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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

TO

BULGARIA

Sofia, BULGARIA

8 to 19 April 2013

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

NUCLEAR REGULATORY AGENCY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
BULGARIA

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REPORT TO

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Mission date:	*8 to 19 April 2013*
Regulatory body:	*Bulgarian Nuclear Regulatory Agency (BNRA)*
Location:	*Sofia, Bulgaria*
Regulated facilities and activities:	*Nuclear Power Plants, Waste Management Fuel Cycle Facilities, Radiation Sources in Industrial and Medical Facilities.*
Organized by:	*International Atomic Energy Agency (IAEA)*

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IAEA-2013

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

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EXECUTIVE SUMMARY

At the request of the Government of the Republic of Bulgaria (Bulgaria), an international team of senior safety experts met representatives of the Bulgarian Nuclear Regulatory Agency (BNRA) from 8 to 19 April 2013 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place mainly at the headquarters of BNRA in Sofia. The international expert team also met representatives of NCRRP from the MoH. The MoH has responsibility for establishing requirements for the radiation protection of patients, workers and the public in relation to occupational and medical exposure control in Bulgaria. The purpose of the peer review was to review the national regulatory framework for nuclear and radiation safety in Bulgaria and its effectiveness.

The IRRS team consisted of 16 senior regulatory experts from 16 IAEA Member States, six IAEA staff members, as well as three observers.

The IRRS team carried out a review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement, and the development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material; waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environmental monitoring; occupational radiation protection; and the interface with nuclear security. The review addressed all facilities and activities regulated by BNRA, including nuclear power units: two of which are in operation and four are now under decommissioning; spent fuel and waste management facilities; radiation sources facilities; and the transport of radioactive materials. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications to the Bulgarian framework for safety of the TEPCO Fukushima Daiichi accident.

The IRRS mission also included discussions on Bulgarian regulatory policy for long-term operation of nuclear power plants and NORM (Naturally Occurring Radioactive Material) legislation and practices.

The responsibilities and activities of the MoH with regard to establishing and implementing requirements for radiation protection of patients, workers and the public, which were covered in this mission, should be further reviewed by the IRRS follow-up mission.

The review compared the Bulgarian regulatory framework for nuclear and radiation safety against IAEA Safety Standards, which are the international benchmark for safety. The mission was also an opportunity for exchanging information and experience between the IRRS team members and their BNRA counterparts.

BNRA provided the IRRS team with advance reference material and documentation, including the results of its self-assessment, in all the areas within the scope of the mission. This included an action plan for improvements developed from the self-assessment. During the mission, observations of regulatory activities and a series of interviews and discussions with BNRA staff were used to help assess the effectiveness of the regulatory system. The IRRS team's activities included observing inspections at the Kozloduy site (at the nuclear power plant and spent fuel and waste facilities) and at two other facilities using industrial and medical sources (the radioactive waste facilities at Novi Han SD and the Tokuda Hospital in Sofia). In these visits, the IRRS team members observed BNRA and NCRRP working practices during inspections, and included discussions with licensee personnel and management. In addition, the IRRS team observed BNRA's participation (from its premises) in an emergency exercise.

Throughout the mission, the IRRS team received full cooperation from all parties. In particular, BNRA and NCRRP staff was very open in the discussions and provided the fullest practicable assistance.

The IRRS team identified a number of good practices and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards.

BNRA has been legally assigned to regulate nuclear and radiation safety in Bulgaria. The MoH, through NCRRP and the Regional Health Inspectorates for Public Health Protection and Control (RIPHPC), also has responsibilities for establishing requirements for radiation protection of workers, patients and the public.

Bulgaria has a clear national policy and strategy for safety, supported by a clear framework for safety. BNRA operates as an independent regulatory body and conducts its regulatory processes in an open and transparent manner. In responding to the accident at TEPCO's Fukushima Daiichi, BNRA reacted and communicated promptly and effectively with interested parties.

The strengths and good practices identified by the IRRS team include the following:

- The application of a no blame policy for the notification of nuclear and radiation safety-related events is legally required;
- The provisions established by BNRA to manage its technical support organizations provide a good basis to use their competencies in an effective manner;
- The process to establish and keep regulations and guides up to date is well structured and involves the relevant interested parties when necessary;
- BNRA has a clear policy of transparency and openness with the public, which covers information on safety-related events and BNRA's role during radiation emergencies; and
- There is a very complete national dose registry system, including comprehensive medical and dose information which will allow future full cause-effect analysis to be performed.

The IRRS team identified issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system. Issues included:

- Demarcation of the respective roles among state authorities in the area of safety and the establishment of formal means of coordination and cooperation of their regulatory functions;
- BNRA resources and competences for oversight of projected facilities and activities;
- Establishing an integrated management system which contributes to achieving BNRA's goals in an efficient manner;
- Comprehensiveness of licensing processes for facilities, so that these include final stages and formal consultation of the public when appropriate;
- Improving procedures governing review and assessment processes for all types of facilities and activities;
- Optimization of inspection processes, including the development and implementation of planned and systematic inspection programmes that cover all facilities and activities, and better coordination between the different regulatory organizations in this regard; and
- Development of additional guides providing further details and corresponding criteria for implementation of the regulatory requirements.

The IRRS team’s findings are summarized in Appendix V.

A press conference was held and an IAEA press release was issued at the end of the mission.

I. INTRODUCTION

At the request of the Government of Bulgaria, an international team of senior safety experts met representatives of the regulatory body of Bulgaria (BNRA) from 8 to 19 April 2013 to conduct an Integrated Regulatory Review Service (IRRS) mission.

The international expert team also met representatives of the NCRRP from the MoH which is the responsible body for the protection of patients, workers and the public in relation to the regulation of occupational radiation protection and medical exposure control in Bulgaria.

The purpose of the mission was to review the Bulgaria regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Bulgaria in January 2012. A preparatory mission was conducted 26 and 27 September 2012 at BNRA Headquarters in Sofia to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by BNRA and selected safety aspects.

The IRRS team consisted of 16 senior regulatory experts from 16 IAEA Member States, 5 IAEA staff members, an IAEA administrative assistant and an IAEA Administrative Observer. A representative from Netherlands and a representative from France attended the mission to observe the implementation of an IRRS mission. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection, enforcement, and development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material, waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environment monitoring; occupational radiation protection; and interface with nuclear security. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the Bulgaria framework for safety of the TEPCO-Fukushima Daiichi accident.

In addition, policy issues were discussed, including: long-term operation of nuclear power plants, and NORM (Naturally occurring radioactive material) legislation and practices.

BNRA, and NCRRP in medical and occupational areas, conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of BNRA self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from BNRA and performed direct observation of BNRA working practices during inspections.

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 conduct a review of the Bulgarian radiation and nuclear safety regulatory framework and activities, to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities regulated by BNRA. The review was carried out by comparison of existing arrangements against the IAEA Safety Standards.

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

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response by:

- Providing Bulgaria and BNRA, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA Safety Standards;
- Providing Bulgaria and BNRA with a review of its regulatory programme and policy issues relating to nuclear and radiation safety, and emergency preparedness;
- Providing Bulgaria and BNRA with an objective evaluation of its nuclear safety, and emergency preparedness and response regulatory activities with respect to IAEA Safety Standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key BNRA staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Bulgaria and BNRA with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Bulgaria, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 26 to 27 September 2012. The preparatory meeting was carried out by Ms Dana Drabova, acting as team leader, the appointed IRRS deputy team leader, Mr Kazumasa Hioki, and the IRRS IAEA team representatives, Mr Jean-Rene Jubin, Mr Magnus Vesterlind, and Mr Peter Zombori.

The IRRS preparatory mission team had discussions regarding regulatory programmes and policy issues with the senior management of BNRA represented by Mr Sergey Tzotchev, chairman, and Mr Nikolay Vlahov, executive secretary, other senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste management (policy and strategy, predisposal and disposal;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Transport of radioactive material;
- Control of medical exposures;
- Occupational radiation protection;
- Control of radioactive discharges and materials for clearance;
- Environmental monitoring;
- Regulatory implications of the TEPCO Fukushima Daiichi accident; and
- Selected policy issues.

Mr Sergey Tzotchev, chairman of BNRA, made presentations on the national context, the legal and regulatory framework as well as the current status of BNRA. The self-assessment process and results to date were presented by Mr Nikolay Vlahov, executive secretary of BNRA.

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 April 2013.

The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was also discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and liaison officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The BNRA Liaison Officer for the preparatory meeting and the IRRS mission was Mr Nikolay Vlahov.

BNRA provided IAEA and the IRRS team with the advance reference material for the review in February and March 2013, including the self-assessment results. In preparation for the mission, the IAEA team

members conducted a review of the advance reference material and provided their initial review comments to the IAEA team coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An opening IRRS team meeting was conducted on Sunday, 7 April 2013 in BNRA premises in Sofia by the IRRS team leader and the IRRS IAEA team coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The agenda for the mission was also presented to the team.

The IAEA team coordinator presented the relevant IAEA Safety Standards for IRRS, and the IAEA deputy team coordinator provided the IRRS team with an overview of the IRRS process. At last, an IAEA review area facilitator presented the expectations regarding the module on the "Regulatory implications from the TEPCO-Fukushima Daiichi Accident" to be applied.

The liaison officer was present at the opening IRRS team meeting, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

Finally, the reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 8 April 2013, with the participation of BNRA senior management and staff. Opening remarks were made by Mr Sergey Tzotchev, chairman of BNRA, and Ms Marta Ziakova, IRRS team leader. Mr Sergey Tzotchev gave an overview of the Bulgaria context and BNRA activities. This presentation was completed by information provided by Nr Nikolay Vlahov, on the self-assessment and the action plan developed accordingly.

During the mission, a review was conducted for all the review areas with the objective of providing Bulgaria and BNRA with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday, 19 April 2013. The opening remarks at the exit meeting were presented by Mr Sergey Tzotchev and were followed by the presentation of the results of the mission by the IRRS team leader, Ms Marta Ziakova. Closing remarks were made by Mr Jim Lyons, director of the Division of Nuclear Installation Safety of the IAEA.

A joint IAEA and BNRA press conference took place at the end of the mission during which an IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

National policy and the strategy of the Republic of Bulgaria for nuclear safety and radiation protection are established by the national laws, in particular the Act on the Safe Use of Nuclear Energy (ASUNE). ASUNE was approved by the Government and submitted for discussion and adoption to the Parliament. It was adopted by the Parliament in 2002 and promulgated in the Official Journal. ASUNE was amended in October 2010 to consider new EU legislation, amended international conventions and treaties and revised IAEA Safety Standards, as well as the experience gained from the implementation of the law. The work to review and revise regulations based on the revised ASUNE is on-going.

The fundamental safety objective and ten safety fundamental principles as stated in the IAEA Fundamental Safety Principles (SF-1) have been incorporated in Article 3, Para. 2 of ASUNE.

The National Strategy for Research and Development through 2020 was adopted by the Parliament in 2011. According to this strategy, research and development (R&D) including nuclear and radiation safety is carried out by individual scientists and academic foundations. National policy for R&D and innovation is implemented by the Ministry of Education, Youth and Science (MEYS) and the Ministry of Economy, Energy and Tourism (MEET).

Application of a no blame policy for the investigation of nuclear and radiation safety-related events is required under the Article 17 of the 'Regulation of the conditions and procedure for notification of the nuclear regulatory agency about events in nuclear facilities and sites with sources of ionising radiation.' It is the view of the IRRS Team that this constitutes an important element for promoting safety culture at national level.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 2.3 (g) states that** *"In the national policy and strategy, account shall be taken of the promotion of leadership and management for safety, including safety culture."*
GP1	**Good Practice: The application of a no blame policy for the investigation of nuclear and radiation safety-related events is commendable.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Under the national laws (e.g. Energy Act, ASUNE, Environmental Protection Act, Health Act, Disaster Protection Act, Spatial Development Act, Defence-Related Products and Dual-Use Items and Technologies Export Control Act) and their supporting regulations, responsibilities within the national safety framework have been allocated to the following governmental and regulatory organizations: The Ministry of Economy, Energy and Tourism, Bulgarian Nuclear Regulatory Agency (BNRA), the MoH, the Ministry of Environment and Water, the Ministry of Interior, the Ministry of Defence, the Ministry of Agriculture and Food, the Ministry of Transport, Information Technology and Communications, the Ministry of Education, Youth and Science and the State Agency for National Security.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

BNRA is established and maintained by virtue of Chapter Two "State Regulation" of ASUNE. According to Article 4 (1) of ASUNE, the regulation of the safe use of nuclear energy and ionising radiation, the safety of radioactive waste management and the safety of spent fuel management falls under the responsibility of the chairman of BNRA.

As stated in Article 4 of the ASUNE, BNRA (through the person of the chairman) is an independent authority granted executive power within the regulatory regime prescribed under the act. The legislation provides BNRA with a strong de jure independence based, inter alia, on the following requirements:

- BNRA is prohibited from promoting the use of nuclear energy or sources of ionising radiation;
- No additional functions of BNRA are permitted that may contradict with safety;
- Political independence of the top management by giving a 5 years mandate to the chairman; and
- Financial independence – BNRA has its own line in the State Budget.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

Responsibilities for safety are clearly established in the legal framework. Article 3, Para. 2 (1) of ASUNE states: "Responsibility for ensuring nuclear safety and radiation protection rests entirely with the persons responsible for facilities and activities (licensees) under this Act and may not be delegated to other persons".

In addition, according to Article 77 of ASUNE, licensees generating radioactive waste are obligated to deliver this waste to the Radioactive Waste State-Owned Company within time limits established by regulations. Until this delivery, licensees are responsible for the safe management of radioactive waste. Furthermore, Article 76 of ASUNE states that "The Radioactive waste outside the place of generation shall be managed solely by the Radioactive Waste State-Owned Company."

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

According to Article 13 of ASUNE, the Minister of Health, the Minister of Environment and Water; the Minister of Interior; the Minister of Defence; the Minister of Agriculture and Food; the Minister of Transport, Information Technology and Communications; the Minister of Education, Youth and Science; and the chairman of the State Agency for National Security exercise specialised control within their competence areas specified by the legislation.

ASUNE Article 26 states that the basic norms for radiation protection and the requirements, procedures and clearance levels shall be established by a regulation adopted by the Council of Ministers on a motion by the Minister of Health, the Minister of Environment and Water and BNRA. Regulations also require that the limits for authorized discharges from nuclear facilities and facilities with sources of ionising radiation shall be agreed with the Minister of Health. There are no clear written procedures established for the coordination and cooperation of activities between BNRA and all the authorities with responsibilities in the control of discharges to the environment.

Omissions or undue duplications of requirements ought to be avoided thanks to a process of consultation between the relevant ministries and state authorities for all draft regulations. This process is well-established by the Rules of Procedure of the Council of Ministers and their Administration.

However, there have been cases where multiple regulations have been issued inadvertently for a single safety area. Analyses conducted by BNRA indicate that the root cause of this is the Legal System Arrangements, which permit regulations to be adopted by the Council of Ministers through a Decree, or issued by order of a Minister. However, BNRA does not have a seat in the Council of Ministers, so it is possible that other ministries issue regulations of their own (with or without involving the council of ministries) and BNRA is not automatically involved even if its area of expertise is covered. This creates the following gaps:

- Regulations adopted by a Decree from the Council of Ministers are supposed to follow consultations with all the state authorities concerned. Responsibility for this rests with the developing organization. However, if the developing organization omits to send the proposed regulations to BNRA, there is no unit within the Council of Ministers charged with monitoring this;
- Regulations issued by order of a Minister do not require any consultations outside the ministry, except if the ministry decides to circulate them.

In order to minimize the likelihood of omissions or undue duplications, BNRA has initiated a process of continuous review of published requirements in the Official Journal. This is done by BNRA's Administrative and Legal Services Division.

For medical applications efforts should be made to optimize the regulatory functions between BNRA and the MoH to avoid duplication within their regulatory systems and inspections, or consider putting the regulatory functions related to medical applications under one authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 7, states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
R1	**Recommendation: The government should ensure BNRA is involved formally during the development of all regulations dealing with matters of nuclear safety, nuclear security and radiation protection. Where there is a potential overlap of regulatory responsibilities, the regulations need to be clear in regard to the demarcation of the respective roles and so avoid duplication of activities.**

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

The Regulation on Basic Norms of Radiation Protection issued in 2012 sets dose limits for workers and the public.

A system has been created for application of protective measures for reducing the radiological risk from non-regulated radioactive sources (sources which are not under any kind of regulation) and to radiological contamination from previous activities or emergencies. BNRA's process following the discovery of an orphan source, or of radioactive sources in metal scrap, or of illicit trafficking are defined in its procedures.

BNRA and the MoH jointly control activities with Naturally Occurring Radioactive Material (NORM), assess the radiological risk and determine the necessary radiological protection measures in accordance

with the Regulation on Radiation Protection during Work Activities with Materials with Increased Concentration of Natural Radionuclides (2012).

The Regulation No.25, MoH, 2005 sets requirements for the protection of persons in cases of chronic irradiation as a result of manufacturing, trading or using of raw materials, products and goods with elevated content of natural or man-made radionuclides.

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

Bulgaria's principles for spent fuel and radioactive waste management are defined in the National Strategy for Spent Nuclear Fuel and Radioactive Waste Management, 2004, and later updated in the Strategy for Spent Fuel and Radioactive Waste Management until 2030, adopted by the Council of Ministers in January 2011.

Based on this strategic plan (and also according to ASUNE and the Regulations on Radioactive Waste Management), radioactive waste of category 2a (according to the Bulgarian classification) will be disposed of in a dedicated near surface disposal facility to be commissioned in 2015.

For radioactive waste in category 2b and high level waste from the reprocessing of spent nuclear fuel, geological disposal is considered to be the most suitable management option. According to the 2011 Strategic Plan, by 2013 a programme for geological disposal of HLW and intermediate level waste Cat. 2b shall be elaborated.

The 2011 strategic plan also promote the country's involvement in projects for regional and international initiatives. It is however pointed out that the search for international solutions must not jeopardize the current national program**.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: GSR Part 1 Para. 2.28 states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states."*
(3)	**Basis GS R Part 1 Para. 2.29 states that** *"In strategies for radioactive waste management, account shall be taken of the diversity between types of radioactive waste and the radiological characteristics of radioactive waste."*
(4)	**BASIS: GSR Part 1 Para. 2.30 states that** *"Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal."*
S1	**Suggestion: The government should consider ensuring that interim targets and deadlines are defined when finalizing the programme for geological disposal of Category 2b intermediate level waste (according to the Bulgarian classification system) and high level waste.**

According to the Bulgarian legislation, financial provisions for radioactive waste management and decommissioning are made under two specific funds: the Radioactive Waste Fund and the Nuclear

Facilities Decommissioning Fund, both of which are established under the auspices of the Minister of Economy, Energy and Tourism.

According to the Regulation on the Terms and Methods of Determining, Collection, Spending and Control of Funds and the Contribution Due to Nuclear Facilities Decommissioning Fund, the NPP licensee is required to pay monthly instalments into the Nuclear Facilities Decommissioning Fund as a percentage of its income from electricity sales. In 2007, following the shutdown of Kozloduy Units 3-4, the amount was set at 7.5%. The methodology for determining these contributions is based on estimates of the total decommissioning costs and the remaining operating lifetime of the NPP. The contributions are periodically reviewed, for example by applying new more advanced calculation models and taking account of recent plant performance.

In addition, according to the Regulation on the Terms and Methods of Determining, Collection, Spending and Control of Funds and the Contribution Due to RAW Fund, the NPP licensee is also required to pay monthly contributions to the Radioactive Waste Fund; this is also defined as a percentage of its income from electricity sales. The methodology defining this contribution was developed by the State Enterprise Radioactive Waste (SE RAW) and approved by the Management Board of the Fund. The methodology is based on estimates of the total annual cost of waste management in respect of volume and radioactivity.

Two important parameters that need to be considered when determining these funds are the estimate of the costs of managing spent fuel and the costs of disposal of radioactive waste. According to the information provided during this mission, the costs of spent fuel management (including the cost for its disposal and the cost of the radioactive waste from its reprocessing) falls under the Nuclear Facilities Decommissioning Fund, whereas the costs of the management of all other radioactive wastes fall under the Radioactive Waste Fund.

While the cost of the disposal of radioactive waste in the near surface disposal facility can likely be estimated with a reasonable degree of confidence and margins, the cost of geological disposal of spent fuel related waste and of ILW category 2b radioactive waste is rather more difficult to estimate.

A programme for developing a geological disposal facility is not yet established. However, the team observes that the financial provisions for radioactive waste and decommissioning need to be made as early as, and as accurately as possible, for example to ensure that there are adequate mechanisms in place to ensure the availability of the corresponding funds when needed. Consequently the proper estimation of the costs of all individual activities of the strategy is of major importance and this will need to be a priority if a programme for a geological disposal facility is to be developed in a timely manner.

1.8. COMPETENCE FOR SAFETY

The Government has established requirements for the necessary competences for the operation and for 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

According to BNRA, it currently has a sufficient number of experienced and qualified staff. However, in the future, more nuclear facilities and more multilateral and bilateral activities will require further human

resources. Maintaining the necessary competences within BNRA might be a challenge after experienced staff members have retired.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 11, states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
S2	**Suggestion: The government should consider making further provisions for maintaining the competence of a sufficient number of suitably qualified and experienced staff in BNRA.**

1.9. PROVISION OF TECHNICAL SERVICES

In accordance with the Regulation on Basic Norms of Radiation Protection, all occupationally exposed persons in Category A (under the Bulgarian system) shall be subject to systematic individual monitoring. This individual monitoring for occupationally exposed persons is carried out by persons accredited for performing this work by the Bulgarian Accreditation Service. The accredited persons are required to submit current data about the activities undertaken, the numbers of workers involved, the periodicity of monitoring, and the measuring instruments used.

The Bulgarian Institute of Metrology (BIM) performs calibration and assessment of the conformity of instruments and approves the types of instruments in use.

The Minister of Environment and Water, as well as the Minister of Health are responsible for the implementation of state policy in the area of environmental protection. According to the Environmental Protection Act (EPA), the Minister of Environment and Water operates the national system for monitoring of the environment, part of which is the radiological monitoring. Additionally, the Minister of Environment and Water is the decision-making authority in respect to Environmental Impact Assessments (EIA).

1.10. SUMMARY

The Republic of Bulgaria has a clear national policy and strategy for safety, mainly set out in laws, in particular ASUNE, supported by a clear framework for safety. BNRA operates as an independent regulatory body. The no-blame policy formally required in the notification Regulation is considered as an important component for the promotion of a good safety culture at national level.

It is recommended that the government should make provision for the effective coordination of their regulatory functions. Consideration should be given to further developing interim targets and deadlines for the geological disposal programme.

Finally it is suggested that the government should consider making necessary provision for maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Bulgaria is a contracting party of relevant international treaties and conventions that establish common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and radiation for peaceful purposes and that provide for an effective coordinated international response to a nuclear or radiological emergency. Bulgaria is contracting party to the Convention on Nuclear Safety and Joint Convention on Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. It is also formally committed to the implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on Import and Export of Radioactive Sources. There are formal agreements in place on cooperation on safe use of nuclear energy, transportation of nuclear materials and for emergency preparedness. These include Greece, FYR of Macedonia, Moldova, Slovak Republic, Romania, Russia, Turkey, Ukraine and the USA.

BNRA uses the IAEA safety fundamentals, requirements and guides as a basis for developing and maintaining the safety-related regulations. Fundamental safety principles set in Safety Fundamentals of IAEA Safety Standards Series are transposed into "Act on the Safe Use of Nuclear Energy" (ASUNE).

The existing regulations are periodically revised taking into account the latest developments in IAEA Safety Standards. BNRA quality management procedures (e.g. QMS-RG-P-02) require BNRA staff, when developing or revising regulations or guides, to incorporate the relevant international documents, good practices and lessons learned.

Representatives of BNRA actively 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 also takes part in a number of international organizations, working groups and committees important for enhancing harmonized approaches for safety as well as for exchange of regulatory and operating experience. That includes: ENSREG, ISOE, WENRA, WANO, WWER Forum, HERCA, Scientific and Technical Committee under the EURATOM Treaty, the European platform on qualification of personnel using sources of ionizing radiation as well as the working groups on transport.

BNRA and Kozloduy NPP were subject for a number of peer-review missions (e.g. IRRT, IPPAS, OSART, ASSET and WANO). ASUNE provides for the legal basis for periodic self-assessments of national safety framework and international peer reviews. Furthermore, BNRA staff has been participating in international peer reviews such as IRRS, IPPAS and EPREV.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The licensees are required to report to BNRA, events important to safety. Regulatory requirements require the licensee to investigate, analyse and report these events. When relevant, the licensee is requested to disseminate, information to similar nuclear power plants, designers and manufacturers of defective equipment as well as operating organizations associations such as WANO.

The main requirements for use and dissemination of operating experience are established in:

- ASUNE;
- Regulation of the conditions and procedure for notification of the nuclear regulatory agency about events in nuclear facilities and sites with sources of ionising radiation;
- Regulatory guide on safe operation of NPP (provides for recommendations and guidance for utilization, dissemination and exchange of operating experience).

BNRA analyses both domestic and foreign operating and regulatory experiences stemming from various sources to identify lessons learned in order to improve safety of facilities and activities. The sources used by BNRA for collecting information on operating and regulatory experience include inter alia: KNPP event reports, IAEA IRS and INES reports, the IAEA publications (including IRRS reports), Convention reports, information from the WWER Regulators Forum, international seminars and conferences.

Pursuant to ASUNE provisions, the chairman of BNRA has to submit "... information about events in the nuclear facilities and the sites with ionising radiation of the Republic of Bulgaria to the specialised international organizations whose member the country is, as well as to state bodies, juridical persons and citizens."

The process on evaluation of events reported from KNPP as well as other operating experience information including IAEA/NEA IRS and INES is part of BNRA management system. BNRA has established an expert group to review domestic events as well as international operating and regulatory experience to improve safety of KNPP and BNRA regulatory performance. This group decides which events need to be reported to IRS database or to other relevant operating experience exchange forums (e.g. WWER forum). BNRA staff explained that the relevant information on measures taken in response to events which took place in foreign nuclear facilities is shared during annual IRS, WWER forum and other international meetings. However, it was agreed that BNRA does not use the IRS website-based system to provide the international community with experience feedbacks in a comprehensive manner, using the relevant format.

When necessary, the aforesaid expert group decides also when the licensee should analyse the respective operating experience from foreign nuclear power plants and should provide BNRA with the results of this analysis. Lessons learned and measures taken in response to events, which occurred in foreign nuclear facilities, are reported by the licensee to BNRA every year and upon request.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
S3	**Suggestion: BNRA should consider improving its processes for sharing information internationally on lessons learned and on measures taken in response to information received via international reporting networks by using established formats.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties […]."*
GP2	**Good Practice: The BNRA operational and regulatory experience feedback system covers the use of information received during BNRA participation in international workshops, seminars and other fora. Results from BNRA participation in international forums are described in reports along with the suggestions for incorporation of international experience in the BNRA activities. Such reports are disseminated through the BNRA intranet. Referring to those reports the BNRA chairman ensures the implementation of raised issues or suggestions thereto.**

2.3. SUMMARY

The IRRS team concluded that Republic of Bulgaria and BNRA fulfil their international obligations and participate in the relevant international arrangements, including international peer reviews. They promote international cooperation to enhance safety. Although elements are in place for use and dissemination of both national and international operating and regulatory experience in order to contribute to safety, BNRA should consider improving the process for providing information to international operating experience feedback systems by using established formats.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The regulatory body for radiation and nuclear safety in Bulgaria was created in 1957. When the Act on the Safe Use of Nuclear Energy (ASUNE) was issued in 2002, the Committee for Use of Atomic Energy for Peaceful Purposes (CUAEPP) became the Bulgarian Nuclear Regulatory Agency (BNRA). BNRA is the licensing authority for nuclear facilities and radiation sources. BNRA is responsible for nuclear and radiation safety. Both, BNRA and the Minister of Health have responsibilities for radiation safety in the area of occupational, medical and public radiation protection, while the Minister of Health has the sole responsibility for medical exposure.

BNRA rules of procedure, proposed by the chairman and approved under a decree by the Council of Ministers (CM), define the organization structure including the number of positions in each department of the organization. Changes of the department and number of personnel in the departments of BNRA require an approval of the CM. The last amendment of the rules of procedures was made in 2012. The organization structure of BNRA is given in Appendix IX.

A CM Decree (2012) limits the number of managers in the Bulgarian administration to 15 % of the personnel. As a consequence, BNRA has decreased its overall number of divisions by three. Other than the three technical departments, there are the department of international cooperation and the department of support functions. It is interpreted that the executive secretary is obliged to act as a quality manager by the Administrative Act. The inspector responsible for the oversight of the management system of the licensees is also responsible for development of the BNRA management system. There is internal audit unit for the financial auditing and verification that BNRA activities comply with laws. The internal auditor reports to the chairman of BNRA. The organization of the management system development and maintenance need further attention in the organizations of BNRA to ensure effective development and implementation of the system.

BNRA has its line in the state budget, which for 2013 amounts to about 5.8 million BGN. The budget is directly negotiated with the Ministry of Finance. BNRA has a possibility to contract technical support from national or international expert organizations (TSO) and on average about 1 million BGN per year is spend on support. Almost 40% of BNRA budget is allocated to fund the Bulgarian participation to the Joint Institute for Nuclear Research in Dubna and to the IAEA.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The foundation for independence of BNRA is given in the ASUNE and BNRA rule of procedure. Legislation describes BNRA's governmental position, regulatory duties as well as regulatory responsibilities and financial arrangements to ensure conduct of regulatory activities.

The legislation defines no other responsibilities or duties of BNRA that would be in conflict with regulatory control. The radiation protection is a shared responsibility with the Minister of Health through NCRRP. The oversight of radiation sources in medical applications by BNRA and the MoH needs to be defined more precisely to ensure that all the regulatory duties are carried out properly without any omission or overlaps.

With regard to inspections, there are six resident inspectors at the Kozloduy Nuclear Power Plant site (KNPP), all of them retired, former employees of the KNPP. The recruitment of resident inspectors from

the retired KNPP staff may challenge the impartiality of the resident inspections. When starting to work for BNRA they took part in the training program. However, after a few days training for the new employees as civil servants they are considered ready to start inspections. Moreover, the topic "conflict of interest" is treated in the Conflict of Interest Prevention and Ascertainment Act. The declaration of absence of conflict of interest is made annually and should include the financial and non-financial aspects. However there is no guidance how to review this issue and also to provide BNRA staff with clear expectations to ensure impartiality.

In addition, the IRRS team observed that the responsibilities of NCRRP divisions of Medical Exposure and of Inspection may challenge the impartiality in providing services and regulatory activities. NCRRP should have a clear guidance on impartiality.

This issue of impartiality has also been raised by the IRRS team for the advisory councils, as discussed in chapter 3.4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.6 states that** *"Requirements 3 and 4 in Section 2 stipulate that the government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence. The staff of the regulatory body shall remain focused on performing their functions in relation to safety, irrespective of any personal views. The competence of staff is a necessary element in achieving effective independence in decision making by the regulatory body."*
S4	**Suggestion: BNRA and NCRRP should further consider improving the process for ensuring the impartiality of its staff. Special attention should be paid to BNRA's resident inspectors, and NCRRP's different roles related to medical activities with radiation sources. Further provisions should be also considered to be included in the rule of procedures of the Advisory Councils to address potential conflict of interest.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

In 2002 BNRA carried out, under a Phare project, a very comprehensive analysis of staff competencies and skills, including regulatory needs and further challenges to the regulatory authority. Based on that analysis BNRA personnel was increased at that time by 22 positions to 102 positions - mostly for the departments of regulatory control of nuclear facilities and review and assessment.

By 2007, based on the assessment of needed competences, the number of positions had been gradually increased from 102 to 114 in the BNRA rules of procedure. However, the actual number of staff is 99. There are difficulties in recruiting experienced experts to work as civil servants. The number of vacancies represents 13 % of overall staff and it may have a negative impact on BNRA work.

The strategy-planning period in Bulgaria is three years and includes also planning of personnel. However, there is no document that gives evidence that they will hire additional personnel to the amount of 114. Each post has a job description and related requirements for the qualification in accordance with the Bulgarian administration requirements.

From the documentation received and the discussions and observations during the mission there seems to be an insufficient number of experts or lack of redundancy in several important nuclear and radiation

safety specific areas at present e.g. there are only single experts in areas such as PSA, civil structures / external hazards, mechanical engineering / pressure vessels, Instrumentation and Control and Quality Assurance (with some of these experts doubling-up to cover multiple disciplines) which might affect the capabilities of BNRA to fulfil its regulatory functions in the future.

Specific attention should be paid to the need of new specific areas of competences for the review process of near surface radioactive waste disposal facilities to be authorized for commissioning in 2015. This means that all the steps in the licensing process (site approval, design approval, construction permit and commissioning permit), should have been completed by 2015, and this very tight schedule will certainly increase the work load of the regulatory staff in the radioactive waste management area. There is limited expertise available at present to certain areas of new activities (e.g. geology, geochemistry, hydrogeology, radionuclide transport).

Other areas deserving more attention are the resource needs to complete the BNRA plan for new regulatory guides and developing and implementing a new BNRA integrated management system. The arrangements for assessing resource needs should cater better for the range of technical discipline areas.

The IRRS team observed that the inspection programme of the MoH is extensive, but is not always realistic and so can be challenging to achieve. In the audit made by NCRRP, it has been found that there is a lack of resources in the regional health inspectorates.

BNRA training plan for the year has four topical areas: training provided by state Administration, external courses and seminars, training for new comers and special topics. The IRRS team noted that BNRA has not established or documented the full content of the necessary competence and skills of staff for each position, including inspectors, through a systematic assessment of the required knowledge and abilities required for each position. The IRRS team could not verify the efficiency of the training provided by BNRA. As well, there is no formal qualification process to ensure that a person has obtained and retained the full range of knowledge and abilities to perform effectively as an inspector. BNRA should complete its comprehensive programme for developing the competence matrix within its approved plans, implement the methodology and utilize the results of the reviews to ensure the availability of the needed competences in a timely manner through recruitment and training of the BNRA staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**GSR part 1 Requirement 18 states that "***Staffing and competence of the regulatory body 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."*
(2)	**GSR part 1 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."*
(3)	**GSR part 1 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."*
R2	**Recommendation: BNRA should make efforts to fill its vacancies and to ensure there is sufficient competent staff to fulfil its regulatory duties. Special attention should be paid to the on-going licensing process for disposal facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R3	**Recommendation: The MoH should ensure that there are sufficient human resources to fulfil the regulatory duties of its inspection divisions.**
(1)	**BASIS: GSR Part 1 Para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
S5	**Suggestion: BNRA should consider enhancing its training programme for current and new inspectors and other BNRA staff involved in the management and implementation of the regulatory activities. The programme should include the verification of adequate knowledge and abilities of staff before they are certified as inspectors and ensure that suitable proficiency is maintained. The efficiency of the programme should be verified periodically.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

BNRA has two advisory council one for nuclear safety and the other for the radiation safety - Advisory Council on Nuclear Safety and Advisory Council on Radiation Protection. As BNRA is an independent organization reporting to the Prime Minister, the systematic request of the position of advisory councils further enhances the transparency of BNRA decision-making.

ASUNE article 9 defines the task of the advisory council to assist the BNRA chairman by expert advices on the scientific aspects of nuclear safety and radiation protection. However according to BNRA management system procedure, Advisory Councils are asked to provide advice on the following topic like legislation and development of acts and regulations, licensees' safety improvement programs, safety research initiatives, national reports of Bulgaria, exchange of operating experience and evolution of TSO support deliverables.

The IRRS team considers that above mentioned topics go beyond scientific advice. The role and consultation of the advisory councils is not systematically described in the BNRA management system procedures. BNRA should consider reviewing the role of advisory councils and their mandates for consistency purpose. In addition to the procedure of requesting advice through chairman request, these mandates should specify when advice is requested. It should be also beneficial to explain how the advice is made available for BNRA staff. BNRA should review its practices with advisory councils and set in line with GS-G-1.1 and the newly published guide on technical support and advice to regulatory body, GSG-4.

The advisory councils are composed of experts from scientific institutes, universities, experts from licensee's/licensees' organization and TSO experts. The presence of representatives from licensees or TSO might in some cases introduce a potential conflict of interest or impartiality in the decision to be taken by the council. As an example this was potentially the case when the site permit of Belene NPP was discussed and when the revision of ASUNE was performed in 2012. It should be advised to address the potential conflict of interest in the rule of procedure of the advisory councils.

BNRA assigns TSO to support the review and assessment activities and independent control of releases. There are 16 national TSO organizations with which BNRA has made a memorandum of understanding

and these organizations deliver BNRA competence data annually on the specified nuclear safety specific areas. The volume of TSO support depends on the oversight activities of BNRA and an annual plan is made. During major licensing activities BNRA has to use international TSOs as national TSOs are involved in the licensee's safety demonstration. Long-term contract with TSOs is made only during major licensing activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.19 states that** *"Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits shall be set for the degree of control and direction by the regulatory body over the work of the support organization. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services."*
GP3	**Good Practice: BNRA has established a memorandum of understanding with broad spectrum of national technical support organizations and keeps an annually updated database on the available competences in these organizations providing support on the radiation and nuclear safety of nuclear facilities.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

BNRA has established both formal and informal mechanisms for communication between BNRA and authorized parties to ensure possibilities for professional and constructive liaison. Based on the experience and stakeholder feedback, liaison and communication work very well between BNRA and the authorized parties. Formal and most frequently used mechanisms are through correspondence between BNRA and authorized parties, and inspections on the authorized activities and organizations. It is also possible for BNRA to invite authorized parties to a formal meeting or the authorized parties can request a meeting for clarification of the requirements. The chairman of BNRA has an active role in the oversight of the NPPs. He has daily conference call with the manager of the NPP and the chairman visits NPPs every second month meeting mangers at the plant and BNRA site inspectors. The BNRA chairman conducts walk-downs at the NPP and visits the control room. The mechanisms established allow possibilities for frank and open discussions to foster mutual understanding on safety related issues.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

BNRA's regulatory activities and decisions have to be based on legislation. They are outlined in the Acts and regulations for both nuclear safety and radiation safety. Regulatory activities and core processes are detailed in the management system, which is at the time of IRRS mission in a transition to IMS. The decisions are made in a structured manner and the chairman of BNRA signs licensees and permits. The technical departments prepare assessment reports that are submitted to the relevant deputy chairman after whose review the preparation of the licences and permits are made. The justifications and decisions are stored in databases.

Changing regulatory requirements presented in the legislation, regulations and regulatory guides is made following a process described in the management system. The process includes active participation of the involved stakeholders as well as advisory councils. Although the regulatory guides are not legally binding, the licensee has to come with a proposal to meet the intent of the regulations and it must be approved by BNRA.

3.7. SAFETY RELATED RECORDS

Provisions for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities are set out in the legislation, regulatory guides and licence conditions. For the use of nuclear energy the safety related data should be submitted to BNRA on a regular basis or in case of an event.

BNRA control of the documentation related to regulatory activities (Assessment, Licensing and Inspection) is done through the Electronic Information System (EIS) and Archiving System. The EIS includes different modules: Cases Register, Licensing and permission of nuclear facilities and radioactive sources, Licensing Specialized training, Inspections, Events, Radioactive Waste and List of legal persons licensed.

The tracking of documents between the licence applications, judgments and BNRA decisions is made in the EIS. The fulfilment of the conditions in licences and permits can be followed in the same EIS. The MoH keeps the register for doses.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

According to ASUNE, BNRA shall provide the public, legal persons and state authorities with objective information about the status of nuclear safety and radiation protection. Information is made publicly available in accordance with the national legislation and the international obligations. In the environmental impact assessment phase public hearing is organized by the Ministry of Environment and construction investment phase it is organized by the Minister of Economy, Energy and Tourism. BNRA takes part in these public information activities on its expertise. There is no obligation for BNRA to consult the public during licensing processes and BNRA practices do not include such activities.

BNRA implements a policy of transparency and openness with the public, the media and all government and non-governmental organizations in respect to safety issues, events and any other subject related to the safety of the public and the environment. A system to inform the public on the radiation situation in the country in both normal conditions and in nuclear and radiological emergency is established. The BNRA chairman report to the Prime Minister and he takes part in the CM meetings when nuclear or radiological safety is discussed. BNRA organizes courses on nuclear and radiation safety to media.

Extensive range of safety related information is provided through BNRA web site. The regulations and guides are there available for comments. The events are reported on the web site in in addition to Bulgarian, in Russian and English within 24 h. In the vicinity of nuclear facilities BNRA normally takes part in public meeting organized by municipal on request. The EU stress test result and actions were discussed in local public meetings.

BNRA should consider enhancing its public information by including public consultation to licensing process particularly in the vicinity of regulated faculties or activities with risk of public exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
GP4	**Good Practice: BNRA periodically invites the media to seminars, training activities and exercises.**
(1)	**BASIS: GSR Part 1 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 occurrences, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public."*
GP5	**Good Practice: BNRA publishes events at nuclear facilities and radioactive sources on its web page and makes them publicly available in multiple languages within 24 hours from the notification of BNRA.**

3.9. SUMMARY

The IRRS team concluded that the relation with the licensee and the public, as well as regulatory stability are in compliance with the IAEA Safety Standards. The IRRS team recommended ensuring appropriate resources for oversight of projected additional facilities and activities. The IRRS team suggested BNRA should consider enhancing the effectiveness of the staff training programme as well as further developing the use of advisory councils. The IRRS team commended BNRA for the management of its TSOs. BNRA's public information for events is seen as a good practice.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The Bulgaria Nuclear Regulatory Agency (BNRA) has been developing and implementing a Quality Management System (QMS) since 2002. Not all QMS documents had been revised in the period from 2002 to 2012 because there was no process that required periodical review. As a consequence neither the experience from their use had been considered nor the development of the concept of integrated management system. BNRA has established and implemented a management system but there is no documented and systematic way to improve it. Not all regulatory activities and support activities have been defined by documented processes. The description of the processes is not complete or in detail: e.g., module 7 inspection (the inspection procedures do not include a planned and systematic program that defines the frequency or level of effort for inspections), and module 10 emergency preparedness and response (BNRA personnel who need to be activated to join the emergency team are not formally established nor are they included into the management system. Hardcopies of the documents are available at the emergency centre, which are not controlled copies).

The QMS includes around 70 documents. As a result of the self-assessment for the IRRS mission BNRA developed a plan, approved by the chairman, to establish the basis for transition from the QMS to an integrated management system (IMS). Also as a result of the self-assessment, most of the QMS have been recently reviewed and now there is a list of all 65 QMS which indicate who is responsible and the periodicity of the review (3 or 5 years). One of the objectives of the Strategic Plan 2012-2014 of BNRA is to develop and implement an integrated management system which takes into account safety requirements consistent with other applicable requirements towards the BNRA activities, ensuring the priority to safety and meeting the requirements of the IAEA Safety Standards GSR Part 1 and GS-R-3.

Priority of safety over all other aspects derives from the Act on the Safe Use of Nuclear Energy (ASUNE) and the Policy Statement of BNRA. In 2010 BNRA developed and implemented guidelines for supporting the Safety Culture Oversight Process (SCOP). These guidelines aim at establishing a structured process for the identification, collection, classification, trending and reporting of data relevant to the safety culture in the licensees' organizations (NPP). However, the QMS documents could more explicitly address the safety culture of the regulatory body itself.

4.2. MANAGEMENT RESPONSIBILITY

The task and management responsibilities are stated in ASUNE, the rules of procedures of BNRA and in recently reviewed QMS. In the policy statement the Management of BNRA declares that "The Management will develop, implement, review and improve an integrated management system, which gives priority to safety and foster the development of safety culture". In practice, the executive secretary is the QMS manager. In the Transition plan it is stated that a team has to be assigned to accomplish the transition from QMS to IMS. The team has to include as a minimum the executive secretary, a lawyer and at least one representative of each department of BNRA. Training has to be organized for the team, to ensure basic knowledge on the implementation of a process approach and specific knowledge and practical skills on analysis, development, documenting and improvement of the processes. The responsibilities of the team are made clear in the Transition plan. The executive secretary is responsible for the development of the IMS and will report to the chairman. There is no document that describes a detailed overview of all the processes that have to be described, when it has to be ready and what resources would be needed for the development and implementation of an IMS. BNRA are planning to have this document prepared in June 2013.

In order to be transparent and open, BNRA in practice use several means to communicate with the stakeholders, e.g. public discussions, a dialogue with applicants, draft regulation published on the web site for opinion and public discussion. If asked BNRA gives all information to the municipalities near the NPP. BNRA organizes trainings for journalist. But there is no QMS document how to deal in a systematic way with the feedback from the stakeholders.

A three year strategic plan describes the strategic goals. These goals are further developed into objectives the achievement of which is assured by annual plans (annual plans on inspection, development of guides etc.). There are no indicators for effectiveness besides financial ones. Several Acts require different elements of planning. The QMS does not document all these different elements of planning.

The progress of the execution of the plan is made at each level of managers. At the end of the year the divisions report on their activities. There is an annual report of BNRA to the Council of Ministers. The QMS does not establish a mechanism for control of the status of execution of the plan. There is a draft document that describes the structure and content of the BNRA Performance Indicator System including methods for determining indicators, purpose of the separate indicators and who is responsible for data collection, calculation, assessment and reporting of individual indicators.

4.3. RESOURCE MANAGEMENT

The legislation determines the total number of BNRA staff and the kind of functions. Almost all employees of the Agency have a higher education (master's degree) and long professional experience in the field of regulation, design, construction and operation of nuclear facilities and sites with SIR. Not all the staff positions are filled in because of lower salary BRNA is offering as compared to the NPP, the amount of people that are retiring and the decision made on the Belene project. It should be noted that 51% of the positions are occupied by employees to age 45 years and 17 % will retire within 5 years. There is a succession plan that makes it possible to recruit young people in a lower position, to train them and to work together with the employee who will retire. Because it is not possible to hire experienced employees (due to a lower salary than NPPs are offering) BNRA has started to hire young people from universities. If there is a vacancy it is possible to start with an internal selection process provided there are internal candidates. This procedure is much shorter than an external procedure.

The competence requirements for the staff positions (e.g. education level, years of work experience) are specified in the Administration Law (ranking system) and in the job description. Education level, training and years of experience are the key elements of the competence requirements. The appraisal system is linked to the ranking system. If an employee performs extraordinarily she/he is promoted to the next rank within the same level. After 3 years there is always a promotion to the next rank because of the criteria on years of experience.

There is an annual training programme with four modules (I. for every civil servant, II. special BNRA training, III. individual training programme and IV. external lectures). During mid-term performance review the training programme is discussed with every individual. But there is no systematic and structured training process documented. There are no provisions for verification of the knowledge after training.

The IRRS team made the observation that the required competences are not described in detail and that there is no provision for verification of the knowledge after training, therefore it is questionable how it is possible to make an assessment if the required competences are met.

By the end of this year a competence matrix will be available. Based on this matrix a structured training programme will be prepared. There is a draft procedure which establishes that (1) the training should end

with an examination or a certification (2) formal feedback on internal training is needed and (3) terms of reference for each position (detailed required competence and required level) are to be prepared.

4.4. PROCESS IMPLEMENTATION

Methods for identification and development of processes, documentation of processes, process maps and the scope of process owner responsibility, control of records are all elements of QMS. These processes are not completely documented (see 4.1). There are few process maps but they are not approved and the process of making other process maps is stopped because BNRA planned to start an IMS. The Transition plan (Para. 4.20-4.23) states that the IMS should have a process approach which includes all these elements.

Processes, documents (included changes) and other information are published on the intranet, discussed in managerial meetings and in meetings of the division.

The documents are stored on paper and on electronic media. The electronic documentation system was developed in 2003. The traceability of the documents is possible using the index number or key words. There is no electronic workflow system.

BNRA does not have a process on managing organizational changes. If a change to the organization requires a modification of the Rules of Procedures for BNRA, it has to be approved by the Council of Ministers. According to the transition plan the process on managing organizational changes will be one of the elements of the new IMS.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

According to the Administration Act BNRA completes twice a year a self-assessment questionnaire of 300 pages on the administrative services. There is no documented procedure for the self-assessment and there are no performance indicators, there is only a draft document that describes the structure and content of the BNRA Performance Indicator System (see 4.2).

In compliance with the Act on Internal audit in the public sector there is an independent audit unit within BNRA. There is one auditor in BNRA and the focus of the audits is on financial questions or on compliance of the activity with legislative requirements. The results of the internal audit are reported to the chairman, the chairman will order for action. The process of internal audit is well described.

The National audit office performs a financial audit of BNRA activities every year. The National audit office can decide to do a full scale audit. A full scale audit had been done in 2005 and in 2008. The audit team is composed of technical and financial experts. The audit in 2005 did not provide recommendations, the audit in 2008 resulted in two recommendations.

There are no written procedures on management system reviews. In practice reviews take input from various sources e.g. reports from the divisions, feedback from applicants, yet there is no systematic review process and there is no defined review methodology.

The identifications of non-conformances should be the result of an internal audit, feedback from applicants, etc. Each employee may identify non-conformances or potential ones. Practice is that employees can report to the head of their unit, division or even the chairman. There is no procedure for reporting problems or non-conformances, or for giving suggestions for improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GS-R-3 Para. 2.1 states that "***The regulatory body shall establish, implement, and assess and improve a management system that is aligned with the goals of the organisation and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:* *Bringing together in a coherent manner all the requirements for managing the organisation;* *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;* *Ensuring that health, environment, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."*
(3)	**BASIS: GS-R-3 Para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* *Ensuring a common understanding of the key aspects of safety culture within an organization;* *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* *Reinforcing a learning and questioning attitude at all levels of the organization* *Providing the means by which the organization continually seeks to develop and improve its safety culture."*
(4)	**BASIS: GS-R-3 Para. 4.1 states that "***Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system."*
R4	**Recommendation: BNRA should upgrade the existing management system to an integrated management system which is in line with the goals of the organization and contributes to their achievement. This management system should address, promote and more strongly support the safety culture. Adequate resource should be identified and assigned for the development and maintenance of this integrated management system.**

4.6. SUMMARY

BNRA has been developing and implementing a Quality Management System since 2002 but it is not systematically improved. Most of the QMS documents have been recently reviewed.

BNRA has not established an integrated management system. However, a plan has been approved by the chairman to upgrade the existing QMS. Adequate resources should be allocated for the development and maintenance of this integrated management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Chapter 3 of the "Act on the Safe Use of Nuclear Energy" (ASUNE), articles 14 to 44, establish legal provisions for the authorization process for safe use of nuclear energy and ionizing radiation, and on the safety of radioactive waste management and spent fuel management. The authorizations include licences and permits. ASUNE authorizes the chairman of Bulgarian Nuclear Regulatory Agency (BNRA) to issue, amend, supplement, renew, suspend and revoke licences and permits. Accordingly, ASUNE prescribes the activities and stages where a licence or permit is required, the activities prohibited, the time period for issuing an authorization, the contents of authorization, validity period for a licence and requirements for renewal/revalidation of an authorization, ASUNE is supported by "Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy". The regulation includes general provisions, authorizations procedure, scope and contents of authorization, submission requirements and contents of the submissions. In addition, specific regulations have been promulgated establishing detailed requirements for nuclear power plants, sources of ionizing radiation, radioactive waste management, decommissioning, emergency preparedness, physical protection, qualification, research reactors, safeguards, etc., to support the authorization process and activities.

Under the management system documentation, BNRA has issued the "Procedure for Issuing Licences and Permits for Activities Involving Nuclear Facilities" (No.QMS-LA-P-01), as well as the "Procedure for Order of Issuing Licences and Permits for Activities with Sources of Ionizing Radiation" (No.QMS-LA-P-02). These procedures describe the policy and principles of BNRA for the authorization process, responsibilities of individuals and organizational units in the authorization process, details of the process flow including review and assessment of authorization applications, documents generated during the authorization process, as well as safekeeping of documents. The interaction with other regulatory bodies is described in the same procedures.

The authorization process of BNRA for nuclear power plants and nuclear fuel cycle facilities covers all steps starting from siting to decommissioning. However, provision for release of buildings and sites from regulatory control upon completion of decommissioning activities is not addressed in legal or regulatory framework. Although it is understood within the organization that upon completion of the decommissioning activities and ensuring that no hazard from ionizing radiation exists, the facility may be released from the regulatory control but it is not categorically mentioned in the legislative or regulatory framework. 'Release from regulatory control' is one of the licensing stages and the end point of authorization process as mentioned in IAEA Safety Standards. The IRRS team considers that such provision should be addressed in legal and regulatory framework for authorization.

ASUNE (article 24) provides the right of appeal before the Supreme Administrative Court against any administrative act (an authorization is considered as an administrative act). According to the Bulgarian legal system an appeal against a decision can only be made at a higher level and since the authorization is issued by the BNRA chairman, an appeal cannot be made to the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**Basis: WS-R-5 Para. 9.2 states that** *"The facility shall not be released from regulatory control, nor shall authorization be terminated until the operating organization has demonstrated that the end state in the decommissioning plan has been reached and that any additional regulatory requirements have been met. The regulatory body shall evaluate the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	end state of the site by performing a thorough inspection of the remainder of the facility after decommissioning activities have been completed to ensure that the end point criteria have been met."
(2)	**BASIS: SSG 12 Para. 2.5 states that "***Licences and authorizations should be granted or denied in accordance with the national legal and governmental framework and should cover all stages of the lifetime of the nuclear installation, namely, site evaluation, design, construction, commissioning, operation, decommissioning and subsequent release of the site from regulatory control."*
(3)	**BASIS: SSG 12 Para. 3.100 states that** *"Once the regulatory body has accepted the evidence provided, the licence can be terminated and the licensee can be relieved of further licensing responsibilities."*
R5	**Recommendation: BNRA should establish a process within the regulatory framework for the release of nuclear facilities and related activities from regulatory control.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS AND NUCLEAR FUEL CYCLE FACILITIES

The authorization stages for nuclear facilities include permits for siting (site selection), permit for design, permit for construction, permit for commissioning, licence for operation and licence for decommissioning. Separate permits and licences are issued to each unit and any other nuclear facility at a site of nuclear power plant. In addition, permits are required for:

a. activities leading to modification of:
    i. structures, systems and components important to safety;
    ii. limits and conditions for operation that provide the basis for issuing of the operating licence;
    iii. internal rules for conduct of licensee activities including instructions, programmes, technical specifications and other documents attached to the licence;
b. import or export of nuclear material; and
c. commercial transactions involving nuclear facilities and nuclear material.

An application for obtaining an authorization from BNRA for respective authorization stages is accompanied with the documentation mentioned in ASUNE and the licensing regulation. In order to support the decision making during the authorization process, BNRA has established a process for assessment of application and documents submitted with the application. The process comprises the following three main stages:

a. Review of formal compliance – to ensure that the submissions conform to the statutory requirements;
b. Essential review – for preparation of an expert opinion on the application submissions;
c. On-site inspection – to verify the information and data presented in the application submissions.

The validity of the operating licence is up to ten years and further operation requires licence renewal from BNRA. A decision on licence renewal is made on the basis of an assessment by BNRA staff of the updated safety assessment report (based on periodic safety review report) submitted by the licensee.

In addition to the provisions for the authorization of facilities, articles 64 and 65 of ASUNE establish legal provisions for issuing licences to individuals and specialised training facilities respectively. "Regulation on the Terms and Procedure for Obtaining Vocational Qualification and on the Procedure for Issuing of Licences for Specialized Training and of Individual Licences for use of Nuclear Power" prescribes the terms and procedures for such licensing.

The existing legislative and regulatory framework related to authorization of nuclear facilities and sources of ionizing radiation does not include provisions for public participation or consultation with the public during various steps of the authorization process. Neither any process has been established within BNRA under its management system for such consultation during authorization stages. It is mentioned that such consultation is required in IAEA Safety Standards GSR Part 1 as well as SSG-12. Nevertheless, BNRA has a well-established system for public information and a fairly good amount of information is shared with the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: SSG 12 Para. 2.42 states that** *"The public should be given an opportunity to present their views during certain steps of the licensing process, where appropriate. If a site is near a State's national border, there should be appropriate cooperation, including public participation, with neighbouring State(s) in the vicinity of the nuclear installation."*
(3)	**BASIS: SSG 12 Para. 2.43 states that** *"Transparency, along with public participation and involvement in the regulatory process, reinforces the credibility of the regulatory body and enhances local public confidence in the nuclear regulatory regime. The process for public participation should allow individuals or societal groups to challenge the issuing of a licence or authorization if it appears to jeopardize health or safety."*
(4)	**BASIS: SSG 12 Para. 2.44 states that** *"Throughout the lifetime of the nuclear installation, the public participation process, including participation of local, national and international interested parties, should be open, transparent, well described and balanced, and should ensure that security sensitivities and commercial proprietary information are respected. For example: […]* *(b) Regular meetings, formal hearings and other appropriate means of communication should be:* *i. Open to the public, the media and other interested parties;* *ii. Announced a reasonable period of time before the meeting or hearing takes place.* *(c) The public should be given the opportunity to present their opinions at meetings and formal hearings and via other appropriate means of communication.* *(d) Comments from the public should be addressed at all steps of the licensing process."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(5)	**BASIS: SSG 12 Para. 2.45 states that** *"A process for consideration and resolution of concerns should be established in national regulations and guides."*
S6	**Suggestion: BNRA should consider establishing a process to consult, where appropriate, the interested parties, including the public, during the licensing process so that they are able to present their views, and their concerns are addressed.**

Policy Discussion on the Long Term Operation of Nuclear Power Plants

The policy discussion on Long Term Operation (LTO) was introduced by a presentation from BNRA on its LTO approach.

In Bulgaria, the LTO issue concerns units no. 5 and 6 of Kozloduy nuclear power plant, which started commercial operation in 1987 and 1991, respectively, and have operational licences until 2017 and 2019. BNRA stressed that these units have undergone a large-scale modernization programme in the period 1999-2008, and this was taken into account in the periodic safety review (PSR) in 2008-2009.

With regard to the future, in addition to regulatory requirements set in the PSR, BNRA identified two key issues that deserve special attention in view of LTO:

- ageing management; and
- enhancement of the safety level with the aim to approach, as close as reasonably practicable, a level set for new reactors.

Consequently, BNRA has imposed specific LTO related licence conditions to the operator of Kozloduy NPP. At the end of 2012, the licensee therefore submitted to BNRA a programme for integrated plant assessment for review. On this basis, a Lifetime Extension Programme will be developed and implemented by the operator from 2013 to 2017.

The IRRS team noted with satisfaction that BNRA had evaluated the LTO approach against the related IAEA Safety Standards and had concluded that they were fully consistent.

The IRRS team provided feedback on the LTO experience in other countries. In Pakistan for example, an ageing management programme was introduced as part of an LTO approach, and additional environmental assessment had to be carried out following a modification of the dose criteria for public exposure. In France, the structure of the LTO approach is very similar to that presented by BNRA, with a focus, on one hand, on ageing management, and on the other hand, on safety upgrades taking as a reference the safety level of Generation III reactors.

Regarding severe accident management in case of core melt, BNRA stressed that a lot of measures had already been taken, and several types of mitigation measures were being studied for Bulgarian NPPs. Due to the complexity of the issue and the investigation activities going on, the actual implementation of the concept for retention of the molten core and prevention of containment basemat melt-through is planned to take place within the frame of the PSR follow up safety improvement actions. This timeframe was confirmed to be consistent with other countries. The actual implementation of some of these safety improvements might occur after the next PSR since long studies are required, for example for additional prevention of basemat melt-through. Besides, following the stress tests that were carried out after the TEPCO Fukushima Daiichi accident, several countries required severe accident equipment to have seismic qualification beyond the design basis level; the precise definition of this beyond design basis level of seismic qualification requires additional review in Bulgaria as well as in other countries.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

According to the Regulation on Radioactive Waste Management, radioactive waste management facilities are considered nuclear facilities and as a consequence, predisposal and disposal facilities fall under the authorization process of nuclear facilities. During the step by step process of the development of nuclear facilities, authorizations under the form of permits, approval and licences are given by BNRA to the operator from site selection permit to decommissioning.

Authorizations for the different steps of the licensing process are given on the basis of Preliminary Safety Analysis Report for the siting stage, Intermediate Safety Analysis Report of the construction permit and a Final Safety Analysis Report for the licence for operation.

Disposal facilities for radioactive waste are considered nuclear facilities and follow the above described licensing process. Disposal facilities are consequently meant to receive a licence for decommissioning at the end of the development process.

Safety of disposal facilities relies on the concept of passive safety and as a consequence the closure of disposal facilities is of major importance in terms of safety compared to other radioactive waste management facilities.

Despite the fact that, according to the definition given in ASUNE, "decommissioning" includes closure, the consideration given to this step in the regulation on radioactive waste management, in particular in the case of disposal facilities for radioactive waste should be enhanced. In particular the conditions for closure should be specified and the licensing aspects related to this step for disposal facilities should be specified. Consideration should be given to the development of a regulatory guidance dedicated to disposal of radioactive waste addressing the specific aspect of closure of the disposal facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 24 states that** *"The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."*
(2)	**BASIS: GSR Part 1 Para. 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity.* *[…]* *For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure)."*
(3)	**BASIS: SSR 5 Requirement 2 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."*
(4)	**BASIS: SSR 5 Requirement 19 states that** *"A disposal facility shall be closed in a way that provides for those safety functions that have been shown by the safety case to be important after closure. Plans for closure, including the transition from active management of the facility, shall be well defined and practicable, so that closure can be carried out safely at an appropriate time."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(5)	**BASIS: SSR 5 Para. 4.39 states that** *"The disposal facility has to be closed in accordance with the conditions set for closure by the regulatory body in the facility's authorization […]."*
S7	**Suggestion: BNRA should consider ensuring that, for radioactive waste disposal facilities, the conditions for closure of the facility, including the licensing aspects, are clarified.**

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES

According to Article 56 (1) of ASUNE, all activities with sources of ionizing radiation (SIR) can be performed only on the basis of licences or permits except those practices that are exempted because the radiation risk is negligible. According to Enc No 2 Art 73(4) of Regulations for licensing certain activities with SIR are not subject to authorization regime but subject to control under ASUNE. These include some x-ray or electron devices used in dentistry, element analysis, luggage inspection, microscopes, etc., as well as sealed sources of category 5. Following this the graded approach authorization is reasonably applied. For medical application of SIR, all facilities, sources, activities/practices are subject to authorization except practices of intraoral dental radiology and peripheral bone densitometry which are subject to notification only.

ASUNE attaches conditions for responsibilities, operator competences, design and performance criteria, including inventory control and keeping records on the SIR, what information needs to be reported to BNRA, appointing qualified persons responsible for SIR internal control, as well as provisions for immediate notification to BNRA of any incident/accident with SIR.

The authorizations are being granted for performing certain types of activities, which are defined in the conditions of the licences, formulating the scope of the licence (article 13 of the Regulation on Licensing). In some cases, separate licences may be issued to one facility for separate activities such as for industrial radiography facility which may hold one licence for the use of SIR and one for SIR transport. Each medical practice (diagnostic radiology, nuclear medicine, radiation therapy, cardiology, orthopedic, etc.) needs a separate licence, which specifies all modalities within the practice (e.g., conventional X-ray, CT and mammography) and the specific number of installed equipment within each modality. An amendment has to be applied when new equipment is installed or new modalities are introduced in the licensed department. New practices need separate licence.

According to Article 14(1) Para. 4, Article 15(2) and Article 38(2) of the Health Act (2011), the responsibility of protection of the public is given to the Regional Health Inspectorates (RHI) and NCRRP. Finally, several sections of the Health Act take provision for radiation protection and safety of the patient. Following this, the MoH and BNRA have joint responsibility for radiation protection and safety of members of the public and radiation workers at facilities and activities with SIR for all ionizing radiation application (medical, industrial, research, etc.). The MoH has the main responsibility for regulatory control of medical exposure of the patient.

During the commissioning phase of facility or application with SIR a Statement and/or Conclusion from the MoH (NCRRP) is issued regarding the compliance of the site, the technical design with the relevant legal and regulatory requirements. For medical exposure, this includes also the quality assurance programme. This document is obligatory for the authorization of the SIR by BNRA.

The mechanism of information exchange between BNRA and the MoH (NCRRP and RHI) is not a formalized process and would depend on a case-by-case basis, while it is not clear if it is applied for all

types of radiation application (medical, industrial, etc.) consistently. Should there be any disagreement between BNRA and the MoH (NCRRP and RHI), discussion would then begin to reach to a consensus.

According to Article 20 of ASUNE, a licence shall be issued for a term of validity not exceeding ten years. The activities under permits are usually implemented in short term (construction, import /export etc.). The licence validity period is left for the discretion of BNRA inspectors, based on their experience and expertise, since BNRA does not have an objective and clearly established criteria for consistent implementation on this period.

The justification principle of the use of SIR is applied for new practices introduced in the country. However, the approval of new practices is based on the assessment of the information and the justification provided by the applicant. If needed, BNRA contacts experts from the MoH. On the other hand, justification assessments are not performed with clearly defined criteria for new activities (new applications) with already existing and approved practices.

Recycling of radioactive sources is not currently practised and Bulgaria does not produce radioactive sources. Licences for the re-use of source may be issued.

Entities with radioactive sources carrying out radioactive waste generating activities (including disused radioactive sources) bear the cost of their management for their entire life (Cradle-to-Grave) by contributing to the Radioactive Waste Fund established by ASUNE. In case of bankruptcy of a facility, the SIR that the facility possesses will still be the responsibility of facility management. The state, through BNRA, takes actions (regain and recovery) only when the SIR become orphan.

According to Art 73 of ASUNE, any radioactive substances and other SIR, for which the owner is unknown, shall constitute state property. Found orphan sources are secured and handed over to SERAW for safe storage.

BNRA maintained a database of SIR since 1992 whereas data from 2004 is maintained similar to RAIS. Information about all sealed sources (category 1 – 5), device (model, manufacturer, serial No, etc.), unsealed sources, x-ray devices and accelerators, licensees, issued licences and permits and licence conditions, etc., is maintained.

Since 1998 BNRA maintains database for the radiation emergency situations (incidents) with radioactive sources in the country. BNRA submits to INES the relevant reports and publishes information regarding such cases on a regular basis on its web page.

ASUNE Art 59 states that a permit for import of a sealed source belonging to Category 1, 2 or 3 and having radioactive half-life exceeding five years shall be issued if it is ensured that the SIR will be returned to the manufacturer after source useful life. Extension of manufacturer's source life-time is considered by BNRA.

For the import and export of SIR, the Council Regulation (Euratom) No 1493/93 (shipments between Member States) is applied. Transfers of radioactive sources in Categories 1 and 2 take place only with the prior notification of the exporting State and, as appropriate, consent by the importing State. In practice, ANNEX I of EU No 1493/93 directive is required for all source categories 1- 5.

A permit for import / export of SIR is issued by BNRA for shipments between Bulgaria and non EU countries. For shipments within the EU the issuance of such a permit is not required. In all cases, a certificate for import / export is issued, as shipment declaration between the supplier and the end user. According to ASUNE [article 17(4)], the import of radioactive waste in Bulgaria is prohibited.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.37 states that** *"Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure."*
(2)	**BASIS: GSR Part 3 Para. 2.31 states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."*
S8	**Suggestion: BNRA should consider establishing objective and clear criteria for the issuing and renewal of licences regarding the validity period of the licences and permits for SIR.**
(1)	**BASIS: GSR Part 3 Para. 3.63 states that** *"The regulatory body, in cooperation with other relevant authorities, agencies and professional bodies, as appropriate, shall establish the requirements for regulatory control of the practice, and for review of the justification."*
S9	**Suggestion: BNRA should consider defining and applying criteria for the justification of new practices, and activities with already approved practices with SIR.**
(1)	**BASIS: CoC Para. 26 states that "***If the conditions in paragraphs 24 and 25 with respect to a particular import or export cannot be satisfied, that import or export may be authorized in exceptional circumstances with the consent of the importing State if an alternative arrangement has been made to ensure the source will be managed in a safe and secure manner."*
S10	**Suggestion: BNRA should consider establishing a process and defining procedures for the import and export of radioactive sources in exceptional cases where the ordinal import or export procedure cannot be applied.**
(1)	**BASIS: GSR Part 1 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."*
S11	**Suggestion: BNRA should consider issuing guidance on the content of documents, especially those related to safety and security that the applicant submits to BNRA during the authorization process.**

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Bulgaria is implementing the measures for accelerated decommissioning, as planned by the National Strategy for Management of Radioactive Waste and Spent Nuclear Fuel and based on the concept of immediate dismantling. The stage of safe enclosure of reactor buildings was reconsidered and duration of decommissioning process was reduced by 5 years with the objective to reach "brown field" state by 2030. This time limit is specified by the National Strategy (adopted by the Council of Ministers on 05.01.2011).

The basic requirements are provided by the Regulation on Safe Decommissioning (2004) and by the Regulatory Guide on structure and content of a NPP decommissioning plan (2010).

It has been recognized also in the self-assessment that there is no regulation or guidance to ensure the application of the final controls to verify the achievement of the end state of the decommissioned facility and the compliance with the requirements for the release of buildings and sites from the regulatory control.

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

According to ASUNE, a permit or licence is required for every transport of radioactive material. Permits are required for single shipments of radioactive or nuclear material and for transits through Bulgaria of radioactive materials (including radioactive waste, spent fuel, etc.). Licences are required for multiple shipments of radioactive material (excluding fissile material and radioactive waste) in Bulgaria.

There are relatively few transports of fissile material, all of which relate to Kozloduy NPP. In regard to the transport of non-fissile (or fissile-excepted) material, about 50 licensees and about 20 permits were issued during the last 5 years.

Adopting a single regime for transport licensing does not fully align with a graded approach, particularly for the transport or transit of very low level radioactive materials. The IRRS team therefore suggests that BNRA should consider whether it is appropriate to exempt very low radioactive materials from requiring a licence or permit for transport. Nevertheless, the IRRS team agrees that these transports should at least be subject to a notification process that would allow BNRA to act if it has particular concerns.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either exempted or approved by means of a notification process."*
(2)	**BASIS: GSR Part 3 Para. 2.31 states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."*
S12	**Suggestion: BNRA should consider exempting the transport of very low level radioactive material from an authorization in accordance with a graded approach.**

All the types of authorization (i.e. "unilateral" and "multilateral" approvals) listed in IAEA's transport regulation in Para. 802 of TS-R-1 are regulated by licence or permit for transport in Bulgaria.

There is ever no design, manufacturing or testing of packages, of special form of radioactive material, or of low level dispersible material in Bulgaria (to-date only foreign designed packages have been used). This means that Bulgarian unilateral approval does not yet exist, though IRRS team agree there is no urgent need for this at present.

Furthermore, according to the discussion with the BNRA staff, the responsibility for approval of package design has not been appointed to BNRA in the ASUNE if the package is not used in an actual transport of radioactive material.

While it is recognised that there is no current necessity for such an authorization process, The IRRS team suggests that the government should consider appointing a competent authority to address this gap.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: TS-R-1 Requirement 802 states that "***Competent authority approval shall be required for the following:* *(a) Designs for: […]* *iii. Packages containing 0.1 kg or more of uranium hexafluoride (see Para. 805);* *iv. All packages containing fissile material unless exempted by Para. 417 (see Paras 812–814, 816 and 817);* *v. Type B(U) packages and Type B(M) packages (see Paras 806–811, 816 and 817);* vi. *Type C packages (see Paras 806–808). […]"*
(2)	**BASIS: TS-R-1 Requirements 805, 808, 811, 814 state that** *"[...] The competent authority shall establish an approval certificate stating that the approved design meets the requirements [...] and shall attribute to that design an identification mark."*
(3)	**BASIS: TS-R-1 Requirement 833 states that "***Each approval certificate of the design of a package […] shall include the following information: [...]."*
S13	**Suggestion: The government should consider appointing a competent authority (e.g. BNRA) for approval of package design to address cases where such approvals cannot be included in a licence or a permit for transport.**

5.7. SUMMARY

The legal and regulatory framework for the authorization of nuclear facilities and sources of ionizing radiation is available in ASUNE and "Regulations on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy". The authorization issued by BNRA includes licences and permits which are issued during various stages of the authorization process. BNRA also issues licences to certain individuals working in certain positions and special training institutions for providing training in the area of nuclear safety and radiation protection. The chairman of BNRA has the authority to issue, amend, renew, suspend and revoke licences and permits. In addition, internal processes followed for issuing authorization are described in procedures and instructions issued under the management system of BNRA. In general the legal and regulatory framework for the authorization process of BNRA and the authorization stages established are in line with the IAEA Safety Standards. However, certain issues have been identified by the IRRS team. The issue of non-availability of a defined process for release of site and facility from regulatory control formed the basis for a recommendation. Some of the issues that led to suggestions are that public consultation is not made during licensing stage; conditions for the closure of a radioactive waste disposal facility are not clearly defined in the regulatory framework; objective, clear criteria and procedures on renewal of authorization for SIR including a validity period are not established; criteria to justify new practices and activities with SIR are not defined. The team observed that BNRA publishes incidents with SIR on its website which in the opinion of the team is a good practice.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

In accordance with the Act on the Safe Use of Nuclear Energy (ASUNE), anyone using nuclear energy, sources of ionising radiation (SIR), or performing activities involving radioactive waste management or spent fuel management is required to undertake review and assessment. Such reviews and assessments are used to evaluate nuclear safety and/or radiological protection at the nuclear facilities / sites, and so identify non-compliances with legal requirements and implement improvements. Information on the nature and content of these reviews and assessments is set out in the respective Regulations.

Under Bulgarian law, the regulators (BNRA and the MoH) need to review and assess the documentation submitted in support of applications to proceed with activities, or to receive a licence or permit.

The general approach followed is to focus exclusively on whether all legal and regulatory requirements are met. The scope of review and assessment activities is focussed, only to a limited extent on other matters, such as helping to inform the scope of future inspection plans, or to provide objective evidence on the safety performance of licensees. Instead the assessment output appears to be focussed exclusively on documenting compliance, or otherwise, with legal requirements and so support of regulatory decision-making.

In preparation for this mission (as a finding from its self-assessment), BNRA re-issued its internal procedure QMS-AA-P-01, which governs review and assessment activities for nuclear, fuel cycle and RAW facilities. A second procedure governing review and assessment for sources and transport (QMS-AA-P02) was similarly re-issued by BNRA. QMS-AA-P01 appears to be in use for NPP, fuel cycle and RAW facilities and decommissioning activities reviews and assessments. However, in other areas covered by ASUNE (e.g. transport of radioactive substances, control of discharges and environmental monitoring), procedures describing and providing guidance on how to undertake review and assessment have either yet to be written, or it was unclear as to the extent to which they are implemented in practice. Details of the extent to which procedures for review and assessment are established and implemented are provided in other sections of this report. Areas where QMS-AA-P-01 might reasonably be improved in regard to the review and assessment of NPPs are identified later in this section.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures."*
(2)	**BASIS: GSR Part 1 Requirement 26 states that "***Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R6	**Recommendation: BNRA and the MoH should establish as appropriate or improve the existing procedures governing the review and assessment activities for all types of facilities and activities under their regulation and oversight.**

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The documents to be submitted to BNRA for NPPs are prescribed in detail in the Licensing Regulation. The documents relate to the issuing or amendment (etc.) of licences and permits required under ASUNE or to the conditions attached to licences and permits issued by BNRA. The size of the submissions vary considerably, e.g. between the Intermediate Safety Analysis Report submission for the proposed construction of a new NPP at Belene (which ran to several hundred documents) down to routine permit applications for relatively low risk / hazard proposals. In 2012, BNRA completed 122 reviews and assessments.

BNRA provides relatively little practical guidance for undertaking review and assessment. The above-mentioned QMS-AA-P-01 provides a brief overview of the steps of the process (6 pages of content), but little by way of advice to assessors on what is expected of them.

Application of QMS-AA-P01 leads to safety assessment outputs that can often be rather brief. Around six assessment documents were reviewed over the course of the mission. Notably the assessment of the Intermediate Safety Analysis Report submission for Belene was an extremely detailed piece of work that appeared to be of high quality and had clearly taken a considerable amount of effort (notably with considerable input from BNRA's TSOs) to produce. However, this document is not the norm.

Routine assessments (called expert opinions) produced by BNRA typically contain just a few paragraphs of assessment comment, with the majority of the document (which are often just 3-5 pages) taken up with procedural information such as the name of regulations the assessment was performed under (but not the specific regulation(s)) and references listing the documents submitted by the licensee. These reports are mainly overview statements of the assessors' final opinions after the completion of their review and assessment work. In the examples seen during the mission, these statements were typically a few sentences along the lines that a certain requirement was not met because of a particular reason. Areas where the assessor considered the licensee had met the requisite requirements passed without any justifying comment in the expert opinion. In some cases the expert opinions quote a safety standard (e.g. from IAEA), but in the cases seen this was often just the document title and never the aspect (element) of the standard against which the assessment had been against. We were however advised that some expert opinions do indeed quote and discuss the specific aspects of the standard reviewed against.

We saw no instances where the assessment report recorded what work had actually been done (e.g. what concerns the assessor had and how these were resolved). This prompted question about whether BNRA keeps other records to document the detail of the assessments and reviews it has undertaken. We were informed that though there are no formal requirements to maintain an auditable trail of the work performed (e.g. task files), assessors maintain records of their review and assessment activities and that these are stored on a common computer drive and/or in document folders, albeit in an ad-hoc manner.

BNRA keeps and maintains a live review and assessment plan. There are also daily teleconferences with the licensee, attended by both directors managing assessment staff, at which the licensee notifies BNRA of forthcoming submissions. In addition the resident site inspectors advise the organization of forthcoming submissions. Through these means, the assessment plan produced at the start of the year (used mainly to identify major submissions and so allow planning for assessor availability and budgeting to secure the services of TSOs) is kept up to date and BNRA is able to complete its reviews and assessments within the timescales specified within ASUNE.

BNRA employs a relatively simple, but nevertheless effective, method for keeping track of its review and assessment work. Though the process is primarily paper-based, a central computer database is also used to keep track of the work.

Quality control is achieved through the line managers, who approves the work of their staff and then collates the expert opinions for cascading upwards to the next level and (where necessary) further collation. BNRA considers this management approval to be both technical and procedural. However, as the managers, though highly experienced, are probably not always technically competent for every technical discipline of their staff, it is difficult to see how this process can be effective in all instances. In particular, there is no process of technical peer review of assessment outputs. Indeed such a process would be difficult under the present arrangements for managing review and assessment activities given that most reports do not record the detailed basis for their conclusions.

BNRA ensures a graded approach to its NPP review and assessment work primarily through how the assessment tasks are allocated – the more safety-significant the task, the greater the range of technical opinions sought. There is also a proportionality aspect in that the licensee normally submits less documentation when the risks or hazards are lower. In this way the more important submissions receive a wider breadth and depth of assessment. The most important assessments, such as those for the 2008-9 Periodic Safety Reviews at Kozloduy, start-ups after refuelling outages and the more recent Intermediate Safety Analysis Report for Belene utilised most (if not all) of BNRA's assessment staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.39 states that** *"The regulatory body shall record formally the basis for its decision on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation […]".*
(2)	**GSR Part 1 Para. 4.26 states that** *"The regulatory body shall be able to justify its decisions if they are challenged".*
(3)	**BASIS: GSR Part 1 Para. 4.14 states that** *"The regulatory body shall establish and implement a management system whose processes are open and transparent."*
(4)	**BASIS: GS-R-3 Para. 5.21 states that** *"Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable."*
R7	**Recommendation: BNRA should ensure that their review and assessment reports (e.g. expert opinions) and supporting records (the auditable trail) provide appropriate detail in regard to what review and assessment activities were undertaken and what standards or criteria were applied (i.e. the aspects/elements of the standards considered) so that the basis for all the decisions taken, and in particular positive decisions, is clear.**
(1)	**BASIS: GS-G-1.2 Para. 4.1 states that** *"The regulatory body should ensure that the findings and decisions of the review and assessment process are subjected to a suitable process of peer review."*
S14	**Suggestion: BNRA should consider developing a suitable and systematic process of technical peer review for its review and assessment documentation, especially for key assessments.**

6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

BNRA's review and assessment activities for regulating NPPs are divided between two Departments, one which has an exclusive assessment focus and the other, a General Department, which in addition has responsibility for licensing and inspection. The Departments are themselves divided into Divisions. It is clear from the organizational structure that BNRA has only very limited resources in several technical areas. For instance there are only single experts in areas such as PSA, civil structures / external hazards, mechanical engineering / pressure vessels, Instrumentation and Control and Quality Assurance (with some of these experts doubling-up to cover multiple disciplines).

In addition there are no experts currently employed who are experts in Water Chemistry (where the previous expert retired and it has not been possible to replace her) and Human Factors (which is not currently considered as a specific review and assessment technical discipline by BNRA). BNRA's approach to ensuring it has adequate staffing for its work is described in Chapter 3 of this report. The shortages in water chemistry and human factors have contributed to the recommendation on staffing in Chapter 3.

Training in the review and assessment area appears to be managed well by BNRA. A thorough process was described in which new recruits (recent graduates) are selected through a competitive examination process and then trained according to their individual needs. The training programme includes 3-month placements at Kozloduy NPP training centre, modular training on aspects of regulation, overseas placements (arranged by IAEA), training by experts (e.g. lectures and courses run by invited experts from foreign regulators / IAEA and by eminent external experts and scientists) and then "on the job training" mentored by more experienced specialists. The in-post training of qualified specialists however, appeared less thorough. BNRA encourages its staff to attend the lectures provided by eminent external experts and scientists (there were 8 of these in 2012) and some staff are given the opportunity for placements with overseas organizations (such as IAEA). Currently the expert's competence is assessed during the annual judgement of competences in accordance with the legal requirements and the individual Job descriptions. However, there are currently no formal procedures for deciding when an individual is "competent", though a procedure is understood to be currently under development.

BNRA utilises TSOs for major review and assessment activities. These are chosen from an accredited list which identifies which organizations are competent to perform which functions. Recent examples have included the assessments of the Intermediate Safety Analysis Report submission for the proposal at that time for construction of a new NPP at Belene and for the 2008/9 PSRs at Kozloduy. In general however, BNRA prefers to perform its review and assessment work in-house.

There was little evidence of advisory bodies being utilised as part of BNRA's review and assessment processes. For instance, this aspect is not mentioned in QMS-AA-P-01 and those interviewed during the mission could not name a time when they had been advised by BNRA's Nuclear Safety Advisory Council (which is set up to advise the Chair in regard to matters of nuclear safety). This was particularly surprising given that the Council was used to provide advice to BNRA following the Fukushima accident. However, this advice was not promulgated to the staff undertaking review and assessment work. This has contributed the recommendation on the use of advisory bodies made in Chapter 3.

BNRA, as the regulator of a relatively small nuclear programme, does not have the capability to perform independent calculations in support of its assessments. It does however have access to TSOs with this capability and makes use of this when necessary. For instance TSOs were employed to do an extensive array of calculations in support of the assessment of the Intermediate Safety Analysis Report submission for the proposed construction of a new NPP at Belene.

6.2.3. BASES FOR REVIEW AND ASSESSMENT

BNRA regulates the safety of NPPs to detailed regulations enacted in support of ASUNE. In particular, the Regulation on Ensuring the Safety of Nuclear Power Plants (RESNPP) provides a suitably comprehensive list of principle-level requirements and acceptance criteria for ensuring safe power plant operation at all lifetime stages.

A limited number of guidance documents are also provided by BNRA (14 at present, of which 10 have relevance to operational NPPs). These include a specific guide on deterministic safety assessment and two guides addressing how to carry out and then use probabilistic safety assessments. The guides inform the licensee of what is required to meet the RESNPP regulations and are used by the assessors to determine whether or not the submission meets requirements. The coverage of these guidance documents is however rather limited, which means there is no supporting guidance in many technical areas (for example all the engineering disciplines (e.g. mechanical and civil) have no specific guidance at present). BNRA is well aware of this and is in the process of developing plans to expand its guidance suite. BNRA expects to have defined these plans by June this year.

Where guidance is provided, this is not particularly detailed. For the most part the guides rely heavily on IAEA Safety Requirements, repeating these word for word in many instances. They do not, for instance, provide the level of detailed advice set out in IAEA Safety Guides or other generally accepted international standards. The relatively limited coverage and depth of regulatory guides for NPP review and assessment has contributed to the recommendation in Chapter 9.

In the absence of guidance, BNRA relies on the knowledge and experience of its assessors in regard to national and international standards. The extent to which such standards are applied is hard to gauge though, since limited detail is provided in the expert opinion. Instances where assessors believe a standard is met are usually not documented other than by implication (through statements that they have no objection to the requested permission being granted).

In using IAEA Safety Standards as the main basis for its regulations and guidance, there is a high degree of alignment between Bulgarian and international practice. One area of discrepancy was however identified during the mission, where it was noted that the 9 minimum topics for the scope of Periodic Safety Reviews (PSR) listed in RESNPP do not align with the 14 safety factors listed in IAEA's Safety Guide NS-G-2.10. 4 areas appeared at first sight not to be covered: Equipment Qualification, Research, Procedures and Human Factors. More detailed discussions however revealed that the first 3 of these are addressed in practice, though under different headings to those used by IAEA. There is however no requirement for the licensee to review Human Factors and so it is suggested that this be added to RESNPP (see suggestion in Chapter 9).

Here it should also be noted that although BNRA currently has no human factors expertise (see Section 6.2.2 above), Kozloduy employs a number of Human Factors experts, and elsewhere in RESNPP there are a number of requirements relating to this technical discipline. These facts mean that this shortfall in the regulations may not necessarily mean this aspect of nuclear safety is not being properly managed by the licensee.

6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT

BNRA adopts a thorough approach to ensuring the comprehensiveness of the safety submissions it receives. Indeed its diligent assurance that all regulatory requirements have been met is the prime focus of its review and assessment process. It is however harder to judge the quality of the safety assessments given the limitations in the reporting and documenting arrangements highlighted above. That said, the assessment of the Intermediate Safety Analysis Report submission for Belene was an extremely detailed

piece of work that appeared to be of high quality and had clearly taken a considerable amount of effort (notably with considerable input from BNRA's TSOs) to produce. However, the extent of other assessments is not so self-evident.

As noted in section 6.2.1, the scope of BNRA's assessments is decided by management. All the instances looked at during this mission appeared to have an appropriate scope of assessment given the limited technical resources BNRA has at its disposal (see the recommendation on staffing in Chapter 3). For the largest assessments, such as those for the 2008-9 Periodic Safety Reviews at Kozloduy, start-ups after refuelling outages and the more recent Intermediate Safety Analysis Report for Belene, BNRA conducts a full scope assessment.

The results of BNRA assessments are reported back to the licensee by sending a letter summarising the collated expert opinions. BNRA does not however supply the individual Expert Opinion reports that contributed to this. There is also feedback to the licensee through the daily teleconferences and regular / topical meetings that BNRA holds with Kozloduy.

Most BNRA assessments do not involve supporting site inspection. Instead BNRA assessments are mostly a desk-top exercise based on the paperwork submitted by the licensee. For the most important assessments however, e.g. for start-ups after refuelling outages, specialist assessment staff are heavily involved in site inspection activities and contribute to the organization's decision on whether or not to permit the unit to start. BNRA's assessment staff are also involved in a range of topical inspections conducted according to its annual inspection plan. Given it is regulating just one NPP, BNRA considers these activities provide the assessors with sufficient familiarity with the plant to inform their on-going assessment work.

BNRA does not devote any resources to the development of relevant tools and methods (e.g. computer codes for safety analysis). This is appropriate given the present size of the Bulgarian nuclear power programme.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

During the authorization process, the BNRA inspector(s) overseeing the proposal for issuing/renewing licences or permits for SIR perform a review of the documents submitted by the applicant. In case of gaps, i.e. where discrepancies with the regulatory requirements are identified, or there is a need for additional clarification, a letter is sent to the applicant. The letter identifies the perceived irregularities and sets a deadline of not less than 14 days for the submission of the necessary explanation or further documentation. These letters are signed by the BNRA chairman or the vice chairman and are sent to the applicants by mail as a "registered letter with acknowledgment of receipt". Inspectors might also conduct inspections should they decide these are necessary to support the review and assessment process.

A graded approach to review and assessment of a facility or an activity is applied by the BNRA personnel; however, there are no specific criteria for this and procedures have yet to be fully and consistently implemented. Instead, opinions are subject to each inspector's experience and expertise, which might therefore lead to inconsistencies in the outcomes of the review and assessment. This has contributed to the recommendation in Section 6.1.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

According to the Regulation for Safety of Spent Fuel Management, the design of a SF management facility shall include preliminary SAR for storage and transport within the site and handling of SF during normal operation and in the event of design and beyond design basis accidents. After the construction of the facility, the SAR needs to be updated to reflect the current state of the facility.

The SAR has to contain technical and organizational measures, safety analysis and assessment, justification of the performance of main safety functions, the identification of risk of initiating events considered in the design, the demonstration of the achieving of the objectives and safety criteria. The SAR also needs to reflect the physical condition of the facilities throughout their entire operational lifetime and in the period of decommissioning.

The most important requirements for the content of the preliminary SAR, which is submitted with the request for issuing the permission for approval of the selected site for the nuclear facility, are reviewed. It is pointed out that it is obligatory to attach the decision on the Environmental Impact Assessment Report (according to Chapter 6 of the Environmental Protection Act) to the request for approval of the selected site for nuclear facility.

Performance of assessments and analyses as part of the licensing process of all nuclear facilities, including facilities pertaining to the nuclear fuel cycle, is based on the ASUNE and its supporting regulations.

It is important to note that the procedure for assessments and analyses of nuclear facilities cited in Section 6.2 (QMS-AA-P-01) applies to fuel cycle facilities. In carrying out its assessment, BNRA takes into account requirements for the performance of assessments for the purposes of safety analysis, for instance the performance of deterministic safety assessments, the use of probabilistic safety assessments for the management of safety, the implementation of probabilistic safety assessments and the development of a management system for activities and facilities. In performing the assessments, resources and experience of engineering TSOs are also used.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING ACTIVITIES

As part of the licensing process for radioactive waste management facilities, authorizations are successively given for permits and licences on the basis of a Preliminary Safety Analysis Report for the siting stage, an Intermediate Safety Analysis Report for the licence for operation and a Final Safety Analysis Report for the licence for decommissioning.

The radioactive waste management regulation, ASUNE as well as the Regulation on the Procedure for Issuance of Licences and Permits for Safe Use of Nuclear Energy also refer to the need to produce safety assessments as part of the licensing process, in order to support the demonstration of safety of the relevant facility or activity and as a basis for regulatory decision-making.

The regulations also require a periodic review of waste management facilities every ten years.

The periodic safety reviews are performed for the radioactive waste (RAW) management facilities operated by State Enterprise Radioactive Waste Management (SE RAW) at Kozloduy NPP and the Novi Han irradiation facility. A safety assessment for separate sites in these nuclear facilities is performed. In all assessments, the generally accepted analytical approaches are applied, including analyses of the possible events (internal and external) applying detailed analysis methods.

The updated safety analysis reports are submitted to BNRA for review as part of the processes for the renewal and/or issuing of the relevant licences for operation.

The licences for operation of Kozloduy units 1 and 2 as facilities for management of RAW were issued in 2010. The same licence has been issued for units 3 and 4 in 2013. The licence for the operation of Novi Han was renewed in June 2011 for a period of 8 years.

The licensing process for near surface disposal facilities is at a preliminary stage. BNRA is starting to evaluate the approval of the site, and in a few months, will receive an application for the approval of the

design. To meet current plans, the disposal facility has to receive a commissioning permit by 2015. This means that all the steps in the licensing process (site approval, design approval, construction permit and commissioning permit) will need to be completed to a very tight schedule. This schedule will have a significant impact on BNRA's radioactive waste management review and assessment staff and so is relevant to the recommendation on staffing in Chapter 3.

Decommissioning

The basic requirements for decommissioning are provided in the Regulation on Safe Decommissioning (2004) and in the Regulatory Guide on Structure and Content of a NPP Decommissioning Plan (2010).

BNRA has issued permits to SE RAW for operation of Kozloduy Units 1 to 4 as facilities for radioactive waste management. SE RAW has in addition applied for a licence to commence decommissioning at Units 1 and 2, which BNRA is considering.

At present there are no nuclear facilities in Bulgaria that have a licence for decommissioning.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Each transport of radioactive material has to be covered by a permit or a licence. The applications for such licences or permits are reviewed and assessed by BNRA staff from two separate departments depending upon whether fissile or non-fissile material is being transported.

The documentation needed in support of an application for a permit or licence for transport are clearly listed in the Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy.

These documents constitute the basis (in combination with inspection) for reviews and assessments to confirm compliance with the requirements stipulated in the relevant regulations. These requirements are based on, and globally in line with, the IAEA Safety Standards for transport.

The process for reviewing and assessing transport activities regulated by BNRA follows BNRA's generic approach to managing reviews and assessments. In particular, applying a single systematic approach to the regulation of all transport activities means that the review and assessment process for the transport of very low level radioactive material does not fully align with a graded approach.

The assessment and the review for the approval required by IAEA transport regulation are included in the process for the review and assessment of applications for licence or permit for transport activities. In Bulgaria, these approvals are almost exclusively related to the transport of fresh and spent fuel (i.e. fissile materials) to and from Kozloduy NPP. After the first assessments carried out several years ago, the assessments for these approvals have been limited to an endorsement of the assessment made by the competent authority of the country of origin of the package designs. TS-G-1.1 (Rev. 1) however states that such assessments should be made independently, primarily because of the nature of the criticality hazard and the importance of maintaining sub-criticality at all times during transport. The IRRS team therefore suggests that BNRA should independently and periodically assess the criticality safety of the package design used in Bulgaria to transport nuclear material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"The regulatory body shall review and assess relevant information … to determine whether facilities and activities comply with regulatory requirements [...]."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: TS-G-1.1 (Rev. 1) Para. 802.2 states that** *"in the case where competent authority approval is required, an independent assessment by the competent authority should be undertaken, as appropriate, [...]."*
(3)	**BASIS: TS-G-1.1 (Rev. 1) Para. 810.1 states that** *"Information given by the applicant […] the design. Through the mechanism of multilateral approval the design of a Type B (M) package is independently assessed by competent authorities in all countries through or into which such packages are transported."*
(4)	**BASIS: TS-G-1.1 (Rev. 1) Para. 812.1 states that** *"Multilateral approval is required for all package designs for fissile material (IF, AF, B(U)F, B(M)F and CF) […]. It is therefore necessary that competent authorities independently assess and approve all package designs for fissile material."*
S15	**Suggestion: BNRA should consider undertaking independent and periodic reassessments, based on IAEA Transport Safety Standards for multilateral approval, of the design of transport packages in use in Bulgaria, and in particular the justification of sub-criticality.**

6.7. SUMMARY

This IRRS team looked at review and assessment practices in Bulgaria for regulating a wide range of types of nuclear and radiological facilities and activities, focussing mostly on BNRA's review and assessment for nuclear facilities. BNRA is considered to have efficient processes for nuclear safety reviews and assessments applying standards strongly in line with IAEA Safety Standards.

In some cases however the IRRS team found review and assessment processes are not governed by formal, written procedures, leading to findings on the quality and consistency of the assessments performed. In the cases where there are written procedures, such as within BNRA, aspects were nevertheless identified where these procedures might reasonably be improved or, in the case of radioactive sources, implemented more effectively.

For example, the availability of technical guidance, either to inform licensees of how to meet legal requirements, or to provide assessors with advice on how to conduct their assessments, is limited or absent in many areas. Nevertheless, the regulations we reviewed are very detailed and align well with IAEA Safety Standards. In two areas however, relating to the topical coverage of NPP Periodic Safety Reviews and to criticality assessments performed for the transport of fissile materials, we noted omissions compared to IAEA guidance.

7. INSPECTION

7.1. GENERIC ISSUES

Based on the provisions of the Act on the Safe Use of Nuclear Energy (ASUNE), BNRA is responsible for the regulatory oversight of the safe use of nuclear energy, ionizing radiation, and safe management of spent nuclear fuel and radioactive waste, and has the right to exercise regulatory control over nuclear safety, physical protection and radiation protection. The ASUNE includes provisions for BNRA to have free access at any time to the regulated licensees and sites, and to require from the competent officers of the operator any data, reports, explanations and other information, including measurements and tests, as shall be necessary to clarify the technical status and operating conditions of the facility. BNRA also has authority for regulatory oversight, including control, of nuclear facilities from design through decommissioning phases.

The nuclear installations and facilities subject to regulatory inspection by BNRA are those situated on the Kozloduy site, the Novi Han site, the site of the shutdown research reactor in Sofia, and planned new nuclear power plants and national repository of RAW. In addition, there are 1,243 licensees and 370 permit holders for sources of ionizing radiation (SIR); and 1,585 sites with sources for industrial, medical, scientific, and other uses.

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

The BNRA inspection procedures, QMS-IA-P-02, "Procedure for Inspection Activities in Nuclear Installations" and QMS-IA-P-03, Procedure for Inspection sources, clearly define an inspection process that uses planned and reactive inspections, as well as, for the nuclear facilities at the Kozloduy site, relying heavily on the permanently assigned six resident inspectors at the site, which provides for implementing inspections as a continuous activity. Inspections can be either announced or unannounced, although as a matter of policy, unannounced inspections and the Kozloduy site are implemented through the resident inspectors. In addition, reactive inspections are generally considered to be unannounced, since they are conducted in response to plant events. The inspection methods used by BNRA consist of monitoring and walk-down of the facilities, review of procedures, records, and documentation, discussions and interview with personnel, and tests and measurements.

The BNRA inspection procedure QMS-IA-P-02 identifies areas for inspection at nuclear facilities that directly reflect the IAEA Safety Guide. BNRA has a similar inspection procedure for sources in QMS-IA-P-03. The inspection procedures also generally identify the period (2 years for nuclear power units in operation, 3 years for the other nuclear facilities) over which these areas must be covered. Planning for inspections includes development of an annual inspection plan for the facilities. The inspection procedures do not, however, include a planned and systematic program that defines the frequency for specific inspections that need to be conducted, nor does it identify the level of effort needed for each inspection. Without having the specific inspections that need to be conducted identified in an established program, there is no means to ensure that the inspections conducted will address all areas of BNRA responsibility are covered within the defined period.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 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. In this programme, it shall specify the types of inspections (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body [...]. The manner, extent, and frequency of inspections shall be in accordance with a graded approach."*
(3)	**BASIS: GS-G-1.3 Para. 4.3 states that** *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility."*
(4)	**BASIS: GS-G-1.3 Para. 4.9 states that** *"The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility. In determining the intervals between inspections and the level of effort to be applied, the regulatory body should take into account the relative significance for the safety of the facility of each authorization stage and each inspection area."*
(5)	**BASIS: GS-G-1.3, Para. 4.1 states** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Appropriate information and guidance should be provided to the inspectors and each inspector should be given adequate training in following this guidance […]."*
R8	**Recommendation: BNRA and the MoH should formalise and implement planned and systematic inspection programmes and overall plans for the programme of inspections. The programme should establish intervals between inspections and the level of effort to be applied, and be developed based on the appropriate considerations, to ensure that the inspections cover all areas of responsibilities of the regulatory bodies within an established inspection program period.**

7.1.2. INSPECTION PROCESSES AND PRACTICES

For inspections conducted by the resident inspectors, the BNRA inspection procedure specifies that the resident inspectors conduct daily checks for specified topics in accordance with an established monthly plan. In addition, and specifically for the resident inspectors, the inspection procedure establishes a clear expectation that the inspectors spend most of the period of their inspection (stated as 60% of their time in the procedure) and the head of the General Department clarified that this goal was intended to emphasize that the resident staff focused their inspections in observation, walk downs, and interviewing in the field, and less emphasis on desktop reviews of documents. This establishment of a quantitative expectation is considered a good practice, in that it provides clarity of the head of Department expectations for direct inspection efforts for the resident staff.

The team noted that the inspection approach for other areas of oversight of the regulatory body, namely sources, medical, and transportation, seemed to be mostly desktop review of documents as discusses in modules 7.5 and 7.7. BNRA and NCRRP should consider establishing expectations that emphasize observation, walk downs, and interviewing in the field during conduct on inspections for non-resident inspectors at nuclear facilities, as well as inspectors for sources, medical, and transportation activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-G-1.3 Para. 3.6 states that** *"In planned inspections, the observation and assessment of continuing safety activities are usually emphasized in order to assess the effectiveness of the operator's performance. Less emphasis is usually placed on carrying out detailed 'desktop' reviews of programme descriptions and related procedures for reviewing paperwork."*
GP6	**Good Practice: Establishing a clear, objective goal that provides a clear expectation that the focus of resident inspection is direct observation and assessment in the field.**
S16	**Suggestion: BNRA and the MoH should consider establishing expectations for its inspectors, other than resident inspectors, that make it clear that staff in the process of conducting an inspection should place emphasis on observation and assessment of continuing safety activities in the field.**

For planned and reactive inspections at nuclear facilities, the team leader is responsible for preparation of an inspection report, with input from all participating inspectors, and is provided to the licensee. There is also a monthly report that documents the results of the resident inspections. For each inspection**,** the team leader or head of the Division of resident inspector develops a protocol of findings that documents any deficiencies identified during the inspection. The inspection reports and protocols of findings are used to inform the development of the annual inspection plan.

The team observed an on-site inspection of the mobile diesel generators (DGs) that are being procured by the operator to address information evaluated following conduct of the post-Fukushima stress test. The inspection was conducted as a meeting with the licensee, at which the inspectors questioned the licensee on how they would ensure the use and capacity of the mobile DGs would continue to ensure safety and other critical functions are met for beyond design basis external events. The inspectors spent little time in the field in observation and assessment, which is likely the result of the very limited time available for the team to observe an inspection that resulted in an abbreviate inspection. The licensee was still in the process of evaluating which of 7 current options would be implemented, including how the severe accident management guidelines (SAMGs) would be modified to incorporate consideration of the mobile diesel generators. The team viewed this discussion as not appropriate for inspection, since the purpose of inspections is to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization, and this inspection was conducted prior to application for approval of the mobile DGs had even been developed, and the proposed modification was still in the design phase. The observation by the team is that this approach in effect provided guidance to the licensee on what they would need to address in their application, and could be viewed as consulting the licensee on a pending application. This has the potential to compromise the independence of the regulatory body, potentially making the regulator a party to the design development, and also potentially compromise the primary responsibility of the operator for safety of the facility. The team noted that the ASUNE includes a provision, in Art. 98 (2) 1., that BNRA includes a responsibility for BNRA to *"carry out: preventive regulatory control, in the issuance of licences and permits for activities under this Act...*" Since the licensee had not yet proposed, nor had the authorization been issued, for how these mobile DGs

would be connected to the nuclear plants, it was both (1) not appropriate to apply the inspection program at this stage of the regulatory regime, and (2) the potential encroachment of the regulator during the development of the licensee's application may challenge both the independence of the regulator as well as potentially diminishing the prime responsibility of the authorized party.

The team's observations of inspections for other activities are covered in Modules 7.4 and 7.5.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 Para. 4.49 states that "***Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party […]."*
(3)	**BASIS: GSR Part 1 Para. 4.33 states that "***Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(4)	**BASIS: GSR Part 1 Para. 2.14 states that "***The legal framework for safety shall be established in such a way that the authorized party retains the prime responsibility for safety throughout the lifetime of facilities and the duration of activities, and shall not delegate this prime responsibility."*
S17	**Suggestion: BNRA should consider how it uses the inspection program during the pre-application for authorization period, and its potential to encroach on the licensee's prime responsibility for safety by influencing the content of the subsequent application and the resultant impact on the independence of the regulatory body.**

7.1.3. INSPECTORS

BNRA has assigned six resident inspectors to the Kozloduy site. These inspectors have varied backgrounds and specialties that provides for implementing inspections as a continuous activity. Three of these inspectors have strong operations backgrounds, one is a health physics specialist, one is a specialist for a range of technical issues (including maintenance, modifications, and testing), and one an expert in RAW management. The team noted that all of the inspectors are former operators or staff from the Kozloduy nuclear facility. These six inspectors provide for inspections of all activities at the site, including nuclear power plants in operations, in decommissioning or planning for decommissioning, wet and dry fuel storage facilities, as well as RAW processing and storage at the site. The BNRA inspection procedure also contains specific provision for resident inspector for the suppliers of goods and services.

BNRA also conducts thematic inspections that usually involve a team of inspectors. The team is usually comprised of inspectors from BNRA headquarters, and can include resident inspectors on the team.

ASUNE establish the legal authority for all inspectors to conduct inspections, and that mandates that the licensee shall provide free and prompt access to nuclear facilities, as well as to all information related to nuclear safety.

The team evaluated the training program for inspectors, which is discussed further in Module 3.3, Staffing and Competence of the Regulatory Body.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

For each planned inspection, the designated team leader, with participation by all inspectors in the team, develops a draft programme specific to that inspection, which is reviewed by the head of the General Department, approved by the deputy chairman, and provided to the licensee by an order from the chairman. Thus the majority of the inspections (other than resident and reactive inspections) are pre-planned and announced. For each area and theme inspected, QMS-IA-P-02 provides written guidelines that the inspectors use to identify the areas to be inspected, methods to be used, criteria for selection of samples, and relevant technical information. This inspection procedure provides information that appears to provide sufficient guidance for inspection personnel to support consistency in the inspection process.

Reactive inspections are conducted in response to unplanned, unexpected events at a licensed nuclear facility. The head of the appropriate Department defined the need for a reactive inspection based on preliminary information received and an analysis of the safety risk posed by the event. The inspection procedure provides criteria that the head of the appropriate Department would use in making their decision whether or not to conduct the reactive inspection.

For each planned and reactive inspection, the team leader conducts and entrance meeting with the operator to describe the purpose and objectives of the inspection, and an outcome meeting at the end of the inspection to provide a summary of the findings, the deadlines for implementing corrective actions, and to provide the licensee with the opportunity to discuss their programme to address the weaknesses and discrepancies identified during the inspection. During the inspection, individual inspectors discuss their findings with the licensee counterparts, and with the team leader. The discussion with the team leader provides for consistency, and checks for objectivity and impartiality across the team.

The resident inspectors at the Kozloduy NPP conduct inspections that cover areas listed in procedure QMS-IA-P-02, with guidelines for each area established in Appendix 1 of the procedure. The head of the Division of NPP resident control provides a daily status call to the BNRA deputy director and associated heads of Departments regarding the safety status of the operating units and RAW facilities. The head of the Division of resident inspectors issues a monthly report on the results of the on-site inspections, which includes evaluation of the safety culture at the Kozloduy nuclear power plant.

An additional aspect of the inspection of nuclear power plants is the regulatory control of safety culture. This is still a developing area with BNRA, for which procedure QMS-IA-I-02 was developed for monitoring the licensee's safety culture. This procedure was adopted for trial use, and an assessment of the licensee's safety culture was conducted in 2012. BNRA is encouraged to continue development and implementation of the process for assessment of safety culture at the nuclear facility.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

Every year BNRA prepares an annual inspection plan, which includes all nuclear facilities (including Fuel Cycle Facilities - both wet and dry spent fuel storage facilities (SFSF). Inspections at FCF are conducted in the same way as in all other nuclear facilities. No issues unique to inspection of fuel cycle facilities were identified.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Regular inspections are conducted at all waste management facilities.

The team accompanied BNRA inspectors on an inspection at the Solid and Liquid Waste processing facility in the Kozloduy NPP site. The facility is operated by the State Enterprise RAW, the governmental organization responsible for radioactive waste management.

The inspection focused on the licence conditions for the transportation of liquid radioactive waste from the NPP units to the processing facility, and in particular on the administrative procedures followed by the operator. The inspection included a visit to the installations. The inspection was already planned, and the operator, who received the agenda of inspection one week before, was ready with all the documentation to be inspected and all the relevant managers responsible were available for discussing with the inspectors. At the end of the inspection, the outcome was discussed with the operator and in a few days BNRA will communicate to SE RAW the results of the inspection including the findings of the inspectors. These will be recommendations that SE RAW has to follow and the implementation of which will be verified in a follow up inspection.

In addition to planned inspections, unplanned inspections may take place as necessary.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES

The RPEP department of BNRA carries out inspections at facilities and activities with SIR. The RPEP department applies QMS-IA-P-03, "Procedure Inspection Sources" for establishing its inspection activities. Inspections are planned (periodic), reactive, and pre-authorization inspections for commissioning of new sites with SIR. Depending on their scope inspections may be comprehensive, covering the entire range of issues related to the safe use of ionizing radiation, or thematic that cover only selected areas in the inspection process.

Due to the large number of sites with SIR (especially in medical applications) and the limited number of BNRA inspectors, the BNRA inspection plan does not cover all licensed facilities and BNRA relies, specifically in medical facilities, on the inspections conducted by the MoH (NCRRP and RHI).

The RPEP department prepares an annual inspection plan which is based on radiation risk of facilities and activities. Facilities with category 1 SIR, unsealed sources (nuclear medicine) and radiotherapy equipment are inspected every year; Category 2 sources once in 2 years; Category 3 and 4 sources once every 3 years,; x-ray machines for therapy, diagnostic applications once every 4 years, and other lower risk activities once every 10 years. Inspections of SIR may be announced or unannounced. All planned inspections are announced, while reactive inspections, usually triggered by information received directly by BNRA or the MoH, may be unannounced.

Following the inspection the inspector issues a written report. If the inspector identifies a violation, they issue a protocol of finding with mandatory written prescriptions if appropriate. For more serious violations, the process for proposing and for the chairman issuing administrative enforcement measures, as described in Module 8, apply.

BNRA and the MoH conduct joint inspections during the commissioning phase and authorization phases for facilities with SIR, including medical facilities. If there are security elements to the inspection, the Ministry of Interior (MoI) participates as well. After authorization, separate or joint inspections may be performed. BNRA inspections focus on safety of the SIR, while the MoH also focuses on patient radiation protection and safety. In the case of joint inspection, the MoH inspectors provide their input to BNRA, which issues the inspection report, protocols of findings (if any), as well as administrative measures. In case of separate inspections, the MoH inspectors do not coordinate with BNRA unless a violation of the legislation occurs. BNRA and the MoH should establish written procedures for the cooperation and coordination between these authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 7 states that** *"[...] the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties".*
R9	**Recommendation: BNRA and the MoH should establish procedures for effective coordination of inspection activities for SIR.**

According to the Health Law, as discussed in Module 5.5, the MoH has the responsibility for the radiation protection and safety of members of the public, patients and radiation workers at facilities and activities with SIR for all ionizing radiation application (e.g., medical, industrial and research). Although the MoH performs inspections at facilities or activities with SIR for the verification of radiation protection, in practice they are mainly focused on protection of the workers and/or patients (for medical application). It appears that there is need to ensure that the inspection process addresses radiation protection of members of the public from SIR more appropriately and consistently. Moreover, clear procedures between BNRA and the MoH have not been established in this field.

Since the authorization that is issued by BNRA refers to all radiation protection safety and security areas, including radiation safety of the public from SIR, BNRA and the MoH should coordinate to ensure the scope of inspections includes radiation protection of the public, especially for medical applications. This issue, identified by the team, is another aspect of the inspection programme development and scope that is the subject of the first recommendation in this Module.

The team observed a joint inspection by NCRRP and BNRA, and noted that each regulatory authority used separate check-lists. Few checks were done through actual observation and assessment of on-going activities to verify the level of actual implementation of the requirements for medical exposure. This is an example that supports the suggestion in Module 7.1.2 that BNRA and the MoH should consider establishing expectations for all inspectors that they should place emphasis on observation and assessment of continuing safety activities in the field.

In 2012, 195 inspections were conducted by BNRA (58 of those planned, 40 reactive (ad hoc) and 97 for SIR commissioning). In 12 cases prescriptions were issued, while in 3 cases acts for violation. This number of inspections corresponds to less than 10 % of the total authorization of facilities and activities with SIR.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Although, at present, there are no nuclear facilities in Bulgaria that have a licence for decommissioning (see Para. 6.4), BNRA is developing a QMS regulatory guide on inspection of nuclear installations undergoing decommissioning.

7.7. INSPECTION OF TRANSPORT ACTIVITIES

BNRA staff from two separate departments is responsible for conducting inspections of transport activities, depending upon whether fissile or non- fissile material is being transported.

Every year, BNRA staff prepares an annual inspection plan including the transport activities for which inspections will be conducted. This annual plan is not defined on basis of a planned and systematic inspection program. According to the discussions with BNRA staff, it has been identified that the principal informal "decision making criteria" to define, in the annual inspection plan, which licensee or

permit holder will be inspected is related to the level of radioactive risk. This process leads BNRA to conduct inspections every time for transport of spent fuel and for transport of fresh fuel, almost every time for transport of high level of radioactive material, and time to time for others transport radioactive material the occurrence depending on the radiation risk of radioactive material transported and on the numbers of the shipments made by the licensee.

In 2012, about ten planned (announced and unannounced) inspections and about the same number of unplanned (reactive) inspections were conducted for the transport of (non-fissile) radioactive material. Some of the unplanned inspections were carried out as a part of the assessment and review of applications fora licence or permit for transport.

BNRA's current practice for inspection of the transport of fissile material is to inspect almost every transport of fresh fuel (90%) and spent fuel (100 %), with the participation of resident inspectors of the Kozloduy NPP.

The IRRS team considers that the numbers of inspection of transport activities is appropriate to the extent of transport activities in Bulgaria.

7.8. SUMMARY

Based on the documents reviewed, on the interviews conducted, and three site visits to observe inspections, the IRRS team concludes that BNRA conducts extensive inspection activities, although the program lacks a planned and systematic inspection programme, as well as lacking written guidelines to inspectors that would ensure a systematic and consistent approach to inspection. BNRA and NCRRP inspectors conducted these inspections in a competent and professional manner. Based on the interactions between the inspectors and the licensees' and permit holders' staff, the communications between BNRA and NCRRP inspectors and the operators appeared to be open, frank, and safety-focused. The inspection at the Kozloduy NPP identified that inspections are used by BNRA as implementation of preventive regulatory control were not consistent with the IAEA Safety Standards for use of inspections to verify implementation following issuance of an authorization or permit. During the observation of the inspections at the SIR and Kozloduy, the team observed that the inspectors spent most of their time in desktop reviews or discussions with the licensee and not observing activities in the field.

The IRRS team acknowledges that BRNA's inspection practice is generally in line with the IAEA requirements but there is room for improvement. The recommendations and suggestions provided by the IRRS team are aimed to optimize the existing inspection processes, including development and implementation of a planned and systematic inspection program, in BNRA, and coordination of inspection activities across the responsible regulatory organizations.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

The legal authority for BNRA to take enforcement action, and the various enforcement actions available, is established in the Act on the Safe Use of Nuclear Energy (ASUNE), the Administrative Violations and Sanctions Act, and in the Criminal Code.

In the case of non-compliance, BNRA has the authority to apply preventive administrative measures. When the inspectors identify non-compliance, they first discuss the issue with the licensee for correction. If the licensee in not responsive, the inspector can issue a verbal warning, and if necessary a written warning, which is a letter to the licensee. If the issue is more significant, or if the licensee is not taking appropriate action, the inspector documents, the non-compliance in a Protocol of Findings, as discussed in Module 7. The inspectors are authorized in the ASUNE to issue written prescriptions that document the violation and can include written mandatory directives to the licensee, including specifying the time by which the licensee must correct the non-conforming condition, take actions to prevent recurrence, and report completion to the inspector. The ASUNE contains prescriptive limits on the limits of the inspectors' authority.

For more serious violations, for repeat violations, or if the licensee does not complete the mandatory directive in the prescribed time period, the inspector would document the violation in a written statement of infractions, and propose imposition of enforcement measures to be issued by the chairman. These enforcement measures include amending or revoking a licence, issuing orders to perform specific technical actions including modifications to systems and structures or amendment to licensee training programs, and issuing an enforcement decree upon which a fine or administrative sanction shall be determined.

The chairman may also issue administrative penalties in the form of fines for specific violations for performing activities involving nuclear power plants or sources without a licence or permit, violates the conditions of a licence, or for anyone who interferes with the performance of the duties of an inspector.

The licensee has appeal rights at various levels of administrative measures, administrative enforcement measures and sanctions that are specified in the ASUNE and the Administrative Violations and Sanctions Act.

This provides a graded approach to enforcement, and is based on the significance of the non-conformance or violation, as well as the licensee's actions to correct and prevent recurrence of the violation.

The team identified that BNRA does not have an enforcement policy that defines the criteria for application of the various measures, including how to determine the safety significance of a violation, the criteria to be used in determining which measure to apply, and the interface between the regulatory and legal authorities. During discussion with BNRA, they stated that they had identified the absence of an enforcement policy, and were already working on developing one. This was not identified in the BNRA self-assessment or the associated findings, and is therefore included in the IRRS findings.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 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 of with any conditions specified in the authorization."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R10	**Recommendation: BNRA should establish and implement a formal, documented, enforcement policy.**

During the assessment of SIR, the team noted that while inspectors at SIR have the authority to issue mandatory written prescriptions, though BNRA inspectors can issue written prescriptions to licensees and permit holders for violations identified during an inspection, any action to direct the operator to cease activities or shut down a facility can only be ordered by the chairman. The team considered that for sources, including medical uses, the potential impact of an unsafe activity on members of the public, patients and radiation workers at facilities and activities with SIR could potentially be immediate and severe. Currently the inspectors of SIR have no legal authority to direct the cessation of activities, or shut down an SIR facility, or to take corrective action if there is an imminent likelihood of safety significant conditions that could compromise the safety of the public, patients, or radiation workers at a facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events."*
S18	**Suggestion: BNRA should consider giving the inspectors specifically for radiation sources the authority to take on-site enforcement actions including a directive to discontinue activities or shut down the facility or the activity if necessary.**

8.2. ENFORCEMENT IMPLEMENTATIONS

The specific implementation of enforcement is discussed in Section 8.1. The team also evaluated the training of inspectors on enforcement. There is classroom training provided for inspectors, although, as referenced in Chapter 7 and discussed in Section 3.3, there is not an established training program that identifies the requisite knowledge, skills, and abilities for inspectors on enforcement.

8.3. SUMMARY

BNRA uses a graded approach to enforcement, with clear delegation and assignment of responsibilities for the inspectors, and for the application of enforcement, administrative enforcement and administrative penalties.

BNRA should develop and implement an enforcement policy to ensure a consistent application of enforcement and other measures to provide for the prevention and termination of violations.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

BNRA has the authority to issue regulatory guides that implement associated regulations, although it has no independent authority to issue the regulations themselves. According to Article 5 Para. 17 of the Act On The Safe Use Of Nuclear Energy (ASUNE), the BNRA chairman develops and submits draft regulations for the application of the Act to the Council of Ministers for adoption through consensus. The ASUNE specifies the areas that have to be covered by regulations. 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-1 "Procedure on Development of Regulations" and
- QMS-RG-2 "Procedure on Development of Regulatory Guides".

In addition the procedure QMS-RG-1 was revised in 2004 and 2013. These procedures provide appropriate guidance to BNRA staff for these activities.

Regulations

After the decision is made to develop a new regulation, or to revise an existing regulation, BNRA 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. Potentially 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 informal commenting. At this stage the Advisory bodies of the BNRA chairman (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 the BNRA website and the portal for public consultations and commenting (www.strategy.bg). In addition potentially many interested parties are informed by BNRA directly through email-lists of its existence. The commenting period is a minimum of two weeks, in many cases one month. Again, at this stage the advisory bodies of the BNRA chairman can be involved. 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 including the resolved answers. Finally, the revised draft goes to the Council of Ministers (CM) and is adopted provided unanimous approval is obtained. Approved regulations are published on the BNRA website. Regulations are periodically (two years at the latest) reviewed.

The procedure is well developed, and the relatively short period of two years for review is outstanding.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that "***Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
GP7	**Good Practice: The process to develop and revise regulations is described well in a dedicated procedure which involves interested parties and the public at different stages. The process of requiring a periodic, two-yearly review of regulations is a good practice.**

Regulatory Guides:

The procedure on development of regulatory guides is generally similar to the one for regulations, with the main difference that the issuing is done by BNRA.

Issued regulatory guides are periodically reviewed (5 years at the latest). The process to develop regulatory guides has been started with the "Regulatory Guides Development Programme (RGDP)".

These planned regulatory guides are nearly all geared towards NPPs. Regulatory guides for other nuclear installations are only in the planning stage so far. Ten regulatory guides have been developed and 9 additional regulatory guides are planned in the "Regulatory Guides Development Programme". The development of regulatory guides is not given a high priority as there are only two (nearly) identical units in Bulgaria located at Kozloduy.

So far the regulatory guides issued contain only high level safety principles and requirements. Detailed requirements and the associated criteria that one would expect to be available in regulatory guides are part of the Licence Conditions (assembled in Appendix 2 of the Operating Licence of the nuclear power plant Kozloduy). Presently, for BNRA this administrative instructions process is a practical alternative to issuing 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 or the design permit).

The current practice of developing only very few regulatory guides with additional administrative instructions in licences and permits is not considered optimal. A potential applicant for the construction and operation of a nuclear power plant or any other nuclear facility would only be informed of the detailed requirements and the associated criteria by steps during the licensing process (permit by permit) and therefore the regulatory uncertainty and the economic risk would be very high. These facts could significantly discourage potential applicants.

Therefore it is recommended that BNRA develops and introduces appropriate regulatory guides to describe and make available acceptable methods to fulfil the principles and requirements of the regulations. Regulatory guides should contain detailed requirements and the associated criteria to provide practical guidance. In this process BNRA should rely on existing international or national guides or standards for nuclear facilities (e. g. IAEA, EN, IEC, ISO).

Areas identified by the IRRS team where additional detailed requirements and guidance seem necessary include:

- technical guidance to address all areas of nuclear safety relevant to the content of safety analysis documentation to be submitted by licensees;
- criteria for the development of effluent and environmental monitoring programs;
- criteria for the revision of the environmental monitoring program taking into account factors such as land and water uses or changes in activities in the area as well as a definition of an adequate period for the revision;
- guides for protection, safety and security of radiation sources; and

- guidelines for the authorized parties on how to implement the requirements for different radiation sources (including medical exposures) given in the regulations according to a graded approach (provided by BNRA and the MoH (NCRRP and RHI)).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 32 states that "***The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GS-G-1.4 Para. 3.13. states that "***The principal purpose in establishing a system of regulations is to codify safety requirements of general applicability. The development of any particular regulation will involve a balance between the need for flexibility (to permit easy adaptation of the regulation to developing circumstances and technology) and the need to include detailed requirements (to facilitate determination of whether the requirements have been met)."*
R11	**Recommendation: BNRA should develop regulatory guides providing detailed requirements and corresponding criteria for implementing the requirements of the existing regulations.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Fundamental legal requirements for nuclear power plants are established in the "Nuclear Act", ASUNE. Article 33 states that, "the site and selected technical design shall be approved by an order of the NRA chairman when they meet all nuclear safety and radiation protection requirements, standards and rules […]". The Act 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.

Specific safety requirements to the site, the site selection process, the NPP design, the construction of NPP (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 was developed with due consideration of the IAEA Safety Standards and the WENRA reference levels for operating NPPs. WENRA has clearly marked Bulgaria as one of the first countries to address all WENRA Nuclear Safety Reference Levels.

For reactor operation BNRA has developed the Regulatory Guide on "Safe Operation of NPPs".

Decommissioning of NPPs is governed by a separate "Regulation on Ensuring the Safety During Decommissioning". BNRA is already in the process of revising this Regulation (scheduled for completion at the end of 2014), and plans to incorporate the revised WENRA reference levels.

The need for an effective safety management system is already stated in the "Nuclear Act" (ASUNE). Specific requirements are provided by a Regulatory Guide on "Management Systems for Facilities and Activities".

The regulations cover most requirements of IAEA and WENRA, on reactor operation, in specific

- Operational Limits and Conditions
- Personnel qualification and training
- Monitoring of safety performance

- Accident management
- Operating procedures
- Maintenance, testing, surveillance and inspection.

The IRRS team notes that human factors are not included in the existing regulations. The next revision should include Human Factors in the list of factors identified in the NPP regulations for the content of PSRs (for detailed description see Chapter 6).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: NS-G-2.10 Para. 3.2 states that** *"A comprehensive assessment of overall plant safety is a complex task. Experience shows that the task can be divided into a number of elements. These elements are termed safety factors in this Safety Guide."*
(2)	**BASIS: NS-G-2.10 Para. 4.1 states that** *"The 14 PSR safety factors have been selected on the basis of States' experience. These 14 safety factors are divided into five subject areas to facilitate the review … (12) The human factor […]."*
(3)	**BASIS: NS-G-2.10 Para. 4.2 states that** *"The 14 PSR safety factors selected apply to all the facilities on the plant site, including radioactive waste management facilities (see Para. 3.1), and are considered sufficient for a comprehensive review of safety. However, the set of safety factors may vary according to the specific needs of the State and the particular nuclear power plant under consideration, and they should be agreed upon before the PSR is initiated."*
S19	**Suggestion: BNRA should consider expanding the list of factors identified in its NPP Regulations for the content of PSRs to include Human Factors (HF)**.

BNRA identified that the IAEA Safety Standard SSR-2/1 – "Safety of Nuclear Power Plants: Design" is not yet completely covered by the regulations. Therefore, BNRA has started a revision of the related requirements to mend that deficiency in the near future. In this context it is also planned to adopt the revised WENRA Nuclear Safety Reference Levels.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

Requirements for the safety of nuclear fuel cycle facilities are covered by ASUNE and the "Regulation for safety of spent fuel management". The regulation includes the basic requirements for providing nuclear safety and radiation protection in the management of spent nuclear fuel according to the provisions of ASUNE, the specific organizational measures and technical requirements for providing the safety during site selection, design, construction, commissioning and operation of facilities for spent nuclear fuel management. Also, matters related to the technical safety, fire and physical protection, emergency planning and emergency preparedness of the spent nuclear fuel management facilities are defined in the regulation according to the defence in-depth concept.

The regulations cover the essential requirements of the IAEA Safety Standards.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

As part of the licensing process for radioactive waste management facilities, authorization are successively given for permits and licences on the basis of Preliminary Safety Analysis Report for the

siting stage, Intermediate Safety Analysis Report of the licence for operation and Final Safety Analysis Report for the licence for decommissioning.

Radioactive waste management regulation, ASUNE as well as the Regulation on the Procedure for Issuance of Licences and Permits for Safe Use of Nuclear Energy also refer to the need to produce safety assessments, as part of the licensing process, in order to support the demonstration of safety of the concerned facility or activity and as a basis for the decision to be taken.

In addition, structure and content of safety analysis reports for nuclear facilities are specified in the Regulation on the Procedure for Issuance of Licences and Permits for Safe Use of Nuclear Energy.

According to the information received and the discussions during the mission, it is rather difficult to obtain a clear understanding of the terminology related to the demonstration of safety of radioactive waste management facilities and activities. Moreover, it is rather difficult to understand the aspects covered by the different terms used (safety analysis, safety assessment), the hierarchy between the different terms and contents and the expectations from the regulator on these different supporting documentations requested as part of the licensing process. Consequently, it would be beneficial for BNRA, as well as for the operator, to clarify the terminology and the expectations of the different supporting documents requested for demonstrating the safety of radioactive waste management facilities and activities in general and in particular for demonstrating the safety of radioactive waste disposal facilities.

The regulation for safe management of radioactive waste includes all general safety requirements for radioactive waste management activities and facilities. In the case of radioactive waste disposal, the Regulation on the "Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy" and the "Regulation for Safe Management of Radioactive Waste" are used to lay down the basic requirements for disposal of radioactive waste.

Given the significance of the safety assessment to regulatory decision-making, it is important that the process by which regulatory authorities review safety assessments is systematic, logical and defensible, and based on clear regulatory requirements and review criteria. In the case of radioactive waste disposal, the length and complexity of the licensing processes and regulatory review may suggest the need to have specific guidance on particular issues, for instance long term safety requirements (modelling scenarios, consideration of human intrusion, record maintenance, timescale for radiological criteria, etc.).

Clear requirements and criteria assist the operator to establish an accurate assessment context and to focus on the key regulatory issues when developing conceptual and mathematical models as part of the safety assessment. In turn, this ensures that the regulatory authority receives a safety assessment that is closely suited to its needs and, therefore, can be used in its decision-making processes.

From the documents provided and from the discussions during the mission, it appears the existing regulations or guidance do not specifically address these issues.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SSR 5 Requirement 11 states that** *"Step by step development and evaluation of disposal facilities. Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS SSR 5 Para. 4.4 states that** *"The step by step approach to the development of a disposal facility also allows opportunities for independent technical review, regulatory review, and political and public involvement in the process. The nature of the reviews and involvement will depend on national practices and on the facility in question. Technical reviews by, or on behalf of, the operator and the regulatory body may focus on site selection and evaluation and design options, the adequacy of the scientific basis and analyses, and whether safety standards and requirements have been met."*
(3)	**BASIS: SSR 5 Para. 3.29 states that** *"[...] the range of possible events and processes causing disturbances that it is reasonable to include in such considerations has to be subject to agreement by the regulatory body and subsequent approval by inclusion in the safety case [...]."*
S20	**Suggestion: BNRA should consider the development of regulatory requirements for assessment of disposal such as e.g. assessment timescales, modelling scenarios, consideration of human intrusion and record maintenance.**

Radioactive Waste Classification

The radioactive waste "categorization" is provided in the "Regulation on the Safe Management of Radioactive Waste" (2004). The system for "categorization" is oriented towards the disposal of radioactive waste. The categories are as follows:

Category 1 – transitional radioactive waste that may be cleared within a period of not more than 5 years.

Category 2 – low and intermediate level waste subdivided into as follows:

category 2a – short-lived low and intermediate level waste that contain mainly short-lived radionuclides, and small amounts of long-lived alpha radionuclides;

category 2b - long-lived low and intermediate level waste containing long-lived alpha radionuclides exceeding the limits for category 2a;

Category 3 – high level waste with heat release to be considered for the purpose of storage and disposal.

An increasing generation of radioactive waste characterized by a very low concentration of radioactivity, but above clearance levels, is foreseen in Bulgaria in the next years, in connection with the start of decommissioning activities in the four units of Kozloduy NPPs.

Most of this waste, according to the IAEA Safety Guide on Radioactive Waste Classification (IAEA GSG-1, 2009), would follow under the Very Low Level Waste classification. The management of this waste, in contrast to exempt waste, does require consideration from the perspective of radiation protection and safety, but the extent of the provisions necessary is limited in comparison to the provisions required for waste in the higher classes. This may suggest that BNRA, in the on-going revision process of the Regulation on the safe management of radioactive waste, could take into consideration the modification of the current classification system to be in line with the IAEA international classification system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**Basis: GSR 5 Requirement 9 states that** *"Characterization and classification of radioactive waste. At various steps in the predisposal management of radioactive waste, the radioactive waste shall be characterized and classified in accordance with requirements established or approved by the regulatory body."*
(2)	**Basis: GSR 5 Para. 4.10 states that** *"Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties."*
(3)	**Basis: GSR 5 Para. 4.12 states that** *"Radioactive waste may be classified for different purposes, and different classification schemes may be used in the successive steps in waste management. The most common classification is that made from the perspective of its future disposal."*
(4)	**Basis: GSG 1 Para. 2.17 states that** *"Substantial amounts of waste arise from the operation and decommissioning of nuclear facilities with levels of activity concentration in the region of or slightly above the levels specified for the clearance of material from regulatory control.[…]The management of this waste, in contrast to exempt waste, does require consideration from the perspective of radiation protection and safety, but the extent of the provisions necessary is limited in comparison to the provisions required for waste in the higher classes (LLW, ILW or HLW) […]."*
S21	**Suggestion: BNRA should consider modifying the classification of radioactive waste to be in line with the IAEA international classification.**

As explained in module 11, a need for review of the requirements relating to the dose constraints for the protection of the public in the "Regulation on Safe Management of Radioactive Waste" is seen to make them consistent with the "Regulation on Basic Norms of Radiation Protection".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 22 Para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body […]."*
S22	**Suggestion: BNRA should consider to review the requirements relating to dose constraints for the protection of the public in the "Regulation on Safe Management of Radioactive Waste" to make them consistent with the "Regulation on Basic Norms of Radiation Protection".**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES

The requirements regarding Radiation Sources Facilities are covered by ASUNE, the "Regulation on the Radiation Protection during Activities with Sources of Ionizing Radiation" and the "Regulation on Radiation Protection during Work Activities with Materials with Increased Concentration of Natural Radionuclides".

ASUNE and the regulations define the basic requirements and rules for radiation protection during activities with sources of ionizing radiation and materials with increased concentration of natural

radionuclides as well as the conditions and the procedures for accounting of the sources of ionizing radiation. The regulations specify technical and organizational rules for conforming to the established basic norms for radiation protection in Bulgaria. The regulations cover the essential requirements of IAEA Safety Standards.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The requirements regarding decommissioning activities are covered by ASUNE, the "Regulation on Safe Decommissioning" (2004) and by the "Regulatory Guide on Structure and Content of a NPP Decommissioning Plan" (2010).

From the document provided and the discussions during the mission, there was evidence that there is no regulation or guides to ensure the application of the final controls to verify the achievement of the end state of the decommissioned facility and the compliance with the requirements for the release a site, a building or a structure from the regulatory control (see recommendation in Section 5.1).

9.7. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

Extensive legislation regulating the transport of radioactive material is in force in Bulgaria. In particular, the "Regulation on the Conditions and Procedure of Transport of Radioactive Material" is based on the requirements of the IAEA transport regulation TS-R-1 (2005 Edition). The Regulation stipulates additionally that other more general regulations for the transport (e.g. by road) of dangerous goods issued by the Minister responsible for transport also apply to the transport of radioactive materials. These modal regulations are in line with international modal regulations for transport of dangerous good (ADR/RID/ICAO/IMDG/ADN) which are in line with the requirements of the IAEA transport regulation.

The IAEA transport regulation is reviewed and updated periodically. The IAEA Safety Standard on transport regulations TS-R-1 was updated in 2012 as SSR-6. However, the present IRRS mission is based on the 2009 edition of TS-R-1, because the IRRS self-assessment process preceded the issuance of SSR-6. The Bulgarian regulation for transport is not amended at each revision of the IAEA standards, but a review is carried out as part of wider processes aimed at keeping regulations up to date. BNRA has confirmed that a review of their transport regulations has been done and the implementation of the modifications of the regulations is being carried out (which will include the requirements of the Council Directive 2006/117/EURATOM and the Standard Document for the Supervision and Control of Shipments of Radioactive Waste and Spent Fuel).

In practice, the different schedules for revising the different regulations lead to duplications, conflicts and discrepancies between specific requirements of the transport regulations, requirements of the modal regulation and the IAEA transport regulations. The IRRS team points out, for example, the following discrepancies:

- there are no transitional arrangements;
- there is no specific notification process in case of non-compliance neither in the BNRA transport regulations) nor in the Regulation of the Conditions and Procedure for Notification of the Nuclear Regulatory Agency about Events in Nuclear Facilities and Sites with Sources of Ionising Radiation ;
- there is no specific requirement about undeliverable consignments ;
- there is no requirement for presence of a feature as a seal (as evidence that the package has not been opened) for industrial package for fissile material.

The IRSS team considers that, other than the absence of a requirement for a notification process in cases of non-compliance, these discrepancies are only of limited relevance to safety. However, for the notification process a Suggestion is made below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: TS-R-1 Requirement 309 states that** *"In the event of non-compliance with any limit in these Regulations applicable to radiation level or contamination:* *(a) the consignor shall be informed of the non-compliance by […]* *(b) the carrier, consignor or consignee, as appropriate, shall: […]* *(c) the communication of the non-compliance to the consignor and the relevant competent authority(ies), respectively, shall be made as soon as practicable and it shall be immediate whenever an emergency exposure situation has developed or is developing."*
S23	**Suggestion: BNRA should implement a notification process in case of non-compliance in transport activities.**

BNRA commissioned a TSO to undertake a full review of existing international guidance for transport in 2010. This review led to the preparation of a several national new guidance documents for transport (currently in draft). BNRA plans to review these documents in order to finalize this guidance. The documents include guidance on the following topics:

- planning and preparing for emergency response to transport accidents;
- radiation protection programmes for the transport of radioactive material;
- management system for the safe transport of radioactive material;
- compliance assurance for the safe transport of radioactive material.

BNRA has however issued a guide to applicants wishing to apply for a transport licence which clearly identifies all the information that needs to be supplied.

The IRRS team encourages BNRA to continue and finalise its guidance on transport activities. Completing this programme will address the recommendation of section 9.1 for transport activities.

9.8. SUMMARY

All areas of BNRA's competence are covered by regulations and a few regulatory guides. The need for each regulation is explicitly defined by ASUNE.

Regulations and guides reflect the IAEA Safety Standards and other relevant international requirements but in many cases do not provide detailed requirements and the associated criteria. It seems necessary to develop and introduce appropriate regulatory guides to describe and make available acceptable methods to fulfil the principles and requirements of the regulations. The need for new and more detailed regulatory guides is seen for many technical areas of the licensing process.

The procedures to develop, amend and revise regulations and regulatory guides are stringent and comply with the state of the art. Well-defined review periods trigger regular updates which are keeping regulations and guides up to date. A comprehensive renewal programme for all regulations is presently undertaken and already in an advanced stage.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL REQUIREMENTS

Basic Responsibilities

The Bulgarian legislative framework for preparedness and response to nuclear or radiological emergencies is in place. The Disaster Protection Act (2006) (DPA) gives the Ministry of Interior the responsibility for preparing the National Disaster Protection Plan, which is adopted by the Council of Ministers. Emergency planning is carried out at municipal, regional and national level, as well as at on-site level.

There is the Unified Rescue System in place in Bulgaria, covering all types of disasters, including nuclear and radiological. Therefore, the National Disaster Protection Plan covers all disasters as well. It includes detailed off-site emergency plan for the Kozloduy NPP as a separate document, which is complemented by regional plans. In addition, the Kozloduy NPP maintains its own on-site emergency plan. Territorial level planning includes 28 districts in line with the territorial division of the country and 264 municipalities.

DPA is harmonized with the Act on the Safe Use of Nuclear Energy (ASUNE) with respect to requirements for the development of emergency plans (on-site and off-site), their content, necessary human resources and other.

The Ministry of Interior is the National Coordinating Authority for emergency preparedness and leads the National Headquarters for Coordination and Control (NHCC) in case of emergencies of all kinds.

Other organizations involved on the national level are: The MoH, the Ministry of Environment and Water, the Ministry of Defence (armed forces), the Ministry of Agriculture and Food, the State Agency for Metrological and Technical Surveillance.

Assessment of Threats

There are three documents that establish the threat assessment in the country: assessment for transport of radioactive material, operator's threat assessment and the national level threat assessment. The last one is a part of the national plan. The threat assessments are based on the DPA which states in its Art. 9 "Disaster protection plans shall certainly contain analysis and evaluation of disaster risks […]". One of the annexes of the National Nuclear and Radiological Emergency Plan includes the results of the threat assessment for radioactive sources used in Bulgaria. BNRA is currently working on the threat assessment to be included into a single document being in line with the aforementioned legislation. In general terms, all five categories defined in GS-R-2 are present in the Bulgarian EPR regulation (State Gazette No.94 of 29 November 2011). In addition to these categories, more specific criteria are defined for practical purposes.

The emergency planning zones for precautionary, urgent and long terms protective actions are 2 and 30 and 50 km (or more if needed) respectively. In the 2 km zone there is no population which means that no precautionary actions are considered to be implemented. The zoning is to be reviewed in view of the recent international developments.

10.2. FUNCTIONAL REQUIREMENTS

Establishing Emergency Management and Operations

The role of BNRA is defined in the national system of emergency and response in connection with nuclear and radiological emergencies. The BNRA chairman takes decision on the level of activation of BNRA according to the emergency plan. The two deputy chairmen and other personnel may substitute the chairman in case of his unavailability. BNRA recommends protective actions based on the internal assessment to the National Headquarters for Coordination and Control (NHCC).

In case of a nuclear or radiological emergency, NHCC is led by the Minister of Interior and includes leaders of all concerned institutions. NHCC takes decisions for implementation of protective measures at the national level. On regional and local levels the respective headquarters can take decision depending on the scale of the events. In case of radiological emergencies response on the scene is led by the civil protection along with fire fighters, paramedics and police.

During a conventional emergency with the potential to be a radiological emergency, the response organizations are obliged by the regulations to notify BNRA.

Identifying, Notifying and Activating

BNRA has the role of Competent Authority (domestic and abroad) and National Warning Point under the Notification and Assistance Conventions. Primary phone contact in the IAEA address book is an official personal mobile phone of the Head of the Emergency Planning and Preparedness Division. The back-up for this phone number is call forwarding to another BNRA employee of the Emergency Planning and Preparedness Division.

For all kinds of emergencies including nuclear and radiological emergencies, there are 6 call centres ("112" emergency number) covering the entire country. The call centres are under the Ministry of Interior. BNRA employees, primarily the Head of the Emergency Planning and Preparedness Division, are contacted through these call centres if necessary.

The BNRA emergency team has 24 positions, out of which 17 are in the BNRA emergency centre and 7 are at other locations (NPP, EU (Brussels), IAEA (Vienna), NHCC (3), Municipality of Sofia). When the BNRA emergency plan is activated, the team can be fully or partially activated. A pool of 65 personnel is available to activate the team. The emergency team works in two shifts of 12 hours each. There are three personnel assigned for each position on average. Activation of the BNRA emergency plan is decided by the BNRA chairman or his deputy. Activation of the emergency team is performed by the Head of the Emergency Planning and Preparedness Division and/or other employees of the division.

BNRA's notification point (international, domestic notifications) and activation of the BNRA emergency team is not based on formal roster for duty officers. In addition BNRA does not formally maintain an emergency team in standby, nor keep official status of personnel availability for activating the team. The system currently in place is not periodically tested either.

For facilities of threat Category I, a national system for classification is established which is in line with GS-R-2.

A special guide was developed for the control of scrap metal yards and processing facilities. All reprocessing facilities are equipped with portal detectors; similarly detectors are installed on the belt before the melting of the scrap metals. Based on the emergency regulation, scrap metal operators are obliged to have an Emergency Plan for the case if a radioactive source is found. Facilities have employees or they have contract with external companies to make the measurements if an alarm is activated and they are obliged to notify BNRA for further actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 4.16 states that** *"Notification points shall be established that are responsible for receiving emergency notifications of an actual or potential nuclear or radiological emergency. The notification points shall be continuously available to receive any notification or request for assistance and to respond promptly or to initiate an off-site response."*
(2)	**BASIS: GS-R-2 Para. 4.27 states that** *"Arrangements shall be made for response organizations to have sufficient personnel available to perform their assigned initial response actions."*
(3)	**BASIS: GS-R-2 Para. 5.9 states that** *"Sufficient numbers of qualified personnel shall be available at all times in order that appropriate positions can be promptly staffed as necessary following the declaration and notification of a nuclear or radiological emergency."*
S24	**Suggestion: BNRA should consider improving its notification point system and emergency team availability by formally establishing a roster for duty officers and relevant emergency team positions in order to be able to respond promptly and perform initial response actions.**

Taking mitigatory actions

The national plan and local plans have specific Annexes defining response to nuclear and radiological emergencies. In case of a small scale radiological accident the regional civil protection headquarters is making decisions. The BNRA emergency team will be activated without the nuclear safety subgroup and it would recommend protective actions to the regional headquarters.

Taking urgent protective action

The regulation on EPR provides the general basis for intervention levels for taking urgent protective actions. The GSG-2 criteria were taken into account as well.

Urgent protective actions are decided upon by the NHCC. Potassium iodide (KI) pills are pre-distributed in the 30 km zone around the NPP. Age limit is 45 years. Evacuation is planned for 30 km zone. There are 8 possible gathering points planned, but depending on actual conditions 2 or 3 will be used at a time. The time estimate for evacuation is 8 hours for specific sectors in the 30 km zone.

According to bilateral and international agreements communication are send to neighbouring countries in case of emergencies. Particular attention is given to interactions with Romanian authorities as their nearest border is inside the zone where urgent protective actions are to be taken. Nonetheless, there are no effective operational arrangements to provide instructions and to implement protective actions beyond Bulgarian borders. In this respect the sirens system for alarming the population does not extend over the border and the emergency planning zones are not contiguous across the border (the emergency planning zones have different sizes in the two countries).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 4.48 states that** *"For facilities in threat category I or II arrangements shall be made for effectively making and implementing decisions on urgent protective actions to be taken off the site. …These arrangements shall include the following:* *(a) The specification of off-site emergency zones for which arrangements shall be made for taking urgent protective action. These emergency zones shall be contiguous across national borders, where appropriate, and shall include:* *[…]* *ii. An urgent protective action planning zone, for facilities in threat category I or II, for which arrangements shall be made for urgent protective action to be taken promptly, in order to avert doses off the site in accordance with international standards […]."*
R12	**Recommendation: The government should take steps for the harmonization of emergency preparedness and response arrangements with Romania in order to implement decisions on urgent protective actions across its national borders.**

Providing information and issuing instructions

Warning and instructions to the public are provided through various channels. Sirens are used to alarm people and to transmit voice messages. Vehicles with loudspeakers are also used for voice messaging.

Sirens within a 12 km radius around the NPP are under direct control of the NPP. Sirens from 12 up to 30 km radii area around the NPP are also activated at the operator's discretions, but activation is technically carried out by the local civil protection. This aspect may add an additional 12 km zone with respect to implementing the measures, if the triggering by civil protection fails. The existing siren system within the 30 km is being upgraded and will enable the Kozloduy NPP to activate the whole system within the whole 30 km zone avoiding in this way possible misunderstandings with additional zoning.

Another way to provide information to the public is the national radio and TV broadcasting network. Civil protection may interrupt (override) the radio programs and may transmit voice messages over the radio frequencies. For TV civil protection provides text messages to be displayed by the TV networks. This system is used for all types of disasters and can be geographically targeted. In addition there are some specific standard videos ready to be aired on TV to instruct people, including nuclear emergencies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 4.53 states that** *"Upon declaration of an emergency class the public shall be promptly warned of the emergency and informed of the actions that they should take. There shall be no undue delay that could jeopardize the effectiveness of the protective actions."*
GP8	**Good practice: Instructions recommended by BNRA can reach the public through an efficient system developed and maintained by the Ministry of Interior by sending voice and text messages through the national radio and TV broadcasting networks.**

Protecting emergency workers

Requirements for protecting emergency workers are defined in emergency regulation. The responsible organizations for dose control of the emergency workers in case of an emergency are the employer and the MoH.

In accordance with the Regulation on emergency planning and emergency preparedness in case of nuclear or radiological emergency, the off-site and on-site emergency plans include evaluation of predicted dose for the personnel, population, members of the emergency team and persons who participate in the implementation of the protective measures. During an emergency, workers must have passive and active dosimeters. Civil Protection has a system to monitor and register doses of personnel accessing the protective zones.

Assessing the initial phase

The NPP operator makes its own assessment based on the on-site emergency plan. For off-site actions the off-site emergency plan for the Kozloduy NPP is used.

The BNRA emergency team subgroup for nuclear safety assessment is responsible for assessing the accident on BNRA's behalf. To their support they have real time access to over 12.000 NPP operating parameters via The Safety Parameters Display System (SPDS) and Post Accident Monitoring System (PAMS). The BNRA emergency team subgroup for radiation protection monitors the environmental radiation situation via an early warning system, which consist of 35 gamma dose rate meters distributed across the country (more densely around the NPP) and 2 automatic aerosol detectors for suspended particles which are complemented by other non-automatic detectors maintained by the MoH and the Ministry of Environment and Water.

Public information

BNRA issues press releases on its own until NHCC is activated. The time limit for these is not set in the plan. After NHCC is activated BNRA provides drafts to NHCC, which coordinates press releases. The BNRA emergency plan requires a time limit of 4 hours for the first coordinated press release, which seems quite high and needs to be reduced. The NHCC has a specific group dealing with public information and BNRA has a representative in this group whenever needed.

BNRA uses its regular website to publish press releases as well. To meet the press, the training centre meeting room is used.

Outreach activities are being made through seminars, exercises and other activities. They include general topics as well as emergency preparedness and response. In addition open-door-sessions are organized for schools, students and the civil population. In addition the annual report is being shared with public presentation at the end of the year.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 4.82 states that** *"All practicable steps shall be taken to provide the public with useful, timely, truthful, consistent and appropriate information throughout a nuclear or radiological emergency."*
S25	**Suggestion: BNRA should consider reducing the time limit of four hours currently defined in its plan for the first press release.**

10.3. REQUIREMENTS FOR INFRASTRUCTURE

Organizational aspects

BNRA has established 22 procedures for emergency preparedness and response, which are part of its management system. The BNRA emergency plan is one of these documents being on the top. The maximum review period is 2 years for top level documents, 5 years for low level documents whereas there are 8 emergency preparedness related documents (user manuals) without a defined review period according to the BNRA quality management system. The documents are available in electronic form on the internal network and external disk drives. Hardcopies of the documents are available at the emergency centre, but these are not controlled copies. The contact details of BNRA personnel who need to be called to join the emergency team are not formally established nor are they included into the management system to be reviewed systematically.

The BNRA emergency team has a dedicated Emergency Centre and the personnel of the division operate on partially dedicated premises and uses partially dedicated equipment (printers, faxes, scanners, video conference). Similarly some of the personnel of the Division for Emergency Planning and Preparedness have additional IT responsibilities for the whole BNRA.

Communication equipment at BNRA includes dedicated lines, faxes, radio communication, video conferencing and phones, including satellite. There are just few phones ready, but more can be set up in a short time. There is one fax for incoming messages, which is connected to a PC in order to enable automatic forwarding of faxes to on-call personnel. This fax does not have back-up. Similarly there is one fax for outgoing messages. Radio communication is not in standby at the emergency centre. If there is a need to use it (telephone network failure), radio stations will be provided by the Ministry of Interior. Satellite phones are mobile type and work only outside the premises. There are no plans to upgrade the system with dock station and roof antenna. There is a diesel generator for electricity back-up of the emergency centre.

The emergency preparedness division keeps a list of radiation measurement equipment, but there is no complete list of the emergency team’s equipment. The communications arrangements are not documented either. The emergency equipment and communication systems are used as part of regular BNRA work to ensure their operability and readiness to use. Only diesel (monthly), satellite phone (annually) and measurement equipment are regularly tested. But there is no plan for testing of equipment in general. Appropriate documentation (lists of equipment, procedures for regular testing) is needed for maintaining and testing to ensure their availability at all times.

Training, drill and exercises

BNRA has a general annual training plan, which includes emergency preparedness topics. Emphasis is given to initial training of new employees, which lasts 6 months. There is a special chapter on EPR. Other than that, there are just few training sessions organized on EPR topics. There is no training plan or a systematic approach, dedicated to emergency preparedness, which would schedule refreshing of knowledge and skills for emergency team members. There is no tracking of participation that could ensure long term ability to perform the expected tasks.

BNRA participates at regular national and international exercises as well as exercises jointly organized with the Kozloduy NPP. The joint exercises are conducted every two months. Due to regular workload of BNRA personnel, the majority of times personnel of the Division of Emergency Planning and Preparedness participate in these exercises. Exercises are analysed and feedback from participants is collected and reported. This feedback and specific actions for improvement are confirmed by the BNRA chairman.

The IRRS team observed a four hour exercise with emergency scenario driven by the Kozloduy NPP simulator. The BNRA emergency team was almost fully activated. The team performed at high level, with dedication to perform the assigned tasks, a strong leadership was also clearly demonstrated. During the debriefing meetings, areas for further improvement were identified both by the players and by the IRRS team.

National full scale exercises related to the NPP are organized every five years by the Ministry of Interior (MoI).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para. 5.31 states that** *"The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 4. The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The arrangements shall include on-going refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training."*
R13	**Recommendation: BNRA should improve current arrangements for initial and refresher radiation emergency training by introducing a systematic approach (e.g. preparing annual and long term training plans for all kinds of emergency trainings).**
(1)	**BASIS: GS-R-2 Para. 5.18 states that** *"Emergency plans shall include, as appropriate:* *[…]* *(d) procedures, including communication arrangements, for contacting any relevant response organizations] and for obtaining assistance from fire fighting, medical, police and other relevant organizations […]."*
S26	**Suggestion: BNRA should consider including the communication arrangements into its emergency plan, in order to have them properly documented.**
(1)	**BASIS: GS-R-2 Para. 5.37 states that** *"[…] the off-site response organizations shall establish a quality assurance programme, in accordance with international standards, to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the functions specified in Section 4 in an emergency (see Para. 5.25). This programme shall include arrangements for inventories, resupply, tests and calibrations, made to ensure that these items and facilities are continuously available and functional for use in an emergency. Arrangements shall be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons learned from research, operating experience (such as the response to emergencies) and emergency drills and exercises (see Paras 3.8, 3.16, 5.33 and 5.39)."*
S27	**Suggestion: BNRA should consider including its emergency supplies, equipment, communications system and facilities as part of the quality assurance programme to ensure their high degree of availability and reliability (i.e. by introducing periodic testing).**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S28	**Suggestion: BNRA should consider ensuring availability and update status of relevant emergency related documents (e.g. by including them into its management system or by some other documented means).**

10.4. SUMMARY

Emergency preparedness and response in Bulgaria has the necessary legal grounds. The national emergency plan and its implementation provide for efficient response to nuclear or radiological emergency. While the general impression of the IRRS team was that planning for radiation emergencies is taken seriously in Bulgaria with similar priority as for conventional emergencies.

BNRA has a relevant role in the national emergency infrastructure and has a dedicated department devoted to emergency preparedness and response. Nonetheless, the IRRS team found issues that should be prioritized to be fully in line with IAEA Safety Standards. BNRA should improve its emergency system by formalizing duty officer system; by more systematic emergency training, testing of its equipment and communications systems; and maintaining emergency related documents. In addition, the Bulgarian Government should ensure implementation of urgent protective actions around the NPP (harmonizing planning zones with actual zones in Bulgaria and across its borders).

On the other hand the IRRS team found good practices that other countries could take as reference, regarding the public information about protective actions through a national radio network by Civil Protection overriding the programme directly seems exemplary and also the BNRA outreach programme.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The legal basis for medical exposure control is mainly based on the Health Act and specific requirements given in Regulation No 30 on the Conditions and Terms for Providing Protection of Individuals in Relation to Medical Exposure (Regulation 30). This regulation is now under revision and a draft has been finalized. General requirements for radiation protection and safety of medical exposure are also given in Regulation on Basic Norms on Radiation Protection (Regulation on BNRP). Under the Health Care Institution Act there are regulations on establishing Medical Standards for radiotherapy (Regulation No. 48), nuclear medicine (Regulation No. 6) and medical imaging (Regulation No. 27).

There are two authorities involved in the regulatory framework of radiation protection and safety related to medical applications; BNRA and the MoH. Under the MoH the main institution in the area of radiation protection and safety of medical exposures is NCRRP. Radiation health control is carried out by the Radiation Control Department at NCRRP and by Radiation Control Divisions at 5 Regional Health Inspectorates (RHI).

Justification:

Regulation 30 has requirements to assure for proper justification of medical exposure that are mostly in compliance with the IAEA GRS Part 3. Only medical doctors and dentists can refer patient to examinations and procedures giving rise to medical exposure (Article 7). The referral has to include medical indication and full supporting medical documentation (Article 8). It also states that the referrer shall consult the "Diagnostic Radiation Passport" of the patient, although this is yet to be implemented. The Bulgarian Association of Radiology has established referral guidelines in "Rules of good practice in diagnostic imaging, but there is no requirement in the regulation that referral guidelines should be taken into account by the referrer in the justification process as required by IAEA GSR Part 3 Para. 3.157. The need for a proper referral as a prerequisite to conduct a medical exposure should be stated more explicitly in Regulation 30 as required by IAEA GSR 3 Para. 3.150. Regulation 30 requires that patient, carers and comforters are informed of the benefits and risks, that biomedical research must be approved by an ethics committee and that health screening programs must be approved by the MoH (NCRRP).

Radiological medical practitioners (defined in Regulation 30, Article 9) have the final responsibility for the individual justification of medical exposure. However, if the radiologist concludes that an examination is not justified for a hospitalized patient, but is defined in the "clinical pathway" (as regulated in the Health Insurance Act) for that patient, the hospital will not get reimbursement for that patient. This system puts the radiologist in a difficult position, and unjustified examinations can be performed.

Generic justification of new procedures is required in Regulation BNRP (Article 49 (1)), but the responsibility for generic justification is not given to the MoH (NCRRP) as required by GSR Part 3, Para. 3.155. In addition, there is no established mechanism which assures that the MoH (NCRRP), in conjunction with professional bodies, takes this responsibility. Today, generic justification of new diagnostic procedures is performed locally at the hospitals, and the MoH (NCRRP) is not routinely involved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 3 Para. 3.155 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances of technological developments."*
R14	**Recommendation: The MoH should ensure that generic justification of radiological procedures is carried out in conjunction with the appropriate professional bodies.**
(1)	**BASIS: GSR Part 3 Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified."*
(2)	**BASIS: GRS Part 3 Para. 3.156 states that** *"The justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medial practitioner […]."*
(3)	**BASIS: GRS Part 3 Para. 3.150 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless: (a) The medical exposure has been justified […]."*
S29	**Suggestion: The government should consider allowing for exceptions from the defined clinical pathway that require medical exposure, if the exposure of the individual patient is not justified. This is to allow the radiological medical practitioner to assure proper justification.**

Optimization:

Regulation 30 has requirements to assure for proper optimization of medical exposure that are mostly in compliance with the IAEA GRS Part 3. Regulation 30 gives requirements on design and operational considerations, quality assurance and quality control. Independent audits of the quality system are also required to be performed periodically. Acceptance criteria and performance criteria for medical radiological equipment are given in Annex 8-10 of the regulation. Registrants and licensees are required to establish "typical doses" for patients and to assess them against national diagnostic reference levels (DRL) established by NCRRP. DRLs are based on national dose surveys and NCRRP has established a good system for establishing and revising national DRLs. The establishment of "typical doses" locally at the hospitals is in its initial phase. The draft regulation requires also individual dose of patient to be recorded. A requirement to perform calibration, traceable to a standard dosimetry laboratory, of dose displays on radiological equipment is now introduced in the draft revision of Regulation 30. A requirement on proper calibration of dose devices on radiological equipment is essential to assure for proper dosimetry for medical exposure (typical doses and DRLs).

Dose constraints for carers and comforters and volunteers in biomedical research are not properly implemented as a tool in optimization of radiation protection and safety for these persons, as required by GSR Part 3 (Para. 3.148, 3.172 and 3.173), but clear requirements to protect these individual are given in in Regulation 30 (Article 16, 18-20). Regulation 30 also gives requirements for appropriate radiation protection of pregnant and breast feeding women and criteria and guidelines for release of patients after radionuclide therapy. However, release criteria for implanted sealed sources after therapeutic procedures (like brachytherapy) are not established as required by IAEA GSR 3 Para. 3.148. Qualification criteria and formal recognition for medical physicists and medical physicist experts are defined and their responsibilities are given in Regulation 30 (Article 26 and 27), however there is a shortage of medical physicist in diagnostic imaging in Bulgaria. However, hospitals contract medical physicists to do quality

control of their equipment. As a result, medical physicists are not yet involved in all the required tasks given in the regulation in all hospitals, like being involved in optimization of radiological protocols. To increase awareness of radiation protection, NCRRP have made posters and information material for different patient groups. They have also started to develop guidelines within medical exposure (establishment of "typical doses"). However, more guides are needed to help the registrants and licensee to implement the requirements given in Regulation 30.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Para. 3.166 states that "***In accordance with Para. 3.153(d) and (e), the medical physicist shall ensure that:* *(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;* *(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;* *(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standard dosimetry laboratory."*
S30	**Suggestion: BNRA and the MoH (NCRRP) should introduce a requirement to assure that dose displays on radiological equipment are calibrated and that the calibration is traceable to a standard dosimetry laboratory.**

Education in radiation protection and safety:

BNRA have licensed three training providers to cover mandatory training in radiation protection and safety for medical health professionals involved in medical exposure. According to the Regulation on Qualification, all health professionals involved in medical exposure need to obtain an individual certificate from one of the training providers. The professionals must take a refresher course every year and have their certificate renewed every five years. It was observed during the site visit made at Tokuda Hospital in Sofia that only a few of the staff had a valid re-training certificate, mainly due to a shortage of available training providers. Additionally, there is no common training criteria (learning outcomes) and each training provider develops their own training curricula which are not harmonized. Development of learning outcomes should be done in cooperation with the MoH (NCRRP) and appropriate professional bodies.

In the draft revision of Regulation 30, there is a requirement for obligatory course in radiation protection in the curricula for physicians and dentists. A closer cooperation with educational institutes should be considered to implement more training on radiation protection and safety for medical exposure in basic and post-graduate curricula for health professionals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Para. 2.22 states that** *"The government shall ensure that arrangements are in place for the provision of the education and training services required*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	for building and maintaining the competence of persons and organizations that have responsibilities relating to protection and safety."
(1)	**BASIS: GSR Part 3 Para. 3.149 states that** *"The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals specified in these Standards only if they: (b) meet the respective requirements for education, training and competence in radiation protection."*
S31	**Suggestion: The government should consider ensuring sufficient training providers to accommodate the number of health professionals involved in medical exposure in the country. BNRA should consider ensuring, during the licensing process of training providers, that health professionals involved in medical exposure get a proper and harmonized level of training in radiation protection and safety in medical exposure.**

11.2. OCCUPATIONAL RADIATION PROTECTION

General information and legislation

The scope of the review included occupational radiation protection in all practices, including the nuclear power plants, spent fuel and radioactive waste management facilities, medical applications, industry and research. In Bulgaria there are two governmental organizations which act in the area of occupational radiation protection, BNRA and the MoH. The main authority of the MoH in the area of occupational radiation protection is NCRRP.

The occupational radiation protection inspections activities are carried out through eight inspectorates. In the radiation control section of NCRRP there are three inspectorates, one located at the NCRPP for inspections at nuclear and waste facilities, a second NCRRP inspectorate for nuclear and waste facilities located at the NPP and finally one local inspectorate connected to the NCRRP for other sources of ionizing radiation. Each local inspectorate has a medical doctor as coordinator and one or more occupational radiation protection specialists.

There is a procedure for inspections containing procedural, content and format requirements. There are also working instructions on how to operate, for example, surface contamination meters. Every year there is an annual meeting to compare results between the inspectorates, and in 2012 the NCRRP carried out audits in the local health inspectorates.

During meetings and interviews with a representative of NCRRP which is connected to the MoH and through visits to the "Radioactive waste Novi Han SD" (Specialized Department of State Enterprise "Radioactive Waste") questions that had arisen during the analysis of the advanced reference material were answered and additional information was collected.

Occupational radiation protection (ORP) legislation is based on the two main acts and regulations, the act on the safe use of nuclear energy, published in 2002 and the Regulation on basic norms of radiation protection (BNRP) published in 2012. The BNRP regulation is based on the 2012 Euratom proposal for a Council Directive laying down basic safety standards for the protection against the dangers arising from exposure to ionizing radiation. The proposal is also based on IAEA GSR Part 3 and is adopted by the European Economic and Social Committee. The ORP Regulations are therefore up-to-date.

Optimization of radiation protection

At Kozloduy units 5 and 6 ALARA is dealt through an ALARA committee, and there are procedures for setting up the committee and organizing the meetings. Around four meetings of the Committee are organized per year. A yearly collective effective dose budget is established, for the operation and for outages. The measured collective doses are compared against the planned doses. The collective dose in man Sv and the maximum individual dose in mSv for the units 5 and 6 have shown a trend for reduction since 2005. The collective annual doses for these two units compare well in relation to collective annual doses from similar NPPs operated in other countries. As part of the licensing requirements, the operator sends an annual report on ORP which is analysed both by BNRA and NCRRP.

For the other areas of ORP, including areas such as industrial radiography, interventional radiology and nuclear medicine clinics where the individual annual doses may approach the annual dose limits, there is no trend analysis or annual report summarizing the findings, with the possible exception of ad-hoc analysis performed through the National Dose Registry.

GSR Part 3 sets the basis for establishing dose constraints in the area of ORP. However, in the BNRP Regulation, dose constraints are calculated by applying a safety factor to the annual dose limit. This method of establishing dose constraints is not consistent with GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 11 states that** *"The government or regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized."*
(2)	**BASIS: GSR Part 3 Para. 1.28 states that** *"The selection of the value for the dose constraint or the reference level would be based on the characteristics of the exposure situation, including:* *The nature of the exposure and the practicability of reducing or preventing the exposure;* *The expected benefits of the exposure for individuals and society, or the benefits of avoiding preventive actions or protective actions that would be detrimental to living conditions, as well as other societal criteria relating to the management of the exposure situation;* *National or regional factors, together with a consideration of international guidance and good practice elsewhere."*
S32	**Suggestion: NCRRP should consider reviewing the optimization processes for occupational radiation protection for all practices and take the necessary steps to assure the optimization.**

Requirements for radiation protection programmes and worker responsibilities

The requirements of content on radiation protection programs are established in the Regulation on radiation protection during activities with sources of ionising radiation (SIR) published in 2004. The responsibilities of the occupationally exposed worker as to the use of individual monitoring devices, personal protective equipment and the reporting of unsafe conditions in the workplace are given in the Regulation on Individual Monitoring of Exposure number 32 published in 2005.

Training in radiation protection

Requirements for training in ORP are established in the Regulation number 74: Regulation on the terms and procedure for obtaining of vocational qualification and on the procedure for issuing of licences for specialised training and of individual licences for use of nuclear power, published in 2007. Five levels of training are recognized. The first level is basic ORP training for occupationally exposed workers (OEW). The third level of training is for radiation protection officers (RPO), and the fifth level of training is for qualified experts. All training is performed in training centres authorized by BNRA. Refresher training at all levels is obligatory every year. Local training in local procedures by the RPO is also carried out. NCRRP inspectors are highly trained mostly with post-graduate training in the relevant area.

Outside ORP in NPP there are no recognized experts in specific areas in BNRA and NCRRP, such as in industrial radiography for example. The training in ORP in these areas is therefore carried out by, for example, experienced industrial radiography operators under the supervision of NCRRP staff.

Individual monitoring

There are six external dosimetry services operating in Bulgaria. There is one film dosimetry service operated by NCRRP monitoring around 5,000 OEW, a TLD service operating at KNPP for the NPP staff, and four other TLD services. In total around 10,000 OEWs are individually monitored. The services provide measurement for $H_p(10)$ (effective dose) for photons and are accredited in the ISO standard 17020 by a service provided by the Ministry of Economics, Energy and Tourism. The accreditation has five year validity and two external audits are performed over the five year period.

The exchange frequency of the $H_p(10)$ monitors for photons is monthly for the NPP workers and three monthly for the OEW in other practices – most of which is performed by film dosimetry. The three month dosimeter exchange period should be reviewed as the dose as registered on the film dosimeter is subject to fading over time and as there are OEW working with, for example, industrial radiography, where a monthly dosimeter exchange is considered relevant for optimized ORP.

There is no accredited extremity monitoring service which measures $H_p(0.07)$ nor a service for monitoring of the eye lens dose $H_p(3)$ whose annual limit has been recently reduced to 20 mSv. For certain activities such as OEWs that handle directly radiopharmaceuticals in nuclear medicine clinics, of for interventional radiography, the annual dose to the extremities or to the eye lens can reach values of the order of the annual dose limits. It is therefore recommended that external monitoring for such activities be considered and that the NCRPP investigate the cases when $H_p(3)$ measurement is necessary.

There is no accredited neutron dosimetry service. The neutron dosimetry at KNPP is being performed by foreign accredited dosimetry service. There are also other OEWs working in other practices that handle neutron sources are not monitored for neutrons. It is therefore recommended that in the short term an ISO 17025 accredited neutron individual monitoring service be contracted to carry out this service. The ISO 17025 accredited service would not need to be accredited by the Bulgarian government as mutual recognition programs are in place. In the medium term, a neutron dosimetry service can be established in Bulgaria.

There are two Whole Body Counting laboratories in operation. One is at the Kozloduy NPP and performs routine measurements of the NPP and SE RAW Kozloduy personnel. The second is at the NCRRP laboratories. Both laboratories are accredited in ISO 17020 standard by the Bulgarian accreditation service of the Ministry of Economics, Energy and Tourism.

There is no Bulgarian service provider for in-vitro (urine and faeces) bioanalysis of internal radionuclides. Although the activity of the open sources handled in Bulgaria is generally low, with the exception of the medical uses of radiopharmaceuticals, a number of alpha and beta emitting radionuclides are handled

whose intake can only be determined by in-vitro bioassay. In-vitro analysis is also important for a more precise estimation of the committed effective dose when a measurement above the minimum detectable activity is found in the Whole Body Counter. In-vitro bioanalysis is certainly necessary in the case of a radionuclide release from a nuclear installation and will become important when large scale decommissioning operations are established.

It is therefore recommended that the Regulator establish a memorandum of understanding with an ISO 17025 accredited laboratory so as to be able to perform in-vitro measurements on internally deposited alpha, beta or gamma emitters. In the medium term, it is suggested that a radionuclide chemistry laboratory for excreta measurements be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Para. 3.38 states that** *"Registrants and licensees and employers shall ensure that monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of these Standards".*
R15	**Recommendation: BNRA and NCRRP should:** i. **for certain workplaces in practices, identify where external individual monitoring for extremities and the eye lens is necessary for verification of compliance with annual dose limits and when necessary require that this monitoring be carried out by an accredited service;** ii. **require that neutron dose measurement through an authorized or ISO 17025 accredited service be provided to those occupationally exposed workers who are exposed to neutron fields so that compliance of the received doses against the annual dose limits may be verified.**
S33	**Suggestion: NCRRP should consider forming an agreement with a laboratory for in-vitro bioassay measurements through a memorandum of understanding so that timely measurements are available when necessary.**

National dose registry

As established in Regulation 28 of 2005 of the MoH, from 2011 a national registry for recording doses has been operated by NCRRP. It contains personal and professional data on OEWs. It contains also information on the radiation source and other conventional risk factors such as chemicals in the workplace environment. External and internal dose results are registered giving the annual and five year running dose, and also the lifetime dose. Special and emergency exposures are also included. Work place monitoring results and the results of medical surveillance, the date and type of training courses and additional data on health conditions, if relevant, are included, together with the evaluation of whether the OEW is fit to work or not. This is a very complete and ambitious national data registry which allows a complete evaluation of any possible causes of medical conditions which may or may not have been caused by ionizing radiation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Para. 3.107 states that** *"If employers, registrants and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' records of occupational exposure by the regulatory body or a State registry, or by a relevant employer, registrant or licensee, as appropriate."*
GP9	**Good practice: The National Dose Registry as established by the Regulation 28 and as operated by NCRRP contains information not only on the doses received by occupationally exposed workers but also medical and workplace monitoring data, training information and information on exposure to conventional chemicals in the workplace in such a way that all the relevant information for future cause-effect analysis can be found in one database.**

Workplace monitoring and calibration

The calibrations of the workplace monitoring equipment (γ dose rate meters and α and β surface contamination meters) are made by the National Metrology Institute. The establishment of traceable neutron calibration fields for individual dosimeters and portable dose rate measuring equipment should be studied as a short term project by the National Metrology Institute. The accreditation service establishes a maximum three year calibration interval. The dose rate meters available for inspections at NCRPP measure either in ambient dose equivalent H*(10) or in photon dose equivalent H_x. When equipment replacement is considered, it is recommended that dose rate meters which measure only in H*(10) are purchased.

11.3. CONTROL OF DISCHARGES AND MATERIALS FOR CLEARANCE; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

The Bulgarian legislation establishes requirements for the control of radioactive discharges, materials for clearance, environmental monitoring and control of public exposure in laws and regulations related to nuclear power plants, nuclear research facilities, spent fuel and radioactive waste management and disposal facilities, and for facilities using Sources of Ionizing Radiation (SIR) for industrial, medical, and research applications.

The Regulation on The Procedure for Issuing the Licences and Permits for the Safe Use of Nuclear Energy as required in ASUNE includes appropriate specific conditions for the control of discharges, monitoring of the environment and evaluation of the radiological impact on the population in the different stages of the licensing process for Nuclear Facilities (NF) and activities with SIR.

Control of radioactive discharges

The Regulation on Basic Norms on Radiation Protection (BNRP), , sets an annual dose limit for the protection of the public of 1 mSv and establishes a generic dose constraint for each facility of 0.2 mSv/y for the optimization of protection and safety. Lower dose constraints are established in the Regulation on Ensuring Safety of NPP (0.15 mSv/y) and Research Nuclear Facilities (0.10 mSv/y). For facilities using SIR the dose constraint applied is 0.2 mSv/y. The Regulation on Safe Management of Radioactive Wastes, , establishes a generic value of 0.3 mSv/y for radioactive waste management and disposal facilities. BNA has initiated the revision of the Regulation on Safe Management of Radioactive Wastes and a draft document is available for discussion proposing a dose constraint of 0.15 mSv/y for waste

management activities and 0.10 mSv/y for radioactive waste disposal facilities (see suggestion 22 in Section 9.4).

According to the BNRP the dose constraint is envisaged and substantiated within the licensing procedure, is specified in the licence or permit conditions and shall not exceed the values established in the regulations. For radiation protection purposes and for radiation monitoring and protection planning, the use of secondary limits is a requirement. BNRP includes annual activity and concentration limits for air and water derived from the annual dose limit for the protection of the public, requiring the application of the summation rule when various radionuclides are present. Discharge limits, corresponding to doses below the specific constraints, must be included in the authorizations of NF and facilities with SIR.

ASUNE [Article 26/3] states that the basic standards for radiation protection and the requirements, procedures, and clearance levels shall be established by a regulation adopted by the Council of Ministers on a motion by the Minister of Health, the Minister of Environment and Water and BNRA. Regulations also require that the limits for authorized discharges from NF and facilities with SIR shall be agreed with the Minister of Health. According to ASUNE, the BNRA chairman is responsible for issuing licences and permits. However there are no clear written procedures established for the coordination and cooperation of activities between BNRA and all the authorities with responsibilities in the control of discharges to the environment (see recommendation in Chapter 1).

The programs for monitoring of discharges of nuclear facilities at Kozloduy site include conditions for on-line monitoring, sampling and analysis, detection limits and quality control. Calibration of measuring equipment is performed by the Bulgarian National Institute of Metrology on a yearly basis and performance test are made periodically by the operator in accordance with the program conditions. The programs have been reviewed by the operator on request of BNRA for implementing EC Recommendations, the data on actual discharges are provided yearly to the EC in compliance with the requirements of Euratom Art. 37.

For nuclear facilities, in compliance with Regulations, radioactive effluents are considered in the Safety Analysis Report for the different stages of the licensing process, taking into account the releases and the site characteristics and including the dose assessment due to planned and actual discharges. The preliminary and operational effluent control programmes are developed by the licensee and approved by BNRA. BNRA is considering to develop a specific written regulatory guide defining all necessary information for the development of the effluent control programs that should be submitted by the applicant. The process of developing this guide has not been started yet (see recommendation 11 in Chapter 9).

For the KNPP site, the discharge limits for gaseous releases were revised in 2007, based on a new dose constraint of 0.05 mSv/y, so that the total dose constraint for liquid and gaseous releases for the whole site is 0.1 mSv/y. Derived activity and concentration limits are set for the control of discharges from each effluent treatment system, allocating these values between the facilities on the site in accordance with their historical discharges and operational experience. The specific effluent limits and conditions are included in the Technical Specifications that are part of the operation licence.

Licensees verify compliance with discharge limits in accordance with the requirements of the effluent control program and assess the environmental impact to the public due to actual discharges on a yearly basis. For dose calculation, the EC PC-CREAM code is applied, using specific site parameters when available. Estimated annual doses to the public due to actual discharges from KNPP are less than 0.01 mSv.

As part of the regulatory control BNRA evaluates the information about discharges provided by the licensee in monthly, quarterly and annual reports and has established an independent monitoring program

for discharges that is implemented by a TSO. The "Procedure for independent regulatory control of KNPP radioactive releases" describes the scope, criteria and details of the program. Specific inspections on the implementation of the program for the control of discharges are performed on a regular basis and site inspectors also perform daily verification about discharges and relevant instrumentation conditions. Nevertheless, BNRA has no written procedures about the methodology used in the assessment of effluent control programs and its results (see recommendation in Section 6.1).

All information about discharges is also provided in electronic files and stored in a BNRA internal data base. A summary of the information about annual discharges and dose assessment for the public is included in the annual report of BNRA to Parliament. It is also made available to the public through the web side.

For facilities with SIR, specific Regulations give very detailed information on the requirements of radioactive effluent treatment and control systems. BNRP has provisions for establishing the discharge limits. Documentation submitted during the licensing process includes information about the actual discharge limits and specific conditions on radioactive effluent treatment and control systems, but the discharge limits are not included in the authorizations. The actual discharge limits and specific conditions on radioactive effluent treatment and control systems should be clearly defined in the operation licence for facilities with SIR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 29 Para. 3.123 states that "***The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges."*
(2)	**BASIS: GSR Part 3 Requirement 31 Para. 3.131. states that** *"[…] (b) Shall ensure that radioactive waste is managed in accordance with the requirements of these Standards and the requirements of other applicable IAEA standards, and in accordance with the relevant authorization; […]."*
(3)	**BASIS: WS-G-2.7 Para. 2.7 states that** *"[...] The discharge to the environment of effluents containing small amounts of radioactive material, carried out in a controlled fashion, may be the most reasonable option. The regulatory body should set limitations for the discharge to the environment of such effluents […]."*
(4)	**BASIS: WS-G-2.3 Para. 3.37 states that** *"Discharge limits will be written and attached or incorporated into the authorization and will become the legal limits with which the operator or licensee should comply. […]."*
S34	**Suggestion: BNRA should consider including in the licence conditions for facilities with sources of ionizing radiations the specific discharge limits and the requirement for the conditions of treatment and control of releases where appropriate.**

Material for clearance

The requirements for clearance in Bulgarian legislation have been recently updated, following the recommendations of GSR Part 3. The clearance of material exceeding the generic values established in the Regulation on BNRP must be approved by BNRA and restrictive conditions on the use of this material must be set in agreement with the MoH. The delivery of each batch shall be accompanied by a certificate including the results from measurements of the radionuclide composition and levels of surface contamination.

The Regulation for the Safe Management of Radioactive Wastes assigns the responsibility for safe management of materials for clearance; establishes requirements for the storage and labelling and requires the waste management program to include the processes for characterizing and controlling the materials to be subjected to clearance from regulatory control.

In Bulgaria there is very limited experience in clearance of materials from regulatory control. A Regulatory Guide on clearance of materials defined in the Regulation on BNRP is currently under preparation with the support of European experts in the framework of a European project.

Environmental monitoring

According to Regulations, monitoring of the environment is considered at all stages of the licensing process of facilities. For NF the environmental monitoring programme includes pathways, sampling points, type and frequency of sampling and analysis, detection limits, technical characteristics of equipment and quality control programs. The density of sampling points decreases with the distance from the plant, taking into account the "statutory-zones" defined in the Regulations and establishes control locations for every type of sample. The environmental monitoring programs are reviewed by the licensees when relevant changes take place in the facilities and regularly on a five yearly basis. The proposal for revision hast to be submitted to BNRA for approval prior to implementation. There are no specific written guides from BNRA concerning the environmental monitoring programs and their revisions (see recommendation Chapter 9).

At KNPP the licensee assesses the results obtained from environmental monitoring and sends a yearly report to BNRA in accordance to licensing conditions. BNRA assess the information submitted by the licensee about the results of the environmental monitoring programs and carries out inspections as part of the regulatory control on a regular basis.

The annual report of the operator is submitted to BNRA in accordance to licence conditions and is put in a BNRA internal data base. A summary of the results of the monitoring programmes and the main conclusions of the review are included in the BNRA annual report to Parliament, and included in an internal data base that can be consulted on its web page. BNRA has no written procedures about the methodology used in the assessment of results from environmental monitoring programs (see recommendation in Section 6.1).

The MoH performs the independent monitoring program covering an area of 90 km around the plant on Bulgarian territory. This programme was first implemented three years before the KNPP started operation, and covers the pathways, samples and analysis relevant for assessing the impact of the facility on the environment, but it is relatively small compared with programme implemented by the facility. The analysis is performed by the NCRRP accredited laboratory and the results are included in the MoH annual report. The MoH is responsible for the implementation of the national environmental network as required by the Art. 35 of the Euratom Treaty. Results are provided to the EC in compliance with Art. 36.

The Regulation on BNRP requires the Minister of Health to assess the doses to the general public considering the population as a whole, the critical groups, the doses from external exposure and doses from internal exposure, determining the type and concentration of radionuclides. For this assessment the results of the radiation monitoring of the living environment must be used. NCRRP performs the required dose assessment taking into account the results of its independent monitoring program. The estimated annual doses are included also in their annual report and values are below 0.01mSv.

Policy Discussion on NORM Legislation and Practices

A policy discussion was held on the topic of Naturally Occurring Radioactive Materials (NORM). The meeting started with a preliminary presentation by BNRA.

BNRA recently initiated a project to implement international recommendations and European legislation regarding NORM. The project consists of three parts:

- Assessment of the current situation (inventory and assessment of industries and activities where problems could occur);
- Development of regulation; and
- Improvement of inspection.

In 2010 ASUNE was amended with an extra paragraph and a new regulation was introduced at the end of 2012.

The enterprises that could be working with NORM were notified by a letter and were instructed to conduct an assessment of their situations; instructions were also placed on the BNRA website. At this stage, BNRA has received only one result of these requested assessments; it is in expectation of the results from the other enterprises.

IRRS team members shared the practice of their national regulatory body with BNRA. Thus it was presented that Spain has started a quite similar project some time ago. Regulations approved in 2001 entrusted the regional authorities to request NORM industries a radiological impact assessment. In an earlier stage response was not as expected and regulations were modified in 2010 requesting directly the industries to provide assessments and analysis to the regulator.

The IRRS team stresses that it is of utmost importance to have as much information from the industries as possible. For example, Spain is working with regulatory instructions, which are mandatory, and guides to instruct the industries to deliver the right information (the requirement to use the guidelines applied to all situations and reporting only when exceeding the 1mSv dose to workers). Spain also has published the complete assessment studies of some industries to stand as an example for other industries. Spain is now in the stage of planning inspections to check if the assessments and analyses have been done correctly by the industries.

Bulgaria is especially interested in good practices on disposal of the NORM. According to the IRRS team if the NORM fits the criteria of Radioactive Waste, it should be treated accordingly. In other cases it is a problem recognized by the other participants in the discussion, in this situation other management solutions have to be found.

During the meeting the IRRS team emphasized that NORM can be a serious radiation protection problem not to be taken lightly. An example was given on how a NPP worker entering the plant found out he was contaminated by NORM to an amount that he was no longer allowed to enter the plant. The example shows that NORM possesses a real threat capacity with regard to radiation protection.

11.4. SUMMARY

The established laws and regulations relevant to medical exposure are nearly up to date and provide a good basis to assure that medical exposure are justified and optimized (assuming draft regulation is approved). Some challenges have been identified for implementation of generic and individual justification and optimization of medical exposure. There is potential for improvements in the system of

personal certification of training in radiation protection and safety for health personnel involved in medical exposure.

The laws and Regulations relevant to occupational radiation protection area are up-to-date and in line with the IAEA GSR Part 3. The occupational radiation protection in the operational nuclear power plants is optimized; the indicators used to measure the performance of the licence in this area are adequate for comparison with those from operational NPPs of similar design.

The laws and regulations relevant to the control of discharges, material for clearance and environmental monitoring are basically in agreement with the requirements of IAEA GSR Part 3. The system of limitation, surveillance and control of radioactive effluents, the methodology for assessing the doses to the population and the environmental monitoring programs are in line with international practices. Provisions are in place for developing detailed guidance for the clearance of material. For facilities that use SIR it is suggested to include the discharge limits in the operation licence where appropriate. Consideration could be given to the development of detailed regulatory guides and written procedures about BNRA's review and assessment processes in this field.

It should be considered to include for medical and occupational exposures the NCRRP and the regional health inspectorates in the upcoming IRRS follow-up mission.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

The Act on the Safe Use of Nuclear Energy (ASUNE) which came into force in 2002 (Amended in 2010) provides the legal framework for regulation of the nuclear safety and security as well as the accounting for, and control of nuclear material activities. The following ASUNE chapters describe the legal provisions for regulatory control of above areas: Chapter Three "Authorization process", Chapter Five "Regulatory control", Chapter Seven "Physical protection", Chapter Nine "Application of Safeguards".

ASUNE, in Article 16 requires that anyone who is using nuclear energy, sources of ionising radiation or is involved in radioactive waste management and spent fuel management is required to comply with nuclear safety, radiation protection and physical protection requirements. Safety and security measures have to be considered during the stages of design, sitting, construction, commissioning, operation and decommissioning. Article 33 and 35 of ASUNE define that permits for siting, design, construction and commissioning as well as licences for operation and decommissioning of nuclear facility shall be issued only if the applicant has ensured conformity of the installation and declared activity with the requirements, standards and rules of nuclear safety and radiation protection and provided for necessary requisite physical protection measures.

The separate elements of safety and security interface are addressed in a regulations such as the Regulation on Emergency Planning and Emergency Preparedness in Case of Nuclear and Radiological Emergencies, the Regulation on ensuring the safety of Nuclear power plants, and the Regulation of the conditions and procedure for notification of the nuclear regulatory agency about events in nuclear facilities and sites with sources of ionising radiation. Among other they require:

- plant safety to be seen as encompassing the measures for accounting and control of nuclear material and physical protection;
- reporting both safety and security events;
- integration of safety and security measures during emergency management. This is ensured through coordination of development on-site emergency and off-site emergency plans with all other existing plans for physical protection and other emergency plans. To ensure proper coordination and interface of all organizations involved, the joint general exercises are required to perform at least once a year. It is worth to note that special access measures are in place to ensure the proper safety measures to manage the emergency.

However, BNRA recognized that the actual regulatory framework does not provide a comprehensive set of requirements on implementation of safety and security measures in an integrated manner. Therefore, BNRA has drafted the *Regulation on Providing of Physical Protection of Nuclear Facilities Nuclear Material and Radioactive substances* which is now under finalisation and planned to be published by the end of the 2013 and which will replace the existing one under the same title.

The IRRS team deemed that BNRA has taken the relevant steps to established proper arrangements within the governmental and legal framework for nuclear security and with the state system of accounting for, and control of, nuclear material.

12.2. REGULATORY OVERSIGHT ACTIVITY

The legal framework establishes BNRA as the single organization responsible for regulation of the nuclear safety and security as well as the accounting for, and control of nuclear material. This enables effective and efficient regulatory oversight of the above areas. In general, the ASUNE does not make difference between the oversight and enforcement activities in the nuclear safety, security and the accounting for, and control of nuclear material.

Although no special regulation and procedure on safety/security interface assessment and as well as inspection exist, BNRA staff has recognized the significance of security impact onto safety and vice versa. Therefore the aforesaid draft *Regulation on Providing of Physical Protection of Nuclear Facilities Nuclear Material and Radioactive substances* is expected to include safety and security interface issues and will include the requirements for implementation and development of security culture.

The IRRS team reviewed evidences that BNRA has established a formal safety culture evaluation process for nuclear installations under its management system. The nuclear security culture concept is planned to be introduced after new regulation on *Regulation on Providing of Physical Protection of Nuclear Facilities Nuclear Material and Radioactive substances* will be issued.

BNRA has planned to strengthen the review process of existing plant modifications by including an additional step on the evaluation of the impact of the modifications onto security.

In addition it was confirmed that emergency preparedness exercises involve safety and security interfaces. The existing regulations require, in the exercise for threat categories I and II, the participation of the largest possible number of representatives of the executive bodies who have responsibilities in accordance with the off-site emergency plan. Security events (including lower level events which are selected for trend analysis), according to existing legislation, are part of operational experience feedback programme and due to their nature are treated separately from safety events. Safety events are analysed with a purpose to improve both the safety and security. The review of events in a safety domain are performed by staff responsible for nuclear safety and then appropriate division responsible for security is informed about potential vulnerabilities of the plant design.

12.3. INTERFACE WITH OTHER AUTHORITIES

Pursuant provisions of ASUNE, the BNRA chairman is responsible for regulatory control over nuclear safety, security and system of accounting for, and control of nuclear material. The BNRA chairman carries out interactions with other competent authorities of the executive power and proposes to the Council of Ministers measures for co-ordination of such activities. Those authorities are Minister of Health; Minister of Environment and Water; Minister of Interior; Minister of Defence; Minister of Agriculture and Food; Minister of Transport, Information Technology and Communications; Minister of Education, Youth and Science; and the chairman of the State Agency for National Security.

In the area of the nuclear security, BNRA interacts with the following competent authorities:

- The State Agency for National Security (shall provide the licensee and the BNRA chairman with a threat assessment for each particular nuclear facility or for the cases of transport of nuclear material)
- the Ministry of Interior (provides the security of the nuclear facilities which determined by decision of Council of Ministers as vital to the physical protection).

12.4. SUMMARY

The legal framework provides clear responsibilities and interaction with the competent authorities having responsibilities in security area. Although the separate elements of safety and security interface, especially those in emergency response area, are addressed in the regulations, BNRA continues safety and security integration and new regulations and regulatory documents are being prepared.

13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

13.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

Emergency preparedness activities following the accident

BNRA as the Bulgarian competent authority and national warning point under the emergency conventions was notified of the TEPCO Fukushima Daiichi accident via the unified system for information exchange in incidents and emergencies. Having realized the seriousness of the situation the emergency response organization of BNRA was activated on 12 March 2011 according to BNRA's emergency response plan. Activation mainly involved the accident assessment group of the emergency response organization which remained in duty for about one month. During this period of time a team of about 12 experts continuously collected, analysed and forwarded information on the events and accident progression on the Fukushima site. BNRA as a participant in the Bulgarian Unified Rescue System under the leadership of the Ministry of Interior continuously performed its role as an advisory organization in nuclear and radiation emergencies.

The first information on the accident was released to the media within 18 hours after the accident by BNRA. Extremely intensive media interest followed the activity of the BNRA emergency staff. Three assigned spokespersons provided information to the media and the public on a daily basis; TV crews visited the BNRA emergency centre and broadcasted real-time programmes and interviews.

Data collection from international channels continued parallel to the accident progression at the Fukushima site. BNRA used its bilateral relations with the neighbouring countries Romania and Greece as well is with US NRC and with the EURDEP collaboration platform to share information and gather data and results. Analysis results and radiation monitoring information on the accident were uploaded to the website of BNRA with a daily or higher frequency during the first months following the accident amounting to altogether 28 communications. The information provided by BNRA included press releases, information to the Government, enterprises and citizens, including Bulgarian citizens living in Japan. Citizens in Bulgaria were requested not to take any precautionary or protective action without explicit instructions from expert organizations. Bulgarian citizens living in Japan were advised to follow the instructions released by the Japanese authorities.

The intensity of interest of the public in the information provided by BNRA can be characterized by the number of hits on the BNRA website. This number was between 500 and 4000 just prior to the accident and went above 31000 in the first days after the accident. This number remained around 10000 throughout March 2011. The monthly total hit-numbers are even more illustrative, there were 31, 306, 112 and 60 thousand hits in February, March, April and May 2011, respectively.

The radiation level was continuously monitored at several locations in Bulgaria. BNRA cooperated in radiation monitoring with the following institutions: National Centre for Radiobiology and Radiation Protection within the MoH, the Executive Environmental Agency within the Ministry of Environment and Water, the Sofia University, the Institute for Nuclear Research and Nuclear Energy, and the laboratory of NPP Kozloduy. Daily measurements were conducted on aerosols, caesium and iodine isotopes, rainwater and milk from 23 March until 10 May 2011.

Radiation released in Fukushima and propagated to Europe was first detected in Bulgaria on March 26 at its highest point, the Mussala summit. The measured radioactivity was negligible and did not necessitate any specific protective measures. The measurements were continued by early May showing a maximum value on 5 April 2011 and gradually fading away afterwards. All measured results have been sent to the IAEA Incident Emergency Centre (IEC) trough USIE system.

Immediate actions required from the NPP operator

On 21 March 2011 the Bulgarian Prime Minister invited the management of the Kozloduy NPP and requested the initiation of an immediate review of the safety of the power plant and the spent fuel pools in order to assess the ability of the plant and of the other facilities to withstand or adequately respond to external events similar to those resulting in the TEPCO Fukushima Daiichi accident. Following the meeting of the Prime Minister with the NPP management BNRA provided details of the required investigations. Accordingly the operator was instructed to review and prove the operability of those systems and system components that are necessary in severe accident management; in coping with extreme external events (like earthquake, flooding, extreme weather conditions); for ensuring continuous power supply onsite and for continuous heat removal and existence of an ultimate hit sink. Review of the procedures and instructions was also requested to verify their applicability in handling design basis and beyond design basis accidents. A program of the review was to be elaborated within one month time while the review was to be performed within three months.

Results of the assessment by the NPP were submitted to BNRA in June 2011. They did not reveal any serious non-compliance with the design requirements and demonstrated the applicability of the procedures and instructions involved and thus no need for urgent safety enhancing action was identified. The NPP staffs were found to be well trained to be able to cope with situations similar to those in the Fukushima accident. BNRA accepted the report of the licensee and considered the measures reported as adequate.

On 31 May 2011 the Kozloduy NPP management was requested to initiate and conduct the targeted safety re-evaluation also called Stress Test initiated by the European regulatory association WENRA and requested by the EU nuclear regulatory organization ENSREG. The safety re-evaluation was performed according to the pre-set schedule; the results are summarized in the next section.

BNRA self-assessment

BNRA did not deem necessary to introduce changes into its regulatory practice, except that certain inspections were held at times earlier than originally scheduled. BNRA reviewed the National Emergency Response Plan as well as its own emergency response plan in the light of its activity related to the accident but did not identify any issue or inconsistency therein that would need correction.

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

The technical issues to be considered in the light of the accident have been systematically collected in the programme of the targeted safety re-evaluation of nuclear safety (in brief Stress Test programme) as discussed above. Bulgaria performed the Stress Test exercise and prepared its National Report to be peer reviewed by ENSREG. The major issues identified by the Stress Test are briefly summarized below based on the Bulgarian National Stress Test Report.

As for the earthquake-resilience of the Kozloduy NPP it is concluded that there are no capable faults with high energy potential in the vicinity of the power plant and the site is located at a stable part. The spent fuel pools at the site need no specific extra protective measures against earthquakes. For the operating units 5 and 6 the Stress Test results suggest installation of additional mobile emergency diesel generators (this issue is further commented by the team in the next section) and further investigations for alternative heat removal possibilities to be used in specific accident circumstances.

Investigations related to external flooding potential demonstrated that in all conceivable circumstances the Kozloduy NPP is fully protected against flooding.

Impacts of other extreme meteorological phenomena on the structures and structure components of the various facilities were analysed in details. The analysis demonstrated that the plant in general and its systems in particular are in accordance with the design requirements and it is concluded that in most cases the structures and components have necessary capability of withstanding extreme meteorological impacts, the exceptions are explicitly listed in the report. BNRA acknowledged that the weaknesses and margins have been properly identified.

In assessing the possibilities of loss of power supply and loss of ultimate heat sink the Stress Test concluded that in case of the spent fuel storage facility no further measures are needed, whereas the mobile diesel generators shall be able to supply the necessary power in case of a station blackout to the reactors of units 5 and 6. Assessment of the possibility of obtaining emergency water supply from a nearby dam is planned. It is also shown that the time available before core melt is fairly long as long as the spray pools are available, thus the primary objective in this respect is to prevent loss of water from these pools. BNRA required extension of the considerations on supplying power and make-up water in shut down state of the reactors and on the use of the mobile emergency diesels for the spent fuel pools.

The severe accident management investigation concluded on the necessity of installation of additional hydrogen recombiners and of water and oxygen measuring channels in the containment. Besides these newly established requirements actions decided after the periodic safety review in 2008 are also to be continued and completed. BNRA agreed with the actions decided by the NPP and requested further steps including the revision of the on-site and off-site emergency response plans; establishing an off-site emergency response centre and studying the possibility of localization of molten core in severe accident.

CONCLUSION [1]

The IRRS team considers that BNRA reacted promptly and effectively to the challenges posed by the TEPCO Fukushima Daiichi accident. It provided information to the governmental organizations and the general public in a timely manner based on the available international sources.

Bulgaria participated in the European Stress Test programme and performed the investigations and analyses requested by the programme. It was concluded that the safety of Kozloduy NPP would not be particularly challenged by events similar to those occurred in Fukushima and no urgent safety increasing actions were deemed necessary.

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

Revision of the nuclear and radiation safety regulations

Following the latest amendment of the Act on Safe Use of Nuclear Energy in 2010 the revision of the underlying regulation was initiated in the same year. This revision process was influenced and enhanced by the TEPCO Fukushima Daiichi accident. A programme has been prepared for reviewing the 20 regulations related to nuclear and radiation safety being in the responsibility of BNRA.

The analysis program started in January 2011 and the primary objective was to set the regulations in conformance with the law. The programme was accepted in February by the chairman of BNRA. The programme has recently been updated to take into account certain delays suffered as well as the consequences of the accident on the regulatory requirements. The Second Extraordinary Meeting under

the Convention on Nuclear Safety has also resulted in inputs to the revision. The regulations to which the Fukushima accident has some impact are related to the safety of NPPs (the revision is to be started in 2013); emergency preparedness and response (revision performed but needs to be revisited for aspects raised by the accident); safety of spent fuel and safety of radioactive waste management (both to be completed soon); safety of decommissioning (new draft is to be discussed); safety of research reactors (to be started) and regulations on special statutory areas (to be started). The initial deadline of completion was mid-2014; the revised deadline is end of 2014.

Safety upgrading of the nuclear installations

The targeted safety re-evaluation (Stress Test) of the Kozloduy NPP resulted in an Action Plan with a number of planned safety enhancement measures as discussed in the previous section. The tasks to be performed are listed in the National Stress Test Report, in the National Action Plan compiled based on the Stress Test as well as in the National Report prepared to the Second Extraordinary Meeting under the Convention on Nuclear Safety. These tasks are briefly referred to here.

The licensee developed an Action Plan following the targeted safety re-evaluation (Stress Test) of the Kozloduy NPP (KNPP). The Action Plan, approved by BNRA, contains a number of planned safety enhancement measures as discussed in the previous section. The tasks to be performed are listed in the National Stress Test Report, in the National Action Plan compiled based on the Stress Test as well as in the National Report prepared to the Second Extraordinary Meeting under the Convention on Nuclear Safety. These tasks are briefly described here.

One of the most important measures to be implemented is the installation of two additional mobile diesel generators if the built in diesels should lose their operability for any reason. Prior to the events at Fukushima, there was only one mobile diesel generator for the whole site. BNRA and the licensee agreed that as a conservative measure in the case of extreme beyond design basis events that would affect all on-site facilities simultaneously, the licensee would add the two additional mobile diesel generators, along with additional modifications to provide the capability to charge the station batteries from these mobile diesel generators.

The storage location of these mobile diesel generators, as indicated to the IRRS team during the site visit, seems to have the same vulnerability in case of extreme external events as the buildings of the in-built diesels. The IRRS team was informed later during the visit that the existing large power mobile generator will be stationed outside the plant at an elevated site; the housing of the new mobile diesel generators is subject of further investigation and considerations.

Another physically realized enhancement measure is the installation of additional hydrogen recombiners in the containment.

Further actions related to the possible threats by extreme external events encompass various investigations related to possible alternative and additional cooling water supply and heat sink solutions as well as development of emergency procedures and counter flooding measures.

In the management of severe accidents a major action is establishing an NPP off-site Emergency Response Centre. A further important step is the introduction of the Severe Accident Management Guidelines for reactor shutdown conditions and for the spent fuel pool.

Review of the on-site and off-site Emergency Response Plans was decided and performed and the application of symptom based emergency operating procedures is foreseen for a number of shut-down operating modes of the operating Kozloduy units. Various methods are to be developed to provide direct water injection into the reactor core and into the spent fuel pool using mobile fire protection devices.

The ENSREG review process provided further recommendations to the NPP to increase its capability withstanding adverse effects of extreme external conditions and severe accidents. One of them is the assessment of the consequences of extreme events on the infrastructure, especially the road conditions around the NPP. Another important action is the assessment of the organizational and technical measures necessary to cope with multi-unit core melt events.

Developing the regulatory framework

The Stress Test and the ENREG peer review following it established a number of tasks to be performed by BNRA in order to make use of the lessons identified from and deficiencies revealed after the TEOCO Fukushima Daiichi accident. These tasks are summarized in the National Action Plan compiled as the result of the Stress Test and its evaluation. According to this Action Plan BNRA shall first of all develop a programme to review the regulatory requirements in the light of the lessons learned from the accident. The second group of actions covers revision of the regulations as well as of the regulatory guidelines. Review of BNRA activities following the present IRRS mission is also foreseen.

BNRA plans to update the bilateral agreements with the regulatory bodies of the countries neighbouring Bulgaria.

The operability of the BNRA Emergency Response Centre has been substantially enhanced by the installation of the replicas of the Safety Parameter Display System and the Post Accident Monitoring System of Units 5 and 6 of the NPP.

The team was informed that the majority of the actions related to the Stress Test conclusions have been or shall be completed in the period of 2012-2014; only two actions remain for the subsequent years.

CONCLUSION [2]
The IRRS team observes that the conclusions of the Stress Test are duly summarized in a National Action Plan. The team notes that the revision by BNRA of its activity did not reveal the necessity of any change in the working methods nor in the regulatory practice of BNRA.

13.4 CONCLUSIONS BY REVIEWED AREAS

Module 1: Responsibilities and Functions of the Government

Responsibilities are clearly allocated in the governmental legal and regulatory framework for safety.

Responsibilities and functions of each authority in emergency/accident situations are specified by the National Off-site Emergency Plan, which has been updated after TEPCO Fukushima Daiichi Nuclear Power Plant Accident.

In emergency situations the Ministry of Interior has the overall responsibility. BNRA is responsible for giving advice to the Ministry of Interior on accident progression and intervention.

CONCLUSION [3]
The IRRS team considers that the necessary governmental legal and regulatory framework exists, responsibilities and functions are properly allocated among the relevant authorities, and the regulatory body is committed to act as necessary.

Module 2: Global Nuclear Safety Regime

Bulgaria is a contracting party of relevant international treaties and conventions that establish common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and radiation for peaceful purposes and that provide for an effective coordinated international response to a nuclear or radiological emergency. These include but are not limited to the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

By the provisions of ASUNE Article 5 the BNRA chairman is assigned to perform the functions of a competent authority and a contact point for notification of an accident and for provision of assistance according to the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The Bulgarian Government demonstrates fulfilment of its obligations under the Convention on Nuclear Safety as well as openness and transparency by hosting international peer review missions such IRRT/IRRS, OSART, IPPAS and other.

In the light of the Fukushima accident BNRA has started a revision and updating process of the existing bilateral agreements especially with neighbouring countries. A bilateral agreement with the Serbian regulatory authority was initiated.

CONCLUSION [4]
The IRRS team concludes that no concern was raised with regard to the fulfilment of the Bulgarian government's obligations under international treaties and conventions. The necessary further actions have been planned to revise and to update and where necessary to initiate new bilateral agreements with the neighbouring countries.

Module 3: Responsibilities and Functions of the Regulatory Body

The team found that during the TEPCO Fukushima Daiichi accident BNRA was an independent nuclear and radiation safety regulator reporting to the Prime Minister. BNRA has the right to intervene and/or take timely actions to ensure safety during normal operation as well as during an emergency/accident. They have the appropriate structure and responsibilities in place ensuring that they can set requirements and conduct oversight to minimize the possibility of an accident to occur, and in the event of an accident, mitigate the consequences. These actions are pre-planned and described in procedures up to and following a severe accident. BNRA takes seriously its responsibility to inform the public on the radiation situation and the consequences to the population, environment and society.

BNRA promptly requested nuclear facilities to conduct their own safety assessments and participate in the EU stress tests and they asked the Advisory Council on Nuclear Safety for their opinions on the results of the EU stress tests conducted.

CONCLUSION [5]
With regard to the TEPCO Fukushima Daiichi accident, the IRRS team found that BNRA's actions were consistent with its responsibilities and functions.

Module 4: Management system

The IRRS team noted that the National Action Plan foresees that no actions were necessary for taking into account the implications of the accident in the management system of BNRA. According to the National Action Plan long-term exercises are periodically conducted in Bulgaria. One of the objectives of these exercises for the national and district response structures, longer than 24 hours, is to test the capability of the teams to work for long periods in extreme conditions including staff shift changes. The conclusion in the Action Plan is that there is no need of taking additional actions in this field.

BNRA stated that if in case of a prolonged accident there is a lack of adequate resources (e.g. experienced employees) they can always invite experienced staff from one of its TSOs to take part in the emergency team. However this has never been tested in exercise because the TSOs have never taken part in emergency exercises.

CONCLUSION [6]
The IRRS team concludes that TSO staff should take part in emergency exercises in order to be trained and exercised in their availability and capability to properly act in accident situations which last for long periods.

Module 5: Authorization

Following the TEPCO Fukushima Daiichi accident, BNRA required the Kozloduy NPP to perform reassessment in various areas in the light of the EU stress test requirements. On the bases of these assessments an Action plan has been developed which include various actions: the provision of mobile diesel generators; the provision of a mobile generator to recharge station batteries; ensuring a power supply for systems associated with spent fuel pool cooling; updating of the internal and the external emergency plan; the construction of an off-site emergency centre; the provision of symptom based emergency operating procedures; the development of SAMGs; the provision for direct water injection in the reactor core, the steam generators, the spent fuel pool and the containment by mobile fire protection equipment.

Some of those actions should be performed on the basis of a permit for modification issued by BNRA.

In addition, BNRA also initiated an assessment of its regulatory framework and identified certain actions related to the improvement of regulations. The assessment, however, did not identify the need for any action related to further improvement in the authorization process or stages.

CONCLUSION [7]
The IRRS team considers that BNRA recognized the necessity and importance for safety improvement based on experience feedback of TEPCO Fukushima Daiichi accident and required the licensee for a thorough reassessment (stress tests). The improvements envisage in the Action plan will undergo the regulatory authorization process of modification approval where it is required by the legislative framework. The team feels that BNRA is committed to act as necessary and initiating necessary actions.

Module 6: Review and Assessment

Bulgaria uses its Regulation on Ensuring the Safety of Nuclear Power Plants (RESNPP) to ensure that a comprehensive set of postulated initiating events with the potential for serious consequences is identified. Details of what needs to be considered are prescribed in an annex to the Regulation. This list appears to

cover all aspects that might be expected based on international guidance. No review of its approach was considered necessary by BNRA in light of the Fukushima accident because all the relevant areas are already addressed in RESNPP. However, BNRA recognises that there is a need to improve the coverage of its regulatory guidance (see the Regulations and Guides section of this report for further details) to further support the Regulation. BNRA's subsequent participation in the ENSREG Stress Tests process validated this view.

BNRA's approach already catered for design extension conditions prior to the Fukushima accident. Specifically, Article 14 of RESNPP requires the licensee to assess beyond design basis accidents and provides details as to which assessments are required. BNRA's approach led, through the periodic reviews conducted in the early 90s and the more recent reviews in 2008/9, to several design extension measures being installed at Kozloduy as part of a far wider programme of plant upgrades. For instance, the plant already had an alternative steam generator feed system powered by mobile diesel generators, passive filtered venting and passive autocatalytic recombiners installed prior to the Fukushima accident. That said, a number of further measures were identified during the Stress Tests process as discussed in the previous sections of this chapter, which the licensee is partway through addressing as part of Bulgaria's National Action Plan.

CONCLUSION [8]
The IRRS team considers BNRA has taken a proactive approach to the review and assessment of design extension conditions and required a number of beyond design measures by the time of the TEPCO Fukushima Daiichi accident. Bulgaria's subsequent participation in the ENSREG Stress Tests has improved confidence in the safety of Kozloduy and in BNRA's regulatory approach in this area.

Module 7: Inspection

BNRA has identified some inspections that have been conducted following the Fukushima accidents, taken directly from the specific event sequences from the accident. These have been conducted as part of the annual inspection plans. As discussed in Module 7.1, BNRA should consider the full scope of inspections needed to evaluate postulated beyond-design basis events, even for those beyond the specific sequences at Fukushima. Prioritisation of inspections, establishment of a schedule and time frame for completion of the inspections, and development of specific inspection protocols for each inspection could further support BNRA inspectors.

The on-site inspection observed during the IAEA mission was conducted to consider a potential proposal that the licensee is developing from several options for use of alternate electrical power source from a mobile diesel generator, including use of non-safety related pumps previously installed to provide redundancy for plant operation and events. BNRA should consider in its inspection programme the plant modifications resulting from the stress-tests.

BNRA conducted inspections that verified the robustness of the emergency power supply and identified safety measures to improve the robustness of the storage handling system. In addition BNRA conducts on-going inspections and evaluations of emergency preparedness drills and exercises that include investigations of the actual arrangements between the operator's headquarters and the plant management in case of an emergency.

CONCLUSION [9]
The IRRS team concludes that the inspection practice of BNRA was not fundamentally influenced by the lessons learned from the accident. Inspection of the completion of the National Plan by the licensee is foreseen, yet a full scope inspection programme would be beneficial to be developed.

Module 8: Enforcement

BNRA implemented graded practices for enforcement, with a follow up statement that response to an evolving accident would take priority, which is the appropriate focus.

BNRA chairman is legally provided with sufficient enforcement power to modify or revoke the licence, or to direct specific modifications to systems and structures, etc. However, in its enforcement policy to be developed in respect to the recommendation in Module 8, BNRA should include specific considerations of streamlining the chairman's enforcement authorities in the specific case of extreme natural external events leading to severe beyond-design basis accidents.

CONCLUSION [10]
The IRRS team considers BNRA has the basis for a proper enforcement policy. Further actions are deemed necessary for the development of a policy taking also into account possible issues related to cope with extreme external conditions.

Module 9: Regulations and Guides

In the area of regulations and guides BNRA promptly reacted to the Fukushima accident. An action plan was devised quickly which contains one major item to allow necessary modifications of the legally binding legislation and to develop the corresponding regulatory guides.

All regulations affected by lessons learned from Fukushima are planned to be modified. The necessary changes to both the legislation and the regulations have been identified and are in different stages of adoption. The need for additional regulatory guides had been identified and a "Regulatory Guides Development Programme (RGDP)" was started. The process of revising regulations was started with the "physical protection regulation" where the revision is already finished and the final draft is available. The requirements regarding emergency preparedness and the emergency plan have been reviewed and are being revised due to conclusions from "Lessons learned". As part of the RGDP regulatory guides "RR-05 Deterministic Safety Assessment" and "RR-07 PSA of Nuclear Power Plants" have already been developed.

During the process it was also decided to adopt all requirements arising from the revised WENRA reference levels as soon as possible and therefore more regulations are being revised.

CONCLUSION [11]
The IRRS team considers that the necessary actions have been recognised and the regulatory body is committed to act as necessary. The necessary further actions have been planned and initiated and they are already partly completed.

Module 10: Emergency Preparedness and Response

The Fukushima accident gave BNRA an opportunity to test their system, which functioned adequately. With respect to public relations activities, which were primary since the accident happened at a large

distance from Bulgaria, there were no specific templates but the press releases were issued and the media inquiries were well serviced.

The national off-site plan has been updated due to the accident. Additional scenarios were considered with stronger earthquakes, larger floods and beyond designs basis scenarios. The later was one of the results of the EU stress tests, in which Bulgaria participated.

Beyond design basis scenarios were strengthened and the on-site emergency plan of the NPP was updated accordingly. Multi-unit events are now being considered (e.g. the unit that suffers an accident is no longer supported by the other unit). Plans at all levels have been updated.

As for protective actions preparedness, after the accident at Fukushima it was decided to pre-distribute iodine pills in the 30 km zone around Kozloduy NPP, which was implemented in 2012. Before, there were stock piles to be distributed during an emergency.

The NPP upgraded their equipment with two new mobile diesel generators and satellite communications. In addition new a generator for the on-site emergency centre was bought. The off-site emergency centre will be constructed in Kozloduy the nearest town to the NPP (the location of the centre has been selected).

CONCLUSION [12]
The IRRS team considers that during the Fukushima accident BNRA demonstrated its commitment to act in emergency. After the accident appropriate actions have been taken and initiated in Bulgaria, taking into account the results of the EU Stress Tests, in which Bulgaria participated, as well.

APPENDIX I – LIST OF PARTICIPANTS

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APPENDIX II – MISSION PROGRAMME

	Sunday, 07 April 2013	**Venue**
10:00 – 18:00	Initial IRRS Team Meeting	BNRA, Sofia

	Monday, 08 April 2013	**Venue**
09:30 – 12:00	Entrance meeting Opening Remarks – Bulgarian officials and IRRS Team Leader Introduction of the IRRS Team and Counterparts Presentation of mission agenda (Liaison Officer, Nikolay Vlahov) Overview by BNRA (Chairman, Mr. Tzotchev) on - National context including regulated activities and facilities; - Bulgaria legal and regulatory framework for safety; - BNRA organization, responsibilities, functions and management system; - International involvement; - Preparation of IRRS mission, including self-assessment Participants: IRRS Team Members, BNRA Team Members and, as needed, Representatives of authorized parties and others	Sheraton Hotel, Sofia
13:30 – 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts (Parallel discussions)	BNRA, Sofia
17:00 – 18:00	Daily IRRS Team Meeting	BNRA, Sofia
From 18:00	Report writing	

	Tuesday, 09 April 2013	**Venue**
09:00 – 12:30	IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
13:30 – 17:00	IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
17:00 – 18:00	Daily IRRS Team Meeting	BNRA, Sofia
from 18:00	Report writing	

	Wednesday, 10 April 2013	**Venue**
09:30 - 14:00	Costas Hourdakis and Teodros Hailu: Observation of inspection in industrial facility Eva Friberg: Observation of inspection in medical facility John Hunt: visit of Industrial or medical Facility for occupational radiation protection	BNRA, Sofia Sofia

	Marjan Tkavc and Rodrigo Salinas: meeting with the Civil Protection and the 112 Emergency Organization	
07:00 – 17:30	Marta Ziakova and Jean-Rene Jubin: Plant walk down and meeting with management (NPP in operation and under decommissioning, dry SFSF…) James Clifford and Ivan Lux: NPP inspection observation and Fukushima issues Mario Dionisi, Lucila Ramos and Gerard Bruno: RAW facility inspection observation	Kozloduy NPP SE RAW
09:00 – 12:30	Other IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
13:30 – 17:00	Other IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
18:00 – 19:00	Daily IRRS Team Meeting	BNRA, Sofia
from 19:00	Report writing	

	Thursday, 11 April 2013	**Venue**
09:00 – 12:30	Marjan Tkavc and Rodrigo Salinas: Emergency exercise observation and discussion	BNRA, Sofia
09:00 – 12:30	Other IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
13:30 – 17:00	Other IRRS Team Experts: Interviews and Discussions with Counterparts	BNRA, Sofia
17:00 – 18:00	Daily IRRS Team Meeting	BNRA, Sofia
from 18:00	Report writing	

	Friday, 12 April 2013	**Venue**
09:00 – 12:00	IRRS Team Experts: Report Writing and Review Interviews and Discussions with Counterparts (if required)	BNRA, Sofia
13:30 – 15:30	Policy Discussion No.1: Long-term operation Policy Discussion No.2: NORM legislation and practices Participants: IRRS Team – Team Lead and relevant IRRS Team Experts -, BNRA: Chairperson, N. Vlahov and relevant Counterparts	BNRA, Sofia
13:30 – 17:00	Secretariat edits the preliminary Draft Report IRRS Team Members: Report cross–review	BNRA, Sofia
17:00 – 18:00	Daily IRRS Team Meeting	BNRA, Sofia
from 18:00	Report writing	

	Saturday, 13 April 2013	Venue
09:00 – 12:30	IRRS Team Discussion of Draft Mission Report	BNRA, Sofia
13:30 – 17:00	IRRS Team Finalization of Draft Mission Report	BNRA, Sofia
from 18:00	Secretariat edits the report	

	Sunday, 14 April 2013	Venue
09:00 – 17:00	Social Event	
from 17:00	IRRS Team Report Writing (if required)	

	Monday, 15 April 2013	Venue
09:00 – 17:00	IRRS Team Expert Discussions of Recommendations, Suggestions and Good Practices with counterparts	BNRA, Sofia
13:30 – 15:30	Policy Discussions (if necessary)	BNRA, Sofia
17:00 – 18:00	Daily IRRS Team Meeting	BNRA, Sofia
from 18:00	Secretariat edits the report	

	Tuesday, 16 April 2013	Venue
09:00 – 17:00	IRRS Team discussion and cross-review in order to finalize the draft report	BNRA, Sofia
12:30 – 13:30	*Lunch*	
13:00 – 18:00	IRRS Team discussion of the report, including Executive Summary	BNRA, Sofia
from 18:00	Secretariat finalizes the text	

	Wednesday, 17 April 2013	Venue
09:00 – 10:30	IRRS Team: finalization and submission of the Draft to BNRA	BNRA, Sofia
10:30 – 17:00	BNRA reviews the draft IRRS Team Lead: finalization of Executive Summary, preparation of Exit Meeting and press release	BNRA, Sofia
17:00 – 18:00	IRRS Team discussion of Executive Summary	BNRA, Sofia

	Thursday, 18 March 2013	Venue
09:00 – 12:30	IRRS Team and BNRA: Discussion of the draft report based on BNRA written comments	BNRA, Sofia
13:00 – 17:00	IRRS Team: Meeting to review BNRA comments and finalize the report BNRA reviews the draft	BNRA, Sofia

	Friday, 19 March 2013	Venue
09:00	Submission of final draft	BNRA, Sofia
10:00 – 12:00	Exit Meeting Press Conference	Sofia
From 13:00	IRRS Team Member Departure	

APPENDIX III – SITE VISITS

Facilities visited:	
1.	Kozloduy NPP
2.	Tokuda Hospital Sofia
3.	Novi Han Irradiation Facility

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	BNRA Lead Counterparts
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	
	K. Hioki	S. Tzotchev
2.	**GLOBAL NUCLEAR SAFETY REGIME**	
	D. Brandisauskas	A. Rogatchev
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	
	M.-L. Järvinen	N. Vlahov
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	
	A. Van Limborgh	N. Yankova
5.	**AUTHORIZATION**	
	F. Mansoor (Generic Issues and Nuclear Power Plant)	P. Stoyanova, N. Todorov, I. Gorinov
	C. Hourdakis (Radiation Sources Facilities)	N. Todorov
	M. Dionisi, G. Bruno (Fuel Cycle Facilities)	I. Gorinov
	M. Dionisi, G. Bruno (Waste Management Facilities, Decommissioning)	A. Alexiev
	V. Leblanc (Transport of Radioactive Material)	A. Bakalova
6.	**REVIEW AND ASSESSMENT**	
	A. Hart (Generic Issues and Nuclear Power Plant)	T. Ganchev, N. Todorov, I. Gorinov
	C. Hourdakis (Radiation Sources Facilities)	N. Todorov
	M. Dionisi, G. Bruno (Fuel Cycle Facilities)	I. Gorinov
	M. Dionisi, G. Bruno (Waste Management Facilities, Decommissioning)	A. Alexiev
	V. Leblanc (Transport of Radioactive Material)	A. Bakalova
7.	**INSPECTION**	
	J. Clifford (Generic Issues and Nuclear Power Plant)	V. Miliovsky, N. Todorov, I. Gorinov
	C. Hourdakis (Radiation Sources Facilities)	N. Todorov

	IRRS EXPERTS	BNRA Lead Counterparts
	M. Dionisi, G. Bruno (Fuel Cycle Facilities)	I. Gorinov
	M. Dionisi, G. Bruno (Waste Management Facilities, Decommissioning)	A. Alexiev
	V. Leblanc (Transport of Radioactive Material)	A. Bakalova
8.	**ENFORCEMENT**	
	J. Clifford (Generic Issues and Nuclear Power Plant)	V. Miliovsky, N. Todorov, I. Gorinov
	C. Hourdakis (Radiation Sources Facilities)	N. Todorov
	M. Dionisi, G. Bruno (Fuel Cycle Facilities)	I. Gorinov
	M. Dionisi, G. Bruno (Waste Management Facilities, Decommissioning)	A. Alexiev
	V. Leblanc (Transport of Radioactive Material)	A. Bakalova
9.	**REGULATIONS AND GUIDES**	
	G. Roos (Generic Issues and Nuclear Power Plant)	I. Raycheva, N. Todorov, I. Gorinov
	C. Hourdakis (Radiation Sources Facilities)	N. Todorov
	M. Dionisi, G. Bruno (Fuel Cycle Facilities)	I. Gorinov
	M. Dionisi, G. Bruno (Waste Management Facilities, Decommissioning)	A. Alexiev
	V. Leblanc (Transport of Radioactive Material)	A. Bakalova
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	
	M. Tkavc, R. Salinas	M. Nizamska
11.	**CONTROL OF MEDICAL EXPOSURES, OCCUPATIONAL RADIATION PROTECTION, CONTROL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE AND ENVIRONMENTAL MONITORING**	
	E. Friberg, J. Hunt, L. Ramos, T. Hailu	J. Vasileva, V. Badulin, A. Alexiev, L. Katzarska, A. Bakalova
12.	**INTERFACE WITH NUCLEAR SECURITY**	
	D. Brandisauskas	I. Gorinov
13.	**REGULATORY IMPLICATIONS OF THE TEPCO DAI-ICHI ACCIDENT**	
	I. Lux	B. Stanimirov

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**GP1**	The application of a no blame policy for the investigation of nuclear and radiation safety-related events is commendable.
	R1	The government should ensure BNRA is involved formally during the development of all regulations dealing with matters of nuclear safety, nuclear security and radiation protection. Where there is a potential overlap of regulatory responsibilities, the regulations need to be clear in regard to the demarcation of the respective roles and so avoid duplication of activities.
	S1	The government should consider ensuring that interim targets and deadlines are defined when finalizing the programme for geological disposal of Category 2b intermediate level waste (according to the Bulgarian classification system) and high level waste.
	S2	The government should consider making further provisions for maintaining the competence of a sufficient number of suitably qualified and experienced staff in BNRA.
2. GLOBAL NUCLEAR SAFETY REGIME	**S3**	BNRA should consider improving its processes for sharing information internationally on lessons learned and on measures taken in response to information received via international reporting networks by using established formats.
	GP2	The BNRA operational and regulatory experience feedback system covers the use of information received during BNRA participation in international workshops, seminars and other fora. Results from BNRA participation in international forums are described in reports along with the suggestions for incorporation of international experience in the BNRA activities. Such reports are disseminated through the BNRA intranet. Referring to those reports the BNRA chairman ensures the implementation of raised issues or

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		suggestions thereto.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S4**	BNRA and NCRRP should further consider improving the process for ensuring the impartiality of its staff. Special attention should be paid to BNRA's resident inspectors, and NCRRP's different roles related to medical activities with radiation sources. Further provisions should be also considered to be included in the rule of procedures of the Advisory Councils to address potential conflict of interest.
	R2	BNRA should make efforts to fill its vacancies and to ensure there is sufficient competent staff to fulfil its regulatory duties. Special attention should be paid to the on-going licensing process for disposal facilities.
	R3	The MoH should ensure that there are sufficient human resources to fulfil the regulatory duties of its inspection divisions.
	S5	BNRA should consider enhancing its training programme for current and new inspectors and other BNRA staff involved in the management and implementation of the regulatory activities. The programme should include the verification of adequate knowledge and abilities of staff before they are certified as inspectors and ensure that suitable proficiency is maintained. The efficiency of the programme should be verified periodically.
	GP3	BNRA has established a memorandum of understanding with broad spectrum of national technical support organizations and keeps an annually updated database on the available competences in these organizations providing support on the radiation and nuclear safety of nuclear facilities.
	GP4	BNRA periodically invites the media to seminars, training activities and exercises.
	GP5	BNRA publishes events at nuclear facilities and radioactive sources on its web page and makes them publicly available in multiple languages within 24

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		hours from the notification of BNRA.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R4**	BNRA should upgrade the existing management system to an integrated management system which is in line with the goals of the organization and contributes to their achievement. This management system should address, promote and more strongly support the safety culture. Adequate resource should be identified and assigned for the development and maintenance of this integrated management system.
5. AUTHORIZATION	**R5**	BNRA should establish a process within the regulatory framework for the release of nuclear facilities and related activities from regulatory control.
	S6	BNRA should consider establishing a process to consult, where appropriate, the interested parties, including the public, during the licensing process so that they are able to present their views, and their concerns are addressed.
	S7	BNRA should consider ensuring that, for radioactive waste disposal facilities, the conditions for closure of the facility, including the licensing aspects, are clarified.
	S8	BNRA should consider establishing objective and clear criteria for the issuing and renewal of licences regarding the validity period of the licences and permits for SIR.
	S9	BNRA should consider defining and applying criteria for the justification of new practices, and activities with already approved practices with SIR.
	S10	BNRA should consider establishing a process and defining procedures for the import and export of radioactive sources in exceptional cases where the ordinal import or export procedure cannot be applied.
	S11	BNRA should consider issuing guidance on the content of documents, especially those related to safety and security that the applicant submits to

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		BNRA during the authorization process.
	S12	BNRA should consider exempting the transport of very low level radioactive material from an authorization in accordance with a graded approach.
	S13	The government should consider appointing a competent authority (e.g. BNRA) for approval of package design to address cases where such approvals cannot be included in a licence or a permit for transport.
6. REVIEW AND ASSESSMENT	**R6**	BNRA and the MoH should establish as appropriate or improve the existing procedures governing the review and assessment activities for all types of facilities and activities under their regulation and oversight.
	R7	BNRA should ensure that their review and assessment reports (e.g. expert opinions) and supporting records (the auditable trail) provide appropriate detail in regard to what review and assessment activities were undertaken and what standards or criteria were applied (i.e. the aspects/elements of the standards considered) so that the basis for all the decisions taken, and in particular positive decisions, is clear.
	S14	BNRA should consider developing a suitable and systematic process of technical peer review for its review and assessment documentation, especially for key assessments.
	S15	BNRA should consider undertaking independent and periodic reassessments, based on IAEA Transport Safety Standards for multilateral approval, of the design of transport packages in use in Bulgaria, and in particular the justification of sub-criticality.
7. INSPECTION	**R8**	BNRA and the MoH should formalise and implement planned and systematic inspection programmes and overall plans for the programme of inspections. The programme should establish intervals between inspections and the level of effort to be applied, and be developed based on the appropriate

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		considerations, to ensure that the inspections cover all areas of responsibilities of the regulatory bodies within an established inspection program period.
	GP6	Establishing a clear, objective goal that provides a clear expectation that the focus of resident inspection is direct observation and assessment in the field.
	S16	BNRA and the MoH should consider establishing expectations for its inspectors, other than resident inspectors, that make it clear that staff in the process of conducting an inspection should place emphasis on observation and assessment of continuing safety activities in the field.
	S17	BNRA should consider how it uses the inspection program during the pre-application for authorization period, and its potential to encroach on the licensee's prime responsibility for safety by influencing the content of the subsequent application and the resultant impact on the independence of the regulatory body.
	R9	BNRA and the MoH should establish procedures for effective coordination of inspection activities for SIR.
8. ENFORCEMENT	**R10**	BNRA should establish and implement a formal, documented, enforcement policy.
	S18	BNRA should consider giving the inspectors specifically for radiation sources the authority to take on-site enforcement actions including a directive to discontinue activities or shut down the facility or the activity if necessary.
9. REGULATIONS AND GUIDES	**GP7**	The process to develop and revise regulations is described well in a dedicated procedure which involves interested parties and the public at different stages. The process of requiring a periodic, two-yearly review of regulations is a good practice.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R11	BNRA should develop regulatory guides providing detailed requirements and corresponding criteria for implementing the requirements of the existing regulations.
	S19	BNRA should consider expanding the list of factors identified in its NPP Regulations for the content of PSRs to include Human Factors (HF).
	S20	BNRA should consider the development of regulatory requirements for assessment of disposal such as e.g. assessment timescales, modelling scenarios, consideration of human intrusion and record maintenance.
	S21	BNRA should consider modifying the classification of radioactive waste to be in line with the IAEA international classification.
	S22	BNRA should consider to review the requirements relating to dose constraints for the protection of the public in the "Regulation on Safe Management of Radioactive Waste" to make them consistent with the "Regulation on Basic Norms of Radiation Protection".
	S23	BNRA should implement a notification process in case of non-compliance in transport activities.
10. EMERGENCY PREPAREDNESS AND RESPONSE	**S24**	BNRA should consider improving its notification point system and emergency team availability by formally establishing a roster for duty officers and relevant emergency team positions in order to be able to respond promptly and perform initial response actions.
	R12	The government should take steps for the harmonization of emergency preparedness and response arrangements with Romania in order to implement decisions on urgent protective actions across its national borders.
	GP8	Instructions recommended by BNRA can reach the public through an efficient system developed and maintained by the Ministry of Interior by

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		sending voice and text messages through the national radio and TV broadcasting networks.
	S25	BNRA should consider reducing the time limit of four hours currently defined in its plan for the first press release.
	R13	BNRA should improve current arrangements for initial and refresher radiation emergency training by introducing a systematic approach (e.g. preparing annual and long term training plans for all kinds of emergency trainings).
	S26	BNRA should consider including the communication arrangements into its emergency plan, in order to have them properly documented.
	S27	BNRA should consider including its emergency supplies, equipment, communications system and facilities as part of the quality assurance programme to ensure their high degree of availability and reliability (i.e. by introducing periodic testing).
	S28	BNRA should consider ensuring availability and update status of relevant emergency related documents (e.g. by including them into its management system or by some other documented means).
11. ADDITIONAL AREAS	**R14**	The MoH should ensure that generic justification of radiological procedures is carried out in conjunction with the appropriate professional bodies.
	S29	The government should consider allowing for exceptions from the defined clinical pathway that require medical exposure, if the exposure of the individual patient is not justified. This is to allow the radiological medical practitioner to assure proper justification.
	S30	BNRA and the MoH (NCRRP) should introduce a requirement to assure that dose displays on radiological equipment are calibrated and that the

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		calibration is traceable to a standard dosimetry laboratory.
	S31	The government should consider ensuring sufficient training providers to accommodate the number of health professionals involved in medical exposure in the country. BNRA should consider ensuring, during the licensing process of training providers, that health professionals involved in medical exposure get a proper and harmonized level of training in radiation protection and safety in medical exposure.
	S32	NCRRP should consider reviewing the optimization processes for occupational radiation protection for all practices and take the necessary steps to assure the optimization.
	R15	BNRA and NCRRP should: i. for certain workplaces in practices, identify where external individual monitoring for extremities and the eye lens is necessary for verification of compliance with annual dose limits and when necessary require that this monitoring be carried out by an accredited service; ii. require that neutron dose measurement through an authorized or ISO 17025 accredited service be provided to those occupationally exposed workers who are exposed to neutron fields so that compliance of the received doses against the annual dose limits may be verified.
	S33	NCRRP should consider forming an agreement with a laboratory for in-vitro bioassay measurements through a memorandum of understanding so that timely measurements are available when necessary.
	GP9	The National Dose Registry as established by the Regulation 28 and as operated by NCRRP contains information not only on the doses received by occupationally exposed workers but also medical and workplace monitoring

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		data, training information and information on exposure to conventional chemicals in the workplace in such a way that all the relevant information for future cause-effect analysis can be found in one database.
	S34	BNRA should consider including in the licence conditions for facilities with sources of ionizing radiations the specific discharge limits and the requirement for the conditions of treatment and control of releases where appropriate.

APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

AREA	NO.	CONCLUSION
TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT	**C 1**	The IRRS team considers that BNRA reacted promptly and effectively to the challenges posed by the TEPCO Fukushima Daiichi accident. It provided information to the governmental organizations and the general public in a timely manner based on the available international sources. Bulgaria participated in the European Stress Test programme and performed the investigations and analyses requested by the programme. It was concluded that the safety of Kozloduy NPP would not be particularly challenged by events similar to those occurred in Fukushima and no urgent safety increasing actions were deemed necessary.
PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT	**C 2**	The IRRS team observes that the conclusions of the Stress Test are duly summarized in a National Action Plan. The team notes that the revision by BNRA of its activity did not reveal the necessity of any change in the working methods nor in the regulatory practice of BNRA.
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**C 3**	The IRRS team considers that the necessary governmental legal and regulatory framework exists, responsibilities and functions are properly allocated among the relevant authorities, and the regulatory body is committed to act as necessary.
GLOBAL NUCLEAR SAFETY REGIME	**C 4**	The IRRS team concludes that no concern was raised with regard to the fulfilment of the Bulgarian government's obligations under international treaties and conventions. The necessary further actions have been planned to revise and to update and where necessary to initiate new bilateral agreements with the neighbouring countries.

AREA	NO.	CONCLUSION
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**C 5**	With regard to the TEPCO Fukushima Daiichi accident, the IRRS team found that BNRA's actions were consistent with its responsibilities and functions.
MANAGEMENT SYSTEM	**C 6**	The IRRS team concludes that TSO staff should take part in emergency exercises in order to be trained and exercised in their availability and capability to properly act in accident situations which last for long periods.
AUTHORIZATION	**C 7**	The IRRS team considers that BNRA recognized the necessity and importance for safety improvement based on experience feedback of TEPCO Fukushima Daiichi accident and required the licensee for a thorough reassessment (stress tests). The improvements envisage in the Action plan will undergo the regulatory authorization process of modification approval where it is required by the legislative framework. The team feels that BNRA is committed to act as necessary and initiating necessary actions.
REVIEW AND ASSESSMENT	**C 8**	The IRRS team considers BNRA has taken a proactive approach to the review and assessment of design extension conditions and required a number of beyond design measures by the time of the TEPCO Fukushima Daiichi accident. Bulgaria's subsequent participation in the ENSREG Stress Tests has improved confidence in the safety of Kozloduy and in BNRA's regulatory approach in this area.
INSPECTION	**C 9**	The IRRS team concludes that the inspection practice of BNRA was not fundamentally influenced by the lessons learned from the accident. Inspection of the completion of the National Plan by the licensee is foreseen, yet a full scope inspection programme would be beneficial to be developed.
ENFORCEMENT	**C 10**	The IRRS team considers BNRA has the basis for a proper enforcement policy. Further actions are deemed necessary for the development of a policy taking also into account possible issues related to cope with extreme external conditions.

AREA	NO.	CONCLUSION
REGULATIONS AND GUIDES	**C 11**	The IRRS team considers that the necessary actions have been recognised and the regulatory body is committed to act as necessary. The necessary further actions have been planned and initiated and they are already partly completed.
EMERGENCY PREPAREDNESS AND RESPONSE	**C 12**	The IRRS team considers that during the Fukushima accident BNRA demonstrated its commitment to act in emergency. After the accident appropriate actions have been taken and initiated in Bulgaria, taking into account the results of the EU Stress Tests, in which Bulgaria participated, as well.

APPENDIX VII – BNRA REFERENCE MATERIAL USED FOR THE REVIEW

[1]	IRRS Questions and Answers:
-	*Module 1: Responsibilities and Functions of the Government*
-	*Module 2: Global Nuclear Safety Regime*
-	*Module 3: Responsibilities and Functions of the Regulatory Body*
-	*Module 4: Management System of the Regulatory Body*
-	*Module 5: Authorization*
-	*Module 6: Review and Assessment*
-	*Module 7: Inspection*
-	*Module 8: Enforcement*
-	*Module 9: Regulations and Guides*
-	*Module 10: Emergency Preparedness and Response*
-	*Module 11: Control of Medical Exposures, Occupational Radiation Protection, Control of Discharges and Materials for Clearance; Environmental Monitoring for Public Radiation Protection.*
-	*Module 12: Interface with Nuclear Security*
-	*Module 13: Regulatory Implications of the TEPCO Fukushima Dai-Ichi Accident*
[2]	**Relevant Documentation**
BNRA Internal Documents	
1. -	*Rules of Procedure of the Nuclear Regulatory Agency*
2. -	*Policy statement*
3. -	*Quality Manual*
4. -	*Internal regulatory function related procedures and guides*
EU Directive	
1.	*EU Directive 2009_71 Nuclear safety*
Legislation	
1. -	*Constitution of the Republic of Bulgaria*
2. -	*Administration and Civil Servants Acts*
3. -	*Administrative Procedure and Criminal Codes*
4. -	*Administrative Violations and Sanctions Act*
5. -	*Conflict of Interest Prevention and Ascertainment Act*
6. -	*Access to Public Information Act*
7. -	*Act on the Safe Use of Nuclear Energy*
8. -	*Energy Act*
9. -	*Spatial Development Act*
10. -	*Environmental Protection Act*
11. -	*Defence-Related Products and Dual-Use Items and Technologies Export Control Act*
12. -	*Carriage by Road Act*
13. -	*Disaster Protection Act*
14. -	*Health Act*
15. -	*Health and Safety at Work Act*
16. -	*Medical Devices Act*
Policy Issue 1:	
	Long Term Operation of Nuclear Power Plants
Policy Issue 2:	
	NORM (Naturally Occurring Radioactive Material) Legislation and Practices

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010).
2. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
3. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
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 (Interim Edition), IAEA, Vienna (2011).
5. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
6. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009).
7. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Facilities Using Radioactive Material Safety, , Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006).
8. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012).
9. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011).
10. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003).
11. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Safety Requirement Series No. NS-R-5, IAEA, Vienna (2008)
12. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
13. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002).
14. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002).
15. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).
16. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002).
17. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)

18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)

19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. NS-G-2.9, IAEA, Vienna (2003)

20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. NS-G-2.10, IAEA, Vienna (2003)

21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)

22. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999)

23. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)

24. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

25. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)

26. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)

27. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)

28. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)

29. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)

30. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

31. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999)

32. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No.WS-G-2.3, IAEA, Vienna (2000)

33. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No.WS-G-2.4, IAEA, Vienna (2001)

34. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No.WS-G-2.5, IAEA, Vienna (2003)

35. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003)

36. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)

37. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX IX – ORGANIZATIONAL CHART