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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION

TO

INDIA

Mumbai, India

9 to 20 June 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service

IRRS

Integrated
Regulatory
Review Service

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
FOLLOW-UP REPORT TO
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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

Mission dates:	*9 to 20 June 2022*
Regulatory body visited:	*Atomic Energy Regulatory Board (AERB)*
Location:	*Mumbai, India*
Regulated facilities and activities in the mission scope:	*Nuclear Power Plants and extended scope including radiation sources facilities and activities*
Organized by:	*International Atomic Energy Agency (IAEA)*

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

CONTENTS

EXECUTIVE SUMMARY

At the request of the Government of India, an international team of senior safety experts met representatives of the Atomic Energy Regulatory Board (AERB) from 9 to 20 June 2022 to conduct an IRRS extended follow-up mission. The purpose was to review the actions taken to address the recommendations and suggestions made during the IRRS initial mission in 2015 and to review regulatory activities in relation to the radiation sources facilities and activities.

A preparatory virtual meeting for the mission was organized virtually from 21 to 23 July 2020 with AERB to discuss the purpose, objectives, scope and detailed preparations of the review. It was agreed that the review will be extended to include radiation sources facilities and activities which was not part of the initial mission.

The IRRS team comprised 7 senior regulatory experts from 5 IAEA Member States and 3 IAEA staff members.

The IRRS review addressed the findings from the initial mission which was limited in scope and only covered nuclear power plants (NPPs), and included an extended review for modules 5 to 9 for the radiation sources facilities and activities regulated by AERB. The mission was also used to exchange information and experience between team members and the Indian counterparts in the areas covered by the mission.

In preparation for the IRRS extended follow up mission, AERB conducted a self-assessment of the status of recommendations and suggestions made in 2015. AERB conducted also a self-assessment in relation to the regulatory activities conducted to regulate radiation sources facilities and activities. The results of the self-assessments and supporting documentation were provided to the IRRS team as advance reference material (ARM) prior to the mission. The mission included interviews and discussions with AERB staff, including the provisions of new evidences as requested by the IRRS team. It was noted that the AERB made extensive preparation to ensure the success of the mission. In additonal, two policy issues were discussed in the course of the mission in order to share experiences on:

- Safe management of Disused Sealed Radioactive Sources (DSRS); and
- Regulation of radioactive waste from radiation facilities handling unsealed sources.

Overall, the IRRS team concluded that AERB showed a strong commitment and professionalism to ensure that nuclear and radiation safety is implemented in the country. AERB has considered the recommendations and suggestions made by the 2015 mission in a systematic manner and significant improvements have been made in many areas. Of the original 13 recommendations and 21 suggestions, 11 recommendations and 20 suggestions have been closed, and the IRRS team did not make any new finding in relation to the topics covered during the IRRS initial mission. With respect to radiation sources facilities and activities, the IRRS team concluded that AERB generally implements the regulatory process and safety requirements in accordance with the IAEA safety standards.

Since 2015, the Government has increased AERB resources for regulatory oversight which in turn enabled AERB to amend their requirements and carry out restructuring to comply with its legal and regulatory responsibilities. The IRRS team noted a number of achievements in the following areas:

- improved inspection programme, including enhanced training and strengthening the powers of inspectors;

- staff qualification and training programmes aimed at building and maintaining expertise necessary for discharging its responsibilities;
- process for regularly reviewing regulations and guides.

The IRRS team identified a Good Practice in relation to the integration of regulatory processes within e-LORA, an online platform used by the applicants, authorized parties and AERB. E-LORA significantly improved the efficiency of managing the information to be submitted by an applicant / authorized party, based on a graded approach.

The IRRS team recognized the systematic approach to integrate the approval of equipment with the need for a consent to an applicant prior to procuring a radiation source and the issuance of a consent to operate a facility or conduct an activity with radiation sources, as a Good Performance.

The IRRS team acknowledged that AERB has increased its participation within the global nuclear safety regime and the IRRS team encouraged the Government of India to ensure AERB has sufficient resources for continued international engagement on the development of safety standards and the exchange of information on nuclear and radiation safety.

However, areas for improvement were identified and the IRRS team made 3 recommendations and 3 suggestions in the following areas:

- Safety assessments which have to be part of the application for a consent in systematic manner;
- Submission of independent verifications of the safety assessments of radiation sources facilities and activities when appropriate in accordance with a graded approach;
- Establishment of comprehensive radiation protection programmes for all facilities and activities;
- Revision of the frequency of planned inspections and the duration of validity of regulatory consent in accordance with a graded approach;
- Development of a national policy and strategy to define responsibilities in regaining control over orphan sources; and
- Revision of regulations and guides, where appropriate, to ensure consistency with the IAEA safety standards and clarification of the hierarchy of the regulatory documents.

Throughout the mission, the IRRS team received the full cooperation in regulatory and technical areas and policy issues by all parties. In particular, the AERB staff provided excellent assistance and demonstrated extensive openness and transparency.

At the end of the mission, IAEA issued a press release.

I. INTRODUCTION

At the request of the Government of India, an international team of senior safety experts met representatives of the Atomic Energy Regulatory Board (AERB) of India from 9 to 20 June 2022 to conduct an Integrated Regulatory Review Service (IRRS) extended follow-up mission. The mission took place at AERB Headquarters in Mumbai. The purpose of this peer review was to review India's progress in implementing the recommendations and suggestions identified in the initial IRRS mission which was carried out from 16 to 27 March 2015 and to review regulatory activities in relation to the radiation sources facilities and activities for Modules 5 to 9.

The extended follow-up review mission was formally requested by the Government of India on 24 September 2019. A preparatory mission was conducted virtually on from 21 to 23 July 2020 to discuss the purpose, objectives, and detailed preparations of the follow-up review in connection with regulated facilities, activities and exposure situations in India and their related safety aspects and to agree the scope of the IRRS follow-up mission.

The IRRS Team consisted of 7 senior regulatory experts from 5 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the areas covered by the initial mission and of the extended topic on radiation sources facilities and activities.

In preparation for the IRRS follow-up mission, India conducted a self-evaluation of the status of recommendations and suggestions set out in the initial IRRS mission report and prepared a self-assessment follow-up report accordingly. India also conducted a self-assessment of the extended scope of the mission and prepared a preliminary action plan accordingly. The results of India's self-assessments and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) for the mission in April 2022.

During the mission, the IRRS team performed a systematic review of all topics by reviewing the ARM, additional information provided, and by conducting interviews with management and staff of AERB, as well as direct observations of regulatory oversight activities of use of the radiation sources. The IRRS team also met representatives from the Department of Atomic Energy.

Throughout the mission, the IRRS team received the full cooperation by all parties. In particular, the staff of AERB provided excellent assistance and demonstrated extensive openness, professionalism and transparency.

II. OBJECTIVE AND SCOPE

The purpose of this Integrated Regulatory Review Service (IRRS) extended follow-up mission was to conduct a review of the implementation of the thirteen recommendations and the twenty-one suggestions that were given to India during the IRRS initial mission conducted from 16 to 27 March 2015, and to review regulatory activities in relation to the radiation sources facilities and activities for Modules 5 to 9.

The IRRS extended follow-up mission scope included the scope of the initial mission covering the following areas: responsibilities and functions of the government; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body related to regulation of nuclear power plants, including authorization, review and assessment, inspection, enforcement, the development of regulations and guides, emergency preparedness and response. The Government of India asked the IAEA to extend the scope of the mission by adding the subject of radiation sources facilities and activities in relation to the core regulatory functions: authorization, review and assessment, inspection, enforcement, and regulations and guides.

The review was carried out by comparison of existing arrangements against the IAEA safety standards and the Code of Conduct on safety and security of radioactive sources.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in India and in other Member States from the knowledge gained and experiences shared between India Counterparts and IRRS reviewers, and through the evaluation of the effectiveness of India's regulatory infrastructure for nuclear and radiation safety.

III. BASIS FOR REVIEW

A) Preparatory work and IAEA Review Team

At the request of the Government of India, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) extended follow-up mission was conducted. The preparatory meeting was carried out by the appointed Team Leader Mr Ramzi Jammal, Deputy Team Leader Mr George Wilson, the IAEA Coordinator Mr Jean-René Jubin, and IAEA Deputy Coordinator Mr Ronald Pacheco. Subsequently, due to COVID-19 related circumstances, Mr Kevin Williams took on the role of deputy team leader.

The IRRS extended follow-up mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of AERB represented by Mr G. Nageswara Rao, Chairman of AERB, other senior management and staff. The discussions resulted in agreement that the scope of the review would include the scope of the initial mission conducted from 16 to 27 March 2015, which was limited to nuclear power plants (NPPs), extended to also cover radiation sources facilities and activities.

Mr Deepak Ojha, deputy Liaison Officer of AERB made presentations on the legal and regulatory framework in India and Mr Vivek Piplani presented the self-assessment process and preliminary conclusions on the progress made for implementing the 2015 IRRS initial mission findings. IAEA staff presented the IRRS principles, follow-up mission process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS extended follow-up mission in India. The proposed composition of the IRRS team was discussed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visit, lodging and transportation arrangements were also addressed. AERB confirmed that India appointed Mr C. S. Varghese, Executive Director of AERB, as Liaison Officer (LO) and Mr Deepak Ojha, Head, Directorate of Radiation Protection and Environment, as Deputy Liaison Officer (DLO). It was agreed the roles and responsibilities of IRRS Team members, the Liaison Officer and the Counterparts.

AERB provided IAEA with the advance reference material (ARM) for the review on 7 April 2022. In preparation for the mission, the IAEA team members reviewed the ARM and provided their initial impressions to the IAEA 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 VI.

C) Conduct of the review

The initial IRRS Team meeting took place on Monday, 13 June 2022 at AERB Offices in Mumbai, directed by the IRRS Team Leader and the IAEA 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 IRRS team. In this respect, the IRRS Team Leader, the deputy Coordinator and the expert for radiation sources facilities and activities held a briefing meeting on the extended topic on 8 June 2021 then started to conduct the review of the extended scope of the mission.

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.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *A National Policy and Strategy for Safety has been established throughout the legal framework, however it has not been promulgated as a statement of the Government's intent.*	
(1)	**BASIS: GSR Part 1 Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
(2)	**BASIS: GSR Part 1 para. 2.3. states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy."*
R1	**Recommendation:** The Government should adopt and publish national policy and strategy for safety as a statement of the Government's intent.

Changes since the initial IRRS mission

Recommendation 1: Since the initial mission in 2015, the Government of India constituted a committee for drafting a National Policy for Nuclear & Radiation Safety and a National Strategy for Nuclear & Radiation Safety. Drafts of the Safety Policy and the Safety Strategy (Drafts) were prepared in accordance with IAEA GSR Part 1 (Rev. 1) and IAEA Safety Fundamental Principles (SF-1). It was explained to the IRRS team that after internal reviews within the Department of Atomic Energy (DAE), the Drafts were sent to the Atomic Energy Commission (AEC), as the body responsible in India for formulating policy with regard to atomic energy. After a review, AEC approved the Drafts. The drafts were then subject to external experts review for a review from a public perception point of view, followed by an inter-ministerial consultation in 2020 and 2021. Comments were received and incorporated. The IRRS team understood that once the Drafts are approved by the AEC and have undergone Ministerial consultation, there is high confidence that the Policy and Strategy will be signed by authorised signatory on behalf of the Government. In August of 2021, the final versions of the Policy and the Strategy were submitted to the Government for approval. The existence of the Policy and Strategy was demonstrated to the IRRS team, and the IRRS team noted the 2021 letter to the Government seeking approval and issuance of the Policy and Strategy. Once approved, the Policy and Strategy will be published.

Status of the initial mission findings

Recommendation 1 (R1) is closed on the basis of progress made and confidence in the effective completion as National Policy for Nuclear & Radiation Safety and a National Strategy for Nuclear & Radiation Safety have been drafted and approved by the AEC, and are awaiting imminent signature by the Government.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

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

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IRRS team noted that while the AERB has necessary functional independence, the governmental framework for atomic energy has both the nuclear industry through the DAE and the regulatory body reporting to the Atomic Energy Commission (AEC) and there isn't clear separation of nuclear regulation with the potential to compromise the independence of Atomic Energy Regulatory Board (AERB).*	
(1)	**BASIS: GSR Part 1 Requirement 4 states that** *"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."*
R2	**Suggestion:** The Government should embed in law, the AERB as an independent regulatory body separated from other entities having responsibilities or interests that could unduly influence its decision making.

Changes since the initial IRRS mission

Recommendation 2: The Atomic Energy Regulatory Board (AERB) was established by the Government of India with reporting to the Atomic Energy Commission. AEC is the high-level governing body with overall responsibility for policy matters relating to the use of nuclear energy in India. AERB is administratively responsible and accountable to AEC which also exercises overall governance of the nuclear industry through the DAE organisational framework to the operating organisations including the Nuclear Power Corporation of India (NPCIL) and Bharatiya Nabhikiya Vidyut Nigam Limited (BHAVINI).

In 2015, the IRRS team noted the professionalism and integrity of AEC, NPCIL and AERB senior staff towards ensuring the regulatory decision-making processes/arrangements were completed independently and did not notice instances, in which de-facto AERB independence was compromised. It was noted that AERB has been established using the legal provisions of the AEA, and that with the statutory and legal provisions of the AEA and various rules framed thereunder, and the powers conferred by its constitution, AERB has the necessary legal authority for its regulatory activities. Furthermore, the mandate of AERB does not include any functions other than regulation of nuclear and radiation safety. These aspects provide functional independence for AERB as a regulatory body. However, the IRRS team noted that as the governance framework of atomic energy has both the nuclear industry and regulatory body reporting to the AEC, there is not clear separation of the regulatory body and its decision making, such that the potential to compromise the independence of the AERB exists. The IRRS team concluded that in order to ensure that the independence of the regulatory body is clear and transparent, the Government should strengthen the legislative framework by creating in law, the AERB as a regulatory body separated from entities having responsibilities or interests that could unduly influence its decision making.

A number of proposals intended to establish a separate regulatory body in law have been made both before and after the 2015 IRRS mission. After the 2015 Mission, in 2016 the Government

proposed to move a fresh bill to create as a separate statutory authority called the Nuclear Safety Regulatory Authority (NSRA) in the Parliament. A Committee was constituted by the Government for re-examination of the Bill in 2017 and subsequently the Bill was withdrawn.

While the NSRA bill 2015 is no longer being pursued, in 2020 the Government constituted a committee to determine an alternative means to strengthen the de jure independence of the AERB. The proposal developed by the committee seeks to amend the AEA, 1962 to establish the regulatory body under the AEA, 1962, as a statutory authority for the purpose of ensuring nuclear and radiological safety, and seeks to unify the rules under the AEA, 1962. It was demonstrated to the IRRS team that the proposal for the statutory amendment has been developed, and that the proposals have been recently submitted in a report to Government. The proposals are not publicly available, and the IRRS team was not able to view the proposal in detail. While the IRRS team acknowledged that important steps have been taken to address Recommendation 2, the proposal is not yet sufficiently complete to satisfy the recommendation, as many more steps, reviews and decisions are required before the Act could be amended. Furthermore, the IRRS team did not have enough information to determine whether the proposal to establish a statutory regulatory body – which would go a great distance towards meeting the requirement of effective independence - would sufficiently address the issues of independence.

Another concern relating to the independence of the AERB is the relationship with the DAE. DAE provides the necessary administrative support to AERB in regard to its budget, parliamentary work and accounting matters. In order to provide clarification that there is no interference from DAE in the functioning of AERB, an arrangement for communication and administrative support between DAE and AERB that reaffirms the functional independence of AERB has been proposed. It has been explained to the IRRS team that the working arrangement is currently being examined by a committee constituted in May 2021 (reconstituted in September 2021) under Chairmanship of Secretary, AEC. AERB expects that the formal arrangement will be in place shortly.

One outstanding concern the IRRS team had is the appeal process for decisions of the AERB, which provides that appeals of the AERB's regulatory decisions are to be heard and decided by AEC. While it was explained to the IRRS team that the AEC's review of the AERB decisions would not diminish the decision of AERB in terms of safety, the IRRS team was not able to confirm the nature and the scope of the AEC's oversight of AERB regulatory decision under appeal.

Status of the initial mission findings

Recommendation 2 (R2) remains open as the regulatory body has not yet been embedded in law as an independent body shielded from the potential for undue influence over its decision making.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

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

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

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

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

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

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IRRS team noted the significant commitment and progress in India to developing solutions for managing radioactive waste. However, there was no evidence of the existence of a formal national radioactive waste management strategy.*	
(1)	**BASIS: GSR Part 1 para. 2.28. states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities [3, 7]. The strategy shall include appropriate interim targets and end states...."*
(2)	**BASIS: GSR Part 1 para. 2.29. states that** *"In strategies for radioactive waste management, account shall be taken of the diversity between types of radioactive waste and the radiological characteristics of radioactive waste."*
R3	**Recommendation:** The Government should promulgate a national radioactive waste management strategy in support of the Government declaration on the management of radioactive waste.

Changes since the initial IRRS mission

Recommendation 3: In 2016, the Government of India constituted a committee for drafting a radioactive waste management policy, in line with the recommendation from the 2015 IRRS mission. It was explained to the IRRS team that a draft of the India's Policy on Management of Radioactive Waste was prepared in accordance with the IAEA's "Policies and Strategies for Radioactive Waste Management" (NW-G-1.1). A correlation between the policy and the NW-G-1.1 was shown to the IRRS team that provided substantial evidence of alignment.

After internal reviews within DAE were completed on the draft policy, the draft was sent to the Atomic Energy Commission (AEC), the body responsible for formulating policy with regard to atomic energy. After a review, in 2017, AEC approved the policy. The Government of India then constituted a committee for drafting the strategies for implementation of the waste management policy. Following a Departmental review and an inter-ministerial consultation in which comments were received and incorporated, a final version of both the Policy and the Strategy for Management of Radioactive Waste were submitted to the Government for approval, alongside the Policy and Strategy for Nuclear & Radiation Safety.

The IRRS team understood that once these documents are approved by the AEC and have undergone Ministerial consultation, there is high confidence that they will be signed by the authorized signatory on behalf of the Government. In August of 2021, the final versions of the Policy and the Strategy were submitted to the Government for approval. The existence of the Policy and Strategy was demonstrated to the IRRS team, and the IRRS team noted the 2021 letter to the Government seeking approval of the Policy and Strategy. Once the documents are signed, they will be published.

Status of the initial mission findings

Recommendation 3 (R3) is closed on the basis of progress made and confidence in the effective completion as India's Policy on Management of Radioactive Waste and Strategy for Management of Radioactive Waste have been drafted and approved by AEC and are awaiting imminent signature by the Government.

1.8. COMPETENCE FOR SAFETY

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

1.9. PROVISION OF TECHNICAL SERVICES

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

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *To date, India has invited only two IAEA services, namely OSART in 2012 and the recent IRRS mission.*	
(1)	**BASIS: GSR Part 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 taking more benefit from the various IAEA peer review services by inviting more international reviews.

Changes since the initial IRRS mission

Suggestion 1: Since the 2015 mission, there has been an increase in the participation of India in international peer reviews. India invited the Extended IRRS Follow-up Mission (2022), which includes a review of the Legal and Regulatory Framework for Radiation Sources. Also since 2015, Indian experts participated as Team members for IRRS missions in 8 countries (Armenia, Indonesia, South Africa, Kenya, Austria, U.K., Australia and Nigeria). India explained that the Regulatory Framework for Safety and Facilities and Activities in India have undergone various other international peer reviews, for example, during India's participation in the CNS Review Meeting in 2017 and in the process for participating in CNS 2020, which finally did not take place due to the prevailing pandemic situation due to COVID-19, taking advantage of the multilateral peer review and the sharing of good practices among the participating countries. Also since 2015, the AERB has further expanded its bilateral and multilateral co-operation arrangements. AERB has entered into bilateral arrangements with regulatory bodies (CNSC, ONR, BAERA and VARANS) of four more countries i.e. Canada, UK, Bangladesh and Vietnam. With regard to expansion of multilateral arrangements, India has become a Participant in CSNI & CNRA of OECD/NEA and Member of Atomic Energy Research (AER), Hungary. India has expressed that this expansion aims to further strengthen the exchange of information and experience in the field of nuclear and radiation safety. India invited 11 WANO peer reviews since 2015 and also provided experts to WANO for its peer review program. The IRRS team also recognized that the IMS document AERB/IMS/L-1 includes guidance on taking part in international cooperation activities and on identifying opportunities to improve and strengthen the regulatory processes by taking into account, among other things, international peer review exercises.

Status of the initial mission findings

Suggestion 1 (S1) is closed as there has been increased participation in international peer reviews since the initial mission. The IRRS team encourages the Government of India to continue to increase this participation, especially by inviting more IAEA peer review missions to India.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Established AERB system of use of feedback information and international contribution is a mature process. However, the element missing is the closure of the feedback loop by sharing the results of the use of external experience.*	
(1)	**BASIS: GSR Part 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..."*
S2	**Suggestion:** The AERB should consider including in its process on managing regulatory and operating experience the feedback on measures taken in response to internationally reported events.

Changes since the initial IRRS mission

Suggestion 2: Since the 2015 mission, the AERB has amended its Procedure for Management of Operating Experience Activities [AERB/IMS/L-III/OPSD/20] to include a requirement in response to Suggestion 2. The new provision of the procedure requires that the measures taken in response to international experience are to be shared with the international community. Measures taken have, in fact, been shared with the international community through the web-based IAEA-IRS (WBIRS) on a number of instances, as demonstrated to the IRRS team. India has explained that safety measures taken in Indian NPPs based on external experience were also shared with the international nuclear community through other fora, like the CNS and the CANDU Senior Regulators Forum (CSRM).

Status of the initial mission findings

Suggestion 2 (S2) is closed as the process on managing regulatory and operating experience has been amended to include a requirement of sharing with the international community the measures taken in response to international operational experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The AERB applies the graded approach to its regulatory functions, however there is an absence of documented guidance on how to apply it.*	
(1)	**BASIS: GSR Part 1 Requirement 26 and para 4.40 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.* *4.40. 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."*
(2)	**BASIS: GSR Part 1 Requirement 19 and para 4.16. state that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.* *4.16. The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost effective manner so as to build confidence."*
(3)	**GSR Part 1 para. 4.3. (a, b) states that** *"The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. The regulatory process shall provide a high degree of confidence, until the release of facilities and activities from regulatory control, that: (a) Safety is optimized, the balance between operational benefits and potential consequences for people and the environment being taken into account. (b) Safety assessments carried out for facilities and activities demonstrate that an adequate level of safety has been achieved, and that the objectives and criteria for safety established by the designer, the authorized party and the regulatory body have been met."*
(4)	**GSR Part 1 para. 4.46. states that** *"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*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	graded approach."
(5)	**GSR Part 1 para. 4.67. states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities."*
R4	**Recommendation:** The AERB should establish guidance for individual staff members for the implementation of the graded approach in all its regulatory processes.
S3	**Suggestion:** The AERB should consider formalizing the process for integrated assessment of licensees' performance using the system of SPIs. The results of the SPI process should be transparent to the interested parties and the public.
Observation: *AERB staff are required to complete a wide range of tasks or activities in addition to the assigned activities outlined within their primary area of technical expertise In the important area of EPR there is no dedicated full-time expert.*	
(1)	**GSR Part 1 Requirement16 and para. 4.5. state 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.* *4.5. The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
S4	**Suggestion:** The AERB should consider evaluating its resource allocation across the organization to ensure sufficient full-time specialists are available and dedicated to those areas which are not currently covered.

Changes since the initial IRRS mission

Recommendation 4: Revision no. 01 of Integrated Management Manual System (IMS) Level-I was issued in February 2021 (IMS Level I, rev. 1). This manual references the graded approach in Chapter 2, Mission, Vision and Organisational Policies. Point 2.3 indicates that one AERB organisational policy is to "apply graded approach to ensure effective and efficient utilization of resources." The document also mentions in Chapter 3.15, Organisational Strategy, point 6, "Using graded approach, based on risk associated and complexity of the facility or activity being regulated, as applicable, while discharging its mandate which include resources utilization commensurate with the associated risks". According to Chapter 5, Regulatory and Management Processes, the graded approach is applied in the management processes and in the regulatory processes.

Subsequently, the document "Guidance for application of graded approach in regulation of facility and activities" (IMS Level II-B, rev. 0) was issued in October 2021. The document covers the graded approach in regulatory functions as well as the graded approach in regulatory processes –

developing regulatory documents, licensing, review & assessment, inspection, enforcement and Emergency Preparedness and Response (EPR).

The implementation of the graded approach is mentioned explicitly in IMS Level-I, rev.1, and detailed guidance on the implementation aspects are covered in IMS Level-IIB, rev. 0. The guidance from the document IMS Level-IIB is used in the further development of IMS Level II and III procedures.

Suggestion 3: During the initial IRRS mission, AERB was in the process of developing Safety Performance Indicators (SPIs) and the system was in a trial phase. Since then, AERB developed a new set of SPIs in order to assess the safety performance of operating NPPs and documented the Assessment of Safety Performance of NPPs based on SPIs in the IMS level III "Procedure for Assessment of Safety Performance of NPPs". The Advanced Reference Material (ARM) referenced document no. AERB/IMS/L-III/OPSD/23 revision 1 that was first published and approved in February 2020. During the follow-up mission, the IRRS team was provided with revision 2 issue 1 of the same document. AERB provided proof of calculating the safety performance indicators for all types of NPPs. The annual SPIs analysis is shared with NPCIL and a shorter version of the analysis is made publicly available in the annual report and also in a dedicated section from the AERB web page.

Suggestion 4: The AERB has developed and implemented its IMS addressing the requirements of IAEA GSR Part 2, with respect to the functional requirements for the regulatory body. The allocation of resources within the management system are commensurate with the risks associated with facilities and activities in accordance with a graded approach. AERB has formed a Resource and Documentation Division (R&DD) to manage the key resources and document development activities of AERB and a Human Resource (HR) Plan was formalized. Additionally, in 2017, a Directorate of Radiation Protection and Environment (DRP&E) was created that has the responsibility to look after the regulatory aspects related to Radiation Protection, Environment, and EPR. Within AERB, the Directorate of Regulatory Inspection (DRI) and Directorate for Regulatory Affairs and Communication (DRA&C) were established.

During the mission, the Human Resource Plan document AERB/IMS/L-III/RDD/08, from May 2022, was presented. The plan addresses HR policy, strategy and planning and guidelines on HR planning. The reviewer noted that these requirements pertain mainly to Level II documents and a level III document, like HR plan should be more a working/implementation document. The AERB representatives pointed out that a new level II procedure, "Resource Management," was under development that will include an HR policy, strategy and planning currently addressed in the HR Plan. Currently the resource needs are established within each division, taking into account the responsibilities allocated, but there is not yet a document that gathers all data in a coherent manner.

Following the modification of the AERB organisational structure in order to cover all regulatory processes established in the IMS, the organisational chart was updated and the Nuclear and Radiological Emergency Monitoring Centre (NREMC) that support the Emergency Response Monitoring Organization is covered in Level II IMS document of DRP&E.

Status of the initial mission findings

Recommendation 4 (R4) is closed on the basis of progress made and confidence in the effective completion as the guidance already developed is further implemented in the working documents.

Suggestion 3 (S3) is closed as the AERB developed a new set of SPIs and the SPIs are calculated on an annual basis for all NPPs and shared with the interested parties and the public.

Suggestion 4 (S4) remains open as the prepared draft HR plan is yet to be finalized.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The independence of the AERB's decision making vis-a-vis the interfaces with licensees needs reinforcement.*	
(1)	**BASIS: GSR Part 1 Requirement 17, paras. 4.6. and 4.9. state that** *"The regulatory body shall perform its functions in a manner that does not compromise its effective independence.* *4.6. Requirements 3 and 4 in Section 2 stipulate that the government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making. This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence. The staff of the regulatory body shall remain focused on performing their functions in relation to safety, irrespective of any personal views. The competence of staff is a necessary element in achieving effective independence in decision making by the regulatory body.* *4.9. To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion.*
R5	**Recommendation:** The AERB should review the implementation of its policy and existing arrangements to ensure it maintains independence in the performance of its regulatory functions.

Changes since the initial IRRS mission

Recommendation 5: Since the initial mission, AERB has taken several steps to reinforce the independence from the licensee organisations in the performance of its regulatory functions and decision making through the following actions:

- The inspection process was reviewed and reinforced by the establishment of the Directorate of Regulatory Inspections. Further the inspection frequency was increased with focus on specific safety areas to include the safety related systems;
- The establishment of the newly formed Directorate of Radiation Protection and Environment (DRP&E) that is mandated to manage the Monitoring of Emergency Preparedness and Response;
- The continuation of implementing the existing MOU between TSO (BARC) and AERB, which includes a conflict-of-interest clause indicating that an expert reviewer supporting the Licensee cannot support AERB at the same time. According to this MOU, the experts working for AERB have to expressly declare any contractual arrangements with its licensees, to rule out any conflict-of-interest issues.

The IRRS team was provided with the document AERB/IMS/L-IIB/R&DD/3, entitled "Procedure for Formation, Functioning and Self-Assessment of Safety Committees of AERB." In chapter 2.4.2

of this procedure, provisions for the conflict of interest are outlined which requires non AERB members to submit a declaration that they are not in a position of conflict of interest.

Status of the initial mission findings

Recommendation 5 (R5) is closed on the basis of progress made and confidence in the effective completion as the existing provision on avoiding any potential conflict of interest are in force.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The AERB has identified competence gaps but does not yet have a fully developed competence needs analysis process This will ensure a resilient regulatory organization with the essential knowledge, skills and abilities needed to regulate NPPs.*	
(1)	**BASIS: GSR Part 1 Requirement 18, paras. 4.11. and 4.13. state that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.* *4.11. 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.* *4.13. 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."*
R6	**Recommendation:** The AERB should fully develop its recently initiated process to analyse its competence needs to secure the essential knowledge, skills and abilities needed to regulate NPPs.
Observation: *The AERB does not have competences in the area of human and organizational factors and in the area of public communications (ref. par. 3.1.).*	
(1)	**GSR Part 1 Requirement 18 and para. 4.11. state that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.* *4.11. 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."*
S5	**Suggestion:** The AERB should consider ensuring that a sufficient number of staff with specialised competence, knowledge, skills and abilities in the area of human and organizational factors (HOF) and communications are available.

Changes since the initial IRRS mission

Recommendation 6: Since the initial mission, AERB has included in the IMS Level-I document requirements for human resource competency development and knowledge management. After the IRRS mission in 2015, AERB completed the competency mapping exercise. AERB competence mapping assessment was based on IAEA SARCON guidelines and the organisational structure of the time. In 2016, the AERB management acted on the gap analysis and initiated training activities for the existing staff according to the identified training needs. Training activities are ongoing to fill the previously identified gaps. However, the competency mapping should be periodically reviewed in order to be updated, if the case may be.

Based on the identified competency, AERB developed and implemented a Technical Authorization programme in order to qualify the employee to participate in safety review and regulatory inspection activities.

Suggestion 5: Following the IRRS mission in 2015, in order to ensure a sufficient number of staff with specialised competence, knowledge, skills and abilities in the area of Human and Organizational Factors (HOF) and communications, AERB decided on the strategy to identify the individuals from among the existing technical staff for having the formal qualification for these specialisations and provide additional training in human factors engineering.

The AERB has created a Resources and Documentation Division (R&DD) having responsibilities to manage human resources related to Human, Organizational and Technical factors. Since the initial mission, all AERB senior personnel have received specialised training in soft skills, communication, and the subject of HOF. Training on HOF was provided to AERB employees during 2018 and 2019.

Since the initial mission, AERB has formed a dedicated Directorate for Regulatory Affairs and Communication (DRA&C), having responsibilities in the area of public communication. Currently, 9 people are employed within the Directorate, out of which 4 have direct responsibilities on public communication.

Status of the initial mission findings

Recommendation 6 (R6) is closed on the basis of progress made and confidence in the effective completion as the AERB developed the process to analyse its competence needs to secure the essential knowledge, skills and abilities needed to regulate NPPs and implemented the internal technical authorization programme.

Suggestion 5 (S5) is closed on the basis of progress made and confidence in the effective completion as the internal training and authorization programme from the Directorate for Regulatory Affairs and Communication (DRA&C) is in progress.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

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

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

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

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

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

3.7. SAFETY RELATED RECORDS

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

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *Engagement with the media, outreach to and consultation with the general public and the population in the vicinity of the NPP needs improvement in accordance with the IAEA safety standards.*	
(1)	**BASIS: GSR Part 1 Requirement 36, paras. 4.66. (a,d,e) and 4.67. state that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.* *4.66. The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:* *(a) Communication with interested parties and 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;* *(e) Making information on incidents in facilities and activities, including accidents and abnormal occurrences, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public.* *4.67. The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities.*
(2)	**BASIS: GS-R-3 para. 3.6. states that** *"The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."*
(3)	**GSR Part 1 para. 4.8. states that** *"The authorized party has an obligation to inform the public about the possible radiation risks associated with the operation of a facility or the conduct of an activity, and this obligation shall be specified in the regulations promulgated by the regulatory body …"*
R7	**Recommendation:** The AERB should establish a communications strategy to effectively engage with the media, and communicate and consult with the general public and the population in the vicinity of NPPs. This includes consultation with

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	the general public on draft safety codes and standards.

Changes since the initial IRRS mission

Recommendation 7: AERB has created the Directorate of Regulatory Affairs and Communications (DRA&C) and a Section within the Directorate, dedicated for public communication and outreach for the media, general public at large and the population within the vicinity of NPP's.

AERB through DRA&C is mandated to develop the process on public communication and outreach – established through AERB Constitution Order S.O 4772. AERB decided to elaborate a Strategy for Public Communication and Outreach program in accordance with the policies established in the Integrated Management System Manual. IMS Level I indicate the Public Communication and Outreach as associated process to the core processes and covers the policies related to Public Communication and Outreach. Also Annexure-III of IMS Level-I indicate the Level-II document on Strategy & Plan for implementation of Regulatory Processes in DRA&C.

The level II document Strategy & Plan for implementation of Regulatory Processes in DRA&C (revision 1), includes chapter 4.1.2 Strategy for public communication and outreach. The previous version of the document (revision 0) mentioned the communication processes and did not refer to a communications strategy that would enable AERB to effectively engage with the media, and communicate and consult with the general public and the population in the vicinity of NPPs. Currently the document has been revised but has not yet been issued.

The document, Strategy & Plan for implementation of Regulatory Processes in DRA&C, dated December 2021 is currently in a draft stage as it is under internal review process.

Status of the initial mission findings

Recommendation 7 (R7) remains open as the draft document on Strategy & Plan for implementation of Regulatory Processes in DRA&C, that includes the Strategy for public communication and outreach, is currently a draft document and is yet to be issued.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IMS is currently under development, but only parts have been applied. Currently, there are redundancies between QMS and IMS. The AERB IMS and QMS are separately managed by two committees of the same composition.*	
(1)	**BASIS: GSR Part 1 paras. 4.14. and 4.16. state that** *"4.14 The regulatory body shall establish and implement a management system whose processes are open and transparent. The management system of the regulatory body shall be continuously assessed and improved.* *4.16. The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfillment of its obligations in an appropriate, timely and cost effective manner so as to build confidence."*
R8	**Recommendation:** The AERB should finalize and fully implement its integrated management system (IMS), based on GS-R-3.
Observation: *The AERB has piloted safety culture review in OPSD and later on performed a review in NPSD. The process used for safety culture assessment does not include consulting with all contributing staff prior to deciding the action plan.*	
(1)	**BASIS: GS-R-3 para. 3.4. states that** *"Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system."*
(2)	**BASIS: GS-G-3.1 para. 2.5. states that** *"The management system shall be used to promote and support a strong safety culture by… providing the means by which the organization continually seeks to develop and improve its safety culture."*
S6	**Suggestion:** The AERB should consider implementing its safety culture review process throughout the organization, including the consultation of staff on the safety culture action plan before its implementation.
Observation: *The AERB does not have an internal process for assessing licensees' organizational changes during all life cycle phases of a NPP.*	
(1)	**BASIS: GSR Part 1 paras. 4.15. (1) and 4.62. state that** *"4.15 The management system of the regulatory body has three purposes: (1) The first purpose is to ensure that the responsibilities assigned to the regulatory body are properly discharged.* *4.62. The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	graded approach."
(2)	**BASIS: GS-R-3 paras. 5.28. and 5.29. state that** *"5.28. Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified. 5.29. The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."*
R9	**Recommendation:** The AERB should review organizational changes of NPPs and develop internal procedures to assess whether the licensees' organizational changes are planned, categorized, implemented and monitored in a manner that does not compromise safety.

Changes since the initial IRRS mission

Recommendation 8: AERB finalized the establishment of the Integrated Management System (IMS) in 2018 which superseded the former quality management system. The IMS was developed in accordance with the requirements set up in the IAEA Safety Standards GSR Part 2 Leadership and Management for Safety which was published in 2016.

When IAEA published the two new IAEA Safety Guides GSG-12 Organization, Management and Staffing of the Regulatory Body for Safety and GSG-13 Functions and Processes of the Regulatory Body for Safety, AERB conducted a gap analysis between the content of the IMS and those two safety guides. IMS documents were updated accordingly in 2021, including the IMS Manual (the Level-I document).

The IRRS team observed that the documentation of the management system is comprehensive, well controlled, clearly identified and readily accessible by all, including the AERB staff located in its Regional Centres, thanks to the Intranet of the organization. Most of the documents and records ('processes' documents') are kept in electronic form in two separated and redundant systems at AERB and Disaster Recovery Data Centre, located at the Safety Research Institute of Kalpakkam, reducing the risks of information loss. Hard copies are kept for all records according to AERB's retention schedule.

The IRRS team noted that the Sub-Committee 4 (EC-SC-4) of the Executive Committee (EC) is responsible to monitor the management system. EC-SC-4 reports and, when appropriate, submits recommendations to EC in relation to the improvement of the IMS. In this regard, the IRRS team reviewed the minutes of the 30th EC-SC-4 meeting held on 30 May 2022 which included indeed an action requesting proposals to be submitted to EC.

Suggestion 6: To conduct the Safety Culture Self-Assessment (SCSA), AERB established a project team. This project team developed a detailed roadmap which was finalized on 13 November 2019. The roadmap was then submitted for approval to EC. The SCSA data were collected from October 2020 to March 2021 through a survey sent to all staff, a series of focus group discussions, and interviews of senior managers. The SCSA resulted in the identification of 12 issues that were presented and discussed with the senior management of the AERB. To ensure non bias process, the interviews were conducted by external experts. Based on the SCSA report an action plan was drafted. The IRRS team noted that the action plan was presented to the staff during a colloquium (open house discussion) organized on 20 May 2022 with a purpose to seek input from staff regarding the findings and the action plan. This discussion with staff was recorded. Only minor

comments were received from staff without impacting the action plan. At the time of the IRRS extended follow up mission, the action plan was under implementation.

The IRRS team was informed that once the action plan will be completed, AERB plans to establish a formal process within the IMS based on the experience gained from this first experience; the objective would be to conduct a SCSA every 5 years.

Recommendation 9: Organizational changes of nuclear power plants (NPPs) in operation are regulated by AERB Safety Code on Nuclear Power Plant Operation (AERB/NPP/SC/O (Rev.1). It provides (para 10.4) "Modifications relating to the organisational aspects, which are relevant to the safe operation of the plant, shall be submitted to AERB."

For support the review and assessment of the NPP organization changes and to clarify the associated expectations and criteria, the IRRS team noted that AERB established two procedures in 2021 and 2022 within the IMS:

- AERB/Level-III/OPSD/09 for review of organizational changes in operating NPPs; and
- AERB/Level-III/NPSD/25 for review of organization changes in nuclear power projects covering construction and commissioning.

The IRRS team noted that these procedures appear to be comprehensive, and the team was informed that, since the inception of the procedures, AERB had not yet had the opportunity to review any licensee request for an organizational structure modification. However, an example on the implementation of the AERB/Level-III/OPSD/09 procedure in relation to the approval of a new Competent Person (conducting & certifying certain important equipment tests in NPPs) was provided as an example.

As the two procedures' content are similar, the IRRS team encouraged AERB to merge both of them to ensure strict consistency when reviewing organizational changes during construction, commissioning and operation of NPPs, while contributing to the reduction of the number of IMS documents.

Status of the initial mission findings

Recommendation 8 (R8) closed as AERB established an integrated management system in accordance with GSR Part 2.

Suggestion 6 (S6) is closed as AERB conducted a SCSA throughout the organization, with the clear participation of the staff.

Recommendation 9 (R9) is closed as AERB has developed internal procedures to review organizational changes in NPPs.

4.2. MANAGEMENT RESPONSIBILITY

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

4.3. RESOURCE MANAGEMENT

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

4.4. PROCESS IMPLEMENTATION

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

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The AERB is developing its internal and external audit and review programme. It performs independent internal management system audits twice a year. A single audit covers all functions of the audited division. The full scope audits might not be the most effective way to identify deficiencies.*	
(1)	**BASIS: GS-R-3 para. 6.1. states that** *"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement."*
S7	**Suggestion:** The AERB should consider a wider implementation and optimization of its audit and review programme of the integrated management system (IMS), e.g. deep dive audits of specific functions.

Changes since the initial IRRS mission

Suggestion 7: The Resources and Documentation Division (RDD) is responsible for the management of the audit programme. A full scope audit is conducted once a year and covers all divisions of AERB. The audit team is mainly composed of AERB staff. In order to ensure no conflict of interest in the composition of the team, no team member on the audit group belongs to same division that is being audited. The IRRS team was informed that auditors are duly trained on audits and IMS. Audit reports are prepared by audit groups and given to the audited division as well as RDD. RDD compiles all reports in a single report sent to EC-SC-4.

The IRRS team was informed that deep dive audits of specific functions are still not conducted. However, in response to Suggestion 7, AERB has established the process of self- assessment to be conducted by the divisions in such a manner that all processes are covered over a period of 3 years. The full scope audit above-mentioned is used to check whether the divisions comply with this new requirement.

The IRRS team is of the opinion that significant progress has been made and welcomed self-assessments, conducted periodically, which widen the audit and review programme of the IMS. Self-assessments complement independent assessment (audits) in providing additional insights for monitoring the performance of the IMS. Nevertheless, the IRRS team encouraged AERB to review its audit programme in order to consider the inclusion of deep dive audits of specific functions to improve further the effectiveness of the independent review. This could be done in adjusting, for instance, the scope and frequency of the full scope audit.

Status of the initial mission findings

Suggestion 7 (S7) is closed as AERB has wider audit and review programme of the IMS by adding self-assessments of all processes over a 3-year period.

5. AUTHORIZATION

5.1. GENERIC ISSUES

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

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The current template for licences/consents issued by the AERB does not cover all the related legal issues applicable for the case.*	
(1)	**BASIS: SSG-12 para. 2.12. states that** *"The objective of granting authorizations in the licensing process is for the regulatory body to establish regulatory control over all activities and facilities where safety is concerned. ... Licences, authorizations, permits and other regulatory instruments are the principal documents issued by the regulatory body that, at each step of the licensing process, relate the legal and regulatory framework to the duties of the person or organization responsible for the nuclear installation and its activities. ..."*
(2)	**BASIS: SSG-12 para. 2.14. states that** *"Licence conditions are additional specific obligations with the force of law. ... Licences should state explicitly, or should include by reference or attachment, all conditions imposed by the regulatory body."*
(3)	**BASIS: SSG-12 para. 2.40.(q) states that** *"Procedures for, information about and identification of the legal framework for challenging the licence or part of the licence."*
S8	**Suggestion:** The AERB should consider developing or amending the safety code or guide specifying the template for the specific licenses.
Observation: *While detailed and comprehensive requirements are prescribed for PHWR type reactors (including the list of required PIEs), non PHWR reactors which are operating or are under construction require similar comprehensive requirements.*	
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
(2)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
S9	**Suggestion:** The AERB should consider specifying the detailed and specific licensing requirements for all NPP types which are operating, under construction, or planned in the country.
Observation: *According to the actual AERB requirements, only Level-1 PSA for full power operation is required, as part for the supporting material for applicable licensing cases, while the latest general design requirements extend to all states and rely on several probabilistic criteria.*	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: SSR 2/1 para. 5.76. states that** *"The design shall take due account of the probabilistic safety analysis of the plant for all modes of operation and for all plant states, including shutdown, with particular reference to:* *a) Establishing that a balanced design has been achieved such that no particular feature or postulated initiating event makes a disproportionately large or significantly uncertain contribution to the overall risks, and that, to the extent practicable, the levels of defence in depth are independent;* *b) Providing assurance that small deviations in plant parameters that could give rise to large variations in plant conditions (cliff edge effects) will be prevented (see footnote 5);* *Comparing the results of the analysis with the acceptance criteria for risk where these have been specified."*
S10	**Suggestion:** The AERB should consider requiring full scope Level-1 and Level-2 PSA analyses within the scope of required safety analyses for demonstrating the satisfaction of the applicable licensing criteria for all reactor types.

Changes since the initial IRRS mission

Suggestion 8: All the licenses of operating Nuclear Power Plants (NPPs) and consents of nuclear projects issued after the 2015 IRRS mission, follow the template as specified in AERB/SG/G-7 which identifies the conditions to be added to a license. Since 2015, the use of the safety guide has been applied to the issuance of 17 licenses of operating NPPs. For consistency, the SG/G-7 template for operating NPPs & Research Reactors and Nuclear Projects is incorporated in IMS level-III documents. All licensing conditions with respect to NPPs, Fuel cycle Facilities, and disposal and transfer of waste are encompassed in the IMS level-III document of OPSD. This IMS Level III document of OPSD also includes format for authorization of the RSO and Competent Persons to carry out inspections and testing. Specifically, procedures titled, 'Formats of Regulatory Consents issued by OPSD to Operating Nuclear Power Plants,' 'AERB/IMS/L-III/OPSD/44 (Level III),' and 'Licensing of Nuclear Projects', 'AERB/IMS/L-III/NPSD/04' reflect the license conditions.

Suggestion 9: Safety Codes on design of PHWRs and LWRs were developed. The safety code on Design of PHWR is in process of revision. AERB has also taken up development of a safety code on design of fast breeder reactor based on safety criteria document. The AERB safety guide for design basis event for water cooled NPP's has been expanded to be applicable to PWR and BWR also. In addition, AERB is updating the design guides (REGDOCS) with a focus to make them technology neutral / include technology specific chapters, as necessary. A document development plan has been formulated in this regard which sets priority for development / revision of REGDOCs. The requirements specified in IAEA safety standards have been incorporated into the revised documents with clear instructions on applicability in the document and included in the reference section. While not all REGDOCs have been updated, they are in various stages of revision. The revisions will be complete progressively no later than the next two years.

Suggestion 10: AERB has taken up strengthening PSA related requirements through revision of the REGDOCs relevant to NPP. This includes full scope PSA Level-1 and PSA Level-2 as requirements.

Status of the initial mission findings

Suggestion 8 (S8) is closed as demonstrated through development of IMS Level-III documents based on AERB/SG/G-7 to incorporate license conditions for applicability to Nuclear Power Plants, Factories, and the disposal of waste and transfer of waste.

Suggestion 9 (S9) is closed on the basis of progress made and confidence in the effective completion as demonstrated by the revision/development of the design guides, the establishment of a systematic and planned schedule, and the inclusion of the requirements of IAEA safety standards into the design guides.

Suggestion 10 (S10) is closed as applicable reactor types that should incorporate full scope Level-1 and Level-2 PSA analyses were identified and the requirements added to the AERB Safety codes.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

As per legislation in India, no person (individual or corporation) is allowed to use, possess, store, etc. radiation sources without a consent. The facilities and activities using radiation sources regulated by AERB include: 541 radiotherapy centres, 428 nuclear medicine centres, 691 industrial radiography facilities, 54 well logging facilities, 13 industrial accelerators, 21 medical cyclotron, 2566 interventional radiology equipment, 6795 computed tomography equipment and more than 100000 radiological diagnostic equipment.

The India legal framework for radiation safety includes:

- Atomic Energy Act from 1962;
- Atomic Energy (Safe Disposal of Radioactive Waste) Rules from 1987; and
- Atomic Energy (Radiation Protection) Rules from 2004.

The safety provisions to be complied with during authorization process are further detailed in safety codes, standards, safety guidelines, safety guides, safety manuals and technical documents (see module 9).

The responsibility of regulatory control of radiation sources was transferred in 2001 to AERB, which, since then, regulates facilities and activities using radiation sources. AERB regulates all stages of the life cycle of facilities, including siting, design, construction, commissioning, operation and decommissioning. It also regulates import and export of radiation sources. In relation to transport of radioactive materials, the role of AERB is limited to the approval of package design, and shipment approval for transport as another regulatory authority is responsible to oversee the transport of dangerous goods TDG Class 7. When the IRRS team inquired about the role of other Government agencies in regulating transport of dangerous goods TDG Class 7, limited information was provided.

The IRRS team noted the Department of Atomic Energy (DAE) is responsible for emergency preparedness and response related to recovery of control over orphan sources.

Atomic Energy (Radiation Protection) Rules, 2004 lists facilities and activities together with their associated risk.

These Rules also provide the documents which are required to apply for a consent for the operation of a facility or to conduct an activity taking into account their level of risk (high, moderate or low). Thus:

- A “licence” is required for the facilities and activities associated with highest risk such as particle accelerators. A license is granted by the Chairman, AERB;

- An “authorization” is required for the facilities and activities associated with a high risk. It is granted by the head of the RSD, AERB;
- A “registration” is required for the facilities and activities associated with moderate or low risk. It is granted by the head of the RSD, AERB.

The “approval”, for sealed sources, radiation generating equipment and equipment containing radioactive sources, for the purposes of manufacture and supply is granted by Chairman, AERB.

The consent required for siting, design, construction, commissioning, operation and decommissioning of a radiation facility is granted by the Chairman, AERB or the Head of RSD, AERB according to a graded approach.

Table 1 below describes different types of consents.

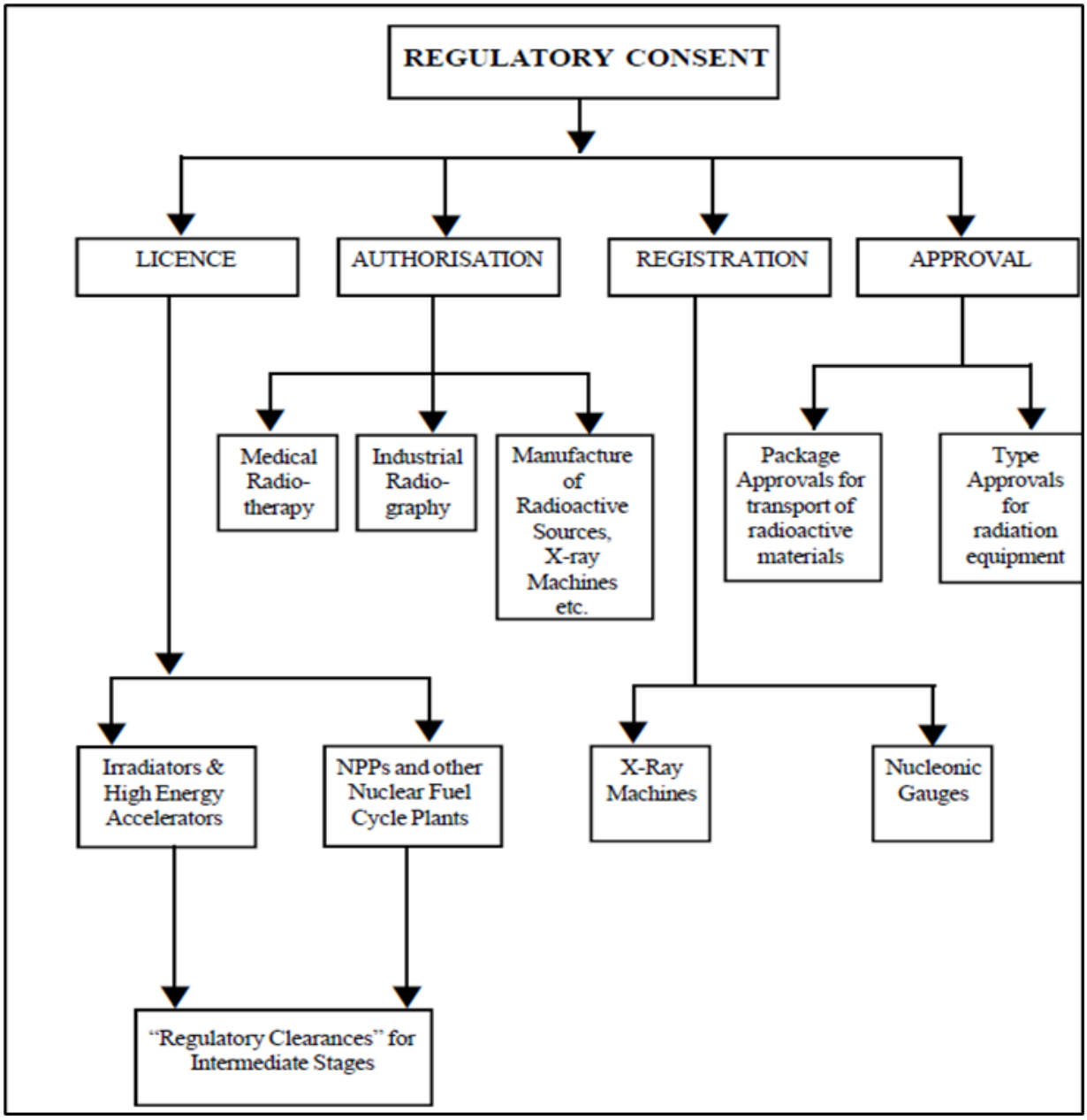

Table 1: Different types of consents for facilities and activities with radiation sources as given in AERB Safety Code AERB/SC/G 2000.

The IRRS team noted that the use of terms for a consent, i.e. license, authorization, registration and approval, is different than terminology used in IAEA Safety Standards GSR Part 3. The IRRS team was informed that AERB is revising Safety Code AERB/SC/G 2000 to also make the terminology used for consenting process consistent with RPR, 2004. . AERB is duly considering the IAEA safety standards, including GSR Part 3, to conduct this revision. This issue is addressed in SF3 in module 9.

AERB has established provisions in relation to a graded approach for exercising its regulatory oversight (authorisation, review & assessment, inspections and enforcement) in a manner commensurate with the radiation risk associated with facilities and activities. However, the IRRS team noted some inconsistencies in the implementation of these graded approach provisions.

The validity of a license, an authorization or a registration is for 5 years, and an approval for 3 years, unless otherwise specified, as per the AERB Safety Guide on Consenting Process for Radiation Facilities, AERB/RF/SG/G-3. Though each category of consents covers the facilities with comparable radiation risk, the duration of the validity of consents is not consistent and does not reflect a graded approach. In this regard, the IRRS team reviewed an example where a consent for the use of X-ray for research purpose had the same validity period of a consent for operating a radiotherapy facility. The inconsistencies were also observed in the frequency of planned inspections of different practices with different level of risk. For instance, the planned frequency of inspections of computed tomography (CT) and X-ray equipment used for research are the same. The IRRS team was informed that AERB is currently revising the graded approach-related provisions, e.g., the duration of the validity of consents, to improve the application of a graded approach throughout all core regulatory processes in a consistent way.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team observed some inconsistencies in terms of the duration of validity of regulatory consents and the frequency of inspections which are not determined according to a graded approach.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 2.5 (3) states that** *"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 authorization5 that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach".*
(2)	**BASIS: GSG-13 para. 3.218 states that** *"The priority and frequency of inspections should reflect the risk associated with the radiation source and the complexity of the facility or activity, as well as the possible consequences of an accident and the type and frequency of any regulatory non-compliances found by inspections."*
SF1	**Suggestion: The AERB should consider completing the revision of the frequency of planned inspections and the duration of validity of regulatory consent in order to be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.**

The intention to carry out an activity using radiation sources is to be notified by an applicant to AERB through the e-Licensing of Radiation Applications platform (E-LORA). This notification is the first step of the authorization process. Any practice using ionization radiation should be duly justified.

Before issuing a consent to operate a facility or to conduct an activity using radiation sources, an applicant should receive from AERB, a consent to procure a source from a supplier holding a consent for doing so. Only Indian suppliers can supply radiation sources. The systematic approach to integrate an approval of equipment, either imported or produced in India, together with a consent to an applicant to first procure a source and later issue a consent to operate a facility or conduct an activity with sources, is recognized as a good performance.

The IRRS team observed that provisions for safety assessment, required by legal provisions, are not fully in line with IAEA GSR Part 4. Thus, safety assessment report is not systematically required to be part of the documentation to be submitted to apply for a consent; it is only required for "radiation processing facilities (gamma / particle accelerator)" and "medical cyclotron" facilities. Moreover, the operating organization are not required to organize an independent verification of their safety assessments submitted to the regulatory body. However, the IRRS team observed that some elements of safety assessment are included in the radiation protection programme provided by the applicant.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Safety assessment is not required systematically as a part of the documentation to be submitted to apply for a regulatory consent. It is only required for "radiation processing facilities (gamma / particle accelerator)" and "medical cyclotron facilities".*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24 para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 3 Requirement 7 para. 3.39 states that** *"Any person or organization applying for authorization:[…]* *(c) Shall assess the nature, likelihood and magnitude of the expected exposures due to the source and shall take all necessary measures for protection and safety;* *(d) Shall, if there is a possibility for an exposure to be greater than a level as specified by the regulatory body, have a safety assessment made and submitted to the regulatory body as part of the application; […]".*
RF1	**Recommendation: The AERB should require, in a systematic manner, safety assessments to be part of the application for a consent.**
Observation: *The operating organizations are not carrying out an independent verification to increase the level of confidence in the safety assessment.*	
(1)	**BASIS: GSR Part 4 Requirement 21 para. 4.66 states that** *"The operating organization shall carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
RF2	**Recommendation: The AERB should require the applicant to submit an independent verification of the safety assessment of facilities and activities, when appropriate in accordance with a graded approach.**

For some practices, radiation protection programme is required to be submitted by the applicant before granting a consent by the regulatory body. Submitted or not, all operating organizations should be required to have a radiation protection programme. In this respect, radiation protection

programme does not completely address organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Radiation protection programme is required to be submitted by the applicant for some practices while for other the operator should have it in the facility. Radiation protection programme does not completely address organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace.*	
(1)	**BASIS: GSR Part 3 Requirement 21 para. 4.66 states that** *"Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure."*
RF3	**Recommendation: The AERB should require a comprehensive radiation protection programme for all facilities and activities.**

About 74 AERB staff members, located at four different locations, contribute to authorization processes. The recruitment process is based on strict criteria to assure the adequate level of competence of the recruited staff. Furthermore, AERB has an effective training programme to develop further the competence of its staff in this area.

Consenting Process in e-LORA

The authorization process is conducted through an online platform, e-LORA. This is a sophisticated, comprehensive, and user-friendly electronic information system, operational since 2013. e-LORA guides applicants through the relevant authorization process, including for providing the required documentation in a specific format required by AERB. The applicants have to upload in e-LORA the demonstration of safety as prescribed in practice specific safety codes, safety standards, safety guidelines, safety guides, safety manuals and technical documents available on the AERB web site. Majority of data such as calibration date of an equipment are provided by an applicant in e-LORA. e-LORA establishes hold points for key steps of the process to obtain a consent to operate a facility or conduct an activity. e-LORA contains a pool of radiation professionals who have been approved by the AERB, including radiation safety officers and radiation workers who are a subject of personal dosimetry control, and also contains a list of approved equipment.

A consent can be issued only when all requirements are met. Whereas "licenses" or "authorizations" can only be issued only after AERB review & assessment. For "registration", applications are processed electronically through the e-LORA system with minimal human intervention by incorporating appropriate business logics. The IRRS team met AERB staff and a user, both highlighted that e-LORA has significantly improved the effectiveness and efficiency of the regulatory processes, including for consents, review & assessment, and inspection. e-LORA lets to a better use of AERB resources. Although the platform is still subject to minor improvements, e-LORA enables that authorization and all core regulatory processes are fully integrated and documented.

The IRRS team was informed that AERB recently has established a set of electronic safety performance indicator (e-SPI) in e-LORA in order to measure the safety compliance of the facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *AERB developed a sophisticated, comprehensive and user-friendly online platform, e-LORA. e-LORA is key system for managing regulatory activities in relation to radiation sources. E-LORA is used by applicants for a consent, authorized parties, as well as AERB staff for authorization, review and assessment, inspection and enforcement. The platform incorporates logic-based on the legal hold-points in authorization process, it improves the application of an effective graded approach therefore a better use of the AERB's resources while improving the regulatory performance. The system largely prevents subjectivity in decision-making by individual staff members of the regulatory body. e-LORA also incorporates set of electronic safety performance indicator (e-SPI) in order to measure the safety compliance of authorized parties from all regulatory processes.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 para. 4.16 states that** *"The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost effective manner so as to build confidence."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 22 para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
GPF1	**Good Practice: The integration of regulatory processes within e-LORA, an online platform used by all applicants, authorized parties and AERB, was noted as a good practice. E-LORA significantly improves the efficient management and process of information to be submitted by an applicant or authorized party in accordance with a graded approach. The logic hold-points set up in e-LORA contributes to efficiency and effectiveness of the regulatory processes and objectivity of its decisions. The system provides unique capabilities to assess electronic safety performance indicator (e-SPI) in order to measure the safety compliance of authorized party.**

Management of disused sources

The Mayapuri accident occurred in 2010. It demonstrated the loss of regulatory control for a disused source. As a result of this event, several changes were introduced by the government in order to prevent recurrence of such events. The IRRS team was briefed by the Department of Atomic Energy (DAE) personnel on emergency preparedness and response. In the event of the discovery of an orphan source, the Crisis Management Group (CMG) is activated, and DAE is then in charge for the recovery and storage of the source. The CMG comprises multiple government agencies' representatives including from AERB. Overall, DAE is responsible for planning, recovery and the management of orphan sources including associated costs and therefore has established the relevant Standard Operating Procedures for gaining control over orphan sources. This service is available on a 24/7 basis.

Once a source is declared disused by an owner, the owner is required to return the radioactive source to the original supplier of the source. For doing so, the owner has to be authorized by AERB. Other options for managing disused sources include provisions for sale or transfer of the sources with prior approval of AERB. According to the regulations, the short-term storage is considered as an acceptable management option whereas the Guidance on The Management Of Disused Radioactive Sources published in 2018 states that short-term storage is not in itself a management option but rather a necessary interim step in implementing one or more of the management options.

Large scrap metal operators and recycling facilities are equipped with monitoring equipment capable of detecting the presence of orphan source. Large transit nodal points, e.g., harbours and airports, are also equipped with such equipment. The IRRS team was informed that a draft strategy for the management of radioactive waste will include necessary provisions for harmonizing the management of orphan sources in scrap metals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no National Strategy for regaining control over orphan sources and for the management of disused radioactive sources. There are no instruments for financial provisions by which the applicant for a regulatory consent is required to submit to the AERB to ensure safe management of disused sources.*	
(1)	**BASIS: SSG-17 Section 7 para. 7.2 states that** *"As indicated in para. 3.15, the government should establish a policy and strategy for the control of radioactive waste in general and of radioactive material recovered in the metal recycling and production industries in particular. The policy and strategy should also cover radioactive waste arising from any contamination that might result from the rupture of an orphan source or the melting of radioactive material with scrap metal. The policy and strategy should be developed in cooperation with the metal recycling and production industries, the regulatory body and organizations for the management of radioactive waste."*
(2)	**BASIS: Guidance on the Management of Disused Radioactive Sources associated with the Code of Conduct para 11 states that** *"Each State should establish a national policy and strategy for the management of disused sources that reflects the State's long-term commitment to their safe and secure management."*
SF2	**Suggestion: The Government should consider developing a national policy and strategy to define responsibilities in regaining control over orphan sources. This policy and strategy should include the instruments for ensuring financial provisions by which the AERB will require the applicant to get a regulatory consent to ensure safe management of disused sources.**

POLICY ISSUE 1 - THE SAFE MANAGEMENT OF DISUSED SEALED RADIOACTIVE SOURCES (DSRS)

The regulatory control of radioactive sources from cradle to grave, including when a source has become a disused sealed radioactive source (DSRS), should be exercised to prevent incidents, accidents and/or malicious acts. In India, only few institutes possess Category 1 DSRS, but many operators possess lower categories of sealed radioactive sources, in particular categories 4 and 5. In co-ordination with DAE, AERB has established mechanisms for the safe management of DSRS, including administrative control during the consent process, inspections, and review and assessment of Safety Status Reports. However, several issues were identified, including: an absence of original foreign supplier to receive DSRS, financial provisions for management DSRSs in case of bankruptcy and associated requirement for an applicant for a consent, role of government and regulatory body in managing DSRSs, criteria to be used for cost of disposal of DSRSs,

enforcement actions, non-availability of transport containers and trained manpower for packaging, and denials of shipments of radioactive material by airlines. The host counterpart requested international experience and views of the IRRS team on these topics.

The AERB initiated the policy discussion with a short presentation, and the experts then shared their regulatory experiences, summarized as follows:

- Canada is the largest producer of Co-60 sources in the world. A financial guarantee is required as a prerequisite to the issuance of a license related to Category 1 and 2 sources. The amount of funds required for a financial guarantee for this purpose is set on a case-by-case basis using the assessment related to a particular safety case, e.g. it depends on a number and characteristics of sources possessed by an operator. The funds are generally guaranteed in favour of the regulator, CNSC, as the beneficiary of the financial guarantee. CNSC also prescribes the timeframe for decontamination and management of DSRS. For other categories of sources, an insurance scheme has been introduced few years ago, such that in case of bankruptcy, DSRS will be managed safely. CNSC has also experiences with radioactive sources that have gotten stuck in well-logging wells. In such cases, the sources are left where they are, but under regulatory control, i.e., the well will be sealed and monitored for leakage of the source. The regulator maintains a record of the location of the source, as such sources will be subject to regulatory control for decades or longer.
- In Slovenia, a financial guarantee is required as a prerequisite to issue an authorization related to high risk sources e.g., Category 1 and 2. The amount of money to be used as a financial guarantee is based on expenses needed to store a source in the Central Radwaste Storage Facility (Central Storage). The expenses, based on physical parameters, are provided in legislation and are approved by the Government. The legislation prescribes options related to a management of a DSRS, i.e. a source might be returned to its original or other supplier or to a new user performing the same or other type of a practice or it can be stored as a radioactive waste in the Central Storage. It also prescribes a timeline for reporting to the Regulatory Body that a source became disused and the time in which an operator should transfer a source. Any transfer should be reported in prescribed time to the Regulatory Body. The regime is valid for all categories of sources. As a rule, the operator of the Central Storage has provisions to assure safe transport of DSRS. The regulatory regime encourages reuse and recycling of DSRSs as DSRSs are not to be treated as a waste, e.g. DSRS already stored in the Central Storage are routinely sent to Germany for recycling in last years. In Slovenia a six-year campaign was conducted to find all orphan sources from past activities.
- NRC is regulating DSRS in the USA. The decommissioning plan should be put in place. The final solution for a management of a DSRS should be found in two years after they are declared as DSRS.
- The IAEA published in 2018 the Guidance on the Management of Disused Radioactive Sources as a supplement of the Code of Conduct on the Safety and Security of Radioactive Sources. One of the main issues dealt with in the guidance is how, when and who should declare a source to be a disused source. To date, borehole disposal of DSRS has been utilized in two instances, namely, Categories 4 and 5 DSRS have been disposed in Malesia, and all categories of DSRS have been disposed in Gana.
- The Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (Joint Convention), provides an opportunity for discussing and sharing knowledge and experiences among Contracting Parties pertaining

to best practices and experiences in the management of radiation sources, including disused sources.

POLICY ISSUE 2 – REGULATION OF RADIOACTIVE WASTE FROM RADIATION FACILITIES HANDLING UNSEALED SOURCES

Radio-nuclides in unsealed form are being widely used in hospitals for nuclear medicine imaging and radionuclide therapy. 99mTc, 18F, 68Ga, 131I, 177Lu, 90 Y radionuclides are most commonly used in hospitals in India. During their use, contaminated solid waste is produced. Discharges to the environment take place in the form of airborne or liquid effluents. These discharges are currently regulated by the AERB as per the provisions of Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 (GSR-125). In preparation for this policy discussion, India noted the following issues: i) Discharge limit: For liquid discharges, the gross total activity per year, daily discharge limit and monthly average concentration limit for discharge of radioactive effluent from hospitals to the sewerage system are specified. However, for example, in the case of I-131, activity concentration can be achieved with dilution, but to meet the same, large tanks are to be constructed in hospitals where radionuclide therapy using I-131 is carried out; ii) Hospitals using unsealed radionuclides which are volatile in nature are expected to handle the source in fume-hood and some amount of activity is getting released through the rooftop of the building by using the stack. The activity released through gaseous route may remain unaccounted; iii) The existing criteria, as envisaged in the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 (GSR 125) , for discharge of radioactive effluent from hospitals to the sewerage system depends on the total activity and monthly average concentration limit irrespective of the associated radiological impact criteria; iv) Excreta from patients undergoing radionuclide therapy.

The host counterpart requested international experience and views of the IRRS team on the prevailing regulatory practices in other countries on the following: a) Discharge of radioactive effluents /human excreta generated from the nuclear medicine facilities. b) The requirement for interim storage of radioactive effluents to meet the discharge limits. c) Management of airborne releases from radiation facilities d) The dose constraint for radioactive effluents / human excreta to the sewerage system.

AERB initiated the policy discussion with a short presentation, and the experts then shared their regulatory experiences, summarized as follows:

- Canada adopted the ICRP recommendation that the patient undergoing radiotherapy or any other medical application is not to be considered as a radiation source. Canada supported and endorsed the IAEA 2010 position that there is no benefit in storing I-131 excretions from patients for the purpose to delay and decay. Many scientific studies have shown, for example, that the collection of the urine in storage tanks poses an unjustified higher exposure risk to workers than the risk to the public if the storage is not applied. Canadian studies have compared I-131 concentrations in general public sewers away from hospitals against those near hospitals where a large number of I-131 ablation therapy took place. The studies demonstrated that the I-131 concentration did not exceed the public dose limit of 1 mSv per year. Other studies of sludge have been done in multiple cities and demonstrated that I-131 are negligible in comparison to background levels. In conclusion, holding tanks do not have a significant safety benefit in the protection of the public and the environment. Canada noted that India is on the right track to phase out the expansion of the I-131 holding tanks, and recommends that India ask licensees to model the patient pathways to determine the potential doses from the excretion, rather than looking at the emission factor. When assessing an application, the applicant should have to submit to the AERB its plans and

proposed modelling, and based on the specifics of the plan, the regulator should determine whether the plans will meet the discharge limit to ensure the protection of the public and the environment. Canada noted that the CNSC's website has links to Licence Application Guides that could be a resource for the host counterpart.

- In Slovenia, justification is the key consideration in this area. In radiation protection, every action should be justified. If it is demonstrably safe to discharge, then it is not justified to use holding tanks. Slovenia has had two systems – with tanks and without – but always accompanied by verification of safety. In line with the Canadian comments, it is recommended that India follow the ICRP and model, design, and then demonstrate that safety is being maintained. Regarding solid waste Slovenia introduced a system of controls such that solid waste contaminated with radiopharmaceuticals might easily trigger alarms monitors in scrap yards.
- In addition to the discussions, the USA highlighted its focus on providing instructions to the patient in terms of how to act to limit and prevent exposure to the patient and others.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

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

6.1.2 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

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

6.1.3 BASES FOR REVIEW AND ASSESSMENT

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

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

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

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The requirements for design extension condition handling have been recently elaborated for LWRs, however the corresponding requirements for other reactor types are not yet in place.*	
(1)	**BASIS: SSR2/1 Requirement 20 states that** *"A set of design extension conditions shall be derived on the basis of engineering judgment, deterministic assessments and probabilistic assessments for the purpose of further improving the safety of the nuclear power plant by enhancing the plant's capabilities to withstand, without unacceptable radiological consequences, accidents that are either more severe than design basis accidents or that involve additional failures. These design extension conditions shall be used to identify the additional accident scenarios to be addressed in the design and to plan practicable provisions for the prevention of such accidents or mitigation of their consequences if they do occur."*
S11	**Suggestion:** The AERB should consider addressing the design extension conditions (DEC) without core melt (multiple failure situations and rare external events) and DEC with core melt (severe accident) in other regulatory documents in addition to the newly published safety codes.

Changes since the initial IRRS mission

Suggestion 11: AERB stipulated the regulatory requirements and provided guidance related to beyond design basis accidents including severe accidents through its regulatory documents. AERB had also constituted a committee to bring the clarity on severe accidents to be considered in the design, dose criteria, definitions of Design Basis Accident (DBA), Beyond Design Basis Accident (BDBA), exclusion zone, sterilised zone and Emergency Planning Zone (EPZ). Five safety guides have been revised since the 2015 IRRS mission addressing DEC requirements. In addition, a schedule of planned revisions to other safety codes and guides has been developed. While not all

guides have been updated, they are in various stages of revision. The revisions will be completed progressively no later than the next two years.

Status of the initial mission findings

Suggestion 11 (S11) is closed on the basis of progress made and confidence in the effective completion as evidenced by the revision to add DEC to AERB/NPP-PHWR/SC/D and in the development of AERB/NPP-SFR/SC/D.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Legal Framework and Review & Assessment Process

Atomic Energy (Radiation Protection) Rules provides the legal framework for radiation protection and the safety of radiation sources, including provisions for review and assessment of facilities and activities. Constitution Order (S. O. 4772) addresses review and assessment as one of the functions of AERB. Review and assessment are also required in Safety Code AERB/SC/G on Regulation of Nuclear and Radiation Facilities.

Initial review and assessment are conducted when reviewing and assessing evidences provided by an applicant for a consent. On-site visits can be conducted as part of the review and assessment process as appropriate according to a graded approach.

AERB conducts review and assessment over the lifetime of facilities and the duration of the activities. Except for registration, review and assessment are conducted in a systematic manner, including when a new application is provided to renew a consent. For registration, the assessment is carried out on the basis of pre-defined business logics. When significant safety-related modifications of a practice are planned, review and assessment are conducted in order to issue or decline a consent for such modification. Each operator is required to submit Periodic Radiation Safety Status Report to AERB quarterly or annually as identified in consents. This Periodic Report contains self-assessment conducted by an operator. The updated data contained by the reports should be in addition loaded in e-LORA, such as new calibration dates or the updated list of workers as well as review of safety systems including measurement. The content and form of the reports are prescribed. In time period between two consents, regular or reactive inspections are conducted as foreseen in Annual Inspection Plan.

Organization and Technical Resources for Review and Assessment

About 70 members of AERB's staff located at four locations of AERB are involved in the review and assessment. The IRRS team was informed that the competence of the AERB staff conducting review and assessment is ensured through a recruitment process and a training programme. AERB stated that, due to the stringent recruitment process, staff members are specialised for specific review and assessment. AERB pays specific attention to competence for review and assessment of new practices.

Whenever additional resources are required to conduct review and assessment, AERB staff from other organizational units can be involved in consideration of the needed skills and competencies. In addition to the qualified staff, AERB benefits from advice from safety review committees for the purpose of authorization, namely Safety Review Committee for Applications of Radiation (SARCAR), Safety Review Committee for Radiation Processing Plants (SRCRPP), Accelerator and Laser Safety Committee (ALSC) and Safety Committee for Hadron Therapy Facilities (SCHTF). The advice of the committees is not binding for AERB final decision.

Performance of Review and Assessment

The documentation submitted by an applicant or an authorized party is reviewed to ensure its completeness. If any aspect of the documentation submitted is missing or insufficient, AERB sends a formal letter to address the issue. Authorization is only granted after all changes required by AERB have been made. When non compliances are identified from a Periodic Safety Status Report, the authorized party is required to take appropriate corrective actions. Inspections are conducted when appropriate. All communication between AERB, and applicants and authorized parties is documented in e-LORA. That includes the results of review and assessment.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IRRS team noted that the AERB guidance documents, while allowing provisions for conducting unannounced inspections, did not contain specific guidance for implementing unannounced inspections.*	
(1)	**BASIS: GSR-1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
(2)	**BASIS: GS-G-1.3 para. 4.1. states that** *"To ensure that all nuclear Facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with the new concerns that arises."*
R10	**Recommendation:** The AERB should add specific guidance to their inspection planning documents to perform unannounced inspections with defined purpose and periodicity at all NPPs.

Changes since the initial IRRS mission

Recommendation 10: AERB issued document AERB/IMS/L-III/DRI/05, "Guidelines for Conducting Unannounced Regulatory Inspections of Nuclear Facilities." This document provides guidance to Directorate of Regulatory Inspection officials and the Inspection Team Members for conducting unannounced regulatory inspections of nuclear and industrial facilities.

AERB conducts unannounced inspections to observe and evaluate the activities performed by the licensee under real circumstances and to know the actual state of the facility and the way in which it is being operated or maintained. Unannounced inspections are conducted as a part of the routine inspection program. They are also performed as a reactive inspection in response to a specific significant event at the facility.

Status of the initial mission findings

Recommendation 10 (R10) is closed as AERB has issued and implemented specific guidance for conducting unannounced regulatory inspections of nuclear facilities.

7.1.2. INSPECTION PROCESSES AND PRACTICES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *The IRRS team noted that there are no inspection guides for performing the required decommissioning inspections.*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GS-G-1.3 para. 4.1. states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail."*
S12	**Suggestion:** The AERB should consider developing inspection guides for implementing inspections during the decommissioning of a NPP.

Changes since the initial IRRS mission

Suggestion 12: AERB issued Directorate of Regulatory Inspection reference document "Checklists for carrying out the Regulatory Inspection of Nuclear Facilities" in April 2021. This document provides guidance for inspection during the decommissioning phase of nuclear power plants and research reactors. The checklist covers the areas related to Organization and Management of the utility, availability of approved documents, Quality Assurance, Radiological Safety, Radioactive Waste Management, Environment Monitoring, Emergency Preparedness, Industrial Safety Aspects, Training, Documentation and Records. This checklist will aid the inspector to carry out inspection in the decommissioning phase of the NPPs in future.

Status of the initial mission findings

Suggestion 12 (S12) is closed as AERB has developed inspection guidance for implementing inspections during decommissioning of an NPP.

7.1.3. INSPECTORS

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

7.2. INSPECTION OF NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IRRS team recognized that the level of inspection effort at an NPP consists of two week-long inspections per year, performed by an inspection team consisting of 6 to 8 members. The AERB places a large burden of their inspection activities upon the information received from the NPP because continuous supervision of NPPs is ensured by the AERB by carrying out review of performance reports, reports on radiological safety aspects, event reports, etc. The IRRS team also identified, through interviews with inspectors, that the AERB does not require nor do they routinely inspect the reactor shutdown and start-up that occurs during a shutdown for maintenance activities.*	
(1)	**BASIS: GSR Part 1 Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(3)	**BASIS: GSR Part 1 para. 4.50. states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(4)	**BASIS: GS-G-1.3 para. 2.3.(d) states that** *"Sufficient numbers of personnel, who have the necessary competences for the efficient and safe performance of their duties, are available at all times and throughout all stages of the facility's lifetime."*
S13	**Suggestion:** The AERB should consider increasing the frequency of routine on-site inspections at NPPs commensurate with the size of India's nuclear programme. The increased frequency of inspections would allow for additional independent verification and more effective regulatory oversight of NPPs.

Changes since the initial IRRS mission

Suggestion 13: After 2015, the AERB undertook an effort to assess the regulatory inspection process of AERB vis-a-vis the overall regulatory oversight of the nuclear power plants. The review included considerations of multiple options of increasing the on-site surveillance, including increasing the number of inspections by headquarter staff, the inspections by staff of regional centres and the deployment of on-site observers (Site Observation Teams (SOTs)).

AERB carried out a detailed review of the overall process of regulatory inspections of all facilities under its regulatory purview. In order to prioritize this exercise and have an assessment independent from the licensing and safety review processes, a dedicated division, the Directorate of Regulatory Inspection (DRI), was created to integrate and improve effectiveness of inspection activities of AERB and to recommend measures to achieve synergy and convergence of purposes and resources for the Reactor Inspection programme of AERB.

AERB has enhanced the regulatory presence at sites by increasing the frequency of regulatory inspections. AERB has also started deploying the onsite SOTs to have continuous on-site regulatory presence. Presently, onsite SOTs have been deployed at four sites where NPPs under construction/commissioning are co-located with operating NPPs. Onsite SOTs independently provide first-hand information to AERB Headquarters daily. In other operating NPPs the frequency of regulatory inspections has also increased.

The frequency of regulatory inspections of operating NPPs may vary from five to eight per year in NPPs where onsite SOTs are not posted and three to four times a year where onsite SOTs are posted. Special planned inspections have been included in the annual inspection programme to oversee specific activities such as biennial shutdown jobs, containment building integrated leak rate tests, and other activities. As of 2022, the baseline inspection frequency and total inspection days at a NPP Site have been increased from 10 days per year to approximately 30 days per year with visits occurring almost every 3 months.

Status of the initial mission findings

Suggestion 13 (S13) is closed as AERB performs additional inspections at NPPs with increased frequency.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Generic Issues

The legal basis for inspections of facilities and activities are:

- Atomic Energy Act from 1962;
- Atomic Energy (Safe Disposal of Radioactive Waste) from 1987; and
- Atomic Energy (Radiation Protection) Rules from 2004.

The Central Government has empowered AERB by Constitution Order (S.O. 4772) as the competent authority to conduct inspections of facilities and activities using radiation sources. AERB conducts planned inspections and reactive inspections. Either type of inspections can be announced or unannounced. AERB is also empowered:

- to order corrective actions and verify their proper implementation;
- to suspend or revoke authorizations;
- to temporary or permanent close of facilities;
- to take any relevant enforcement actions.

Safety Code No. AERB/SC/G Regulation of Nuclear and Radiation Facilities and related AERB/SG/G-4 Safety Guide on Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities describe objective, procedure, scope and implementation of inspection programme. In 2014, AERB issued the manual AERB/RF/SM/G-3 Regulatory Inspection and Enforcement in Radiation Facilities to be used by inspectors with a typical checklist for regulatory inspection for specific practices.

In 2017, AERB established the Directorate of Regulatory Inspection (DRI) to coordinate the AERB inspection programme. DRI has about 30 authorized inspectors dedicated to inspections. Around ten of them are working in regional centres. Besides inspectors within DRI, authorized inspectors are employed within other organizational units of AERB. However, these inspectors have also other regulatory duties. Altogether around 80 AERB staff are authorized as regulatory inspector. Authorization is given by the Chairman, AERB for a period of five years. The IRRS team was informed that the AERB has initiated the recruitment of additional inspectors, in particular to work at three regional offices. When necessary, external expert can join an inspection team. The IRRS team was informed that the Chairman, AERB has powers to authorise as regulatory inspectors, experts who are not AERB staff.

Regulatory inspectors have different academic background. However, they are mainly medical physicists and health physicists. Recently, AERB has established a programme to ensure the appropriateness of the inspector competence taking into account academic qualification, training, experience, web based on-line assessment and interview conducted by the AERB assessment committee. The authorization process for inspectors is prescribed by the internal procedure AERB/IMS/L-III/DRI/5 (Revision No. 1, 2019). The web-based on-line assessment has two levels: M1. basic competence; and M2. specific competence. The authorization of an inspector specifies the empowerment of the inspector, e.g., either he/she has the authority or to take on-spot actions. Recently, AERB has decided to grade inspection competences regarding facilities and activities in

two levels C1 and C2. The "C2 Inspectors" are allowed to conduct inspection of specific areas independently.

AERB develops inspection programmes using the procedure AERB/RF/SM/G-3 Regulatory Inspection and Enforcement in Radiation Facilities. Majority of inspections are announced through e-LORA. The frequencies of inspections are recommended in Annexure-7 Frequency of Planned Regulatory Inspections for Radiation Facilities. AERB strives to establish and implement the inspection programme according to a graded approach. Frequency of regular inspection is from one to three years for high and medium risk practices. For other practices, only inspections based on sample basis are conducted. However, among them, some practices are authorized as highest risk practices. This issue is addressed in SF1.

AERB prepares an Annual Inspection Programme while detailed inspection programme is developed on quarterly basis. In the last years, around 600 planned inspections and 150 reactive inspections are conducted every year. During a COVID-19 pandemic, AERB developed specific questionnaires to be answered by operators and conducted also remote inspections. AERB initiated for the first time, an inspection campaign on the use of X-ray for diagnostic practices. For such type of inspections, the inspectors have a specific empowerment to be able to take on-the spot enforcement actions if they identify important violations with prescribed requirements.

The inspections are generally conducted by a team of two inspectors, one of them is the lead inspector who is authorized to take enforcement actions.

A typical check list mentioned above includes inspection of technical and administrative measures as well as measurements to be conducted by an inspector. As regulation is not fully in line with IAEA GSR Part 3, IRRS team noted that some components of safety requirements are not given in check list and therefore not inspected. This issue is addressed in SF3.

Each inspection is concluded by an exit meeting when the inspectors inform the operator about identified non-compliances. The inspection report is prepared at the AERB offices. It is drafted by the team leader, reviewed and approved by the director of DRI. The report is sent to the operator using e-LORA. Required corrective actions are documented in the inspection report. The implementation of non-compliances is tracked in e-LORA. Regulation provides appeal on corrective actions required by AERB. The inspected operators are obliged to provide evidence about the implementation of corrective actions in due time using e-LORA. When needed, a follow up inspection can be conducted. In case other enforcement actions are needed AERB has the authority to use other enforcement actions when necessary.

Site Visits

The IRRS team observed an inspection conducted by a team of AERB inspectors at an operating gamma irradiation facility in Mumbai, operated by the Board of Radiation & Isotope Technology (BRIT). The inspection was conducted in a professional and comprehensive way. During an entrance meeting, the inspectors addressed first the non-compliances identified in e-LORA. The on-site visit included a testing of selected safety systems and walkdown. Identified non-compliances were immediately orally reported to the BRIT counterparts. At the exit meeting, inspectors informed the operator about the inspectors' findings to be documented in the inspection report together with required corrective actions. The IRRS team noted that during the inspection a typical check-list has been used by the inspectors which does not completely reflect details of the safety systems specific to the facility to be inspected and position of safety systems in controlled and supervised area.

In relation to the competence management of operators of facilities, the operator pointed out the need for refresher training of operators which was, at time of the mission, not covered by the regulation.

During the discussions with the operator, the operator stated to the IRRS team that AERB should be congratulated for efficiency of E-LORA. The operator emphasised that a use of this platform improves the transparency of AERB regulatory decisions.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The IRRS team noted that the AERB does not have any formal arrangements with relevant Government agencies where enforcement action requires the involvement of the police, justice ministry, or other authorities.*	
(1)	**BASIS: GS-G-1.3 para. 5.16. states that** *"procedures should stipulate which other governmental organizations, if any, should be informed in the event of enforcement notifications."*
S14	**Suggestion:** The AERB should consider establishing formal arrangements with other Government agencies and procedures for implementing the formal arrangements in the event enforcement actions require the involvement of those agencies.

Changes since the initial IRRS mission

Suggestion 14: The AERB has developed procedure AERB/IMS/L-III/DRA&C/08, "Procedure for National Co-ordination with Relevant Agencies," that provides guidance for coordinating with other government agencies regarding certain enforcement actions. The Directorate of Regulatory Affairs & Communication (DRA&C) is the nodal directorate in AERB responsible for dealing with national coordination matters. This procedure provides the relevant guidance for AERB coordination with other government agencies. This procedure was approved and issued in December 2021.

The AERB has developed procedure AERB/IMS/L-IIA/DRA&C/01, "Implementation of ISM Processes in DRA&C", that provides guidance for the DRA&C to be followed to fulfil their assigned responsibilities. This includes DRA&C's authority of the national coordination process. DRA&C carries out review of regulatory activities of the AERB and identifies the agencies/institutes/professional organizations for liaison. This procedure provides the necessary guidance for AERB to enter the national cooperation/coordination agreements.

The AERB has established procedures for implementing formal agreements in the event enforcement actions require the involvement of those agencies.

Status of the initial mission findings

Suggestion 14 (S14) is closed as AERB has issued and implemented guidance for national coordination with other Government agencies in the event enforcement actions require the involvement of those agencies.

8.2. ENFORCEMENT IMPLEMENTATION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS
Observation: *The AERB does not have the guidance to implement the legislation that empowers the AERB to impose penalties.*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GSR Part 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: GS-G-1.3 para 5.13. states that** *"The regulatory body should have the authority to impose or recommend penalties, such as fines on the operator as a corporate body or on individuals, or to institute prosecution through the legal process, depending upon the legal systems and authorization practices in the State concerned. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature or for deliberate and wilful non compliance."*
S15	**Suggestion:** The AERB should consider developing and implementing enforcement procedures that describe the process to impose penalties.

Changes since the initial IRRS mission

Suggestion 15: The AERB has developed two procedures to provide the necessary guidance to impose penalties. The first of these procedures is AERB/IMS/L-III/OPSD/17, "Procedure on Enforcement Action for Operating Nuclear Power Plants (NPPs), Research Reactors (RRs) & Other Fuel Cycle Facilities." This procedure provides the guidance for taking enforcement actions against a licensee by the AERB. This procedure is also intended to describe key considerations that are required to ensure the enforcement actions to be taken meets the policies, management expectations, and criteria outlined in the enforcement policy.

The second procedure developed to provide guidance is AERB/IMS/L-IIC/L&SC/01, "Procedure for Initiation of Penal Actions." This procedure provides guidance to AERB for the necessary actions required for initiation of penal action. Using this procedure and following the Code of Criminal Procedure, 1973, the AERB will file a complaint with the police. Further course of action is by police authorities and adjudication of matter by judicial authorities to impose any necessary Penal Action as per the countries legal system. This document was still under final review at the time of the IRRS mission and had not yet been approved and issued.

Status of the initial mission findings

Suggestion 15 (S15) is closed on the basis of progress made and confidence in the effective completion as the "Procedure for Initiation of Penal Actions" has been drafted, reviewed by the AERB Legal Cell, and has been reviewed by the Executive subcommittee. The remaining steps include review in Executive Committee, concurrence by the Chairman, AERB and issuance by the Executive Director.

8.3. ENFORCEMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Enforcement Policy and Process

Enforcement is based on:

- Atomic Energy Act from 1962 and
- Atomic Energy (Safe Disposal of Radioactive Waste) from 1987 and
- Atomic Energy (Radiation Protection) Rules from 2004.

Central Government empowers AERB by Constitution Order (S.O. 4772) as a competent authority designated to take enforcement actions. Atomic Energy Act addresses offences and penalties. Enforcement is further elaborated in Safety Code No. AERB/SC/G Regulation of Nuclear and Radiation Facilities where methods of enforcement are stated, i.e. as stated there the enforcement actions may include one or more of the following:

a) a written directive for satisfactory rectification of the deficiency or deviation detected during inspection;
b) written directive to consentee for improvement within a reasonable time frame;
c) orders to curtail or stop activity;
d) modification, suspension or revocation of operating consents; and
e) penalties.

This Safety Code also addresses appeal against regulatory decisions. Namely, appeal against AERB decision should be sent to the Atomic Energy Commission whose decision shall be final. This arrangement could unduly influence the independence of the regulatory decisions.

As instructed in this safety code, detailed guidelines and procedures for enforcement action are prepared by AERB. AERB published Safety Guide on Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities where further details on mentioned enforcement actions are elaborated, e.g., initiation of a penal action. Criteria to be used when applying enforcement actions are also given there. The Safety Guide also addresses the power of an inspector to act on the spot.

AERB developed a manual AERB/RF/SM/G-3 Regulatory Inspection and Enforcement in Radiation Facilities to document the AERB enforcement policy elements. Inspector findings are categorised using four categories. Factors to be taken into account in deciding which enforcement action is appropriate in each case are elaborated in detail. The IRRS team noted that the manual does not address appeal.

Enforcement Implementation

The IRRS team was informed that enforcement actions are routinely exercised except initialisation of a penal action. In general, corrective actions stated in the inspection report are put in place and no further enforcement is necessary. Enforcement actions other than written directives require a show cause notice. The response of the affected operator and a show cause notice are analysed by SARCAR which recommends appropriate enforcement actions. The enforcement actions are documented in E-LORA system to be used also for other regulatory processes. When appropriate hearing is organized. The final decision stays with the AERB Chairman.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

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

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

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

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Preparation of regulations and guides is based on Atomic Energy Act 1962 which empowers Chairman, AERB to issue safety codes and standards. Issuing safety codes, guides and standards by AERB is addressed in AERB Constitution Order (S.O. 4772). The IRRS team noted Acts and Regulations are issued by the Central Government.

AERB Safety Guide AERB/SG/G-6 (Rev. 1) Development of Regulatory Safety Documents for Nuclear ad Radiation Facilities from 2013 addressed the development of safety documents. It defines the classification of documents in decreasing order of hierarchy:

a) safety codes;

b) safety standards;

c) safety guidelines

d) safety guides;

e) safety manuals; and

f) technical documents.

Safety codes are issued by Board of AERB while safety standards are issued by the Chairman, AERB. Safety codes and standards are mandatory. AERB has published six safety codes and six standards related to facilities and activities using radiation sources. Safety codes and standards address either a specific practice, e.g., industrial radiography, or a general safety area, e.g., regulation of nuclear and radiation facility. AERB also issues Safety Directives which are mandatory.

The Chairman, AERB approves safety guides, safety manuals and technical documents. These documents are supplementing implementation of requirements given in act, rules, directives, codes and standards but are not mandatory. Safety Guidelines tackle particular subjects. They are addressing subjects for which no specific code was issued, such as safety of accelerators, nucleonic gauges and well logging applications, gamma irradiation chamber and criteria for planning, preparedness and response for nuclear and radiological emergency. Altogether four safety guidelines were published and 11 safety guides. Safety manuals are supplementary documents to help in fulfilling the requirements of the safety code and implementing the recommendations of safety guides. Two safety manuals were prepared, i.e., on inspection and enforcement and on medical management for persons exposed in radiation accident. Technical documents contain scientific or technical information on certain topics of safety significance and/or regulatory concern.

IRRS Team was informed that the AERB has a process of issuing mandatory as well as non-mandatory documents which was developed through several years. IAEA team noted that several documents were issued before 2014 when IAEA GSR Part 3 was published. Hence the system of

regulations and guides are not fully in line with IAEA safety standards. Thus, dose constraints as a tool for optimisation are not fully implemented, annual dose limit for the lens of the eye for occupational exposed worker is 150 mSv in a year and concepts of existing and emergency exposure situation are not fully incorporated. The IRRS team noted that inconsistency between AERB documents, Atomic Energy (Radiation Protection) Rules from 2004 giving categorisation of facilities and activities and categorisation in AERB Safety Code AERB/SC/G on Regulation of Nuclear and Radiation Facilities.

IRRS team was informed that major revision of a system of documents is planned in near future in order to incorporate IAEA GSR Part 3 requirements in the regulatory system. In addition, IAEA safety standards guides, i.e., SSGs, published by the IAEA are considered to be systematically introduced in the AERB system of codes, standards, guides and other documents (under preparation). The gap analysis has been prepared and demonstrated. The IRRS team was informed that AERB decided that regulatory safety documents would generally be in line with the hierarchy of the IAEA safety standards for ensuring better harmonization with international standards and establishing a documentation system oriented to operator needs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current AERB system of safety codes, safety standards, safety guidelines/guides, safety manuals and technical documents do not contain complete and consistent requirements given in IAEA GSR Part 3. The current regulatory system does not follow appropriate hierarchy of regulatory requirements and guides which may affect the effectiveness of regulatory regime.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSG-13 para. 3.20 states that** *"The overall purpose of guides is to advise authorized parties on how to comply with laws and regulations, and on how to implement the regulatory requirements, thus improving effectiveness and efficiency and enhancing safety."*
SF3	**Suggestion: The AERB should consider continuing reviewing and, when appropriate, revising regulations and guides to ensure consistency with the IAEA safety standards. When doing so, the AERB should appropriately consider the hierarchy of the regulatory documents, including those setting the regulatory requirements.**

AERB Safety Guide AERB/SG/G-6 (Rev. 1) Development of Regulatory Safety Documents for Nuclear and Radiation Facilities includes details related to the development of any regulation or guide prepared by AERB. Resources & Documentation Division is responsible for managing the development of documents. This Safety Guide describes is comprehensive and comprises all the steps of the development process, i.e., from the preparation of Safety Document Development Proposal up to the publication of the document on the AERB site. Drafts are uploaded in AERB website for seeking comments from interested parties, including public. AERB promotes the documents, e.g., through leaflets.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL EPR REGULATORY REQUIREMENTS

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

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The emergency classification system promulgated by the AERB is not fully consistent with the IAEA safety standards and could potentially delay the initiation of urgent protective actions under some emergency conditions. Regulatory requirements for notification procedures and declaration of offsite emergency by the offsite authorities are also not fully consistent with IAEA safety standards. Regulatory requirements do not specify a time frame for completion of the declaration and notification of emergency class to off-site officials.*	
(1)	**BASIS: GS-R-2 para. 4.19. states that** *"The operator of a facility…shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency, and determination of the appropriate level of response."*
(2)	**BASIS: GS-R-2 para. 4.19. states that** *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements [that] include a system for classifying all potential nuclear and radiological emergencies [...] such as below: general emergencies [...]. Upon declaration of this class of emergency, actions shall be promptly taken to mitigate the consequences and to protect people on the site and within the precautionary action zone and urgent protective action planning zone; site area emergency [...]."*
R11	**Recommendation:** The AERB should review and revise the regulatory requirement on declaration of an offsite emergency to ensure that it is consistent with IAEA safety requirements.
S16	**Suggestion:** The AERB should consider setting response time objectives for declaration and notification of emergencies.
Observation: *SG/EP-5 has been promulgated and it is being implemented in the emergency plans, though at present it is not reflected in the NPP plan examined.*	
(1)	**BASIS: GS-R-2 para. 3.8. states that** *"The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention."*
S17	**Suggestion:** The AERB is encouraged to continue the implementation of the recently published regulatory requirements, for example those contained in SG/EP-5.
Observation: *There is no regulatory requirement for MOU with external services that may be called upon to assist the facility during an emergency, even though it is reportedly be implemented by some NPP. The need for a clear assignment of operational control and authority, and for a clear statement on who is responsible for external services safety when they are at the facility is not addressed in the regulations.*	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	**BASIS: GS-R-2 para. 4.40. states that** *"For facilities in threat category I, II or III arrangements shall be made to provide technical assistance to the operational staff. Teams for mitigating the consequences of an emergency (damage control, fire fighting) shall be available and shall be prepared to perform actions in the facility. [...] Arrangements shall be made to obtain support promptly from police, medical and fire fighting services off the site. Off-site support personnel shall be afforded prompt access to the facility and shall be informed of on-site conditions and the necessary protective actions."*
S18	**Suggestion:** The AERB should consider establishing a regulatory requirement for emergency plans to include clear statements on operation control and on responsibility for personal protection of external services when they are at the facility, and for this to be reflected in documented agreements with external services.

Changes since the initial IRRS mission

Recommendation 11: Since the initial mission, AERB has made a substantial effort in restructuring its regulatory framework regarding declaration of an emergency with a focus on being in-line with IAEA safety standards. Existing regulation has been updated and incorporated into new safety code (Nuclear and Radiological Emergencies - NRE) and guides (e.g. NRE-1 on nuclear facilities). The change has been carried out not only by drafting new or updated regulation but also through extensive stakeholder participation where a new system for classification and notification has been introduced. This process has also changed the way actual emergency exercises are carried out and exercises are now challenging the licensee on identification and classification of emergencies. This topic is also captured by which exercises are observed and findings are noted. As a result, the regulation is in place while the code and guides are being developed.

The IRRS team noted the existence of a new clear approach where the licensee is responsible for the classification and declaration of emergencies. The declaration is made on-site by the Site Emergency Director (SED) and communicated to off-site authorities that are carrying out protective action decisions. The IRRS team was informed that this update of the regulatory codes and guides is still on-going, whereas change itself has been introduced via the stakeholder meetings and conduct of off-site emergency exercises. A template for Off-Site Emergency Preparedness & Response Plan has been issued and thoroughly communicated with the licensees. In this template the update on responsibility for declaration is incorporated and it is now part of the emergency exercise procedure that has been tested and verified. The Safety Code on Management of Nuclear and Radiological Emergencies (NRE) has been drafted in 2018 (rev.1) and current version (rev. 5) is to be sent for public comments and waiting for final approval after that. The Regulatory Guide on managing emergencies in nuclear facilities (NRE-1) has been updated to revision 1 version and it is in process to be reviewed for comments by various review groups. The text itself has been fully revised and it has incorporated several existing safety guides into one single guide. While the regulatory code and guides will be finalized later, the regulatory changes have been developed, implemented, and tested.

Suggestion 16: The IRRS team noted that the new version of safety guide for managing nuclear and radiological emergencies has been established to include the expected time targets. The IRRS team noted that the new version of safety guide for managing nuclear and radiological emergencies (NRE-1) includes requirements for prompt declaration and notification of emergencies. The IRRS

team reviewed the draft of NRE-1 as well as the results of an exercise and the IRRS team noted the expectation on the licensee to follow time targets and if there are discrepancies, AERB will address those with the licensee.

Suggestion 17: Since the initial mission, AERB has continued to work on AERB/NRF/SG/EP-5. AERB has implemented the regulatory requirement for all operating NPP's. AERB has incorporated AERB/NRF/SG/EP-5 into the recently developed guide NRE-1. The IRRS team reviewed NRE-1 and determined that it will also incorporate safety guides on site emergency (EP-1) and off-site emergency plans (EP-2), safety guide on operating organization for emergencies (O-6), and safety guide on criteria for planning, preparedness and response (EP-5). AERB has informed the licensees of the new requirements and NRE-1 was effectively used during a recent NPP exercise. While the regulatory infrastructure has been updated, AERB is encouraged to continue their process to review and approve the off-site EPR plans.

Suggestion 18: The regulatory requirements (Clause 5.3.3 & 5.3.4 of SC/NRE) and guidance related to protection of external services has been incorporated in revised AERB documents. The revised regulatory requirement requires licensee to assess the extent and conditions for which assistance from off-site emergency services may need to be provided. The licensee has been assigned the responsibility to inform the external services personnel about on-site conditions and equip them with instructions and means for protecting themselves as emergency workers. The requirements for MoU with external assistance agencies and the necessary arrangements have been included in the draft AERB Guide (Section 5.7 of AERB/SG/NRE-1). More detailed requirements for operative control, personal protection and training for external services staff are also stated in safety guide NRE-1.

Status of the initial mission findings

Recommendation 11 (R11) is closed on the basis of progress made and confidence in the effective completion as the regulatory requirement on declaration of an offsite emergency has been established and the new Code on emergencies (NRE) is close to being published to be followed with its associated safety guide (NRE-1).

Suggestion 16 (S16) is closed on the basis of progress made and confidence in the effective completion as there is clear regulation and practical guidance to the licensee for declaring emergencies in accordance with time expectations.

Suggestion 17 (S17) is closed as SG/EP-5 has been implemented. In addition to EP-5, several safety guides are incorporated into an overarching document NRE-1 which addresses all aspects of emergency response.

Suggestion 18 (S18) is closed on the basis of progress made and confidence in the effective completion as the licensee has been assigned the responsibility to make necessary contracts with external services for their assistance.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *AERB/NPP/SC/O and AERB/SG/O-6 provide inconsistent requirements on responsibility for directing site response actions following the declaration of an Offsite Emergency. The role of the Site Emergency Director and of his alternate during an offsite emergency is not clear.*	
(1)	**BASIS: GS-R-2 para. 5.7. states that** *"The positions responsible within each operating and response organization for the performance of the response functions identified in Section 4 shall be assigned in the emergency plan."*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
R12	**Recommendation:** The AERB should revise applicable safety codes and safety guides to clarify the designation and responsibilities of the Site Emergency Director, Advisor to the Offsite Emergency Director, and the Offsite Emergency Director for managing the onsite and offsite response organizations.
Observation: *The habitability of the site emergency control centre is not suitable for protracted severe emergencies. However, the IRRS team was informed that post Fukushima Daiichi NPP accident, the AERB has taken action to establish technical requirements for construction of onsite emergency support centre (OESC) at all NPP site. (See Fukushima module).*	
(1)	**BASIS: GS-R-2 para. 5.27. states that** *"For facilities in threat category I, an on-site emergency control centre, separated from the [facility] control room, shall be provided to serve as [a] meeting place for the emergency staff who will operate from there in the event of an emergency. Information about important [facility] parameters and radiological conditions in the [facility] and its immediate surroundings should be available there. The room should provide means of communication with the control room, the supplementary control room and other important points in the [facility], and with the on-site and off-site emergency response organizations. Appropriate measures shall be taken to protect the occupants for a protracted time against hazards resulting from a severe accident."*
S19	**Suggestion:** The AERB should consider ensuring that the NPPs continue the implementation of seismically and environmentally qualified site emergency support centres at all sites and that this be implemented as a regulatory requirement.
Observation: *Emergency exercises are evaluated by AERB observers. A formal report is issued by the AERB, containing recommendations for improvement. However, the IRRS team noted that there is no regulatory requirement for the facility operator to satisfactorily test all emergency functional objectives over a certain period.*	
(1)	**BASIS: GS-R-2 para. 5.33. states that** *"The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body."*
(2)	**BASIS: GS-R-2 para. 5.36. states that** *"The performance of exercises at facilities in threat categories I, II or III shall be evaluated against established response objectives that demonstrate that identification, notification, activation and other initial response actions can be performed in time to achieve the practical goals of emergency response."*
S20	**Suggestion:** The AERB should consider establishing regulatory requirements for licensees to test all emergency functional objectives over a determined period of time.
Observation: *The IRRS team noted that there is not a comprehensive list of procedures necessary to support the consistent implementations of key response functions in EPR plans for all NPPs.*	
(1)	**BASIS: GS-R-2 para. 5.21. states that** *"The operating and response organizations shall develop the necessary procedures, analytical tools and computer programs in order to be able to perform the functions specified to meet the requirements for emergency response established in Section 4."*

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
S21	**Suggestion:** The AERB should consider identifying a comprehensive list of procedures for NPPs to develop in support of implementation of the emergency response plans.

Changes since the initial IRRS mission

Recommendation 12: AERB has reviewed the organizational framework for emergency management at the site level. As per the latest organizational framework, the entire responsibility for on-site actions has been entrusted to the licensee (Clause 6.1.3 of AERB/SC/NRE). The licensee has to designate Site Emergency Director (SED) as the authority for directing on-site response actions at all times. Thus, SED will remain at the site and provide recommendation to Responsible Officer (RO) on public protective actions during the early phase of emergency, without any need for relocation from the Site Emergency Control Centre (SECC) located at the NPP Site. Guidance provided through AERB/SG/O-6 on this subject is being included as part of AERB/NF/SG/NRE-1. The safety code for operation for NPPs (AERB/NPP/SC/O), will also be revised for consistency. There is still ongoing regulatory process to publish updated regulatory requirements, including NRE-1.

Suggestion 19: The regulatory requirement for NPP Sites to have an On Site Emergency Support Centre (OESC) which shall remain functional even under very low probable events (including extreme external events) has been incorporated in revised AERB requirements (Clause 6.5.4 of AERB/SC/NRE). The design of the OESC has been reviewed and approved by AERB. The construction of OESC at NPP Sites is in progress. The design requirements are also brought out in AERB Design Safety Code (AERB/NPP-LWR/SC/-D) and in the current draft of AERB/NPP/PHWR/SC/-D. Also, safety code of NRE and safety guide NRE-1 has more detailed habitability requirement. At this time there is construction ongoing and most of the OESCs are scheduled to be completed 2022-2023. Some sites have their design requirements still under review and once approved, actual construction can begin on those sites as well. A detailed plan and schedule outlines the expectations and intended completion dates.

Suggestion 20: AERB has now stipulated the requirement for conduct of emergency exercises to test the effectiveness of functional objectives of decision making, command and control, coordination, resources and field actions to achieve goals of emergency response (Clause 6.6.4 of AERB/NRF/SC/NRE). Various types of exercises to achieve functional objectives have been identified including the periodicity of these exercises. The overall framework for conduct of off-site emergency exercise including their frequencies have been revised following a consultation process involving all stakeholders. The frequency of the exercises is included in approved templates of the plant and site EPR plan. There is now regulatory requirement to establish periodicity for exercising different response functions. These are communicated with stakeholders and introduced into AERB guidance document. AERB has already released template documents on this topic and taken to a stakeholder consultation process so that currently the implementation is underway. The operator NPCIL has released guidance document for emergency exercises so that they cover all the necessary response functions with periodical cycle.

Suggestion 21: The regulatory requirements for developing necessary procedure and analytical tools have been clearly specified in revised AERB requirements (Clause 6.4.1 and 6.4.4 of AERB/NRF/SC/NRE). In line with the same, comprehensive list of procedures necessary for emergency response has been identified. The list of relevant procedures is identified in AERB Safety Guide (AERB/SG/NRE-1) and the Template for off-site EPR Plan. AERB has issued a

template for Off-Site Emergency Preparedness & Response Plan which includes now a list of procedures for emergencies. This can be seen as practical implementation of the same regulatory requirement that is now in draft Safety Guide NRE-1.

It was also noted that since the first version of National Disaster Management Plan was issued 2016 (updated 2019), AERB has had a role to issue rules, norms and codes for emergency management that are applicable to all organizations involved in disaster management. AERB has the role to review the response arrangements according to national plan.

Status of the initial mission findings

Recommendation 12 (R12) is closed on the basis of progress made and confidence in the effective completion as there is clear regulation and practical guidance to the licensee regarding the roles and responsibilities for the emergency directors to effectively manage the emergency response.

Suggestion 19 (S19) is closed as AERB has established the requirements for OESCs according to seismic and environmental requirements and schedule for the completion of the projects exist.

Suggestion 20 (S20) is closed as the new regulation is established and implemented/tested during emergency response exercises.

Suggestion 21 (S21) is closed as the updated regulation has been established and updated in the applicable safety guide.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
Observation: *The lack of an adequate internal emergency plan and framework, and the absence of reliable mechanisms to get prompt and accurate information on the situation at the affected plant poses a challenge to AERB ability to perform its emergency response functions effectively.*	
(1)	**BASIS: GS-R-2 para. 3.5. states that** *"[…] In the event of a nuclear or radiological emergency, the regulatory body shall act as an adviser to the government and [response organizations]in respect of nuclear safety and radiation protection."*
R13	**Recommendation:** The AERB should develop and implement its own internal emergency arrangements including detailed procedures, for fulfilling its emergency response role.

Changes since the initial IRRS mission

Recommendation 13: The Directorate of Radiation Protection and Environment (DRP&E) is responsible for planning and implementation of emergency response efforts. EPR is one of the core regulatory processes of AERB; it is described in Level 1 IMS document. There are also level 2 documents for AERB emergency response organization and Level 3 document for each of the four cells of AERB response organization. In order to effectively carry out their role during an emergency, an Emergency Response Monitoring Organization (ERMO) has been established. The ERMO functions are supported by Nuclear and Radiological Emergency Monitoring Centre (NREMC). Plan and procedures exist for the functioning of NREMC and ERMO. These have been tested by activation of NREMC during the recent OSEE conducted at NPP sites and as part of a mock-exercise.

AERB is participating in NPP exercises and developing lessons learned and issuing internal exercise reports with observations. These observations are then assigned to relevant part of the organization for improvements. There has been orientation training for staff in January 2020 and at least three orientation training for management before exercise in 2022. There is training program for new staff that includes emergency management training. There is also refreshment training in every 5 years.

The IRRS Team recognized that under IAEA's conventions for emergencies, Department of Atomic Energy, Crisis Management Group (DAE-CMG) has been assigned with functions of National Warning Point (NWP) and Competent Authority. In the new AERB safety code (NRE) there are roles and responsibilities assigned and DAE-CMG is responsible for coordinating the actions and providing technical support to other authorities.

The IRRS Team noted that AERB has the ability to evaluate NPP accident progression and actions taken. AERB carries out independent review of situation that includes monitoring of an emergency situation. AERB monitoring includes observation, collection of data, analyses and assessment of the emergency situation and response actions by the licensee. These tasks require prompt flow of information from the licensee. Any advice to the licensee on the mitigatory and response actions, is made under the principle that it does not undermine the prime responsibility of the licensee's role to manage the emergency. To ensure adequate protection of people and environment during an emergency, AERB provides independent assessment of the emergency situation to the government. AERB can also inform public of its assessment on the emergency.

Status of the initial mission findings

Recommendation 13 (R13) is closed as the AERB has defined its roles and responsibilities through the development of internal documents and response capabilities according to new IMS structure.

IRRS FOLLOW-UP MISSION TEAM

APPENDIX I - LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
JAMMAL Ramzi	Canadian Nuclear Safety Commission (CNSC)	ramzi.jammal@cnsc-ccsn.gc.ca
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JANŽEKOVIČ Helena	Slovenian Nuclear Safety Administration (SNSA)	helena.janzekovic@gov.si
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PACHECO JIMENEZ Ronald	Division of Radiation, Transport and Waste Safety	r.pacheco@iaea.org
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LIAISON OFFICERS		
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APPENDIX II - MISSION PROGRAMME

FIRST WEEK

<table>
<tr><th>Time</th><th>WED 8</th><th>THU 9</th><th>FRI 10</th><th>SAT 11</th><th>SUN 12</th></tr>
<tr><td>9:00-11:00</td><td rowspan="4">Arrival of Team Leader, IAEA Deputy Coordinator and IRRS Reviewer responsible for the Extended Topic: Radiation Sources Facilities and Activities</td><td>Entrance Meeting
for the Extended Topic</td><td rowspan="2">Site visit</td><td rowspan="2">Writing of the report</td><td rowspan="6">Day Off

/

Arrival of the rest of the IRRS Team</td></tr>
<tr><td>11:00-12:30</td><td>Interviews</td></tr>
<tr><td>12:30-13:30</td><td colspan="3">Lunch</td></tr>
<tr><td>13:30-16:00</td><td rowspan="2">Interviews</td><td rowspan="2">Interviews</td><td rowspan="3">Writing of the report</td></tr>
<tr><td>16:00-17:00</td><td rowspan="2">IRRS Reviewers' Briefing
on the Extended Topic</td></tr>
<tr><td>17:00-18:00</td><td colspan="2">Daily Debriefing</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td></tr>
<tr><td>20:00</td><td></td><td colspan="3">Writing of the report</td><td></td></tr>
</table>

SECOND WEEK

Time	MON 13	TUE 14	WED 15	THU 16	FRI 17	SAT 18	SUN 19	MON 20
9:00-10:00	Arrival of the rest of the IRRS Team *** Extended Topic Interviews (cont'd)	Entrance Meeting	Interviews	TM write Report TL and DTL review introductory part	Discussion Counterpart/Expert Finalisation			Exit Meeting Press release Farewell
10:00-11:00						**Written comments by the Host**		
11:00-12:30		Interviews		**Draft text to TL**				
12:30-13:30	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		Farewell Lunch
13:30-14:30	Initial IRRS Team Meeting (See agenda) - Attended by the LO -	Interviews	Interviews	2nd Policy discussion	**Submission of the Draft to the Host**	Finalisation of the Report	Social Event	Departure of IRRS Team Members
13:30-16:00				Secretariat edits the report / Cross-reading	Host reads Draft and prepares written comments / TL finalises the presentation / TC drafts the Press Release			
16:00-17:00		1st Policy discussion / Interviews	Interviews	Preliminary Draft Report Ready	Discussion of Executive Summary	**Presenting the final Draft of the Report to the Host**		
17:00-18:00		Daily Team Meeting	Daily Team Meeting: **Discussion of findings**	Daily Team Meeting	Team discusses the Mission and provides IAEA with feedback			
18:00-20:00	Dinner				Cultural Function	Official Dinner	Dinner	
20:00		Writing of the report	Secretariat edits Report TM write Report	TM Read Draft	Refreshments			

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	LEAD COUNTERPART	SUPPORT STAFF
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Anna Mazur	Shri Souman Sinha, DRA&C	Shri Susheel Kumar, NSAD Dr. Garima Sharma, DAE
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Anna Mazur	Shri Vivek Piplani, OPSD	Shri Gour M. Behera, DRA&C Smt.V. Anuradha, DRA&C Dr. Garima Sharma, DAE
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Maria Oprisescu	Shri S.C Utkarsh, Head, NSAD	Smt. Mahalakshmi, RSD Shri Mayank Verma, NPSD Smt. Purva Awasthi, OPSD
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Jean-René Jubin	Shri A. K. Panda, DRI	Shri Sekhar Bhattacharya, R&DD Smt Manju Saini, RSD Shri P. Bansal, OPSD Smt. Pammy Goswami, OPSD
5.	**AUTHORIZATION**		
	Kevin Williams Helena Janžekovič	Shri D. Bhattacharya, OPSD (NF)	Shri V. R. Dhotre, NPSD Shri Soumyadip Dey, OPSD
		Dr. Pankaj Tandon, RSD (RF)	Dr.G. Sahani, RSD Shri. Amit Sen, RSD Shri. Bibek Mishra, RSD Smt. Smriti Sharma, RSD Shri Subrat Pathak, RSD

	IRRS Experts	LEAD COUNTERPART	SUPPORT STAFF
6.	**REVIEW AND ASSESSMENT**		
	Kevin Williams Helena Janžekovič	Shri D. V. Pimpale, NPSD (NF)	Shri Dhanesh Nagrale, NSAD Shri Anjit Kumar, NPSD Shri Nishant Sangam, OPSD
		Smt. Mahalakshmi, RSD (RF)	Shri Alok Pandey, RSD Smt. Arti Tripathi, RSD Shri G.K.Panda, RSD Shri. S. Kar, RSD Shri. Pramod Dixit, RSD
7.	**INSPECTION**		
	Bob Orlikowski Helena Janžekovič	Shri Rajnish Kumar, NPSD (NF)	Shri Avinash Srivastava, DRI Shri Sunil Pagar, OPSD Shri B.K. Singh, DRAC
		Shri R. K. Singh, RSD (RF)	Shri D. M. Rane, RSD Dr. Pradeep Kumar, DRI Shri. Manoranjan Dash, RSD
8.	**ENFORCEMENT**		
	Bob Orlikowski	Shri Rajnish Kumar, NPSD (NF)	Shri Avinash Srivastava, DRI Shri Sunil Pagar, OPSD Shri B.K. Singh, DRAC
		Shri R. K. Singh, RSD (RF)	Shri D. M. Rane, RSD Dr. Pradeep Kumar, DRI Shri. Manoranjan Dash, RSD

	IRRS Experts	LEAD COUNTERPART	SUPPORT STAFF
9.	**REGULATIONS AND GUIDES**		
	Helena Janžekovič	Dr. R. B. Solanki, ERSD	Smt. Sonal Gandhi, RDD Shri Rajoo Kumar, RDD Shri. Neeraj Dixit, RSD
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Jukka Kupila	Dr. S. K. Dubey, DRP&E	Shri Shyam Vyas, DRP&E Dr. S. P. Lakshmanan, DRP&E Shri Ritu Raj, DRP&E Shri Jolly Joseph, RSD

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

Section	Module	R/S	Recommendation/Suggestion
1.3	1	R2	The Government should embed in law, the AERB as an independent regulatory body separated from other entities having responsibilities or interests that could unduly influence its decision making.
3.1	3	S4	The AERB should consider evaluating its resource allocation across the organization to ensure sufficient full-time specialists are available and dedicated to those areas which are not currently covered.
3.8	3	R7	The AERB should establish a communications strategy to effectively engage with the media, and communicate and consult with the general public and the population in the vicinity of NPPs. This includes consultation with the general public on draft safety codes and standards.

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2022 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
5.3	5	SF1	The AERB should consider completing the revision of the frequency of planned inspections and the duration of validity of regulatory consent in order to be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.
5.3	5	RF1	The AERB should require, in a systematic manner, safety assessments to be part of the application for a consent.
5.3	5	RF2	The AERB should require the applicant to submit an independent verification of the safety assessment of facilities and activities, when appropriate in accordance with a graded approach.
5.3	5	RF3	The AERB should require a comprehensive radiation protection programme for all facilities and activities.

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
5.3	**5**	**GPF1**	**The integration of regulatory processes within e-LORA, an online platform used by all applicants, authorized parties and AERB, was noted as a good practice. E-LORA significantly improves the efficient management and process of information to be submitted by an applicant or authorized party in accordance with a graded approach. The logic hold-points set up in e-LORA contributes to efficiency and effectiveness of the regulatory processes and objectivity of its decisions. The system provides unique capabilities to assess electronic safety performance indicator (e-SPI) in order to measure the safety compliance of authorized party.**
5.3	**5**	**SF2**	**The Government should consider developing a national policy and strategy to define responsibilities in regaining control over orphan sources. This policy and strategy should include the instruments for ensuring financial provisions by which the AERB will require the applicant to get a regulatory consent to ensure safe management of disused sources.**
9.3	**9**	**SF3**	**The AERB should consider continuing reviewing and, when appropriate, revising regulations and guides to ensure consistency with the IAEA safety standards. When doing so, the AERB should appropriately consider the hierarchy of the regulatory documents, including those setting the regulatory requirements.**

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY AERB

A) Module 1

Nil

B) Module 2

AERB Management Document

1. AERB/IMS/L-III/OPSD/20 (Rev.1)

Additional Documents:

2. AERB Annual Reports (2015 to 2020)
3. CNS Reports 2014, 2017&2020
4. Actions posted on WBIRS for IRS report nos. 8039, 8241, 8326, 8335, 8769, 8777 & 8823

C) Module 3

Acts, Rules and Policies

1. AERB Constitution Order No. SO-4772
2. The Environmental Protection Act, 1986

AERB Management Documents

3. Integrated Management System of AERB (IMS Level-I)
4. Integrated Management System Level-IIB on Guidance for Application of Graded Approach in Regulation of Facilities and Activities
5. Integrated Management System Level-III Procedure on Assessment of Safety Performance of Operating NPPs
6. IMS Level-III Human Resource (HR) plan & its management procedure for AERB (AERB/IMS/L-III/RDD/08), May 2022
7. Integrated Management System (Level-IIB) document on 'Procedure for Formation, Functioning and Self-Assessment of Safety Committees of AERB' (AERB/IMS/L-IIB/R&DD/3), July 2017
8. Integrated Management System (Level-IIA) document on 'Strategy & Plan for implementation of Regulatory Processes in DRA&C' (AERB/IMS/L-IIA/DRA&C/01, Rev.1), draft dated December 2021

D) Module 4

AERB Safety Codes

1. AERB Safety Code on Regulation of Nuclear & Radiation Facilities (AERB/SC/G)
2. AERB Safety Code on Nuclear Power Plant Operation (AERB/NPP/SC/O (Rev.1))

AERB Management Documents

3. Integrated Management System of AERB (IMS Level-I)

E) Module 5

Acts, Rules and Policies

1. Atomic Energy (Radiation Protection) Rules, 2004

AERB Safety Codes

1. Draft AERB Safety Code No. AERB/NPP-PHWR/SC/D (Rev 2) on Design Of Heavy Water Reactor Based Nuclear Power Plants
2. Draft AERB Safety Code No. AERB/NPP-SFR/SC/D (Revised R1) on Design Of Sodium Cooled Fast Reactor Based Nuclear Power Plant

AERB Safety Code no. AERB-SC-G**AERB Safety Guides**

3. AERB Safety Guide on Design Basis Events for Water Cooled Nuclear Power Plants (AERB/NPP-WCR/SG/D-5 (Rev.1))
4. AERB Safety Guide on Design of Electrical Power Systems for Nuclear Power Plants (AERB/NPP/SG/D-11 (Rev.1))
5. AERB Safety Guide on Accident Management Programme for Water Cooled Reactor Based Nuclear Power Plants (AERB/NPP-WCR/SG/D-26)
6. AERB Safety Guide No. AERB/SG/G-7, November 2001 on Regulatory Consents For Nuclear And Radiation Facilities: Contents And Formats
7. AERB Safety Guide No. AERB/NPP-WCR/SG/D-5 (Rev.1) on Design Basis Events For Water Cooled Nuclear Power Plants
8. AERB Safety Guide no. AERB-RF-SG-G3

AERB Management Documents

9. OPSD IMS Level III procedure on Formats of regulatory consents issued by OPSD to operating nuclear power plants (No. AERB/ IMS/L-III/OPSD/44)
10. NPSD IMS Level III procedure on Licensing of Nuclear Projects (No. AERB/ IMS/L-III/NPSD/04

F) Module 6

Acts, Rules and Policies

1. Atomic Energy Act, 1962
2. AERB Constitution Order - Presidential (gazette) notification issued by the Central Government (SO 4772)
3. Atomic Energy (Radiation Protection) Rules, 2004
4. Atomic Energy (Radiation Protection) Rules, 2004
5. Atomic Energy (Safe Disposal Radioactive Wastes) Rules 1987

1. **AERB Safety Codes** AERB Safety Code on Site Evaluation of Nuclear Facilities (AERB/NF/SC/S (Rev.1))
2. AERB Safety Code on Design of Light Water Reactor Based Nuclear Power Plants (AERB/NPP-LWR/SC/D)
3. AERB Safety Code no. AERB-SC-G
4. AERB Safety Code No. AERB-RF-MED-SC-3 (Rev. 2)
5. AERB Safety Code No. AERB-RF-MED-SC-1 (Rev. 1)
6. AERB Safety Code No. AERB-RF-IR-SC-1 (Rev.1)
7. AERB Safety Code No. AERB-RF-RPF-SC-1 (Rev.1)
8. AERB Safety Code No. AERB-RF-MED-SC-2 (Rev. 2)

AERB Safety Standards

9. AERB Safety Standard No. AERB -SS-3 (Rev.1)
10. AERB Safety Standard No. AERB-RF-IR-SS-1 (Rev.1)
11. AERB Safety Standard No. AERB-RF-IRRAD-SS-6

AERB Safety Guides

12. AERB Safety Guide on Design Basis Events for Water Cooled Nuclear Power Plants (AERB/NPP-WCR/SG/D-5 (Rev.1))
13. AERB Safety Guide on Design of Electrical Power Systems for Nuclear Power Plants (AERB/NPP/SG/D-11 (Rev.1))
14. AERB Safety Guide on Deterministic Safety Analysis for PHWRs (AERB/NPP-PHWR/SG/D-19)
15. AERB Safety Guide on Accident Management Programme for Water Cooled Reactor Based Nuclear Power Plants (AERB/NPP-WCR/SG/D-26)
16. AERB Safety Guide on Standard Format and Contents of Safety Analysis Report for Nuclear Power Plants (AERB/NPP/SG/G-9).
17. AERB Safety Guidelines No. AERB-RF-IGD-SG-1
18. AERB Safety Guide No. AERB-RF-RS-SG-2
19. AERB Safety Guide No. AERB-RF-RS-SG-3
20. AERB Safety Guide no. AERB-RF-SG-G3
21. AERB Safety Guide no. AERB-SG-G-4

AERB Management Documents

22. Integrated Management System of Atomic Energy Regulatory Board (AERB IMS Level-I) via AERB/IMS/L-1/01 dated Feb 2021 R-01
23. AERB/IMS/L-III/RSD/14 : Procedure for Implementation of Graded Approach in Core Regulatory Processes of RSD

Additional Documents:

24. AERB, Report of the Committee for Severe Accident Management 'Proposed AERB Design Requirements for Addressing Beyond Design Basis Accidents in Nuclear Power Plants' (2009)

G) Module 7

AERB Safety Guides

1. AERB Safety Guide on Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities (AERB/SG/G-4)

AERB Management Documents

2. Integrated Management System of AERB (IMS Level-I)

H) Module 8

Acts, Rules and Policies

1. The Atomic Energy Act, 1962
2. Atomic Energy (Radiation Protection) Rules, 2004

3. Atomic Energy (Safe Disposal Radioactive Wastes) Rules 1987

AERB Safety Codes

4. AERB Safety Code no. AERB-SC-G

AERB Management Documents

5. Integrated Management System of AERB (IMS Level-I)
6. Procedure for Authorisation of AERB officials as Inspectors for Nuclear and Radiation Facilities, AERB/IMS/L-III/DRl/05 (Revision No. 1)
7. Procedure for Enforcement against Radiation Facilities, AERB/IMS/L-111/RSD/ 12

I) Module 9

AERB Safety Guides

1. AERB safety guide no. AERB-NRF-SG-G-6 (Rev.1).

J) Module 10

AERB Safety Codes

1. R5-Draft AERB Safety Code on "Management of Nuclear and Radiological Emergencies" (AERB/NRF/SC/NRE)
2. Draft AERB Safety Code on "Design of PHWRs" (AERB/SC/PHWR-D, Rev.2), 2019.
3. AERB Safety Code on "Design of LWRs" (AERB/NPP-LWR/SC-D), 2015.

AERB Safety Guides

4. R1-Draft AERB Safety Guide on management of Nuclear and Radiological Emergencies in Nuclear Facilities" (AERB/SG/NRE-1)

AERB Management Documents

5. Integrated Management System of Atomic Energy Regulatory Board (AERB IMS Level-I) via AERB/IMS/L-1/01 dated Feb 2021 R-01
6. IMS Level IIA "Implementation of Integrated Management System (IMS) Processes in Directorate of Radiation Protection & Environment (DRP&E) via AERB/IMS/L-llA/DRP&E/01 (Level-II) dated June 22, 2018.
7. IMS Level II "Plan for Monitoring of Nuclear and Radiological Emergency Response" AERB/IMS/L-IIA/DRP&E/02 (Level II).
8. IMS Level III "Procedure for Functioning of Communication Cell (CC), NREMC" AERB/IMS/L-III/DRP&E/03 (Level III).
9. IMS Level III "Procedure for Functioning of analysis Cell (AC), NREMC" AERB/IMS/L-III/DRP&E/04 (Level III).
10. IMS Level III "Procedure for Functioning of Emergency Assessment Cell, NREMC" AERB/IMS/L-III/DRP&E/05 (Level III).
11. Procedure for functioning of media and public information cell (M&PIC), nuclear and radiological emergency monitoring centre (NREMC), AERB/IMS/L-III/DRP&E/06 (Level III).

Additional Documents:

12. DRP&E Constitution order issued via CH/AERB/00/12/2017/79, dated, October 24, 2017
13. Approved Template for Off-Site Emergency Preparedness & Response Plan of NPP, letter no AERB/OPSD/61011/2019/504 dated May 01, 2019.
14. Approved Templates for plant and Site Emergency Preparedness & Response Plan of NPP
15. Guidance document on conduct of Off-site Emergency Exercise letter no AERB/OPSD/61011/2019/504 dated May 01, 2019.Technical Document on Precautionary and Urgent Protective Actions in Response to Early Phase of a Nuclear Emergency submitted to Chairman AERB via BARC/EMAD/ AVK/20 19/236791 dated December 12, 2019.
16. AERB Guidelines document on Development of Initiating Conditions and Emergency Action Levels for Classification of Emergency in PHWRs via No. AERB/EG-EAL/2019 dated February 05, 2019.A comprehensive note to all stakeholders on revision of requirement for emergency preparedness and response, September 2020.
17. Stakeholder meeting on revised template for off-site EPR plan and modified off-site emergency exercise methodology, November 30, 2018.
18. Stakeholder consultation meeting on revised off-site emergency exercise framework, July 2021.

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GSR PART 3** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
4. **IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
6. **IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
7. **IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
8. **IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
9. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.1-** Organization and Staffing of the Regulatory Body for Nuclear Facilities
10. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
11. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
13. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
14. **IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** - Application of the Management System for Facilities and Activities
15. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
16. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
17. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
18. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211** - A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

APPENDIX VIII - AERB ORGANIZATIONAL CHART