

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

Islamabad, Pakistan

*28 April to 9 May 2014*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



**Pakistan Nuclear Regulatory Authority**



**INTEGRATED REGULATORY REVIEW SERVICE (IRRS)**  
**REPORT TO**  
**PAKISTAN**





# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

## REPORT TO

### PAKISTAN

**Mission date:** 28 April to 9 May 2014  
**Regulatory body:** Pakistan Nuclear Regulatory Authority (PNRA)  
**Location:** Islamabad, Pakistan

<b>Regulated facilities and activities:</b>	<i>Nuclear Power Plants, Research Reactors, Waste Management Facilities, Radiation Sources Applications and Facilities, Decommissioning Activities</i>
<b>Organized by:</b>	<i>International Atomic Energy Agency (IAEA)</i>

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

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## EXECUTIVE SUMMARY

At the request of the Government of Pakistan, an international team of nuclear and radiation safety experts met representatives of the Pakistan Nuclear Regulatory Authority (PNRA) from 28 April to 9 May 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the mission was to review Pakistan's regulatory framework for nuclear and radiation safety.

The review compared Pakistan's regulatory framework for safety against IAEA Safety Standards. The mission was also used to exchange regulatory information and experiences among the IRRS reviewers and the PNRA counterparts in the areas covered by the IRRS.

The IRRS team was comprised of seventeen highly experienced regulatory experts from fifteen IAEA Member States, one observer (Japan), three IAEA staff and one IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; waste management and decommissioning; occupational radiation protection; control of radioactive discharges and materials for clearance; and environmental monitoring associated with authorized practices for public radiation protection. Additionally, two policy issues were discussed. These included licensing of software-based digital I&C systems for nuclear power plants (NPPs) and development of practice-specific regulations.

The mission included interviews and discussions with PNRA staff, observations of inspections, and discussions with representatives of the Ministry of Finance and the Pakistan Atomic Energy Commission (PAEC). Inspections were observed at the research reactor at the Pakistan Institute of Nuclear Science and Technology and Shifa International Hospital. The IRRS reviewers observed the working practices during the inspections conducted by PNRA staff, including discussions with licensee management. The IRRS reviewers also observed PNRA's performance in the National Radiation Emergency Control Centre during an emergency exercise conducted at the Chashma nuclear power plant.

PNRA provided the IRRS team with advance reference material and documentation including the results of its self-assessment that was conducted in the areas to be reviewed during the IRRS mission. PNRA conducted a thorough and self-critical self-assessment in preparation for the IRRS mission. Throughout the mission, the IRRS team was extended full cooperation by all parties, particularly the staff of PNRA.

The IRRS team identified a number of good practices as well as recommendations and suggestions in areas where improvements will enhance the effectiveness of the PNRA regulatory framework and processes in line with the IAEA Safety Standards. The IRRS team recognized that many of the issues identified during the review had already been identified during PNRA's self-assessment and are addressed in the associated action plan.

The IRRS team made the following general observations:

- The Pakistan Government puts safety as its first priority when developing nuclear energy and technology, and has established its regulatory framework for nuclear and radiation safety;
- PNRA is an independent and competent regulatory body, empowered with the full scope of regulatory powers required by the IAEA standards. The Government provides the resources necessary to support PNRA's rapid expansion;

- Ordinance No. III of 2001 and the associated regulations, which are mainly based on IAEA safety standards, provide the binding legal framework for nuclear and radiation safety in Pakistan. PNRA management is dedicated to improving PNRA's capability to effectively regulate nuclear and radiation safety; and
- To ensure the safe operation of the nuclear power plants in Pakistan, PNRA is conducting effective regulatory activities for licensing, inspection, enforcement, lessons learned and emergency preparedness for nuclear power plants.

The IRRS team identified areas where Pakistan or PNRA face significant challenges, including:

- Ensuring a consistently high level of safety as Pakistan implements its ambitious nuclear power programme and use of nuclear technology;
- Improving public communication and awareness regarding PNRA's role in assuring nuclear and radiation safety in Pakistan;

The IRRS team identified a number of good practices, as well as recommendations and suggestions where improvements are necessary or desirable to continue enhancement of the effectiveness of PNRA's regulatory processes in line with the IAEA Safety Standards.

Good practices identified included:

- The Government's willingness and PNRA's use of financial resources outside the normal budget process;
- PNRA's well-developed training programme to maintain PNRA staff technical and regulatory competence during rapid expansion of PNRA;
- The development and implementation of a national public awareness programme for nuclear and radiation safety;
- PNRA's self-assessment of safety culture; and
- Extensive and in-depth long-term, operations focused training for some inspectors.

Issues identified by the IRRS team that may need improvement or warrant additional attention in order to enhance the overall performance of the Pakistan regulatory system include:

- The IAEA Fundamental Safety Principles should be fully incorporated into the Pakistan safety framework and the primary responsibility for safety should be clearly assigned;
- The legal responsibilities and obligations with respect to the financial provisions for the management of radioactive waste, spent fuel and decommissioning should be clearly stipulated.
- Procedures for appeal against regulatory decisions should be developed;
- The National Radiation Emergency Coordination Centre at PNRA should be modernized;
- Regulations and regulatory guides, taking into account the latest IAEA Safety Standards, should be finalized and issued; and
- Inspections and enforcement should include an appropriate focus on safety-significant issues.

The IRRS team noted that development of a long term national strategy for nuclear and radiation safety would be helpful considering the ambitious nuclear power programme in Pakistan.

All of the IRRS mission findings are summarized in Appendix V.

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

## I. INTRODUCTION

At the request of the Government of Pakistan, an international team of senior safety experts met representatives of the Pakistan Nuclear Regulatory Authority (PNRA) from 28 April to 9 May 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the mission was to conduct a peer review of the Pakistan regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Pakistan in November 2006. Due to circumstances beyond PNRA's control, the mission was postponed. A subsequent request for the mission was received in August 2011. A preparatory mission was conducted from 12 to 14 March 2013 at PNRA Headquarters in Islamabad, Pakistan, to discuss the purpose, objectives, scope and detailed preparations of the requested review.

The IRRS review team consisted of seventeen highly experienced regulatory experts from fifteen IAEA Member States, three IAEA staff members, one IAEA administrative assistant and one observer. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; waste management and decommissioning; occupational radiation protection; control of radioactive discharges and materials for clearance; and environmental monitoring associated with authorized practices for public radiation protection.

In addition, policy issues were discussed, including licensing of software-based digital I&C systems for NPPs and development of practice-specific regulations.

PNRA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics using the advance reference material, conducting interviews with PNRA management and staff, and performed direct observation of PNRA's working practices during inspections. Meetings with the Ministry of Finance and the Pakistan Atomic Energy Commission were also organized.

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

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of Pakistan's radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all core modules for facilities and activities regulated by PNRA, with the exception of control of medical exposures and transport of radioactive materials. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

The IRRS mission results will facilitate regulatory improvements in Pakistan and other Member States from the knowledge gained and experiences shared between PNRA staff and IRRS reviewers and through the evaluation of the effectiveness of the Pakistan regulatory framework for nuclear safety and its good practices.

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

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

### **III. BASIS FOR THE REVIEW**

#### **A) PREPARATORY WORK AND IAEA REVIEW TEAM**

At the request of the government of Pakistan, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 12 to 14 March 2013. The preparatory meeting was carried out by the appointed Team Leader, Mr Liu Hua; Deputy Team Leader, Ms Olga Makarovska and the IRRS IAEA Team representatives, Team Coordinator, Mr David Graves; Deputy Team Coordinator, Mr Ahmad Al Khatibeh and Emergency Preparedness and Response Review Area Facilitator, Mr Peter Zombori.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of PNRA represented by Mr Anwar Habib, Chairman of PNRA, and other PNRA senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Research reactors;
- Radioactive waste management facilities;
- Radiation sources activities;
- Decommissioning;
- Occupational radiation protection;
- Control of radioactive discharges and materials for clearance;
- Environmental monitoring associated with authorized practices for public radiation protection;
- Waste management;
- Emergency preparedness and response; and
- Selected policy issues.

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

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion of the tentative work plan for the implementation of the IRRS mission in Pakistan, originally scheduled for November 2013. However, due to scheduling conflicts, the mission was re-scheduled to 28 April to 9 May 2014.

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

The PNRA Liaison Officers for the preparatory meeting and the IRRS mission were appointed (Mr Zaheer Ayub Baig, Mr Naeem Arshad and Mr Saleem Zafar).

PNRA provided IAEA (and the review team) with the advance reference material for the review at the end of February 2013 including the self-assessment results. In preparation for the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

## **B) REFERENCE FOR THE REVIEW**

The most relevant IAEA safety standards were used as review criteria. A more complete list of IAEA publications used as references for this mission is given in Appendix VII.

## **C) CONDUCT OF THE REVIEW**

An opening IRRS review team meeting was conducted on Sunday, 27 April, in Islamabad, by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview of the IRRS, the focus areas and specific issues of the mission, the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and evaluation of mission findings among all reviewers. The agenda for the mission was also discussed. Two PNRA Liaison Officers, Mr Baig and Mr Arshad, also attended and participated in the meeting, and presented logistical arrangements planned for the mission and a general overview of PNRA. The reviewers also reported on their first impressions of the advance reference material.

The IRRS mission entrance meeting was held on Monday, 28 April with the participation of PNRA senior management and staff, as well as PAEC officials. Opening remarks were made by Mr Anwar Habib, Chairman of PNRA and Mr Liu Hua, IRRS Team Leader. IRRS Team Coordinator, Mr David Graves gave a short presentation on the IRRS process. Mr Faizan Mansoor of PNRA presented PNRA's regulatory processes, and Mr Naeem Arshad of PNRA presented a summary of PNRA's self-assessment.

During the mission, the requested subject areas were reviewed with the objective of providing Pakistan and PNRA with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, document review, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday, May 9, 2014. The opening remarks at the exit meeting were presented by Mr Zaheer Ayub Baig, IRRS liaison officer, and were followed by comments from Mr Mohammad Iqbal, Member Corporate of PNRA, the presentation of the results of the mission by IRRS Team Leader, Mr Liu Hua, and remarks by Mr Mohammad Anwar Habib, Chairman of PNRA. Closing remarks were made by Mr James Lyons, Director, Division of Nuclear Installation Safety with IAEA.

An IAEA press release was issued following completion of the mission as per IAEA practice following each mission.

# 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

## 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In Pakistan the policies and strategies for nuclear safety and radiation safety are mainly expressed through legislative framework for safety. This legislative framework includes Ordinance No. III of 2001 (PNRA Ordinance) and associated Pakistan Nuclear Regulatory Authority (PNRA) regulations. The Ordinance defines functions and powers of PNRA, including planning, developing and executing comprehensive policies and programmes for the protection of life, health and property against the risk of ionizing radiation.

PNRA has agreed in the 19th meeting of the Authority in 2007 to adopt the IAEA Safety Fundamentals SF-1. Nevertheless, the fundamental safety objective and fundamental safety principles established by the SF-1 document are not yet fully reflected in the Pakistan legislative framework for safety.

The safety objective stipulated by the Ordinance does not explicitly describe the scope of its application (for all civilian facilities and activities) and duration of its application (for all stages over the lifetime of a facility or activity).

To achieve the fundamental safety objective, ten fundamental safety principles of SF-1 are to be embedded in appropriate parts of the legislation. The fundamental safety principle establishing the prime responsibility for safety is not completely incorporated into the existing framework for safety. For details see Section 1.4 of this module. The fundamental principle of leadership and management of safety is incorporated for nuclear installations, but not for radiation facilities. The Fundamental safety principle of protection of present and future generations stipulated in existing legislation does not explicitly address harm to future generations. Full application of fundamental safety objective and fundamental safety principles (as per IAEA SF-1) would help to apply graded approach more consistently throughout the regulatory practices.

In 2005, the government of Pakistan published the Energy Security Plan, and accordingly the Pakistan Atomic Energy Commission (PAEC) developed an ambitious nuclear power development programme with intention to construct a number of new nuclear power units. To ensure that the priority of safety will be ensured for these development programs, the government should consider preparing and promulgating a long term strategy on nuclear and radiation safety for the next 5-10 years. The strategy should include (but not be limited to) the following items: current situation and definition of challenges; principles and objectives; tasks and priorities; projects; measures to ensure full and timely implementation; and verification and validation measures.

The IRRS team has concluded that the legislation provides for a graded approach to large extent. The legislative framework for safety only partially incorporates the fundamental safety objective. Finally, most of the safety principles established in the IAEA Safety Fundamentals SF-1 are incorporated in the legislation.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The safety objective in the Ordinance does not explicitly mention the scope of its application (for all civilian facilities and activities) and duration of its application (all stages over the lifetime of a facility or an activity). Fundamental safety principles such as priority for safety, leadership and management for safety or protection of present and future generations are not fully embedded in the Pakistan legislative framework for safety.*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS:</b> GSR Part 1 Requirement 5 states that <i>“The Government shall provide a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.”</i>
R1	<b>Recommendation:</b> The Government should ensure that the fundamental safety objective and fundamental safety principles of IAEA SF-1 are incorporated in the Pakistan framework for safety.
	<b>Observation:</b> A national safety strategy is not envisaged by the government (long term safety strategy on nuclear and radiation safety) that would reflect existing Energy Security Plan and associated PAEC Nuclear Power Development Program.
(1)	<b>BASIS:</b> GSR Part 1 requirement 1 and Para. 2.3 states that <i>“The government shall establish a national policy and strategy for safety”, “National policy and strategy for safety shall express a long term commitment to safety”, “The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy.”</i>
S1	<b>Suggestion:</b> The Government should consider developing a long term strategy for safety that would include necessary safety measures to reflect the development plans for the nuclear power programme of Pakistan.

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Ordinance of 2001 and the associated PNRA regulations, which are mainly based on IAEA Safety Standards, provide binding legal framework for nuclear and radiation safety in Pakistan. The Ordinance establishes PNRA as the competent national authority for regulation of safety of nuclear installations and radiation facilities, the protection against risks arising from ionizing radiation and in the determination of the extent of civil liability for nuclear damage resulting from any nuclear incident. It also defines the facilities and activities under regulatory control. Details on regulatory and legislative framework are provided in Chapters 3 and 9 of the report.

The National Policy on Control and Safe Management of Radioactive Waste (Policy) was promulgated by the Government in 2005. This Policy demonstrates commitment from the government for the safe management of radioactive waste in Pakistan. It assigns responsibility to PAEC to establish and maintain the Central Radioactive Waste Management Fund (CRWMF) and in compliance with the Policy, PAEC is maintaining the CRWMF. In addition to the Policy, the legal framework for safety currently does not stipulate (at appropriate levels) legal responsibilities and obligations in respect of financial provision for the management of radioactive waste, spent fuel and for decommissioning of facilities.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> Responsibilities and obligations for the management of the Central Radioactive Waste Management Fund envisaged by the National Policy on Control and Safe Management of Radioactive Waste are not stipulated in the national legislative framework.
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS: GSR Part 1 para 2.5 (16) states that</b> <i>“Framework for safety shall set out... responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities ... “</i>
R2	<b>Recommendation: The Government should ensure that relevant parts of the legislative framework stipulate legal responsibilities and obligations in respect of financial provisions for the management of radioactive waste, spent fuel and decommissioning of facilities.</b>

### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As specified above, the legislative framework (through the Ordinance) established PNRA as the administrative body having full regulatory control of (civilian) nuclear and radiation safety in Pakistan. The Government has provided the regulatory body with the competences and resources necessary for fulfilling its statutory obligation for regulatory control of facilities and activities defined in the Ordinance. The Authority consists of a Chairman, two full time members and seven part time members appointed by the Federal Government. Based on the Ordinance, PNRA reports and receives instructions from the Federal Government. There was no formal evidence provided to the team how this reporting channel is organised in practice. It is necessary that the reporting channel indicating the position in the Federal Government to whom PNRA Chairman reports is officially notified by the Federal Government to allow for correct functioning of the regulatory body. Legal provisions for appealing the regulatory decisions at the level of PNRA are in place, internal procedures to guide this process within the authority are missing (see Chapters 5 and 8 for details). PNRA is the independent state body with the ability to make final regulatory decisions which can only be challenged in a court. The decision making process is independent of other bodies; however some processes require prior consultation or consent by other governmental bodies. For details on coordination with different authorities see Section 1.5.

The IRRS team was informed by PNRA that it has sufficient numbers of qualified staff and sufficient financial resources for the proper discharge of its assigned responsibilities.

PNRA is funded from the State budget and licence fees. Fees represent about 25 percent of PNRA’s annual budget, the rest of the budget comes from the State through different channels. Since its establishment, PNRA expanded quite rapidly both in terms of capacity building and institutional strengthening. For example, the number of technical staff increased from 38 in 2003 to 283 at present. During this period, significant analytical and training capabilities were also established within PNRA. From the point of view of resource management for this expansion, PNRA took very active approach and did not rely only on increase of annual budget from the Federal Government or rapid increase in licencing fees. During the period from 2005 to 2011, PNRA developed, justified and got approval for six Public Sector Development Projects. Funds from these projects significantly contributed to meet financial requirements of PNRA for its rapid expansion. The IRRS team considers this proactive approach to (financial) resource management as a good practice. This statement was also supported by results of the IAEA Education and Training Appraisal (EduTa) mission and the Education and Training Review Service (ETRES) mission conclusions. These missions also concluded that facilities developed by PNRA can be also utilised by the IAEA as a regional training centre for capacity building for regulators of embarking countries.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>To secure appropriate financing for its very ambitious expansion, PNRA adopted a very active resource management strategy and did not rely only on increases of the annual budget from the Federal Government or increases of licence fees. During the years 2005 to 2011 PNRA developed, justified and received approval for six Public Sector Development Projects dedicated to capacity building and institutional strengthening. Funds from these projects significantly contributed to meet the financial requirements of PNRA for its rapid expansion.</i>
(1)	<b>BASIS: GSR Part 1, Requirement 3 states that</b> <i>“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.”</i>
GP1	<b>Good Practice: PNRA adopted a very active resource management strategy to secure appropriate financing for its rapid expansion and did not rely only on increased annual budgets from the Federal Government or increase the licensing fees. Funds from Public Sector Development Projects significantly contributed to meet financial requirements of PNRA for very ambitious capacity building and institutional strengthening.</b>

### 1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

PNRA has the authority under the Ordinance to require demonstration of compliance with its regulations. The Ordinance allows for the transfer of responsibility for disposal of radioactive waste by arrangements with the approval of the Authority. Under the terms of the National Policy on Control and Safe Management of Radioactive Waste the State guarantees safe management of all radioactive waste. With respect to legal responsibilities and obligations see text in Section 1.2.

The principle of prime responsibility for safety is not completely addressed in the framework for safety (as mentioned in Section 1.1). The responsibility for safety is not fixed for the entire lifetime of the installation and as such the principle that compliance with regulatory requirements does not relieve licensees from their prime responsibility for safety is missing.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>The principle of prime responsibility for safety is not completely addressed in the framework for safety.</i>
(1)	<b>BASIS: GSR Requirement 5 states that</b> <i>“The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.”</i>
(2)	<b>BASIS: GSR Requirement 6 states that</b> <i>“The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.”</i>
	<b>Reference is made to Recommendation R1 in Section 1.1.</b>

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

PNRA regulates nuclear and radiation safety, physical protection and emergency preparedness. This positions PNRA as the national regulator of facilities and activities involving ionising radiation. Having all these regulatory functions integrated in the same entity reduces the number of interfaces with other organisations.

Interaction with other governmental administrative or regulatory bodies may be addressed in several different ways, for instance:

- Memorandum of Understanding (MoU) with the Ministry of Foreign Affairs for export/import control;
- Non Objection Certificate (NOC) with the Pakistan Environmental Protection Agency for environmental impact assessments.

Within PNRA there is no systematic approach to coordinate and liaise with other authorities and there are no formalised processes or guides for this coordination and liaison.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>Coordination and liaison between PNRA and other authorities having responsibility for safety are not formalised in all cases.</i>
<b>(1)</b>	<b>BASIS: GSR Part 1 Requirement 7 states that</b> <i>“The Coordination of different authorities with responsibilities for safety within the regulatory framework for safety. Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.</i>
<b>(2)</b>	<b>BASIS: GSR Part 1 para. 2.18 states that</b> <i>“Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: ...”</i>
<b>R3</b>	<b>Recommendation:</b> <b>PNRA should ensure that appropriate and documented coordination and liaison between PNRA and other authorities having responsibility for safety are formalized where appropriate or needed.</b>

## 1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

Unregulated sources of artificial origin are dealt with according to the National Policy on Control and Safe Management of Radioactive Waste (Radioactive Waste Policy). The sources of natural origin are not regulated. According to the Radioactive Waste Policy: “In case of management of orphan sources, sources cleared by PNRA for disposal, the expenditure will be borne by the government of Pakistan”. The Policy for protective actions to reduce radiation risks associated with orphan radioactive sources is in force.

The PNRA approved a national strategy for locating and securing orphan radioactive sources. According to this strategy the PNRA plays the main and coordination role in the national system for the gaining and

regaining control over orphan radioactive sources. The PNRA is responsible to locate, recover, secure and coordinate for the safe disposal of the orphan sources. The PNRA as a national focal point reports to IAEA Incident and Trafficking Database (ITDB). Up to now seven events were reported. At the PNRA, the Directorate of Physical Protection and Nuclear Security has responsibility in this area. PNRA supports the 24h on-duty response system that includes six response teams in the regions. PNRA has its own resources including trained manpower, infra-structure equipped with necessary equipment (including protective equipment and containers), labs, mobile-labs etc. Potentially exposed public are identified using mass media announcement requesting them to report to specified locations and, if applicable, monitored for the contamination and medically examined at dedicated hospitals.

The IRRS team concludes that a system for protective actions to reduce radiation risks associated with orphan radioactive sources is in force in Pakistan.

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

The National Policy on Control and Safe Management of Radioactive Waste envisages provisions for management of radioactive waste generated by Nuclear Power Plants, Nuclear Research Reactors, radioactive sources used by industry and hospitals and research establishments. This policy does not mention spent nuclear fuel, decommissioning and disposal.

A corresponding national strategy was approved by PAEC in 2011. The strategy does not fully implement appropriate interim targets and end states, the interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, the responsibility for institutional control after the closure of a disposal facility for radioactive waste, appropriate research and development programs in relation to the disposal of radioactive waste, in particular programs for verifying safety in the long term.

Neither the policy nor the corresponding strategy for nuclear spent fuel management and decommissioning are established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A policy for nuclear spent fuel management and decommissioning is not established.</i>
(1)	<b>BASIS: GSR Part 1 para. 2.28 states that</b> <i>“The decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states...”</i>
(2)	<b>BASIS: GSR Part 1 para. 2.30 states that</b> <i>“Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized”</i>
S2	<b>Suggestion: The Government should consider including the policy for decommissioning of facilities and the safe management of spent nuclear fuel in the existing radioactive waste management policy.</b>
	<b>Observation:</b> <i>The Pakistani Government approved the National Policy on Control and Safe Management of Radioactive Waste. However, the corresponding national strategy prepared by PAEC is not in full compliance with the requirements of GSR Part 1. The document is not promulgated at governmental level. Strategies for decommissioning of facilities and safe management of spent nuclear fuel are not established.</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS: GSR Part 1 para. 2.28 states that</b> <i>“The decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states...”</i>
S3	<b>Suggestion:</b> <b>The Government should consider developing a national strategy for the decommissioning of facilities and for the safe management and disposal of radioactive waste with appropriate interim targets and end states.</b>

### 1.8. COMPETENCE FOR SAFETY

The importance of capacity building has been recognized by the government of Pakistan at the early stage of nuclear power programme development. For the capacity building dedicated university branches and institutes such as the Pakistan Institute of Engineering and Applied Sciences (PIEAS), the Karachi Institute of Power Engineering (KINPOE) and the CHASNUPP Centre for Nuclear Training (CHASCENT) have been established as national resources for capacity and competence building. Institute capabilities were strengthened through cooperation with international partners. The above mentioned institutes have been established by the PAEC to train graduates in the field of nuclear safety, power and system engineering. Graduates from these institutes are employed by all parties having a role in ensuring safety, security and protection in use of nuclear energy and ionising radiation.

In 2006, in addition to these institutes, PNRA has also established its own centre for capacity building with the name "School for Nuclear and Radiation Safety" (SNRS) under the public sector development program (see Chapter 1.3). At present this school is incorporated in "National Institute of Safety and Security" (NISAS) which is part of PNRA. PNRA actively participates in IAEA Technical Cooperation (TC) projects for developing competency of its staff through fellowships, scientific visits, workshops and training courses. PNRA has also established contacts with regulatory bodies, including those of China (NNSA), USA (NRC), and Slovakia (UJD) for training and capacity building.

### 1.9. PROVISION OF TECHNICAL SERVICES

Technical services essential for nuclear and radiation safety are available in Pakistan. Currently, Pakistan Institute of Science & Technology (PINSTECH) and Karachi Institute of Radiotherapy and Nuclear Medicine (KIRAN) are providing personal dosimetry services to their own radiation workers as well as to other radiation workers at national level on commercial basis. However, the operating NPPs, i.e. C-1, C-2 and K-1 are providing personal dosimetry services to their own radiation workers.

Environmental monitoring capability is under development at PNRA. In order to ensure that the environmental radioactivity levels across the country are within allowable regulatory limits, PNRA launched a project to establish National Environmental Radioactivity Surveillance Program (NERSP). Following the obligations of section 39 (1) of PNRA Ordinance, this project is aimed to plan, implement and co-ordinate national program of environmental surveillance to monitor any build-up of environmental radioactivity that might affect the public.

PNRA regulations do not require service providers for individual monitoring and calibration services to be authorized or approved by regulatory body. See Chapter 11 for additional information.

## **1.10. SUMMARY**

In Pakistan, policies and strategies for nuclear safety and radiation safety are mainly expressed through legislation. National Policy on Control and Safe Management of Radioactive Waste was issued by the Government. The IRRS team proposes that both for radiation and nuclear safety and radioactive waste management the policies should be complemented by strategies (plans) that would include appropriate details on their implementation. In case of the National Policy on Control and Safe Management of Radioactive Waste all responsibilities and obligations needs to be stipulated in the legislative framework in respect of financial provisions for the management of radioactive waste, spent fuel and for decommissioning of facilities.

The Ordinance and associated PNRA regulations provide binding legal framework for nuclear and radiation safety in Pakistan. Fundamental safety objective and fundamental safety principles as of IAEA SF-1 document are not fully embedded in the framework for safety.

The Ordinance establishes PNRA as the competent national authority for regulation of peaceful use of nuclear energy and ionising radiations. PNRA is independent in its decisions by the law. The team suggested that more formalized system of coordination and liaison with other relevant authorities should be set by PNRA to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.

To ensure a high level of nuclear safety, the government of Pakistan pays significant attention to the development of a national long-term competence for the nuclear energy sector.

To secure appropriate financing for its very ambitious expansion, PNRA adopted very active resource management strategy.

## **2. GLOBAL NUCLEAR SAFETY REGIME**

### **2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION**

The government of Pakistan is party to a number of international conventions for ensuring protection and safety in the utilization of nuclear energy and radiation for peaceful purposes. Conventions that legally bind the Pakistani government for peaceful uses of nuclear energy and nuclear application include:

- Convention on Nuclear Safety;
- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency;
- Convention on Physical Protection of Nuclear Material.

In addition to legally binding instruments, Pakistan has expressed political commitment support to the Codes of Conduct on the Safety and Security of Radioactive Sources.

Pakistan is not party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. This Convention is one of the cornerstones of the global safety regime and important especially for countries with significant nuclear programme that include nuclear power plants, research reactors, etc.

Pakistan is a member of Network of Regulators of Countries with Small Nuclear Programs (NERS) and IAEA's Response and Assistance Network (RANET). Representatives of PNRA actively participate in the development of IAEA safety standards. PNRA is the member of number of IAEA committees. The safety regulations being implemented in Pakistan are mainly based on IAEA safety standards.

In order to strengthen the global safety regime, the Government of Pakistan has requested several international peer reviews in the area of regulatory control and safety of facilities and activities. These peer reviews include:

- IAEA Design Safety Review Services (DSRS);
- Operational Safety Review Team (OSART);
- International PSA Review Team (IPSART);
- Integrated Regulatory Review Team (IRRT);
- Radiation Safety and Security of Radioactive Sources Infrastructure Appraisal (RaSSIA);
- Peer Review of Operational Safety Performance (PROSPER);
- Emergency Preparedness Review Mission (EPREV);
- Review of Accident Management program (RAMP).

In addition to inviting peer reviews to Pakistan, PNRA and PAEC experts regularly participate in IAEA and World Association of Nuclear Operators (WANO) missions.

Benchmarking with the international regulatory practices has been considered vital for the effective nuclear regulatory system. To broaden the base for its regulatory decision makings, the team is of the opinion that PNRA should consider to have formal mechanisms for obtaining international experience and diverse opinions on emerging safety concerns as appropriate. Therefore PNRA should consider having formal agreements of cooperation with regulatory bodies from countries with advanced nuclear power

programme. At present, PNRA has formal agreement of cooperation with the Chinese regulatory body (NNSA), which is the safety authority of the vendor of Chashma NPP.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>Pakistan is not party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 14 states that</b> <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i>
(2)	<b>BASIS: GSR Part 1 para 3.2 states that</b> <i>“The features of the global safety regime include a) international conventions that establish common obligations and mechanisms for ensuring protection and safety ...”</i>
S4	<b>Suggestion:</b> <b>The Government should consider becoming party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.</b>

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

PNRA has well established means for exchanging operating and regulatory experience with other member states and authorized parties. Mostly, information is exchanged through Nuclear Event Web based System (NEWS) and Unified System for information exchange in Incidents and Emergencies (USIE). Information about the operational feedback experience of NPPs is shared through IAEA International Reporting System of nuclear power plant operating experience (IRS). PNRA’s National Radiation Emergency Coordination Centre (NRECC) disseminates information received from NEWS and information from IRS is disseminated through IRS national coordinator.

Information is also gathered directly through cooperation with regulators in countries having similar types of nuclear power plants, i.e. China. Pertinent or significant events are forwarded to relevant inspectors and experts of PNRA, as well as to licensees. PNRA has established different technical groups to perform analysis of experience feedback and lessons learned. The event reports received through IRS and NEWS are analysed for application in Pakistan to improve safety of NPPs. National events are evaluated as part of the inspection programme (see Chapter 7).

Pakistan shares good practice and experience feedback with the international community through activities under Convention on Nuclear Safety.

## 2.3. SUMMARY

The government of Pakistan is party to a number of international conventions for ensuring protection and safety in the utilization of nuclear energy and radiation for peaceful purposes. However, Pakistan is not party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. It invites regularly international peers to receive experience feedback on the status of its safety framework. Pakistani representatives work actively in most of the IAEA and WANO activities.

### **3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**

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

Section 13 of the Ordinance that establishes the Pakistan Nuclear Regulatory Authority (PNRA), provides the PNRA with the authority to establish one or more Directorates which shall execute, enforce and supervise all decisions of the Authority and all nuclear and radiation safety measures vested in the Authority under the provisions of this Ordinance or the rules and regulations made there under. In accordance with this legal authority PNRA has established an organizational structure to perform the activities bestowed upon it by the Ordinance. The PNRA organizational chart is included in Appendix VIII.

The Chairman of PNRA reports directly to the Prime Minister, which allows PNRA to operate free from potential conflict of interest. Therefore these reporting arrangements grant PNRA independence. The Chairman has 2 Members reporting to him. Member Executive is responsible for two groups, headed by a Director General each, being the Inspection and Enforcement Group and the Technical Group. The Inspection and Enforcement Director General manages the Regional Nuclear Safety Directorates, The Technical Director General manages the Nuclear Safety, Transport and Waste Safety, Radiation Safety and Physical Protection and Nuclear Security directorates. In addition the Administration Directorate and the Finance Directorate also report to the Member Executive.

Member Corporate heads 2 corporate functions, being Capacity Building and Corporate issues. The Capacity Building Group houses the National Institute for Safety and Security (NISAS), National Dosimetry and Calibration Laboratory, National Environmental Radioactivity Surveillance Programme, Safety Analysis Centre. Where-as the Director General Corporate looks after the Information Services, Policies and Procedures, Regulatory Affairs, Centre for Nuclear Safety and Human Resources and Establishment functions. Audit and Planning is reporting to Chairman and International Cooperation and Establishment are under Member Corporate.

Sections 15 and 40 of the Ordinance authorize PNRA to appoint staff, advisors and consultants to assist in performing the duties of PNRA. Section 41 of the Ordinance makes provision for funding of the PNRA activities, which includes funding of human resources. PNRA has a long term human resource plan, which is pre-approved, to provide for human resources.

According to the Ordinance, PNRA has the authority to issue licences (Section 19), to grant authorisations (Section 20), to authorise prior to licensing (Siting, Section 21), to authorise radioactive waste discharges and disposal (Section 22), to authorise nuclear powered vehicles, vessels, aircraft or means of transport to carry nuclear material to enter Pakistan (Section 23), to cancel authorisations (Section 24), and to control contaminated foodstuff (Section 27). According to Section 16 (2) (d) of the Ordinance, PNRA approves the licensees' emergency plans. Section 41 of the Ordinance makes provision for funding of the PNRA activities. All the processes have been captured in a Management System Manual. The organizational structure of PNRA enables it to discharge its responsibilities and perform its functions effectively commensurate with the radiation risks associated with facilities and activities.

All work activities of PNRA are planned and scheduled in an annual work plan. Performance against objectives is reviewed on a quarterly basis. Performance results are reported, transparently, annually in a report. This management initiative leads to the application of resources in discharging its responsibilities and performing its functions in an ordered manner and according to the graded approach. The Chairman, has ultimately, the responsibility for all activities of PNRA.

PNRA does not currently have a written procedure to change its organisational structure (Details captured in Chapter 4).

### 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The Ordinance provides PNRA with independence administratively, financially and technically from its licensees and users of nuclear and radiation technology. The mandate of PNRA is to protect public, workers and the environment against nuclear & radiation hazards. In executing its responsibilities, PNRA applies the processes of authorization, review and assessment, inspections, etc., in respective work units. These internal processes allow PNRA perform its responsibilities without any undue influence from the applicant/ licensees. Regulatory decisions are made, in general, against pre-defined criteria and with sound basis to ensure safety. Further, the decisions are subjected to review & evaluation by the higher levels of authority within PNRA. The Ordinance provides PNRA with the power to intervene in any facility or activity that may present potential radiation risks, irrespective of the costs to the authorized party.

Section 46 of Ordinance allows PNRA to resolve conflicts between Directorates and licensees through the establishment of special tribunals. The tribunal has not been established, but is part of the dispute resolution regulations. There is a draft regulation, dated 2007, on dispute resolution, which is open for review by stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>The draft regulation to establish the tribunal on dispute resolution between PNRA and its licensee has not been approved.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 21 states that</b> <i>“The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.”</i>
R4	<b>Recommendation: PNRA should approve the regulation that allows PNRA to formally resolve conflicts between PNRA and its licensees through the establishment of special tribunals.</b>

### 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

PNRA has a structured approach to human resource development and management. Considering the expansion in the nuclear and regulatory programme, PNRA has increased the number of staff from 38 in 2003 to 283 at present. In terms of new employees, PNRA directly recruits fresh graduates from Universities. At PNRA, different training courses are conducted by the NISAS e.g., Level - I Basic Professional Training Course. To prepare these new officials for their duties they are rotated through appropriate disciplines (Directorates) in the organisation to be familiarised with the activities in the organisation. After completion of their initial training, these new employees are offered a choice of specialisation. Training in the chosen area of specialisation is addressed in the next paragraph.

PNRA has, for established employees, an internal development and improvement programme. This competency development process is based on IAEA TECDOC 1254. A training needs assessment report is derived from a procedure for training needs assessment (PNRA-NISAS-WP-012) and a procedure for competency development of Staff (PNRA-NISAS-WP-001). Training needs identified in this process are addressed in a training plan. Most training is provided in-house. Where it is not possible to provide in-house training, staff development is externalised in by means of universities, agreements with other

organisations, such as the IAEA, etc. These processes are referred to as part of the knowledge management system in PNRA-MSM-001.

PNRA has, with future developments in the industry in mind, developed a long term plan for future human resource requirements and for succession planning (Manpower roster). This plan has been approved at Governmental level to make provision for the staffing requirements (numbers) and financial resources. Recruitment is primarily from universities. However, when expertise from external resources is required, the government of Pakistan rules for employment are followed. PNRA has a team approach towards tasks to be performed. This approach allows for the sharing of knowledge amongst all levels of seniority in the organisation.

PNRA is investing resources to develop staff fluent in the Chinese language. PNRA is currently entering two staff members per year into a program that consists of six months of Chinese language training in Pakistan, one year of training in China, and a six month assignment with the Chinese regulator. This is important to safety because PNRA is reviewing and licensing reactor designs from China.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>PNRA has a very well developed and established training programme, supported by a training needs assessment and procedure for competency development, to develop, rotate and maintain the necessary competence and skills of staff of the regulatory body.</i>
<b>(1)</b>	<b>BASIS: GSR Part 1 Requirement 18 para. 4.13 states that</b> <i>“A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. ...”</i>
<b>(2)</b>	<b>BASIS: GS-R-3 para. 4.4 states that</b> <i>“Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization’s objectives.”</i>
<b>GP2</b>	<b>Good Practice:</b> <b>PNRA has a very well developed and established training programme to develop and maintain the necessary competence and skills of staff of the regulatory body that allows keeping a high level of competence during PNRA’s growth.</b>

### **3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS**

PNRA Ordinance Section 15 authorises PNRA to obtain services from advisors and consultants. The process is defined in PNRA Management System Manual (Ref PNRA-MSM-001). Advice and opinions from experts are provided in accordance with an agreement, to higher management, who has the responsibility to make the appropriate decision.

The Centre for Nuclear Safety (CNS) and Safety Analysis Centre (SAC) have been established within the PNRA as technical Support Organisation (Ref PNRA-MSM-001)

The Centre for Nuclear Safety (CNS) and Safety Analysis Centre (SAC) provides specialist technical support to staff. In case that the expertise does not exist within the organisation, PNRA hires services through external organisations. There are several cooperation agreements signed with various other organisations in countries such as China, Slovak Republic, etc. For the appointment of experts from other countries, PNRA has to follow the Government rules and procedures. Although care is taken when

experts are appointed to perform tasks, PNRA does not have a documented process to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>PNRA does not have a process to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.</i>
<b>(1)</b>	<b>BASIS:</b> <b>GSR Part 1 Requirement 20 para. 4.20 states that</b> <i>“Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services. If this is not possible domestically, then the necessary advice or assistance shall be sought from organizations in other States or, as and where appropriate, from international organizations which have no such conflicts of interest.”</i>
<b>R5</b>	<b>Recommendation:</b> <b>PNRA should develop arrangements to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.</b>

### **3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES**

PNRA has established mechanisms of communication with authorised parties on safety related matters. For example at HQ level, NSD communicates with the NPPs for authorization and review & assessment while the Regional directorates communicate with the licensees for inspection, enforcement & operator licensing.

There are various forms of meetings, which include scheduled and unscheduled meetings. In case of issues recorded during inspections or events, this would be followed up systematically in accordance with the inspection programme. The Management System Manual contains a flow diagram for periodic follow-up inspections (PNRA-MSM-001). Meetings are also scheduled in the different work plans. (For example, NSD Work plans for 2014). The minutes of these meetings are available.

At the initial stage of any activity framework is planned and a work plan is mutually agreed. Frequent meetings, as required by the particular situation, are held with the licensees so as to foster mutual understanding. Furthermore, licensees are continuously informed about the regulatory processes. Licensees are given the opportunity to comment when regulations are developed or modified.

PNRA also fosters mutual understanding and respect by following core values which include mutual respect and caring & compassionate attitude.

The licensees` submissions are reviewed at PNRA by the relevant experts and comments, contained in a report, based on sound technical justification and regulatory requirements are communicated to the licensees. The basis of rejection is also communicated. Discussion in the form of correspondence and meetings are also held if required.

### **3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL**

Regulatory processes are established in the Management System Manual (PNRA-MSM-001), for all nuclear facilities in accordance with PAK/909. Radiation facilities are regulated in accordance with PAK/908. Equipment manufacturers are authorized in accordance with PAK/907. Technical and administrative regulations specify the acceptance requirements as applied to all facilities (PAK/904, 910, 911, 912, 913, 914, 915, 916 and 923). Before carrying out announced inspections, inspection procedures mentioning objectives, scope, acceptance criteria, etc. are communicated to the licensee, ahead of time. In

case of review and assessment regulations, codes and standards provide guidance to licensees. All decisions of the regulatory body are captured in reports.

PNRA has a defined procedure for the development and modification of procedures (PNRA-MSM-001 and PNRA-WP-004). The continuous enhancement of safety, as a general objective, is captured in regulations (PAK/904 and 911)

The regulatory decision making process is based on the regulatory requirements defined in PNRA regulations. The regulatory decisions are mainly based on consultative process among various directorates to ensure the consistency in regulatory decision-making. Furthermore, record of all the previous regulatory decisions is taken into account during finalization of new regulatory decisions. All of these processes are mapped out in the Management System Manual (PNRA-MSM-001). All documents are taken up into a configuration management system, which is mapped in the Management System Manual.

### 3.7. SAFETY RELATED RECORDS

Records are kept by PNRA and licensees. All authorisations contain a requirement for record keeping. The range of documents, include, amongst others, Site Evaluation Report, Preliminary Safety Analysis Report, Final Safety Analysis Report, Periodic Safety Review, reports etc. More detail is provided on the range of documents in the table below. PAK/913 section 24 specified the requirements for document control and records for Nuclear Power Plants. For radiation facilities the requirements are specified in PAK/904 in sections 20 and 24. Record maintenance is also verified through inspections performed by PNRA (PNRA-NSD-WP-001). Regulations require specific operational records to be submitted in support of its regulatory function, for example, the discharges of effluents (PAK/913, Section 24). Records of operational issues are amongst others, used in the verification program.

Records are stored by PNRA as follows:

Registers of sealed radioactive sources and radiation generators	Director General Inspection and enforcement-DG (I&E). An inventory is kept at DG (I&E) office of sealed sources and diagnostic X-ray facilities. Sealed source registers contains information on the users and the source related technical information. The X-ray facility records contain information on the facility and its equipment.
Records of occupational doses;	Radiation Safety Directorate (RSD)
Records relating to the safety of facilities and activities;	Nuclear Safety Directorate and Regional Directorates (NSD)
Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;	Waste Safety Directorate – (WSD) no plants at this phase as yet.
Records of events	Nuclear Safety Directorate(NSD)
non-routine releases of radioactive material to the environment	Waste Safety Directorate (WSD)
Inventories of radioactive waste and of spent fuel	WSD for waste, Regional Directorate for spent fuel

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

PNRA has developed the procedures-PNRA-WP-001- “Procedure for Preparation and Revision of Regulatory Guides” and PNRA-WP-004 “Procedure for Preparing PNRA Regulations” for issuing, adopting, promoting and amending safety regulations and guides.

The document PNRA-WP-004 “Procedure for Preparing PNRA Regulations” describes the nature and extent of any mechanisms for consultation with interested parties during the development of safety regulations. The main parties include licensees, public and relevant government departments.

PNRA has several means of communicating with interested parties, such as publishing information on the web page, annual reports, etc. PNRA does not have feedback or information sessions with the media and the public. The communication mechanisms in place, are primarily aimed at providing information, and therefore do not promote two way communication. These communication mechanisms are also not suitable to reach all of the population, taking into consideration, amongst others, means of communication, language, access to information, literacy, etc.

PNRA has recently developed a public awareness programme to educate the public and the young generation on radiation safety. This programme is implemented in collaboration with educational institutes and national organisations. The objective of this programme is to inform the public about PNRA, types of radiation, applications of ionizing radiation, hazards of radiation and nuclear safety in Pakistan. It should be ensured that this programme reaches the population at all levels.

PAK/914, the Regulation on Nuclear or Radiological Emergency, requires all facilities to have public warning systems (Section 8(5)). However, PNRA does not have public communication forums to establish two-way communication between the Regulator, the public and the media on issues related to Regulatory business.

PNRA does not have a procedure that provides public information associated with the facility risk, in accordance with graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>PNRA has recently approved a public awareness program to address radiation, nuclear safety and regulatory practices for graduate students, general public, selected Ministries, government employees, applicable industries and health professionals. The target group will be addressed by means of lectures, symposiums and pamphlets.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 36 states that</b> <i>“Communication and consultation with interested parties The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.”</i>
GP3	<b>Good Practice: PNRA has an approved public awareness programme to address radiation safety and regulatory practices in the generic public domain.</b>
	<b>Observation:</b> <i>A suitable programme to communicate with authorities, licensees and the public in regions of interest regarding regulatory and operational issues at facilities does not exist and there is no mechanism for feedback of information to PNRA from these affected areas.</i>
(1)	<b>BASIS: GSR 1 Part para. 4.66 states that</b> <i>“The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public .....”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS: GRS Part 1 para. 4.67 states that</b> <i>“The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about ....”</i>
(3)	<b>BASIS: GRS Part 1 para. 4.69 states that</b> <i>“Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach.”</i>
R6	<b>Recommendation: PNRA should develop effective mechanisms of communication, and hold meetings to inform interested parties, the public and the media to keep these parties informed on the decision making process and on the risk of radiation, in accordance with the graded approach.</b>

### 3.9. SUMMARY

PNRA is well structured and have access to funds to perform its duties. Decision making processes are well mapped and responsibilities well distributed. PNRA has the ability to make decisions independently. There is adequate functional separation from PNRA and those who promote or apply nuclear technology. Staffs have integrity. PNRA does not have an approved conflict resolution procedure.

PNRA has sufficiency and competent staff. Staff planning makes provision for the long term programme for PNRA. The PNRA training programme is highly recommended, since it allows for rotation and it is suitable from introduction up to detailed specialised staff. The PNRA ordinance makes provision for the appointment of advisors and consultants. Although care is taken of conflict of interests when the appointment of technical support is considered, it is not written.

PNRA has an adequate schedule of meetings with authorised parties to enable a professional relationship. All decisions are documented. PNRA has a well-documented system to ensure consistency in the regulatory process, though some procedures are still pending.

The Management System Manual captures all processes. Decisions can be made consistently and objectively by the regulatory body because practically all processes have been mapped and acceptance criteria are captured in regulations and guides.

Changes in regulatory requirements are transparent, because the process of establishing regulations is open for public participation.

The Management System Manual PNRA-MSM-001 in Section 6.3 deals extensively with the document control system. Registers and inventories are maintained at various Directorates, as appropriate. All records are kept by the PNRA and licensees. Records are used in both the inspection and licensing departments to demonstrate and manage safety of facilities and activities, as appropriate. PNRA-WP-004-“Procedure for Preparing PNRA Regulations” describes the nature and extent of mechanisms for consultation with interested parties during the development of safety regulations.

PNRA has several means of informing interested parties, such as publishing information on the web page, annual reports, etc. PNRA does not have frequent planned feedback or information sessions with the media and the public, which does not promote two-way communication.

PAK/914, on emergencies at nuclear and radiological facilities, requires all facilities to have public warning systems (Section 8(5)). PNRA does not have a process to demonstrate that public information activities are conducted, in accordance with a graded approach, to reflect the radiation risk associated with the facility risk.

## 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

### 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

PNRA started with the introduction of management system soon after its establishment in 2001. In 2003 the PNRA quality management system was subject to the IRRT mission. It was recognised that the management system was under development. It was the IRRT mission's suggestion that the PNRA should proceed with the establishment of a quality management programme taking into account the observations of the mission.

The current PNRA management system is developed with consideration of the Ordinance No. III of 2001 and to a large extent considers the requirements of IAEA standards. The management system is documented in a "Management System Manual", which was issued in 2010.

In 2014 the PNRA completed the self-assessment in view of the IRRS mission and has benchmarked its management system against GSR-3. As a result of the self-assessment PNRA prepared an action plan for eliminating the found weaknesses. Under the preparation in final stage of revision 1 of the "Management System Manual" which considers, apart from requirements of GSR-3, as well as, requirements of the draft IAEA standard, GSR Part 2 "Leadership and Management for Safety".

A detailed structure of the integrated management system, covering the PNRA activities, is defined in management system documentation which consists of the "Management System Manual" and related procedures (152). The "Management System Manual" is the essential document of the PNRA management system and provides guidance to the work of PNRA. The "Management System Manual" describes the PNRA vision, mission, values and policy statement, the organizational structure, resources, processes and how the effectiveness and efficiency of the management system is measured. The management system documentation is available on the PNRA intranet pages.

PNRA activities are defined by documented processes, which are divided into core processes, support processes and management processes. Promotion of continual improvement of the management system is reflected in the use of policies and strategies, plans and feedback information, in performing internal audits, self-assessments and management reviews of management system.

Priority to safety is promoted in the PNRA "Policy statements", which state "Safety first". Further the regulations issued by PNRA ensure that safety overrides all other demands.

PNRA promote and support safety culture in its activities. However, safety culture is not properly documented in the "Management System Manual". Safety culture statement and attributes are in the process of development. PNRA should consider that safety culture is integrated into all processes and activities.

The "Management System Manual" supports the implementation of a graded approach. Some regulatory activities like inspections, review and assessment, authorization etc. are implemented on the principle of a graded approach. However, the graded approach process is not documented in the Management System Manual. The policy and the principles for the implementation of the graded approach are planned to be developed.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** *The Management System Manual does not include some key issues required by GS-R-3, namely Safety Culture, Graded Approach, Responsibility of the Organization for the Management System, Authorities and Responsibilities of Process Owners, The Control of Processes Contracted to External Organizations, and Managing Organizational Changes.*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<b>BASIS: GS-R-3 para. 2.5 states that</b> <i>“The management system shall be used to promote and support a strong safety culture ...”</i>
(2)	<b>BASIS: GS-R-3 para. 2.6 states that</b> <i>“The application of management system requirements shall be graded so as to deploy appropriate resources...”</i>
(3)	<b>BASIS: GS-R-3 para. 2.7 states that</b> <i>“Grading of the application of management system requirements shall be applied to the products and activities of each process.”</i>
(4)	<b>BASIS: GS-R-3 para. 3.14 states that</b> <i>“The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.”</i>
(5)	<b>BASIS: GS-R-3 para. 5.6 states that</b> <i>“For each process a designated individual shall be given the authority and responsibility for...”</i>
(6)	<b>BASIS: GS-R-3 para. 5.10 states that</b> <i>“The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.”</i>
(7)	<b>BASIS: GS-R-3 para. 5.28 states that</b> <i>“Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.”</i>
(8)	<b>BASIS: GS-R-3 para. 5.29 states that</b> <i>“The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised.”</i>
S5	<p><b>Suggestion:</b> PNRA should consider issuing the new revision of the PNRA Management System Manual, which incorporates</p> <ul style="list-style-type: none"> <li>• Safety Culture,</li> <li>• Graded Approach,</li> <li>• Responsibility of the Organization for the Management System,</li> <li>• Authorities and Responsibilities of Process Owners,</li> <li>• The Control of Processes Contracted to External Organizations</li> <li>• and Managing Organizational Changes,</li> </ul> <p><b>in accordance with its self-assessment action plan.</b></p>

### 4.2. MANAGEMENT RESPONSIBILITY

A management commitment is expressed through the PNRA Policy Statements which are documented in the “Management System Manual”. The PNRA management at all levels demonstrates commitment to the establishment, implementation, assessment and continual improvement of the management system. The PNRA management has defined vision, mission, values and policy statements. The management at all levels also participates in preparation of the “Management system manual”. The implementation of safety culture self-assessment is strongly supported by the PNRA management.

PNRA identified the interested parties and their needs. The satisfaction of interested parties is maintained by offering its advisory services and taking care of their needs within the scope of its legislative framework. A mechanism has been established to obtain feedback from selected interested parties.

PNRA representatives conduct regular meetings with selected interested parties on the basis of Annual Meetings Calendar prepared in advance and departmental annual plan for the different groups of selected

interested parties, i.e. for licensees of NPPs, for licensees of radiation sources and for the general public awareness. Meetings with NPPs are on a quarterly basis, meetings with radiation facilities are foreseen at least every year. The selected interested parties' satisfaction is assessed also through performance assessment questioners delivered to the licensees.

PNRA regularly performs the assessment of the satisfaction of PNRA employees through interviews, meetings and different questionnaires related to the safety culture self-assessment process.

The goals, strategic plan and the objective of PNRA are developed and they are measurable. In finalizing stage is the strategic plan for the years 2014 – 2018 where common goals are developed. On the basis of strategic plan and the document “Task and Project of Directorates/Projects for year 2013- 2014” each department prepares its own annual plan. Departmental annual plans are measured on a quarterly basis by Directorate of Regulatory Affairs (RAD) to check the compliance of the plans. At the end of the year each department demonstrates the implementation of the plan,

On the basis of the strategic plan and annual plan, PNRA developed 12 performance indicators. Based on these indicators the PNRA performance is assessed every year. The results are issued in the PNRA Annual Report.

### **4.3. RESOURCE MANAGEMENT**

The PNRA senior management is responsible for determination of resources (human, working environment, infrastructure, information and knowledge as well as material and financial resources).

In a view of a foreseen expansion of the nuclear power programme in the future, PNRA has created an environment for implementation of a successful system for education and training. PNRA developed the training process which is defined in Management System Manual.

As required in GS-R-3 para. 4.1, senior management has been determining the needs for resources. Based on the governmental procedure PNRA developed its own policy for recruitment in which measures to increase the knowledge of new comers are defined and included in “Long Term Staffing Plan for the period until 2020”. The document “Job description of PNRA officers” was developed as well. Senior management determines the competence requirements for employees at all levels, provides trainings and take other actions to achieve the required level of competence. PNRA determines “Training Needs Assessment Report” for 5 consecutive years” in accordance with “Procedure for training needs assessment (PNRA –NISAS–WP-012). The programme defines, for each post, the requirements regarding competences of the PNRA employees (i.e. professional education, required additional trainings, skills, experience and knowledge). The realization of the program is monitored regularly by relevant departments and Human and Resource Department. According to the SARIS self - assessment report and the Management System Manual, Revision 0, the evaluation and effectiveness of training is assessed through their outcomes namely inspection reports, assessment reports, etc.) and feedback provided by Department of human resources) (HRD) and NISAS of the exams conducted after the courses.

PNRA developed a comprehensive system for performing education and training for the PNRA employees and its stakeholders. A good practice is captured in Chapter 3.

The “Management System Manual” and “Outcomes of the Self-Assessment for Core Questions (GSR Part 1 and the GS-R-3)”, state that management provides the infrastructure and working environment necessary for regulating the safety of nuclear installations and radiation facilities and ensures that the work is carried out in a safe manner.

PNRA takes care for the environment in the scope of its work (introduction of less paper environment). It also seems that the PNRA has created an employee friendly organization (creative working methods, career planning, promotion system, baby care).

#### 4.4. PROCESS IMPLEMENTATION

PNRA has developed and implemented the management system which is based on a process approach. The “Management System Manual” defines the processes, their sequence and interactions. The processes are divided into three groups namely, management processes, core processes and support processes. Core processes are related to the main regulatory activities while the management processes and support processes enable the performance of core processes.

The authorities and responsibilities of the process owners are not defined in the “Management System Manual”. The implementation of this suggestion is captured in Section 4.1 of this Chapter.

PNRA has developed the “Procedure on Revision of Documentation”. PNRA issues the management system documentation and the list of management system documents on the internal website (intranet), so each employee can be familiar with last status of documents. However from the list of documentation it is not evident for some documents if they are regularly reviewed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>The status of review of some PNRA management system documents is not always evident or identified.</i>
(1)	<b>BASIS:</b> GS-R-3 para. 5.12 states that “ <i>Documents shall be controlled. ...</i> ”
S6	<b>Suggestion:</b> PNRA should consider documenting the status of review of relevant documents.

Originals of several documents related to ensuring documentation of the regulatory review and approval process, were observed with original signatures, with no other existing copies. All records appeared to be stored in common or close location raising a concern about its protection and preservation. Establishing a document control system to ensure protection and preservation regulatory related records should be considered as well.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Several documents containing original signatures, documenting transactions with the operator, and documenting internal reviews and approvals were observed. From discussion with PNRA staff, there does not appear to be in place a process to ensure duplication of such records to assure preservation of the information and retention. This presents a potential vulnerability of information related to the regulatory basis for licensing and related basis for decision.</i>
(1)	<b>BASIS:</b> GS-G-1.4 section 5.22 states that “ <i>The regulatory body should establish a system to control the preparation, review, approval, issuance, revision, distribution and storage of documents</i> ”.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS: GS-G-1.4 section 5.26 states that</b> <i>“The effectiveness of the document control system should be evaluated on the basis of the capability of retrieving documentation under different conditions and for different search criteria (such as by date, source, type or subject). Numerical indicators relating to the time necessary for retrieving the documentation may be established and monitored, and deviations may be recorded and corrected. Systems and conditions for the storage of records should also be reviewed periodically. Guidance on quality assurance for document control and records is provided in Ref. [6].”</i>
(3)	<b>BASIS: GS-R-3 para. 5.21 states that</b> <i>“Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.”</i>
S7	<b>Suggestion: PNRA should consider establishing a document control system to ensure protection and preservation of regulatory related records, which addresses retention and archiving of records.</b>

Some of the processes are not identified in the “Management System Manual” such as managing organizational changes and the control of processes contracted to external organizations. A suggestion for PNRA to develop these two processes is identified in Section 4.1.

### 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

PNRA defined a system to perform activities connected to measurement, assessment and improvements.

PNRA management system effectiveness is monitored through self-assessments independent assessments and management reviews meetings on a regular basis.

A self-assessment was performed in 2014 using the IAEA SARIS tool. Additionally, to the document “Outcomes of the Self-Assessment for Core Questions (GSR Part 1 and the GS-R-3)”, PNRA provided “Summary Report on Self-Assessment” that was of very high quality. The summary report can serve the regulatory body as base for preparation a comprehensive action plan and IRRS team reviewers can get a realistic picture in the functioning of PNRA. As a result of self-assessment, PNRA identified weaknesses and options to improve their management system. Further each department conduct self-assessments on the basis of their annual plans and prepare action plan for improvements.

The self-assessment of the safety culture presents a great improvement in the development of management system.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>PNRA has been implementing the self-assessment of safety culture, which, exceeds the requirements of GS-R-3. This is proof of high commitment of the PNRA management to the implementation, assessment and continual improvement of the management system.</i>
(1)	<b>BASIS: GS-R-3 para. 6.2 states that</b> <i>“Senior management and management at all other levels in the organisation shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture”.</i>
GP4	<b>Good Practice: PNRA conducts self-assessment of safety culture.</b>

PNRA has established a dedicated directorate with the responsibility to conduct independent assessments and audits (RAD), which is responsible for conducting independent assessments of PNRA directorates on behalf of senior management. The consolidated audit reports are communicated to the higher management which in response directs the respective work unit to take corrective actions, if seemed necessary. Audits are performed every second year for each organizational unit. However, it would be beneficial if audits were more process oriented rather than department orientated and if considered interfaces among processes.

Management reviews are conducted every year where the functioning of PNRA is assessed. On management reviews implementations of goals and objectives, all kinds of assessment reports, feedback experience from stakeholders, lessons learned from the good practices and other organisations, management issues etc. are discussed to identify the necessary improvements.

PNRA has been reviewing the management system for its improvements. All Directorates have been requested to identify the non-conformances, which would be resolved during revision of the management system. An “Annual Plan” of corrective action was developed. PNRA has developed performance indicators to evaluate its performance and then identify the areas/corrective actions to improve it. However the implementation of preventive actions may be reflected in the “Management System Manual”, revision 1.

#### **4.6. SUMMARY**

PNRA started with activities relating to the management system soon after its establishment in 2001. A comprehensive management system was implemented in 2010 when the revision 0 of the “Management System Manual” was issued. The management system is developed, to a great extent, in accordance with GS-R-3. As a result of the self-assessment performed against IAEA SARIS tool in 2014, PNRA continued to improve its management system and to revise the “Management System Manual” considering the requirements of GS-R-3 and draft standard IAEA GSR Part 2. The new revision of the “Management System Manual” is now in a final stage of preparation.

Apart from the activities connected to improvement of the management system, PNRA is currently implementing a set of actions for assessing its own safety culture. In 2013 the PNRA invited IAEA to conduct the Workshop on identification the methodology to perform safety culture. After the IAEA workshop the PNRA has developed the procedure to conduct safety culture self-assessment. The insights of the self-assessment of safety culture are currently being addressed.

## 5. AUTHORIZATION

### 5.1. GENERIC ISSUES

The authorization process in Pakistan may take the following forms:

Licence - a legal document issued by PNRA granting authorization to perform specified activities related to a facility or activity.

Permit - a legal document issued by granting authorization to perform single time specified activities (e.g., fuel load in a nuclear power plant etc.).

Registration - a legal document issued by the PNRA granting authorization after receiving the first application from an applicant considering initiating a nuclear/radiation activity and indicating that minimum safety requirements can largely be ensured.

No Objection Certificate (NOC) - a legal document issued by the PNRA indicating that it does not object to an activity (e.g. import/export).

Licensed activities in Pakistan are divided in three main groups:

- Nuclear Installations
- Radiation Facilities other than Nuclear Installations
- Nuclear Safety Class Equipment and Components Manufacturers

The authorization is initiated by submission made by applicants at the different stages of the operational life of the licensed facility. Safety review and assessment for the purpose of authorizations is one of the major functions of PNRA and it is governed by the PNRA management system manual. The approvals issued for these facilities/installations during their licensing life, and associated submission requirements, depend on which group they belong and are described in specific regulations. This matter is expanded in the subsequent sections of this Chapter.

Amendments to licences may be authorized at the request of the operator as a result in changes in design, operation, or scope of activities carried out.

Authorizations issued by PNRA generally take the form of licences with associated specific conditions (i.e. generic and time bounded) and limits along with the authorization for different stages during licensing process. General conditions usually re-iterate some important regulatory requirements and also describe those specific requirements that have not been covered in regulatory framework.

Decisions on licensing for nuclear installations are documented in safety evaluation reports including internal deliberations, major issues identified, and recommendations for conditions to be incorporated in the licence. The decision for granting authorization is made by the competent authority within the PNRA and is communicated to the licensee in written form and is recorded in the specific files. PNRA retains records of the documented review and approval process during the lifetime of the installation.

The Technical Support Organization, namely the Centre for Nuclear Safety (CNS) is integrated within the regulatory structure. However, it is located within the corporate part of the organization, separate from the executive part responsible for licensing and compliance activities thus assuring independence. The CNS performs independent reviews and assessments in support of the executive branch during the licensing process. Review results from the CNS and from consultants are reviewed by the relevant department in the executive branch before being conveyed to the proponent.

Inconsistency was observed between licences issued for certain activities/installation and the definition of Nuclear Installations as defined in the ordinance. We noted that the PINSTECH Molybdenum-99 production facility could be, strictly speaking, categorized as a Nuclear Installation, which is not reflected in the current practice (issuance of a radiation facility licence). The format of the licence for this facility is more akin to that, in term of format and content, as that for a nuclear installation; however, we could not conclude on whether the measures in place as described in the licence and the additional requirements arising from compliance with the regulation were commensurate with risks posed by operation this facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>The category of licence issued by PNRA to some of the facilities is not demonstratively consistent with the definition of Nuclear Installation as defined in the Ordinance.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 22 that</b> <i>“The Regulatory body shall ensure that regulatory control is stable and consistent.... The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body”</i>
S8	<b>Suggestion:</b> <b>PNRA should consider revisiting the current licences and ensure their categorization is consistent with the definition of Nuclear Installation as defined in the Ordinance.</b>

PNRA does not have a procedure for appeal against its decisions regarding granting of authorization to a facility/activity and conditions attached with the authorization (both for power reactors and research reactors). The team discussed this issue with PNRA and learned that although a formal process does not exist, several elements related to the process are in place and requests for appeals have been accepted and resolved. One key element is paragraph 46 of the Ordinance that allows PNRA to establish tribunals to resolve disputes between Directorates and Licensees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A formal documented process to allow appeals against its decisions regarding granting of an authorization to a facility, and activity and conditions attached with the authorization is not in place.</i>
(1)	<b>BASIS: GSR Part 1 para. 4.32 states that</b> <i>“The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.”</i>
(2)	<b>BASIS: GSR Part 1 para. 2.5 (11) states that</b> <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: ... (11) Provision for appeals against decisions of the regulatory body; ...”</i>
R7	<b>Recommendation:</b> <b>PNRA should develop procedures for appeal against regulatory decisions.</b>

## 5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Pakistan has three operating power reactors, Karachi Unit 1 and Chashma Units 1 and 2. Pakistan also has two new units under construction, Chashma Units 3 and 4. In addition to the licensing of the power reactors, PNRA also licenses the operating personnel.

Regulation PAK-909 governs the licensing of all nuclear installations in Pakistan. This includes the requirements for licence application, and authorizations steps issued through the life of a facility. Authorizations issued include:

- Site Registration
- Construction Licence
- Permission for Commissioning
- Permission to Introduce Nuclear Material into the Installation
- Operating Licence
- Revalidation of Operating Licence
- Licensing Beyond Design Life
- Licence for Decommissioning of a Nuclear Installation
- Removal from Regulatory Control

Licensees submit overall project schedule and schedule for submission of documents during authorization process and accordingly. PNRA correspondingly develops a schedule for review and assessment of these submissions, and communicates its plans to the licensee. PNRA agrees on codes and standards to be used by the licensee before initiating review and assessment process and licensing submissions are prepared in line with the agreed code and standards. In cases, where national codes and standards are not available, the applicant may follow USNRC regulations, IAEA standards or applicable standards of other countries demonstrating equivalence or more restrictive guidance to agreed codes and standards.

PNRA has addressed aging management through a combination of processes. PNRA only grants operating licences for a period of 10 years. At the conclusion of the 10-year period the licensee must submit a periodic safety review (PSR) for PNRA review. In the case of operation beyond the design life, the licensee must submit a PSR along with an update to the documents submitted for the initial licence.

PNRA also has a process, criteria, and guidance for the application process for modifications to power reactors.

Additionally, PNRA issues licences for reactor shift supervisors, shift engineers, and reactor operators; the licensing requirements for these positions are contained in PAK 913.

Related to nuclear power plants, PNRA also licenses manufacturers of Nuclear Safety Class equipment manufactured in Pakistan. Regulation PAK-907 provides necessary submissions in support of an application. Regulatory reviews include desktop review of the application for acceptability, inspection and audit of the manufacturer facilities to assess application of quality assurance principles and technical capability, and demonstration of capability through mock-up manufacturing in testing. Licences for nuclear safety class equipment manufacturers are normally issued for a period of 5 years at the terms of which they are required to be revalidated.

A self-assessment conducted in 2014 by PNRA identified several areas for improvement. One issue the team identified to emphasize is the need for PNRA to develop regulatory guides for defining format and contents of licensing submissions for nuclear facilities. Although the PNRA structure allows for the use of NRC, IAEA and other guidance when PNRA guidance does not exist, the team is concerned that without guidance developed by PNRA some stakeholders may not fully understand or embrace the basis for the guidance and how the guidance supports the regulations. PNRA is continuing to resolve this issue following the self-assessment action plan.

Also identified in PNRA’s self-assessment was the need for PNRA to involve the public in the authorization/licensing process for NPPs. The team concurs with the PNRA assessment and encourages progress in these areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>PNRA has not developed guidance for licensing submissions defining format and content for nuclear facilities, which may result in applicants not fully understanding the regulatory requirements and expectations.</i>
(1)	<b>BASIS: GSR Part 1 para. 4.62 states that</b> <i>“The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization.”</i>
S9	<b>Suggestion:</b> <b>PNRA should consider continuing to develop guidance defining format and technical contents of licensing submissions for nuclear power plants and research reactors.</b>
	<b>Observation:</b> <i>PNRA lacks processes to involve the public in the authorization and licensing processes for NPPs.</i>
(1)	<b>BASIS: SSG-12 para. 2.44 (d) states that</b> <i>“Comments from the public should be addressed at all steps of the licensing process.”</i>
S10	<b>Suggestion:</b> <b>PNRA should consider developing processes to involve the public in authorization and licensing processes for NPPs.</b>

Policy Issue 1: Software Based Safety Systems

PNRA staff and members of the IRRS review team discussed licensing of digital control systems for NPPs. Attributes discussed included system diversity, redundancy, separation, potential acceptance criteria, vendor inspections, cyber security, and impact of digital I&C systems on operator training and licensing. There was a good exchange of information and experiences, with the status of implementation discussed for Pakistan, Germany, China, Czech Republic and the United States. The meeting topics also included operator licensing as it relates to the operators interface with digital systems.

**5.3. AUTHORIZATION OF RESEARCH REACTORS**

PNRA currently licenses two research reactors, PARR-1 and PARR-2, both located at the PINSTECH national research institute. PARR-1 is a 10 MW pool type Material Test reactor located in a containment building. It is a multipurpose reactor equipped with beam tube and irradiation systems, and is currently primarily used for medical isotope production (Iodine-131 and Mo-99). PARR-2 is a 30 kW tank in pool type reactor similar to the Chinese Miniature Neutron Source and SLOWPOKE reactor designs. PARR-2 is primarily used for neutron activation analysis.

The licensing process for research reactors is governed by Regulation PAK-909 and is essentially the same as that for Nuclear Power Plants.

Revalidation of Operating Licences (i.e. licence renewal) is required to be supported, among other things, by the conduct of a Periodic Safety Review and associated Integrated Implementation Plan. Licences are normally issued for a period of 10 years, but may be of shorter period depending on the status of on-going actions. The team considered the current limitations of 5 years at PARR-1 and 1 year at PARR-2 to be an appropriate means of assuring that the licensee completes the actions necessary to comply with the revised regulatory requirements.

Regulation PAK-923 also provides requirements on modifications to research reactors. Requirements specific to operation of research reactors, including the establishment and need for reviews by the Safety Review Committee are in regulation PAK-923.

Regulation PAK-923 includes requirements for licensees to implement measures for the management of ageing of research reactors. Ageing management programs were evidenced during the visit for both PARR-I and PARR-2. Periodic updating of measures to address ageing is carried out at the time of performance of Periodic Safety Reviews.

For research reactors two categories of positions require a licence issued by PNRA (certification), namely the reactor operators and shift supervisors. PNRA reviews and approves the Systematic Approach to Training (SAT) based training program for those positions. Licensing/certification consists of a written examination by the licensee (subject to review by the regulator), and then finally oral and operating examination by PNRA.

Regulatory reviews were available and traceable. Comments regarding retrievability and preservation of records were provided in Chapter 3.

The self-assessment carried-out by PNRA in 2014 identified the same gap regarding the establishment of guidance on format and content of licensing submissions in support of the various phases of licensing for research reactors. A Suggestion to this effect is already included in Section 5.2, and is in fact applicable for all nuclear facilities.

#### **5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES**

Radioactive waste predisposal management is provided in Pakistan at the waste management facilities that are located at the nuclear facilities sites: K-1 NPP, C-1& C-2 NPP and Pakistan Institute of Nuclear Science and Technology (PINSTECH).

Pakistan Atomic Energy Commission (PAEC) has been assigned the responsibility for safe disposal of radioactive waste. PAEC has declared PINSTECH as one of the facilities for collection of waste from the northern part of the country and K-1 NPP from the southern part.

PNRA has the power to authorize radioactive waste management facilities. Waste management facilities are licensed as part of the nuclear facilities according to the PAK/909 (Rev.1). In particular the licence for the radioactive waste repository closure is required.

Pakistan has good expertise regarding the regulating of the operation of predisposal radioactive waste management facilities and well defined regulatory infrastructure to ensure safe operation of these facilities. PNRA is in the process of performing the review of the safety analysis of K-1 additional Radioactive Waste Storage Area (RAWSA) and licensing of PINSTECH predisposal radioactive waste management facility.

C-1 NPP applied for the construction of an Extended Storage Facility for Low Level Radioactive Waste. Based on the review and assessment of C-1 applications, PNRA allowed construction of this facility. PNRA extended time specific licence condition regarding Storage of Radioactive Waste up to 2014 on the request of C-1 after analysis and verification through review and assessment and inspections.

At the current date there are no regulatory activities for licensing of disposal facility because the disposal facility has not yet been sited/constructed. Siting and site evaluation of a disposal facility is in progress in Pakistan. A separate licence shall be required for establishment of independent spent fuel storage or a pre-disposal radioactive waste management installation in case the installation is not covered under licence of any operating nuclear power plants or a research reactor.

PAK/915 “Regulations on Radioactive Waste Management” is in force and includes basic general requirements for the radioactive waste treatment, storage and disposal. In particular, it states that Licensees shall ensure that the treatment and conditioning of radioactive waste is carried out in accordance with the waste acceptance requirements.

PNRA is currently working on a revision to PAK/915 incorporating different types of disposal facilities for radioactive waste.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Regulatory requirements for the development of different types of disposal facilities for radioactive waste are not yet in place.</i>
(1)	<b>BASIS:</b> <i>SSR-5 Requirement 2 states that “The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met”.</i>
S11	<b>Suggestion:</b> <b>PNRA should consider finalising regulations on the different types of disposal facilities for radioactive waste.</b>

The licensing of establishment of independent spent nuclear fuel storage is covered under PAK/909.

PNRA is using PAK/913 for safety regulation of the storage of spent nuclear fuel at the nuclear power plant sites. PNRA does not have specific regulations for the management of spent nuclear fuel, in particular to cover the activities for the removal of spent nuclear fuel from spent fuel pool at nuclear power plants.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>PNRA is using PAK/913 for the safety of spent nuclear fuel stored at NPP but there is no specific regulations/requirements for the safe management of spent nuclear fuel covering steps beyond the current conditions of storing spent fuel in the spent fuel pool.</i>
(1)	<b>BASIS:</b> <i>GSR Part 1 Requirement 32 states that “Regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based”.</i>
S12	<b>Suggestion:</b> <b>PNRA should consider finalising specific requirements for the safe management of spent nuclear fuel in anticipation of storing spent fuel outside the existing spent fuel pools.</b>

## 5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES

PNRA is responsible to ensure appropriate regulatory control for the safe operation of more than 3500 (3040 Diagnostic X-ray, 146 Industry, 63 Research/Education, 69 Medical, 92 Importers and 91 others) licensed facilities. The majority of licences issued are for diagnostic X-ray. The total amount of sealed sources in Pakistan is 3045 (Cat-I=114, Cat-II=76, Cat-III=91, Cat-IV = 435 and Cat-V = 2329).

According to the Ordinance, PNRA is the only regulatory authority for authorization and licensing of radiation facilities and activities and has set the formal authorization and licensing process with full authority to modify the authorizations (including authorization conditions necessary for safety) in line

with the requirements specified in the Regulations for the “Licensing of Radiation Facility(ies) other than Nuclear Installation(s)- PAK/908”. All the applicants have to follow these regulations, including the requirements for notification, licensing and authorization, in order to install and operate radiation facilities, unless exempted from the requirements (i.e., they meet exemption criteria in a Section 7 of PAK/904.

The PNRA grants a single authorization to a facility for performing various separate activities (e.g. operation, maintenance, engineering activities, etc.), if the applicant submits an adequate demonstration of safety in support of the application for authorization of a facility or an activity. PNRA Ordinance, Clause (3) of Section 19 provides the legal requirements for the applicant to submit a safety demonstration. In addition, the mechanism of safety demonstration is specified in regulations PAK/908. If an applicant does not provide all the information or the evidence required by the Authority under these regulations within specified timeframe the deadline can be further extended by the Authority if enough justification for this is provided by the applicant, otherwise the application can be rejected.

Besides, more than one licence can be granted to the same person or institution if different types of activities with radiation sources (i.e., Radiotherapy, Nuclear Medicine, Radiology, Irradiators, Industrial Radiography, Nuclear Gauges, etc.) are carried out.

The format and contents of the documents to be submitted by the applicant in support of an application for authorization are communicated to the applicants in advance. The format of documents is specified in approved application forms which are available at PNRA website. Some regulatory guidance is available related to the application process. PNRA has issued a few guides on the format and content of documents to be submitted by the applicant in support of an application for authorization, such as regulatory guide “Quality assurance in nuclear medicine“ (2009) and other documents like “Guidelines for preparation of physical security plan for sealed radioactive sources“ (2010). However, development of the regulatory guide “Guidance for preparation of licence applications of radiation facilities” remains in progress during 2014.

PNRA verifies the competence of the Radiation Protection Officer (RPO) and other workers through their credentials (i.e. basic qualification and duration of “on the job training”). The credentials are verified at the time of granting of authorization, renewal of licence and routine inspections.

PNRA put in place a mechanism for implementation of qualification criteria for radiation workers. To do so, PNRA promulgated in 2012 the following amendments to the “Regulations on Radiation Protection PAK/904 “The licensee shall designate/employ a RPO/Health Professional/Medical Professional as deems necessary fulfilling the qualification and training criteria established by the Authority for the accomplishment of the requirement of these regulations”. In practice this consists of three to six months of on the job training for Radiotherapy/ Nuclear Medicine, Radiology, Conventional Diagnostic Radiology, Irradiators, Industrial Radiography, Nuclear Gauges, etc.

However, the qualification criteria issued by PNRA for radiation workers does not cover the qualification requirements for all radiation workers. The full set of criteria of qualification in protection and safety for radiation workers in all types of activities with radiation sources is in draft form as a part of Rev. 1 of Regulations PAK/908 “Regulations for the Authorization of Radiation Facilities”.

Sealed radiation sources containing long-lived radionuclides can be purchased by the users/importers only under the condition that the manufacturer/supplier accepts the return of these sources when they become no longer in use (i.e. spent or disused sources). This condition has to be included as binding for the suppliers in the purchase contract, and without this the No Objection Certificate (NOC) for import will not be granted by PNRA. The user/importer is also required to provide copies of the shipping and other related documents to the PNRA when applying for NOC for import/export of sealed sources.

There are three Regional Nuclear Safety Directorates: RNSD-I, RNSD-II, RNSD-III. The functions of these Directorates among others are registration, licensing, review and assessment of safety performance of radiation facilities. After receipt of a satisfactory compliance report, a licence valid for one calendar year is issued to the applicant.

Newly licensed facilities in 2013	RNSD-I	RNSD-II	RNSD-III	Total
X-ray	511	194	66	771
Other than x-ray	15	1	13	29
Total	526	195	79	800

During the authorization process, PNRA performs pre-licensing inspections to assess if the applicant is competent enough to comply with relevant applicable requirements to ensure safety. Moreover, such confirmation of compliance is ensured by the regulatory body during periodic inspections.

However, quite a number of radiation facilities operate without renewed licences (a licence valid for one calendar year), total defaulter facilities in 2013 year represented 10% of the total of authorized facilities. Non-compliance with the regulatory requirements is generally managed through reminder letters, but practice of sending reminders and follow up letters did not efficiently serve the purpose of timely renewal of licences.

The authorization & licensing process is established in PNRA regulations PAK/908. In general a graded approach is applied for authorization of radiation facilities. This is addressed in relevant procedures for licensing of various types of facilities. There are practice specific requirements for the document that are submitted with the application. However, optimisation of regulatory resources/efforts in the authorisation of radiation facilities is not fully implemented, as:

- several licences can be issued for one legal person for the same type of activities with radiation source in several premises;
- several licences can be issued for one legal person for the use of the radiation sources in different practices;
- licences for all types of activities with the radiation sources, including low risk sources, are valid for one calendar year.

PNRA has stopped to issue several licences for each X-ray machine in one premise.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>The qualification criteria issued by PNRA for radiation workers do not cover the qualification requirements for all radiation workers. The full set of criteria of qualification in protection and safety for radiation workers in all types of activities with radiation sources is in draft form as a part of Rev. 1 of Regulations PAK/908.</i>
<b>(1)</b>	<b>BASIS: BASIS: GSR Part 3 para. 2.32. states that</b> <i>“The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety“</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S13	<b>Suggestion:</b> PNRA should consider finalising and issuing the regulation to establish a full set of qualification criteria in protection and safety for radiation workers in all types of applications of radiation sources.
	<b>Observation:</b> <i>Optimisation of regulatory resources/efforts in the authorization of radiation facilities is not fully implemented. Validity of licences for all types of activities is the same (1 year) despite the associated level of risk.</i>
(1)	<b>BASIS:</b> GSR Part 1 para. 4.3 states that "... The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."
(2)	<b>BASIS:</b> GSR Part 1 para. 4.5 states, that "... The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach...."
S14	<b>Suggestion:</b> PNRA should consider optimising the duration of licences for activities with radiation sources.

### 5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

PNRA shall be notified by the licensee, three years prior to permanent shutdown of operation of the nuclear installation. Records and reports related to decommissioning to be kept by the operating organization and the reports to be submitted to the regulatory body are mentioned in national regulations PAK/909, PAK/913 and PAK/923. Management system for the records maintained by the operator is described in licensee's management system.

The concept of clearance is applicable for material resulting from decommissioning activities has been addressed in section 12 of PAK/915.

Necessary provisions for protection against, and mitigation of, potential exposures that may result from an incident or accident that may occur during decommissioning activities have been made in Regulations on Management of a Nuclear or Radiological Emergency PAK/914.

PNRA has not yet issued any authorization for decommissioning, however, it is expected that in the near future, PNRA will carry out this activity due to decommissioning of NPP (K-1).

PAK/909 (Rev.1) provides the list of documents that shall be submitted by the applicant during different stages of the licensing process. The documents that shall be submitted with the application for the licence for decommissioning (as applicable) are:

- a) Final Decommissioning Plan
- b) Technical Specifications during decommissioning
- c) Quality Assurance Program for Decommissioning
- d) Emergency Preparedness Plan
- e) Physical Protection Program
- f) Radiation Protection Program
- g) Environmental Monitoring Program
- h) Radioactive Waste Management Program

However, the team noted that a site remediation plan is not a requirement of the regulation. The new regulation PAK/930, which is at final stage of approval, addresses this aspect.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>The list of documents to be submitted with the application for the licence for decommissioning does not include a plan for the remediation of the site. See also observation in Section 6.6.</i>
<b>(1)</b>	<b>BASIS: SSG-12 para. 3.83 states that</b> <i>“Decommissioning comprises: the preparation and approval of a detailed decommissioning plan; the actual decommissioning activities; the management of waste arising from these activities; demonstration that the decommissioning end point is achieved; and the updating of all existing safety related documents, as appropriate, including documents on physical protection and emergency response and the plan for remediation of the site”.</i>
<b>S15</b>	<b>Suggestion: PNRA should consider finalising and issuing the proposed regulation PAK/930 addressing site remediation considerations and decommissioning of facilities using radioactive material.</b>

## **5.7 SUMMARY**

Since its creation in 2001, PNRA has progressively established a regulatory framework covering activities licensed in Pakistan. This includes internal processes to review applications and submissions, and documentation of the basis for recommendation on licensing decision. Although some aspects of the framework remain incomplete, plans are in place to ensure completion.

Areas of improvements are suggested to ensure completeness and consistency of the existing regulatory framework, including in the regulations themselves and in the guidance provided to licensees.

## 6. REVIEW AND ASSESSMENT

### 6.1. GENERIC ISSUES

Pakistan since 2001, has been implementing a framework governing safety assessments for submissions related to activities and facilities it regulates. This framework includes new regulations, guidance to licensees in the form of regulatory guides, and internal procedural documents detailing the internal review processes and generic bases for the reviews. The regulations are listed in the PNRA references in Appendix VI.

Content of necessary submissions is generally included in the regulation or in guidance documentation. Some elements of this framework are still under development, including the production of new regulations and guidance. The different steps in the conduct of the assessment process are documented and traceable. One element of the review is the confirmation of completeness and adequacy of format of applications prior to proceeding with detailed reviews.

PNRA internal working procedure PNRA-WP-11005 provides guidance for the review and assessment process of the Directorate of Nuclear Safety (NSD) that is applicable to all review activities including both licensee submittals and internal documents. The procedure outlines the documents that are used by staff to form the basis of their conclusions. Where Pakistani regulations and requirements are not available, the process requires the staff to utilize USNRC documents, IAEA safety standards and Industry Codes and Standards.

The PNRA review process includes utilization of Technical Support Organization (TSO) namely “Centre for Nuclear Safety (CNS)” to conduct reviews of submissions such as Site Evaluation Report (SER), Safety Analysis Reports, Periodic Safety Review Reports, Quality Assurance Programs, Radiation Protection Program, Pre-service inspection (PSI) and In-service Inspection (ISI) program and other safety related submissions as applicable. The review conclusions are prepared in the form of safety evaluation reports and comments which are then evaluated, approved and communicated by PNRA to the licensee. For conducting the review, CNS has necessary expertise in all areas of review and assessment of nuclear power plants. CNS also has the provision to obtain technical assistance under agreements of cooperation with other technical support organizations such as Nuclear and Radiation Safety Centre of China, North China Regional Office and VUJE of Slovak republic.

The process of utilizing external guidance appears to work with some limitations. In some cases, such as for the quality assurance plan, available guidance may not be adequate to assure consistent implementation of the Pakistani requirements. This is another example related to the recommendation on the need to develop PNRA specific guidance stated in Section 5.2.

The PNRA review process includes utilization of external resources if NSD cannot conduct the review, the resolution of comments, final review and approval, and communication with the Licensee. The key considerations and conclusions are documented in a safety evaluation report. However, as discussed elsewhere in this report, the PNRA process does not include the consideration of input of additional stakeholders such as the public.

To assure the quality control of review and assessment documents PNRA performs quality assurance administrative inspections. These inspections verify the quality process used to develop the content of licensing submittals.

PNRA has the authority to establish Advisory bodies. These have been set-out for fixed duration to provide assistance and recommendation on specific subjects. Since 2001, two advisory bodies have been established, namely the “Advisory Committee on Research and Development” between 2004 and 2006,

and the “Advisory Committee on IAEA Safety Standards” between 2004 and 2008. The constituency of these bodies was essentially composed of retired PAEC members, further emphasizing the need to develop a framework to establish a rigorous process for the management of potential conflicts of interest (see Recommendation R5 in Section 3.2).

The extent of submissions, assessments, and groups involved in the assessments vary depending on the nature of the facilities involved. The following sections provide specific details depending on the types of facilities involved.

PNRA is aggressively developing staff and has technical expertise in almost every area of nuclear power plant review and assessment. However, if consultancy is required in specific area, the qualified and experienced staffs from the regulatory bodies and technical support centres of advanced countries are involved.

PNRA has an internal review and oversight process that involves senior leadership within the organization. However, PNRA does not currently utilize an independent oversight committee to assess the work of the staff.

PNRA has provisions for staff members to escalate differing technical opinions to achieve additional review to facilitate resolution.

## **6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS**

PNRA performs safety reviews and assessment for nuclear power plants during siting, design, construction, modification and operation of NPPs. PNRA also performs reviews of PSR submittals required every ten years as part of the process for revalidation of the operating licence. PNRA requires about one year to perform this review. Operation beyond the reactors original design life includes the review of a PSR as well as an update to the content of the original licensing materials. This represents a three year review process. This process was completed for the assessment of the licence for operation beyond the design life for the KANUPP reactor

In the process of review and assessment of the nuclear facility or activity, the following submissions are required by PNRA for granting construction and operating licences:

- Site Evaluation Report (SER)
- Preliminary Safety Analysis Report (PSAR)
- Overall Quality Assurance Program (OQAP)
- Probabilistic Safety Analysis Report (PSA)
- Final Safety Analysis Report (FSAR)
- Probabilistic Safety Analysis Level One Plus Report (PSA Level 1 plus) for nuclear reactors only
- Commissioning Reports up to introduction of nuclear materials
- Technical Specifications/ Operating Policies and Principles
- Radiation Protection Program
- Emergency Preparedness Plans
- Inspection Program
- Fire Protection Program

- Environmental Monitoring Program duly approved by appropriate Environmental Protection Agency (EPA)
- Radioactive Waste Management Program
- Pre-service Inspection (PSI) and In-service Inspection (ISI) Program
- Physical Protection Programme
- Decommissioning Strategy

A 2014 self-assessment conducted by PNRA identified two areas for improvement associated with this module:

- PNRA lacks a procedure for handling confidential and proprietary information of licensee is yet to be developed
- PNRA lacks a process to communicate the results of regulatory reviews to the public and other stakeholders (see Section 3.8).

### **6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS**

The review and assessment process for Research Reactors is essentially the same as that for of Nuclear Power Plants, including planning, identification of codes standards and acceptance criteria, and conduct of regulatory reviews. Specific regulations grading the requirements to research reactor applications were produced or are in the planning. At this stage, regulations for the design of research reactors remain outstanding. It should be noted that the design of the existing research reactors predated the formation of PNRA and no new applications are anticipated at this time.

Reviews of applications from licensees, associated regulatory reviews, including the development of project specific review plans were observed. Observations confirmed application of the, and traceability of the regulatory basis for approvals.

PNRA's regulation PAK-923 Section 7 defines quality assurance requirements for all stages of the life of a research reactor. Section 7(3) further states:

“The graded approach shall be adopted so as to reflect planned and accepted differences in the application of specific quality assurance requirements to research reactors. The extent of the detailed quality assurance program that is required for a particular research reactor or experiment shall be governed by the potential for hazard of the research reactor and the experiment and shall meet the requirements of the Authority.”

The application of the graded approach in such a case appears to be left as a burden to the licensee, with little guidance or further regulation to provide criteria and regulatory expectations.

During a visit to the PINSTECH site, IAEA team members observed that representatives from the operator appeared unaware of elements of new regulatory requirements arising from a revision to PAK-923 in 2012, namely the requirement to provide basic radiation protection training to maintenance staff. From interviews, team members noted that newly promulgated/amended regulations may be issued with minimally defined gap analysis, roll-out and transitional provisions. Section 9.2 contains a recommendation for this matter.

Based on the same visit to the PINSTECH site, the team members observed a disagreement between the licensee and the regulator regarding expectations for compliance. The team concluded that a contributor could be in part due to the changing regulatory structure and the lack of clear implementation guidance

for the new regulatory requirements and the lack of established requirements for the implementation of new programs. Chapter 9 provides a recommendation on this matter.

#### **6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES**

The predisposal facilities at NPPs and research reactors are reviewed as one part of the safety analysis report against acceptance criteria agreed with the licensee. PNRA has the experience of review and assessment of licensee's submissions related to predisposal management of radioactive waste.

Because a disposal facility has not been constructed in Pakistan, PNRA has no experience in the area of review and assessment of a national disposal facility.

#### **6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES APPLICATIONS**

PNRA has established process for review and assessment of applications for authorization of facilities and activities. The process is described in working procedure "Procedure for review and assessment of documents" (PNRA-WP-12020). There is another draft document on "Procedure for review and assessment of licence applications for radiation facilities" which is currently under development stage. The new document includes enhancements to the implementation of a graded approach to the review and assessment process.

Review and Assessment is performed by PNRA at each stage of licensing for facilities and activities. The applicant is required to submit relevant information required by PNRA Ordinance 2001 and PAK/908. PNRA review and assessment of submitted information is performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.

The review and assessment performed by PNRA is commensurate with the radiation risks associated with any particular facility or activity, in accordance with a graded approach.

The graded approach is mainly based on radiation risks associated with a facility or activity.

The scope and duration of PNRA's review is dependent on the potential risks associated with the facility or activity. For example, the shielding requirements for a diagnostic radiology facility and therapeutic facility are different from each other and the qualification criteria of a radiation protection officer (RPO) (as prescribed in Regulations (PAK/904) is more stringent for high radiation risk facilities. Moreover, the licence conditions also vary with respect to the risk associated with the facility or activity.

Documents subject to regulatory review include: the designation of a RPO, qualification of personnel, arrangements of waste management, security of the sources, safety analysis reports (SAR), quality assurance program (QAP), facility design and shielding design of the facility, technical specifications (TS)/operating policies and procedures (OPP), emergency preparedness plans (EPP), radiation protection program, ALARA policy, dosimetry program, special reports/incident reports, exercise scenarios, post exercise reports, compliance of post inspection report and others. If PNRA is satisfied through review, assessment, and pre-licensing inspection that the approval of the authorization/licence is appropriate, the licence is issued to the applicant.

The results and decisions of reviews and assessment are properly recorded in the form of official correspondence. These evaluations form the basis for any authorization and conditions associated with the authorization.

All three Regional Nuclear Safety Directorates RNSD-I, RNSD-II, RNSD-III perform review and assessment of safety performance. Regional Directorates have well trained inspectors for making regulatory assessments of documents submitted by the applicant. These inspectors are certified using a

training programme “Professional training course on radiation safety & radioactive waste management (Level-II)”).

The relevant directorates (like Directorate of Radiation Safety, Directorate of Transport and Waste Safety, Directorate of Physical Protection and Nuclear Security, etc.) at PNRA HQ perform review and assessment of the licensees’/applicants’ submitted documents like Radiation protection program, waste management program, physical security plan, etc. Quality control is assured during the process of review and assessment of documents. The process includes: assigning a reviewer, tasking the review to a relevant group by the relevant director review and comment on the document, analysis of comments by the relevant director with the relevant group. If the analysis is not approved, documents are returned to the reviewer. If the analysis is approved, comments are forwarded for discussion with DGs/RNSDs for acceptance. If comments are not accepted by DGs/RNSDs, the document is returned to the relevant directorate. If comments are accepted necessary action is taken like issuance of licence, communication to the applicant/licensee, etc.

Other information submitted by the applicant is to demonstrate optimization of protection. This includes safety cases, safety analysis reports, quality assurance program, radiation protection program, emergency contingency plans, etc.

PNRA would benefit from finalising and approving the procedure for review and assessment of licence applications for radiation facilities, including the criteria, in what cases submitted documents are to be reviewed in Regional Directorates, and when these submitted documents are to be sent to the supporting Directorates at Headquarters.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A procedure for review and assessment of applications for the licence for radiation facilities has not been finalised. Criteria to determine when documents are to be reviewed in Regional Directorates, and when these should be sent to the Directorates of Headquarters for review are not defined.</i>
(1)	<b>BASIS:</b> <i>GSR Part 1 para. 4.33 states that “Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.</i>
(2)	<b>BASIS:</b> <i>GSR Part 1 para. 4.28 states that “There shall be consistency in the decision making process of the regulatory body.”</i>
S16	<b>Suggestion:</b> <b>PNRA should consider finalising and approving the procedure for review and assessment of licence applications for radiation facilities, including the criteria, in which cases submitted documents are to be reviewed in Regional Directorates, and when these submitted documents are to be sent to the Directorates of Headquarters.</b>

## 6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

PNRA has experience for the review of initial decommissioning plan of nuclear facilities on the basis of IAEA safety standards in the areas of decommissioning. However, PNRA has no experience of review of final decommissioning plan. It is expected that first final decommissioning plan will be provided to PNRA in 2019 for the K-1 NPP.

PNRA regulations PAK/909, PAK/911, PAK/912, PAK/913, PAK/915 and PAK/923 deal with the aspects of decommissioning, however, the detailed specific regulation on decommissioning (PAK/930) is at the final stages of approval (see Suggestion S15 in Section 5.6).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>The detailed specific regulations on decommissioning (PAK/930) are at the final stages of approval.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 32 states that</b> <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based”</i>
	<b>Reference is made to Suggestion S15 in Section 5.6.</b>

## 6.7. SUMMARY

PNRA has the necessary elements to ensure that reviews and assessment of activities it regulates are soundly based. Those reviews are carried out by qualified staff, and reviews are documented and retrievable.

Areas of improvements include the definition of formal implementation plans after promulgation of new regulatory requirements, the development of enhanced guidance documents, and refined implementation of application the graded approach.

## 7. INSPECTION

### 7.1. GENERIC ISSUES

#### 7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

PNRA Ordinance 2001, Clause 29 provides the legal basis for carrying out regulatory inspections of nuclear facilities and activities. Accordingly, any member of the authority, any officer of the authority or any other person authorized in that behalf of the authority may enter any premises at any time for the purpose of satisfying himself as to whether the provisions of the Ordinance and the corresponding rules and regulations are adequate.

PNRA Ordinance 2001, Clause 29, and PAK/909, Section 11 provide the legal basis, so that the licensee has to provide regulatory inspectors with free and prompt access to any area of the facility, to all personnel of the facility and to all relevant documentation for the purposes of regulatory inspections.

PNRA internal working procedure NSD-WP-001-R1 is the basis for the development of inspection programs for nuclear power plants.

PNRA develops and implements inspection programs on the basis of PAK/909 for nuclear facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. The inspection program specifies the types of regulatory inspections (including scheduled inspections and unannounced inspections) and the areas to be inspected, in accordance with a graded-approach.

PNRA develops a detailed inspection plan to inspect various activities during siting, manufacturing, construction, commissioning, operation and decommissioning/closure of nuclear installations. PNRA shares its overall regulatory inspection plan schedule at the commencement of the year and monthly for specific inspections with the licensee.

PNRA does have a graded-approach for evaluating system performance including significance of issues, but does not have a risk-based graded approach for event-based findings. During discussions with PNRA officials, IAEA was informed that the evaluation of human factor involvement in events was not analysed and the impact considered in the overall significance. When an event occurs, there are many aspects to evaluate and assess to understand the contributions especially for operator performance. A calculation of risk contribution without the addition of the operator performance may result in a lower significance and PNRA may process a lower level finding. However, if the human element is evaluated the contribution to overall risk could result in a more significant value.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>PNRA does not have the capability to quantitatively evaluate risk for event-based findings. Human Factors Engineering (HFE) is not sufficiently considered, and is only considered from a qualitative perspective.</i>
(1)	<b>BASIS:</b> <b>GSR Part 1 para. 4.54 states that</b> <i>“The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.”</i>
S17	<b>Suggestion:</b> <b>PNRA should consider developing a tool to systematically include human factors in evaluating risk for event-based findings.</b>

### **7.1.2. INSPECTION PROCESSES AND PRACTICES**

PNRA undertakes announced inspections according to the inspection plan; however, unannounced/reactive inspections are also conducted in special circumstances at nuclear facilities. They are performed in response to special situations or events requiring regulatory intervention and investigation.

According to PNRA, the depth and scope of the regulatory inspections of the facilities or activities is commensurate with the radiation risks associated with the facility or activity, in accordance with a graded-approach. PNRA assesses all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions: Prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.

After the inspection PNRA issues inspection reports that include a summary of inspections, findings with corrective action recommendations (requirements) and a defined timeline for implementation of corrective actions. The concerned PNRA Regional Directorate bears the responsibility for the follow-up of corrective actions.

During the team interviews of PNRA a few areas have been identified where PNRA could improve their inspection practices:

During review of general surveillance procedures it was noted that guidance was provided to inspectors and that a consistent approach to review the potential finding is conducted with Group Heads and Regional Directors. However, this system of review may allow inconsistencies. It was also observed that the variance of the threshold could result in subjective inspector opinion influencing the outcome of the findings.

During the reviews of the inspection reports it became clear, that the practice of documenting findings did not result in immediate actions by the licensees. Following issuance of the report and sending a letter to the licensee, if actions are not taken by the licensee then PNRA would allow the opportunity for licensees to respond following issuance of a Directive Letter (i.e., second chance). A different action may be warranted for significant issues.

During review of programme type inspection reports some issues identified were titled “recommendations”. These contained observations as well as requirements, sometimes having no regulatory basis. PNRA should consider communicating observations to the licensee verbally. Issues identified as recommendations that are truly findings should be captured in the appropriate section of the report and appropriate enforcement action should be taken.

During the interviews and reviews it became obvious that the use of the language was not coordinated or sufficiently systematic between facilities or through PNRA headquarters. The terms used were not well-defined. This could lead to confusion for inspectors and licensees. Examples include: 6-monthly versus bi-annual, annual in the yearly plan when it is actually performed bi- annually, recommendation versus requirement or observation. The use of language/terminology in the inspection plans and reports should be systematic, consistent and well-defined between different plants, units, and inspectors.

### **7.1.3. INSPECTORS**

The inspectors undergo a four-month long level 1 and 2 training to provide the necessary knowledge about the legal, regulatory and procedural framework and about nuclear installations in general. After that they are moved to a regional directorate to receive more (on-the-job) training. Selected operationally focused inspector trainees receive simulator courses and are even taking part in the licensee’s training of its operational crews.

During the interviews it was found that the training of the inspectors may not be sufficiently systematic and also not all inspectors receive site-specific simulator and technology training. Inspectors typically complete training for level 1 (basic training) and selected inspectors complete level 2 (specific training) prior to reporting to the site. Not all inspectors require simulator training due to being assigned to specialty areas. Operational inspectors are not consistently given identical training.

PNRA has three Regional Directorates with sufficient numbers of inspectors available that coordinate with each other to perform joint inspections, if necessary, and exchange experts on specific topics. On an as-needed basis, PNRA may obtain expert opinion of advisors in safety-related matters.

In the area of radiation sources, the number of inspections at facilities and activities is approximately 2,500 per year. PNRA formalized qualification criteria of its inspectors to ensure effective implementation of the inspection program and enable the identification of significant safety issues. The competence of inspectors is achieved through a formal training program organized by National Institute of Safety and Security.

In accordance with requirements, inspectors must fulfil various criteria regarding qualification, general working experience, and additional experience for the specific field of inspection (Nuclear Safety, Research Reactor, Radiation Safety or Physical Protection). At the end of the qualification process inspectors have to pass a formal internal examination.

In some cases the training of new inspectors includes a three-year assignment to the licensee, receiving the same training as the licensed reactors operators. This type of training is considered by IAEA to be outstanding and could be an example for other countries.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>Three to four PNRA operationally-focused inspectors are extremely well trained in the simulator along with the licensed operators. This type of training could be an example for other countries.</i>
<b>(1)</b>	<b>BASIS: GSR Part 1, Requirement 11, para. 2.36 states that</b> <i>“The government:</i> <i>a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;</i> <i>b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body’s responsibilities in relation to safety.”</i>
<b>GP5</b>	<b>Good Practice:</b> <b>Selected operationally focused PNRA inspectors complete an initial 8-week simulator course and they are assigned to the licensed operator crew for additional training for a minimum of three years.</b>

## **7.2. INSPECTION OF NUCLEAR POWER PLANTS**

PNRA internal working procedure NSD-WP-001-R1 provides the basis for the development of inspection programmes for nuclear power plants.

For each planned inspection, a plan specific to that inspection is developed and provided to the licensee prior to the inspection. Thus the majority of the inspections are pre-planned and announced.

Reactive inspections are conducted in response to unplanned, unexpected events. The head of Regional Directorate defines the need for a reactive inspection based on preliminary information received.

For each planned and reactive inspection, the team leader conducts an entrance meeting with the licensee to describe the purpose and objectives of the inspection. An outcome meeting is conducted at the end of the inspection to provide a summary of the potential findings, and to provide the licensee with the opportunity to discuss their programme to address the weaknesses and discrepancies identified during the inspection. During the inspection, individual inspectors discuss their findings with the licensee counterparts.

Due to unavoidable circumstances it was not possible to visit a nuclear power plant site and observe an inspection.

### **7.3. INSPECTION OF RESEARCH REACTORS**

The PINSTECH facility contains two research reactors, PARR-1 and PARR-2. PNRA conducts a set of inspections of PARR-1 such that the full inspection scope is covered on an annual basis. PNRA conducts these inspections using staff members that are based in the Islamabad PNRA headquarters that travel to the site for a day at a time. The inspection of PARR-2 is similarly conducted every year.

The annual inspection plan of PARR 1 involves monthly inspections for the control room and annual inspections in each of the following areas: Operation, quality assurance, radioactive waste management, physical protection, maintenance activities, emergency drills, and training.

Two team members visited the PINSTECH research reactor facility to observe the process of inspecting. Three PNRA inspectors conducted an inspection in the area of maintenance that consisted of an entrance meeting with licensee management and staff, the inspection as outlined in a written inspection plan, and an exit meeting. PNRA issues written inspection reports with recommendations and findings following the inspection.

The team members observed open communication between PNRA and the licensee, follow-up to previously identified inspection findings, and performance of checklist inspection items.

However, the team members considered that the inspection was not specific enough in scope and not appropriately focused on safety consequence. This conclusion was based on the observation of the inspection and follow-up discussions with PNRA staff. Through discussions the team learned that the inspection preparation process was not used to focus the inspection plan so that the inspectors would emphasise the inspection elements that were most important to safety. Additionally, the inspection appeared to focus primarily on programmatic aspects and did not challenge technical aspects of the maintenance activities.

The team members concluded that PNRA should evaluate the scope of their inspections to assure inspectors implement a graded-approach thus allowing them to focus on safety significant activities in an increased level of detail.

Additionally, the team members concluded that PNRA should identify inspection targets in advance of their inspections to allow them to better identify safety significant aspects of the activities, search for applicable operating experience, and solicit input from technical experts as needed.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>Inspection of PARR-1 research reactor was not specific enough and lacked technical depth and safety focus.</i>
(1)	<b>BASIS:</b> <b>GSR Part 1 para. 4.50 states that</b> <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection ...”</i>
S18	<b>Suggestion:</b> <b>PNRA should consider defining the scope of inspections more clearly before the activity to assure that appropriate focus on safety and technical details are achieved.</b>

### 7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

The system of inspection and enforcement is same as for other nuclear facilities (See Sections 7.2 and 7.3).

There is no disposal facility in Pakistan, so PNRA has no experience in the area of inspections for these facilities.

The existing predisposal radioactive waste management facilities are located at nuclear power plants and research reactor premises. PNRA has ample experience of conducting inspections in the area of predisposal radioactive waste management that are done within the regime of the inspections at the NPPs and other facilities.

### 7.5. INSPECTION OF RADIATION SOURCES FACILITIES

The draft general procedure of inspection is prescribed per PNRA internal working procedure “Inspection Program for Radiation Facilities” to confirm compliance with regulatory requirements and with any conditions specified in the authorization. The inspection program specifies the types of regulatory inspections (including scheduled inspections and unannounced inspections) and the areas to be inspected, in accordance with a graded-approach.

A comprehensive set of internal working procedures on inspection methodologies are given in PNRA-WP internal documents (PNRA-WP-21002, PNRA-WP-21004, PNRA-WP-21006, PNRA-WP-21008, and PNRA-WP-21010) that include specific check lists for inspections.

Inspections performed by PNRA are conducted in accordance with an annual inspection plan, prepared by each of the regional offices independently and approved by the Regional Director. PNRA implements a graded-approach in the conduct of its inspection program, applying its inspection resources in a manner that is consistent with the safety significance of the regulated activity.

The inspection methodology for radiation safety includes pre-inspection preparation, entrance meeting with management of licensee, practical observation and assessment how staff conducts their activity, interviews and reviews of records. Independent measurements are also conducted. Upon completion, an exit meeting with the licensee management is conducted to present the results.

PNRA inspectors perform measurements and verifications of the functionality of equipment, which are subsequently used by the licensee. The majority of licensees, except major hospitals, are not able to perform measurements due to a lack of available TSOs and qualified experts.

PNRA inspectors perform inspections as part of the assessment at licensing or re-licensing stage.

The inspection frequency of radiation facilities varies from semi-annually for more safety significant activities (i.e., radiotherapy, nuclear medicine, industrial radiography) to annually for less safety significant activities (i.e., diagnostic radiology, fixed industrial gauges, etc.). IRRS team considers it necessary to review the frequency of inspections and that the intervals do not reflect a sufficient graded-approach, specifically for less safety significant activities such as dental X-ray.

Inspections reports contain the identification data of the legal entity or person being inspected, the scope of the inspection, the inspected area, evidence of safe practice, discrepancies or observation, and if any, directives or recommendations. The final report serves to present the formal inspection results to the licensee and is issued by the Regional Director.

Inspection reports and enforcement actions are not provided to the public or external parties.

PNRA reported that approximately 2,500 inspections were completed in 2013, and fifteen of them were unannounced inspections in various radiation facilities.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>Some licensees do not perform quality control tests of radiology equipment and workplace monitoring. PNRA conducts some measurements during the inspections that are adopted by the licensee as a substitute for their own measurements.</i>
<b>(1)</b>	<b>BASIS:</b> <b>GSR Part 1 para 4.49 states that</b> <i>“Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.”</i>
<b>R8</b>	<b>Recommendation:</b> <b>PNRA should enforce the regulatory requirement that the licensees conduct their own QC measurements.</b>
	<b>Observation:</b> <i>Findings in the inspection report do not take into consideration safety significance of inspection findings.</i>
<b>(1)</b>	<b>BASIS:</b> <b>GSR Part 1 para. 4.51 states that</b> <i>“The regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party.”</i>
<b>S19</b>	<b>Suggestion:</b> <b>PNRA should consider issuing a procedure to establish categorization of inspection findings using graded-approach to ensure timely enforcement action is taken.</b>

The IRRS team accompanied two PNRA inspectors that visited Shifa International Hospital in Islamabad to observe the inspection at the radiotherapy and nuclear medicine departments. The inspection verified elements in accordance with PNRA internal working procedures.

The IRRS team observed that PNRA and the licensee interactions constituted good communications. The management of the facility were involved during the inspection and exit meeting.

IAEA had a separate discussion with the licensee without the presence of PNRA, the licensee expressed that in their view they have very open communication with PNRA inspectors.

The objective of the IAEA site visit was met. The inspection was systematic and comprehensive and conducted in a professional manner with full cooperation of the licensee.

## **7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES**

Practical decommissioning of any facility in Pakistan has not yet commenced. As per national regulation PAK/911, the activities associated with decommissioning are considered as part of the operation of the facility or activity, and special consideration has been given to incorporate the features that will facilitate decommissioning.

One of the NPPs in Pakistan (K-1) will probably be the first installation to be decommissioned. Therefore, PNRA has yet to acquire experience with this specific activity. The utility will submit final decommissioning plan at least three years before the termination of the operation of the nuclear installation. Furthermore, the utility has provided the assurance of provision of funds for decommissioning.

## **7.7. SUMMARY**

Based on the documents reviewed, on interviews conducted, and the site visits to observe inspectors, the IRRS team concluded that PNRA conducts extensive inspection activities, although aspects of the program lack a planned and systematic approach.

PNRA conducted inspections in a competent and professional manner. Based on the interactions between the inspectors and the licensees, the communications between PNRA inspectors and the licensees appeared to be open and safety-focused.

Due to unavoidable circumstances it was not possible to visit a nuclear power plant site and observe the regulator.

The IRRS team acknowledged that the PRNA inspection practice is generally in-line with the IAEA requirements, but areas for improvement were identified. IRRS team recommendations and suggestions are aimed to optimize the existing inspection processes, including development and implementation of a planned and systematic inspection program and coordination of inspection activities across the regulatory organization.

## 8. ENFORCEMENT

### 8.1. ENFORCEMENT POLICY AND PROCESSES

PNRA has issued regulation PAK/950 for enforcement within the legal framework for responding to non-compliances by parties specified in the authorization. PAK/950 defines the administrative procedures and guidelines governing the use and implementation of PNRA enforcement actions.

Enforcement actions as prescribed in the Ordinance, the enforcement regulation combined with PNRA internal guidance, are taken against non-compliances specified in the authorization and are dependent on the safety significance. The more severe enforcement actions may require referral to the Court of Law for penalties or potential imprisonment. To date, the higher level enforcement has not been executed, therefore there is limited experience in PNRA regarding the effectiveness of such actions.

For facilities and activities with radiation sources, the order to correct observed non-compliances is issued in a post-inspection report. The inspected licensee is required to inform PNRA about its fulfilment of remedial measures in writing. Due to repeated exchanges with the licensee the enforcement process is unnecessarily lengthened. Therefore, initiation of enforcement measures is delayed.

As a result of their self-assessment, PNRA has identified that a procedure for formal interactions with relevant government agencies is needed and the draft document is scheduled to be issued in June 2014.

An example of an effective enforcement action was a work stoppage notice being issued to an industrial radiography facility. PNRA immediately served the licensee with a "show cause notice".

PNRA does not have a mechanism allowing the licensee a right of appeal to the final decision. The enforcement policy originally was to contain the right of appeal but that portion was removed upon legal advice to issue it as a separate document.. The remaining portions of the enforcement policy were approved and issued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A mechanism to allow the licensee a right of appeal does not exist. A regulation is being developed and PNRA needs to issue this document.</i>
(1)	<b>BASIS:</b> <i>GSR Part 1 para. 2.5 (11) states that “The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: ... (11) Provision for appeals against decisions of the regulatory body; ...”</i>
(2)	<b>BASIS:</b> <i>GSR Part 1 para. 4.32 states that “The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.”</i>
	<b>Reference is made to Recommendation R7 in Section 5.1.</b>
	<b>Observation:</b> <i>Follow-up inspections are carried out rarely in the inspection practice for radiation sources. A compliance report received from the licensee is usually accepted as proof that corrective actions are performed.</i>
(1)	<b>BASIS:</b> <i>GS-G-1.5 para. 3.76 states that “... The regulatory body shall ensure that the operator has effectively implemented any remedial actions.”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS:</b> GS-G-1.5 para. 3.88 states that “Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the operator has responded to regulatory and enforcement measures.”
S20	<b>Suggestion:</b> PNRA should consider establishing a procedure for follow-up inspections to ensure that corrective actions have been implemented for safety significant issues.

### 8.2. ENFORCEMENT IMPLEMENTATION

PNRA takes enforcement actions in the event of deviations from, or non-compliance with, the regulatory conditions and requirements.

PNRA enforcement actions taken against non-compliances with regulatory requirements or with any conditions specified in the authorization are dependent on the safety significance of the non-compliance, in accordance with a graded-approach.

PNRA enforcement actions may include written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties (after prosecution by a court of law) and, ultimately revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance.

The authorized party is held accountable for addressing non-compliances, for performing a thorough investigation and for taking all the measures that are necessary to prevent recurrence of the non-compliance.

For all cases of NPP non-compliance, PNRA conducts discussions, regulatory meetings, and further assessment of the issue through follow-up inspections, etc.

At each significant step in the enforcement process, PNRA identifies and documents the nature of the non-compliance and the period of time allowed for corrective actions, and communicates this information in writing to the authorized parties.

In the event that unforeseen radiation risks are identified, whether or not they are due to non-compliance with regulatory requirements or authorization conditions, PNRA requires the authorized parties to take appropriate corrective actions to reduce the risks.

Finally, PNRA generally ensures and confirms that the licensee effectively implements all remedial actions arising from regulatory enforcement actions.

### 8.3. SUMMARY

PNRA uses a graded-approach to enforcement, with clear delegation and assignment of responsibilities for the inspectors, and for the application of enforcement, administrative enforcement and penalties (penalties are part of a legal process and are only applied following prosecution by a court of law).

PNRA should improve the enforcement processes to ensure a consistent and timely application of enforcement for significant findings to ensure violations are addressed.

## 9. REGULATIONS AND GUIDES

### 9.1. GENERIC ISSUES

The system of regulations and guides is based on the Ordinance, which was published by the government of Pakistan, as the basic legal document in the regulatory framework. The system of regulations of PNRA is based at articles 16 and 56 of the Ordinance:

**16. Functions and powers of the Authority.** (2) Without prejudice to the generality of the foregoing powers, the following shall be the powers and functions of the Authority, namely:

(a) to 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;

**56. Power to make regulations.** (1) The Authority may, by notification in the official Gazette, make regulations, not inconsistent with this Ordinance and the rules, for carrying out the purposes of this Ordinance.

The Procedure for Preparing PNRA Regulations (PNRA-WP-004) is based at national legislative system. The need for the development of the Regulations may arise from a) Obligations of the PNRA Ordinance, b) Obligations of international conventions, c) feedback of regulatory/licensing experience, d) International practice and experience. This basis of regulations was also stipulated in the Management System Manual (MSM), which was signed by the Chairman.

It was stated in the "Procedure for Preparation and Revision of Regulatory Guides" (PNRA-WP-001) that the need to develop the guides was identified on the basis of implementing experience feedback, considering technological advancement worldwide and international approach.

PNRA established a legal hierarchy pyramid, under the authorization of the provisions in the Ordinance, which is composed of the Ordinance on the top, regulations in the middle, and regulatory guides at the bottom. The hierarchy establishes clear links between the Ordinance, regulations and guides. There are seventeen PNRA nuclear safety regulations and eight PNRA nuclear safety regulatory guides in total. Six of the regulations concerning licensing and enforcement were categorized in the Administrative regulations, and the other eleven regulations concerning the safety of the nuclear installations, facilities and activities were categorized into the technical regulations. Seven regulations are being revised/amended, and two new regulations are being developed, including seven regulations on radiation protection and safety of sources as well as three guides for the implementations of regulations which specify some of principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based.



There is a detailed annual work plan to develop/revise regulations/guides at the Directorate level. A five year strategy plan has been drafted to develop and enhance the regulatory framework and is expected to be approved by the end of this year.

PNRA follows a comprehensive process for the development of its regulations including rigorous internal reviews at different levels within PNRA which is followed by inviting comments from the interested parties. As per procedure, only the regulations are placed on the website for comments from the general public, but the regulatory guides are not provided to

interested parties for comments. The entire process of developing a new set of regulations or revising existing regulations takes approximately two years.

The Directorate of Policies & Procedures in PNRA is responsible for the development of the legal framework. PNRA follows a comprehensive process for the development of its regulations including rigorous internal reviews at various levels within PNRA which is followed by inviting comments from the stakeholders such as the licensee, the Government, and the general public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A mechanism to consult with interested parties for preparing and revising guides is not in place.</i>
(1)	<b>BASIS:</b> <i>GSR Part 1 para. 4.61 states that “... These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. ...”</i>
R9	<b>Recommendation:</b> <b>PNRA should establish a mechanism for consultation with interested parties in the preparation of regulatory guides.</b>

Although most of the regulations and guides of PNRA are established in reference to IAEA safety standards, there is no mechanism to ensure that the PNRA regulations and guides are fully harmonized with the requirements in IAEA safety standards. This may result in using out-of-date safety standards.

PNRA’s legal framework is generally based on the necessity of regulatory activities, which is largely completed at the level of regulations, however, still incomplete at the level of guides. In areas where the PNRA regulations are not available, relevant latest USNRC regulations or IAEA safety standards are deemed to be applicable. In case the nuclear safety standards of another country are proposed to be followed, the applicant/licensee must demonstrate that these standards offer the same or better level of safety, quality and reliability.

The PNRA regulations are reviewed five years after their promulgation in the light of feedback from interested parties, licensing experience and current international standards and practices, and are revised if required.

During a site visit, the operator was unaware of some of the new requirements arising from new or amended regulations, resulting in differing opinions between the regulator and licensee. No formal process has been established to identify the impact of changes to regulatory requirements, the identification of gaps with existing practices, and transitional plans for implementation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Implementation/transition plans for new requirements introduced in amended regulations were not present. The lack of such a process may contribute to differing opinions regarding interpretation of regulatory compliance.</i>
(1)	<b>BASIS:</b> <i>GSR Part 1 para. 2.5 (9) states that “The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S21

**Suggestion:** PNRA should consider developing plans/procedures for implementing the new requirements arising from new or amended regulations.

The relevant PNRA regulations do not require that licensees develop and implement integrated management system, which is the requirement of GS-R-3. The PNRA regulations still require that licensees have a quality assurance program, which is only one part of the management system.

### 9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The technical specified requirements regarding the safety of nuclear power plant are mostly provided by the PAK/910 for site evaluation, PAK/911 for design, PAK/913 for Operation, PAK/914 for emergency preparedness and response, PAK/915 for waste management, which has been built in fully reference of the IAEA Safety Standards of the time.

The safety criteria for the nuclear power plant (and the other nuclear installation) is derived from the PNRA regulations and guides, the latest USNRC regulations and guides, the latest IAEA safety standards, and the safety criteria of the technology exporting country. The list of safety criteria is proposed by the applicant and approved by PNRA.

The requirements in the PNRA regulations for the NPP generally reflect IAEA safety standards and are identical in most of the provisions.

The Probabilistic Safety Analysis is a mandatory requirement of PAK/909 through the requirement of submitting the design PSA report for internal initiating events at full power in the construction licence application, and the PSA level-1 report in the application for the Permission to Introduce Nuclear Material in the Installation. PNRA issues the operating licence for a maximum of 10 years, which can be revalidated. The latest Periodical Safety Review report was obliged to be submitted in case of the application of revalidation of operating licence, as basis for the approval of revalidation.

There are several deviations between PAK/911 and SSR-2/1. Mainly the new PAK/911 which is undergoing revision is identical with the new IAEA SSR-2/1.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** PAK 911 does not include the following design requirements:

1. For the Fundamental Safety Functions: the function of removal of heat from the fuel store.
2. For the Plant States: The DEC (Design Extension Conditions)
3. For the Design Limits: A set of design limits for all operational states and accident conditions.

(1)

**BASIS:** SSR 2/1 Requirement 4 states that “the safety function includes “(ii) removal of heat from the reactor and from the fuel store”.

(2)

**BASIS:** SSR 2/1 Requirement 13 states that “the Plant states shall typically cover: (d) Design extension conditions, including accidents with significant degradation of the reactor core.”

(3)

**BASIS:** SSR 2/1 Requirement 15 states that “a set of design limits consistent with the key physical parameters for each item important to safety for the nuclear power plant shall be specified for all operational states and for accident conditions.”

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>S22</b>	<b>Suggestion:</b> PNRA should consider finalising and issuing PAK/911 to include removal of heat from the fuel store, Design Extension Conditions and a set of design limits for all operational states and accident conditions.
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There are several deviations between PAK/913 and SSR2/2. Mainly the new PAK/913 which is undergoing revision is identical with IAEA SSR2/2.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><b>Observation:</b> PAK 913 does not include the following design requirements:</p> <ol style="list-style-type: none"> <li>1. Monitoring and review of safety performance.</li> <li>2. For the Accidents Management: The Accidents Management.</li> <li>3. For the Maintenance, testing, surveillance, inspection,               <ul style="list-style-type: none"> <li>- The requirement of surveillance program.</li> <li>- The requirement of cooperation between different maintenance groups.</li> <li>- The requirement of not to overburden of stuff.</li> <li>- The requirement of maintenance under the DID principle.</li> <li>- The requirement of maintenance using the PSA.</li> </ul> </li> </ol>
(1)	<b>BASIS:</b> SSR 2/2 Requirement 9 states that “The operating organization shall establish a system for continuous monitoring and periodic review of the safety of the plant and of the performance of the operating organization.”
(2)	<b>BASIS:</b> SSR 2/2 Requirement 19 states that “The operating organization shall establish an accident management programme for the management of beyond design basis accidents.”
(3)	<b>BASIS:</b> SSR 2/2 para. 8.2 states that “The operating organization shall establish surveillance programmes for ensuring compliance with established operational limits and conditions and for detecting and correcting any abnormal condition before it can give rise to significant consequences for safety.”
(4)	<b>BASIS:</b> SSR 2/2 para. 8.11 states that “The Coordination shall be maintained between different maintenance groups.”
(5)	<b>BASIS:</b> SSR 2/2 para. 8.12 states that “A management system for managing and correcting deficiencies shall be established and shall be used to ensure that operating personnel are not overly burdened.”
(6)	<b>BASIS:</b> SSR 2/2 para. 8.13 states that “The operating organization shall ensure that maintenance work during power operation is carried out with adequate defence in depth.”
<b>S23</b>	<b>Suggestion:</b> PNRA should consider finalising and issuing PAK/913 to include monitoring and review of safety performance, accidents management and complete surveillance programme.

PAK/913 imposes more specific requirements than SSR 2/2 for health conditions and education backgrounds for the different reactor operators, such as shift supervisor, shift engineer, and operation personnel.

### **9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS**

PNRA has not formally stipulated requirements for the design of research reactor however; it uses IAEA standards as requirements. PAK/923 requires the licensee to implement defence in depth principle in design. The requirement of basic safety functions, the reactor states including the extensive shutdown arose in PAK/923. PAK/910 “Regulation on safety of nuclear installation-site evaluation” gives requirements for siting. Even though there is no plan to build a new Research Reactor in Pakistan, PNRA is considering to involve the design requirement of Research Reactor in the drafting new PAK/911, by referencing clause, to extend the scope of nuclear power plants into nuclear installations.

### **9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES**

The regulatory requirements for radioactive waste management are defined in the PAK/915. According to these requirements radioactive waste disposal facilities shall be licensed by PNRA. Each waste generating facility shall be responsible for management of its radioactive waste safely and securely. In case of intention to process/store waste generated by other facilities, the operator has to apply for authorization.

According to PAK/915 the licensee shall be responsible for the safe management of the radioactive waste and its security and shall take necessary steps to keep the radioactive waste minimum.

The licensee shall carry out safety assessments and shall develop a safety analysis report, and shall ensure that siting, design, construction, commissioning, operation, shutdown/closure and decommissioning/surveillance after closure of facilities related to radioactive waste management are carried out in compliance with regulatory requirements.

Regulations PAK/909 and PAK/915 include requirements for licensing of disposal facility. Also, PAK/909 covers the requirements for various stages of the licensing process of the disposal facility. PAK/913, PAK/923 and PAK/915 put responsibility for the safety of predisposal radioactive waste management facilities and activities on the operator/licensee.

PNRA regulations do not cover specific requirements for the storage of spent nuclear fuel, decommissioning of the facilities and no specific guidance for the safe management of highly active spent radioactive sources (see Suggestion in the Section 5.4)

### **9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES**

PNRA has developed several regulations and guides applicable on radiation sources (e.g., PAK/908, PAK/904, PAK/950, PAK/916, PAK/900, PAK/914, PAK/915) which specify some of principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based.

Regulations and guides do not fully reflect the latest IAEA safety requirements. The system of regulations in the country does not fully reflect graded approach. The regulation on Radiation Protection (PAK/904) covers the main provisions for the safety of radiation sources: requirements for medical, occupational and public exposure control as well as some emergency procedures for the licensee. The regulation on licensing (PAK/908) includes all main requirements Licensing and Authorizations as well as some details for licensing processes.

Assessment system for ensuring that all regulations and guides are in place is not established. There is a PNRA procedure regarding categorization of sources or practices in which IAEA categorization is used. The documents on processes have different legal basis than the Ordinance. The system of regulations and guides is user-friendly.

PNRA does not fully establish which requirements, regulations, guides and industrial standards are applicable to each type of facility or activity. The legal reference for the regulations and guides is not clear in some documents, even for the procedures.

PNRA established requirements for radiation protection that do not fully comply with GSR Part 3. Elements related to the prime responsibility for safety are missing for sources. There are no references for the types of exposure situation regarding planned, existing and emergency exposure situations. It is not required that the user ensures that protection and safety are effectively integrated into the overall management system of the facilities and activities for which they are responsible. The graded approach for the application of the requirements in planned exposure situations is not commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures. Investigations and feedback of information on operating experience, for conducting formal investigations of abnormal conditions arising in the operation of facilities concerning disseminated information on lessons learned for protection and safety is not adopted in any regulation. Human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research is not mentioned in the set of regulations. The IRRS team was informed that Radon is not an issue for Pakistan and that PNRA does not have any requirements concerning Radon concentrations in houses and workplaces. PNRA has established an appropriate regulation for concentrations of radionuclides in the food but that does not take into account other commodities.

There are three guides in support of regulations. There is a draft plan for the regulations and regulatory guides that have to be prepared in the next five years. A comprehensive guidance for quality assurance is established. Consistency is missing between some regulations and guides, for example: guidance on the release of patients from hospital does not comply with the applicable regulation.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
	<b>Observation:</b> <i>The regulation on radiation protection (PAK/904) does not comply with GSR Part 3. The supplementing set of guides for radiation protection for all types of radiation sources is not finalized and approved.</i>
<b>(1)</b>	<b>BASIS: GSR Part 1 Requirement 32 states that</b> <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
<b>(2)</b>	<b>BASIS: GSR Requirement 33 states that</b> <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards....”</i>
<b>R10</b>	<b>Recommendation: PNRA should revise and issue a regulation for radiation protection that is in compliance with GSR Part 3.</b>
<b>S24</b>	<b>Suggestion: PNRA should consider developing and issuing supplementary radiation protection guides for all types of applications of radiation sources .</b>

PNRA is in the process of issuing guidance on the format and content of documents to be submitted by the applicant in support of an application for radiation facilities/practices. Plans include review of the regulation for the Licensing of Radiation Facilities other than Nuclear Installations – (PAK/908) and development of five regulatory guides. Graded approach is used in the drafted documents.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>The regulation for the Licensing of Radiation Facilities other than Nuclear Installations – (PAK/908) is under revision. The supplementing set of guides on radiation protection for different types of radiation sources application is not finalized and approved.</i>
(1)	<b>BASIS: GSR Part 1 Requirement 24 para. 4.33 states that</b> <i>“Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks.”</i>
(2)	<b>BASIS: GSR Part 1 Requirement 24 para. 4.34 states that</b> <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization”.</i>
S25	<b>Suggestion: PNRA should consider finalising and issuing the revised regulations for authorization of radioactive facilities and supplementary guides taking into account graded approach.</b>

### Policy Issue 2: Practice Specific Regulations

The second policy issue discussed during the mission was "Practice Specific Regulations". The issue was presented by PNRA team mentioning that the existing regulations of PNRA are generic whereas various countries follow practice specific regulations. Accordingly, PNRA intends to understand the feedback of application of practice specific regulations and pros and cons of the two approaches. Experts from Canada, Cuba, Egypt, Japan, Slovenia, South Africa, Ukraine and the IAEA shared their practices on this policy issue. It was noted that mostly generic regulations are used in requirement level documents while practice specific approach is used in guidance documents. Practice specific approach may be easier for implementation by licensees and easy for verification by inspectors however this may need higher expertise level both at the licensee and regulatory body level. Furthermore, each time a new practice is introduced, new set of regulations would be needed which may be challenging. It was highlighted that IAEA uses generic approach and if a regulatory framework is based on IAEA documents then adopting practice specific approach may cause difficulty in following up the updates in IAEA documentation. Nevertheless, IAEA practice specific guidance documents are available to be followed as guidance level documents.

### **9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES**

Regulation PAK/909 includes requirements for licensing of decommissioning activities. PAK/930 (is being finalized) covers the regulations on decommissioning of facilities using radioactive materials including nuclear power plants and research reactors, fuel cycle facilities, manufacturing plants, medical facilities, research and university laboratories and other research facilities. Furthermore, PAK/930 covers the criteria for the release of the site from regulatory control, but these regulations do not apply to mill tailings, waste disposal sites or waste repositories.

### **9.7. SUMMARY**

All areas of PNRA’s responsibility are covered by PNRA regulations. Regulations and guides closely reflect IAEA safety standards. PNRA’s regulations and guides are produced based on the scope of its regulatory activities, although the scope of existing regulatory guides does not cover all types of facilities and activities.

The procedure for preparing PNRA regulations and guides covers the whole range of activities, under which the regulation and guides are developed. PNRA does not involve interested parties in preparation and revision of regulatory guides.

## **10. EMERGENCY PREPAREDNESS AND RESPONSE**

### **10.1. GENERAL EPR REGULATORY REQUIREMENTS**

#### **Basic responsibilities**

The National Disaster Management Authority (NDMA) acts as national coordinating body for disaster management. Its roles and responsibilities are defined in the NDMA Act 2010. The functions and responsibilities of provincial and district disaster management authorities are also clearly defined by the NDMA Act 2010.

The system of Radiation Emergency Response Plans (RERP) consists of the licensees' plans (threat category I-IV), off-site plans and the national RERP. Licensees are obliged to prepare and regularly update their RERPs following PNRA's regulations. According to its authorization PNRA approves the licensees' RERPs. Off-site emergency plans are prepared for the areas around the NPP sites by the local off-site authorities. NPP operators are required by PNRA regulation to closely contribute to the preparation process of emergency response plans of local off-site authorities. In case of emergency the local government may request support of the provincial and/or federal government, if consequences are beyond its control. Off-site emergency plans are approved by the Local/District governments. These off-site emergency plans are also submitted to PNRA for acceptance, and this acceptance process provides further opportunity for harmonization of off-site plans with on-site ones. If PNRA does not accept the off-site plan, concluding that off-site emergency organizations are not prepared to cope with possible radiation emergencies, then PNRA does not issue the authorization for operation of the nuclear facility. The process of preparation of the National Radiation Emergency Response Plan is being finalized and PNRA has an advisory function in its implementation. While the licensees' emergency plans and the local off-site emergency plans are in place the national plan for managing radiation emergencies is still in a draft form. PNRA defined in the Self-Assessment Action Plan an action for finalizing the national plan for response to a nuclear or radiological emergency.

PNRA is responsible for controlling, regulating and supervising all matters related to nuclear safety and radiation protection measures in Pakistan. Based on the Ordinance PNRA ensures, co-ordinates and enforces preparation of emergency plans for actions to be taken following all foreseeable types of nuclear incidents that might happen in nuclear and radiological facilities and related activities, which might affect the public. PNRA issued several regulations relevant for the Emergency Preparedness and Response (EPR) framework. These regulations provide detailed requirements for licensing of all facilities and activities that belong to the scope of PNRA regulatory supervision, and for management of a nuclear or radiological emergency. The requirements in these regulations are self-consistent and they follow a graded approach considering the risk significance of the different facilities and activities in Pakistan. The prime responsibility for on-site emergency management lies with the licensee. The functions and responsibilities of the operators/licensees of nuclear/radiation facilities are clearly defined in regulations issued by PNRA.

PNRA is responsible to advise the Federal Government departments or Provincial Government departments, educational and research institutions, public or private industry and other undertakings on questions related to nuclear safety and radiation protection. This responsibility is implemented by different means: PNRA (i) advises on and coordinates the structure and content of the emergency response plans at different levels; (ii) organises training courses on EPR related topics for different stakeholders (first responders, medical practitioners, scrap metal dealers, etc.); (iii) issues informative brochures to different stakeholders and the public. By these means PNRA covers all aspects of coordination and providing advice to governmental organizations and the public.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>Pakistan does not yet have a national radiation emergency response plan. There is draft plan which contains important elements of a national radiation emergency response plan, but it is yet to be completed and promulgated.</i>
(1)	<b>BASIS:</b> <b>GS-R-2 para. 5.13 states that</b> <i>“Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies. These arrangements for a co-ordinated national response shall specify the organization responsible for the development and maintenance of the arrangements; shall describe the responsibilities of the operators and other response organizations; and shall describe the co-ordination effected between these arrangements and the arrangements for response to a conventional emergency....”</i>
S26	<b>Suggestion:</b> <b>The Government should consider finalizing and promulgating the National Nuclear and Radiological Emergency Response Plan.</b>

### Assessment of threats

PAK/914 provides detailed requirements for the assessment of hazards and hazard categories. These requirements are in line with the requirements of GS-R-2. The full range of postulated events is required to be included in the threat assessment: very low probability events, external events and non-radiological hazards as well.

GS-R-2 requires the licensee to assess the adequacy of the EPR arrangements by using probabilistic safety analysis of the facility. The PNRA regulations do not require the licensee to assess the adequacy of the EPR arrangements by using PSA which is not in-compliance with GS-R-2 requirements. This issue was identified and addressed in PNRA’s Action Plan.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>According to the hazard assessment section of the Self-Assessment “probabilistic safety assessment is not currently used to assess the adequacy of the operator’s emergency response arrangement.”</i>
(1)	<b>BASIS:</b> <b>GS-R-2 para. 3.13 states that</b> <i>“In designing a threat category I facility “[a] probabilistic safety analysis of the [facility] shall be carried out in order... to assess the adequacy of [the operator’s] emergency [response arrangements]”.</i>
R11	<b>Recommendation:</b> <b>PNRA should require that licensees in hazard category I utilise probabilistic safety analysis for the purpose of assessing the adequacy of their emergency response arrangements.</b>

### 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

PNRA issued requirements on management of a nuclear or radiological emergency in PAK/914. This regulation is to be applied to all facilities and activities licensed by PNRA. However, the draft National Radiation Emergency Response Plan covers also emergencies arising from radiation sources of an unknown or untraceable origin and any other source or activity.

GS-R-2 served as a basis for preparing this regulation. Starting from the practical goals of emergency response, through the definition of basic responsibilities and assessment of threats until all functional and infrastructural requirements, PAK/914 strictly follows the original version of GS-R-2 with some minor

changes in the formulation of the requirements that made them applicable to licensees, as those are defined in Section 4 of the PAK/914.

### **Establishing emergency management and operations**

Regulatory requirements on the licensee's emergency management structure are listed in PAK/914. These requirements address the need for the on-site emergency response to be promptly executed and managed without impairing the performance of the continuing operational safety functions. The effectiveness of the licensee's emergency management function is verified by PNRA through (i) its inspection program that is harmonized in between the regional resident headquarters unit of PNRA and the experts of NRECC; and (ii) observing and evaluating the regular exercises of licensees.

### **Identifying, notifying and activating**

The regulatory requirements for licensees to classify emergencies are listed in PAK/914. The emergency classification scheme is identical with the one described in GS-R-2. Detailed requirements for immediate notification requirements for operating nuclear power reactors are given in PAK/913 and in PAK/914 for other facilities and practices. The timing requirements stated in PNRA regulation are generally consistent with the international standards, although certain time objectives are somewhat less strict than those in GS-G-2.1.

PNRA performs regular inspection of tests and drills on identification and notification that are performed by the licensees. Whenever licensees are found not to meet the requirements PNRA initiates regulatory enforcement action to improve performance.

### **Taking mitigatory actions**

The regulatory requirements for taking mitigatory actions follow the ones in GS-R-2. Symptom-based EOPs and SAMGs are available for both NPP sites; these provide the basis for the most important mitigatory actions.

The licensees in hazard category I-III are required by PNRA regulations to ensure the availability of emergency services to support the response. The potential need for external services, like fire fighter support or specific additional diesel-generators are foreseen in the on-site plans. The capabilities of providing and accepting external services are regularly tested during the NPPs integrated exercises. Integrated exercises are required to be organized on a regular basis with the involvement of off-site organizations and, specifically, together with those, which provide external support to certain emergency response actions.

### **Taking urgent protective action**

PNRA established regulations for the protection of the public during an emergency and defines generic criteria for urgent protective actions that are fully consistent with IAEA standards.

The arrangements for emergency planning zones are identical to such in GS-R-2. The practice is that PNRA requires the licensee either to follow IAEA guidance (GS-G-2.1 Appendix II) or elaborate methodology on defining the size of the emergency zones. The licensee's proposal on establishing the appropriate size of emergency zones has to be submitted to PNRA for approval.

### **Providing information and issuing instructions**

PNRA is responsible for regulations regarding the role of licensees in providing instructions to the public and keeping it informed during an emergency. These regulatory requirements are fully consistent with the IAEA standards.

Providing information, issuing instructions and keeping the public informed is a regular objective of partial and integrated exercises. Licensees prepare the necessary information using predefined templates and forward them to off-site authorities responsible for coordination and management of response. According to the off-site plans they are responsible to issue this information to the media and the public.

### Protecting emergency workers

Regulations regarding the protection of on-site emergency workers are fully consistent with the IAEA standards. According to PNRA regulation, licensees are responsible for the protection of off-site workers involved in on-site support to the licensee as well. The same protection requirements are to be applied for them as for the on-site responders.

PNRA is not responsible for regulations regarding the protection of off-site emergency workers. Nevertheless, according to the general practice followed in Pakistan the requirements in PAK/914 are also applied to and followed by off-site emergency workers.

### Assessing the initial phase

PNRA’s regulations regarding the assessment of the initial phase are stated in PAK/914 and they follow the GS-R-2 requirements. These regulations require the consideration of both radiation levels and plant/site conditions in the assessment of the initial phase. The licensee’s ability to assess the initial phase is addressed by PNRA when licensing operators, as well as during regular inspections and exercises.

Although Operational Intervention Levels (OIL) are used for initiating concrete interventions, they were taken from earlier IAEA publications. These OILs are not necessarily consistent with the new concepts recently published by the IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Operational Interventional Levels (OILs) are in use in Pakistan, in compliance with the IAEA standards. However, the actual values of these OILs are based on an earlier IAEA document and are not consistent with the new concepts and frameworks published in GSG-2.</i>
(1)	<b>BASIS: GS-R-2 para. 4.71 states that</b> <i>“For the precautionary action zone and the urgent protective action planning zone, arrangements shall be made for promptly assessing any radioactive contamination, releases of radioactive material and doses for the purpose of deciding on or adapting the urgent protective actions to be taken following a release of radioactive material. This capability shall ...”.</i>
(2)	<b>BASIS: GSG-2 para. 5.13 states that</b> <i>“Appendix II provides selected examples of default OILs for deposition, levels of individual contamination, and contamination levels for food, milk and water, together with a plain language explanation of the OILs”.</i>
S27	<b>Suggestion:</b> <b>PNRA should consider reviewing and revising the OILs where necessary.</b>

### Managing the medical response

PNRA established requirements for medical response for the licensees as part of general arrangements for responding to a nuclear or radiological emergency. PAK/914 regulates the licensee’s responsibilities to provide medical care and treatment on the site. It requires the licensee to make arrangements for provision of appropriate specialized treatment to any person who receives a dose that could potentially result in severe deterministic health effects. PAK/914 sets requirements regarding the preparedness for such cases. Special arrangements and facilities are in place to deal with a limited number of overexposed and/or contaminated victims.

The regulatory requirements are consistent with the ones stated in GS-R-2, nevertheless, following the Fukushima Dai-ichi accident, there are some reviewing and upgrading efforts going on by PNRA to better address compliance with these requirements.

#### **Taking agricultural countermeasures, countermeasures against ingestion and longer-term protective actions**

PNRA issued requirements for the radionuclide contamination in food and agricultural products in PAK/914. PNRA has the capability to perform environmental monitoring and to measure contamination of food stuffs. The licensees are obligated to establish the capabilities to monitor (normal operation and emergency, as well) food and environmental contamination. They are obliged to determine if the food/agricultural products comply with the criteria and to formulate recommendations for actions to the local government. The local government is responsible to implement these countermeasures. Regulation and criteria for these countermeasures are given in PAK/914. These regulations were adapted following requirements of corresponding section of GS-R-2; therefore they are fully consistent with them.

#### **Mitigating the non-radiological consequences of the emergency and the response**

PNRA regulations for licensees on protecting emergency workers partly cover requirements to consider non-radiological impacts on workers. It was pointed out in the self-assessment that some further update of these requirements will be necessary in harmony with the newest IAEA requirements. This issue was addressed in the Action Plan. PNRA decided to revise PAK/914 to add requirements for the licensees to mitigate non-radiological consequences for their own emergency workers.

#### **Conducting recovery operations**

Requirement and criteria for conducting recovery operations including, for example, transitions threshold, workers protection and response criteria are given in PAK/914 and PAK/904 consistently with GS-R-2.

#### **Conducting recovery operations**

Requirement and criteria for conducting recovery operations including, for example, transitions threshold, workers protection and response criteria are given in PAK/914 and PAK/904 consistently with GS-R-2.

### **10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE**

#### **Authority**

PNRA has full authority for the regulation of licensees with respect to EPR. The authorization covers all facilities and practices on the territory of Pakistan.

#### **Organisation**

Regulatory requirements for the staffing of licensees' emergency response organisation are stated in PAK/914. These regulations are identical with GS-R-2 requirements. The organizational structure and staffing of different units in the structure of the licensees' Emergency Response Organization is given in the licensees' ERP, and it is to be approved by the PNRA.

#### **Coordination of emergency response**

PNRA issued regulatory requirements on the coordination of the licensee's activities. PAK/914 requires the coordination of on-site and off-site emergency responses. Practical details of coordination are described in the local off-site plans that need also to be reviewed, commented and accepted by PNRA. Licensees are responsible to train and exercise off-site officials on the protective actions. This is an example of coordination between licensees and off-site organizations.

## Plans and procedures

PNRA issued requirements regarding emergency plans and procedures for licensees in PAK/914 in line with GS-R-2. Based on its authorization PNRA approves the licensees' emergency plans. PNRA ensures, through regular observation and evaluation of licensee's exercises and performing inspections according to annual plans, that the licensee emergency plans are adequately implemented.

PNRA is progressing with the elaboration of a regulatory guide for the licensees of radiation facilities and activities (hazard categories III and IV) on preparation of emergency response plans to ensure harmonization and quality assurance for those plans. In case of NPPs the licensees are advised to follow USNRC regulatory guidance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>PNRA is progressing with the preparation of a regulatory guide that will provide detailed description on how to prepare emergency response plans and implement related regulatory requirements for radiation facilities belonging to hazard category III and IV.</i>
(1)	<b>BASIS: GS-R-2 para. 3.9 states that</b> <i>“In fulfilling its statutory obligations, the regulatory body... shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;... shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):... the requirements for incident reporting;... and emergency preparedness arrangements.”</i>
S28	<b>Suggestion:</b> <b>PNRA should consider finalising and issuing the regulatory guide for hazard categories III and IV.</b>

## Logistical support and facilities

PNRA's regulatory requirements on EPR logistics and facilities for the licensees are listed in PAK/914. These requirements address all infrastructure elements and are fully consistent with requirements contained in GS-R-2.

The effectiveness and adequacy of logistical support and facilities are verified through exercises and inspections. PAEC is performing calibration of radiation monitoring equipment with a frequency of 1 year. Functional testing of measuring devices is part of PNRA's regular inspection programme.

## Training, drills and exercises

PNRA issued regulatory requirements for the licensees' EPR regime on training, drills and exercises in PAK/914 and those are fully consistent with GS-R-2 requirements. Licensees submit their annual training and exercise program to PNRA for review and acceptance. The PNRA evaluates the systematic training programmes of the licensees through exercises and inspections. Partial and integrated exercises are observed and evaluated by PNRA staff. For the evaluation of exercises PNRA establishes check lists and evaluation criteria. PNRA performs regular inspections through its regional offices. National Radiation Emergency Coordination Centre (NRECC) staff is involved in the elaboration, conduct and evaluation of inspections in specific EPR areas.

The preparation, conduct and evaluation of emergency exercises are consistent with the IAEA standards. The licensee prepares the exercise manual (with the objectives, scope, timeline etc.), which is reviewed and approved by the RB. The evaluation criteria are developed prior to the exercise. The evaluation is done by the licensee, by the PNRA staff and by the QA team of PAEC.

## Quality assurance programme

PNRA's QA related requirements are identical with the GS-R-2 requirements with the exception that their scope does not cover activities and practices belonging to hazard category IV. GS-R-2 explicitly requires this for all hazard categories, but PAK/914 establishes the requirements only for I-III.

PNRA verifies the effectiveness of the licensee's quality assurance programme through management audits and other inspection programmes that are performed on a regular basis according to the annual plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>A quality assurance program is explicitly required by GS-R-2 for all hazard categories, but PAK/914 established the requirements only for categories I-III.</i>
(1)	<b>BASIS:</b> <b>GS-R-2 para. 5.37 states that</b> <i>“The operator of a facility, practice or source in threat category I, II, III or IV and the off-site response organizations shall establish a quality assurance programme, in accordance with international standards, ...”</i>
R12	<b>Recommendation:</b> <b>PNRA should revise its relevant regulation to include quality assurance for EPR requirements of category IV radiation activities.</b>

## 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

PNRA advises the government for public protection and other related issues in case of an emergency. PNRA also assists off-site response organizations and licensees in radiological assessment by deploying its radiation monitoring teams located at its regional offices and headquarters. PNRA is the National Competent Authority for domestic and foreign emergencies and the National Warning Point, designated under the Early Notification and Assistance Conventions. PNRA regularly takes part in IAEA General Conferences and NCA representative meetings.

Implementing their functions, complex tasks, operation of equipment, maintenance of NRECC, response for incident and emergencies PNRA staff follows written procedures. PNRA communicates on predefined templates and communication channels with on-site personnel and at national level. PNRA maintains a general management system and the EPR related functions are implemented under this general management system. PNRA runs a general training program in which EPR related elements are included, based on the proposal of NRECC staff.

The roles and responsibilities of on-site and off-site emergency response organisations are regularly exercised. Training courses, table top and field exercises have been performed to train the first responders like fire fighters, rescue, medical doctors, police, security agencies and border monitoring personnel.

PNRA operates the National Radiation Emergency Coordination Centre within its premises. It has a sufficient amount of instruments for measurements, communication tools, mobile laboratories, etc. PNRA verifies the effectiveness of its arrangements based on its own self-assessment methodology and also by the reviewing of the Regulatory Affairs Directorate every 2 years. Another means of verification is performing exercises. In preparing for, conducting and evaluating an exercise PNRA follows the IAEA guidance.

The NRECC establishes its own strategic plan from which they derive annual work plan within the framework of the entire PNRA plan. This and the self-assessment provide the sustainability for continuous improvement program. Inviting the different international missions are also a proof of this intention and means of implementation.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><b>Observation:</b> <i>The National Radiation Emergency Coordination Centre located at PNRA has limited physical space, given its emergency response role. The implementation of EPR assessment and coordination is largely paper-based and consequence analysis and decision-making aids and tools are not state-of-the-art.</i></p>
(1)	<p><b>BASIS:</b> <i>GS-R-2 para. 5.25 states that "Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions specified in Section 4. These items and facilities shall be selected or designed to be operational under the postulated conditions ..."</i></p>
R13	<p><b>Recommendation:</b> <b>The Government should continue supporting the modernisation of PNRA's National Radiation Emergency Coordination Centre.</b></p>

### 10.5. SUMMARY

PNRA advises the government for public protection and other related issues in case of an emergency. PNRA assists offsite response organizations and licensees for radiological assessment by deploying its radiation monitoring teams located at its regional offices and headquarters. PNRA is the National Competent Authority for domestic and foreign emergencies and the National Warning Point, designated under the Early Notification and Assistance Conventions.

The prime responsibility for on-site emergency management lies with the licensee. Their functions and responsibilities of the operators/licensees of nuclear/radiation facilities are clearly defined in PNRA regulations. PNRA issued detailed requirements on management of a nuclear or radiological emergency. The regulation covers all critical functional areas and the infrastructure necessary to develop and maintain adequate arrangements for response. PNRA requires very low probability events, external events and non-radiological hazards to be included in the threat assessment as well. In this regard probabilistic safety assessment techniques need to be incorporated in the practice.

The roles and responsibilities of on-site and off-site emergency response organisations are regularly exercised. Training courses, table top and field exercises have been performed to train the first responders like fire fighters, rescue, medical doctors, police, security agencies and border monitoring personnel. The preparation, conduct and evaluation of emergency exercises are consistent with the IAEA standards.

PNRA operates the National Radiation Emergency Coordination Centre within its premises. It has a sufficient amount of instruments for measurements, communication tools, mobile laboratories, etc. It was observed that in NRECC the space is limited, the work of situation assessment and coordination is largely paper-based and the consequence analysis and decision aiding tools are not state-of-the-art. Modernisation of NRECC would be an essential action at least before the start-up of new NPP units.

## **11. ADDITIONAL AREAS**

### **11.1. OCCUPATIONAL RADIATION PROTECTION**

#### **Legal and regulatory framework**

PNRA has established a legislative and regulatory framework to provide for occupational radiation protection. This framework is mainly based on the Pakistan Nuclear Regulatory Authority Ordinance and national regulations called Regulations on Radiation Protection (PAK/904).

PNRA specifies dose limits for occupational exposure and apprentices of age 16 to 18 years, and it is strictly prohibited that a person under age 16 is subjected to occupational exposure.

The dose limits specified in PNRA regulations are consistent with GSR Part III, Schedule III, except for that for lens of eyes. In addition, 500mSv is specified in PNRA regulation (PAK/914), even though the emergency worker shall not receive in excess of 50mSv other than the cases defined in GSR Part 3. These deviations have resulted from that GSR Part 3 has adopted new values for lens of eyes and emergency workers from 2009 based on the ICRP recommendations, however PNRA regulations (PAK/904) and (PAK/914) have already promulgated in 2004. PNRA has a plan to revise the regulations to adopt recently introduced international standards, which will be initiated from 2015.

Through the IRRS review, it was identified that PNRA did not establish a strategy for occupational radiation protection against  $^{222}\text{Rn}$  exposure in workplaces, and an appropriate reference level for  $^{222}\text{Rn}$  yet. The status of occupational radiation protection for  $^{222}\text{Rn}$  exposure is still on investigation stage. PNRA has measured  $^{222}\text{Rn}$  activity in 17 selected medical facilities, especially in workplaces located in basement in 2013.

PNRA or other relevant authority in Pakistan does not determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted yet. PNRA currently has no plan on how to treat aircrew exposure.

#### **General Responsibilities of Registrants, Licensees and Employers**

PNRA regulations assign to licensees responsibilities for the protection of workers from occupational exposure, and for the compliance with the requirements of the regulations.

PNRA requires the licensees to ensure that occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in the regulations are not exceeded. PNRA also requires the licensees to ensure that emergency workers that they have been clearly and comprehensively informed in advance of the associated health risks, as well as of available protective measures. This requisition is based on the “Regulations on Management of a Nuclear and Radiological Emergency” (PAK/914) of PNRA. For dose keeping, PNRA regulations require the licensees shall maintain the exposure records of radiation workers, at least, until the worker attain or would have attain the age of 75, and for not less than 30 years after the termination of the work involving occupational exposure.

PNRA requires licensees to ensure that occupational exposure is optimized so that the exposure be kept as low as reasonably achievable. For controlling occupational exposures, priority is given to implementing design and technical measures rather than administrative controls or personal protective equipment.

PNRA also requires licensees to ensure appropriate training monitoring equipment and personal protective equipment are provided.

## General Responsibilities of Workers

IAEA safety standards recommend clear separation of responsibilities between workers and licensees. PNRA regulations are solely binding on licensees' obligations, thus do not address the matters concerned with the responsibilities of workers directly. The regulations require that licensees shall ensure these responsibilities. For example, PNRA regulations do not require workers to properly use the monitoring equipment and the personal protective equipment and clothing, but licensees are required to ensure this.

PNRA fully notices this discrepancy between PNRA regulations and corresponding IAEA safety standards. PNRA is considering whether such requirement could be addressed in the forthcoming revision of Regulations on Radiation Protection (PAK/904) planned for 2015 and additionally preparing a Regulatory Guide (now in draft version) to implement this aspect.

## Requirements for Radiation Protection Programmes

PNRA requires licensees to establish and implement a sound radiation protection programme. This programme includes designation of area (controlled or supervised), display of warning symbols, proper instructions at access points, etc.

PNRA requires that the licensees provide appropriate means for change of clothing, contamination survey and personal protective equipment.

During the mission, a regulatory inspection was carried out at Shifa International Hospital by three PNRA inspectors accompanied by three members of the IRRS team. The licensee's activities related to the occupational exposure were well planned, organized and implemented following relevant regulations and procedures under supervision of Radiation Safety Officers.

PNRA inspectors utilized systematic and comprehensive inspection checklists for nuclear medicine and radiotherapy, respectively. The checklists "Regulatory Inspection of Nuclear Medicine Centre" and "Regulatory Inspection of Radiotherapy Centre" cover almost all activities for occupational radiation protection in medical facilities.

These checklists were first developed in June 2007 based on the relevant IAEA documents and PNRA regulations. They were revised in April 2014 and improved taking into account technical progress in the medical field and PNRA's own inspection experience.

## Monitoring Programmes and Technical Services

PNRA regulations do not require service providers for individual monitoring and calibration services to be authorized or approved by PNRA.

PNRA regulations require the licensees to keep records of occupational dose, workplace monitoring and training.

The Ordinance does not include the dosimetry service within the regulatory framework. Therefore, there is no legal basis to regulate dosimetry service providers.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<b>Observation:</b> <i>A strategy for establishing control of <sup>222</sup>Rn exposure and its reference level is not in place. PNRA has not determined whether assessment of the aircrew exposure due to cosmic radiation is warranted.</i>
(1)	<b>BASIS:</b> <b>GSR Part 3 para. 5.27 states that</b> <i>"The regulatory body or other relevant authority shall establish a strategy for protection against exposure due to <sup>222</sup>Rn in workplaces, including the establishment of an appropriate reference level for <sup>222</sup>Rn. [...]."</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS: GSR Part 3 para. 5.30 states that</b> <i>“The regulatory body or other relevant authority shall determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted.”</i>
	<b>Reference is made to Recommendation R10 in Section 9.5.</b>
	<b>Observation:</b> <i>A regulation for the general responsibility of radiation workers is not in place.</i>
(1)	<b>BASIS: GSR Part 3 Requirement 22 states that</b> <i>“Workers shall fulfil their obligations and carry out their duties for protection and safety.”</i>
(2)	<b>BASIS: GSR Part 3 para. 3.83 (a) to (f) states that</b> <i>“Workers: (a) Shall follow any applicable rules and procedures for protection and safety as specified by the employer, registrant or licensee; [...] (f) Shall accept such information, instruction and training in protection and safety as will enable them to conduct their work in accordance with the requirements of these Standards.”</i>
	<b>Reference is made to Recommendation R10 in Section 9.5.</b>
	<b>Observation:</b> <i>An authorization or approval system for dosimetry service providers by the regulatory body is not in place.</i>
(1)	<b>BASIS: GSR Part 3 Requirement 2 states that</b> <i>“The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations.”</i>
(2)	<b>BASIS: GSR Part 3 para. 3.73 (c) states that</b> <i>“The regulatory body shall be responsible, as appropriate, for authorization or approval of service providers for individual monitoring and calibration services”</i>
S29	<b>Suggestion:</b> <b>PNRA should consider the need for approval or authorization of service providers for individual monitoring and calibration services.</b>

### 11.2. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

#### Control of radioactive discharges and materials for clearance

National regulations establish requirements for the control of radioactive discharges for both nuclear and non-nuclear installations (PAK/915). In accordance with these regulations, for obtaining an authorization for carrying out any activity involving releases of radioactive materials to the environment, applicants have to submit to the regulatory body for approval information on:

- the characteristics and activity of the material to be discharged;
- the potential points and methods of discharge, the significant exposure pathways by which discharged radionuclides can deliver public exposure;
- estimate the doses to the critical groups (representative person) due to the planned discharges;
- estimate dose constraint applicable to the public in relation to the discharges; and
- on its basis determine applicable discharge limits.

Responsibilities of both regulator and licensee have also been established in the regulations.

Regarding the control of radioactive discharges, although the bases for present regulations are the standards of Safety Standards Series publication 115 (BSS-115), relevant requirements of GSR Part 3, GSR Part 5 and WS-G-2.3 are reflected. Evidence provided indicates full compliance with requirements established by national regulations for the case of nuclear installations. However, for the case of non-nuclear installations these requirements have not been fully implemented in practice.

PNRA Regulation PAK/915 establishes also requirements for the control of materials for clearance, again reflecting the requirements of BSS-115. Criteria for clearance of materials containing a mixture of radionuclides of artificial origin and for clearance of bulk amounts of materials containing a mixture of radionuclides of both artificial and natural origin have not addressed in present regulations. A draft of an updated version of PAK/915, which includes clearance criteria in agreement with requirements of GSR Part 3, is in process of approval. Recommendation R11 in Section 9.5 addresses compliance with GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Small users (non-nuclear installations) are not complying with the requirement to provide information about the expected radiological impact to the public when applying for an authorization.</i>
(1)	<b>BASIS:</b> <b>GSR Part 3 para. 3.132 states that</b> <i>“Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate: ... (b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public; (c) Shall assess the doses to the representative person due to the planned discharges; (d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body; ...”</i>
S30	<b>Suggestion:</b> <b>PNRA should consider consistently enforcing the implementation of its requirement for all users to provide information about the expected radiological impact to the public.</b>

### **Environmental monitoring associated with authorized practices for public radiation protection purposes**

Requirements relevant for this topic are included in regulatory documents PAK/904, PAK/909, PAK/913 and PAK/915. In general, these requirements reflect requirements published in GSR Part 3 and RS-G-1.8. Issues in this topic were raised with regard to the information on monitoring results to the public and with regard to completion of reports on monitoring results submitted periodically to PNRA by PINSTECH. For the last observation, it was noticed that annual reports sent by PINSTECH to PNRA do not include the results of the assessment of doses to the public due to effluents releases. It was also observed that reported measurements do not include information on relevant radionuclides that could be potentially released from the installation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<b>Observation:</b> <i>Public information through PNRA annual reports does not include information on results of environmental monitoring programmes nor assessments of doses to the public due to releases.</i>
(1)	<b>BASIS:</b> <b>RS-G-1.8 para. 3.18 states that</b> <i>“In view of the increasing public awareness of environmental issues, the regulatory body...should make available to the public summary information on environmental monitoring with an adequate explanation of its significance..”</i>

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS:</b> GSR Part 3 para. 3.136 states that <i>“The regulatory body shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.”</i>
S31	<b>Suggestion:</b> PNRA should consider making available to the public summary information on the results of environmental monitoring programmes and assessments of doses to the public due to releases.

### 11.3. SUMMARY

Regulations in the areas covered in this chapter are based on requirements of BSS-115. Therefore some requirements from GSR Part 3 are not in place for some areas, namely:

- Exposure to radon in workplaces;
- Exposure of aircrew due to cosmic radiation;
- Responsibilities of workers for safety;
- Authorization or approval of service providers for individual monitoring,

Additionally, the followings observations, related with the protection of the public and public information, were made:

- Small users (non-nuclear installations) are not required to provide information about the expected radiological impact to the public when applying for an authorization;
- Public information through PNRA annual reports does not include information on results of environmental monitoring programmes nor assessments of doses to the public due to releases.

Updated versions of regulatory documents, full in line with the requirements of GSR Part 3, have been already drafted, and it is expected that they will be approved in the near future.

## APPENDIX I – LIST OF PARTICIPANTS

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## IRRS TEAM AND COUNTERPARTS



## APPENDIX II – MISSION PROGRAMME

### First Week, 26 April to 4 May

Time	SAT	SUN	MON	TUE	WED	THU	FRI	SAT	SUN														
9:00-10:00	Arrival of Team Members	Initial Team Meeting: <ul style="list-style-type: none"> <li>• IRRS process</li> <li>• Main objectives</li> <li>• Report writing</li> <li>• Schedule</li> <li>• First observations</li> <li>• In-Group discussions</li> <li>• PNRA presentation</li> </ul>	Entrance Meeting	Interviews	Visits	Interviews	Visits	Interviews	Visits/EPR exerc.	TC writes introductory parts	TM write Report TL and DTL review introductory part	<ul style="list-style-type: none"> <li>• Discussing and improving Draft Report</li> <li>• Cross-Reading</li> <li>• TL, DTL, TC and DTC read everything</li> </ul>	Reading, Cross-reading of the Report	Free day, Social Tour									
10:00-11:00																							
11:00-12:00																							
12:00-13:00					Interviews																		
13:00-14:00																							
14:00-15:00																							
15:00-16:00					Interviews																		
16:00-17:00																							
17:00-18:00					Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting														
19:00-24:00			Writing of the report	Writing of the report	Secretariat edits Report TM write Report	Writing of the report	TM Read Draft	Secretariat edits the report															

## Second Week, 5 to 9 May

	MON	TUE	WED	THU	FRI				
<b>9:00-10:00</b>	Individual discussions of Rs, Ss and GPs with counterparts	Cross-Reading TL, DTL, TC and DTC read everything Finalisation	Submission of the Draft to the Host		Discussion with Host	Submission of the Final Draft	9:00-10:00		
<b>10:00-12:00</b>						Exit Meeting Press Conference	10:00-12:00		
<b>13:00-15:00</b>	Policy Discussions	Discussion of the report by the team	TC, DTC prepare Executive Summary and exit presentation	Host reads Draft TL finalises Executive Summary and exit presentation TC Drafts the Press Release	Written comments by the Host  Team meeting for finalisation of the Report	Departure Home	13:00-15:00		
<b>15:00-17:00</b>	Individual discussions of modules with counterparts						15:00-17:00		
<b>17:00-18:00</b>	Daily Team Meeting						Discussion of Executive Summary	Briefing of the Director Finalisation of the press release	17:00-18:00
<b>19:00-21:00</b>	Secretariat includes changes						Secretariat finalises text	Free	Free
<b>21:00-24:00</b>		21:00-24:00							

### APPENDIX III – SITE VISITS

<b>Facilities visited:</b>
1. Shifa International Hospital
2. Research Reactors, PINSTECH
3. Radioactive Waste Facility, PINSTECH

**APPENDIX IV – LIST OF COUNTERPARTS**

	<b>IRRS EXPERTS</b>	<b>SUJB Lead Counterparts</b>
<b>1.</b>	<b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>	
	Petr Krs	Naveed Maqbul
<b>2.</b>	<b>GLOBAL NUCLEAR SAFETY REGIME</b>	
	Petr Krs	Mohammad Ayub
<b>3.</b>	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	
	Adriaan Joubert	Faizan Mansoor
<b>4.</b>	<b>MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>	
	Darja Slokan Dusic	Naeem Arshad
<b>5.</b>	<b>AUTHORIZATION</b>	
	Christian Carrier, Richard Rasmussen and Irena Raciene	Muhammad Rahman, Samina Kanwal, Mishkat Ali and Muhammad Muneer
<b>6.</b>	<b>REVIEW AND ASSESSMENT</b>	
	Christian Carrier, Richard Rasmussen and Irena Raciene	Zia Hussain Shah, Samina Kanwal, Mishkat Ali and Muhammad Muneer
<b>7.</b>	<b>INSPECTION</b>	
	Gerhard Roos and Malcolm Widmann	Mohammad Qayyum, Samina Kanwal, Mishkat Ali and Muhammad Muneer
<b>8.</b>	<b>ENFORCEMENT</b>	
	Gerhard Roos and Malcolm Widmann	Mohammad Qayyum, Samina Kanwal, Mishkat Ali and Muhammad Muneer

	<b>IRRS EXPERTS</b>	<b>SUJB Lead Counterparts</b>
<b>9.</b>	<b>REGULATIONS AND GUIDES</b>	
	Liguang Hu, Ivica Bosnjak and Rustem Paci	Shahid Rashid and Muhammad Muneer
<b>10.</b>	<b>EMERGENCY PREPAREDNESS AND RESPONSE</b>	
	Geza Macsuga and Peter Zombori	M. Nadeem Hussain
<b>11.</b>	<b>CONTROL OF MEDICAL EXPOSURES, OCCUPATIONAL RADIATION PROTECTION, CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE AND CHRONIC EXPOSURES AND ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION</b>	
	Jae-Seong Lee and Juan Tomas Zerquera	Rizwan Ali Khan and Muhammad Muneer

**APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
<b>1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>	<b>R1</b>	The Government should ensure that the fundamental safety objective and fundamental safety principles of IAEA SF-1 are incorporated in the Pakistan framework for safety.
	<b>S1</b>	The Government should consider developing a long term strategy for safety that would include necessary safety measures to reflect the development plans for the nuclear power programme of Pakistan.
	<b>R2</b>	The Government should ensure that relevant parts of the legislative framework stipulate legal responsibilities and obligations in respect of financial provisions for the management of radioactive waste, spent fuel and decommissioning of facilities.
	<b>GP1</b>	PNRA adopted a very active resource management strategy to secure appropriate financing for its rapid expansion and did not rely only on increased annual budgets from the Federal Government or increase the licensing fees. Funds from Public Sector Development Projects significantly contributed to meet financial requirements of PNRA for very ambitious capacity building and institutional strengthening.
	<b>R3</b>	PNRA should ensure that appropriate and documented coordination and liaison between PNRA and other authorities having responsibility for safety are formalized where appropriate or needed.
	<b>S2</b>	The Government should consider including the policy for decommissioning of facilities and the safe management of spent nuclear fuel in the existing radioactive waste management policy.
	<b>S3</b>	The Government should consider developing a national strategy for the decommissioning of facilities and for the safe management and disposal of radioactive waste with appropriate interim targets and end states.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
<b>2. GLOBAL NUCLEAR SAFETY REGIME</b>	<b>S4</b>	The Government should consider becoming party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.
<b>3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	<b>R4</b>	PNRA should approve the regulation that allows PNRA to formally resolve conflicts between PNRA and its licensees through the establishment of special tribunals.
	<b>GP2</b>	PNRA has a very well developed and established training programme to develop and maintain the necessary competence and skills of staff of the regulatory body that allows keeping a high level of competence during PNRA's growth.
	<b>R5</b>	PNRA should develop arrangements to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.
	<b>GP3</b>	PNRA has an approved public awareness programme to address radiation safety and regulatory practices in the generic public domain.
	<b>R6</b>	PNRA should develop effective mechanisms of communication, and hold meetings to inform interested parties, the public and the media to keep these parties informed on the decision making process and on the risk of radiation, in accordance with the graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
<b>4. MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>	<b>S5</b>	PNRA should consider issuing the new revision of the PNRA Management System Manual, which incorporates <ul style="list-style-type: none"> <li>• Safety Culture,</li> <li>• Graded Approach,</li> <li>• Responsibility of the Organization for the Management System,</li> <li>• Authorities and Responsibilities of Process Owners,</li> <li>• The Control of Processes Contracted to External Organizations</li> <li>• and Managing Organizational Changes,</li> </ul> in accordance with its self-assessment action plan.
	<b>S6</b>	PNRA should consider documenting the status of review of relevant documents.
	<b>S7</b>	PNRA should consider establishing a document control system to ensure protection and preservation of regulatory related records, which addresses retention and archiving of records.
	<b>GP4</b>	PNRA conducts self-assessment of safety culture.
<b>5. AUTHORIZATION</b>	<b>S8</b>	PNRA should consider revisiting the current licences and ensure their categorization is consistent with the definition of Nuclear Installation as defined in the Ordinance.
	<b>R7</b>	PNRA should develop procedures for appeal against regulatory decisions.
	<b>S9</b>	PNRA should consider continuing to develop guidance defining format and technical contents of licensing submissions for nuclear power plants and research reactors.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<b>S10</b>	PNRA should consider developing processes to involve the public in authorization and licensing processes for NPPs.
	<b>S11</b>	PNRA should consider finalising regulations on the different types of disposal facilities for radioactive waste.
	<b>S12</b>	PNRA should consider finalising specific requirements for the safe management of spent nuclear fuel in anticipation of storing spent fuel outside the existing spent fuel pools.
	<b>S13</b>	PNRA should consider finalising and issuing the regulation to establish a full set of qualification criteria in protection and safety for radiation workers in all types of applications of radiation sources.
	<b>S14</b>	PNRA should consider optimising the duration of licences for activities with radiation sources.
	<b>S15</b>	PNRA should consider finalising and issuing the proposed regulation PAK/930 addressing site remediation considerations and decommissioning of facilities using radioactive material.
<b>6. REVIEW AND ASSESSMENT</b>	<b>S16</b>	PNRA should consider finalising and approving the procedure for review and assessment of licence applications for radiation facilities, including the criteria, in which cases submitted documents are to be reviewed in Regional Directorates, and when these submitted documents are to be sent to the Directorates of Headquarters.
<b>7. INSPECTION</b>	<b>S17</b>	PNRA should consider developing a tool to systematically include human factors in evaluating risk for event-based findings.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<b>GP5</b>	Selected operationally focused PNRA inspectors complete an initial 8-week simulator course and they are assigned to the licensed operator crew for additional training for a minimum of three years.
	<b>S18</b>	PNRA should consider defining the scope of inspections more clearly before the activity to assure that appropriate focus on safety and technical details are achieved.
	<b>R8</b>	PNRA should enforce the regulatory requirement that the licensees conduct their own QC measurements.
	<b>S19</b>	PNRA should consider issuing a procedure to establish categorization of inspection findings using graded-approach to ensure timely enforcement action is taken.
<b>8. ENFORCEMENT</b>	<b>S20</b>	PNRA should consider establishing a procedure for follow-up inspections to ensure that corrective actions have been implemented for safety significant issues.
<b>9. REGULATIONS AND GUIDES</b>	<b>R9</b>	PNRA should establish a mechanism for consultation with interested parties in the preparation of regulatory guides.
	<b>S21</b>	PNRA should consider developing plans/procedures for implementing the new requirements arising from new or amended regulations.
	<b>S22</b>	PNRA should consider finalising and issuing PAK/911 to include removal of heat from the fuel store, Design Extension Conditions and a set of design limits for all operational states and accident conditions.
	<b>S23</b>	PNRA should consider finalising and issuing PAK/913 to include monitoring and review of safety performance, accidents management and complete surveillance programme.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<b>R10</b>	PNRA should revise and issue a regulation for radiation protection that is in compliance with GSR Part 3.
	<b>S24</b>	PNRA should consider developing and issuing supplementary radiation protection guides for all types of applications of radiation sources .
	<b>S25</b>	PNRA should consider finalising and issuing the revised regulations for authorization of radioactive facilities and supplementary guides taking into account graded approach.
<b>10. EMERGENCY PREPAREDNESS AND RESPONSE</b>	<b>S26</b>	The Government should consider finalizing and promulgating the National Nuclear and Radiological Emergency Response Plan.
	<b>R11</b>	PNRA should require that licensees in hazard category I utilise probabilistic safety analysis for the purpose of assessing the adequacy of their emergency response arrangements.
	<b>S27</b>	PNRA should consider reviewing and revising the OILs where necessary.
	<b>S28</b>	PNRA should consider finalising and issuing the regulatory guide for hazard categories III and IV.
	<b>R12</b>	PNRA should revise its relevant regulation to include quality assurance for EPR requirements of category IV radiation activities.
	<b>R13</b>	The Government should continue supporting the modernisation of PNRA’s National Radiation Emergency Coordination Centre.
<b>11. ADDITIONAL AREAS</b>	<b>S29</b>	PNRA should consider the need for approval or authorization of service providers for individual monitoring and calibration services.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<b>S30</b>	PNRA should consider consistently enforcing the implementation of its requirement for all users to provide information about the expected radiological impact to the public.
	<b>S31</b>	PNRA should consider making available to the public summary information on the results of environmental monitoring programmes and assessments of doses to the public due to releases.

## APPENDIX VI – PNRA REFERENCE MATERIAL USED FOR THE REVIEW

### GENERAL DOCUMENTS

- Annual Report of PNRA year 2013
- PNRA Organizational Structure
- Sixth National Report of Pakistan August 2013

### LEGAL DOCUMENTS

- **PNRA Ordinance No. III 2001**
- **List of Regulations**
- **List of Guides**

#### PNRA Regulations

	Title & Number	Date of Issuance
1.	Pakistan Nuclear Regulatory Authority Enforcement Regulation (PAK/950)	23 December 2010
2.	Regulations on the Safety of Nuclear Research Reactor(s) Operation (PAK/923)	10 February 2012
3.	Regulations for the Safe Transport of Radioactive Material - (PAK/916)	20 April 2007
4.	Regulations on Radioactive Waste Management (PAK/915) amended up to March 8, 2010	13 July 2005
5.	Regulations on Management of a Nuclear or Radiological Emergency - (PAK/914)	1 September 2008
6.	Regulations on Safety of Nuclear Power Plants-Operation (PAK/913) amended up to November 3, 2008	22 December 2004
7.	Regulations on the Safety of Nuclear Power Plants-Quality Assurance (PAK/912)	11 September 2003
8.	Regulation on the Safety of Nuclear Power Plant Design (PAK/911)	21 January 2002
9.	Regulations on the Safety of Nuclear Installations – Site Evaluation (PAK/910)	1 September 2008
10.	Regulation for Licensing of Nuclear Installation(s) in Pakistan (PAK/909) revision 1	29 June 2012
11.	Regulations for the Licensing of Radiation Facilities other than Nuclear Installations (PAK/908)	5 October 2004
12.	Regulations for Licensing of Nuclear Safety Class Equipment and Components Manufacturers – (PAK/907)	1 September 2008

13.	Regulations on Radiation Protection (PAK/904) amended up to March 28, 2012	5 October 2004
14.	Regulations on Transaction of Business of Pakistan Nuclear Regulatory Authority - (PAK/901)	9 August 2012
15.	Regulations on Licensing Fee by Pakistan Nuclear Regulatory Authority – (PAK/900)	3 November 2008

### **PNRA Regulatory Guides**

1.	Quality Assurance In Nuclear Medicine (PNRA-RG-904.01)
2.	Guidance for the users of iodine-131 in nuclear medicine centres (PNRA-RG-904.02)
3.	Probabilistic safety assessment of NPP level-1 (PNRA-RG-911.01)
4.	Format and contents of application for design Modifications in nuclear power plants (PNRA-RG-913.02)
5.	Format and contents of application for modifications in technical specifications and operating policies and Principles of NPP (PNRA-RG-913.03)
6.	Dosage and distribution of potassium iodide tablets (a thyroid blocking agent) In radiation emergencies (PNRA-RG-914.01)
7.	Transportation of radioactive material by road in Pakistan (PNRA-RG-916.01)
8.	Registration / Licensing and Issuance of NOC to the Exporter(s) of Radiopharmaceuticals (PAK-9801)

### **MANAGEMENT SYSTEM MANUAL & PROCEDURES**

- PNRA Management System Manual
- List of Procedure
- List of procedures as in Central Registry
- Procedure for Preparation and Revision of Regulatory Guides: PNRA-WP-001
- Procedure For Preparing PNRA Regulations: PNRA-WP-004
- PNRA Enforcement Procedure: WP-PNRA-003
- Procedure for Format, Contents and Process of Preparation of Internal Working Procedures: PNRA-WP-005
- Procedure for licensing of Operating Personnel for Nuclear Power Plants

### **SELF-ASSESSMENT REPORTS**

- Comprehensive self-assessment summary report (based on SARIS, GSR Part 1)
- Action plan

## APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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

18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. NS-G-2.9, IAEA, Vienna (2003)
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. NS-G-2.10, IAEA, Vienna (2003)
21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
22. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999)
23. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
24. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
25. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
26. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
27. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
28. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
29. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
30. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
31. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No. WS-G-2.1, IAEA, Vienna (1999)
32. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
33. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No. WS-G-2.4, IAEA, Vienna (2001)
34. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No. WS-G-2.5, IAEA, Vienna (2003)

35. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003)
36. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
37. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – ORGANIZATIONAL CHART

# Organization Structure of PNRA

