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INTERNATIONAL REGULATORY REVIEW TEAM
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Strengthening of Nuclear Safety Regulatory Authority

**DEPARTMENT OF TECHNICAL
CO-OPERATION**
Division for Africa and East Asia & Pacific

**DEPARTMENT OF NUCLEAR SAFETY
AND SECURITY**
Division of Nuclear Installation Safety

FOREWORD

by the

Director General

The IAEA International Regulatory Review Team (IRRT) programme assists Member States to enhance the organization and performance of their nuclear safety regulatory body. Such a regulatory body must work within the framework of its national legal system, which in turn should ensure both the independence and the legal powers available to the regulatory body. Additionally the national administrative and legislative system should ensure that the regulatory body has sufficient funding and resources to carry out its functions of reviewing and assessing safety submissions; licensing or authorizing nuclear safety activities, establishing regulations and criteria; inspecting nuclear facilities and enforcing national legislation. The regulatory body should be resourced and staffed by capable and experienced people to a level commensurate with the national nuclear programme. IRRT missions focus on all these aspects in assessing the regulatory body's safety effectiveness. Comparisons with successful practices in other countries are made and ideas for improving safety are exchanged at the working level.

An IRRT mission is made only at the request of a Member State. It is not an inspection to determine compliance with national legislation, rather an objective review of nuclear regulatory practices with respect to international guidelines. The evaluation can complement national efforts by providing an independent, international assessment of work processes that may identify areas for improvement. Through the IRRT programme, the IAEA facilitates the exchange of knowledge and experience between international experts and regulatory body personnel. Such advice and assistance will enhance nuclear safety in all nuclear countries. An IRRT mission is also a good training ground for observers from newly formed regulatory bodies in developing countries who follow the evaluation process. This approach, based on voluntary co-operation, contributes to the attainment of international standards of excellence in nuclear safety at the regulatory body level.

Essential features of the work of the IRRT experts and their regulatory body counterparts are the comparisons of regulatory practices with international guidelines and best practices, and a joint search for areas where practices can be enhanced. The implementation of any recommendations or suggestions, after consideration by the regulatory body, is entirely voluntary.

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

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SUMMARY

At the request of the Pakistan Authority, an IAEA team of six experts visited the Pakistan Nuclear Regulatory Authority (PNRA) to conduct a Full Scope International Regulatory Review Team (IRRT) mission. The purpose of the mission was to review the effectiveness of the regulatory body of Pakistan and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety. The IAEA had previously conducted a Pre-IRRT mission to Pakistan in 1997. In 1997, an independence of the Pakistan Nuclear Regulator from the management of the operating organization and utilities as required by the IAEA Safety Standards did not exist.

Since that time, there have been many changes both to the legislation and the regulatory authority. In January 2001, the Government of Pakistan promulgated an Ordinance (Pakistan Nuclear Regulatory Authority Ordinance No. III of 2001) that provides for the establishment of the PNRA for the regulation of nuclear safety, radiation protection, and transportation and waste safety in Pakistan. In order to execute its regulatory task without undue interference the regulatory body has been separated by this ordinance from the bodies responsible for developing, promoting or operating nuclear installations.

In the opinion of the team the new ordinance together with the complementary legal instruments incorporate all legal prerequisites to provide for an independent sustainable Pakistan nuclear regulatory system.

The team also realized that the PNRA is a highly competent organization, which has the technical capability to deal with regulatory and technical areas for which it is responsible and that since its establishment the PNRA has gradually made major progress in improving its effectiveness. The achievements include, among others, steps towards improved legislative arrangements through putting into force new regulations (secondary legislation) and guides as well as working procedures, an inspection programme, a training programme, inspection plans, policies on enforcement, training and authorization.

However, the IRRT team also recognized that the newly established PNRA is still in the process of fully implementing its regulatory regime. Several areas were identified where the existing momentum should be maintained to further improve its future performance. These areas include the finalization of regulations and the review of existing and/or the development of guidance on the new regulations, completion of the administrative procedures for enforcement, the review of inspection procedures, completing PNRA's internal procedure for emergency response and engaging other governmental bodies to provide a strong capability for an integrated response to nuclear events. It was also the view of the IRRT team that in order to achieve and maintain a high level of nuclear, radiation, radioactive waste and transport safety external (national and international) technical support to the PNRA independent from licence holders is essential. The team believes that any management decisions arising from the IRRT report should take account of these considerations.

The reviewers identified a number of good practices which have been recorded for the benefit of other nuclear regulatory bodies. They also made recommendations and suggestions which indicate where improvements are necessary or desirable to further strengthen the regulatory body in Pakistan. These recommendations and suggestions are made to an organization which is

seeking to improve its performance and many of them are related to areas in which the PNRA has already implemented a programme for change.

PNRA staff put a considerable effort into the preparation of the mission. There was full cooperation during the review and technical discussions with PNRA personnel, and the organization and administrative support was excellent. PNRA counterparts were enthusiastic and interested in obtaining international advice.

INTRODUCTION

At the request of the Pakistan Authority, an IAEA team of six experts visited the Pakistan Nuclear Regulatory Authority (PNRA) to conduct a Full Scope International Regulatory Review Team (IRRT) mission.

The purpose of the mission was to review the effectiveness of the PNRA and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety in the following specific predetermined areas: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; authorization process; review and assessment; inspection and enforcement; development of regulations and guides; emergency preparedness.

The review was conducted from 1 to 12 December 2003. Before the mission, the PNRA made available a collection of Advance Reference Material (ARM) for the team to review. This material was comprised of a large number of legal, regulatory and internal documents, all of which were in English.

During the mission the team performed a systematic review of the predetermined topic areas using the PNRA responses to the IAEA questionnaire, the ARM, interviews with PNRA staff and direct observation of their working practices.

The team carried out interviews with the staff of the PNRA at its headquarters. In addition, the inspection process was observed during a planned inspection at the Chashma Nuclear Power Plant (CHASNUPP) that was being performed by PNRA staff from the Regional Office. During their visit at CHASNUPP team members also had discussions with senior operating staff regarding regulatory body – licensee interactions.

In carrying out the review the team recognized that the PNRA was established in 2001 and has taken major steps, within a short time-scale, to develop its regulatory system and effective regulatory supervision of nuclear installations in the Islamic Republic of Pakistan.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Experts: Petr Krs and Jongile Majola

1.1. GOVERNMENTAL STRUCTURE

The Islamic Republic of Pakistan became an independent sovereign state in 1947. The Constitution was passed on 10 April 1973 by the National Assembly which consisted of members elected by the people of Pakistan.

The Constitution of the Islamic Republic of Pakistan provides for a Federal Parliamentary System of government, with the President as the Head of State and the popularly elected Prime Minister as the Head of Government. The federal legislature is defined by this Constitution as a bicameral institution (Parliament) composed of the National Assembly and the Senate.

The administration of the country is governed by the Federal Government, Provincial Governments (four provinces), Local Governments and other Governmental Agencies or Departments. The composition of the Federal Government is as follows:

- Head of State
- Head of Government
- National Assembly
- Federal Ministers
- Federal Government Ministries
- Federal Government Departments/Authorities
- Attorney General
- Judiciary

Within this structure the PNRA acts as the Federal Government Authority for the regulation of nuclear matters, based on the PNRA Ordinance No. III of 2001 (hereafter referred to as the PNRA Ordinance 2001) and other general rules of conduct for government and state affairs. By this, the PNRA is a fully independent nuclear regulatory body in the structure of authorities of state administration, and reports directly to the Prime Minister. Through the Prime Minister, the Chairman of the Authority has direct access to the Government, when matters related to nuclear safety or other responsibilities of the authority are under discussion.

Major interfaces of the PNRA within the overall state administration structure of Pakistan are:

- Ministry of Interior and Defence: Co-ordinates with the PNRA in the development and implementation of emergency preparedness measures, physical protection measures, and security. This Ministry is also responsible for land planning and construction affairs.
- Ministry of Environment: Co-ordinates with the PNRA in evaluating environmental impact assessment issues.

- Ministry of Health: Co-ordinates with the PNRA in implementing the regulations in the health facilities and hospitals where ionizing radiation is used.
- Ministry of Communication and Railways: Co-ordinates with the PNRA in the safe transport of nuclear and radioactive materials.
- Ministry of Industries, Labour and Manpower: Is responsible for industrial safety.
- Public Administration: Has off-site responsibility for emergency preparedness and emergency response.
- Pakistan Atomic Energy Commission (PAEC): In general, is responsible for promoting nuclear energy, in particular, it is responsible for the operation of nuclear installations including both nuclear power plants (NPPs) in Pakistan, research facilities and waste management and storage facilities.

The process of establishing links to allow for co-ordination among the PNRA and other governmental and non-governmental bodies having competence in areas related to nuclear safety or other responsibilities of the authority is in progress (see also 2.1.1 for recommendations and suggestions related to this issue).

1.2. LEGISLATIVE FRAMEWORK

In Pakistan, similar to other countries, the regulatory body has gone through a gradual process towards independence. The activities related to the promotion of the use of nuclear energy started in Pakistan as early as 1955. In 1965, the Pakistan Atomic Energy Commission Ordinance was promulgated under which the Pakistan Atomic Energy Commission (PAEC) became a statutory body. According to this Ordinance, all nuclear installations were owned and operated by the Federal Government through the PAEC.

In 1985, the Directorate of Nuclear Safety and Radiation Protection (DNSRP) was established as the regulatory authority. This was however part of the PAEC. In 1990, the Pakistan Nuclear Safety and Radiation Protection Regulations were promulgated. The regulations were applicable to all establishments which dealt with nuclear energy and ionizing radiation.

The Government of Pakistan signed the Convention on Nuclear Safety in 1994. As a result of this, a first step was taken by the Government to separate the regulatory functions from the promotional aspects of its nuclear programme and the Pakistan Nuclear Regulatory Board (PNRB) was established in 1994. The PNRB was a semi-independent entity from the PAEC, as five of its seven members had no link with the Commission. The executive arm of the PNRB was the DNSRP.

The effort to establish a regulatory framework independent from the promotion of the use of nuclear energy and ionizing radiation was completed in 2001, when the President of the Islamic Republic of Pakistan promulgated the “Pakistan Nuclear Regulatory Authority Ordinance”. To do this he exercised his exclusive powers, when the National Assembly and the Senate were suspended, based on the “Proclamation of Emergency” of 14 October 1999. This order by the President of Pakistan has been published for general information as the PNRA Ordinance 2001.

Normally, under article 89(1) of the Constitution of the Islamic Republic of Pakistan (which was passed on 10 April 1973), ordinances are valid for a period of four months.

However, given that the constitution is held in abeyance by the Provisional Constitution Order (PCO) No. 1 of 1999, and that article 5(a)(1) of the PCO makes ordinances promulgated by the President of Pakistan or the Governor of a Province not subject to the limitations on duration prescribed in the Constitution, the PNRA Ordinance 2001 will remain in force unless it is repealed. Therefore, the continued existence and independence of the PNRA appear to be assured.

The Constitution of Pakistan is the supreme law, and no other law contravenes it. The provisions of the Constitution are applied directly. It stands on top of the current nuclear legislative structure applied in Pakistan (see Appendix I). The Rules of Business define the basic framework for the conduct of state and government affairs. The layers of the legislation for the safe regulation of nuclear facilities consist of:

- The PNRA Ordinance 2001 which provides for the establishment of the Pakistan Nuclear Regulatory Authority for the regulation of nuclear safety, radiation protection, transport and waste safety in Pakistan, and the extent of civil liability for nuclear damage resulting from any nuclear incident;
- A set of implementing regulations – secondary legislation - (five in power, six in different stages of development) covering all major areas such as siting, construction, operation and decommissioning of nuclear installations, radiation protection, radioactive waste management, transport, emergency planning, quality management, etc.;
- Regulatory guides, up to now mostly taken over from the former nuclear regulatory arm of PAEC, DNSRP.

Any international treaties, which have been ratified by the constitutionally established procedure, promulgated and having entered into force with respect to the Islamic Republic of Pakistan, are considered as a part of the national legislation. They supersede any contradicting national legislative act.

The entering into force of the PNRA Ordinance 2001 creates an obligation on the PNRA to adapt, adopt or develop secondary legislation (i.e. regulations). Until the secondary legislation adopted or developed by the PNRA is in place, previously issued regulations shall be applied, insofar as they do not conflict the PNRA Ordinance 2001.

It was noted by the experts, that even though the PNRA Ordinance 2001 does not explicitly mentions the process of decommissioning, however, the first draft is being developed.

It is the standard practice, that legally binding regulations to be issued by authorized bodies of state administration are subject to review regarding their consistency with the rest of the prevailing legislation. This is done by a competent body (or bodies) of state administration. In the past this practice was exercised in the case of regulations developed by the PNRA. However, the team was informed that in the last case (PAK/913 “Regulations on Safety of Nuclear Power Plants – Operations”) the Ministry of Law has rejected, up to now, the request for a consistency check. In the opinion of the team the practice of consistency checks of draft regulations prepared for issuance by the PNRA has to be continued, of course in a way that respects internal rules of conduct of government business in Pakistan. In connection with this, the availability of legal advice to the PNRA was brought to the attention of the counterparts by the team (see also Section 3.1 of this report).

When complete, the new state of the art legislative framework for the use of nuclear energy and ionizing radiation will form sufficient grounds for the consistent execution of all functions and responsibilities of the independent nuclear regulatory authority in Pakistan. Supported by the appropriate regulatory guidance, it should allow all the potential applicants to develop their licensing cases in a systematic and effective manner. In the view of the team, formal plans (including responsibilities and timetables) for (a) the development of the remaining secondary legislation (Regulations) and (b) the review of existing and/or the development of new guidance on the secondary legislation (Regulatory Guides) shall help the management to finalize the consolidation of the new legislative framework in a defined timeframe and scope.

The regulations (including those under development) and guides are listed in Appendix I.

1.2.1. Recommendations and Suggestions

(1) **BASIS:** The IAEA Safety Standards Series GS-R-1 “Legal and Governmental Infrastructure for Nuclear Radiation, Radioactive Waste and Transport Safety” (hereafter referred to as the IAEA SSS GS-R-1) states in paragraph 3.2. that: *“In fulfilling its statutory obligations, the regulatory body (1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;”* and paragraph 3.4. that: *“In order to discharge its main responsibilities the regulatory body (9) shall ensure, that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations;”*

- (a) Recommendation: The PNRA management should establish a comprehensive formal plan (including responsibilities and timetables) to:**
- **Finalize the development of the new secondary legislation (Regulations); and**
 - **Review existing and/or develop new guidance on the new secondary legislation (Regulatory Guides);**
- with the aim of facilitating the consolidation of the new legislative framework within a defined timeframe and scope.**

1.3. BUDGET AND FINANCIAL RESOURCES OF THE REGULATORY BODY

In addition to the legal and political independence, the financial independence of the PNRA is ensured through the funding mechanisms available to the PNRA. The PNRA budget is defined every year in the frame of the State Budget allocated to general state administration. The funds of the Authority are comprised of grants from the Federal Government and income from authorizations and the issuance of licences.

The PNRA drafts a budget proposal and presents it to the Office of the Prime Minister. Approval of the final State Budget rests with the Parliament. Since the establishment of the PNRA, the amount of funds made available to the Authority has remained stable. Moreover, the PNRA has access to additional funds in case of unforeseen circumstances. The PNRA management has reported no major difficulties in planning and receiving from the State Budget the financial resources it needs. Nevertheless, in relation to the budgeting of the

PNRA, the team is finally of the opinion that as the Authority gradually develops into a full-fledged nuclear regulator, executing all of its duties and responsibilities, and continuing to follow the evolution in technology and methodology, the demand (need) for additional funds for the PNRA will increase. This may be even more relevant if the plans for new nuclear power plant (NPP) units and waste management facilities start to be realised, and/or the expansion of nuclear technologies in other areas such as medicine and industry takes place.

The PNRA also has authority and financial resources within its budget to acquire external technical support and initiate research and development (R&D) work, as necessary, to support its activities. However, the same constraints mentioned above, with respect to the financing of core PNRA activities, apply to these funds.

Despite limited resources available both in the short- and mid- term, the PNRA should develop an effective mechanism to define the research and development programme needed to ensure that its competence and knowledge are maintained at the state-of-the art level.

1.3.1. Recommendations and Suggestions

(1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 6.17. that: *“The achievement of a high level of nuclear radiation, radioactive waste and transport safety in States depends on operators discharging their prime responsibility for safety and on the regulatory body being competent, efficient and adequately resourced. Achievement of a high level of safety will be greatly facilitated by an adequate supporting infrastructure for nuclear radiation radioactive waste and transport related activities.”*

a) Recommendation: The Government and, as appropriate, concerned organizations should (continue to) pay attention to, and provide for adequate resources for:

- **External independent technical support to the PNRA,**
- **The Research and Development programme of the PNRA to ensure that its competence and knowledge are maintained at state-of-the art level.**

1.4. INDEPENDENCE OF THE REGULATORY BODY

As mentioned earlier in Section 1.1 of this report, the PNRA Ordinance 2001 and Rules for conduct of governmental affairs establish all the legal prerequisites for the independence of the nuclear regulatory body in Pakistan.

There is a clear legal separation between the responsibilities and functions of the PNRA and those organizations or bodies that are charged with the promotion or use of nuclear installations or the conduct of nuclear activities.

There is a direct reporting line of the PNRA to the Government. The Chairman has access to the Prime Minister (and the Federal Government), when matters related to nuclear safety or other responsibilities of the office are discussed.

As an illustration of its independence, the PNRA ordered the shut down of the Karachi Nuclear Power Plant (KANUPP) in 2002 to resolve outstanding safety issues. There was not any evidence found by the team of political pressure regarding this or any other regulatory body decision.

The PNRA is in the process of developing and formalising links with other parts of the governmental structure that are directly or indirectly involved in area of its competence. When established, these interfaces will allow the PNRA to enhance the effective discharge of its responsibilities (see also Section 2.2 of this report).

The PNRA has the authority to communicate independently its regulatory requirements, decisions and opinions and their basis to the public. However, this authority (responsibility) has not yet been exercised to a large extent. In the future, efforts in this area will be characterised by a more pro-active approach by the PNRA to engaging the public and other stake holders (see Section 2.2 and 3.2 of this report). Involvement of PNRA management in this task and appointment of a person responsible for communication with public relations skills will be a good step forward to resolving this issue.

The PNRA has the authority to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information. However, the link to the IAEA is through one of the major licensees – the PAEC. This was found by the team not to be in line with prevailing international practice (see also Section 2.4 of this report).

In the view of the experts, the PNRA has no authorities or functions assigned to it which may jeopardize its regulatory responsibility and independence. The regulatory body can make judgements and take enforcement action, without pressure from interests that may conflict with safety.

1.4.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 2.6. that: *“The regulatory body shall have the authority to: (11) communicate independently its regulatory requirements, decisions, and opinions, and their basis, to the public...”*
 - (a) **Recommendation:** The PNRA should establish the means, including processes, to communicate independently its regulatory requirements, decisions, and opinions, and their basis, to the public. The details of how this may be achieved are at the discretion of the PNRA, however, the Secretary of the Authority and the management and staff of the PNRA would normally be expected to play a significant role.
 - (b) **Recommendation:** The PNRA should consider arranging for training in making presentations, communicating risk information to non-technical people and on handling the media (television, radio, newspapers, etc.) to be provided to the permanent members and key management and staff of the Authority, whom may be called upon to address stakeholders and the media, on behalf of the PNRA.

- (c) **Suggestion: The PNRA should complete and then implement the plan it has for improving public awareness (PA) of its role in nuclear, radiation, transportation and nuclear waste safety.**

1.4.2. Good practice

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 2.2 (2) that: *“A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.”*

- (a) **Good practice: Pakistan has established an effective separation of the nuclear regulatory body from organizations and bodies charged with promotion of the use of nuclear energy and ionizing radiation. The head of the regulatory body reports directly to the Prime Minister. This feature, among others, strongly support the independence of the PNRA as required in IAEA Safety Standards.**

2. AUTHORITY, RESPONSIBILITY AND FUNCTIONS OF THE REGULATORY BODY

Experts: Petr Krs and Jongile Majola

2.1. REGULATORY AUTHORITY

Section 1.2 of this report described the legislative framework establishing the Pakistan Nuclear Regulatory Authority (PNRA) as an ongoing corporate body with perpetual succession. The legislative framework confers certain powers, functions, responsibilities and resources that make the PNRA the sole national competent authority for the regulation of the safety of nuclear installations, the protection of risks arising from ionizing radiation, the extent of civil liability for nuclear damage resulting from any nuclear incident, and related or ancillary matters.

Although it may be necessary to provide training and periodic refresher courses on the legislative and regulatory framework for nuclear regulation in Pakistan, as it is completed, the management and staff of the PNRA appear to have a good understanding of the authority, responsibilities and functions assigned to them by the PNRA Ordinance 2001.

To judge the extent to which the authority, responsibilities and functions given to the PNRA by the legislative framework in Pakistan meet international standards for nuclear regulatory bodies, the provisions of the PNRA Ordinance 2001 have been compared to those addressed in the IAEA SSS GS-R-1, and recognized good international practice.

Identifying the linkages and relationships between the authority of the PNRA and the requirements stipulated in the IAEA SSS GS-R-1 shows that the PNRA is not only empowered to develop safety principles and criteria, or to make rules, regulations, and orders, or to establish codes of practice and policies, and to issue guidance, but also, among other authorities, to:

- Require an operator to conduct a safety assessment (pursuant to section 19(3) of the PNRA Ordinance 2001, PAK/909, the “Regulation for Licensing of Nuclear Installations in Pakistan (PAK/909)(Rev. 0)”, and section 6 of PAK/912, the “Regulations on the Safety of Nuclear Power Plants – Quality Assurance (QA) (PAK/912)(Rev. 1)”);
- Require an operator to provide necessary information, including information from its suppliers, even if this information is proprietary (section 28 of the PNRA Ordinance 2001);
- Issue, amend, suspend or revoke authorisations and to set conditions (sections 19 – 25 of the PNRA Ordinance 2001 and section 14(11) of PAK/909);
- Require an operator to perform a systematic safety assessment or perform a periodic safety review (PSR) over the lifetime of facilities (section 11 of PAK/909 and subsections 10.1 – 10.6 of PAK/913, the “Regulations on the Safety of Nuclear Power Plant Operations (PAK/913)(Rev. 1)”);
- Enter a site or facility at any time to carry out an inspection (section 29 of the PNRA Ordinance 2001);

- Enforce regulatory requirements (by dint of a number of relevant paragraphs in sections 16 and 45 of the PNRA Ordinance 2001);
- Communicate directly at the highest level with governmental authorities when it is considered necessary (article 3(4) of the Rules of Business, 1973, and the linkages to key related agencies established by sections 4(5)(b) – (d) of the PNRA Ordinance 2001);
- Obtain such documents and opinions from private or public organizations or persons as may be necessary or appropriate (primarily section 28, but also sections 14 and 15, of the PNRA Ordinance 2001);
- Communicate independently its regulatory requirements, decisions, and opinions, and their basis, to the public (sections 16(2)(j) of the PNRA Ordinance 2001);
- Make available to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate (paragraph 16(2)(j) and section 39(2) of the PNRA Ordinance 2001);
- Liaise and co-ordinate with other governmental and non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and the transport of dangerous goods (section 39(2) of the PNRA Ordinance 2001); and
- Liaise with the regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information (sections 38 and 39 of the PNRA Ordinance 2001).

Based on this analysis, the legislation promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transportation safety in Pakistan provides the PNRA with authority commensurate with recognized international practice and standards. The authority assigned to the PNRA is in compliance with the requirements of the IAEA SSS . GS-R-1. Having established the overall adequacy of PNRA authority, at least in the legislation, we turn next to the responsibilities and functions defined by its legislative and regulatory framework.

2.2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

According to the Ordinance 2001, the PNRA is responsible for controlling, regulating and supervising all matters related to nuclear safety, radiation safety, transport and waste safety, and the extent of civil liability for nuclear damage resulting from any nuclear incident.

The Authority, consisting of the Chairman, who serves as the Chief Executive Officer of the PNRA, two full-time members, seven part-time members and a non-voting Secretary, all appointed by the Federal Government of Pakistan, carries out this mandate assisted by a complement of technical and support staff, who serve as the executive arm of the PNRA, charged with carrying out the day-to-day responsibilities and functions of the Authority.

One key responsibility and function of the PNRA is to establish a framework of legal and guidance instruments (e.g. rules, regulations, orders, codes of practice, policies and guides) on which to base its regulatory actions. Examples of these are listed in Appendix I.

The rules, regulations, orders, codes of practice, policies and guidance devised, adopted, made or issued by the PNRA, and forming its regulatory framework, incorporate the safety principles and criteria of the Authority, which it is empowered to establish by sections 16(2)(a), 16(2)(b), and sections 55 and 56 of the PNRA Ordinance 2001.

To expedite its fulfilment of this key responsibility of establishing a regulatory framework, the Authority has established, promoted, or adopted and adapted regulations and guides upon which its regulatory actions are based, by examining:

- past and existing practices,
- equivalent documents of international organizations and other regulatory bodies,
- the nuclear technology used in Pakistan,
- the legislative framework within which it has to work, and
- the results of research and development projects.

The PNRA has produced some regulations and guides, but the work on the regulatory framework is not yet complete. The Authority has sought to fill any gaps it identifies as it proceeds with developing and implementing the framework.

The responsibilities and functions of the PNRA extend beyond establishing a regulatory framework. The authority, obligations and powers of the PNRA engender other responsibilities and functions, which the Authority must discharge on behalf of the Government and citizens of Pakistan. These functions and responsibilities have been reviewed through the prism of international (state of the art) requirements described in the IAEA SSS GS-R-1. The results of the review show (see more detailed information in Appendix VII) that the responsibilities and functions of the PNRA include:

- Reviewing and assessing submissions on safety from operators, both prior to authorisation and periodically during operation as required. The PNRA accomplishes this through a programme it has developed for that purpose, using national and international standards.
- Providing for issuing, amending, suspending or revoking of authorisations, subject to conditions, as necessary. The PNRA has set the requirements, and developed processes for the discharge of this function or responsibility.
- Setting conditions of authorisations that specify:
 - The facilities, activities, or inventories of sources covered by the authorisation;
 - The requirements for notifying the regulatory body of any modifications to safety-related aspects;

- The obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;
 - Any limits on operation and use (such as dose or discharge limits, action levels, or limits on the duration of the authorisation);
 - Conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;
 - Any additional separate authorisations that the operator is required to obtain from the regulatory body. The PNRA sets such conditions and issues such authorisations using the authority conferred to it by the PNRA Ordinance 2001;
 - The requirements for incident reporting;
 - The reports that the operator is required to make to the regulatory body;
 - The records that the operator is required to retain and for how long; and
 - The emergency preparedness arrangements.
- Carrying out regulatory inspections.
 - Ensuring that corrective actions are taken if unsafe or potentially unsafe conditions are detected.
 - Taking the necessary enforcement action in the event of violations of safety requirements.
 - Establishing a process for dealing with applications, such as applications for the issuing of an authorisation, accepting a notification, or the granting of an exemption, or the removal from regulatory control.
 - Providing guidance to the operator, on developing and presenting safety assessments or any other required safety-related information.
 - Ensuring that operating experience is appropriately analyzed and that lessons to be learned are disseminated.
 - Ensuring that appropriate records relating to the safety of facilities and activities are retained and retrievable.
 - Ensuring that the its regulatory principles and criteria are adequate and valid, and that they take account of international standards and recommendations.
 - Establishing and informing the operator of any requirements for systematic safety reassessment or periodic review.
 - Advising the government on matters relating to the safety of facilities and activities.
 - Confirming the competence of personnel responsible for the safe operation of the facility or activity.
 - Confirming that safety is managed adequately by the operator. The PNRA discharges the function and responsibility through its inspection programme and periodic safety reviews.

Furthermore, the PNRA has other functions and responsibilities relating to how it co-operates with other relevant authorities, advises them, and provides them with information in the following areas:

- Environmental protection;
- Public and occupational health;
- Emergency planning and preparedness;
- Radioactive waste management, including the determination of national policy;
- Public liability, including the implementation of national regulations and international conventions concerning third party liability;
- Physical Protection: The mandate of the PNRA does not extend to safeguards but covers physical protection, pursuant to section 16(2)(f) of the PNRA Ordinance 2001.

Perhaps unsurprisingly, given the limited contacts and co-ordination of activities between the PNRA and the other potentially relevant authorities, no conflicts between the Authority and such entities have arisen, been noted, or are expected to arise. Furthermore, the scope and level of PNRA activity in these areas has precluded any material conflicts with the Authority's main regulatory functions or other nefarious (i.e. negative) effects that may have led to the diminution of the responsibility of the operator for safety.

In a number of areas, the responsibilities and functions of the PNRA appear either not to be aligned, or to require improvement or to need to be augmented to make them consistent, with the IAEA SSS GS-R-1. These are:

- Developing policy documents. Except for perhaps the quality management policy, the Authority has hitherto not given a lot of priority to developing and elaborating policies in stand-alone documents distinct from regulations, regulatory guides and internal procedures of the PNRA. This situation is likely to change as the relatively new regulatory body evolves.
- Establishing a process for changing conditions of authorisations. This process is not addressed explicitly by the PNRA, even though the Authority has the power to set conditions (as noted above, including, in particular, sections 19(4) and 25(b) of the PNRA Ordinance 2001). It is expected that this issue will be addressed in the PNRA review and assessment programme.
- Ensuring that proprietary information is protected. Although there are processes and criteria for classifying and handling information and documents, and, pursuant to section 51 of the PNRA Ordinance 2001, PNRA members, management and staff make a declaration of fidelity and secrecy, no written procedure has been established to guide and control the handling of proprietary licensee information.
- Providing an explanation of the reasons for the rejection of a submission. Nothing in the PNRA Ordinance 2001 enjoins the Authority to accept applications or submissions that do not meet its requirements. A regulatory body should reject submissions that are not within its mandate or that are never likely, by their very

nature, to meet its regulatory requirements. This issue is expected to be addressed in the PNRA review and assessment programme.

- Communicating with, and providing information to, other competent governmental bodies, international organizations and the public. The PNRA is charged with this function and responsibility through paragraph 16(2)(j) and sections 39(2) and 39(3) of the PNRA Ordinance 2001. Also, the provision for co-operation with international organizations, in section 38 of this ordinance implicitly gives the PNRA the authority to carry out this function, internationally.
- Water and consumption of food: The PNRA has not yet established contacts or liaisons with other relevant regulatory authorities in this area.
- Land use and planning: The PNRA has not yet established contacts or liaisons with other relevant regulatory authorities in this area, but it receives No Objection Certificates (NOCs) from them as part of licence application submissions from operators of nuclear installations.
- Safety in the transport of dangerous goods: Transport across the borders of Pakistan requires a No Objection Certificate from the PNRA. The Authority has also written to the Civil Aviation Authority, the Directorate of Technical Procurement at the Pakistan Atomic Energy Commission (PAEC), and the Ministry of Railways, informing them of the PNRA role in, and regulatory requirements for, the transport of radioactive material or goods.
- Independent radiological monitoring in and around nuclear facilities: The PNRA does not do so at this time, but plans to carry out such a function in the future.
- Independent testing and quality control measurements: The PNRA is currently not carrying out such functions but witnesses the tests and quality control measurements of operators.
- Initiating, co-ordinating and monitoring safety-related research and development work in support of its regulatory functions: The PNRA is not performing this function at this time except for support for the research by the university students it has recruited.
- Providing personnel monitoring services: This function is expected to be difficult to carry out, but the PNRA plans to do it in future.
- Monitoring of nuclear non-proliferation: This function is not part of the mandate of the PNRA.
- Regulatory control of industrial safety: This function is not part of the mandate of the PNRA; however, from time to time, the Authority feels morally obliged to exert such control at nuclear installations, in view of the deference to the PNRA by, and the absence at nuclear installations of inspectors from, the Ministry of Industry. The regulatory control of industrial safety is normally covered by an Ordinance whose responsibility for implementation lies with the Ministry of Industry.

2.2.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.1. that: *“In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.”*

The PNRA has a process and plans for developing regulations and guides, some of which incorporate policies, but stand-alone policy documents do not seem to figure prominently in the PNRA document hierarchy or priorities.

- (a) Recommendation: The PNRA should consider including policies in its hierarchy of documents and develop them as needed according to agreed priorities.**

- (2) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.3. that: *“In order to discharge its main responsibilities, as outlined in paragraph 3.2., the regulatory body: (4) shall ensure that proprietary information is protected...”*

The PNRA has a procedure for handling secret information but none yet formally for proprietary information.

- (a) Recommendation: The PNRA should consider developing an explicit procedure for handling and protecting proprietary information.**

- (3) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.4. that: *“The regulatory body shall co-operate with other relevant authorities, advise them, and provide them with information on safety matters in the following areas, as necessary:
(4) radioactive waste management (including determination of national policy)...
(7) water use and consumption of food...
(8) land use and planning...
(9) safety in the transport of dangerous goods...”*

The PNRA is an independent autonomous body which, pursuant to article 3(4) of the Rules of Business, 1973, reports to the Chief Executive (the Prime Minister) of Pakistan, through its Chairman, with seemingly limited other proactive, systematic, and formal interaction with its non-licensee and non-PNRA member ancillary stakeholders.

Given its autonomy, its reporting relationships, and the opportunities for improving the way it interacts with its stakeholders that the review team has identified, favourable consideration of the following recommendations should strengthen the PNRA’s ability to discharge its responsibilities for engaging its stakeholders.

- (a) Recommendation: The PNRA should identify, develop and maintain a list of contacts at key governmental and non-governmental bodies with which it needs to liaise and co-ordinate its activities, to improve its regulatory performance (i.e. to increase its regulatory effectiveness and efficiency). In particular, the PNRA should identify the other relevant authorities in waste management, water and food consumption, land use and planning, and safety in the transport of goods, and develop contacts and liaisons with**

them, right from the early stages of the development of the PNRA regulatory framework.

- (b) **Suggestion: Links with key governmental and non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and the transport of dangerous goods should be formalised, for instance through memoranda of agreement (MOA) or understanding (MOU).**

2.3. PUBLIC INFORMATION

The PNRA is charged with communicating with, and providing information to, the public, through section 16(2)(j) of the PNRA Ordinance 2001. At present, this communication is limited to a web site and a system of press releases, which is yet to be used.

Although the public is not directly involved in the process for granting authorisations, be they licences, permits, registrations or no objection certificates, it is expected that communication with the public will increase in future. The authority intends to increase its effectiveness in this area, through a programme of public awareness which is under development.

2.3.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.2. that: *“In order to discharge its responsibilities, as outlined in paragraph 3.2., the regulatory body: (6) shall communicate with, and provide information to other competent governmental bodies, international organizations, and the public...”*

Recommendations for improvements in this function and responsibility, with respect to the public, have been presented in the previous Section 1.4.1 of this report dealing with the authority of the PNRA.

- (a) **Suggestion: The PNRA should consider encouraging the operator to develop a programme for public awareness, including communicating incidents to the public, before the regulatory authority makes such an announcement. This has been identified as a good practice in some countries.**

2.4. INTERNATIONAL CO-OPERATION AND LIAISON

As noted above, section 38 of the PNRA Ordinance 2001 gives the PNRA the authority from which the responsibility for international co-operation and liaison flows. As part of discharging this responsibility, The PNRA has established formal links with the regulatory body of China. These links facilitate co-operation on a number of fronts, including the exchange of information and the training of PNRA staff.

Representatives of the Authority have taken part in some international meetings of regulatory bodies or had some informal exchanges with counterparts from a number of countries.

Thus, except for the connections with China, the scope of PNRA links and liaisons with regulatory bodies of other countries appears to be limited. This raises questions about the degree to which the PNRA is kept abreast of developments within the international nuclear regulatory community, and the extent to which it can incorporate these (e.g. international agreements, conventions and treaties) into its regulatory framework.

PNRA liaisons with international organizations like the IAEA also appear to be constrained. For instance, the official channel for contact between the PNRA and the IAEA is through the Pakistan Atomic Energy Commission (PAEC), a licensee of the Authority. This is most unusual.

2.4.1. Recommendations and Suggestions

(1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 2.6. that: *“The regulatory body shall have the authority to: (14) liaise with the regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information...”*

(a) Recommendation: The PNRA should consider creating a mechanism for keeping abreast of international developments, particularly conventions and treaties in areas such as waste management and transportation, to facilitate their incorporation into the national regulatory framework, to maintain the regulatory framework at the state of the art.

(2) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.2. that: *“In order to discharge its responsibilities, as outlined in paragraph 3.2., the regulatory body: (6) shall communicate with, and provide information to other competent governmental bodies, international organizations, and the public...”*

The scope of PNRA links and liaisons with regulatory bodies of other countries and international organizations appears to be limited. The Authority has formal links only with the regulatory body of China and liaises with the IAEA through the one of its licensees.

(a) Recommendation: The PNRA should continue to increase efforts to widen the scope of its links and liaisons with regulatory bodies of other countries and with international organizations, to promote co-operation and the exchange of regulatory information.

(b) Recommendation: The PNRA should seek government approval for direct contact and accreditation as a Government of Pakistan contact for liaison with the IAEA. It is most unusual, and not at all in line with accepted international practice, for official and primary contact between a nuclear regulator and the IAEA to be done through a licensee of the regulator.

3. ORGANIZATION AND INDEPENDENCE OF THE REGULATORY BODY

Experts: Petr Krs and Jongile Majola

3.1. ORGANIZATIONAL STRUCTURE

The primary task of the PNRA is to oversee and assess the nuclear safety and radiation protection of nuclear installations and activities in Pakistan. The PNRA is an independent body of state administration, which reports to the Government through the Prime Minister. PNRA independence from the organizations or bodies charged with promotion or use of nuclear technology is established in law.

The Authority comprises of a Chairman, two full time members (Executive and Corporate) and seven part time members. The Authority meets at least three times per year to discuss and/or approve policy matters related to areas of the PNRA competence. The next level of the PNRA structure consists of three technical directorates at the Head Office, and three Regional Nuclear Safety Directorates (RNSDs) located at Islamabad, Chashma and Karachi, which report to the Executive Members through their respective Directors General. The regional directorates cover all of Pakistan and are responsible for the licensing and inspection of nuclear and radiation facilities within their respective zones. There is an independent department of corporate affairs led by the Corporate Member of the Authority, which is responsible for human resource development, education and training of regulatory staff, public awareness, and information on safety related matters to the public, etc. This department is presently concentrating on three aspects, namely, the Quality Management & Education and Training unit, the Public Awareness unit and the Safety Research and Development (SR&D) unit (see Appendix II for the PNRA Organizational Structure).

The Chairman is the chief executive officer of the Authority and, according to section 5 of the PNRA Ordinance 2001, the Chairman is responsible for the day to day administration of the affairs of the authority, as specified by the law. The Chairman of PNRA reports directly to the Prime Minister. According to the PNRA Ordinance 2001, the Chairman and members of the Authority are appointed by the Government of Pakistan for a term of four years; they are eligible for re-appointment for a period of four years but not for more than two consecutive terms. The Chairman is assisted by a Secretariat.

Issues related to policies/decision-making are discussed in the Authority meetings headed by the Chairman and including two full-time members and seven part-time members. The Authority is a state budget legal entity with headquarters in Islamabad. The structure, activity, organization and functions are delineated/proposed by the Chairman.

The PNRA Ordinance 2001 defines the Chairman as a primary distributor of budgetary credits in consultation with members of the Authority and the Director of Finance. The Directorates of Administration and Finance assists the Chairman in the implementation of his authorities related to administration and budgetary issues.

The specialized functions of the Authority are carried out by the following departments reporting to the Executive Member of the Authority:

Directorate of Nuclear Safety (NSD): This directorate deals mainly with the safety of nuclear power plants and assists the Chairman of the Authority in the implementation of his

regulatory and control functions related to NPPs. The functions of NSD include development of regulations, licensing, re-licensing, safety analysis, review and assessment, inspection and enforcement, Periodic Safety Review (PSR), disseminating information on safety related events and maintenance of database of facilities.

Directorate of Radiation Safety (RSD): This directorate deals mainly with the Radiation Protection and Emergency Preparedness and assists the Chairman in performing his regulatory and control functions related to sources of ionizing radiation. Main activities include development of the regulatory framework for radiation safety, nuclear and radiation emergencies, ALARA implementation, occupational radiation protection, radiological protection of patients, protection of the public and the environment - monitoring and analysis etc.

Directorate of Transport and Waste Safety (WSD): This directorate deals mainly with the Transport and Waste Safety of radioactive material and assists the Chairman in performing his regulatory and control functions related to activities in this area, including development of the regulatory framework for Transport and Waste Safety, physical protection, regulatory oversight over technologies of radioactive waste management, maintaining and disseminating information on safety related events, assimilating and disseminating current international safety developments, providing guidance and assistance to regional directorates, regulation of disposable radioactive waste, technologies of disposable radioactive waste management and decommissioning etc.

Regional Directorates of Nuclear Safety (RNSDs): There are three regional directorates situated respectively in Islamabad, the Chashma Nuclear Power Plant (CNPP) site at Chashma and in Karachi. These deal mainly with the safety of NPPs and nuclear facilities other than NPPs and assist the Chairman in the implementation of his regulatory and control functions related to inspection and enforcement, the licensing of all facilities (excluding NPPs), public awareness, training and certification of occupational workers, the review and assessment of all facilities, the licensing of personnel at nuclear facilities, and the licensing of research reactors.

The PNRA structure includes the **Department of Corporate Affairs** as one complete section dealing with matters related to human resource development, education and training of regulatory staff, public awareness, information to the public on safety related matters, regulatory effectiveness, regulations rules and standard operating procedures, legal affairs, creation of a technical support center, acquiring the services of advisors and advisory committees, safety research and development, severe accident analysis, advice on export control, co-ordination of international affairs and training, etc. This section is placed under the supervision of the Corporate Member who directly reports to the Chairman of the Authority. The structure also includes the post of a Director General which is vacant at present.

There is a project planed to educate the public on the harmful effects of radiation and to deal with the media. It has to initiate its work soon.

The work related to Human Resource Development and Education and Training has already started.

Two task forces, namely, the Special Task Force under Executive Member and the Task Force for the Development of Symptom Based Emergency Operating Procedures under

Corporate Member, have been established. The objectives of the first task force are to implement the IAEA Projects (RAS/9/26 & 27), assess safe operation of the NPP and radiation facilities through environmental monitoring using gamma-ray-spectrometry, to educate operators of radiation facilities on radiation safety and to maintain a database of radiation sources and users. The objectives of the second task force are to independently conduct simulations and accident analyses as required in Chapter 16 of the Final Safety Analysis Report (FSAR).

There are no technical Advisory Committees created to provide competent and independent advice to the Chairman on important issues related to nuclear safety and radiation protection.

In general, the present organizational chart of the PNRA seems to be well structured. However, the team is of the opinion, that the effective and reliable discharge of the PNRA competencies would be more supported if the internal audit function would be included to the organizational structure. Moreover, the responsibility for internal quality management should not be assigned to the organizational unit not directly reporting to the head of the organization.

3.1.1. Recommendations and Suggestions

(1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 4.9. that: *“The government or the regulatory body may chose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. ... The advice may be technical or non-technical.”*

a) **Suggestion: The PNRA should consider, including in internal plans, the establishment of technical Advisory Committees to the Chairman, as there are appropriate provisions in the PNRA Ordinance 2001.**

3.2. STAFFING AND TRAINING

Staffing

The PNRA currently employs 114 persons. According to their basic education, they can be divided into the following groups: engineers, physicists, other scientists, technical staff, and general administration staff. The staff distribution amongst the sections and units is as follows:

- The PNRA has sixty (60) professionals, forty-eight (48) of whom report to the Executive Member. Of these forty-eight, twenty-six (26) are at the headquarter level and twenty-two (22) belong to the three Regional Nuclear Safety Directorates (RNSD): RNSD-I has six (6), RNSD-II nine (9) and RNSD-III has seven (7) professionals;
- Eleven (11) professionals work in the Nuclear Safety Department, while the Waste Safety Department incorporates six (6) professionals and the Radiation Safety Department seven (7); they report to the Executive Member as well;
- Five (5) professionals belong to the section reporting to the Corporate Member of the Authority. In addition, the four (4) professionals at the Chairman Secretariat also partially report to the Corporate Member.

The rest of the employees are administrative and PNRA top management staff. The Organizational Chart of the PNRA is included in Appendix II.

The number of staff employed by the PNRA has been gradually increasing since the establishment of the PNRA through the recruitment of new personnel. Thirteen new scientist/engineers were recruited to the PNRA recently. The PNRA is now in the process of the second recruitment drive for fifteen scientists/engineers, which is planned to start soon.

Since the Authority was established only two years ago, a lot was achieved to develop an effective mechanism to ensure that the PNRA fulfils its statutory obligations and provides an effective control of nuclear, radiation, radioactive waste and transport safety in Pakistan. However, it appears to the team that to undertake all the functions and responsibilities, the number of PNRA staff shall increase gradually, based on periodic evaluation of human resource availability against the work to be done.

A marked non-balance between responsibilities assigned and staff allocated was noted by the team for the branch headed by the Corporate Member. As there are legislative, quality assurance (QA), research and development (R&D), public affairs, self-assessment and other important activities to be delivered by this branch, assignment of only five professionals seems not to be sufficient. Lack of workforce in this area is partially compensated by part-time use of experts from the executive branch (see organizational chart).

Another area where PNRA staff resources appear insufficient is in the area of emergency preparedness. The current officer is skilled and has a number of years' experience in the area; however, other members of staff assigned to this area have limited experience. It is not clear that an understudy for the emergency preparedness officer has been identified. If the existing individual were to be absent or to leave the PNRA, there would be no backup. Also, based on the number of challenges faced by the PNRA in the emergency preparedness area (see Section 8.0), additional skilled staff are needed.

In the view of the experts, the PNRA exercises its authority and carries out its assigned functions without compromising its regulatory responsibility and independence. However, the workload of the staff will most probably require further adjustments and assessment by the PNRA management to meet existing and future demands. Similar to budgeting, the execution of plans for new NPP units and waste management facilities as well as the expansion of nuclear technologies in other areas will also increase the demand for strengthening the PNRA workforce. Availability and access to independent technical support to the PNRA is another important aspect in the consideration of the adequacy or sufficiency of human resources.

3.2.1 Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 4.6. that: *“The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.”*

- (a) **Suggestion:** The PNRA management should continue its recruitment campaign, with the view to provide sufficient staff not only in the executive branch, but also to satisfy corporate (administrative support) activities. The adequacy of staffing in different departments and units should be assessed on a periodic basis and, based on the results, appropriate adjustments should be implemented by the PNRA management. Accessibility to independent external technical support should be considered in this connection.

Training

The PNRA invests substantial resources in terms of both personnel and monetary costs in the training of its staff. Significance of training is even higher since there is an aggressive recruitment campaign going on to strengthen the professional workforce of the PNRA up to seventy five in 2005. The QM&ET unit implemented a programme with the objective to provide basic knowledge to new as well as existing staff members in the field of nuclear, radiation, transport and waste safety. While starting education and training activities, the following four key areas were identified and some fundamental decisions were taken; these are:

Competency Framework: To adopt the IAEA TECDOC- 1254 “Training the staff of the regulatory body for nuclear facilities: A competency framework” to PNRA practice and carry out a systematic training needs assessment (TNA) to identify competency gaps and devise a strategy to fill these gaps.

School for Nuclear Safety: To establish a school for nuclear safety for imparting training in nuclear, radiation, transport and waste safety.

Training Materials and Trainers: To use the already existing materials, training modules and training courses available through the IAEA or other multilateral or bilateral arrangements and to use distance learning materials for e-learning available at the IAEA web site. As far as the trainers are concerned, the PNRA believes it has adequate qualification in-house to train new entrants (with only few exceptions in specialized areas where IAEA assistance would be required).

Other Means of Training: To enhance its participation in technical assistance projects of the IAEA and to increase the number and quality of workshops/seminars/scientific visits for sharing knowledge in focused areas relevant to the present and future PNRA needs.

The PNRA also looks after the fellowship programme concurrently initiated with the Pakistan Institute of Engineering and Applied Sciences (PIEAS), where fifteen young scientist/ engineers are attending a two-year masters programme in nuclear engineering, medical physics and system engineering. PNRA bears all the expenditures incurred on their studies in respect of tuition fees, monthly stipend, study tours and attachment with hospitals in Pakistan. This is a continuous programme in which five engineers/scientists are awarded fellowships at PIEAS each year.

Competency Framework

As stated above, based on the suitability in terms of implementation and relevance to the work of the PNRA, it was decided to adopt the four-quadrant competency model given in IAEA-TECDOC-1254 as the competency framework for education and training of PNRA staff. Systematic assessment of the PNRA training needs is now being performed in

collaboration with Lahore University of Management Sciences (LUMS) to identify the gaps in competency of the PNRA staff so as to design the training strategy to fill these gaps. This is a costly endeavor for the PNRA and, as the Authority does not have the required expertise to carry out such a systematic training need assessment on its own, the services of consultants from LUMS were procured with a cost sharing of about 30% by IAEA under TC Project PAK/9/023 “Strengthening of Nuclear Regulatory Authority in Pakistan”. Technical expertise in this assessment is provided by the PNRA while LUMS consultants are acting as facilitators. The study is in an advanced stage now and it is expected that it will be completed by December 2003.

School for Nuclear Safety

In order to train the newly recruited direct inductees, a school called “PNRA School for Nuclear Safety” was also established under PNRA auspices. The purpose of the School is to design and deliver a structured training programme for newly recruited as well as existing technical personnel in the area of nuclear, radiation, waste and transport safety. The syllabus of the school may be subject to modifications so as to be able to fill the gaps in the competency of the staff identified through the systematic assessment of PNRA training needs (see paragraph above). Short training courses for radiation protection in diagnostic and interventional radiology also will be offered based on training material provided by the IAEA.

Other Means of Training

It is the opinion of experts that the PNRA is using well the education and training activities available through IAEA Technical Assistance and Regional Assistance Projects. The TC Project (PAK/9/023) “Strengthening of Nuclear Regulatory Authority in Pakistan” has been a great contributor to capacity building at the PNRA in the area of education and Training. It was reported, that nineteen fellowships/scientific visits and an equal number of experts mission were conducted under this project. Two national workshops, one on review, assessment, inspection and enforcement activities of NPPs, and the other on the design of NPPs were held and were participated by a large number of persons even from the operating organization. The PNRA intends to hold another workshop in the area of Probabilistic Safety Assessment and Risk-Informed Decision Making in March 2004, in collaboration with the IAEA in Islamabad. The PNRA is also participating in TC-Project RAS/9/028 “Asian Safety Network” with the aim of knowledge sharing among Asian States. Apart from these, the PNRA is participating in the following IAEA-sponsored projects RAS/9/018, RAS/9/021, RAS/9/022, RAS/9/026, and RAS/9/027. The PNRA is of the opinion, that restriction to just one TC Project for a newly established regulatory authority in the process of capacity building is counter to the real needs of the authority. Experts also noted certain restrictions because of the unavailability of more direct links to the Agency as is the norm for most regulatory authorities in the world (see also Section 2.4. of this report).

The PNRA staff show great interest in increasing its competence in a number of areas and it is believed, that staff will support the implementation of the new training policy. It is understood that the effort and support from the management and necessary resources should be maintained to successfully continue the implementation of a systematic approach to the individual training of PNRA personnel in order to ensure consistency in the conduct of regulatory activities.

3.2.2. Good practice

(1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 4.7. that: *“In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes.”*

a) **Good practice:** **The PNRA has developed a sound training policy, which takes into account the needs of the organization and the individuals, as well as recent scientific and technological developments. The training programme is tailored to the needs of the PNRA being a newly established regulatory authority which is in the process of capacity building.**

3.3. QUALITY MANAGEMENT

The PNRA quality management programme is still under developed. To-date, the Authority has developed a policy for quality management, incorporated it into a draft quality manual describing the quality management system the Authority proposes to use.

The PNRA quality management system is based on a combination of the IAEA TECDOC 1090 (“Quality assurance within regulatory bodies”, IAEA, June 1999) the ISO 9001:2000 quality management system, and quality management and quality assurance systems of other regulators. The steps taken so far include:

- Determining the PNRA processes (i.e. core processes) covered by the quality management system;
- Defining and documenting the process structure and describing the processes;
- Developing technical procedures for quality management, and
- Defining candidate performance indicators to be used.

The PNRA is developing a process for implementing its regulatory effectiveness indicators programme within a framework of regulatory self-assessment.

While the PNRA programme under development includes the basic principles and elements of quality management, it is too early to judge or not clear that it enjoys:

- A clear commitment from all levels and areas of PNRA management and that management is taking the lead to get it developed and implemented;
- There is enough interaction with and incorporation of outside expertise and experience to facilitate the development of the system in-house. (Note that the system must be developed primarily in-house for it to be successfully implemented within the PNRA); and
- Active involvement, at the early stages, of all parts of the organization, to start and facilitate the usually long organizational learning and adoption process.

Addressing these issues and observations will put the PNRA quality management programme on a firmer footing. Once implemented, it will help:

- Improve understanding and communication of PNRA work and information;

- Help the PNRA retain, manage, share and integrate knowledge;
- Make the PNRA more transparent, with optimised processes and clearly defined accountabilities internally;
- Keep the focus on PNRA priorities and core activities; and
- Provide a framework for continuous improvement.

3.3.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA Safety Standards Series GS-G-1.1 “Organization and Staffing of the Regulatory Body for Nuclear Facilities” (hereafter referred to as GS-G-1.1) states in paragraph 3.9. that: *“For a regulatory body to fulfil its statutory obligations, it should develop a regulatory management system with the necessary arrangements for achieving and maintaining a high quality of performance in regulating the safety of nuclear facilities under its authority.”*
 - a) **Suggestion:** The PNRA should proceed with establishment of a quality management programme, taking account of some of the observations noted above.

4. AUTHORIZATION PROCESS

Experts: Claudio T. M. Camargo and Marjan F. Levstek

The PNRA Ordinance 2001 establishes the Pakistan Nuclear Regulatory Authority (PNRA) and provides the legislative basis “for regulation of nuclear safety and radiation protection in Pakistan and the extent of civil liability for nuclear damage resulting from any nuclear incident”. Section 16(2) defines powers and functions of the PNRA, and specifically under 16(2)(h), “to grant authorization, or issue license for the production, storage, disposal, trade in and use of any nuclear substance, radioactive material or any other substance or equipment used for production or use of nuclear energy as the Authority may, by notification in the official Gazette, specify”.

The authorization process is based mainly on section 19 of the PNRA Ordinance 2001. In section 19 it states: (1) “No person shall, unless he is exempted as may be prescribed by regulations, or unless he is the holder of a licence issued by the Authority:

- (a) acquire, design, manufacture, construct, install or operate any device that contains any radioactive material or produce ionizing radiation including consumer products, sealed sources, unsealed sources and radiation generators including, mobile radiography equipment;
- (b) establish installations and facilities which contain radioactive materials or devices which produce radiation including irradiation facilities, mines and mills processing radioactive ores, installations processing radioactive substances, nuclear installations and radioactive waste management facilities;
- (c) explore for mine and mill, extract, acquire, handle, use for medical, industrial, veterinary, or agriculture purposes, or for education, training or research, etc., sell, lease, lend, buy, transfer, import, export, convert, enrich, produce, store, process, reprocess, fabricate, transport, dispose of any radioactive ores, radioactive material, nuclear substance or any other substance as the Authority may, by notification in the official Gazette, specify.”

Furthermore, sections 21 to 22 also prescribe that:

- No person shall commence construction of any nuclear installation without first obtaining an authorization for the purpose from the Authority as may be prescribed by regulations (for the purposes of this section, “construction” includes the siting, designing and construction of buildings for, and every stage of setting up of a nuclear installation).
- No person shall discharge, or dispose of, radioactive waste to the environment without first obtaining an authorization for the purpose from the Authority as may be prescribed by regulations.

4.1. TYPES AND STAGES OF AUTHORIZATION

The authorization process in Pakistan results in the issuance of the following legal documents:

- **Licence** - a legal document issued by PNRA granting authorization to perform specified activities related to a facility or activity, which may require renewal after a term of

validity. For nuclear installations the PNRA issues two types of licenses i.e., construction and operating licence.

- **Permit** - a legal document issued by the 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 (e.g. for the registration of the site of a nuclear or radiation facility) 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. granting authorization to facilitate a licensee or a permit holder import or export of nuclear material or radiation equipment (e.g., import of fuel for a nuclear power plant, or radiation sources/apparatus, etc.).

4.1.1. Licensing procedure for nuclear facilities

Regulation for Licensing of Nuclear Installation(s) in Pakistan - PAK/909 (Rev. 0) sets the licensing procedure for nuclear installations in Pakistan.

When a decision has been taken to construct a nuclear facility the applicant notifies the PNRA Chairman in writing as early as possible of his intention to establish and operate a nuclear installation.

The licensing procedure for nuclear installation(s) in Pakistan consists of the following stages:

- (i) Registration of Site.
- (ii) Issuance of the Construction Licence.
- (iii) Issuance of the Operating Licence.

All the activities performed by the PNRA for an issuance of a licence follow Internal Working Procedure “Procedure for issuance of authorization to nuclear installations”, No. PNRA-WP-00003, Rev. 0, September 2003. The procedure consists of ten steps, ranging from the first notification of intent by an applicant, to licensing beyond the design life of the installation.

The documents submitted pursuant to regulation PAK/909 are reviewed by the PNRA. The requirements for format and content of the documents to be submitted by the operator in support of applications for authorization have not yet been established in PNRA regulations. However, the PNRA and the licensee have agreed upon the adoption of the US NRC guides pursuant to Section 5(2) of PAK/909 for a specific case - preparation of CHASNUPP Unit 1 Preliminary Safety Analysis Report (PSAR) and Final Safety Analysis Report (FSAR).

On the basis of the reviews and all other information that the PNRA may have, the Authority takes the final decision with regard to issuing a licence, including the terms and conditions to be attached thereto, as deemed to be necessary.

Normally an operating licence is valid for a period of up to ten years. Six months before its expiry, the licensee has to apply for its revalidation along with submittal of the latest

Periodic Safety Review (PSR). These revalidations of an operating license usually can be granted up to the design life of the nuclear installation.

The decision whether or not to seek to re-licence beyond the design life rests entirely with the licensee. In the case of a positive decision, the licensee is required to furnish evidence that the structures, systems and components important for safety are capable of performing their intended functions in a safe manner for the duration of the extended life. An application for re-licensing may be submitted at the earliest 10 years before the end of the expected design life but no later than 3 years before the expiration of the current licence.

According to the regulation PAK/909 section 4 (11), the license granted shall normally be valid, subject to, among other conditions, compliance with applicable requirements and amendments, which may be formally notified by the PNRA from time to time.

The above mentioned Internal Working Procedure does not address explicitly how the process for changing the conditions of the authorizations is established. It is expected that the process will be addressed in the PNRA review and assessment programme, which is still in draft form.

The experts have gone through many examples of changing authorization conditions, being aware that the process is basically the same as that adopted for the issuance of an authorization. Although this process is not explicitly regulated by any internal procedure, it should be performed according to IAEA standards.

To familiarize themselves with the adopted working practices, the IRRT experts examined the process of issuing the Operating Licence for CHASNUPP Unit 1. Considering the above mentioned three stage licensing procedure, the unit has been granted a site registration, a construction license and a fuel load permit. Until all the prerequisites for obtaining the operating license have been fulfilled, the plant is allowed to operate by permits which release formal hold-points. Knowing that the terms of any authorization are binding for the licensee the conditions therein must be clear and unambiguous. However, it was found that the examined fuel load permit is not fully in accordance with the IAEA standards. When defining “the conditions that the Licensee shall undertake” relevant deadlines for their implementation were not always clearly defined.

The first refuelling was set as the first hold point for some of the conditions. The old Procedure for licensing NPPs in Pakistan, No. DNSRP-NILREG-007/90, of February 14, 1990 was followed, supplemented by the Office Memorandum of PAEC of 19.12.1991 “Implementing instructions for licensing of nuclear power plants in Pakistan”. The memorandum introduces requirements for licensing related to the format of documents to be submitted by the licensee and defines the basis for the safety review.

Intermediate steps and hold-points requiring the consent of the regulator were introduced by a decision of the Board, which was following the steps during commissioning and which was giving consent for all the steps. The decisions of the Board were given to the licensee in the form of Interoffice Memoranda.

Since some of the conditions were not fulfilled on time, the licensee notified the PNRA of these delays in writing and requested a waiver from the conditions until the second refuelling. The PNRA analysed the case and found that there were no unresolved safety issues. Therefore the PNRA responded by allowing the operation of CHASNUPP Unit 1 until the second refuelling.

Presently all conditions are fulfilled by the licensee and the PNRA has already drafted the Operating Licence.

So far as the IRRT experts were able to see, the PNRA has conducted the associated review and assessment process and formally recorded the basis for all of these decisions in accordance with requirements of IAEA standards on these matters.

4.1.1.1. Recommendations and Suggestions

(1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 5.6. that: *“Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure...”*

(a) Recommendation: The PNRA should consider developing an explicit procedure for changing the conditions of authorizations.

(2) **BASIS:** The IAEA Safety Standards Series GS-G-1.4 “Safety Guide Documentation for Use in Regulating Nuclear Facilities” (hereafter referred to as the IAEA SSS GS-G-1.4) defines in paragraph 5.10. to 5.21. the format and content of a licence.

(a) Suggestion: In the preparatory process of issuing the Operating Licences it is suggested that the format and content given in the IAEA SSS GS-G-1.4 is applied.

4.1.2. Licensing of shift personnel

Regulations on the Safety of Nuclear Power Plants Operations (PAK/913), (Rev. 1) in its Appendices IV to VI to Annex I define criteria for licensing of shift personnel. Criteria for licensing the following shift personnel positions are defined:

- Shift Supervisor
- Shift Engineer, and
- Reactor Operator

(For additional comments regarding the use of Draft Rev. 1 of PAK/913 refer to Section 7.1 of this report).

The criteria consist of pre-requisites that define conditions related to qualification, training and experience for the candidates to become eligible to take the written licensing examination.

Licensing Examination consists of written, oral and operating examinations. Written examinations are conducted by the licensee while the oral and operating examination of the individuals qualified by written examination are conducted by the Authority. Eligibility

Criteria define the minimum educational qualification for each position, experience of shift operation at a nuclear power plant, and the condition to qualify for the written, operating and oral examinations.

The paragraph on the “Issuance of License”, in Appendices IV to VI to Annex I of PAK/913, sets the detailed procedure from the written examination up to the issuance of the licence. The written examination consists of the following subjects: Radiation Protection, Nuclear Safety and Technical Specification, Operating Policies and Principles, Nuclear General and Conventional General. The syllabus for the courses for the training/retraining and for the written examination is prepared by the licensee and has to be approved by the Authority. The pass marks for the written test are defined. The licensee has to apply to the Authority for licensing of operating personnel and attach for each candidate a certification of medical (including psychological) fitness of the candidate. The candidate is normally allowed only two attempts to clear the operating and oral licensing examinations. In very exceptional cases and on specific intervention of the licensee a third chance may be allowed by the PNRA Chairman or an officer designated by the Chairman. Upon successfully passing the written, operating and oral examinations the operator license is issued to the candidate by the respective Regional Director.

The paragraph on Retraining of Operation Personnel sets the criteria for retraining of the licensed personnel and internal examination. It determines the validity of the licence, its extension, cancellation, invalidation or suspension. Licensed individuals who fail to perform the licensed duties for a certain period of time can re-acquire the operator license or have to undergo complete re-examination, depending of the time gap. Periods for retention of records are fixed; provision for licensing of foreign nationals is given and the procedures for waiver and exemptions are defined.

Internal procedure “Procedure for licensing of nuclear power plant operating personnel” No. PNRA-WP-00004, Rev.1, September 2003, issued on the basis of PAK/913, Rev. 1, is a practical guide for the implementation of PAK/913 requirements.

4.1.3. Licensing of NPP modifications

Section 8 of the Regulation on the Safety of Nuclear Power Plants Operations (PAK/913) (Rev. 1) defines modifications as:

- (i) Modifications to structures, systems and components;
- (ii) Modifications to the operational limits and conditions;
- (iii) Modifications to instructions and procedures; or
- (iv) A combination of the above; and
- (v) Modification of organizations.

(For additional comments regarding the use of Draft Rev. 1 of PAK/913 refer to Section 7 of this report).

Section 8.3. of PAK/913 (rev. 1) sets the requirements that the following proposed modifications shall be submitted to the Authority for prior approval: modifications to structures, systems and components important to safety, modifications which affect the bases on which the operating license was issued, modifications to the operational limits and conditions, and to procedures and other documents originally approved by the Authority. Any

other proposed modifications shall also be submitted to the Authority for prior approval. Modifications shall be categorised according to their safety significance.

The text, as it is drafted, sets the requirement that, in addition to the proposed modifications to structures, systems and components important to safety that have to be submitted to the PNRA for prior approval, any other proposed modifications also have to be submitted to the Authority for prior approval. That would mean that for all modifications the licensee has to seek approval of the regulatory body. This is not in accordance with the IAEA Safety Standards and would also represent an unnecessary burden to the licensee and an unjustified workload to the PNRA.

The PNRA uses the “Internal Management Procedure for review of design modifications of nuclear installations,” No. PNRA-WP-1104, Rev. 1 of July 2003. This procedure describes the methodology for the review of all such proposed modifications submitted by the licensee/applicant (the Process Flow Chart for Design Modification Review is presented in Appendix VI).

4.1.3.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-G-1.4 defines in Appendix A.14. that: *“Any modification proposed that may have a significant effect on safety related aspects should be implemented only if it has been authorized...”*
 - (a) **Suggestion: In the review process of the draft regulation PAK/913 attention should be given to Sub-Section 8.3, to define in accordance with the IAEA Safety Standards the modifications that would require the PNRA prior approval.**

4.2. AUTHORIZATION AND OTHER PROCESSES

The PNRA Ordinance 2001 defines the power of the PNRA to issue, cancel and suspend an authorization or a licence.

Sub-sections (2) to (5) of Section 19 state that:

- (2) The Authority may, on application made to it accompanied by such fee, information and documents, as may be prescribed by regulations; issue a licence for carrying out such activities as are specified in the licence for such period as may be so specified.
- (3) The Authority may require an applicant to demonstrate by submitting the required information that the activity for which the licence is required would not be hazardous to public or the environment.
- (4) The Authority may prescribe terms and conditions that may be attached to a licence.
- (5) The Authority may require the establishment of effective reporting procedure in respect of radiation accidents and ensure that the plans for mitigating the effects of nuclear incidents have been prepared.

Section 20 states that:

- (1) The Authority may, on application made to it accompanied by such fee, information and documents, as may be prescribed by regulations, grant an authorization for carrying out of such activities as are specified in the authorization for such period as it may specify.
- (2) The Authority may specify terms and conditions that may be attached to an authorization.

Section 24 introduces the power to cancel or suspend an authorization or a licence:

- (1) Where any person has been found to have contravened any of the provisions of this Ordinance, the rules and regulations, or has consistently failed to comply with the terms and conditions of an authorization or, as the case may be, a licence, the Authority may, subject to sub-section (2), cancel or suspend the authorization or, as the case may be, the licence.
- (2) Before taking any action under sub-section (1), the Authority shall issue a notice to such person to show cause and give him an opportunity of being heard or an opportunity to rectify the omission subject to such conditions as the Authority may specify.

Section 25 defines actions to be taken subsequent to cancellation or suspension of licence:

In case the Authority cancels or suspends a licence under Section 24, it may subsequently undertake all or any of the following actions in respect of the installation or facility covered under the licence, namely:

- (a) ask the licensee to put the installation or facility in safe state and shut down the installation or facility;
- (b) permit the licensee to continue operating the installation or facility under such term and conditions as the Authority may specify; or
- (c) appoint another person to take over the operation of the installation or facility.

The Regulation for Licensing of Nuclear Installation(s) in Pakistan - PAK/909 (Rev. 0) sets regulatory requirements for the licensing of nuclear installations.

Internal Working Procedure “Procedure for issuance of authorization to nuclear installations”, No. PNRA-WP-00003, Rev. 0, September 2003 describes the authorization process of the PNRA to be followed by its staff so that they can carry out their functions in a systematic, effective, consistent and transparent manner. This procedure also describes various stages of the PNRA authorization process along with the steps followed for issuing these authorizations.

4.3. DOCUMENTS PRODUCED BY THE REGULATOR

Sections 19 and 20 of the PNRA Ordinance 2001 empowers the PNRA to prescribe terms and conditions that may be attached to the licence/authorization.

In the authorization process the PNRA produces several types of internal documents as a result of an interactive process of responding to licensees’ submissions, as well as

documents which are a result of communication with the licensee, and several types of authorizations.

The first step in the authorization process for major projects is usually to reach an agreement with the applicant on the mode of submission of the required documents and the schedule for the review process, to facilitate the planning of the applicant's activities.

As part of the review process a task force is established. It may raise queries with the applicant, evaluate the applicant's responses to the queries and hold review meetings to resolve pending issues. The queries, responses and further actions arising from this process are recorded in "action sheets" that are signed by both, the PNRA and the applicant. The task force may also identify needs for additional information and/or revision of the original submission. After completion of the review process, the task force forwards its final assessment report to the Director NSD along with a justification for acceptance or rejection of the application.

A review co-ordinator prepares a case for issuance of a permit/licence. He recommends terms and conditions, if any, to be attached to the permit/licence. The Director NSD may also recommend additional terms and conditions. Terms and conditions are an integral part of the permit/licence.

The director NSD formally communicates PNRA decisions regarding the issuance of a permit/licence to the applicant in writing.

4.4. DOCUMENTS PRODUCED BY THE LICENSEE/APPLICANT

Section 19(3) of the PNRA Ordinance 2001 states that the Authority may require an applicant to justify in writing, that the activity for which the licence is required would not be hazardous to public or the environment.

Section 4 of the Regulation for Licensing of Nuclear Installations in Pakistan - PAK/909 (Rev. 0) defines the documents that have to be submitted by the applicant for each step in the PNRA authorization process for a nuclear installation.

Before applying for site registration, construction licence and the operating licence, the applicant has to submit a No Objection Certificate (NOC) from the relevant departments of the Federal, Provincial and Local governments.

An applicant who intends to obtain the registration of a site for a nuclear installation has to submit, together with the application, a Site Evaluation Report (SER). After approval of the SER and registration of the site, the applicant has to establish design and safety criteria in accordance with the nuclear regulations and guides and submit them for approval by the PNRA. After completion of the preliminary design the following reports have to be submitted to the PNRA for review, approval and issuance of the construction licence: Preliminary Safety Analysis Report (PSAR), Overall Quality Assurance Programme (OQAP) and models and results of the Probabilistic Safety Analysis (PSA) Report, Level 1.

After completion of the detailed design and the safety analysis, the licensee has to submit an application for introducing nuclear materials into the systems of the nuclear

installation accompanied by the Final Safety Analysis Report (FSAR), Probabilistic Safety Analysis Level One Plus Report (PSA Level 1 plus), Commissioning Reports up to introduction of nuclear materials, Technical Specifications, Radiation Protection Programme, Emergency Preparedness Plan, Inspection Programme, Fire Protection Programme, Environmental Monitoring Programme duly approved by the appropriate Environmental Protection Agency (EPA), Radioactive Waste Management Programme, Pre-service Inspection (PSI) and In-service Inspection (ISI) Programme, Physical Protection Programme, Decommissioning Strategy and any other report/technical document requested by the PNRA.

With the application for an operating licence the applicant will submit commissioning reports of the various systems in the installation, results of the first start-up and full capacity tests, and updates of all the documents which were submitted with the application for the construction licence.

Six months before the expiry of the licence, the licensee shall apply for its revalidation along with an updated report of latest Periodic Safety Review (PSR).

A licensee may apply to the PNRA for re-licence beyond the design life. The following documents for assessment and verification have to accompany the application: updated report of latest Periodic Safety Review (PSR), revised Final Safety Analysis Report (FSAR), Probabilistic Safety Analysis Report (level one plus) based on actual plant design and operation data, Decommissioning Programme, an evaluation of the potential impact on the environment, and any other report/technical document requested by the PNRA.

5. REVIEW AND ASSESSMENT

Experts: Claudio T. M. Camargo and Marjan F. Levstek

5.1. ESTABLISHMENT AND USE OF REVIEW AND ASSESSMENT CRITERIA

Section 5 of the Regulation for Licensing of Nuclear Installation(s) in Pakistan - PAK/909 (Rev. 0) sets the requirements for the use of nuclear safety standards. In accordance with Section 5, all nuclear installations in Pakistan have, for the purposes of siting, design, construction, commissioning, operation and decommissioning, to conform to the latest regulations which are issued. Currently these regulations are:

(a) For nuclear power plants:

- (i) Regulation on the Safety in Nuclear Power Plants Siting (PAK/910).
- (ii) Regulation on the Safety in Nuclear Power Plants Design (PAK/911).
- (iii) Regulation on the Safety in Nuclear Power Plants Quality Assurance (PAK/912) and related regulatory guides.
- (iv) Regulation on the Safety in Nuclear Power Plants Operations (PAK/913) and related regulatory guides.

In those areas where PNRA regulations and regulatory guides do not provide the necessary guidance, the relevant latest US Nuclear Regulatory Commission regulations/guides are deemed to be applicable. Alternately, the licensee may choose to follow the latest revisions of the applicable IAEA Safety Standards and Requirements along with the relevant safety guides issued there under. However, if nuclear safety standards of another country are proposed to be applied, it shall be demonstrated by the licensee to the full satisfaction of the PNRA that the standards proposed to be used offer the same or better standards of quality, safety and reliability that would have been offered by the nuclear safety standards mentioned above.

5.2. MANAGEMENT OF REVIEW AND ASSESSMENT

5.2.1 Leadership

The first step of the review and assessment process is the designation of a team leader by the Executive Member PNRA. The team leader will be a senior management level person, having a wide variety of experience in PNRA regulation and processes. The team leader will be provided with all necessary resources. He will be accountable for completing the task efficiently, effectively and professionally

5.2.2. Human resources

The Executive Member PNRA will designate team members in consultation with the Director NSD and the team leader. The team members will consist of the staff with relevant experience. Less experienced personnel may be part of the team, but they will work under direct supervision of the senior team members.

5.2.3. Planning

The Director NSD and team leader discuss and finalise with the applicant the schedule of submissions as required by the Regulations. The schedule will indicate the dates on which the documents will be received at the PNRA. The team leader will elaborate the

detailed plan and schedule for various activities of the review and assessment process, which are finalised after discussions with the applicant.

5.2.4. Management of the KANUPP relicensing process

The IRRT experts were introduced to this process through the presentation of the work conducted on the KANUPP extension-of-life submittal.

5.3. PERFORMANCE OF REVIEW AND ASSESSMENT

5.3.1. Review and Assessment Process

PNRA's internal working procedure for issuance of authorization to nuclear installations No. PNRA-WP-00003, Rev. 0, September 2003, briefly defines the review and assessment process at the Regulatory Body.

The review and assessment of applicant's submissions is performed according to an established process. The main steps of this process include formation of a task force, review of the submission by the task force, formulating an evaluation report and preparing a case for issuance or rejection of an authorization/licence.

The review process itself consists of reviewing the format and content of the submissions to verify completeness, identifying and querying issues that are not acceptable to the PNRA or where further clarification is required, and resolving these issues to the satisfaction of the PNRA. The respective clarification can be achieved in the course of correspondence with the applicants and/or during review meetings. Action sheets are prepared for each query resulting from the review process. The PNRA may also hire consultants/advisors from within and outside the country, if necessary.

After completion of the review, the task force submits its evaluation report to the Director NSD, recording the bases for acceptance or rejection of the analysis and information presented by the applicant. The review co-ordinator accordingly prepares a case for issuance of an authorization/licence. The case is processed through the Director NSD. The decision to issue the licence is made by the Executive Member PNRA, who also approves the licence conditions that then become an integral part of the licence. In addition to the terms and conditions recommended by the review co-ordinator, the Director NSD and the Executive Member PNRA may also specify additional conditions for the licence.

5.3.1.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA Safety Standards Series GS-G-1.2 "Safety Guide on Review and Assessment of Nuclear Facilities by the Regulatory Body" (hereafter referred to as the IAEA SSS GS-G-1.2) requires in paragraph 3.2. that: *"The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met... Consideration should be given to the extent to which the regulatory body's internal guidance may be made available to operators ..."*
 - (a) **Suggestion:** The PNRA should consider giving higher priority to the preparation and implementation of the "PNRA Review and Assessment

Programme” and consider the possibility that the Programme is made available to the operators.

5.3.2. Conduct of the review and assessment

Apart from defining the review and assessment process in the organizational sense, the procedure described above does not really set out working instructions to be followed in the review and assessment process nor a guidance on the safety objectives to be met. This will, in accordance with the PNRA's schedule, be a subject of the PNRA Review and Assessment Program that is under preparation.

As mentioned in Section 4.1.1 of this report, the experts examined the process of issuing the Operating Licence for CHASNUPP Unit 1. That review and assessment of the submissions was started by the former nuclear regulator Pakistan Nuclear Regulatory Board (PNRB) and is now being continued by PNRA. For a specific objective, namely the preparation of severe accident analyses for the CHASNUPP Unit 1, PNRB formed a task force from its own staff. The analyses constitute the bases that will enable the licensee to prepare Severe Accident Management Guidelines (SAMGs) to help fulfil the conditions for the Fuel Load Permit issued by the PNRB in November 1999.

This activity has an historical background since the decision to support the licensee in the preparation of SAMGs was taken before the PNRA had been established, at a time when the PNRB was still part of the Pakistan Atomic Energy Commission (the licensee). The present situation, after the Establishment of PNRA, is rather peculiar in the sense that the members of the task force are now employees of PNRA so that PNRA actually advises the licensee in the fulfilment of the licensee's obligations related to the Fuel Load Permit. PNRA therefore has to be seek to avoid taking responsibility for the SAMGs, which otherwise might jeopardize its independence in regulating this area.

5.3.2.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 requires in paragraph 2.2. (5) that one of the basic requirements for the legislative and governmental mechanisms of States is: *“No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.”*
 - (a) **Recommendation:** The PNRA should not take any responsibility for the content of the resulting Severe Accident Management Guidelines.
 - (b) **Suggestion:** The PNRA should consider encouraging the licensee to provide for an independent review of the Severe Accident Management Guidelines. It could be achieved by the support of the IAEA in the form of RAMP (Review of Accident Management Programmes) mission.

5.4. INTEGRATED ASSESSMENT OF OPERATIONAL SAFETY

In fulfilling its statutory obligations, the PNRA continually conducts review and assessment of submissions on safety from the operator during the operational phase of nuclear

power plants. Complementarily, inspection and enforcement activities are conducted to ensure compliance with regulation requirements and license conditions.

Generally there is a need for a systematic integrated safety assessment to be conducted periodically on nuclear power plant operational safety, confirming that the safety is adequately managed and that the plant performance ensures an acceptable level of safety. Among other things, this requires a comprehensive combination of the results both from inspection and enforcement and from review and assessment activities.

PNRA carried out a kind of integrated safety assessment for Chashma Nuclear Power Plant in 2001. The experts examined the relevant PNRA reports, where the findings were ranked in four categories according to their safety significance based on a survey of review and assessment results and of inspections findings.

Within this context, PNRA representatives confirmed their intention to implement integrated safety assessments on a biannual basis, whereby the main regulation to be considered should be PAK/913. Compliance with the requirements laid down in PAK/913 should be explicitly covered.

Along the same lines, the experts were of the opinion that, when revising PAK/913, the PNRA should consider including in it additional specific requirements for licensee event reporting that are currently addressed through plant Technical Specifications.

5.4.1. Recommendations and suggestions

(1) **BASIS:** The IAEA SSS GS-G-1.2 requires in paragraph 2.18. that: *“For routine operation the regulatory body should require that the operator report regularly on adherence to safety objectives and compliance with specified regulatory requirements, and on efforts made to enhance safety. The regulatory body should review and assess the reports and should perform inspections to confirm compliance with regulatory requirements and to confirm that the facility is able to continue in operation”*.

(a) **Suggestion:** **The PNRA should consider the possibility of implementing a process of systematic integrated safety assessment of nuclear power plant operational safety, combining results of review and assessment and inspections findings, as well as plant safety performance indicators. This assessment should be performed on a periodic basis. Compliance with the requirements of regulations PAK/913 should be explicitly addressed.**

5.5. USE OF CONSULTANTS

Section 40 of the PNRA Ordinance 2001 gives possibility to the PNRA to appoint consultants or borrow their services from other organizations as it may consider necessary for the efficient performance of its functions on such terms and conditions as it may deem fit. The method and procedure of appointment of consultants shall be regulated by rules to be made with the prior approval of the Federal Government, while borrowing their services may be mutually settled between the lending organization and the Authority.

Management procedure for review of design modifications of nuclear installations, No. PNRA-WP-1104, Rev. 1 of July 2003 in its Section 6.0 defines the role of the

consultants. The role of consultants will be defined in writing, including, but need not be limited to, submission of proposals, suggestions, conclusions, etc., in writing. However, the role of consultants will be of an advisory nature. The PNRA will give due considerations to the submissions of the consultant, however, final decisions regarding acceptance, rejection, conditional acceptance of the modification will be made by the PNRA.

However, the team noted that sufficient resources of independent expertise in the area of review and assessment are currently not available in Pakistan.

5.5.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 requires in paragraph 4.3. that: *“If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants...”*
 - (a) **Recommendation:** The PNRA should consider developing a capability for the technical support by independent external consultants in the areas where there is not enough expertise or manpower available within the PNRA and preparing a method and procedure of their appointment.
 - (b) **Suggestion:** The PNRA should consider seeking assistance of IAEA for the development of independent expertise in the areas where not enough independent expertise is available.
 - (c) **Suggestion:** The PNRA should consider developing links with other regulatory bodies directly or through IAEA in the area of review and assessment of submissions in authorization process of NPPs.

5.6. SELF-ASSESSMENT OF REVIEW AND ASSESSMENT ACTIVITIES

The arrangements within the regulatory body, which are at present under preparation, are intended to ensure that the findings and decisions have been subjected to a suitable peer review process, conforming to the national practice and the overall quality management system of the PNRA.

The PNRA has started developing a system of management auditing of Regional Nuclear Safety Directorates (RNSD). “Guidelines for performance of objectives and criteria for Regional Nuclear Safety Directorates, No. PNRA-TP-00001 of August 2003”. The guidelines define criteria for performance of the following activities:

- inspection,
- enforcement,
- review and assessment,
- licensing of operating personnel.

The management may perform an audit of the performance of RNSD based on the self-assessment criteria defined in the guidelines.

A set of regulatory performance indicators is being developed as a part of a Quality Management System. The indicators following NEA and IAEA experience will be used also for assessing the review and assessment activities of the PNRA.

5.7. RELATIONS WITH THE LICENSEE

On December 4-5, 2003, two IRRT members visited the Chashma Nuclear Power Plant, located on the Indus River about 280km southwest of Islamabad. This Section summarizes the IRRT members' meeting with licensee management.

The IRRT members met with the Chashma Acting Plant Manager (senior manager on site) and about 15 members of the Chashma "management team," including several representatives from PAEC. No representatives of the PNRA were present. The IRRT members sought the licensee's opinion of the regulatory interface and licensee recommendations for improvements to the PNRA.

The licensee was complimentary of their relations and interactions with the PNRA headquarters and regional staff. The PNRA Individuals are courteous and professional, discussions are open and transparent, and the PNRA staff are highly competent and qualified. The licensee considered communications to be effective and that PNRA responses to licensee submittals and requests have been timely. When appropriate, problems may be elevated to proper levels of management for resolution. Licensee management felt that both the PAEC and the PNRA had a good understanding of the PNRA Ordinance 2001 and regulations, and that the PNRA maintained a suitable level of independence. PAEC is always afforded an opportunity to comment on proposed regulations.

The licensee made several suggestions for PNRA improvement. The PNRA may need additional resources and staff, particularly when regulatory activity associated with Chashma Unit 2 is commenced. Financial resources may be needed to enable the PNRA to obtain certain technical expertise (possibly from outside Pakistan), to conduct certain research activities, and to obtain analytical tools (such as thermal-hydraulic or fuel modelling tools). When asked about regulations and inspection procedures, the licensee suggested that the PNRA may need to develop more regulatory guidance in the areas of licensing, design, and quality assurance. This guidance would be appropriate prior to the initiation of activities for Chashma Unit 2. Regarding inspection procedures, the licensee acknowledged the transparency of inspection scheduling and agreed that occasional unannounced inspections are appropriate.

6. INSPECTION AND ENFORCEMENT

Experts: Lyn Bevington and Richard Wessmann

6.1. OBJECTIVES OF INSPECTION AND ENFORCEMENT

6.1.1. The Legislative basis for Inspection and Enforcement

The PNRA appears to have a strong legislative foundation for conducting both their inspection and enforcement activities. The legislative basis that allows the PNRA to perform inspections of the Licensees' facilities and activities is set down in the PNRA Ordinance 2001. Section 16 of the PNRA Ordinance 2001 defines the functions and powers of the PNRA and in particular section 16(2)(i) empowers the PNRA *"to inspect all nuclear installations, radiation generator, nuclear material, nuclear substance or radioactive material to ensure that regulations concerning safety measures are properly followed"*. Furthermore section 29 of the PNRA Ordinance 2001 empowers the PNRA to enter any premises for the purpose of ensuring compliance with the rules and regulations made there under.

The legislative bases for regulatory enforcement are set down in sections 24(1) and 24(2) of the PNRA Ordinance 2001 and in sections 9(1), 9(2) and 16 of the Nuclear Safety and Radiation Protection Regulations of 1990. Offences under the PNRA Ordinance 2001 and the associated Regulations are defined in Section 44 of the PNRA Ordinance 2001.

The PNRA and the Licensees understanding of the requirements of the legal basis for inspection and enforcement activities were examined during the review. The Regulator and the Licensee did not believe there was any lack of understanding, or clarity in the interpretation of the PNRA Ordinance 2001 and the regulations. This was because of the extensive discussions that had taken place in advance of the PNRA Ordinance 2001 and also on the new Regulations before they are promulgated.

6.1.2. Objectives of Inspection and Enforcement

The objectives of the PNRA approach to inspection and enforcement are described in the documents entitled "Inspection Programme For Nuclear Power Plants" and the "Enforcement Programme" respectively. The PNRA's objective for regulatory inspection is to *"...provide a high level of assurance that all activities performed by the Licensee during all stages of the authorization process and during all phases of the life cycle of a nuclear facility are executed safely and are consistent with the regulations of PNRA and commitments of Licensee..."* The PNRA strategy toward enforcement is based on the promotion of activities to encourage compliance, verification activities to assess the level of compliance and the application of graduated enforcement measures in response to violations by the licensee.

6.2. MANAGEMENT OF INSPECTION

6.2.1. Inspection structure and resources

The PNRA has established an Inspection and Enforcement structure that operates through its Regional and Headquarters Nuclear Safety Directorates. Region II (RNSD II) is responsible for the regulatory inspection of CHASNUPP and Region III (RNSD III) is responsible for the regulatory inspection of KANUPP. The Regional Inspectors are based at the

Nuclear Power Plant sites and are, in effect, resident inspectors. Each Region is led by a Director who is also based on the NPP sites and is able to exert close supervision of the inspection activities. There are currently 9 Inspectors allocated to Region II and 7 Inspectors allocated to Region III. However the Regional Inspectors also inspect other activities involving the use of ionising radiation, such as sealed sources and X-ray generators in their respective regions. For the purposes of regulating the NPPs the PNRA allocates approximately 2-3 person years of Regional staff effort to inspection.

The PNRA have a cadre of Specialist Inspectors available in the Headquarters Directorates based at Islamabad. These Specialist Inspectors are involved with review and assessment but also carry out inspection activities in a range of thematic areas: for example, specialist inspections for compliance with requirements for Quality Assurance, Engineering, Radiation Protection, Emergency Preparedness and Waste Management.

During the IRRT review both the Licensee and the PNRA's inspection staff expressed their belief that the numbers and organization of the existing staff are currently both sufficient and effective. However additional resources will be needed if the proposed Unit 2 for CHASNUPP goes ahead.

6.2.2. Inspection Planning

The PNRA plans NPP inspection activities on an annual basis. The plans are described in the document entitled "Inspection Programme for Nuclear Power Plants". The inspection plan for both CHASNUPP and KANUPP are contained in separate Appendixes to this document. The inspection plans for the NPP sites, including the routine and thematic activities are produced by the respective regions and submitted to Headquarters for information. There does not appear to be a formal planning process between the regions and Headquarters.

6.2.2.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA Safety Standards Series GS-G-1.3 "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body" (hereafter referred to as the IAEA SSS GS-G-1.3) states in paragraph 4.8. that: "*Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections*".

- (a) **Suggestion: The PNRA regions should consider formally involving the Headquarters Directorates in the inspection planning process.**

The current NPP inspection plans contain the areas of activity that are to be inspected, the frequency of inspection, the estimated amount of effort to be expended and which organization within the PNRA is responsible for performing the inspection: Headquarters, the regions or both. Schedules are produced to supplement the plans to identify when the planned activities are to be carried out. Periodically the region provides the inspection schedule to the Licensee.

6.3. PERFORMANCE OF REGULATORY INSPECTION

6.3.1. Types of inspections

Regulatory inspection is carried out by the PNRA using both the regional resident inspectors and the headquarters specialist inspectors. The Regional Inspectors perform the routine inspection activities and are also assisted by the Headquarters Specialist staff when carrying out thematic inspections. Reactive inspections are carried out by all inspectors in response to unplanned events at the NPP sites. Unannounced inspections are also included in their inspection programme, however it appears that these are relatively infrequent.

6.3.2. Internal guidance

The inspections are carried out in line with the current plan and to the procedures and guidance identified in the Inspection Programme. Annexure IV to the Inspection Programme contains a list of the procedures/guides that are to be used for NPP inspection activities.

Examination of the existing Inspection Procedures by the IRRT Experts identified that these documents have a clear structure that defines the objectives of each inspection. The procedures are comprehensive and contain details of the inspection activities that should be undertaken and the supporting guidance/reference material. However, the main point of reference or basis for inspection in the procedures appeared to be the contents of the Final Safety Analysis Report (FSAR). There was no description or reference in the procedures to provide a clear link to the requirements set down in extant regulations such as the Nuclear Safety and Radiation Protection Regulations 1990.

6.3.2.1. Recommendations and suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 5.12. that: *“The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations.”*. Furthermore, paragraph 2.3. of the IAEA SSS GS-G-1.3 states that: *“Regulatory inspection is performed to make an independent check on the operator and the state of the facility, and to provide a high level of confidence that operators are in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that :(a) all applicable laws, regulations and licence conditions and all relevant codes, guides, specifications and practices are complied with...”*

- (a) **Recommendation:** The PNRA procedures should identify the pertinent regulatory requirements, including regulations, against which compliance is to be verified during inspection.

The PNRA Inspection Programme for NPPs defines the preparatory activities that are needed prior to conducting an inspection. These requirements follow the international best practice identified in the IAEA SSS GS-G-1.3. However, examination of a selection of inspection procedures identified that only a few of these requirements for preparation set down in the PNRA Inspection Programme were included as prerequisites for inspection activities.

- (2) **BASIS:** The IAEA SSS GS-G-1.3 states in paragraph 4.14. that: *“Preparation may include a review of the following:*
- *regulatory requirements relating to the inspection area;*
 - *past operating experience relating to the inspection area;*
 - *findings of previous inspections and enforcement actions relating to the inspection area;*
 - *past correspondence between the regulator and the operator relating to the inspection area;*
 - *the safety documentation and operational limits and conditions;*
 - *documentation on operation and design for the facility;*
 - *the operator’s management procedures and quality assurance programme.”*
- (a) **Suggestion:** The PNRA should consider strengthening the requirements for the preparation of inspection activities in their procedures to reflect international best practice.

6.3.3. Methods of inspection

The PNRA carries out planned and reactive inspections that are mainly announced to the Licensee beforehand. However some unannounced inspections are also carried out. Additionally, Inspectors make daily visits to the Main Control Room (MCR) and they conduct weekly plant tours of the radiation controlled area. The inspections involve the processes of monitoring and observation; discussions and interviews; examinations of procedures, records and documents; and tests and measurements. The PNRA inspection process was observed during a planned inspection at CHASNUPP that was being performed by staff from the region who were examining Plant Chemistry records and discussing the contents of these records with the plant chemistry manager. The inspection was conducted in a frank and open manner together with a questioning approach from the Inspectors.

6.3.4. Inspection reports and findings

The PNRA requires that the results of each inspection are entered into an inspection report. The type of report that is produced depends on the nature of the inspection activity undertaken. The inspection findings and reports are provided to the Licensee. However, it was not clear from the distribution list attached to the inspection reports that there is a procedure to disseminate the reports to provide pertinent information to other parts of the PNRA to assist the regulatory process.

6.3.4.1. Recommendations and suggestions

- (1) **BASIS:** The IAEA SSS GS-G-1.3 states in paragraph 4.33. that: *“Inspection reports should be distributed according to established procedures in order to provide for the following:*
- *information to regulatory staff responsible for review and assessment;*
 - *information to regulatory staff responsible for regulations and guides;*
 - *a means of sharing information with other site inspectors working at different locations;”* furthermore paragraph 3.19 of the IAEA SSS GS-G-1.1 states that: *“An inspection may result in a requirement for additional review and assessment or for enforcement actions. For this reason, irrespective of how inspections are organised, there should be strong and effective links with all other units of the regulatory body.”*

- (a) **Suggestion: The PNRA should consider introducing into their procedures a clearly defined process for the distribution of inspection reports to ensure that information is shared with relevant staff.**

The follow up of inspection findings was examined during the review. The PNRA have a programme to monitor and follow up inspection activities. In general open items appeared to be dealt with in a timely manner. However examples were found where some inspection findings had remained open for some time. The approach to dealing with open inspection findings should be strengthened.

6.4. REGULATORY ENFORCEMENT

The PNRA arrangements for enforcement are described in the internal working procedure entitled “PNRA Enforcement Programme”. This document sets down the PNRA overall policy on enforcement along with the enforcement powers of PNRA staff, the enforcement programme and a description of the enforcement process. The powers to enforce regulatory requirements appears to have a strong legislative foundation. The foundation is distributed over two parts of the national legislation, the PNRA Ordinance 2001 and the Nuclear Safety and Radiation Protection Regulations of 1990.

Under the PNRA Ordinance 2001, the PNRA may cancel or suspend a licence or authorization (section 24(1)) and also issue a notice of violation under section 24(2)). The Nuclear Safety and Radiation Protection Regulations of 1990 empower the PNRA to direct any person (in the event of a violation of any provision of the PNRA Ordinance 2001, the regulations or of the terms and conditions of a licence) to take such action to be taken as deemed necessary (Clause 9(1)). Furthermore in the event a violation of the terms and conditions of a licence or breach of regulations posing greater risk to the public, workers or the environment by the operation of the installation than that when the licence was granted, the inspector, with the approval of the Director, may order work to be stopped or suspended (Clause 9(2)).

Examples of written communication between the PNRA and the licensees regarding violation or non compliance were examined and there was found to be a clear reference to the regulatory basis for the enforcement action.

The IRRT experts were informed that a new administrative procedure defining the enforcement process was under development.

6.4.1. Recommendations and suggestions

- (1) **BASIS:** The IAEA SSS GS-G-1.3 states in paragraph 5.14. that: *“The regulatory body should adopt clear administrative procedures and guidelines governing the use and implementation of enforcement actions.”*

- (a) **Suggestion: The PNRA should consider continuing with the development and implementation of the administrative procedure for enforcement action.**

6.5. SELF ASSESSMENT OF INSPECTION AND ENFORCEMENT ACTIVITIES

Discussions between the IRRT experts and the PNRA have identified that arrangements for the self-assessment of inspection and enforcement activities are in the process of being developed. This activity should be encouraged.

7. DEVELOPMENT OF REGULATIONS AND GUIDES

Experts: Claudio T. M. Camargo and Marjan F. Levstek

Section 16(2)(a) “Functions and powers of the Authority” of the PNRA Ordinance 2001, gives to PNRA the power 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. Sections 55. and 56. are more specific and define that the Authority may, with the approval of the Federal Government, by notification in the official Gazette, make rules for carrying out the purposes of this Ordinance and by notification in the official Gazette, make regulations, not inconsistent with this Ordinance and the rules, for carrying out the purposes of this Ordinance.

Regulation for Licensing of Nuclear Installation(s) in Pakistan PAK/909 (Rev. 0) in Section 5 “Applicable Nuclear Safety Standards” allow in those areas where PNRA regulations and regulatory guides do not provide the necessary guidance, use of the relevant latest US Nuclear Regulatory Commission regulations/guides. Alternatively, the licensee may choose to follow the latest revisions of the applicable IAEA Safety Standards and Requirements along with the relevant safety guides issued there under. However, if nuclear safety standards of another country are proposed to be applied, it shall be demonstrated by the licensee to the entire satisfaction of the PNRA that the standards proposed to be used offer the same or better standards of quality, safety and reliability than would have been offered by the nuclear safety standards mentioned above.

7.1. PROCESS FOR DEVELOPMENT OF REGULATIONS AND GUIDES

The PNRA is in the process of preparation of regulations based on the PNRA Ordinance 2001. Regulations PAK/913 establish requirements for the operation of a nuclear power plant and is the basis for the licensing of shift personnel and will also be the basis for issuing the operating licence for CHASNUPP Unit 1. PAK/909 (Rev. 0) in Section 5 makes a provision for the nuclear installations to conform to the latest regulations which have been issued. In the case of PAK/913 a draft has been prepared and internally approved. A letter was sent to the licensee informing him that PAK/913 had been prepared and internally approved and therefore it should be applied. Since some deficiencies of the regulation have already been identified and taking into account the results of a legal screening, some changes to the text will be introduced. The licensee will be informed of any change to the text.

The PNRA has developed an internal guide “Guidelines for Preparing PNRA Regulations, No. PNRA-NSD-GL1 of September 26, 2003.”

The IRRRT experts have been provided with the plan for the development of new regulations. They have been informed that, in the short term, no new regulatory guides are envisaged to be issued.

As pointed out in the IAEA SSS GS-G-1.4 “In order to develop regulations and guides, the regulatory body should have two basic resources: qualified staff and information”. The PNRA seems to be fulfilling adequately these two basic conditions. However, according to recognized international practices, the production of regulations and guides should follow a systematic approach, being covered by the regulatory body’s quality management system.

Although the PNRA quality management system is still under development, activities related to the development of regulations should follow a strategic plan which would provide a vision over the regulatory needs and aims and set the priorities for further developments. This will promote both regulatory effectiveness and efficiency.

IRRT experts attention was dedicated to the particular legal status of the Regulation on the Safety in Nuclear Power Plants Operations (PAK/913), draft Revision 1, which, although not already published in the national Gazette, has been applied by a PNRA Chairman's letter No. PNRA-NSD-05(10)/01.

7.1.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 requires in paragraph 5.26. that: *“The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.”*
 - (a) **Recommendation:** The PNRA should give the highest priority to the promulgation of Regulation on the Safety in Nuclear Power Plants Operations (PAK/913), Rev. 1.
- (2) **BASIS:** The IAEA SSS GS-G-1.4 states in paragraph 3.1. that: *“A systematic approach should be adopted for the production of regulations and guides, and the regulatory body's quality management should cover these activities.”*
 - (a) **Suggestion:** To foster regulatory effectiveness and efficiency the PNRA should consider the adoption of a systematic approach for the development of regulations and guides by following applicable recommendations provided in the Section 3 of the IAEA SSS GS-G-1.4.

7.2. REVIEW AND REVISION OF REGULATIONS AND GUIDES

“Guidelines for Preparing PNRA Regulations, No. PNRA-NSD-GL1 of September 26, 2003” has been developed as an internal guide to be followed in the process of development of regulations. Subchapter (xx) of Chapter 2. of the guide lays down the requirements on the frequency of review and revision of the regulations. The regulations can be revised as often as necessary. Under normal circumstances, they should be reviewed at least once every three years and such reviews will be duly recorded.

Furthermore Sub-chapter (x) of Chapter 9 of the “Procedure for preparing PNRA internal documents, No. PNRA-QP-00002, Rev. 0, September 2003” sets the requirement that all internal Documents/Procedures will be reviewed at least once annually and if required will be revised.

8. EMERGENCY PREPAREDNESS

Experts: Lyn Bevington and Richard Wessman

8.1. INTRODUCTION

In the Islamic Republic of Pakistan, the Federal Government is responsible for overall national management of, and response to, emergencies. The Government has established emergency response programmes for dealing with different types of national emergencies. On a local level, management of activities regarding emergencies is performed by the local and district management/executive bodies (i.e. District Nazim, etc). For nuclear power plant emergencies, response on a facility level is conducted by the licensee (i.e. Pakistan Atomic Energy Commission - PAEC).

A National Crisis Management Centre (NCMC) is established in Islamabad which works under the Cabinet Secretariat (Ministry of Interior) to co-ordinate emergency response and protective measures at the national level. The NCMC carries out its activities through the ministries, administrative institutions and local executive bodies of governmental and non-governmental organizations. Several Governmental Ministries would be expected to undertake response measures in the case of a nuclear accident. For example, the Environmental Protection Act No. XXXIV of 1997 requires preparation of emergency contingency plans for coping with environmental hazards and pollution caused by accidents, natural disasters and calamities including those from radioactive substances.

Specific requirements on nuclear safety and radiation protection matters are regulated by the Pakistan Nuclear Regulatory Authority (PNRA). Under section 39(2) of the PNRA Ordinance 2001, the PNRA is directed to *“ensure, co-ordinate and enforce preparation of emergency plans for actions to be taken following foreseeable types of nuclear incidents that might affect the public. Such plans shall include arrangements for reporting and communication, the co-ordination of actions between the various public bodies involved, the training of personnel and the provision of necessary facilities and instrumentation”*. In case of a nuclear accident or radiological emergency, the Chairman PNRA acts as an advisor to the Government of Pakistan on actions undertaken to mitigate the consequences of the nuclear accident or radiological emergency situation.

The Directorate of Radiation Safety, PNRA, inherited various regulatory programmes and documents from the PAEC when the PNRA was established. The PNRA is in the process of developing or revising additional regulations and guides to regulate licensee activities in relation to emergency planning and preparedness. For example, the draft of PAK/914, Rev. 0, “Regulation on Nuclear Accident or Radiological Emergency Management” has been prepared and presently is under departmental review. The PNRA is also in the process of co-ordinating interfaces for prevention and management of nuclear accidents or radiological emergency situations among the Federal government infrastructure.

Pakistan is a State Party to the Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency. The PNRA has been appointed by the Government of Pakistan as the Competent Authority and being the Contact Point, i.e. National Warning Point (NWP) in accomplishment of the duties according to these Conventions.

The PNRA has established a National Radiation Emergency Co-ordination Centre (NRECC) for receipt and dissemination of information in response to nuclear accidents or radiological emergencies happening domestically or abroad. The NRECC, under the PNRA Directorate of Radiation Safety, will co-ordinate radiological monitoring in support of licensee and other off-site authorities. The PNRA is developing procedures for the conduct of operations of the NRECC (Emergency Procedures for Nuclear Accident or Radiological Response by PNRA Headquarters).

The licensee (PAEC) is aware of the regulatory requirements and manages its facilities, including the Karachi Nuclear Power Plant (KANUPP) and the Chashma Nuclear Power Plant (CHASNUPP). The facility licensees are required to establish on-site and off-site emergency plans. In the event of an emergency situation at the facility, the licensee, in accordance with its on-site emergency plan, will activate its emergency organization. Activation of the off-site emergency organization will be in accordance with the off-site emergency plan.

The PNRA maintains regulatory oversight of the licensee's emergency preparedness programme and co-ordinates with other off-site governmental response organizations. At this time, active collaboration of the PNRA with other governmental, public or private bodies is yet to be arranged and the PNRA states that serious efforts are underway to establish close liaison with the NCMC to seek off-site organizational support to assess, monitor and mitigate consequences in case of a nuclear accident or radiological emergency. Each participating organization is expected to establish its own component plan for actions under its scope for actions to be taken in case of an emergency.

The PNRA maintains communications facilities and radiological monitoring and other protective equipment available at the NRECC. The PNRA also maintains a Mobile Radiological Monitoring Laboratory (MRML) and emergency response teams.

The supervision and the review of the emergency planning and the preparedness activities is being performed by the Radiation Safety Directorate (RSD) in co-ordination with other technical directorates of the PNRA. The officers of the NRECC participate in the national and international training courses/workshops on emergency planning and preparedness and in the conduct of exercises. New employees receive training on emergency planning and preparedness.

8.2. INFRASTRUCTURE AND REGULATORY FRAMEWORK FOR EMERGENCY PREPAREDNESS

The PNRA Ordinance 2001 provides for the establishment of the Pakistan Nuclear Regulatory Authority (PNRA) for the regulation of nuclear safety and radiation protection in Pakistan. Section 39(2) states:

“The Authority shall ensure, co-ordinate and enforce preparation of emergency plans for action to be taken following foreseeable types of nuclear incidents that might affect the public. Such plans shall include arrangements for reporting and communication, the co-ordination of action between the various public bodies involved, the training of personnel and the provision of necessary facilities and instrumentation.”

The PNRA has initiated actions to co-ordinate emergency preparedness among the Government ministries, but arrangements are not yet in place.

Regulations implementing the requirements of the Ordinance have been established by Pakistan; however some were promulgated before the establishment of the PNRA. The following documents include portions that provide requirements or guidance in the area of emergency preparedness:

- Regulation for Licensing of Nuclear Installation(s) in Pakistan – PAK/909 (Rev. 0), promulgated September 21, 2001.
- Regulations on the Safety of Nuclear Power Plants Operations - PAK/913 (Rev. 1), not formally promulgated, but is being followed by the PNRA and licensees.
- Supplemental guidance in the area of emergency preparedness, issued prior to the establishment of the PNRA, is contained in Regulatory Guide PAK 1406, “Preparedness of the Licensee for Emergencies at Nuclear Power Plants”

PAK/909 requires that Emergency Preparedness Plans accompany a licensee’s application for introducing nuclear materials into the system(s) of the nuclear installation. PAK/909 reflects the authority of the PNRA. PAK/913 (Rev. 1) provides direction regarding emergency preparedness. It has not been promulgated but it provides “requirements” regarding emergency preparedness in Sections 2.25-2.33.

The PNRA is taking additional actions to strengthen regulations associated with emergency preparedness. Although regulations promulgated governing the safety of nuclear power plant operations (PAK/913) address emergency preparedness for nuclear power plants, the PNRA has recognized that there is a gap in the regulations regarding the more general requirements for preparedness and response to nuclear accidents and radiological emergencies. The PNRA is in the process of developing PAK/914, “Regulation on Nuclear Accident or Radiological Emergency Management,” to address this need. As currently drafted, PAK/914 will address transportation emergencies, provide requirements for off-site authorities, and set on-site and off-site licensee emergency plan requirements for licensees other than nuclear power plants. The IRRT views development of this regulation as a good initiative.

The PNRA approach to developing regulations includes preparing a draft document, soliciting comments from licensees and (in the past) requesting the Ministry of Law to review the document. The PNRA does not provide the proposed regulations to other government agencies that may be affected by the proposed regulation. This is relevant in the area of emergency preparedness and response where multiple public bodies may be involved in the response to a nuclear accident or radiological emergency.

8.2.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 6.2. that: *“Despite all the precautions that are taken in the design and operation of nuclear facilities and the conduct of nuclear activities, there remains a possibility that a failure or an accident may give rise to an emergency.... Such emergencies may include transport accidents. Adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to emergencies.”*

- (a) **Recommendation:** The Government of Pakistan should establish arrangements among the ministries and the PNRA to assure adequate preparations exist at a national level to respond to emergencies involving nuclear activities.
- (2) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 6.3. that: *“Government shall ensure that competent authorities have the necessary resources and that they make preparations and arrangements to deal with any consequences of accidents in the public domain...”*
- (a) **Recommendation:** Prior to promulgation, the PNRA should provide proposed regulations, (such as PAK/914) to other ministries and agencies that may be affected by the regulation so that they can provide their comments and make appropriate preparations and arrangements.
- (3) **BASIS:** The IAEA SSS GS-R-1 states in paragraph 3.2. that: *“In fulfilling its statutory obligations, the regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based...”*
- (a) **Recommendation:** The PNRA should complete and promulgate PAK/914, which will provide regulations covering emergency response to radiological events other than events at nuclear power plants, such as transportation events.

8.3. PNRA RESPONSE TO EMERGENCIES

The PNRA Ordinance 2001 includes provisions for radiation emergency plans. As stated in section 39 (2), “The Authority shall ensure, co-ordinate and enforce preparation of emergency plans for actions to be taken following foreseeable types of nuclear incidents that might affect the public. Such plans shall include arrangements for reporting and communication, the co-ordination of action between the various public bodies involved, the training of personnel and the provision of necessary facilities and instrumentation.”

Although the focus of this portion of the PNRA Ordinance 2001 is toward licensees, effective “co-ordination of action between the various public bodies involved” cannot be assured without the PNRA itself establishing a plan or procedure on how it will respond to a radiation emergency.

The PNRA is in the process of developing a procedure to describe how the PNRA will respond during a nuclear emergency event. This is an important concept, as licensee on-site and off-site emergency response plans cannot be effectively implemented in responding to events that may have national (and, possibly, international) implications unless the national regulatory authority has associated plans and procedures to deal with emergencies involving nuclear activities. It is also important that other organizations (licensee, local, etc.) involved in response to nuclear emergencies are made aware of the regulatory authority’s plans and procedures so that they can effectively interact with the national authority. A draft copy of a PNRA procedure (Emergency Procedures for Nuclear Accident or Radiological Response by PNRA Headquarters) was shown to the IRRT. The procedure includes activities that will be

taken by the PNRA in response to an emergency, identifies individual and organizational responsibilities, describes the conduct of operations in the NRECC, and identifies communications arrangements, etc. The IRRT views this effort as a good initiative.

The IRRT noted that the PNRA has taken other actions to improve the Authority's ability to respond to radiological emergency events. These include measures such as establishing the NRECC, providing response and monitoring equipment and obtaining a mobile radiological monitoring van, and conducting training, drills, and exercises for the PNRA staff. The PNRA is also seeking technical resources (manuals, guidelines, etc., from international sources).

8.3.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA Safety Standards Series GS-R-2 "Preparedness and Response for a Nuclear or Radiological Emergency" (hereafter referred to as the IAEA SSS GS-R-2) states in paragraph 5.13. that: "*Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies.*"
 - (a) **Recommendation:** The PNRA should complete and promulgate the Authority's emergency response documents that provide current arrangements for co-ordination and protocols, including communications arrangements, for operational interfaces that facilitate an effective integrated response (by the licensee, local responders, and the national government) to a nuclear power plant emergency event.
 - (b) **Suggestion:** After the PNRA promulgates their emergency response documents, the Authority should interact directly with other response organizations (ministries, licensee, local, etc.) to assure effective mutual understanding of roles and responsibilities.

8.4. GOVERNMENTAL AND LICENSEE RESPONSE TO EMERGENCIES

As discussed in Section 8.2., above, the Ordinance establishes certain requirements for emergency plans. Pursuant to the Ordinance, the PNRA (and its precursor organization) has addressed emergency preparedness for nuclear power plants in PAK/913, Regulations on the Safety of Nuclear Power Plants Operations. Section 2.25 of PAK/913, Rev. 1, provides, in part, the following requirements: "The emergency plan of the local government shall cover the activities to be carried out by the local government." Section 2.26 specifies certain items to be included in the emergency plan of the licensee, including chain of command and communications and actions to be taken by individuals and organizations involved in the implementation of the plan. Note that Rev. 1 of PAK/913 has not yet been promulgated.

The PNRA states that the licensee for Chashma is revising on-site and off-site emergency response plans and they are to be submitted in December 2003. It is expected that these plans would be received and reviewed by the Authority prior to issuing the Chashma operating license. The KANUPP on-site emergency plan was revised in December 1990 and the KANUPP off-site emergency plan was revised in December 1990. The off-site plan is entitled "Karachi Emergency Relief Plan (KERP) for Nuclear Hazards." The PNRA states

that the KANUPP on-site and off-site plans were recently revised (October 2003) and were submitted to the PNRA in November 2003.

According to the Advance Reference Material that was provided to the IRRRT, in the case of an accident at a nuclear facility, the population around the facility is informed about the situation by the off-site authorities, based on information provided by the licensee. However, the PNRA states that public protective actions would not be initiated unless the local authorities received direction from the PNRA, via the Government infrastructure.

Discussions with the PNRA indicate that the PNRA does not interact directly with local government authorities regarding their emergency preparedness planning activities for responding to an event at a nuclear power plant. The PNRA relies on the representation of the licensee, as opposed to confirming directly that local governments have adequate plans in place and that they are prepared to respond to a nuclear event. (The PNRA notes that a response infrastructure already exists to deal with other types of emergencies, and that this infrastructure receives oversight from the relevant ministries.)

Discussions with the PNRA also indicate that a previous version of PAK/913 shows communications linkages which include PAEC (pre-dates PNRA). The focus of communications is for “notification” activities relating to the occurrence of a nuclear event, and that communications for decision making and exchange of information during event response are not described in promulgated documents that could be used by the various governmental entities. The PNRA also stated that they may explore arrangements for telephonic conferencing between the Chashma on-site emergency control centre, the off-site (local) emergency control centre, the National Radiological Emergency Control Centre (NRECC), and the National Crisis Management Centre (NCMC). Arrangements for notification and telephonic conferencing involving an event at KANUPP would be expected to follow a similar arrangement. Diagrams prepared by the PNRA for notifications and communications during event response at the KANUPP and Chashma Nuclear Power Plants are attached as Appendix VIII and IX.

8.4.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-2 states in paragraph 5.10. that: *“Arrangements for the co-ordination of emergency response and protocols for operational interfaces between operators and local, regional and national governments shall be developed, as applicable. The arrangements shall include the organizations responsible for emergency services and for response to conventional emergencies. The arrangements shall be clearly documented and this documentation shall be made available to all relevant parties.”*

The IAEA SSS GS-R-2 states in paragraph 4.13. that: *“Upon notification of a nuclear or radiological emergency warranting an off-site response, the off-site notification point shall promptly notify all appropriate off-site response organizations. Upon notification, the off-site response organizations shall promptly initiate the pre-planned and co-ordinated response appropriate to the emergency class or the level of emergency.”*

- (a) Recommendation: The PNRA should interact directly with local government organizations associated with emergency response to an event at a nuclear power plant to confirm their readiness to respond.**
- (b) Suggestion: The PNRA should complete its review of the KANUPP on-site and off-site emergency response plans to determine that they meet current regulations.**
- (c) Suggestion: The PNRA should complete activities to implement telephonic conferencing capability between response organizations to assure a coordinated response to a nuclear power plant event.**
- (d) Suggestion: The PNRA should receive and complete its review of the revised Chashma On-Site and Off-Site Emergency Plans before issuing the Chashma operating license.**

8.5. PUBLIC EDUCATION AND AWARENESS

PAK/913, Rev.1, includes provisions for public education and awareness regarding a possible nuclear power plant emergency. Section 2.29 states: “Sufficient information for the public, which may be involved in an emergency situation, shall be supplied as part of the emergency preparedness provisions.”

During discussion with the PNRA and the Chashma licensee, licensee representatives stated that they plan to prepare and disseminate information about the Chashma facility and emergency preparedness for an event at the facility to the public living in the vicinity of the facility. This is viewed as a good initiative that will help to provide an effective public response, in the event of an emergency at Chashma. (A similar initiative would be appropriate at the KANUPP facility).

The PNRA also stated that they have made educational presentations regarding nuclear matters to schools, medical doctors and district health officials. They also have provided the DNSRP/PAEC radiation information brochure to various organizations and members of the public.

PAK/913 includes requirements that the licensee’s emergency plan include provisions for alerting response personnel and public authorities. The IRRT reviewed portions of the CHASNUPP Off-Site Emergency Plan (Rev.3), 1999, and confirmed that these regulatory provisions are being met. Discussion with the PNRA indicated that local authorities would inform the public of actions to be taken in the event of an emergency at Chashma. They would contact the mosques who, in turn, would inform the public via loudspeakers that are at every mosque. The PNRA stated that local authorities would either telephone the mosque or rely on local civil defence personnel to contact the mosque. It was not clear, however, if procedures, checklists, etc. for this action have been established. Regarding the Karachi Emergency Relief Plan (KERP) for Nuclear Hazards, December 1990, the IRRT determined that a process is in place to notify local authorities in the event of an emergency at KANUPP. Details of the local public notification process for the mosques and the public, such as procedures and checklists, could not be confirmed.

8.5.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-2 states in paragraph 4.84 that: *“The operator, the response organizations, other States and the IAEA shall make arrangements for co-ordinating the provision of information to the public....”*
 - (a) **Suggestion:** The PNRA should encourage that the licensee for both Chashma and KANUPP provide information regarding emergency preparedness to the public (including mosques, civil defence) living in the vicinity of the nuclear power plant.
 - (b) **Suggestion:** The PNRA should confirm that local authorities have established arrangements to contact local public representatives/mosques so that information regarding an emergency at the nuclear power plant can be efficiently relayed to the public.

8.6. PROVISIONS FOR MINIMIZING THE EXPOSURE OF INDIVIDUALS

PAK/913, Rev. 1, includes provisions for emergency preparedness; however, it has not been promulgated. Section 2.26 (iv) states that the emergency plan of the licensee shall include: “Provisions for minimizing the exposure of individuals to ionizing radiation and for ensuring medical treatment of casualties...”

The IRRT reviewed portions of the Chashma on-site and off-site emergency plans and discussed these provisions with the PNRA and the licensee. The Chashma licensee has the capability and equipment to implement actions to meet this requirement and the PNRA has the capability and equipment to verify the licensee’s actions (mobile vans and detection equipment).

Both the Chashma licensee and the PNRA have stocks of potassium-iodide (KI) medication, which may be provided in an emergency to individuals that may be exposed to the radioactive plume during the early phase of a large radioactive material release from a nuclear power plant. This action, which may be taken as a supplement to evacuation or sheltering, may reduce the potential for radioactive iodine uptake by the human thyroid. The shelf life of existing stocks of KI held by both the Chashma licensee and the PNRA has expired. Both the PNRA and the licensee have initiated action to obtain new stocks of KI.

8.6.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-2 states in paragraph 4.8. that: *“Arrangements shall be made at the national level to treat people who have been exposed or contaminated....”*
 - (a) **Suggestion:** The PNRA should seek prompt delivery of sufficient quantities of potassium-iodide so that it may be available for use during the response to nuclear power plant emergency.

8.7. EMERGENCY PREPAREDNESS DRILLS, EXERCISES AND TRAINING

The PNRA Ordinance 2001, section 39, includes requirements that the Authority ensure the preparation of emergency plans for action to be taken following foreseeable types

of nuclear incidents that might affect the public. Further, it requires that such plans shall include arrangements for the training of personnel. Provisions of the PNRA Ordinance 2001 are implemented, in part, by PAK/913, Regulations on the Safety of Nuclear Power Plants Operations. As noted previously, Revision 1 to PAK/913 has not been promulgated.

Section 2.30 of PAK/913, Revision 1, provides requirements for the exercising of emergency plans. It states: "The emergency plan shall be tested in an exercise before the commencement of operations. There shall thereafter at suitable intervals be exercises of the emergency plan, some of which may be witnessed by the Authority. Some of these exercises shall be integrated and shall include the participation of as many as possible of the organizations concerned." Additional requirements are provided in Section 2.32 of the proposed PAK/913. Guidance regarding maintaining emergency preparedness, including training and exercises, is provided for nuclear power plant licensees in Section 9 of PAK 1406, "Preparedness of the Licensee for Emergencies at Nuclear Power Plants."

The IRRT experts discussed regulatory requirements for drills, training, and exercises with the PNRA and the Chashma licensee. Selected PNRA inspection checklists and records of drills and exercises were shown to the IRRT experts, and activities during the conduct of drills were discussed. However, the IRRT noted that the PNRA has not developed an inspection procedure for inspecting emergency preparedness activities, drills and exercises. The IRRT experts also toured the National Radiation Emergency Response Center (NRECC), in the PNRA Headquarters building. Additionally, as part of the site visit, the experts toured the Chashma on-site Emergency Co-ordination Center (ECC), in the Chashma administration building, and the Chashma Alternate Emergency Co-ordination Center (AECC), located about 7 km from the Chashma facility in the "colonial area." Details of the KANUPP emergency preparedness facility were not reviewed by the IRRT.

The IRRT experts believe that the PNRA is taking appropriate actions to assure the Chashma licensee is implementing regulatory requirements regarding drills, exercises, and training. A drill was conducted before initial fuel loading, in 1999, and two additional drills have been conducted. PNRA inspectors have observed all these drills, using a comprehensive inspection checklist. The drills at Chashma involved the facility, the PNRA Regional Nuclear Safety Directorate (RNSD-II), the PNRA Contact Point at the NRECC, the local Off-site ECC, and multiple off-site organizations in the emergency planning zone. The licensee is planning a drill in early 2004; this is likely to take place prior to the issuance of the Chashma operating license. The licensee has a robust emergency response facility, a modern mobile van and equipment, and a personnel training programme.

The PNRA is taking actions to provide the capability to respond to nuclear emergencies. The PNRA has an emergency response facility (NRECC) and mobile monitoring capability, and is taking actions to improve its analytical capability. The PNRA provides emergency response training to its staff. Nuclear power plant emergency scenarios have been used, classroom training is employed and staff members have attended external symposia. PNRA participation in licensee exercises at the NRECC is limited to notification and assessment of the licensee actions. As noted in Section 8.3, the PNRA is developing an internal procedure for response to emergencies. The PNRA will then need to train its own managers and staff on this procedure. (Initial training on the draft procedure was conducted for selected technical support personnel of the PNRA and the NRECC chain of command in November 2003).

Discussions with the PNRA indicate that the integration of all the organizations involved in emergency response may not have been fully exercised during the conduct of a full integrated exercise. Exercises have not involved the communication chain involving the Chairman PNRA, Secretary (Cabinet Division), Provincial Chief Secretaries, Off-Site Emergency Co-ordinators down to the local District Commissioners. (See Appendix VIII). This communication path is the one that would be followed in an actual emergency where the PNRA would be providing direction to the local authorities to take protective measures (e.g., evacuation, sheltering, administration of potassium-iodide) for the public. Additionally, it is not clear that an integrated exercise has been conducted that directly involves a co-ordinated response from the four emergency centres that would be staffed during an actual response. As discussed in Section 8.4 of this report, direct interaction between these centres, preferably by telephonic conference, would be desirable to assure an effective, co-ordinated emergency response to an actual event. These centres are the facility on-site ECC, the PAEC HQ ECC, the NRECC, and the local Off-site ECC. (See Appendix IX).

8.7.1. Recommendations and Suggestions

- (1) **BASIS:** The IAEA SSS GS-R-2 paragraph 5.35. states that: *“The officials off the site responsible for making decisions on protective actions for the population with the precautionary action zone and/or the urgent protective action planning zone shall be trained in the strategy for protective action and shall regularly participate in exercises.”*
 - (a) **Recommendation:** The PNRA should involve all government organizations (National, provincial, and local) in an integrated exercise that would ensure all functions and organizational interfaces could be addressed during an actual emergency response.
 - (b) **Suggestion:** The PNRA should conduct internal training on the Authority’s own emergency response procedure, once the procedure is completed.
- (2) **BASIS:** The IAEA SSS GS-R-2 paragraph 5.33. states that: *“Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II, or III.....are tested at suitable intervals.”*
 - (a) **Suggestion:** The PNRA should give high priority to completion of the Chashma emergency response exercise (scheduled for early 2004).
- (3) **BASIS:** The IAEA SSS GS-G-1.3 states in paragraph 4.1. that: *“To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail.”*
 - (a) **Suggestion:** The PNRA should develop an inspection procedure (that may include the existing checklist) for inspecting emergency preparedness activities.

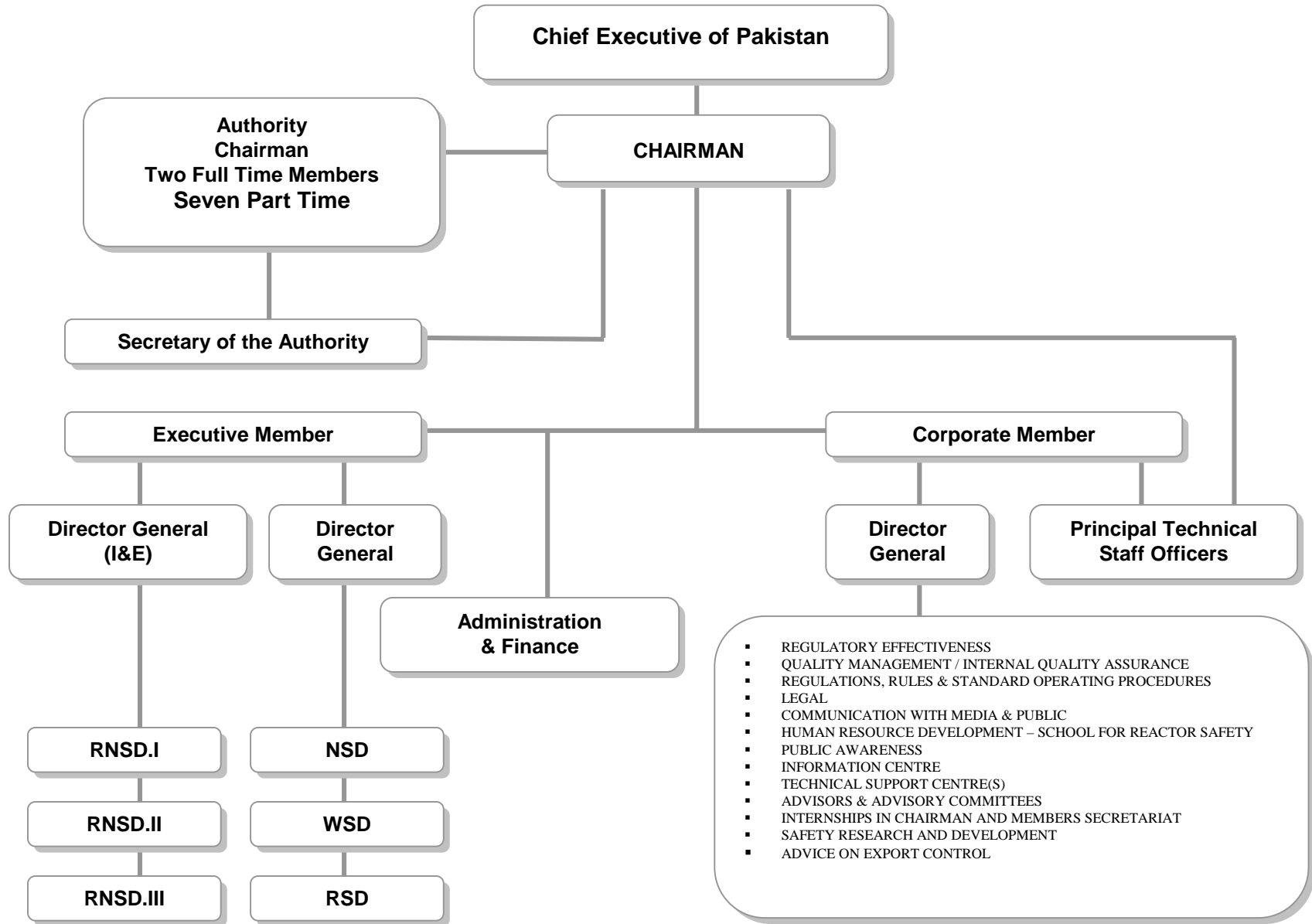
ABBREVIATIONS/ACRONYMS

AECC	Alternate Emergency Co-ordination Center
ARM	Advance Reference Material
CHASNUPP	Chashma Nuclear Power Plant
CNPP	Chashma Nuclear Power Plant
DNSRP	Directorate of Nuclear Safety and Radiation Protection
ECC	Emergency Co-ordination Center
EPA	Environmental Protection Agency
FSAR	Final Safety Analysis Report
IRRT	International Regulatory Review Team
ISI	In-service Inspection
KANUPP	Karachi Nuclear Power Plant
KERP	Karachi Emergency Relief Plan
LUMS	Lahore University of Management Sciences
MCR	Main Control Room
MOA	Memoranda of agreement
MOU	Memoranda of Understanding
MRML	Mobile Radiological Monitoring Laboratory
NCMC	National Crisis Management Centre
NOC	No Objection Certificate
NPPs	Nuclear Power Plant
NRECC	National Radiation Emergency Co-ordination Centre
NSD	Nuclear Safety Directorate
NWP	National Warning Point
OQAP	Overall Quality Assurance Programme
PAEC	Pakistan Atomic Energy Commission
PCO	Provisional Constitution Order
PIEAS	Pakistan Institute of Engineering and Applied Sciences
PNRA	Pakistan Nuclear Regulatory Authority
PNRB	Pakistan Nuclear Regulatory Board
PSA	Preliminary Safety Analysis
PSAR	Probabilistic Safety Analysis Report
PSI	Pre-service Inspection
PSR	Periodic Safety Review
QA	Quality Assurance
R&D	Research and Development
RAMP	Review of Probabilistic Safety Assessment
RNSD	Regional Nuclear Safety Directorate
RSD	Radiation Safety Directorate
SAMGs	Severe Accident Management Guidelines
SER	Site Evaluation Report
SPD	Strategic Plans Division
SSS	Safety Standards Series
TNA	Training Needs Assessment
WSD	Waste Safety Directorate

APPENDIX I: LIST OF REGULATIONS AND GUIDES

Number	Description	Status	Approving Authority
	Pakistan Nuclear Safety and Radiation Protection Ordinance	Gazette notified 24 January 1984	Gov. of Pakistan
	Nuclear Safety and Radiation Protection Regulations	Gazette notified 12 September 1990	PNRB
	Pakistan Nuclear Regulatory Authority Ordinance No. III of 2001 (the PNRA Ordinance 2001)	Gazette notified 22 January 2001	Gov. of Pakistan
PAK/909	Regulations for Licensing of Nuclear Installation(s) in Pakistan	Gazette notified 9 October 2001	PNRA
PAK/910	Regulations on Safety of Nuclear Power Plants – Siting Rev. 0	Approved by PNRB in Oct. 1998	PNRB
PAK/911	Regulations on Safety of Nuclear Power Plants – Design Rev. 1	Gazette notified 21 January 2001	PNRA
PAK/912	Regulations on Safety of Nuclear Power Plants – Quality Assurance Rev. 1	Gazette notified 11 September 2003	PNRA
PAK/913	Regulations on Safety of Nuclear Power Plants – Operations	Rev. 0 approved by PNRB in Oct. 1998. Rev. 1 under process of approval	PNRB
PAK/904	Regulations on Radiation Protection	Planned	
PAK/914	Regulations on Nuclear Accidents and Radiological Emergency Management	Planned	
PAK/915	Regulations on Disposal of Radioactive Waste Management	Planned	
PAK/916	Regulations on Transport of Radioactive Materials	Planned	
PAK/917	Regulations on the Decommissioning of Nuclear Installation(s)	Planned	

APPENDIX II: ORGANIZATIONAL CHART OF THE PNRA



APPENDIX III: ADVANCE REFERENCE MATERIAL

№	DOCUMENT
1.	LIST OF ORDINANCE, REGULATIONS AND GUIDES
2.	PAKISTAN NUCLEAR REGULATORY AUTHORITY ORDINANCE 2001
3.	PAKISTAN ATOMIC ENERGY COMMISSION ORDINANCE 1965
4.	PAKISTAN NUCLEAR SAFETY AND RADIATION PROTECTION ORDINANCE 1984
5.	RADIATION PROTECTION REGULATION -1990
6.	PAKISTAN NUCLEAR REGULATORY BOARD ORDINANCE 1994
7.	PAK/909- LICENSING OF NUCLEAR POWER PLANTS
8.	PAK/910- LICENSING OF NUCLEAR POWER PLANT SITING
9.	PAK/911- LICENSING OF NUCLEAR POWER PLANT DESIGN
10.	PAK/912- QUALITY ASSURANCE OF NUCLEAR POWER PLANTS
11.	PAK/913 -LICENSING OF NUCLEAR POWER PLANT OPERATION
12.	GUIDELINES FOR PREPARING PNRA REGULATIONS
13.	PROCEDURE FOR PREPARING PNRA INTERNAL DOCUMENTS
14.	ANSWERS TO IRRT QUESTIONNAIRE (A-G)
15.	ANSWERS TO MODULES 1 AND 2
16.	BASIC INFORMATION (A-G)
17.	PNRA INSPECTION PROGRAMME
18.	PNRA ENFORCEMENT PROGRAMME
19.	PNRA TRAINING MANUAL (DRAFT)
20.	TRAINING POLICY
21.	LIST OF INSPECTION PROCEDURES FOR NUCLEAR POWER PLANTS
22.	PROCEDURE FOR ISSUANCE OF AUTHORIZATION TO NUCLEAR INSTALLATIONS
23.	PAK/1406 REGULATORY GUIDE ON EMERGENCY PREPAREDNESS
24.	NATIONAL REPORT ON THE CONVENTION ON NUCLEAR SAFETY

APPENDIX IV: PNRA DOCUMENTS RECEIVED DURING THE MISSION

1. "Validity of PNRA Ordinance – 2001," Legal Opinion, Private Communication, PNRA
2. "Rules of Business 1973," Government of Pakistan
3. "Regulations on the Safety of Nuclear Power Plants – Quality Assurance (PAK/912)(Rev. 1)," Government of Pakistan, Islamabad, 10 September 2003
4. "Pakistan Nuclear Safety and Radiation Protection (PNSRP) Ordinance No. IV of 1984," Amendment/Replacement of Schedules III, V, VI, VII and VIII, Pakistan Atomic Energy Commission, Islamabad, 13 June 1998
5. "Quality Manual," Pakistan Nuclear Regulatory Authority, January 2002
6. "The Safety of Nuclear Installations," IAEA Safety Standards Series No. 110, Safety Fundamentals, IAEA, Vienna, 1993
7. "Legal and Governmental Infrastructure for Nuclear Radiation, Radioactive Waste and Transport Safety," IAEA Safety Standards Series No. GS-R-1, Requirements, IAEA, Vienna,
8. "Organization and Staffing of the Regulatory Body for Nuclear Facilities," IAEA Safety Standards Series No. GS-G-1.1
9. "Documentation for Use in Regulating Nuclear Facilities," IAEA Safety Standards Series No. GS-G-1.4
10. "M.Sc. Projects of PNRA Fellows at PIEAS in the Fields of Nuclear Engineering and Medical Physics (Session 2001 – 2002)," Private Communication, PNRA
11. Procedure for licensing of nuclear power plants in Pakistan, No. DNSRP-NILREG-007/90, February 14, 1990
12. Implementing instructions for licensing of nuclear power plants in Pakistan, Office Memorandum of PAEC, December 19, 1991
13. Procedure for licensing of nuclear power plant operating personnel, No. PNRA-WP-00004, Rev.1, September 2003
14. Management procedure for review and assessment of design modifications of nuclear installations, No. PNRA-WP-1104< Rev.1, July 2003
15. Regulatory position for permission to operate KANUPP for interim period before completion of re-licensing requirements, No. PNRA-NSD-03(23)
16. Letter: Interim operation of KANUPP before completion of re-licensing activities No. PS-2.12/2002, 14 November, 2003
17. Order of Director NSD to form the Task Force, No. DNSRP-03(23), 13 November, 2001
18. PNRA schedule for licensing of KANUPP beyond design life time, 26 February, 2003
19. Codes and standards followed during renewal of OL of KANUPP safety evaluation report and on FSAR for Chashma NPP Unit-1, No. DNSRP-FSER-CNPP, 19 April, 2002
20. Report on Safety Assessment of Chashma Nuclear Power Plant, issued in January 2002
21. Letter No. PNRA-NSD-05 (10)/01, from Chairman PNRA to PAEC informing that Revision 1 of regulations PAK/913 has been approved and has to be used
22. Office Memorandum PNRA-4 (32)/2003, April 9, 2003, Constitution of PNRA Executive Council
23. Inspection Procedure for CNPP Fire Fighting Programme Implementation No. PNRA/RNSD-II-IP-012 Rev 0
24. Inspection Procedure for Radioactive Waste Management of Nuclear Power Plants No. PNRA/RNSD-II-IP-009 Rev 0
25. Inspection Procedure for Chemistry and Radiochemistry Control in PWR Nuclear Power Plants. No. PNRA/RNSD-II-IP-15 Rev 0

26. Inspection Procedure for Radiation Protection
27. Inspection Report PNRA/RNSD-II-PIR-04/2001 Periodic Review of Design Modification Records of CHASNUPP, December 2001
28. Inspection Report PNRA/WSD-6(11)/2001 Review of Violation of FSAR regarding liquid radioactive releases from CHASNUPP. 27-28 May 2003
29. PNRA Operating Inspection Report CHASNUPP Unit-1OIR No. 2002-11-01
30. PNRA Operating Inspection Report CHASNUPP Unit-1OIR No. 2002-11-04
31. PNRA Surveillance Test Inspection Report CHASNUPP Unit-1 STIR No. 02-01-02
32. PNRA Surveillance Test Inspection Report CHASNUPP Unit-1 STIR No. 01-05-01
33. Preliminary Findings of Chemistry Control Inspection 3-4 December 2003
34. PNRA Letter on Violation of CHASNUPP Technical Specifications 24-11-2003
35. PNRA Violation Notice CHASNUPP Technical Specifications 25-11-2003
36. Draft PAK/914 – Regulation on Nuclear Accident or Radiological Emergency Management
37. Emergency Procedures for Nuclear Accident or Radiological Response by PNRA Headquarters
38. KANUPP On-site and Off-site Emergency Response Plans of 1990
39. Chashma On-site and Off-site Emergency Response Plans of 1999
40. PNRA Checklist for Emergency Preparedness Inspections
41. Mobile Radiological Monitoring Laboratory (MRML) Equipment Checklist
42. PNRA-WP-12008, Radiation Emergency Exercise Plan
43. Licensee Telephone Lists – Chashma
44. PNRA Telephone Lists – PNRA Headquarters
45. Licensee ECC maps, charts, and procedures
46. “Living With Radiation” – brochure prepared by PAEC
47. PNRA record of Chashma pre-fuel load Emergency Drill

APPENDIX V: SYNOPSIS OF RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Recommendations

- R.1. The PNRA management should establish a comprehensive formal plan (including responsibilities and timetables) to:**
- **Finalize the development of the new secondary legislation (Regulations); and**
 - **Review existing and/or develop new guidance on the new secondary legislation (Regulatory Guides);**
- with the aim of facilitating the consolidation of the new legislative framework within a defined timeframe and scope**
- R.2. The Government and, as appropriate, concerned organizations should (continue to) pay attention to, and provide for adequate resources for:**
- **External technical support to the PNRA independent from licence holders,**
 - **The Research and Development programme of the PNRA to ensure that its competence and knowledge are maintained at state-of-the art level.**
- R.3. The PNRA should establish the means, including processes, to communicate independently its regulatory requirements, decisions, and opinions, and their basis, to the public. The details of how this may be achieved are at the discretion of the PNRA, however, the Secretary of the Authority and the management and staff of the PNRA would normally be expected to play a significant role.**
- R.4. The PNRA should consider arranging for training in making presentations, communicating risk information to non-technical people and on handling the media (television, radio, newspapers, etc.) to be provided to the permanent members and key management and staff of the Authority, whom may be called upon to address stakeholders and the media, on behalf of the PNRA**
- R.5. The PNRA should consider including policies in its hierarchy of documents and develop them as needed according to agreed priorities.**
- R.6. The PNRA should consider developing an explicit procedure for handling and protecting proprietary information.**
- R.7. The PNRA should identify, develop and maintain a list of contacts at key governmental and non-governmental bodies with which it needs to liaise and co-ordinate its activities, to improve its regulatory performance (i.e. to increase its regulatory effectiveness and efficiency). In particular, the PNRA should identify the other relevant authorities in waste management, water and food consumption, land use and planning, and safety in the transport of goods, and develop contacts and liaisons with them, right from the early stages of the development of the PNRA regulatory framework.**

- R.8. The PNRA should consider creating a mechanism for keeping abreast of international developments, particularly conventions and treaties in areas such as waste management and transportation, to facilitate their incorporation into the national regulatory framework, to maintain the regulatory framework at the state of the art.**
- R.9. The PNRA should continue to increase efforts to widen the scope of its links and liaisons with regulatory bodies of other countries and with international organizations, to promote co-operation and the exchange of regulatory information.**
- R.10. The PNRA should seek government approval for direct contact and accreditation as a Government of Pakistan contact for liaison with the IAEA. It is most unusual, and not at all in line with accepted international practice, for official and primary contact between a nuclear regulator and the IAEA to be done through a licensee of the regulator.**
- R.11. The PNRA should consider developing an explicit procedure for changing the conditions of authorizations.**
- R.12. The PNRA should not take any responsibility for the content of the resulting Severe Accident Management Guidelines.**
- R.13. The PNRA should consider developing a capability for the technical support by independent external consultants in the areas where there is not enough expertise or manpower available within the PNRA and preparing a method and procedure of their appointment.**
- R.14. The PNRA procedures should identify the pertinent regulatory requirements, including regulations, against which compliance is to be verified during inspection.**
- R.15. The PNRA should give the highest priority to the promulgation of Regulation on the Safety in Nuclear Power Plants Operations (PAK/913), Rev. 1.**
- R.16. The Government of Pakistan should establish arrangements among the ministries and the PNRA to assure adequate preparations exist at a national level to respond to emergencies involving nuclear activities.**
- R.17. Prior to promulgation, the PNRA should provide proposed regulations, (such as PAK/914) to other ministries and agencies that may be affected by the regulation so that they can provide their comments and make appropriate preparations and arrangements.**
- R.18. The PNRA should complete and promulgate PAK/914, which will provide regulations covering emergency response to radiological events other than events at nuclear power plants, such as transportation events.**

- R.19. The PNRA should complete and promulgate the Authority's emergency response documents that provide current arrangements for co-ordination and protocols, including communications arrangements, for operational interfaces that facilitate an effective integrated response (by the licensee, local responders, and the national government) to a nuclear power plant emergency event.**
- R.20. The PNRA should interact directly with local government organizations associated with emergency response to an event at a nuclear power plant to confirm their readiness to respond.**
- R.21. The PNRA should involve all government organizations (National, provincial, and local) in an integrated exercise that would ensure all functions and organizational interfaces could be addressed during an actual emergency response.**

Suggestions

- S.1. The PNRA should complete and then implement the plan it has for improving public awareness (PA) of its role in nuclear, radiation, transportation and nuclear waste safety.**
- S.2. Links with key governmental and non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and the transport of dangerous goods should be formalised, for instance through memoranda of agreement (MOA) or understanding (MOU).**
- S.3. The PNRA should consider encouraging the operator to develop a programme for public awareness, including communicating incidents to the public, before the regulatory authority makes such an announcement. This has been identified as a good practice in some countries.**
- S.4. The PNRA should consider, including in internal plans, the establishment of technical Advisory Committees to the Chairman, as there are appropriate provisions in the PNRA Ordinance 2001.**
- S.5. The PNRA management should continue its recruitment campaign, with the view to provide sufficient staff not only in the executive branch, but also to satisfy corporate (administrative support) activities. The adequacy of staffing in different departments and units should be assessed on a periodic basis and, based on the results, appropriate adjustments should be implemented by the PNRA management. Accessibility to independent external technical support should be considered in this connection.**
- S.6. The PNRA should proceed with establishment of a quality management programme, taking account of some the observations noted above.**
- S.7. In the preparatory process of issuing the Operating Licences it is suggested that the format and content given in the IAEA SSS GS-G-1.4 is applied.**

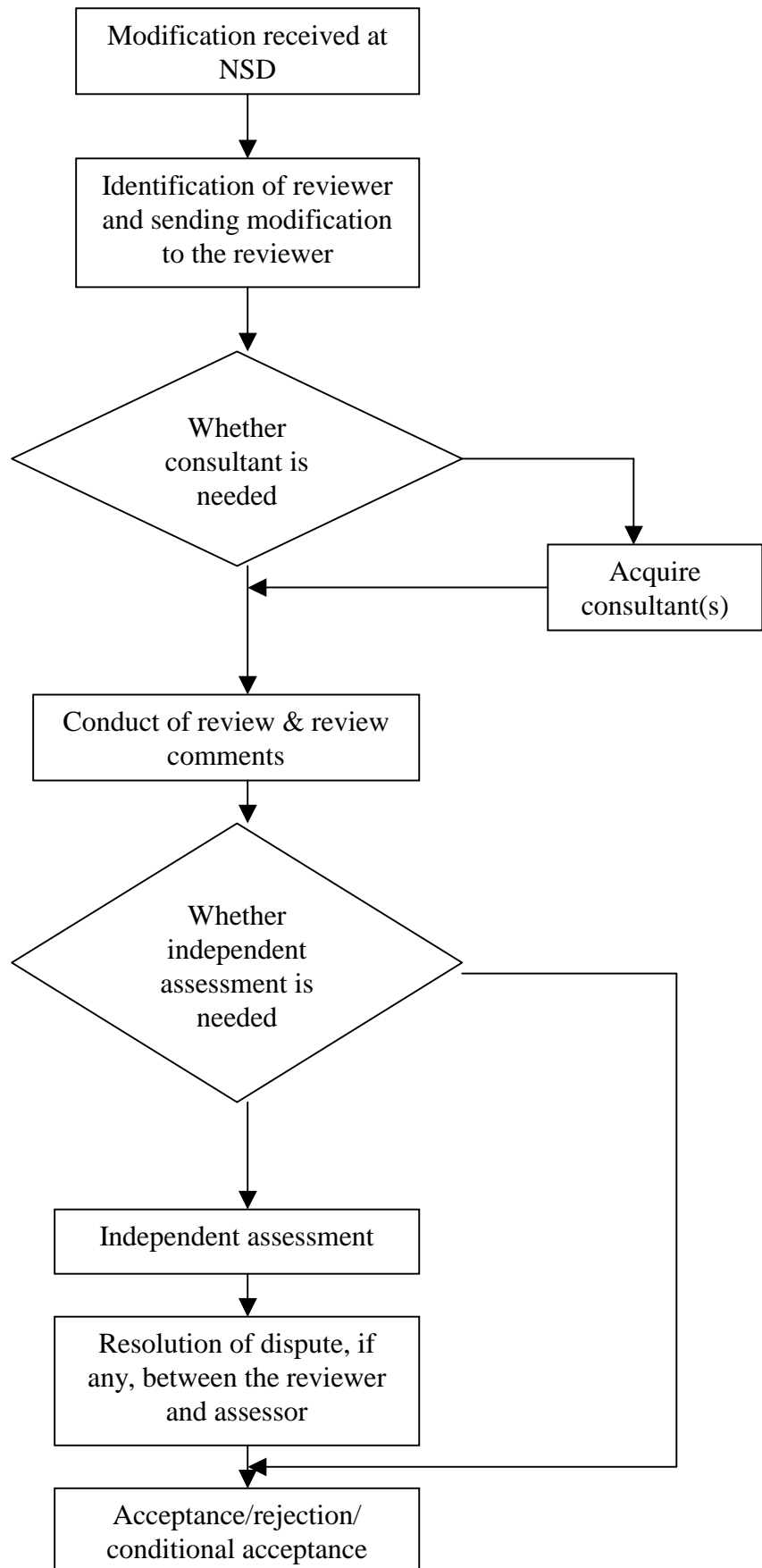
- S.8. In the review process of the draft regulation PAK/913 attention should be given to Sub-Section 8.3, to define in accordance with the IAEA Safety Standards the modifications that would require the PNRA prior approval.**
- S.9. The PNRA should consider giving higher priority to the preparation and implementation of the “PNRA Review and Assessment Programme” and consider the possibility that the Programme is made available to the operators.**
- S.10. The PNRA should consider encouraging the licensee to provide for an independent review of the Severe Accident Management Guidelines. It could be achieved by the support of the IAEA in the form of RAMP (Review of Accident Management Programmes) mission.**
- S.11. The PNRA should consider the possibility of implementing a process of systematic integrated safety assessment of nuclear power plant operational safety, combining results of review and assessment and inspections findings, as well as plant safety performance indicators. This assessment should be performed on a periodic basis. Compliance with the requirements of regulations PAK/913 should be explicitly addressed.**
- S.12. The PNRA should consider seeking assistance of IAEA for the development of independent expertise in the areas where not enough independent expertise is available.**
- S.13. The PNRA should consider developing links with other regulatory bodies directly or through IAEA in the area of review and assessment of submissions in authorization process of NPPs.**
- S.14. The PNRA regions should consider formally involving the Headquarters Directorates in the inspection planning process.**
- S.15. The PNRA should consider strengthening the requirements for the preparation of inspection activities in their procedures to reflect international best practice.**
- S.16. The PNRA should consider introducing into their procedures a clearly defined process for the distribution of inspection reports to ensure that information is shared with relevant staff.**
- S.17. The PNRA should consider continuing with the development and implementation of the administrative procedure for enforcement action.**
- S.18. To foster regulatory effectiveness and efficiency the PNRA should consider the adoption of a systematic approach for the development of regulations and guides by following applicable recommendations provided in the paragraph 3 of the IAEA SSS GS-G-1.4.**

- S.19. After the PNRA promulgates their emergency response documents, the Authority should interact directly with other response organizations (ministries, licensee, local, etc.) to assure effective mutual understanding of roles and responsibilities.**
- S.20. The PNRA should complete its review of the KANUPP on-site and off-site emergency response plans to determine that they meet current regulations.**
- S.21. The PNRA should complete activities to implement telephonic conferencing capability between response organizations to assure a co-ordinated response to a nuclear power plant event.**
- S.22. The PNRA should receive and complete its review of the revised Chashma On-Site and Off-Site Emergency Plans before issuing the Chashma operating license.**
- S.23. The PNRA should encourage that the licensee for both Chashma and KANUPP provide information regarding emergency preparedness to the public (including mosques, civil defence) living in the vicinity of the nuclear power plant.**
- S.24. The PNRA should confirm that local authorities have established arrangements to contact local public representatives/mosques so that information regarding an emergency at the nuclear power plant can be efficiently relayed to the public.**
- S.25. The PNRA should seek prompt delivery of sufficient quantities of potassium-iodide so that it may be available for use during the response to nuclear power plant emergency.**
- S.26. The PNRA should conduct internal training on the Authority's own emergency response procedure, once the procedure is completed.**
- S.27. The PNRA should give high priority to completion of the Chashma emergency response exercise (scheduled for early 2004).**
- S.28. The PNRA should develop an inspection procedure (that may include the existing checklist) for inspecting emergency preparedness activities.**

Good practices

- G.1. Pakistan has established an effective separation of the nuclear regulatory body from organizations and bodies charged with promotion of the use of nuclear energy and ionizing radiation. The head of the regulatory body reports directly to the Prime Minister. This feature, among others, strongly support the independence of the PNRA as required in IAEA Safety Standards.**
- G.2. The PNRA has developed a sound training policy, which takes into account the needs of the organization and the individuals, as well as recent scientific and technological developments. The training programme is tailored to the needs of the PNRA being a newly established regulatory authority which is in the process of capacity building.**

APPENDIX VI: PROCESS FLOW CHART FOR DESIGN MODIFICATION REVIEW



APPENDIX VII: PNRA RESPONSIBILITIES AND FUNCTIONS

The following analysis relates the responsibilities and functions of the PNRA, as defined in its legislative and regulatory framework, to international standards and requirements, as laid out in the IAEA SSS GS-R-1, “Legal and Governmental Infrastructure for Nuclear Radiation, Radioactive Waste and Transport Safety.” It illustrates how the responsibilities and functions of the PNRA meet, or fail to meet, recognized good international practice and standards.

Apart from defining and elaborating a regulatory framework, the PNRA responsibilities and functions include:

- Reviewing and assessing submissions on safety from operators, both prior to authorisation and periodically during operation as required. The PNRA accomplishes this through a programme it has developed for that purpose, based on its own regulations and standards, and IAEA safety standards or United States Nuclear Regulatory Commission (NRC) standards, in the absence of Pakistani equivalents. The PNRA has set the regulatory requirements for the initial review and licensing of nuclear installations in PAK/909. The requirements for periodic reviews are set in PAK/913, while those for self-assessment have been set in section 6 of PAK/912.
- Providing for issuing, amending, suspending or revoking of authorisations, subject to conditions, as necessary. PNRA has set the requirements, and developed processes, using its authority (sections 19 – 25 of the PNRA Ordinance 2001 and section 14(11) of PAK/909), for the discharge of this function or responsibility.
- Setting conditions of authorisations that specify:
 - The facilities, activities, or inventories of sources covered by the authorisation, pursuant to sections 19(1)(a)–(d) and sections 21, 22, 23, and 27 of the PNRA Ordinance 2001, as well as regulations, most of which are under development (e.g. PAK/908 “Regulations on Licensing of Radiation Facilities Other Than Nuclear Installations (PAK/908)(Rev. 0)”), specifying the conditions under which authorisations may be given;
 - The requirements for notifying the regulatory body of any modifications to safety-related aspects, pursuant to sections 19(4) and 20(2) of the PNRA Ordinance 2001 and subsection 8.3 of PAK/913;
 - The obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel, pursuant to PAK/909 and other regulations, some in existence, others planned;
 - Any limits on operation and use (such as dose or discharge limits, action levels, or limits on the duration of the authorisation), as empowered by sections 19(4) and 20(2) of the PNRA Ordinance 2001, or stipulated in PAK/909 and in the “Pakistan Nuclear Safety and Protection Regulations, 1990, as amended on 13 June 1998;
 - Conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities, as empowered sections 19(4) and 20(2) of the PNRA Ordinance 2001. Although, the PNRA has not yet

developed or set such conditions, it plans to use these powers to do so in future, as necessary;

- Any additional separate authorisations that the operator is required to obtain from the regulatory body. The PNRA sets such conditions and issues such authorisations (e.g. before the issuance of an operating licence for a nuclear power plant), using the authority conferred to it by sections 19(4) and 20(2), and sections 20 – 23 of the PNRA Ordinance 2001;
 - The requirements for incident reporting, pursuant to subsection 2.20 in PAK/913, sections 5 and 43 in PAK/904 “Regulations on Radiation Protection (PAK/904)(Rev. 0)”, and the “Emergency Response Regulations” under development. Also, the operator incorporates the requirements in turn in its technical specifications and operating policies and principles. The PNRA might consider encouraging the operator to report incidents to the public, before the regulatory authority makes such an announcement, an identified good practice in some countries;
 - The reports that the operator is required to make to the regulatory body, pursuant to section 19(5) of the PNRA Ordinance 2001 and the requirements established in PAK/909 and PAK/904. Operators submit reports, some of them monthly, pursuant to regulatory requirements and licence conditions referencing the reporting requirements in the Final Safety Assessment Reports (FSARs) of nuclear power plants;
 - The records that the operator is required to retain and for how long, in keeping with the requirements of, for example, subsection 31(3) of PAK/904 with respect to dose/exposure records, or subsection 7.8 in PAK/913 with respect to the retention of records relating to structures, systems, and components important to safety and section 9 in PAK/913 with respect to record retention. Also, authorisations may have conditions referencing the record retention periods stipulated in FSARs; and
 - The emergency preparedness arrangements, in accordance with section 39 of the PNRA Ordinance 2001 and subsections 2.25 – 2.23 of PAK/913. The “Emergency Preparedness Regulations” which are under development are likely to set further requirements or conditions.
- Carrying out regulatory inspections. Sections 29 and 16(2)(i) of the PNRA Ordinance 2001 empower PNRA to carry out inspections. The Authority has developed an inspection programme for nuclear power plants (PNRA-WP-00001) and a set of procedures for conducting inspections. The Regional Directorates of the PNRA are charged with implementing this programme and related procedures.
 - Ensuring that corrective actions are taken if unsafe or potentially unsafe conditions are detected, pursuant to section 16(2)(e) of the PNRA Ordinance 2001. The PNRA has developed an enforcement programme which is described in an internal working procedure (PNRA-WP-00002).

- Taking the necessary enforcement action in the event of violations of safety requirements, pursuant to sections 16(2)(e) and 45 of the PNRA Ordinance 2001. The PNRA enforcement programme (PNRA-WP-00002) describes how the Authority enforces compliance with its regulatory requirements.
- Establishing a process for dealing with applications, such as applications for the issuing of an authorisation, accepting a notification, or the granting of an exemption, or the removal from regulatory control. The PNRA carries out this function and discharges its responsibilities based on its authority in sections 19 – 25 (authorisation) and section 48 (exemptions) of the PNRA Ordinance 2001 and the requirements it has set in its regulations, PAK/909 and PAK/908. The Authority has developed a procedure for the issuance of authorisations (PNRA-WP-00003). However, the procedure does not directly address exemptions.
- Establishing a process for changing conditions of authorisations. This process is not addressed explicitly by the PNRA, even though the Authority has the power to set conditions (as noted above, including, in particular, sections 19(4) and 25(b) of the PNRA Ordinance 2001). It is expected that the process will be addressed in the PNRA review and assessment programme.
- Providing guidance to the operator, on developing and presenting safety assessments or any other required safety-related information. The operators and PNRA have agreed to use the US NRC Nuclear Safety Regulatory Guide 1.70 (for the operator) and US NRC Nuclear Regulatory Guide (NUREG) 800 (for the regulatory body) for guidance, pursuant to section 5 of PAK/909 (the regulation on the licensing of nuclear installations), which specifies applicable nuclear safety standards and alternate guides to be used in the absence of PNRA equivalents.
- Ensuring that proprietary information is protected. Although there are processes for and criteria for classifying and handling information and documents, and pursuant to section 51 of the PNRA Ordinance 2001, PNRA members, management and staff make a declaration of fidelity and secrecy, no written procedure has been established to guide and control the handling of proprietary licensee information.
- Providing an explanation of the reasons for the rejection of a submission. Nothing in the PNRA Ordinance enjoins the Authority to accept applications or submissions that do not meet its requirements. A regulatory body should reject submissions that are not within its mandate or that are never likely, by their very nature, to meet its regulatory requirements
- Communicating with, and providing information to, other competent governmental bodies, international organizations and the public. The PNRA is charged with this function and responsibility through sections 16(2)(j) and 39(2) and 39(3) of the PNRA Ordinance 2001. Also, the provision for co-operation with international organizations, in section 38 of this ordinance implicitly gives the PNRA the authority to carry out this function, internationally.
- Ensuring that operating experience is appropriately analyzed and that lessons to be learned are disseminated. Sections 2.39 and 2.45 of PAK/913 establish requirements relating to the use of operating experience by licensees. On its part, the PNRA reviews inspection reports and produces annual reports with trends on

the compliance performance of licensees. The results of the analysis are used to inform inspection programme activities for the following year. The PNRA also reviews the operating experience information from event/incident reports from the IAEA and other regulators (particularly the Chinese nuclear regulatory body).

- Ensuring that appropriate records relating to the safety of facilities and activities are retained and retrievable. Section 9 of PAK/913 establishes the requirements for the retention of records. In addition, the PNRA inspects the documents of operators and verifies that they are retained and retrievable.
- Ensuring that its regulatory principles and criteria are adequate and valid, and that they take account of international standards and recommendations. Section 5 of PAK/909 establishes applicable safety standards for the licensing of nuclear installations in Pakistan. The PNRA establishes regulatory principles and criteria that follow international standards.
- Establishing and informing the operator of any requirements for systematic safety reassessment or periodic review. The PNRA has informed operators and set requirements through PAK/909 and section 10 of PAK/913, in respect of this function and responsibility.
- Advising the government on matters relating to the safety of facilities and activities. As required of it under section 16(2)(j) of the PNRA Ordinance 2001, the Authority, through its Chairman, advises the Government of Pakistan, according to an established protocol.
- Confirming the competence of personnel responsible for the safe operation of the facility or activity. The PNRA has set regulatory requirements in subsection 6(2)(v) of PAK/909 and in subsections 3.1 – 3.14 and Annex I of PAK/913 for confirming the competence and the licensing of such personnel.
- Confirming that safety is managed adequately by the operator. The PNRA discharges the function and responsibility through its inspection programme and periodic safety reviews.

Furthermore, the PNRA has other functions and responsibilities relating to how it co-operates with other relevant authorities, advises them, and provides them with information in the following areas:

- Environmental protection: Based on its authority to advise relevant authorities (section 16(2)(j) of the PNRA Ordinance 2001), The PNRA provides advice to the Environmental Protection Agency, either through its Chairman, or some other designated PNRA officer, as needed or whenever asked. Indirect contacts exist between the Authority and the National Electric Power Regulatory Authority (NEPRA), the arm of the Ministry of Water and Power responsible for regulating electricity generation and transmission in Pakistan, through the process of issuance of No Objection Certificates to licensees common to the PNRA and NEPRA.
- Public and occupational health: The PNRA advises the Ministry of Health on matters related to the safety of facilities and activities, according to the authority given it by section 16(2)(j) and section 39 of the PNRA Ordinance 2001. The

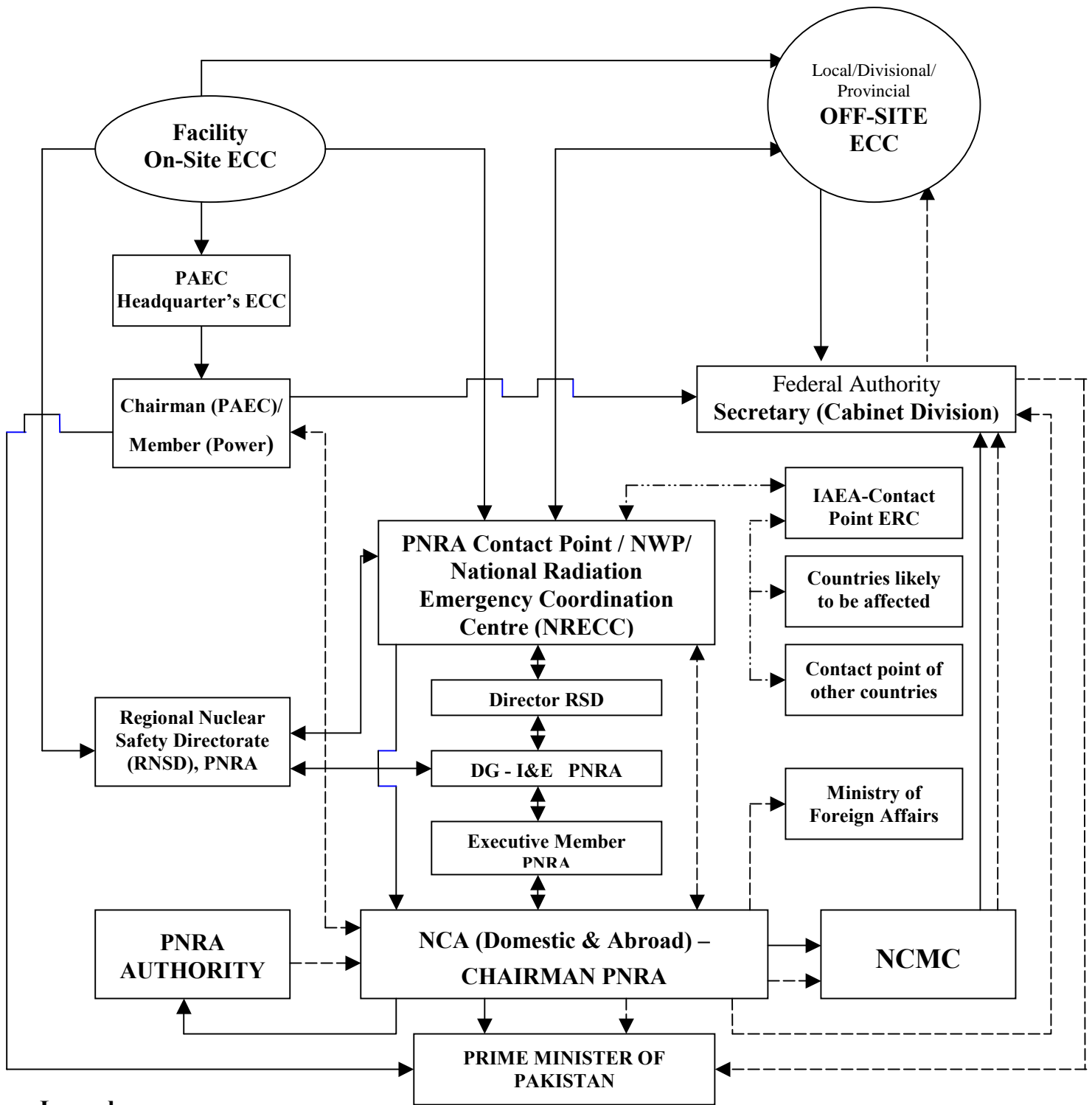
Authority has undertaken to verify, and adjust accordingly, its linkages with other relevant authorities in this area.

- Emergency planning and preparedness: Pursuant to sections 16(2)(j) and 39 of the PNRA Ordinance 2001, the PNRA advises the Civil Defence Organization and Public Administration authorities on matters relating to the safety of facilities and activities.
- Radioactive waste management, including the determination of national policy: The interaction with other relevant authorities is not yet fully defined. The framework for regulating this area is under construction. Once the PNRA directorate charged with developing this framework (the Directorate of Transport and Waste Safety) has completed work on the regulations for radioactive waste (PAK/915), the Directorate of Nuclear Safety will be in a position, pursuant these regulations and sections 16(2)(c) and 16(2)(h) of the PNRA Ordinance 2001, to issue licences for waste storage facilities and activities. No distinct licences for waste storage facilities or activities have been issued yet by the PNRA. Such facilities and activities at nuclear installations are addressed through conditions referencing the appropriate sections of their Final Safety Analysis Reports. Otherwise, the national policy is to send radioactive sources to their country of origin when no longer needed in Pakistan.
- Public liability, including the implementation of national regulations and international conventions concerning third party liability. Through sections 30 – 33 of the PNRA Ordinance, the PNRA has the power to fix the level or extent of civil liability for an operator in case of various nuclear incidents. Note that Pakistan is not a signatory to the Convention on Third Party Liability.
- Physical Protection and Safeguards: The mandate of the PNRA does not extend to safeguards but covers physical protection, pursuant to section 16(2)(f) of the PNRA Ordinance 2001. The Authority co-operates closely with the Pakistan Atomic Energy Commission, the Ministry of the Interior, and the Ministry of Defence, on matters relating physical protection and the safety of facilities and activities.
- Water and consumption of food: The PNRA has not yet established contacts or liaisons with other relevant regulatory authorities in this area.
- Land use and planning: The PNRA has not yet established contacts or liaisons with other relevant regulatory authorities in this area, but it receives No Objection Certificates from them as part of licence application submissions from operators of nuclear installations.
- Safety in the transport of dangerous goods: Transport across the borders of Pakistan requires a No Objection Certificate from the PNRA. The Authority has also written to the Civil Aviation Authority, the Directorate of Technical Procurement at the Pakistan Atomic Energy Commission (PAEC), and the Ministry of Railways, informing them of the PNRA role in, and regulatory requirements for, the transport of radioactive material or goods.

Lastly, but not least, the PNRA has other additional regulatory functions such as:

- Independent radiological monitoring in and around nuclear facilities: The PNRA, through the power conferred to it by section 39(1) of the PNRA Ordinance 2001, may conduct such activities; it does not do so at this time, but plans to carry out such a function in the future.
- Independent testing and quality control measures: Pursuant to section 16(2)(k) of the PNRA Ordinance 2001, the PNRA may carry out such activities, as necessary, for putting into effect the provisions of its Ordinance. The PNRA is currently not carrying out such functions but witnesses the tests and quality control measurements of operators.
- Initiating, co-ordinating and monitoring safety-related research and development work in support of its regulatory functions: Section 16(2)(k) of the PNRA Ordinance 2001 gives the PNRA the authority to carry out these functions. Initial work in this area consists of research projects using graduate students sponsored by the PNRA. These projects are related to PNRA activities and are supervised by PNRA professionals. The PNRA plans to co-ordinate its research and development programme with national universities, in support of its regulatory function.
- Providing personnel monitoring services and conducting medical examinations: This function is expected to be difficult to carry out, but PNRA plans to do it in future.
- Monitoring of nuclear non-proliferation: This function is not part of the mandate of the PNRA.
- Regulatory control of industrial safety: This function is not part of the mandate of the PNRA; however, from time to time, the Authority feels morally obliged to exert such control at nuclear installations, in view of the deference to the PNRA by, and the absence at nuclear installations of inspectors from, the Ministry of Industry. The regulatory control of industrial safety is normally covered by an Ordinance whose responsibility for implementation lies with the Ministry of Industry.

**APPENDIX VIII: EMERGENCY NOTIFICATION SCHEME AMONG THE FACILITY,
REGULATORY BODY AND OFF-SITE AUTHORITIES**

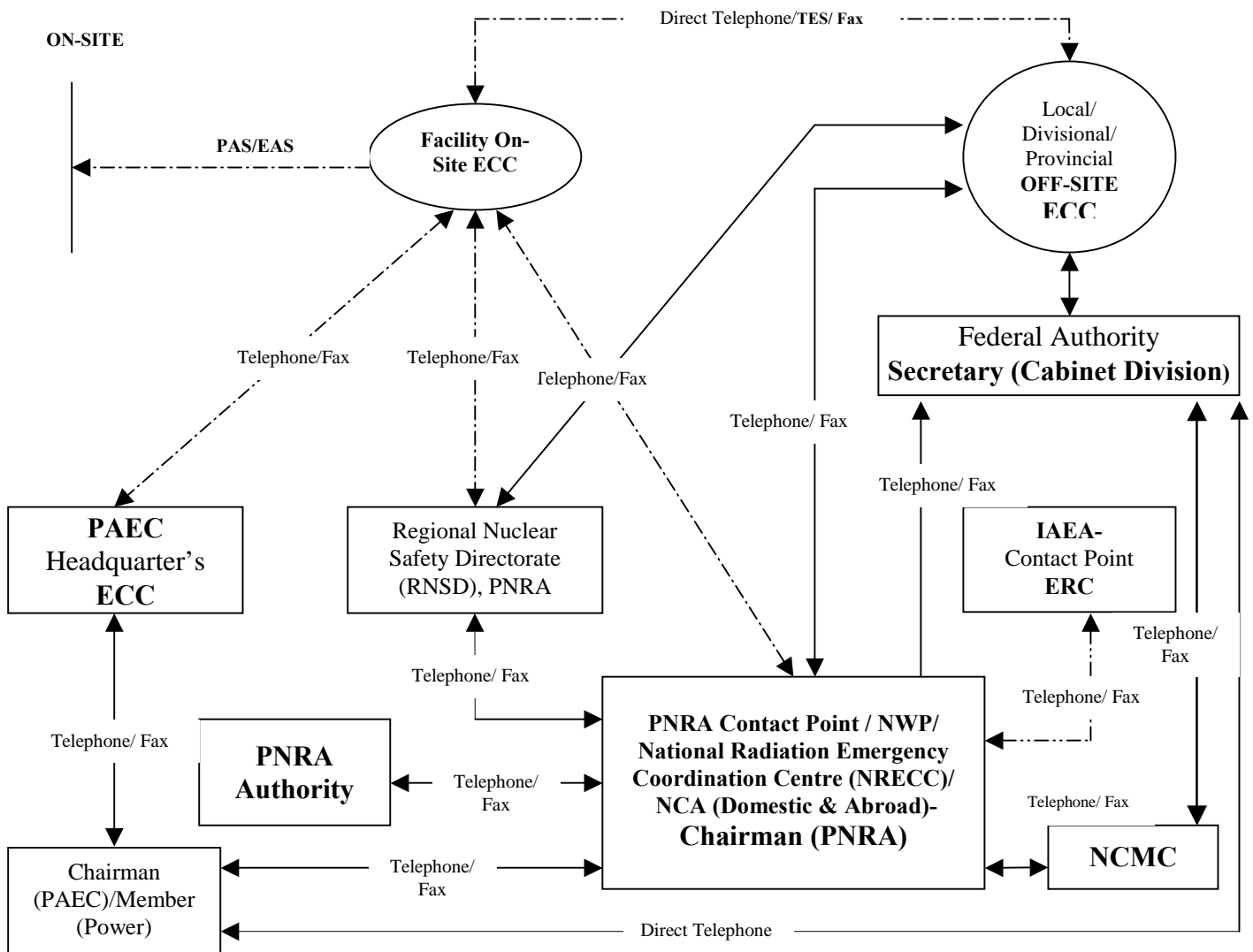


Legend:

- ▶ National Notification
- - -▶ National Recommendation
- · - · -▶ International Notification

- ECC = Emergency Control Center
- RSD=Radiation Safety Directorate
- I&E-Inspection & Enforcement
- PAEC=Pakistan Atomic Energy Commission
- NCA=National Competent Authority
- NCMC=National Crisis Management Center

APPENDIX IX: EMERGENCY COMMUNICATION SCHEME AMONG THE FACILITY, REGULATORY BODY AND OFF-SITE AUTHORITIES



Legend:

TES=Emergency Telephone System
 EAS=Emergency Alarm System
 PAS=Public Address System
 ECC = Emergency Control Center
 PAEC=Pakistan Atomic Energy Commission
 NCA=National Competent Authority
 NCMC= National Crisis Management Center

- ➔ Facility Communication
- ➔ National Communication
- ➔ International Communication

APPENDIX X: TEAM COMPOSITION

Mr. Gunter Giersch (Team Leader)	Safety Assessment Section Division of Nuclear Installation Safety, IAEA
Mr. Lyndon Bevington	Safety Assessment Section Division of Nuclear Installation Safety, IAEA
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Mr. Jongile Majola	Canadian Nuclear Safety Commission (CNSC) Canada
Mr. Petr Krs	State office for Nuclear Safety (SÚJB) Czech Republic
Mr. Marjan Levstek	Slovenian Nuclear Safety Administration (SNSA) Slovenia
Mr. Richard Wessman	US Nuclear Regulatory Commission (US NRC) USA
Ms. Ingrid Biela (Secretary)	Safety Assessment Section Division of Nuclear Installation Safety, IAEA