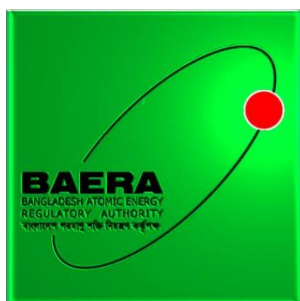


**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
MISSION
TO
BANGLADESH**

Dhaka, Bangladesh

27 November to 8 December 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



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**REPORT OF THE
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Mission dates:	<i>27 November to 8 December 2022</i>
Regulatory body visited:	<i>Bangladesh Atomic Energy Regulatory Authority (BAERA)</i>
Location:	<i>Dhaka, Bangladesh</i>
Regulated facilities, activities, and exposure situations in the mission scope:	<i>Nuclear power plants, research reactors, waste management facilities, radiation sources facilities and activities, emergency preparedness and response, transport, decommissioning, patient protection in medical exposures, occupational exposure control, environmental monitoring, control of discharges and public exposure</i>
Organized by:	<i>IAEA</i>

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IAEA-2022

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

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EXECUTIVE SUMMARY

At the request of the Government of Bangladesh, an international team of senior safety experts met representatives of the Bangladesh Atomic Energy Regulatory Authority (BAERA) at its headquarters, from 27 November to 8 December 2022, to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at BAERA headquarters in Dhaka. This was the first full scope IRRS mission that Bangladesh has hosted since IRRS programme began in 2006.

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

The IRRS team consisted of 15 senior regulatory experts from 10 IAEA Member States, and 6 IAEA staff members. The Bangladeshi counterparts for the mission were mainly from BAERA and representatives from the Ministry of Sciences and Technology also participated in the mission.

The review covered the IRRS core modules 1 to 10: the responsibilities and functions of the government, the global safety regime, the responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, development of regulations and guides, and emergency preparedness and response. The review did not include the optional module on safety and security interface, as an IPPAS mission is scheduled for 2023. Facilities, activities, and exposure situations reviewed included nuclear power plants, research reactor, radioactive waste management facilities and decommissioning, radiation sources in industrial, agricultural, research and medical applications, transport of radioactive materials, occupational exposure, medical exposure, and public exposure.

In preparation for the IRRS mission, BAERA conducted a self-assessment and prepared a preliminary action plan to address areas that it had identified for improvement. The results of the self-assessment and other supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all the topics presented in the advance reference material. The IRRS team recognised the extensive preparation and assessment work undertaken by BAERA and the dedication of its staff.

The IRRS mission included discussion on two policy issues: Use of vendor country's codes and standards and regulations and interaction with stakeholders, during which members of the IRRS team and senior staff of BAERA shared views and regulatory experiences. The mission also included observations of regulatory activities, as well as interviews and discussions with management and staff of BAERA including the Chairman, who is also President of the Advisory Council.

As part of the mission, visits were undertaken to Rooppur Nuclear Power Plant Project Site at Ishwardi, BAEC TRIGA Research Reactor, Central Radioactive Waste Processing and Storage Facility at AERE, Savar, Institute of Nuclear Medicine and Allied Science, Square Hospital, Bangladesh Industrial X-ray in Dhaka. The IRRS team observed regulated activities and the performance of inspection activities, including discussions with the licensee personnel and management. Senior members of the IRRS team met the Minister, Senior Secretary and officials of the Ministry of Science and Technology and the Project Director of Rooppur Nuclear Power Plant Project. Discussions with the ministry focused on the responsibilities and functions of the government, national policies, and the regulatory framework for safety and the function and independence of BAERA.

As a country with an embryonic nuclear power programme, Bangladesh is engaged in a major undertaking for the supervision of the construction and safe commissioning of Rooppur NPP. This was recognized by the Bangladesh Government, taking numerous measures, such as:

- Establishing BAERA as an independent regulatory body for oversight of nuclear and radiation safety of facilities and activities on the basis of the BAER Act;
- Updating the legal framework for nuclear and radiation safety by commencing the revision to the NSRC Rules, which define the fundamental principles and rules to be applied for the protection of workers, the public, and the environment;
- Seeking to enhance the competence of BAERA to perform its regulatory functions effectively and to oversee the work performed by the technical support organizations in regulatory functions such as review, assessment, and inspection.

There is strong support and advocacy at the highest level in the Bangladesh government for the role and function of BAERA as the independent nuclear and radiation safety regulator in Bangladesh. The government's commitment to ensure that BAERA delivers its mandate extends to the full approval of its operational and development budgets.

The IRRS team recognized that Bangladesh has a committed regulatory body for ensuring continuous improvement of safety and the protection of people and the environment, in part demonstrated by inviting the IRRS mission. However, the independence of BAERA's regulatory decision making is paramount and the Government needs to ensure that this is protected.

The Government continues to provide support and resources for BAERA to enable it to grow its capability and capacity to maintain effective oversight of all nuclear and radiation facilities and activities in Bangladesh.

The IRRS team identified areas of good performance of BAERA, including in relation to the use of expert committees to inform regulatory decision making associated with the NPP, use and availability of the TSO on the Rooppur NPP site, and the establishment of the BAERA Code of Ethics which provide clear commitment to an ethical approach in its regulatory activities.

The IRRS team identified issues which need improvement and believes that consideration of these will enhance the overall performance of the regulatory framework in Bangladesh.

The IRRS team recognized that BAERA continues to update its regulatory requirements, ensuring alignment with the IAEA Safety Standards, and encouraged BAERA to further enhance the regulatory framework for the effective oversight of facilities and activities.

The IRRS team made a number of observations during the mission. Areas that warrant specific mention and focus are highlighted here:

- Establishing a comprehensive national policy and strategy for safety in accordance with the IAEA fundamental safety objective and principles, and developing and implementing a strategy to apply and implement the policy following a graded approach
- Completing the revision of the NSRC Rules and issuing associated regulations and guides.
- Developing BAERA's human resource plan to ensure that there is a sufficient number of competent, trained, qualified, and certified staff to perform all its functions effectively, ensuring an appropriate level of oversight of all facilities and activities
- Ensuring BAERA effectively implements a fully documented safety management system across all the organisation, ensuring it clearly assigns roles, responsibilities and authorities

- The need for BAERA to ensure that a national dose register and a framework for the protection and safety of the public against exposure that includes an assessment of doses is established and maintained
- The need for BAERA to establish appropriate mechanisms for informing and consulting with interested parties, including the public, on the radiation risks associated with facilities and activities, regulatory processes and significant decisions of the regulatory body and amendments to regulations and guides, in a transparent manner
- The need for BAERA to ensure operating organizations develop, implement, and routinely test their emergency preparedness and response arrangements and establish arrangements for the review and provision of advice on off-site emergency plans to the Government and response organizations

The IRRS team acknowledged that some of the issues have already been identified in BAERA's action plan for improving the national regulatory infrastructure as a result of its self-assessment.

This report identifies areas for improvement that need to be addressed to improve the legal and regulatory framework for nuclear and radiation safety in Bangladesh. As a country with plans for a significant nuclear power programme, it is important that the Government of Bangladesh and BAERA work together to deliver the cultural and transformational improvements required.

The IRRS team acknowledges the full support and cooperation of BAERA and all other parties participating in the IRRS mission to Bangladesh. The reviews of regulatory, technical, and policy issues were conducted in a constructive, open and transparent manner throughout the mission.

I. INTRODUCTION

At the request of the Government of Bangladesh, an international team of senior safety experts met representatives of the Bangladesh Atomic energy Regulatory Authority (BAERA) from 27 November to 8 December 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the governmental, legal and regulatory framework for nuclear and radiation safety of Bangladesh. The review mission was formally requested by the Government of Bangladesh in October 2017. A preparatory meeting was conducted 7-8 May 2019; however, the mission was postponed twice due to unforeseen circumstances. On request of BAERA, a second preparatory meeting was organized at the IAEA Headquarters in Vienna on 26-27 April 2022 to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Bangladesh and their related safety aspects and to confirm the scope of the IRRS mission, the status of the self-assessment, and the logistics for the mission.

The IRRS team consisted of 15 senior regulatory experts from 10 IAEA Member States and 6 IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response. The scope of regulatory activities reviewed during the mission covered nuclear power plant, research reactor, waste management facilities and decommissioning activities, radiation sources facilities and activities in industrial and medical applications, transport of radioactive material, occupational radiation protection, control of medical exposure, public and environmental exposure control. In addition, two policy issues were discussed, namely Using vendor's codes and standards and regulations and Interaction with stakeholders.

BAERA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of BAERA self-assessment and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the Bangladesh advance reference material, conduct of interviews with management and staff from BAERA and direct observation of BAERA regulatory activities at regulated facilities. In addition, the Team Leads held a meeting with the Minister of Science and Technology represented by officials of the Ministry of Science and Technology and the Project Director of the Rooppur Nuclear Power Plant Project.

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

II. OBJECTIVE AND SCOPE

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

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Bangladesh, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 7 to 8 May 2019 in BAERA. However, the mission was postponed twice due to unforeseen circumstances. A second preparatory meeting was organized at the IAEA Headquarters in Vienna on 26-27 April 2022. It was carried out by the appointed Team Leader Mr Mark Foy, Deputy Team Leader Mr Michael Franovich and the IRRS IAEA Team representatives, Mr Zia Shah and Mr Hilaire Mansoux.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of BAERA, Engr. Md. Muzammel Haque, Chairman BAERA, Dr. Satyajit Ghose, Project Director of Nuclear Regulatory Infrastructure Development Project of and other senior management and staff in presence of Mr. Ziaul Hasan, Senior Secretary, Ministry of Science and Technology, Bangladesh. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Research Reactors;
- Radioactive Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control; and
- Selected policy issues.

The BAERA counterparts made presentations on the national context, the current status of BAERA and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Bangladesh in November / December 2022.

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

The BAERA Liaison Officer for the IRRS mission was confirmed as Dr Satyajit Ghose and Dr Debashis Datta as Deputy Liaison Officer.

BAERA provided IAEA with the advance reference material (ARM) for the review at the end of September 2022, in preparation for the mission, the IAEA review team members reviewed the ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Saturday, 26 November 2022 in Dhaka, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission, including the proposed interview schedule between the reviewers and the counterparts.

The IRRS entrance meeting was held on Sunday, 27 November 2022. Opening remarks were made by Engr. Md. Muzammel Haque, Chairman of BAERA. Mr Mark Foy, IRRS Team Leader and Mr. Zia H. Shah Team coordinator gave an overview of the expectations for the mission. Dr. Satyajit Ghose gave an overview of the Bangladeshi context, BAERA activities and the results of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Bangladesh and BAERA with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions with BAERA, visits to facilities and direct observations of regulatory inspections at authorized facilities.

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

The IRRS exit meeting was held on Thursday, 8 December 2022 at BAERA Headquarters. The opening address at the exit meeting was presented by Dr Satyajit Ghose, Project Director, BAERA, followed by speech of Engr. Md. Muzammel Haque, Chairman BAERA. The mission results were presented by the IRRS Team Leader Mr Mark Foy. The official closure of the mission was made by Ms Anna Bradford, IAEA, Director, Division of Nuclear Installation Safety of the IAEA.

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

In 2016, Bangladesh established Vision 2041, which is a strategic effort to modernize the country with the aim of substantially improving economic conditions for its population. Through the government's strategies over the next two decades, Bangladesh is expected to experience an accelerated pace of social and economic change that will be rapid and transformational. The Government's 2021-2041 Perspective Plan, "Making the Vision 2041 a Reality", addresses a broad range of complex economic and infrastructure issues and their associated strategies. To achieve this transformation, the power and energy sector has been identified as a challenge and vital pathway to success. The government estimates an increase of approximately 9.3 percent in energy demand between 2021 and 2041 in-line with increases in GDP under the national plan. Nuclear power is intended to play a significant role within a diversified power and energy portfolio. The government has assigned a high priority to the Rooppur nuclear power plant project. The plan further notes that in developing the nuclear power option, the Government will review experience with nuclear power to ensure Bangladesh achieves international standards of safety.

Several national policies, laws, and rules shape the Bangladesh Government's agenda for nuclear and radiological safety. The government has had longstanding aspirations for adding nuclear energy to its existing nuclear and radiological programs. For the nuclear power program, the Government approved a Bangladesh Nuclear Power Action Plan (BANPAP) in 2001 which covered all the aspects of safety, security and safeguard issues including the key roles of interested parties. At the time, the plan supplemented existing rules and policies that have been further augmented by various legislative acts and policies. Specifically, two key documents address nuclear and radiation safety issues namely the Bangladesh Atomic Energy Regulatory Act, BAER Act No. 19 of 2012 (BAER Act), establishing BAERA as a new independent regulatory body, and "SRO No 205-Law/97 Nuclear Safety and Radiation Control Rules" (NSRC Rules), which is currently undergoing revision.

The 2022 draft Policy and Strategy of Nuclear Safety and Safety Culture (Nuclear Safety Policy – NSP) contains a proposed requirement for facilities or organizations to apply risk management as a matter of priority. When finalized and enacted, the Nuclear Safety Policy further commits the Bangladesh Government to the highest standards of safety and security. It will reaffirm the Government's commitment to the objectives of the Convention on Nuclear Safety and indicates that Bangladesh will conform to IAEA standards including the Safety Fundamental Principles. The commitments or reaffirmations are expressed in the draft Nuclear Safety Policy.

The IRRS team observed that the BANPAP is over twenty years old and focused on NPP projects. The draft proposed NSP covers only the safety aspects of nuclear facilities and activities in Bangladesh, and it needs to be aligned with the requirements in IAEA safety standard GSR Part 1 (Rev. 1) including radiation facilities and activities. Further, IAEA requires use of a graded approach to safety and regulatory activities. Simply stated, the application of a graded approach is essential to enabling regulatory bodies to use their generally limited resources to ensure the safety and security of nuclear installations, its employees, and the general public. This expectation should be established in a national safety policy and strategy, which should be supported by governing laws. The IRRS team has observed a lack of this overarching expectation. The IRRS team is of the view this deficiency contributes to BAERA's challenges with implementing the graded approach concept and a need for clear strategies. The IRRS team has placed emphasis on this matter supported by numerous observations throughout this report. Issuing the NSP, which the Government has identified in the action plan, provides a path to remedy these issues and the observation below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The existing BANPAP is over twenty years old and focuses on NPPs, and is under review. Bangladesh has not issued a national policy and strategy for nuclear and radiation safety.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 1 states that <i>“National Policy and Strategy for Safety. - The government shall establish a national policy and strategy for safety, the implementation of to apply the fundamental safety principles established in the Safety Fundamentals.”</i>
(2)	BASIS: Safety Fundamentals Principle 3, para. 3.15 states that <i>“Safety has to be assessed for all facilities and activities, consistent with a graded approach.”</i>
R1	Recommendation: The Government should issue a comprehensive national safety policy and strategy for all facilities and activities, which is consistent with IAEA Safety Standards.

The IRRS team observed that the BAER Act requires authorization holders to establish and maintain a safety culture that encourages a questioning and learning attitude for nuclear safety as well as radiation protection and discourages complacency. Similar provisions were also contained in the NSRC 1997 Rules.

BAERA issued its own Code of Ethics in 2018 with a clear commitment to an ethical approach to its regulatory activities with a supporting statement from the BAERA Chairman. The Code of Ethics stipulates expectations for managers and staff regarding behaviours, attitudes, and organisational values directly associated with a strong safety culture. In creating its ethics code, BAERA undertook a benchmarking against the ethics codes and practices of several external organisations (India AERB, Regulatory Affairs Professionals Society, and IEEE). The BAER Act requirements for safety culture for licensees, and the manner in which BAERA developed the Code of Ethics and the quality of the code is considered as an area of good performance.

The IRRS team was informed of ongoing efforts by BAERA to promote safety culture including hosting of workshops with stakeholders and international experts. The IRRS team was of the view that the national level commitment to support and sustain a strong safety culture is well formed and initiatives in this regard should be continued.

The IRRS team considers that through various existing laws and policies, and ongoing efforts to issue modern and updated policies and regulations, the Bangladesh Government is clearly committed to nuclear and radiation safety.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The BAER Act of 2012 provides the principal legal framework for nuclear and radiological safety. The mission, functions and authority of BAERA are detailed in the Act. Section 11 contains 36 specific provisions that clearly establishes the roles and responsibilities of BAERA for carrying out the purposes of the Act and NSRC Rules, with exceptions identified by the team. The BAER Act covers activities and facilities and potential exposures pertinent to Bangladesh. The provisions in the BAER Act establish BAERA as an independent regulatory body with functions for licensing, inspection, review and assessment, enforcement. Types of facilities and activities subject to licensing, spent nuclear fuel and radioactive waste and decommissioning are also defined in the Act, as well as expectations for authorization holders.

To further define the framework for safety, the Government issued a National Policy for the Management of Radioactive Waste and Spent Nuclear Fuel. Two other legislative acts establish requirements regarding the Rooppur NPP project and future nuclear plants. The Bangladesh Atomic Energy Commission Act of 2017 sets responsibilities of BAEC as owner of the NPP and the Nuclear Power Plant Act of 2015 establishes the Nuclear Power Plant Company Bangladesh Limited (NPCBL) as the NPP operator. The

IRRS Team observed that the NPCBL clearly defines the functions of the company and includes clear provision regarding safety and security and adherence to requirements for operations, compatible with the BAER Act provisions.

The national regulatory framework provides for coordination of the regulatory and safety functions of the various authorities having responsibilities for safety and regulation. For the Rooppur NPP, Bangladesh has implemented mechanisms for consultation and to coordinate efforts between many organizations and stakeholders who have roles in nuclear energy development. This mechanism is referred to as a nuclear energy programme implementing organization (NEPIO) for embarking countries.

The IRRS team was provided with details of how the NEPIO operates in practice. Key features are a National Committee under the Prime Minister, Technical Committee under the Minister, MoST, and various working groups for a wide number of issues, as well as a coordination committee under BAEC. During interviews with senior level Government officials, the IRRS team was informed that standard government protocol requires that minutes are prepared summarising outcomes of all meetings and these are made publicly available for transparency.

As an independent regulator, BAERA is responsible for regulating nuclear and radiation safety in all facilities and activities. Coordinating functions with other government entities are outlined in the BAERA management system and further discussed in Section 1.5.

For a graded approach to management of risk of facilities and activities, the IRRS team observed that there is some inherent gradation in regulatory activities. However, the Government has not promulgated laws and statutes regarding a graded approach to licensing, oversight, inspection, and other activities. A systematic application of a graded approach to core regulatory functions is necessary for resource optimization so that the regulatory body can address issues accordingly. There is no uniform approach or strategy within BAERA to establish a graded approach across regulatory activities. The graded approach is also a means for consistent regulatory decision making commensurate with the risk posed by an installation. The IRRS team has several observations regarding inconsistent application of a graded approach. Recommendation R1 in section 1.1 addresses this issue.

The Government of Bangladesh has established a governmental and legal framework for safety that will continue to evolve and mature. However, the regulatory framework warrants improvements in several areas as reflected throughout this report.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Historically the regulatory functions had been within BAEC prior to 2013. The Act firmly establishes BAERA as the safety, security and safeguards regulatory body for all facilities and activities. The BAER Act and NSRC 1997 Rules establish responsible authorities, authorisation process, describe safety and security of radioactive and nuclear materials, nuclear safety, radiation protection, quality assurance, physical protection, illicit trafficking and safeguards, transport and waste safety, emergency preparedness and response, nuclear liability and coverage. The IRRS team was informed that the Act is largely modelled from both IAEA handbooks on nuclear law.

The IRRS team conducted interviews with BAERA members and other senior government officials. There is strong support and advocacy at the highest level in the Bangladesh government for the role and function of BAERA as the independent nuclear and radiation regulator in Bangladesh. The government officials expressed strong commitment to safety, independence of BAERA and ensuring that BAERA is appropriately resourced to deliver its mandate.

The IRRS team noted that the significant prominence of the Rooppur NPP project and its prime importance to Bangladesh, combined with the position of BAERA within the Ministry of Science and Technology, the ministry responsible for the delivery of the NPP project, means there is the potential in the future for the

independence of BAERA’s decision making to be compromised. This arrangement does not satisfy Requirement 4 of GSR Part1 regarding independent decision making of the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The position of BAERA within the Ministry of Science and Technology, which is responsible for the delivery of the Roopur NPP programme, has the potential to compromise the independent decision making of BAERA.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.”</i>
R2	Recommendation: The Government should implement measures that ensure there is no potential to compromise the independent decision making of BAERA

The IRRS team examined the role of the BAERA Advisory Council (AC) and use of outside experts. As empowered by the BAER Act, Section 16, BAERA formed the AC consisting of reputed scientists, engineers, physicians and representatives from different ministries to seek advice on the scientific and regulatory aspects of nuclear safety and radiation protection. The BAER Act is very specific on the membership qualifications and experience required by members of the AC, and that the BAERA Chairman shall preside over the AC and approve the agenda. The IRRS team was informed that candidate members of the AC are nominated by BAERA and appointed by the Government. The IRRS team was informed of AC activities and provided with example meeting minutes which BAERA makes publicly available. Separately, Section 17 provides BAERA with the discretion to form expert committees comprising one or more members, or any of its employees, or one or more invited experts for assisting its functions.

Under its legal authority, BAERA has formed these expert committees a number of times, making effective use of the independent expert technical advice where significant technical challenges needed to be considered by the regulator, it is clear that BAERA has co-opted world leading experts to provide the best advice in these key areas.

The IRRS team was informed of a significant example to illustrate BAERA’s independent decision-making when using expert committees to augment BAERA’s own technical capabilities. A soil stabilization effort involved determination of the adequacy of existing soil conditions and use of engineered soil to strengthen the foundations of the Roopur NPP site and the plant’s earthquake resilience. Multiple international and domestic experts convened during a series of meetings to peer review and comment on the plant’s proposed approach. BAERA independently assessed the experts’ opinions and recommendation and imposed certain requirements on the licensee to demonstrate safety through core samples, soil testing, geotechnical and structural analyses, and long-term performance monitoring. This practice is considered an area of good performance for an embarking country.

The IRRS team reviewed if provisions exist to guard against potential conflicts of interest that could erode trust and confidence in BAERA’s independent decision making. This is covered in detail in section 3.4.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The BAER Act outlines responsibilities of the authorization holder specifically to ensure nuclear safety, radiation protection, management of radioactive waste and spent fuel, physical protection, emergency preparedness including verification thereof, during all the phases of nuclear installation or radiation facility from siting to decommissioning. There are also several legal instruments that provide BAERA with the power to impose the requirements and conditions of a licence.

Collectively the BAER Act, NSRC Rules, NPP Act of 2015, the pending Nuclear Safety Policy, the authorization procedure, and other supporting processes make clear that authorization holders are responsible for safety. There is no ambiguity in the legal framework that authorized parties are responsible for safety, and the IRRS team considers that the intent of GSR Part 1 and GSR Part 3 regarding prime responsibility for safety is satisfied.

The IRRS team identified several challenges that complicate licensee compliance with Bangladesh national legal and regulatory framework for safety. These challenges include not updating the 1997 NSRC Rules and at the time of the mission no regulations have been enacted by BAERA, aligned to current IAEA Safety Standards.

The team acknowledges that BAERA has drafted a number of regulations and is working towards enactment of regulations that would facilitate licensees and permit holders consistent and coherent compliance with the regulatory framework. This should be expedited by BAERA, using the flexibility it has through the Act to propose rules and/or regulations for appropriately maintain an up-to-date framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Nuclear Safety and Radiation Control Rules were promulgated in 1997, and have not been updated, nor have new rules been issued. As a consequence, there are no rules consistent with the BAER Act.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 2 states that <i>“Establishment of a framework for safety - The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i>
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R3	Recommendation: The Government should make and implement as a priority, suitable arrangements that establish and maintain an appropriate governmental, legal and regulatory framework for safety, starting with the revision of the NSRC-1997 Rules, to be consistent with the BAER Act and IAEA Safety Standards.
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1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

Coordination of authorities having responsibility for safety with the regulatory framework is conducted under several arrangements. For the Rooppur NPP, the government implemented a NEPIO approach which is addressed in section 1.2.

The IRRS team was informed that the Government established an all-hazards approach to disaster management that’s inclusive of nuclear and radiological emergencies. The Government enacted the Disaster Management Act in 2012 and formed the National Disaster Management Council (NDMC) headed by the Prime Minister for development of policy and planning and directing relevant activities regarding National Disaster Management. The government created a new office named the Department of Disaster Management to implement provisions of the NDMC Act. The BAER Act of 2012 designated BAERA as coordinator to formulate the national nuclear and radiological emergency plan and for all activities concerning mitigation of an emergency situation. As a result of these measures, the government finalised the National Nuclear and Radiological Emergency Preparedness and Response (NNREPR) Plan.

For facility authorisations, BAERA staff informed the IRRS team of typical coordination activities regarding Government review of environmental impact assessment submitted to the Department of Environment (DOE), the environmental regulator for Bangladesh, for review and the MOU with the Department of Environment, in the Ministry of Environment, and technical exchanges of information on radiological impacts.

Policy Discussion - Interaction with stakeholders

In the current national nuclear power programme, there are many inter-related issues with different governmental organisations and agencies that BAERA must address. There is a Governmental Rules of Business, that provides:

- a step-by-step decision-making process with clear definition of respective roles and interactions,
- a conflict resolution procedure.

However, BAERA advised that these interactions always have to be improved to make them more effective. With this objective, BAERA wanted to discuss with the mission the interaction process and timelines for decisions and the dispute resolution process in regulatory inspections, the need to resolve any conflict issues, the involvement of stakeholders in the conflict resolution process, etc.

The discussion was about the various national practices for ensuring effective interactions between the regulatory body for nuclear and radiation safety with other governmental organizations or agencies when there are diverging views and lack of agreement on a specific topic.

Some team members explained that for their regulatory body, whether under national agreement or not, is free to interact with any other government organization. In some other countries, it is general practice to have MoU's for bilateral cooperation and coordination. MoU's are considered useful to provide a clear understanding of and framework for engagements and detailed discussions, helping to ensure a harmonised approach and setting out arrangement to resolve conflicts.

In relation to solving a conflict between the regulator and another organisation, it was explained that in general, when the topic is about safety of the facility, the regulatory body has the responsibility to decide, regardless of the agreement with other organisation or not. In some cases, a meeting is organized at the ministry level to solve any issues or misunderstandings.

At national level, it is usually not a challenge to resolve a conflict. It is much more difficult when it involves local or regional organizations.

The team suggested BAERA to identify all its stakeholders, the nature of the relationship they have with them, the needs of each stakeholder and BAERA, the expectations of each, the role of the stakeholder, the overall objectives of any relationship, the risks to a successful relationship and how it could be mitigated. This can be seen as a first step to facilitate successful interactions and reduce the risk of unresolved conflict.

Finally, it was suggested that BAERA might consider proactively seeking feedback from its stakeholders to better understand how they perceive BAERA and the relationship they have with them. This could then be used to better inform how BAERA works with individual stakeholders in the future.

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

The NSRC Rules provide expectations for the control of existing exposure situations including naturally occurring radioactive materials (NORM). Information provided in the ARM detailed that NORM existing exposure situations are managed by BAERA's radiation, transport, and waste division. Although legal values in the form of concentrations for radon are specified in the 'rules', BAERA has no framework to address where radon may be a radiological issue, nor to address any other existing exposure situations, such as past practices which were never subject to radiological control.

The Safety Fundamentals (SF-1) details that radiation risks may arise in situations other than in facilities and activities. One type of situation concerns radiation of essentially natural origin such as radon gas in dwellings and workplaces, a second type of situation concerns exposure that arises from human activities conducted in the past that were never subject to regulatory control, or that were subject to an earlier, less

rigorous regime of control. A generic recommendation regarding adequacy of regulations and guides in module 9 has been made by the IRRS team. Development and adoption of a regulatory framework for all exposure situations should be part of those regulations and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: <i>BAERA does not have a regulatory framework for considering all existing exposure situations.</i>	
(1)	BASIS: SF-1 Requirement Principle 10 para. 3.39 states that <i>“Radiation risks may arise in situations other than in facilities and activities that are in compliance with regulatory control. In such situations, if the radiation risks are relatively high, consideration has to be given to whether protective actions can reasonably be taken to reduce radiation exposures and to remediate adverse conditions. One type of situation concerns radiation of essentially natural origin. Such situations include exposure to radon gas in dwellings and workplaces, for example, for which remedial actions can be taken if necessary. However, in many situations there is little that can practicably be done to reduce exposure to natural sources of radiation. A second type of situation concerns exposure that arises from human activities conducted in the past that were never subject to regulatory control, or that were subject to an earlier, less rigorous regime of control. An example is situations in which radioactive residues remain from former mining operations.”</i>
(2)	BASIS: GSR Part 3 Requirement 1 states that <i>“Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied for all exposure situations.”</i>
(3)	BASIS: GSR Part 3 para. 5.3 states that <i>“The government shall include in the legal framework for protection and safety (see Section 2) provision for the management of existing exposure situations.”</i>
(4)	BASIS: GSR Part 3 Requirement 50 states that <i>“The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.”</i>
R4	Recommendation: BAERA should develop a regulatory framework to consider all existing exposure situations.

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

At present radioactive waste in Bangladesh is produced as a result of the operations related to the TRIGA Mark II research reactor, radioisotope production facility, nuclear medicine practices (24 nuclear medicine facilities), radiotherapy installations (21 installations) and industrial applications (including 25 industrial radiography facilities, 55 nucleonic gauge facilities, 4 gamma irradiation facilities and 5 nuclear well logging facilities). Decommissioning of these facilities will also generate radioactive waste. Further, the Bangladesh government has identified the need to potentially regulate wastes arising from NORM industries. Additionally, construction of the Rooppur Nuclear power plant has commenced, which will introduce additional radioactive waste streams as it begins operation that will require safe management and disposal.

The Bangladesh Government approved the National Policy for Management of Radioactive Waste and Spent Nuclear Fuel in 2019. This Policy sets out the principles, goals and requirements to ensure the safe management of radioactive waste, spent nuclear fuel, disused sealed radioactive sources and wastes from NORM industries in Bangladesh. The policy calls for establishment of a national Radioactive Waste Management Company (RWMC) and a national fund for decommissioning and radioactive waste

management. The strategy and mechanisms for establishment of the RWMC and Fund are however not yet finalised.

Bangladesh policy for disused sealed radioactive sources and spent nuclear fuel entails return to country of origin.

Beyond the National Policy for Radioactive Waste Management and Spent Fuel no explicit national policy for decommissioning has been established. The government is encouraged to address this aspect as part of Recommendation 1 in Section 1.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Whilst the Government of Bangladesh has approved a national policy for management of radioactive waste and spent nuclear fuel, no clear strategy and timeframes for implementation of the policy has been developed.*

(1)

BASIS: GSR Part 1 (Rev. 1) para. 2.28 states that *“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities [3, 7]. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government shall ensure continuity of responsibility between successive authorized parties.”*

R5

Recommendation: The Government should establish and implement as a priority a strategy for the effective implementation of the policy, including the establishment of the RWMC as well as the decommissioning and radioactive waste management fund.

In accordance with the provisions of the BAERA Act, decommissioning means all administrative and technical actions taken to allow the removal or withdrawal of some or all of the regulatory controls from a installation but any repository or nuclear installations used for the disposal of residues from the mining and processing of radioactive material, which are closed but not decommissioned shall not be included in it.

Decommissioning is recognised as a distinct stage in the lifecycle of a facility that requires authorisation from BAERA. Further, section 22 of the BAERA Act prescribes that a decommissioning fund, for the purpose of financial activities related to decommissioning of nuclear installations, be constituted by Government subject to prescribed rules.

The National Policy for Radioactive Waste Management and Spent Fuel details the actions to be followed by Government for establishment of financial resources required for decommissioning and the long term management of radioactive waste and spent nuclear fuel, however no explicit national policy for decommissioning has been established nor have any rules for establishment of decommissioning has been established nor have any rules for establishment of a decommissioning fund been established. Recommendation R3 in section 1.4 addresses this issue.

1.8. COMPETENCE FOR SAFETY

BAERA established a plan for human resource development (HRD) required by the BAER Act. Development of regulatory staff involves national and international activities under a Regulatory Infrastructure Development Project (2019 to 2025). Under the law, the regulator is empowered to use expertise from the TSO for the regulatory body of the vendor’s country. BAERA has used this mechanism to provide expert capability, develop its own technical capability and competencies and assist with knowledge transfer. Nuclear education programs were also established at two public universities. In addition, BAERA conducts training courses for radiation control officers for applicants and licensees.

Competencies are defined in recruitment standards and the required qualifications for personnel in the government's service regulations. In accordance with the service requirements, the regulatory body has its own selection criteria comprising technical qualifications, written and oral examination process, and national security clearance for final appointment.

The Ministry of Science and Technology is leading the development of a national HRD plan for the Rooppur NPP project. The Team was informed that two committees were established; one committee identifies HR needs and the other committee identifies potential HR sources. As a result, several initiatives were created for capacity building. These activities included work with IAEA, Japan, Korea, India, the vendor (Russian Federation) as well as developmental opportunities in the national education system and the nuclear institute within BAEC. Ultimately, BAEC and BAERA will bring together all the above activities into a document as an integrated national HRD plan.

However, the IRRS team has several observations and recommendations on need for BAERA to improve competency profile development and specific training. Recommendation R7 in section 3.3 addresses this issue. The IRRS team is of the view that BAERA senior management attention and support is warranted to address this issue.

1.9. PROVISION OF TECHNICAL SERVICES

Technical services are afforded through BAEC. In addition to research and development, BAEC provides dosimetry services, calibration services, non-destructive testing services, irradiation services, radioactive waste management services, environmental monitoring and radioactivity testing and monitoring in Bangladesh.

Under the BAER Act, BAERA may invoke technical assistance from BAEC's laboratories for a range of activities including radioactivity testing and monitoring services, radioactivity measurement of imported food and allied materials; radioactivity measurement of exportable food, environmental radiation monitoring - among the numerous other service available.

BAERA has a Technical Division and Training Division which is responsible for conducting the local training course for the radiation workers including radiation control officers, and it also provides in-house radiation safety training.

1.10. SUMMARY

There is strong governmental support for including safety in the nuclear energy development programme. In addition to this, the Government also supports the different institutes, medical facilities and universities to establish a safety infrastructure.

The Government of Bangladesh established a governmental and legal framework for safety that needs to continue to evolve and mature. Funds are provided through an annual development project (ADP) for strengthening the nuclear safety infrastructure of the regulatory body.

The IRRS team identified several areas for improvement:

- A comprehensive national safety policy and strategy for all facilities and activities needs to be issued. The policy needs to be consistent with IAEA standards including greater emphasis on the graded approach to management of risks of all facilities and activities.
- Measures should be implemented to ensure no adverse impact to the independent decision making of BAERA

- The NSRC Rules need to be replaced with updated requirements, and the regulatory framework improved to enable greater flexibility to make timely updates of requirements thus maintaining the framework, including all exposure situations.
- A strategy is needed for the effective implementation of the National Policy for Management of Radioactive Waste and Spent Fuel, including the establishment of the RWMC as well as the decommissioning and radioactive waste management fund.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Bangladesh participates in the global nuclear and radiation safety regime. Bangladesh has been a member state of IAEA since 1972 and is a contracting party to the following international treaties and conventions:

- Nuclear Non-Proliferation Treaty (1979)
- Convention on Early Notification of a Nuclear Accident (1988)
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1988)
- Comprehensive Nuclear-Test-Ban Treaty (1996)
- Convention on Nuclear Safety (1996)
- International Convention for the Suppression of Acts of Nuclear Terrorism (2007)
- Convention on the Physical Protection of Nuclear Material (2005) and its amendment (2017)
- Treaty on the Prohibition of nuclear weapons (2017)

However, Bangladesh is not yet a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention). Bangladesh Government is encouraged to consider becoming a contracting party to the Joint Convention. The benefits of the Joint Convention include: (1) fostering an international approach to spent fuel and radioactive waste management, and sharing expertise related thereto (2) assuring the public that national arrangements for spent fuel and radioactive waste management conform to international standards and (3) highlighting the opportunities to receive assistance, in the case of a country having limited resources to improve its infrastructure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Bangladesh is not party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.*

(1) **BASIS: GSR Part 1 (Rev. 1) Requirement 14 states that** *“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”*

(2) **BASIS: GSR Part 1 (Rev. 1) para. 3.2 states that** *“The features of the global safety regime include a) international conventions that establish common obligations and mechanisms for ensuring protection and safety ...”*

S1 **Suggestion: The Government should consider becoming party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.**

Bangladesh participates in IAEA safety standard review committees and actively participated as member of the NID technical working group (IAEA Technical working group for nuclear infrastructure development) for three years from 2017-2019. Further, Bangladesh is a member of the IAEA Regulatory Cooperation Forum (RCF) as a recipient country and participates in various activities under this forum.

Bangladesh has made a political commitment with regard to the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and appointed a contact point for its supplementary Guidance on the Import

and Export of Radioactive Sources. However, Bangladesh has not submitted, to the IAEA, the notification confirming commitment to the Guidance on the Import and Export of Radioactive Sources and Guidance on the Management of Disused Sources, supplement to the Code of Conduct on the Safety and Security of Radioactive Sources nor has it submitted its responses to the Importing and Exporting State Questionnaire. Further Bangladesh has not notified to the IAEA its commitment in connection with the IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Bangladesh has not expressed its political commitment to the IAEA Guidance on the Import and Export of Radioactive Sources, and on the Management of Disused Sources, supplementary to the Code of Conduct on the Safety and Security of Radioactive Sources.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 14 states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 3.2 states that <i>“The features of the global safety regime include a) international conventions that establish common obligations and mechanisms for ensuring protection and safety ...”</i>
S2	Suggestion: The Government should consider expressing its political commitment to the IAEA Guidance on the Import and Export of Radioactive Sources, and on the Management of Disused Sources, supplementary to the Code of Conduct on the Safety and Security of Radioactive Sources.

Bangladesh has sought to learn from the global safety regime, having received several IAEA peer review and advisory service missions including Site and External Events Design Review Service (SEED), Technical Safety Review (TSR) - Conceptual Design Safety of Rooppur NPP, Integrated Nuclear Infrastructure Review (INIR), State’s System of Accounting for and Control of Nuclear Material (SSAS) and this Integrated Regulatory Review Service (IRRS) mission reported here. Additionally, Bangladesh is preparing for hosting IAEA advisory and review missions International Physical Protection Advisory Service (IPPAS), Emergency Preparedness Review Service (EPREV), INIR Phase-3 and pre-Operational Safety Review Team (OSART).

Bangladesh has signed several agreements with IAEA such as provision of technical cooperation, regional cooperative agreement (RCA), safeguards and additional protocol to safeguards agreement, designation of safeguards inspectors.

Bangladesh has signed bilateral agreements with several countries including the Russian Federation, Peoples Republic of China, United States of America, France, Italy and the People’s Republic of Belarus, on peaceful uses of nuclear energy and science and technology. In addition, interagency agreements have been signed with organizations and institutions of various countries like the Russian Federation, India, Malaysia and China.

The advance reference material (ARM) summary report highlights that most of the obligations of the Vienna Convention on Civil Liability for Nuclear Damage and the Protocol to amend the Vienna Convention on Civil Liability for Nuclear Damage have been addressed in relevant sections of the BAER Act.

The ARM mentions that the BAER Act and the Nuclear Safety and Radiation Control (NSRC) Rules – comply with IAEA Safety Standards and Guides. As per NSRC Rules, BAERA can use IAEA guides and standards when BAERA documents do not have the relevant information or the information is outdated or incomplete. The same Rule further also provides for the use of relevant rules and regulations of other countries (mostly the vendor’s country) where this is considered necessary because of gaps in Bangladesh’s

framework. Schedule IX of the NSRC Rules also lists a number of other specific applicable rules and regulations, primarily IAEA safety standards. However, the NSRC Rules references superseded IAEA publications. Recognising that the IAEA Safety Standards have gone through many revisions in last three decades, BAERA needs to develop its regulatory infrastructure based on the current IAEA safety standards and the NSRC Rules need to be revised accordingly. Recommendation R3 in section 1.4 addresses this issue.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Under the authorization process, BAERA requires licensees to submit processes and arrangements for reporting incidents and event. The IRRS team noted that only few incident and event reports were reported by the licensees and although an evaluation is made within the relevant division of BAERA, a formal process for assessment and evaluation of these reports is not available. In addition, such events and the lessons learnt are not disseminated to other licensees.

As a result of BAERA interaction with the regulatory bodies of the NPP vendor country, India, Belarus and Spain, as well as participation in IAEA Regulatory Cooperation Forum activities, some regulatory experiences are being received and utilized in BAERA regulatory activities. In addition, BAERA is also receiving international experiences shared through the IAEA-supported Nuclear Events Web-based System (NEWS). However, the IRRS team noted that BAERA does not have a formal process to receive, analyse and disseminate international operating and regulatory experience in nuclear and radiation safety.

Potential sources of operating and regulatory experience that can assist BAERA include the IAEA Incident Reporting System for Operating Experience (IRS) and IAEA Incident Reporting System for Research Reactors (IRSRR), websites of various regulatory bodies and other international forums.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no formal process within BAERA to obtain, analyse and disseminate the international operating and regulatory experiences and the lessons learned with authorized parties or within the regulatory body. Moreover, no formal process is in place at BAERA for evaluating event or incident reports of the licensee to learn lessons and dissemination of this information to other licensees.*

(1) **BASIS: GSR Part 1 (Rev. 1) Requirement 15 states that** *“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”*

(2) **BASIS: GSR Part 1 (Rev. 1) para. 3.4 states that** *“The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.”*

(3) **BASIS: GSR Part 1 (Rev. 1) para. 3.5 states that** *“To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgation of new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international*

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	<i>networks also covers descriptions of good practices that have been adopted to reduce radiation risks.”</i>
R6	Recommendation: BAERA should make necessary arrangements to collect national and international operating and regulatory experiences, carry out analysis to identify the lessons from such experiences and for dissemination of the experiences and the lessons for use by the authorized parties, BAERA and other relevant stakeholders.

2.3. SUMMARY

Bangladesh participates in the global safety regime and is a contracting party to several international conventions and treaties on nuclear and radiation safety. The IRRS team made observations with regards to fulfilling gaps in its international obligations and strengthening its existing process for gathering assessing and sharing of operating and regulatory experience. Areas for improvement identified by the IRRS team include:

1. Becoming a contracting party to the Joint Convention
2. notifying to the IAEA its commitment to the guidance on the Import and Export of Radioactive Sources as well as IAEA Guidance on the Management of Disused Sources, supplementary to the Code of Conduct on the Safety and Security of Radioactive Sources and submitting a response to the Importing and Exporting State Questionnaire
3. making necessary arrangements for gathering assessing and sharing of operating and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The regulatory authority for nuclear and radiation safety in Bangladesh is the Bangladesh Atomic Energy Regulatory Authority (BAERA), which reports to the MoST. BAERA's top management consists of a Chairman and four Members of the Authority, with the Chairman serving as the chief executive of the Authority. They are appointed by the Government and are full-time officers of the Authority.

BAERA has seven divisions headed by Directors with four divisions having responsibilities for regulatory functions including development of regulations & guides, licensing and authorization, review and assessment, and inspections and enforcement. Additionally, there are divisions responsible for administrative and establishment functions, financial and accounting matters of the organization, and international affairs. Further, BAERA has hired a legal advisor to provide legal support and advice as and when needed.

The IRRS team noted that while responsibilities of various divisions are defined, delegation of power to various levels within the organization is not consistent with the associated risks and importance of the activity. Consequently, most decisions and approvals are submitted to the highest level in the organisation and application of a graded approach is not evident.

The facilities and activities regulated by BAERA include the construction of the country's first nuclear power plant at Rooppur, a 3MW TRIGA Mark II research reactor, a centralised radioactive waste processing and storage facility, a radioisotope manufacturing facility and more than four thousand eight hundred (4800) radiation facilities using radioactive sources or radiation generators.

The financial resources of BAERA have two major components the licensing fee and the grants from the Government. BAERA submit its budget requirements every year to the Government through the MoST and after Government approval. It receives the grants directly from the Ministry of Finance. The chairman has full authority on spending the funds. The IRRS team was informed during the discussion with BAERA counterparts that about 60% of the financial resources are generated by BAERA from licensing fees while 40% is provided by the Government. In addition, BAERA receives additional funding for building its capacity and nuclear regulatory infrastructure development through the development project of the Government of Bangladesh.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Under the Act, BAERA is empowered to issue licences, perform review and assessment, conduct inspections and take certain enforcement actions without any intervention from any other organization. In conducting its activities, BAERA can hire expert services from outside the organization such as support from technical support organizations (TSO). BAERA is also empowered to issue regulations with prior approval of the Government. Further BAERA can determine and enforce necessary standards, codes and manuals for carrying out the purposes of the Act.

To address potential conflicts of interest, the expert services contracted by BAERA for the NPP project are limited to the regulatory body of the vendor country, the TSO of the regulatory body of the vendor country and regulatory bodies of other countries. However, in future situations may arise where BAERA may needs to hire services from other technical support organizations or experts where conflict of interest may need more focus. Although the management system manual of BAERA mentions that while selecting providers of external expert support, exclusion of conflict of interest is taken into account, no formal process or procedure exists within the regulatory body on the mechanism for considering and addressing conflict of interest. Recommendation R8 in section 3.4 addresses this issue.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Since the start of nuclear power programme, BAERA focused on the development of competent staff for the regulation of nuclear new build. The staff requirement and competence needs were assessed with the support of the regulatory bodies of the vendor country and India as well as through IAEA missions. The development of competence programme was mainly based on the practices of supporting countries and the IAEA SARCoN model.

The methodology included developing competence profile, performing competence gap analysis and identifying necessary training needs. Accordingly, qualification and training requirements for the staff have been identified and documented and approval thereof has been obtained from the Government.

The level of competence required of employees is determined by the director of the relevant division based on the functional tasks of the division and the staffing of the unit. The IRRS team established that foundation training is given to new staff shortly after taking up their appointment, which is supplemented by further on the job training.

The team noted the need for additional training of technical staff for regulation of radiation sources.

The qualification requirements are being addressed through higher education programmes in foreign countries under government funded scholarships while training requirements are addressed by arranging training courses internally within the organization, on-the-job training and training with the assistance of the regulatory bodies of vendor country and India as well as through IAEA TC program initiatives and participation in RCF activities.

The IRRS team observed that the training is mainly focussed on the nuclear power program while training programmes for other areas are missing. Qualification criteria for inspectors outside the NPP project have not been formulated neither have any specific training requirements for non NPP inspectors been established.

As part of the ARM, BAERA highlighted the need to strengthen personnel numbers and competencies related to inspections during construction of nuclear power plant and undertaking of conformity assessment. It is important for BAERA to also focus on training of its manpower on commissioning since commissioning is to start in near future. Recommendation R22 in Section 7.1 addresses this issue.

The approved total staff complement of BAERA is 164, however there are currently 147 employed members of staff. During the discussion, the IRRS team was informed that the balance of experienced staff to newer members was consistent across the divisions. BAERA also advised that where current vacancies exist across the organization, these will be filled by future recruitment plans.

The management system manual and other documents provided by BAERA (e.g., ARM summary report, Self-Assessment Report of BAERA, etc.) do not address succession planning within the organization. The team was informed that apart from the eligibility criteria for qualification, seniority is the main criteria for succession for various positions up to Director level.

Discussions with staff from specific regulatory functions in BAERA indicated that there are challenges as a consequence of having a significant proportion of new recruits, this challenge is likely to become more significant as the demands of the Rooppur project for competent regulatory staff increase.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Although some competency requirements, along with corresponding training requirements have been identified for regulatory staff working on Rooppur NPP, there is an absence of a comprehensive suite of competency profiles and associated training programmes for other regulatory roles in BAERA.*

(1) **BASIS: GSR Part 1 (Rev. 1) para. 4.13 states that** *“A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.”*

(2) **BASIS: GSR Part 2 para. 4.23 states that** *“Senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and of the actions taken.*

R7 Recommendation: BAERA should develop competency profiles for all regulatory roles. BAERA should then implement specific training programmes, which are based on the competency profiles.

Observation: *Discussions with staff within BAERA highlighted concerns in regard to the balance between new and experienced regulatory staff across the organization.*

(1) **BASIS: GSR Part 1 (Rev. 1) Requirement 16 states that** *“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”*

(2) **BASIS: GSR Part 1 (Rev. 1) para. 4.5 states that** *“The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively.”*

S3 Suggestion: BAERA should consider establishing a process to periodically assess the deployment of human resources across its organization required to ensure it has an appropriate balance between new and experienced regulatory staff that will enable it to perform all of its functions effectively.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Act includes provision for the establishment by BAERA of an Advisory Council. The composition of the advisory committee is prescribed in the BAERA Act. The prescribed members of the Council comprise subject specialists and officials from various government ministries and organizations. The IRRS team noted that BAERA has no formal process to address potential conflict of interest in the selection of the members so that independent opinion, which is generally expected from such bodies, are obtained.

The BAER Act does not contain provisions nor does a written process exist to ensure technical or policy support received from members of the BAERA Advisory Council or other outside experts is provided in a manner that avoids potential conflicts of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The BAER Act does not contain provisions to address potential conflict of interest regarding advice provided to BAERA by members of the advisory council or other outside experts.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.20 states that <i>“Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.”</i>
(3)	BASIS: GSR Part 1 (Rev. 1) para. 4.21 states that <i>“If the necessary advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the regulatory body, the seeking of this advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest.”</i>
R8	Recommendation: BAERA should establish formal requirements to manage potential conflicts of interest from members of the advisory council or other external experts.

BAERA has powers to establish expert committees comprising BAERA staff and external experts. Several such committees were established as part of the review of the siting and design and construction review of Rooppur NPP.

BAERA may, with prior approval of the Government, enter into co-operation agreements to carry out its functions in a smooth and effective manner. MoST and Rostechndzor (the nuclear regulatory authority of the Russian Federation) have signed an inter-agency agreement (IAA) for cooperation in the field of nuclear safety regulation and providing technical support to BAERA including human resource development.

BAERA and JSC “VO “Safety” (Foreign Trade Organization “Safety” of the Federal Nuclear and Radiation Safety Authority of Russia (Gosatomnadzor of Russia)) have signed a general framework contract for support of BAERA on nuclear regulatory infrastructure development including review, assessment, inspections and HRD.

The IRRS team queried how BAERA exercises the role of intelligent customer to evaluate the work done by the TSO and using the input in its regulatory decision-making process. The counterparts informed and also showed examples of its evaluation, assessment and use of the inputs provided by the TSO for the regulatory decision making. However, a formal documented procedure addressing this subject is missing. Recommendation R11 in section 4.5 addresses this issue.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

BAERA communicates with its licensees and authorized parties through official letters and correspondences as well as official meetings as needed or upon request. In addition, informal means of communication are used for the exchange of ideas and sharing information. Regulatory requirements, queries, decisions, etc., are communicated to the applicant and licensees through written correspondence.

Further, the IRRS team noted that BAERA deploys resident inspectors to Rooppur NPP, who are supported by experts from the TSO. This provides a mechanism for prompt communication and engagement on emerging regulatory and safety issues.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The BAER Act, NSRC Rules and a few established policies are available providing high level principles and criteria for performing regulatory functions. Further the IRRS team noted that some regulations and policies are currently under development, which when completed and approved would partially address some of the identified gaps in the regulatory framework

It is important to have a complete set of rules, regulations, policies and guides in the regulatory framework as a basis for all subsequent regulatory functions to provide consistency and avoid subjectivity in regulatory decision making.

In addition, well defined management system processes and procedures along with clearly established roles and responsibilities are vital for stability and consistency in the way the regulatory body works and avoiding inconsistency in dealing with similar cases.

The IRRS team noted that although BAERA has established its management system manual, supporting documents such as processes, procedures, internal guidance for regulatory staff, etc., are needed for completeness of the management system. Recommendation R11 in section 4.5 addresses this issue.

The IRRS team noted that guidance documents need to be developed to provide licensees and applicants with practical solutions and measures to meet the requirements set out in regulations and rules. Recommendation R28 in section 9.1 addresses this issue.

In addition, participation and involvement of relevant stakeholders in the process for the development of regulations and regulatory guides will bring transparency, ownership and stability in the overall regulatory system. While a limited group of stakeholders have already been involved in these processes, broader stakeholder involvement, including the general public, has so far not been effectively addressed by BAERA. Recommendation R29 in Section 9.1 addresses this issue.

3.7. SAFETY RELATED RECORDS

BAERA maintains a national register for radiation sources. The IRRS team noted that records of doses from occupational exposure are prepared by licensees and submitted to BAERA as part of the application process for the renewal of authorizations. This information is stored by BAERA in files relating to the individual facilities and activities. BAERA has no formal system for consolidating, trending and analysing these records.

If a radiation worker is providing services at more than one facility, there is no provision within the existing system for accumulated doses. As a result, the total doses received by such workers annually cannot be determined. Moreover, maintaining dose records only on facility files also makes the retrievability and accessibility of the information difficult and time consuming.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The record of occupational doses of workers are maintained on a facility specific basis. There is no provision within the existing national system for collating the recorded doses received at multiple facilities. As a result, the total dose received by workers cannot be assessed against dose limits and for optimisation of occupational exposure.*

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| (1) | BASIS: GSR Part 1 (Rev. 1) Requirement 35 states that <i>“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.”</i> |
| (2) | BASIS: GSR Part 1 (Rev. 1) para. 4.63 states that <i>“The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:</i>
- <i>Records of doses from occupational exposure;”</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(3)	BASIS: GSR Part 3 Requirement 19 states that <i>“The government or the regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and the regulatory body shall enforce compliance with dose limits for occupational exposure.</i>
(4)	BASIS: GSR Part 3 para. 3.105 states that <i>“Records of occupational exposure shall include: c) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, exposures and intakes in each such employment;</i>
R9	Recommendation: BAERA should make provisions for establishing and maintaining a national dose register to ensure implementation of the radiation protection principles of dose limitation, optimisation of protection, and retention of records.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

In 2020, BAERA developed a communication manual describing the principles, objectives and scope of communication. It also identified its key stakeholders including the authorization holders, ministries, agencies, research organizations, institutes and universities, experts and scientists, medical and health professionals, professional groups, suppliers of equipment and services, standardization organizations, TSO, consultants, media, public, etc.

While focus is being given to interacting on specific matters with certain stakeholders like authorized parties, ministries, governmental organizations and to certain extent with media; targeted interaction with public is not evident. The IRRS team noted that limited information is available to the public through the BAERA website, and information posters on possible radiation risk associated with medical practices are displayed at licensed facilities (e.g., medical facilities). Nevertheless, a formal process or mechanism of informing and consulting with the public regarding possible radiation risks associated with facilities and activities regulated by BAERA as well as the processes and decisions of BAERA does not exist.

Furthermore, there is no formal mechanism for feedback of information from the public to BAERA. No activity involving direct communication with the general public has so far been undertaken by BAERA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Although there is a requirement in the legal framework for BAERA to inform and consult with interested parties, including the general public, on possible radiation risks, the processes and decisions of BAERA, and where they undertake amendments to regulations and guides, this is not consistently applied. Furthermore, there is no formal consultation or feedback process.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 36 states that <i>“The regulatory body shall promote the establishment of appropriate means of informing and consulting ... the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.66 states that <i>“The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform ... the public and for informing the decision making process. This communication shall include constructive liaison such as: a) Communication with ... the public on regulatory judgements and decisions; d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(3)	<p>BASIS: GSR Part 1 (Rev. 1) para. 4.67 states that <i>“The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing ... the public ... about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities, and other interested parties, as appropriate.”</i></p>
R10	<p>Recommendation: BAERA should establish appropriate mechanisms for informing and consulting with interested parties, including the general public, on the radiation risks associated with facilities and activities, regulatory processes and significant decisions of the regulatory body and amendments to regulations and guides, in a transparent manner.</p>

3.9. SUMMARY

BAERA is empowered to issue licences, perform reviews and assessments, conduct inspections and take certain enforcement actions. It can also constitute an Advisory Council to provide advice on regulatory matters and acquire the services from external TSOs, to support it in performing regulatory functions. However, a formal process to address conflict of interest is not established.

Staff competence requirements, especially for regulating nuclear power program, has been determined with the assistance of technical support organizations and IAEA. However, enough consideration is not given for the competence development of staff working in other areas. A complete set of regulations and regulatory guides are missing in the regulatory framework, the management system documentation also lacks the necessary supporting documents and ensuring consistency of regulatory control can be an issue. There are also some issues with the occupational dose records.

Ministries, other government organizations, authorization holders, institutes and universities, experts and scientists, medical and health professionals, professional groups, media, public, etc., have been identified as key stakeholders in the BAERA communication manual. While focus is being given to interacting on specific matters with certain stakeholders, the interaction with the general public is not direct. A formal process or mechanism of informing and consulting with the public is clearly missing.

The gaps mentioned above have been identified during the mission and accordingly various recommendations and suggestions have been made as described in sections 3.1 to 3.8 above.

4. MANAGEMENT OF THE REGULATORY BODY

BAERA has a documented management structure and is in the process of developing its management system documentation which will be built upon its “Management System Manual”. The management system is intended to ensure that BAERA meets its goals, mission and vision.

BAERA states it has an overriding priority to safety and through BAERA’s Code of Ethics its staff are to ensure safety and protection of workers and the public in the practices using ionizing radiation and nuclear energy.

The stated hierarchy of the documentation of the management system is:

1. mission, vision and policies
2. Management System Manual
3. processes and procedures
4. working documentation (plans, programs, schedules, inspection checklists, etc.)

BAERA identified in the ARM that their management systems need to be developed further and applied throughout the organization. The IRRS team noted that there is a need to develop further processes and procedures and that certain existing processes need further supporting documentation to enable them to be implemented in a consistent manner.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

BAERA has a chairman who acts as the executive head of the organization and is supported by four members of the Authority. Next in the management chain of responsibility are the project director who has specific executive powers, the divisional directors head the various divisions within BAERA, and focal points may be assigned to perform specific tasks.

The chairman has a wide range of responsibilities assigned to him including defining policies and goals, resource management and approval of management system documentation.

The IRRS team was informed that much of BAERA’s documentation and decisions need clearance from the chairman and that formal communication between the divisions also goes through him. Article 14 of the BAERA Act states that the Authority may delegate all or any of its powers to any member, officer or employee, however, it was noted by the IRRS team that delegation of responsibility often was not put into practice. An example of this is that the chairman’s signature being required even in the process for issuing routine inspection documentation. These organizational practices, of decisions and approvals being made at the highest level, without applying a graded approach consistent with the associated risks or importance could be leading to inefficiencies.

The IRRS team observed that familiarization with and commitment to the recently developed management system is not always evident throughout the organization. This in part may be due to the lack of a comprehensive suite of management system documentation and proactive communication on its requirements.

Senior management should continue to develop and improve the management system to enhance safety. All levels of management need to strongly advocate for the management system and its implementation to ensure that there is the commitment to safety throughout the organisation. Recommendation R11 in section 4.5 addresses this issue.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Chairman has overall responsibility for integration of safety into the management system and oversees its development through coordination meetings that are held with the four members of the Authority and divisional directors.

In view of the fact that the managements system is not completely developed, the IRRS team was not able to come to a conclusion regarding the integration of safety into the current management system.

The need to perform an independent assessment of leadership for safety and of safety culture is discussed in section 4.6.

4.3. THE MANAGEMENT SYSTEM

The “Management System Manual” was developed in November 2021 and is aligned with the safety goals of BAERA. It is the key defining document of the management system which describes the elements and structure of the management system. The “Management System Manual” envisages the need to include processes, associated procedures and other lower-level documentation within it.

The “Quality Management Representative” has experience in the field of management systems, knowledge of the quality of nuclear and radiation safety regulation and safety culture. They are responsible for the management system, which in practice means receiving and collating information on processes and procedures.

Much of the associated hierarchy of documentation that will define the details, including procedures and lower-level documentation have yet to be developed. In addition, certain existing processes need further supporting documentation to enable them to be implemented in a consistent manner.

The responsibility for the management system as a whole is assigned to the “Management System Representative” with the individual divisions having the responsibility for developing their own processes and procedures to be forwarded to the “Quality Management Representative” for incorporation into the management system.

The management system had not yet been completed for all existing work practices. Recommendation R11 in section 4.5 addresses this issue.

4.4. MANAGEMENT OF RESOURCES

The Chairman has ultimate responsibility for determining the resource requirements of BAERA, which he seeks to discharge through close working with the four members of the Authority and the divisional directors.

Competencies required of divisional directors are determined by the Authority on the basis of the organizational structure of BAERA for nuclear and radiation safety regulation.

The “Staffing, Competency Assessment and Training for Regulatory Personnel” guidance provides BAERA’s approach for managing human resource issues and includes creation of competence profiles for each division. There are no downstream procedures made in connection with this guide.

The “Bangladesh Atomic Energy Regulatory Authority Service Regulations” and other documentation establish requirements for the educational qualification and work experience for the various posts and govern the management of human resources within BAERA.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The “Management System Manual” identifies the BAERA processes as being core processes, management processes, regulatory support sub-processes. Each process will have an identified process owner having full

responsibility, along with the head of the organizational division/project, for its development, documentation, and implementation.

The management system is not complete as all of the associated processes, procedures and lower-level documentation have not been developed but are in the process of development. The development of the processes and procedures is to be done at divisional level and then forwarded to the “Quality Management Representative” for the incorporation into the management system. In the instances where processes are available, some processes consist simply of flow-charts, these flowcharts lack the necessary documented detail for the process. There is need for consistency in the way management system documents are configured and standardised.

The development of a coherent set of processes and procedures as a part of BAERA’s integrated management system is an essential enabler to ensure that the management system is effectively implemented. In addition, the IRRS team observed that there was not always the evident commitment throughout the organisation to the very recently developed management system. There is room for reinforcing the commitment to BAERA management system in the management and across BAERA’s organization.

Senior managers should take the lead in showing commitment to the development and implementation of the management system. Any lack of such commitment will lead to the management system not being applied throughout the organization. Management system leadership should have a top-down approach whilst there should be a bottom-up approach to its implementation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The management system is incomplete and inconsistently implemented across the organisation.</i>	
(1)	BASIS: GSR Part 2 Requirement 3 states that <i>“Responsibility of senior management for the management system - Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.”</i>
(2)	BASIS: GSR Part 2 Requirement 10 states that <i>“Processes and activities shall be developed and shall be effectively managed to achieve the organization’s goals without compromising safety.”</i>
R11	Recommendation: BAERA should develop a coherent set of processes and procedures as part of its integrated management system and ensure that the management system is consistently implemented throughout the organization.

4.6. CULTURE FOR SAFETY

The Management System Manual states BAERA safety culture principles are:

- Safety is a recognised value
- Distribution of responsibilities
- Included in all activities
- Leadership in safety assurance
- Training

BAERA published a regulatory guide entitled “Safety Culture Self-Assessment” in July 2022. The guide describes methods to perform self-assessment, however it does not have an associated supporting procedure. Recommendation R11 in section 4.5 addresses this issue.

The “Management System Manual” states that it is the responsibility of the chairperson to arrange BAERA activities based on the principles of safety culture. But it is the responsibility of the “Quality Management Representative” to organise safety culture assessment of BAERA.

Each member of BAERA staff is subject to an annual performance assessment by its divisional management, this assessment includes their application of BAERA’s code of ethics and safety culture issues. These assessments are reviewed by an ethical and safety committee which is composed of senior management of BAERA along with members from outside of the organisation. As part of this review two awards for safety culture/ethics are presented each year to technical and administrative staff.

With the ongoing development of the management system and the development in July 2022 of the regulatory guide “Safety Culture Self-Assessment” the focus on the assessment of safety culture is emerging within the organisation.

There has been no systematic and independent assessment of the leadership for safety or safety culture management in line with the regulatory guide “Safety Culture Self-Assessment”.

The IRRS team noted staff concerns that the leadership needs to give greater emphasis to the development and implementation of the management system and the development of safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The focus on safety culture has only recently emerged within BAERA, and as a consequence, BAERA has not yet performed a comprehensive and independent assessment of leadership for safety and of safety culture.*

(1)	BASIS: GSR Part 2 para. 6.10 states that “ <i>Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety (i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization).</i> ”
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R12	Recommendation: BAERA should perform an independent assessment of leadership for safety and safety culture throughout the organization.
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4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The “Management System Manual” requires that processes of the BAERA Management system have a process owner and criteria for measuring the effectiveness or efficiency of the process. Furthermore, the process owners are responsible for evaluating the effectiveness of the processes and, if necessary, updating them, or taking corrective actions for their proper functioning.

Whereas BAERA undertakes regular reporting on its performance to the MoST, it has not undertaken a systematic review of the whole management system, nor has it undertaken a regular review of performance of and against the requirements of its own management system and to identify non-conformances, corrective actions and improvements as necessary. Recommendation R11 in section 4.5 addresses this issue.

4.8. SUMMARY

In complying with GSR Part 2 BAERA management should seek to establish, apply, sustain and continuously improve their management system to ensure safety.

In particular BAERA should :

- Develop its management system to include all the necessary documentation and ensure that it is applied throughout the organization;
- Ensure that safety culture is subject to a systematic and independent assessment.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The NSRC Rules set out requirements for authorization of different stages of the lifetime of facilities and activities. Eight categories of licence are provided for in the NSRC Rules and BAERA has the power to suspend, cancel and control import and export of nuclear and radioactive materials. The Act also sets out responsibilities of the authorization holder during the period of authorization.

The BAER Act establishes authorization requirements for the various stages of the lifecycle of facilities and activities, including, as appropriate, siting, design, construction, commissioning, operation, decommissioning and release from regulatory control. It also allows for authorizations to be issued at other relevant stages. The Act requires that regulations be published, prescribing the application of these requirements. BAERA has not issued a comprehensive set of regulations in this regard. These should be developed by BAERA at the earliest opportunity. Recommendation R27 in section 9.1 addresses this issue.

NSRC Rules provide requirements on licensees as well as exemptions to licensing. The NSRC Rules also provide requirements on classifications, stages, duration, renewal, amendment, surrender, and registration of the licenses.

Recently, BAERA issued a regulatory guide to provide guidance on authorization requirements and content of detailed information to be submitted by the applicant for NPP licences; requirements for authorizations for transport of radioactive materials; import and export of nuclear materials; purchase, own, handle, store of nuclear material and radioactive waste management facilities. Information is provided on authorization for workers at NPPs. While this document is intended to apply to all facilities, it does not include the authorization process for radiation facilities.

A procedure describing, in detail, the activities of authorization process under the management system, including staff responsibilities, for processing an authorization application, such as what to do, when and how to do it, is not in place. Recommendation R11 in Section 4.5 addresses this issue.

Roles and responsibilities in the authorization process are defined. Applicants have a set of requirements to follow under the BAER Act and the NSRC Rules. The Authorization Procedure outlines additional requirements to be followed. The process flow charts that were provided show that within BAERA the NuRID/NSSSD takes the lead on assessing the application and obtains input from inspections and the TSO, Internal and External Review Committees with the Authority making the final decision.

Other agencies are indirectly involved in the authorization process. BAERA issues a notification to the applicant to direct them to obtain confirmation from other Ministries that may have input into the safety of the facility (such as police, emergency preparedness, and local hospitals).

The BAER Act requires that the Authority organize public participation activities through seminars, workshops, electronic and print media and internet for information and consultation with interested parties regarding the possible risks associated with the facilities and activities. Specifically, BAERA organized workshops with interested and knowledgeable parties, such as local university experts, prior to issuing the design/construction licence for the Rooppur NPP.

The authorization procedure does not include steps for public consultation when decisions on authorizations are being made. The main considerations in the decision for issuing an authorization are the inspections conducted by BAERA as well as review and analysis of the safety assessment. Transparency along with public participation and involvement in regulatory processes such as issuing authorizations, can reinforce the credibility of the regulatory body and enhances local public confidence in the nuclear regulatory regime. Recommendation R10 in Section 3.8 addresses this issue.

When an authorization is issued, terms and conditions are included in the licenses relating to safety and protection as well as economic safety measures or compensation for the possible damage to the people and the environment.

The NSRC Rules establish criteria for exempting certain sources, including materials and objects, with very low radioactivity levels within authorized practices. However, the rules do not establish clearance criteria. The application of graded approach warrants removing from regulatory control those sources, including materials and objects, with very low radioactivity levels within authorized practices. This will help to target licensees and regulatory body’s resources on safety significant matters. BAERA is expected to establish criteria and radiation levels for the licensees to be able to request the clearance and for it to approve such requests in a consistent manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>BAERA does not have established criteria and levels for clearance of sources within authorized practices, including materials and objects, from regulatory control.</i>	
(1)	BASIS: GSR Part 3 Requirement 8 states that “ ... <i>The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.</i> ”
(2)	BASIS: GSG-13 para 3.48. states that “ <i>In this respect, the government or the regulatory body is required to determine within the regulations: (b) Which sources, including materials and objects, within notified or authorized activities may be cleared from further regulatory control. The regulatory body is required to use as the basis for this determination the criteria for clearance specified in Schedule I of GSR Part 3 [3], or to specify any clearance levels on the basis of these criteria. By means of these arrangements, the regulatory body is required to ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification or authorization unless the regulatory body so specifies (see para. 3.12 of GSR Part 3 [3]).</i> ”
R13	Recommendation: BAERA should establish criteria and radiation levels for clearing sources, including materials and objects, from regulatory control.

The BAER Act allows for the appeal or review of a decision by the Authority should a decision be made to suspend or cancel an authorization. The IRRS team was informed that in practice, for appeals related to conditions of a licence, such as for date extensions, the operator would make a request to BAERA and this is considered.

Evaluation of a sample of licences confirmed that while the licences prescribe authorized actions linked with the eight categories of licence prescribed in NSRC Rules, the licences do not contain specific limits on operations or criteria for effluent releases.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Licences do not prescribe the limits, conditions and controls on the authorized activities in a systematic manner.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.30 states that “ <i>Authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance and engineering activities). The regulatory body shall verify, by appropriate means, the competence of individuals having responsibilities for the safety of authorized facilities and activities.</i> ”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.31 states that <i>“In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.”</i>
(3)	BASIS: GSR Part 1 (Rev. 1) Requirement 23 states that <i>“Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.”</i>
(4)	BASIS: GSR Part 3 Requirement 31 states that <i>“Radioactive waste and discharges - Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization.”</i>
S4	Suggestion: BAERA should consider establishing a systematic approach to prescribe in the licence the limits, conditions and controls on the authorized activities.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

An application for an authorization requires various supporting documentation. For example, a siting license requires information in accordance with NSRC Rules-1997, a nuclear facility Site Safety Assessment Report (SSAR), an Environmental Impact Assessment (EIA) Report, General Quality Assurance Plan (QAP(G)) and Quality Assurance Plan for Siting (QAP(S)). Effectively, the licensing documentation is being updated throughout the subsequent stages of authorization for the NPP.

Safety Assessments are required to be completed for the authorization of the nuclear power plant at different stages. A Preliminary Safety Assessment Report (PSAR) is required at the design/construction phase and a Final Safety Analysis Report (preliminary revision) for the commissioning licence and the Final Safety Analysis Report (final revision) for the operating licence. As discussed in the Section 6 on Review and Assessment, BAERA relies on the requirements of the vendor country for producing the safety assessment. The operator conducts an independent review of the safety assessment through a review by BAEC. BAERA also has independent assessments; It is first reviewed by BAERA staff and external support organizations in Bangladesh, such as academic institutions or other organizations. Then the results of that review are shared with the JSC VO “Safety”, the Russian regulatory body’s TSO, for an independent assessment.

BAERA has requirements for the authorization of certain positions that work in nuclear power plants. These include Managing Staff, Executive Staff and Operational Staff. This is further broken down into 25 different positions that require authorization. Requirements for obtaining an authorization for these positions are documented in the Authorization Procedure and the Regulatory Guide “Authorization of NPP Personnel Performing Safety Related Functions”. If a permit is granted, it has a 2-year term and further testing/examinations are required on a 2-year frequency. Requirements for renewal of licences/certifications are also provided in the authorization procedure. The regulatory guide contains detailed guidance for each job position requiring authorization, including key functions of the position, education requirements, work experience, basic knowledge requirements and training.

5.3. AUTHORIZATION OF RESEARCH REACTORS

The current operating licence was issued in 2013, taking into consideration the applicable IAEA safety standards at that time, which have since been superseded. The Act authorizes BAERA to direct the applicant to provide additional information as may be necessary for consideration of the application and set conditions relating to safety in accordance with the national and international standard.

The initial licence expired in 2020. BAERA is currently considering the application for licensing renewal and have issued an interim notice that operations could continue under previous conditions.

BAERA required the authorized party to conduct periodic safety reviews and update the safety analysis report for the purpose of licence renewal.

The BAER Act and NSRC Rules prescribe obligations of the authorized party with respect to the operation of the research reactor, as well as roles and responsibilities of BAERA. The authorized party is required to keep the necessary records to assess the safety of the research reactor operation, including the authorized party event report, and present these records to the regulatory authority as required or on request.

Reactor operators and senior reactor operators are licensed based on an international adopted regulation by NSRC Rules. The examination and licensing of personnel are implemented in accordance with an internal BAERA procedure, namely, the “Procedure for Conducting Examination & Issuance of Licence for Reactor Operator/Senior Reactor Operator for Research Reactor”.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

At present a central radioactive waste processing and storage facility (CWPSF) has been authorised. Licences approving operations are required to be renewed annually. A number of other facilities are also approved for release of radioactive material following a period of storage for decay. In the absence of clearance levels, BAERA uses exemption levels. Recommendation R13 in section 5.1 addresses this issue. Disused sealed sources that are not destined for return to supplier are transported to the CWSPF for storage.

Section 18 of the BAERA Act prescribes that siting, design, construction, commissioning, operation and decommissioning of a radioactive waste management facility as well as closure of a waste disposal facility requires prior authorisation from BAERA. Radioactive waste management facilities undertaking disposal or release of radioactive material meeting exemption criteria are issued with a class G licence but may as applicable also require other classes of licence related to transport, storage and processing of radioactive material.

The licence for the CWPSF does not contain specific limits on operations or criteria for effluent releases. Suggestion S4 in section 5.1 addresses this issue.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The NSRC Rules establish an authorization process that requires any person to apply to BAERA for an authorization to conduct identified practices, unless the practice is exempted. This requires all practices to be authorized by BAERA to follow the same process regardless of the safety significance, which is not commensurate with the level of risk of each practice. Implementing a graded approach to the authorization process as provided for in the Act will achieve efficiencies for the licensees as well as BAERA.

The BAER Act requires any party intending to carry out activities to submit a notification letter to BAERA in respect of their intention and a subsequent application for an authorization.

Another limitation of the current regulatory framework is the absence of clearance criteria for removing sources from regulatory control, including materials and objects, that no longer pose a significant radiation risk. Recommendation R13 in section 5.1 addresses this issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA's process for the authorization of radiation sources facilities and activities does not implement the various options provided for in the Act.*

(1)	BASIS: GSR Part 1 (Rev. 1) para. 2.5 states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: (3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;”</i>
(2)	BASIS: GSR Part 3 Requirement 6 states that <i>“Graded Approach - The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.”</i>
(3)	BASIS: GSG-13 para. 3.76 states that <i>“The concepts of notification, authorization by registration, and authorization by licensing broadly represent a graded approach to regulatory control based upon the levels of risk or the nature of the facility or activity.”</i>
R14	Recommendation: BAERA should implement the options for the authorization process of radiation sources facilities and activities, as provided for in the Act, including registration and authorization, applying a graded approach.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The BAERA Act requires prior approval and authorization of decommissioning activities. Decommissioning activities will be granted type G licence. There are currently no active decommissioning activities in Bangladesh, consequently no authorisations for decommissioning have been issued by BAERA.

5.7. AUTHORIZATION OF TRANSPORT

Class D licences apply to the transport of nuclear and radioactive material.

Transport of radioactive material, and nuclear material, involves IP-2, IP-3, Type A, Type B, Type C package designs. Information for applicants for transport authorizations is available on the BAERA website.

Application forms, which include new applications or renewal of existing authorizations, are cited in the NSRC Rules.

The regulatory requirements for transport authorization are in place but there is no formal procedure. Recommendation R11 in section 4.5 and Suggestion S4 in section 5.1 address this issue.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The NSRC Rules require the authorization holder to classify areas as controlled or supervised and to establish rules and procedures for the protection and safety for workers and other persons. They also require the workers to follow all instructions, rules and procedures issued by the authorization holder regarding radiation protection.

Requirements for the monitoring and recording of occupational exposures in planned exposure situations are established in the NSRC Rules. The authorization holder is responsible for maintaining medical record for each worker, including occupational exposure records. However, the retention period for the records does not completely align with IAEA GSR Part 3 (till attaining 70 years of age in the NSRC Rules instead of 75 years in IAEA GSR Part 3). Recommendation R27 in section 9.1 addresses this issue. The

authorization holder shall transfer the record to BAERA after this retention period or after exemption from his licensed responsibility.

There is no national dose register as stated in GSR Part 1 (Rev. 1) para. 4.63. Recommendation R9 in section 3.7 addresses this issue.

There are no regulatory requirements regarding authorization, approval, and accreditation of personal dosimetry service providers in Bangladesh, as stated in GSR Part 1 (Rev 1) Requirement 13 para 2.41. Recommendation R27 in section 9.1 addresses this issue.

The BAEC Health Physics Division (HPD) provides services for monitoring occupational exposure by monitoring exposed workers, regarding internal and external dosimetry, and workplaces throughout the country, in accordance with NSRC Rules. BAERA has not authorised these activities undertaken by HPD. HPD uses TLDs for individual monitoring of radiation workers who are being monitored quarterly. Annually, HPD monitors about 9000 radiation workers from about 4000 licensees. HPD is the only dosimetry service provider in the country.

The Institute of Nuclear Science and Technology (INST), part of BAEC's Atomic Energy Research Establishment (AERE), has a Health Physics and Radioactive Waste Management Unit (HPRWMU), operating the Secondary Standard Dosimetry Laboratory (SSDL) and performing external and internal radiation dosimetry. The SSDL is a part of the IAEA international network to ensure that the calibration conforms to internationally accepted standards.

The NSRC Rules require the authorization holder to:

- provide adequate education, training, and requalification arrangements for the human resources involved in the authorized practice are available; and such education, training and requalification programmes are approved by BAERA;
- ensure every worker is informed of the potential health risks involved in his job, instructed about the precautions to be taken and give appropriate training and retraining on radiation protection relevant to his duties;

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Safety requirements for medical exposure are mainly stipulated in the NSRC Rules. BAERA has published three regulatory guides in medical exposures area. Requirements for education, training and competence in the relevant specialty are specified. BAERA has training programs on radiation safety and protection for Radiation Control Officers (RCO), but procedure for authorization of qualified experts is not yet established.

The IRRS team was informed that there are 21 radiotherapy facilities, 24 nuclear medicine facilities and around 5000 X-ray facilities licensed by BAERA.

Authorizations are issued in the form of 'licence' for operation, in a single stage process, for all types of medical equipment. BAERA conducts regulatory inspection prior to issuance of licence for each equipment installed in a hospital, irrespective of its hazard potential. For example, each time a hospital procures a new X-ray equipment, BAERA has to conduct a visit for its authorization. Recommendation R14 in section 5.5 addresses this issue.

BAERA is the only authority involved in approval of medical equipment using radiation technology in Bangladesh. A Class E licence is issued to the suppliers of medical equipment, which enables them to import the equipment for supply to end users. However, provisions are not established by BAERA to ensure that registrants and licensees, who are suppliers of medical equipment fulfil their obligations as per Requirement 17 of IAEA GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA does not require suppliers/importers of medical equipment to fulfil their obligations for the safety of radiation generators and radioactive sources.*

(1)	BASIS: GSR Part 3 Requirement 17 para.3.49 states that “ <i>Registrants and licensees who are manufacturers or other suppliers of radiation generators and radioactive sources shall ensure that the following responsibilities are discharged, as applicable: ... (c) Making information available, in the appropriate language understandable to users, on the proper installation instructions for operating and maintenance, and instructions for protection and safety. (d) Ensuring that the protection provided by shielding and by other protective devices is optimized.</i> ”
R15	Recommendation: BAERA should require suppliers and manufacturers to fulfil their obligations for the safety of radiation generators and radioactive sources.

Requirements on radiation protection of pregnant and breast-feeding patients, quality assurance, patient dosimetry and calibration of measuring & monitoring instruments are specified in the NSRC Rules.

Diagnostic Reference Levels (DRLs) are provided in the NSRC Rules for routine diagnostic radiology and nuclear medicine procedures, but there is no requirement for licensees to periodically assess their local DRLs. The published DRLs have not been reviewed and updated to take into account technological advancements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no requirement for licensees and registrants to conduct local periodic assessments for those radiological procedures for which DRLs have been established. Further, review of the DRLs has not been carried out to address advancements in technology, and an action plan for such a review is not available.*

(1)	BASIS: GSR Part 3 para.3.169 states that “ <i>Registrants and licensees shall ensure that: Local assessments are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established. A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required....do not yield the expected medical benefit to the patient.</i> ”
(2)	BASIS: SSG 46 para. 2.35 states that “ <i>... At some predetermined interval, typically three to five years, there should be a review of the established national or regional DRL values. More frequent surveys may be necessary ... will reflect the improvements made as a result of using the existing DRLs.</i> ”
R16	Recommendation: BAERA should require the licensees to conduct local periodic assessments of radiological procedures for which DRLs have been established.
S5	Suggestion: BAERA should consider establishing a mechanism for the review of the DRLs for diagnostic medical exposures at pre-determined intervals.

With regard to justification of medical exposures, the NSRC Rules place obligations on a medical practitioner to conduct radiological examinations on any person only if there are clear clinical needs. However, referral guidelines (appropriateness criteria) are not available to the referring medical practitioner for justification of a radiological procedure for an individual patient.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Referring Medical practitioners do not have guidelines supporting them in the justification of the medical exposure of an individual patient in a radiological procedure.*

(1)	BASIS: GSR Part 3 para.3.158 states that <i>“Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.”</i>
(2)	BASIS: GSR Part 3 para.3.155 states that <i>“Medical exposures shall be justified by weighting diagnostic...benefits...against the radiation detriment that they might cause, with account taken of benefits and the risks of alternative techniques.”</i>
(3)	BASIS: SSG 46 para. 2.59 states that <i>“National or international referral guidelines should be used as an important tool in the application of the process of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing evidence based referral guidelines. “</i>
R17	Recommendation: The Government should ensure relevant professional bodies adopt evidence based referral guidelines for use by the referring medical practitioners.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The NSRC rules place all of the responsibilities to assess the discharge and impact on the representative person on the applicant. Where the general public may be exposed, BAERA request a prospective assessment is performed by the applicant and submitted as part of the application process.

BAERA has responsibilities including:

1. Radiation hazard assessment to control occupational, public and medical exposures;
2. Regulatory investigations of Naturally Occurring Radioactive Materials (NORM) exposure for people and environment hazard control;
3. Approve designated radiation control officers to comply the regulatory requirements for control of occupational, public and medical exposure.

There was no evidence that a comprehensive assessment of public exposure is considered by BAERA as part of the authorization process for individual facilities and activities. BAERA staff informed the IRRS team that they review the assessments submitted by the applicant, but there is no established procedure followed by the regulator to verify potential exposures to the public from any application. Recommendation 11 in section 4.5 addresses this issue.

The NSRC Rules require the authorization holder to ensure that for the source that they are responsible for, measures are optimized in accordance with the requirements of the standards, as appropriate, for restricting public exposure to contamination in areas accessible to members of the public, but this is limited to enclosed spaces. There was no evidence presented to the IRRS team on the consideration of assessment of public exposure from all pathways as part of the authorization process.

The NSRC Rules clearly specify the dose limit but constraints for public doses are absent. Dose constraints are used for medical purposes, but no evidence was provided to the IRRS team that dose constraints are, or have been used for public exposure in Bangladesh, as a result optimization of public doses is not possible. There is a generic recommendation regarding adequacy of regulations and guides in module 9 (9.1). That recommendation to develop a comprehensive set of regulations and guides, should include development and adoption of dose constraints for public exposure.

The IRRS team noted that authorizations issued by BAERA didn't include limits on discharges, which was verified during site visits. Suggestion S4 in section 5.1 addresses this issue.

BAERA has no regulatory framework to address where radon may be a radiological issue, nor to address any other existing exposure situations, such as past practices which were never subject to radiological control or that were subject to an earlier, less rigorous regime of control. BAERA should ensure that regulations and guides adequately consider application of public dose constraints, together with all exposure situations. Recommendations R27 and R28 in section 9.1 address this issue.

Before issuing authorizations for facilities and activities with the potential of exposure to the public, BAERA undertakes monitoring around the source to determine the dose rate around the source. However, BAERA does not undertake monitoring or verification programmes to assess the impact of unlimited discharges to the environment. The IRRS team was informed that a small monitoring programme was undertaken by a third party, which was not appropriate to assess the total dose to the public from authorized activities. Although BAERA can assess in part the potential doses to the public, the major constituents of dose may not be assessed, hence BAERA is unable to demonstrate the public has been adequately protected from radioactive releases and that the legal limit has not been exceeded.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA's existing monitoring programme for the protection of the public is not adequate. BAERA does not assess the total dose to the public to demonstrate compliance with the dose limits.*

(1)	BASIS: GSR Part 3 para. 3.135 states that <i>“The regulatory body shall be responsible, as appropriate, for: (a) (ii) Assessing doses from public exposure; (c) making provision for an independent monitoring programme; (d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of the monitoring data provided by the registrants and licensees and with the use of independent monitoring and assessments; (f) verification of compliance of an authorized practice with the requirements of these standards for the control of public exposure.”</i>
(2)	BASIS: GSR Part 3 para. 3.136 states that <i>“The regulatory body shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.”</i>
R18	Recommendation: BAERA should establish a framework for the protection and safety of the public against exposure, including an assessment of doses to the public and making the information available.

The NSRC Rules provide general principles of exemption on the basis of individual or collective dose limits. The NSRC Rules provide specific activity concentrations for all media, it does not detail specific reference levels for specific commodities. Regulations controlling the import of commodities containing radiation or the selling of products containing radiation are restricted by the requirements of the NSRC Rules.

5.11. SUMMARY

BAERA authorizes nuclear and radiation facilities and activities in Bangladesh in accordance with established regulatory requirements. There are opportunities for improvement in line with IAEA Safety Standards. In certain cases, BAERA is already working on improvements in these areas and the recommendations provided will help to further strengthen these improvements.

During the authorization process for all facilities, there is no consideration of dose to the public. Furthermore, BAERA does not have a means to independently monitor for radiological releases which would provide assurance that the exposures to the people of Bangladesh remain within limits.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Review and assessment is performed by BAERA prior to authorization and then during the lifetime of the facility. The purpose, scope and criteria for review and assessment are derived from the BAER Act and NSRC Rules. The latter identify applicable Standards, Codes and Guides for different regulated facilities and activities. The BAER Act demonstrates that the Authority has the responsibility to develop a system or process for review and assessment of regulatory activities, as well as carrying out the review and assessment. BAERA uses information submitted by the authorized party or applicant, as well as information collected through other sources, such as inspections.

All reviews consist of examining the authorized party's submitted documentation on its management mechanisms and operational procedures, and verification of the safety analysis. For complex facilities and activities, additional submissions by the authorized party on engineered systems will also be examined by the regulatory body. This safety analysis will cover normal operations, anticipated operating occurrences and accident conditions in order to demonstrate that the safety of the facility or activity meets the requirements set out by BAERA.

The duration of the review depends on the number and volume of documents submitted as well as the assessment of the potential nuclear and radiation hazard of the facility or activity being reviewed. These reviews may result in actions being placed on the licensee, either as a request for clarification or a change to the design of the facility.

While BAERA described how review and assessment activities are conducted, there is no specific regulation or procedure that governs these activities, and the rigour of review and assessment is dependent on the knowledge and experience of the individual reviewers. Senior officers take the lead on the review and assessment of more complex radiation facilities. There is a flow chart process for conducting the review and assessment activities of different stages authorization but there is no internal guidance for conducting review and assessment activities. Recommendation R11 in section 4.5 addresses this issue.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Many BAERA staff have been recently recruited and there are a number of defined competence requirements for NPP, a systematic training programme is in place, but is not fully implemented for undertaking review and assessment activities. Recommendation R7 in section 3.3 addresses this issue.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The basis for review and assessment is documented in the NSRC rules. In practice, both BAERA and the licensee use more recent IAEA safety standards and codes. The NSRC Rules should be updated to reflect current practice. Recommendation R3 in section 1.4 addresses this issue.

Prior to granting an initial authorization, BAERA requires that a safety assessment be submitted. This is reviewed and assessed by BAERA. More complex facilities and activities are required to submit more detailed safety assessments, in accordance with a graded approach. Guidance on the documents to be submitted are included in the authorization procedure.

One of the initial tasks of the review and assessment is to confirm the completeness of the submissions. If additional information is necessary, BAERA will request this information be provided by the licensee. These requests for additional information or questions of the regulatory body are formally documented.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

BAERA verifies the adequacy of the safety assessment case-by-case in accordance with the application for authorization. There is no guidance on how to perform the review and assessment on the submitted documents in support of applications. Any proposed modification that might significantly affect the safety of a facility or activity is subject to a review and assessment by ad-hoc expert committees, established by the Chairman, prior to approval by BAERA.

BAERA assesses the risks associated with nuclear facilities for normal operation, anticipated operating occurrences and accident conditions. These assessments are performed prior to issuing an operating licence for the facilities.

There is no internal guidance for the performance of review and assessment activities. Without formal procedures, the review and assessment process may be affected due to subjectivity, lack of consistency, completeness, and inconsistent application of the graded approach. Besides, there are no processes established to interconnect the review and assessment with other core regulatory process, like inspections and authorizations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>BAERA does not have internal guidance to systematically perform review and assessment of facilities and activities and to integrate the outcome of this process with other core regulatory processes.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.46 states that <i>“For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.28 states that <i>“There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties.”</i>
R19	Recommendation: BAERA should establish specific guidance that ensures a consistent and systematic review and assessment of all facilities and activities, and integration with other core regulatory processes.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

Generally, BAERA relies upon the requirements of the vendor country for ensuring that safety of the NPP is adequate. This, along with a shortage of resources, has led to BAERA using the expertise and resources of the vendor country’s regulatory TSO. This demonstrates good cooperation at an international level, however, also indicates that BAERA needs to further develop the competencies in the technology being deployed. BAERA needs to have the capacity and knowledge to understand the advice that the TSO is providing and to be able to use this information to make informed decisions. Recommendation R7 in section 3.3 addresses this issue.

The safety assessment of nuclear facilities is carried out in accordance with the plan approved by the head of the NuRID/NSSSD. It starts with a review by BAERA staff on the submission, which includes a confirmation that all required material was provided. From there, they may reach out to national expertise, such as other organizations or universities for the expert opinions on specific topics. These comments are then forwarded on to the Russian TSO for an independent review of the material, prior to further consideration by BAERA. This aids further development of competencies, sharing of operating and

regulatory experience, adoption of good international practices and having a harmonized approach to the quality and effectiveness of review and assessment.

BAERA uses review committees to provide input into the review and assessment of an NPP authorization. During the siting licence process, this includes both an Internal Review Committee, as well as an External Review Committee. During the design and construction licence process, this includes an Internal Review Committee, External Experts and TSOs.

BAERA has established criteria for determining if the safety analysis is acceptable. The NSRC Rules have a list of codes and standards that are required to be used for assessing safety. In summary, IAEA requirements are used as the first benchmark, but then Russian GOST codes are also used heavily as well as applicable US codes. By trying to adapt the project to multiple codes, this has led to cases where there are differences between these codes. In these cases, BAERA attempts to always use the most conservative approach. Since different codes and standards are used, based on different underlying principles, mixing the application of standards may be challenging.

During the selection of the design of the Rooppur NPP by BAEC, BAERA took a technology-neutral approach. The only requirement that BAERA issued was that the NPP needed to be based on an existing, proven design with a reference plant. As such, BAEC elected to build a VVER plant, with the Russian Novovoronezh NPP being the reference plant.

The review and assessment conducted for nuclear power plants is performed in accordance with the stage of the facility. Each stages reviews information that is relevant, with more detailed and final information being provided in subsequent stages.

For the Rooppur NPP project, BAERA has an established code freeze date. This practice established regulatory certainty for operators. However, the general contract also has a provision that allows for changes to be made should there be extraordinary circumstances, such as significant operational experience from the reference plant and from elsewhere, under which there is broad agreement that safety improvements are required.

Safety analyses are completed for various plant states and considers normal operation, anticipated operating occurrences and accident conditions. Postulated initiating events and the specified state of systems and components affecting the accident development scenarios is used to confirm compliance of the NPP with safety criteria and/or the design limits. The results of this have been incorporated into the emergency preparedness and response plan (NNREPRP) as well as the draft Regulation on emergency preparedness and response for a nuclear or radiological emergency.

Both external and internal hazards are considered in the regulation of the nuclear power plants. During the siting authorization process, external events are considered in the regulatory guide “Site evaluation for the safety of nuclear power plants”. This includes both natural and human-caused events. Internal hazards are considered as part of vendor documentation.

The review and safety assessments have led to modifications being made to the NPP. During the review of the information provided in support to the siting licence application, BAERA staff identified the need to add in a river barrier as the river is subject to change over the lifetime of the facility.

Periodic safety reviews will be conducted for nuclear power plants. The Authorization Procedure indicates that a safety assessment should be carried out periodically, or at the request of BAERA. Typically this will be conducted every 10 years, which will line up with the licence period.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The regulatory guide on the content of the safety analysis report for the research reactor is used by the authorized party to prepare the updated safety analysis report, and by BAERA to review and assess the

safety of research reactor. The Act requires the licensee to conduct a periodic safety review (PSR). Recently, the first periodic safety review was carried out by the licensee based on the relevant IAEA Safety Standards. BAERA is reviewing and assessing the results of the PSR, which will inform the regulatory decision on continued operation of the facility, but there is no clear plan to guide the review and assessment process. Recommendation R11 in section 4.5 addresses this issue.

BAERA should develop an adequate regulatory guide to describe the interaction with authorized parties during the review and assessment process, as well as the process for information submission. Recommendation R27 in section 9.1 addresses this issue.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Following receipt of an application BAERA confirms to the applicant the list of safety case documents to be submitted in support of the application depending on the stage of licence applied for. Typical licensing stages include siting, design and construction, commissioning, provisional approval of operation followed by approval of operation.

As part of the annual licence renewal, licensees submit updates to the radiological protection programme, emergency planning arrangements, quality assurance arrangements, area and personnel monitoring results. The IRRS team however noted that while an update to the safety analysis report was submitted to the regulatory authority in 2014, updates are not submitted as part of the annual licence renewal.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no evidence that a regular review of the safety of the CWPSF was undertaken by BAERA at defined frequencies.*

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.39 (a) states that <i>“The regulatory body, in accordance with a graded approach, shall ensure that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities...”</i>
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(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.40 states that <i>“The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach....”</i>
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R20	Recommendation: BAERA should define the frequency for and undertake regular review and assessment of the safety of the CWPSF.
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6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The review and assessment of information provided by the licensee is performed prior to granting the authorization for facilities and activities associated with radiation sources, and for subsequent authorization renewals.

There are high risk and complex radiation sources facilities and activities in Bangladesh.

The review and assessment process for radiation sources facilities and activities is not well documented in BAERA guidance, and as a consequence, review and assessment are heavily dependent on the expertise and knowledge of the reviewer.

There are no processes to use the outcomes of the review and assessment to input into other core regulatory processes such as inspection, or vice versa. Recommendation R19 in section 6.1 addresses this issue.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There are currently no active decommissioning activities in Bangladesh. Consequently, there is no review and assessment of decommissioning activities required.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The NSRC Rules identify IAEA SSR-6 (1990) and its associated IAEA Guidance Documents, which have been superseded, however a rule allows the use of SSR-6 (Rev.1). The BAER Act also provides a direct link by referring to transport requirements prescribed by regulations that are consistent with the international rules and regulations for transport of radioactive material.

The IRRS team was informed that the approach used for review and assessment involves:

- An application for a transport authorization, which must include a copy of the certificate of conformity of the package design issued in the country of origin of the package design (by the operator) for IP-2, IP-3, and Type A package types, and the associated package design safety report. No technical analysis is undertaken by BAERA
- An application for a transport authorization, which must include a copy of the Competent Authority approval certificate of the package design issued by the country of origin (competent authority) of the package design for Type B and Type C package types and the associated package design safety report. No technical analysis is undertaken by BAERA.

BAERA has no competence to assess package designs. Its review and assessment of package designs is an administrative process of validation of the certification of package designs issued in another country and there is no technical assessment of the package designs.

In addition, BAERA confirmed there are no documented procedures for a package design review and assessment process for IP-2, IP-3, Type A, Type B, and Type C packages.

Recommendations R7 in section 3.3 and R11 in section 4.5 address these issues.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Applicants for authorization are required to demonstrate compliance with the NSRC Rules as part of the review and assessment process, including the preparation of instructions and work procedures for the internal control of radiation protection. This includes the risk assessment, classification, monitoring and surveillance of areas, information and training of occupationally exposed workers, protective measures, and individual dose monitoring and recording.

NSRC Rules also require the authorization holder or the employer to designate a Radiation Control Officer (RCO) who is approved by BAERA.

NSRC Rules require the authorization holder to adapt the working conditions of a female worker who has notified pregnancy with respect to occupational exposure, in order to ensure that the embryo or foetus is afforded the same broad level of protection as required by the members of the public. The planned special exposures are not authorized for the workers who are women of reproductive capacity.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The NSRC Rules and the relevant regulatory guides form the basis for review and assessment of medical facilities by BAERA. There are 14 technical staff involved in the review and assessment of all types of radiation facilities, out of which 7 are senior staff with experience, while others have joined only within the

past six months to one year. The IRRS team identified the need for robust competence development training and conduct of assessment by BAERA on the appropriate deployment of technical staff for the regulation of radiation sources. Recommendation R7 and Suggestion S3 in section 3.3 address this issue.

BAERA has not developed an internal guidance document for use by its staff for the review and assessment of submissions applying a graded approach. Recommendation R19 in section 6.1 addresses this issue.

The IRRS team observed that documents reviewed for the issuance of a licence for diagnostic and interventional radiology equipment do not include the performance test report of the equipment. Further, requirements are not specified for acceptance and QA of software (eg. Treatment planning systems used in radiotherapy) that could influence delivery of medical exposures and for periodic radiological reviews.

BAERA regulatory guides in medical exposure areas recommend investigation and reporting of unintended or accidental medical exposures by the licensee. The IRRS team observed that no incident/accident has been reported to BAERA from medical facilities in the past few years. Guidance or requirements for licensees on reportable events and the mechanism for sharing of operational and regulatory experience feedback is not established. Recommendation R6 in section 2.2 addresses this issue.

The periodicity for calibrations of sources giving rise to medical exposure or the period for retention of records of calibration, dosimetry and quality assurance by the licensees is not specified by BAERA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA has not established the requirements for independent verification of the calibration of radiotherapy equipment, quality assurance of radiotherapy planning systems, periodic radiological reviews. BAERA should specify the periodicity of calibration of sources/equipment, and retention period for relevant records related to medical exposure.*

(1)	BASIS: GSR Part 3 para. 3.167 states that <i>“In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that: (a) All sources are calibrated. (b) Calibrations are carried out at the time of commissioning a unit prior ... and at intervals approved by the regulatory body; (c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use; ... ”</i>
(2)	BASIS: GSR Part 3 para. 3.171 states that <i>“Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include... (a) Measurements of the physical parameters of medical radiological equipment made... (iv) After any installation of new software or modification of existing software that could affect protection and safety of patients”.</i>
(3)	BASIS: GSR Part 3 para. 3.182 states that <i>“Registrants and licensees shall ensure that radiological reviews are performed periodically. ... shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility”.</i>
(4)	BASIS: GSR Part 3 para. 3.184 states that <i>“Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance.... ”</i>
R21	Recommendation: BAERA should establish a comprehensive set of requirements for ensuring optimisation of protection and safety of medical exposures, quality control of medical equipment and record retention.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

The NSRC rules place the responsibilities on the applicant to assess the impact of all discharges on the public at the application stage. Following granting of the authorization, there is no information or assessment made that any appropriate retrospective assessment is undertaken by BAERA to determine that public doses are in compliance with the dose limit and the representative person has been appropriately protected.

BAERA undertakes a form of review when the licence is renewed by the applicant. For the most hazardous sources the authorization renewal frequency is annual. The regulator does not undertake any environmental monitoring or review any monitoring undertaken by the operator to verify that the doses received by the public are in compliance with the dose limit. Recommendation R18 in section 5.10 addresses this issue.

6.11. SUMMARY

BAERA conducts review and assessment activities, in accordance with a graded approach, in support of the authorization process. However, there are no procedures across all reviewed areas to document how these activities are to be conducted which would ensure a level of consistency.

Specifically for NPPs, BAERA places high reliance on vendor country codes and standards, where none exist in Bangladesh. In addition, BAERA is also reliant upon its TSO to support the review and assessment function. Across all nuclear and radiation facility types, BAERA should look to improve its capacity and capability to ensure that it has the competence to understand and act upon the advice provided by the TSO.

7. INSPECTION

7.1. GENERIC ISSUES

BAERA carries out regulatory inspections on regulated facilities and activities to verify compliance with the respective licence conditions. The divisions in BAERA initiate and implement programmes for conducting inspections. The powers of the BAERA inspectors are conferred to them in the BAER Act as well as the NSRC Rules.

The inspection process is documented in the Regulatory Inspection Procedure. The inspection process includes both planned and reactive inspections, as well as announced and unannounced inspections. Annual inspection plans for the regulated facilities and activities are developed that includes the various types of inspections as may be deemed appropriate.

The BAER Act empowers the regulator to appoint inspectors. Where necessary to conduct a more detailed and in-depth inspection, consultants can be appointed and used to support the BAERA Inspectors.

Training of Inspectors is provided by the appointed TSO for NPP inspectors, and an inspector badge is also issued to appointed NPP inspectors, which is not necessarily the practice for inspectors of other facilities and activities.

For facilities and activities other than NPPs training records are kept. Furthermore, there is no formalised inspector training, qualification, and certification programme in place within BAERA for the appointment of inspectors. A systematic inspector training, qualification and certification programme will contribute to a consistent and improved compliance assurance programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is an absence of a clear basis for the formal appointment of Inspectors in BAERA.*

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.11 states that <i>“The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.13 states that <i>“A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.”</i>
(3)	BASIS: GSG-13 para. 8.228 states that <i>“The regulatory inspection programme should give due consideration to leadership and the management system at the authorized party, and to human, technological and organizational factors. Accordingly, the inspectors’ training and qualification programme should be tailored to develop competences in these areas.”</i>
R22	Recommendation: BAERA should develop an Inspector Training, Qualification and Certification process for all facilities and activities.

In general checklists for performing inspections are not available for facilities or activities, such as emergency preparedness and response, transport, radiation sources facilities and activities, radiation protection, and the general guidance of inspections is not consistently applied.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: BAERA guidance to inform regulatory inspectors is not consistently applied. Areas where this was evident included EPR, transport, radiation sources and facilities, radiation protection.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 27 states that “The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.”
(2)	BASIS: SSR 6 (Rev.1) Requirement 303 states that “The competent authority shall assure compliance with these Regulations.”
(3)	BASIS: GSG-13 para. 3.225 states that “The regulatory inspection programme should be comprehensive and consistent with the overall regulatory strategy. The inspection programme should be thorough enough to ensure that the regulatory objectives and requirements are being met, thereby providing the regulatory body with a confidence that the authorized party is effectively maintaining the safety of the facility or activity. The inspection programme should also be developed so that the regulatory body can determine whether the authorized party conducts activities in accordance with previously established procedures, and has an effective self-assessment process capable of prompt identification and correction of actual and potential problems.”
R23	Recommendation: BAERA should ensure consistent application of the inspection guidance by its inspectors across all facilities and activities.

Furthermore, there is no systematic tracking of inspection outcomes to support inspectors in the preparation for inspections and follow-up on non-compliances or areas for improvements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: BAERA does not have a formalised system for tracking and trending of the results from regulatory inspections from all facilities and activities.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.46 states that “For an integrated safety assessment, the regulatory body shall first organize in a systematic manner the results obtained. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.”
(2)	BASIS: GSG-12 para. 5.56 states that “Non-conformances should be reported in sufficient detail to allow their proper review. The causes of non-conformances (and other emerging issues negatively affecting the regulatory work or safety issues) should be determined and their potential consequences should be evaluated. Trends in non-conformances and associated causes should be analysed to identify repeat occurrences, common issues, and weaknesses.”
(3)	BASIS: GSG-13 para. 3.235 states that “As part of the inspection programme, on a regular basis the regulatory body should compile and assess data on the performance of authorized parties, the results of the regulatory inspection programme (inspection findings, corrective actions, and inspection reports) and trends in these data and results. This information should be used to identify potential areas for improvement in the performance of authorized parties and regulatory processes. The reports of such assessments and analyses should be shared and communicated within the regulatory body.”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R24	Recommendation: BAERA should implement a system for tracking and trending the results of regulatory inspections, and communicate this information within the regulatory body and to licensees, where appropriate.
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The IRRS team observed inspections performed by BAERA and interacted with the staff of two medical institutions and one industrial facility about the regulatory relations, transparency and predictability of regulatory requirements and timelines for approvals. Licensees expressed the regulatory relations to be generally satisfactory. In the discussions with the licensees, concerns were noted regarding the absence of criteria for reporting abnormal situations to BAERA and the need to improve the provision of guidance on regulatory requirements and adherence to timelines for approvals.

During the visit to Rooppur NPP, it was apparent that the operator values the regulatory presence and oversight, and as a fact that there are good communication channels with the inspectors on site.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

Announced and unannounced inspections are performed in accordance with the Inspection Procedure and as scheduled in an annual inspection plan by the BAERA inspectors. Unannounced inspections are typically targeted inspections with a specific scope and objective when important to safety activities are performed.

The NSSSD division has 13 NPP inspectors. A resident inspector is permanently stationed on site, with six other inspectors that are rotated every 15 days. The BAERA inspectors are also supported by the TSO, JSC VO Safety. The IRRS team has been informed that in 2015 six NPP inspectors were recruited of which only one is still employed in the organisation as the Resident Inspector. The IRRS team was advised that retention of NPP inspectors is a challenge, with a subsequent impact on the level of inspector knowledge and experience.

The IRRS team observed an inspection at the Rooppur NPP. The inspection team was led by the resident inspector who has more than five years of experience. The experience of the rest of the inspection team varied from seven months to 2.5 years and included a mix of speciality areas such as mechanical, civil, nuclear engineering, etc. Gaps identified in the areas are material sciences, metallurgy as well as welding and non-destructive testing techniques. Further, different set of skills would be required in the near future for the commissioning and operational phase of the Rooppur NPP. Recommendation R8 and Suggestion S3 in section 3.3 address this issue.

Comprehensive inspections are conducted quarterly. Daily inspections are also performed including targeted inspections as necessary. Comprehensive inspections are typically team inspections with support from the TSO. Targeted inspections are conducted to verify whether the construction quality complies with the relevant requirements, codes, standards, and design specifications. These inspections are based on safety class, seismic category, and quality class of the components, following a graded approach. The Inspection Procedure however, although referring generically to the implementation of a graded approach in inspections, it does not provide guidance on how to implement the graded approach for NPP inspections. The regulatory body should develop guidance on the implementation of the graded approach that are implemented for NPP inspections. Recommendation R11 in section 4.5 addresses the issue.

The licensee is required to notify BAERA of the schedule of key activities, and they are further required to submit detailed reports and records when the activity is completed, to verify compliance with the respective requirements, codes, standards and specifications. There is a requirement in the BAER Act to inform BAERA of safety significant non-compliances or deficiencies. The formal regulatory requirements that provide details on reporting of non-compliances or deficiencies has not been established in a graded manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no regulatory requirement for applicants or operators to inform the regulator of safety significant non compliances or deficiencies in a timely and graded manner.*

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.66(e) states that <i>“Making information on incidents in facilities and activities, including accidents and abnormal occurrences, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 3.4 states that <i>“The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.”</i>
(3)	BASIS: GSG-13 para. 8.220(e) states that <i>“Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the authorized party and duly reported to the regulatory body as required.”</i>
R25	Recommendation: BAERA should establish regulatory requirements for the reporting of safety significant non compliances and deficiencies in a timely and graded manner.

BAERA has appointed JSC VO Safety as a TSO to support site inspection activities as well as performing conformity assessments during manufacturing of pressure equipment. During the observation of the plant inspection, three of seven TSO site representatives were available to support BAERA.

The representatives of BAERA’s TSO are permanently based near the site and available to support BAERA’s regulatory inspection activities as may be required during construction, installation and commissioning phase of the project. The TSO representatives do not only provide expert advice as may be required for an inspection but are actively involve with on-the-job training and knowledge transfer. This is considered an area of good performance.

7.3. INSPECTION OF RESEARCH REACTORS

Opening meetings are conducted at the start of inspections with the authorization holder. During the inspection, inspectors check the compliance with regulatory requirements and licence conditions, verify the statements in the safety assessment for review, and follow-up whether corrective actions have been implemented. A prescribed checklist is used, including boxes to record observations, in case of non-conformities or areas for improvement are identified. The checklist covers license conditions and technical specifications including safety limits, limiting safety system settings, limiting conditions for operations, surveillance requirements, and administrative controls. At the end of the inspection, the team conducts an exit meeting with reactor management personnel to inform them of the significant findings. The findings are usually discussed and agreed between the team members, and provided officially to the licensee in the form of an inspection report.

Inspection results are not communicated to the public, and BAERA should establish a suitable mechanism to notify the public. Recommendations R10 in section 3.8 addresses this issue.

The inspections are conducted by scientists and engineers. There is no systematic training programme to ensure that the inspectors have the required knowledge, skills and attitude. The training they receive is in the form of workshops conducted by IAEA. Competencies of inspectors need to be analysed and a

systematic training programme should be developed to enhance their competencies, based on a gap analysis. Recommendation R7 in section 3.3 addresses this issue.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

In line with the graded approach, inspections at the CWPSF are conducted approximately once every two years. The IRRS team was informed that inspections of waste management practices at other facilities are implemented as part of the holistic inspection of each individual facility. This was deemed to be aligned with the graded approach. The IRRS team noted that whilst unannounced inspections are provided for in the BAERA Act, unannounced inspections are seldom conducted.

The IRRS team observed the conduct of an inspection at the CWSPF. At the start of the inspection, the inspector issued the licensee with a letter confirming the scope of the inspection to be conducted. The licensee acknowledged the inspection scope by counter signing the letter.

The inspector used a standardised checklist for conduct of the inspection. The process of inspection was observed to be aligned with the IAEA recommendations.

The IRRS team observed that due to the low frequency of inspections (once in two years) at the waste management facility, different inspectors conducted the inspection each time. Consequently, the inspector undertaking the inspection of the facility may not always be familiar with the facility being inspected. Further the IRRS team was informed that there is no systematic training programme to ensure that the inspectors have the required knowledge, skills and attitude. Training received was in the form of workshops conducted by IAEA. Competencies of inspectors need to be analysed and a systematic training programme should be developed to enhance their competencies, based on the gap analysis. Recommendation R7 in section 3.3 addresses this issue.

The management of the operating organisation expressed a view that more frequent interaction with BAERA would greatly assist them in timeously addressing regulatory issues and improving their level of compliance.

There was no evidence a systematic tracking of inspection outcomes to support inspectors in the preparation for inspection and following up on non-compliances or areas for improvements, identified in previous inspections. Recommendation R24 in section 7.1 addresses this issue.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The IRRS team was informed that BAERA uses inspection checklists for the inspection for different radiation facilities and activities. The IRRS team observed that there is no systematic review and update of inspection checklists used by BAERA to ensure they remain fit for purpose.

There is no inspection programme with inspection procedures for radiation facilities that would include, but not limited to predetermined criteria for inspections, categorisation of inspection findings that could lead to enforcement actions, format and contents of inspection checklists, specific inspection procedures, revision of inspection documentation, etc. Recommendation R23 in section 7.1 addresses this issue.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

There is currently no active decommissioning of facilities in Bangladesh. Consequently, there are no planned inspections related to decommissioning activities.

7.7. INSPECTION OF TRANSPORT

All transports of Category 1 sources are subjected to inspection. The frequency of the inspections of authorized parties for transport is based on the activity of the source. The risk-based approach to prepare the inspection plan is not documented. Recommendation R11 in section 4.5 addresses this issue.

The existing inspection documents do not contain a sufficiently detailed scope of areas of verification to demonstrate compliance with SSR-6 (Rev.1) requirements. Recommendation R23 in section 7.1 addresses this issue.

The IRRS team noted that BAERA does not have a documented inspection process and there is no systematic review of outcomes of inspections. This would be an expected component of a documented inspection process. Recommendations R11 in section 4.5 and R8 in section 3.3 address these issues.

Training of inspectors is primarily on-the-job training with new recruits accompanying experienced inspectors, later acting as lead inspector with an experienced inspector as support. In addition, reviewing inspection reports and suggesting follow up actions, studying the transport regulations, inspection, and enforcement procedures also form part of inspector training. Whilst the elements of the approach currently being used would be expected to be included in an inspector training programme, there is no documented systematic and holistic training programme for the various inspections of facilities and activities. Also, no evidence was provided of refresher training, external training, or training records. Recommendations R11 in section 4.5 and R19 in section 6.1 address these issues.

The IRRS team was informed that several experienced inspectors have been transferred from the regulatory oversight of radiation facilities and activities to the nuclear safety division within BAERA. Suggestion S3 in section 3.3 addresses this issue.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Inspections consist of interviews of management and employees involved in radiation use and radiation protection, a review of the authorized party's documentation and records regarding radiation protection, and observations of work techniques and work practices. During inspections, inspectors use checklists which include occupational exposure items. They review and verify the authorized party's compliance with regulatory radiation protection requirements and conditions in the authorization. Compliance requires the designation of an RCO; classification, monitoring and surveillance of controlled and supervised areas; calibration, testing and maintenance of equipment; competence and training of workers; and records of occupational dose and compliance with dose limits.

7.9. INSPECTION OF MEDICAL EXPOSURE

BAERA has 14 technical staff to carry out inspections of radiation facilities, of which 7 experienced inspectors are involved in the inspection of radiotherapy and nuclear medicine facilities. BAERA has specified the inspection frequency for different medical facilities based on a graded approach, but only the annual inspection plan for X-ray facilities, that were surveyed for the issuance of a licence, was available.

The IRRS team was informed that while conducting planned inspections of medical facilities, BAERA proactively engages with the X-ray facilities in the same city to spread awareness on regulatory and safety requirements. It was noted that during one recent exercise, around 50 X-ray facilities were surveyed over a period of one week at Gopalganj district and followed up for obtaining a licence for operation. The IRRS team recognizes this proactive approach of BAERA as an area of good performance.

BAERA has developed specific inspection checklists for all medical practices. Training of new inspectors is through on-the-job training with mentoring by senior inspectors. BAERA should establish a systematic inspector training and certification programme and develop internal guidance documents for inspection considering that except for the senior staff, the technical staff have limited experience in medical exposures area. Recommendations R22 and R23 in section 7.1 address this issue.

Site visits were conducted at two medical institutions, Square Hospital, Dhaka, and Institute of Nuclear Medicine and Allied Sciences, Dhaka. Square Hospital possesses diagnostic radiology, linear accelerator and brachytherapy equipment. The scope of inspection was limited to the inspection of one X-ray and the

linear accelerator facility. The inspection started with initial meeting with licensee, and verification of permits, availability of trained manpower, personnel dose records, quality assurance tests, equipment calibration records etc as per the inspection checklist. The documentation checks were followed by a walkthrough of the facility. The inspectors conducted a radiological survey of the installation. At the INMAS, Dhaka, the IRRS team observed the inspection of a nuclear medicine SPECT facility where the inspectors verified documents and conducted contamination checks. The IRRS Team noted that BAERA does not verify the sampling and monitoring of effluents from nuclear medicine therapy wards (by the licensee) prior to their release to public sewers, and no discharge limits are specified. Suggestion S4 in section 5.1 addresses this issue.

It was observed that the inspection checklists were not comprehensive. BAERA does not have a system for tracking and trending of the results from regulatory inspection activities and follow up on regulatory non-compliances. Recommendation R24 in section 7.1 addresses this issue.

7.10. INSPECTION OF PUBLIC EXPOSURE

The NSRC rules place responsibility for monitoring and assessment on the operator, including the optimization of public exposure for enclosed spaces, and no further evidence was presented to the IRRS team on the use of optimization or dose constraints for public doses and whether inspection by the regulator addresses optimization of public doses. The development of appropriate regulations and guides for dose constraints will allow dose optimization for the public to be reviewed as part of site inspection. Recommendations R27 and R28 in section 9.1 address this issue.

The absence of a regulatory framework for the management of existing exposure situations in Bangladesh means that there are no inspections in this area. The IRRS team was informed that the Ministry of Health and Family Welfare may undertake some targeted programmes. Once suitable regulation is in place to address existing exposure situations, an appropriate inspection regime can be developed. Recommendation R4 in section 1.6 addresses this issue.

A review of potential doses received by the public is not currently considered in the development of the inspection plan. Inspections for non-nuclear sites are based on a check list for each type of practice. The IRRS team was informed that these check lists were developed to both audit the radiation sources and following regulatory experience. However, for sites discharging to the environment there is no provision in the inspection check list for a consideration of total public dose.

Inspections undertaken to demonstrate compliance with the public dose impact of any authorised site need to be proportionate and to the risk posed, adopting a graded approach. BAERA does not consider public dose as part of that checklist.

The authorizations issued by BAERA to operators do not limit discharges. Therefore, the regulatory inspection does not verify that discharges were within the predictions in the operator's application. As BAERA does not undertake or review any environmental monitoring associated with the discharge it is unable to demonstrate compliance with dose limits. Suggestion S4 in section 5.4 addresses this issue.

7.11. SUMMARY

BAERA has the legal mandate to appoint inspectors to verify compliance with authorised conditions by conducting inspections, and to require that corrective measures are implemented in a prescribed time frame.

The absence of a comprehensive inspection programme needs to be addressed by BAERA to ensure it is able to effectively gain assurance on safety of facilities and activities.

The inspection process is documented in the Regulatory Inspection Procedure. However, the degree of implementation of the inspection procedure varies across the organization. In some instances, such as for sources, BAERA does not follow a systematic approach to inspection.

Another area of concern is the lack of a systematic approach to training across the organization. Some training records are kept, however, there is no formal inspector training and qualification programme.

An aspect that may impact the effective implementation of the inspection plans in certain functions, is that several experienced inspectors have transferred from other functions in BAERA to NSSSD.

By addressing the shortcomings identified in the module, BAERA will establish an improved and consistent compliance assurance programme that will contribute to enhanced compliance with authorised conditions, rules, regulations, and requirement and to nuclear and radiation safety in general.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Possible enforcement actions are provided in the BAER Act and includes provisions relating to Offences and Penalties. The Inspection Procedure includes guidance on enforcement actions including restriction of specific activities, as well as amendment, suspension or cancellation of an authorization. In addition, the “Enforcement Procedure” details amongst others different levels of enforcement measures ranging from Verbal Warnings, Improvement Notices, Orders and Monetary Penalties. The draft “Enforcement Procedure” is for information only and therefore has no legally binding requirements or practices.

Although Section 6 of the “Inspection Procedure” as well as the draft “Enforcement Procedure” provide some guidance on possible enforcement measures, no clear criteria for grading of non-compliances and associated enforcement actions has been defined.

The Act empowers BAERA to make regulations related to matters concerning inspections and enforcement. No enforcement policy and regulations are in place that will provide the procedure for appeals and defining criteria for grading of non-compliances and implementation of associated enforcement actions in a graded and consistent manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA has no enforcement policy or associated guidance for responding to non-compliances with requirements or authorization conditions by authorized parties consistently, using a graded approach.*

(1) **BASIS: GSR Part 1 (Rev. 1) para. 4.54 states that** *“The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach”*

(2) **BASIS: GSG-13 para. 3.305 states that** *“The regulatory body should have the authority to impose or to recommend penalties; for example, fines on the authorized party, whether a corporate body or an individual; or to institute prosecution through the legal process, depending on the legal system and the authorization practices of the State. The use of penalties is usually reserved for serious non-compliances with regulatory requirements and for repeated violations of the authorization conditions of a less serious nature.”*

R26 **Recommendation:** **BAERA should develop an enforcement policy and associated guidance to ensure it takes enforcement action consistently, adopting a graded approach, in response to non-compliances with requirements or authorization conditions by authorized parties.**

8.2. ENFORCEMENT IMPLEMENTATIONS

The enforcement actions that can be imposed by BAERA include the issuance of notices to require improvements by taking specific corrective actions within a given timeframe, and also to stop operations. These actions are generally communicated to the licensee by written correspondence, however, in specific cases the inspectors may verbally communicate the enforcement action on the spot. This approach has been confirmed in the site visits for nuclear facilities.

Decisions are made by inspectors based on their professional experience and judgment and the advice received from external experts participating in the inspection. Discussions with RTWSD revealed the non-compliances raised during inspections are often resolved by discussion between the inspector and the authorized party. It was not evident that the inspectors receive specialized training on the implementation of enforcement actions. Recommendation R22 in section 7.1 addresses the issue.

Follow-up of the implementation of corrective actions is mainly done through subsequent inspections. The authorized party is requested to inform BAERA of the completion of corrective actions. The IRRS team was informed by BAERA that no cases of conflicts, objections or contradicting views with the authorized party have ever occurred that may lead to an appeal or to escalating the enforcement process to higher levels. Indeed, this was also confirmed by an authorized party during site visits to the BTRR Research Reactor. The regulatory body has no process for informing the public on the enforcement actions when needed. The IRRS team was also informed that it is not a practice of the regulatory body to inform the public. Recommendation R10 in section 3.8 addresses the issue.

For NPP, a number of enforcement notices have been issued to the licensee since 2016. These notices emanated from review and assessments, inspections as well as incidents on site. There have been no appeals to the decisions by the BAERA. No evidence for enforcement action for other facilities and activities was provided, and as a consequence the IRRS team was unable to judge whether enforcement is consistently and effectively applied across all facilities and activities.

8.3. SUMMARY

Possible enforcement actions are outlined in the BAERA Act, whilst the “Regulatory Inspection Procedure” includes provisions on enforcement management and actions that can be imposed by BAERA. The offences and penalties are specified in the BAERA Act and include fines and or imprisonment, and seizure of sources. There is however no enforcement policy and regulations in place to ensure implementation of enforcement actions in a graded and consistent manner.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The BAER Act empowers BAERA, with prior approval of the government, to make regulations for exercising regulatory control of nuclear and radiation safety, security and safeguards. The IRRS team noted that a regulation on site evaluation for the safety of NPPs was developed in 2015, and several other regulations have been drafted. However, since the entry into force of the BAER Act, BAERA has not enacted any regulations, with the prior approval of the Government and by finally publishing in the Official Gazette to formally notify licensees.

The NSRC Rules from 1997 are not fully consistent with both the BAER Act and the latest version of IAEA Safety Standards, they continue to be used as the main instrument for the regulation of safety in Bangladesh. Observations regarding the consistency between the NSRC Rules and the BAER Act are discussed in section 1.4 of this report. Recommendation R4 in section 1.4 addresses this issue.

The IRRS team was informed that BAERA is currently working in the preparation of revised rules to replace the NSRC Rules as well as a set of BAERA regulations. The expectation of BAERA is that the new rules and various draft regulations should be approved in 2023.

Whilst BAERA and the Government may decide which areas should be covered by rules or regulations, the IRRS team considers it necessary to identify gaps in the current regulatory framework and expedite the creation of a consistent and comprehensive regulatory framework. Recommendation R3 in section 1.4 addresses this issue.

BAERA has an action plan but does not systematically formulate and update regulatory guides to facilitate consistency in the implementation of the regulatory requirements by the licensees.

The IRRS team identified several generic issues regarding regulations and guides, as follows:

- BAERA does not consistently issue formal guidance on the format and contents of the documents to be submitted by the applicant in support of an application for an authorization.
- Although a flowchart exists, a detailed process to develop, revise, and promote regulations and guides has not been established.
- The regulatory requirements for medical exposure are not in line with IAEA GSR Part 3.
- There are no appropriate regulations and guidance for occupational exposure. The only applicable requirements are in the NSRC Rules, but they are insufficient.
- BAERA does not have a regulatory framework to address existing exposure situations. Although legal values in the form of radon concentrations are specified in the NSRC Rules, BAERA has no regulatory framework that requires identification of the locations where radon may be a radiological issue and how these issues should be addressed.

The IRRS team noted that BAERA self-identified the need to develop guidance on management of orphan sources and the safe source management as part of their action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Although BAERA uses published guides, existing national and vendor country's regulatory documents for its regulatory requirements, it does not have a comprehensive set of regulations and associated guides to assist the licensees to comply with the regulatory requirements.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that <i>“Regulations and guides - The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that <i>“Review of regulations and guides - Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.”</i>
(3)	BASIS: GSR Part 1 (Rev. 1) para. 4.34 states that <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety the regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based related information as specified in advance or as requested in the authorization process.”</i>
R27	Recommendation: BAERA should take all necessary actions to expedite the enactment of a comprehensive set of regulations that specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.
R28	Recommendation: BAERA should issue a comprehensive set of guides to explain the requirements of the regulations and how to comply with them.

The IRRS team was informed that some interested parties are consulted in the process of drafting regulations and guides, but there is not a systematic approach yet to involve interested parties, as well as to notify the interested parties and the public about new regulations and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: BAERA does not have a systematic approach to involving interested parties and the general public in the process of establishing regulations and guides.	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 34 states that <i>“Promotion of regulations and guides to interested parties - The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.61 states that <i>“The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience”</i>
R29	Recommendation: BAERA should consult with interested parties in the development of regulations and guides and should notify interested parties and the general public about the principles and associated criteria for safety in its regulations and guides.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The NSRC Rules state the mechanism of applicable regulations and guides. It refers to applicable IAEA requirements, INSAG, USNRC 10CFR applicable parts, ASME codes, Bangladesh National Building Codes, Fire Safety Codes, etc. But these are old and not updated. The use of vendor's norms, codes and standards is also permitted. If any contradiction occurs, then BAERA follows a conservative approach to ensure safety. BAERA has developed several draft regulations, guides and procedures, establishing a regulatory basis for the safe operation of NPP.

The Inter-Governmental Agreement General Contract (IGA) on NPP construction between Bangladesh and vendor country, enables BAERA to follow Bangladesh Normative documents, IAEA Safety Standards, and vendor country's normative documents listed in the contract for NPP design and construction.

BAERA received the IAEA SEED mission in August 2015, BAERA established committees, including national and foreign experts on the BAERA and Governmental levels following which BAERA developed "Regulation on Site Evaluation for NPPs" and "Regulatory Guidance on Site Evaluation for the Safety of NPPs" in parallel with collaboration with IAEA. The regulation took account of IAEA SSR-1 "Site Evaluation for Nuclear Installations" (2019) and published the site evaluation guide in December 2015 before the site license was issued in June 2016.

Regarding the design requirements for the NPP, BAERA adopted the requirements of the vendor country, "Federal Rules and Regulations in the Area of Atomic Energy Use General Provisions for Nuclear Power Plant Safety Assurance (NP-001-15)". This is equivalent with IAEA SSR-2/1 (Rev. 1) and BAERA assessed IAEA standards with respect to "their applicability to the vendor country" by self-assessment, which confirmed there are no gaps between them. Although the vendor country requirements were published in 2015 and SSR-2/1 (Rev. 1) was published in 2016, the requirements of revision were captured in advance.

BAERA's relationship with the TSO JSC VO "Safety" of the Russian Federation has facilitated access to regulatory knowledge and experiences. This relationship provides BAERA with opportunities to help them improve the capability to develop regulations and guides.

BAERA does not have clear processes to develop, revise and promote regulations and guides for site evaluation, design, and operation of NPPs. In addition, an applicable list of regulations and guides has not been clearly defined. Recommendations R27 and R28 in section 9.1 address these issues.

Policy Discussion - Using vendor's codes and standards and regulations

Currently, BAERA has drafted some regulations, guides and procedures establishing the regulatory basis for the safe operation of the Rooppur NPP under BAER Act and is using relevant rules and regulations of the vendor country's regulator for the NPP licensing process. BAERA is in the process of a systematic transition to development and implementation of its own regulations, codes and standards as well as the harmonisation of the country's regulatory framework with the IAEA Safety Standards and international best practices. NSRC Rules under Clause 15.2, allow the use of IAEA safety standards and rules in case there are gaps in national legislation or if it becomes outdated. If IAEA standards and guides are inadequate, the standards, codes and guides published by any national regulatory authority or internationally accepted bodies may be adopted under Article 15.3 of NSRC rules. Currently BAERA is making use of the vendor country's codes, rules and standards for the design review of Rooppur NPP and for the regulatory oversight of construction, commissioning and operation.

The purpose of this policy issue discussion was to share the experience of other countries on using codes and standards during different phases of a nuclear power plant programme, including design, construction, commissioning and operation phases, where there are no national regulations, guides, codes or industrial standards.

The IRRS team gave an overview of different approaches in their respective countries during the discussions, which is summarized below:

- The regulatory policies, principles, and regulations, being based on IAEA safety standards are technologically neutral, corresponding IAEA guidance is used if they have not been developed by the regulatory body and industrial codes and standards of the vendor country are also used for the design review, during construction, for equipment manufacturing, commissioning and operation. These codes and standards are agreed with the licensee for each design. Furthermore, compliance verification against acceptance criteria specified in codes and standards is checked as part of regulatory oversight.
- It is important to define the regulatory approach to be followed, either prescriptive or performance-based approach. The selected approach defines overall regulatory philosophy, adopting a performance or goal setting approach requires defining a set of high-level principles. The selection of codes and standards rests with the licensee, who must demonstrate to the satisfaction of regulatory body that the intent of regulations and the principles are met.
- In one of the performance-based approaches, technical specifications are defined and endorsed by the regulatory body. Codes and standards on electrical, mechanical, nuclear are part of the technical specifications. Internationally accepted codes and standards, including industrial standards such as ASME, IEEE and IEC are contained in the technical specifications and followed by the licensees.
- For the countries considering multiple technologies, the regulations, regulatory requirements and guides are technologically neutral, they define principles, criteria and targets that the design must achieve, without specifying a particular code or standard. This will aid future consideration of advanced technologies, where governments' have ambitions for a number of technologies to be deployed from a range of vendor countries, who will likely adopt different codes and standards.
- In some countries considering advanced technology deployment, regulatory guides were revised to make them technology neutral. In instances where industry has initially been unable to meet the specified guidance, the licensee and regulator agreed an alternative approach that ensured compatibility with the regulatory requirements.
- In some instances, the criteria used by the regulatory body are generic; the licensee needs to demonstrate where they cannot meet the code that the alternative solution provides an equivalent level of safety.
- In European countries, the regulatory requirements are generally consistent with the IAEA Safety Standards. However, it was highlighted that the Western European Nuclear Regulators Association has developed a set of Safety Reference Levels for existing reactors. Covering important aspects of nuclear safety, they focus on the safety functions that ensure the integrity of an NPP is maintained. It was suggested that these might be a good reference for BAERA as it considers the way forward on this topic and possibly establishing a more detailed set of regulatory principles.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

Currently, BAERA is using the existing NSRC Rules for its regulatory requirements, but no specific rules and regulations are in place. A guide for the content of safety analysis report exists, which is in line with relevant IAEA SSG-20.

In practice, the current IAEA safety standard are used by the authorized party and BAERA. This was obvious when performing the review and assessment of submitted documents during the time of modernization of research reactor and licensing renewal. However, there is no formalized process in place to ensure that new developed IAEA requirements are systematically checked and if appropriate adopted

into the legislative framework. The issues for regulations and guides for research reactors are covered in section 9.1.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

BAERA has recognised the need to update the NSRC Rules of 1997 and consequently draft regulations on the management of radioactive waste were developed in December 2021, these are however not yet finalised and enacted.

Furthermore, no specific guides related to radioactive waste management facilities have been prepared by BAERA.

Recommendations R27 and R28 in section 9.1 address this issue.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The only regulatory requirements applicable to radiation sources facilities and activities are contained in NSRC Rules, which are very general and not comprehensive.

In 2002, the BAEC acting as the regulatory body published three regulatory guides for radiation protection in nuclear medicine, radiotherapy, and x-Ray medical diagnostics. These regulatory guides need to be revised.

No other regulatory guide has been published for radiation sources facilities and activities in the past twenty years. Recommendation R28 in section 9.1 addresses this issue.

The IRRS team was informed that to compensate the absence of regulatory guides, the licensees are appropriately informed about BAERA procedures after they have submitted their applications for authorizations. The licensees can also access some of the internal procedures and forms used by BAERA through its website.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

BAERA has recognised the need to update the NSRC Rules and consequently draft regulations on the safety requirements for decommissioning of nuclear power plant facilities were developed in September 2022, these are however not yet promulgated. New regulations applicable to decommissioning of facilities and activities other than nuclear power plants have not yet been developed.

Furthermore, no specific guides related to decommissioning have been prepared by BAERA.

Recommendations R27 and R28 in section 9.1 address this issue.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The IRRS team was informed that the current regulatory requirements for the transport of radioactive material and nuclear material in Bangladesh are cited in the NSRC Rules and the BAER Act, both documents refer to SSR-6 (Rev.1).

To be able to enforce the requirements of SSR-6 (Rev.1), BAERA needs to establish a document assigning responsibilities for all actions prescribed in SSR6 (Rev.1) and ensure the licensees are informed accordingly.

The draft “Regulation on Safe Transport of Nuclear and Radioactive Material” provided in the advance material by BAERA, does not fully reflect the requirements of SSR-6 (Rev.1).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The draft “Regulation on Safe Transport of Nuclear and Radioactive Material” does not fully reflect the requirements of SSR-6 (Rev.1).*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 33 states that <i>“The Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.”</i>
(2)	BASIS: SSR 6 (Rev.1) Requirement 103 states that <i>“In certain parts of these Regulations, a particular action is prescribed, but the responsibility for carrying out the action is not specifically assigned to any particular person. Such responsibility may vary according to the laws and customs of different countries and the international conventions into which these countries have entered. For the purpose of these Regulations, it is not necessary to make this assignment, but only to identify the action itself. It remains the prerogative of each government to assign this responsibility.”</i>
R30	Recommendation: BAERA should revise and enact the “Regulation on Safe Transport of Nuclear and Radioactive Material” to reflect the latest IAEA Safety Standard and ensure the responsibility for carrying out all prescribed actions are specifically assigned to a consignor, carrier, or consignee, as appropriate.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The NSRC Rules establish requirements for various responsibilities of employers and authorization holders regarding occupational exposure in planned exposure situations and they also provide guidelines for chronic exposures.

There are no regulations and guides regarding occupational exposure. Recommendations R27 and R28 in section 9.1 address this issue.

The IRRS team identified deficiencies in regard to compliance with GSR Part 3. These include, but are not limited to the following:

- No application of the concept of dose constraints;
- There is no provision for female workers for protection of the breastfed infants;
- There is no provision for authorization holder to not offer benefits as substitutes for measures for protection and safety is not stated within NSRC Rules.
- Requirements regarding engineered controls, administrative controls and personal protective equipment are established, but the hierarchy of these preventive measures is not explicitly stipulated.
- There is no provision for establishing a strategy for protection against exposure due to 222 Rn in workplaces.
- There are no provisions for the protection of workers during remediation of areas with residual radioactive material.
- There are no provisions for occupational exposure for the occupational exposure of aircrew and space crew due to cosmic radiation.
- The reduction in dose limits to the lens of the eye have not been adopted.

As a result, BAERA should harmonize the regulatory framework for the protection and safety of workers in planned exposure situations and existing exposure situations with IAEA GSR Part 3. Recommendation R27 in section 9.1 addresses this issue.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The safety requirements of medical exposures are provided in the NSRC Rules. Three regulatory guides published by BAEC in 2002 are in use to provide guidance to the licensees:

1. Regulatory Guide on Radiation protection in nuclear medicine, 2002
2. Regulatory Guide on Radiation protection in radiotherapy, 2002
3. Regulatory Guide on Radiation protection in medical diagnostic radiology, 2002

The NSRC Rules prescribes the acceptable standards to which the licensee should comply. However, multiple standards/documents are listed for every medical practice. The requirements of these standards are varying and some are superseded. Recommendation R3 in section 1.4 addresses this issue.

IRRS team also noted that ‘Medical Exposures’ as defined in the NSRC Rules, 1997 does not include exposure of volunteers as part of a programme of biomedical research. It was informed that there are no such programmes authorized by BAERA as on date. However, it is not clear under which category of exposures the biomedical research volunteers will be considered by BAERA for regulatory control in future. This needs to be addressed in the revision of the Rules

NSRC Rules establish the activity limits only for discharge of patients undergoing therapeutic procedures in nuclear medicine, but does not include limits or criteria for discharge of patients undergoing therapy using permanently implanted sealed sources.

The regulatory requirements for medical exposure are not in line with IAEA GSR Part 3. BAERA has also identified in its self-assessment that further development of the regulatory system in area of safety of medical exposure is needed to implement requirements of IAEA GSR Part 3 in national practice. Recommendations R27 and R28 in section 9.1 address this issue.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The NSRC Rules place the requirement for the assessment of the impact of releases on the applicant. There is no information provided by BAERA on how the applicant should assess public exposure or how BAERA will review that assessment. Guidance needs to be developed by BAERA on how applicants and BAERA will assess the impact of discharges on the public. Recommendations R27 and R28 in section 9.1 address this issue.

The 2002 regulatory guide on nuclear medicine from the Nuclear Safety and Radiation Control Division of BAEC provides guidance on radioactive waste management for hospitals and notes “The regulatory body should be informed of the quantity of ¹³¹I discharged to sewer so it can monitor the possible impact on the environment and public”. The IRRS team observed that discharges to the sewer are not limited by the authorization, and neither BAERA nor the operator undertake any appropriate environmental monitoring or assessment of total dose from actual discharges.

The development of a regulatory framework for all exposure situations will need to be supported by an appropriate set of regulations and guides. Recommendations R27 and R28 in section 9.1 address this issue.

9.11. SUMMARY

Bangladesh does not have in place a comprehensive and consistent system of regulations and guides covering all safety areas.

The NSRC Rules were not reviewed after the BAER Act was enacted in 2012. The regulatory requirements of the NSRC Rules are not comprehensive and in line with the latest version of relevant IAEA Safety Standards in most safety areas.

The IRRS team identified the following areas for improvement:

- expedite a comprehensive set of regulations and associated set of guides;
- provide for consultation with interested parties and the general public in the development of regulations and guides;
- revise the regulations on safe transport of nuclear and radioactive material to comply with IAEA Safety Standards.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

Authority and responsibilities to regulate the on-site emergency arrangements of the operating organizations are assigned to BAERA under the BAER Act 2012.

A National Nuclear and Radiological Emergency Preparedness and Response Plan (NNREPRP) was prepared under coordination of BAERA and published by the Government in 2020. The NNREPRP describes the capabilities, responsibilities and authorities of different agencies involved in Emergency Preparedness and Response (EPR). This plan has been developed to meet the requirement of Standing Order of Disaster 2019 in line with Disaster Management Act 2012. Further, BAERA is mandated to make regulations and guides related to EPR consistent with the Act or Rules with prior approval of the Government as per Article 69 (26) of the BAER Act 2012.

Section 2.2 of the NNREPRP states that an approved EPR plan (plant, site and off-site) should be in place prior to the commissioning of the facility. BAERA has also been assigned the following responsibilities: (1) review and assessment of the documentation elaborating the operator's emergency arrangements during the licensing process, (2) approval of the operator's emergency plan; and (3) conduct of inspections on EPR arrangements of operating organizations.

BAERA and the National Nuclear and Radiological Emergency Management Centre (NNREMC) have been assigned the role of integrating and coordinating the actions of response organizations, including the operating organization, for emergency arrangements. Further, the NSRC rules prescribes that an emergency response plan and an emergency reporting system is mandatory, whether required by licence condition or not.

Within BAERA, the responsibilities for regulating the EPR of operating organizations is undertaken by the NuRID/Nuclear Emergency Management and Research Reactor Safety Section of Nuclear Safety Security and Safeguard Division. The application of a graded approach is followed by BAERA in regulating the EPR of operating organizations (NPP, radiation facility, transport of radioactive material etc). However, the IRRS team noted that there is no documented internal procedure describing BAERA's infrastructure, processes and other arrangements for EPR activities. Recommendation R11 in section 4.5 addresses this issue.

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

Although BAERA is mandated to develop regulations, guidelines, codes and manual, these are not yet finalised and approved. The process for developing regulations on emergency preparedness and response for a nuclear or radiological emergency was initiated in March 2021. A final draft has been prepared and reviewed by BAERA and is planned to be submitted for external review such as experts, MoST, NDMC etc. The IRRS team was informed that the anticipated timeframe for publication of this regulation is November 2023. Moreover, the process to formulate guidelines, elaborating the associated criteria to comply with the requirements in the regulation has not been initiated. The IRRS team noted that, when considered together, the BAERA Act, NNREPRRP, NSRC rules and the draft regulation are in line with many of the requirements and associated criteria of IAEA safety standards for EPR. However, several deficiencies related to compliance with the IAEA safety standards were noted by the IRRS team, including:

1. Inconsistency on definitions of emergency alerts, facility emergency, site area emergency and general emergency relating to dose base categorization in the draft regulation of EPR and table 3 of regulatory guide on identification and investigation of an accident at the nuclear power plant. Dose base categorization of DBA and DEC are generally avoided. Other nuclear or radiological emergency for an emergency in category IV that warrants taking protective actions and other

response actions at any location are not taken as a class of nuclear or radiological emergency as per GSR Part 7.

2. BAERA has not specified a requirement to ensure that EPR plans for category III facilities are made available (for industrial irradiation facilities, some hospitals), for which on-site events are postulated that could warrant protective actions and other response actions.
3. Although required under the BAERA Act 2012, emergency plans are not available for transport of radioactive material.
4. The response to a nuclear and radiological emergency requires an integrated approach and the involvement of all concerned agencies of the country. The IRRS team noted that the roles and responsibilities of national and local level response organizations are described in NNREPRP. Combined responsibilities are assigned for some actions (such as hazard assessment, taking mitigatory action, taking of urgent protective action, etc.), however, the roles of the lead organization with prime responsibilities and other supporting organizations are not clearly assigned and designated.
5. The initial phase of an emergency needs prompt implementation of urgent protective action such as ITB, sheltering, evacuation, etc. Responsibility of coordination is assigned to both BAERA and NNREMC without clear demarcation of their roles, this may delay effective implementation of the response.
6. Calculation of dose projection for the early phase of the emergency situation has to be supported with the availability of computational tools, with input from plant conditions including source term estimation, meteorological conditions as part of the decision support system. The IRRS team noted that there are no explicit requirements relating to the need for both operating and response organisations to have available necessary computational and analytical tools that have been validated.
7. Lack of diverse lines of communication between the operating organisation and the response organisations in line with the principle of defence in depth.
8. Responsibility to recommend early protective actions is not assigned to any response organization for intermediate phase and late phase of emergency exposure situation.
9. The IRRS team found that requirements of GSR Part 7 are not fully addressed. In particular protection of off-site emergency services personnel, revision of plans of response organizations on account of any change at the facilities and availability of new information, establishing appropriate emergency arrangements by the time the source is brought to the site, generic criteria on dose to avoid or minimise severe deterministic effect and to reduce stochastic effect and in giving sufficient authority to operating organization prompt protective action even that could result in off-site consequences, require attention.

Recommendation R4 in section 1.4 and recommendations R27 and R28 in section 9.1 address these issues.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The roles and responsibilities of response organizations for a nuclear or radiological emergency in the Bangladesh NNREPRP are not clearly specified or assigned, potentially compromising the ability to take prompt corrective actions in the event of an emergency.*

(1)	BASIS: GSR Part 7 Requirement 2 states that <i>“The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned.”</i>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	BASIS: GSR Part 7 para. 5.38 states that <i>“For facilities in category I or II, arrangements shall be made for effectively making decisions on and taking urgent protective actions, early protective actions and other response actions off the site in order to achieve the goals of emergency response, on the basis of a graded approach and in accordance with the protection strategy”.</i>
R31	Recommendation: The Government should make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned in the NNREPRP.

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

Verifying the adequacy of the on-site EPR arrangements of operating organizations requires core regulatory processes to be clearly defined in coordination with off-site response organizations. BAERA has established a mechanism and methodology for this. However, BAERA has not developed predetermined criteria and checklists to be used when undertaking EPR related inspections. Recommendation 23 in section 7.1 addresses this issue.

BAERA has not established requirements related to (1) the conduct of exercises and drills (2) systematically testing and evaluating the effectiveness of EPR arrangements and (3) the taking of appropriate corrective actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: <i>BAERA has no documented requirement for the systematic evaluation of exercises and does not have a plan of scheduled evaluations.</i>	
(1)	BASIS: GSR Part 7 para. 6.30 states that <i>“The exercises shall be systematically evaluated (also as per para. 4.10(h) and 6.33) and some exercises shall be evaluated by the regulatory body.”</i>
(2)	BASIS: GSG 13 para. 3.330 states that <i>“In order to meet the above requirement 6.30 of GSR part 7, the regulatory body should develop necessary evaluation guidelines and checklists. As appropriate, this evaluation should assess the adequacy of coordination and integration of the on-site emergency arrangements with those off-site.”</i>
S6	Suggestion: BAERA should consider developing and implementing a suitable methodology and plan for the evaluation of exercises.

Quarterly exercises are carried out for the research reactor with involvement of multiple response organizations in Bangladesh. However, BAERA was not able to present evidence of BAERA’s participation in such exercises, including relevant reports. There was no evidence presented of similar exercises for other licensees. Exercise programmes for the new NPP are required to be developed, commensurate with the stage in life cycle. These exercise programmes generally include on-site and off-site emergency exercises, carried out through table-top exercises, integrated command and control exercises, field exercises, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Onsite and off-site emergency exercise programmes to test all specified functions of response organizations are not developed by operating organizations.*

(1)	BASIS: GSR Part 7 para. 6.30 states that <i>“Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or II, and the national level programmes for category IV or V are tested at suitable intervals.”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para. 2.24A states that <i>“The training, drills and exercises shall cover a full range of postulated emergencies (e.g. events affecting several facilities on the same site, emergency exercises of long duration and emergencies with transboundary consequences).”</i>
(3)	BASIS: GSG 13 para. 3.329 states that <i>“The review and assessment should consider whether the on-site emergency arrangements: Include an exercise programme to ensure that all the emergency arrangements are tested satisfactorily within a specific period.”</i>
(4)	BASIS: GSG 13 para. 3.333 states that <i>“The regulatory body is part of the coordinating mechanism that is required to be established by the government in accordance with para. 4.10 of GSR Part 7 [7]. The coordinating mechanism ensures that emergency arrangements are coordinated, consistent and are in place for all postulated nuclear or radiological emergencies”.</i>
R32	Recommendation: BAERA should ensure that operating organizations develop, implement and routinely test their emergency preparedness and response arrangements.
R33	Recommendation: The Government should ensure that off-site emergency response arrangements are routinely tested.

Mechanisms for review and approval of EPR plans of operating organizations exist within BAERA. However, review of off-site plans of the District Authorities are not carried out by BAERA. Recognising that there are numerous interfaces from multiple response organizations expected during an emergency exposure situation, strong coordination and integration of these is required. This responsibility is assigned to BAERA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA does not advise on or review the off-site emergency plan of the District Authority.*

(1)	BASIS: GSR Part 1 (Rev. 1) para. 2.24 states that <i>“In preparing an emergency plan and in the event of an emergency, the regulatory body is required to advise the government and response organizations and to provide expert services in accordance with the responsibilities assigned to it”.</i>
R34	Recommendation: BAERA should establish arrangements for the review and provision of advice on off-site emergency plans to the Government and response organizations.

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

At present BAERA has limited resources which the IRRS team considers are insufficient for the required technical assessments and to enable it to successfully fulfil all of the required EPR functions during a nuclear or radiological emergency.

Training of BAERA personnel, including involvement in emergency exercises, is necessary for BAERA to understand and fulfil its role effectively, including regulatory oversight and monitoring. It was noted by the IRRS team that BAERA has recently participated in the IAEA ConvEx exercises as part of training of its staff.

BAERA has not fully established the infrastructure and resources required within its own organization to appropriately assess and respond to an emergency, and for providing advice to operating organizations, the Government of Bangladesh, and the general public and media. The regulatory authority also needs to establish arrangements to deploy its personnel during an emergency.

The IRRS team has been informed that BAERA intends to establish an infrastructure including an emergency communication centre through the NuRID project by 2025, which is intended to include equipment, tools, and communication systems. This emergency centre will also interconnect the BAERA head office and the RNPP site.

Recognizing that current facilities and activities being regulated and the timeframes for commissioning of the NPP, the IRRS team was of the view that the establishment of the EPR organization and arrangements in BAERA, as well as the national infrastructure, need to be expedited.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *BAERA does not have a plan to respond to an emergency, nor the infrastructure to collect information on the progress of an emergency, to independently assess plant conditions and progression of an emergency, or consider the protective actions taken by operating organizations and other response organizations.*

(1)	<p>BASIS: GSR Part 1 (Rev. 1) para. 2.24 states that <i>“In preparing an emergency plan and in the event of an emergency, the regulatory body shall advise the government and response organizations, and shall provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks) in accordance with the responsibilities assigned to it.”</i></p>
(2)	<p>BASIS: GSR Part 1 (Rev. 1) para. 3.339 states that <i>“The regulatory body should, as applicable, put Mechanisms in place to:</i></p> <ul style="list-style-type: none"> <i>(a) Send staff to appropriate locations during a nuclear or radiological emergency;</i> <i>(b) Collect data on the progress of the emergency either directly or remotely, which may require having access to the authorized party’s systems;</i> <i>(c) Analyse and draw conclusions on the likely progression of the emergency;</i> <i>(d) Advise the appropriate response organizations, which includes the authorized party, of its findings;</i> <i>(e) Ensure secure and reliable communication between its staff and other organizations.</i> <p><i>3.340. The regulatory body should develop and implement internal training and exercise programmes to ensure that the emergency arrangements are tested and that staff are familiar with the roles they will be expected to undertake in the event of a nuclear or radiological emergency.”</i></p>
(3)	<p>BASIS: GSR Part 7 para. 6.17 states that <i>“Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified”.</i></p>
R35	<p>Recommendation: BAERA should develop and ensure it can adequately resource a plan to respond to an emergency and for coordinating and performing its assigned functions during an emergency.</p>

10.5. SUMMARY

The IRRS team noted that when considered together the BAERA Act, NNREPRRP, NSRC Rules and the draft regulation are generally consistent with the IAEA safety standards. However, several deficiencies related to compliance with the IAEA Safety Standards were noted by the IRRS team. The primary areas for improvement noted by the IRRS team were:

- BAERA needs to establish a plan and procedures relating to its assigned functions during an emergency and ensure it has adequate resources to deliver the plan;
- the roles and responsibilities of response organization for preparedness and response for a nuclear or radiological emergency need to be clearly specified and assigned;
- a systematic evaluation of exercises and ensuring development of exercise programmes needs to be undertaken by BAERA;
- BAERA needs to establish arrangements for the review of the off-site emergency plans of response organizations.

11. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

The IRRS Mission also covered the national regulatory implications of the COVID-19 pandemic with a focus on any impact on business continuity in maintaining delivery of statutory duties and responsibilities for safety. This section presents relevant feedback and main conclusions drawn by the IRRS team from the discussions and evaluations made in the course of the mission, with the objective to identify ways to strengthen governmental, legal and regulatory frameworks for safety.

11.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

When the COVID 19 outbreak occurred in Bangladesh, the Prime Minister Offices established special task force and an advisory body to manage the pandemic nationwide, which included measures to reduce the impact of the pandemic on the population. One of the first measures undertaken was the implementation of remote working for national authorities in addition to usual measures of mask wearing, social distancing, and hygiene. Later in the pandemic, the population was advised to receive vaccinations initially on an emergency basis, and later vaccination of staff was made a pre-requisite to resume office working and face to face meetings.

11.2 REGULATORY FRAMEWORK

The IT infrastructure of BAERA was strengthened by the provision of remote access to various intranet and document management systems. This resulted in arrangements for BAERA employees being able to work from home without any significant difficulty or impacting the regulatory framework. BAERA implemented the measures and took additional precautions to ensure the continuance of its regulatory functions, such as having a skeleton staff in the offices with the provision of only one person per room. Since the rooms were normally occupied by more than one staff individual, only about half of the BAERA staff were able to work from the office at any time. This resulted in alternate working remotely and from the office during the pandemic with daily rotation to allow staff to progress urgent business. This ensured the handling of any regulatory work that needs physical presence was delivered in a manner consistent with the measures imposed by the government.

BAERA also reorganized its meeting procedures to minimize the impact of the pandemic, it provided masks and disinfectants to its workers, and imposed isolation for individual staff who tested positive with COVID-19. These measures meant that the pandemic only had minimal impact on the activities associated with implementation of the regulatory framework in Bangladesh.

11.3 REGULATORY FUNCTIONS

BAERA remained fully functional during the peaks of the COVID 19 pandemic. Previous experience of BAERA, particularly on having online meetings with its external (international) technical support organizations, facilitated the transition to online working. Similarly, an established automated document system, which allows electronic signing of official documents, helped this transition.

BAERA informed the IRRS team that except for about three months that the staff was not allowed to work from headquarters, its ability to continue discharging regulatory responsibilities was not significantly impaired. Changes in discharging its regulatory functions included virtual inspections using video conferences. Although the scope of the inspection had to be focused on paper reviews, the inspection objectives were achieved in the majority of cases.

No budget cuts were imposed to the BAERA by the government during the pandemic. Although, training of its staff and the inspection activities on site and abroad were impacted.

Local training of staff was by online training, similar to other international approaches. However, the effectiveness of the training, based on the feedback received from the trainees, and to a lesser extent was found to have decreased.

When the COVID-19 pandemic began, BAERA was performing a significant number of inspection activities regarding Rooppur Nuclear Power Plant, both on site for construction and abroad for the manufacturing of safety significant items.

To minimize the impact of the pandemic on BAERA inspections, BAERA

1. Requested its technical support organization to continue equipment manufacturing inspections in the vendor country and inform BAERA on the outcome of inspections and regulatory intervention as required. The reporting frequency of the TSO in the vendor country was also enhanced.
2. Re-evaluated its inspection plans and changed the type of some inspections adopting a range of inspection activities to also include virtual and hybrid in support of hold point requirements associated with the NPP in Rooppur, these were applied using a graded approach. BAERA considered the safety classification of the item manufactured, relation of the item to safety systems, whether it was final or semi product, type of original inspection and the schedule of the project in its graded approach.
3. Allowed the extension of licences in response to request for licence renewals during the period of the pandemic and moved to virtual inspections in support of the decision to issue licences. This was confirmed during the visits to local facilities in Dhaka: Square Hospital, the Institute of Nuclear Medicine and Allied Science and the local NDT company.
4. Used a remote surveillance system that produces images of its central storage facility and of the storage pits, installed by an NDT company, to observe the facility.

The pandemic restrictions did not affect the authorization of radiation facilities and that of RNPP. The inspections and controls before issuing a licence continued without interruption.

A general experience is that regulatory body staff responded well to the challenges faced during the COVID 19 pandemic with commitment to the need for remote working. Inspection of local facilities and activities were carried out, after re-assessment of the inspection plans, by BAERA inspectors with necessary measures taken for the travel and interactions.

11.4 EMERGENCY PREPAREDNESS AND RESPONSE

BAERA adapted its arrangements for emergency response, developed a preliminary plan to address future pandemics. This will be made part of its relevant regulations and guidance as standard operating procedure (SOP) during all types of pandemic situation. Additionally, BAERA reviewed and approved the revision of the EPR plan for the research reactor in 2021.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
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GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

	Saturday, Nov. 26	Sunday, Nov. 27	Monday, Nov.28	Tuesday, Nov.29	Wednesday, Nov. 30	Thursday, Dec. 01	Friday, Dec. 02		
09:15	Arrival of team members	10:00-11:30 Entrance Meeting Agenda TBD	Interviews	Interviews Visit to Ministry of Science and Technology	Interviews Visits DTC writes introductory parts of the Report	Team writes the Report	Discussion and improving the Report Cross-reading TL, DTL, TC and DTC reads everything		
10:00						<i>Draft report to TI</i>			
11:00								TL and DTL review introductory part	
12:00									
13:00	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		
14:00	IRRS Initial Team Meeting	Interviews	Interviews Depart for Visit to Roopur NPP	Interviews Site Visits	Interviews Visits DTC writes introductory parts of the Report	Policy Discussion	Finalization of the draft Report		
15:00				16:00		Daily Team Meeting		Daily Team Meeting	Editing of the Report
16:00				<i>Discussion of Findings</i>	Cross-reading by team members				
17:00				Daily Team Meeting	Daily Team Meeting	Daily Team Meeting		Daily Team Meeting	Daily Team Meeting
20:00				Team members: Writing of Report	Team members: Writing of Report	Daily Team Meeting <i>Discussion of Findings</i>		Team members: Writing of Report	Team reads the draft

	Saturday, Dec. 03	Sunday, Dec. 04	Monday, Dec. 05	Tuesday, Dec. 06	Wednesday, Dec. 07	Thursday, Dec. 08							
09:15	Social Event Schedule TBD	Discussion of Recommendations, Suggestions and Good Practices with counterparts by module	Cross-reading of the Report		Common read through and finalization of the Report by the team		Host reads the Draft Report	Team Discussion and Feedback	<i>Submission of the Preliminary Report to Host</i>				
10:00			Finalization of the Report	TL, DTL, TC and DTC read everything		<i>Submission of draft</i>			Plenary (Team + Host) to discuss Host comments and finalize the report	Written comments of Host	Team meeting to resolve comments	Exit Meeting	
11:00				Lunch	Lunch		Lunch	Lunch				Lunch	Publication of Press Release
12:00													Lunch
13:00		Individual discussions of Recommendations, Suggestions and Good Practices with counterparts	Discussion of the Report by the Team	TC, DTC prepare Executive Summary and exit presentation	Host reads the draft Report	TL finalizes Executive Summary and exit presentation	TC drafts the press release	Plenary (Team + Host) to discuss Host comments and finalize the report (Cont.)	Departure of team members				
14:00		Daily Team Meeting								Discussion of Executive Summary and delivery to Host	Briefing the IAEA Manager	Finalization of press	
15:00			Dinner	Dinner	Dinner	Goodbye Dinner Hosted by BAERA							
16:00		Secretariat updates the Report					Secretariat finalizes the Report	Free					
17:00			Dinner	Dinner	Dinner	Goodbye Dinner Hosted by BAERA							
18:00		Secretariat updates the Report					Secretariat finalizes the Report	Free					
19:00	Dinner		Dinner	Dinner	Goodbye Dinner Hosted by BAERA								
20:00		Secretariat updates the Report				Secretariat finalizes the Report	Free						

APPENDIX III – SITE VISITS



APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES		
	FRANOVICH Michael X.	Dr. Satyajit Ghose	Dr. Md. Masudul Kabir Mr. AKM Raushan Kabir Zoardar Dr. Md. Abdur Rob Sheikh Mr. G.Q.Rabbani Mozumder
2.	GLOBAL NUCLEAR SAFETY REGIME		
	MANSOOR Faizan	Dr. Md. Masudul Kabir	Dr. Satyajit Ghose Mr. G.Q.Rabbani Mozumder
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
	MANSOOR Faizan	Dr. Md. Abdur Rob Sheikh	Dr. Satyajit Ghose Dr. Md. Masudul Kabir Dr. Debashis Datta
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
	BREJZA Paul	Dr. Debashis Datta	Dr. Satyajit Ghose Dr. Mahabubur Rahman Dr. Md. Abdur Rob Sheikh Ms. Soma Shill
5.	AUTHORIZATION		
	ALI JAFRI Mishkat BESTER Peter DALE Paul KAMOUN Ashraf NAKAJIMA Tsuyoshi PATHER Thiagan PERRIN Marie Line SIVARAMAKRISHNAN Mahalakshmi STEVENSON Jeff WHITTINGHAM Stephen RECIO Manuel	Dr. Satyajit Ghose	Dr. Meherun Nahar Engr. Mustafijur Rahman Dr. Debashis Datta Dr. Jahanara Begum Mr. AKM Raushan Kabir Zoardar

	IRRS EXPERTS	Lead Counterpart	Support Staff
6.	REVIEW AND ASSESSMENT		
	ALI JAFRI Mishkat BESTER Peter DALE Paul KAMOUN Ashraf NAKAJIMA Tsuyoshi PATHER Thiagan PERRIN Marie Line SIVARAMAKRISHNAN Mahalakshmi STEVENSON Jeff WHITTINGHAM Stephen RECIO Manuel	Dr. Debashis Datta	Dr. Meherun Nahar Engr. Mustafijur Rahman Dr. Mahabubur Rahman Dr. Md. Abdur Rob Sheikh
7.	INSPECTION		
	ALI JAFRI Mishkat BESTER Peter DALE Paul KAMOUN Ashraf NAKAJIMA Tsuyoshi PATHER Thiagan PERRIN Marie Line SIVARAMAKRISHNAN Mahalakshmi STEVENSON Jeff WHITTINGHAM Stephen RECIO Manuel	Dr. Md. Abdur Rob Sheikh	Dr. Satyajit Ghose Dr. Debashis Datta Dr. Meherun Nahar Engr. Mustafijur Rahman Mr. AKM Raushan Kabir Zoardar Dr. Md. Maidul Islam Ms. Soma Shill
8.	ENFORCEMENT		
	ALI JAFRI Mishkat BESTER Peter DALE Paul KAMOUN Ashraf NAKAJIMA Tsuyoshi PATHER Thiagan PERRIN Marie Line SIVARAMAKRISHNAN Mahalakshmi STEVENSON Jeff	Md. Mustafizur Rahman	Dr. Md. Maidul Islam Ms. Soma Shill

	IRRS EXPERTS	Lead Counterpart	Support Staff
	WHITTINGHAM Stephen RECIO Manuel		
9.	REGULATIONS AND GUIDES		
	ALI JAFRI Mishkat BESTER Peter DALE Paul KAMOUN Ashraf NAKAJIMA Tsuyoshi PATHER Thiagan PERRIN Marie Line SIVARAMAKRISHNAN Mahalakshmi STEVENSON Jeff WHITTINGHAM Stephen RECIO Manuel	Dr. Satyajit Ghose	Dr. Debashis Datta Dr. Md. Abdur Rob Sheikh
10.	EMERGENCY PREPAREDNESS AND RESPONSE		
	DUBEY Santosh	Dr. Meherun Nahar	Dr. Satyajit Ghose Dr. Jahanara Begum Dr. Md. Maidul Islam

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	R1	The Government should issue a comprehensive national safety policy and strategy for all facilities and activities, which is consistent with IAEA Safety Standards.
	R2	The Government should implement measures that ensure there is no potential to compromise the independent decision making of BAERA
	R3	The Government should make and implement as a priority, suitable arrangements that establish and maintain an appropriate governmental, legal and regulatory framework for safety, starting with the revision of the NSRC-1997 Rules, to be consistent with the BAER Act and IAEA Safety Standards.
	R4	BAERA should develop a regulatory framework to consider all existing exposure situations.
	R5	The Government should establish and implement as a priority a strategy for the effective implementation of the policy, including the establishment of the RWMC as well as the decommissioning and radioactive waste management fund.
2. THE GLOBAL SAFETY REGIME	S1	The Government should consider becoming party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.
	S2	The Government should consider expressing its political commitment to the IAEA Guidance on the Import and Export of Radioactive Sources, and on the Management of Disused Sources, supplementary to the Code of Conduct on the Safety and Security of Radioactive Sources.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R6	BAERA should make necessary arrangements to collect national and international operating and regulatory experiences, carry out analysis to identify the lessons from such experiences and for dissemination of the experiences and the lessons for use by the authorized parties, BAERA and other relevant stakeholders.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R7	BAERA should develop competency profiles for all regulatory roles. BAERA should then implement specific training programmes, which are based on the competency profiles.
	S3	BAERA should consider establishing a process to periodically assess the deployment of human resources across its organization required to ensure it has an appropriate balance between new and experienced regulatory staff that will enable it to perform all of its functions effectively.
	R8	BAERA should establish formal requirements to manage potential conflicts of interest from members of the advisory council or other external experts.
	R9	BAERA should make provisions for establishing and maintaining a national dose register to ensure implementation of the radiation protection principles of dose limitation, optimisation of protection, and retention of records.
	R10	BAERA should establish appropriate mechanisms for informing and consulting with interested parties, including the general public, on the radiation risks associated with facilities and activities, regulatory processes and significant decisions of the regulatory body and amendments to regulations and guides, in a transparent manner.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R11	BAERA should develop a coherent set of processes and procedures as part of its integrated management system and ensure that the management system is consistently implemented throughout the organization.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R12	BAERA should perform an independent assessment of leadership for safety and safety culture throughout the organization.
5. AUTHORIZATION	R13	BAERA should establish criteria and radiation levels for clearing sources, including materials and objects, from regulatory control.
	S4	BAERA should consider establishing a systematic approach to prescribe in the licence the limits, conditions and controls on the authorized activities.
	R14	BAERA should implement the options for the authorization process of radiation sources facilities and activities, as provided for in the Act, including registration and authorization, applying a graded approach.
	R15	BAERA should require suppliers and manufacturers to fulfil their obligations for the safety of radiation generators and radioactive sources.
	R16	BAERA should require the licensees to conduct local periodic assessments of radiological procedures for which DRLs have been established.
	S5	BAERA should consider establishing a mechanism for the review of the DRLs for diagnostic medical exposures at pre-determined intervals.
	R17	The Government should ensure relevant professional bodies adopt evidence based referral guidelines for use by the referring medical practitioners.
	R18	BAERA should establish a framework for the protection and safety of the public against exposure, including an assessment of doses to the public and making the information available.
6. REVIEW AND ASSESSMENT	R19	BAERA should establish specific guidance that ensures a consistent and systematic review and assessment of all facilities and activities, and integration with other core regulatory processes.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R20	BAERA should define the frequency for and undertake regular review and assessment of the safety of the CWPSF.
	R21	BAERA should establish a comprehensive set of requirements for ensuring optimisation of protection and safety of medical exposures, quality control of medical equipment and record retention.
7. INSPECTION	R22	BAERA should develop an Inspector Training, Qualification and Certification process for all facilities and activities.
	R23	BAERA should ensure consistent application of the inspection guidance by its inspectors across all facilities and activities.
	R24	BAERA should implement a system for tracking and trending the results of regulatory inspections, and communicate this information within the regulatory body and to licensees, where appropriate.
	R25	BAERA should establish regulatory requirements for the reporting of safety significant non compliances and deficiencies in a timely and graded manner.
8. ENFORCEMENT	R26	BAERA should develop an enforcement policy and associated guidance to ensure it takes enforcement action consistently, adopting a graded approach, in response to non-compliances with requirements or authorization conditions by authorized parties.
9. REGULATIONS AND GUIDES	R27	BAERA should take all necessary actions to expedite the enactment of a comprehensive set of regulations that specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.
	R28	BAERA should issue a comprehensive set of guides to explain the requirements of the regulations and how to comply with them.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R29	BAERA should consult with interested parties in the development of regulations and guides and should notify interested parties and the general public about the principles and associated criteria for safety in its regulations and guides.
	R30	BAERA should revise and enact the “Regulation on Safe Transport of Nuclear and Radioactive Material” to reflect the latest IAEA Safety Standard and ensure the responsibility for carrying out all prescribed actions are specifically assigned to a consignor, carrier, or consignee, as appropriate.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	R31	The Government should make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned in the NNREPRP.
	S6	BAERA should consider developing and implementing a suitable methodology and plan for the evaluation of exercises.
	R32	BAERA should ensure that operating organizations develop, implement and routinely test their emergency preparedness and response arrangements.
	R33	The Government should ensure that off-site emergency response arrangements are routinely tested.
	R34	BAERA should establish arrangements for the review and provision of advice on off-site emergency plans to the Government and response organizations.
	R35	BAERA should develop and ensure it can adequately resource a plan to respond to an emergency and for coordinating and performing its assigned functions during an emergency.

APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

E1	Policy and Strategy of Nuclear Safety and Safety Culture
E2	National Energy Policy, 2005
E3	Power System Master Plan, 2016
E4	Bangladesh Nuclear Power Action Plan (BANPAP)
E5	Bangladesh national report for CNS Meeting, 2020
E6	National Policy for the Management of Radioactive Waste and Spent Nuclear Fuel, 2019
E7	National Nuclear and Radiological Emergency Preparedness and Response Plan (NNREPRP), 2020
E8	Agreement between the Government of the Russian Federation and the Government of the People’s Republic of Bangladesh on partnership in the construction of a nuclear power plant in the People’s Republic of Bangladesh, 2012
E9	General contract (EPC contract) for Rooppur NPP construction
E10	Agreement on the establishment of the Nuclear Power Information Center in Dhaka between Rosatom (Russian Federation) and the Government of Bangladesh, 2013
E11	Agreement between the Government of the Russia Federation and the Government of the People’s Republic of Bangladesh on cooperation on the import into the Russian Federation of spent nuclear fuel from the Rooppur nuclear power plant, 2017
E12	General Framework Contract (GFC) between BAERA and JSC VO Safety, 2016
E13	Cooperation Agreement between Rostechnadzor and BAERA in the field of nuclear and radiation safety regulation in the peaceful uses of atomic energy, 2012
E14	Memorandum of Understanding on cooperation in the implementation of the Rooppur NPP construction project in Bangladesh between Rosatom (Russian Federation), the Ministry of Science and Technology of Bangladesh and the Department of Atomic Energy of the Government of India, 2018
E15	Arrangement for the Exchange of Technical Information and Cooperation in the Regulation of Nuclear Safety and Radiation Protection between Atomic Energy Regulatory Board (AERB), India and Bangladesh Atomic Energy Regulatory Authority (BAERA), 08 April 2017
E16	Memorandum of understanding between BAERA and GAN of Belorussia (draft)
E17	Contract No. BAERA-VOS-CNT-001/2016, dated: 02.05.2017; Contract No. BAERA-VOS- CNT- 002/2019, dated: 30/01/2020
E18	Contract No. BAERA-VOS-CNT-003/2021, dated: 30/12/2021 for the period from January 2022 to December 2024
E19	BAER Act, 2012
E20	Environmental Conservation Act, 1995
E21	Disaster Management Act, 2012
E22	Nuclear Power Plant Act, 2015
E23	Code of Ethics, 2018
E24	BAERA Citizen’s Charter
E25	Bangladesh Atomic Energy Commission Act, 2017
E26	Nuclear Safety and Radiation Control Act (NSRC Act), 1993
E27	Public procurement Act, 2006
E28	NSRC Rules, 1997

E29	Regulation on emergency preparedness and response for a nuclear or radiological emergency (draft)
E30	BAERA Service Regulation, 2019
E31	Regulation on management of radioactive waste (draft)
E32	Regulation on safety in the transport of radioactive materials by air, ground and water transport (draft)
E33	National Plan for Disaster Management 2016-2020, 2017
E34	Regulation on Physical Protection (draft)
E35	Safeguards, nuclear materials accounting and control regulation (draft)
E36	Safety requirements for decommissioning of nuclear power plant facilities (regulation) (draft)
E37	Public procurement Rules, 2008
E38	Reserved
E39	Regulatory Guide on Staffing, competency assessment and training for regulatory personnel
E40	Guidelines on internal audit
E41	Regulatory Guidance for identification and investigation of an accident at the nuclear power plant
E42	Regulatory Guidance for authorization of NPP personnel performing safety related functions
E43	Safeguards, nuclear materials accounting and control guidance (draft)
E44	Safety culture self-assessment guidelines
E45	Guidelines on self-assessment of the regulatory body within the framework of the management system
E46	Regulatory Guide on radiation protection in nuclear medicine, 2002
E47	Regulatory Guide on Radiation protection in radiotherapy, 2002
E48	Regulatory Guide on Radiation protection in medical diagnostic X-ray, 2002
E49	Regulatory Guidance on Site evaluation for the safety of nuclear power plants, 2013
E50	Guidelines on the format and content of safety analysis report for research reactor
E51	Inspection procedure
E52	Authorization procedure
E53	Enforcement regulatory procedure
E54	Management system manual (E54)
E55	Communication manual
E56	Check-lists for all types of BAERA nuclear and radiation safety regulatory management activities (for self-assessment)
E57	Regulatory inspection at 3 MW TRIGA Mark II research reactor (Inspection check-list)
E58	Instructions ("check-list") for use by the regulator's employees during safety oversight during installation and testing localizing safety systems for Rooppur NPP
E59	Inspection program for the construction of an atomic energy facility (Check lists)
E60	Medical centre (nuclear medicine) inspection checklist (or information sent by the licensee)
E61	APA flowchart
E62	Inspection process of BAERA
E63	Management process flowchart
E64	GRS Complain
E65	Flowchart of QM Process
E66	Recruitment process flowchart

E67	BAERA communication process
E68	Inventory management system
E69	Authorization process
E70	Annual report of the Center for Research Reactor
E71	Radiation Control Officer (RCO) report
E72	Inspection reports
E73	Standing Orders on Disaster, 2010
E74	Report on emergency exercises conducted by authorization holder of research reactor and reviewed by BAERA
E75	NuRID project
E76	Front page of BAERA Internet Portal

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
5.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements Series No. SSR-6, IAEA, Vienna (2012)
16.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018)
17.	INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
18.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Guide Series No GSG-2, IAEA, Vienna (2012)

19.	INTERNATIONAL ATOMIC ENERGY AGENCY - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
20.	INTERNATIONAL ATOMIC ENERGY AGENCY - Occupational Radiation Protection, Safety Guide Series No. GSG-7 , IAEA, Vienna (2018)
21.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)
22.	INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
23.	INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).
24.	INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
25.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
26.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
27.	INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
28.	INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001)
29.	INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
30.	INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
31.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
32.	INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
33.	INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
34.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
35.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
36.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)

37.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)
38.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
39.	INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
40.	INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
41.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)
42.	INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
43.	INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
44.	INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
45.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
46.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
47.	INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
48.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide Series No SSG-46, IAEA, Vienna (2018)
49.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
50.	INTERNATIONAL ATOMIC ENERGY AGENCY – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
51.	INTERNATIONAL ATOMIC ENERGY AGENCY –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
52.	INTERNATIONAL ATOMIC ENERGY AGENCY – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
53.	INTERNATIONAL ATOMIC ENERGY AGENCY - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
54.	INTERNATIONAL ATOMIC ENERGY AGENCY - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
55.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
56.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
57.	INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)

58.	INTERNATIONAL ATOMIC ENERGY AGENCY - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
59.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
60.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
61.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – ORGANIZATIONAL CHART

ORGANOGRAM of Bangladesh Atomic Energy Regulatory Authority Ministry of Science and Technology

