



**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
FOLLOW-UP MISSION
TO
BULGARIA**

Sofia, Bulgaria

11 to 18 April 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



NUCLEAR REGULATORY AGENCY



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Bulgaria

Mission date: *11 to 18 April 2016*
Regulatory body: *Bulgarian Nuclear Regulatory Agency (BNRA)*
Location: *Sofia, Bulgaria*
Regulated facilities and activities in the scope: *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-2016

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 12 to 18 April 2016 to conduct the IRRS follow-up mission. The peer review took place mainly at the headquarters of BNRA in Sofia. The international expert team also met representatives of the Minister of Health (MoH). The MoH has responsibilities for establishing requirements for the radiation protection of patients, workers and the public in Bulgaria. The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2013 IRRS Mission.

The review compared the Bulgarian regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Team members and their counterparts from Bulgaria in the areas covered by the IRRS.

The IRRS Team consisted of 6 senior regulatory experts from 6 IAEA Member States and 3 IAEA staff members.

The IRRS Team carried out a review of the measures undertaken following the recommendations and suggestions of the 2013 IRRS missions 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 mission included interviews and discussions with BNRA and the MoH staff. The IRRS Team was provided with advance reference material and comprehensive documentation including the status of recommendations and suggestions set out in the initial IRRS mission report.

The IRRS Team concluded that the recommendations and suggestions from the 2013 IRRS mission have been taken into account systematically by a comprehensive action plan. Significant progress has been made in all areas and many improvements have been implemented in accordance with the action plan.

During this follow-up mission, the IRRS Team determined that 13 out of 15 recommendations and 31 of 34 suggestions made by the 2013 IRRS mission had been effectively addressed and therefore could be considered closed. The IRRS Team made the following general observations:

- The high turnover of the staff and the difficulty for BNRA to maintain a sufficient number of suitably qualified and experienced staff due to uncompetitive financial conditions, an issue already identified during the mission in 2013, remains a matter of concern despite the efforts made by BNRA;
- A clear demarcation of responsibilities has been clarified between the MoH and BNRA as well as formal means of coordination and cooperation have been established in the area of safety to prevent undue duplication and omissions within the regulatory system;

- BNRA has strengthened its inspection process of facilities and activities in introducing a mid-term inspection programme to ensure that all areas regulated by BNRA are covered within a specific period;
- The BNRA management system was upgraded significantly including identification of all relevant processes, production of related documents and extensive training of BNRA staff on the new system;
- BNRA has substantially improved the emergency preparedness arrangements, including establishing a systematic emergency training.

The IRRS Team raised two new suggestions that indicate where improvements are still necessary to continue enhancing the effectiveness of regulatory functions in line with the IAEA safety standards:

- BNRA to continue negotiations with the Council of Ministers and Ministry of Finance for sufficient financial resources allowing for competitive salaries to reduce the high turnover of staff;
- The MoH to consider developing a formal systematic programme to ensure that the inspections cover all areas regulated by the MoH within a given period, in accordance with a graded approach.

The findings by the IRRS Team of 2013 that remain open can be found in Appendix IV.

The new IRRS Team findings are summarized in Appendix V.

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 nuclear and radiation safety experts met representatives of the Bulgarian Nuclear Regulatory Agency (BNRA) from 12 to 18 April 2016 to conduct the IRRS follow-up mission. The IRRS Team also met representatives of the Ministry of Health (MoH). The MoH also has responsibilities for radiation protection of patients, workers and the public in Bulgaria.

The initial IRRS mission that took place from 8 to 19 April 2013 and an international team of senior experts in nuclear and radiation safety met representatives of BNRA and the MoH to review the Bulgaria regulatory framework for nuclear and radiation safety.

The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2013 IRRS Mission. The peer review took place at the headquarters of BNRA in Sofia. The review mission was formally requested in June 2014. A preparatory meeting was conducted on 15 September 2015 at the IAEA Headquarters in Vienna to discuss the purpose, objectives, scope and detailed preparations of the review.

The IRRS Team consisted of 6 senior regulatory experts from 6 IAEA Member States and 3 IAEA staff.

The IRRS Team carried out a review of the measures undertaken following the recommendations and suggestions of the 2013 IRRS missions 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; radioactive 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.

After the initial 2013 IRRS mission, an action plan was developed by BNRA and the MoH based on its findings. The detailed results of this action plan implementation 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 and discussions with BNRA and MoH staff.

During the entire course of the preparation and the mission the IRRS team received excellent support and cooperation from the host institutions.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the Bulgarian radiation and nuclear safety regulatory framework and activities, specifically the measures undertaken following the recommendations and suggestions of the 2013 IRRS mission. The review was carried out by comparison of existing arrangements against the IAEA Safety Standards.

The IRRS review scope included all facilities and activities regulated by BNRA. According to the conclusion of the 2013 IRRS mission, the responsibilities and activities of the Ministry of Health (MoH) with regard to establishing and implementing requirements for radiation protection of patients, workers and the public, which were covered in 2013, were further reviewed by the IRRS follow-up mission.

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, the MoH and IRRS reviewers, and through the evaluation of the effectiveness of the Bulgarian nuclear and radiation regulatory framework and its good practices.

III. BASIS FOR REVIEW

A) Preparatory work and IAEA Review Team

At the request of the Government of the Republic of Bulgaria (Bulgaria), a preparatory meeting for the Integrated Regulatory Review Service (IRRS) follow-up mission was conducted on 25th September 2015 in Vienna, Austria.

The preparatory meeting was carried out by the appointed Team Leader, Ms Marta Ziakova, Deputy Team Leader, Mr Gerhard Roos and the IAEA representatives, Mr Jean-Rene Jubin and Mr Teodros Hailu. The Bulgarian team was led by the BNRA Chairperson, Mr Latchesar Kostov.

During the meeting, the representatives of Bulgaria provided the IRRS mission preparatory team with an overview on the progress made in response to the 2013 IRRS mission recommendations and suggestions.

The preparatory meeting participants agreed that the scope of the follow-up mission will be the same as the 2013 IRRS mission. This was followed by a discussion on the work plan for the implementation of the IRRS follow-up mission in Bulgaria from 12 to 18 April 2016. The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transportation arrangements were also addressed.

The Bulgarian Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Ms. Yuliya Dimitrova, Executive Secretary of BNRA.

BNRA and the MoH provided the IAEA and the IRRS Team with the advance reference material for the review in February 2016. In preparation for the mission, the IRRS Team 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 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 references for this mission is given in Appendix VII.

C) Conduct of the review

An initial IRRS Team meeting was conducted on Monday, 11 April 2016, in Sofia by the IRRS Team Leader and the 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. They also presented the agenda for the mission.

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

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

The IRRS entrance meeting was held on Tuesday, 12 April 2016, with the participation of senior management and staff of BNRA and the MoH. Opening remarks were made by Mr. Latchesar

Kostov, the BNRA Chairperson, and Ms Marta Ziakova, IRRS Team Leader. Ms Yuliya Dimitrova gave an overview of the major regulatory changes in nuclear and radiation safety since 2013 and presented the status of progress made regarding previous IRRS findings.

During the mission, a review was conducted for all the review areas with the objective of providing Bulgaria with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions.

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

The IRRS exit meeting was held on Monday 18 April 2016. The opening remarks at the exit meeting were presented by Mr. Latchesar Kostov 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 Jean-René Jubin on behalf of Mr Greg Rzentkowski, Director, Division of Nuclear Installation Safety.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

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

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

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

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

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

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

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

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Recommendation 1: The MoH and BNRA established arrangements for cooperation and coordination in safety areas where both organizations have responsibilities.

Since then, BNRA has been a member of the working groups of the MoH which is responsible to elaborate the regulations under Art.65 of the Health Act. This participation prevents issuing regulations inadvertently without consulting BNRA.

To assure clear division of responsibilities between the MoH and BNRA, a Memorandum of Understanding has been signed to establish a clear demarcation of the respective roles of each organization. This prevents duplication within the regulatory system, including inspection of facilities and activities.

Status of the finding in the initial mission

Recommendation 1 (R1) is closed as arrangements have been established for preparation of regulations and for avoiding duplication when regulating facilities and activities.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

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

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- 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.

Changes since the initial IRRS mission

Suggestion 1: The draft document "Programme for Investigating the Possibility for Construction of a Geological Disposal Facility for HLW and ILW, Category 2b" was presented to the IRRS Team. The original draft document was revised for compliance with the EU Directive on Radioactive Waste Management. In the document short-term and mid-term strategy, responsible organizations and funding sources for HLW and ILW have been established. The programme for geological disposal introduces a two-stage approach (pre-licensing and licensing) and defines specific activities together with specified deadlines and responsibilities for activities to be conducted.

The draft document is expected to be approved by the Minister of Energy.

Status of the finding in the initial mission

Suggestion 1 (S1) is closed on the basis of progress and confidence in the effective completion as the programme for geological disposal, including interim targets and deadlines, is expected to be adopted by the Minister of Energy.

1.8. COMPETENCE FOR SAFETY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- 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.

Changes since the initial IRRS mission

Suggestion 2: Because of the limits imposed on salaries and rewards for public servants in the governmental system, it is not possible to retain BNRA staff. BNRA is not able to compete for experts in various nuclear safety areas due to better financial conditions offered by private companies in Bulgaria or organizations abroad. Consequently, the regulatory body regularly loses highly qualified staff who received long and expensive training. This high level of staff turnover results in weakening the regulatory system in Bulgaria.

Status of the finding in the initial mission

Suggestion 2 (S2) is open as BNRA still has difficulty to maintain a sufficient number of suitably qualified and experienced staff.

1.9. PROVISION OF TECHNICAL SERVICES

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

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

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

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.
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Changes since the initial IRRS mission

Suggestion 3: The IRRS Team noted that BNRA recently modified its procedures regarding operating experience feedback (OEF). These procedures establish arrangements for enhancing BNRA's reporting to the International Reporting System (IRS).

The procedure QMS-AA-I-01 "Instruction on the Operation of the NPP Event Analyses Team (EAT)" was significantly revised in 2015 to strengthen BNRA's reporting system. A new para. 3.4 was added concerning the responsibilities of the EAT: "Discussion of corrective measures and other actions taken by licensees in response to events reported to the IRS and preparation of feedback information to be published in the system."

Based on this procedure, the tasks of the EAT have been improved to share relevant national experiences through the IRS. The EAT holds periodic and, when necessary, ad hoc meetings to discuss corrective measures and other actions taken by licensees in response to reported events from the IRS. The EAT also reports appropriate OEF at the international level through the IRS, using established formats.

In addition to the management of current events, in November 2015, BNRA reviewed all external events recorded in the IRS database during the last 5 years. Those events were also analysed by the licensee. From this review, no corrective action was identified.

Status of the finding in the initial mission

Suggestion 3 (S3) is closed as BNRA has improved its processes for contributing to and using the IRS.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

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

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Suggestion 4: In order to improve the process of ensuring impartiality of the officials from the NPP "Kozloduy" Resident Control Division, BNRA organized training courses on the "Obligations of the State Administration Officials in Connection with the Prevention of Conflict of Interest and Compliance with Ethical Standards".

Within the scope of these training courses, the following topics are addressed:

- Conflict of Interest Prevention and Ascertainment Act (2010);
- Code of Conduct for civil servants (2004);
- Code of Ethics for the BNRA staff (2008).

Special attention was paid to the principles which should guide BNRA personnel, such as the principles of legality, loyalty, impartiality, political neutrality, accountability, incompatibility, lack of connectivity.

For the staff of the MoH the terms and conditions for exercising state health control are already defined by Decree No.36 on the terms and conditions for exercising state health control of the MoH. Requirements of Art.14 of the Health Act state that the "state health inspectors may not engage in any form of activity that is subject to state health control".

When joining the organization, all newcomers of the MoH are acquainted with the provisions of the Code of Ethics for employees, recently updated. The employees in the Common Radiation Monitoring Inspectorate can only obtain the status of state health inspectors upon signing of the "declaration of independence and impartiality of state health inspectors at the NCRRP". Every year state health inspectors participate in training courses that now cover impartiality issues more intensively.

With regard to a possible conflict of interest in the work of the Advisory Councils to the Chairman of BNRA, new rules have been adopted by the Nuclear Safety Advisory Council (NSAC) and the Radiation Protection Advisory Council (RPAC). Representatives of the licensee may no longer be members of the Councils. They may only be invited to Council meetings as observers or to present the views of licensees on issues discussed by the Councils.

Status of the finding in the initial mission

Suggestion 4 (S4) is closed as BNRA and the MoH have intensified training with regard to impartiality issues. In addition, the rules for membership in the NSAC and RPAC were changed to avoid potential conflict of interest.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.
R3	Recommendation: The MoH should ensure that there are sufficient human resources to fulfil the regulatory duties of its inspection divisions.
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.

Changes since the initial IRRS mission

Recommendation 2: Some activities in the nuclear field had been postponed, e.g. licencing of a new unit, and therefore there is no urgent need to increase the number of positions in BNRA. At the time of the follow-up mission there were 114 positions of which 101 were occupied. In 12 selection processes, 17 new employees have been hired for the open positions. However, during the same period 17 staff members have left BNRA. These numbers show that there is a high turnover of staff that can lead to the loss of competencies.

To be able to cope with the ongoing licensing process of the national radioactive waste disposal facility, the company RISKAUDIT has been contracted for technical support. This arrangement allowed BNRA to proceed with the licensing process with sufficient level of expertise and without delay.

Recommendation 3: To be able to carry out its regulatory duties, the MoH prepared a plan for resource development. Based on this plan they run selection processes to hire specialists for each vacant position. Due to uncompetitive financial conditions it is difficult to hire new staff. After new staff is hired and trained to gain the required competences they often leave their job due to better financial conditions in the private sector. The situation with human resources in MoH has not changed.

Suggestion 5: BNRA adopted new methodologies in training and retraining of its employees.

A new “Qualification and Training Procedure (QTP)” was drafted in 2015 and put into effect in 2016. The procedure establishes qualification and training policy and objectives and formalises the training and re-training processes. The procedure requires initial training and certification of new inspectors, preparation of re-training arrangements and training plans, assessment of training needs by division using e.g. “Systematic Assessment of Regulatory Competence Needs

(SARCoN)” and Competence Assessment Toolkit (CAT) instruments, documentation of training results, analysis of system effectiveness.

Concerning certification, the procedure establishes an “Inner Qualification Commission (IQC)”. This commission consists of the most experienced BNRA staff and has the responsibilities to organise exams for new inspectors. Those successfully passing the exams receive a qualification certificate. This certificate is a prerequisite for the BNRA Chairman to include the newcomer in the list of inspectors.

A newcomer has to complete an individual training programme (ITP). The ITP is developed based on the competence analysis for the job (CAT and job description) and includes a variety of training modules based on the BNRA basic training courses, self-learning and on-the-job training. After successful completion of the self-learning and basic training courses, the newcomer participates in inspections as observer.

The QTP also includes requirements for periodic reassessment of competences, based on SARCoN and CAT, providing the basis for the annual training plan, as well as periodic review of training effectiveness.

New procedures within the Management System cover the requirements on training as well as on verification of competences. The initial training as well as retraining of BNRA staff has been established using a systematic approach.

Status of the finding in the initial mission

Recommendation 2 (R2) is closed as it is superseded by Suggestion SF1.

Recommendation 3 (R3) is open as it is necessary to create conditions which will allow to hire and keep necessary personnel to fulfil the regulatory duties of the MoH.

Suggestion 5 (S5) is closed as BNRA adopted a systematic process for training and retraining of its employees.

New observation from the follow-up mission

It has been identified by the IRRS Team that despite the successful effort of BNRA to fill the vacancies by selection processes (17 new employees have been hired) the number of staff has not increased. This was caused by the fact that in the same period 17 employees had left (out of which 6 had retired) because BNRA is not able to compete for qualified experts with licensees, private companies in Bulgaria and organizations abroad. If this trend is not changed it can cause the loss of competence in BNRA. It is also necessary to take into account that the training of new staff is a costly and time consuming process.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Due to financial restrictions, BNRA is not able to compete for qualified experts with private companies in Bulgaria and organizations abroad, which makes it difficult to fill all vacancies.*

(1)

BASIS: GSR Part 1 (Rev.1) Requirement 18 states that “*The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.*”

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	BASIS: GSR Part 1 (Rev.1) Para.4.11 states that <i>“The regulatory body has to have appropriately qualified and competent staff. [...]”</i>
SF1	Suggestion: BNRA should consider continuing negotiations with the Council of Ministers and Ministry of Finance for a higher budget for salaries to be able to pay competitive salaries to reduce the high turnover of staff.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

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

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

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

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

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

3.7. SAFETY RELATED RECORDS

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

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

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

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

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

4.2. MANAGEMENT RESPONSIBILITY

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

4.3. RESOURCE MANAGEMENT

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

4.4. PROCESS IMPLEMENTATION

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

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Recommendation 4: The IRRS Team found that a project to upgrade the management system (MS) from 2013 has been established and is close to being finished. An external consultant was contracted by BNRA to provide additional expertise and the necessary “outside view”. The BNRA project team includes the Executive Secretary, the Departments’ Directors and the State Inspector in the field of MS.

The project was prepared in 2013 and 2014 and implemented in 2015. Some related activities were:

- the review of the existing MS and identification of gaps with regard to the requirements of GSR Part 1, GS-R-3, as well as determination of measures to address these gaps;
- the determination of the MS processes, their scopes and objectives, the process owners and performance indicators;
- the revision of the existing documents and, when necessary, the development of new MS documents.

Extensive training of the BNRA staff was carried out on the requirements of GS-R-3 and ISO 9001:2015, the structure and the scope of the MS, the identified management, core and supporting processes, as well as on conducting of internal audits.

At the time of the follow-up mission, the revision of some documents and their approval were still on-going and were expected to be finalized within 2016. Within the project about 30 documents were developed or modified, including:

- the Policy Statement;
- the MS Manual;
- the procedures on regulatory control of facilities and activities;
- a procedure for document control;
- a procedure on qualification and training;
- a procedure for implementation of enforcement activities.

Status of the finding in the initial mission

Recommendation 4 (R4) is closed on the basis of progress and confidence in the effective completion as the upgrade of the management system is close to be completed.

5. AUTHORIZATION

5.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R5 **Recommendation:** BNRA should establish a process within the regulatory framework for the release of nuclear facilities and related activities from regulatory control.

Changes since the initial IRRS mission

Recommendation 5: The "Regulation on the procedure for Issuing Licenses and Permits for Safe Use of Nuclear Energy" was revised and adopted in 2015 to introduce provisions for the release of buildings and sites from regulatory control upon completion of decommissioning activities. Article 62a of this regulation states that "*(1) The site of a nuclear facility shall be released from regulation by an order of the Chairman of the NRA under Art. 28, para. 1 pt. 2, after having proven a compliance with the statutory dose criteria and the conditions of the license for the decommissioning of the nuclear facility are fulfilled*". Moreover, the safety guide on "Release of Buildings and Sites from Regulatory Control" was finalized and published. It provides guidance to the licensee covering all different aspects of the release from regulatory control. It addresses, inter alia, the whole process to be followed and associated criteria, as well as responsibilities and requirements for the release of buildings and sites.

Status of the finding in the initial mission

Recommendation 5 (R5) is closed as the revised regulation as well as the associated safety guide were issued in 2015 to cover the release of buildings and sites from regulatory control.

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Suggestion 6: BNRA collected and reviewed the experience of several countries for the consultation with interested parties, including the public, related to nuclear facilities. Based on these examples, BNRA drafted a proposal to amend the "Regulation on the procedure for Issuing Licenses and Permits for Safe Use of Nuclear Energy" in order to involve the public in major decision-making processes. Thus, it is stated under the proposed new Article 8a "(1) In the process of issuing the initial operating license for an NPP, the BNRA Chairman shall provide the public with the opportunities to participate in the decision-making process." This draft was endorsed by the BNRA Chairman and submitted to the major licensees for comments. After

receipt of the licensees' comments, BNRA would consult the public. BNRA's objective was to submit a final draft by summer 2016 to the Government of Bulgaria.

BNRA stated its commitment to ensure public involvement in the licensing process when possible, in accordance with the 2009 EU Directive on Nuclear Safety and its amendment from 2014.

Status of the finding in the initial mission

Suggestion 6 (S6) is open as the development of regulatory provisions for consultation is at an early stage.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Suggestion 7: BNRA established a plan for the development of regulatory guides. In addition, the regulation on radioactive waste management was revised in 2013 and now contains some conditions for closure in Chapter Nine, Section VI – Closure, and for the post-closure period in Section VII – Post closure control. Several regulatory guides were developed or have been planned to be developed under a contract with RISKAUDIT.

In order to enhance the licensing process related to disposal of radioactive waste, by addressing the specific aspect of closure of the disposal facilities, BNRA planned to develop a regulatory guide on “Conditions for Closure of Radioactive Waste Disposal Facilities, Including the Licensing Aspects”. This aims to address different issues related to decommissioning and waste management. In particular, the regulatory guide was expected to cover the practical implementation of the requirements for licensing aspects of disposal facilities, addressing their closure. The development of this regulatory guide was part of the contract with RISKAUDIT. The IRRS Team reviewed minutes from 2015, scheduling the completion of the guide for September 2016 and defining the following scope:

- Technical design for closure;
- Closure plan – defining of the end point of the closure; schedule of the stages and activities during closure; directions for rehabilitation activities; level of detail for describing the complete inventory of the disposed RAW in the facility; programs and schedules for surveillance and maintenance of SSC which have to be available in the process of closure; description of the monitoring programs, methods and technical means for inspection of the site after completing the process of closure;
- Licensing issues – explanations for release of control of the disposal site (incl. responsibilities for post-closure control).

Status of the finding in the initial mission

Suggestion 7 (S7) is closed on the basis of progress and confidence as the completion of the regulatory guide is expected by September 2016.

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- 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.
- S9** **Suggestion:** BNRA should consider defining and applying criteria for the justification of new practices, and activities with already approved practices with SIR.
- 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.
- 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.

Changes since the initial IRRS mission

Suggestion 8: The “Procedure for Authorization of Activities with SIR”, QMS-LA-P-02, was revised and issued in February 2016. The revised Procedure includes provisions on the factors that need to be assessed in determining the terms of validity of the license related to the site or the radiation source and criteria for determining the term of validity of the license or permit issued by BNRA.

The procedure also indicates that the term of validity of an authorization is 3 to 5 years for sealed sources of categories 1 and 2, work with unsealed sources of classes I and II, use of accelerators of 10MeV, transport of radioactive sources, production of SIR, and work with radioactive sources or accelerators when performing maintenance services, installation, dismantling, construction and repair work at facilities.

The term of validity is 5-10 years for sources of categories 3 and 4, work with unsealed sources from class III or above, use of accelerators of up to 10MeV, use of X-ray equipment, and work with X-ray equipment or apparatus for performing maintenance services, installation, dismantling, construction and repair work at facilities. The particular term of validity within the provided range is decided on such factors as e.g. the useful life of the source or the duration of the project if the source is to be exported to the manufacturer.

The procedure also has provisions on the term of validity of permits for activities with SIR: one year for construction of a facility, installation and preliminary testing; one year for decommissioning of a facility with a radioactive substance; and three years for temporary storage of radioactive substances, obtained during carrying out activities with SIR or related to such activity.

Suggestion 9: A “Procedure for Authorization of Activities with SIR”, QMS-LA-P-02, has been revised and issued in February 2016, and is being implemented by BNRA. The procedure includes a new chapter on justification of new practices with sources or activities in authorized existing practices. The Procedure has provisions that the applicant is required to reconsider the justification of an already authorized activity when new data or evidence is available; or new

circumstances or facts including new technology or methods arise, including practices more efficient or safer. When there is any reason for reconsidering the justification of the activity, BNRA inspectors might also request the licensee to submit new justifications for consideration, and should the submitted justification not be validated, the specific activity license might be withdrawn/revoked or terminated in accordance with Articles 22 and 23 of ASUNE Articles 3.39 and 3.40 of QMS–LA–P–02 also describe unjustified or forbidden practices such as deliberately adding radioactive substances in food and goods production, toys production and import and export of these goods.

Suggestion 10: The “Procedure for Authorization of Activities with SIR”, QMS-LA-P-02, revised 2016, includes new provisions for the import of SIR category 1, 2 and 3 sources in extraordinary circumstances. Article 4.55 indicates that the import of SIR for the purpose of usage by legal entities without the intention to possess the source or obtain a license might be allowed in exceptional circumstances, on the condition that both safe transport and adequate storage conditions have been fulfilled. Article 4.56 indicates that the use of SIR imported in exceptional circumstances can only be used when a licence for use is provided by BNRA. The procedure also has provisions, in Articles 4.59 and 4.60, on the requirements that need to be fulfilled by the exporting state in such exceptional cases, and in Article 4.61 that BNRA might deny issuance of a SIR import permit/consent in the absence the established conditions.

Bulgaria does not produce and export radioactive sources, except a few sources that have been sent to the manufacturer at the end of their useful life. Therefore, although importing a source in exceptional circumstance might happen, it was concluded that exporting circumstances would be unusual for Bulgaria.

Suggestion 11: A guide that describes the content and form of the documents, required for the issuance, renewal, amendment and termination of licenses and permits for activities with SIR has been developed and issued in 2016. This guide covers the detailed instructions and basic requirements for the form and content of the documents to be prepared and submitted by the applicants. The guide also contains the forms of application for authorization that should be filled in by the applicant. Also, a list of documents is included that have to be submitted, such as documents related to the management and organizational structure, staffing level and qualification, description of SIR and related activities, description and means of individual protection, instructions for radiation protection, facility emergency plan, expert conclusion for medical fitness of personnel from the National Centre for Radiobiology and Radiation Protection (NCRRP), internal rules and procedures defining the responsibilities and obligations, programme for monitoring radiological characteristics of the work environment and individual monitoring, and documents on the provision of the technical support system used. The guide is made available to applicants on the BNRA website.

Status of the finding in the initial mission

Suggestion 8 (S8) is closed as criteria for determining the validity of authorizations have been established and included in a revised procedure for authorization.

Suggestion 9 (S9) is closed as BNRA has revised its procedure to include the need for reassessing the justification of authorized practices should any new information be available that necessitates such a reconsideration.

Suggestion 10 (S10) is closed as the new “Procedure for Authorization of Activities with SIR” includes provisions for import of SIR for category 1, 2 and 3 sources in exceptional circumstances.

Suggestion 11 (S11) is closed as a guide on the form and content of documents to be submitted in applications for authorization has been developed and made available on the BNRA website.

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

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

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S12 **Suggestion:** BNRA should consider exempting the transport of very low level radioactive material from an authorization in accordance with a graded approach.

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.

Changes since the initial IRRS mission

Suggestion 12: BNRA has not foreseen the transport of radioactive substances with very low radioactivity to be exempt from the licensing regime. It argued that the practical experience in the licensing activity "transport of radioactive material" indicated that there was no basis and it was no necessity for this exemption, even in cases where the radiation risk was assessed as negligible.

Furthermore, BNRA stated that the existing licensing regime for the transport of radioactive substances provides traceability and control of the transportation of unsealed and sealed sources and other radioactive materials, which is mandatory in terms of safety and security, regardless of the activity of the material transported.

Suggestion 13: According to legislation requirements, as set by ASUNE, the "Regulation for Issuing Licenses and Permits for Safe Use of Nuclear Energy" and the "Regulation on the Conditions and Order for Transportation of Radioactive Substances", for each transport a permit is issued. The applicant is required to provide, among others, the certificate of the transport container, which is a mandatory document for the authorization of transport. There is no possibility of issuing a permit for the transport of nuclear or radioactive material with non-approved packages.

BNRA considered that the designation of the competent authority in Bulgaria for approval of packages for the transport of nuclear material, was not needed for several reasons, including:

- Bulgaria does not produce packages for the transport of nuclear or radioactive material and has no resources and intention to produce and test such packages;
- BNRA may request an independent assessment to verify the sub-criticality or to be examined the technical aspects of a transport package;
- the establishment and maintenance of laboratories, installations, as well as competent staff for the testing of packages for the transport of nuclear material, is not justified.

Status of the finding in the initial mission

Suggestion 12 (S12) is closed as the decision for exempting from licensing regime the transport of radioactive substances with very low radioactivity is at the discretion of BNRA.

Suggestion 13 (S13) is closed as BNRA has sufficiently justified not to establish a service for approval of package design or to appoint an authority for it.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Recommendation 6: BNRA revised the “Procedure for Analysis and Safety Assessments of Nuclear Facilities”, QMS-AA-P-01 to cover the reviews, analyses and assessments related with the safe management of radioactive waste facilities, which are nuclear facilities by definition. The modified Procedure defines the responsibilities of all three departments of BNRA involved in the process of the review, analyses and assessments of the safety of all types of nuclear facilities, namely: Department Analyses and Assessments of Safety, General Department Nuclear Safety and Department Radiation Protection.

In order to improve the existing procedure for review and assessment of procedures for SIR, BNRA modified its “Procedure for Analysis and Assessment of Radiation Protection in Activities with SIR” No. QMS-AA-P-02 and issued it as a new “Procedure for Analysis and Assessment of Documents Related to Safe Use of SIR”. Analysis and evaluation of radiation protection, physical protection and emergency preparedness are included for all stages of the licensing process for all types of facilities and activities with SIR. Annex 1 of the procedure includes a checklist, which is completed by the BNRA inspectors in carrying out analyses and assessments in issuing licensing documents for activities with SIR. The checklist covers necessary details that have to be reviewed. For the assessment of complex facilities and activities, the procedure has provisions for acquiring services of technical support organizations.

The MoH procedure for review and assessment is broadly described in Decree No.30 of the MoH which envisages the establishment of an expert council to the Minister of Health on medical exposure. The expert council is expected to include national consultants in radiotherapy, diagnostic imaging, nuclear medicine and invasive cardiology, a representative of the Bulgarian Association of Radiology and the Bulgarian Society of Biomedical Physics and Engineering. The expert council has the responsibility to "consider and give opinions on the introduction of new methods and new radiological procedures related to medical exposure, which are not included in the medical standards in radiotherapy, diagnostic imaging, nuclear medicine and invasive cardiology". The process is further elaborated in the MoH procedure No.RD-02-279, Sofia, 8 December 2015, and “Evaluation of the adequacy of the Investment Project” No.60 of the MoH.

Status of the finding in the initial mission

Recommendation 6 (R6) is closed as BNRA and the MoH have improved their procedures for review and assessment of nuclear and radiation facilities to meet the requirements of IAEA safety standards.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.
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.

Changes since the initial IRRS mission

Recommendation 7: BNRA revised its Procedure No.QMS-AA-P-01 which requires the review reports (e.g. expert opinion) to include details regarding what kind of review and assessment activities are completed; which regulations, standards and criteria are applied (e.g. regulatory requirements and recommendations of the standards and regulatory guides considered); as well as the bases and justification for the decision.

Suggestion 14: BNRA modified its Procedure No.QMS-AA-P-01 describing the peer review process when performing key assessments (with a significant impact in terms of ensuring nuclear safety and radiation protection). The process has following main steps:

- Initial review and assessment of the application is performed at department level and the department's expert opinion is provided to the Deputy Chairman;
- The Deputy Chairman distributes the expert opinion to the experts available in other departments of BNRA for their assessment and evaluation;
- The opinions/assessments of these departments are discussed in meetings where relevant inspectors, division heads and department directors are also involved.

In addition, if considered necessary, external consulting services are hired, which aim to confirm or reject the conclusions made in the implementation of key assessments.

Status of the finding in the initial mission

Recommendation 7 (R7) is closed as BNRA modified its procedures for review and assessment by including necessary details.

Suggestion 14 (S14) is closed as the peer review process of BNRA is found suitable and systematic.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

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

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

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

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

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

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Changes since the initial IRRS mission

Suggestion 15: The procedure for Analysis and Safety Assessments of Nuclear Facilities QMS-AA-P-01 was amended, in order to include the analyses and assessments of transport packages of nuclear fuel, including analysis of criticality, in cases when transporting new nuclear fuel for the first time. Following the discussions with BNRA staff, the procedure applies for other than first time transports of nuclear fuel, as well.

According to the amended QMS-AA-P-01:

- BNRA activities include the review and assessment of compliance with regulations concerning the design basis and functioning of the transport packages during the transportation of nuclear material (para 3.1);
- the BNRA Chairman may assign the review and assessment of the submitted documents, fully or partially, to external consultants.

Realizing the necessity of performing an independent examination and assessment of the sub-criticality during transport and storage of new types of fresh nuclear fuel in the transport package, an external expert service was conducted at the Scientific Research Section of the Sofia University “St. Kliment Ohridski”.

From the discussions with the counterparts it appears that:

- external expert services are conducted on a contract basis by the Technical Support Organizations (TSOs), which signed an Annual Framework Agreement with BNRA.
- experts from the external expert service conduct independent calculations, assessments, tests and measurements, when appropriate, and prepare reports where the results and the conclusions are reported;
- these kinds of external expert services are available when needed;
- external expert reports facilitate BNRA in taking regulatory decision, in particular concerning the use of appropriate transport packages for transportation of fresh nuclear fuel assemblies.

An example of assessment of sub-criticality during the transportation of new fresh fuel for Units 5 & 6 to Kozloduy NPP by contracting external expert services “External expert report on the implementation of the requirements for sub-criticality during transport and storage of fresh fuel assemblies of TBCA-12 type in the transport package TK-C5 type” was presented.

Status of the finding in the initial mission

Suggestion 15 (S15) is closed as BNRA has established a procedure for independent reassessment of transport packages for nuclear material.

7. INSPECTION

7.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.
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.
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.

Changes since the initial IRRS mission

Recommendation 8: The procedure QMS-IA-P-02 was revised to address all aspects of the regulatory inspection process, including policy and principles, responsibilities, planning, preparation, conduction and follow-up of inspections. One of the key objectives of this revision was to introduce a mid-term planning of inspections in order to ensure all areas regulated by BNRA are covered within a 3 year period. Among other modifications, BNRA completely updated the list of regulated areas and associated sub-areas. Based on this list, an overall inspection programme was established and is described in annex 1 of the procedure. The overall inspection programme provides for each area and sub-area, the frequency of inspections and appropriate level of resources to be allocated. The annual inspection plan for all nuclear facilities is developed on the basis of the overall inspection programme, covering all foreseen inspections for the coming year.

Similarly, BNRA issued another new procedure, QMS-IA-P-03, in February 2016, on inspection of activities and facilities using SIR. For the development of this new procedure BNRA used the same approach and structure as employed for the procedure QMS-IA-P-02. Article 4.2 of this procedure identifies areas and topics that are subject to inspection at facilities with SIR. The Procedure also has provisions for determining the frequency of inspections at facilities and activities with SIR based on categorization of radioactive sources and radiation intensity of radiation generators.

In addition, the procedure describes the arrangements established to coordinate and conduct joint inspections by BNRA and the MoH. During inspections for commissioning, joint inspections are conducted. At the time of the IRRS follow-up mission, a plan for joint inspections for 2015-2017 was being implemented.

Regarding the inspections conducted by the MoH, Decree No.36 requires that every facility be visited at least once a year, which is not realised. Therefore the revision of Decree No.36 is planned. The MoH provides guidance for planning and organizing inspections at the beginning of each year, which stipulates the category of facilities and the minimum frequency of inspection in the facilities. Based on this guidance, each health inspectorate determines the number of inspections to be performed within a year and assigns inspectors who would then develop an annual plan for inspection of specific facilities, which is implemented when approved by the management. The health inspectorates develop an annual plan with the intention to inspect all facilities with SIR. If it cannot be fully implemented, the inspectors give priority to inspection of high risk facilities and activities.

Suggestion 16: Both procedures on regulatory inspections QMS-IA-P-02 (Nuclear installations) and QMS-IA-P-03 (Sources of ionizing radiation) were revised to require BNRA inspectors to emphasise observations and assessment of safety-related activities in the field. It is stated in para 3.7 of QMS-IA-P-02 that “During the inspections the main focus is observation of work and personnel, walk downs to SSCs and interviewing in the field.” This issue is also addressed under the chapter 3 of the procedure QMS-IA-P-03 related to inspection methods and techniques.

BNRA explained that training courses organized for its inspectors to address that inspection should focus on observation and assessment in the field and the detailed desktop review of licensee documents are to be done, usually, at the office during the preparation of the inspection.

Inspectors of the MoH are expected to use the “Standard Operating Procedures for Conducting Inspections in Facilities with SIR”. The procedure has provisions for inspection, such as verification of data and the functional status of installations, relevant documentation on personnel data of occupationally exposed personnel and evidence of individual monitoring; workplace radiation level measurement and other relevant parameters, and recording of conclusions on radiation safety status of the facility or activity. For medical applications of SIR, further verifications of patient exposure, including quality assurance programmes are made. The procedure also includes a checklist in Annex I that needs to be filled in by inspectors.

Suggestion 17: BNRA stated that the technical discussions observed by the IRRS Team in 2013 during a regulatory inspection at the Kozloduy Nuclear Power Plant site, which were the basis for this suggestion, were irrelevant and not in compliance with BNRA’s policy for inspections. BNRA confirmed that discussions on technical specifications and solutions should not take place during inspections.

In the revised procedures related to inspections in nuclear installations, BNRA incorporated the requirement that regulatory inspections cannot diminish the licensees’ prime responsibility for safety. Moreover, the IRRS Team was informed that the policy for regulatory inspections, and more broadly the content of the procedures related to inspections, are addressed during inspector training.

Status of the finding in the initial mission

Recommendation 8 (R8) is closed and superseded by Suggestion SF2 as only BNRA established overall inspection programmes to ensure that all areas under its responsibility are covered, whereas the MoH has not established an overall inspection programme.

Suggestion 16 (S16) is closed as, both BNRA and the MoH, have established procedures that clearly state the expectation of inspectors during inspection of facilities and activities.

Suggestion 17 (S17) is closed as BNRA took measures to strengthen the common understanding about role and objectives of regulatory inspections as well as the fundamental principle related to the responsibility for safety.

New observation from the follow-up mission

According to the Health Act and Decree No.36, the Chief State Health Inspector is responsible for ensuring the safety of human health by establishing requirements and conducting inspections of all facilities using SIR.

At the date of the mission, the MoH had no systematic overall inspection programme including inspection frequency of the different facilities and activities. Unsuccessful attempts are made to cover all facilities with SIR each year. It was indicated that a revision of the Decree was initiated to ensure that the frequency of inspections will be determined on established criteria, based on the associated risk to facilities and activities in accordance with the graded approach.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The MoH has no systematic overall inspection programme which includes an inspection frequency for the different facilities and activities in accordance with the graded approach.*

(1)	BASIS: GSR Part 1 (Rev1) para. 4.50 states that <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of 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.”</i>
(2)	BASIS: GSR Part 1 (Rev1) para. 4.52 states that <i>“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.”</i>
SF2	Suggestion: The MOH should consider developing a formal systematic inspection programme which establishes a frequency of inspections to ensure that the inspections cover all facilities and activities regulated by the MoH within a given period, in accordance with a graded approach.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

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

7.3. INSPECTION OF FUEL CYCLE FACILITIES

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

7.4. INSPECTION OF WASTEMANAGEMENT FACILITIES

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

7.5. INSPECTION OF RADIATION SOURCES FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R9 **Recommendation:** BNRA and the MoH should establish procedures for effective coordination of inspection activities for SIR.

Changes since the initial IRRS mission

Recommendation 9: BNRA and MoH signed a cooperative agreement for joint inspections in February 2016. The agreement covers joint inspections and has provisions for information exchange to improve coordination. The document identifies thematic areas covered during inspection and the roles of BNRA and MoH inspectors during the joint inspections. It includes provisions that the result of the inspection, including recommendations, should be communicated to both organizations.

Planned joint inspections are conducted in accordance with an established programme that covers 3 years. BNRA and the MoH developed a joint inspection programme for 2015 – 2017. The 2016 joint inspection plan was established for 10 facilities, out of which 6 were medical facilities and 4 industrial facilities.

Article 15 of the agreement also requires BNRA and the MoH to inform one another of the results of individual inspections conducted in accordance with their respective competence. It also has provisions for individual inspections at facilities to be performed in accordance with the “Procedure for Inspection at Facilities with SIR” (QMS-IA-P-03) of BNRA and the Standard Operating Procedure for conducting inspection of the MoH.

Status of the finding in the initial mission

Recommendation 9 (R9) is closed as a formal agreement has been signed between BNRA and the MoH.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

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

7.7. INSPECTION OF TRANSPORT ACTIVITIES

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

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
R10	Recommendation: BNRA should establish and implement a formal, documented, enforcement policy.
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.

Changes since the initial IRRS mission

Recommendation 10: BNRA developed a new “Procedure for the Implementation of Enforcement Activities in the Nuclear Regulatory Agency”, No.QMS-IA-P-04, 2015. The content of the procedure covers the policy, principles, general requirements and factors to be taken into account in deciding which enforcement action is appropriate. However, the observation that formed the basis for this recommendation was that the IRRS Team could not find how BNRA determines the safety significance of a violation so that the decision on enforcement action is consistent with the safety significance. The new procedure does not address the process/criteria for determining safety significance of the violation.

Suggestion 18: BNRA explained that according to Art.150 pt.1 of ASUNE suspension and limitation of the activity was considered to be an administrative enforcement measure and, according to the Act, the inspectors have the right to propose to the Chairman of BNRA to apply such measures whereas the inspectors are not authorized to impose such measure by themselves. The inspectors have the right to issue mandatory directives to inspected persons which may not coincide with the administrative enforcement measures. BNRA argues that inspectors are given the right for taking corrective action if there is an imminent likelihood of safety significant events, with the exception of discontinuing of activities or shutting down the facility.

According to BNRA, in order to provide powers to the BNRA inspectors to impose administrative enforcement measures, it would be necessary that the ASUNE is revised. The IRRS Team considered that the situation was not in compliance with para.4.58 of GSR Part 1 (Rev.1).

Status of the finding in the initial mission

Recommendation 10 (R10) is open as neither criteria, nor a process for determining safety significance of a violation that may facilitate decision making on appropriate enforcement action have been established by BNRA.

Suggestion 18 (S18) is open as the on-site inspectors are not authorized to enforce the cessation of activities or the shutting-down of a facility if there is an imminent likelihood of safety significant events.

8.2. ENFORCEMENT IMPLEMENTATIONS

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

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- R11** **Recommendation:** BNRA should develop regulatory guides providing detailed requirements and corresponding criteria for implementing the requirements of the existing regulations.

Changes since the initial IRRS mission

Recommendation 11: The IRRS team found that BNRA addressed the recommendation in a very systematic way.

BNRA has developed and issued the following 5 regulatory guides

- Criteria for Authorization and Control of Radioactive Discharges and for Environmental Monitoring,
- Security Plans Related to Nuclear Material and Other Sources of Ionizing Radiation,
- Safety in Activities with Particle Accelerators,
- Safety in Use of Nuclear Gauges, and
- Radiation Protection in Medicine.

One draft safety guide on “Periodic Safety Review for Nuclear Power Plants” is ready to be issued after adoption of the relevant new safety regulation, and additional safety guides (e.g. “Safety in Activities with Gamma Irradiators) are being prepared.

A plan for further development of safety guides has been created and is continuously updated.

A graded approach was applied to the assessment of the areas where specific guides are needed and to the identification of the respective level of details.

For identified areas, existing international guides and standards (e.g. IAEA, EN, IEC, ISO) were considered and, as applicable, used as basis for the development of the BNRA safety guides.

Status of the finding in the initial mission

Recommendation 11 (R11) is closed on the basis of progress and confidence in the effective completion as BNRA has developed several regulatory guides, while more are under preparation.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- 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).

Changes since the initial IRRS mission

Suggestion 19: In the draft new regulation “Ensuring the Safety of Nuclear Power Plants” a section on periodic safety review is included. One of the areas covered is human factors.

In the draft safety guide “Periodic Safety Review for Nuclear Power Plants” more detailed requirements regarding Human Factors (HF) are included. The guide is based on the WENRA Reference Levels and on IAEA SSG-25 “Periodic Safety Review for Nuclear Power Plants”. The scope and detailed requirements for “Human Factors Issues” are included in an Appendix.

Until the draft regulation and the safety guide are approved and would be available, BNRA had issued immediately after the IRRS mission in 2013 a policy paper informing the licensee on pending changes/amendments in the contents of the scheduled PSRs and the new boundary conditions. The plan to revise the corresponding requirements and issue a safety guide for “Periodic Safety Review for Nuclear Power Plants” was also communicated.

Status of the finding in the initial mission

Suggestion 19 (S19) is closed as the revision of the requirements and development of a new safety guide covering the topic of PSR show that the human factor aspects are sufficiently covered.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

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

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.
S21	Suggestion: BNRA should consider modifying the classification of radioactive waste to be in line with the IAEA international classification.
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”.

Changes since the initial IRRS mission

Suggestion 20: The “Regulation on Radioactive Waste Management” has been revised and adopted, and now includes some clarifications in Chapter Eleven – Safety Assessment. Article 60 indicates some conditions to the timescales for maximum radiological impact for the different facilities; requirements concerning initiating events (Article 31); scenarios for unlikely events and human intrusion (Article. 60, para.3); as well as for model implementation and other assumptions in Articles 57, 58, 59 and requirements concerning record maintenance in Article 44 and Article 50.

A new guide “Post-closure Safety Assessment of Near-surface Disposal Facility” is planned to be developed as one of the regulatory guides covering different issues related to the decommissioning and waste management under a contract with RISKAUDIT. Conditions for closure of Radioactive Waste Disposal Facilities, including the licensing aspects are foreseen to be included in another guide under the same contract. RISKAUDIT is expected to propose a

structure and contents of the new guide. The IRRS Team was informed that the scope will include a practical implementation of the regulatory requirements, detailed instructions to the licensee for the application of the requirements concerning long term safety (modelling scenarios, consideration of human intrusion, record maintenance, timescale for radiological criteria, etc.) in the context of the post-closure safety assessment.

Suggestion 21: A revision of the “Regulation on the Safety of Radioactive Waste Management” has been made by BNRA. In Chapter Four – “Radioactive waste classification” of the new regulation, six radioactive waste categories are defined in compliance with the IAEA RAW classification.

VLLW is waste with levels of specific activity slightly exceeding the clearance levels, established by the “Regulation on Basic Norms for Radiation Protection”. According to these regulations, for such type of waste, the application of specific measures for radiation protection is not required and a high level of isolation and containment are not necessary. This category waste can be landfill disposed according to Art.18 of the “Regulation on the Safety of Radioactive Waste Management”. For this category waste there is also a legislative framework for the application of the concept for release from regulatory control.

Suggestion 22: BNRA has reviewed the requirements relating to dose constraints for the protection of the public in the revised “Regulation on Safe Management of Radioactive Waste” and made them consistent with the existing “Regulation on Basic Norms of Radiation Protection”. Dose constraints for the public exposure are synchronized between the two regulations.

Status of the finding in the initial mission

Suggestion 20 (S20) is closed on the basis of progress and confidence in the effective completion of the development of the guide, scheduled to be finalized in September 2016.

Suggestion 21 (S21) is closed based on the new classification of radioactive waste which complies with the IAEA RAW classification.

Suggestion 22 (S22) is closed as dose constraints in the regulations for the management of radioactive waste are consistent with the “Regulation on Basic Norms of Radiation Protection”.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES

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

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

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

9.7. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S23 **Suggestion:** BNRA should implement a notification process in case of non-compliance in transport activities.

Changes since the initial IRRS mission

Suggestion 23: A notification process in the case of non-compliance is introduced in Article 55 of the “Regulation on the Conditions and Procedure of Transport of Radioactive Material”, which has been amended and published in 2014.

The regulation states the responsibilities of the consignor and/or the licensed carrier to notify BNRA in case of any event in nuclear facilities and facilities with SIR, to take appropriate actions to mitigate the consequences of the event and to prevent a recurrence of similar circumstances.

Instructions to the involved parties - carrier, consignor and consignee - on the practical implementation of the Regulatory requirements are presented in the regulatory guide “Safe Transport of Radioactive Material – Management of Non-compliance”. The guide covers the main topics in case of non-compliance with a regulatory limit applicable to radiation level or to radioactivity contamination.

Status of the finding in the initial mission

Suggestion 23 (S23) is closed as BNRA has established a notification process in the case of non-compliance in transport activities.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL REQUIREMENTS

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

10.2. FUNCTIONAL REQUIREMENTS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- | | |
|------------|---|
| 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. |
| 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. |
| S25 | Suggestion: BNRA should consider reducing the time limit of four hours currently defined in its plan for the first press release. |

Changes since the initial IRRS mission

Suggestion 24: BNRA formalized its notification system. A 24/7 on-call duty officer position has been established and the technical personnel of the Division of Emergency Planning and Preparedness (emergency division in subsequent text) have been officially appointed to this position by the BNRA chairman. The personnel rotate weekly with handovers on the first working day in a week at 11am. The on-call officer has a procedure to follow for responding to notifications and for the handover. The on-call officer uses a dedicated official mobile phone for receiving notifications and for communicating with other BNRA staff. The backup of the on-call officer is the head of the emergency division.

The BNRA emergency plan was updated to reflect this change. The weekly rotation of personnel for on-call officer duty is planned three months in advance. The plan is approved by the director of the Nuclear Safety Department of BNRA.

In order to improve the emergency team availability, BNRA introduced a system for tracking availability of the emergency team personnel. The BNRA technical secretary prepares a list of availabilities for all team positions on the first working day in a week. The list is given to the head of the emergency division as an input for the two-month plan for emergency team availability. In case of a problem (e.g. a lot of personnel not present for a given time), consultation with the BNRA chairman is foreseen, followed by necessary actions.

In addition, BNRA reorganized the emergency team composition, merging the team for response to nuclear emergencies and the team for response to radiological emergencies into a single team to provide higher availability of personnel for specific team positions.

Recommendation 12: BNRA initiated meetings with the regulatory authority of Romania (CNCAN) in the name of the Bulgarian Government. There were two meetings held at the IAEA headquarters (May and September 2015) and one at BNRA headquarters in January 2016. An agreement was signed between BNRA and CNCAN at the January meeting to cooperate in the

following areas: nuclear safety, regulatory control and exchange of information in case of an emergency. The agreement forms the basis for solving the issue of cross-border harmonization. BNRA and CNCAN agreed to hold regular meetings, two to three times per year.

CNCAN informed BNRA that local authorities in the 30 km zone around the Kozloduy NPP are instructed to act upon a notification from the NPP shift supervisor. BNRA proposed as a solution that the NPP notifies the local authorities in Romania at the same time as the local authorities in Bulgaria. CNCAN proposed a single point of contact for notification of local authorities in Romania.

At the date of the IRRS follow-up mission, BNRA was working with the NPP on changing the on-site emergency plan to include direct notification of local authorities in Romania. The NPP already translated notification forms to Romanian and English. A change in the regulation on emergency preparedness and response was also planned to reflect this new direct notification across the border. The contact point for Romanian local authorities was not provided yet.

Suggestion 25: BNRA reduced the time limit from four to two hours maximum. The BNRA emergency plan has been updated to reflect the change.

Status of the finding in the initial mission

Suggestion 24 (S24) is closed as BNRA has formally established a roster for duty officers and implemented a system to ensure availability of emergency team.

Recommendation 12 (R12) is closed on the basis of progress and confidence in completion as a formal agreement between BNRA and CNCAN provides a crucial step for harmonization between both countries.

Suggestion 25 (S25) is closed as the time limit for the first press release has been reduced in the BNRA emergency plan.

10.3. REQUIREMENTS FOR INFRASTRUCTURE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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).
S26	Suggestion: BNRA should consider including the communication arrangements into its emergency plan, in order to have them properly documented.
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).
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).

Changes since the initial IRRS mission

Recommendation 13: Introducing systematic emergency training was an important undertaking. Therefore, BNRA requested assistance from the IAEA, formulated in the technical cooperation project BUL9/024 on "Implementation of National Program for Systematic Training of the Emergency Team of BNRA for Improving the Emergency Preparedness and Response". The project included consultancies at the IAEA and at BNRA, and scientific visits to Finland and Hungary. It was completed successfully in December 2015.

BNRA approved a "Procedure on Emergency Training" (QMS-EP-1-06) in March 2016. The procedure includes a matrix of competences, types of trainings (initial, periodic), levels of expertise, a list of courses, as well as instructions for conducting training courses and records keeping, among others.

The emergency training is now part of the overall training scheme of BNRA. The annual BNRA training plan contains a special section on emergency training, and is approved by the BNRA chairman. The use of an integrated organizational plan for training ensures a better coordination in this area.

Records of trainings are kept for each emergency team member in order to ensure sufficient participation.

Only few training events were organized so far; more were planned for the rest of 2016. The special initial training was on-going, because new staff had recently joined BNRA.

Suggestion 26: BNRA improved its emergency plan by including all emergency communication arrangements.

Suggestion 27: BNRA approved a new procedure (QMS-EP-I-05) on testing and ensuring emergency supplies, equipment, communications and facilities. The procedure lists all items and gives instructions on their testing, including testing period and criteria for successful completion of tests. It also contains checklists to be used during actual tests.

In addition, two existing procedures on the diesel generator (QMS-EP-G-09) and on equipment for field use (QMS-EP-I-01) were amended to include availability and testing of supplies for the diesel generator and the equipment.

Suggestion 28: The upgraded BNRA management system now also covers all emergency procedures, instructions and guidance. The documents are available in hardcopies in the emergency centre as controlled copies and in electronic format in pdf at the BNRA shared space on the internal network and, in addition, at the emergency centre shared space.

Status of the finding in the initial mission

Recommendation 13 (R13) is closed as BNRA has introduced emergency training systematically and started the implementation of the annual emergency training program for 2016.

Suggestion 26 (S26) is closed as BNRA updated its emergency plan by including communication arrangements.

Suggestion 27 (S27) is closed as BNRA approved new internal procedures to ensure availability of its emergency supplies and equipment.

Suggestion 28 (S28) is closed as the upgraded BNRA management system now also covers all emergency procedures, instructions and guidance.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
R14	Recommendation: The MoH should ensure that generic justification of radiological procedures is carried out in conjunction with the appropriate professional bodies.
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.
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.
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.

Changes since the initial IRRS mission

Recommendation 14: The MoH plans to officially establish an Expert Council on Medical Exposure, which is already providing advice and support to medical exposure issues.

According to Article 3 of draft Decree No.30, the Expert Council will consist of national consultants in radiotherapy, diagnostic imaging, nuclear medicine and invasive cardiology, a representative of the Bulgarian Association of Radiology and the Bulgarian Society of Biomedical Physics and Engineering. The Expert Council will have the responsibility to "consider and give opinions on the introduction of new methods and new radiological procedures related to medical exposure, which are not included in the medical standards in radiotherapy, diagnostic imaging, nuclear medicine and invasive cardiology". The existing Article 17 of the Ordinance No.30 of 2005, which refers to the justification of screening programs, will also be included in the amended Decree No.30. For existing medical practices, the procedure for Authorization of Activities with SIR, QMS-LA-P-02, 2016, is applied, which sets criteria, requirements and rules for grounds of new and already approved practices with SIR for medical exposure.

Decree No.30 is expected to be published in autumn 2016.

Suggestion 29: The National Consultant in diagnostic imaging (i.e. the Bulgarian Association of Radiology) sent a letter to the National Health Insurance Fund proposing that "in specific clinical cases, the diagnostic imaging expert may change or refuse diagnostic radiation justifying its decision in the interest of the patient, without ceasing reporting on the clinical pathway".

The proposal of the National Consultant in diagnostic imaging will be introduced into the amendments to Decree No.30 on the “Terms and Conditions for the Protection of Individuals Subject to Medical Exposure”.

Suggestion 30: The MoH introduced relevant requirements in the draft Decree No.30., including provisions regarding

- the types of x-ray equipment that must have a calibrated measuring device traceable to secondary dosimetry standards;
- availability of patient dose registers and dosimetry phantoms for quality assurance of newly installed angiographic systems, CT scanners, digital X-ray radiology systems and mammography systems.
- re-calibration frequencies.

It was explained to the IRRS Team that the Secondary Standard Dosimetry Laboratory of the MoH has basic necessary diagnostic radiology level calibration and measurement capabilities.

Suggestion 31: BNRA and the MoH amended the “Regulation on the Terms and Procedure for Obtaining of Vocational Qualification and on the Procedure for Issuing of licenses for Specialized Training and of Individual Licenses for Use of Nuclear Power”. The regulation covers both nuclear and non-nuclear activities, including medical exposure.

According to the regulation, there are three professional groups. Professionals from two of these groups require training, the third being a group of qualified radiation protection experts. The regulation identifies the professionals that do not require individual licenses, like medical physicists, or individuals not directly involved in activities with SIR. In this respect the number of people for whom training is considered necessary has decreased.

In February 2016, one more organization was licensed for conducting specialized training.

BNRA stated that with the new development of the revised regulation and the additional training provider, the number of organizations which conduct specialized training for activities with SIR is sufficient to cover the needs for training of health professionals involved in medical exposure.

The regulation also provides elements of the training curricula, in order to enhance homogeneity. Its Appendix defines the minimum obligatory courses included in the training programs of all licensees who carry out specialized training, including health professionals involved in medical exposure.

BNRA amended the licenses of the organizations which carry out specialized training and reviewed the training programs submitted by the licensees.

Status of the finding in the initial mission

Recommendation 14 (R14) is closed on the basis of progress and confidence in the effective completion as a draft decree is expected to be adopted by autumn 2016.

Suggestion 29 (S29) is closed on the basis of progress and confidence in the effective completion as a draft decree is expected to be adopted by autumn 2016.

Suggestion 30 (S30) is closed on the basis of progress and confidence in the effective completion as a draft decree is expected to be adopted by autumn 2016.

Suggestion 31 (S31) is closed as the regulation on training for radiation workers has been adopted.

11.2. OCCUPATIONAL RADIATION PROTECTION

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.

Recommendation: BNRA and NCRRP should:

R15 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.

Changes since the initial IRRS mission

Suggestion 32: According to the MoH “Standard Operating Procedure for Carrying out Inspections at Sites with SIR”, during inspection, the inspectors are required to make a review of individual doses and the relevant operating procedures and their implementation. If they find that there has been an increase in individual doses over time, the inspectors are required to make recommendations for optimization of doses for radiation workers.

Every year, the MoH prepares a national report on the doses to workers and the population and provides guidance and recommendations for dose optimization. A sample annual report was presented to the IRRS Team. It included analytical data and assessments for different nuclear and non-nuclear, occupationally exposed workers (e.g. radiologists, cardiologists, industrial radiographers, etc.).

Revision of the legislation concerning the optimization of occupational radiation protection is also foreseen upon the transposition of the EC Directive 2013/59/Euratom.

Recommendation 15: Individual monitoring for extremities is carried out for about 100 persons from nuclear medicine facilities (PET-scanners) and working in dismantling of ionization chamber smoke detectors at the State Enterprise (SE) “Radioactive Wastes”.

For such facilities BNRA requires the licensee to provide for personal dosimetry for its radiation workers, for both effective dose and extremities. Dose constraints are also set as 8mSv for effective dose and 200mSv for equivalent dose of extremities.

With regard to personal dosimetry of lens of the eye, the MoH conducted a study of the medical procedures under X-ray control in order to assess the individual equivalent dose of ophthalmic lens for medical personnel. Several publications have been made in peer reviewed scientific journals. These results will be used as a basis for specifying the requirements of the draft Decree

No.32 on the “Terms and Conditions for Carrying out Individual Dosimetric Control of Persons Working With SIR”, which has been initiated in June 2015.

Presently, eye lens dosimetry is performed for surveys and projects and not as a routine dosimetry service to radiation workers. However, the routine dosimetry service for eye lens is foreseen to be carried out upon the completion of surveys and projects, as required.

Neutron dosimetry is performed for 100 occupationally exposed workers at 8 facilities (linear accelerators for radiotherapy and cyclotrons for the production of isotopes for PET-scanners) and Kozloduy NPP. The service is provided by the “Laboratorii Protekta” OOD and its contracted enterprise Celostátní služba osobní dozimetrie, s.r.o.(CSOD). CSOD is authorized by the regulatory authority of the Czech Republic, State Office for Nuclear Safety. However, CSOD has not been accredited in terms of ISO 17025.

Suggestion 33: The MoH has contacted the Institute for Radiological Protection and Nuclear Safety (IRSN), France, and the Greek Atomic Energy Commission (GAEC), for conclusion of a memorandum for bio-substrate measurement. However, this has not been finalized yet and there is currently no memorandum of understanding between the MoH and other laboratories.

Status of the finding in the initial mission

Suggestion 32 (S32) is closed as the MoH prepares annual reports on analysis of occupational radiation exposure for all radiation workers.

Recommendation 15 (R15) is closed on the basis of progress and confidence in the effective completion as it is foreseen that routine dosimetry service for the eye lens will be carried out upon the completion of surveys and projects, whereas neutron monitoring services are already provided by an authorized organization.

Suggestion 33 (S33) is closed on the basis of progress and confidence in the effective completion as the MoH is in the process of establishing an MoU for bioassay measurements with laboratories abroad.

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

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.
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Changes since the initial IRRS mission

Suggestion 34: In order to optimize the work of the inspectors and to unify the approach and the method for the definition of adequate terms in the licenses issued by BNRA for activities with SIR, the “Procedure for Authorization of Activities with SIR” has been revised. The discharges from the unsealed sources including medical activities are regulated by this revised procedure.

The monitoring of discharges is conducted based on the licensing requirements. Discharge limits are established as conditions of the licence for operation with SIR and activities on facilities, in which radioactive discharges are expected.

Status of the finding in the initial mission

Suggestion 34 (S34) is closed as discharge limits are established by licence conditions and are monitored.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

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

12.2. REGULATORY OVERSIGHT ACTIVITY

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

12.3. INTERFACE WITH OTHER AUTHORITIES

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

IRRS FOLLOW-UP MISSION TEAM



APPENDIX I - LIST OF PARTICIPANTS

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APPENDIX II - MISSION PROGRAMME

Time	MON - 11 April	TUE - 12 April	WED - 13 April	THU - 14 April	FRI - 15 April	SAT - 16 April	SUN - 17 April	MON - 18 April
9:00-10:00	Arrival of Team Members	Entrance Meeting	Interviews	TM write Report TL and DTL review introductory part		Discussion Counterpart/Expert		Exit Meeting
10:00-11:00				Interviews	Draft text to TL			
11:00-12:00		Lunch				Lunch		Lunch
12:00-12:30			Lunch		Lunch			
12:30-13:30		Interviews		Lunch		Lunch		Lunch
13:30-15:00	Interviews		Interviews		Secretariat edits the report		Cross-reading	
15:00-16:00		Interviews		Interviews		Secretariat edits the report		Cross-reading
16:00-17:00	Initial Team Meeting (Attended by the LO): • IRRS process • Main objectives • Report writing • Schedule • First observations		Daily Team Meeting		Daily Team Meeting: Discussion of findings		Daily Team Meeting	
17:00-18:00		Dinner		Dinner		Dinner		Dinner
18:00-19:00	Dinner		Dinner		Dinner		Dinner	
19:00-20:00		Dinner		Dinner		Dinner		Dinner
20:00-	Dinner		Writing of the report		Secretariat edits Report TM write Report		TM Read Draft	

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	BNRA Lead Counterpart	BNRA Support Staff
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT		
	ZIAKOVA Marta ROOS Gerhard	KOSTOV Latchesar	DIMITROVA Yuliya, STANCHEV Valentin, KUNCHEV Angel, TASEV Iliya, HADJIDEKOVA Valeria, DJUNOVA Zhana, ORLIN Stoyanov
2.	GLOBAL NUCLEAR SAFETY REGIME		
	ZIAKOVA Marta ROOS Gerhard	ROGATCHEV Alexander	VLAHOV Nikolay
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
	ZIAKOVA Marta ROOS Gerhard	DIMITROVA Yuliya KUNCHEV Angel	KATZARSKA Lidia, VLAHOV Nikolay, TASEV Iliya, HADJIDEKOVA Valeria, ORLIN Stoyanov
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
	ZIAKOVA Marta ROOS Gerhard	VASILEVA Neli	
5.	AUTHORIZATION		
	MANSOOR Faizan JUBIN Jean-Rene	TODOROV Nikolay	VLAHOV Nikolay, DTANCHEV Valentin, TODOROVA Victoria, KAZAKOVA Svetla, DOSIEVA Deyana
6.	REVIEW AND ASSESSMENT		
	MANSOOR Faizan JUBIN Jean-Rene	GANCHEV Tinko	TODOROVA Victoria, DOSIEVA Deyana

	IRRS Experts	BNRA Lead Counterpart	BNRA Support Staff
7.	INSPECTION		
	MANSOOR Faizan JUBIN Jean-Rene	DRAGANOV Veselin TODOROV Nikolay KUNCHEV Angel	BOTSOEV Hristo, KAZAKOVA Svetla, DOSIEVA Deyana, TASEV Iliya, PAVLOVA Mimi, ORLIN Stoyanov
8.	ENFORCEMENT		
	MANSOOR Faizan JUBIN Jean-Rene	STOYANOVA Pepa	BOTSOEV Hristo, KAZAKOVA Svetla, DOSIEVA Deyana, TASEV Iliya, PAVLOVA Mimi, ORLIN Stoyanov
9.	REGULATIONS AND GUIDES		
	ZIAKOVA Marta ROOS Gerhard	ALEXIEV Alexey	GANCHEV Tinko, TODOROV Nikolay, STANCHEV Valentin, KATZARSKA Lidia, BONEV Emil
10.	EMERGENCY PREPAREDNESS AND RESPONSE		
	TKAVC Marjan	NIZAMSKA Marina	
11.	CONTROL OF MEDICAL EXPOSURES, OCCUPATIONAL RADIATION PROTECTION, ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION		
	HAILU Teodros HOURDAKIS Costas SNEVE Malgorzata	KUNCHEV Angel	TASEV Iliya, PAVLOVA Mimi, TSRYNCHEV Tsvetelin, ORLIN Stoyanov, DOSIEVA Deyana, SABINOVA Vera, TODOROV Nikolay, BADULIN Victor

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

Section	Module	R/S	Recommendation/Suggestion
1.7.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	S2	The Government should consider making further provisions for maintaining the competence of a sufficient number of suitably qualified and experienced staff in BNRA.
3.3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R3	The MoH should ensure that there are sufficient human resources to fulfil the regulatory duties of its inspection divisions.
5.2.	AUTHORIZATION	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.
8.1.	ENFORCEMENT	R10	BNRA should establish and implement a formal, documented, enforcement policy.
8.1.	ENFORCEMENT	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.

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2016 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
3.3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	SF1	BNRA should consider continuing negotiations with the Council of Ministers and Ministry of Finance for a higher budget for salaries to be able to pay competitive salaries to reduce the high turnover of staff.
7.1.	INSPECTION	SF2	The MOH should consider developing a formal systematic inspection programme which establishes a frequency of inspections to ensure that the inspections cover all facilities and activities regulated by the MoH within a given period, in accordance with a graded approach.

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY BNRA

1. Letter to appoint BNRA participants in MoH regulations working groups
 - available in Bulgarian only
2. Orders of the Minister of Health for working groups established to elaborate the regulations under art.65 of Health Law
 - available in Bulgarian only
3. Memorandum of Understanding of 25.09.2015
 - available in Bulgarian only
4. Joint Inspection Program
 - available in Bulgarian and English
5. Draft Programme for Investigating the Possibility for Construction of a Geological Disposal Facility for HLW and ILW, Category 2b
 - available in Bulgarian and English
6. SERAW Letter No. 71-00-113 of 2 September 2013 to the NRA – Invitation letter for of a NRA representative in the working group for elaboration of a “Programme for Investigating the Possibility for Construction of a Geological Disposal Facility for HLW and ILW, Category 2b”
 - available in Bulgarian only
7. State Enterprise Radioactive Waste (SERAW) Letter No. P-04-14-2756 of 06 October 2014 to the Ministry of Energy – the SERAW submit to the Ministry of Energy the draft of a “Programme for Investigating the Possibility for Construction of a Geological Disposal Facility for HLW and ILW, Category 2b”
 - available in Bulgarian only
8. Ministry of Energy Letter No. 02-00-119 of 4 June 2015 to the NRA – An updated information on the current status of the “Development of a Programme for Investigating the Possibility for Construction of a Geological Disposal Facility for HLW and ILW, Category 2b” of the “Action plan according to the Strategy for Spent Nuclear Fuel Management and Radioactive waste Management until 2030”
 - available in Bulgarian only
9. Letters to the Government and Parliament
 - available in Bulgarian only
10. List of selection procedures 2013-2015
 - available in Bulgarian only
11. Obligations of the State Administration Officials in Connection with the Prevention of Conflict of Interest and Compliance with Ethical Standards
 - available in Bulgarian only
12. Protocol № ПД-35-85 dated 04.06.2015 on the instruction of the BNRA staff from the NPP "Kozloduy" Resident Control Division
 - available in Bulgarian only
13. Decree № 36 on the terms and conditions for exercising state health control of the Minister of Health
 - available in Bulgarian

14. Operational rules of the NSAC to the Chairman of the BNRA, QMS-MO-P-01
 - available in Bulgarian only, extracts in English
15. Operational Rules of the ACRP to the Chairman of the BNRA, QMS-MO-P-02
 - available in Bulgarian only, extracts in English
16. Decree ПД-26-96/04.06.2015 for determining the composition of the NSAC
 - available in Bulgarian only
17. Decree ПД-22-101/24.2.2014 for determining the composition of the ACRP
 - available in Bulgarian only
18. BNRA Qualification and Training Procedure
 - draft, available in Bulgarian only
19. Summary of Analyses of BNRA competence - report RD-35-23/29.01.2016
 - available in Bulgarian and English
20. Program for the development and implementation of an IMS
 - available in English
21. Minutes of training - RD-35-138/02.09.2015, RD-35-participation 148/28.09.2015, RD-35-195/27.11.2015
 - available in Bulgarian only
22. Plan for the revision of IMS documents for the year of 2016
 - available in Bulgarian only
23. IMS Manual Content
 - available in English
24. Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy
 - extract
25. Safety Guide Release of Buildings and Sites from Regulatory Control PP-11/2016
 - Content in English
26. Programme of the IAEA seminar
 - available in English
27. Report ПД-35-88/10.06.2015
 - available in Bulgarian only
28. Draft text for amendment of the Regulation
 - available in Bulgarian and English
29. Regulation for Safe Management of Radioactive Waste, Promulgated in the SG No. 76 of 30 August 2013
 - available in English
30. Plan for the Development of Regulatory Guidelines (according to the Recommendations and Suggestions from the IRRS Mission of the IAEA, 2013)
 - available in Bulgarian only
31. “Annual Program for the Period April 2015 – March 2016” under Contract No. 582/08 “Assistance to the Bulgarian Nuclear Regulatory Agency (BNRA) in Activities relating to the Decommissioning of Kozloduy NPP Units 1-4”
 - available in English
32. Procedure for Authorization of Activities with SIR, QMS-LA-P-02, 2016

- extract
- 33. Procedure for Analysis and Assessment of Documents, Related to the Safe Use of SIR, QMS-AA-P-02, 2016
 - available in Bulgarian only
- 34. Procedure for Authorization of Activities with SIR, QMS-LA-P-02, 2016
 - extract
- 35. “Procedure for analyses and assessment of documents related to safe usage of SIR (identical № QMS-AA-P-02, 2016)
 - available in Bulgarian only
- 36. Procedure for Authorization of Activities with SIR, QMS-LA-P-02, 2016
 - extract

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GSR PART 3** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
4. **IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
6. **IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
7. **IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
8. **IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
9. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.1**- Organization and Staffing of the Regulatory Body for Nuclear Facilities
10. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
11. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3**- Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
13. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
14. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.1** - Application of the Management System for Facilities and Activities
15. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
16. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
17. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
18. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
19. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.11** - A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

APPENDIX VIII - BNRA ORGANIZATIONAL CHART

