessment, ensure that proposed modifications are well-justified and meaningful.

3.7. SAFETY RELATED RECORDS

BNRA ensures the establishment, maintenance, and utilisation of safety-related records in compliance with the legislative requirements, and maintains comprehensive public registers, including authorizations, and oversees specific records required for safety. This includes the National Register of Sources of Ionising Radiation. Specific obligations for the authorised parties are in place for accounting and control of high activity sources in the Regulation for Radiation Protection. MoH maintains the register of radiation workers for the purpose of monitoring doses from occupational exposure, archived for decades, ensuring long-term traceability.

While BNRA maintains safety related records to support its regulatory functions, authorised parties bear the primary responsibility for maintaining their own records.

The legal framework establishes requirements on record-keeping and submission requirements for authorised parties. They are obligated to maintain records necessary for safe operations, including dosimetric data and safety documentation. These records, such as operational data, safety system statuses, and facility conditions, are routinely reviewed by on-site inspectors and analysed by BNRA to enable adequate regulatory oversight. Any incoming or outgoing correspondence and related regulatory actions, statements, decisions, etc. are documented and recorded in the BNRA document system. This includes information which BNRA receives from the Kozloduy NPP site. The report contains information such as operating data, status of structures, systems and components and deviations by days and weeks. Additionally, BNRA has access to real-time monitoring of critical parameters at its Emergency Centre. Licensees must also document all decommissioning-related activities as per specific regulations.

Access to authorised parties' records is a key part of BNRA's regulatory oversight. Inspectors are granted full access to information and use these records for incident investigations and operational assessments. BNRA inspectors have the right to unimpeded access to the licensees and facilities and may require any data, facts, explanations and other information, including measurements and tests, as shall be necessary to clarify the technical status and the operating conditions of the facility, including personnel competence, as well as disclosure of any other information associated with ensuring nuclear safety and radiation protection.

Records relating to deviations, incidents, and accidents are managed in a systematic manner. Licensees are also obliged to report events, including non-routine radioactive releases, in a structured format, enabling thorough analysis and follow-up corrective actions.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

BNRA prioritises transparency in its communication and consultation efforts to foster trust in nuclear safety and radiation protection. Its established policies and frameworks ensure a broad engagement with the public and other stakeholders, reflecting the principles of independence, justification, and open dialogue. BNRA's Integrated Management System includes the core process Communication and Consultations with the Stakeholders, which guides the provision of information to the stakeholders.

The Communication Policy of BNRA identifies key stakeholders such as the public, state institutions, NGOs, media, educational institutions, licensees, and international organizations. BNRA's website serves as a main communication channel, providing reliable and regularly updated information on nuclear safety, regulations, operational decisions, and radiation risks. This includes drafts of regulations and guides for public review and enhancing stakeholder participation. Important decisions related to the issuance of new or amendments of existing licences and their summary are published on the Agency's website. Social media platforms like Facebook and LinkedIn supplement this effort, presenting updates with engaging visuals to achieve broader outreach.

The regulatory body's proactive voluntary organization of dedicated sessions for press representatives constitutes an area of good performance. This demonstrates that BNRA recognises the importance of addressing misconceptions and general gaps in understanding that often surround these complex subjects. It ensures that media professionals are equipped with accurate knowledge about the risks and realities of nuclear power and radiation. Such initiatives are crucial for cultivating a media environment capable of presenting balanced, informed perspectives and provide an invaluable platform for building relationships with the press and establishing a foundation for effective crisis communication.

Public consultations and meetings are organised as part of the Environmental Impact Assessment (EIA) processes, particularly for new nuclear projects. These consultations actively involve local and regional stakeholders, including neighbouring countries, to discuss radiation risks and gather input on regulatory decisions. Representatives of BNRA take part in these public hearings and meetings organised by the

municipal authorities from the vicinity of nuclear facilities. Results from these discussions are transparently incorporated into decision-making, fostering confidence in the process. The public is thus given the opportunity to comment on nuclear safety and radiation protection related issues throughout the licensing process for new nuclear installations, but not necessarily directly through BNRA's administrative procedures.

Annual press conferences allow BNRA to highlight yearly activities and significant developments and provide media representatives (public) with further information on safety related aspects. This is complemented through the publication of an Annual Report, which is accessible online. Recognising the critical role of media in public awareness, BNRA recently started to provide ad-hoc sessions with journalists, which shall enhance their understanding of nuclear safety and radiation protection. These sessions aim to equip media personnel with the necessary context to report responsibly and accurately, particularly during emergencies.

3.9. SUMMARY

The IRRS team concluded that Bulgaria's regulatory framework is robust and stable. The regulatory body operates independently with a defined budget and competent, experienced staff. The regulatory framework is stable, oversight is consistent and safety-related records are well maintained. BNRA maintains active and transparent liaison with stakeholders, including authorised parties and the public, ensuring effective communication and stakeholder engagement in regulatory processes.

The coordination mechanism between BNRA and MoH needs further improvement, because it lacks sufficient detail regarding mutual cooperation in radiation protection creating potential risks of gaps, overlaps, or conflicting requirements.

Budgetary provisions support BNRA's activities, and systematic training is conducted for staff. However, remuneration levels remain insufficient to attract and retain qualified personnel, particularly given the increasing workload. A recent salary increase is a positive step, but competitive remuneration must be sustained in the long-term to mitigate staffing challenges. Ongoing vacancies, increasing workload and planned expansion of the nuclear programme necessitates proactive recruitment, training, and knowledge preservation to meet future regulatory demands effectively.

Knowledge management practices are in place, and staff are trained systematically. However, a comprehensive knowledge management system addressing the risks of knowledge loss due to staff turnover or retirement has yet to be finalised.

Capacity Building and Sustainability

BNRA is facing challenges related with the human resources capacity and availability. The average age of the existing personnel is increasing, with most of the key staff approaching retirement age. At the same time, the pool of experts in the nuclear field is limited, and the number of students enrolling in relevant technical disciplines is declining. Due to uncompetitive financial benefits offers by BNRA, some BNRA staff left the organization and recruiting new talent has been challenging.

To address these issues, BNRA developed the "Strategy for Building Professional Capacity in the BNRA 2023 – 2032", including recruitment programmes, HR planning, enhancement of qualifications, increase of staff salaries, etc.

During the policy discussion, experts shared their country's experience in addressing the challenges. A summary of successful actions taken by regulatory bodies is provided below:

- Recognition of regulatory body with special status in the government to secure incentive to regulatory staff;
- Initiation of public communication programmes to better explain the work and contributions of the regulatory body in ensuring nuclear and radiation safety;

- Using international peer reviews and other insights as part of communication with the governments. Additionally, raising issues with the media and within the government to secure more resources;
- Promoting safety culture within the organization and making it part of the regular training and re-training;
- Conducting outreach programmes to engage young people, targeting students in schools and universities with special emphasis to encourage females to study Science Technology Engineering and Mathematics (STEM) subjects. The outreach programmes may begin at the kindergarten level, with appropriate training materials developed to suit this audience;
- Establishing organizational alumni programmes to benefit from experienced retired staff, as mentors for young professionals;
- Directly hiring university graduates and offering master's degree programmes at the cost of the regulatory body;
- Introducing a flexible working environment to allow staff to work from home in agreement with the supervisor;
- Introducing artificial intelligence (AI) and digitizing records to facilitate knowledge management and transfer, and
- Making regulatory careers more appealing by offering competitive salaries and benefits, such as participation in international activities, engagement with new technologies (i.e. SMR), housing and medical subsidies.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. RESPONSIBILITY

BNRA management is responsible for ensuring the development, implementation, evaluation, and continuous improvement of the Integrated Management System (IMS). The BNRA Management Policy Statement clearly indicates a commitment to continuous improvement of the integrated management system, with the goals of ensuring that safety remains a priority, and developing an effective safety culture. Key elements of the IMS include defined organizational policies and goals, necessary resources, and an appropriate organizational structure.

The Executive Secretary is the management representative responsible for coordinating IMS development, overseeing audits, updating IMS documentation, and reporting the IMS status to the BNRA Chairperson. The BNRA Chairperson assigns a working group to support the management representative. BNRA Directors are accountable for implementing IMS requirements, documenting related processes and activities, and ensuring that their teams effectively achieve the objectives.

BNRA defined the organization's strategic objectives within a three-year Strategic plan (QMS-MO-P-05/5) in consideration of the mission to protect human, society, future generations and the environment from the hazards arising from exposure to ionising radiation. BNRA establishes annual activity targets, aligned with the strategic plan, to achieve the defined goals for the period. BNRA Directors oversee the implementation of the plans which include specific activities and tasks. The Directors assess whether a revision is required every year, usually at mid-year. At the end of the year, the executive secretary consolidates inputs from implementation reports on the various plans and prepares a comprehensive report on BNRA's annual performance.

The IRRS Team observed that BNRA has developed a set of policies including a Management Policy Statement, a knowledge management policy, and a communication policy, among others. While the Management Policy Statement contains several elements promoting safety and a culture of safety, BNRA has not developed a dedicated safety policy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA has not established a dedicated safety policy within its integrated management system.*	
(1)	**BASIS: GSR Part 2, Requirement 3, para. 4.2 states that** *"Senior management shall be responsible for establishing safety policy"*
R8	**Recommendation: BNRA should establish a safety policy as part of its integrated management system.**

The IRRS Team observed that the Management Policy Statement does not include statements on health, environmental, security, quality and economic considerations nor provide an appropriate framework for action, establishing and reviewing goals, setting objectives, and reflecting management commitment to providing adequate financial, material and human resources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA's Management Policy Statement does not include key elements, such as health, environmental, security, quality, etc.*	
(1)	**BASIS: GS- G- 3.1, para. 3.11 states that** *"The policies:* • *should contain statements on safety, health, environmental, security, quality, and economic considerations;* • *Should provide an appropriate framework for action and for establishing and reviewing goals and objectives;* *Should commit management to providing adequate financial, material and human resources."*
S5	**Suggestion: BNRA should consider improving its Management Policy Statement to be in line with IAEA Safety guides**.

4.2. THE MANAGEMENT SYSTEM

BNRA implements an integrated management system based on the requirements of the IAEA safety standards GSR Part 1 (Rev. 1), GSR Part 2, and ISO 9001:2015. The BNRA management system is developed and implemented using a graded approach.

The BNRA management system integrates all interrelated elements of the organization, such as structure, resources, processes and practices, and organizational culture, that facilitate the implementation of policies, achievement of goals, and attainment of effective performance of BNRA's regulatory functions.

The BNRA IMS Manual describes the management system, management responsibilities, resource management, measurement, evaluation, improvement, interaction with interested parties, and processes. However, the manual does not explicitly state that the information security management system is part of the integrated management system. This issue was identified in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA's IMS manual does not include the Information Security Management System.*	
(1)	**BASIS: GSR Part 2, Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organisational-factor, societal and economic elements, so that safety is not compromised."*
S6	**Suggestion: BNRA should consider updating the Integrated Management System manual to include the Information Security Management System.**

The BNRA management system is categorised into three levels. The first level of documents are strategic documents that include the policy statement, management system manual, strategic plans, and orders defining the functions and staffing of administrative units. The second level of documents are procedures, instructions, guides, plans, and lists that detail the execution of processes, clarify responsibilities and communication methods, and offer guidance for administrative tasks. The third level of documents are records that represent the outcome of process executions.

The IMS Manual, job descriptions, and other documents, outline the responsibilities and authority related to the Integrated Management System processes and activities, including, control implementation and decision-making. The BNRA Chairperson is responsible for all regulatory decisions and delegates the authority for making regulatory decisions to the Deputy Chairperson(s). Draft decisions undergo several levels of consultation and verification, including reviews by legal experts. If necessary, BNRA may consult with external experts.

BNRA management system documentation is controlled in accordance with the document control procedure (QMS-AS-P-02), which outlines the steps for developing, verifying, coordinating, approving, and distributing internal documents, as well as the format, structure, content, and identification of these documents. All BNRA internal documents are published on the internal directory and the intranet, which ensures that all employees have access to the management system documents.

BNRA documents are archived in accordance with the Instruction on the Organization of Work (QMS-AS-I-04/1), in the Institutional Archive. Additionally, documents created in electronic format are stored on the BNRA server, which has successfully undergone a certification process for compliance with ISO/IEC 27001.

BNRA implements a records retention schedule in accordance with the Regulation on the Organization, Processing, Expertise, Storage, and Use of Documents in the Institutional Archives of State and Municipal Institutions. This schedule also complies with other regulatory documents related to the agency's activities, including the Accountancy Act, Public Procurement Act, and Access to Public Information Act.

Although the IMS manual provides some provision for change management, BNRA does not have a comprehensive, documented process for managing changes that could have significant safety implications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA does not have a documented process for managing organizational changes that could have significant implications for safety.*	
(1)	**BASIS: GSG-12 para. 4.60 states that** *"The need for changes may arise unexpectedly, and the regulatory body should put a process in place for managing organizational changes. This process should be established in the very early stages of the establishment of the regulatory body since changes often take place during the initial growth of a regulatory body."*
(2)	**BASIS: GSG-12 Appendix II, II.24. states that** *"The regulatory body should put in place a process for managing organisational change for changes made in response to external or internal initiatives. The process should ensure that the potential impact of proposed changes on the effectiveness of the regulatory body is systematically assessed. Changes should not be implemented without adequate review and should be modified (e.g. by means of compensatory measures) if they impact negatively on the effectiveness with which the regulatory body discharges its mandate".*
S7	**Suggestion: BNRA should consider documenting the process for managing organizational changes.**

4.3. MANAGEMENT OF PROCESSES AND ACTIVITIES

BNRA processes are defined and documented in the IMS Manual. The IMS processes outline responsible individuals, purpose, scope, and performance evaluation indicators in Appendix 2. The IMS processes are executed under controlled conditions, as described in associated procedures and instructions. IMS processes are organised into three groups, i.e., management, core and support processes.

Management processes include policy, strategy, planning, risk management, assessment of the functioning of the IMS, and improvement.

Core processes include control of the safety of nuclear facilities; control of the safety SIR activities; control of the specialized training and the issuing of certificates of competency; development of regulations and guides, emergency preparedness process, application of safeguards, stakeholder communication, and consultation.

Support processes include financial management and control, professional capacity management, management of products and services from external suppliers, records management, archive, infrastructure management, and international cooperation.

The hierarchy, sequence, and interaction of the processes are defined in Appendix 1 of the IMS manual. However, the sequencing and interactions require further clarification.

The IRRS Team observed that the process descriptions do not include some elements, such as, the input data (documents and information) that initiates the process, and the interfaces between processes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA process descriptions do not include the input data (documents, information) that initiate the processes as well as the interfaces with other processes.*	
(1)	**BASIS: GSG-12, para. 5.66 states that** *"For each process, the following should be identified and documented:* • *The interfaces with other processes, to explain how the process fits into the integrated management system and its significance for the regulatory activity;* • *……* *The inputs to the process, including the necessary information, in accordance with an evidence-based approach to regulation…."*
S8	**Suggestion: BNRA should consider improving its processes descriptions in line with IAEA Safety Guides**.

BNRA delegates activities such as technical services and maintenance, safety assessments and analyses, expertise, equipment calibration, guides development, consulting, and other safety-related services to external contractors. The preparation, signing, and execution of contracts with these service providers adhere to the Public Procurement Act and relevant Bulgarian legislation. To ensure effective planning, execution, completion, and reporting of contracts and to promote the legal and efficient use of public funds, the Instruction for Public Procurement Cycle Management (QMS-FA-I-07) and the Audit Pathways Instruction (QMS-FA-I-01) have been approved and implemented.

The IRRS team observed that the BNRA management system does not include arrangements to retain the responsibility for safety when contracting out processes. The IRRS team acknowledges that BNRA plans to update the procurement procedure to include this provision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA's IMS does not include provisions to retain responsibility for safety when contracting out any process.*	
(1)	**BASIS: GSR Part 2 Requirement 11, para 4.33 states that** *"The organisation shall retain responsibility for safety when contracting out any processes and when receiving any item, product or service in the supply chain"*
R9	**Recommendation: BNRA should include in its Integrated Management System, requirements to retain responsibility for safety when contracting out any process.**

4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The IMS manual includes a clause on measurement, evaluation, and improvement. The effectiveness of the IMS is monitored and measured to assess how well the processes meet established goals and to identify opportunities for improvement.

BNRA performs internal audits and self-assessments to identify non-conformities, and implements corrective actions, as necessary. However, the IRRS team notes that there is no guidance provided to ensure that the results of self-assessments contribute to continuous improvement such as, guidance on the timing and format of the self-assessment.

Self-assessments are conducted on various aspects of BNRA activities, including administrative services, financial management and control, internal audit activities, achievement of operational goals, anti-corruption measures, nuclear safety and radiation protection performance, media relations, international inspections, and stakeholder feedback. The instructions for the management of non-conformities and corrective actions are outlined in the procedure, QMS-MO-P-09, but there have been no instances where the use of the procedure was required.

The internal audits of the IMS are assigned by order of the BNRA Chairperson. Audits are conducted according to an annual programme which is developed based on a risk assessment and previous audit results. An action plan is prepared to implement the recommendations of the internal audit, which includes corrective actions, deadlines and responsibilities. Internal audit of all organizational units and activities of BNRA are aimed at providing confidence in the adequacy and effectiveness of risk management, control and governance processes.

These audits are carried out by the Internal Audit Unit, which is directly subordinate to the BNRA Chairperson. The employees are trained as internal management system auditors. The IRRS team notes that the Head of the Internal Audit Unit and the internal auditor are certified as internal auditors in the public sector. Employees do not audit their own processes and activities which maintains objectivity.

The IRRS Team observed that senior management does not conduct an annual review of the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA does not periodically review its Integrated Management System.*	
(1)	**BASIS: GSR Part 2 Requirement 13, para. 6.6 states that** *"Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organisation to be accomplished, with account taken of new requirements and changes in the organisation."*
(2)	**BASIS: GSG-12 para. 5.48 states that** *"The integrated management system review should cover all significant sources of information on performance, including the following:* • *Outputs from different forms of assessment, including self-assessments of senior management itself;* • *Results delivered and objectives achieved by the regulatory body and its processes and activities;* • *Non-conformances and the progress and effectiveness of corrective and preventive actions;* • *Feedback from operating experience, including lessons learned and good practices from other organisations;* • *Opportunities for improvement."*
R10	**Recommendation: BNRA should conduct a management review periodically.**

4.5. LEADERSHIP AND CULTURE FOR SAFETY

The BNRA mission is to ensure the protection of human, society, future generations, and the environment from the harmful effects of ionising radiation, as established in the ASUNE. To fulfil this mission, BNRA management is committed to the Policy Statement that states that nuclear safety and radiation protection in the use of nuclear energy and ionising radiation sources take priority over all other aspects. It also contains a clear commitment to prioritising safety and supporting the development of a safety culture, openness, and transparency.

In line with the BNRA mission, senior management developed and issued a Strategic Plan, which identifies the Agency's primary priorities and strategic objectives for the period from 2024 to 2026. The strategic objectives are further broken down into annual activity targets to achieve the defined goals over the period. Direct supervisors develop employee work plans that are aligned with the annual targets. The IMS integrates all interrelated elements of the organization, enabling it to pursue its policy and achieve BNRA's goals effectively and efficiently.

BNRA senior management also works to enhance direct communication with employees by organizing meetings within organizational departments and with all staff. Employees also have the option to meet with senior managers individually. Additionally, an anonymous comment and suggestion box enables employees to raise concerns or offer suggestions.

As per the IMS procedure, QMS-MO-P-09, employees may identify non-conformances, propose improvement measures, and provide feedback on any corrective actions taken. Open communication between employees and supervisors facilitates the prompt resolution of issues regarding technical, human, or organizational factors.

The IRRS team observed that there was no clear Safety Culture improvement programme including, the conduct of safety culture self-assessments (SCSA) with a clearly defined methodology, scope, and frequency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA does not conduct self and independent assessments of leadership for safety and of safety culture.*	
(1)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organisation."*
(2)	**BASIS: GSR Part 2 Requirement 13 para. 6.4 states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety."*
R11	**Recommendation: BNRA should conduct self and independent assessments of leadership for safety and safety culture throughout the organization.**

4.6. SUMMARY

BNRA management is responsible for the IMS and ensures its development, implementation, evaluation, and continuous improvement. BNRA implements an IMS using a graded approach and based on the requirements of the IAEA safety standards.

The IRRS team noted that there are some areas for improvement including establishing a dedicated safety policy within the management system and including an Information Security Management System and a process for managing organizational changes in the IMS manual.

BNRA processes are defined and documented in the IMS Manual however, further improvements should be made to include provisions to retain the responsibility for safety when contracting out processes.

BNRA should conduct periodic reviews of its IMS and establish a clear Safety Culture improvement programme which includes a specific programme for conducting safety culture self-assessments.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Legal provisions for the authorization of the safe use of nuclear energy and ionising radiation along with safety of radioactive waste management and spent fuel management are established in the ASUNE. This Act specifies all activities requiring notification, licensing, permit or registration and empowers BNRA to issue, amend, supplement, renew, suspend and revoke licences, permits, or certificates. All nuclear facilities and any practice with sources of ionising radiation can only be carried out after obtaining relevant authorization from BNRA. BNRA is the only regulatory body to issue an authorization which meets the requirements of para 2.12 of GSR Part 1 (Rev. 1).

The Act also outlines the roles and powers of various state bodies involved in nuclear energy and ionising radiation. Importantly, it prohibits these bodies from exercising regulatory functions related to nuclear safety and radiation protection if they are involved in financing or supporting the implementation of nuclear and radiation activities. The regulations related to nuclear safety and radiation protection are adopted by the Council of Ministers on the recommendation of the Chairperson of BNRA and the relevant authorities.

The Act enables regulations that outline the authorization process, submission requirements, validity period, and renewal, exemption, and clearance criteria. Specific regulations have also been promulgated that establish detailed requirements for nuclear power plants, sources of ionising radiation, radioactive waste management, decommissioning, emergency preparedness, physical protection, qualification, research reactors, and safeguards, etc.

Pursuant to Articles 37a, 37b and 37c of the ASUNE, licensees with lifetime licences are obliged to carry out a periodic safety review (PSR) of the nuclear facility at least once every 10 years. The Chairperson of BNRA could issue an order determining the deadline for submission of next Periodic Safety Review results, which shall not exceed the time limit of 10 years. The scope and requirements for conducting such periodic safety reviews are specified in the Regulation on Ensuring the Safety of Nuclear Power Plants (RESNPP). Licensees with time-limited licences must perform the periodic safety review and submit the results as part of the process for extending the licence term.

In accordance with the RESNPP, the operating organization carries out a comprehensive periodic review of all aspects of safety for the nuclear power plants, to assess its compliance with the licensing basis, current safety requirements and standards, and internationally recognised best practices.

BNRA has various management system procedures for effective implementation of the regulations. These procedures describe the policy and principles for the authorization process, responsibilities of individuals and organizational units in the authorization process, details of the process flow, documents generated during the authorization process, as well as retention of records.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

There is a statutory obligation under the ASUNE that requires the approval of the Council of Ministers' for building nuclear power plants in the country. For this purpose, the proposal must be submitted by the Minister of Energy. The Minister of Energy organises a hearing of the proposal in which state bodies and local self-government bodies, representatives of public organizations and interested physical and legal entities can participate. The notification is carried out through the mass media or through other suitable means at least one month before the hearing. Various assessment reports such as environmental impact, social & economic significance, radioactive waste & spent nuclear fuel management, and assessment of the hearing results are required to be submitted with the proposal for building NPPs in the country.

The ASUNE also establishes general requirements for individuals eligible for licensing, including the necessity of having adequately qualified and certified personnel with appropriate education and training for

all licensed activities. The certificates of competence are issued by the Chairperson of BNRA to individuals involved in ensuring or controlling nuclear safety and radiation protection, as well as to instructors of full-scope simulators and qualified radiation protection experts. Additionally, certificates may also be issued by licensed trainers for specialised training in nuclear facilities and radiation sources. Licences for specialised training, as well as certificates of competency, are issued, amended, terminated, or withdrawn in accordance with the regulations.

The participation of the public in the regulatory decision-making process for the authorization of nuclear facilities is well defined. As part of the process of issuing a licence, BNRA publishes a summary on its webpage that includes a comprehensive description of the documents submitted by the relevant applicant. Any person can make proposals in writing regarding the summary. All proposals are reviewed and discussed during the process of review and assessment of the authorization application. If the proposals need additional clarification, meetings are organised with the persons who made the proposals.

The authorization encompasses all stages of the facility's lifecycle including site-selection permit, design permit, construction permit, commissioning permit, licence for operation and licence for decommissioning. Modifications of SSCs important to safety, limits and conditions for operation and decommissioning as well as amendments in instructions, programmes, technical specifications, and other documents are implemented only after issuance of relevant permits. There are different types of authorization which are issued for the various stages in the lifetime of a facility or the duration of an activity. For a facility, the stages in the lifetime include site evaluation, design, construction, commissioning, operation, shutdown, and decommissioning. This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas which satisfies the intent of section 4.29 of GSR Part 1 (Rev. 1).

The regulatory framework established by BNRA defines requirements for various documentation that must be submitted to obtain various authorizations during various stages of the licensing process of the nuclear facility. The regulatory framework also specifies the deadlines for the Chairperson of BNRA to respond to submitted applications and empowers him to set timelines for applicants and licensees to address any non-compliances or deficiencies in their application and associated documents. The regulatory framework also empowers BNRA to make amendments in authorizations already issued to applicants and licensees on their request. The licensee or the permit holder is required to formally request the Chairperson of BNRA to document the circumstances that necessitate an amendment to their licence or permit. If the licensee does not request an amendment of the licence or permit within the stipulated timeframe, the Chairperson notifies the licensee in writing which indicates that section 4.39 of GSR Part 1 (Rev. 1) is satisfied. If the licence or the permit holder does not request the relevant amendment within 14 days of receiving this notification, the Chairperson may proceed to amend the licence or permit ex officio.

BNRA has developed various regulatory guides for its licensees that provide sufficient guidance on implementing the requirements defined in various regulations. Furthermore, procedures are also established that provide sufficient guidance to employees regarding issuance of licences and permits, renewal, termination and withdrawal as well as the implementation of control on fulfilling regulatory requirements. However, the IRRS team observed that some guideline documents for format and contents of regulatory licensing submissions were not in place.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA has not comprehensively developed guidelines addressing the format and content of licensing submissions for nuclear power plants.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 24, para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
(2)	**BASIS: SSG 12, Section 2, para. 2.18 states that** *"The documents submitted to the regulatory body in the framework of the licensing process should be updated, as appropriate, during the lifetime of the nuclear installation. These documents should be incorporated as part of the licence, if necessary; the content of such submissions to the regulatory body may be divided or combined into different documents, as appropriate, depending on national regulations, regulatory regimes and practices."*
S9	**Suggestion: BNRA should consider issuing guideline documents for all licensing submissions so that applicants may be able to submit relevant details in their submissions.**

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

According to the ASUNE, spent fuel storage installations are nuclear facilities, so the authorization approach is the same as for nuclear power plants. The general requirements, criteria, processes, and arrangements for authorization of fuel cycle facilities are the same as those described in section 5.1 and 5.2.

The Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy defines the requirements for documents to be submitted to BNRA along with the permit or licence application for all stages of the facility's lifecycle. The stages include siting, design, construction, commissioning, operation, and decommissioning.

BNRA has issued the Procedure for Issuing Licences and Permits for Activities in Nuclear Facilities (QMS-LA-P-01). The purpose of this procedure is to describe the licensing process which includes the policy and principles of BNRA for the authorization process, responsibilities of individuals and organizational units, details of the process flow, documents generated during the authorization process, as well as retention documents.

The storage of spent fuel takes place at the KNPP in two different nuclear facilities, an interim pool spent fuel storage facility and a dry spent fuel storage facility. The licence holder for the two storage facilities is the KNPP.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Radioactive waste management facilities are authorised by BNRA under the ASUNE. The authorization procedure for radioactive waste management facilities, including disposal facilities, follows the BNRA process applicable for all nuclear facilities as described in Section 5.1 and 5.2.

The Regulation on the Procedure for Issuing Licences and Permits (RPILPSUNE) lists the information and the documents that should be submitted for permit or licence applications for all stages of the facility's lifecycle, including siting, design, construction, commissioning, operation, and decommissioning/closure.

The requirements for each stage of the licensing process are addressed in the RPILPSUNE, including the specifics for the closure phase of a disposal facility as well as for the approval of a site for construction of a RAW facility. The operation licence is issued for a maximum term of 10 years. For the renewal of the operation licence, a safety assessment report based on a periodic safety review (PSR) is required.

The specific process related to siting is defined in the Regulation on Safe Management of Radioactive Waste (RSMRW), including the scope and the conditions of the siting process. The Regulatory Guide on Structure and Content of a Safety Analysis Report of a Centralized Facility for Storage of Low and Intermediate Level Waste includes details relevant to this specific safety analysis report.

The predisposal management of VLLW and short-lived LILW takes place at the KNPP by the State Enterprise Radioactive Waste (SE RAW) under their nuclear facilities operation licences. The RAW from the nuclear applications in Bulgaria (institutional waste, mainly DSRS) are stored in the centralized RAW storage facility, Novi Han, operated by the SE RAW. The National RAW Disposal Facility for short-lived LILW is at the end of its construction stage.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

There is a statutory obligation under the ASUNE that any activities involving the use of radiation sources in Bulgaria shall be justified and performed after submitting a notification to or obtaining a certificate of registration, a permit or a licence from BNRA. The Act clearly specifies all activities that require an authorization and the related requirements.

The documents that an applicant shall submit to BNRA for an authorization are determined in the ASUNE and the Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy (RPILPSUNE). Application forms for notification and the different authorization types, as well as instructions on the type and the content of the documents to be submitted are provided on the BRNA website.

The application for a permit for the construction, assembly, and preliminary testing of a facility with radiation sources shall be accompanied by a report from MoH confirming that the proposed site complies with the health protection regulatory requirements. For medical facilities, a confirmation of compliance with health protection regulations shall also be submitted. A formalized process for information exchange between BNRA and MoH is in place. For the authorization of facilities with sealed radioactive sources a confirmation of compliance from MoI regarding physical protection is also required.

Currently 1,268 licences for facilities and activities with radiation sources are active. More specifically: 1,048 for medical and veterinary applications, 96 for industrial applications, 12 for scientific applications, 32 for control applications, 34 for transport of radioactive sources, 44 for services and 2 for the production of radiation sources. Moreover, 274 permits were issued for the construction, installation, and preliminary testing of sites with radiation sources and temporary storage of radioactive substances, along with 84 registration certificates. The currently valid licences and permits for activities with radiation sources represent a total number of 6,371 radiation sources in the country.

The regulatory framework defines the practices or radiation sources that are exempted completely or partially from the regulatory control based on specific exemption criteria. Specific clearance criteria are also provided. Furthermore, requirements for the reuse or recycling, import and export of radioactive sources have been established.

BNRA is the competent authority for the regulatory control of the shipments of radioactive materials. For the shipment of sealed radioactive sources, the sender must obtain a written declaration from the consignee confirming the granting of an authorization in the destination EU member state. Moreover, before the import of radioactive sources from countries outside the EU, the Bulgarian customs shall ensure that a related authorization has been granted by BNRA.

Licences are issued for different stages of the life cycle of facilities or radiation sources. Before issuing an authorization, BNRA performs preventive regulatory inspections to verify compliance with the regulatory requirements.

The regulatory framework defines specific requirements concerning orphan sources. Moreover, a related strategy for the recovery of orphan sources is included in the national strategy for spent fuel and waste management.

The conditions included in the licences or permits are based on the type and specificities of the regulated activities with radiation sources by applying a graded approach in line with the Regulatory Guide on Application of a Graded Approach to Activities with Sources of Ionising Radiation. The findings of CNRRP inspections are also used by BNRA to formulate conditions that are incorporated into the licences.

The validity period of licences does not exceed 10 years. Permits are issued for activities that are usually completed in a short term.

Radiation Protection Officers (RPOs) are designated by the authorised parties. They shall be trained and certified by training providers recognized by BNRA. The certification of the RPOs is valid for five years.

BNRA maintains the National Registry of Sources of Ionizing Radiation (see section 3.7) including information on sealed and unsealed sources, X-ray devices and accelerators, authorised parties, issued authorization documents, and licence conditions, etc. Moreover, BNRA has developed a database for the tracking of radiation sources. The licensees can enter information about the sealed and unsealed sources, and radiation generators in their facilities that can be accessed only by BNRA. This tool strongly facilitates the regulatory functions as it allows BNRA, among others, to systematically check the status of radiation sources in facilities and to track the import and export of radioactive sources in real time. The use of the database can be considered as an area of good performance.

For the authorization of new facilities and activities or the amendment of an authorization due to changes with an impact to radiation safety, the applicant shall submit to BNRA a safety assessment that has been independently verified. However, this independent verification is not carried out for safety assessments submitted to BNRA for the renewal of licences or as part of the regulatory oversight of facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The safety assessments prepared for the renewal of licences or as part of the regulatory oversight of facilities and activities are not independently verified before being submitted to BNRA.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 21 states that** *"The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body".*
S10	**Suggestion: BNRA should consider requesting an independent verification of safety assessments from all operating organizations, including those applying for a licence renewal based on the graded approach.**

5.6. AUTHORIZATION OF DECOMMISSIONING OF FACILITIES

Decommissioning activities of nuclear facilities and decommissioning of facilities with sources of ionising radiation is authorised according to the ASUNE since the regulatory framework requires licensees to obtain a licence from BNRA to carry out decommissioning activities. For the application for a decommissioning licence of a nuclear facility, the Regulation on the Procedure for Issuing Licences and Permits (RPILPSUNE) lists what the application should contain and the documents that should be submitted. The

authorization procedure for decommissioning of nuclear facilities follows the BNRA process applicable for all nuclear facilities, as described in Section 6.1 and 6.2.

In Bulgaria major decommissioning projects are ongoing for four reactor units at Kozloduy site (KNPP 1-4). These have been authorised for decommissioning and received a decommissioning licence by BNRA.

The final stage of decommissioning is a "brown-field", which is described in the national strategy for spent fuel and waste management. After performing the decommissioning activities listed in the decommissioning plan, a final report explaining how the licensee fulfils the obligations set by the decommissioning licence, including the licence conditions and established dose criteria, will be submitted to BNRA. After review of the final report, the BNRA Chairperson issues an order to declare that the nuclear facility site shall be released from regulatory control under the ASUNE.

The IRRS team was informed that the renewal of the decommissioning licence for Units 1 and 2 at Kozloduy was recently issued for a period of ten years, and after this period the decommissioning activities should be finished. The decommissioning licence also includes a number of licence conditions such as, the routine reporting requirement for the licensee, and the requirement that the licensee shall have a three-year plan for the activities to be carried out to ensure that they have the sufficient human, financial and infrastructure resources.

5.7. AUTHORIZATION OF TRANSPORT

BNRA is the Competent Authority in charge of regulating transportation of radioactive and nuclear materials. BNRA developed the "Regulation on the Conditions and Procedure of Transport of Radioactive Material" based on the requirements of the IAEA transport regulation TS-R-1 (2005). The transport regulations are currently in the process of being updated, which is described in section 9.7. The ASUNE requires a permit or licence for every transport performed of radioactive and nuclear materials, including transit through Bulgaria by any mode. Permits are required for single shipments of radioactive or nuclear materials or for transits through Bulgaria. Licences are required for multiple shipments of radioactive material. Licences are normally approved for 5 years. BNRA approves the licences and permits, which includes the requirements for package approval, in accordance with the ASUNE, Regulation for Issuing Licences and Permits for Safe Use of Nuclear Energy, and Regulation on the Conditions and Procedure of Transport of Radioactive Material.

The applicant must submit the necessary documents to BNRA, including approval from relevant authorities for the transport package. The specific documents to be attached with the application are described in the Regulation for Issuing Licences and Permits for Safe Use of Nuclear Energy. If there are any deviations from the applicable requirements, the applicant must provide a description of these deviations, explain the reasons and circumstances behind them, and outline any special measures planned to address the non-compliance. A transport permit cannot be issued without the approval of BNRA. Bulgaria also adheres to its obligation not to licence shipments of spent fuel or radioactive waste to destinations south of 60 degrees south latitude for storage or disposal. Bulgaria does not manufacture transport packages for radioactive material.

BNRA has a process and requirements in place to approve special arrangements, but this approval has not been necessary yet. There is no current package or special form radioactive material design and testing in Bulgaria. According to discussion with BNRA staff, this capability is not currently necessary as there are no interested parties. The IRRS team observes that an authorization process would need to be developed if this should change in the future.

The available information shows that BNRA adheres with the IAEA standards and guides related to authorization of transport activities to the extent possible and hence no suggestion/recommendation is served in this area.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The regulatory framework for occupational exposure includes the ASUNE, the Health Act, the Regulation on Radiation Protection (RRP), enforced by BNRA, and the Regulation n° 32 on the Conditions and Procedure for Individual Dosimetric Control of Persons Working with Sources of Ionizing Radiation, enforced by MoH. There are also additional regulations specific to certain activities with complementary requirements regarding occupational exposure (e.g. Regulation on radiation protection in industrial radiography).

BNRA is the only organization that can issue licences, certificates of registration and permits for nuclear activities. According to the Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy and the application forms for a licence, occupational exposure documents must be submitted within the application process for all activities related to nuclear facilities, facilities with SIR, and transport, etc. This may include, inter alia, the following documents:

- radiation protection organization, including the designation of a radiation protection officer;
- assessment of expected exposure doses and the associated radiation protection measures;
- occupational exposure monitoring;
- radiation protection programme, including the designation of controlled and supervised areas; and
- expert medical opinion on fitness for duty of the employees to carry out activities involving work with ionising radiation.

BNRA reviews the occupational exposure documents and verify that the regulatory requirements are met, with respect to the justification and optimization of protection and safety, dose constraints and compliance with dose limits, and clearly defined responsibilities and measures for the radiation protection of workers.

Radon concentrations in the workplace are assessed by the National Centre for Radiobiology and Radiation Protection (NCRRP). According to the ASUNE, BNRA must be notified for workplace radon exposure cases specified in the Radiation Protection Regulations (RPP), i.e. when the reference level of 300 Bq.m-3 is exceeded. The IRRS team was informed that BNRA has not received any notifications of exceedances.

The IRRS team observed that the cosmic radiation exposure of the Bulgarian airline crew was assessed, and the individual doses were found to be less than 1mSv. If the airline's activity significantly changes, e.g. there is an increased frequency of flights, the employer will conduct a new dose assessment.

According to the Health Act, MoH is responsible for establishing and maintaining a register of persons who work or have worked with sources of ionising radiation. The individual dosimetric control data, for these workers, is archived in the register. The conditions and procedure for registration, processing and storage of the data is determined by the Regulation on the conditions and procedure for carrying out individual dosimetric control of persons working with sources of ionising radiation issued by MoH.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The legal framework for medical exposure regulatory control is based on the Health Act and on the Regulation on Protection during Medical Exposure (Regulation No. 2). The Health Act also includes regulations for medical standards in radiotherapy, nuclear medicine, and medical imaging. MoH has the main responsibility for control of medical exposure of patients. However, it is the BNRA Chairperson who issues the licences, permissions, and certificates of registry for the use of sources of ionising radiation for medical purposes.

For a new installation, or to undertake modifications of the facility, it is required to obtain a permit for the construction, assembly, and preliminary testing of the sources of ionizing radiation. Once MoH confirms that the site complies with health radiation protection regulations, a report of compliance is issued, and sent to the applicant. The report is also submitted to BNRA, as part of the authorization process for the safe use

of sources of ionising radiation for medical exposures, in accordance with the requirements for operational and design considerations defined in the RRP.

If a non-compliance with Regulation No. 2 is identified by MoH, it should be reported to BNRA, and if any non-compliance has not been remediated at the time of licensing, BNRA can include an additional requirement in the licence to assure that the remediation actions are taken.

The cooperation between MoH and BNRA is assured by a memorandum of understanding (MoU), and by an agreement on the procedure for joint inspections. However, the IRRS Team has learned that a timely and comprehensive report of such events does not always occur. Hence, BNRA is unable to act in order to ensure that the necessary corrections have been implemented.

The roles, responsibilities, qualification and required competencies/certification for healthcare workers, Medical Physicist and Medical Physicist Expert involved in the protection and safety of individuals undergoing medical exposures are well established in regulations. The National Centre for Radiobiology and Radiation Protection (NCRRP) is responsible for training and certifying these professionals and maintains a list of medical physics experts, including their names and areas of expertise, which is published on the NCRRP website.

General requirements for justifying the use of radiation for medical purposes, including special circumstances involving foetuses, children, and asymptomatic individuals, are outlined in regulations. Regulation No. 2 clearly defines the role of the prescribing physician and the role of the physician responsible for the medical exposure in the justification of the medical exposure of individuals. The clear definition of the roles provides for a thorough understanding of this requirement, which can have a positive impact in its implementation and is recognized as an area of good performance.

For the approval of new practices or methods, the NCRRP, national consultants in relevant medical fields, and representatives from the Bulgarian Association of Radiology and the Bulgarian Society for Biomedical Physics and Engineering are consulted.

The requirements for the prevention and minimization of the consequences of unintended medical exposures, and radiation protection for pregnant and breast-feeding patients are also established. However, licensees are not reporting the incidents to the NCRRP as required in the regulations, and thus the NCRRP has identified the need for raising awareness amongst health workers and health organizations.

The criteria for releasing patients, requirements for establishing dose constraints and optimization of radiation protection in medical exposure are also established in regulations. However, there is no guidance for the healthcare workers and health organizations to implement these requirements This issue is further addressed in Suggestion **S25** in Chapter 9.9.

The companies offering various services, such as, maintenance, assembly, dismantling, measurement, etc., regarding medical equipment are also subject to authorization. The external assessment of the quality of activities related to the use of sources of ionising radiation for medical purposes is not a part of the authorization process but rather it is covered by inspections conducted by the competent authorities of MoH.

The National Centre for Radiobiology and Radiation Protection (NCRRP) is responsible for collecting and analysing data to establish the National Diagnostic Reference Levels (DRLs) and is currently in the process of updating these levels, as well as, establishing DRLs for new imaging modalities. In the past the collection of data was done analogically, but due to the increasing use of Dose Monitoring Software by the licensees, the NCRRP is now able to collect the dose information directly from that software. This results in a significant increase of data to be analysed. The number of medical facilities has increased substantially in the last decade, which contributes to the amount of data to analyse. However, the human resources of NCRRP have not increased accordingly, which leads to having insufficient human resources for completing the task of establishing the national DRLs. This issue is further addressed in Recommendation **R6** in Chapter 3.3.

The initial methodology that NCRRP used to establish the national DRLs involved consultation with the relevant professional bodies and BNRA. However, the IRRS team notes that NCRRP has not continued consultation even though the technology and its medical applications have rapidly evolved. Consultation with the relevant professional bodies and BNRA should be resumed to assure that the national DRLs reflect the best practices in medical imaging. This action was included by MoH in the initial action plan prepared for the mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The National Centre for Radiobiology and Radiation Protection (NCRRP) has currently insufficient manpower for data collection. Further NCRRP is not consulting with the relevant professional bodies and BNRA to establish the DRLs for new imaging modalities, and to update the DRL previously established.*	
(1)	**BASIS: GSR Part 3, Requirement 34, para. 3.148 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
(2)	**Basis: GSR Part, 3 Requirement 2, para. 2.17 states that** *"The government shall ensure that the regulatory body has the legal authority, competence and resources necessary to fulfil its statutory functions and responsibilities."*
S11	**Suggestion: The National Centre for Radiobiology and Radiation Protection (NCRRP) should consider consulting with the relevant professional bodies and BNRA to establish the DRLs for new imaging modalities, and to update the DRLs previously established.**

Despite a substantial increase in the number of medical facilities over the past decade, BNRA did not increase staffing levels due to the difficulty in recruiting individuals qualified for safety assessment, an environment of an ageing workforce and inadequate funding for the regulatory authority. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The radiation protection requirements for existing exposure situations are set out in the RRP and the Regulation on Radiation Protection during Work Activities with Materials with Increased Concentration of Natural Radionuclides. The BNRA Chairperson must approve permitted activity levels for radioactive discharges and monitor conditions for authorised effluents to ensure radiation protection and good practices. The Chairperson, according to Article 15 of the ASUNE, is responsible for issuing permits for the reclamation of sites contaminated with radioactive substances. Additionally, the ASUNE also makes provision that a licence is required for manufacturing consumer products, including medical devices with radioactive substances. All relevant information for the manufacturing or importing of consumer products that may be a new type of practice, must be provided to the BNRA Chairperson and the Minister of Health.

Provisions are also in place for the BNRA Chairperson to approve permitted activity levels of radioactive discharges from nuclear facilities. The Regulation on the Procedure for Issuing Licences for Nuclear Energy

mandates specific conditions for monitoring and evaluating radiological impacts in licences and permits for the use of safe nuclear energy. The BNRA Chairperson may approve permitted levels of radioactive discharges from nuclear facilities, with conditions for radiation monitoring of the discharges.

5.11. SUMMARY

The authorization process for nuclear and radiation facilities and activities in Bulgaria covers all lifecycle stages and has clear interconnections between stages. The process defines BNRA actions, responsibilities, and obligations with consideration of the graded approach. However, BNRA needs to further develop guidance documents on specific topics to be used by the applicant and licensees.

Activities with sources of ionizing radiation, including design, production, commissioning, operation, decommissioning, storage, and disposal, are regulated through a combination of notification and licensing systems. NCRRP and MoH should ensure that there are adequate human resources to effectively discharge the assigned responsibilities.

The graded approach is detailed in the Regulatory Guide on Application of a Graded Approach to Activities with Sources of Ionizing Radiation aligning with the IAEA's relevant publications. BNRA has a clearly defined procedure for implementing this approach, ensuring that all actions are consistent and appropriately scaled according to the risks and nature of each activity. The Bulgarian regulatory framework establishes requirements for the control of radioactive discharges, materials for clearance, environmental monitoring, and control of public exposure through well-defined authorization processes.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

BNRA reviews and assesses applicants' or licensees' submissions to ensure compliance with legal and regulatory requirements. Under the ASUNE, facilities and activities using nuclear energy or ionizing radiation, as well as those involved in radioactive waste and spent fuel management, must conduct regular safety and radiation protection assessments. These assessments must address accident prevention, mitigation measures, and the effectiveness of physical and administrative barriers to protect workers and the public from the harmful effects of ionizing radiation hazards. This review and assessment of information is performed prior to authorization and over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body.

The BNRA Chairperson ensures preventive regulatory control when issuing licences, permits, and certificates, in line with the requirements of the ASUNE. BNRA also ensures, in accordance with a graded approach, that authorised parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities, such as periodic safety reviews for nuclear power plants.

These comprehensive safety reviews are submitted to BNRA for assessment and ensures that safety improvements identified in the reviews are implemented in a timely manner. BNRA review and assessment process is aligned with IAEA GSR Part 1 (Rev. 1) on governmental, legal, and regulatory frameworks for safety, covering all regulated facilities and activities. BNRA apart from review and assessment within their organization outsource some specialized areas to some technical support organizations in accordance with the Procedure for Review and Assessment of Information relevant to Safety of Nuclear Facilities (QMS-AA-P-01), the Procedure for Regulatory Review of Documents for Activities with SIR (QMS-AA-P-02) and the Procedure for Applying Licensing Regime for Activities with SIR (QMS-LA-P-02). These procedures are aligned with international standards, such as those from the International Atomic Energy Agency (IAEA), including GSR Part 1 (Rev. 1) and GSG-13, which provide guidance for regulatory review.

Guidelines on implementing the requirements defined in the regulations under the ASUNE are contained in:

- Regulatory Guide on Structure and Content of a Safety Analysis Report of a Centralized Facility for Storage of Low and Intermediate Level Waste RG-3/2010;
- Regulatory Guide on Deterministic Safety Assessment RG-5/2010;
- Implementation of the Probabilistic Safety Analysis (PSA) in Safety Management of Nuclear Power Plants RG-6/2023;
- Regulatory Guide on PSA of Nuclear Power Plants RG-7/2010;
- Regulatory Guide on Safe Operation of Nuclear Power Plants RG-10/2011;
- Qualification of Structures, Systems and Components Important to Safety of Nuclear Power Plants RG-21/2021;
- Regulatory Guide on PSR of Nuclear Power Plants RG-18/2018;
- Regulatory Guide on Ageing Management of Structures, Systems and Components of Nuclear Power Plants RG-20/2018;
- Regulatory Guide on Determining the Importance of Operational Events in Terms of Nuclear Safety and Radiation Protection (INES scale level) RG-22/2021;
- Regulatory Guide on Internal Fires Protection in Nuclear Power Plants RG-1/2023.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

The Procedure for Review and Assessment of Information Related to the Safety of Nuclear Facilities (QMS-AA-P-01) outlines the process that BNRA follows for review and assessment of nuclear facilities. This includes safety analyses and assessments submitted by applicants to meet regulatory requirements, as well as documents related to licensing, permits, and ongoing compliance with issued licences. BNRA also reviews any other necessary information required for regulatory safety decisions.

According to paragraph 3.1 of the Procedure, BNRA performs review and assessment of, among others, the following information:

- Safety analyses and assessments submitted to comply with regulatory requirements;
- Safety analyses and assessments submitted together with applications for issuing licences and permits;
- Documents submitted in implementation of conditions of the issued licences and permits;
- All other documents necessary for making regulatory decisions regarding the safety of nuclear facilities including design modifications and periodic safety review.

BNRA applies a graded approach to the review process by tailoring the level of detail, resources, and effort to the potential risks posed by the facility or activity. Factors considered include the likelihood and potential consequences of accidents, the complexity and maturity of the facility, and the potential for radioactive material release during normal operation or accidents. The goal is to ensure that all safety objectives and regulatory criteria are met, and that radiation risks are maintained at acceptable levels.

The review process itself is divided into several stages: planning and coordination, review and assessment of completeness and accuracy of the submitted information, documentation of the results, and regulatory decision-making. BNRA evaluates compliance with the safety requirements set out in the ASUNE, the associated regulations, BNRA-specific guidelines, IAEA standards, and good international practices. If necessary, additional data is requested from the applicant.

The procedure specifies the organization and management of the review process, including the following stages:

- Planning and coordination of the activities related to the review and assessment;
- Conducting the review and assessment, including review of the completeness of the information and verification of the facts and data;
- Documenting the assessment results;
- Regulatory decision making.

When all the necessary data is received, the review continues with an assessment and verification of compliance with:

- Safety requirements for implementation of the activity as defined by the Act and the Regulations;
- Guidance for implementation of the safety requirements included in BNRA regulatory guidelines;
- Applicable IAEA safety standards;
- Good international practices and applicable experience from conducting assessments of similar nuclear facilities.

In implementation of the provisions of the ASUNE, the Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy (RPILPSUNE), and the RESNPP, the applicants and licensees submit to BNRA safety relevant information over the lifetime of the facility or the duration of the activity, associated mainly with:

- Applications for the issuance of authorizations, such as licences, permits, approval orders;
- Implementation of conditions of issued authorizations;

- Demonstration of compliance with legal and regulatory requirements;
- Periodic safety reviews;
- Implementation of prescriptions and recommendations as a result of inspections;
- Reporting of events, operational experience, safety performance indicators, etc.

The findings from the review are documented in a report that includes the scope of the review, the safety standards applied, the results of the assessment, conclusions, and recommendations for regulatory decisions. These reports are verified by division heads and reviewed by department directors before being finalized. If needed, external services may be contracted to provide additional expertise, and the review process ensures that all necessary actions are taken in a structured and documented manner to make informed safety decisions.

During the review and assessment of safety demonstrations submitted for nuclear facilities, the compliance with the safety requirements and guidance is verified, including national regulations and regulatory guides, as well as IAEA safety standards and international good practices (expressed e.g. in regulatory documents and applicable review results of other regulatory authorities).

The IRRS team noted that there is no detailed mechanism for evaluating the outcomes of TSO support to be used in the regulatory decision-making process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA is lacking a detailed mechanism for the evaluation of TSO results for use in its decision-making process.*	
(1)	**BASIS: GSG-12, para. 6.53 states that** *"The regulatory body should have competence to decide which of its activities need support from external organizations (e.g. consultants, research institutes and dedicated support organizations) and to establish criteria for the service(s) needed, as well as to evaluate the outcome, i.e. the regulatory body should be an intelligent customer (see Appendix I)..."*
S12	**Suggestion: BNRA should consider strengthening its mechanism to assess the work done by the TSO for utilizing in regulatory decision making.**

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The Procedure for Review and Assessment of the Information Related to the Safety of Nuclear Facilities (QMS-AA-P-01), specifies the process for the review and assessment of fuel cycle facility licence applications. This includes the planning and coordination of activities, conducting the review and assessment, documenting the results and regulatory decision making. The general approach is the same as for other nuclear facilities described in sections 6.1 and 6.2.

The Regulation on Ensuring the Safety of Spent Fuel Management, states that the licensee shall plan and carry out periodic and systematic safety assessments of the facilities, assessments of the radiation impact on the environment over reasonable periods of time during the design operating life of the facilities and ensure safe operation with a level of safety in accordance with the applicable regulatory requirements. The assessment period shall not exceed 10 years.

The IRRS team was informed that periodic safety assessments are performed in accordance with the Regulatory Guide on Periodic Safety Review (PSR) of Nuclear Power Plants, applying a graded approach and expert judgement, but there is no specific guidance for the PSR of fuel cycle facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no specific guidance for conducting PSR of fuel cycle facilities.*	
(1)	**GSG-13 paragraph 3.43 states that** *"In order to fulfil these requirements, the regulatory body should issue regulations and guides that describe the safety assessments to be performed by the authorized party for the facility or activity, and how these should be submitted for review by the regulatory body prior to the granting of the authorization at each lifetime stage."*
S13	**Suggestion: BNRA should consider further developing regulatory guidance to clarify the requirements for the conduct of the PSR for Fuel Cycle Facilities.**

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Review and assessment of waste management facilities are performed by BNRA to verify that the information submitted by applicants or licensees comply with the related regulatory requirements and licence conditions. Review and assessment of the submitted documents are performed using the Procedure for Review and Assessment of the Information Related to the Safety of Nuclear Facilities, and follows the general approach described for other nuclear facilities, as described in Section 6.1 and 6.2.

The periodic safety review (PSR) of waste management facilities is performed at least every ten years, as set out in the Regulation of Safe Management of Radioactive Waste and follows the Regulatory Guide on Periodic Safety Review of NPPs. The IRRS team observed that there is no specific regulatory guide that outlines the specific contents of a PSR for waste management facilities. This issue is further addressed in Suggestion **S19** in Chapter 9.1.

The IRRS team was informed that the review of the application for the operation of the near surface disposal facility is in its final stages and during the review process international consultants have been used to support some parts of the review. For the review and assessment of the site selection of a deep geological repository, that will take place in the future, BNRA will have to use international consultants with the necessary expertise.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

BNRA performs review and assessment of the information submitted by applicants, licensees and permit holders to determine whether the facilities and activities with radiation sources comply with the related regulatory requirements and the conditions included in the authorization documents. Such information is provided to BNRA for evaluation at all stages of the life cycle of facilities through:

- The applications for authorization and the related documentation;
- Documents demonstrating compliance with the conditions of the authorization;
- Documents demonstrating compliance with the regulatory requirements;
- Documents demonstrating compliance with given regulations and recommendations as a result of the regulatory control;
- Reports on occurred events, operational experience, and the status of radiation protection.

The criteria for regulatory review and assessment are consistent with the requirements of the ASUNE and the regulations for the various types of facilities and activities, as well as the provisions of the related regulatory guides and internal procedures.

The Procedure for Regulatory Review of Documents for Activities with SIR defines the frequency for submitting information (reports, statements, etc.) for review and assessment in accordance with a graded approach.

In case of modification, renewal, or termination of an authorization, a regulatory review of the submitted required documents should be conducted in line with the Procedure for Regulatory Review of Documents for Activities with SIR.

Sixteen (16) members of BNRA staff participate in the review and assessment of facilities and activities with radiation sources. The IRRS Team was informed that the number of reviewers is considered insufficient for BNRA to respond efficiently to the continuously increasing review and assessment workload. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

It is a common practice of BNRA to assign TSOs or Qualified Experts (QEs) to support the review and assessment activities. The TSOs or QEs are selected after an evaluation carried out by a 3-member committee. During the evaluation, the committee considers, among other criteria, information concerning conflict of interest.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The review and assessment for the decommissioning of nuclear facilities follow the Procedure for Review and Assessment of the Information Related to the Safety of Nuclear Facilities as described in Section 6.1 and 6.2. The decommissioning plan is a part of the documentation the applicant submits to BNRA and is included in the review and assessment for authorization.

The IRRS team was informed that the review of the renewal of the decommissioning licence for KNPP Unit 1 and 2 was performed using competences from three of the departments within BNRA and no external consultants were used.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The primary transport activities in Bulgaria are import, export, domestic, and transit shipments of sources in different package types including Type A packages and foreign Competent-Authority-approved Type B packages. Review and assessment activities are focused on shipment approval and approval of foreign Competent-Authority-approved packages as part of the transportation licence or permit approval. Other transport package types and activities (Type B package design, special form radioactive material design, etc.) are not anticipated or currently practiced in Bulgaria.

BNRA performs review and assessment of licences and permits for transportation of nuclear and radioactive materials by two different departments depending on whether nuclear (fissile) or non-fissile material is being transported. The Procedure for Review and Assessment of Information Related to the Safety of Nuclear Facilities (QMS-AA-P-01) and Procedure for Regulatory Review of Documents for Activities with Sources of Ionizing Radiation (QMS-AA-P-02/3) describe the processes used for review of licences and permits for fissile or non-fissile material respectively. The Regulation for Issuing Licences and Permits for Safe Use of Nuclear Energy clearly states the documentation needed for review while the Regulatory Guide on the Application of the Requirements for Safe Transportation of Radioactive Materials (PP – 19/2018) contains specific guidance that is used by BNRA staff for review of more complex areas such as the radiation protection programme or emergency plan. In combination with pre-licensing inspection, these documents constitute the basis for reviews and assessments to confirm compliance with the requirements in the relevant regulations.

The IRRS team reviewed a permit for one-time shipment of fresh fuel to Kozloduy NPP that was issued in 2024 and included a new design of fresh fuel. The IRRS team noted that the review included an independent

assessment to verify the sub-criticality of the foreign Competent Authority approved package as part of the required validation process.

The IRRS team was informed that there have been delays in the review and assessment of applications as a result of the resource challenges described in section 6.5. These delays have not yet affected the ability of licensees to perform authorized activities. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The review and assessment for occupational exposure is included within the Procedure for Review and Assessment of the Information Related to the Safety of Nuclear Facilities and the Procedure for Regulatory Review of Documents for Activities with SIR.

BNRA is responsible for the review and assessment of authorization documents related to occupational exposure. This includes documents issued by MoH, for example, expert conclusions regarding the assessment of the workers fitness for the assigned work.

According to the Regulation on Procedure for Issuing Licences and Permits, any licence and permit shall contain general and special conditions specifying the rights and obligations of the licensee or permit holder. The general conditions of the licence or permit are determined in accordance with the type of the activity and may comprise requirements related to the provision of radiation protection; obligations related to notification in case of deviations from normal operation, incidents and accidents, obligations related to provision of information on the fulfilment of the licence or permit conditions, and requirements related to periodical submission of information regarding the fulfilment of the licence or permit conditions, etc. Regarding occupational exposure, the conditions of a licence may include, inter alia, the following requirements:

- the obligation to submit an annual report to BNRA on the results of the individual dosimetric control of occupationally irradiated workers;
- the obligation to submit, at defined intervals, a summary report on the state of radiation protection when carrying out permitted activity with SIR, which includes:
    - assessment of the individual doses of the occupationally exposed workers received during the implementation of the authorised activity, including a list of workers who received an annual effective dose of more than 6 mSv;
    - radiation monitoring results (including updated information on the technical means used for radiation monitoring at the facility);
    - analysis of significant events and cases of unintended exposure that occurred during the implementation of the authorised activity;
    - up-to-date information and data on occupationally exposed workers of category A and category B, the medical supervision and specialized training of these persons, as well as information on external workers; etc.

The IRRS team was shown an example of a licence issued for a facility with SIR and noted the presence of requirements regarding occupational exposure which allow BNRA to periodically review and assess this area.

MoH also participates in the review and assessment of the periodic health surveillance of exposed workers and the control of the doses received by occupationally exposed workers in the undertakings to confirm compliance with occupational exposure requirements.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

MoH is responsible for the review and assessment of the requirements in Regulation No. 2, pertaining to medical exposure, including:

- justification of medical exposures in various cases
- optimization of medical exposures in various cases (design, conduct, source calibration, dosimetry of patients, reference levels, dose constraints)
- quality assurance for medical exposure and
- results of the radiological review of the facilities

MoH conducts preliminary inspections which consist of on-site verification that the information described in the documents submitted by the applicant, for obtaining the report of compliance, is correctly implemented.

The second level of justification (according to the ICRP definition) is assessed, ensuring that radiological procedures included in the Medical Standards are considered justified. New methods and procedures undergo justification in accordance with Regulation No. 2, with the involvement of representatives from expert councils of the Law on Medical Facilities. These councils include representatives from relevant medical specialties, the Bulgarian Association of Radiology, and the Bulgarian Society of Biomedical Physics and Engineering.

Once MoH ascertains the compliance with the regulatory requirements specific for medical exposure, a report is issued and provided to the applicant. This report is required for the application for licensing with BNRA.

For the licensing process BNRA conducts a review and assessment of the documents submitted by the applicant, according to the Regulation on Radiation Protection, including the report from MoH.

When BNRA does not have the necessary staffing resources required for an independent review and assessment of the documents submitted by the applicant during the licensing process, it has the possibility of consulting with a Radiation Protection Expert, through the public procurement procedures of the Bulgarian Government. There are no TSO's for support in review and assessment of compliance with the regulations pertaining to radiation safety and protection regulations for facilities and activities which involve medical exposures.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

BNRA has the mandate to perform review and assessments for applications involving public exposures as a result of planned exposure situations and other facilities and activities. This is performed to evaluate the compliance to legal and regulatory requirements. The ASUNE states that organizations working with nuclear energy must conduct assessments for nuclear safety and radiation protection at nuclear facilities and that the licensees must also implement measures to improve safety based on national and international knowledge in the field.

The conduct of regulatory review and assessment as part of compliance assessment, follows a graded approach. One of the main factors considered is the level of risk associated with the release of radioactive material, including potential accidents, operational events, and low probability/high consequence accidents. The maturity and complexity of the facilities are also considered.

Compliance with public exposure standards is monitored by the Public Radiation Health Control structure of MoH. All exposure sources (food, water, environment) are monitored through an annual monitoring programme approved by the Minister of Health. MoEW oversees the state policy on environmental protection, use and conservation of water, and earth subsurface. It manages the National System for Environmental Monitoring and makes decisions on environmental impact assessments.

Provisions in the RRP allows for the Minister of Health, through the National Centre for Radiobiology and Radiation Protection (NCRRP), to assess the doses of external and internal exposure for the public and representative individuals. The RRP further requires organizations to create, approve, and implement radiation monitoring programmes to evaluate public exposure. Further to the NCRRP assessment, the regulations require, for permitted activities involving radioactive discharges, that a screening assessment of the effective doses to the public under normal conditions is conducted. The operating licences for all Kozloduy NPP units have requirements for radiation protection, monitoring, and reporting. Periodic reports submitted to BNRA include information on conditions, releases, dose monitoring results, and environmental radiation monitoring, including a public exposure assessment. BNRA reviews and assesses the discharges from the NPP site and perform verification of the discharges to the environment.

A permit system is provided for in the ASUNE, which the BNRA Chairperson can issue for reclamation (remediation) of sites contaminated with radioactive substances. The prerequisite documents must account for analysis of contamination levels, risk factors, exposure pathways, and the spread of radioactive contamination during reclamation activities.

A reference level of 300 Bq.m-3 is set to limit radon exposure in indoor workplaces. The same level applies to dwellings and public buildings. If levels exceed 300 Bq.m-3, measures must be implemented to reduce the radon activity concentrations. The RRP outlines existing exposure situations which include exposure from commodities incorporating radionuclides and high concentrations of naturally occurring radionuclides. It further allows for authorised activities involving effluent discharges, which must be monitored and evaluation of radioactive discharges into the environment. These are required to be submitted to the Regulatory Body and reviewed and assessed accordingly.

6.11. SUMMARY

BNRA has a well-established formal process for reviewing and assessing information submitted by applicants and licensees to ensure that their facilities and activities comply with legal and regulatory requirements. The review procedures are outlined in two key internal documents: the Procedure for Review and Assessment of the Information Related to the Safety of Nuclear Facilities and the Procedure for Regulatory Review of Documents for Activities with SIR, both of which are part of BNRA's Quality Management System. These procedures ensure that safety improvements identified during reviews are effectively implemented.

However, BNRA faces challenges in conducting complex and multi-disciplinary assessments due to a lack of sufficient in-house expertise. BNRA is encouraged to make provisions for assessment of TSO work before using it in decision-making. Furthermore, BNRA is encouraged to develop guidance for conducting PSR of fuel cycle facilities with consideration of the graded approach.

7. INSPECTION

7.1. GENERIC ISSUES

BNRA has regulatory staff that are designated as inspectors by order of the BNRA Chairperson. The inspectors are located on-site and at BNRA headquarters. The inspectors conduct inspections in accordance with an inspection plan that is approved by the BNRA Chairperson, and inspection procedures that outline the methods for conducting the inspections at a high level. BNRA inspectors conduct planned, reactive, and announced inspections of all nuclear facilities and of nuclear activities. BNRA inspectors also conduct planned, reactive, and announced or unannounced inspections of radiation source facilities and activities. The relevant sub-sections provide further information on inspections of the various nuclear and radiation facilities and activities.

BNRA inspectors conduct inspections in accordance with inspection procedures QMS-IA-P-02/3 and QMS-IA-P-03/3. The inspection procedures cover preparation of the baseline inspection programme (for nuclear facilities) and annual inspection plans, planning of each inspection, conduct of the inspection and reporting of the inspection results. BNRA inspectors conduct inspections using a combination of techniques such as document reviews, discussions with licensees, walkdowns of facilities and observations of activities.

The IRRS team noted that the inspection procedures do not include detailed guidance on how to perform the specific types of inspections or on the verification checks that the inspector should perform during the inspections. The gap in the procedures apply to multiple nuclear facilities and activities including nuclear power plants, fuel cycle facilities, decommissioning facilities, waste management facilities, occupational exposure, and transport. This issue was partly identified in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA does not have detailed instructions on how to perform the different types of inspections nor detailed guidance for performing verifications against regulatory requirements.*	
(1)	**BASIS: GSG-13, para. 3.262 states that** *"The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Each inspector should be given adequate training in following this guidance."*
S14	**Suggestion: BNRA should consider further developing detailed procedures and guidance for conducting inspections in nuclear facilities, and associated activities.**

7.2. INSPECTION OF NUCLEAR POWER PLANTS

BNRA has inspectors who support the regulation of the nuclear power plant at BNRA headquarters, and six (6) resident inspectors located on-site. The BNRA Chairperson has the authority to designate inspectors under the ASUNE. BNRA management assigns mandatory training to potential inspectors and upon completion and demonstration of readiness, the management recommends to the Chairperson that the candidate is ready to be designated as an inspector. The Chairperson issues an order that delegates all legal powers of an inspector to the qualified individual. BNRA inspectors complete training every year to maintain their inspector competencies, address any identified gaps and pursue continuous improvements.

The IRRS team noted that many inspectors are in their second careers and are approaching a second retirement. This situation may present a workforce challenge to BNRA in ensuring that qualified inspectors

continue to be available to implement the inspection programme. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

The inspectors conduct various types of inspections including planned, reactive, announced and unannounced inspections. Planned inspections include inspections of thematic areas by BNRA inspectors and daily routine inspections and surveillance of the plant by BNRA resident inspectors. The IRRS team noted that a resident inspector usually participates in the thematic inspections depending on their availability and expertise. Reactive inspections are generally focused on areas that have emergent concerns or have indicators that suggest that an inspection may be required.

The IRRS team noted that the majority of these inspections are announced and BNRA does not frequently perform unannounced inspections. The IRRS team noted that BNRA inspectors have the ability to perform this type of inspection, if required, and there is a consistent and strong understanding among BNRA and KNPP staff that the inspectors may exercise the option to conduct an unannounced inspection at any time.

BNRA has the ability to conduct joint inspections of the nuclear power plant with other government agencies, such as MoEW, but does not engage in this activity frequently. The IRRS team noted that there is enabling legislation to allow joint inspections, however; there are no procedures or documentation that outline the interface between these organizations.

BNRA prepares a baseline inspection programme that is conducted on a 3-year frequency and identifies the required inspections of the nuclear power plant facility and activities. The methodology for identifying these areas is based on using the OSART guidelines and recommendations from BNRA management on focus areas identified from the previous performance of the authorised party. The BNRA Chairperson approves the programme and empowers the inspectors to conduct the identified inspections over a period of three years. BNRA staff use this approved inspection programme to prepare an annual plan for thematic areas and nuclear power plant areas. In addition, BNRA staff consider findings from previous inspections and incorporates these aspects into the preparation of the annual plan. The plan also balances the available resources and expertise for the conduct of the inspections.

The IRRS team observed that while the inspection programme consists of inspecting many relevant and important areas, there are gaps with respect to performing inspections of areas that consider in more details authorization and regulatory requirements. The IRRS team considers that the methodology for developing the 3-year inspection programme should be enhanced to include the appropriate regulatory requirements which would improve the effectiveness of the inspection programme and plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The methodology for developing the three-year inspection programme for operating nuclear power plants is primarily focused operational aspects of NPPs and does not comprehensively consider authorization and regulatory requirements.*	
(1)	**GSR Part 1 (Rev. 1), Requirement 29, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization."*
S15	**Suggestion: BNRA should consider improving the methodology for developing the inspection programme.**

BNRA inspectors conduct nuclear power plant inspections in accordance with the inspection procedure, QMS-IA-P-02/3. The inspection procedure covers preparation of the baseline inspection programme and

annual plans, planning and conduct of inspections, and reporting of inspection results. BNRA inspectors conduct inspections using a combination of techniques such as document reviews, discussions with licensees, walkdowns of the nuclear power plant and observation of activities conducted in the units. However, the IRRS team noted that the inspection procedure does not include detailed guidance on how to perform the specific types of inspection nor the inspector verification checks during the inspection. This issue has been self-identified by BNRA in the ARM and the action plan. The IRRS team concludes that BNRA should enhance their inspection procedure to provide more detailed guidance on the conduct of inspections. This issue is further addressed in Suggestion **S14** in Chapter 7.1.

The IRRS team also noted that the inspection procedure included templates to promote the consistent representation of inspection results to the authorised party. The IRRS team reviewed a sample of inspection reports and noted that the sections clearly identified the regulatory requirement that the inspector verified, the observations made by the inspector and the actions required to correct the situation. Depending on the severity of the observation, the inspectors clearly communicate a recommendation to the BNRA Chairperson to issue enforcement action. The IRRS team also noted that the inspectors verbally describe the inspection findings to the authorised party during the inspection exit meeting. The IRRS team concluded that the inspection results are clearly communicated in a written inspection report to the authorised party.

The IRRS team observed that BNRA routinely hires inspectors who are former nuclear industry employees and as a result, they may have a certain level of familiarity with staff from the authorised party. The IRRS team also noted that BNRA has implemented a conflict-of-interest course that is currently being updated to enhance inspector independence. A high level of familiarity between the resident inspectors and the authorised party may lead to an increased level of complacency based on the assumption that both parties are competent, and therefore the possibility of errors is unlikely. The IRRS team is of the view that BNRA should strengthen measures to ensure inspector independence and maintain this capability throughout their careers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *BNRA practice of hiring regulatory staff that are former nuclear industry employees may present challenges in terms of maintaining inspector independence.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 18 para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
(2)	**BASIS: GSR Part 1 (Rev. 1), Requirement 17, para. 4.8 states that** *"To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety."*
(3)	**BASIS: GSG 12, para. 6.67 states that** *"To maintain the effective independence of the regulatory body, special consideration should be given when individuals are recruited form authorized parties. The regulatory body should ensure that staff operate professionally and within their remit in relation to safety…"*
S16	**Suggestion: BNRA should consider strengthening measures to maintain effective independence of regulatory staff including NPP site inspectors.**

Site Visit to Kozloduy Nuclear Power Plant:

The IRRS team visited the Kozloduy Nuclear Power Plant (KNPP) site where two operating nuclear reactors are located. BNRA has a site office for their resident inspectors located on the site. The IRRS team had the opportunity to meet with the KNPP executives and discuss matters related to regulatory interactions with BNRA.

The IRRS team also observed resident inspectors performing a routine field inspection of the Main Control Room, electrical room and electronic module rooms for safety systems. The IRRS team noted that the inspectors demonstrated strong expertise with regards to station knowledge. The inspectors were able to arrange access to all areas that were inspected without difficulty. Many areas that were visited were controlled access areas where a key is required for opening the door prior to entry. This measure is in place for all plant employees in order to maintain the safety of the equipment and personnel. The inspectors demonstrated that access to the facility was available throughout the visit.

The IRRS team also noted that the inspectors performed inspections in pairs and performed daily walkdowns of the plant which ensures that inspector knowledge of the current plant condition is maintained. The resident inspectors meet with BNRA staff every day to share the current status of the plant with BNRA headquarters. This measure ensures that BNRA is staying current with its regulatory oversight of the authorised party and can implement reactive measures due to any emergent concerns. The IRRS team recognizes this practice as an area of good performance.

During the site visit, the IRRS team observed good interactions and communications between the regulatory staff and the authorised party at various levels such as executive, certified staff and field operators.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

The procedure for inspection activities in nuclear facilities covers all nuclear facilities, including both spent nuclear fuel facilities. The general approach is the same as for other nuclear facilities described in sections 7.1 and 7.2.

Inspections of fuel cycle facilities are included in the three-year cycle of the Overall Inspection Programme for Nuclear Facilities. This programme includes the main inspection areas that must be covered. Specific sub-areas are defined for each inspection area, however, detailed instructions or guidelines for the inspectors to follow regarding these fuel cycle facilities have not been developed. This issue was included in the initial action plan prepared by BNRA for this mission and is further addressed in Suggestion **S14** in Chapter 7.1.

Site visit to Dry Spent Fuel Storage Facility (DSFSF) at Kozloduy NPP

The IRRS team visited the dry spent fuel storage facility at KNPP and received information on the processes of managing spent fuel at the installation. The team also met with one of the resident inspectors to discuss their inspection activities regarding the spent fuel facilities.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

BNRA conducts inspections of waste management facilities in line with the Procedure for Inspection Activities in Nuclear Facilities, as described in section 7.1. Planned inspections are performed according to the three-year plan which is included in the procedure for inspections. Annual inspection plans are prepared and the IRRS team was informed that they are shared with the licensees of the different facilities. The inspections cover a number of areas which are included in the procedure. The procedure does not contain detailed instructions on the different types of inspections that are performed, nor the detailed verification checks during the inspection. This issue was included in the initial action plan prepared by BNRA for this mission and is further addressed in Suggestion **S14** in Chapter 7.1.

The IRRS team was informed that approximately 5 to 6 inspections of waste management facilities are performed yearly, including the RAW storage facility Novi Han, the SE RAW facilities and the national disposal facility for low- and intermediate level short-lived waste (under construction). In addition to those inspections, one of the assigned resident inspectors at the KNPP site conducts daily oversight of on-site radioactive waste facilities.

Site visit to SE RAW – Kozloduy

The IRRS team visited SE RAW – Kozloduy (the State Enterprise Radioactive Waste Management) in Kozloduy and received an informative presentation on the processes of low and intermediate level short-lived waste that takes place in the SE RAW processing facility.

IRRS team members also met management representatives of the NPP and SE RAW. The management of SE RAW communicates with the Deputy Chairperson of BNRA on a regular basis and sends the operational status of the facilities to BNRA. The annual inspection plan is communicated to SE RAW and they are aware of the planned inspections of their facilities at KNPP. Before each inspection they receive a formal letter which includes the specific details regarding the inspection. At the closing meeting of the inspection the findings are presented by the inspector.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

BNRA conducts inspections of facilities and activities with radiation sources in line with the Procedure for the Inspection Activity in Facilities with Sources of Ionising Radiation (PIAFSIR). The procedure defines the basic principles and requirements for the implementation of the inspection activities; the order of planning, preparation, implementation, and documentation; organization of resources and management of results from inspections in facilities and activities with radiation sources. The regulatory documents used for the conduct of inspections are specified in PIAFSIR. Moreover, inspectors record the results and conclusions of the inspections in a protocol of findings using the template provided in PIAFSIR.

Planned inspections are performed according to long-term programmes (up to 10 years) and annual inspection plans that are prepared based on a graded approach. The inspections can be either announced or unannounced. The areas and topics that can be included in the scope of planned inspections are described in PIAFSIR. The minimum frequency for planned inspections is defined in accordance with a graded approach. Additional unplanned and reactive inspections may be conducted that are not initially included in BNRA annual inspection plans.

A specific programme is prepared for each inspection that shall be approved by BNRA's Director of Radiation Protection. In addition, an inspection order is issued by the BRNA Chairperson.

The findings and conclusions of the inspections are communicated to the authorised parties with a finding protocol. Moreover, they are used as feedback information for the regulatory process by BNRA in line with the provisions in PIAFSIR.

In 2023, BNRA performed 77 planned and 26 unplanned inspections of facilities and activities with radiation sources. In addition, 8 inspections were conducted to check the commissioning status of new facilities.

BNRA staff includes 16 members that participate in the inspections of facilities and activities with radiation sources. As the IRRS team noted, the number of the inspectors is considered insufficient for BNRA to respond efficiently to the continuously increasing inspection workload due to the increase in the number of facilities and activities with radiation sources in the country. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

In complex and thematic inspections, representatives of other authorities may participate. Planned joint inspections are organised and coordinated by the BNRA Director of Radiation Protection. An MoU signed

between MoH and BNRA and the related agreement include specific provisions for the joint inspections performed by the two organizations.

Site visit to Acibadem City Clinic

The IRRS team observed an inspection of the Radiotherapy Department of the Acibadem City Clinic in Sofia. The Radiotherapy Department is equipped with three (3) linear accelerators, one (1) HDR brachytherapy system and one (1) CT simulator. The inspection was performed by two (2) BNRA inspectors and 1 person from NCRRP as an observer.

The inspection was conducted in line with a programme approved by the BNRA Director of Radiation Protection. An entrance meeting was held to discuss the scope and the inspection areas with the clinic's representatives. The meeting was followed by the planned inspection activities (i.e. walk downs, observations, interviews and checking of documentation). Due to time restrictions, the IRRS team could not attend the inspection exit meeting. However, the IRRS team was informed after the completion of the inspection that a finding protocol will be sent to the facility with the associated results and conclusions.

The cooperation of BNRA's inspectors with the Acibadem City Clinic representatives was good throughout the inspection which contributed to its successful performance. BNRA inspectors performed the inspection activities according to the approved programme.

The IRRS team members had the opportunity to interview the Acibadem City Clinic representatives who highlighted the contribution of BNRA's prescriptions and instructions to the continuous improvement of radiation protection and safety in the facility. Moreover, they addressed as challenges the demanding paperwork for authorization purposes and the occasional difficulties in communicating with BNRA personnel. The latter was attributed to a possible BNRA staff shortage.

According to the agreement between BNRA and MoH, findings identified during inspections conducted by the NCRRP and Regional Health Inspectorates shall be reported to BNRA. However, the IRRS team was informed during the inspection that NCRRP only reports inspection findings concerning severe violations to BNRA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NCRRP does not report all inspection findings to BNRA.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 36, para. 4.66 states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:* *……* *(e) Making information on incidents in facilities and activities, including accidents and abnormal events, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public".*
S17	**Suggestion: NCRRP should consider improving the reporting of the inspection findings concerning radiation source facilities to BNRA.**

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

BNRA conducts inspection of decommissioning activities in line with the Procedure for Inspection Activities in Nuclear Facilities, as described in section 7.1. Planned inspections are performed according to the three-year plan which is included in the procedure for inspections. Annual inspection plans are prepared and the IRRS team was informed that the annual plan is shared with the licensees of the different facilities. The inspections cover a number of areas, and the areas are included in the procedure. The procedure does not contain detailed instruction on the different types of inspections performed nor the detailed verification checks during the inspection. This issue was included in the initial action plan prepared by BNRA for this mission and is further addressed in Suggestion **S14** in Chapter 7.1.

The IRRS team was informed that inspections of decommissioning activities at KNPP Units 1-4 were performed in 2023 as part of the renewal of the decommissioning licence for Units 1 and 2. In addition to those inspections, one of the resident inspectors at KNPP conducts daily oversight of the on-site decommissioning activities.

7.7. INSPECTION OF TRANSPORT

Transportation activities are performed both at nuclear facilities and facilities with sources of ionising radiation. Therefore, inspections of transportation activities are described in both the Procedure for Inspection Activities in Nuclear Facilities (QMS-IA-P-02/3) and Procedure for the Inspection Activity in Facilities with Sources of Ionizing Radiation (QMS-IA-P-03/3). Transportation inspections are carried out by two separate departments within BNRA depending on whether the radioactive material being shipped is nuclear (fissile) material or not. BNRA inspectors for transportation of nuclear material and those that inspect facilities with SIR are trained and qualified and receive refresher training to ensure their competency is maintained and improved based on changes in transport requirements.

An annual inspection plan is developed by BNRA that covers both nuclear facilities and facilities with sources of ionizing radiation (SIR). Due to the radiation risk of fissile material, BNRA plans to inspect each shipment of fresh fuel to KNPP and spent fuel shipment from KNPP as resources allow. There have been five (5) fresh fuel shipments since 2022 and three (3) spent fuel shipments from 2020 to 2021 with inspection of each of the shipments. Inspection of these shipments are performed both by specialized and resident inspector staff and is coordinated with the Police, Customs, and Border Guard as necessary. In addition, nine (9) transits of fresh fuel have recently occurred through Bulgaria and an inspection of one of the shipments was performed. BNRA was unable to inspect additional shipments due to the ongoing issues with human resources. This issue is further addressed in Recommendation **R5** in Chapter 3.3.

For facilities with SIR, QMS-IA-P-03/3 requires that ongoing transportation inspections be performed at least every four years. However, in practice, inspection of transportation is normally performed during each facility inspection, which can be every two or three years as well based on the relative radiation risk of the facility. Recently, BNRA has begun the process of inspecting transportation at a separate time from the facility inspection to reduce the length of the facility inspection. A specific condition on inspection is being added to each transportation licence during the next licence renewal and transportation will be inspected at that facility separately from that point forward. Inspections are also performed at facilities with SIR as a part of the review and assessment of a licence application. The IRRS team considers the inspection planning for transportation activities according to a graded approach based on the relative radiation risk appropriate for the transportation activities performed in Bulgaria.

With regard to performance of inspections, as stated above, BNRA inspectors conduct transportation inspections in accordance with QMS-IA-P-02/3 and QMS-IA-P-03/3. Each inspection procedure covers the preparation for each inspection, implementation and documentation of the inspection results. For the implementation of each inspection, BNRA inspectors use a combination of methods and techniques such as walkdowns and direct observations, review of internal documents and records, interviews with personnel,

and independent tests and measurements. However, the IRRS team noted that both inspection procedures do not include detailed guidance on how to perform the inspection of transportation activities or on the verification checks that the inspector should perform during the inspection. This issue was partly identified in the ARM and is part of the action plan. The IRRS team concludes that BNRA should enhance their inspection procedures to provide more detailed guidance on the conduct of inspections. This issue is further addressed in Suggestion **S14** in Chapter 7.1.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Both BNRA and MoH carry out inspections in the area of occupational radiation protection.

On-going, thematic and targeted inspections of health and radiation control are carried out by MoH. The conditions and procedures for the exercise of state health control are defined in Regulation 36. MoH inspectors verify compliance with the health and radiation requirements for the site, the health status of those working with sources of ionising radiation and the availability of means for individual and general protection of staff.

During BNRA inspections, verification of compliance with the dose limits specified for occupational exposure are performed according to the Procedure for the Inspection Activity in Facilities with Sources of Ionizing Radiation. The inspection scope also includes the verification of compliance with the normative limits for occupational exposure (limits of the annual effective dose for personnel of category A and B), and the review of documentation for reporting and control of the received individual effective doses (including dose registrations, individual dosimetry cards, radiation passports, etc). The inspection programme is sent to the authorised party before the inspection and lists specific topics and areas regarding occupational exposure that will be reviewed during the inspection. The inspector documents their conclusions regarding each of the areas and topics in the protocol of findings for the inspection.

According to the Procedure for Inspection Activities in Nuclear Facilities, radiation protection is included in BNRA's long-term inspection plan. During these inspections, BNRA inspectors review, inter alia, records of occupational exposure and compliance with dose limits, radiation protection training records, organization for ensuring radiation protection, application of the optimisation principle, arrangements regarding controlled areas etc. The IRRS team noted for these inspection activities, no detailed guidance is included in the inspection procedure nor detailed verification checks during the inspection. This issue is further addressed in Suggestion **S14** in Chapter 7.1.

BNRA has not carried out any inspections regarding occupational exposure due to radon in the workplace because a notification has not been submitted to BNRA by MoH (see section 5.8). Measurement assessments regarding radon concentration have been performed in workplaces by MoH (NCRRP). For activities involving naturally occurring radioactive materials (NORM), BNRA carries out on-site inspections which includes the topic of occupational exposure. Compliance with requirements on existing exposure situations can also be performed through documented inspections by MoH (NCRRP).

All the inspectors in the Department of Radiation Protection are trained and qualified regarding the control of occupational exposure. The IRRS team was informed that the number of BNRA and MoH inspectors responsible for radiation protection inspections, which includes occupational exposure, is not sufficient because the number of activities the inspectors are responsible has significantly increased. This issue is further addressed in Recommendations **R5** and **R6** in Chapter 3.3.

Joint inspections carried out by inspectors from BNRA and MoH in nuclear and radiation facilities with SIR are possible but rare. Regarding occupational exposure, the scope of their inspections is not intended to overlap, but to complement each other. The IRRS team was informed by stakeholders that this is not clear and there appears to be overlap.

Cooperation between BNRA and MoH with regard to inspections on the subject of occupational exposure

The 2016 agreement between BNRA and MoH regarding inspections in facilities with SIR describes the planning and conduct of joint inspections, the coordination of joint activities and the information exchange between BNRA and Health Control authorities. The agreement is general and does not describe the details necessary for mutual cooperation in the areas of medical, occupational and public exposure. This issue is further addressed in Suggestion **S4** in Chapter 3.1.

There is no agreement between BNRA and MoH regarding inspections in nuclear facilities which is needed for the effective conduct of inspections in overlapping areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no formalized agreement between BNRA and MoH regarding inspections of occupational exposures at nuclear facilities.*	
(1)	**BASIS: GSG 12, para 4.46 states that** *"Where the responsibilities of the regulatory body and other organizations interact or have an interface, liaison between these bodies should be established by means of a formal agreement specifying each body's responsibilities, the areas of interface and the means for resolving any conflicts between different requirements. It should be ensured that no conflicting requirements are placed upon an authorized party."*
S18	**Suggestion: BNRA and MoH should consider developing an agreement for the conduct of inspections of occupational exposures at nuclear facilities.**

7.9. INSPECTION OF MEDICAL EXPOSURE

BNRA is responsible for the inspection of facilities and activities using sources of ionising radiation involving medical exposures to verify compliance with the "Regulation on Radiation Protection". The aspects related to medical exposure are inspected by MoH according to the requirements of Regulation No. 2. BNRA and MoH can conduct separate or joint inspections. The cooperation between the two organizations is defined in a MoU and an agreement document which describes the responsibilities of each during joint inspections.

For a description of BNRA's procedures for inspections of facilities and activities with radiation sources which involve medical exposures and are in line with the PIAFSIR, please see section 7.5. on inspection of radiation sources facilities and activities.

MoH conducts preliminary, planned, thematic and targeted (or responsive) inspections (Regulation No. 36) of facilities with ionizing radiation sources involving medical exposures. Inspection methods include document reviews, interviews, site observations, and activity monitoring. Equipment-specific requirements are addressed using tailored checklists.

Preliminary Inspections

During preliminary inspections, the state health radiation control verifies radiation safety when working with medical sources of ionizing radiation to determine compliance with the requirements in the Health Act. This applies to the design, construction and commissioning of facilities using ionising radiation sources for medical purposes (Regulation No. 36).

A report is issued by MoH to document compliance with the requirements of:

- Regulation No. 13, regarding radiation protection when working with X-ray devices for medical purposes.
- Regulation No. 6, concerning the design, implementation, and maintenance of buildings serving public needs in education, healthcare, culture, and the arts.
- Medical Standards for radiotherapy (Regulation No. 6), nuclear medicine (Regulation No. 11), and medical imaging (Regulation No. 9).

During preliminary inspections, compliance with the education, training, and qualification requirements for medical staff, as outlined in Regulation No. 2 and the Medical Standards, is verified. This includes confirmation of training certificates in radiation protection and medical certificates for the health surveillance of workers exposed to occupational radiation.

Inspections are performed using standard operating procedures with methods that include document reviews, interviews and on-site assessments. The readiness of a site for commissioning is confirmed through measurements.

Planned and Thematic Inspections

The frequency, type, and scope of planned inspections are outlined in annual plans, approved by the Director of the NCRRP or Regional Health Inspections (RHI), and are based on MoH guidelines and site-specific characteristics. Facilities are classified into three levels of risk (Regulation No. 36) and the frequency of inspections is defined accordingly.

Planned and thematic inspections verify compliance with medical standards including education, training and qualification requirements for staff (RPO, RPE, MPE, Radiographers, Physicians, etc.). During inspections, referral processes for radiological procedures, qualifications of prescribing physicians and confirmations by radiologists or specialists in nuclear medicine or radiotherapy are assessed.

Reactive (targeted) Inspections

Reactive health-radiation control is initiated in response to reported radiation incidents or accidents (Article 74, Paragraph 1 of Regulation No. 36). These inspections are conducted under orders from RHI directors and may involve representatives from other departments or organizations. The goal is to identify exposed individuals, assess health risks, refer them for specialized monitoring and, if necessary, perform biological dosimetry.

Inspection of Radiation Protection of Medical Exposure of Patients

During inspections of radiation protection of medical exposure of patients, the following aspects are verified:

- Dosimetric records for medical radiological procedures in patient and institutional medical documentation.
- Availability of the required minimum number of medical physics experts for quality assurance and radiation protection in radiotherapy, nuclear medicine and diagnostic imaging.
- Calibration and metrological checks of measuring instruments every two years.
- Existence and implementation of quality assurance programmes, including protocols for optimal equipment use developed with expert input.
- Dosimetric validation for new radiotherapy methodologies.
- Typical dose measurements for diagnostic and interventional X-ray procedures, as well as radiopharmaceutical activities in nuclear medicine compared to national diagnostic reference levels.
- Procedures for managing accidental or unintended exposure, including registration, analysis and follow-up.

- Radiation protection protocols for pregnant and lactating women.
- Written procedures for patient discharge after nuclear medicine examinations, including dose rate measurements at a 1-meter distance to ensure compliance with regulatory limits.

Once compliance has been confirmed, MoH issues a report of compliance which is later used for the licensee application to BNRA.

7.10. INSPECTION OF PUBLIC EXPOSURE

BNRA inspectors conduct inspections separately or together with representatives of other competent authorities authorised by the ASUNE. An important controlling authority is MoH. Consumer products involving radioactive material are controlled through a provision of the ASUNE, in which the person introducing the product submits specific information to the BNRA Chairperson and the Minister of Health for its intended use. Market surveillance is used to determine and assess consumer products with radioactive material. The Minister of Health, in collaboration with the BNRA Chairperson, can stop the sale or offering of consumer products that do not meet regulatory criteria.

The application of dose constraints in public exposure to radiation is crucial for BNRA. On-site inspections are performed for areas with higher public exposure risk. Radioactive releases from nuclear facilities are evaluated as part of facility design and are authorised through operating licences. Inspecting discharges from nuclear power plants and other facilities and activities are performed as a key component of safety programmes and includes procedures to monitor radioactive releases.

The inspections involving public exposures cover release limits, assessment of target values, release measurements, environmental radiation monitoring and repairs/modifications to radiation monitoring equipment through document review, interviews and on-site observations. The examination of discharges from nuclear power plants is a component of the safety inspection programme outlined in the Procedure for Inspection Activities in Nuclear Facilities, and it involves checking limitations and monitoring radioactive releases from the facility.

7.11. SUMMARY

BNRA conducts inspections of nuclear and radiation facilities and activities in accordance with approved inspection plans and procedures. The inspectors have the authority to conduct all types of inspections and to access the facilities at any time. BNRA inspectors conduct planned, reactive and announced inspections and issue a report to communicate the inspection findings to the authorised party.

The IRRS team observed that BNRA should improve the inspection procedures for the conduct of inspection activities for nuclear power plants, fuel cycle facilities, decommissioned facilities, waste management facilities, occupational exposure and transport. In addition, the methodology for developing the inspection programme for nuclear power plants should be updated to consider regulatory requirements in a comprehensive manner.

The IRRS team acknowledges BNRA’s efforts to update the training course on conflict-of-interest. BNRA should strengthen measures to maintain inspector independence throughout the inspectors’ careers.

The IRRS team identified that the NCRRP does not report all inspection findings regarding radiation source facilities to BNRA which is not in accordance with the agreement between BNRA and MoH. It was also noted that there is no formalized agreement between BNRA and MoH regarding inspections of occupational exposures at nuclear facilities.

The IRRS team concludes that BNRA has implemented strong inspection practices.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

BNRA enforcement powers are enabled by the national legal framework that includes the ASUNE and the Administrative Violations and Sanctions Act (AVSA). The ASUNE and the AVSA grant enforcement powers to the BNRA Chairperson and the Chairperson delegates specific authorities to the inspectors, to carry out control under the ASUNE and the secondary legislation on its implementation. The IRRS team noted that the enforcement instruments are outlined in the legislation and allow for the application of the graded approach in addressing situations that require corrective actions.

BNRA enforcement capability includes a wide variety of enforcement actions and allows for the possibility of prosecution. The inspectors may issue written recommendations or written instructions for ensuring nuclear safety and radiation protection in the inspection report. The inspectors may also propose that the Chairperson impose an order, administrative penalty, written warning, stop work, limit activity and revoke an authorization. The Chairperson may also impose enforcement measures to address unforeseen situations or risks that are emergent. BNRA does not have the capability to issue verbal enforcement actions and must communicate enforcement in writing.

The Chairperson may also inform other government departments of inspection findings that are under their organization's mandate. The Chairperson may also recommend prosecution in the event that a crime has been committed. The IRRS team notes that appropriate enforcement measures are available and implemented in accordance with the graded approach.

BNRA has established an enforcement policy that is outlined in the document, QMS-IA-P-04/2, Procedure for the Implementation of the Administrative Penal Activity (PIAPA). The PIAPA outlines the programme for implementation of the available enforcement actions. However, the IRRS team noted that the procedure does not include information on all enforcement powers and mechanisms outlined in the Acts, for example, coercive measures under the ASUNE and violations under the AVSA. Coercive measures include the ability to stop work, limit an activity, revoke an authorization, perform testing of a facility and amend the design for emergency measures, etc. The IRRS team noted that BNRA has established a working group that is currently updating the procedure with all the missing enforcement actions. This issue has been self-identified in the ARM and in the action plan.

The IRRS team considers that the enforcement policy should be updated to reflect all enforcement mechanisms in a comprehensive manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The enforcement policy does not include all enforcement actions that can be exercised by BNRA pursuant to the national legal framework.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
R12	**Recommendation: BNRA should update the enforcement policy to include all enforcement actions.**

8.2. ENFORCEMENT IMPLEMENTATIONS

According to the related provisions of the national regulatory framework, BNRA may impose coercive measures, including penalties, depending on the nature of the violations and their impact on radiation protection and safety in nuclear facilities and activities. Based on the findings of the inspections, BNRA inspectors may issue written prescriptions, draft a statement of establishment of the administrative violation (SEAV), propose to the BNRA Chairperson to issue an order to impose coercive administrative measures and make proposals for amendment, suspension, termination and revocation of authorizations. The BNRA Chairperson considers the Protocol of findings and PIAPA before imposing coercive administrative measures. The IRRS team noted that all orders are subject to appeal.

Prescriptions are mandatory for the authorised parties and include instructions for performing the activities in line with the related regulatory requirements and authorization conditions. The authorised parties are required to implement corrective actions in a certain period of time and notify BNRA. Failure to complete the implementation of the prescription in the specified period constitutes an administrative violation for which an administrative penalty may be imposed.

BNRA inspectors draft the SEAV in collaboration with a lawyer and it is issued to the offender for signing or noting any objections (orally or in writing). Within 14 days from its delivery, the statement is forwarded to the BNRA Chairperson with a proposal for issuing a penal decree.

The BNRA Chairperson may also issue an order for the imposition of coercive administrative measures that shall be taken within a certain period of time. These measures can include suspension or restriction of the activity for which an authorization has been issued, a notification has been submitted or a registration has been made; or an order to carry out a modification of established limits and conditions of operation, or amendments to the structures, systems, and components related to safety, etc.

For administrative violations envisaged in the ASUNE, the BNRA Chairperson can issue a penal decree, based on the suggestion of an inspector, imposing administrative penalties for individuals and property sanctions for legal entities.

The IRRS team noted that BNRA inspectors do not have the powers to immediately issue enforcement verbally or in writing in the event of a situation where there is clear and present danger. The practice at the nuclear facilities is that the inspector may speak with the manager of the ongoing work and request that they take action. The inspectors must issue a written prescription in order to communicate that corrective action is required. The inspector may recommend to the Chairperson to impose enforcement actions.

The IRRS team reviewed several examples of inspection reports with recommendations and proposals to the Chairperson to issue an order to address administrative violations. The IRRS team also reviewed an example of a prosecution that was referred to the Chairperson for issuing enforcement action as per the mandate of BNRA. The IRRS team noted that the enforcement actions were effectively applied to the situation in consideration of the graded approach. During the site visits, it was also observed that the interactions between the authorised parties and BNRA allowed for appropriate discussions and indicated the effectiveness of the graded approach to enforcement. The authorised party also demonstrated open communications with regards to self-reporting to BNRA.

The IRRS team also noted that the possibility to appeal a decision or enforcement action is available to authorised parties. In keeping with the graded approach, there were several opportunities for the authorised parties to discuss items of concern with BNRA before escalating to a severe level of enforcement.

8.3. SUMMARY

BNRA effectively implements enforcement measures and applies the graded approach. The BNRA enforcement policy, outlined in the Procedure for Implementation of the Administrative Penal Activity, reflected some of the enforcement capability of BNRA but should be updated to comprehensively reflect the enforcement capability of BNRA as enabled by the national legislation.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The nuclear legislation of Bulgaria is mainly based on the ASUNE and 19 regulations, which are secondary level legislative acts with their legal basis in the ASUNE. BNRA has a regulatory framework associated with the state regulation of the safe use of nuclear energy and ionizing radiation and with the safety of radioactive waste management and spent fuel management.

According to the ASUNE, the BNRA Chairperson develops and submits draft regulations for the application of the Act to the Council of Ministers for adoption through consensus. BNRA has no independent authority to issue the regulations themselves.

BNRA has the authority to issue regulatory guides that implement associated regulations. The basis for the development of regulatory guides is in the corresponding regulations.

The ASUNE specifies the areas that have to be covered by regulations and provides their legal basis.

The processes to develop, amend and revise regulations and regulatory guides are very well described in two internal procedures established by BNRA, in 2003 and 2009, respectively:

- QMS-RG-P/01/01 “Procedure on Development of Legislative Acts (Regulations)” and
- QMS-RG-P/02/01 “Procedure on Development of Regulatory Safety Guides”.

The internal review periods are 2 years for regulations and 5 years for regulatory guides.

The procedures QMS-RG-P/01/01 and QMS-RG-P/02/01 were last revised in 2013 and 2015, respectively. These procedures provide appropriate guidance to BNRA staff for these activities.

There are two periodically renewed 3-year programmes for review and development of regulations and regulatory guides, the Programme for Review and Development of Statutory Instruments Related to Nuclear Safety, Radiation Protection, Physical Protection, Emergency Planning and Response and the Programme for Review and Development of Regulatory Safety Guides, both presently for the period of 2024 to 2026 (endorsed by the chairperson of BNRA, order RD-22-38/19.02.2024).

The review process is based on a review report to the Chairperson by the responsible department followed by an order from the Chairperson to the responsible department. The review report indicates the potential reasons for a revision together with a suggestion of reaffirmation or revision of the document. In case of a suggested revision, the review report lists the issues to be revised (together with the corresponding documents in an annex), a timeline, as well as the participants and leader of a responsible task force.

Regulations

After a decision to develop a new regulation or to revise an existing regulation, the BNRA Chairperson forms a task force and identifies a task leader. If other ministries are affected by the contents of the regulation, BNRA may ask them to join in the task force. Potential interested parties are informed and asked for their input at the beginning of the development or revision process.

The process is well structured with a clear timeline. Once a first draft exists, it is distributed to the interested parties for preliminary commenting. At this stage the advisory bodies of the BNRA Chairperson (Advisory Council on Nuclear Safety and Advisory Council on Radiation Protection) can be involved. Once the internal process is finished, the final draft is delivered to the different ministries and published on BNRA’s website and the portal for public consultations and commenting. In addition, potential interested parties are informed of the final draft by BNRA directly through email-lists. The commenting period is a minimum of two weeks. All comments received are tabled and the questions are resolved with the commentators. In case of contradicting comments, meetings are held to resolve the issue. Once a consensus has been reached, the commentators receive the table of comments including the resolved answers. Finally, the revised draft –

together with additional material, especially the table of comments - goes to the Council of Ministers (CM) and is adopted, provided unanimous approval is obtained. Approved regulations are promulgated in the State Gazette and published on BNRA's website. Regulations are periodically (two years at the latest) reviewed.

The internal Procedure on Development of Legislative Acts (Regulations) is well developed, and the relatively short period of two years for review is outstanding but also very challenging.

Regulatory Guides

The Procedure on Development of Regulatory Guides is generally similar to the one for regulations, with the main difference being issuance of regulatory guides is performed by BNRA itself.

Issued regulatory guides are periodically reviewed (5 years at the latest).

The current practice of developing only very few regulatory guides with additional administrative instructions in licences and permits is not considered optimal. For a potential applicant for the construction and operation of a nuclear power plant, an SMR or any other nuclear facility could not obtain the detailed guidance and the associated criteria beforehand but only by steps during the licensing process (permit by permit). This leads to regulatory uncertainty for potential applicants.

The IRRS team is of the view that BNRA should develop appropriate regulatory guides to describe and make available acceptable methods to fulfil the principles and requirements of the regulations. Regulatory guides should contain detailed guidance and the acceptance criteria associated with the requirements. This issue was partly identified in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no complete set of regulatory guides at BNRA to provide sufficient regulatory guidance to the applicants and licensees to ensure compliance to regulatory requirements.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 34 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
S19	**Suggestion: BNRA should consider developing additional regulatory guides to describe acceptable methods to ensure compliance with the requirements of the regulations.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Fundamental legal requirements for nuclear power plants are established in the ASUNE. Article 33 states that, "the site and selected technical design shall be approved by an order of the NRA Chairperson when they meet all nuclear safety and radiation protection requirements, standards and rules […]". The ASUNE also specifies that a separate licence or a separate permit for design, construction and commissioning shall be issued for each unit and for any other nuclear facility on the site of a NPP.

A major recent amendment of the ASUNE – switching from operating licences valid for 10 years to unlimited licences combined with periodic safety reviews every 10 years triggered the revision of several existing regulations and regulatory guides.

Specific safety requirements to the site, the site selection process, the NPP design, the construction of NPPs (including NPP safety systems, operating systems, RAW management systems, etc.), the commissioning of NPPs and operation of NPPs are specified by the Regulation on Ensuring the Safety of NPPs. This regulation is presently revised with due consideration of the IAEA Safety Standards, the relevant EU directives and the WENRA reference levels for operating NPPs.

The regulations are detailed in the following regulatory guides:

- Regulatory Guide on Internal Fire Protection in Nuclear Power Plants (2023)
- Regulatory Guide on Deterministic Safety Assessment of Nuclear Power Plants with Pressurized Water Reactors (2022)
- Regulatory Guide on PSA Application in NPP Safety Management (2023)
- Regulatory Guide on PSA of Nuclear Power Plants (2010)
- Regulatory Guide on Safe Operation of Nuclear Power Plants (2011)
- Regulatory Guide on PSR of Nuclear Power Plants (2018)
- Regulatory Guide on Ageing Management of Structures, Systems and Components of Nuclear Power Plants (2018)
- Regulatory Guide on Qualification of Structures, Systems and Components Important to the Safety of Nuclear Power Plants (2021)
- Regulatory Guide on Determining the Importance of Operational Events in Terms of Nuclear Safety and Radiation Protection (INES scale level) (2021)

The regulations (and corresponding regulatory guides) cover most requirements of IAEA and WENRA on reactor operation, specifically:

- Operational limits and conditions
- Personnel qualification and training
- Monitoring of safety performance
- Accident management
- Operating procedures
- Maintenance, testing, surveillance and inspection
- Qualification of SSCs important to safety
- Fire protection in nuclear power plants
- Deterministic safety assessment of NPPs with pressurized water reactors
- PSA application in NPP safety management.

For reactor operation BNRA is currently revising the Regulatory Guide on Safe Operation of NPPs.

The need for an effective safety management system is already stated in the ASUNE. Specific requirements are provided by the Regulatory Guide on Management Systems for Facilities and Activities (issued 2011 and not revised since).

The development of regulatory guides was not given a high priority so far as there are only two very similar types of NPPs in Bulgaria located at Kozloduy: So far, the regulatory guides issued contain only high level guidance. Detailed guidance and the criteria associated with the requirements that one would expect to be available in regulatory guides are part of the licence conditions (Appendix 2 of the Operating Licence of the nuclear power plant Kozloduy). Presently, for BNRA this administrative instruction process is a practical alternative to issuing a greater number of regulatory guides. Detailed requirements and associated criteria are also included in the permits issued as part of the licensing process (e.g. the siting permit and the design permit).

Aware of potential challenges in the near future due to the new build projects of advanced NPPs and SMRs, especially one or two AP 1000 reactors at the Kozloduy site and the private interest in building one or more

SMRs for the supply of electrical power and industrial steam at an industrial site, BNRA supported by TSOs is working proactively on a concept to adjust the regulatory framework to this new situation. It is anticipated by BNRA that the regulations for NPPs need to be revised to have more general requirements and be detailed by regulatory guides covering specific topics for specific types of plants. Work on a report analysing these challenges and suggesting solutions has been started to be in a good position for decisions on further activities as soon as possible.

BNRA identified that during the ongoing revision of the Regulation on Ensuring the Safety of Nuclear Power Plants and the Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy, as well as the Regulatory Guide on Safe Operation of Nuclear Power Plants – triggered by an amendment of the ASUNE - the new versions of the IAEA Safety Standards, the EU Basic Safety Standards Directive (Council Directive 2013/59/Euratom) and the updated WENRA safety references should also be taken into account.

The IRRS team noted that despite a review frequency of 2 and 5 years for regulations and regulatory guides respectively, a timely adoption of changing international requirements does not always seem to be followed in a systematic manner. Necessary revisions of regulations, regulatory guides and procedures due to changes and developments in international requirements in a systematic and timely manner seem to be lacking.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing processes of review and revisions of regulations and regulatory guides are not being followed in a systematic and timely manner by BNRA.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
S20	**Suggestion: BNRA should consider implementing the processes of review and revision of regulations and guides in a systematic and timely manner.**

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The ASUNE establishes the context and framework related to management of spent fuel.

The general requirements for ensuring nuclear safety and radiation protection in spent nuclear fuel management are included in the Regulation for Ensuring the Safety in Spent Nuclear Fuel Management. This regulation specifies the criteria relating to:

- Requirements for ensuring nuclear safety and radiation protection in spent nuclear fuel management;
- Requirements for all stages of the facilities' life-cycle for management of spent nuclear fuel – site selection, design, construction, commissioning, operation and decommissioning;
- Specific requirements for the design and operation of facilities for spent nuclear fuel management with "pool-type" and "dry" storage technology.

BNRA is entitled to issue regulatory guides to provide sufficient regulatory guidance to applicants and licensees to ensure compliance with the requirements specified in the Regulation for Ensuring the Safety in Spent Nuclear Fuel Management. However, no regulatory guide regarding the fulfilment of these requirements has been published. This issue is further addressed in Suggestion **S19** in Chapter 9.1.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The national legislative and regulatory framework for regulating radioactive waste management facilities covers all the stages of their lifecycle. In addition to the more specific regulations for waste management facilities, the regulatory requirements for nuclear facilities also apply to waste management facilities as described in section 9.1.

The framework for radioactive waste management and spent fuel management activities includes the following:

- ASUNE
- Regulation on Safe Management of Radioactive Waste
- Regulation for Safety of Spent Fuel Management
- Regulation on Conditions and Procedure for Transfer of RAW to the State Enterprise "Radioactive Waste"
- Regulation for Radiation Protection

In Bulgaria there is no disposal facility in operation. However, the near surface disposal facility is in the late stages of construction and a deep geological repository for disposal of long-lived intermediate and high-level radioactive waste is envisaged.

The IRRS team observed that in the Regulation on Safe Management of Radioactive Waste there are general provisions for the different types of disposal facilities and more specific requirements for siting of a near surface disposal facility. However, in order to implement the route for management of long-lived intermediate level waste and high-level waste, specific requirements for safety of a deep geological repository must be established. The development should take into account the different steps of the licensing process (siting, design, construction, operation, closure and post-closure).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no specific requirements for long-lived intermediate and high-level waste which will be disposed of in a deep geological repository.*	
(1)	**BASIS: SSR-5 Requirement 2 para 3.8 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
S21	**Suggestion: BNRA should consider developing specific requirements for long-lived intermediate and high-level waste.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The ASUNE sets the requirements for the regulatory control of all the facilities and activities with radiation sources. It defines the types of authorizations required for the different types of facilities and activities, as well as the information that shall be submitted to BRNA by applicants or authorization holders. The procedure and the required documentation for the authorization of facilities and activities are also described in the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy.

BNRA has developed the following regulations related to facilities and activities with radiation sources:

- Regulation on Radiation Protection
- Regulation on the Conditions and Procedure for Notification of the Nuclear Regulatory Agency about Events in Nuclear Facilities and Sites with Sources of Ionising Radiation and during Transport of Radioactive Material
- Regulation on Radiation Protection in Industrial Radiography
- Regulation on Radiation Protection During Work Activities with Materials with Increased Concentration of Natural Radionuclides
- Regulation on the Terms and Conditions for Acquiring Professional Qualification and on the Procedure for Issuing Licences for Specialized Training and Certificates of Competency for the Use of Nuclear Energy.

All the regulations under the ASUNE for activities with sources of ionising radiation are based on a graded approach, in line with the Regulatory Guide on Application of a Graded Approach to Activities with Sources of Ionising Radiation.

The IRRS team was informed that guidance addressing the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources is not in place.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no guidance for the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.*	
(1)	**BASIS: GSR Part 3 Requirement 3, para. 2.37 states that** *"The regulatory body, in consultation with the health authority, shall ensure that provisions are in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency."*
S22	**Suggestion: BNRA in consultation with MoH should consider developing a guidance for the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.**

Moreover, BNRA has developed the following regulatory procedures and instructions:

- Procedure for Applying the Authorization Regime for Activities with Sources of Ionizing Radiation
- Procedure for Inspection Activity in Sites with SIR
- Procedure for Implementing an Administrative Penalty Activity in BNRA
- Instruction for Monitoring the Safety Culture of Licensees
- Procedure for Regulatory Review of Documents for Activities with SIR

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The regulatory framework regarding decommissioning activities is covered by the ASUNE and the regulations that apply to nuclear installations and nuclear power plants also apply during decommissioning, as described in sections 9.1 and 9.2. The specific regulation i.e. the Regulation on Safety during Decommissioning of Nuclear facilities addresses specific issues related to safety during decommissioning activities including requirements for decontamination of a facility, waste management and the decommissioning plan.

BNRA has developed the following specific regulatory guides in order to facilitate its regulatory functions related to decommissioning activities:

- The Regulatory Guide on Structure and Content of Decommissioning Plan.
- The Regulatory Guide on Release from Regulatory Control of Buildings and Sites

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

According to the ASUNE, transport activities are performed on the basis of a licence or permit and these activities are under BNRA's regulatory control. The Regulation for Issuing Licences and Permits for Safe Use of Nuclear Energy contains the specific requirements for a transportation licence or permit. The primary regulation regarding the transport of radioactive material is the Regulation on the Conditions and Procedure of Transport of Radioactive Material, which mainly based on the 2005 edition of the IAEA transport regulation TS-R-1. The transport regulation also contains requirements for more general regulations for the transport (e.g. by road) of dangerous goods issued by the Ministry of Transport (MoT), which apply to the transport of radioactive materials and are in line with international modal regulations for transport of dangerous goods (ADR, RID, etc.). BNRA develops the transport regulations in coordination with other relevant authorities such as MoT among others.

IAEA performs periodic review and update of its transport regulations, and the current regulations were updated in 2018 as SSR-6. There have been previous updates in 2012 and 2009. Regulations in Bulgaria are reviewed every two years as part of the process described in BRNA Procedure for Development of Regulatory Documents (QMS-RG-P-01/1). However, the Bulgarian transport regulations have not been updated since 2014 and are currently based on the IAEA transport regulations from 2005. This has the potential to result in denial or delay of shipment in international commerce due to the discrepancies between specific requirements of the transport regulations and IAEA transport regulations. Examples include the fissile exception criteria and no transitional arrangements, ageing management, and compliance assurance requirements to the transport regulations and radiation doses to persons due to transport. The compliance assurance discrepancies have already been identified by BNRA and included in the initial action plan prepared for the mission.

BNRA has undertaken past efforts to update the transport regulations but those have not been completed. There is a current effort to update the transport regulations in which the first step has been completed to analyse for compliance with SSR-6, Revision 1. The IRRS team encourages BNRA to continue this process to update the transport regulations to completion even as the IAEA transport regulations are currently being revised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current transport regulations are not up to date in line with international transport requirements on the transport of radioactive materials.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 33 states that** *"Regulations and guides shall be reviewed as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
S23	**Suggestion: BNRA should consider updating their transport regulations in line with the IAEA's SSR-6.**

BNRA has developed a comprehensive regulatory guide related to transport of radioactive material. The Regulatory Guide on the Application of the Requirements for Safe Transportation of Radioactive Materials (PP – 19/2018) contains guidance in many areas for both applicants for licences and permits as well as for consignors, carriers, and consignees and their implementation of the transport regulations for shipments. For applicants it includes for example, guidance on the radiation protection programme, emergency planning and response, the management system, and training among other areas. Additional guidance is also found on BNRA website that includes templates and a checklist for applicants to ensure it is clear what information is required to apply.

BNRA has also issued guidance on the management of non-conformities during transport in the Regulatory Guide on Safe Transport of Radioactive Materials – Management of Non-Conformities (PP – 14/2016). This provides specific guidance on actions to be taken in the event of non-compliance when transporting radioactive material to prevent and limit the possible consequences of any non-compliance found, including investigation, corrective actions, and notification of BNRA. The IRRS team considers the guidance for transport an area of good performance.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The regulatory framework for occupational exposure is mainly based on the ASUNE, the Health Act, the Regulation on Radiation Protection (RRP) issued by BNRA and Regulation No. 32 issued by MoH on the Conditions and Procedure for Individual Dosimetric Control of Persons Working with Sources of Ionising Radiation. There are also additional regulations specific to certain activities with complementary requirements regarding occupational exposure (e.g. Regulation on Radiation Protection in Industrial Radiography). The IRRS team was informed that stakeholders could be involved by BNRA in the process of elaboration of these additional specific regulations. These acts and regulations are in compliance with the Directive 2013/59/EURATOM.

This regulatory framework requires justification for the use of ionising radiation, the optimisation of radiation protection of individuals subject to occupational exposure and establishes dose limits for occupational exposure. It also requires the monitoring and recording of occupational exposure, compliance by workers, cooperation between employers and authorised persons (undertakings) and the designation of a radiation protection officer (RPO) to undertake functions and obligations with respect to radiation protection supervision and to perform relevant radiation protection tasks. For workers who are not regular employees of the licensee, the allocation of responsibilities of the employer and the undertaking for protection and safety is clearly addressed in the RRP. The IRRS team was informed that individual doses are considered personal data and the confidentiality of exposure records by the employers is guaranteed through the national general act on protection on personal data. Individual dosimetric control of external and internal irradiation must be carried out by dosimetric laboratories accredited for this activity by the Executive Agency “Bulgarian Accreditation Service” under ISO 17020.

The radiation protection programme in Bulgaria can also be called the radiation protection instruction. Typical content of the radiation protection instruction for SIR facilities is found in the RRP. For NPPs, the topics that shall be covered by the radiation protection programme are listed in the Regulation on Ensuring the Safety of Nuclear Power Plants.

The regulatory framework also requires the assessment of occupational exposure and workers’ health surveillance. The medical surveillance, including initial and periodic medical examinations of Category A or Category B workers, is mandatory to determine their medical fitness for the work. The periodic medical examination is performed at least once a year, in order to determine whether the respective workers are still in a health condition allowing them to perform their assigned duties.

The statutory obligation under the ASUNE requires that activities at nuclear facilities and involving sources of ionising radiation are to be performed solely by professionally qualified personnel holding a certificate

of competency. For this purpose, personnel undergo initial and supporting specialized training in accordance with curricula developed for each specific position. The Regulations on the Terms and Conditions for Acquiring Professional Qualification and on the Procedure for Issuing Licences for Specialized Training and Certificates of Competency for the Use of Nuclear Energy (RTCAPQPILSTCCUNE) establishes the requirements for selection and qualification of personnel for carrying out activities in nuclear facilities and with SIR. There are also requirements in the RRP regarding the information, instruction and training for protection and safety. However, it doesn't clearly require employers, registrants, and licensees to prohibit benefits as substitutes for measures of protection and safety. According to BNRA, this would be identified by the relevant competent authorities (BNRA, MoH, Ministry of Labor) during the periodic review and assessment of the radiation protection programme and would be punishable by law.

The RRP states that workers undertaking remedial actions shall be subject to radiation protection requirements for planned exposure situations. It also covers occupational exposure at working places due to existing exposure situations (remediation of areas with residual radioactive material, radon in workplaces, air crew). As Bulgaria doesn't send people into outer space, no regulatory framework has been established for radiation protection of individuals in space-based activities.

The RRP also establishes that the licensees shall ensure operational radiation protection based on classification of areas and premises, classification of workplaces and access regimes. The licensees shall exercise supervision over the compliance with the radiation protection requirements established for the controlled areas by the respective internal documents (instructions, rules, orders, procedures) and by the license and permit conditions.

The RRP establishes special arrangements regarding protection and safety for pregnant and breastfeeding female workers. Special arrangements also exist regarding the dose limits and operational radiation protection for apprentices and students between 16 and 18. The Act on vocational education and training and the Regulation on the Conditions and Procedure for Conduct of Training through Work (dual training system) specify that the practical training under an employer in a real working environment shall be conducted in the relevant licensees under the guidance of a mentor designated by the employer. The mentor shall supervise the implementation of assigned tasks, shall provide practical advice during work and shall evaluate the effectiveness of implementation. The public register of licensees which perform dual training is maintained by the Minister of Economy and Industry. Currently the Kozloduy NPP is the only licensee which is allowed to perform the dual training in environment of ionizing radiation. The IRRS team was informed that the requirement that persons under the age of 18 years are allowed supervised access to controlled areas is established in the document: The Rules of safety, radiation protection in Kozloduy NPP (ID: 10.P3.00ПВЈІ.067)

However, there is no explicit regulatory provision ensuring that persons under the age of 18 are allowed access to a controlled area only under supervision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Regulatory requirements do not ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision.*	
(1)	**BASIS: GSR Part 3, Requirement 28, para. 3.116 states that** *"Employers, registrants and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S24	**Suggestion: BNRA should consider introducing a requirement ensuring that persons under the age of 18 years are allowed access to controlled areas only under supervision.**

As the regulations within the regulatory framework for occupational exposure are detailed, BNRA has determined it is not necessary to publish specific guidance documents in this area. However, some guidance on occupational exposure is included in the Regulatory Guide on Application of a Graded Approach to Activities with Sources of Ionising Radiation.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The regulatory requirements for facilities and activities for the use of ionising radiation sources involving medical exposures are defined in the ASUNE and in the RRP. The ASUNE also defines the types of authorizations required for facilities and activities using ionizing radiation for medical exposures and the information required for submission of the application for authorization to BNRA. Section 9.5 on regulations and guides for radiation sources facilities and activities describes the template documents for application for authorization and guidance documents published by BNRA, which are also valid for facilities and activities which use ionising radiation sources involving medical exposures. The legal framework for specific medical exposure regulatory control is based on the Health Act and on the Regulation No. 2. The Health Act also includes regulations for medical standards in radiotherapy, nuclear medicine, and medical imaging:

- Regulation No. 13, regarding radiation protection when working with X-ray devices for medical purposes.
- Regulation No. 6, concerning the design, implementation, and maintenance of buildings serving public needs in education, healthcare, culture, and the arts.
- Medical Standards for radiotherapy (Regulation No. 6), nuclear medicine (Regulation No. 11) and medical imaging (Regulation No. 9).

The regulatory requirements for the competency of health care workers in radiation protection of medical exposures are defined in Regulation No. 2. This regulation also specifies the duties of the Medical Physicist and the Medical Physicist Expert and the requirements for their qualification. General requirements concerning justification of the use of radiation are given in Section II, Justification of Medical Exposure in Regulation No. 2. However, MoH has not issued any guidance documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *MoH has not issued guidance documents to assist registrants and licensees to implement the principles of radiation protection for all medical exposure situations.*	
(1)	**BASIS: GSR Part 3 Requirement 3, para. 2.29 states that** *"The regulatory body shall establish requirements for the application of the principles of radiation protection specified in paras 2.8–2.12 for all exposure situations and shall establish or adopt regulations and guides for protection and safety."*
S25	**Suggestion: MoH should consider establishing guidance for the protection and safety of medical exposures.**

MoH does not have any guides to assist registrants and licensees to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures, and that unintended or accidental medical exposures shall be promptly investigated and, if appropriate, corrective actions shall be implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *MoH does not have guidance for registrants and licensees to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures and to promptly investigate unintended or accidental medical exposures.*	
(1)	**BASIS: SSG-46, para. 2.82. states that** *"Unintended and accidental medical exposures do occur, and the regulatory body is required to ensure that a system is put in place and all practical measures are taken to prevent such exposures, and, if such an exposure does occur, that it is properly investigated and corrective actions are taken (Requirement 41 of GSR Part 3 [3]). Arrangements should be put in place to respond promptly in order to mitigate any consequences. The regulatory body should require written records to be kept of all unintended and accidental medical exposures and should provide guidelines on what information is to be included in these reports. The more significant events are required to be reported to the regulatory body (para. 3.181(d) of GSR Part 3 [3]). The regulatory body should provide guidance on which events should be reported to them."*
S26	**Suggestion: MoH should consider developing guidance to assist registrants and licensees to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures, to promptly investigate unintended or accidental medical exposures and, if appropriate, implement corrective actions.**

MoH has not issued guidance documents for the release of patients who have undergone therapeutic radiological procedures with implanted sealed sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *MoH has not issued guides for the release of patients who have undergone therapeutic radiological procedures with implanted sealed sources.*	
(1)	**BASIS: GSR Part 3 Requirement 34, para. 3.149(b) states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:* *(…)* *(b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources."*
S27	**Suggestion: MoH should consider developing guidelines for the release of patients who have undergone therapeutic radiological procedures with implanted sealed sources.**

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Regulations have been established for public exposures in the Republic of Bulgaria. Clearance levels for workplaces handling sources of ionising radiation have been established in the ASUNE and further elaborated on in associated regulations. The Regulation on the Procedure for Issuing Licences and Permits for the Safe Use of Nuclear Energy includes conditions for controlling discharges, monitoring the environment and evaluating the radiation impact on the public. The ASUNE also allows for protection of the public from planned exposure situations where the release of radioactive substances is governed by the ASUNE, the RRP, and the Regulation on the Safety of Nuclear Power Plants. BNRA regulatory framework makes provision for guidance on public exposure through RG-15/2016 - Regulatory Guide on Criteria for Authorization and Control of Radioactive Discharges and for Environmental Monitoring.

The RRP states that radioactive materials from regulated activities can be released without restriction if the specific activities of radionuclides do not exceed clearance levels. The clearance levels for release of radioactive materials do not apply to discharges to the environment or residues from industrial activities. The dose limits for public exposures include the summary from internal and external exposures for a year from all authorised facilities and activities. The effective dose limit for the public is 1 mSv per year. The RRP stipulates that nuclear energy and ionising radiation shall be used in accordance with nuclear safety and radiation protection requirements and principles with a view to ensuring the protection of human life, health and the living conditions of the present and future generations, the environment and property against the harmful impact of ionising radiation.

The Minister of Health, through the NCRRP, is responsible for evaluating the doses of external and internal exposure of the public and representative individuals. Enterprises conducting activities involving the discharge of radioactive substances into the environment must conduct radiation monitoring and assess emissions from nuclear facilities. They are required to report the results to the Minister of Health and the BNRA Chairperson.

The RRP states that the reference level for radon in air of dwellings and public buildings is 300 $Bq.m^{-3}$ and if this level is exceeded, measures must be taken to reduce radon levels in buildings.

9.11. SUMMARY

There are regulations in the areas of BNRA's competence for the regulatory oversight of nuclear and radiation facilities and associated activities, however, the guides are not comprehensively developed.

Regulations and guides are generally in line with IAEA safety standards and other relevant international requirements, however, in many cases do not provide detailed requirements and the associated criteria. The need for new and more detailed regulatory guides is seen for many technical areas of the licensing and supervision processes.

The procedures to develop, amend and revise regulations and regulatory guides are comprehensive. Well-defined review periods trigger regular reviews and updates which, for the most part, help to keep regulations and guides up to date. However, not all regulations and guides have been updated with regard to changed IAEA requirements, e. g. in the area of medical exposures, transport, radioactive waste management etc. This necessary update should be an area of focus to ensure meeting international requirements.

A plan on how to deal with foreseen challenges due to probable new build of advanced reactors and SMRs is being developed and can lead to further improvements of the overall regulatory system.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

Emergency preparedness and response in case of a nuclear or radiological event is part of the general national arrangements for protection in case of a disaster. The main legislative and regulatory requirements for the structure and organization of emergency preparedness are specified in the Disaster Protection Act (DPA), the ASUNE, Ministry of Interior Act (MIA), Regulation on Emergency Planning and Emergency Preparedness in case of Nuclear and Radiological Emergencies (REPEPNRE) and RRP.

The roles and responsibilities for emergency preparedness and response (EPR) in case of a nuclear or radiological emergency are specified and assigned in the DPA, the ASUNE, REPEPNRE, RRP and off-site emergency plan of KNPP.

According to Article 123 of the ASUNE, BNRA has joint responsibility with the MoI to propose regulations defining the regulatory requirements for emergency preparedness and response in the event of a nuclear or radiological emergency. The REPEPNRE defines the terms and procedures for development of emergency plans, the persons applying emergency plans, allocation of their responsibilities, the provisions to mitigate and eliminate the consequences, the arrangements for warning of the public, as well as measures for testing emergency preparedness and the requirements for emergency planning areas.

According to the ASUNE provisions, BNRA carries out EPR regulatory and response activities. Its organizational structure is based on the BNRA Rules of Procedure which includes the responsibilities of BNRA in EPR and describes the organizational structure, functions and number of personnel. The IRRS team noted that there is a dedicated "Emergency Planning and Preparedness Division" which is responsible for EPR regulatory oversight activities related to the nuclear facilities and includes 5 staff positions. There are currently 2 vacant positions and there are difficulties finding suitable specialists. According to the Rules of Procedure of BNRA act, this structure should implement the following responsibilities:

- Planning and carrying out inspections;
- Conducting assessments for compliance with the regulatory requirements;
- Participation in the Emergency team, under the authority of the BNRA Chairperson, for action in case of an accident and transboundary transfer of radioactive substances;
- Organises the training of the members of the Emergency team of BNRA;
- Control the implementation of the conditions of issued licences and permits for activities in nuclear power plants, SNF facilities and RAW management facilities;
- Participation in the preparation of draft regulations;
- Develops BNRA Emergency plan in case of a nuclear or radiological emergency, maintains emergency preparedness and participates in national and international exercises for emergency response.

The BNRA Radiation Protection Department is responsible for carrying out regulatory activities for facilities using sources of Ionising Radiation. Based on the BNRA Rules of Procedures, it carries out regulatory control to verify the compliance of the on-site EPR arrangements of operating organizations with the regulatory requirements – ASUNE, REPEPNRE, RRP, etc.

According to the Procedure for Inspection Activity in Facilities with Sources of Ionising Radiation, the SIR Division performs inspections to assess radiation protection and emergency planning and preparedness of facilities and activities with sources of ionising radiation and sites with radioactive substances.

The process for development of the EPR regulations is not clear, including how potential conflicts are solved during the development. In addition, a coordination mechanism to harmonise the potential findings identified during inspection by BNRA and FSCPGD and how the results of the separate inspections are

shared between these organizations to ensure consistency among requirements for emergency arrangements is not in place.

The on-site Emergency Response Plan is approved by the 5 national organizations including BNRA. However, there is no clear process for approval of the on-site plan, considering the plan should be approved during the licensing process.

The responsibilities for development, implementation, and maintenance of the BNRA EPR programme and the EPR regulatory activities are assigned to the Emergency Planning and Preparedness Division. This Division is composed by 5 positions, of which 2 are currently vacant. Therefore, not all the responsibilities are discharged in an effective manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Emergency Planning and Preparedness Division lacks staff to effectively carry out its responsibilities effectively.*	
(2)	**BASIS: GSR Part 7 Requirement 2 para. 4.8 states that** *"The government shall ensure that response organizations, operating organizations and the regulatory body have the necessary human, financial and other resources, in view of their expected roles and responsibilities and the assessed hazards, to prepare for and to deal with both radiological and non-radiological consequences of a nuclear or radiological emergency, whether the emergency occurs within or beyond national borders."*
S28	**Suggestion: BNRA should consider analysing the workload of the EPR division and increase the number of positions with required staff accordingly.**

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

The main regulations and guides that include requirements to be implemented and fulfilled by the operating organizations are:

- ASUNE
- Regulation on Emergency Planning and Emergency Preparedness in Case of Nuclear and Radiological Emergencies
- Regulation on Radiation Protection;
- Regulation on the Procedure of Issuing Licences and Permits for the Safe Use of Nuclear Energy;
- Regulation on Ensuring the Safety of Nuclear Power Plants;
- Regulation on Safe Management of Radioactive Waste;
- Regulation on the Conditions and Procedure for Transport of Radioactive Material.

Based on review of the documents and interviews, the content of the EPR regulations and guides take into account parts of paragraphs of GSR Part 7 that are applicable to facilities, activities and response organizations.

Provisions of these regulations include responsibilities for operating organizations covering the following:

- Promptly execute and safely and effectively manage the on-site emergency response including the transition from normal operations to operations under emergency conditions;
- Promptly Classify the emergency, declare the emergency class, initiate the on-site emergency response, and notify and provide sufficient information to the off-site notification point;
- Decide on and take mitigatory actions on-site;

- Initially assess the hazards and development of hazardous conditions throughout the emergency and take necessary urgent protective actions to protect all persons present at the site in an emergency;
- Ensure suitable, reliable and diverse means of communication for use in taking protective actions on the site and for communication with relevant off-site officials;
- Communicate effectively with the public in a nuclear or radiological emergency and consistently with relevant off-site response organizations;
- Safely and effectively manage radioactive waste generated in an emergency;

However, the regulations do not include the following:

- Performance of a hazard assessment as a basis for a graded approach in establishing the on-site EPR;
- Assess and determine, at the preparedness stage, when and under what conditions assistance from off-site emergency services may be needed to be provided on the site;
- Protection strategy including the protection of emergency workers responding on the site;
- Set conditions, criteria, and objectives to be met to terminate the emergency on the site and to provide relevant information in this regard to relevant off-site officials;
- Document, protect and preserve to the extent practicable, data and information important for an analysis of the emergency and emergency response;
- Analyse the emergency and the emergency response with the aim to identify actions to be taken to avoid other emergencies and to improve emergency arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *EPR requirements are lacking in important aspects such as hazard assessment, termination of emergencies, etc. Further, some roles and responsibilities in EPR are not clearly defined between different national organizations including BNRA and there is no appropriate coordination mechanism.*	
(1)	**BASIS: GSR Part 7 Requirement 2 para. 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements, and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization (see also paras 1.12 and 4.5)."*
(2)	**BASIS: GSR Part 7 Requirement 3 states that** *"The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency."*
(3)	**BASIS: GSR Part 7 Requirement 4 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency."*
(4)	**BASIS: GSR Part 7 Requirement 18 states that** *"The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity."*
(5)	**BASIS: GSR Part 7 Requirement 19 states that** *"The government shall ensure that the nuclear or radiological emergency and the emergency response are analysed in order to*

	identify actions to be taken to avoid other emergencies and to improve emergency arrangements."
R13	**Recommendation: The government should review and revise the regulation on emergency preparedness and response in line with IAEA safety requirements.**

All licensees should implement the provisions established by REPEPNRE in the development of their EPR programme. The IRRS team noted that a hazard assessment and emergency preparedness categories are not in place and the graded approach is not implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The requirements for EPR programmes are similar for all facilities and activities and do not consider the graded approach.*	
(1)	**BASIS: GSR Part 7 Requirement 2, para. 4.13 states that** *"The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the requirements for such arrangements."*
(2)	**BASIS: GSR Part 7 Requirement 4, para. 4.19 states that** *"For the purposes of these safety requirements, assessed hazards are grouped in accordance with the emergency preparedness categories shown in Table 1. The five emergency preparedness categories (hereinafter referred to as 'categories') in Table 1 establish the basis for a graded approach to the application of these requirements and for developing generically justified and optimized arrangements for preparedness and response for a nuclear or radiological emergency."*
S29	**Suggestion: BNRA should consider applying a graded approach in the development of EPR requirements for different nuclear and radiation facilities and associated activities.**

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

According to the ASUNE, BNRA carries out regular and specific inspections of licensees and permit holders which cover the operator's EPR arrangements as part of regular oversight.

BNRA carries out annual inspections according to an established 3-year inspection programme. The on-site emergency arrangements are part of the inspection programme and inspections of emergency preparedness are conducted on a yearly basis for NPP. Inspections of emergency planning are included in BNRA's annual inspection plan.

The team was informed that during these inspections the following are checked:

- Emergency plan, emergency instructions and procedures, interaction with local authorities and exchange of information with the regulatory authority;
- Preparation of an initial assessment of the accident, estimated assessment of environmental discharges and intervention levels and application of protective measures;
- Training of personnel on the emergency plan, conduct of exercises and training, preparation of exercises, documentation and feedback.

Following the graded approach in the annual inspection plan, one inspection at Kozloduy NPP and one inspection at threat category 3 nuclear facilities (State Enterprise Radioactive Waste) are planned.

Annually, BNRA prepares a schedule for joint exercises with the Kozloduy NPP. Several types are included in the schedule – an exercise with a severe accident at the Kozloduy NPP, a general emergency exercise for the plant – 2 times a year and an exercise of a full-scale simulator for data exchange.

After the exercises, a report is drawn up with the observed gaps and measures for their correction and improvement of the organization and communications. In some of the joint exercises, on-site BNRA inspectors are also involved.

BNRA has developed an Instruction for Exercises and Training of the Emergency Team that describes the procedure for preparation and conduct of exercises and drills in which BNRA participates.

Although objectives are in place for conducting drills and exercises for the BNRA Emergency team, specific criteria for evaluating the implementation of these goals have not been developed.

Every five years a national full-scale exercise is held to test the off-site Kozloduy NPP Emergency Plan arrangements. During these exercises, the coordination and interaction between the operator and the organizations responsible for responding in the event of an accident at the Kozloduy NPP is assessed.

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

The assignment and division of responsibilities in case of nuclear or radiological emergency are described in The Disaster Protection Act (DPA), the Regulation on Emergency Planning and Emergency Preparedness in Case of Nuclear and Radiological Emergencies (REPEPNRE) and the National Disaster Protection Plan (NDPP).

According to the DPA, the Government of the Republic of Bulgaria has established the Unified Rescue System (URS) for protection of the population in case of all types of disasters. The main parts/units of the URS are Fire Safety and Civil Protection General Directorate (MoI), Regional Directorates of MoI, Bulgarian Red Cross, and Centres of Emergency Medical Assistance. (BNRA is one of these parts.

BNRA's roles in a national response are detailed in the REPEPNRE and in the NDPP. These responsibilities are developed in the BNRA Emergency plan in case of nuclear or radiological emergency supported by a number of instructions for its implementation. These include the Instruction for the activity of BNRA Emergency Team, Instruction for notification to the IAEA, EC and other countries in case of nuclear or radiation emergency, Instruction for training and drills of BNRA Emergency team etc.

The main responsibilities of BNRA are:

- To provide decision making support for implementing protective actions
- Notification and periodic exchange of information with the IAEA, EC, and neighbouring countries, as well as the countries that may be affected;
- Provide requests of assistance through the RANET;
- Perform analyses and determine prognoses of facility conditions and the emergency's development.

BNRA's Emergency Team (ET) is composed of BNRA employees but there is not enough experts/staff to fill some of the positions of BNRA's ET. This could jeopardize prolonged/continuous emergency actions of the team in case of severe emergency.

To ensure a high level of competence, BNRA conducts several types of training, drills, and exercises for members of the ET.

For the EPR infrastructure, BNRA has established the Emergency centre where the ET performs activities during all accidents, emergencies, and exercises. The centre is equipped with following systems and tools:

- Communication equipment and video-conferencing system
- Workstation providing access to the national system of radiation monitoring
- Workstation with JRODOS system
- Workstations for receiving on-line information on the safety parameters of Units 5 and 6 of Kozloduy NPP
- Diesel generator

There is no comprehensive description of the EPR process integrated into the management system. In the case of the team's prolonged/continuous emergency response during a major emergency event, there are not enough experts/staff to fill all positions in the BNRA ET.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Certain elements of the EPR process are missing, including description of the EPR programme in BNRA's IMS.*	
(1)	**BASIS: GSR Part 7 Requirement 26 states that** *"The government shall ensure that a programme is established within an integrated management system to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary for effective response in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 para. 3.1 states that** *"…This capability relates to an integrated set of infrastructural elements that include, but are not limited to: authority and responsibilities; organization and staffing; coordination; plans and procedures, tools, equipment and facilities, training, drills and exercises; and a management system."*
R14	**Recommendation: BNRA should develop a comprehensive EPR process as part of its IMS.**

The procedure for training and exercises to qualify members of BNRA ET does not include provisions for the establishment of success criteria. This issue was identified in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no criteria in place for assessing the effectiveness of the EPR training and exercise programme.*	
(1)	**BASIS: GSR Part 7 Requirement 26 states that** *"Personnel who are assigned to positions in all operating organizations and response organizations to perform the functions necessary to meet the requirements established in Section 5 shall be qualified and shall be assessed for their initial fitness and continuing fitness for their intended duties."*
(2)	**BASIS: GSR Part 7 para. 3.1 states that** *"…This capability relates to an integrated set of infrastructural elements that include, but are not limited to: authority and responsibilities; organization and staffing; coordination; plans and procedures, tools, equipment and facilities, training, drills and exercises; and a management system."*
(3)	**BASIS: GSR Part 7 para. 6.33. states that** *"The conduct of exercises shall be evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response (see para. 3.2)."*
R15	**Recommendation: BNRA should review and revise its procedures to include assessment of the effectiveness of its EPR training and exercise programme.**

10.5. SUMMARY

Bulgaria has established a unified emergency management system for all types of emergencies regardless of cause, size, location or complexity to reduce loss of life, property and harm to the environment. The national legislation contains a few Acts and Regulations which set out a national framework for emergency preparedness and emergency response in case of an emergency, including nuclear and radiological emergencies. However, the following areas need further improvement:

- Increase the staff in charge with implementation of the EPR programme at BNRA;
- Review and revise the EPR regulations in line with IAEA safety requirements;
- To implement a graded approach in the development of the regulations;
- To consolidate the BNRA EPR process in its IMS; and
- To review and revise the dedicated procedure for training and exercise.

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	R1	**Recommendation:** The Government should adopt the national policy and strategy for safety addressing all elements as a statement in line with IAEA safety fundamentals.
	S1	**Suggestion:** BNRA should consider initiating the development of a comprehensive national policy and strategy for safety to be adopted by the government.
	R2	**Recommendation:** The government should adequately increase BNRA's budget to cater for regulatory activities associated with the planned expansion of their nuclear power programme.
	R3	**Recommendation:** The government should ensure that there is a comprehensive long-term strategy for human resource development and retention by considering adequate remuneration of regulatory staff in comparison with other national nuclear organizations.
	R4	**Recommendation:** The Government should finalise the revision of Strategy for Spent Fuel and Radioactive Waste Management.
2. THE GLOBAL SAFETY REGIME	S2	**Suggestion:** BNRA should consider further developing the process for participation in international activities, to more effectively benefit from international experience.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S3	**Suggestion:** BNRA should consider to further improve the mechanism for more effective participation in the International Reporting System for Operating Experience.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S4	**Suggestion:** BNRA should consider further strengthening and detailing the mechanism of the coordination and cooperation with MoH.
	R5	**Recommendation:** BNRA should plan for and continue its efforts to fill current and future vacancies and update the "Strategy for Building Professional Capacity in BNRA 2023 - 2032".
	R6	**Recommendation:** MoH should ensure that there are sufficient human resources available in line with increasing workload in the area of radiation protection.
	R7	**Recommendation:** BNRA should finalise and implement a comprehensive Procedure for Knowledge Management with emphasis on the implementation of key aspects of the competency management process.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R8	**Recommendation:** BNRA should establish a safety policy as part of its integrated management system.
	S5	**Suggestion:** BNRA should consider improving its Management Policy Statement to be in line with IAEA Safety guides.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S6	**Suggestion: BNRA should consider updating the Integrated Management System manual to include the Information Security Management System.**
	S7	**Suggestion: BNRA should consider documenting the process for managing organizational changes.**
	S8	**Suggestion: BNRA should consider improving its processes descriptions in line with IAEA Safety guides.**
	R9	**Recommendation: BNRA should include in its Integrated Management System, requirements to retain responsibility for safety when contracting out any process.**
	R10	**Recommendation: BNRA should conduct a management review periodically.**
	R11	**Recommendation: BNRA should conduct self and independent assessments of leadership for safety and safety culture throughout the organization.**
5. AUTHORIZATION	S9	**Suggestion: BNRA should consider issuing guideline documents for all licensing submissions so that applicants may be able to submit relevant details in their submissions.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S10	**Suggestion: BNRA should consider requesting an independent verification of safety assessments from all operating organizations, including those applying for a licence renewal based on the graded approach.**
	S11	**Suggestion: The National Centre for Radiobiology and Radiation Protection (NCRRP) should consider consulting with the relevant professional bodies and BNRA to establish the DRLs for new imaging modalities, and to update the DRLs previously established.**
6. REVIEW AND ASSESSMENT	S12	**Suggestion: BNRA should consider strengthening its mechanism to assess the work done by the TSO for utilizing in regulatory decision making.**
	S13	**Suggestion: BNRA should consider further developing regulatory guidance to clarify the requirements for the conduct of the PSR for Fuel Cycle Facilities.**
7. INSPECTION	S14	**Suggestion: BNRA should consider further developing detailed procedures and guidance for conducting inspections in nuclear facilities, and associated activities.**
	S15	**Suggestion: BNRA should consider improving the methodology for developing the inspection programme.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S16	**Suggestion:** BNRA should consider strengthening measures to maintain effective independence of regulatory staff including NPP site inspectors.
	S17	**Suggestion:** NCRRP should consider improving the reporting of the inspection findings concerning radiation source facilities to BNRA.
	S18	**Suggestion:** BNRA and MoH should consider developing an agreement for the conduct of inspections of occupational exposures at nuclear facilities.
8. ENFORCEMENT	R12	**Recommendation:** BNRA should update the enforcement policy to include all enforcement actions.
9. REGULATIONS AND GUIDES	S19	**Suggestion:** BNRA should consider developing additional regulatory guides to describe acceptable methods to ensure compliance with the requirements of the regulations.
	S20	**Suggestion:** BNRA should consider implementing the processes of review and revision of regulations and guides in a systematic and timely manner.
	S21	**Suggestion:** BNRA should consider developing specific requirements for long-lived intermediate and high-level waste.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S22	**Suggestion: BNRA in consultation with MoH should consider developing a guidance for the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.**
	S23	**Suggestion: BNRA should consider updating their transport regulations in line with the IAEA's SSR-6.**
	S24	**Suggestion: BNRA should consider introducing a requirement ensuring that persons under the age of 18 years are allowed access to controlled areas only under supervision.**
	S25	**Suggestion: MoH should consider establishing guidance for the protection and safety of medical exposures.**
	S26	**Suggestion: MoH should consider developing guidance to assist registrants and licensees to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures, to promptly investigate unintended or accidental medical exposures and, if appropriate, implement corrective actions.**
	S27	**Suggestion: MoH should consider developing guidelines for the release of patients who have undergone therapeutic radiological procedures with implanted sealed sources.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	S28	**Suggestion:** BNRA should consider analysing the workload of the EPR division and increase the number of positions with required staff accordingly.
	R13	**Recommendation:** The government should review and revise the regulation on emergency preparedness and response in line with IAEA safety requirements.
	S29	**Suggestion:** BNRA should consider applying a graded approach in the development of EPR requirements for different nuclear and radiation facilities and associated activities.
	R14	**Recommendation:** BNRA should develop a comprehensive EPR process as part of its IMS.
	R15	**Recommendation:** BNRA should review and revise its procedures to include assessment of the effectiveness of its EPR training and exercise programme.

APPENDIX II – LIST OF PARTICIPANTS

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GROUP PHOTO

APPENDIX III – LIST OF IRRS REVIEWERS AND COUNTERPARTS

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Eszter RETFALVI	Svetlana FRANTSOVA	Yuliya DIMITROVA
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Eszter RETFALVI	Atanas DOBREV	Yuliya DIMITROVA Neviana RASHKOVA Gergana MITKOVA
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Karel KUNZEL	Peter VANKOV	Yuliya DIMITROVA Gergana SIMOVA
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Sherif BAKR	Tanya MILEVA	Bogdana ZHELYAZKOVA-
5.	**AUTHORIZATION**		
	Muhammad RAHMAN Jaime GARCIA de la SEN Sotirios ECONOMIDES Åsa ZAZZI Jeremy TAPP Mathilde FOURNIER Paula Alexandra de ALMEIDA SANTOS	Orlin VELICHKOV Deyana DOSIEVA	Hristo BOTSOEV Katia CHIPAROVA Nikolay GROZEV Nikolay TODOROV Victoria TODOROVA Lidiya KATSARSKA Jana DJOUNOVA

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
	Wilcot SPEELMAN		Kremena IVANOVA Ilia TASEV
6.	**REVIEW AND ASSESSMENT**		
	Muhammad RAHMAN Jaime GARCIA de la SEN Sotirios ECONOMIDES Åsa ZAZZI Jeremy TAPP Mathilde FOURNIER Paula Alexandra de ALMEIDA SANTOS Wilcot SPEELMAN	Elizabeth TSVETANOVA Nikolay TODOROV	Yuriy GRIGOROV Iva NIKOLOVA Hristo BOTSOEV Deyana DOSIEVAKatia CHIPAROVA Nikolay GROZEV Victoria TODOROVA Lidiya KATSARSKA Jana DJOUNOVA Kremena IVANOVA Ilia TASEV
7.	**INSPECTION**		
	Anupama BULKAN Jaime GARCIA de la SEN Sotirios ECONOMIDES Åsa ZAZZI Jeremy TAPP Mathilde FOURNIER Paula Alexandra de ALMEIDA SANTOS Wilcot SPEELMAN	Hristo BOTSOEV Deyana DOSIEVA	Katia CHIPAROVA Nikolay GROZEV Nikolay TODOROV Victoria TODOROVA Lidiya KATSARSKA Jana DJOUNOVA Kremena IVANOVA Ilia TASEV

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
8.	**ENFORCEMENT**		
	Anupama BULKAN	Sofia KALEVA	Valentine VELEFF
9.	**REGULATIONS AND GUIDES**		
	Gerhard ROOS Jaime GARCIA de la SEN Sotirios ECONOMIDES Åsa ZAZZI Jeremy TAPP Mathilde FOURNIER Paula Alexandra de ALMEIDA SANTOS Wilcot SPEELMAN	Pepa STOYANOVA	Deyana DOSIEVA Radosveta MARKOVA
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Petre MIN	Lyudmila SIMEONOVA	Krasimira IVANOVA

APPENDIX IV – MISSION PROGRAMME

First Week

<table>
<tr><th>Time</th><th>SAT
16 Nov</th><th>SUN
17 Nov</th><th>MON
18 Nov</th><th>TUE
19 Nov</th><th>WED
20 Nov</th><th>THU
21 Nov</th><th>FRI
22 Nov</th><th>SAT
23 Nov</th><th>SUN
24 Nov</th></tr>
<tr><td>9:00-10:00</td><td rowspan="11">Arrival of Team Members</td><td rowspan="2"></td><td rowspan="2">Entrance Meeting</td><td rowspan="3">Interviews</td><td rowspan="3">Visits</td><td rowspan="3">Interviews</td><td rowspan="3">Interviews</td><td rowspan="3">Coordinator(s) Write(s) introductory parts</td><td rowspan="3">TM write Report

Drafts sent to Team Leads</td><td rowspan="3">Discussing between TM and improving Draft Report

TL, DTL, TC and DTC read everything
•
Secretariat edits the report</td><td rowspan="11">Free day, Social Tour</td><td rowspan="11">Review of the Report by the Team Leads</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td><td rowspan="3">Lunch with Host</td></tr>
<tr><td>12:00-13:00</td><td colspan="5">Standing lunch</td><td>Lunch break</td></tr>
<tr><td>13:00-15:00</td><td rowspan="2">IRRS Initial Team Meeting
• Welcome
• 5 minutes/TM self-intro
• Refresher training</td><td rowspan="3">Interviews</td><td rowspan="3">Interviews</td><td rowspan="2">Visits</td><td rowspan="2">Interviews</td><td rowspan="3">Interviews
Discussions with Team Lead if necessary</td><td rowspan="3">TL and DTL review introductory part</td><td rowspan="3">Secretariat edits the report
First Draft Report Ready

Cross-reading by TM</td><td>Secretariat edits the report:
New Draft Report Ready</td></tr>
<tr><td>15:00-16:00</td><td rowspan="2">Finalisation of the Draft Report (focus on Observation Boxes)</td></tr>
<tr><td>16:00-17:00</td><td>Initial Team Meeting
• Mission logistics (LO)
• Discussion of first impressions
• Closing</td><td>Interviews</td><td colspan="2">Written preliminary findings delivered</td></tr>
<tr><td>17:00-18:00</td><td></td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td colspan="2">Daily Team Meeting:
Discussion of findings</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td></td></tr>
<tr><td>18:00-20:00</td><td>Team Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td></td></tr>
<tr><td>20:00-24:00</td><td></td><td>Writing of the report</td><td>Writing of the report</td><td>Daily Team Meeting:
Discussion of findings</td><td>Writing of the report</td><td>TM cross-read Draft</td><td>Secretariat edits the report</td><td></td></tr>
</table>

Second Week

<table>
<tr><th></th><th colspan="2">MON
25 Nov</th><th>TUE
26 Nov</th><th colspan="3">WED
27 Nov</th><th colspan="2">THU
28 Nov</th><th>FRI
29 Nov</th></tr>
<tr><td>9:00-10:00</td><td>Policy Discussions
Topic 1</td><td rowspan="2">Individual Discussions of Recommendations, Suggestions and Good Practices</td><td rowspan="3">Discussion of the Report by the Team</td><td colspan="3" rowspan="2">Common read through and finalisation of the Report by the Team</td><td rowspan="3">Host reads Draft Report</td><td></td><td>Submission of the IRRS Mission Preliminary Report</td></tr>
<tr><td>10:00-11:00</td><td>Policy Discussions
Topic 2</td><td rowspan="2">Team discusses the Mission and provides IAEA with feedback</td><td rowspan="2">Exit Meeting
Publication of Press Release</td></tr>
<tr><td>11:00-12:00</td><td colspan="2"></td><td colspan="3">Submission of the Draft to the Host</td></tr>
<tr><td>12:00-13:00</td><td colspan="9">Standing lunch</td></tr>
<tr><td>13:00-15:00</td><td rowspan="2">Individual Discussions of Recommendations, Suggestions and Good Practices</td><td rowspan="2">Finalization / Cross-Reading of contributions to the report

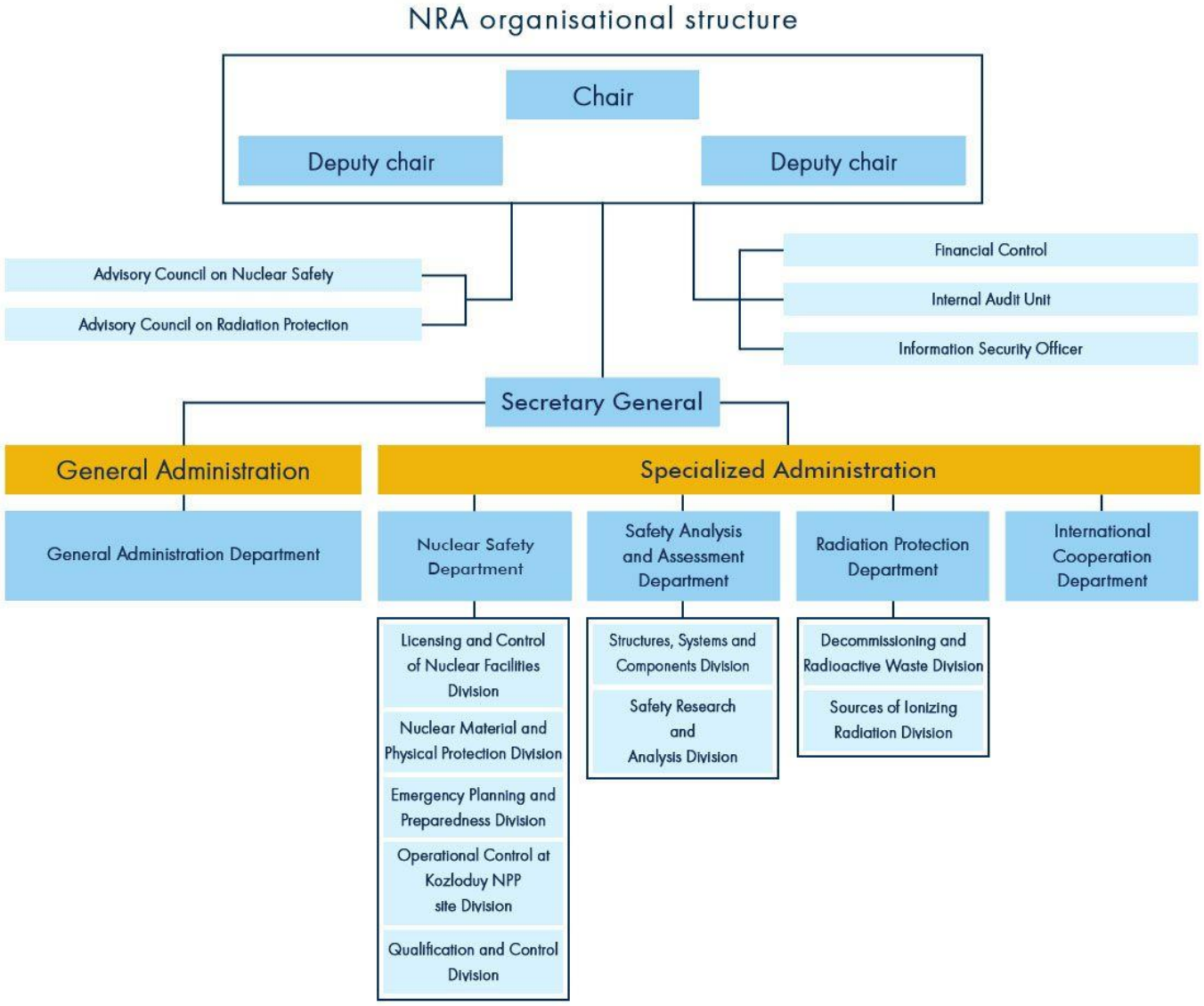
Team Leads read everything</td><td rowspan="3">Discussion of the Report by the Team</td><td rowspan="3">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="2">Host reads Draft Report</td><td rowspan="2">TL finalises Executive Summary and Exit Presentation</td><td rowspan="2">TC Drafts the Press Release</td><td colspan="2">Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="4">Departure</td></tr>
<tr><td>15:00-17:00</td><td colspan="2">Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-18:00</td><td colspan="2">Daily Team Meeting</td><td colspan="3">Finalization of Executive Summary</td><td colspan="2">Briefing of the Senior IAEA Manager;
Finalisation of the press release and
of the Preliminary Report</td></tr>
<tr><td>18:00-20:00</td><td colspan="2">Dinner</td><td>Dinner</td><td colspan="3">Dinner</td><td colspan="2" rowspan="3">Farewell Dinner</td></tr>
<tr><td>20:00-21:00</td><td colspan="2" rowspan="2">Secretariat updates Report</td><td rowspan="2">Secretariat finalises Report</td><td colspan="3" rowspan="2">Free</td></tr>
<tr><td>21:00-24:00</td></tr>
</table>

APPENDIX V – SITE VISITS

- Kozloduy NPP
- Kozloduy State Enterprise Radioactive Waste Management (SE RAW)
- Controltest Ltd.
- Theta Consult Ltd.
- Acibadem City Clinic

APPENDIX VI – ORGANIZATIONAL CHART OF BNRA



APPENDIX VII – BNRA'S REFERENCE MATERIAL USED FOR THE REVIEW

- 9th National Report of Bulgaria under the CNS
- ARM Summary Report
- BNRA IRRS Action Plan
- Evidence 1-4
- SARIS Final Report – Republic of Bulgaria
- SARIS – List of Documents

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. **INTERNATIONAL ATOMIC ENERGY AGENCY –** Leadership and Management for Safety, General Safety Requirements Part 2, No GSR Part 2, IAEA, Vienna (2016)
4. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No GSR Part 3, IAEA, Vienna (2014).
5. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety assessment for facilities and activities, General Safety Requirements Part 4, No GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Predisposal Management of Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
7. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
8. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
9. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Specific Safety Requirements No SSR-1, IAEA, Vienna (2019)
10. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements No SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements No SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Specific Safety Requirements No SSR-3, IAEA, Vienna (2016)
13. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements No SSR-4, IAEA, Vienna (2017)
14. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Disposal of Radioactive Waste, Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
15. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018)
16. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Classification of Radioactive Waste, General Safety Guide No GSG-1, IAEA, Vienna (2009)
17. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide No GSG-2, IAEA, Vienna (2011)
18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide No GSG-6, IAEA, Vienna (2017)
19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide No GSG-7, IAEA, Vienna (2018)
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide No GSG-9, IAEA, Vienna (2018)

21. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide No GSG-12, IAEA, Vienna (2018)
22. INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide No GSG-13, IAEA, Vienna (2018)
23. INTERNATIONAL ATOMIC ENERGY AGENCY Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide No GSG-16, IAEA, Vienna (2022)
24. INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide No GS-G-2.1, IAEA, Vienna (2007)
25. INTERNATIONAL ATOMIC ENERGY AGENCY - Application of the Management System for Facilities and Activities, Safety Guide No GS-G-3.1, IAEA, Vienna (2006)
26. INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide No RS-G-1.8, IAEA, Vienna (2005)
27. INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide No SSG-1, IAEA, Vienna (2009)
28. INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides No SSG-2 (Rev. 1), IAEA, Vienna (2019)
29. INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-3 (Rev. 1), IAEA, Vienna (2024)
30. INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-4, IAEA, Vienna (2010)
31. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide No SSG-5 (Rev. 1), IAEA, Vienna (2023)
32. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide No SSG-6 (Rev. 1), IAEA, Vienna (2023)
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