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Experiences of Member States in Building a Regulatory Framework for the Oversight of New Nuclear Power Plants: Country Case Studies

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EXPERIENCES OF MEMBER STATES IN BUILDING A REGULATORY FRAMEWORK FOR THE OVERSIGHT OF NEW NUCLEAR POWER PLANTS: COUNTRY CASE STUDIES

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EXPERIENCES OF MEMBER STATES IN BUILDING A REGULATORY FRAMEWORK FOR THE OVERSIGHT OF NEW NUCLEAR POWER PLANTS: COUNTRY CASE STUDIES

INTERNATIONAL ATOMIC ENERGY AGENCY
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For further information on this publication, please contact:

Nuclear Infrastructure Development Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
Email: Official.Mail@iaea.org

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FOREWORD

An effective regulatory framework is essential to the success of a national nuclear power programme. It establishes necessary requirements, authorizes activities and verifies compliance with safety, security and safeguards requirements. The regulatory framework needs to be developed and implemented in a phased approach to support the nuclear power programme. In this regard, the sharing of practical experiences of Member States that have advanced through the process of embarking on a nuclear power programme is expected to benefit those Member States that are considering, or are in the planning phases of, such a programme.

This publication presents the experiences of selected Member States in developing their regulatory framework for a new or expanding nuclear power programme, including the roles and responsibilities of the regulatory body and its organization and staffing; planning and issuing of regulations and guides; establishment of a system of licensing; and implementation of a siting, construction and commissioning oversight programme to respond to the needs of the nuclear power programme. The publication does not evaluate the information provided against IAEA safety standards, security recommendations and relevant guidance, as this is the purpose of the peer review and advisory services offered by the IAEA.

The target users for this publication are decision makers, advisers and senior managers in the governmental organizations, utilities, industrial organizations and regulatory bodies in countries adopting nuclear power programmes, as well as countries providing technology and support for these programmes.

This publication is the product of experts from several national regulatory bodies in advanced newcomer countries and a country with an expanding nuclear power programme. The IAEA is grateful to all those who assisted in the drafting and review of this publication. The IAEA officers responsible for this publication were M. Ceyhan of the Division of Nuclear Power and T. Kobetz of the Division of Nuclear Installation Safety.

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The decision to establish a nuclear power programme is a significant undertaking by any country. Such a decision should be based on a commitment by the government to use nuclear power safely, securely and peacefully. This commitment requires establishing a sustainable national infrastructure that provides governmental, legal, regulatory, managerial, technological, human resource, industrial and stakeholder support for the nuclear power programme throughout its life cycle. The IAEA has developed the Milestones Approach to help Member States embarking on nuclear power to understand and develop the necessary infrastructure requirements in a phased way. The Milestones Approach is documented in the IAEA guidance publication Milestones in the Development of a National Infrastructure for Nuclear Power [1]. The IAEA has also published Evaluation of the Status of National Infrastructure Development [2] to provide guidance to evaluate the status of the development of national infrastructure for nuclear power.

Experience has shown that the establishment of an independent, adequately resourced and competent regulatory body often lags the implementation of the overall infrastructure for the programme. Recurrent weaknesses observed in International Regulatory Review Service (IRRS), International Physical Protection Assessment Service (IPPAS) and Integrated Nuclear Infrastructure Review (INIR) missions include a lack of competent staff, insufficient financial resources, insufficient independence, lack of an appropriate regulatory framework and inability to hire external experts. In addition, the development and implementation of regulations and guides, a licensing process and an inspection programme on a timescale consistent with the nuclear power plant implementation schedule are also observed as challenges.

In this regard, the IAEA has solicited input from Member States that are either building their first nuclear power plants or are expanding the use of nuclear power in their country to better understand the challenges they faced and the approaches they took in implementing a regulatory framework to oversee the nuclear power programme.

Inputs were sought from several newcomer countries at different stages of implementation of their nuclear power programmes. In addition, the experience of countries already operating nuclear power plants was sought.

Inputs were received from Bangladesh, Belarus, Pakistan, Turkey and the United Arab Emirates. Four of the countries, namely Belarus, Bangladesh, Turkey and the United Arab Emirates are ‘nuclear newcomer’ countries which are in different stages of implementation of a new nuclear power programme. In contrast, Pakistan is an example of a country with a history of nuclear power operation which is seeking to expand its programme.

1.2. OBJECTIVES

The primary objective of this publication is to present the experiences of several Member States that are in the process of building or expanding their regulatory framework for a nuclear power programme. The publication also provides insights on IAEA safety requirements and guidance on establishing an effective regulatory framework with reference to IAEA Safety Standards, Security Series, and Safeguards guidance publications. In addition, it demonstrates how those requirements fit into the overall development of a nuclear power programme through the IAEA milestones approach.

1.3. SCOPE

This publication focuses on the development of the regulatory framework in selected Member States that have committed to building their first nuclear power plant and that plan to expand the use of nuclear power in their long-term energy strategy. The publication presents case studies but does not evaluate the information provided against IAEA Safety Standards, Security Series and Safeguards guidance publications, as this is the purpose of the peer review and advisory services offered by the IAEA.

1.4. STRUCTURE

Section 2 provides an overview of the IAEA milestones approach for phased development of a nuclear power programme, and the IAEA Safety Standards, Security Series, and Safeguards guidance publications that are relevant to establishing and implementing the regulatory framework for oversight of a new nuclear power plant.

Section 3 provides a discussion of the experience of the contributing Member States which have recently embarked on a new nuclear power programme or are expanding an existing programme in establishing their regulatory frameworks. The discussion is organized by topic related to regulatory infrastructure development. The Section 3 also provides the summary of the outcome of the Technical Meeting held in June 2019 to gather additional information from Member States.

The case study reports for each contributing Member State are presented in the Appendices.

1.5. CASE STUDY METHODOLOGY

The methodology for gathering data was developed during a consultancy meeting held in Vienna in May 2018. The areas requiring regulatory control by the regulatory body were first identified based on the relevant IAEA standards and guides. A template for individual case studies was developed, giving a set of headings to guide experts to provide consistent information for all countries included in the case study. Contact persons were then identified for each country and the contacts were requested to provide information about their countries' nuclear power programmes according to the template.

A further consultancy meeting was held in January 2019 to continue the work, review progress made with drafting case studies, and to adjust the template and draft report.

A Technical Meeting in June 2019 gathered 41 experts from 20 countries and the IAEA to collect additional information on other Member States' experiences.

A final consultancy meeting held in November 2019 finalized the draft report by incorporating the feedback from the Technical Meeting.

2. PHASED APPROACH TO ESTABLISH REGULATORY FRAMEWORK FOR A NUCLEAR POWER PROGRAMME

2.1. REGULATORY CHALLENGES IN A NEW NUCLEAR POWER PROGRAMME

Careful planning, preparation and investment in the necessary infrastructure including human resources are needed for the successful establishment and implementation of a regulatory framework to provide for effective oversight of the nuclear power.

The roles and responsibilities of the government and regulatory body evolve through the successive phases of a new nuclear power programme. It starts with planning and strategy formulation, establishment of the organisation, recruitment and staffing, development of the management system; then moves to preparation of regulations and guides (using a graded approach), assessment, licensing and inspection of siting, construction and commissioning, and approval of the proposed arrangements for operation; and culminates in regulatory oversight of commissioning and operation of the nuclear power plant.

The dynamic nature of the work requires the leaders of the regulatory body to ensure that it is capable of delivering the regulatory functions and responsibilities needed for the current phase of the programme while simultaneously preparing for oversight of future phases.

Nuclear safety, security and safeguards should be considered in a coordinated manner during each phase of the development of a nuclear power programme. These areas may be covered by one or more regulatory bodies depending on the legal and regulatory structure of the Member State. Member States should ensure effective cooperation and coordination between those bodies responsible for these key areas, both nationally and internationally.

The demonstration of compliance with international legal instruments, internationally accepted safety standards, nuclear security guidance and safeguards obligations and guidance is essential in establishing a nuclear power programme responsibly.

2.2. ESTABLISHING SAFETY INFRASTRUCTURE

The IAEA safety standards provide requirements and implementing guidance that could be adopted by Member States to ensure that they establish a competent and effectively independent regulatory body in a timely manner to support the overall nuclear power programme. Figure 1 describes the hierarchy of the IAEA safety standards.

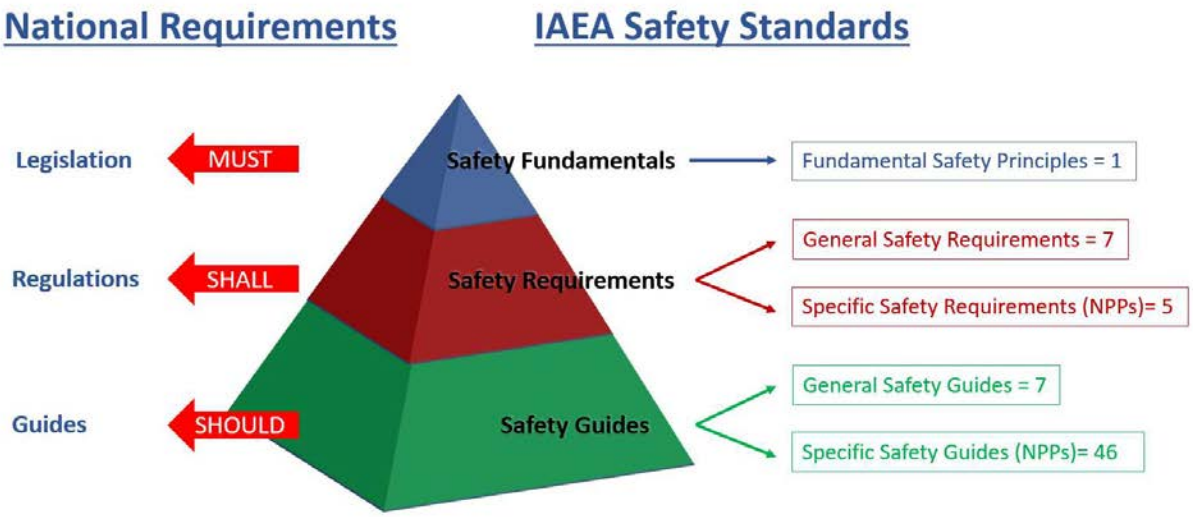


FIG. 1. Hierarchy of IAEA safety standards and their relation to national requirements.

IAEA Safety Standards Series No. SSG-16 (Rev. 1), Establishing the Safety Infrastructure for a Nuclear Power Programme [3], proposes safety related actions in 20 Elements (see Table 1) to be taken in a phased approach during the development of the nuclear power programme, to implement the IAEA safety standards and achieve the foundation for a high level of safety throughout the entire lifetime of the nuclear power plant, including safety in the associated management of radioactive waste and spent fuel, and safety in decommissioning. This safety guide includes actions for the government, regulatory body and operator to implement a safety infrastructure for a new nuclear power programme required to comply with the requirements and guidance from several IAEA safety standards including:

— IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [4], Principle 2: Role of government, mandates that "An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained."
— IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [5], Chapter 2, Responsibilities and Functions of the Government, Requirements 3 and 4, provide the requirements for the government to establish a regulatory body. Chapter 4, Responsibilities and Functions of the Regulatory Body presents 21 Requirements that shall be implemented by the regulatory body to implement its regulatory framework.
— IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [6], provides additional Requirements that regulatory bodies shall implement to ensure that the regulatory body has the appropriate leadership, managements system and safety culture to effectively regulate nuclear facilities and radiological activities.
— IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [7], provides recommendations on meeting the requirements of GSR Part 1 (Rev. 1) [5] in respect of the organizational structure, management and staffing of the regulatory body to support regulatory bodies in carrying

out their responsibilities and functions efficiently and effectively and in an independent manner.

— IAEA Safety Standards Series No. GSG-13, Functions and Processes for the Regulatory Body for Safety [8], provides recommendations on how to implement its core regulatory functions to meet the IAEA safety standards.

The IAEA's IRRS was established to advise Member States on ways to strengthen and enhance the effectiveness of national regulatory frameworks for nuclear, radiation, radioactive waste and transport safety while recognizing the ultimate responsibility of each State to ensure safety in these areas. The IRRS process sets out to accomplish this purpose by enabling structured peer review of national regulatory technical and policy approaches against IAEA safety standards and the sharing of relevant good practices. IAEA Services Series No. 37 [9], *Integrated Regulatory Review Service Guidelines,* provides a systematic approach for a Member State to prepare for, and host, an IRRS mission.

TABLE 1. NUCLEAR SAFETY INFRASTRUCTURE ELEMENTS

Nuclear Safety Infrastructure Elements (SSG-16 (Rev. 1)) [3]	
1. National policy and strategy for safety	**2.** Radiation protection
3. Global nuclear safety regime	**4.** Safety assessment
5. Legal framework	**6.** Safety of radioactive waste management, spent fuel management and decommissioning
7. Regulatory framework	**8.** Emergency preparedness and response
9. Transparency and openness	**10.** Operating organization
11. Funding and financing	**12.** Site survey and site evaluation
13. External support organizations and contractors	**14.** Design safety
15. Leadership and management for safety	**16.** Preparation for commissioning
17. Human resources development	**18.** Transport safety
19. Research for safety and regulatory purposes	**20.** Interfaces with nuclear security

2.3. ESTABLISHING SECURITY INFRASTRUCTURE

The IAEA published Nuclear Security Series NSS-19, Establishing the Nuclear Security Infrastructure for a Nuclear Power Programme [10]. This implementing guide is designed to assist countries in understanding and addressing the key actions to establish an effective national nuclear security infrastructure for a nuclear power programme.

NSS-19 [10] is structured to cover all aspects of the nuclear security infrastructure for a State, including actions related to nuclear material, other radioactive materials and their associated facilities and activities, as well as material out of regulatory control.

The guide sets out actions in nineteen subject areas for development of a nuclear security infrastructure from Phases 1 to 3. See Table 2.

The IAEA's IPPAS provides peer advice on implementing international instruments and Agency guidance on the protection of nuclear and other radioactive material, associated facilities and associated activities. An IPPAS mission compares a State's existing practices against relevant international instruments and IAEA nuclear security publications. IAEA Services Series No. 29 [11], *International Physical Protection Advisory Service (IPPAS) Guidelines,* provides a systematic approach for a Member State to prepare for, and host, an IPPAS mission.

TABLE 2. NUCLEAR SECURITY INFRASTRUCTURE SUBJECTS

Nuclear Security Infrastructure Subjects (NSS-19) [10]	
• National policy and strategy	• Measures against unauthorized removal of nuclear material and sabotage of nuclear facilities
• Legal and regulatory framework	• Measures against unauthorized removal of nuclear material and sabotage during transport
• National threat assessment	• Nuclear Security measures for radioactive material and associated facilities and activities
• Design Basis Threat or threat assessment for design of nuclear security measures	• Security of radioactive material in use and storage
• Management systems for nuclear security: general	• Security of radioactive material in transport
• Protection of sensitive information	• Nuclear security measures for nuclear and other radioactive material out of regulatory control: Preventative measures
• Trustworthiness of personnel	• Nuclear security measures for nuclear and other radioactive material out of regulatory control: Detection measures
• Human resources for nuclear security	• Nuclear security measures for nuclear and other radioactive material out of regulatory control: Response measures
• Promotion of nuclear security culture	• International cooperation
• Sustaining the national nuclear security infrastructure	

2.4. ESTABLISHING SAFEGUARDS INFRASTRUCTURE

IAEA safeguards are a central part of international efforts to stem the spread of nuclear weapons. Any country contemplating a nuclear power programme should have a clear commitment to its international nuclear non-proliferation obligations and should be fully aware of its obligations under safeguards agreements with the IAEA. It should understand that the introduction of nuclear power will require an increase in the capabilities needed to meet its safeguards obligations, at the State and facility level, due to the substantial increase of nuclear material, specified equipment and non-nuclear material relevant to the nuclear fuel cycle present in the country.

The IAEA has published guidance that is aimed at enhancing understanding regarding safeguards obligations of both the States and the IAEA and improving their cooperation in safeguards implementation. IAEA Services Series No. 21, Guidance for States Implementing Comprehensive Safeguards Agreements and Additional Protocols [12], discusses, *inter alia*, how States can support IAEA safeguards implementation through effective cooperation with the IAEA and by adequately addressing three fundamental areas:

— Establishment of laws, regulations and a system of accounting for and control of nuclear material at the national/regional level, which ensure that the requirements of the safeguards agreement and associated protocols and Subsidiary Arrangements are fully met;

— Provision of timely, correct and complete reports and declarations to the IAEA; and

— Provision of support and timely access to the IAEA to locations and information necessary to achieve safeguards objectives.

In relation to the introduction of nuclear power, SVS-21 [12] refers to the IAEA Milestones approach and underlines its recommendation for early planning, preparation and coordination among various stakeholders to address issues related to safety, security and safeguards and the establishment of a dialog with the IAEA.

IAEA Services Series No. 31, Safeguards Implementation Practices Guide on Establishing and Maintaining State Safeguards Infrastructure [13], shares information about effective safeguards implementation practices for the benefit of all States with the aim of enhancing their capacity and capabilities the area of safeguards implementation. This guide also references the Milestones approach and provides a summary with respect to developing safeguards capabilities, including setting up a State or Regional authority responsible for safeguards implementation in the context of Milestones process.

The IAEA's State Systems of Accounting for and Control of Nuclear Material mission (ISSAS) provides peer review of the national SSAS and advice on any improvements to this system. An ISSAS mission covers all aspects of safeguards implementation including Additional Protocol reporting, export control, nuclear material accounting and reporting, as well as the legal and regulatory framework. IAEA Services Series No. 13 [14], *ISSAS Guidelines,* provides a basic structure and common reference for ISSAS missions and provide information and guidance to a host government receiving an ISSAS mission.

2.5. MILESTONES APPROACH FOR THE OVERALL DEVELOPMENT OF A NUCLEAR POWER PROGRAMME

To assist countries embarking on a new nuclear programme or expanding an existing programme, the IAEA has published Nuclear Energy Series No. NG-G-3.1 (Rev. 1), Milestones in the Development of a National Infrastructure for Nuclear Power (Milestones document) [1].

The Milestones document provides an overall picture of the relationship of all the activities that need to be undertaken to build a nuclear power programme. This includes the development or enhancement of the regulatory framework for the oversight of safety, security and safeguards.

The Milestones document identifies three phases in developing the infrastructure necessary to support a nuclear power programme and the associated milestones at the end of each phase. These phases and associated milestones are:

— **Phase 1:** Considerations before a decision to launch a nuclear power programme is taken;

- *Milestone 1:* Ready to make a knowledgeable commitment to a nuclear power programme

— **Phase 2:** Preparatory work for the contracting and construction of a nuclear power plant after a policy decision has been taken;

- *Milestone 2: Ready to invite bids/negotiate a contract for the first nuclear power plant*

— **Phase 3:** Activities to implement the first nuclear power plant.

- *Milestone 3: Ready to commission and operate the first nuclear power plant.*

The safety, security and safeguards publications discussed in the above subsections are aligned with these milestones and phases.

TABLE 3. INFRASTRUCTURE ISSUES FROM MILESTONES DOCUMENT

Infrastructures Issues (NG-G-3.1 Rev. 1) [1]	
1. National position	11. Stakeholder involvement
2. Nuclear safety	12. Site and supporting facilities
3. Management	13. Environmental protection
4. Funding and financing	14. Emergency planning
5. Legal framework	15. Nuclear security
6. Safeguards	16. Nuclear fuel cycle
7. Regulatory framework	17. Radioactive waste management
8. Radiation protection	18. Industrial involvement
9. Electrical grid	19. Procurement
10. Human resource development	

The Milestones document provides guidance on 19 infrastructure issues that need to be considered and addressed during each phase of development, as shown in Table 3, and identifies the three key organizations involved, namely the government, the owner/operator of the nuclear power plant, and the regulatory body.

The IAEA's INIR is a holistic IAEA peer review conducted by a team of IAEA staff and international experts who have experience in nuclear power programmes and infrastructure development. The major objective of the INIR is to assist Member States in determining the status of their nuclear power infrastructure and identifying areas requiring further development in order to reach the corresponding Milestone. IAEA Services Series No. 34 [15], *Guidelines for Preparing and Conducting an Integrated Nuclear Infrastructure Review (INIR),* provides information on the structure and steps involved in the INIR mission. It explains the overall process and the interactions between the requesting Member State and the IAEA.

3. ANALYSIS OF COUNTRY CASE STUDIES

This section provides an analysis of the experiences of the five Member States in the case study in developing their regulatory infrastructure to support embarking on a new nuclear power programme or expanding an existing programme. The aim of this section is to provide the summary of the practices of selected case study countries. Neither the case study countries' practices, nor the extent of their implementation of safety standards is meant to serve as a model for other embarking countries.

The data provided by the experts for each of the countries is summarized in Appendices I-V of this report. Full country case studies are available in IAEA's Infrastructure Bibliography under Issue 7 Regulatory Framework as working material [16]. Information provided in the Appendices and in the working material is provided 'as-is', without warranty of any kind, either express or implied, including, without limitation, warranties of merchantability, fitness for a particular purpose and non-infringement. The IAEA specifically does not make any warranties or representations as to the accuracy or completeness of any such information.

A series of topics related to regulatory infrastructure are presented for discussion. For each topic, a brief introduction is given of the associated issues, based on the relevant IAEA standards and other authoritative sources, leading to the identification of points of interest, followed by an analysis of trends and notable points in each countries experience based on the information provided in the case study reports.

For more detail, the reader is encouraged to consult the case study reports for each country presented in the Appendices to this report. Additional background for each country is available in the IAEA Country Nuclear Power Profiles (CNNP) [17], national reports to the Convention on Nuclear Safety and Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and peer review and advisory mission reports available through the IAEA's web site.

3.1. THE STATUS OF NUCLEAR POWER PROGRAMME IN CASE STUDY CONTRIES

Bangladesh

In 2010, to meet targets for economic growth and electrification, the government adopted a power sector master plan which included a 10% contribution from nuclear power. In 2011, the governments of Bangladesh and the Russian Federation entered into an intergovernmental agreement on cooperation on the use of atomic energy for peaceful purposes. A contract was subsequently signed for construction of two AES-2006 design VVER-1200 reactors at the Rooppur site located on the River Ganges. The construction licence for Unit 1 was issued in 2017, and the construction licence for Unit 2 in 2018. Unit 1 is planned to be commissioned in 2023. Similar units exist at Novovoronezh-2 Nuclear Power Plant (NPP) in the Russian Federation, which has been in operation since August 2016.

Belarus

In 2011, the Government of the Republic of Belarus and the Russian Federation entered into an agreement for cooperation on construction of an NPP in the Republic of Belarus. The Belarusian NPP will consist of two AES-2006 design VVER units with a total capacity of 2400 MWe located at Ostrovets. The construction is performed on a turnkey basis by Atomstroyexport, and the customer and operating organization is 'Belarusian NPP'.

A license for the full range of construction activities for Unit 1 of the Belarusian NPP was issued in April 2014 and for Unit 2 in December 2014. The first unit is scheduled to be commissioned in 2020. The similar NPP design is utilized in the Leningrad-2 NPP in the Russian Federation, which has been in operation since March 2018.

Pakistan

Pakistan has operated a single NPP at the Karachi Nuclear Power Plant (KANUPP) since 1971. An additional one unit of 325 MWe and three units of 340 MWe Chinese-supplied units (CNP-300) came online at the Chashma site between 2000 and 2017. A further two ACP1000 (Hualong One) units are now under construction at KANUPP. A mature operational and regulatory infrastructure exists in the country.

Turkey

In 2010 the Government of Turkey launched its nuclear power programme by entering into and agreement with the Russian Federation an agreement for 'Cooperation in Relation to the Construction and Operation of a Nuclear Power Plant at the Akkuyu Site in the Republic of Turkey'. The NPP at Akkuyu will consist of four AES2006 VVER-1200 units owned by Akkuyu Nükleer AŞ, a Russian-owned project company. The construction licence for the first unit was issued in April 2018 and for Unit 2 in 2019. The lead unit is planned to be commissioned in 2023. Similar units exist at Novovoronezh-2 NPP in the Russian Federation, which has been in operation since August 2016.

A second NPP project is under consideration for the Sinop site on the coast of the Black Sea.

United Arab Emirates

In April 2008, the United Arab Emirates (UAE) government published its *Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy* which set out the rationale and goals for a proposed nuclear energy programme. Thereafter, in December 2010, the Emirates Nuclear Energy Corporation announced that it had selected a consortium led by the Korea Electric Power Corporation to design, build and assist in operation and maintenance of four 1,400 MWe APR-1400 units. A construction licence was issued in 2012 for the first two units at the Barakah site located on the coast west of Abu Dhabi, followed in 2014 by the construction licence for Units 3 and 4. Unit 1 has been connected to the grid in August 2020 and is expected to enter full commercial operation in late 2020. A similar design is utilized in Shin Kori 3 and 4 in Republic of Korea, which has been in operation since January 2016.

3.2. NUCLEAR POWER PROGRAMME IMPLEMENTATION

3.2.1. The issues

The government should formally approve a specific proposed nuclear power programme, as discussed in the Milestones document, and it should decide on the strategy for developing contract arrangements for the nuclear power plant (e.g. competitive bidding, strategic partnerships, 'build-own-operate' or another alternative).

3.2.2. Points of Interest

How effectively did each case study country establish their national position for the introduction of nuclear power? Following this policy decision, what contract arrangements were struck with the NPP vendors? What was planned with regard to the future regulatory framework?

3.2.3. Discussion

In all case study countries, the national government took a policy decision to proceed with the development of a nuclear power programme to meet goals for electricity supply and economic development. The policy decision was taken after substantial study and planning. In Bangladesh, following feasibility studies conducted in previous decades, the government published a Power Sector Master Plan in 2010 that called for a 10% nuclear contribution to meet forecast demand. In Belarus, a report titled 'The Concept of Energy Security of the Republic of Belarus', which included a plan to commission two nuclear power units, was approved by Presidential decree in 2007. The Belarusian law was followed by the enactment in 2008 of a Law on the Use of Atomic Energy in Belarus and, in 2009, by the Master Plan of Key Organizational Measures for Construction of a Nuclear Power Plant. Turkey considered several proposals for a nuclear power programme during previous decades before its decision to proceed with the Akkuyu project. The government of the United Arab Emirates issued a high-level policy on the Evaluation and Potential Development of a Peaceful Nuclear Energy Programme in 2008 before moving to implementation.

All case study countries sourced their NPP technology from an established vendor country, either China, Republic of Korea or Russian Federation in these examples. In all cases a similar reference plant had been previously licensed and was either under construction or in operation in the vendor country. The arrangements were made to facilitate the regulatory process in the host country through the transfer of knowledge and experience from the vendor country regulatory body including the utilization of safety documentation of the reference plant and, in some cases, their Technical Support Organizations (TSO).

All case study countries arranged for the involvement of and support from the vendor country in construction, commissioning and operation of the new NPP. Most countries established their own state entity to be the operator of the facility. In Turkey, the operator is owned by the NPP vendor country via a 'build-own-operate' arrangement. In no case was the private sector directly involved as the owner/operator, as is the situation in some other countries.

Several case study countries had included plans for the development of the necessary regulatory framework when they took the policy decision to embark on a nuclear power programme. For example, the UAE national policy set out commitments for a comprehensive legal framework covering all aspects of nuclear law, including safety, security, non-proliferation and nuclear liability, and for the establishment of an independent nuclear regulatory body with appropriate powers. In Belarus, an INIR review in 2012 found that adequate planning had been done for a regulatory body although at that time gaps remained in the capacity of the regulatory body to deliver its functions. In Turkey, while Türkiye Atom Enerjisi Kurumu (TAEK) – the Turkish Atomic Energy Authority was performing the functions of the regulatory body, the government had made plans to establish a new independent regulatory body through the enactment of a new comprehensive nuclear law.

Various arrangements were made by each country with their vendor for the transfer of knowledge, training, and development for the regulatory body, including technical support and training of regulatory personnel.

3.3. INTERNATIONAL COMMITMENTS

3.3.1. The issues

Embarking countries may already have adhered to many of the relevant international legal instruments for nuclear safety, security, and safeguards. During Phase 2, the embarking country should take the necessary steps to adhere to the remaining relevant international legal instruments for nuclear safety, security, and safeguards. National legislation should have been developed implementing the international instruments to which the country is or intends to become a party.

3.3.2. Points of Interest

Which international legal instruments have the case study countries adopted or intend to adopt?

3.3.3. Discussion

By the end of Phase 2 in their respective programmes, most case study countries had become parties to the relevant instruments for nuclear safety, security, and safeguards as well as nuclear liability. Table 4 summarizes the countries' adoption of the relevant international legal instruments. A few exceptions are observed in different countries. At the time of writing, Bangladesh continues to study the benefits of joining a nuclear liability convention and the Joint Convention; and as does Pakistan.

3.4. LEGAL FRAMEWORK TO SUPPORT REGULATORY FRAMEWORK

3.4.1. The issues

The government of each country that embarks on a nuclear power programme should promulgate laws that provide, establish and maintain an appropriate governmental and legal framework for safety, security, safeguards and civil liability for nuclear damage. The legal framework should inter alia clearly set out the functions and responsibilities of the organisations involved, in particular, those of the regulatory body. The legal framework should also implement the international legal instruments to which the country is or intends to become a party.

3.4.2. Points of Interest

In each case study country, which laws were enacted to provide an effective legal framework for safety, security, safeguards and nuclear liability? What form did the laws take? When were they enacted in relation to the nuclear power programme schedule? Did they build on or replace any prior laws?

TABLE 4. ADOPTION BY CASE STUDY COUNTRIES OF INTERNATIONAL INSTRUMENTS UNDER IAEA AUSPICES

International Instrument	Bangladesh	Belarus	Pakistan	Turkey	UAE
Convention on Early Notification of a Nuclear Accident	X	X	X	X	X
Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency	X	X	X	X	X
Convention on Nuclear Safety	X	X	X	X	X
Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management		X			X
Convention on the Physical Protection of Nuclear Material	X	X	X	X	X
Amendment to the Convention on the Physical Protection of Nuclear Material	X		X	X	X
Vienna Convention on Civil Liability for Nuclear Damage		X			
Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage					X
Convention on Supplementary Compensation for Nuclear Damage					X
Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention				X	X
Comprehensive Safeguards Agreement (CSA) — based on the Structure and Content of Agreements Between States Required in Connection with the Treaty on Non-proliferation of Nuclear Weapons	X	X	*	X	X
Additional Protocol to CSA	X			X	X
Revised Supplementary Agreement Concerning the Provision of Technical Assistance by the IAEA	X			X	X

** Pakistan is not party to Nuclear Non-Proliferation Treaty and has item-specific agreements with the IAEA in the area of application of safeguards.*

3.4.3. Discussion

In each case study country, the government acted in accordance with their national legal system to establish a legal and regulatory framework for the implementation of its nuclear power programme. In all cases, new laws were passed that reflected the obligations of the international instruments that the state has adopted, and which establish an independent regulatory body having the appropriate legal powers.

Most countries enacted the necessary laws early in Phase 2 following the policy decision to embark on the nuclear programme.

For instance, Bangladesh enacted the Atomic Energy Regulatory (BAER) Act in 2012 following the government's decision to implement a nuclear power programme. Belarus passed law No. 426-3 'On Atomic Energy Use' in 2008 which, along with other associated decrees and acts approved by the President and the Council of Ministers, make provisions for the establishment of the regulatory body and principles for protecting people and types of facilities and activities subject to licensing. The UAE government passed Law by Decree No 6 of 2009 to create the legal framework for nuclear activities in the State and to establish a national regulatory body before the award of the contract for supply of the NPP. Pakistan enacted the Ordinance establishing Pakistan Nuclear Regulatory Authority (PNRA) as the regulatory authority in 2001.

In Turkey, when the nuclear program was started the governing law was Law No 2690 which established and gave regulatory powers to TAEK. In July 2018, the government enacted Decree Law No. 702 as a comprehensive nuclear law, establishing a new independent regulatory body named Nükleer Düzenleme Kurumu (NDK) –Nuclear Regulatory Authority– to take over regulatory responsibilities from the TAEK. This law came into force after NPP construction had started, resulting in the need for the future transfer of personnel and work in progress from the old to the new regulatory organisation.

The new legal frameworks thus created for the nuclear power programme in each country generally built on and superseded the pre-existing arrangements for control of radiation sources and other nuclear activities. In Bangladesh, Pakistan and Turkey, the new independent authorities took over regulatory functions formerly carried out by the national atomic energy commissions. In Belarus, the Ministry of Emergency Situations (MES) has been performing regulatory functions for nuclear and radiation activities since 1998. A new department named Gosatomnadzor was created within the Ministry in 2007 to carry out the necessary regulatory functions for the NPP. In the UAE, the new Federal Authority for Nuclear Regulation (FANR) absorbed the former regulatory activities of the Federal Environment Agency (FEA) for control of radiation sources.

A factor related to the legal framework highlighted by several case study countries is the need for consistency and integration of the nuclear law with other legislation in the country which relate to the NPP, such as environmental protection, health and safety, land use and planning, etc.

3.5. REGULATORY FRAMEWORK

3.5.1. Roles and responsibilities of the regulatory body

3.5.1.1. The issues

Once the decision to embark on a nuclear power programme has been made, the Government should develop its regulatory framework for the oversight of the programme. Various international legal instruments and IAEA standards and guidance set out the core functions that the regulatory body should perform for effective regulatory control. The IAEA safety guide GSG-13 discusses the following core regulatory functions and processes:

— Development of regulations and guides

— Notification and authorization of facilities and activities

— Review and assessment of facilities and activities

— Inspection of facilities and activities

— Enforcement

— Emergency preparedness and response

— Communication and consultation with interested parties

IAEA Safety Standards Series No. SSG-16 (Rev. 1) [3] provides guidance on how to implement the applicable safety standards in a phased approach.

Nuclear safety, security and safeguards also should be considered in a coordinated manner during each phase of the development of a nuclear power programme, whether one or more regulatory authorities are involved.

3.5.1.2. Points of Interest

What sort of regulatory body did each country in the case studies set up and what range of activities fall under its regulatory control? How does it carry out its functions and responsibilities? Are safety, security and safeguards dealt with by the same regulatory body or by different authorities?

3.5.1.3. Discussion

In all case study countries, the legislation assigned responsibility to the regulatory bodies for oversight of the new nuclear power plant as well as other, existing activities and facilities in the state such as research reactors and the uses of radiation sources. In all case studies except Pakistan, a single regulatory body was authorized for the oversight of the three technical areas of safety, security and safeguards.

More particularly, all the regulatory bodies in the case study countries were empowered by law to issue regulations and guides (or to recommend their issuance by government), to conduct review and assessment, to authorize activities through a system of licensing, to carry out inspections, and to take enforcement actions including administrative measures and referral for criminal prosecution through the national justice system.

The regulatory bodies in the different countries also had a variety of additional functions and responsibilities, including: establishing a national inventory of radiation sources, establishing a radiation dose register, setting up the state system of accounting for and control of nuclear materials, control of import and export of nuclear material and dual-use items, commissioning or conducting research, fulfilling the state's international obligations, reviewing the radiological aspects of environmental impact assessment report, advising on nuclear liability, and cooperating with and advising other government departments and agencies.

3.5.2. **Organizational establishment and development**

3.5.2.1. The issues

After the government has adopted a nuclear law that provides the regulatory body with the mandate and legal authority, independence, competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities, the regulatory body has the responsibility for structuring its organization and managing its available resources to conduct its functions and to fulfil its obligations effectively (Requirements 3 and 16 of [5]).

Phase 2 is a critical period for the establishment of the regulatory body. Once a nuclear law has been adopted, the regulatory body needs to develop the regulatory framework for the nuclear power programme and to undertake the initial activities. The regulatory body should establish a comprehensive human resources programme to develop the specialized areas of competence to conduct its activities in phases 2 and 3. The development of the work processes, human resources and competencies of the regulatory body is among high priority tasks in phase 2 which continues through phase 3 [18].

3.5.2.2. Points of Interest

How did the regulatory bodies in the case study countries establish and develop their organisations? Were all the needed elements of the regulatory framework in place in time to support the NPP schedule?

3.5.2.3. Discussion

In most case studies, the government passed laws creating the new or re-organized regulatory body in a timely manner during Phase 2 of the NPP project. These regulatory bodies then set about structuring their organization, recruiting staff, and managing available resources to discharge their current responsibilities while planning for future phases.

However, the different regulatory bodies followed various courses in developing their organisations into functioning entities capable of discharging their statutory responsibilities. The degree of pre-planning and the availability of resources were factors that seemed to play a role in the development of the regulatory bodies in the case studies.

For instance, in the UAE, during Phase 1 of the programme before the nuclear law was passed, the Nuclear Energy Programme Implementing Organization (NEPIO) supported the development of the nascent regulatory body. During this phase the NEPIO recruited several experienced senior staff and advisors, among them the Director General of the future regulatory body, to assist in planning and development of the regulatory organisation. After the enactment of the Nuclear Law in 2009, the first Board of Management of Federal Authority for Nuclear Regulation (FANR) was appointed by decision of the UAE Cabinet, and the Board then approved the organisation structure proposed by the Director General.

Significant efforts followed to recruit staff for FANR as a new organisation and to develop the regulatory framework. By the time the application for the first construction licence was received in 2010, FANR employed some 110 people and had implemented a management system, published the needed regulations, and developed a licensing process. The factors that supported this rapid development included clear government policy leadership and detailed planning, combined with the recruitment of experienced expatriate staff to launch the regulatory programme.

In Belarus, the Ministry of Emergency Situations has functioned as the national competent authority since 1995. When the government took the policy decision in 2007 to embark on a nuclear power programme, a Presidential decree created a new entity, named Gosatomnadzor, as a department within the Ministry. Gosatomnadzor's functions cover participation in the NPP authorization process, establishment of requirements for the safety submittals for nuclear installations and ionizing radiation sources, as well as investigation of events, organization of safety expertise, R&D, implementation of control over radioactive waste management, control of physical protection, control over planning of protection measures and compliance with the

rules and regulations on nuclear and radiation safety, personnel training and other functions given in law.

The staff of Gosatomnadzor initially comprised 39 persons in 8 divisions. In 2013, shortly before NPP construction started, following the recommendations of an IAEA INIR mission, the government provided additional human and financial resources to enable Gosatomnadzor to perform its supervisory functions. The number of positions allocated to Gosatomnadzor was increased to 82. In 2016, Gosatomnadzor finalized a plan titled 'The Strategy for the Development of the Department for Nuclear and Radiation Safety of the Ministry for Emergency Situations' to guide its future development and has continued to make intensive efforts to recruit and train new personnel for its organization.

In Bangladesh, after the government took the decision to embark on a nuclear power programme, the Bangladesh Atomic Energy Regulatory Authority (BAERA) was established in 2012 with the enactment of BAER Act. BAERA took over the regulatory functions formerly performed by the Bangladesh Atomic Energy Commission. The regulatory authority consists of a Chairman and four Members appointed by the Government for a fixed tenure of three years and employed as full-time officials of the Authority. As of 2019, BAERA has 30 technical staff, 35 supporting staff and 20 outsourced supporting staff organized in four technical divisions and two support divisions in Dhaka, and an office at the NPP construction site. In addition, BAERA has formed an advisory council and several expert committees to support the Authority to carry out its responsibilities. BAERA recognizes the need to further strengthen its complement of skilled staff to fulfil its responsibilities for regulatory oversight of the national nuclear sector which includes the Rooppur NPP, the existing research reactor, radioactive waste management facility, radiological facilities and medical practices.

The Pakistan Nuclear Regulatory Authority (PNRA) was established pursuant to the PNRA Ordinance of 2001, building on the experience of predecessor organisations. The Authority consists of a Chairman, two full-time Members and seven part-time Members appointed from other relevant government departments and experts from the science, engineering and medical sectors. PNRA has approximately twenty directorates and four regional inspectorates. Each organizational unit of PNRA prepares its organization structure in line with the assigned tasks & functions. PNRA also has an internal technical support organization comprising two support centres, namely the Centre for Nuclear Safety (CNS) and Safety Analysis Centre (SAC), with enough skilled manpower to assist in the regulatory decision-making process. CNS provides technical and scientific support to departments of PNRA involved with review and assessment of submissions of licensees and applicants. PNRA employed approximately 850 officers and staff in 2017.

In Turkey, TAEK has for many years fulfilled the role of the regulatory organisation supervising the nuclear activities in the country. However, the organisation of its successor NDK remains to be fully developed following its legal establishment in 2018.

3.5.3. Independence of the regulatory body

3.5.3.1. The issues

The government should ensure that the regulatory body is effectively independent in its safety and security related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making. To ensure independence in exercising their regulatory functions, there should be an effective separation

between the regulatory body and any other organizations that could unduly influence its decision making. The need for this separation of functions has also been acknowledged and is included for instance in relevant safety standards and as an obligation for the Contracting Parties to the Convention on Nuclear Safety and for Parties to the Joint Convention on the Safety of Radioactive Waste Management and on the Safety of Spent Fuel Management (Requirements 4 and 17 of [5]).

3.5.3.2. Points of Interest

How did the governments in the case study countries ensure the independence of the regulatory body in its safety and security related decision making, and the separation from entities having responsibilities or interests that could unduly influence its decision-making?

3.5.3.3. Discussion

All countries report that their regulatory body is established as a legally independent entity reporting to a government official or ministry having no responsibility for the promotion of the use or utilization of nuclear energy.

In Bangladesh, the BAERA reports to the Minister of Science Technology (MOST) and the Minister appoints the Chairman and Members. While this organisation gives an appearance of potential conflicts, because the nuclear power organisation also reports to the MOST, the BAERA states that it has authority under Act 19/2012 to make its own decisions for the regulatory control of facilities and activities, and to perform its functions without undue pressure or constraint.

In Belarus, the Minister of Emergency Situations reports to the Prime Minister. The head of Gosatomnadzor, which carries out the regulatory functions within MES, is appointed by the President upon the recommendation of the Minister. MES also manages the operation of two facilities for radioactive waste from decontamination following the Chernobyl accident, but mechanisms are in place to manage this potential conflict, such as the functional separation of regulatory and operating roles.[1]

In Pakistan, the PNRA was established by national Ordinance in 2001 as an independent agency reporting to the Prime Minister through the Strategic Plans Division of the Secretariat of National Command Authority.

Turkey has taken steps to strengthen regulatory independence by establishing NDK as the national nuclear regulatory body to take over the functions formerly carried out by the TAEK. NDK is associated with the Ministry of Energy and Natural Resources. In Turkish government system, there is no hierarchical relation between the ministries and associated organizations. Furthermore, the new nuclear law contains provisions ensuring that no organization has the power to influence NDK's regulatory decision making.

In the UAE, the 2009 nuclear law established FANR as an independent body with its own legal personality and budget reporting to the Minister of Presidential Affairs. The law also contains

[1] Report of the Integrated Regulatory Review Service (IRRS) mission to Belarus, IAEA, Vienna (2016).

provisions for the independence, and freedom from conflicts of interest, of the members of the Board of Management of FANR.

Other dimensions of regulatory independence beyond legal status and reporting relationships, such as adequate financial resources, sufficient competent staff, and liaison with other regulatory bodies and international organisations, are discussed in the corresponding sections of this section.

3.5.4. Funding

3.5.4.1. The issues

Adequate and stable financial resources for all regulatory activities and their scientific and technical support should be provided to ensure the independence in regulatory decision making. The funding mechanism should be clearly defined in the legal framework. If the costs of regulatory activities are to be recovered from the licensees, the funding mechanism needs to be designed to prevent its misuse by licensees to reduce regulatory independence. Within its total budget, the regulatory body should have a high degree of control in deciding how the budget is to be distributed between its various regulatory activities for the greatest effectiveness and efficiency (Requirements 3 and 4 of [5]).

3.5.4.2. Points of Interest

What funding mechanisms did the case study countries establish? How was the amount of funding determined? What common factors and differences are observed?

3.5.4.3. Discussion

Most of the regulatory bodies in the case study receive funding from a combination of sources, principally allocations from the national budget and fees paid by licensees.

In Bangladesh, the BAERA prepares an annual budget which is discussed at ministerial level before being approved by the Ministry of Finance. The law defines BAERA's income as composed of licence fees, regulatory service fees, donations and grants, and government annual budget. Income from licensing and other fees is retained by the BAERA. The annual budget is part of the Government general budget and is, therefore, subject to administrative expenditure rules and audits.

In Pakistan, the funds of the PNRA comprise grants from the Federal Government, grants from a Provincial Government, special grants for capacity building projects, income from fees for authorization and issuance of licences, international grants, and receipts from other sources as may be approved by the Authority. Fees represent about 25% of PNRA's budget with the rest coming from the State through different channels.[2] These funds have been adequate to meet the financial needs of PNRA to date.

In Turkey, according to the new nuclear law, the budget of NDK is composed of service fees, income from publications and other similar items, donations and grants, administrative fines applied by NDK, incomes from estates and assets of NDK, and treasury amounts from the

[2] Report of the Integrated Regulatory Review Service (IRRS) mission to Pakistan, IAEA, Vienna (2014).

general budget. The nuclear law states that NDK's incomes must cover its expenditures. Any shortfall is covered by a special item in the budget of the Ministry of Energy and Natural Resources while a surplus is transferred to the following next year's budget. NDK is entitled to determine its service fees.

In the UAE, the nuclear law empowers FANR's Board of Management to adopt the annual budget and balance sheet. FANR's budgeting method is a zero-based system which is reviewed on a yearly basis. During the first several years of its existence, FANR was funded by allocations from the government. Later, in 2014, the UAE Cabinet passed a resolution which requires the holder or holders of a licence for a nuclear facility to pay 90% of FANR's approved budget for each financial year. The Cabinet resolution further sets out a schedule of prescribed licence fees for radiation source and nuclear material users.

Belarus is the sole exception among the case study countries to the trend of levying fees on licensees, in that Gosatomnadzor is funded entirely from the state budget. It develops a budget plan for each year after evaluating the implementation of the previous annual plans and current needs. The annual state budget is approved by the National Assembly of the Republic of Belarus and is ratified by the President. If necessary, funding can also be provided from the budget of the MES to cover unplanned activities in Gosatomnadzor as well as procurement of expert and consultancy services.[3]

3.5.5. Establishment of management systems in the regulatory body

3.5.5.1. The issues

The regulatory body should establish, implement, and improve a management system in accordance with GSR Part 2 [6] that is aligned with its goals and contributes to their achievement (Requirements 19 of [5]). The prescriptions of GSR Part 2 can also be relevant to security and safeguards. Adequate infrastructural arrangements should be established for taking into consideration of interfaces between safety, security and safeguards (Requirements 12 of [5]).

3.5.5.2. Points of Interest

What arrangements has each regulatory body put in place for a management system? What common features and differences are observed. How did each regulatory body manage the development of its management system? When was it completed in relation to the NPP implementation schedule?

3.5.5.3. Discussion

All the regulatory bodies in the case studies report making a commitment to implement an Integrated Management System (IMS) in line with the IAEA safety standards to support the effective and efficient delivery of their services. However, differences can be seen in the approaches taken by each regulatory body and in the timelines for implementation of the IMS in relation to the NPP schedule. The variety of outcomes shows the challenges that the leaders

[3] Report of the Integrated Regulatory Review Service (IRRS) mission to Belarus, IAEA, Vienna (2016).

of a new regulatory body face in developing the organisation for future phases while simultaneously fulfilling current demands for regulatory services.

In Bangladesh, the BAERA is developing an IMS with assistance from the technical support organization of the vendor regulatory body under the long-term framework contract. The IMS development thus lags the regulatory activities needed to support the NPP schedule such as issuance of the site and the construction licences for Units 1 and 2. Currently, the core regulatory processes as well as management and support processes are being described based on the existing legal framework, the BAERA structure and regulatory practices. In parallel, the management system manual is being drafted along with necessary policy documents. Training of personnel, and implementation of the IMS, are planned for the next phase of development.

In Belarus, Gosatomnadzor is developing an IMS in line with IAEA safety requirements according to a plan ordered by the Head of Gosatomnadzor in 2015. (This order therefore trails the issuance of the site and construction licences for the Belarusian NPP.) A working version of the IMS manual has now been approved and will be finalized when all processes have been established and documented. Documentation of additional processes continues with priority to inspection of nuclear and radiation safety at facilities, licensing of facilities and activities, knowledge management, and safety expertise.

The PNRA in Pakistan started developing its management system after its establishment in 2001. By 2010, a comprehensive management system was implemented based on IAEA GS-R-3 (superseded by GSR Part 2 [6]). Since then, the PNRA has continued to improve its management system, considering the updated requirements in GSR Part 2 as well as implementation feedback and international experience. A new revision of the Management System Manual (MSM) was issued in 2016. PNRA has also recently taken steps to develop a common understanding among staff for effective implementation of the MSM by arranging awareness sessions with all PNRA departments.

In Turkey, TAEK had implemented a quality management system in line with requirements for Turkish government organizations and was working on an ISO 9001 quality management system to satisfy the requirements of a safety focused integrated management system with support from the European Council Instrument for Nuclear Safety Cooperation. NDK, the new regulatory body, is expected to base its integrated management system on the experience coming from TAEK.

FANR in the UAE established an IMS early in its programme. The IMS defines a set of core regulatory processes, including regulation and guides, authorisation, and inspection and enforcement, as well as management and support functions including planning, budgeting and financial management, human resources, training and competence, information technology and document control. An International Regulatory Review Service (IRRS) mission to the UAE in 2011 confirmed that the early establishment of the IMS helped FANR to deliver its functions and supported the Safety, Security and Safeguards ‘3S’ culture that FANR’s senior management has committed to. FANR has continued to develop its IMS and has recently obtained ISO certification.

3.5.6. Staffing and competence of the regulatory body

3.5.6.1. The issues

The regulatory body should have appropriately qualified and competent staff. A human resources plan should 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 (Requirements 10 of [5]).

The tasks of the regulatory body in Phases 2 and 3 are complex technically and of a specialized nature. The regulator should develop the capability for granting a construction licence following evaluation of the Preliminary Safety Analysis Report (PSAR) submitted by the applicant, oversee NPP construction, then evaluate the Final Safety Analysis Report (FSAR) to support the issuance of an operating licence. Many of the technical disciplines involved are specific to nuclear power and may not be immediately available in the embarking country. Therefore, new entrant regulators should develop the required competencies.

Since development of the needed competencies requires time, the leadership of the new entrant regulator needs to plan for human resources development at an early stage of the nuclear power programme. Accordingly, it needs to develop a human resources plan that identifies the number of staff necessary, the essential knowledge, skills and abilities to perform all the necessary regulatory functions, and the means of acquiring these competencies (Chapter 2 of [18]).

3.5.6.2. Points of Interest

What initial level of expertise existed in each country? How did the leadership of the new regulatory body in each country plan for and conduct development of human resources? What sources were used for human resources development (internal and/or external)? What role did the vendor country play? Were the human resources in place in time to perform the needed regulatory activities? Was any mismatch evident between the development of the regulator and the NPP schedule?

3.5.6.3. Discussion

Although the existing infrastructure for regulation of radiation sources and other nuclear applications provided a foundation in most cases, each case study country needed additional skilled personnel to perform the regulatory functions for the nuclear power programme. The acquisition of the necessary human resources posed significant challenges for the regulatory body in all cases.

All case study countries reported on their efforts to identify the knowledge, skills and abilities, and the numbers of people, needed to perform the regulatory functions. Most referenced the recommendations contained in the IAEA Systematic Assessment of Regulatory Competence Needs (SARCON) approach.

The new regulatory bodies relied on various sources of recruitment. All sought to employ local personnel. In several cases, the regulatory body and the government encouraged universities to create programmes to educate graduates in the relevant skills. In Belarus, for example, Gosatomnadzor launched a programme of recruitment of graduates from several national universities that were mandated to prepare specialists in physics, radiation chemistry, radiation safety and engineering. In the UAE, FANR provided local students with scholarships to study abroad in disciplines relevant to nuclear power and to take graduate programmes offered by Khalifa University in Abu Dhabi.

The regulatory body in the UAE also employed experienced expatriates to support the launch of the nuclear power programme. The expatriate personnel brought leadership skills and specialist expertise to the regulatory body to support planning and execution. This human resource strategy reflected common practices in other sectors of the UAE economy. However,

factors such as national public service hiring rules, pay levels, language and culture may limit the prospects for employment of expatriate personnel within the national regulatory body in some other countries. By 2019, FANR employed 220 personnel of whom 67% are Emirati. 40% of the workforce are women.

The regulatory bodies in all cases reported establishing in-house training programmes for training of new recruits to develop job-specific competencies as inspectors, technical assessors, and other roles.

Notably, PNRA has established an in-house National Institute of Safety and Security with state-of-the-art facilities for competence development in the fields of nuclear safety, radiation safety, transport and waste safety, regulatory control, nuclear security and management skills.

Gosatomnadzor developed a process to integrate new employees which includes 6-month individual programmes, and internships in various divisions to ensure that new staff have developed a good understanding of regulatory activities in a particular field and of the whole department before commencing autonomous work. FANR implemented a similar intern programme for its new graduate recruits.

The new regulatory bodies also used external sources of training to support their in-house programmes. The external sources of training included national universities and colleges, secondments of staff to regulatory bodies in the respective NPP vendor countries, training provided by other countries with mature nuclear energy programmes, and training provided by international organisations such as the IAEA and the European Union. In Bangladesh, for example, BAERA has signed a general framework contract with the TSO of the nuclear regulatory body in Russia for assistance with different phases of training and development of regulatory staff. Similarly, FANR in the UAE sent new staff to Korea for classroom-based and on-the job training. BAERA has also sent junior managers to India, Japan and the UK for further education and training, and is working with the IAEA technical cooperation programme on capacity building.

In Turkey, regulatory personnel have been transferred from TAEK to NDK to keep the former expertise. The new nuclear law contains provisions for employing staff through routes other than the central government procedures. Regarding the human resources development, staffing and competency management, all plans and programmes developed by TAEK and all the projects are expected to continue under NDK.

Learning new skills takes time, and the experience of the regulatory bodies in the case studies in developing their recruits was no exception to this principle.

In cases where plans for human resource development were implemented without delay after the policy decision to embark on a nuclear power programme, the national regulatory body was able to recruit and train staff in a timely manner to discharge its functions. In the UAE when the operator submitted its first application for a construction licence, FANR already employed sufficient number of staff with relevant experience and skills to undertake the review and assessment of the PSAR.

In other cases, a mismatch is evident between the development of the regulatory body and the demands of the NPP schedule. In Belarus the government granted needed additional human resources to Gosatomnadzor only in 2013 after the construction phase had started. In Bangladesh, the BAERA has identified the need for additional personnel for effective

regulatory control of nuclear and radiological facilities in the country to be recruited in three phases by 2025--three years after the planned date for fuel loading in the NPP.

3.5.7. Utilization of external experts to support regulatory activities

3.5.7.1. The issue

Although regulatory bodies should be provided with adequate human and financial resources to fulfil their responsibilities, in some circumstances the expertise necessary to address a specific issue or programme may not be available within the regulatory body itself. Therefore, regulatory bodies commonly obtain technical or other expert professional advice or services in support of their regulatory functions to augment in-house resources or obtain access to skills that are not available in-house. However, such arrangements should not relieve the regulatory body of its statutory responsibilities (Para 2.16 of [7]).

3.5.7.2. Points of Interest

For what purposes did the regulatory bodies in the case studies employ external support? What types of organisations did they get support from: designated technical support organisations, consultants, or the regulatory bodies of other states, particularly the vendor country? How did their use of external support dovetail with their human resources strategies?

3.5.7.3. Discussion

All the new regulators in the case studies relied on external support to provide needed expertise and to augment their in-house resources. This external support was especially critical during the initial phases of their programmes, when the regulatory bodies did not have sufficient number of competent staff. The external support they obtained covered the development of regulatory infrastructure (policy and procedure development), human resources development, and assistance in directly carrying out regulatory functions including review and assessment and inspection. The sources of support comprised organisations within each country, such as universities and national institutions, and sources abroad including entities within the NPP vendor country, consultants and TSOs, the IAEA and other international bodies.

In Bangladesh, the BAERA augmented its internal resources with support from national institutes and universities. The BAERA also concluded an interagency agreement with Rostechnadzor, the regulatory body in the vendor country, and has contracted with VO Safety, Rostechnadzor's TSO, for technical support during the siting, design, construction, commissioning and operation of Rooppur Nuclear Power Plant. The protocols cover the review and assessment of licensing documents, inspections at the NPP and vendors premises, meetings and workshops on NPP safety topics, development of licensing requirements, inspection procedures, regulations and guides, and human resources development. Bangladesh has obtained additional external support from the national regulatory body of India, and from the IAEA in the form of technical cooperation for capacity building, expert and peer review missions and participation in the Regulatory Cooperation Forum.

Belarus established a national TSO system to support its regulatory body. Sixteen organizations in the country were designated by a 2012 decree of the Council of Ministers to provide technical support to the regulatory authority for nuclear and radiation safety matters. One of the leading organizations is the 'Joint Institute for Power and Nuclear Research (JIPNR) – Sosny' of the National Academy of Sciences, which holds a license to conduct safety review in the field of atomic energy use. However, the development of the necessary competencies of the TSOs in

parallel with the regulatory body was a challenge for the country. The Centre for Nuclear and Radiation Safety was created by decree of the President of the Republic of Belarus in 2017 to enhance the coordination of scientific and technical support to the regulatory authority.

Belarus has also intensified bilateral cooperation since 2014 with the Russian regulatory body Rostechnadzor in the areas of on-the-job training of staff and as a consultant during complex inspections of the Belarusian NPP.

PNRA obtains technical or other expert professional advice to augment its in-house resources. Such advice is never binding and PNRA remains independent and retains full responsibility for its decision-making on safety matters. PNRA has established strong bilateral relationships with organisations in the NPP vendor country, notably the National Nuclear Safety Administration, the China Nuclear Power Operation Technology Corporation and the Nuclear Safety Centre of China. The bilateral agreements with these organizations provide for free exchange of information on matters related to nuclear safety. These Chinese institutes are assisting PNRA in the review and assessment as well as regulatory inspections of NPPs. PNRA also contracted VUJE Inc. of Slovakia to assist in nuclear safety reviews and inspections of NPP. PNRA participates in the Regulatory Cooperation Forum of the IAEA to collaborate on regulatory capacity building among member states with established nuclear power programme and those considering the introduction or expansion of such programmes.

In Turkey, TAEK employed the services of external experts and organizations for the Akkuyu and Sinop projects. Academicians and domestic experts were used to support regulatory activities for NPP siting. Two technical service companies, UJV Rez from the Czech Republic and TÜV-SÜD from Germany, were awarded contracts to support the review and assessment of the construction licence applications comprising the PSAR and supporting documents for units 1 and 2 of the Akkuyu project, respectively. TAEK also signed a protocol with the Turkish Standards Institute to get external support for inspection activities.

Turkey has now established, through the 2018 nuclear law, a national TSO in the form of a government-owned company named NÜTED (Nuclear Technical Support Joint Stock Company). NÜTED has the responsibility to provide all necessary TSO services to NDK. Hiring of staff and capacity building for NÜTED will be implemented in parallel to the needs of NDK.

In the UAE, FANR established inter-governmental agreements and memoranda of understanding with the authorities in the vendor country which provided for exchange of information on the Republic of Korean regulatory framework, the licensing process, and safety assessments for the reference plant; support for vendor inspections; and human resources development through training and staff secondments. These arrangements between FANR and the regulatory authorities in the vendor country provided the dual benefits of enhancing safety by enabling cooperation with experts who were familiar with the NPP technology and facilitating the conduct of FANR's licensing review by making use of the design safety evaluation of the reference plant.

To augment its in-house resources for reviewing the licence applications, FANR also contracted with three Technical Support Organizations located in the USA and Europe. The TSOs were selected based on their qualifications and experience in providing similar services for other nuclear regulatory bodies. Contracts were awarded for work packages composed of different topical parts of the PSAR such as siting, reactor design, safety analysis and radiation protection. A secure, online work environment was created to allow the TSOs to access information and to

draft evaluation reports. FANR provided alignment and direction to the TSOs and retained responsibility for regulatory decisions through its in-house team of seasoned staff. The support provided by TSOs was particularly important during the first construction licence applications. The level of effort contracted to TSOs for subsequent licence applications reduced as FANR staff grew in numbers and in competence.

In addition, FANR engaged other professional organisations on an ongoing basis throughout its programme to provide support in areas such as development of IMS policies and procedures, drafting regulations, business software development, etc.

3.5.8. Prioritization and development of regulations and guides

3.5.8.1. The issues

One of the first activities of the new entrant regulatory body after the decision to embark on a nuclear power programme is the development of regulations and guides to specify the principles, requirements and associated criteria upon which its regulatory judgements, decisions and actions are based. The system of regulations and guides should be in accordance with the legal system of the State and should cover all foreseen nuclear activities in the country. Regulations may be issued by the government in some countries and in others by the regulatory body on behalf of the government. The regulations may be derived from the IAEA safety standards and nuclear security guidance, similar regulations in other countries, or from the rules of the vendor country of the technology, if identified. As a practical matter, the regulatory body may need to prioritize the development of regulations and guides needed for the initial licensing of the nuclear power plant and defer to future development those related to later phases (Requirements 32 of [5]).

3.5.8.2. Points of Interest

What regulations did the new entrant regulatory bodies prioritize and when were they issued in relation to the phases of the nuclear programme? What was the basis for the regulations and guides—IAEA standards, the regulations of another country or the regulations of the vendor country? Which regulatory approach (prescriptive or performance based) was adopted?

3.5.8.3. Discussion

All regulatory authorities in the case studies have been granted the legal power to issue regulations, either directly or through the government. All countries have issued regulations for their nuclear power programme; however, differing levels of completion of the regulatory framework are evident. The specific forms taken by regulations and guides varies according to the practice in the legal system of each country.

Some countries issued regulations early in their programme before completion of Phase 2 (that is, before the award of a contract for supply of the NPP). In the absence of a decision on NPP technology, several regulators chose to develop ‘technology neutral’ regulations. The corresponding IAEA safety standards and guidance are a common reference in such cases. Several countries prioritized the development of regulations needed for the initial stages of NPP licensing and deferred to a later time the regulations related to the operational phase.

A strong theme across all cases is that the regulators in embarking countries referenced the regulations and technical standards of the vendor country (and in some cases third countries) and utilized the requirements to supplement their national framework which generally set out

high level requirements. The ways in which they did so differed from case to case. Some countries issued formal decrees to specify the use of vendor country requirements. In some cases, the licence applicant and future operator proposed standards to the regulatory body based on the reference plant in the vendor country. The adoption of non-mandatory regulatory guides based on vendor country and third country practices was another strategy.

For instance, in Bangladesh Section 30 of the BAER Act-2012 gives the BAERA power to propose regulations for nuclear safety which are approved by MOST after vetting by the Ministry of Law, Justice and Parliamentary Affairs. The BAERA has issued two regulations to date: Regulatory Guidance on Site Evaluation for the Safety of Nuclear Power Plant (2015), and the Bangladesh Atomic Energy Regulatory Staff Service Regulation, (2017).

A provision in the BAER Act allows the rules made under the repealed Nuclear Safety and Radiation Control (NSRC) Act 1993 to continue in force until new, comprehensive and detailed regulations are in place. The NSRC Rules provide a list of applicable standards, codes and guides relevant to different stages of nuclear installations to ensure nuclear safety. The BAERA also recognizes the relevant regulations, codes and standards of the vendor country regulator. A plan has been developed for drafting new regulations and guides related to the NPP with the assistance of the vendor regulatory body.

In the Republic of Belarus, the legislative and regulatory framework consists of a hierarchy of legal documents ranging from laws and presidential decrees, resolutions of the Council of Ministers, resolutions of individual ministries, to technical norms and rules. Gosatomnadzor has the responsibility to draft norms and rules in the field of nuclear and radiation safety which are approved by the Minister.

Belarus has published 28 technical norms related to the NPP. Most rules associated with NPP siting and construction were published before the start of NPP licensing. Rules associated with NPP operation, such as those on emergency preparedness and radioactive waste management, were published later in the programme. A Presidential Decree allows for the use of technical regulations of the Russian Federation (the vendor country) in the absence of similar Belarusian documents when those regulations follow international standards.

The system of regulations and guides in Pakistan is based on articles 16 and 56 of the Ordinance which state that the Authority may devise, adopt, make and enforce such rules, regulations, orders or codes of practice for nuclear safety and radiation protection as may, in its opinion, be necessary. PNRA has follows a legal hierarchy composed of the Ordinance at the top, regulations second, regulatory guides at the next lower level, and industrial codes and standards at the lowest level. PNRA has published six administrative regulations, on topics such as licensing, enforcement and licence fees, and eleven technical regulations on the safety and security of nuclear and radiation facilities and activities.

The regulations and guides of PNRA were originally based on vendor country requirements. Later regulations largely adopted or adapted IAEA safety standards. In areas where PNRA regulations are not available, the relevant latest USNRC regulations or IAEA safety standards may be deemed to be applicable. In cases where the licensee follows an alternative approach to fulfil a regulatory requirement, the licensee should demonstrate that its approach offers the same or better standard of safety and quality.

In Turkey, TAEK issued approximately 20 regulations regarding the safety and security of nuclear facilities prior to the start of the nuclear power programme. However, the variety of

potential technology choices in the early phases of the programme hindered the development of a complete set of regulatory requirements. The 'aggressive' schedule for the implementation of the nuclear programme coupled with the engagement of two different vendors for two different projects added to the difficulties in developing the regulatory framework. TAEK's regulations therefore were mostly technology-neutral, based on adoption of IAEA requirements.

To apply the most recent requirements in the area of nuclear safety, TAEK developed a licensing approach utilizing applicable IAEA, vendor country and third-party requirements to fill the gaps in the current Turkish regulations. This approach included the utilization of a reference plant to facilitate the licensing process. In 2011, TAEK issued a Directive on Determination of Licensing Basis Regulations, Guides and Standards and Reference Plant for Nuclear Power Plant. This Directive defines a Licensing Basis List which consists of applicable Turkish legislation, IAEA requirements, vendor country requirements and, where necessary, third-party requirements. The list is prepared by the applicant through negotiations with TAEK and after approval by the Atomic Energy Commission forms the licensing basis for the project. The Directive also has provisions for the selection and approval of a reference plant representing the NPP units to be installed.

All decrees and regulations issued by TAEK will be effective until NDK issues new regulations in line with the provisions of the 2018 nuclear law.

In the UAE, Article 38 of the Nuclear Law empowers FANR to issue regulations setting out requirements that all operators must follow, and to issue explanatory guides on compliance. The Nuclear Law further states, "in developing regulations and guidelines, the Authority shall take into consideration comments from stakeholders, information made available by experts and internationally recognized standards and recommendations, such as IAEA Safety Standards."

FANR developed a core process in its IMS to describe the method for development of regulations and guides. The process includes steps for consultation of stakeholders and the public on draft documents. Following approval by the FANR Board of Management, completed regulations are published in the UAE Gazette.

FANR aimed at developing high-level requirements suitable for application to all modern reactor technologies. The relevant IAEA safety standards served as the starting point for many regulations. The development of regulations was prioritized to meet the needs at each phase of the nuclear energy programme. FANR first concentrated on the regulations needed for the NPP construction licence application, including the regulations for management systems, siting, NPP design, use of Probabilistic Safety Assessment (PSA), radiation protection, and the required content of the construction licence application. Subsequently, FANR issued additional regulations needed for the operating licence, including regulations for the content of an operating licence application, safety in operation of a nuclear facility, training and certification of NPP operating personnel, nuclear material accountancy and control, security, emergency preparedness, and decommissioning and radioactive waste management.

For regulatory guides to provide compliance criteria, FANR to the extent practicable adopted documents of the vendor country which were specific to the selected NPP technology. Due to the United States origins of the APR-1400 NPP design, this approach led FANR to refer in its guidance both to Republic of Korean standards and to regulatory guides published by the United States Nuclear Regulatory Commission.

3.5.9. Implementation of licensing process

3.5.9.1. The issues

A new entrant regulatory body needs to define during Phase 2 the licensing process and establish the rules and regulations by which the project will be assessed. During Phase 3, the regulatory body should be prepared to assess the safety documentation provided by the future operator and to deliver licences for construction at the beginning of Phase 3 and for nuclear power operation at the end of Phase 3 (Requirements 23 of [5], Paragraph 33 of [18]).

3.5.9.2. Points of Interest

How did the regulatory bodies in the case studies define the licensing process and the associated rules and regulations? What licences did they require to be issued for the NPP? When, in relation to the NPP schedule, were the licensing requirements defined? What use did the regulatory bodies make of the reference plant concept in licensing? How was review and assessment process organized?

3.5.9.3. Discussion

All the case study countries established a system of licensing in their respective nuclear laws where controlled activities that require a licence from the regulatory body being also defined.

However, the licensing systems in the case studies differ in the details of the specific activities for which a licence is required:

— In Bangladesh the BAERA has issued a site licence and design and construction licences for the Rooppur NPP. BAERA anticipates issuing in future a commissioning permit followed by an operating licence for each unit.

— In Belarus, Gosatomnadzor issued a site licence and a two-stage construction licence for each unit (the first stage to authorize construction of building foundations and the second stage for full construction). It expects to issue operating licences for each unit in future. In addition, the Presidential decree on licensing in Belarus stipulates that the design and manufacture of nuclear equipment, and the conduct of safety reviews, are regulated activities which require licences from Gosatomnadzor.

— In Turkey, according to the Decree on Licensing of Nuclear Installations, the licensing process for nuclear installations comprises three successive stages: site licence, construction licence and operating licence. However, in the Turkish system, additional permits are required including permits for commissioning, fuel loading, and test operations which function as hold points in the licensing process.

— FANR in the UAE issued a site selection licence and a site preparation licence, a limited construction licence and a full construction licence for the units at Barakah, and a licence for possession and storage of fresh nuclear fuel. FANR issued the operating license for Barakah Unit 1 in February 2020 and anticipates issuing an operating licence for subsequent units when preparations are complete.

— Pakistan's licensing regulations made under the Ordinance specify site registration, construction licence, fuel load permit and operating licence as the initial stages of licensing for an NPP.

All the case study countries implemented a phased approach to licensing. None of the case study countries attempted to implement a single-step (combined) licence. As International Nuclear Safety Group (INSAG) has observed [18], a single-step licensing process requires the regulator to conduct significant technical review early in the process. Such an approach could exceed the technical capabilities of a new entrant regulator.

Several embarking countries (Bangladesh, Turkey and the UAE) made explicit reference to the use of a 'reference plant' in their licensing processes. All three reported on provisions to accept the use of vendor regulatory body regulations and standards in their regulatory framework for the NPP, as also did Belarus. Only FANR in the UAE, however, reported using the safety assessments done for the reference plant by the regulatory body in the vendor country to support its licensing review. The Belarusian NPP in Belarus has a similar design with the Leningrad-2 NPP in Russia but there is no reported use of the reference plant concept.

All the embarking countries established the main features of their licensing requirements and process during good time during Phase 2 of their programmes. Bangladesh enacted its nuclear law, the BAER Act, in 2012. In Belarus, the governing Presidential decree on licensing was first issued in 2010 (and has since undergone revision). TAEK in Turkey prepared its licensing directive in 2012. FANR in the UAE published its regulation on construction licence application requirements in 2010.

However, the subsequent organisation of the review and assessment procedures, development of the necessary in-house regulatory competencies, engagement of external support, and conduct of the licensing reviews was, as discussed in other sections of this report, a major effort for the regulator in each case.

The basic objective of regulatory review and assessment is to determine whether the applicant's submissions demonstrate compliance with all the regulatory requirements (i.e. regulations, licence conditions, applicable codes and standards, etc.) throughout the proposed life of the facility or activity.

In Bangladesh, after submission of all required documents to BAERA, it started its review and assessment process by its own and external resources implementing the graded approach. The whole review and assessment process was conducted by the Nuclear Safety & Security Division of BAERA with the assistance of external TSOs of the vendor country's regulatory body, local experts and other foreign experts.

In case of Belarus, documents submitted by the applicant were reviewed by the expert organization 'JIPNR-Sosny' according to terms of reference elaborated by Gosatomnadzor. Gosatomnadzor reviewed the expert opinion for compliance with the terms of reference, assesses the conformity of the applicant's organizational and technical capabilities with the licensing requirements and conditions and decided on the whether to issue a license.

In Pakistan, PNRA reviews and assesses licensing submissions of nuclear installations and associated activities. PNRA has established two internal technical support centres. These centres also perform deterministic and probabilistic safety analysis to support review and assessment process.

In Turkey, the licensing includes review and assessment by the NDK of a set of documents for each license application. Turkish licensing system includes '3S' approach. During the evaluation of license application submitted reports and programmes related to the safety, security and safeguards are reviewed by the regulatory body. The approval of physical

protection programme and the nuclear material accountancy and control system of the NPP is a pre-requisite before granting permission to bring nuclear material to the site. The final information regarding the emergency management is reviewed before the permit for fuel loading. For the licensing of Akkuyu NPP's unit 1 the TAEK utilized Czech TSO UJV to support its own review and assessment studies. For unit 2 NDK contracted TÜV SÜD of Germany for the selected parts of the review and assessment studies.

In case of UAE, FANR conducts a thorough review and assessment of the applicant's technical submissions consistent with the nature and potential magnitude of the hazards in order to determine whether the proposed facility complies with applicable safety objectives, principles, and criteria. To fulfil this requirement, FANR documented in its IMS a licensing process consistent with IAEA recommendations. FANR benefited from a strong bilateral relationship with the Korea Institute of Nuclear Safety (KINS), the regulatory body in the vendor country of origin, and from its contracts with TSOs.

3.5.10. Development and implementation of regulatory inspection programme

3.5.10.1. The issues

The regulatory body needs to develop and implement a programme of inspection to independently check on the authorized party and the facility or activity, and to provide confidence that the authorized party is in compliance with the requirements prescribed or approved by the regulatory body (Requirements 27 of [5]).

3.5.10.2. Points of Interest

What programme of inspection did the regulatory bodies in the case studies establish? What is the scope of their programme—for instance, does it cover suppliers as well as the licensee? How is the programme organized? Are other entities such as TSOs or third-party inspection organisations involved in regulatory inspection? What enforcement powers does the regulatory body exercise in cases of non-compliance?

3.5.10.3. Discussion

All the regulatory authorities in the case studies are empowered by their respective legal framework to inspect their licensees' facilities and activities.

All the regulatory bodies have implemented planned programmes of inspection of siting and construction of the NPP to verify compliance with requirements and are preparing for inspection of future commissioning and operation.

In some cases, other ministries or authorities have responsibilities for oversight of different aspects of the NPP such as environmental protection and industrial safety. In Belarus, inspections may involve the participation of several agencies in a comprehensive inspection or comprise routine inspections by individual entities. Overall coordination of the inspection programme in Belarus is carried out by a working group in the Ministry for Emergency Situations. In the UAE, the nuclear regulatory authority has concluded memoranda of understanding to coordinate activities with different agencies which have complementary oversight roles for the NPP, including the Abu Dhabi Environmental Agency, and Occupational Safety and Health Abu Dhabi.

Each of the regulatory authorities in the case studies employ designated inspectors on their staff. All have established regional offices or site resident offices to facilitate inspection of activities at the NPP site.

Several countries (Belarus, Pakistan, Turkey and UAE) report that their inspection programme extends to activities of suppliers. The mechanisms differ, however. In Belarus, Gosatomnadzor inspects the manufacture of safety-related equipment for the NPP to verify technical conformity including aspects such as welding and non-destructive testing. In Turkey, the regulations restrict the supply of safety-related items only to approved manufacturers, while a further regulation requires the NPP owner to hire a third-party inspection organization certified by TAEK/NDK to inspect manufacturing and construction. In Pakistan, inspections are conducted to verify the effectiveness of quality assurance system of the licensees and their contractors/sub-contractors. PNRA also conducts inspections of equipment manufacturing at the site. In the UAE, FANR inspects the activities of the licensee, the prime contractor, and vendors of safety-related items to verify the effective functioning of the licensee's Quality Assurance programme. In the UAE case, the applicable Korean technical code also requires the licensee or manufacturer to engage an authorised inspection agency to conduct technical conformity inspections for safety-related components.

The start of NPP construction instigated a shift in the regulatory bodies' workload away from review and assessment of licensing documents and increased the demand for field inspection. Acquisition of the necessary competencies as the nature of their work evolves is an ongoing challenge for the regulatory bodies.

Several regulatory bodies reported using external support for their inspection programme. For instance, in Bangladesh a team of external experts of the vendor country regulatory body assists the BAERA with inspection at the site during construction. In Belarus, personnel from Rostechnadzor act as consultants during complex inspections of the Belarusian NPP. TAEK signed a protocol with the Turkish Standards Institute which has experience in industrial inspections, while FANR in the UAE engaged external subject matter experts in advisory roles to augment its inspection resources.

All the regulatory bodies in the case studies exercise graded enforcement when violations are found with tools ranging from verbal and written notices, licence suspensions or revocation, and administrative or criminal penalties.[4]

3.5.11. Safeguards

3.5.11.1. The issues

Safeguards implementation requires effective infrastructure in the State, including a national legislative and regulatory system that provides for oversight and control of all nuclear material and nuclear-related activities (Paragraph 1.3 of [13]).

[4] See available peer review mission reports and national reports on the Convention on Nuclear Safety.

3.5.11.2. Points of Interest

What undertakings did each embarking country make regarding non-proliferation? How did each country make the necessary reinforcements in its safeguards capabilities?

3.5.11.3. Discussion

Four of five case study countries are signatories to the Non-Proliferation Treaty and have concluded comprehensive safeguards agreements with the IAEA. Three of the case study countries have additional protocols to their safeguards agreements in force.

The national regulatory bodies in the four countries with comprehensive safeguards agreements were made responsible, through the applicable laws, for administration of the state system of accounting for and control of nuclear material (SSAC).

The regulatory bodies discharged their responsibilities regarding the SSAC by enacting regulations for nuclear material accounting, regulating imports and exports of nuclear material and dual-use items, maintaining records systems and databases, conducting inspections of activities, and submitting the information reports required by the IAEA.

In the UAE, before embarking on the nuclear power programme, a Small Quantities Protocol (SQP) was in force. The SQP has been rescinded and a full scope safeguards regime has been implemented for the NPP. The other embarking countries had pre-existing safeguards systems to address existing nuclear materials and facilities which they enhanced to meet the requirements of the NPP.

Turkey and the UAE report that their licensing systems follow the '3S' approach. Reports and programmes related to safety, security and safeguards are submitted with the relevant license application for review by the regulatory body. Approval of the nuclear material accountancy and control system of the NPP is a pre-requisite for authorisation to bring nuclear material on the site.

Several countries (Belarus, Turkey, and UAE) have received IAEA State System of Accounting for and Control of Nuclear Material Advisory Service (ISSAS) to assist them in enhancing their SSAC to take account of the new nuclear power plants.

The State authority responsible for safeguards implementation in Pakistan is the Pakistan Atomic Energy Commission.

3.5.12. Security

3.5.12.1. The issues

The responsibility for nuclear security rests with each country. Its nuclear security regime, part of the country's overall security regime, comprises its legal and regulatory frameworks and administrative measures governing nuclear security, the organizations responsible for nuclear security, and the nuclear security measures implemented at the state level and the facility level. Establishing an effective national nuclear security infrastructure is a key prerequisite for any State wishing to embark on a nuclear power programme (Paragraph 2.1 of [10]).

Many elements or actions serve to enhance both safety and security simultaneously. In addition, synergies may be realized between the objectives of nuclear security and safeguards objectives

for protection of nuclear material. However, the interfaces between nuclear security and safety should be coordinated to avoid unintended consequences [19].

3.5.12.2. Points of Interest

What regulatory framework did each country establish for nuclear security? How did each country develop its security capabilities? Which organisations are involved? How are the interfaces between security, safety and safeguards managed?

3.5.12.3. Discussion

All case study countries are parties to the Convention on Physical Protection of Nuclear Materials (CPPNM) and all except Belarus are parties also to the Amendment to the CPPNM. In all cases the national regulatory body is empowered to regulate the nuclear security aspects inherent in nuclear facilities and activities. In all cases except Pakistan the regulatory bodies are responsible also for safety and safeguards, following a one-house '3S' approach, to facilitate coordination between these disciplines.

The regulatory bodies in most cases issue regulations for physical protection, review and assess nuclear security measures in licence applications, and inspect their licensees' nuclear security arrangements. For these purposes, the regulatory bodies cooperate with the security and intelligence authorities in their respective countries.

Several countries (Turkey, Belarus, Bangladesh and the UAE) report having hosted, or having the intention to host, peer review missions (IPPAS) to assist them in strengthening their nuclear security framework.

3.5.13. Other regulatory agencies with roles in the nuclear power programme

3.5.13.1. The issues

Where several authorities have responsibilities within the regulatory framework in relation to the nuclear power plant, the government should ensure that there is appropriate coordination of and liaison between the various authorities.

3.5.13.2. Points of Interest

What other authorities had responsibilities regarding the nuclear power plant in each case study country? How was coordination managed between the different authorities?

3.5.13.3. Discussion

In all countries, the nuclear regulatory body has the sole authority for licensing the nuclear power plant regarding nuclear safety, security and safeguards.

However, other authorities also have regulatory or supervisory roles in their own areas affecting the nuclear power plants. Topics common to the case studies that come under separate authorities include environmental impacts, emergency preparedness, and occupational health and safety.

The mechanisms employed for coordination between the nuclear regulatory body and other authorities include clear specification of responsibilities in the relevant legislation, formal

memoranda of understanding between agencies, and participation on joint steering committees and working groups.

For example, in Belarus, the legal framework assigns regulatory oversight of nuclear and radiation safety to MES but the laws also assign specific responsibilities to other ministries, including the Ministries of Health, Natural Resources and Environmental Protection, and Internal Affairs, and the State Security Committee. Recognizing the importance of collaboration during the construction, commissioning and future operation of the NPP, the Government has established an inter-ministerial commission, along with a working group led by MES, and multiple meetings with suppliers, the operator and the regulator.

In the UAE, the Nuclear Law gives FANR the sole responsibility for licensing the nuclear power plant but requires FANR to cooperate with, provide information to, and advise other authorities in areas of the environment, public and occupational health, emergency preparedness, physical protection and safeguards, water use and consumption of food, land use and planning, and safety in the transport of dangerous goods.

To fulfil this responsibility and to ensure seamless administration of the relevant requirements, FANR has established memoranda of understanding and other cooperative mechanisms with the competent authorities who play a role in the regulatory framework for the Barakah NPP.

In Turkey, the new nuclear law defines the interfaces and relations between different governmental organizations with regulatory power such as Ministry of Environment and Urbanization, Ministry of Transport and Infrastructure, Ministry of Health, Ministry of Interior, Disaster and Emergency Management Presidency and other ministries or governmental agencies.

3.5.14. Stakeholder involvement in regulatory processes

3.5.14.1. The issue

There is growing acceptance of the need for transparency and openness in matters relating to nuclear and radiation safety in order to build trust between the regulatory body and interested parties. Requirements for stakeholder communication by the regulatory body are embedded in several IAEA safety standards, including the Fundamental Safety Principles, which state:

"The regulatory body must:

(...)

- Set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes;

- Consult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process." (Paragraph 3.10 of [4]).

3.5.14.2. Points of Interest

What mechanisms have the regulatory bodies in the case studies set up to involve interested parties? Who are the stakeholders that the regulatory bodies engage with, and on what issues are they consulted and informed?

3.5.14.3. Discussion

In all case study countries, the regulatory bodies have adopted policies or are directed by law to inform and engage interested parties. The extent and depth of stakeholder engagement varies in practice, however.

All the regulatory bodies seek stakeholder input on draft regulations and guides before they are finalized. Yet the case study countries interpret the definition of who is recognized as a 'stakeholder' in this process. Some bodies (Gosatomnadzor and FANR) seek explicit public comment on draft documents, in addition to input from the regulated community and from government. Others reportedly consider their licensees and other government ministries as the main stakeholders and do not solicit public input.

Stakeholder participation in other aspects of the regulatory process appears relatively limited in the case studies. Gosatomnadzor perhaps leads the field with the introduction in 2019 of laws to create a basis for public hearings on licensing the operation of the Belarusian NPP. No other regulatory body in the case studies holds public hearings for licensing or other significant regulatory decisions.

The regulatory bodies in several countries (Bangladesh, Belarus and UAE) report that they maintain active programmes of public and stakeholder communication. Through these programmes, they typically provide information to various audiences about the regulatory body and the activities that it regulates, including information on licensing decisions, inspections and other significant developments. Common channels employed for such communication include dedicated web sites, the print and broadcast media, annual reports and publications, and informational meetings.

3.5.15. International cooperation

3.5.15.1. The issue

The organizations and persons involved in the utilization of nuclear energy for peaceful purposes are interdependent in that the performance of one may have implications for all. A serious nuclear incident is likely to be of major significance around the world. Recognition of this mutual dependence in the global regime has led to a number of international legal instruments, mechanisms and arrangements that are intended to enhance safety, security and non-proliferation in all States (Requirements 14 and 15 of [5]).

3.5.15.2. Points of Interest

How have the regulatory bodies in the case studies supported their country's international obligations? What cooperative activities do they participate in?

3.5.15.3. Discussion

All the case study countries contribute to international cooperation in the areas of nuclear safety, security and safeguards.

All the regulatory bodies play active roles in supporting international conventions, such as the Convention on Nuclear Safety, by acting as the national points of contact and participating in review meetings.

Several regulators also contribute to the work of the IAEA through membership of the safety and security standards committees, other advisory groups, and the international reporting system for operating experience. PNRA and FANR report specifically on their work in this area.

All the case study countries have hosted a wide range of international peer review missions regarding their nuclear power programmes and several of them have made the results publicly available through the IAEA web site to enable sharing of insights.

All case study countries have established bilateral relationships with counterpart agencies in other countries. The regulatory body of the vendor country is one element common to all, as in the relationships formed by BAERA, Gosatomnadzor and TAEK with the Rostechnadzor in Russia, PNRA with the authorities in China, and FANR with the Korean regulatory body. The bilateral relationships also embrace countries with mature nuclear power programmes as sources of knowledge and support, for example the relationship between the BAERA and Atomic Energy Regulatory Board (AERB) in India. Several case study countries mention the Regulatory Cooperation Forum hosted by the IAEA as a valuable source of support.

International cooperation requires effort by the parties to manage the process. For a new entrant regulator, this effort can be substantial. Several regulatory bodies have established departments for international cooperation. PNRA for instance has a well-established Directorate of International Cooperation responsible for liaison with the IAEA and international organizations, TSOs, and regulatory bodies for training, support and regulatory affairs.

3.6. CONCLUSIONS FROM THE TECHNICAL MEETING

A Technical Meeting entitled ‘Case Studies: Experiences of Member States in Building a Regulatory Framework for the Oversight of New Nuclear Power Plants’ was held in Vienna from 18-21 June 2019. The meeting was jointly organized by the Department of Nuclear Energy and the Department of Nuclear Safety and Security of the IAEA.

The following observations were made based on the presentations and discussion:

— Almost all participating countries had enacted or drafted a comprehensive nuclear law and established a national regulatory body to address safety, security and safeguards.

— Most participating countries conducted self-assessments to evaluate the status of their infrastructure and hosted different IAEA review and advisory services to help to develop regulatory framework and infrastructure for safety, security and safeguards.

— Utilization of external technical support is envisaged by all participants. Some countries have developed or initiated development of a national TSO in the regulatory body.

— The role of support from the regulatory body of the vendor country was emphasized by many participants.

— International cooperation including bilateral and multilateral arrangements was reported to be an effective way to support the development of a national regulatory framework.

Based on the presentations and discussions, below are summarized the main challenges reported during the meeting:

— The need to align the development of the national legal framework and regulatory infrastructure with the nuclear power project — this aspect may put significant time pressures on the NEPIO and/or the new regulatory body;

— The need for governmental coordination and support for development of the regulatory framework;

— Independence of the regulatory body from organisations engaged in promoting the use of nuclear energy;

— Adequate funding of the regulatory body;

— Human resources development and acquisition of the needed technical and regulatory competencies;

— Restrictions in rules for recruitment and employment of government personnel;

— Retention of qualified staff in the regulatory body;

— Development of detailed processes and procedures in the management system for implementation of the core regulatory functions;

— Contracting with external support organisations;

— Understanding and applying the regulations, standards and practices of the NPP vendor country;

— The existence of multiple NPP technologies, to which different vendor country standards apply;

— Support from the regulatory body in the vendor country of origin

— Language differences and the need for translation of vendor country documents into the language used by the recipient country.

APPENDIX I.
CASE STUDY: BANGLADESH

I.1. NUCLEAR POWER PROGRAMME

The power generation strategy for 2010-2030 was adopted in 2010 under the Power Sector Master Plan 2010 (PSMP 2010). The generation plan is based on the target of achieving 8% average GDP growth and the Government's target to ensure that electricity reaches every household by 2021. Based on these targets and peak load demand forecast, the PSMP 2010 set installed generation capacity targets of 23,000 MW by 2020 (end of Seventh Five years Plan); 24,000 MW by 2021; and 40,000 MW by 2030, of which nuclear power will contribute up to 10% of total generation.

Bangladesh considered implementation of nuclear power project in the early 1960s. Accordingly, Rooppur Nuclear Power Plant project site was selected in 1963 by considering various criteria acceptable at the international level and local conditions such as its geographical location with respect to electrical load distribution of the west zone. The feasibilities in 1960s and in the 1977-78 and 1988 - 89 had identified, affirmed and reaffirmed the technical, economic and financial viability of the Rooppur NPP Project, but the country did not go on to build the nuclear plant. Earlier the project could not be implemented because of resource constraints. It is worth mentioning that financing has been identified as one of the roadblocks and challenges in implementation of the Rooppur NPP. The introduction of nuclear power became a reality for Bangladesh, and the implementation of the NPP project became an Election Pledge by all political parties in 2008. The government has taken practical steps for implementation of the project since 2009. A decision for immediate implementation of the NPP was taken by the national parliament in 2010. A significant number of progresses were made for the implementation of nuclear power program in the country with the partnership of Russian Federation.

The Bangladesh has been a Member State of the IAEA since 1972, and Bangladesh also participated in various Technical Cooperation projects with the IAEA. Since 2008, a significant number of projects has been underway to support the development of the NPP program. Bangladesh has established its Permanent Mission to the IAEA for effective cooperation with IAEA.

Bangladesh has been developing the National Nuclear Infrastructure in the country in partnership with the IAEA and Vendor from 2009 to 2018. For the development of the National Nuclear Infrastructure in the country and achievement of the IAEA milestone goal, Bangladesh has established a NEPIO (its structure is illustrated in Figure 2) and has made significant progress since then.

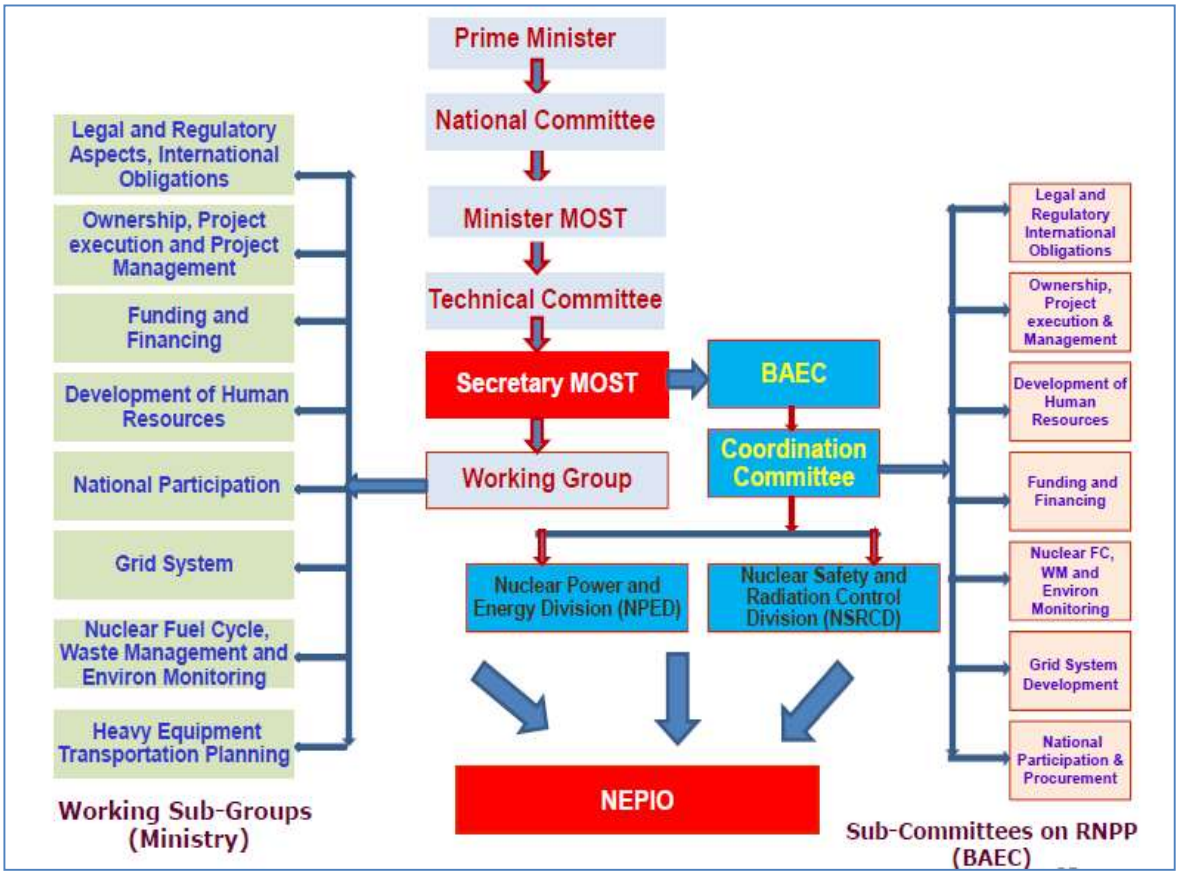


FIG. 2. Organizational structure of Bangladesh Nuclear Power Programme.

Bangladesh has taken all necessary steps required for developing the national nuclear power infrastructure based on the widely used reference document, the 'Milestones in the Development of a National Infrastructure for Nuclear Power (IAEA Nuclear Energy Series No. NG-G-3.1). Accordingly, the whole nuclear infrastructure development activities have been divided into three progressive phases, where the underlying 19 infrastructure issues were addressed in each phase.

In June 2016, the BAERA issued the Siting Licence for the Rooppur NPP, and in November 2017 the Design and Construction Licence for the Rooppur NPP Unit 1, which authorized the BAEC to construct the safety-related structures, systems and components for Unit 1 at the Rooppur site. Subsequently, the BAERA issued the Design and Construction Licence for the Rooppur NPP Unit 2 in July 2018.

Timeline for implementation of Bangladesh nuclear power programme is illustrated in Figure 3.

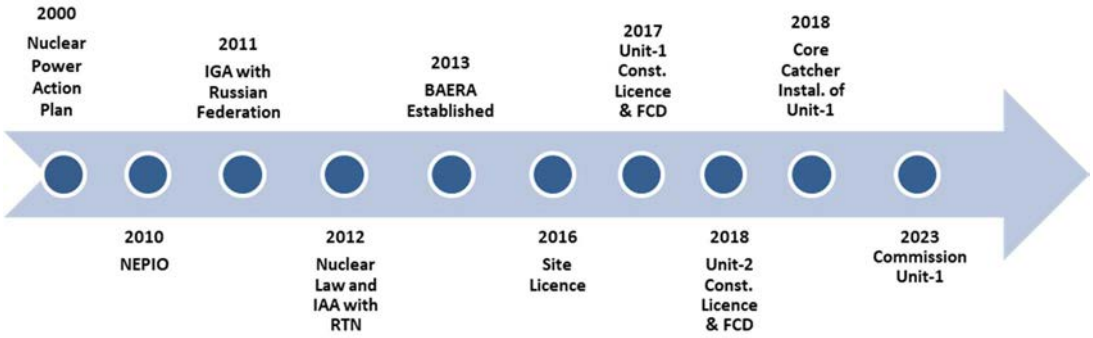


FIG. 3. Timeline of Bangladesh Nuclear Power Programme.

I.2. STATUS OF THE REGULATORY BODY BEFORE THE COUNTRY HAS MADE DECISION ON THE CURRENT NUCLEAR POWER PROGRAM

I.2.1. Pre-existing legal framework

Legislative framework in Bangladesh consists of laws, rules, regulations, guides, codes, and standards; this hierarchical pyramid forms the legal basis for control as given in Figure 4. This legislative and regulatory framework of Bangladesh ensures compliance with international conventions and treaties, and the IAEA safety requirements with almost all the aspects of nuclear safety and security and radiation protection.

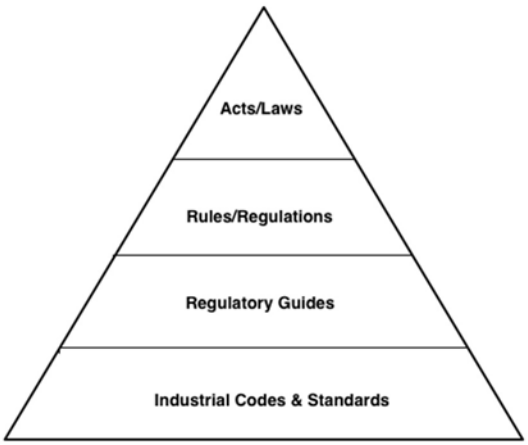


FIG. 4. Hierarchy of regulatory instruments in Bangladesh.

Bangladesh has long since been using atomic energy and related technology in different fields for socio-economic development of the country, and their uses are increasing steadily. The nuclear regulatory body under the Bangladesh Atomic Energy Commission (BAEC) was regulating the nuclear safety and radiation control activities with regard to all radiation sources and materials, practices and nuclear installations in the country within the framework of Nuclear Safety and Radiation Control Act 1993 and Nuclear Safety and Radiation Control Rules-1997. The NSRC Act (No.21) was promulgated on July 22, 1993 to provide for ensuring nuclear

safety and radiation control in the country. The Act confers all necessary powers to the BAEC to regulate uses of atomic energy, radiation practices and management of radioactive waste. The Rules are quite comprehensive in terms of the control of radiation sources and radioactive materials and regulatory supervision of nuclear and radiological facilities including other radiation practices in the country. The regulatory functions and responsibilities are stipulated in the above-mentioned Rules, and the Rules assigned Nuclear Safety and Radiation Control Division of the BAEC, to implement these functions.

However, at that time, the NSRC Act/93 had no provision to create a separate regulatory body rather than the promotional body to oversee the nuclear power program in the country. Therefore, some amendments and expansion were required to implement the act, specifically in terms of the Nuclear Power Program, which was addressed in the Bangladesh Nuclear Power Action Plan (2000).

I.2.2. Organization and roles and responsibilities of the regulatory body

Bangladesh is fully committed to peaceful uses of atomic energy. As such, Bangladesh has signed a number of international and bilateral agreements, protocols and conventions. The Bangladesh Atomic Energy Commission (BAEC), a statutory body, was formed by the Presidential Order No. 15/1973. The Nuclear Safety & Radiation Control Act of 1993 was the primary legislation in Bangladesh. Additionally, there was a Governmental Order HM/hospital-1/ap-2/2001 issued on 01/12/2001, which transferred the control over x-ray machines from the Ministry of Health and Family Welfare to the BAEC. On the contrary, NSRC Act/1993 confers necessary power to the BAEC to conduct regulatory activities in the country. Based on Section 3 and 16 of the Act, the BAEC was the Regulatory Body and had the power to make necessary rules, formulate policies and implement the regulatory control. The Chairman of BAEC was the head of the regulatory body, and the regulatory body was not fully independent before the launching of the country's nuclear power program. Nuclear Safety and Radiation Control Division (NSRCD) was responsible within the BAEC for facilitating implementation of the provisions of the Rules-1997. It worked as the secretariat for the regulatory body and performed all regulatory activities under the NSRC Act & Rules. The regulatory function was exercised by the NSRCD, which was an integral part of the BAEC. The NSRCD carried out the regulatory activities concerning nuclear and radiation safety. It was also responsible for the coordination and support of research and development activities in nuclear field.

The BAEC was the decision-making body regarding licences and some of the permits for nuclear and radiological facilities in the country until 2012. The BAEC consist of one Chairman and four Members in its organisational structure. One of its Members was responsible to oversee the NSRCD. However, Director of the NSRCD was the head of the division, and three technical sections supported the division.

— **Radiation Control Section** was mainly responsible for radiological facilities;

— **Nuclear Safety Section** was mainly responsible for nuclear facilities;

— **Training & Documentation Section** was mainly responsible for training and documentation.

Bangladesh is a State party to the Treaty on the Non-Proliferation of Nuclear Weapons, has a Comprehensive Safeguards Agreement (CSA) and an Additional Protocol in force with the IAEA and has established state system of accountancy for and control of nuclear materials as required under the CSA. Bangladesh is also a party to the Convention on the Physical Protection

of Nuclear Materials. As per the NSRC Act-1993, the NSRCD of the BAEC was responsible to oversee the SSAC in the country before the new nuclear law was enacted in the country. As per the NSRC Act-1993 and NSRC Rules-1997, the NSRCD of the BAEC was also responsible to oversee the security of nuclear and radiological facilities in the country.

I.2.3. Regulations in place

The following rules and guidance documents issued to support its regulatory functions, namely:

— The Nuclear Safety and Radiation Control Rules-1997.

The NSRC Rules were notified in the Bangladesh Gazette on September 18, 1997. The rules are based on the BSS and cover most of the principal elements necessary for an effective nuclear safety and radiation protection regime. Some regulations were drafted in the light of the IAEA's Basic Safety Standards, Transport Regulation TS-R-1 (ST-1 Revised), and IAEA TECDOC-1067, Organization and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of radiation sources.

The following regulatory guides developed and published by NSRCD

— Regulatory guide on radiation protection in Nuclear Medicine, 2002.

— Regulatory guide on radiation protection in Diagnostic x-ray, 2002.

— Regulatory guide on radiation protection in Industrial practices, 2002.

I.3. DEVELOPMENT OF THE REGULATORY FRAMEWORK FOR THE OVERSIGHT OF THE NUCLEAR POWER PROGRAM

The former regulatory framework of Bangladesh under the NSRC Act guaranteed proper consideration for health, safety, security and protection of the people and environment for the nuclear and ionizing radiation-related activities in the country up to the present time.

However, the Government of Bangladesh signed the Convention on Nuclear Safety in 1996 (entry into force: 24 October 1996). According to this Convention, each contracting party is required to establish an effective regulatory framework independent from the promotional aspects of the nuclear energy. Further, according to the recommendations of IAEA Nuclear Energy Series No. NG-G-3.1 and IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) [5], it was necessary to establish an effective nuclear regulatory framework to implement the Nuclear Power program in Bangladesh.

Bangladesh has recognized the national commitments and obligations associated with the introduction of nuclear power and has taken necessary measures for strengthening the nuclear regulatory framework to support successful implementation of the first Nuclear Power Plant Program. In 2012 the Government promulgated a new act named Bangladesh Atomic Energy Regulatory Act-2012 to address the shortcomings of the old NSRC Act-1993. This new act, which was developed based on the IAEA Handbook on Nuclear Law, establishes an independent regulatory body in Bangladesh to ensure the nuclear and radiation safety in a superior way to fulfil requirements set by the IAEA as well as other international instruments.

NSRC Rules of 1997 is the second nuclear regulatory instrument enforced to implement the provisions of the BAER Act of 2012. This requirement was ensured through the process of

issuance of license, permit, inspection, monitoring, etc. The BAER Act of 2012 is related to 3S (Safety, Security and Safeguard) including radiation protection and other aspects.

In addition to the BAER Act-2012, the owner/operator of any nuclear installations must abide by other relevant laws in the country, for instance: the Environmental Conservation Act-1995, which regulates environmental impacts, and the Disaster Management Act-2012 which regulates the role of different organizations and management scheme in case of natural and manmade disasters that encompass nuclear and radiological accidents, etc.

I.3.1. Planning for the establishment of the regulatory framework

The government is responsible for setting national policies and strategies with respect to nuclear safety and radiation control and for providing the regulatory framework required to implement the policies and strategies. The achievement and maintenance of a high level of safety in the site evaluation, design, construction, commissioning, operation, decommissioning, and release from regulatory control of nuclear installations, requires a sound legal and governmental infrastructure, including a regulatory body with well-defined responsibilities and functions. Granting of licenses for the nuclear installations is among the principal functions of such regulatory body. Therefore, specific guidance dealing with the licensing process for nuclear installations needs to be established whether this guidance is included in a broader safety guide or in a stand-alone guide which may be later incorporated into a new structure. The government attaches high priority to the introduction of nuclear power considering its role in improving power generation as a part of its policy on energy security sustainability, reliability, environmental friendliness and other economic advantages. Bangladesh is committed to use atomic energy solely for peaceful purposes for national development. Accordingly, it has signed different international agreements, protocols, etc. prevailing in the nuclear non-proliferation regime. Bangladesh, therefore, can assure that any new nuclear power plants built in Bangladesh will meet the highest standards for health, safety, security and environmental protection. In respect to the national policy and strategy, the Government has established a regulatory framework for proper implementation of the national policy and strategy for Nuclear Safety & Radiation Control activities in the country.

Provisions of the BAER Act-2012 cover nuclear safety, security and safeguards as well as civil liability for nuclear damage in the event of an accident. The objective of the Act is to establish an effective regulatory authority in the country, to ensure the protection of human life, health and living conditions of both present and future generations, the environment and property against the harmful effects of ionizing radiation, and to ensure safety and security of nuclear material and radiation sources, transport safety of nuclear and radioactive materials, radioactive waste and spent fuel management. This Act extends to ensure security and safeguard of nuclear material and radiation sources, civil liability for nuclear damage in any nuclear accident and enables Bangladesh to meet its international obligations on the peaceful uses of atomic energy.

I.3.2. International commitments for safety, security, non-proliferation and nuclear liability

Bangladesh is a contracting party to the following international legal instruments for safe, secure and peaceful use of nuclear energy (see Table 5).

TABLE 5. LIST OF INTERNATIONAL LEGAL INSTRUMENTS TO WHICH BANGLADESH IS A CONTRACTING PARTY IN THE AREAS OF SAFETY, SECURITY AND SAFEGUARDS

International Legal Instruments	**Entry into Force in Bangladesh**
1. Treaty on the Non-Proliferation of Nuclear Weapons	17 September 1979
2. Revised Supplementary Agreement Concerning the Provision of Technical Assistance by the IAEA (RSA)	31 December 1979
3. Application of Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons	11 June 1982
4. Convention on Early Notification of a Nuclear Accident	7 February 1988
5. Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency	7 February 1988
6. Convention on Nuclear Safety	24 October 1996
7. Protocol Additional to the Agreement between the People's Republic of Bangladesh and the IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons	30 March 2001
8. Convention on Physical Protection of Nuclear Materials	10 June 2005
9. Amended Convention on Physical Protection of Nuclear Materials	17 July 2017

Under the provisions of the Convention on Nuclear Safety, BAERA (the competent authority):

- submitted National Reports on the safety measures adopted by the country under the terms of the Conventions to the Review Meetings;
- attended Review Meetings; and
- participated in the country group meetings and in the exchange of questions and responses for clarification of the National Reports.

I.4. DEVELOPMENT OF REGULATORY BODY(S)

Introduction of a nuclear power program requires establishing a national legal and regulatory framework for ensuring nuclear safety and security at different phases of the program. Realizing the situation/deficiency of the previous regulatory regime, the government has taken necessary measures for strengthening nuclear regulatory infrastructure for successful implementation of the Nuclear Power Plant Project. Bangladesh has comprehensively recognized the national

commitments and obligations associated with the introduction of nuclear power. Bangladesh has taken all necessary steps required for developing national nuclear regulatory infrastructure based on the widely used referring IAEA publication, the 'Milestones in the Development of a National Infrastructure for Nuclear Power'. Significant progress has been made in the development of national nuclear power infrastructure followed by the Integrated Nuclear Infrastructure Review (INIR) mission to Bangladesh in 2011 and follow-up mission in 2016. Bangladesh promulgated a nuclear law on establishing a regulatory authority in 2012. The Act was passed by the parliament and signed by the President on June 19th, 2012. Based on this Act, the Bangladesh Atomic Energy Regulatory Authority was established (BAERA) on February 12th, 2013 that suggests a dynamic organizational structure suitable for the age having adequate independence to meet the International/National obligations for ensuring nuclear safety and radiation control in the country and to control and supervise all matters pertaining to the safety of nuclear installations.

I.4.1. Roles and responsibilities of regulatory body(s)

The BAERA is the competent regulatory authority on nuclear safety and radiation protection matters in Bangladesh, and its functions are defined in the new Act19/2012. All regulatory functions described in the BAER Act are in line with the GSR Part-1. According to the new nuclear law, the main role and responsibility of the Authority (BAERA) is to perform the regulatory control activities in the issues and areas of safety, security and safeguard of nuclear and radiological facilities. the major responsibilities and functions of the BAERA are as follows:

- Issuing Guides, Codes, and Standards;
- Notification, Review and Assessment, Authorization, Inspection, and Enforcement;
- Inventory of radioactive and nuclear materials;
- Establishment and maintenance of a state system of accounting for and control of nuclear materials (SSAC);
- Ensure safe transport and storage of radioactive sources;
- Interaction and co-ordination with other governmental or non-governmental bodies;
- Interaction with regulatory bodies of other countries and with international organizations;
- Establish and promote activities related to the international agreements, protocols and convention (in which Bangladesh is a party) on safeguards, physical protection including illicit trafficking of nuclear and radioactive materials, nuclear safety, radiation protection and radiological emergency;
- Establishment of a public participation system through seminars, workshops, electronic and print media and Internet, etc;
- Conduct of research for regulatory purposes; and
- Human resources development and training programs for its employees.

I.4.2. Organizational establishment and development

According to the Act/2012, the regulatory authority consists of one Chairman and four Members. They are appointed by the Government for a fixed tenure of three years and are fulltime officials of the Authority. The Chairman is the Chief Executive of the Authority. The Chairman and the Members exercise powers and perform functions as prescribed or assigned to them under the BAER Act and the Rules. In addition, the Government appoints a full time Financial Advisor and a Secretary to the Authority to cooperate and assist in the activities of the Authority. At present, the BAERA is engaged in issuing licences for such nuclear facilities as a research reactor, radioactive waste facility, the Rooppur NPP, radiological facilities and medical practices. In order to issue licences for different stages of the Rooppur NPP life cycle, the BAERA needs to be strengthened with skilled manpower like scientists, engineers and other categories of staff. Currently, BAERA has 30 technical staff, 35 supporting staff and 20 outsourced supporting staff, but it is not enough for the full fledge operation. So, it is needed to extend the number of officers/staff to 360 in three phases by the end of 2025 in order to perform the regulatory activities properly.

At present, BAERA has its office located in Dhaka and a site office at the Nuclear Power Plant construction site. To assist the Authority in its regulatory functions, presently BAERA comprises four technical divisions and two support divisions. The present organisation structure of BAERA is shown in Figure 5.

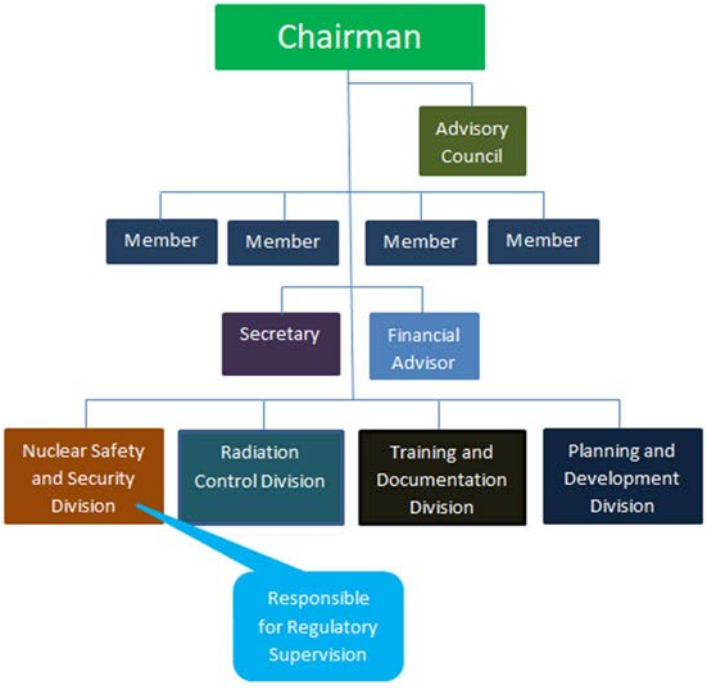


FIG. 5. Organizational structure of BAERA.

In addition, BAERA has formed an advisory council with adequate experts from different disciplines and several expert committees to support the Authority to carry out its responsibilities properly.

I.4.3. Prioritization and development of regulations and guides

The BAERA's approach to developing national regulations under specific article of the Act/2012 conforms to the IAEA Safety Standards, Nuclear Security Series and other internationally recognized practices. The BAERA is empowered to develop and submit regulatory documents under its framework guidance to the MOST. Final approval of regulations is done by the MOST after vetting from the Ministry of Law, Justice and Parliamentary Affairs. The BAERA issued the following regulation and guide after the establishment of its regulatory framework:

Regulations and Guides:

— Bangladesh Atomic Energy Regulatory Staff Service Regulation, 2017.

— Regulatory Guidance on Site Evaluation for the Safety of Nuclear Power Plant, 2015.

There are some provisions existing in the NSRC Rules-97.

— The NSRC Rules-97 states that in order to obtain a licence, each person and each licensee shall follow the applicable standards, codes and guides given in specific schedule in the rules.

— In case it has not been specifically mentioned in the Schedule of Rules, the Authority, generally, shall follow the IAEA standards, requirements & guides.

— Other standards, where the IAEA standards and guides will be found in the judgement of the authority to be inadequate, standards, codes and guides published by any national regulatory or other internationally accepted bodies may be adopted as deemed appropriate by it.

— In that case in Bangladesh, the BAERA recognized the relevant set of regulations, codes and standards of the vendor country regulator and used for setup its regulatory requirements for the licensee under the provision stipulated in the BAERA' second legal instrument Rules-97.

A plan has been developed for drafting the new regulation and guide related to NPP with the assistance of vendor regulatory body through GFC. BAERA drafted some regulations by using its own internal resources and will be reviewed by the external expert panel.

I.4.4. Implementation of licensing process for different stages

I.4.4.1. *Different stages of licensing:*

Authorization procedure for nuclear installation(s) in Bangladesh consists of the following stages: Site License; Design and Construction License; Operation License; Decommissioning License; and Release from Regulatory Control (see Figure 6). However, there is a provision, each step of the licensing process may be divided into several sub-steps or possibly combined as appropriate to facilitate the regulatory process. Combining authorizations or licences (e.g. for Design and Construction) may also give more predictability to the process for the licensee.

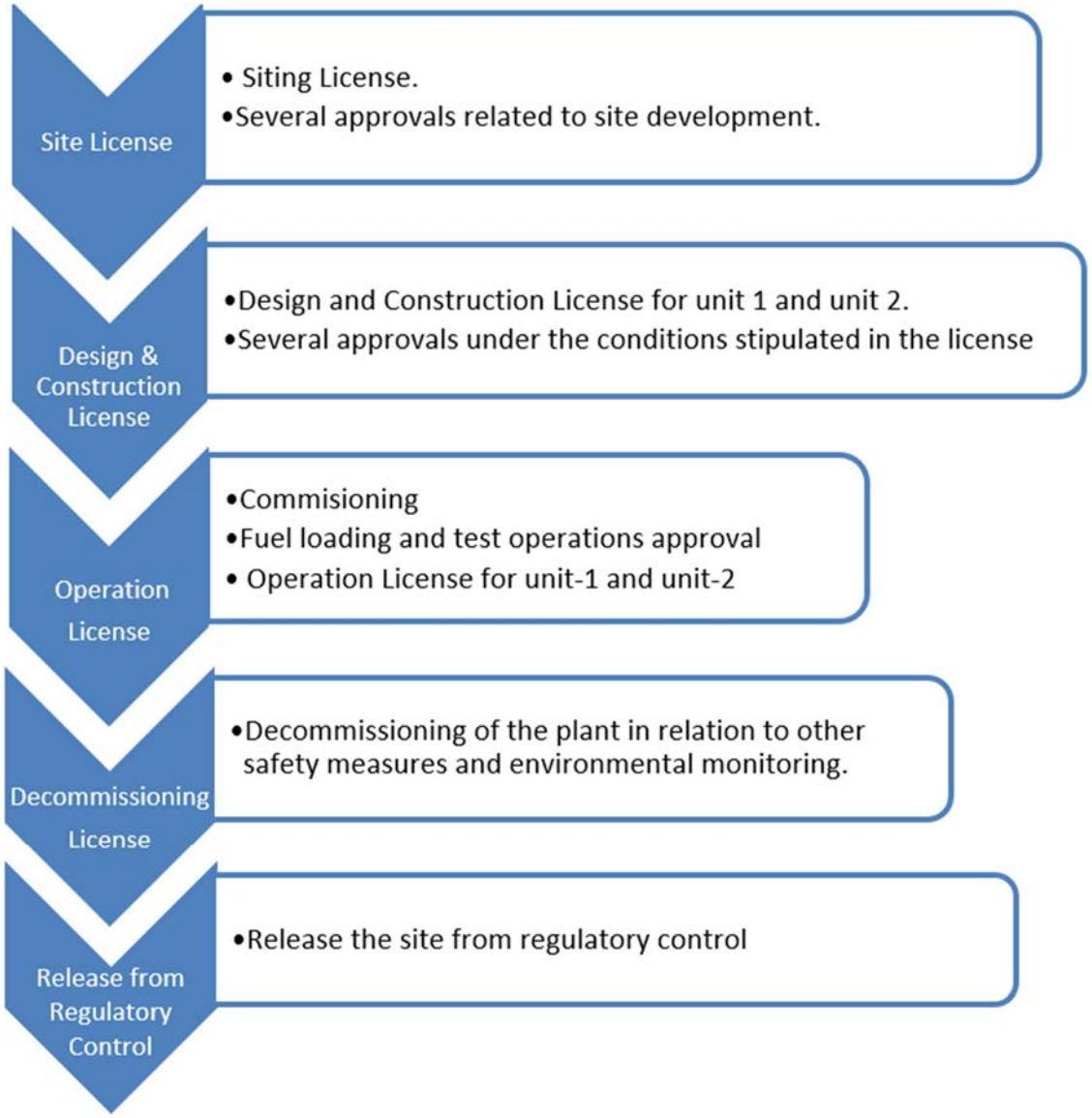


FIG. 6. Nuclear power plant licensing stages in Bangladesh.

I.4.5. Development and Implementation of inspection program

Inspections are being carried out according to technical guidance documents and a system of monitoring is in place to ensure that inspection findings are communicated to the users in a timely and clear manner. In accordance with the Act19/2012, BAERA is the competent authority in the country to exercise necessary powers and take appropriate measures and actions stipulated in the Act. BAERA is responsible to facilitate the implementation and enforcement of the various provisions of the Act and the pertinent Rules.

I.5. CHALLENGES FACED AND THE SOLUTIONS APPLIED

— Development of an effective review and assessment methodology for NPP related documents based on the broad experience of the vendor country and other technology users;

— Acceptance of ‘Reference Plant’ design with site specific modification-→ e.g. strictly following local site criteria;

— Field-specific highly qualified technical manpower to review the PSAR and to conduct inspection during the construction phase;

— Development of NPP related regulatory documents to setup the regulatory requirements;

— Development of a sustainable system for HRD plan and awareness;

— Development of sustainable communication system with other international organizations and regulatory bodies to strengthen its regulatory framework and exchange information in respect to global nuclear safety and security regime;

— Widening Technical Support community including local scientists and experts, neighbour country TSOs and vendor-country TSOs; and

— Openness and transparency to the international community in achieving nuclear safety and confidence of the safe technology implementation.

I.6. PREPARATION FOR FUTURE PHASES

The Integrated Nuclear Infrastructure Review (INIR) is a holistic peer review to assist MSs in assessing the status of their national infrastructure including legislative and regulatory framework for introducing nuclear power program. The INIR mission (for phase 1 & 2) was conducted by the IAEA during 9-11 November 2011 and its follow-up mission was conducted in May 2016. The mission provided the gaps of the regulatory body and national nuclear infrastructure. Based on the gaps an Integrated Work Plan (IWP) for the period 2012-2019 was developed to close all the gaps. This IWP enabled Bangladesh to develop a holistic approach to implementing the IAEA guideline as well as cooperating with national stakeholders and other bilateral partners towards the development of national nuclear power program. BAERA has invited an Integrated Regulatory Review Service (IRRS) mission at the beginning of November 2020 to review the legal and regulatory infrastructure for nuclear and radiation safety in Bangladesh under the IRRS process and to facilitate the enhancement of safety by providing with an objective evaluation of BAERA’s regulatory practices with respect to IAEA safety standards for possible improvements. Preparations including staff training have been taken for the upcoming IRRS and a systematic plan has been developed for future missions/services before the operation phase of the NPP. Conducting the missions/services according to the specific guidelines represents extensive work for the regulatory body. The BAERA has continued to develop its regulatory framework with appropriate knowledge, capabilities and skilled staff to effectively discharge their assigned duties. The BAERA staff must commit to an appropriate level of knowledge to be achieved through formal education, work experience and professional training to handling the licensing, approval and inspection processes during the commissioning and operational phases of NPP with the assistance of the vendor regulatory body.

I.7. SUSTAINABILITY OF THE REGULATORY FRAMEWORK

The Bangladesh regulatory framework should be considered sustainable as it already supports consistent core regulatory processes and activities, while at the same time focusing on the

national program of long-term regulatory framework development, including constant external technical and scientific support.

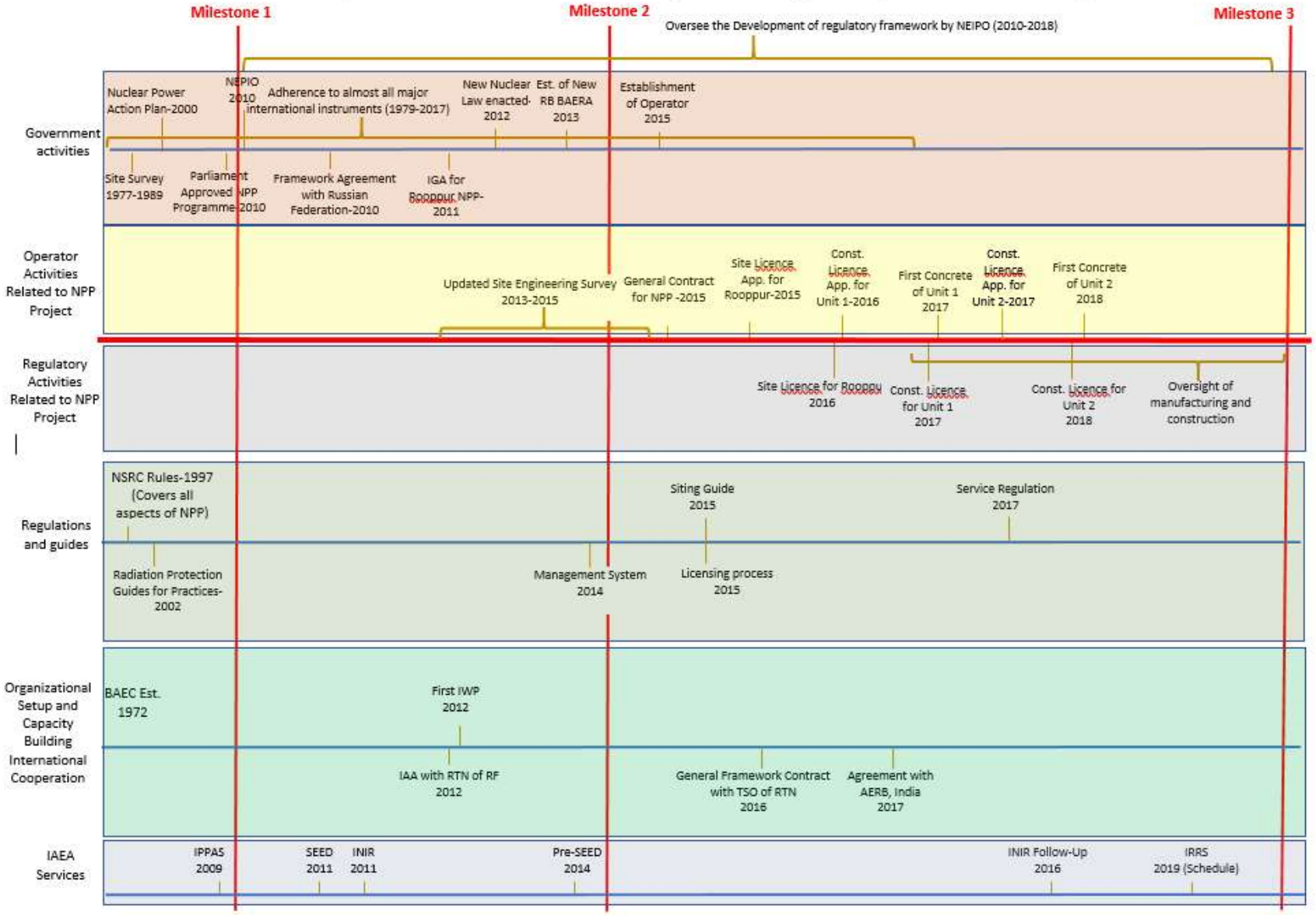
The Bangladesh regulatory framework is under the direct patronage of the Government. The Government is committed to the sustainable regulatory framework development and provides the necessary resources for the regulatory activities.

I.8. LESSONS LEARNED

The main lessons learned are:

- the newcomer country regulatory authority should be reliably supported by the vendor country regulatory authority to share its technology-specific regulatory experience, knowledge and practices;
- broad international cooperation is a huge benefit to achieve a sustainable development of the newcomer country regulatory framework; and
- positive public acceptance of the national nuclear program can be achieved by intensive involvement of the local scientific organisations and communities and general public.

Timelines for Key Activities to Establish and Implement Regulatory Framework - Bangladesh Case



APPENDIX II.
CASE STUDY: BELARUS

II.1. NUCLEAR POWER PROGRAMME

In March 2011, in Minsk (Republic of Belarus), the Agreement was signed between the governments of two countries: the Government of the Russian Federation and the Government of the Republic of Belarus for cooperation in the NPP construction in the territory of the Republic of Belarus. The Agreement stipulates turnkey construction of the Belarusian NPP to be performed by the Russian party. The general contractor for construction is 'Atomstroyexport', (ASE), and the customer and operating organization is 'Belarusian NPP'. Belarusian NPP will consist of two AES-2006 design VVER units with total capacity of up to 2400 (2x1200) MW.[5] This design was selected because it was a Generation 3+ NPP with the following design features: [5]

— a new reactor design with additional safety systems: passive heat removal system; passive filtration system of leakage to the intershell space; double protective enclosure vessel; trap for molten corium in case of a beyond design basis accident;

— maximum implementation of the defence-in-depth principle: setting up barriers to prevent ionizing radiation and radioactive substances discharge into the atmosphere, and the system of technical and organizational measures to protect the barriers, as well as preservation of their efficiency in the course of direct protection of the population;

— AES-2006 design includes fuel matrix, fuel claddings, reactor coolant boundary; sealed enclosure of localization safety systems.

AES-2006 design is also a basis for the Leningrad NPP-2 in operation in Leningrad region of the Russian Federation. The design development included comparison of basic specifications and parameters of an NPP unit with VVER-1200 and the data from the reference NPP with VVER-1000 (V-428) and from foreign NPPs.[5]

According to the General Contract for construction of the Belarusian NPP between 'Belarusian NPP' (Republic of Belarus) and ASE (Russian Federation), the general contractor will perform all necessary works, including survey works, develop detailed design documentation, provides for construction, installation and commissioning works, supply equipment, as well as carry out any other works provided by the contract for two-unit NPP construction and commissioning in the territory of the Republic of Belarus at full responsibility of the General Contractor (turnkey construction) at the industrial site of the NPP. [5]

In August 2013 the license for erecting the foundation of buildings and structures (first part of construction license) for the unit No. 1 of the Belarusian NPP was issued. [5]

Then, in November 2013, the Decree of the President of the Republic of Belarus of November 2, 2013 No.499 was signed, and the construction on the site of the unit No. 1 was started. A full construction license for unit No. 1 authorizing the construction of all buildings and structures as well as the installation of the equipment was issued in April 2014.[5]

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[5] National Report of Belarus to 7th Review Meeting of Convention on Nuclear Safety, 2016.

Regarding Unit 2, in February 2014 the operating organization obtained a part of the license for the right to erect foundation of buildings and structures of the unit No. 2 of the Belarusian NPP. In June 2014 the construction on the site of the unit No. 2 was started. In December 2014 the license for full scope of construction activities was issued for unit No. 2. [5]

Power unit No. 1 of the Belarusian NPP is scheduled for commissioning in 2020, while commissioning of unit No. 2 is planned for 2021.

II.2. STATUS OF REGULATORY BODY BEFORE THE COUNTRY MADE THE DECISION ON THE CURRENT NUCLEAR POWER PROGRAMME

II.2.1. Pre-existing legal framework

In the early stages of the development of the legislative framework in the field of nuclear and radiation safety in the Republic of Belarus, international treaties and sanitary norms and rules of the country were used. An important milestone in the qualitative development of the legislative framework was the adoption in 1998 of the Law on Radiation Safety. With the adoption of the latter, an accounting and control system for ionizing radiation sources was established. In the same period, the Republic of Belarus joined the Convention on Nuclear Safety (1999) and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (2003).

In 2004, the Decree of the President of the Republic of Belarus on licensing of certain types of activities was adopted, which also defined the requirements for licensing activities in the field of nuclear and radiation safety. Later on, the described legislative framework has been continuously improved in line with the requirements of the IAEA and the best international practices.

II.2.1.1. History and development prospects

In 1990-1992 to increase the effectiveness of state supervision over the activities of nuclear- and radiation-hazardous facilities and regulation of nuclear and radiation safety, the Interregional Nuclear and Radiation Safety Inspectorate was established in the State Committee of Belarusian Soviet Socialist Republic to supervise the safe conduct of work in industry and atomic energy (BSSR Gospromatomnadzor). In 1994 BSSR Gospromatomnadzor became a part of the Ministry for Emergency Situations. Table 6 shows the list of regulations in place at the beginning of the nuclear power programme of Belarus.

TABLE 6. REGULATIONS IN PLACE AT THE BEGINNING OF THE NUCLEAR POWER PROGRAMME

1. Law of the Republic of Belarus of January 5, 1998 No. 122-3 'On the radiation safety of the population' (as amended on January 4, 2014)
2. Decree of the President of the Republic of Belarus of December 29, 2006 No. 756 'On some issues of the Ministry for Emergency Situations' (as amended on December 30, 2016 No. 506)
3. Resolution of the Council of Ministers of the Republic of Belarus of July 21, 2003 No. 29 'On the approval of the Instruction on the identification of objects representing increased technological and environmental danger conditionally vulnerable to sabotage' (as amended on 04.10.2007)
4. Resolution of the Ministry for Emergency Situations, Ministry of Health of the Republic of Belarus of August 31, 2006 No. 41/67 'On approval of dose rate limits for making decisions on protective measures during radiation accidents'
5. Resolution of the Ministry for Emergency Situations of the Republic of Belarus, Ministry of Health the Republic of Belarus of October 30, 2006 No. 94/57 'On approval of the Instruction on the procedure for the destruction of property containing radioactive elements, seized, arrested or turned into state revenue'
6. Nuclear safety rules for critical stands, approved by the Ministry for Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72
7. Nuclear safety rules for subcritical stands, approved by the Ministry of Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72
8. Rules for ensuring the safety of research nuclear installations, approved by Resolution of the Ministry for Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72
9. Safety rules for storage and transportation of nuclear fuel at the systems for storage and management of spent nuclear fuel, approved by the Ministry for Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72
10. Safety rules for the storage and transportation of nuclear fuel at nuclear power facilities, approved by Resolution of the Ministry for Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72
11. Rules for the installation and safe operation of actuating mechanisms of reactivity members, approved by Decree of the Ministry of Emergency Situations of the Republic of Belarus of December 30, 2006 No. 72

II.3. DEVELOPMENT OF THE REGULATORY FRAMEWORK FOR THE OVERSIGHT OF THE NUCLEAR POWER PROGRAMME

II.3.1. Planning for the establishment of the regulatory framework

The Ministry for Emergency Situations of the Republic of Belarus (MES, http://mchs.gov.by/) has been designated as a government body that performs regulation and control, including in the field of nuclear and radiation safety.

After the decision was taken to implement the first nuclear program, the Department of Nuclear and Radiation Safety (Gosatomnadzor, www.gosatomnadzor.gov.by) was created within the structure of the Ministry for Emergency Situations as an independent legal entity to fulfil the tasks of state supervision in the field of nuclear and radiation safety, control over compliance with legislation in the field of nuclear and radiation safety.

II.3.2. International commitments for Safety, Security, Non-Proliferation and Nuclear Liability.

International obligations in the area of nuclear and radiation safety of the Republic of Belarus and MES/Gosatomnadzor's role in its fulfilment

In 2016, the Republic of Belarus hosted an IAEA IRRS Mission which identified that the country had a clear commitment to international principles and collaboration. The mission found that the Republic of Belarus has ratified all major international conventions and agreements in the area of nuclear and radiation safety and that it makes extensive use of international peer reviews to get feedback to improve the nuclear safety regime in the country (see Table 11488). Belarus fulfils its international obligations in accordance with the conventions and agreements ratified in the nuclear safety field. Belarus joined most of the conventions and agreements its decision to embark on a nuclear power programme. For example, Convention on Nuclear Safety was ratified in 1998.

In this regard, MES/Gosatomnadzor is responsible for fulfilling the relevant obligations of the country and is endowed with the appropriate powers, competence and financial and human resources necessary to perform the duties assigned to it. In particular, MES/Gosatomnadzor provides preparation (together with other state authorities and organizations) of national reports under the Convention on Nuclear Safety, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, posting questions to the other countries reports and answering questions to Belarusian one, participation in review meetings.

II.4. DEVELOPMENT OF REGULATORY BODY(S)

The authority of MES as a regulatory body for nuclear and radiation safety, including its objectives and functions, is formalized in a range of legislative and regulatory documents:

- Decree of the President of the Republic of Belarus of November 12, 2007 No. 565 (revised on January 31, 2013) 'On Some Measures for the Nuclear Power Plant Construction';
- Law of the Republic of Belarus of July 30, 2008 No.426-3 (revised on 22.12.2011) 'On Nuclear Energy Use';
- Law of the Republic of Belarus 'On Radiation Safety of the Population' of January 5, 1998 No.122-3 (revised on 04.01.2014);
- Provision on the Ministry for Emergency Situations of the Republic of Belarus approved by the Decree of the President of the Republic of Belarus of December 29, 2006 No. 756 'On Some Issues of the Ministry for Emergency Situations'.

TABLE 7. INTERNATIONAL LEGAL INSTRUMENTS TO WHICH BELARUS IS A CONTRACTING PARTY IN THE AREAS OF SAFETY, SECURITY AND SAFEGUARDS

International Legal Instruments	**Entry into Force**
1. Convention on Early Notification of a Nuclear Accident	ratified by the Decree of the Presidium of the Supreme Council of the Republic of Belarus of December 18, 1986 № 1216-XI
2. The Convention on Assistance in the Case of a Nuclear Accident or Radiological situation	ratified by the Decree of the Presidium of the Supreme Council of the Republic of Belarus of December 18, 1986 № 1216-XI
3. The Convention on the Physical Protection of Nuclear Material	ratified by the Decree of the Presidium of the Supreme Council of June 14, 1993 № 2381-XII
4. Agreement between the Republic of Belarus and the International Atomic Energy Agency on the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons of August 31, 1995	
5. The Vienna Convention on Civil Liability for Nuclear Damage	ratified by the Law of the Republic of Belarus of Nov. 11, 1997 № 76-W
6. The Convention on Nuclear Safety	ratified by the Decree of the President of the Republic of Belarus of September 2, 1998 № 430
7. The Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters	Aarhus Convention, ratified by the Decree of the President of the Republic of Belarus of December 14, 1999 № 726
8. Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management	ratified by the Law of the Republic of Belarus of July 17, 2002 № 130
9. The Convention on Environmental Impact Assessment in a Transboundary Context	Espoo Convention, ratified by the Decree of the President of the Republic of Belarus of Oct. 20, 2005 № 487

Alongside MES, the following authorities participate in regulation of nuclear and radiation safety:

- the Ministry of Natural Resources and Environmental Protection;
- the Ministry of Health;
- the Ministry of Internal Affairs;
- and the State Security Committee of the Republic of Belarus.

A set of regulatory functions was delegated to Gosatomnadzor by MES (see the information below 'Main responsibilities of MES and Gosatomnadzor').

II.4.1. Roles and responsibilities of MES and Gosatomnadzor

There is a distribution of responsibilities between the MES and its department Gosatomnadzor. Thus, according to the Provision on the Ministry for Emergency Situations of the Republic of Belarus, the MES is a republican state administrative body regulating and managing prevention and response to natural and man-made emergency situations and civil defence, provision of fire, industrial, nuclear and radiation safety, as well as response to the Chernobyl NPP accident effects. The objectives and functions of Gosatomnadzor are formalized in the Provision on the Department for Nuclear and Radiation Safety of the MES. Within the framework of its activity Gosatomnadzor performs sate supervision in the field of nuclear and radiation safety. [5]

Gosatomnadzor performs the following main functions:

— analyses the experience of the application of the legislation in the sphere of atomic power and ionizing radiation sources use and makes proposals for its enhancement, formulates corresponding drafts of norms and rules in the field of nuclear and radiation safety, organizes the publication of reference and other documents necessary for the execution and improvement of activities in the sphere ensuring nuclear and radiation safety;

— takes part in issuing special permits (licenses) for carrying out activity in the field of nuclear energy and ionizing radiation sources use (the list of the activities subject to licensing is defined by legislation, licensing authority is MES) and in this regard organizes safety review of nuclear facilities and sources of ionizing radiation, expertise of their design and engineering documentation, including with the involvement of independent experts;

— organizes and exercises state supervision over:

  - management of radioactive waste and spent nuclear materials, their disposal;
  - ensuring physical protection of nuclear facilities and sources of ionizing radiation;
  - planning protective measures to ensure the safety of workers and the public in the event of nuclear and radiation accidents;
  - compliance with the requirements of normative legal acts and technical normative legal acts in the field of nuclear and radiation safety;

— performs control over:

  - compliance with the requirements of standards and regulations in the field of atomic energy use;
  - fulfilment of international obligations of the Republic of Belarus to ensure nuclear and radiation safety in the use of atomic energy and sources of ionizing radiation;

- organization and conduct of professional training, retraining and qualification upgrade, training of radiation and nuclear facilities personnel in the safe conduct of work at radiation facilities and nuclear facilities;

- implementation of measures to improve the emergency sustainability and safety of radiation facilities and nuclear facilities;

— organizes and carries out scientific research to ground the principles and criteria of nuclear and radiation safety to increase efficiency of the state supervision;

— ensures functioning of the State system of registration and control over nuclear materials in the Republic of Belarus, as well as the united State system of registration and control, over sources of ionizing radiation, being a competent authority on Agreement on safeguards implementation;

— participates in fulfilment of international obligations of the Republic of Belarus on ensuring nuclear and radiation safety;

— informs public about the level of safety of radiation objects, nuclear installations and atomic engineering objects in accordance with the legislation, etc.

II.4.2. Organizational establishment and development

Gosatomnadzor was established within the structure of the Ministry for Emergency Situations in 2007 with 39 staff and 8 divisions (see Figure 7). Significant support in the development of the organization was provided by the European commission and IAEA. Active development of Gosatomnadzor dates back to IAEA INIR mission in 2012 and its recommendations.

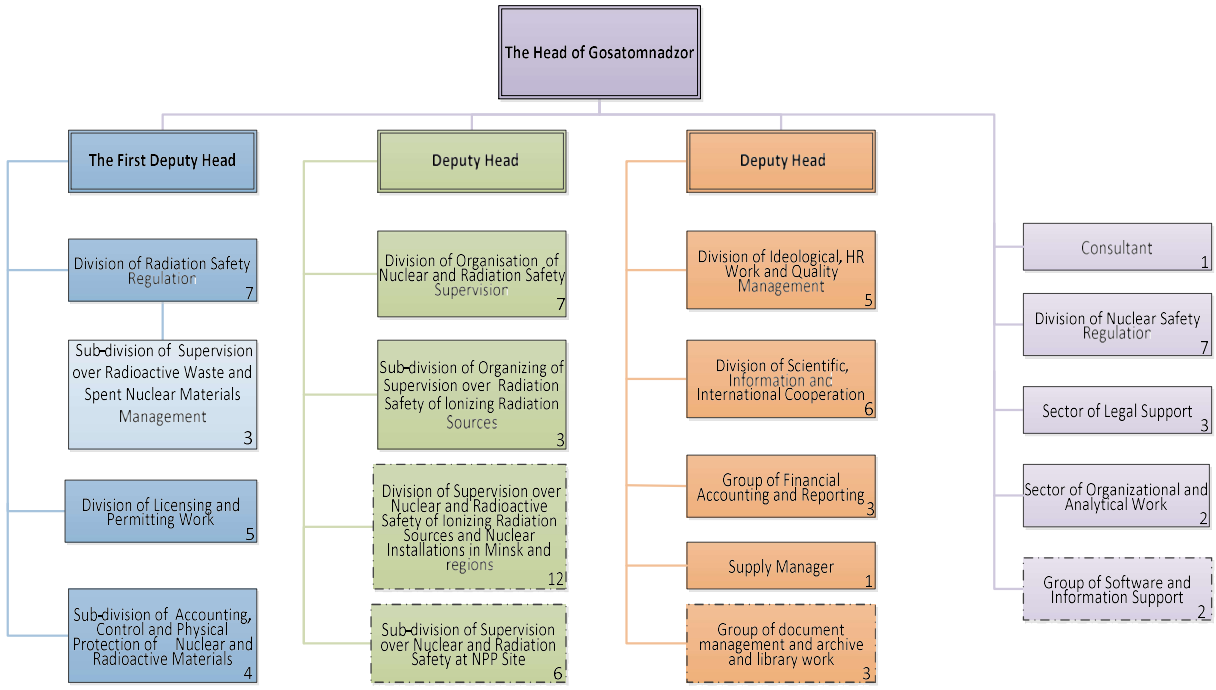

FIG. 7. Organizational chart of Gosatomnadzor.

II.4.3. Prioritization and development of regulations and guides

Legislation in the field of nuclear and radiation safety in the Republic of Belarus has a hierarchical structure which stipulates that normative legal acts of lower legal force are subject to the relevant requirements of the normative legal acts of higher legal force. The legal regulation of the issues of nuclear and radiation safety is carried out on the basis of:

- laws of the Republic of Belarus;
- decrees of the President of the Republic of Belarus;
- resolutions of the Government of the Republic of Belarus;
- regulations of the authorized republican state control bodies responsible for state regulation of activity in the field of nuclear energy use;
- norms and rules in the field of nuclear and radiation safety, as well as other technical normative legal acts.

After the decision in principle to embark on nuclear energy was taken in 2008, the regulatory framework for nuclear and radiation safety was considerably changed. As of today, it is based on two main laws:

- Law of the Republic of Belarus of July 30, 2008 No.426-3 (as amended on December 22, 2011) On the Use of Atomic Energy';
- Law of the Republic of Belarus of January 5, 1998 No.122-3 On Radiation Safety of Population' (as amended on January 4, 2014 No. 106 -3).

and some more normative legal acts, such as:

- Decree of the President of the Republic of Belarus of September 1, 2010 No. 450 'On Licensing of Certain Types of Activities' (as amended on November 26, 2015 No. 475);
- Decree of the President of the Republic of Belarus of February 16, 2015 No.62 'On Provision of Safety during the Construction of the Belarusian Nuclear Power Plant' (as amended on February 18, 2019 No.70), etc.

The Law of the Republic of Belarus 'On the Use of Atomic Energy' regulates relations concerning designing, siting, construction, commissioning, operation, operation limitations, extending of operation period and decommissioning of a nuclear plant and (or) storage facility, as well as relations concerning nuclear materials management in the course of a nuclear plant and (or) storage facility operation, including spent nuclear materials and (or) operational radioactive waste, as well as other relations in the field of nuclear power use. Law of the Republic of Belarus 'On Radiation Safety of Population' determines the basics of legal regulation in regard of population radiation safety; its purpose is to create conditions that ensure protection of people's life and health from harmful effects of ionizing radiation. [5]

II.4.4. Implementation of licensing process for different stages

In the Republic of Belarus, a licensing system for the right to perform activity in the field of atomic energy and ionizing radiation sources use is established according to a separate chapter

of the Provisions on licensing of certain types of activities[6]. The licensing body is the MES. Basic licensed types of activities are the following:

— nuclear energy use;

— ionizing radiation sources use;

— radioactive waste management;

— construction and manufacturing of technological equipment for nuclear energy facilities, designing and production of radiation protection tools for radiation facilities;

— safety review in the field of nuclear energy and ionizing radiation sources use.

Nuclear energy use includes the following works:

— designing, siting, construction, operation, decommissioning of nuclear installations;

— designing, siting, construction, operation, decommissioning of nuclear materials storage facilities;

— management of nuclear materials, nuclear fuel, spent nuclear materials, spent nuclear fuel, operational radioactive waste;

— performing works and providing the operating organizations with safety-related services, including facilities construction.

Performing the above-mentioned works without licenses is prohibited.

Belarusian NPP got a siting licence for Unit1 and Unit 2 in May 2012. Licensing of construction was done in 4 stages (2 for each unit) (see Figure 8):

— licence for erecting foundation of buildings and structures of Unit 1 was issued in September 2013;

— for erecting foundation of buildings and structures of the Unit 2 – in February 2014;

— for full range of construction of Unit 1 – in April 2014;

— for full range of construction of Unit 2 – in December 2014.

[6] Approved by the Decree of the President of the Republic of Belarus of 01.09.2010 No. 450 “On Licensing of Certain Types of Activities”.

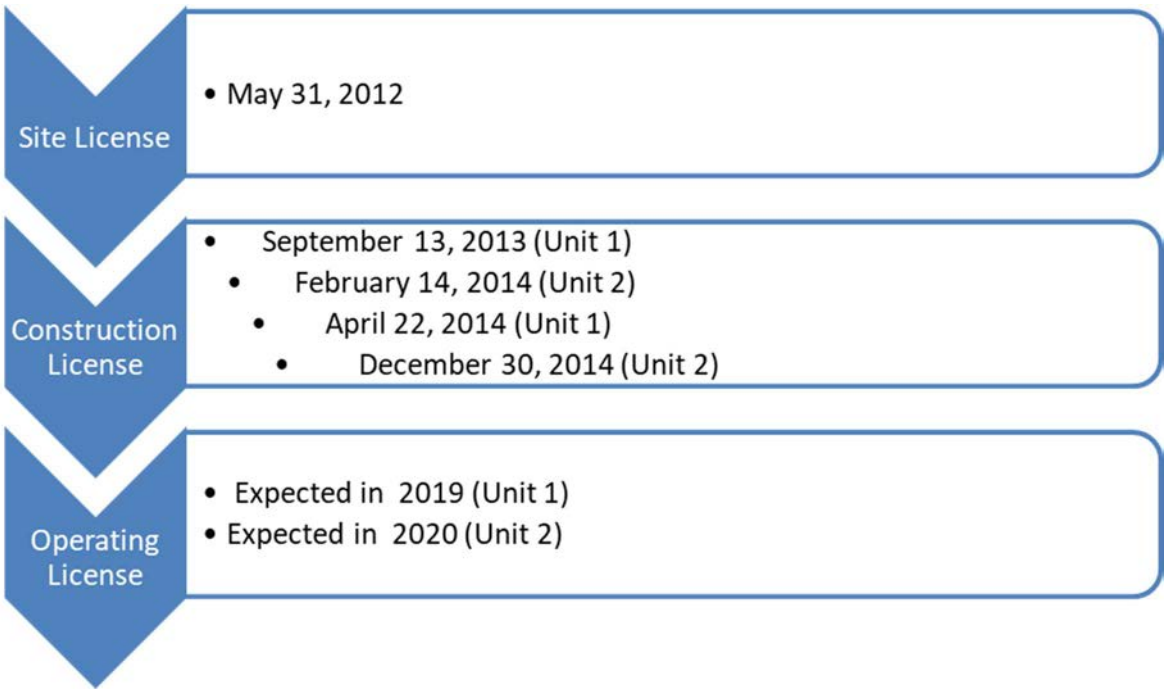

FIG. 8. Licensing steps and implementation for Belarusian NPP.

II.4.5. Implementation of inspection programme

In order to coordinate the implementation of state control (supervision) over the construction of the Belarusian NPP, a Working Group has been established (Resolution of the Council of Ministers of the Republic of Belarus dated December 30, 2011 No. 1791) under the leadership of the Deputy Minister for Emergency Situations. Since 2011, regular meetings of the Working Group have been held, at which analysis and conclusions of the work of the supervisory bodies are presented, as well as proposals and solutions are developed to improve oversight activities. With the commencement of the issuance of the first construction licenses in November 2013, the activities of the Working Group have been intensified, as well as the frequency of inspections, especially in terms of welding technology, installation of pressure vessels and vacuum vessels, pumps, valves and pipelines related to 1, 2, 3 safety classes, as well as the creation and operation of an effective quality system.

The program of inspections of the regulatory body was and is based on the construction schedules for NPP units and is planned on a weekly and semi-annual basis. The detailed procedure for inspections is regulated by legislation at the level of the Government of the Republic of Belarus and regulatory bodies.

II.5. CHALLENGES FACED AND THE SOLUTIONS APPLIED

The ten-year period of establishing regulatory system in nuclear and radiation safety in the Republic of Belarus is surveyed to present the main challenges and lessons learned from the work performed.

The first lesson appears to be in providing for carrying out a ‘pre-employment’ of graduates of specialized educational institutions who train personnel for the nuclear industry to the regulatory body. This lesson is drawn from the situation in Gosatomnadzor in 2013, associated with an increase in staff from 39 to 82. It was necessary to quickly recruit 45 new employees.

This was also done by attracting 22 young professionals, but without relevant regulatory experience. It should have been worthwhile to conduct an advanced selection of candidates for Gosatomnadzor among students and basic training for them on the issues of regulatory activity even during the period of study at universities, which would have greatly facilitated their starting independent work. Since in the case of Belarus, graduates were recruited, it was necessary to work out and apply numerous tools to ensure the rapid introduction of the young newcomers into the independent implementation of regulatory functions. Further on in 2016 IRRS mission acknowledged them being a good practice[7].

The second tells about the necessity of TSO and/or TSO system organization-coordinator establishment simultaneously (in parallel) with the establishment of the regulatory body. In Belarus, the regulatory body was established in 2007, JIPNR-Sosny has been mandated to act as TSO since 2012, TSO system (16 relevant bodies) was established in 2016 and its Coordinator from the part of MES/Gosatomnadzor – in 2017. There is a difference in the speed of development of a Regulatory Body and a TSO. This challenge also requires additional efforts and resources for the rapid involvement of the newly created TSO system into scientific and technical support provision to the Regulatory Body.

The third lesson reflects the wisdom and usefulness of the full use by the newcomer countries of the IAEA Safety Standards Series No. SSG-16 (Rev. 1), Establishing the Safety Infrastructure for a Nuclear Power Program [3], which will allow defining the aims, working out strategies and plans of their implementation from the very beginning.

The fourth lesson is the high added value of obtaining international advice and experience in shaping security policies, thematic strategies, roadmaps and concepts, as well as medium and long-term plans for their implementation from the very beginning of the formation of the regulatory infrastructure. It would be good if a newcomer country had begun with the documenting of its strategic vision from the very start, and this activity could be implemented with the relevant international support.

The fifth lesson relates to the possibility of newcomer countries to get a comprehensive understanding in terms of the purposes of the IAEA review missions – INIR, IRRS, EPREV, ISSAS, IPPAS and others. Their conduction at all stages of regulatory infrastructure development is an excellent tool for improving nuclear and radiation safety, physical protection and emergency preparedness.

The sixth lesson is the need to pay special attention to improving the knowledge of English by specialists of the regulatory body and its TSO from the very beginning of the formation of the regulatory infrastructure in order to ensure an effective and rapid exchange of international experience in the field of nuclear safety.

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[7] GP2 “The regulatory body has established a variety of tools to manage their rapid growth, and has adopted innovative approaches to building a healthy organizational culture. Innovative practices include delegating responsibility for preparing the knowledge management strategy to newer staff, holding day-long meetings with staff to solicit feedback and holding a competition for staff to prepare essays on potential improvements (and establishing working groups to implement these improvements)”

II.6. PREPARATION FOR FUTURE PHASES

The all above described led to the readiness to implement necessary regulatory actions/decisions related to preparation for commissioning of Unit 1 of the Belarusian NPP, including:

- regulation of the safety of fresh nuclear fuel delivery: a set of regulatory actions is undertaken, which includes the licensing of the Belarus rail road (December 2018), as well as conducting a complex inspection of the facility's readiness to receive and store fresh fuel for power unit No. 1 of the Belarusian NPP (November 2018) and a thematic inspection is scheduled before the fresh fuel delivery;

- licensing of the operation of power unit No. 1 of the Belarusian NPP (according to the schedule the commissioning is planned in 2019): the application of the Belarusian NPP for a license was submitted in October 2017, the TOR for safety assessment was prepared and approved by Gosatomnadzor, the safety review is conducted by an expert organization - SSI 'JIPNI-Sosny'. Gosatomnadzor receives methodological support in conducting safety review from the European experts in the framework of technical cooperation projects of the European Commission;

- issuing permits for the right to conduct work in the implementation of activities on the use of atomic energy to employees (personnel) of operating organizations and organizations performing work and (or) providing services in carrying out activities on the use of atomic energy;

- preparation and conduction of public hearings: a legal framework has been created for holding public hearings on the results of the safety assessment. Presidential Decree of February 18, 2019 No. 70 was adopted, as well as Resolution of the Council of Ministers of April 24, 2019 No. 258. This legal framework is based on the IRRS recommendation "MES/Gosatomnadzor should finalize and implement plans to inform and consult with the public when making significant regulatory decisions". Public hearings are held at the stage of decision-making on regulation of activity in the use of atomic energy related to the safety of the Belarusian NPP;

- prioritizing on-the-job training for inspectors and safety assessment experts. For this purpose, well-developed tools of multilateral and bilateral cooperation are used with an emphasis on close cooperation with the regulatory body of the vendor country 'Rostechnadzor'.

Continuous improvement of the regulatory infrastructure in compliance with the main safety principles and IAEA requirements is ongoing. Belarusian Regulatory Authority largely and fully uses the instruments of peer reviews conduction and its recommendations implementation: INIR 2012, IRRS 2016, EPREV 2018, ISSAS May 2019, INIR phase 3 (February – March 2020) and IPPAS (TBD). Also, in 2018 the EU Peer review of the Belarusian NPP stress-tests results was held by a group of the European experts.

Special contribution to the current development and future sustainability of the regulatory activities of the country is made by large-scale international assistance via complex technical cooperation projects of IAEA, European Commission, Regulatory Cooperation Forum, as well as 14 bilateral agreements with foreign regulators and TSOs.

II.7. SUSTAINABILITY OF REGULATORY FRAMEWORK

The sustainability of the regulatory infrastructure is viewed in creating the conditions for retaining experienced employees by establishing various methods of motivation (not only financial) and ensuring sustainable interaction with the TSO system to form a personnel reserve with a special focus on youth.

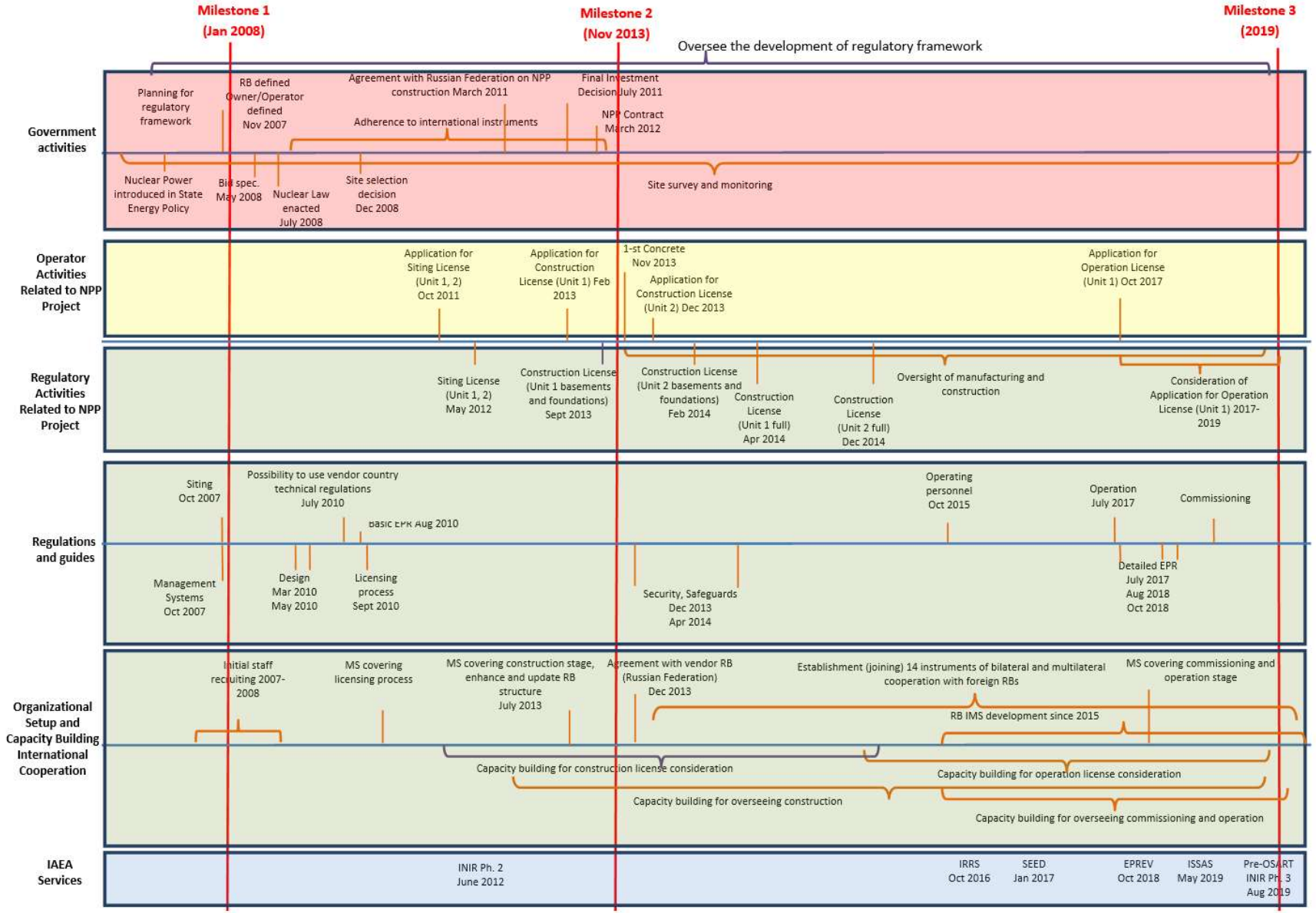
An important component of sustainability is ensuring effective knowledge management, implementation of the IMS and maintaining it in an efficient working condition through the use of best practices and their implementation.

Regular updating of policies and strategies with the involvement of all employees of the regulatory body using the recommendations of the European and foreign experts in the framework of IAEA and EC technical assistance projects and bilateral cooperation is one of the tools to maintain the sustainability of the regulatory infrastructure and its compliance with current global trends in nuclear and radiation safety.

The next step is the implementation of the task of developing, approving and implementing a perspective strategy for the development of TSO system, which is being developed with the assistance of the European experts in the framework of the implementation of technical cooperation projects of the European Commission.

Finally, planning and conducting self-assessments of the state of the regulatory infrastructure, including safety culture, and inviting review missions remains one of the relevant tasks to facilitate the sustainability of the regulatory infrastructure of the Republic of Belarus.

Timelines for Key Activities to Establish and Implement Regulatory Framework – Belarus Case



APPENDIX III.
CASE STUDY: ISLAMIC REPUBLIC OF PAKISTAN

III.1. NUCLEAR POWER PROGRAMME

The present installed electricity generation capacity of Pakistan is around 33,554 MWe. Major sources of electricity generation in the country are fossil fuel fired thermal power plants and hydroelectric plants, which fall under the purview of the Water and Power Development Authority (WAPDA). The share of electricity production from nuclear energy to national grid in the year 2017-18 is about 7.5% of the total power generation.

Nuclear power is a proven base-load electricity generation option to enhance the security of supply and diversity of the power system. The national power program is primarily focused upon installation of new nuclear power plants in order to meet the targets of Energy Security Plan and on continued safe operation of operating plants.

Pakistan Atomic Energy Commission (PAEC) is responsible for the promotion of nuclear energy including nuclear power generation and application of nuclear radiation in industry, medicine, agriculture and research, and development on behalf of Government of Pakistan. PAEC owns and operates all nuclear installations in the country and has more than 45 years of nuclear power plant operating experience. Currently five (5) NPPs are in operation four at Chashma site that is located around 300 km south east of the capital city Islamabad and one unit at coastal site of Karachi. In addition, two NPP units are under construction at Karachi site and further three are in the planning phase.

In order to fulfil the Government's Energy Security Plan of 2005, PAEC has been given the target to enhance the existing nuclear generation capacity to 8800 MWe. by constructing several new NPP units by the year 2030. Accordingly, new sites are being identified for detailed evaluation. Construction of two 1100 MW advanced PWR units is a step in this direction. Pakistan Nuclear Regulatory Authority (PNRA) is the competent authority for regulating nuclear safety and radiation protection aspects of nuclear installations. The safety record of the operation of nuclear power plants has been quite satisfactory as concluded from the findings of the regulatory reviews and inspections and substantiated by international peer reviews.

III.2. DEVELOPMENT OF LEGISLATIVE AND REGULATORY FRAMEWORK FOR THE OVERSIGHT OF NUCLEAR POWER PROGRAMME

The following sections describes the actions performed by the Government of Pakistan and PNRA to establish and implement the legislative and regulatory framework for nuclear power program.

III.2.1. Establishment of the legislative and regulatory framework

The Government of Pakistan has established a comprehensive legislative framework to manage the use of nuclear energy, nuclear safety and radiological protection in the country. In 2001, the Government promulgated the PNRA Ordinance which established Pakistan Nuclear Regulatory Authority as the independent national authority having the responsibility to supervise and regulate all matters related to nuclear safety and radiological protection in the country. The Ordinance assigns PNRA with the responsibility of establishing and implementing regulatory framework to ensure the safe and secure use of nuclear material, radioactive sources and radiation generators in the country.

The legislative and regulatory framework for nuclear safety in Pakistan comprises of three tiers depicting the hierarchy of regulatory documents as shown in Figure 9. The first tier is PNRA Ordinance, followed by PNRA regulations and regulatory guides issued there-under in the subsequent tiers. The highest-level document, PNRA Ordinance, describes the mandate, powers, functions and responsibilities of PNRA assigned by the Government of Pakistan. Under the Ordinance, PNRA is empowered to make and enforce rules, regulations and policies in order to regulate the safety of nuclear installations and protection against risks arising from ionizing radiations.

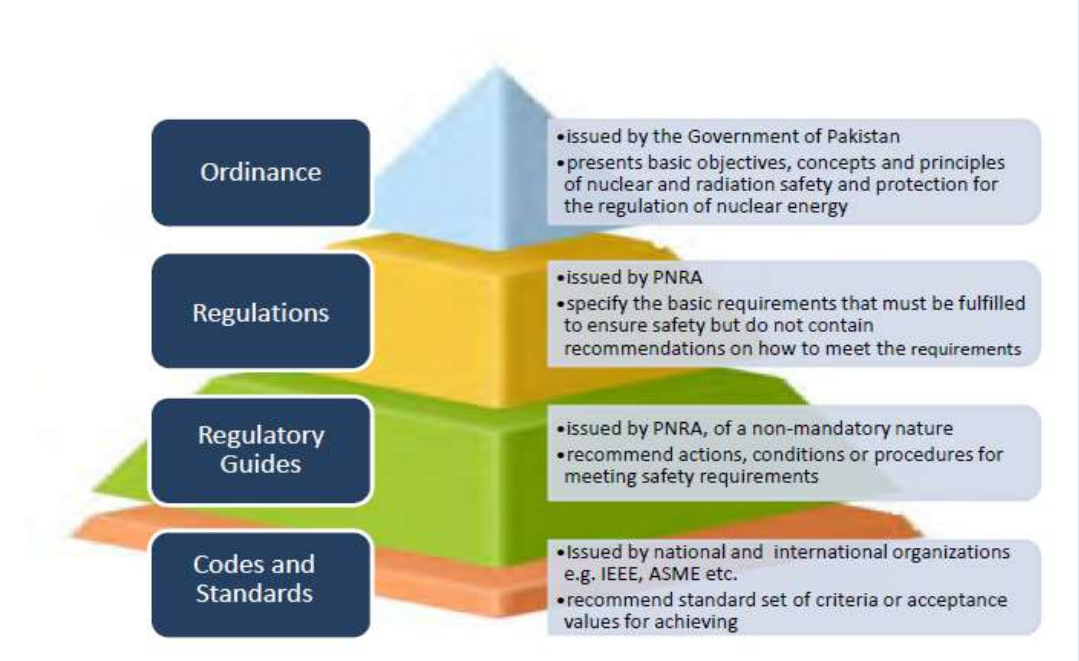


FIG. 9. Structure of regulatory documentation.

III.2.2. International commitments for Safety, Security, Non-Proliferation and Nuclear Liability.

Pakistan is party to four international Conventions related to safety and security of nuclear materials and installations. These include Convention on Early Notification of a Nuclear Accident; Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency; Convention on Nuclear Safety; and Convention on Physical Protection of Nuclear Materials and its amendment. Pakistan has also voluntarily committed to implement codes of conduct related to safety of research reactors and safety and security of radioactive sources. PNRA is the lead organization and contact point from Pakistan to coordinate with the international community on these conventions. PNRA plays a pivotal role in fulfilling the international obligations of Pakistan and actively supports the Government in execution of the activities related to these obligations. PNRA, in capacity of designated national warning point, fulfils the obligations of Pakistan under the Conventions on 'Early Notification of a Nuclear Accident' and 'Assistance in the Case of a Nuclear Accident or Radiological Emergency'. PNRA is also implementing obligations arising from Pakistan's commitment to follow the

Codes of Conduct on Safety of Research Reactors and Safety and Security of Radioactive Sources.[8]

III.3. DEVELOPMENTOF REGULATORY BODY(S)

Pakistan signed the Convention on Nuclear Safety in 1994 which required the Member States to ensure effective separation between the regulatory body and the organizations responsible for the promotion of nuclear energy. As a first step, the Government of Pakistan established 'Pakistan Nuclear Regulatory Board (PNRB)' in 1994 as a quasi-independent regulatory body, as partial fulfilment of the obligations of the Convention. Finally, in 2001, complete fulfilment of international obligation was made when the Government of Pakistan established PNRA as an independent regulatory body in Pakistan. PNRA Ordinance delineates the composition of the Authority which consists of a Chairman, two full-time Members, seven part-time Members and a Secretary. The Chairman and Members of the Authority are designated by the Federal Government. The part-time Members of the Authority include one eminent professional each from the science, engineering and medical sectors; and a representative each from the Ministry of Health, Pakistan Environmental Protection Agency, Pakistan Atomic Energy Commission; and Strategic Plans Division Headquarters.[8]

III.3.1. Roles and responsibilities of regulatory body(s)

Pakistan Nuclear Regulatory Authority has the overall responsibility for controlling, regulating and supervising all matters related to nuclear safety and radiation protection measures in Pakistan. The Ordinance entrusts PNRA with various functions and defines the scope and domain of vested regulatory powers. The regulatory paradigm for nuclear installations and radiation facilities and activities in Pakistan is quite multifarious which includes nuclear power plants, research reactors, radioisotope production facility, nuclear medicine centers, radiotherapy centers, irradiators, industrial and agricultural facilities using radioactive materials, diagnostic radiology centers, etc. The Ordinance mandates the Authority to ensure protection of life, health and property against the potential risk of ionizing radiation from all such installations, facilities and activities by formulating and implementing a comprehensive regulatory framework.[8]

In order to perform its functions, PNRA has devised, or adopted, regulations, regulatory orders for nuclear safety and radiation protection (workers, health and property against the risk of ionizing radiation). Under the Ordinance, PNRA has the mandate to grant authorization/license to nuclear installations and radiation facilities. In addition, PNRA performs regulatory inspections of the licensed facilities and activities in order to ensure compliance with the regulations and other applicable safety standards. In case of non-compliance, PNRA is empowered to take different enforcement actions. PNRA is also empowered to ensure that the licensees have adequate plans for dealing with the nuclear or radiological emergencies and physical protection of nuclear material and facilities utilizing radioactive sources. PNRA also advises the Federal Government departments or Provincial Government departments, educational and research institutions, public or private industry and other undertakings on issues related to nuclear safety and radiation protection. The Authority is also empowered to fix the extent of civil liability for an operator in case of various nuclear incidents.

[8] Pakistan Nuclear Regulatory Authority Annual Report, 2017.

III.3.2. Organizational establishment and development

The organization of PNRA comprises a Chairman, two full-time Members and seven part-time Members, including representatives of the Ministry of Health, Pakistan Environmental Protection Agency, Strategic Plans Division (SPD) of the Joint Staff Headquarters, eminent professionals from the science, engineering and medical sectors and Pakistan Atomic Energy Commission. The Federal Government appoints the Chairman and the Members of the Authority. Chairman is the chief executive officer of the Authority and reports to the Prime Minister through SPD which is the Secretariat of National Command Authority (NCA) headed by the Prime Minister of Pakistan. Figure 10 shows the organizational structure of PNRA.

The organizational structure of PNRA comprises of the executive and corporate wings, headed by Member (Executive) and the Member (Corporate) respectively. The executive wing is responsible for performing core functions of the Authority, whereas, the corporate wing is responsible to drive the Authority as an organization and also provides technical support to the executive wing through its technical support centres. The Secretary of the Authority, the Advisory Committees and the Director General of the Chairman Secretariat, report directly to the Chairman. The latter assists Chairman in matters relevant to planning future activities of PNRA.

Member (Executive) has the overall responsibility of the Executive Wing and is assisted by Director General (Technical) and Director General (Inspections & Enforcement). The former looks after the four Technical Directorates {Directorate of Nuclear Safety (NSD), Directorate of Radiation Safety (RSD) and Directorate of Transport and Waste Safety (WSD), Directorate of Physical Protection and Security (PPSD)} and activities of National Radiological Emergency Coordination Centre (NRECC) which is responsible for coordinating the response of various stakeholders to nuclear accidents or radiological emergencies with stakeholders. Director General (Inspections & Enforcement) looks after three regional directorates and inspectorates. Directorate of Administration and Directorate of Finance also operate under the supervision of Member (Executive).

Member (Corporate) has the overall responsibility of the Corporate Wing. Three Director Generals are working under the authority of Member Corporate, namely Director General (DG) (Corporate), DG (Capacity Building) and DG (Technical Support). DG (Corporate) is responsible for the activities of corporate wing, DG (Capacity building) looks after the progress of projects of national importance undertaken by PNRA and DG (Technical Support) supervises all technical, administrative and financial activities of the two internal technical support centres of PNRA namely CNS and SAC. Further, Directorate of International Cooperation (ICD) and Directorate of Establishment work directly under supervision of Member (Corporate).

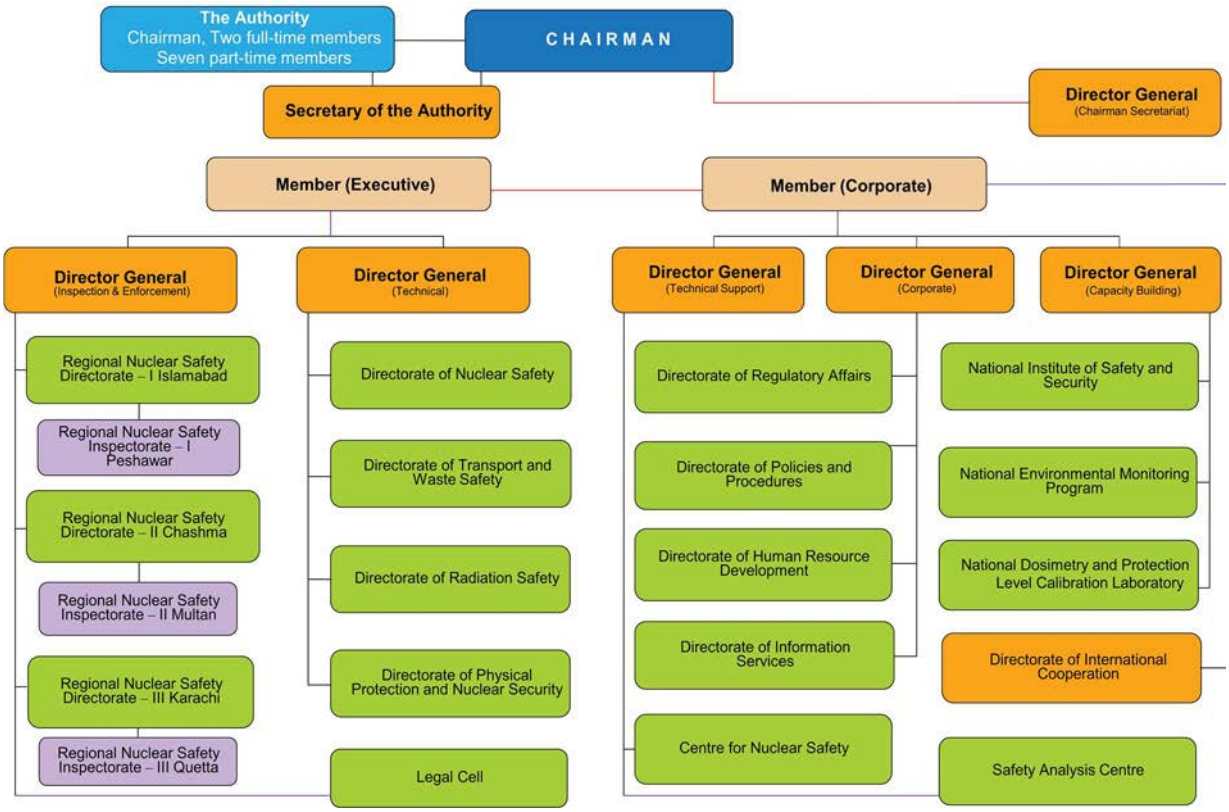


FIG. 10. PNRA organizational chart.

III.3.3. Prioritization and development of regulations and guides

Regulations are developed to set out safety requirements for the applicants/licensees of nuclear installations, radiation facilities, equipment manufacturers and service providers with the aim to perform such activities in a safe manner ensuring protection of workers, public and environment from the harmful effects of ionizing radiation. The development of regulations follows a rigorous process which also includes feedback from all concerned stakeholders including public. The draft regulations are uploaded on PNRA website for comments from the public, licensees and interested parties. This process has been very useful in acquiring acceptance of stakeholders. The regulations once approved by the Authority are notified in the official gazette and are placed at PNRA website (www.pnra.org) for information and use by all concerned.[8]

The regulatory guides play a significant role in developing the understanding and effective implementation of regulatory requirements set forth under PNRA regulations. These guides are issued by PNRA for facilitating its licensees to comply with the regulatory requirements. These bear a non-mandatory status and are placed in the lowest tier of PNRA's regulatory framework. These regulatory guides are not mandatory; therefore, the licensee may choose alternate approaches such that the intent of regulatory requirement(s) is met. In case the licensee adopts an alternate approach to fulfil the regulatory requirement(s), the licensee has to demonstrate that the approach offers the same or better standard of safety and quality.[8]

In order to regulate nuclear installations and associated activities in accordance with national regulations, PNRA performs various regulatory functions such as licensing and authorization; review and assessment; and inspection and enforcement.

PNRA conducts licensing and authorization of all civilian nuclear installations and associated activities in the country. The regulatory oversight encompasses all stages of the lifetime of nuclear installations and includes various licenses and authorizations e.g. site registration, construction license, fuel load permit, operating license, revalidation of operating license, licensing beyond design life, license for decommissioning of a nuclear installation or closure and removal from regulatory control. This is to ensure that nuclear installations remain under regulatory control from site registration till completion of decommissioning and removal of the site from regulatory control. As per regulatory framework, these authorizations and licenses are issued based on verification of safe design and operation practices. The licenses and authorizations normally also impose generic and specific conditions according to the outcome of regulatory processes. PNRA also conducts licensing of operating personnel for nuclear installations in order to ensure that qualified and trained personnel operate these installations according to national regulations and applicable codes & standards.[8] The authorization/licensing process consists of the following stages as shown in Figure 11.

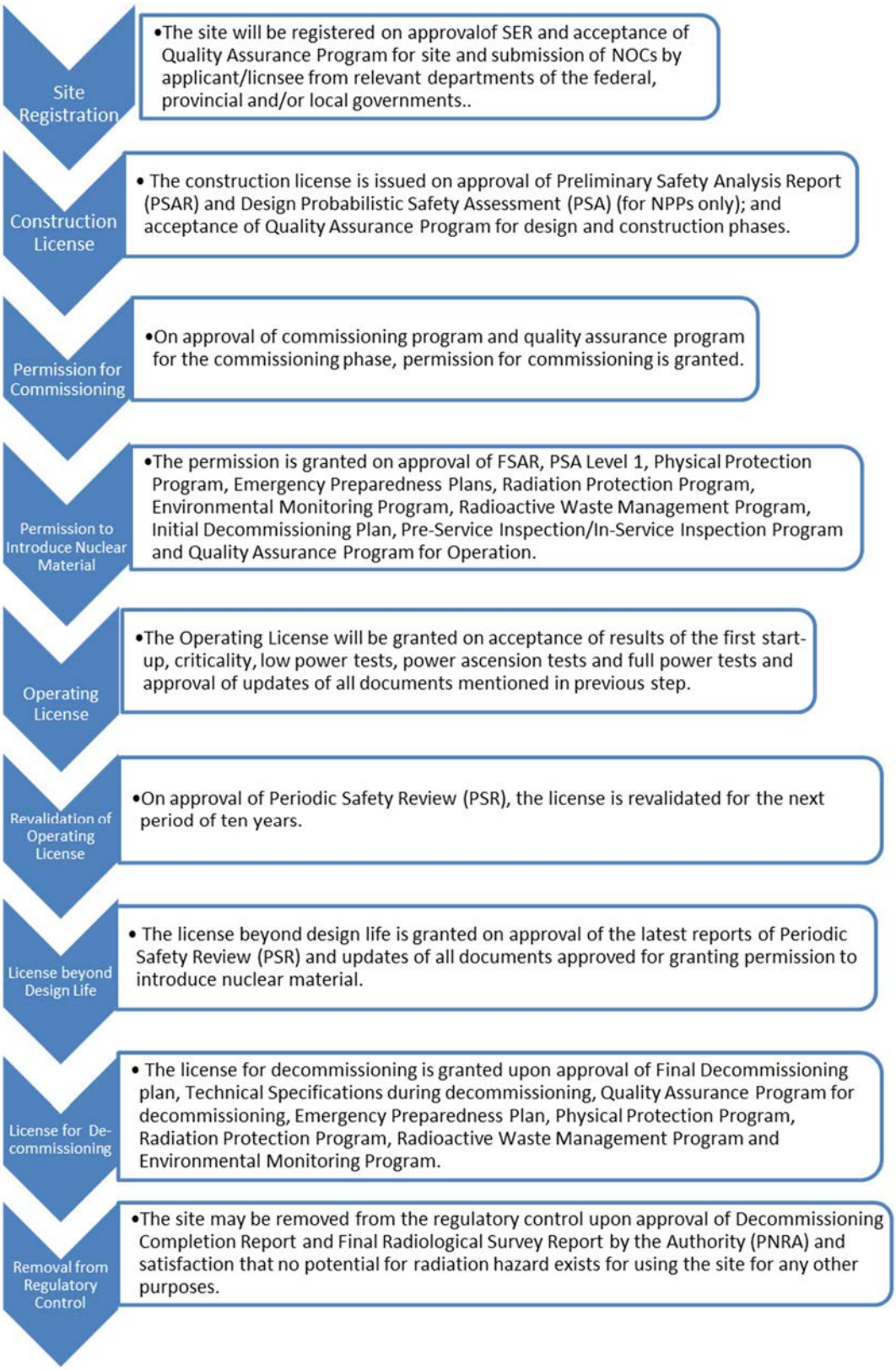


FIG. 11. Licensing steps for nuclear installations.

III.3.4. Development and implementation of inspection programme

PNRA has developed an inspection program which forms the basis for inspection activities of PNRA. For its effective implementation, the regulatory inspections are conducted during all phases of a nuclear installation's life cycle, i.e., construction, commissioning, operation, etc. The regulatory inspections are planned in advance, however, if needed, reactive inspections are also conducted. These inspections may be announced or unannounced. PNRA inspectors perform inspections according to the approved annual inspection plan, procedures, and checklists. In case of any deficiency or non-compliance with national regulations, licence conditions, agreed codes and standards, facility quality assurance programme or procedures (administrative/ technical) observed during inspections, PNRA issues directives to the licensees through inspection reports for implementation of necessary corrective actions within due course of time. A follow-up process is in place to ensure satisfactory implementation of corrective actions in the light of PNRA directives.[8]

Resident inspectors conduct control room inspections and general surveillance of nuclear installations on a daily basis; periodic inspections of plant systems and processes at a defined frequency; participate in daily meetings of the plants; also perform control point inspections of selected licensee's activities.[8]

III.4. CHALLENGES FACED AND THE SOLUTIONS APPLIED

PNRA was established an independent regulatory body in 2001. At that time major challenges faced by PNRA were limited manpower, limited physical infrastructure, limited regulatory framework, ageing of existing manpower and lack of structured training program. To face these challenges, PNRA established Directorate of Human Resource Development (HRD). HRD focused on human resource planning, capacity building and establishment of training infrastructure. It was realized that regulating nuclear installations and radiation facilities is a highly complex task and requires well qualified, knowledgeable, experienced and skilled professionals. Henceforth, rigorous and continuous education and training of the regulatory officials is needed. Similarly, mentoring, coaching and hands on training of the junior officials as well as senior professionals is also considered necessary for enhancing the efficiency and effectiveness of the organization and strengthening regulatory oversight of nuclear installations, radiation facilities and associated activities in the country.

PNRA developed its physical infrastructure through government funded Public Sector Development Program (PSDP) and established offices at various locations within the country.

For the regulatory framework, PNRA chalked out a program to start work on development of regulations and regulatory guides in accordance with the need. Some regulations and regulatory guides were adopted and started work to develop our own regulations in specific areas like licensing, siting, design, operation, quality assurance, etc. Detail of PNRA existing regulations is given in section 1.1.4.8.

For human resource planning, capacity building and establishment of training infrastructure, PNRA took initiative to develop Fellowship Scheme and Direct Recruitment of technical staff. PNRA developed plan for direct recruitment and implemented accordingly. For Fellowship Scheme, PNRA signed MoU with two national institutes that five to ten fellows will join PNRA annually. The fellows were funded by PNRA in accordance with the recruitment plan.

Capacity Building in different disciplines of Nuclear Safety, radiation protection, transport and waste safety, physical protection etc. A three pronged process was established for the capacity

building of the manpower, i.e. In House, National and International. For in-house professional training program, PNRA established a National Institute of Safety and Security through Public Sector Development Project which played very important role for the capacity development of PNRA technical stop. PNRA also attaches its technical staff with the operating organizations for the training purpose. PNRA identified and enlisted some national institutes/organizations to train its technical staff from that institutes/organizations. At international level PNRA sponsors graduates in the Master's Degree Programs at international universities. PNRA also utilized IAEA platform for the training of our technical staff through fellowships, workshops, scientific visits, etc. PNRA has made extensive use of IAEA peer review services during the course of its programme to provide feedback and recommendations. These peer reviews provide an excellent, objective basis for reflection on challenges faced and the solutions.

PNRA periodically conducts competence need assessment (CAN) to identify areas for further improvement and accordingly chalks out plans for competence development. The competence development programme includes education, training and expertise development through in-house endeavours along with competence building through training opportunities offered at national and international institutions and organizations.[8]

III.5. PREPARATION FOR FUTURE PHASES

PNRA is a forward-looking organization. PNRA continuously striving to acquire the attitude of flexibility and willingness to step into filling gaps. To save the time and resources, all the future activities are planned and assigned to the relevant department in a systematic way. The existing regulatory framework is also reviewed periodically for incorporation of new requirements for the emerging technologies. The capacity building of regulators is one of the essential elements for the future activities. The regulators should be well versed in regulating the facility and activity they are facing with. Although regulatory body performs its function following its well-defined processes in management system. Still, there is need to compare the practice with the best one followed internationally. The process may be revised to make it more practicable and realistic. New information may be obtained from updated IAEA and international community relevant documents.

In PNRA, each department assesses and determines the requirements of necessary skilled human resources to carry out the future activities for sharing with the relevant department. All departments coordinate with Senior Management for ensuring availability of necessary human resources. Senior and Top Management assesses the expected future requirements of human resource and takes appropriate steps to make it available accordingly. Schedule and planner for the implementation of the assigned task/activity is prepared by the department. Training/retraining and refresher courses are arranged for involved persons to keep them abreast, aware and prepare for the assigned task in accordance with schedule. Recently, the licensee has submitted the application for acquiring permission to introduce nuclear material (fuel) into the reactors of the under construction. The main licensing document among these is the Final Safety Analysis Report (FSAR), the regulatory review of which is conducted as a project. The review and assessment of FSAR is in progress by a review team having expertise in different technical areas according to a work schedule developed in consultation with the licensee. The work schedule normally consists the tasks for regulatory body (for conducting review at different stages) as well as for the licensee (to provide required information communicated in the form of review queries). The schedule also includes review meetings between the licensee and PNRA at different stages of the review and assessment process.

PNRA conduct rationalization of its manpower keeping in view the future tasks and activities regularly. Based on specialty of the technical manpower and the task/activity to be conducted, the staff are transferred accordingly.

If required, PNRA also approaches IAEA to invite expert missions or arrangement of events for sharing of expertise. PNRA also manages to accomplish the retention of knowledge and succession planning for their staff.

III.6. SUSTAINABILITY OF THE REGULATORY FRAMEWORK

PNRA continually improves its effectiveness through policies, strategies and plans, self-assessment results, independent assessment results, management review, feedback mechanism, non-conformances, corrective actions and preventive actions. The Top Management provides necessary resources for improvement. Implementation plans/processes are prepared to rectify the weaknesses as identified in assessments. The improvement plans are monitored for their completion and effectiveness.

The procedure for preparation and adoption of PNRA regulations requires review of regulations after every five years taking into account obligations of international conventions, feedback from licensing experience, feedback from stakeholders, and current international practices. In this way PNRA keep its regulatory framework sustainable and effective

PNRA knowledge sharing and mentoring programme aims on capturing, retention and sharing of life experiences and tacit knowledge of senior professionals to build organizational competence and information reservoir. PNRA believes that knowledge retention is essential for long-term sustainability of the organizational achievements. In order to transform the tacit knowledge into the explicit knowledge under this programme, seasoned and experienced professionals are invited from within and outside PNRA for sharing their experiences with PNRA employees to improve the organization's performance.[8]

In accordance with PNRA management system, PNRA conducts its overall performance assessment annually against 'Strategic Performance Indicators (SPIs)' and subsequent downstream 'Specific Performance Elements (SPEs)' in order to assess and evaluate the effectiveness of its regulatory processes.

APPENDIX IV.
CASE STUDY: REPUBLIC OF TURKEY

IV.1. NUCLEAR POWER PROGRAMME

Turkey's desire to gain knowledge on the peaceful uses of nuclear technologies led to the signing of an 'Atoms for Peace' agreement with the United States of America (USA) in May 1955. After this cooperation Agreement, Turkey established the Atomic Energy Commission as the nuclear regulatory body with Law no. 6821 on 27 August 1956 and started the studies to build a nuclear research centre and a research reactor and become one of the founding members of IAEA in 1957.

Turkey's first research reactor TR-1 reached criticality on 6 February 1962 in Çekmece Nuclear Research and Training Centre in Istanbul. Later, this reactor was replaced with TR-2 in 1981.

General Directorate of Electrical Power Resources Survey and Development Administration (EIEI) started the first studies in 1965 for the installation of a nuclear power plant. A report was prepared by a foreign consortium suggesting the installation of a 400 MWe pressurized heavy water reactor. After establishment of Turkish Electricity Authority (TEK) in 1970 studies for site selection were commenced in 1974 and TEK gained a site license in 1976 for Akkuyu Site in southern Turkey at the Mediterranean coast.

Atomic Energy Commission evolved to become Turkish Atomic Energy Authority in 13 July 1982 with the Law no. 2690. This law was the main nuclear law in the country until July 2018.

After several attempts without success in previous decades, the Government decided on starting the nuclear programme with Russian Federation. The 'Agreement Between the Government of the Republic of Turkey and the Government of the Russian Federation on Cooperation in Relation to the Construction and Operation of a Nuclear Power Plant at the Akkuyu Site in the Republic of Turkey' (the Akkuyu Agreement) was signed on 12 May 2010.

According to the Akkuyu Agreement a project company will be established by a Russian Consortium to install the NPP. Every completed unit of the NPP will enjoy 15 years of guaranteed electricity sale at a fixed average price over this period. 70% of the electricity produced by the first two units and 30% of the electricity produced for the remaining two units will be purchased by the Government owned Turkish Electricity Trading and Contracting Company (TETAŞ). The rest will be sold by the project company to the free electricity market. At the end of the contract period all the electricity produced will be sold to the free electricity market.

In the frame of Akkuyu Agreement, a project company, Akkuyu Nükleer AŞ, was established as a Turkish company on 13 December 2010 to implement the project for installation of 4 units of AES2006 type WWER-1200 at Akkuyu Site. 100% of the Akkuyu Nükleer A.Ş. is owned by the Russian Consortium according to the Akkuyu Agreement.

Akkuyu Nükleer AŞ was recognized as the 'Owner' of the NPP in accordance with Decree on Licensing of Nuclear Installations, 1983 by TAEK on 7 February 2011. The Site License was transferred to Akkuyu Nükleer AŞ in the frame of Akkuyu Agreement. Since the Site License was dated 1976 and did not contain all the recent information regarding the Akkuyu Site TAEK requested an update to the site report to represent the current conditions and to ensure the application of state-of-the-art methods on the site studies. The updated site report was approved

by TAEK on 6 December 2013. Site Parameters to be applied to the project prepared as a separate report and approved on 9 February 2017.

Akkuyu Nükleer AŞ applied for the construction license on 2 March 2017 for the first unit of the NPP. The limited work permit allowing the construction of non-nuclear buildings was issued on 19 October 2017 and the Construction License was awarded on 2 April 2018. First concrete ceremony took place on 3 April 2018. The planned operation date for the first unit is in October 2023. Akkuyu Nükleer AŞ applied for the construction license of second unit on 22 June 2018. Limited work permit for the second unit was issued on 30 November 2018. Major milestones for the implementation of Akkuyu NPP project is given in Figure 12

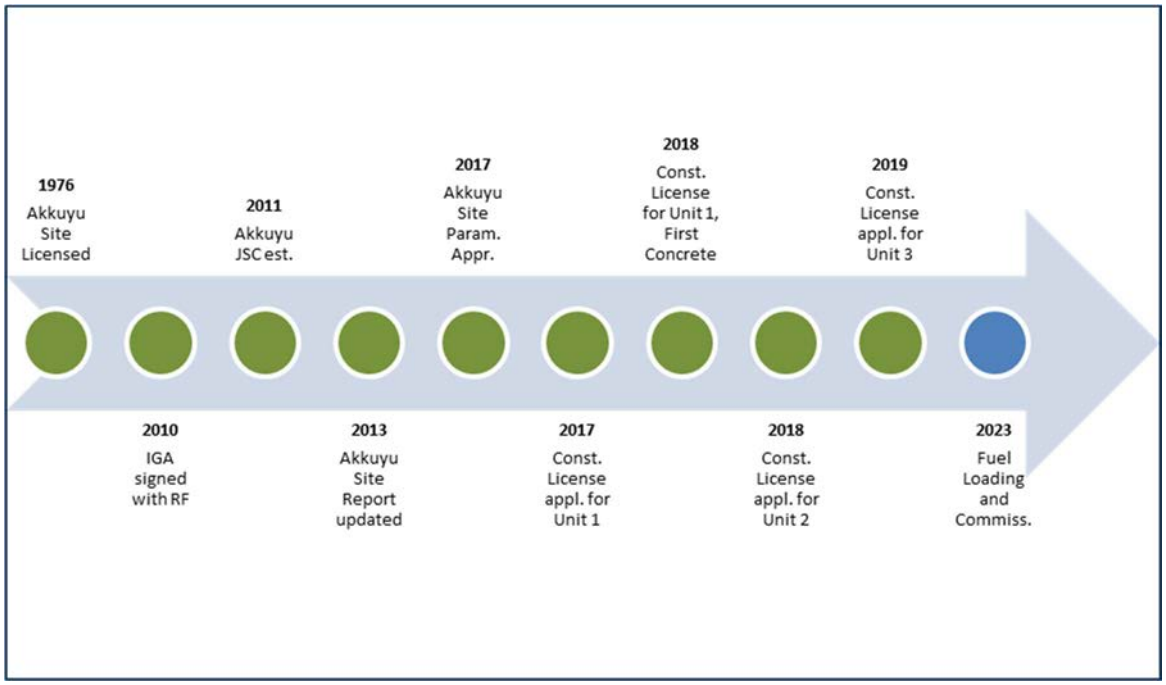


FIG. 12. Major milestones for Akkuyu NPP project.

IV.2. STATUS OF REGULATORY FRAMEWORK PRIOR THE COUNTRY HAS MADE DECISION ON CURRENT NUCLEAR POWER PROGRAMME

IV.2.1. Pre-existing legal framework

Until July 2018, the main Turkish legislative framework regulating nuclear installations consisted of the 'Law on Turkish Atomic Energy Authority, Law No.2690, 1982' which regulated nuclear safety, security and radiation protection and establishing TAEK as the nuclear regulator; the 'Environmental Law' which regulates environmental impact of these facilities and giving the regulatory responsibilities and authorities to Ministry of Environment and Urbanisation; the 'Penal Law', which defines nuclear and radiological crimes and penalties; and the 'Law on Electricity Market' which regulates electricity production licenses and giving regulatory authority to Energy Market Regulatory Authority. There are several other regulatory bodies such as Ministry of Transportation, Ministry of Health etc., which indirectly regulates NPPs in regard of other issues.

Law on Construction and Operation of Nuclear Power Plants and Energy Sale (Law no. 5710) was issued on 9 November 2007. The aim of this law was to provide the procedures and principles for the construction and operation of nuclear power plants and the sale of energy generated from those plants.

In the field of nuclear liability Turkey is a party to the Paris Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960. Its 1982 Additional Protocol is ratified and currently in force in Turkey. A national law on nuclear liability has been drafted in full compliance with Paris Conventions 2004 Protocol but not enacted yet.

IV.2.2. Organization and roles and responsibilities of the regulatory body

Turkish Atomic Energy Authority (TAEK) had been the nuclear regulatory body of Turkey until 2018. It was replaced with newly established Nuclear Regulatory Authority (NDK) on 9 July 2018 with the new nuclear law which was enacted by Decree-Law no. 702 of Council of Ministers. TAEK was established by the Law No. 2690 in 13 July 1982 as a government body reporting to the Prime Minister. However, it had been affiliated with the Ministry of Energy and Natural Resources (ETKB) since 2002. TAEK determined the requirements for the nuclear installations to comply with and awarded the construction license for the first unit of Akkuyu NPP before replaced by NDK.

TAEK had been carrying out the regulatory activities concerning nuclear and radiation safety, together with safeguards and nuclear security. It was also responsible for the coordination and support of research and development activities in nuclear field.

TAEK had a president and three vice presidents, who were appointed by the Prime Minister of the Republic of Turkey. The administrative organs of TAEK included the Atomic Energy Commission, specialized technical and administrative departments and research centres.

Atomic Energy Commission was the decision-making body of TAEK regarding licenses and some of the permits for nuclear installations. President of the TAEK chaired the Atomic Energy Commission which consisted of the Vice Presidents of TAEK, one member from each of the Ministry of National Defence, Ministry of Foreign Affairs, ETKB and of four faculty members in the field of nuclear energy.

TAEK's main organization consisted of four technical and one administrative departmen'. 'Department of Nuclear Safety (DNS)' was mainly responsible for regulatory activities in nuclear safety and security, licensing of nuclear installations (review and assessment of documentation related to nuclear safety), preparation of regulations and inspection of nuclear installations and all related issues

IV.2.3. Regulations in place

Before the initiation of current nuclear programme Turkey had a set of regulatory documents forming a licensing system and defining requirements for safety, radiation protection and safeguards. Regarding nuclear safety and radiation protection, there were two decrees under the Law No.2690. Decree on Licensing of Nuclear Installations sets the licensing process for nuclear installations including steps of licensing, the documents and information needed to be submitted to the regulatory body, authorizing entity for each step and the permissions given to the applicants by each step. Further details on safety principles were addressed in regulations.

TABLE 8. LIST OF REGULATIONS IN PLACE AT THE BEGINNING OF AKKUYU NPP PROJECT IN TURKEY

Decree/Regulation	Issue Date	Scope
1. Decree on Licensing of Nuclear Installations	1983	Establishes the licensing system, defines rules and procedures for licensing, inspections and enforcements
2. Decree on Radiation Safety	1985	Defines general rules for radiation safety regarding producing, using, storing, importing and exporting, acquiring, selling and transportation of the ionizing radiation sources.
3. Regulation on Physical Protection of Nuclear Materials	1979	Defines national aspects of physical protection of nuclear materials
4. Regulation on Working Procedures of Atomic Energy Commission	1985	Defines AEC's working procedures
5. Regulation on the Establishment and Working Procedures of Advisory Committee on Nuclear Safety (ACNS)	1997	Defines procedures for the establishment of ACNS and also defines its working procedures
6. Regulation on Nuclear Material Accounting and Control	1997	Defines rules and procedures for accounting for and control of nuclear materials
7. Regulation on Radiation Safety	2000	Defines requirements for activities utilizing radiation sources
8. Regulation on Nuclear and Radiological National Emergency Preparedness	2000	Defines requirements, responsibilities and interfaces between responsible organizations regarding a nuclear and radiological emergency.
9. Regulation on Safe Transport of Radioactive Material	2005	Defines measures for stages of loading, transportation, unloading, temporary storage as well as delivery to recipient of the packages containing radioactive materials.
10. Regulation on Nuclear Safety Inspections and Enforcement	2007	Defines procedures and rules of the inspections to be carried out for the confirmation of nuclear safety and determines enforcements to be applied in case of nonconformances
11. Regulation on Basic Requirements on Quality Management for the Safety of Nuclear Installations	2007	Defines rules and procedures and requirements to be applied to nuclear installations to assure the quality
12. Regulation on Specific Principles for Safety of Nuclear Power Plants	2008	determines the safety principles to be complied in site evaluation, design, construction, commissioning, operation and decommissioning phases; as well as principles related to the emergency and accident management.
13. Regulation on Design Principles for Safety of Nuclear Power Plants	2008	Establishes safety principles for the design of nuclear power plants.
14. Regulation on Site of a Nuclear Power Plant	2009	Establishes the nuclear safety requirements for siting of nuclear power plants.

Decrees and regulations directly or indirectly related to the safety of nuclear installations before initialization of current nuclear programme are given in Table 8.

IV.3. DEVELOPMENT OF THE REGULATORY FRAMEWORK FOR THE OVERSIGHT OF THE NUCLEAR POWER PROGRAMME

IV.3.1. Planning for the establishment of the regulatory framework

Since the studies in Turkey to achieve competence in the field of nuclear energy started back in 1950's some infrastructure was already in place and some important experience from earlier unsuccessful attempts to install NPPs was gained. This infrastructure and the experience were utilized for the initiation of the latest nuclear energy programme. Turkey established the first nuclear regulatory body back in 27 August 1956 with Law no. 6821 as the Atomic Energy Commission and to benefit from the international experience in the area become one of the founding members of IAEA in 1957. In 1982 Atomic Energy Commission was transformed to TAEK by Law no. 2690. However, TAEK had also some promotional responsibilities and been the operator of some facilities requiring regulatory control.

To improve the regulatory system in Turkey and to achieve full compliance with the international requirements and expectations in the area a draft Nuclear Energy Law had been prepared by TAEK under Ministry of Energy and Natural Resources coordination. This draft law has been enacted with Decree-law no. 702 on 9 July 2018 and with Presidential Decree no.4 on 15 July 2018.

IV.3.2. International commitments for safety, security, non-proliferation and nuclear liability.

Turkey is a party to most of the international legal instruments for safe, secure and responsible use of nuclear energy and has adhered to their provisions (see Table 20026). According to the Constitution of Republic of Turkey all these legal instruments are at the same level with Turkish Laws.

IV.4. DEVELOPMENT OF REGULATORY BODY(S)

Atomic Energy Commission was replaced with the Turkish Atomic Energy Authority in 1982 with the Law no.2690. Regulation of all the activities in the field of peaceful uses of nuclear energy including, issuing regulations, making safety reviews and assessments, granting permissions and licenses, conducting inspections and applying enforcement actions were among the authorities and responsibilities of TAEK.

On 9 July 2018 with enactment of new nuclear law, a new nuclear regulatory body was established as 'Nükleer Düzenleme Kurumu' (NDK – Nuclear Regulatory Authority). All TAEK's regulatory duties, responsibilities and authorities are transferred to the newly established NDK. New nuclear law also contains provisions for the transfer of personnel, budget, effective protocols and agreements together with the continuing projects related to the regulatory activities to NDK. Presidential Decree no.4 on 15 July 2018 converted TAEK to a research and development organization in the nuclear field and gave the responsibility of acting as national radioactive waste management organization. Presidential Decree no.4 on 15 July 2018 and Presidential Decree no.14 on 24 July 2018 made some amendments to the duties, responsibilities and authorities of NDK. Furthermore, Law no 7164 on 14 February 2019 amended Decree-Law 702 to include administrative and criminal sanctions.

TABLE 9. LIST OF INTERNATIONAL LEGAL INSTRUMENTS TO WHICH TURKEY IS A CONTRACTING PARTY IN THE AREAS OF SAFETY, SECURITY AND SAFEGUARDS

International Legal Instruments	Entry into Force in Turkey
1. Convention on Early Notification of a Nuclear Accident	3 February 1991
2. Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency	3 February 1991
3. Convention on Nuclear Safety September	24 October 1986
4. Convention on Physical Protection of Nuclear Materials	8 February 1987
5. Amendment to the Convention on the Physical Protection of Nuclear Material	8 May 2016
6. International Convention for the Suppression of Acts of Nuclear Terrorism	ratified on 5 August 2012
7. Treaty on the Non-Proliferation of Nuclear Weapons	17 April 1980
8. The Agreement between Turkey and the IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear	1 September 1981
9. Protocol Additional to The Agreement between Turkey and the IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons	17 July 2001
10. Comprehensive Nuclear Test Ban Treaty	ratified on 26 December 1999
11. Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960, as amended by the Additional Protocol of 28 January 1964 and by the Protocol of 16 November 1982	23 May 1986
12. Revised Supplementary Agreement concerning the provision of Technical Assistance by the IAEA	11 November 1980

IV.4.1. Roles and responsibilities of regulatory body(s)

Turkish Government System was changed in July 2018. Therefore, some important modifications to the legislative and regulatory structure are being implemented. Turkish regulatory structure was composed of laws, decrees, regulations, guides and codes and standards in that order of hierarchy. In the new legislative system in addition to the laws enacted by the Parliament, the President of the Republic has also authority to issue Presidential Decrees. These Presidential Decrees has the power of law if not replaced with Laws enacted by the Parliament. Another issue is the replacement of TAEK as the nuclear regulatory body with the newly established Nuclear Regulatory Authority (NDK). Consequentially all the regulatory system will be modified to represent the current governmental structure.

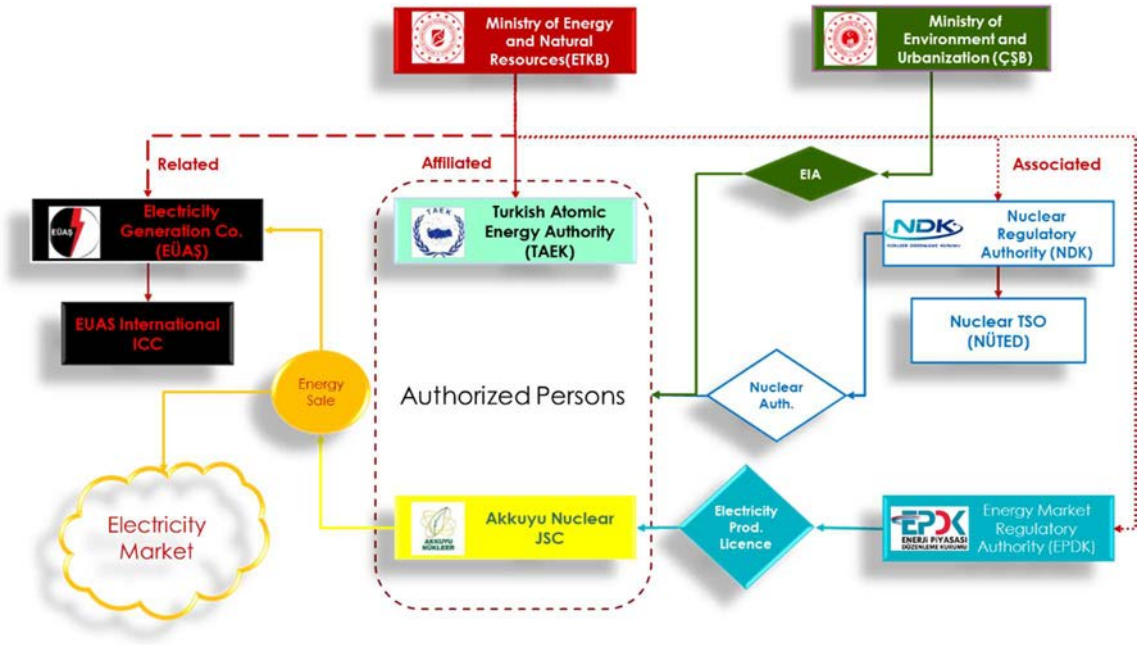


FIG. 13. Organizational structure regarding nuclear energy in Turkey.

Ministry of Environment and Urbanisation (MoEU) establishes principles of national policy, related plans and programs for protection and improvement of the environment, and the prevention of environmental pollution. The MoEU's responsibilities include ensuring the most proper and effective use and protection of land, the protection and improvement of the natural plant and animal habitat and the prevention of environmental pollution. MoEU defines the format of environmental impact assessment report's chapter regarding radiological effects with NDK's assent. These chapters will be reviewed and assessed by NDK.

Energy Market Regulatory Authority (EPDK) is the independent regulatory authority responsible for regulation and supervision of the electricity market in a competitive environment. EPDK issues electricity production licenses.

There are several other regulatory bodies such as Ministry of Transportation, Ministry of Health etc., which indirectly regulates NPPs in regard of other issues. Figure 13 shows the main organizations having roles in the implementation of the nuclear power programme in Turkey.

IV.4.2. Organizational establishment and development

TAEK had a human resources plan. A report regarding human resources planning for Department of Nuclear Safety (DNS) was prepared in 2013. Later, the Report was revised by using the latest scenario according to results of IAEA Expert Mission to review draft national HRD plan in May 2015. The report included a gap analysis and recruitment data for medium term (for Akkuyu and Sinop licensing progress until 2030) and short-term needs. According to this report for the regulatory activities for Akkuyu and Sinop NPP Projects, 120 and 170 technical personnel are required by 2016 and 2020 respectively. DNS hired 20 technical staff in March 2014 and 10 in March 2015 and had about 73 technical staff by June 2016. To reach the required numbers, there was a plan to increase the staff by 20–40 for the licensing of Akkuyu and 40–60 for Sinop licensing.

New nuclear law has provisions for the transfer of regulatory personnel employed in DNS in TAEK to NDK. However, it is not clear yet how the new regulatory system would affect the human resources development plans.

NDK is composed of a Nuclear Regulatory Board and Presidency. The decision-making organ of the NDK is the Nuclear Regulatory Board. This Board consists of 5 people including the President of NDK (who also chairs the Board) and a Second Chairman. All Board members are assigned by the President of the Republic. President of the Republic also appoints President of NDK and Second Chairman. On 5 February 2019 the President of NDK and the Board Members are appointed by a Presidential Decree. The Regulation on Working Procedures and Principles of Nuclear Regulatory Board was issued on 11 April 2019.

The Presidency consists of the President of NDK, two vice presidents, and service units. Presidency of the Republic of Turkey issued 'Regulation on Organization of Nuclear Regulatory Authority' on 25 April 2019. This regulation defines the organizational structure of NDK and duties and responsibilities of its units.

NDK's main organization consists of six technical and five administrative units (see Figure 14).

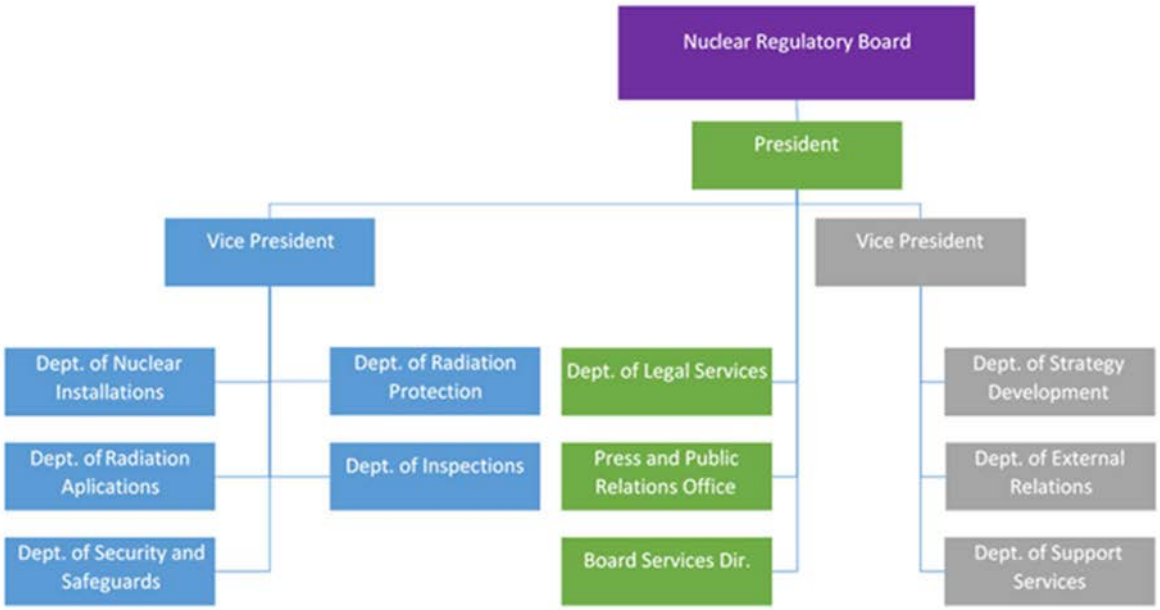


FIG. 14. Organizational chart of the NDK.

IV.4.3. Prioritization and development of regulations and guides

TAEK had the responsibility and authorization to issue decrees and regulations in the field of nuclear energy. Regulations related to nuclear safety were being developed by Department of Nuclear Safety in accordance with the Directive on Preparation of Secondary Legislation. This Directive defines detailed procedures for planning, drafting, consulting with stake holders, reviewing and issuing the regulations, guides and other regulatory documents.

Rules and procedures related to the licensing of nuclear installations were laid out in the 'Decree on Licensing of Nuclear Installations', entered into force in 1983. The decree defined permits and licenses to be obtained, requirements for applications to these permits and licenses, including lists and contents of documents to be submitted, review and assessment procedures, the authorizing entities within TAEK for each authorization, approval mechanisms for modifications during construction and operation, and authorizes TAEK for inspecting the installations throughout their lifetime and enforcing penalties such as limiting, suspending and revoking the licenses.

Law no.2690, the 'Decree on Licensing of Nuclear Installations,1983', the 'Directive on Determination of Licensing Basis Regulations, Guides and Standards and Reference Plant for Nuclear Power Plants, 2012' and the regulations issued by TAEK constituted the basis of the legal framework of nuclear safety for nuclear installations in Turkey.

IV.4.4. Implementation of licensing process for different stages

Prior to July 2018, licensing of nuclear installations was under the responsibility of TAEK regarding nuclear safety, security and radiation protection issues in accordance with the process which is defined in the 'Decree on Licensing of Nuclear Installations, 1983'. According to the decree, licensing procedure was initiated by the applicant to be recognized as the 'Owner'. Licensing process for an NPP comprised of three main stages in succession: Site License, Construction License and Operating License (See Figure 15). There were several permits functioning as hold points during the licensing process. These are limited work permit, commissioning permit, permit to bring fuel to site, fuel loading and test operations permit for operating license. For each authorization, documents required for review and assessment of TAEK were defined in the decree. There was no design approval authorization in Turkey. The Decree also required the Owner to apply for authorization of TAEK for every modification that may have an impact on the safety of nuclear installation. Authorization process for decommissioning stage was not defined in the Decree. The new nuclear law defines decommissioning as an activity which requires authorization. A new regulation will be developed to outline the licensing process in accordance with the provisions of the new nuclear law. Until this regulation is issued, the decree will be in force.

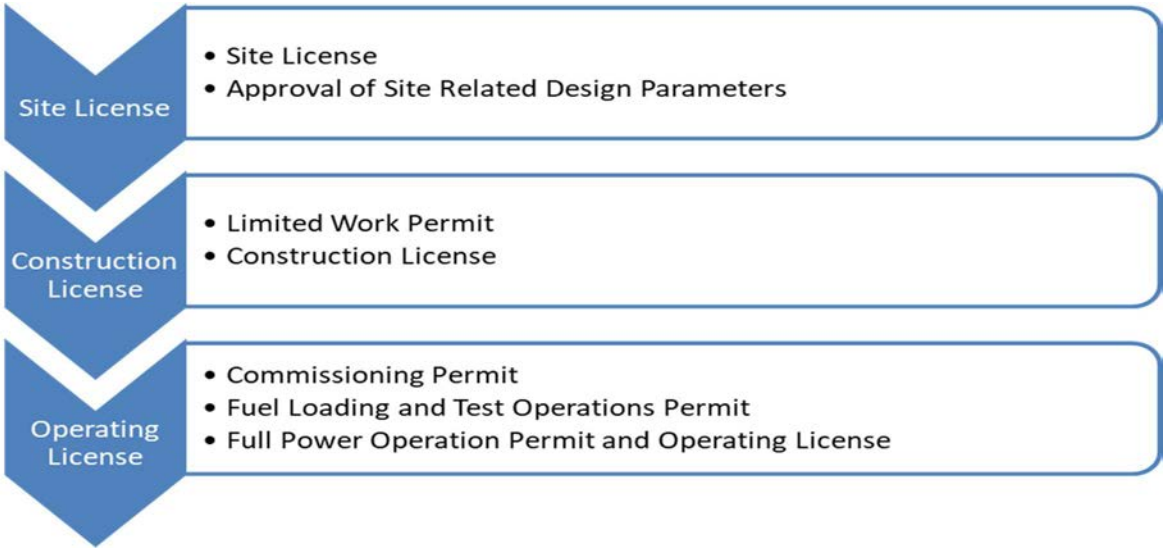


FIG. 15. Licensing steps for nuclear installations in Turkey.

Licensing approach of TAEK was defined in the 'Directive on Determination of Licensing Basis Regulations, Guides and Standards and Reference Plant for Nuclear Power Plants, 2012', which laid out the rules for establishing a licensing basis for NPPs. This Directive is being implemented for the Akkuyu and Sinop Projects. A list of applicable regulations, guides and standards has been determined by the Akkuyu Nükleer AŞ for the Akkuyu NPP Project and by EÜAŞ (with the assistance of future project partners of Japanese Consortium) for Sinop NPP Project. Atomic Energy Commission of TAEK approved the 'List of Licensing Basis for Akkuyu Nuclear Power Plant' on 2 November 2012 and its revision (Rev.2) on 14 November 2014. Akkuyu NPP licensing basis list is mainly composed of Turkish regulations, IAEA Safety Fundamentals and Requirements and Russian Federation Regulations. Relevant standards and guides of Turkey and Russian Federation are also included in the List. Novovoronezh-II NPP in Russian Federation was approved as the reference plant for Akkuyu NPP by Atomic Energy Commission of TAEK on 16 August 2012.

Licenses and permits issued so far for Akkuyu NPP project is given in Table 10.

TABLE 10. LICENSES AND PERMITS ISSUED FOR AKKUYU NPP PROJECT UNTIL 2019

Licence/Permit	**Date**	**Purpose**
Site Licence	1976	Suitability of the site to host an NPP
Approval of Updated Site Report	2013	Updating site studies based on developments after the site license issued in 1976 including changes in the site environment, changes in the regulatory requirements, the proposed NPP project and the lessons learned from the Fukushima accident
Approval of EIA report	2014	To ensure environmental safety
Approval of Site Parameters	2017	Approval of the site parameters to be used in the design of NPP
Limited Work Permit for Unit 1	2017	Commencement of manufacturing and non-safety related construction.
Construction License for Unit 1	2018	Commencement of nuclear safety related construction and installation of systems and equipment
Limited Work Permit for Unit 2	2018	Commencement of manufacturing and non-safety related construction.
Construction License for Unit 2	2019	Commencement of nuclear safety related construction and installation of systems and equipment

IV.4.5. Development and implementation of inspection programme

TAEK conducted inspections based on the 'Regulation on Nuclear Safety Inspections and Enforcement, 2007' for the assurance of the authorized organization's compliance with the conditions set out in the authorization and applicable regulations. Regulatory inspection and

enforcement activities covered areas throughout the lifetime of a nuclear installation. TAEK's main philosophy for the regulatory inspection was 'Trust and Verify'. The scope and content of the inspection to be conducted, not only limited to the authorized organization but also to include its contractor and supplier chains. TAEK had the right to take enforcement actions when it deemed necessary in the event of deviations from, or non-compliance with conditions and requirements. TAEK's regulatory inspections were including a range of planned and reactive inspections over the lifetime of a nuclear installation and inspections of other relevant parts of the operator's organization and contractors/suppliers to ensure compliance with regulatory requirements. The methods of inspection were including examination and evaluation of all records and documentation, and surveillance, monitoring, auditing and interviewing of personnel and management, as well as performing of actual tests and measurements in all phases of the installation. It was foreseen by TAEK, in addition to TAEK staff, outside local or foreign services might be required to be procured for specific inspection tasks for pre-evaluation and obtaining data where necessary.

TAEK conducted inspections to owners of NPP's and their sub constructors. The number and type of inspections were being determined in accordance with their safety significance. TAEK performed inspections during site studies for the determination of site parameters for Akkuyu Project. Since the beginning of the construction with limited work permit in 2017 construction inspections are being performed as well as manufacturing inspections to the manufacturers of important items to safety.

IV.5. CHALLENGES FACED AND THE SOLUTIONS APPLIED

The main challenge was the need for a comprehensive nuclear law. The Law No.2690 was the main law in the nuclear field. However, it was not a comprehensive nuclear law addressing all the issues. It was mainly establishing the Turkish Atomic Energy Authority as an organization to be responsible almost everything regarding the peaceful use of atomic energy from regulation to promotion. Furthermore, it was an old law not representing latest up to date regulatory practices in the world. it was issued in 1982 and only had minor amendments. Due to difficulties in amending and changing an existing law and with no pressing requirement in the lack of a nuclear programme it was found more practical to fix the issues by issuing regulations. A new nuclear law has been drafted under the coordination of Ministry of Energy and Natural Resources with extensive support of TAEK. Although it was not enacted in due time it formed the basis of new regulatory system established by decree-laws and presidential decrees under new governmental system.

Delay in the enactment of a comprehensive nuclear law resulted in initiation of the nuclear programme under the old regulatory system. Transition to the new system causes extra stress over the nuclear programme. Some transition issues foreseen like transfer of experience to new regulatory body and included in the legislation creating the new regulatory system.

Lack of legislation forming a complete set of requirements for the implementation of nuclear programme was another important issue. Advise from the INSAG-26 is used to apply a licensing approach utilizing IAEA requirements and vendor country requirements to patch the gaps in Turkish Regulations. A list of applicable documents has been agreed upon with the owner of the NPP at the beginning of licensing.

Turkey has an ambitious nuclear programme requiring rapid deployment of nuclear power plants from multiple vendors to cope with the fast growth rate of the country and increase the security of energy supply. Training of operating personnel can be planned with the progress of

nuclear programme, but the training of the regulatory personnel should take part well before. At least key personnel with the key abilities especially for review and evaluation of safety assessment documents should be present. Safety inspectors should also be trained and be ready before commencement of the manufacture of important items to safety. There is a need to improve human resources very fast. Although it is possible to recruit new personnel, they are newly graduated people from the universities. It is a challenge to increase their experience. TAEK used international organizations, vendor country regulators, international projects and TSO's to train new recruits. Reference plant approach also utilized to improve the experience of the TAEK staff.

Due to its nature nuclear programme develops rapidly after reaching a maturity level. This rapid development causes political and infrastructural stress over regulatory body. Regulatory body should be independent and well prepared to overcome this stress. It should also be foreseen the experienced regulatory personnel are prone to leave the organization due to their qualifications are highly sought after by the national and foreign industry and international organizations. Either regulatory body should have a plan to be able to fill their absence or create better opportunities to be able to keep them. Under new nuclear law NDK can hire experienced domestic and foreign staff under special contracts outside the national recruitment system.

Legislation affecting the nuclear programme is not just the nuclear legislation. There can be a lot of interfaces between nuclear regulations and other laws and regulations. For example, public procurement laws can negatively affect regulatory performance if they cause delays in procurement of technical support services for regulatory body. It is important to review the non-nuclear regulations and detect possible issues early in the beginning of nuclear programme.

National procurement legislation created challenges during the tenders for hiring TSO's. National procurement legislation is not designed and not foresee procurement of technical services fulfilling requirements of a nuclear regulatory body for this size of a project. It caused delays in hiring of TSO's. An exception to the national procurement legislation added to allow new regulatory body acquire TSO services without applying national procurement legislation requirements.

Several other conventional legislations created contradictions with the nuclear safety and security principles. Amongst these fire safety regulation, conventional construction inspection legislation, regulation regarding the approval of electricity generation facilities can be count. The issues tried to be solved through giving exemptions to nuclear facilities and creating special legislation to take them under the supervision of regulatory body in those respects. However, this result in extra workload to the regulatory body.

Another challenge was the establishment of a nuclear liability system. Turkey is a party to the Paris Convention in this field and its 1982 protocol is in force. A few studies performed for drafting a domestic nuclear liability law, but lack of political interest prevented their conclusion. Although the general principles and requirements are applicable in Turkey the issues to be determined in domestic legislation are not in place. For example, there is no insurance system and no dedicated courts for nuclear liability. A new draft law has been prepared under the coordination of Ministry of Energy and Natural Resources in full compliance with 2004 Protocol of Paris Convention. However, this law has not been enacted yet.

The organizational structure regarding nuclear energy should be established as early as possible. It is difficult to make major modifications to the organizations and their roles during the later phases of the nuclear program. A modern system of nuclear legislation complete with a set of

requirements in proper regulatory documents should be in place as early as possible. Turkey tried to solve this difficulty in later phases by implementing vendor country requirements as suggested by INSAG. However, understanding and implementing requirements coming from a foreign legislative system creates a major challenge for the regulatory body.

As mentioned before TAEK's licensing system included Russian regulatory requirements to patch the gaps in Turkish requirements. Understanding and implementing requirements coming from a foreign legislative system created a major challenge for the regulatory body. TAEK requested the translation of all the foreign documents forming the licensing basis. However, it is difficult to ensure the quality of translations. Regulatory body has to hire translators as early as possible and train them to improve their understanding of the technology. Furthermore, these foreign requirements are a part of a different legislative environment and may create unexpected weaknesses. Regulatory body has to show utmost care when implementing these requirements. Legislative and regulatory system of the origin country has to be well understood by the regulatory personnel. Special aid may be requested from the regulatory body of the vendor country.

IV.6. PREPARATION FOR FUTURE PHASES

Under the new nuclear law, a new nuclear regulatory body established. When it becomes fully functional it should be expected to see new regulations in place especially covering later phases in more details. Also, it should create a system of hiring and training new staff for future phases of review and assessment and inspections. This should be done under the stress of competition with the other stakeholders forming the nuclear industry. Fortunately, new law contains features to allow creation of better conditions for regulatory personnel. It also creates opportunities to fine tune the supervision of the nuclear installations. However, the ambitious nuclear power programme has the potential to create risks by stretching the infrastructural capacity of the country. Especially the human resources should be precisely managed for not allowing any gaps in the system.

Turkey is a party to the Paris Convention. Although this forms the legal basis for nuclear liability there is still a need for a domestic law to create a sustainable insurance system. A draft law has been prepared and it should be enacted. Similarly, funds created for radioactive waste management and decommissioning under new law should become operational by the time the first unit of Akkuyu NPP comes online.

There is also a need for the harmonization of the regulatory requirements applied for Akkuyu and Sinop NPP projects. All foreign requirements relevant to Akkuyu and Sinop NPP projects have to be transposed and adopted into Turkish legislation.

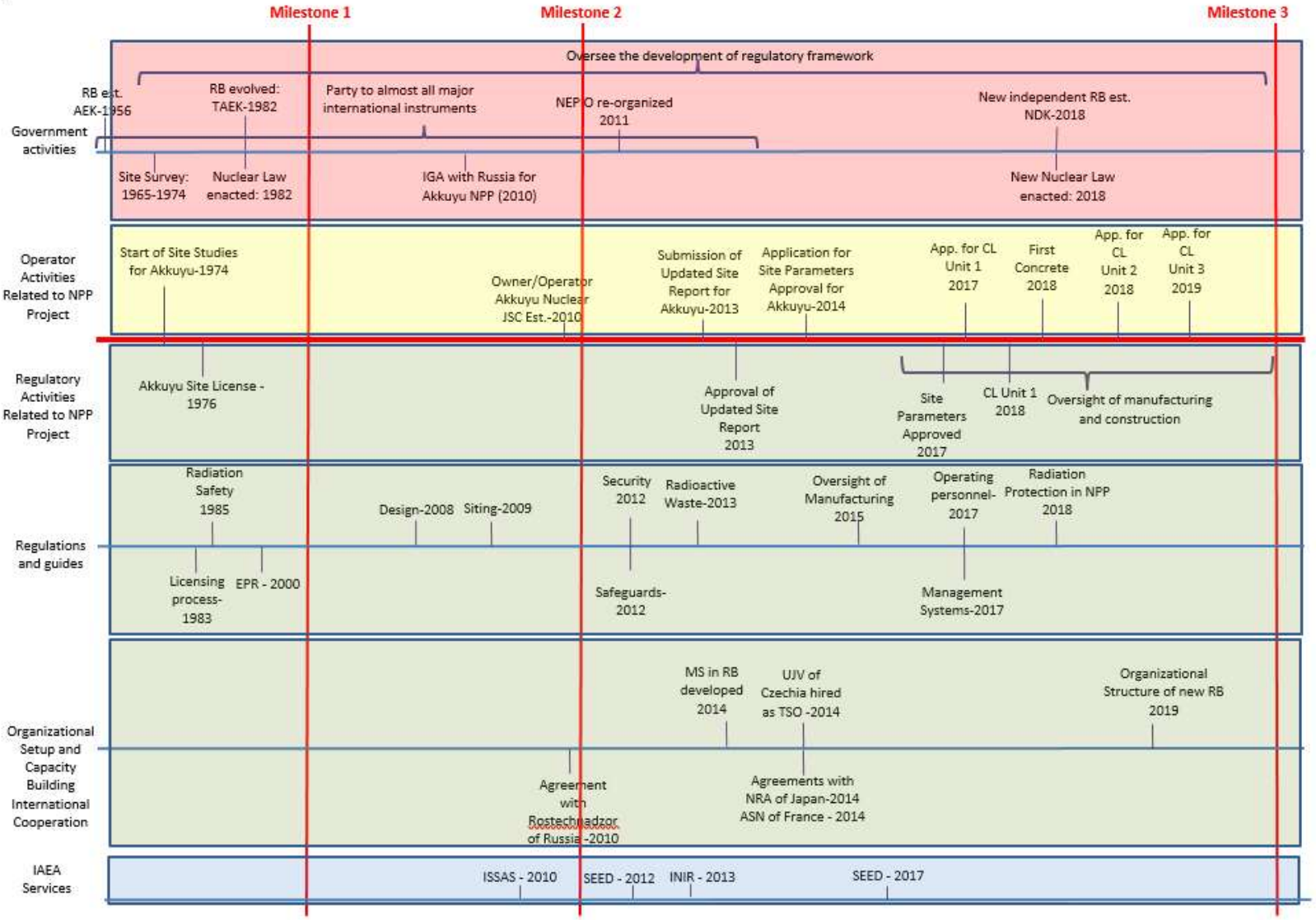
IV.7. SUSTAINABILITY OF THE REGULATORY FRAMEWORK

Turkey has a long and rich history in nuclear area. It is one of the first countries interested in with the benefits of peaceful utilization of nuclear energy. For a long time, it struggled with unsuccessful attempts to install nuclear power plants. However, this struggle brought experience and institutions to establish an infrastructure stable and sustainable enough to bring the country to the verge of first NPP.

Turkey has strong educational institutions, technical and technological infrastructure, international ties to share experience, and infrastructure to rapidly develop human resources.

New regulatory system being established after July 2018 has all the means and opportunities to establish a modern and sustainable nuclear regulatory infrastructure with an independent regulator with enough resources and authorities.

Timelines for Key Activities to Establish and Implement Regulatory Framework – Turkey Case



APPENDIX V.
CASE STUDY: UNITED ARAB EMIRATES

The following text summarizes the development by the United Arab Emirates (UAE) of its peaceful nuclear energy programme during the ten-year period beginning in 2008 with the initial consideration by the Government of the potential development of a peaceful nuclear energy programme, up to the substantial completion of the 4 x 1400 MWe Barakah nuclear power plant.

V.1. UAE NUCLEAR POWER PROGRAMME

In April 2008, after considering various supply options for meeting projected future electricity demands, the UAE Government published an in-depth policy paper titled *Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy* (hereafter referred to as 'The Nuclear Policy'*).*[9]

Analysis conducted by official UAE entities concluded that the national demand for electricity was projected to rise at an annual growth rate of roughly 9% from 2007. The UAE's interest in evaluating nuclear energy was motivated by the need to develop additional sources of electricity to meet these future demand projections and to ensure the continued rapid development of its economy.

The Nuclear Policy outlined the potential role of nuclear energy in the UAE's energy programme and set out the UAE's commitments to operational transparency and sustainability, and to the highest standards of non-proliferation, safety and security throughout the life of the programme.

Following the adoption of the Nuclear Policy, the government began implementation of the programme. The Executive Affairs Authority (EAA) of Abu Dhabi acted as the Nuclear Energy Program Implementation Organization (NEPIO) as recommended by the IAEA. The NEPIO developed an internal strategy document titled 'Roadmap to Success' which set out the steps in the planned development of the programme based on the guidance in the IAEA Milestones document.

The NEPIO incubated the planning and development of the nuclear regulatory body and the owner/operator before they were formally established. This including the recruitment of senior managers to assist with planning. The NEPIO also supported the process of bidding and selection of the supplier of the nuclear power plant technology.

On 23 September 2009, the UAE issued Federal Law by Decree No. 6 of 2009 on the Peaceful Uses of Nuclear Energy ('the Nuclear Law'). The Nuclear Law set in place the legal framework for nuclear activities in the State and formally established the Federal Authority for Nuclear Regulation (FANR) as the independent national nuclear regulatory body.

[9] Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy, 2008.

On 23 December 2009, the President of the UAE in his capacity as the Ruler of Abu Dhabi established by decree the Emirates Nuclear Energy Corporation (ENEC), the organization charged with implementing the UAE nuclear energy programme.

Shortly after its establishment ENEC announced, on 27 December 2009, that following an intensive bidding process it had selected a team led by the Korea Electric Power Corporation to design, build and assist in operation and maintenance of four, 1,400 MWe civil nuclear power units in the UAE.

The UAE strategy for procurement of nuclear technology sought a proven 'Generation III' design which was previously licensed based on internationally recognized standards and with a demonstrated history of safe operation. This strategy was aimed at achieving high standards of safety and minimising project risks.

The APR-1400 is derived from technology licensed in the USA. Republic of Korea has accumulated a good history of operating experience with its fleet of domestic plants. The APR-1400 builds on this experience and includes several improvements in safety technology. The APR-1400 units at Shin-Kori Units 3&4 in Republic of Korea were designated as the reference plants for the UAE facility.

ENEC selected a site for the facility at Barakah on the Arabian Gulf coast approximately 300km west of the city of Abu Dhabi. In July 2012 FANR issued a construction licence which authorized ENEC to construct the safety-related structures, systems and components for Units 1 and 2 at the Barakah site. FANR subsequently issued a second construction licence for Units 3 and 4 in September 2014.

By mid-2018, ENEC had completed the construction and preoperational testing of Unit 1 at Barakah. Fresh fuel for the Unit 1 first core was stored at site under licence from FANR in compliance with all safety, security and safeguards requirements. The issuance of the operating licence for Unit 1 awaits the completion of operational readiness steps by Nawah, the operating organisation, and their verification by FANR. All four units are expected to be operating by 2020.

The milestones and achieved timeline for the UAE peaceful nuclear energy programme are illustrated in Figure 16.

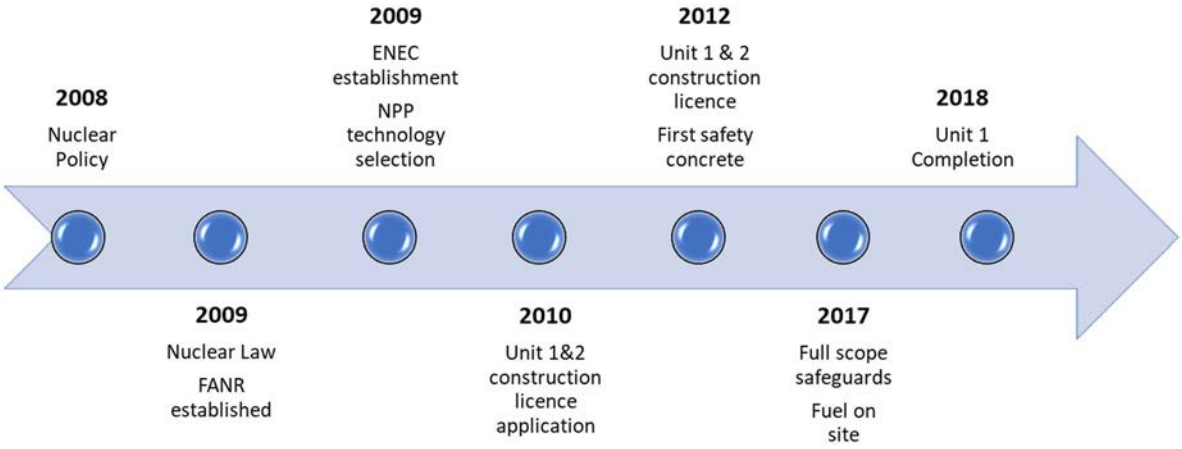


FIG. 16. The milestones and achieved timeline for the UAE nuclear power programme.

V.2. STATUS OF REGULATORY FRAMEWORK BEFORE THE UAE MADE A DECISION ON CURRENT NUCLEAR POWER PROGRAMME

Before the decision to embark on a nuclear energy programme, activities in the UAE were limited to the use of radiation sources in the medical, academic and industrial sectors of the economy. The UAE also participated in various Technical Cooperation projects with the IAEA. The UAE has been a Member State of the IAEA since 1976.

V.2.1. Pre-existing legal framework

UAE Federal Law No. (1) of 2002, as amended by Federal Law No. (20) of 2006 Regarding the Regulation and Control of the Use of Radiation Sources and Protection Against their Hazards, established the Radiation Protection and Control Department (RPCD) in the Federal Environment Agency (FEA) as the regulatory body responsible for regulating and controlling the use of radiation sources.

The above Laws gave the following functions and responsibilities to the RPCD:

- Preparing regulations;
- Authorisation of activities and practices;
- Inspecting, following-up and controlling radiation sources and their uses;
- Supervision of training programmes;
- Preparation of an emergency plan to respond to radiological incidents and accidents at the national level.

V.2.2. Organization

The Director of the RPCD reported to the Director General of the FEA. The RPCD consisted of two sections, namely:

— Radiation Control Section, responsible for preparation of regulations, issuance of authorizations, performance of inspections, enforcement of laws and regulations and setting up radiation protection criteria; and

— Radiation Protection Section**,** responsible for environmental studies (natural and man-made radioactive material), ongoing environmental monitoring programme), dosimetry services, and calibration services.

The legislation also established a Radiation Protection Committee to advise the Director General of FEA. The membership of the Radiation Protection Committee consisted of specialists nominated by other concerned governmental bodies such as the Ministry of Health, Ministry of Interior, local authorities, etc. The Director of the RPCD played the role of rapporteur of the Committee. The responsibilities of the Radiation Protection Committee included approval of regulations and guidelines on radiation safety and practices in the light of scientific and technological development, and provision of opinions and technical advice on matters referred to it by the chairman.

V.2.3. Regulations in place

The RPCD issued three regulations to support its regulatory functions, namely:

— Basic Regulations for Protection Against Ionizing Radiation;

— Regulations for the Safe Transport of Radioactive Materials, and

— Regulations for Radioactive Waste Management.

The UAE signed the Non-Proliferation Treaty in 1995 and concluded a Small Quantities Protocol with the IAEA in 2003. The SQP required a limited accounting system, comprising annual summaries of international transfers, to fulfil the Comprehensive Safeguards Agreement obligations for reporting imports and exports of nuclear material.

The IAEA conducted a Radiation Safety and Security of Radiation Sources Infrastructure Appraisal (RaSSIA) mission in the UAE in 2006. The RaSSIA mission found that Federal Law No. 1 of 2002 established a comprehensive legal basis for regulation although it did not clearly define the roles of the five regulatory bodies it named and did not extend to government uses; and the role of the Radiation Protection Committee needed clarification.

V.3. DEVELOPMENT OF THE REGULATORY FRAMEWORK FOR THE OVERSIGHT OF THE NUCLEAR POWER PROGRAMME

The following sections describes the actions performed by the UAE government and FANR to establish and implement the regulatory framework for nuclear power.

V.3.1. Planning for the establishment of the regulatory framework

The Nuclear Policy set out the goals that guided the establishment of the regulatory framework. The Nuclear Policy committed the UAE to the highest standards of safety, security and non-proliferation, and stated that the UAE will work directly with the IAEA and conform to its standards. Specifically, the Nuclear Policy recognized that “the establishment of an independent, vigilant and effective regulatory authority is a cornerstone for any stable, credible, safe and secure nuclear energy program. Accordingly, a primary UAE objective, in the event that the UAE chose to commission nuclear power plants within its territory, would be to

establish a body authorized and competent to exercise supervision over nuclear safety independently of manufacturers and operators."

The Nuclear Policy envisaged that the new independent regulatory body in the UAE would be endowed with the powers recommended by the IAEA, namely to establish requirements and regulations; issue licenses; inspect and assess facilities and structures connected to facilities; (4 monitor and enforce compliance with regulations; and establish a State System for Accounting and Control (SSAC) of nuclear material (including spent fuel and radioactive waste) in accordance with IAEA Safeguards obligations. Key steps to be taken regarding the regulatory framework were defined in the planning document titled 'Roadmap for Success' prepared by the NEPIO in line with the IAEA Milestones criteria.

Multilateral Instruments Adopted by the United Arab Emirates

- *Convention on Nuclear Safety*
- *Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management*
- *Convention on Early Notification of a Nuclear Accident*
- *Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency*
- *Vienna Convention on Civil Liability for Nuclear Damage, as amended by the 1997 Protocol*
- *Convention on the Physical Protection of Nuclear Material with amendment*
- *Treaty on the Non-Proliferation of Nuclear Weapons (NPT)*
- *Comprehensive Safeguards Agreement Between the UAE and the IAEA*
- *Additional Protocol to the Safeguards Agreement*
- *Illicit Trafficking Data Base of the IAEA*

In the period before FANR's legal establishment, while the organization was still under formation, the senior management appointees planned the development of the regulatory body and the regulatory framework with the assistance of the IAEA and expert consultants.

V.3.2. International commitments for safety, security, non-proliferation and nuclear liability.

The UAE was party to several international safety and non-proliferation agreements before the launch of the nuclear energy programme. To meet the Nuclear Policy commitments on transparency and international cooperation, the UAE became a party to additional instruments as listed in the side box. The UAE has now acceded to all the relevant international agreements in the areas of nuclear safety, nuclear security, and non-proliferation and has implemented these agreements through the national laws and regulatory framework.

V.3.3. Development of the legal framework for nuclear activities

The legal framework establishes the duties and responsibilities of the various organizations necessary for a successful nuclear power programme. Legislation also should implement, or authorize implementation of, the international instruments to which the state is a party.

The legislation that existed in the UAE when the Nuclear Policy was adopted was not designed for a nuclear power programme. The need for development of the legal framework was recognized by the government.

On 23 September 2009, the UAE issued Federal Law by Decree No. 6 of 2009 on the Peaceful Uses of Nuclear Energy—hereafter referred to as 'the Nuclear Law'. The IAEA and other international experts provided assistance in reviewing the text of the Nuclear Law before it was promulgated. The Nuclear Law set in place the legal framework for peaceful nuclear activities in the state in accordance with the international treaties and agreements to which the UAE is a

party, formally established the Federal Authority for Nuclear Regulation (FANR) as the independent nuclear regulatory body and defined the functions and responsibilities of the regulatory body and nuclear operators.

The UAE has continued to develop its legal framework with the enactment of Federal Law by Decree No 4 of 2012 Concerning Civil Liability for Nuclear Damage. This latter law determines civil liability and compensation for nuclear damage in the UAE according to the obligations contained in the Vienna convention.

Other relevant laws in the UAE that relate to the nuclear energy programme include:

— Abu Dhabi Law No. 21 of 2009 Establishing the Emirates Nuclear Energy Corporation;
— Federal Law by Decree No. 2 of 2011 Concerning the Establishment of the National Emergency, Crisis and Disasters Management Authority;
— Federal Law No. 24 of 1999 Concerning the Protection and Development of the Environment (as amended by Federal Law No. (11) of 2006);
— Law No. 1 of 2012 Concerning the Abolishment of the Critical National Infrastructure Authority.

V.4. DEVELOPMENT OF REGULATORY BODY(S)

V.4.1. Roles and responsibilities of regulatory body(s)

The Nuclear Law confers on FANR roles and responsibilities consistent with the IAEA-recommended core regulatory functions of (i) standard-setting through regulations; (ii) authorization; (iii) inspection and monitoring of compliance; and (iv) enforcement.

According to the Law, FANR must supervise the safety and security of nuclear activities in the state, set up and operate the state system of accounting and control of nuclear material (SSAC), and establish frameworks for physical protection and emergency preparedness and response for nuclear facilities and activities. FANR is also responsible for advising the UAE Cabinet on establishing a decommissioning trust fund for nuclear facilities and on setting the fees based on estimates of costs for decommissioning and radioactive waste disposal. Finally, FANR is required to cooperate with and advise other government departments in areas related to its mandate, and to make information on its activities available to the public.

V.4.2. Organizational establishment and development

FANR was formally established in September 2009 through the enactment of the Nuclear Law. In the early phases of the programme before the Nuclear Law was passed, the NEPIO incubated the early development of the regulatory body. During this period, several experienced senior staff members were recruited, including the Director General and department managers, to assist with planning and development of the organization

After FANR was formally established by the enactment of the Nuclear Law, the members of the first Board of Management were appointed by a decision of the UAE Cabinet. The Board approved the proposed organizational structure, which has remained as shown in Figure **Error! Reference source not found.** with only minor changes.

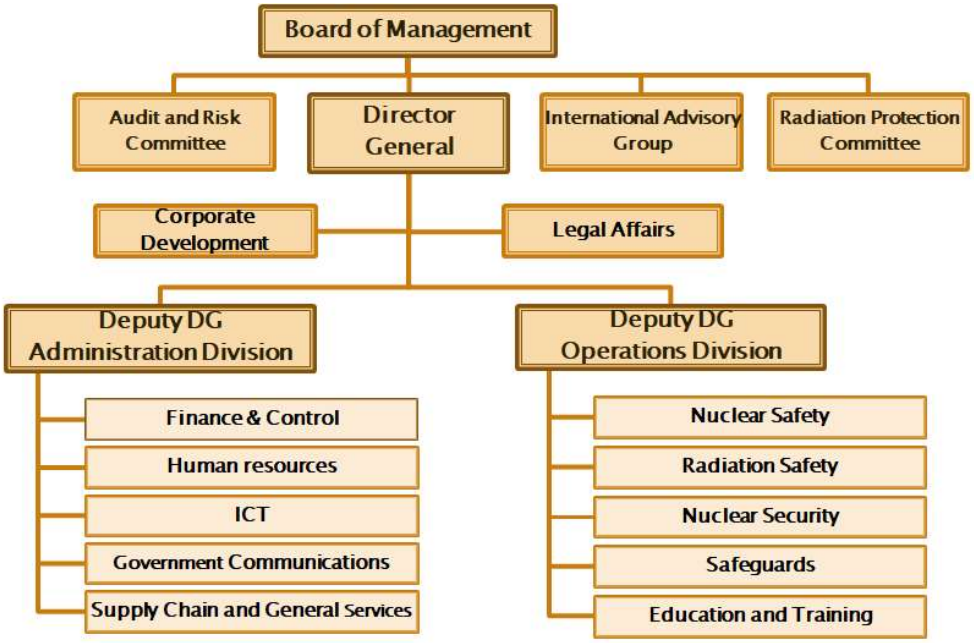


FIG. 17. Organizational chart of FANR.

V.4.3. Prioritization and development of regulations and guides

Article 38 of the Nuclear Law empowers FANR to issue regulations setting out requirements that all operators must follow, and to issue explanatory guides on compliance. The Nuclear Law further states, "*in developing regulations and guidelines, the Authority shall take into consideration comments from stakeholders, information made available by experts and internationally recognized standards and recommendations, such as IAEA Safety Standards.*"

Core process CP1 was developed in the FANR IMS to set out the methods for development of regulations and guides in compliance with the provisions of the Nuclear Law.

Regulatory guides follow the same process as the above, except they may be approved by the Director General and are not published in the official UAE Gazette.

FANR regulations issued before first construction licence application

FANR prioritized the development of regulations for each stage of the nuclear programme. Before receipt of the first construction licence application, FANR had issued the following regulations:

REG-01 Management Systems for Nuclear Facilities

REG-02 Siting of Nuclear Facilities

REG-03 Design of Nuclear Power Plants

REG-04 Radiation Dose Limits & Optimisation of Radiation Protection for Nuclear Facilities

REG-05 Application of Probabilistic Risk Assessment (PRA) at Nuclear Facilities

REG-06 Application for a License to Construct a Nuclear Facility

REG-08 Physical Protection for Nuclear Materials and Nuclear Facilities

V.4.4. Implementation of licensing process for different stages

The Nuclear Law prohibits any person from undertaking a 'Regulated Activity' unless licenced by FANR and sets out penalties for anyone who does so. The specified regulated activities

include the selection of a site, preparation of a site, construction, commissioning, and operation of a nuclear facility.

In 2010 ENEC applied for, and FANR subsequently issued, licences for site selection, site preparation, and limited construction of specified long-lead items in the nuclear steam supply system and site civil works.

In December 2010, ENEC submitted a comprehensive application for a construction licence for the first two units at Barakah. The application included, in accordance with FANR-REG-06, a Preliminary Safety Analysis Report (PSAR) describing the proposed site characteristics, the facility design and safety analysis, and the Quality Assurance programme for construction. FANR granted the construction licence in July 2012. ENEC lodged a further application with FANR in March 2013 for construction of Units 3 and 4. FANR granted the construction licence for Units 3 and 4 in September 2014.

In March 2015, ENEC applied on behalf of Nawah, the proposed operating organization, for a licence to operate Unit 1 and 2. The operating licence application updated the information presented in the construction licence applications and provided new information on the proposed operating organization, training of operating staff, the management system and procedures for the conduct of operations, accident management and emergency response, and physical protection.

The FSAR consisted of 21 chapters describing the safety, security and safeguards aspects of NPP operation, thereby supporting an integrated '3S' licensing approach Additional documents supporting the FSAR were provided under separate cover.

As construction of Unit 1 approached completion, ENEC requested authorization to transport, import and store fresh fuel for the first core load. This application referred to subsections of the operating licence application. FANR granted the licence after reviewing the relevant information in the FSAR and conducting field inspections to verify the availability of the necessary equipment, procedures and qualified personnel for safety, security and nuclear materials accountancy.

V.4.4.1. *Current status of facility licensing*

The licences that FANR issued to ENEC for the Barakah facility are listed in Figure 18. (Omitted from the list are licences for uses of radioactive sources and import/export of regulated items.) ENEC also submitted environmental impact assessments required by the Environment Agency of Abu Dhabi and obtained the consent of that Agency.

By mid-2018, ENEC had completed the construction and preoperational testing of Unit 1 at Barakah. Fresh fuel for the Unit 1 first core was stored at site under licence from FANR in compliance with all safety, security and safeguards requirements. Operating license for Unit 1 was issued in 2020 after the completion of operational readiness steps by Nawah, the operating organisation, and their verification by FANR.

IRRS Mission to UAE, Dec 2011:

- "*FANR has regulations and a review process for effectively conducting the review of the application*."
- *"Review and assessment in FANR with the support of TSOs is organizationally a well-managed process."*

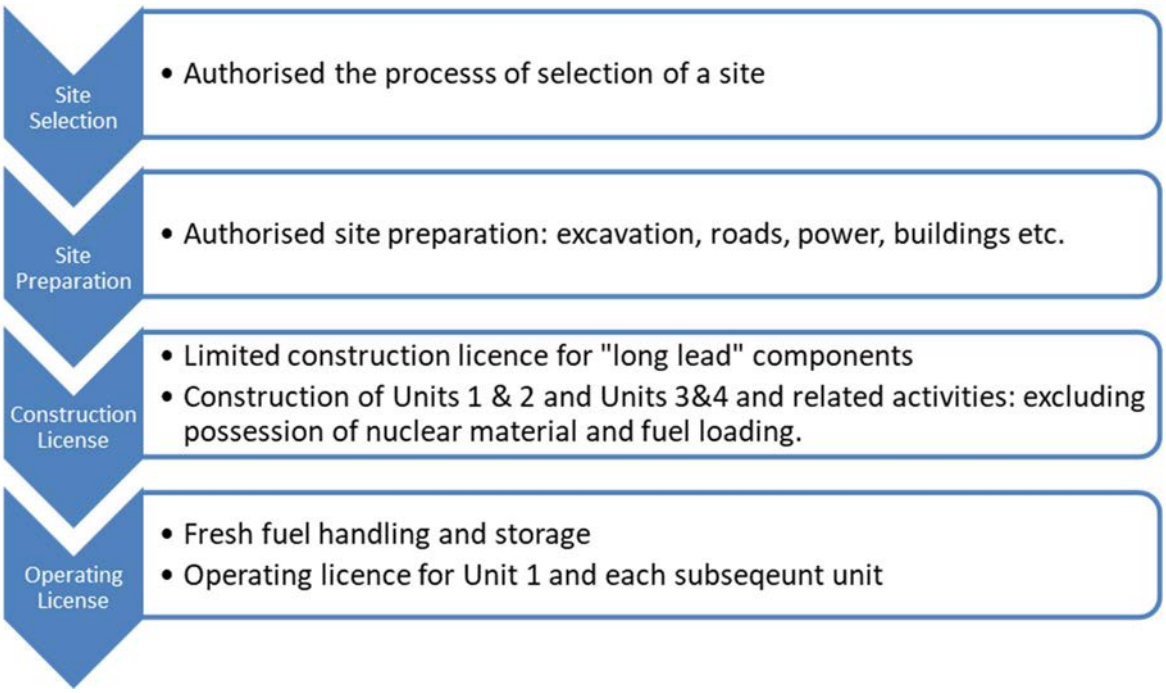


FIG. 18. Licensing steps for Barakah NPP.

V.4.5. Development and implementation of inspection programme

The Nuclear Law gives FANR the responsibility to implement a planned and systematic programme of inspection and enforcement to ensure its licensees comply with the requirements given in the law, regulations and licences, and to take account of the activities of suppliers of products and services to the operator, with powers to enter the relevant sites & facilities, to conduct announced and unannounced inspections and immediate inspections of abnormal occurrences.

Each licensee has the primary responsibility for the safety of its activities. A licensee may contract all or a material part of the regulated activity but remains responsible before the Authority even if certain activities are performed by contractors. Further, regulatory inspections do not diminish the licensee's responsibility for safety nor substitute for its control supervision and verification activities.

Based on the above principles, FANR implemented a programme of inspection of ENEC's activities related to siting, procurement, construction, and preparations for operation of the Barakah facility. The general objectives of the inspection programme were to verify that:

— the licensee's management system and quality assurance programme provide adequate oversight and control of its activities and those of its contractors;

— facilities, equipment and work performance meet requirements of the UAE law, FANR regulations and licences;

— the as-built facility can be operated safely in accordance with the assumptions and safety goals described in the safety analysis report, FANR's safety evaluation and regulatory requirements;

— personnel possess the necessary competence.

V.5. CHALLENGES FACED AND THE SOLUTIONS APPLIED

The UAE has made extensive use of IAEA peer review services during its programme to provide feedback and recommendations. These peer reviews provide an objective basis for reflection on challenges faced and the solutions.

The first such mission hosted by the UAE was an International Nuclear Infrastructure Review (INIR) mission in January 2011. The mission team recognized that the UAE infrastructure was progressing rapidly and was well advanced, having reached Milestone 1 and all elements of Milestone 2 except for the adoption of an international instrument on Civil Liability for Nuclear Damage and promulgation of associated implementing legislation. This observation has since been closed with the UAE's adoption of the Vienna Convention and enactment of Federal Law No. 4 of 2012.

The INIR mission team identified some areas needing further attention as the programme progressed into NPP project implementation. These areas are noted below, along with a statement on the current status.

— Nuclear Safety Culture: The need for sustained attention to safety culture, especially considering the rapid pace of the programme and continued growth of involved organizations.

  FANR has continued to foster a strong nuclear safety culture in its organization and in licensees through various means including the conduct of formal safety culture training and assessments.

— Safeguards: As the UAE rescinds its small quantities protocol and implements a comprehensive safeguards agreement, implementing regulations should be finalized and training conducted.

  The UAE has operationalized its SSAC, rescinded the SQP and successfully implemented the comprehensive safeguards agreement and additional protocol.

— Fuel Cycle and Radioactive Waste: The Government should continue its work in developing its national strategy for the back-end fuel cycle and radioactive waste management, including finalizing its implementation strategy.

  Consultation continues between the involved national entities to develop a national waste management policy and decommissioning funding arrangements.

— Regulatory Framework: Recognizing the regulations already in place, FANR and other regulatory authorities will need to continue to develop and implement regulations and guidance in line with the nuclear power programme's development. Also, coordination among regulatory authorities should be continued, and relationships between them should be formalized, for example between the Environmental Agency – Abu Dhabi and FANR.

  FANR has issued all the regulations that are needed to support the operational phase of the programme. Relationships with many other national authorities have been formalized through Memoranda of Understanding.

The UAE hosted an IRRS Mission in December 2011. The IRRS Review team reported that it was satisfied that the UAE/FANR had in place suitable infrastructure to support the currently regulated activities and plans for future activities. The IRRS Review team also was satisfied that UAE/FANR was in general alignment with the guidance in SSG-16 (Rev. 1) [3]. The IRRS mission team made further observations about the nuclear power programme which are noted below with statements of the current status.

— Sustainability and long-term domestic capacity-building for assuring safety is an important issue. The Team recognizes this is an issue facing all nuclear countries and satisfied that the UAE has made a long-term commitment to sustainability in all aspects of radiation and nuclear safety. In this respect, FANR and the relevant stakeholder organizations should consider targets for developing, on an appropriate timescale, Emirati staff having the necessary competences and experiences to assure safety of facilities and activities in all potential circumstances.[10]

  FANR has continued to cooperate with other national stakeholders to promote the development of Emirati staff having the competencies and experience to take responsibility for the safety of facilities and activities. The current population of Emirati staff employed in FANR demonstrates the commitment made in the Nuclear Policy to the development of Emiratis in the nuclear sector.

— The Government of the UAE should ensure that the development of a National Policy and Strategy for Radioactive Waste Management is brought to conclusion in the shortest timeframe, so that the necessary regulatory and guidance documents can be developed on the basis of this policy and strategy. [10]

  Consultation continues between the involved national entities to develop a national waste management policy and decommissioning funding arrangements.

— The Government should ensure that the roles, responsibilities and organizational relationships and interfaces between all the emergency response organizations are clarified, agreed and formalized as soon as possible.

  This topic was addressed firstly by FANR and National Emergency Crisis and Disaster Management Authority (NCEMA) concluding a Memorandum of Understanding (MoU) which set out roles and responsibilities for planning and response to nuclear and radiation emergencies. FANR continued to play its statutory role of advising and providing information to NCEMA and other civil defence authorities through participation on various coordination committees. With the agreement of other stakeholders, FANR published REG-15 to establish requirements that must be satisfied to ensure effective off-site emergency planning for UAE nuclear facilities. The UAE hosted an EPREV mission in March 2015 which found that the nuclear emergency preparedness and response framework was being effectively built on an existing national crisis and emergency management structure that is clear, well defined and tested, and that roles and responsibilities are clearly defined.

[10] Report of the Integrated Regulatory Review Service (IRRS) mission to The United Arab Emirates, IAEA Vienna (2011).

A follow-up IRRS mission was held in January 2015. The purpose of the follow-up mission was to review the measures undertaken following the recommendations and suggestions from the initial mission conducted in 2011. The Team concluded that the recommendations and suggestions from the 2011 mission had been taken into account systematically by a comprehensive action plan. The main observations of the follow-up mission with regard to the nuclear power programme were as follows:

— The Government of the UAE should develop a National Policy and Strategy for the management and disposal of spent nuclear fuel and radioactive waste.

  As noted above, consultation continues between the involved national entities to develop a national waste management policy and decommissioning funding arrangements.

— FANR should consider developing a procedure, in the integrated management system, to periodically review its regulations and guides to maintain consistency across the different regulated facilities and activities.

  FANR updated the CP1 procedure for management of regulations and guides to include a periodic review of regulations and guides.

— The Government of the UAE should issue the Resolution concerning the administrative penalties and fines, that is required to provide FANR with the necessary authority to apply them.

  The Government issued Cabinet Resolution No. 27 of 2015 *Concerning Administrative Penalties on Violating the Conditions of the Licences issued by the Federal Authority for Nuclear Regulation*. This Cabinet resolution sets out a schedule of fines that FANR may impose for specified violations of FANR regulations and licence conditions.

An INIR Phase 3 mission was hosted by the UAE in June 2018. The mission team found that the UAE is well-focused in its preparations for the operation of the first unit of the nuclear power plant, although some work remains to be done including the need for the operating organisation to finalize all necessary arrangements required to reach operational readiness; the need for the UAE to approve and implement all the appropriate arrangements for radioactive waste management; and the implementation of arrangements required to ensure the long-term sustainability of the nuclear power programme.

V.6. PREPARATION FOR FUTURE PHASES

The risk profile of an NPP with regard to nuclear safety, security and safeguards changes significantly when nuclear material is introduced to the site and nuclear operation commences after Milestone 3. Regulatory oversight of an operating NPP involves skills and procedures different from those applied during the preceding phases, as well as a shift in regulatory culture to be responsive to the issues that may arise during operation including accidents and emergencies.

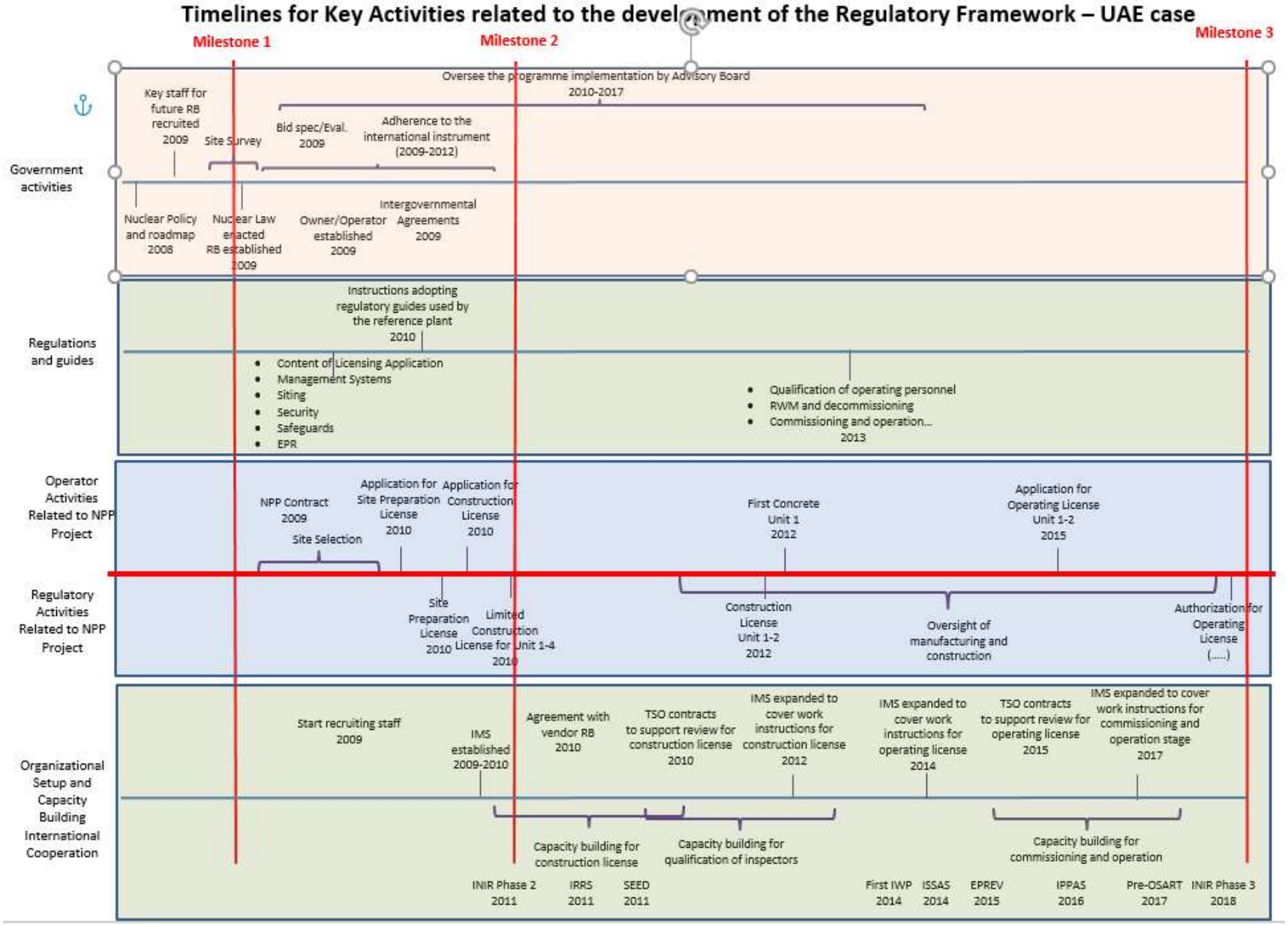
The UAE regulatory body has continued to develop its management system and ‘3S’ culture and has developed procedures and trained staff in the NPP operating context ready to provide oversight of operation in advance of Milestone 3 being completed.

V.7. SUSTAINABILITY OF THE REGULATORY FRAMEWORK

Ten years on from the adoption of its Nuclear Policy, the UAE has advanced in implementing its civil nuclear energy programme. The UAE has operationalized a plan which included international agreements, a legal framework, establishment of an independent regulatory body and an implementing organization, technology procurement, human resource development and capacity building. The UAE experience may serve as a model for other states who to wish to gain international support in deployment of peaceful nuclear energy options.

Good practices and factors contributing to the UAE achievements include leadership from government with clear policy goals and a well-coordinated strategy, recruitment of highly experienced senior staff, productive relationships among UAE national organisations—including interagency working groups on topical issues such as emergency preparedness and capacity building, education, and training—strong bilateral relations with the regulatory body in the vendor country of origin, and vital support from international organisations, particularly the IAEA.

The UAE's progress has shown that, with strong commitment and vision, safe and secure nuclear energy can be developed and sustained. Ultimately, however, the UAE programme is a long-term endeavour. As Ambassador Al Kaabi has noted, the development of a world-class nuclear safety culture takes time. "Strong safety cultures do not come to be from any one action, but rather from long-term, consistent behaviour that must be exhibited by the leadership in all related organizations, including government entities, nuclear regulators, owners, operators, universities, and so forth. The UAE is committed to continuing those actions necessary to build and sustain a world-class nuclear safety culture."


Timelines for Key Activities related to the development of the Regulatory Framework – UAE case
Milestone 1
Milestone 2
Milestone 3
Government activities
Oversee the programme implementation by Advisory Board 2010-2017
Key staff for future RB recruited 2009
Site Survey
Bid spec/Eval. 2009
Adherence to the international instrument (2009-2012)
Nuclear Policy and roadmap 2008
Nuclear Law enacted RB established 2009
Owner/Operator established 2009
Intergovernmental Agreements 2009
Regulations and guides
Instructions adopting regulatory guides used by the reference plant 2010
Content of Licensing Application
Management Systems
Siting
Security
Safeguards
EPR
Qualification of operating personnel
RWM and decommissioning
Commissioning and operation...
2013
Operator Activities Related to NPP Project
NPP Contract 2009
Site Selection
Application for Site Preparation License 2010
Application for Construction License 2010
First Concrete Unit 1 2012
Application for Operating License Unit 1-2 2015
Regulatory Activities Related to NPP Project
Site Preparation License 2010
Limited Construction License for Unit 1-4 2010
Construction License Unit 1-2 2012
Oversight of manufacturing and construction
Authorization for Operating License (.....)
Organizational Setup and Capacity Building International Cooperation
Start recruiting staff 2009
IMS established 2009-2010
Agreement with vendor RB 2010
TSO contracts to support review for construction license 2010
IMS expanded to cover work instructions for construction license 2012
IMS expanded to cover work instructions for operating license 2014
TSO contracts to support review for operating license 2015
IMS expanded to cover work instructions for commissioning and operation stage 2017
Capacity building for construction license
Capacity building for qualification of inspectors
Capacity building for commissioning and operation
INIR Phase 2 2011
IRRS 2011
SEED 2011
First IWP 2014
ISSAS 2014
EPREV 2015
IPPAS 2016
Pre-OSART 2017
INIR Phase 3 2018

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LIST OF ABBREVIATIONS

AES-2006	specific design of PWR with VVER-1200 reactor type
APR-1400	specific design of PWR with 1400 MWe
BAERA	Bangladesh Atomic Energy Regulatory Agency
ENEC	Emirates Nuclear Energy Corporation (UAE)
FANR	Federal Authority for Nuclear Regulation (UAE)
FSAR	final safety analysis report
IMS	integrated management system
INIR	international nuclear infrastructure review
INSAG	International Nuclear Safety Group
IPPAS	international physical protection assessment service
IRRS	international regulatory review service
ISSAS	IAEA state systems of accounting for and control of nuclear material advisory service
MES	Ministry of Emergency Situations (Belarus)
MOST	Ministry of Science and Technology (Bangladesh)
NDK	Nükleer Düzenleme Kurumu (NDK)–Turkish Nuclear Regulatory Authority
NEPIO	nuclear energy programme implementing organization
NPP	nuclear power plant
NSRC	nuclear safety and radiation control
PAEC	Pakistan Atomic Energy Commission
PNRA	Pakistan Nuclear Regulatory Authority
PSA	probabilistic safety assessment
PSAR	preliminary safety analysis report
PWR	pressurized water reactor
SSAC	state system of accounting for and control of nuclear material
SQP	small quantities protocol
TAEK	Türkiye Atom Enerjisi Kurumu—Turkish Atomic Energy Authority
TSO	technical support organisation
UAE	United Arab Emirates
VVER	water water energetic reactor

CONTRIBUTORS TO DRAFTING AND REVIEW

Bastos, J.	International Atomic Energy Agency
Boelme, A.B.	Turkish Nuclear Regulatory Authority
Ceyhan, M.	International Atomic Energy Agency
Crete, J.M.	International Atomic Energy Agency
Dunlop, S	International Atomic Energy Agency
Ghose, S.	Bangladesh Atomic Energy Regulatory Authority
Grant, I.	Consultant (Canada)
Horvath, K.	International Atomic Energy Agency
Kobetz, T.	International Atomic Energy Agency
Kovachev, M.	International Atomic Energy Agency
Maqbul, N.	Pakistan Nuclear Regulatory Authority
Rahman, M.	Pakistan Nuclear Regulatory Authority
Senior, D.	International Atomic Energy Agency
Trafimchik, Z.	Gosatomnadzor (Belarus)

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