IAEA-NS-IRRS-2009/01
**ORIGINAL: English**

# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

**TO**

# PERU

Lima, Peru

***19 to 30 April 2009***

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

**INTEGRATED REGULATORY REVIEW SERVICE**
IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety,

waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (Code of Conduct on the Safety and Security of Radioactive Sources) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than eighty Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and for the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus

contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

# REPORT TO

# THE GOVERNMENT OF PERU

## Lima, Peru

**Mission date:** 19 to 30 April 2009
**Regulatory Body:** IPEN (Instituto Peruano de Energía Nuclear)
**Location:** Offices of the Oficina Técnica de la Autoridad Nacional (OTAN), Lima, Peru

**Regulated activities, facilities and practices:** Research reactor, medical practices, industrial and research applications, waste facilities.

**Organized by:** International Atomic Energy Agency (IAEA)

IAEA Review Team:

| | |
|---|---|
| **RODRIGUEZ MARTI**, Manuel | (Team Leader) |
| **ALTEN**, Serhat | (Deputy Team Leader) |
| **ENGLEFIELD**, Chris | (Reviewer) |
| **BLY**, Ritva | (Reviewer) |
| **PERRIN**, Marie-Line | (Reviewer) |
| **JEREZ VEGUERIA**, Pablo Fabián | (Reviewer) |
| **WALDMAN**, Ricardo | (Reviewer) |
| **TELLERIA**, Diego | (Reviewer) |
| **EVANS**, Stephen | (IAEA Team Coordinator) |
| **CALPENA**, Stéphane | (IAEA Deputy Team Coordinator |
| **PULIMOOD**, Sarah | (IAEA Administrative Assistant) |

IAEA - Issue date: October 2009

## FOREWORD

by Mohamed El Baradei
Director General

The General Conference Resolution of September 2007 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, encourages Member States embarking on new nuclear power programmes to take timely and proactive steps to establish and sustain a competent regulatory body with effective independence and the necessary human and financial resources to fulfil its responsibilities and to consider availing themselves of the Secretariat's recently established Integrated Regulatory Review Service (IRRS)… and notes the growing interest of Member States in the IRRS.

The Agency's safety review services use the IAEA safety standards as a reference point, and play an important part in evaluating their effectiveness. Last year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS), which combined previous services ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security.

The Agency conducted the first full scope IRRS in France in November 2006, covering all regulated nuclear and radiation facilities, activities and practices, including nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research activities, waste facilities, decommissioning, remediation and transport. The French Nuclear Safety Authority requested that the mission also cover public information practices. In March, the French Government hosted a workshop, attended by representatives from over 30 countries, so that regulators of other Member States could learn more about the IRRS and experience gained during the mission. The Agency also conducted IRRS missions to Australia and Japan in June 2007. The Spanish Nuclear Safety Council has offered to organize the next workshop, in late 2008 or early 2009, to disseminate information on the results of IRRS missions conducted in 2007 and 2008.

With its modular approach, the IRRS is contributing towards a more active exchange of knowledge among senior regulators and harmonized regulatory approaches worldwide. Future missions are also scheduled for Canada, Germany, Mexico, Pakistan, Russia, Spain, Ukraine and the USA. I would request all countries to take advantage of this service."

**The number of recommendations, suggestions and good practices is not a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

# Table of Contents

## EXECUTIVE SUMMARY

At the request of the Government of Peru (through the President of the 'Instituto Peruano de Energía Nuclear' (IPEN)) an international team of experts performed a peer review of Peru's statutory framework and national infrastructure for nuclear and radiation safety, in accordance with the Guidelines of the IAEA Integrated Regulatory Review Service (IRRS).

The IRRS mission took place from 19 to 30 April 2009.

Through an evaluation of the effectiveness of Peru's regulatory body, its regulatory activities and organisational structure, this IRRS mission facilitated regulatory improvements in safety and provided the opportunity to share experience and knowledge amongst regulatory body staff and the international reviewers.

Activities, facilities and practices regulated by IPEN include a research reactor, medical practices, industrial and research facilities and activities, waste facilities, decommissioning, remediation and the transport of radioactive materials.

The IRRS Review Team consisted of senior experts from Member States supported by IAEA staff.

The IRRS Team reviewed the following relevant areas: legislative and governmental responsibilities; the authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; emergency preparedness; and the management system of the regulatory body. In addition, at the request of the regulatory body, the mission scope included review of regulatory oversight of the following thematic areas: regulatory control of the research reactor; industrial uses of ionizing radiation; occupational radiation exposure; control of medical exposures; public exposure including waste management; education and training of regulatory staff, transport of radioactive materials and safety and security of radioactive sources.

The mission included a series of interviews and discussions with key personnel at IPEN, its technical office "Oficina Técnica de la Autoridad Nacional" (OTAN) and other organizations, together with observation of inspections of several facilities. OTAN supplied documentation and self-assessment material in advance of the mission (Advance Reference Material (ARM)) and the review team presented its findings based on the IAEA safety standards. Additionally, the team and regulatory body staff discussed a number of policy issues of particular interest to Peru and in the wider global context, relating to the regulation of nuclear and radiation safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of nuclear and radiation safety globally.

The IRRS Review Team noted the open, transparent and learning attitude of the regulatory body staff in performing the self-assessment prior to the mission and their openness throughout this mission. It was evident that significant effort had been put into the preparation of the mission; in particular the self-assessment using the IAEA methodology and tools. During the review the administrative and logistical support was excellent and the team was extended full cooperation in technical discussions with regulatory body personnel.

The IRRS Review Team appreciates and acknowledges IPEN's participation in international cooperation activities and encourages IPEN to continue its active role in the exchange of experience and expertise among regulators.

Given the limited resources within OTAN, the IRRS Team wishes to acknowledge that the staff are fully dedicated to their heavy workload, notably regarding the numbers of activities to be authorised and registered.

The IRRS Review team wants to highlight several major findings:

- IPEN is the regulator, but also a user and promoter of nuclear energy; OTAN is the executive arm of IPEN for regulatory activities.
- There is under-resourcing of OTAN (financial and staff), including inadequate resources for competence-building of OTAN staff.
- The required national regulations should be completed, especially technical regulations and guides.
- National coordination and cooperation between the various Governmental bodies are inadequate (for instance in the fields of emergency preparedness and response, transport, health and mining).
- There is a need to improve both regulatory oversight and operator compliance with safety requirements in general.

The IRRS Review Team identified good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to further strengthen the effectiveness of regulatory oversight. These recommendations and suggestions will support IPEN in improving its regulatory performance. Some of these recommendations and suggestions are related to areas in which IPEN has already initiated improvement actions.

The most relevant good practices identified were:

- A compiled set of procedures for licensing (TUPA) is available to the public.
- Written procedures, specifically; "Authorization of installations" and "Authorization of individual licences", including flow charts of the processes have been prepared and implemented.
- OTAN requires that geological slope instability (such as landslides and past experience of El Niño) that could potentially affect research reactor safety, be evaluated for the site and its vicinity and that remediate actions be taken as necessary. The Licensee has erected an embankment to protect the site against landslides.
- The Radiological Safety Regulation is based on both International Standards and national feedback in the field of radiation safety.

The IRRS Review Team believes that consideration of the following recommendations and suggestions should be given high priority, either because they were identified in several areas of review or because the reviewers considered they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- Amendment to legislation should be considered to address the effective separation of regulatory activities from promotion and operation.
- A national policy on nuclear and radioactive waste management should be developed.
- The Government should consider action, in accordance with Article 24 of Law Decree 21875 to provide IPEN with sufficient financial and human resources to effectively accomplish its assigned functions.
- Safety principles for nuclear installations should be included in the statutory framework.
- IPEN and OTAN as appropriate should establish cooperation agreements and national systematic communications with other relevant competent authorities.
- IPEN should explicitly require that the Licensee establishes a programme for the management of ageing of the research reactor, including in-service inspection.
- IPEN should identify all topics still requiring the development of regulations. A programme and necessary actions to issue these new regulations should be defined with establishing priorities and timescales.
- IPEN/OTAN should develop a continuous training programme for their staff.
- IPEN should develop a detailed regulation on safety culture, including provisions to ensure that a safety culture is fostered and maintained in both the operating organizations and IPEN/OTAN.
- The 'National Plan for Preventing and Attending Disasters' should be revised to incorporate appropriate provisions for nuclear and radiological emergencies to assure that adequate preparations are established and maintained at local and national levels and as appropriate with bordering countries.
- IPEN should revise and update the report on the assessment of radiological threats considering the latest improvements of the IAEA's methodologies/standards and the national experience.

The IRRS Review Team full findings are detailed in Appendix V.

# I. INTRODUCTION

At the request of the Government of Peru (through the President of the 'Instituto Peruano de Energía Nuclear' (IPEN)) an international team of experts performed a peer review of Peru's statutory framework and national infrastructure for nuclear and radiation safety, in accordance with the Guidelines of the IAEA Integrated Regulatory Review Service (IRRS).

A preparatory meeting was conducted in August 2008 at the OTAN office in Lima to determine the purpose, objectives, scope and schedule for the review, followed by a self-assessment workshop in Lima in December 2008.

The purpose of this IRRS mission was to conduct a peer review of the Peruvian statutory framework and regulatory infrastructure for nuclear and radiation safety in all regulated activities and facilities within the agreed scope of the mission. The mission provided a review of the regulatory effectiveness of the regulatory body and provided an exchange of information and experience in the areas covered by the IRRS. The review included legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; authorization process; review and assessment process; inspection and enforcement process; development of regulations and guides; emergency preparedness and the management system of the regulatory body. In addition, at the request of OTAN, the mission scope included review of the following thematic areas: regulatory control of the research reactor; industrial uses of ionizing radiation; occupational radiation exposure; control of medical exposures; public exposure including waste management; education and training of regulatory staff, transport of radioactive sources and safety and security of sealed radioactive sources.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of matters that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear and radiation safety. The regulatory technical and policy issues discussed were identified during pre-mission preparatory meetings for the Peru mission, through the review of Peru's advance reference material and more globally, from insights resulting from conclusions of review meetings of the Convention on Nuclear Safety, international conferences and forums and previous IAEA safety review services to Member States.

Before and during the mission, OTAN made various reference materials available for review. This material consisted of legal, regulatory and internal documents, including the report of the self-assessment made using the IAEA methodology and tools. During the mission the team performed a systematic review of all topics using the self-assessment report, the advance reference material (ARM) and related presentations, interviews with IPEN, OTAN and other staff, together with direct observation of working practices during inspections carried out by OTAN. In addition, there were discussions with the President of IPEN and with the Vice-Minister for Energy.

IRRS activities took place mainly at the offices of OTAN. Discussions and observations were also conducted at remote locations as noted in Appendix III.

## II. OBJECTIVE AND SCOPE

The purpose of the mission was to review the legal and governmental infrastructure for nuclear and radiation safety in Peru, the effectiveness of the regulatory body and to exchange information and experience among Peruvian counterparts and the IRRS team, with a view to contributing to the harmonization of regulatory approaches and creating mutual learning opportunities among senior regulators.

The key objectives of this mission were to enhance safety by:

- Providing Peru (regulatory body and governmental authorities) with a review of the discussions of nuclear, radiation, radioactive waste, transport, safety regulatory technical and policy issues;
- providing Peru with an objective evaluation of its regulatory practices with respect to IAEA safety standards;
- contributing to the harmonization of regulatory approaches among Member States;
- promoting sharing of experience and exchange of lessons learnt;
- providing key staff in Peru with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- providing Peru with recommendations and suggestions for improvement;
- in due course, providing other States with information regarding good practices identified during the review;
- providing the reviewers from member States and IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- providing Peru with an opportunity for self-assessment of its activities against IAEA safety standards using the IAEA self-assessment methodology and tools.

The scope for this IRRS mission, as agreed with OTAN, included:

- Legal and governmental infrastructure for nuclear and radiation safety.
- Research reactors.
- Industrial uses of ionising radiation.
- Occupational radiation exposure.
- Control of medical exposure.
- Public exposure, including radioactive waste management.
- Education and training.
- Transport.
- Emergency planning and preparedness.
- Management system.
- Safety and Security of Radioactive Sources

## III. BASIS FOR THE REVIEW

### PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was conducted by the IRRS Team Coordinator Mr Stephen Evans, NSRW/IAEA, and by the IRRS Deputy Team Coordinator, Mr Stéphane Calpéna, NSNI/IAEA. The reviewers, including the IRRS Team Leader, Mr Manuel Rodriguez and the IRRS Deputy Team Leader, Mr Serhat Alten, were drawn from IAEA Member States. In accordance with the request from the Counterpart, and taking into account the scope as indicated above, it was agreed that the IRRS review team would comprise eight expert reviewers (see Appendix I) and three IAEA staff. The topic areas and the regulatory body counterparts were distributed according to Appendix V.

During the preparatory period advance reference material (ARM) was forwarded electronically by OTAN to the IAEA and distributed to the reviewers. During the mission any relevant further material was freely made available as the mission progressed (a list of the reference material is included in Appendix VII). All details and organizational aspects of the mission were defined with the nominated OTAN Liaison Officer, Mr. Renán Ramirez.

Prior to the mission, a significant amount of work was carried out by the Review Team and IAEA staff in order to prepare the initial impressions about the ARM, to review the OTAN self-assessment report, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary for the conduct of the mission.

A Review Team briefing was conducted on 19 April 2009 in Lima by the IRRS Team Leader, the IRRS Coordinator and the IRRS Deputy Coordinator, during which the specifics of the mission were discussed, together with the basis for the review, background, context and objectives of the IRRS. The OTAN Liaison Officer attended the briefing. Based on the ARM, the reviewers reported their first impressions of the current status of all topic areas within the scope of the mission during this briefing.

### REFERENCES FOR THE REVIEW

The main reference documents provided by OTAN for the review mission are indicated in Appendix VII. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VIII.

### CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted for all review areas with the objective of providing IPEN with recommendations and suggestions and identifying good practices.

The review was conducted through meetings, interviews and discussions with regulatory body personnel; visits to relevant organizations; assessment of the ARM and direct observations regarding national practices and activities particularly in the context of inspections.

The team performed its activities based on the Mission Programme given in Appendix II. The entrance meeting was held on Monday 20 April 2009 with the participation of IPEN and OTAN senior management. Opening remarks on behalf of IPEN were made by the Executive Director of IPEN, Mr Ivan Llamas Montoya (acting for the President of IPEN). Comprehensive presentations by OTAN staff were coordinated by Mr Renán Ramirez, Director of OTAN.

The exit meeting was held on Thursday 30 April 2009 at the Headquarters Offices of IPEN in the presence of Conrado Seminario Arce, President of IPEN and Mr Renán Ramirez, Director General of OTAN, together with the Department Heads of OTAN, and other technical and support staff.

Mr Manuel Rodriguez, IRRS Team Leader, presented the main conclusions of the mission and the IRRS reviewers each provided summaries of their findings. Remarks on the conduct of the mission and expressions of thanks were made by the IRRS Team Coordinator, Mr Stephen Evans, Division of Radiation, Transport and Waste Safety (NSRW) IAEA after which closing remarks were made by the President of IPEN. A preliminary draft of the IRRS mission report was provided to IPEN at the conclusion of the meeting.

# 1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

## 1.1 GENERAL

### *1.1.1 Governmental Structure*

Peru has a governmental structure organized in "Regions". However, public services are carried out centrally, including regulation of facilities and activities using ionizing radiation sources. IPEN (Instituto Peruano de Energía Nuclear) has been established by Law Nº 21875, approved on July 5th, 1977. IPEN is funded through the general budget of the Peruvian Treasury which includes income from fees and fines. IPEN reports to the Ministry of Energy and Mines.

### *1.1.2 Nuclear and radiation facilities and activities*

Peru has two nuclear facilities, a 10 MW pool type RP-10 and a zero power RP-0 research reactor. There is also a radioactive waste storage facility, 'Planta de Gestión de Residuos Radiactivos' (PGRR) for low and/or intermediate level radioactive sources, a radioisotope production facility and a dosimetry laboratory. In addition, Peru has wide-ranging industrial and medical facilities, some of which were visited during the course of the mission.

## 1.2 LEGISLATIVE

### *1.2.1 Safety Legislation*

There are three 'levels' of legislative documents in the Peruvian system:

1 Laws – Approved by the Government.

2 High level implementing regulations called 'Rules of Law', approved by Supreme Decree.

3 Technical regulations, issued by IPEN/OTAN.

The principle legislation is Law Nº 28028 "Regulation on the Use of Ionizing Radiation Sources" of 2003, addressing issues such as authorisation, responsibilities and financial provisions.

This law is implemented through Supreme Decree Nº 039-2008-EM (also known as Rule of Law Nº 28028) of 2008, addressing the details of scope, exemptions, exclusions, notifications, registrations, authorisations of ionizing sources and nuclear facilities, authorisation of individuals, inspections and enforcement including sanctions together with Supreme Decree Nº 009-97-EM "Regulation on Radiological Safety" of 1997, which is broadly based on 'The International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources', Safety Series 155 (BSS 115).

Finally, the 'Unique Text of Administrative Procedures' (TUPA), is a Ministerial Resolution covering OTAN activities and establishes further licensing requirements.

### *1.2.2 Nuclear Legislation*

Law Nº 21875 established IPEN as a centre for promoting of the use of ionizing radiation technology, performing research and development activities on the relevant subjects, and regulating the activities and facilities using ionizing radiation.

The IRRS Team was informed that a Peruvian Congressman is proposing to promote the use of nuclear energy, realized in the form of draft laws on nuclear electricity, the contents of which were not made known to the IRRS team.

Law Nº 27757 and its implementing regulation 'Rule of Law Nº 27757', together establish the import control mechanism for ionizing radiation sources. Supreme Decree Nº 014-2002-EM, 'Regulation on Physical Protection of Nuclear Materials and Facilities' regulates the security aspects of nuclear materials and facilities.

**Nuclear Legislation and Related Regulations**

### *1.2.3 Secondary Safety Legislation*

- There are several technical regulations on the safety norms for various applications of ionizing radiations including principally:
- Norma PR.001.91 "Requisitos para la Vigilancia Radiológica Individual". Approved by Resolution of the President of IPEN (R.P.N ° 062-91-IPEN/AN)
- Norma PR.003.94 "Requisitos Técnico-Administrativos para los Servicios de Dosimetría Personal de Radiación". Approved by Resolution of the President of IPEN (R.P.N ° 005-94-IPEN/AN)

- Norma PR.002.95 “Disposiciones para el manejo Seguro de los Desechos Radiactivos”. Approved by Resolution of the President of IPEN (R.P.N ° 009-95-IPEN/AN)
- Norma IR.011.96 “Aspectos Técnicos y Administrativos para obtener la Licencia de Instalación de Radiología Dental”. Approved by Resolution of the President of IPEN (R.P.N ° 015-96-IPEN/AN)
- Norma IR.012.98 “Requisitos Técnicos de Seguridad Radiológica para Irradiadores Gamma Panorámicos de Categoría II y IV”. Approved by Resolution of the President of IPEN (R.P.N ° 008-98-IPEN/AN)
- Norma IR.013.98 “Requisitos Técnicos de Seguridad Radiológica para el Uso de Irradiadores Gamma Autoblindados de Categoría I”. Approved by Resolution of the President of IPEN (R.P.N ° 009-98-IPEN/AN)
- Norma IR.001.01 “Requisitos de Seguridad Radiológica en Teleterapia”. Approved by Resolution of the President of IPEN (R.P.N ° 007-01-IPEN/AUNA)

All such regulatory documents take the form of a Presidential Resolution signed by the President of IPEN, published in the Official Gazette. They are mandatory for all users of nuclear technologies.

A draft regulation titled “Norms of Radiological Safety Framework for Industrial Radiography” has been recently placed on the IPEN website for public consultation prior to final approval, as the relevant law requires.

Other requirements on safety, based on IAEA safety documents, are being enforced through licence conditions attached to authorisations.

### *1.2.4 State Institutions in the Nuclear Field*

There is only one State regulatory institution in the nuclear field. IPEN was established in 1977 by Law Nº 21875 as the competent body for regulation, but also for promotion, research and development. The organisational chart of IPEN can be seen in Appendix VIII of this report. IPEN discharges its promotion, research and development responsibilities through the Executive Directorate. There are several research and production facilities under IPEN, including two research reactors, a radioactive waste storage facility, a radioisotope production facility, and several laboratories. IPEN also promotes the use of ionising radiation in medical and industrial activities.

There are only general provisions for the safe management of nuclear and radioactive waste in legislation. National policies are yet to be established particularly for radioactive waste management. Negotiations are continuing for sending spent fuel of research reactors to the country of origin.

Peru has a Ministry in charge of transport and there is a regulation addressing terrestrial transport of dangerous goods. By this regulation, regulatory duties relating to terrestrial transport of nuclear and/or radioactive materials are assigned to IPEN. No regulations have been developed for other means of transport such as air or sea transport. IPEN is identified as the sole organisation in charge of transport of nuclear and/or radioactive materials in the above mentioned regulation.

A national emergency response plan is in place for both natural and manmade disasters, however, nuclear or radiological emergencies are not included in its scope. IPEN is identified in Law Nº 28028 as the coordinator for such emergencies. IPEN has developed an internal emergency plan for the research reactors it operates and an IPEN Directive has been issued for activities in case of emergencies in any other facilities or activities.

Although Law Nº 28028 Article 6 makes provision for financial compensation and coverage for nuclear and radiological damages, these provisions have not yet been developed or implemented in practice.

### *1.2.5 Establishment of the Regulatory Body*

By Law Nº 21875 IPEN has been established as the regulatory body for facilities and activities using ionizing radiation sources. The regulatory responsibilities of IPEN have been defined in Article 6 of Law Nº 21875 as issuing norms, licences and regulations in relation to nuclear safety and radiation protection in various activities of production and utilisation of radioactive materials, sources and equipment and inspecting these activities. These responsibilities are elaborated in Article 3 of Law Nº 28028 as regulation, authorisation, control and inspection of the use of ionising radiation sources with respect to nuclear and radiological safety and physical protection and safeguards of nuclear material.

The "Oficina Técnica de la Autoridad Nacional" (OTAN), which reports directly to the President of IPEN, carries out all the regulatory activities of IPEN. According to the implementation regulations relating to Law Nº 28028, Article 4, OTAN is the competent authority and first instance for authorisation, inspection and enforcement for activities and facilities within the scope of this law, whereas the President of IPEN is the second and last instance. Within these definitions, neither IPEN nor its regulatory executive unit OTAN has undertaken the responsibility of review and assessment, explicitly. According to Article 12 of the implementing Rule of Law Nº 28028, authorisations given by OTAN should be based on verification of compliance to nuclear and radiological safety norms, which may be considered as implicit declaration of review and assessment responsibility.

While the scope of Law Nº 28028 has been declared in Article 2 as all activities that cause or create potential for exposure to ionising radiation, Rule of Law Nº 28028 revises the scope of the Law as extending to all natural or legal persons who undertake practices using ionising radiation sources, such as obtaining, possessing, utilising, transferring, acquiring, fabricating, modifying, maintaining, management of radioactive wastes, storing, transporting, importing, exporting, selling, mining, extracting and treatment of nuclear materials, closure, related services, and other activities using ionising radiation sources. The otherwise exhaustive list given in the implementing regulation does not include site rehabilitation; however this is included in Article 56 of Rule of Law Nº 28028 as a requirement for the closure licence.

The annual income of IPEN comprises a budget allocated by the Treasury from the general budget, together with fees for its services and fines which may be imposed by OTAN. However, adequate resourcing of the regulatory body has not been explicitly defined as a governmental responsibility in the Law.

The budget of OTAN is allocated from the budget of IPEN by the President of IPEN. Given OTAN's current regulatory workload, the IRRS Team believes that additional

development of the regulatory body through increases in financial and human resources of OTAN may be required.

By Law 28028 IPEN is recognised as the only competent body for regulatory control of activities and facilities using ionising radiation. IPEN believes this may have some bearing on the reluctance of other organizations to accept they may also have a role in the regulatory process. In consequence, there are currently no formal coordination and cooperation agreements between IPEN and other national agencies. In this respect, IPEN and its regulatory executive body OTAN are seeking in particular, to establish cooperation mechanisms with other governmental organizations in areas such as mining, customs and border control, transport of nuclear and radioactive materials, emergency preparedness and response and security issues.

The mining of uranium is expected to commence in Peru in the near future (prospecting is already underway). For the authorisation of mining activities, the competent body identified in legislation is the Ministry of Energy and Mines, although there are no specific provisions for the case of uranium mines. When the current draft law on uranium mining is approved, the IRRS Team understands that it is expected that authorisation of uranium mining activities will require a binding report from IPEN with regard to regulatory control of the radiation safety aspects.

In accordance with Article 8 of Law Nº 28028, prime responsibility for safety is placed upon the operator of a facility using ionising radiation. While the facilities and activities within the scope have been defined in general terms in Law Nº 28028, it has been clearly established in specific terms in Rule of Law Nº 28028, including exemptions and the means of authorisation.

Article 4 of Rule of Law 28028 defines the mechanism for appeal against regulatory decisions. Through this legislation, the first level of appeal is through OTAN as the first instance and thereafter, to the President of IPEN in a manner consistent with the general legislative infrastructure of Peru. However, the President of IPEN must seek the advice of an ad-hoc committee prior to the final resolution of appeals.

Transfer of responsibilities in the case of successive operators has been addressed in Article 29 of Law Nº 28028, through re-licensing, which requires the statements of transfer and acceptance of responsibility from both operators.

There are some basic requirements without specific details, regarding financial provisions for liability issues and for radioactive waste management and decommissioning, however, clear financial provisions do not appear to be in place, particularly for nuclear installations.

By Article 6 of Law Nº 21875 IPEN is the competent authority for issuing technical regulations, granting, suspending and revoking authorisations. Further details, such as requiring the operator to perform safety reassessment, are handled in licence conditions attached to authorisations.

IPEN has the authority to communicate with the Ministry of Energy and Mines, but not to liaise directly with any other governmental authorities as the situation requires.

IPEN has also the authority to communicate its regulatory requirements and opinions but not directly with the public as necessary. Even though IPEN does not have “de jure” authority to communicate with the public, in practice it communicates with the public without interference from the Ministry.

There is no provision in the legal framework which empowers IPEN to communicate information on incidents and abnormal occurrences reported by operators. However, these have been reported to the national body for emergencies, together with IPEN.

Since there is no provision regarding international dissemination of such information, IPEN does not contribute to incident reporting systems. IPEN also has only a limited capacity to make this information public (through other Ministries). It should be noted however, that IPEN-OTAN is the INES and ITDB contact point for information on nuclear events.

While IPEN's communications with other national bodies must be made only through the Ministry of Energy and Mines, paradoxically, it may liaise directly with international organizations such as IAEA. Furthermore, there are bilateral relations with Argentina and Brazil.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** GS-R-1 para. 2.2(2) states: *"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".*

**2. BASIS:** GS-R-1 para. 4.1 states: *"The regulatory body's reporting line in the governmental infrastructure shall ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or activities".*

**R1. Recommendation:** An amendment to legislation should be implemented requiring the effective separation of regulatory activities from promotion and operation.

**3. BASIS:** GS-R-1 para. 2.2(6) states: *"Adequate infrastructural arrangements shall be made for the safe management of spent fuel and radioactive waste".*

**R2. Recommendation:** A national policy on nuclear and radioactive waste management should be developed**.**

**4. BASIS***:* GS-R-1 para. 2.2(10) states: *"Adequate financial indemnification arrangements shall be made for third parties in the event of a nuclear or radiation accident in view of the damage and injury which may arise from an accident".*

**S1. Suggestion:** Legal provisions should be prepared requiring financial indemnification of third parties in the event of a nuclear or radiation accidents.

**5. BASIS***:* GS-R-1 para 2.2(7) states:*"Adequate infrastructural arrangements shall be made for the safe transport of radioactive material"*

**R3. Recommendation**: Regulations on transport of dangerous materials, including nuclear and radioactive material by air and sea should be developed.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**6. BASIS**: GS-R-1 para 2.2(8) states*: "An effective system of governmental emergency response and intervention capabilities shall be established and emergency preparedness shall be ensured"*

**R4. Recommendation:** The national emergency plan should be amended to include nuclear and radiological emergencies, as appropriate.

**7. BASIS:** GS-R-1 para 2.2(4) states*: "The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities"*

**R5. Recommendation**: The Government should consider action, in accordance with Article 24 of Law Decree 21875 to provide IPEN with sufficient financial and human resources to effectively accomplish its assigned functions and tasks as regulatory body.

## 2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

### 2.1 FULFILLING STATUTORY OBLIGATIONS

Policies and safety principles are defined in Rule of Law 28028. It does not include nuclear safety principles. Nor are nuclear safety principles included in any other national regulations.

IPEN establishes, promotes and adopt regulations upon which its regulatory actions are based. Although it also has the capacity to do so, it does not establish, promote or adopt guides to further develop the safety and radiation protection requirements included in high level regulations.

OTAN reviews and assesses operators' submissions on safety prior to authorization.

Except for the research reactor, for which specific requirements are included in the limits and conditions of the operating licence, no periodic submissions on safety related matters are required, neither through regulations nor in authorisations. Periodic submissions from the research reactor operator are subjected to review and assessment in the same way as documents submitted for authorisation.

Authorizations released by OTAN clearly specify the facilities, activities or inventories of sources covered by the authorization.

A requirement for the licensee to notify OTAN of any modification to safety related aspects is included in the terms of the licence and a list of the documents to be submitted with the application is included as a condition of the licence.

Other aspects related to safety of facilities are included as conditions in authorisations, particularly those related to the licensee's obligations with respect to the facility, equipment and sources, personnel licences, incident reporting, emergency preparedness and records keeping. No requirements are included in authorisations related to discharge limits (except for the research reactor) or radioactive waste conditioning.

According to Article 7 of Law 28028 and its Rule of Law, the regulatory body has the capacity to carry out regulatory inspections. When deviations from regulations are found, implementation of corrective actions is required and made known to the licensee through the inspection record or by a regulatory letter sent by the OTAN Director.

As stated in Rule of Law 28028, Article 85, IPEN has the capacity to impose sanctions in cases of violations of regulations or safety requirements.

OTAN has established processes to deal with applications for authorization, personnel licences, exemptions and removal from regulatory control. Most of the procedures to be followed in those processes, including necessary documents, information and other requirements, are compiled in an administrative regulation called the 'Texto Unico de Procedimientos Administrativos' (TUPA), which can be viewed publicly on IPEN´s website. However IPEN has not yet provided guidance to licensees on developing and presenting safety assessments or any other required safety related information necessary to obtain authorizations.

Limits and conditions included in an OTAN authorization can be modified at any time where the licence-holder applies for a modification authorization during the period of

the licence or at licence renewal once the validity term has expired. For the case of nuclear facilities Article 50 of Rule of Law 28028 allows IPEN at its own initiative, to add new terms and conditions in addition to those imposed in the conditions of licence currently in force.

Where OTAN rejects a submission or application, an explanation of the reasons for the rejection is included in the communication to licensee.

No systematic approach has been developed to collect and disseminate operating experience among licensees and other interested parties, although some technical meetings with users and specialists have been organised to discuss lessons learned from events.

No specific requirements exist about record-keeping relating to the safety of facilities and activities. There is an internal administrative procedures manual (Manual de Disposiciones Internas) updated September 2007 and approved by the President of IPEN. It includes procedures for institutional relationships and record-keeping. Also general regulations require Peruvian public organizations to keep records for a five year period. This is implemented for OTAN´s own records as for any public institution. Most private organizations tend to keep records for a period of three years although it is not a regulatory requirement.

To ensure that its regulatory principles and criteria are adequate and valid OTAN takes reference from international standards and recommendations. The IRRS Team understands these are periodically updated for compatibility with the latest international developments.

As established in Article 6 of Law 21875 IPEN may advise the government on matters relating to the safety of facilities and activities.

OTAN confirms the competence of personnel responsible for the safe operation of the facilities or activities. Personnel are evaluated by the regulatory body before issuing the specific personnel authorization required in Rule of Law 28028, Chapter VIII. Maintenance of personnel qualifications is periodically verified through inspections. The procedure to be followed to obtain a personnel licence is established in the TUPA regulations.

Licensing and inspection are the only means by which OTAN confirms that safety is managed adequately by the operator. They are also OTAN’s prime means of promoting a safety culture amongst individuals and organizations managing radiation sources and for disseminating information on safety in authorized practices to relevant persons and to professional organizations representative of radiation user groups (e.g. radiologists, industrial radiographers).

Whereas OTAN does not have functions additional to those assigned to a regulatory body in international standards, IPEN performs some functions as a facilities operator as well as providing training, personnel monitoring services, environmental radiological monitoring, radiation instruments calibration and verification and quality control measurements that may conflict with its functions as Regulatory Body.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** GS-R-1 para.3.1. states: *"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."*.

**R6. Recommendation**: Safety principles for nuclear installations should be included in the statutory framework, rather than only addressed in the licensing conditions for the RP10 reactor.

**2. BASIS:** GS-R-1 para.3.2. states: *" In fulfilling its statutory obligations, the regulatory body:*
*(1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;"*

**3. BASIS:** GS-R-1 para 3.2. states: *" In fulfilling its statutory obligations, the regulatory body:*
*(3) shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information;"*
**4. BASIS:** GS-R-1 para 5.4 states: *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.*
*The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested. For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages, each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stages.*
**R7. Recommendation**: IPEN should define and implement a programme for regulatory guidance development and issuance to help licensees to:

- comply with safety and radiation protection requirements included in high level regulations;
- develop and present safety assessments or any other required safety related information necessary to obtain authorizations and;
- prepare documents to be submitted in support of applications for all authorizations included in Rule of Law 28028 with adequate format and content.

**5. BASIS:** GS-R-1 para.3.2. states: *" In fulfilling its statutory obligations, the regulatory body:*

*(2) shall review and assess submissions on safety from the operators both prior to authorization and periodically during operation as required;"*

**S2. Suggestion:** IPEN should establish the full range of information to be submitted periodically by operators on safety matters to better accomplish its function on control of facilities and activities. Requirement for submission of such periodic information should be included in regulations or authorizations
**6. BASIS:** GS-R-1 para. 3.2. states: *"In fulfilling its statutory obligations, the regulatory body:*

*(3) shall provide for issuing, amending, suspending or revoking authorizations,*

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
|---|
| *subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):*<br><br>*(iv) any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization);*<br><br>*(v) conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;"*<br><br>**R8. Recommendation**: Requirements related to discharge limits and radioactive waste conditioning should be included in facilities´ authorisations**.** |
| **G1. Good Practice**: Most procedures to be followed in licensing processes, including necessary documents, information and other requirements, are compiled in an administrative regulation called 'TUPA' available on the IPEN Website.<br>**7. BASIS:** GS-R-1 para.3.3. states*: "In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:*<br><br>*(7) shall ensure that operating experience is appropriately analyzed and that lessons to be learned are disseminated;"*<br><br>**R9. Recommendation**: IPEN should ensure a systematic approach to collection, analysis and dissemination of operating experience among licensees.<br><br>**8. BASIS:** GS-R-1 para 3.3. states: *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body*:<br><br>*(8) shall ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable;"*<br><br>**S3. Suggestion**: In addition to existing generic regulations for record-keeping, IPEN should detail specific requirements for record-keeping relating to safety, including retention periods. |

## 2.2 REGULATORY BODY – COOPERATION WITH OTHER RELEVANT AUTHORITIES

Article 8 of Law 21875 on the establishment of IPEN authorises IPEN's President to directly represent IPEN at all levels of Government and internationally on matters related to IPEN's functions and responsibilities.

In Peru there are designated authorities in charge of environmental protection, health; emergency planning and preparedness, mines, public liability, physical protection, water use and consumption of food, land use and planning and transport of dangerous goods. Currently, IPEN does not have routine systematic communications with these authorities or with other competent governmental bodies; IPEN only provides information when officially required.

No specific procedures are in place for the collection of national and international information with an important bearing on safety in authorized practices.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 3.4. states: "*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:*

*(1) environmental protection;*

*(2) public and occupational health;*

*(3) emergency planning and preparedness;*

*(4) radioactive waste management (including determination of national policy);*

*(5) public liability (including implementation of national regulations and international*

*conventions concerning third party liability);*

*(6) physical protection and safeguards;*

*(7) water use and consumption of food;*

*(8) land use, planning;*

*(9) safety in the transport of dangerous goods"*

**R10. Recommendation**: IPEN should establish cooperation agreements and national systematic communications with other relevant competent authorities.

## 2.3 REGULATORY BODY – INTERNATIONAL COOPERATION

IPEN/OTAN has international relationships only in the frame of international organizations such as IAEA, the Pan-American Health Organisation (PAHO) or the World Health Organisation (WHO). No bilateral agreements exist for effective cooperation and information exchange with neighbouring countries although some cooperation activities take place only when promoted and funded by international organizations. IPEN takes part in the IAEA regional cooperation programme 'Latin American Regional Cooperation Agreement' (ARCAL).

## 2.4 POLICY ISSUES DISCUSSED DURING THE IRRS MISSION TO PERU

Policy issues were reviewed in open discussion during the course of several meetings with various individuals. The following persons took part in these meetings:

- Vice Minister of Energy and his adviser
- The President of IPEN
- The Director of OTAN.
- The Head of Authorization at OTAN.
- The IRRS Team Leader.
- The IRRS Deputy Team Leader.

The Mission Coordinator and/or Deputy Coordinator was in attendance at each session.

**National Regulatory Infrastructure Development**

After thorough discussion, a general agreement was reached that to comply most effectively with IAEA requirements, a Member State would not usually have only a single organization identified as the Regulatory Body, to which all responsibilities and functions defined in IAEA international standards have been assigned. In the majority of countries, as in Peru, there are several governmental organizations responsible for various topic areas, including for example, emergency preparedness and response, transport and health. Regulations, experience and resources existing at these various organizations should be used in conjunction with those available at the regulatory body for nuclear and radiation safety both to build a governmental infrastructure for the safety of facilities and activities and to best apply the principles presented in the Safety Fundamentals, as stated in GS-R-1 paragraph 1.3.

The counterparts recognize that in Peru only limited cooperation exists between IPEN and other governmental organizations. The causes of this situation were analyzed and it was concluded that, amongst other reasons, this is because governmental organizations have limited resources that they reserve for the functions directly assigned to them and they avoid resource consuming cooperation with other governmental organizations, especially in areas they feel are outside their direct competence.

Among possible solutions discussed were:

- to use legal instruments to implement a framework that ensures inter-governmental cooperation;
- to foster the establishment of Commissions to facilitate cooperative arrangements between governmental organizations;
- to foster a nationally coordinated approach to international cooperation.

**Uranium Mining Authorisation and Control**

The introduction of uranium mining in Peru is being considered and prospecting has already begun. Draft legislation currently in Parliament suggests that most aspects of this activity will be controlled by the Inspectorate for Mining. There is a need therefore, to ensure due reference is made by legislation to other organizations which should be involved in the regulatory control of mining. IPEN recognizes it should have a major role in the control of the radiation safety aspects, but it is currently not clear how these aspects would be controlled within the broader regulatory process for uranium mining. International advice and assistance should be considered before the draft legislation is finalised.

**Embarking on Nuclear Power**

The government of Peru periodically prepares National Energy Plans.

At the present time no agreed short-term plans exist for the introduction of nuclear power but, for the medium term, the nuclear option is under consideration by Congress and the Ministry of Energy.

Possible mechanisms to increase the knowledge and interest of Peru's Government regarding current regulatory status and future needs related to national infrastructure for safety and security of nuclear facilities and activities were explored, identifying:

- that IPEN should prepare a comprehensive and realistic report to be sent to Government;
- the need for direct Regulatory Body contact with Peru's leaders;
- the benefits of international advisory activities. The report of the IRRS mission for instance, was identified as a particularly useful tool with this objective.

Long before the anticipated deadline to start a nuclear power programme, Peru should begin development of the necessary governmental infrastructure for the safety and security of facilities and activities. Even where a country has no plans for nuclear power development the need for continuous improvement of regulatory infrastructure is essential to maintain adequate regulatory oversight of all activities in the country in accordance with international requirements and undertakings.

**The Independence of the Regulatory Body**

IPEN is currently performing functions both as an operator and a regulator of nuclear and radiation facilities, activities and practices. This creates potential for undue pressure from interests which may conflict with safety. The need to review this situation is now clearly evident because users of nuclear and radiation technologies have expanded greatly in recent years. In addition to the Huarangal Nuclear Centre (research reactor and manufacturing of radionuclides) there are now more than 3,000 other authorised users in industry, health and other fields. Given this rapid expansion, it was agreed that it is advisable to adopt a model for effectively independent regulatory control in accordance with IAEA requirements. This would represent a significant step in Peru's progress towards uranium mining and nuclear power development.

# 3. ORGANIZATION OF THE REGULATORY BODY

## 3.1 GENERAL ORGANIZATION

IPEN has been established as the sole national authority to undertake the responsibilities of a regulatory body in field of nuclear energy, under the Ministry of Energy and Mines. However, IPEN is also charged with promotion, research and development activities. In this respect, IPEN, which reports directly to the Ministry of Energy and Mines and has additional duties, which include being responsible for facilities and activities, is not an effectively independent regulatory body in accordance with IAEA Requirements (notably GS-R-1).

IPEN discharges its promotional, research and development duties through several offices and divisions under an executive director. There are also research and development centres, such as Huarangal Nuclear Center, the Nuclear Medicine Center and others. The Huarangal Nuclear Center includes the RP-10research reactor, a radioactive waste storage facility and a radiation dosimetry service. The roles and responsibilities of each unit of IPEN have been determined through the 'Rule of Organization and Functions of IPEN', a public document with legal provisions for the discharge of IPEN's duties, approved by Supreme Decree 0-2005-EM.

There are two principle offices within IPEN; the Office of Institutional Control (OIC) and OTAN, both of which directly report to the President of IPEN, independently from the Executive Director. OTAN is assigned regulatory activities through the 'Rule of Organization and Functions of IPEN' and Rule of Law Nº 28028. However, by Law Nº 28028 responsibility for regulatory control is assigned to IPEN.

Observations, interviews and the review of documentation, including OTAN workload and duties which cannot be adequately fulfilled, suggest to the IRRS Review Team that financial and human resources assigned to OTAN may be insufficient to enable it to adequately perform its regulatory duties.

IPEN has a Scientific-Technologic Advisory Council at its disposal when expert advice is required. The Review Team was informed that as a general requirement of Peruvian legislation, once a responsibility is assigned by law to an organisation it cannot be delegated. Thus, the use of any such national or international advisory bodies does not relieve IPEN of its responsibilities.

Even though IPEN has an institutional control unit, there is no measure taken for establishing a quality management system, which naturally extends to OTAN. However, the Review Team was informed that there is a national initiative to introduce a management system for all public bodies.

## 3.2 STAFFING AND TRAINING

### *3.2.1 Staffing*

While Article 27 of Law Nº 21875 empowers IPEN to contract national or international experts, it is currently experiencing significant limitations in staffing. In addition, IPEN does not have a defined recruitment strategy.

OTAN employs nine professionals other than the managerial staff and support staff. The IRRS Team understands it has been estimated that 25 to 30 suitably qualified personnel would be needed to effectively discharge OTAN's currently defined regulatory duties.

#### *3.2.2 Training*

Even though there is no training programme to ensure relevant competencies are maintained, OTAN makes use of programmes offered by neighbouring countries. In the period since 1983 seven of the current nine regulatory personnel have been trained abroad in radiation protection and five in nuclear safety. Of these five, only one has previously worked in nuclear safety. No staff have been specifically trained in nuclear safety since 1988. OTAN plans to continue to send regulatory staff for training in radiation protection.

OTAN does not have a specific training programme for its own staff

Due to limitations of financial resources, OTAN uses IAEA support programmes to provide some training for its personnel.

IPEN provides various forms of training for radiation protection. However, these training courses target operators. Moreover, some OTAN personnel undertake the trainer responsibilities in IPEN training services.

### 3.3 ADVISORY BODIES AND RESEARCH ORGANIZATIONS

#### *3.3.1 Technical Support Organizations (TSOs)*

IPEN has several research and development units under its authority, each of which appears to have sufficient competence in certain areas to act as technical support organizations. However, since IPEN is also an operator of facilities and activities, the Review Team was informed that OTAN avoids potential conflicts of interest by not utilizing any of the research and development units under IPEN's authority as technical support organizations.

OTAN carries out reviews and assessment, although present staffing levels and the workload may impact upon the rigour of such activities.

#### *3.3.2 Advisory Bodies*

IPEN has a Scientific-Technologic Advisory Council at its disposal, in cases where advice from experts is required. However, this Council is not used by OTAN.

IPEN also has authority to establish an ad-hoc committee for resolution of appeals and sanctions, as the President of IPEN is the second instance for appeals.

### 3.4 INTERFACES AND LIAISON WITH LICENSEES AND OTHER ORGANIZATIONS

#### *3.4.1 Relations with Operators*

It has been observed that OTAN has established open and frank relationships with operators in performing its regulatory activities. However, limited resources constrain

OTAN's capacity to take advantage of these good relations to enhance its regulatory oversight and promote safety issues, such as safety culture.

### *3.4.2 Public Communication*

IPEN uses its website as a primary tool for public communication, including regulatory information.

There is a general law on transparency which dictates that public authorities provide any requested information, giving due regard to the classification of the information.

## 3.5 INTERNATIONAL COOPERATION

### *3.5.1 Cooperation with the IAEA*

Currently IPEN has good relations with the IAEA, participates in regional TC projects including ARCAL and meetings for which IAEA undertakes a secretarial role, such as the Convention on Nuclear Safety.

### *3.5.2 Bilateral and Multilateral Cooperation*

IPEN has limited bilateral relations with neighbouring countries, notably Argentina and Brazil. IPEN makes extensive use of training courses on radiation protection and nuclear safety provided in Argentina, through IAEA TC Projects.

| | Title | In Force | Status |
|---|---|---|---|
| **CPPNM** | Convention on the Physical Protection of Nuclear Material | 1995-02-10 | accession: 1995-01-11 |
| **VC** | Vienna Convention on Civil Liability for Nuclear Damage | 1980-11-26 | accession: 1980-08-26 |
| **NOT** | Convention on Early Notification of a Nuclear Accident | 1995-08-17 | accession: 1995-07-17 |
| **ASSIST** | Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency | 1995-08-17 | accession: 1995-07-17 |
| **NS** | Convention on Nuclear Safety | 1997-09-29 | Signature: 1994-09-22 ratification: 1997-07-01 |
| **RADW** | Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management | | Signature: 1998-06-04 |
| **PVC** | Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage | | Signature: 1998-06-04 |
| **SUPP** | Convention on Supplementary Compensation for Nuclear Damage | | Signature: 1998-06-04 |
| **ARCAL** | Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (ARCAL) | 2005-09-05 | Signature: 1998-10-20 ratification: 2001-03-28 |
| **RSA** | Revised Supplementary Agreement Concerning the Provision of Technical Assistance by the IAEA (RSA) | 1980-03-25 | Signature: 1980-03-25 |

## 3.6 LEADERSHIP AND MANAGEMENT OF SAFETY

### *3.6.1 Enhancing Regulatory Effectiveness and Competence*

Typically, a regulatory body has a leading role nationally to enhance safety culture among the stakeholders of nuclear energy. IPEN/OTAN has not yet established a formal management system throughout its organisations to implement such responsibilities to an adequate level. However, the IRRS Review Team understands there is a national initiative to implement such a management system in all Peruvian governmental bodies including IPEN/OTAN.

Currently IPEN cannot adequately ensure, through regulations and inspections, that operators also implement appropriate management systems and enhance safety culture in their facilities and activities. Nor does this appear to be currently a part of the programme of regulatory oversight.

### *3.6.2 National Cooperation*

IPEN has not yet established an effective system of communications among other relevant competent authorities for ensuring that all safety concerns are addressed. National cooperation is yet to be formally established to coordinated control of safety relating to issues such as transport of radioactive materials, mining, occupational exposure, emergency preparedness and response, and safety and security of radioactive sources, including illicit trafficking.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
|---|
| **1. BASIS:** GS-R-1 para.4.6 states: "*The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities*."<br><br>**R11. Recommendation**: Human resources, in terms of numbers and skills, should be sufficient to enable IPEN to fully implement its regulatory programme in accordance with its functions and responsibilities. |
| **S4. Suggestion**: A recruitment plan should be developed by IPEN, including the necessary qualifications, experience and expertise, to achieve numbers of staffing having the proper competences to adequately perform regulatory duties.<br><br>**2. BASIS:** GS-R-1 para.4.10 states that: "*Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship shall be fostered*."<br><br>**S5. Suggestion**: IPEN should seek to enhance existing good relations with operators in order to promote safety culture. |

# 4. ACTIVITIES OF THE REGULATORY BODY

## 4.1 AUTHORIZATION

### *4.1.1 Legal Basis*

Article 4 of Law 28028 requires that before commencing operations, natural or legal persons responsible for activities and practices involving ionizing radiation exposure or radiation sources must be authorised by the National Authority (IPEN).

This legal requirement is further developed in Rule of Law 28028 Chapters II, III, IV and V where administrative requirements and specific authorisation or registration regimes are established for radioactive installations and service suppliers, nuclear installations, personnel licences, transport of radioactive sources, design, validation and approval of packages, import and export of ionizing radiation sources and re-use of radioactive sources and elimination of radioactive wastes.

### *4.1.2 Types of Authorizations*

All activities included in the scope of Law 28028 are required to be authorized except some types of low risk radioactive facilities which require a simplified process of registration.

Annex I of Rule of Law 28028 explicitly identifies the following low risk facilities and activities subject to a registration regime: Dental and veterinary radiology equipment, fixed nuclear gauges, radioimmunoassay (in vitro), analysis by fluorescence and x-ray diffraction, packages control and surveillance with x-radiation, elimination of static current, bone densitometry, research and teaching with radioactive sealed sources (of activity no greater than 185 MBq) and possession of industrial gammagraphy equipment without source and containing depleted uranium.

The authorisation process as well as information and documents to be submitted for each authorization are defined in corresponding paragraphs of Rule of Law 28028. Time frames for each authorisation being released by OTAN after review and assessment are also established in the mentioned regulation but the timescales are unusually short for some regulated activities and practices. In consequence, some difficulties with compliance have been reported.

Notification prior to the application is required for all those who intend to start any activities included in the scope of Law 28028.

Article 10 of Rule of Law 28028 enables OTAN to perform inspections of the applicant's facilities or activities prior to (and after) granting the initial authorisation (in accordance with Law 27444, the General Law on Administrative Procedures).

Provisions for exclusion, exemption and clearance are included in Articles 18 to 20 Rule of Law 28028. Clearance should be applied provided that they fulfil clearance criteria specified by the National Authority. No specific clearance criteria have been established in regulations or guides.

A safety review and assessment is performed by OTAN to verify compliance with regulations related to nuclear and radiation safety, security and safeguards, prior to the granting of an authorization, as required in Article 4 of Law 28028 and Article 12 of Rule of Law 28028. Safety related documents and information to be submitted by

applicants are specified (in Rule of Law 28028 as well as in TUPA) for each authorization; however, no regulation or guidance is available on the detailed content of licensing documents.

Safety assessment activities are performed by OTAN according to an internal procedure (Directiva No. 006-03-IPEN/AUNA. Manual del proceso de licenciamiento de instalaciones). It contains a detailed description of the process and forms to document the steps of the process, including inspection of the facility prior to authorization as required. It also provides a pre-formatted safety assessment report, models for the various limits and conditions to be included in authorizations of different types of radioactive facilities and a detailed checklist for specific safety related topics to be covered during the process.

General radiation safety criteria are established in the Radiological Safety Regulation (Supreme Decree nº 009-97-EM), based on the IAEA International Basic Safety Standards (SS 115), including specific requirements for the safety of radiation sources.

Graded requirements for authorizations are introduced through the various types of authorization (register, licence, authorization) and the information and documents required to be submitted for application. Review and assessment tasks to be performed by OTAN are also commensurate to this information, thus introducing some consideration on the potential magnitude and nature of the hazard present at the facility being licensed.

All authorizations granted by OTAN include limits and conditions on safety and security. Specific limits and conditions are developed for authorizations granted for the operation of the research reactor.

Among the limits and conditions for the authorization of radioactive facilities specific requirements for events notification and reporting, security and transport of radioactive sources are included.

Renewal (in effect, revalidation) of authorization is granted at termination of the validity term, in the case of the research reactor following a safety review and assessment process by OTAN. For the case of radioactive facilities and services suppliers only a sworn statement about compliance with limits and conditions is required. No safety review and assessment is performed.

#### *4.1.2.1 Nuclear Installations*

As stated in Article 39 of Rule of Law 28028 nuclear installations are required to obtain the following authorizations: Previous or Site; Construction; Operation; Modification; Closure and Prolonged Stop.

In addition licensees of nuclear facilities are required to obtain specific authorizations for the temporary storage of nuclear material before operating licence is granted and in case of change of licence holder.

A public information period, to be overseen by IPEN/OTAN, is anticipated for site authorization.

During the term of the construction authorization the licensee is requested by Rule of Law 28028 to submit a pre-nuclear commissioning programme subject to OTAN approval before implementation. Result of the pre-nuclear commissioning must be submitted as a necessary requirement for the operation authorisation to be granted.

A provisional operating authorisation is granted to carry out a nuclear commissioning programme. Once completed, test results and proposal for modification of operational technical specifications must be submitted for the operating licence to be granted.

#### *4.1.2.2 Radiation Facilities and Service Suppliers*

As stated in Article 22 of Rule of Law 28028, radiation facilities (other than those required to apply for registration only) must obtain separate authorizations for construction, operation and closure.

These licences may be provisionally granted for a maximum of six months period to allow the licensee to comply with missing requirements at the original submission.

Services suppliers required to be authorized are identified in Annex I of Rule of Law 28028 as Category E practices including installation, maintenance and/or repair of ionizing radiation sources, operational control of radioactive facilities, quality control for x-ray equipment and nuclear medicine facilities, calibration of radiation equipment and radiation beams, radiometry analysis, external or internal dosimetry services and import and/or trade of ionizing radiation sources.

Licensees should apply for a modification authorization where there is a transfer of ownership, changes at the facility or in activities, replacement or enlargement of ionizing radiation sources; changes in the facility layout, new site or a legal address change.

The term of validity for authorization is established in Annex I of Rule of Law 28028 for the different categories of facilities (three to five years), including those required for a simplified registration process.

Before the term for which the licence was granted is complete the licensee must apply for a revalidation.

According to Rule of Law 28028, other activities requiring authorisation, subjected to specific licensing procedures and requirements, are: transport of radioactive sources, design, validation and approval of packages, import and export of ionizing radiation sources, re-use of radioactive sources and elimination of radioactive wastes.

OTAN has established the national register of radioactive sources. It is created and maintained using information provided through the process of authorization of radioactive facilities. No additional action has been taken by OTAN to publicize the requirement for notification included in regulation.

Transfers of radioactive sources are required to be authorized. Limits and conditions included in authorization require notification of any sources transfer. Unauthorized transfers are prevented and prosecuted through periodic inspections to holders.

An IRRS Team review of all documents provided by the applicant and subsequently prepared by OTAN for the authorization process of ‘Gammagrafia Servipetrol Peru S.A’ an industrial gammagraphy facility, revealed adequate compliance with established regulations and practices.

#### *4.1.2.3 Licensing/Certification of Personnel*

Personnel working in radiation facilities and service suppliers, with some identified exceptions, are requested to obtain individual licences when they perform activities entailing exposure to ionizing radiation or services related to radiation sources.

An individual licence is also required for persons performing operation, maintenance, supervision and radiation protection tasks in nuclear installations. Five types of licences are then required: supervisor, operator, radiation protection officer, radiation protection chief and maintenance personnel. In practice a licence for maintenance personnel is only given for those in charge of safety systems inside the reactor building.

For radioactive facilities individual licences are specific to the requested practice.

Education requirements for the application of each licence are established in Rule of Law 28028.

For all these licences to be granted applicants must pass an examination set by OTAN.

The term of validity of individual licences for nuclear installations is two years, for radioactive facilities is the same period as that established for the operating authorization of the practice.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 3.2 (1) states *"In fulfilling its statutory obligations, the regulatory body:*
*(1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;"*

**R12. Recommendation:** IPEN should develop and make public through regulations (and guides as appropriate) clearance criteria to be applied for radioactive substance to be released from regulatory control in compliance with Article 20 of Rule of Law 28028.

**2. BASIS:** GS-R-1 para 5.2 states *"For all facilities and activities, a prior authorization, a notification or an exemption shall be in force. Alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations (such as the routine shipment of radioactive materials in packages approved under detailed transport safety regulations)."*

**S6. Suggestion:** IPEN should take actions to publicise the notification requirement of Article 7 of Rule of Law 28028.

#### *4.1.2.4 Research Reactor*

The IRRS Review Team assessed the regulatory framework dealing with licensing aspects against NSR-4. It should be stressed that in the 'disposiciones finales' of the RP-10 operating licence (Article 13) it is required that the licensee elaborate, adapt and/or revise the prescriptive documents in accordance with NSR4 and N35-G1-1994 (Safety Assessment of Research Reactors). Hence 'de jure' it could be said that the Research Reactor's operating licence covers all IAEA standards for the RP-10 research reactor. However, 'de facto' the following requirements are not in place at this research reactor and are not currently enforced by OTAN. Proper regulations and

enforcement actions should be envisaged rather than just referring to NS-R-4 in the licence.

OTAN should explicitly require the licensee and enforce as appropriate that be established a strategy to deal with safety culture. A SCART (Safety Culture Assessment Review Team) mission or specific IAEA mission should perhaps be of help for IPEN to move forward on this specific topic.

OTAN should explicitly require the licensee and enforce as appropriate that compliance with licence conditions be at any time demonstrated as recommended in IAEA safety standards. Moreover, such demonstrations should remain valid when amending and extending the existing provisional licence for a further short period of time. 'De jure', in Article 13 of the licence it is stated that the "Licensee must comply with Safety Assessment of Research Reactor and Preparation of the Safety Analysis Report (Safety Series no 35-G1, IAEA 1994)".

'De jure', under Rule of Law 28028 (039-2008-EM) regarding modifications, power is given to OTAN to require a specific authorization. In this context justifications and safety demonstrations are requested. But 'de facto', only one of such a type of modification was made to date. This was for a recent change of the reactor's fuel assembly supplier.

OTAN does not require, before the licensee completes its licence submission, that a comprehensive safety assessment and independent verification be conducted to confirm that human factors and the design of the installation including the human–machine interface will fulfil the safety objectives and requirements. It should be noted that only one person within OTAN has the competences and responsibility for regulatory oversight of the research reactors. This is considered to be insufficient by the IRRS Review Team.

The thorough OTAN self assessment, made immediately prior to the IRRS mission, revealed that the use of independent verification and application of ergonomic principles are topics currently not included in regulations. The IRRS self-assessment also states that the regulatory body does not require that the design uses or applies the minimization of human actions that may jeopardize safety as specified in NS-R-4.

The IAEA team noticed that there was no programme within the licence for the research reactor for the collection and analysis of its own operating experience. Additionally, safety significant information should be disseminated to all those concerned and not only to operators. Moreover, OTAN doesn't require that the licensee establish a programme for the collection and analysis of operating experience in similar reactors (existing in: Argentina, Egypt and Algeria for instance). Operating experience is an important aspect which should be properly regulated by OTAN.

Regarding the management system at the research reactors, there are no regulatory requirements for internal audit. Moreover, OTAN does not require that the licensee establish and implement performance-based QA requirements for research reactors for the stages of site evaluation, design, construction, commissioning, operation, utilization, modification and decommissioning. The regulation does not consider either the concept of graded approach for research reactors which should be of benefit of OTAN for its basic regulatory work. Likewise there is no tracking system to monitor changes in regulatory documents and especially the reactor's operating licence conditions which have been reviewed and amended on regular basis; this could be detrimental to the regulatory performance of OTAN.

OTAN does not require the licensee to report any new information which may concern safety at the research reactors and/or any changes to the information previously submitted.

The expert team noticed that there were no regulations to ensure that the Licensee has on site: safety officers, chemists and training officers at the RP-10 facility as requested in NS-R-4. It was also noted that the current regulations do not require the licensee to perform its own inspections (in addition to the Regulatory bodies' inspections) on its own facilities as recommended in IAEA Safety Standards.

OTAN does not require that periodic reviews be performed by the licensee. Such periodic reviews should indeed be conducted to ensure that the safety analysis report, the operating licence conditions (OLCs), operating procedures and any safety related modification including siting, hazards, or design parameters, etc. remain valid, with account taken of current operational issues, such as those relating to ageing, operating experience and currently applicable safety standards.

The safety committee within IPEN is not independent from the manager of the RP-10 research reactor and should instead, be reporting above the RP-10 research reactor's manager. This safety committee does not appear to hold meetings on a regular basis or more often as necessary to deal with safety issues as requested in NS-R-4. OTAN is not regulating or enforcing these aspects though the Licensee is "de jure" supposed to comply with NSR4 recommendations according to the Peruvian licence.

Regarding operating procedures, they are not reviewed independently (e.g. by the safety committee) as recommended by IAEA safety standards and they are not subject to the approval of the RP-10 manager. Such procedures are not being reviewed and updated periodically on the basis of lessons learned. Regulatory mechanisms should be thought out to address these issues.

It was noticed that the regulatory body does not require the licensee to conduct periodic fire and explosion hazards analyses for safety. The RP-10 fire fighting system would have then been improved for instance. The regulation should be drafted and ensured that analyses include assessments of the vulnerability of safety structures, systems and components (SSCs) for fire and explosions; modifications to the application of defence in depth; modifications to fire fighting capabilities; the control of inflammables; the control of ignition sources; maintenance; testing and the readiness of personnel.

Amongst all the licensee's existing documents there are some which do not adequately address the following topics, regulations should be drafted and actions from the regulator should be launched to ensure that the following be taken into account:

- Operation in all states and, where appropriate, the loading, unloading and movement within the reactor of fuel elements and assemblies or other core and reflector components, including experimental devices.
- The maintenance of major components or systems that could affect reactor safety.
- Periodic inspections, calibrations and tests of system structures and components that are essential for the safe operation of the reactor.
- Radiation protection activities.

- The review and approval process for operation and maintenance and the conduct of irradiations and experiments that could affect reactor safety or the reactivity of the core.
- The reactor operator's response to anticipated operational occurrences and Design Basis Accidents, and, to the extent feasible, to Beyond Design Basis Accidents.
- Handling of radioactive waste and monitoring and control of radioactive releases.
- Utilization.
- Modifications.
- Activities of an administrative nature with a possible effect on safety (e.g. control of visitors seeking access to the control room)..

The regulations and/or the regulatory boy should impose upon the licensee that the following be ensured:

- safety analyses of the proposed utilization or modification are conducted;
- the relevant safety documentation is applied;
- requirements for review and approval are met. These may include the requirement to obtain the approval of the regulatory body before proceeding or the establishment of a formal licensing process;
- proper safety precautions and controls are applied with regard to all persons involved in the performance of the modification or experiments, and with regard to the public and the environment;
- QA is applied at all stages in the preparation and performance of the experiment or modification to ascertain whether all applicable safety requirements and criteria have been satisfied;
- all personnel involved in making a proposed modification or in conducting the proposed utilization are suitably trained, qualified and experienced for the task and, if necessary, trained in advance in the effect of this modification or utilization on reactor operation and the safety characteristics of the reactor.

The Regulatory Body should ensure that procedures be established in the operating organization for the review and approval of proposals for experiments and modifications and for the control of their performance, or ensured that this procedure includes all relevant information. Examples of relevant information are given hereafter:

- A description of the purpose of the experiment or modification.
- A justification for the necessity of the experiment or modification.
- The requirements and criteria for design, including their safety assessment.
- A description of the manufacturing processes involved.
- A description of the installation procedures involved.
- A description of the commissioning process.

- A review of the operational procedures and emergency procedures.
- A description of the possible radiation hazards to experimentalists.
- A description of the radiation safety measures necessary to prevent accidental exposure (including the restriction of access to the irradiation facility and to radioactive sources and/or neutron beams).
- A description of the radiation shielding required around the facility to prevent an increase in radiation (direct or scattered) generated in normal and abnormal conditions.
- A description of the need for the disposal of radioactive waste generated in the experiment or modification.
- A list of the relevant documentation that needs to be updated.
- Any special requirements for the training and, if necessary, re-licensing of reactor operators.

The IRRS expert team noticed that there were no regulations or regulatory actions to ensure that the licensee does conduct safety assessments throughout the operational lifetime of the reactor. The scope of such assessments would cover all safety related aspects of operation.

The IRRS expert team noticed that there were no regulations or regulatory actions to ensure that the licensee has established a decommissioning programme which should include consideration that:

- periodic testing and maintenance, modification and experiments, be conducted in a way that facilitates its decommissioning;
- documentation of the reactor be kept up to date and information on experience with the handling of contaminated or irradiated SSCs in the maintenance or modification of the reactor be recorded to facilitate the planning of decommissioning;
- decommissioning plan be prepared to ensure safety throughout the decommissioning process and be submitted for review and approval by the safety committee and OTAN before decommissioning activities are commenced. Such a decommissioning plan should include an evaluation of one or more approaches to decommissioning that are appropriate for the reactor concerned and are in compliance with the requirements of OTAN;
- when developing the decommissioning plan, aspects of the reactor's design to facilitate decommissioning be reviewed, such as the selection of materials to reduce activation and to facilitate decontamination, the installation of remote handling capabilities for the removal of activated components, and the incorporation of facilities for the processing of radioactive waste.
- procedures for the handling, dismantling and disposal of experimental devices and other irradiated equipment that require storage and eventual disposal be established in advance, or as early as possible if the equipment concerned has already been constructed and these procedures are not in place.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** NS-R-4 para 2.19 (13) and (15) states:

*"The systematic consideration of the human–machine interface and human factors shall be included in all stages of design and in the associated development of operational requirements.*

*A comprehensive safety assessment and independent verification shall be carried out to confirm that the design of the installation will fulfil the safety objectives and requirements, before the operating organization completes its submission to the regulatory body.*"

**R13. Recommendation**: Taking into account human–machine interface and human factors for all stages and in the associated development of operational requirements, the Regulatory Body should explicitly require the licensee and enforce that:

- minimization of human actions that may jeopardize safety be considered;
- independent verification and the application of ergonomic principles be performed..

**R14. Recommendation**: The Regulatory Body should explicitly require through regulations and enforce the use of independent verification and the application of ergonomic principles.

**2. BASIS*:*** NS-R-4 para, 2.15 (25); 2.16; 2.23 (17); 7.108 states:

*2.15 (25) "Systematic safety reassessments of the installation in accordance with the regulatory requirement shall be performed throughout its operational lifetime, with account taken of operating experience and significant new safety information from all relevant sources."*

*2.16. "Activities for systematic periodic assessments include, among others, periodic reviews such as self-assessment reviews and peer reviews11 to confirm that the SAR and other selected documents (such as documentation for operational limits and conditions (OLCs), maintenance and training) for the installation remain valid or, if necessary, to make improvements. In such reviews, the cumulative effects of modifications, changes to procedures, the ageing of components, the use of feedback from operating experience and technical developments need to be considered, and it is necessary to verify that selected SSCs and software comply with the design requirements. Specific requirements on these topics for nuclear research reactors are established in Sections 4 (for general purpose and scope) and 7 (for operational issues)."*

*"2.23 (17) A set of operational limits and conditions derived from the safety analysis, tests and subsequent operational experience shall be defined to identify safe boundaries for operation. The safety analysis, operating limits and procedures shall be revised as necessary if the installation is modified.*

*7.108. The operating organization shall conduct safety assessments throughout the operational lifetime of the reactor. The scope of the assessments shall cover all*

*safety related aspects of operation, including radiation protection, site re-evaluation, physical protection and emergency planning. In conducting the safety assessments, the operating organization shall give due consideration to information drawn from operating experience and other relevant sources. A programme of comprehensive periodic review will fulfil this requirement for safety assessments. On the basis of the results of the safety assessments, the operating organization shall implement any necessary corrective actions and shall consider making justified modifications to enhance safety.*

**R15. Recommendation**: OTAN should explicitly require through regulations and enforce that periodic reviews be conducted and that a programme be established for the collection and analysis of operating experience taking into account other similar reactors.

**3. BASIS:** NS-R-4 para 2.19 (15) see above and 7.110 states: "*Some reviews of research reactors shall be performed as peer reviews, i.e. by reviewers from other research reactors which are performing well. Such peer reviews will provide access to the practices and programmes at other research reactors."*

**R16. Recommendation**: The Regulatory Body should explicitly require the applicant, as part of its authorisation submission, to conduct a comprehensive safety assessment and obtain an independent verification. Additionally, some reviews of research reactors could be performed by peers.

**4. BASIS:** NS-R-4 para 7.2 states: *"... A system for reviewing and reporting abnormal occurrences shall be established."*

**R17. Recommendation**: The Regulatory Body should explicitly require through regulations and enforce the licensee's responsibility to report any new information which may concern safety at the research reactors and/or any changes to information previously submitted.

**5. BASIS:** NS-R-4 para 2.12 and 4.1(f) states:
*2.12. "The management of safety at the installation will be effective if the operating organization develops a safety culture to a high level. The safety culture will influence the actions and interactions of all individuals and organizations engaged in activities relating to nuclear technology. The concept of safety culture is described in Ref. [8], which sets conditions at three levels:*

*(a) at the policy level; (b) for managers; and (c) for individuals. Other principles in para. 2.11 refer to other responsibilities of the operating organization to ensure safety. General and specific requirements in respect of organization and responsibilities, the training of personnel, human factors and emergency preparedness for research reactors are established in Sections 4 and 7."*

*4.1. "...In order to ensure rigour and thoroughness at all levels of the staff in the achievement and maintenance of safety, the operating organization shall: ...*

*(f) Be committed to safety culture on the basis of a statement of safety policy and safety objectives which is prepared and disseminated and is understood by all staff."*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**R18. Recommendation**: The Regulatory Body should explicitly require and enforce that licensees develop programmes to foster a positive safety culture**.**

**S7. Suggestion:** The Regulatory Body may wish to consider an advisory or other mission(s), including SCART to promote and reinforce safety culture at research reactors.

**6. BASIS***:* NS-R-4 para 4.7; 4.15; 7.58, 7,82; 7.83 and GS-R-3 para 5.13. states:

*NSR4 - 4.7. Requirements for a quality assurance programme are established and objectives, principles and guidance are provided in Ref. [9]. The objectives, principles and guidance presented in Ref. [9] shall be taken into account in the preparation of the quality assurance programme for a research reactor by means of a graded approach on the basis of the importance to safety of each item, service or process. The graded approach shall be adopted so as to reflect planned and accepted differences in the application of specific quality assurance requirements to research reactors. The extent of the detailed quality assurance programme that is required for a particular research reactor or experiment shall be governed by the potential for hazard of the reactor and the experiment and shall meet the requirements of the regulatory body.*

*NSR4 -4.15. One or more reactor advisory groups or safety committees that are independent of the reactor manager15 shall be established to advise the operating organization on …etc.*

*NSR4 -7.58. Non-routine inspections or corrective maintenance of systems or items important to safety shall be performed in accordance with to a specially prepared plan and procedures. In-service inspections conducted for safety purposes and on a programmatic basis shall be performed in a similar manner.*

*NSR4 -7.82. Administrative procedures consistent with the quality assurance programme shall be developed for the generation, collection, retention and archiving of records and reports. Information entries in logbooks, checklists and other appropriate records shall be properly dated and signed.*

*NSR4 -7.83. Records of non-compliance and the measures taken to return the research reactor to compliance shall be prepared and retained and shall be made available to the regulatory body. The operating organization shall specify the records to be retained and their retention periods.*

*GS R 3 - 5.13. Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves."*

**R19. Recommendation:** OTAN should require of the Licensee and enforce as appropriate that be established a management system including in order of priority:

- a performance based quality assurance, internal audits and an independent assessment process;
- a tracking system to monitor changes for regulatory documents dealing with research reactors;
- records of non-compliance and the corrective measures;
- administrative procedures for the generation, collection, retention and

archiving of records and reports, and that information entries in logbooks, checklists and other appropriate records which are properly dated and signed;

- a graded approach;
- the safety committee of the licensee independent from the manager of the RP-10 reactor and reporting above the reactor manager. Such safety committee should set up meetings on regular basis and as often as necessary to deal with safety issues. (Suggestion minimum should be once a year);
- inspections; corrective maintenance of systems or items important to safety and in-service inspections.

**7. BASIS:** NS-R-4 para.5.7 states: "*In the analysis of the suitability of the site, consideration shall be given to matters such as storage and transport of fresh fuel, spent fuel and radioactive waste."*

**R20. Recommendation**: OTAN should explicitly require and enforce as appropriate that the Licensee maintains a written strategy for dealing with transport and final or intermediate storage of the RP-10 reactor's spent fuel.

**8. BASIS:** NS-R-4 para.7.18; 7.23 and 7.24 states:

*"7.18. The reactor manager shall periodically review the operation of the research reactor, including experiments, and shall take appropriate corrective actions in regard of any problems identified. The reactor manager shall seek the advice of the safety committee or shall call upon advisers to review important safety issues arising in the commissioning, operation, inspection, periodic testing and maintenance, and modification of the reactor and experiments.*

*7.23. The operating organization shall make provision for additional technical personnel such as training officers, safety officers and reactor chemists.*

*7.24. The operating organization shall arrange for the provision of assistance by contractor personnel as required."*

**R21. Recommendation**: OTAN should explicitly require the Licensee and enforce as appropriate that:

- the licensee's responsibilities for safety related topics mentioned in the text above be fulfilled;
- the reactor manager reviews periodically the operation of the research reactor, including experiments.
- provision be made for additional technical personnel such as training officers, safety officers and reactor chemists.
- provision be arranged to seek assistance with contractors.

**9. BASIS:** NS-R-4 para.7.28 states: "*Procedures shall be put in place for the validation of the training to verify its effectiveness and the qualification of the staff."*

**R22. Recommendation**: OTAN should explicitly require the Licensee and enforce as appropriate that procedures be put in place for validation of training to verify its

effectiveness and the qualifications of staff.

**10. BASIS*:*** NS-R-4 para 7.36; 7.60 states:

*"7.36. Requirements shall be established for the frequency and scope of inspection, periodic testing and maintenance, operability checks and calibrations of all items important to safety to ensure compliance with safety system settings and limiting conditions for safe operation.*

*7.60. The frequency of inspection, periodic testing and maintenance of individual SSCs shall be adjusted on the basis of experience and shall be such as to ensure adequate reliability, in accordance with the requirements established in para. 6.35*."

**R23. Recommendation**: OTAN should explicitly require the Licensee and enforce as appropriate that requirements be established for the frequency and scope of inspection of all SSCs and any item important to safety to ensure compliance with safety system settings, reliability and limiting conditions for safe operation including periodic testing, maintenance and feedback experience.

**11. BASIS:** NS-R-4 para.7.40 states: "*The operating organization shall determine the staff positions that require a licence or certificate and shall provide for adequate training in accordance with the requirements of the regulatory body (see also paras 7.11– 7.27). In particular, the reactor manager, the shift supervisors and the reactor operators shall hold a licence or certification issued by an appropriate authority*."

**R24. Recommendation**: The Regulatory Body should explicitly require (and enforce as appropriate) that Licensee OLCs include actions to be taken by operating staff within an allowed time if a limiting condition for safe operation is violated.

**12. BASIS:** NS-R-4 para.7.51 states: "*Operating procedures shall be developed for all safety related operations that may be conducted over the entire lifetime of the facility, (see body of the text for details)".*

**R25. Recommendation**: The Regulatory Body should check if existing licensee's documents address all safety topics dealt with in the licence conditions and the Safety analysis report.

**13. BASIS:** NS-R-4 para 7.57 states: "… *The procedures shall specify the measures to be taken for any changes from the normal reactor configuration and shall include provisions for the restoration of the normal configuration on the completion of the activity. A system of work permits in accordance with the quality assurance requirements shall be used for inspection, periodic testing and maintenance, including appropriate procedures for checking off before and after the conduct of the work.*

*These procedures shall include acceptance criteria. There shall be a clearly defined structure of review and approval for the performance of the work."*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**R26. Recommendation**: The Regulatory Body should explicitly require and enforce that the Licensee, as appropriate:

- establishes operating procedures for abnormal conditions;
- uses the licensee's permit process for inspection and periodic checking of procedures before and after the conduct of the work;

has a clearly defined structure of review and approval for the performance of the periodic testing and maintenance work.

**14. BASIS:** NS-R-4 para 7.68 states: *"Procedures shall be prepared for the handling of fuel elements and core components to ensure their quality, safety and physical protection and to avoid damage or degradation. In addition, OLCs shall be established and procedures shall be prepared for dealing with failures of fuel elements and control rods so as to minimize the amounts of radioactive products released. The integrity of the reactor core and the fuel shall be continuously monitored by a cladding failure detection system, not necessarily on-line. If a failure of fuel is detected, an investigation shall be conducted to identify the failed fuel element. Authorized limits shall not be exceeded and if necessary the reactor shall be shut down and the failed fuel element shall be unloaded (see also paras 7.96– 7.102)."*

**R27. Recommendation**: The Regulatory Body should explicitly require the Licensee and enforce as appropriate that OLCs be established and procedures be prepared for dealing with failures of fuel elements and control rods so as to minimize the amounts of radioactive products released.

**15. BASIS***: NS-R-4 para 6.25; 6.123and 7.71 states:*

*6.25. The capability shall be maintained for shutting down the reactor, removing residual heat, confining radioactive material and monitoring the status of the facility. These capabilities shall be maintained by means of the appropriate incorporation of redundant parts, diverse systems, physical separation and design for fail-safe operation such that the following objectives are achieved:*

*(a) To prevent fires and explosions;*

*(b) To detect and extinguish quickly those fires that do start, thus limiting the damage caused;*

*(c) To prevent the spread of those fires that are not extinguished, and of fire induced explosions, thus minimizing their effects on the performance of essential functions of the facility.*

*6.123. In the design of the means of confinement, the effects of extreme conditions (e.g. explosions within the barrier) and environmental conditions due to accidents, including conditions arising from the external and internal events (e.g. fire conditions and the associated increases in local pressures), shall be taken into account, in accordance with the design basis.*

7.71. The operating organization shall conduct periodic fire safety analyses. These analyses shall include: assessments of the vulnerability of safety systems to fire; modifications to the application of defence in depth; modifications to fire fighting

capabilities; the control of inflammables; the control of ignition.

**R28. Recommendation**: OTAN should explicitly require and enforce as appropriate, that the Licensee conduct:

- periodic fire and explosion hazards analyses for safety (the RP-10 fire fighting system will have to be upgraded and maintained as appropriate);
- hazard analyses dealing with flammable gases, liquids and combustible materials that could produce or contribute to explosive mixtures and be kept to minimum necessary amounts and be stored in adequate facilities to keep reacting substances segregated.

**16. BASIS:** NS-R-4 para 6.128 states: *"Where confinement is dependent on the efficiency of filters, provision shall be made as appropriate for in situ periodic testing of the efficiency of the filters."*

**R29. Recommendation:** The Regulatory Body should enforce that where confinement is dependent on the efficiency of filters, provisions be made as appropriate for in situ periodic testing of the efficiency of the filters.

**17. BASIS:** NS-R-4 para 7.90 states: *"The reactor manager shall establish a procedure for the review and approval of proposals for experiments and modifications and for the control of their performance. This procedure shall include all relevant information" (such as described in the body of the text in this report)."*

**R30. Recommendation:** The Regulatory Body should explicitly require and enforce as appropriate that the Licensee:

- performs a safety analysis for each experimental device, including an analysis of the damage that would be caused to the experimental device by postulated initiating events of the reactor and OLCs;
- reactor manager establishes a procedure for the review and approval of proposals for experiments and modifications and for the control of their performance and that this procedure should take into account all relevant information.

**18. BASIS:** NS-R-4 para 7.109 states: *"The programme of periodic review should cover aspects of the programme for the management of ageing to demonstrate the status of the facility with regard to ageing and to provide a basis for taking actions in relation to ageing. Thus, periodic reviews are operational tools to prevent and mitigate the effects of ageing and of modifications made around the site. Reviews of reactor SSCs carried out by using non-destructive techniques are called in-service inspections. In-service inspections shall be conducted by the operating organization under its programme for the management of ageing."*

**R31. Recommendation**: The Regulatory Body should explicitly require and enforce as appropriate, that the Licensee establishes a programme for the management of ageing including in-service inspection.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**19. BASIS:** NS-R-4 para 6.99 states: "*The possibility of bypassing interlocks and trips of the reactor protection system shall be carefully evaluated and appropriate means of protecting interlocks and trips that are important to safety from being inadvertently bypassed shall be incorporated into the reactor protection system.*"

**R32. Recommendation**: The Regulatory Body should explicitly require the Licensee and enforce as appropriate that the possibility of bypassing interlocks and trips of the reactor protection system be carefully evaluated and appropriate means of protecting interlocks and trips that are important to safety from being inadvertently bypassed be incorporated into the reactor protection system.

**20. BASIS***:* NS-R-4 para 7.8, 7.9, 8.1 and 8.2 states:

*7.8. In the operational stage of the research reactor, the operating organization shall become familiar with decommissioning projects at similar research reactors to facilitate the assessment of the complexity and costs of the ultimate decommissioning of its own reactor. Before decommissioning, the operating organization shall prepare a detailed plan to ensure safety throughout decommissioning.*

*7.9. The operating organization shall prepare periodic summary reports on matters relating to safety as required by the regulatory body and shall submit these reports to the safety committee and to the regulatory body if so required.*

*8.1. For some operating research reactors, the need for their ultimate decommissioning was not taken into account in their design. Nevertheless, all operational activities at research reactors, including inspection, periodic testing and maintenance, modification and experiments, shall be conducted in a way that will facilitate their decommissioning. Documentation of the reactor shall be kept up to date and information on experience with the handling of contaminated or irradiated SSCs in the maintenance or modification of the reactor shall be recorded to facilitate the planning of decommissioning.*

*8.2. A decommissioning plan shall be prepared to ensure safety throughout the decommissioning process. The decommissioning plan shall be submitted for review and approval by the safety committee and the regulatory body before decommissioning activities are commenced. "*

**R33. Recommendation**: The Regulatory Body should explicitly require and enforce as appropriate that the Licensee become familiar with decommissioning projects at similar research reactors to facilitate the assessment of the complexity and costs of the ultimate decommissioning of its own reactor. Furthermore, before the end of the operational stage the Regulatory Body should explicitly require and enforce as appropriate that the licensee has established a decommissioning programme which includes the consideration written in this report.

**21. BASIS:** NS-R-4 para 5.25 states: "*The potential for slope instability (such as landslides, rock slides and snow avalanches) that could affect the safety of the research reactor shall be evaluated for the site and its vicinity*."

**G2. Good Practice:** The Regulatory Body requires that the potential for slope instability (such as landslides, rock slides taking into account past experience of the Nino) that could affect the safety of the research reactor be evaluated for the site

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
| --- |
| and its vicinity and launch remediate actions. The Licensee has erected an embankment to protect the site against landslides. |

#### *4.1.2.5 Industrial and Research Practices*

The country has a number of practices outside the scope of the Code of Conduct on the Safety and Security of Radioactive Sources 2004 (CoC) such as usage of open sources, NORMS and industrial x-radiography

**Scope of law**

In principal, Law 28028 applies to all radioactive materials not covered by specific exemption levels. In addition, as few industrial practices use anything other than sealed sources, there is a limited work for IPEN outside the scope of the Code of Conduct on the Safety and Security of Radioactive Sources. At present, it appears it would not be impossible for a significant increase in use of open sources to occur in the country without the knowledge of IPEN. For this reason it is suggested that IPEN develops measures to ensure it is able to collect information on changes in technologies and practices in current use in the country.

**Relevant Practices**

Open sources are authorised in the same way as sealed sources. Most users are in the medical sector, but there are some hydrological tracer studies (though fewer than in previous years). No other open source use is known to IPEN.

Radiation generators are widely used in the country. X-radiography is used in medical facilities, airports, industrial radiography, food processing, postal services and research facilities, such as for x-ray diffraction studies. There are a few specialist users of x-ray fluorescence.

In the case of radiography, there is a significant difficulty in making effective inspections in the field. This is partly due to the distances involved, but also to the frequency of movement.

NORM – the visit to the IPEN waste disposal facility demonstrated that NORM scaled pipework is generated in the country. This effect is commonly found in the oil and gas exploration industries. Other forms of NORM are likely to be found in the country, but at present all of these are either deliberately exempted from regulation or de facto excluded. However, in certain circumstances NORM can result in (for example) significant exposure to workers in relevant occupations, and it may also be problematic if it enters the metals recycling supply chain.

**Exemption and Exclusion**

At present, other than exemption levels, there are no IPEN/OTAN procedures, licences or standards in place. This means that where NORM exists at higher than exempted levels, the materials are effectively outside the regulatory regime. The country may wish to review its policy on the regulation of NORM, and consider whether some types of NORM that are amenable to regulation, should be more formally controlled than at present. It may be decided for example, that a notification approach could provide a suitably proportionate approach.

**Standards**

IPEN has recently developed a standard on industrial gamma and x-radiography. The draft was published to the IPEN website for public consultation. This is good practice. The draft appears to be comprehensive. It is recommended that IPEN continue to develop, publish, consult on and finalise industrial standards to continue their good practice. Standards on other practices are in development, or planned to be developed and it is recommended that this work is given some priority. The availability of standards enables the user to comply with the requirements of their licence, and is likely to improve safety (and security) outcomes.

Decommissioning procedures require that the user apply for a closure licence. A site cannot be legally closed without going through this process, which is a requirement of Article 27 of 28028. Once the licence is granted, it is the responsibility of the user to clear the site of any residual radioactivity. On completion of clearance work, OTAN is notified and inspects the facility to verify the results. When the OTAN inspector is satisfied then a resolution is issued, releasing the facility and releasing the user from any further responsibility to clear the site of residual radioactivity.

#### *4.1.2.6 Medical Practices*

Exemption is applicable to medical exposures according to Rule of Law 28028. In-vitro studies except radio-immunological (RIA) are exempted.

The notification process is included in the authorization process for the practice.

A prior-authorization process is required for authorisation of construction in teletherapy, brachytherapy and nuclear medicine. There are no specific requirements for radiation safety in laboratories using unsealed sources, although the review team understands that such facilities are expected to be compliant with all applicable radiation safety requirements.

Notification alone is insufficient for authorization of medical exposures. The radiation safety of the patient is demonstrated through QC certification before authorization or the passing of the acceptance tests.

There is no specific process for assessment of medical applications; it is general for all practices.

Little guidance is available on the web page of IPEN. However, TUPA is available electronically including detailed requirements for authorization of medical exposure.

For every authorization for medical uses OTAN issues terms and conditions. Authorizations are for the type of practice.

Requirements for any amendment, renewal or suspension are given in TUPA.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 5.6 states: "*Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure*".
**G3. Good practice:** OTAN written procedures; "Authorization of Installations" and "Authorization of Individual Licences" include useful flow charts of the processes.
**S8. Suggestion:** Authorisation procedures should be scrutinized to determine if they could be further simplified. More emphasis might be given to the comprehensive evaluation of applications. Evaluation should strictly implement the procedure.

## 4.2 REVIEW AND ASSESSMENT

### *4.2.1 General*

Review and assessment should be performed in accordance with Article 4 of Law 28028 where it is established that authorizations will be issued after the National Authority has verified that all the prescribed safety rules on protection of persons, environment protection and safety of radiation sources, physical protection and safeguards were fulfilled as applicable.

Article 12 of Rule of Law 28028 also establishes that authorizations are granted after OTAN has verified fulfilment of regulations about nuclear and radiation safety, physical protection and safeguards as applicable.

These legal mandates are effectively accomplished by IPEN through the review and assessment of information and documents submitted by licensees to obtain the authorizations required in Rule of Law 28028.

As mentioned in paragraph 4.1 above, the authorisation process for nuclear and radioactive facilities (except those requiring only registration), as established in Rule of Law 28028, includes multiple stages, each one requiring a specific authorization. Information and documents to be submitted by applicants are in accordance with the type of facilities and activities to be licensed, so they are coherent with the stage of the regulatory process for which each authorization is requested.

The categorization of facilities and activities included in Rule of Law 28028 text and Annex I, is used as a reference to identify the corresponding required authorizations, and to ensure that review and assessment performed by OTAN is in accordance with the potential magnitude and nature of the hazard associated with each facility, activity or practice to be licensed.

The authorisation process established in Rule of Law 28028 for modification of authorized facilities and activities adequately ensures that review and assessment to be performed by OTAN for amendment or renewal, is consistent with those applied at the time of an initial authorization.

Apart from radiation safety requirements established in the Radiation Safety Regulation (Supreme Decree Nº 009-97-EM) IPEN has not defined its review and assessment principles and associated criteria.

In practice OTAN performs a review and assessment of the operator's technical submissions in order to determine whether the facility, activity or practice complies with safety requirements included in national regulations as well as in international generally accepted regulations and technical standards as appropriate. However, safety objectives, principles and criteria or references used for review and assessment are not included in regulations, guides or OTAN's internal written procedures neither are they documented in safety assessment reports.

Through the above-mentioned review of the operator's technical submissions OTAN satisfies itself that the information provided by the applicant demonstrates the safety of the facility or proposed activity or practice, confirms compliance with regulatory requirements and verifies that the technical solutions implemented by licensees have been proven or qualified by experience or testing or both and are capable of achieving the required level of safety.

OTAN does not prepare a programme for review and assessment of the facilities, activities and practices. However, in most cases a review and assessment programme is unnecessary. For complex authorisation processes, such as for nuclear facilities or for some new technology radioactive facilities a review and assessment programme is advisable.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 5.10 states "The *regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix."*

**S9. Suggestion:** For research reactors as well as complex or new technology radioactive facilities, OTAN should prepare a programme for safety review and assessment of licensees' submissions.

## 4.3 DEVELOPMENT OF REGULATIONS AND GUIDES

### *4.3.1 General*

As established in Article 3 of Law 28028, IPEN is the competent authority in charge of regulation.

Article 20 of Rule of Law 28028 states that radioactive substances are allowed to be released from regulatory control by OTAN provided they fulfil clearance criteria as specified by the National Authority.

Radiation Safety Regulation (Supreme Decree nº 009-97-EM) includes many provisions for which further regulations remain to be issued by the National Authority. At least the following are explicitly required:

- Maximum values for dose constraints (Article 13)

- Annual limit for intakes (Article 21)
- Reference levels for medical exposures (Article 45).
- Criteria to determine when medical facilities are required to employ a medical physicist (Article 51).
- Action levels for remediation in case of chronic exposure situations (Article 61).

No technical regulations for these specific topics have yet been issued.

No regulatory guides have been issued to help licensees achieve better compliance with regulations and laws or safety and security requirements.

The following diagram shows the process followed to issue governmental regulations related to nuclear and radiation safety and security matters in Peru:

The following diagram shows the process by which IPEN issues technical regulations:

Laws and regulations so far issued are listed in Appendix VI. Technical regulations issued by IPEN are also listed in Appendix VI

Laws and 'Rules of Law' mainly contain regulatory framework requirements while detailed technical requirements are typically included in IPEN regulations.

Article 12 of Rule of Law 28028 explicitly assigns to OTAN the determination of detailed regulatory and technical conditions and requirements to be incorporated into individual authorizations.

When developing regulations, consideration of comments from interested parties and feedback based on experience is carried out through consultation and public information processes conducted by IPEN.

Laws and regulations are developed taking reference from internationally recognized safety regulations, standards and recommendations, included those from the IAEA.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 5.26 states *"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".*

**R34. Recommendation**:
IPEN should identify all topics still requiring the development of regulations. A programme and necessary actions to issue these new regulations should be defined with establishing priorities and timescales.

## 4.4 INSPECTION AND ENFORCEMENT

### *4.4.1 Introduction*

OTAN carries out the regulatory inspection duties of IPEN. Inspection can be performed at any facility or activity, announced or unannounced. The authority of inspectors is listed in Article 75 of Rule of Law Nº 28028 which provides inspectors with the necessary tools for performing adequate inspections.

Inspection activities to verify information provided by an applicant or to verify the operational safety of activities are carried out at a frequency determined according to the risk attributed to the facility or activity.

The general regulation; "Procedimiento Nº 001-IPEN/OTAN Inspecciones de Fiscalizacion" makes provision for the conduct of inspection activities. For inspection of the various facilities, various checklists are prepared. Inspectors review the operational records kept since the last inspection, verify the validity of documentation and fill in the appropriate checklist. The findings are recorded in a form signed by both inspector and operator. The regulations include provisions on how to proceed where the operator is unable to, or refuses to sign the completed inspection record.

Where corrective actions arise from the inspection, the operator has a time period for implementation and thereafter, reports to OTAN in writing. If this is not done, then a letter which includes findings and requirements, and a timeframe for corrective

actions set by the regulatory body for cases of non-compliance, is prepared by OTAN and forwarded to the operator. Follow-up inspections are performed for continuing non-compliant cases.

There is no established mechanism for identification of lessons learned through the inspection and communication of this information to licensees.

The scope of inspections is determined according to the risk attributed to the facility or activity. However, inspections extend only to authorised persons. There is no provision for establishing a control mechanism for suppliers or the unlicensed personnel of the operator. In order to be able to inspect any facilities, activities or practices, OTAN issues individual licences to every person who works with radiation sources.

OTAN prepares a written annual inspection plan but it is not officially approved. Being a small organisation, almost all inspectors participate in the preparation of annual plan. The current plan for 2009 includes about 1,800 inspections to be performed (however, it should be noted that, in the Peruvian system, a single visit to an authorised facility may comprise several 'inspections').

OTAN experiences difficulties with inspections at facilities located far from Lima and in difficult geographic locations (such as rainforest areas, with for instance, industrial use of radioisotopes in pipeline construction). OTAN inspections for such activities depend on the transportation provided by the operator.

### *4.4.2 Inspection of Nuclear Installations*

OTAN has only one inspector in the field of nuclear safety. However, inspection of nuclear installations is carried out regularly, two to three times per month. There is a checklist for inspection of research reactors which is used in part during each inspection. Each inspection of research reactors is carried out in a limited scope, but always includes the review of operational records since the last inspection. The general inspection procedure is also applied in research reactors.

However, since the inspection of research reactors is focused on nuclear safety, less attention appears to be paid to radiation protection aspects. While the checklist includes control of radiation monitoring, there is no control of other radiation protection measures.

An inspection at the RP-10 facility was observed by reviewers. This inspection was unannounced and dealt with verification of set points during operation, compliance with licence conditions and the requirements of the provisional licence currently in force.

The nuclear safety inspector gained access without hindrance to the RP10 plant and to all equipment and the relevant documents he requested. The operating staff were open and transparent and collaborated with the inspector. 12 to 15 inspections a year are performed by the inspector, the rest of the time being dedicated to the licensing process, safety review and assessment. Radiation protection at the reactor is not currently addressed by OTAN since the inspector is mainly experienced in nuclear safety and focuses on these aspects. The inspector has a good knowledge regarding nuclear safety of the reactor including about 25 years experience working in nuclear safety and 20 years as a member of the calculation group dealing with safety aspects within IPEN.

From the observation of the inspection, the IRRS Review Team concludes that the licensee relies on the OTAN inspector regarding safety issues rather than dealing with safety directly.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
|---|
| **1. BASIS:** All BSS regarding radiation protection; GS-G-1.1 regarding staffing.<br><br>**R35. Recommendation:**<br>OTAN should include radiation protection as a main topic in the annual inspection programme for the RP-10 facility. |
| **S10. Suggestion:**<br>The capacity for effective regulatory oversight for research reactors should be reinforced with additional inspectors. |

### *4.4.3 Inspection of Medical and Industrial Facilities*

OTAN performs inspections of all medical practices and, according to the written procedure "Procedimiento No 001-IPEN/OTAN Inspecciones de Fiscalizacion", approved by "Memorandum No 393-05-OTAN, 03 de Novembre 2005", the frequency of inspections depends on the risk. Inspection practice and frequency is described in the procedure. No specific training or previous employment as a health professional is required for inspectors. Inspectors have participated in some international and national training courses.

During the inspection, the inspector checks the individual licences of the operator's staff. In practice this appears to be the main focus of an inspection.

The inspector also does radiation monitoring, checks records, asks the staff about radiation safety and follows a checklist. However, there does appear to be insufficient competence for performing inspections of medical exposure (see reports below of IRRS Review Team site visits to observe inspections at the Saint Pablo Hospital and the Instituto Nacional de Enfermedades Neoplasicas).

After the inspection, the inspector prepares a record, which is signed by the licensee and if appropriate, registers the deficiencies found in the inspection, and sets the deadline for resolving them. There is no guidance for setting up this deadline. In practice, the report is prepared only for all new licensees and in cases where there are requirements for corrective actions.

The inspection programme is prepared at the beginning of the year together with the inspectors and the Director of the OTAN. Inspections can be done at short notice if needed.

The regulatory body performs unannounced and announced inspections, according to the type of inspection to be performed. There is no specific plan, but usually inspections before granting a licence are unannounced.

**Medical Facility Site Visit 1:**

An inspection to the San Pablo Hospital was carried out by two OTAN inspectors and observed by three IRRS reviewers. Radiation therapy practice with one linear accelerator was inspected using a checklist. There was a brief entrance meeting without introducing the inspection plan. The Radiation Protection Officer (RPO) was a medical physicist. Additionally an oncologist, two dosimetrists and a technologist were present.

Individual personnel licences were inspected. Calibration of the beam was inspected using worksheets derived from IAEA templates. It was not noticed that the reference ionization chamber used for photon beam calibrations was a small thimble chamber (PTW 31003) with PMMA walls. Graphite-walled ionization chambers usually have better long term stability and more uniform response than plastic walled chambers; however, the latter are more robust and therefore more suitable for routine measurements. The calibration of the chamber was too old according to the requirement, because the IPEN Dosimetry Laboratory was not able to provide the calibration (SSDL letter dated 9 Oct 2008). Previous calibration was made in February 2007.

Quality control (QC) of the accelerator was inspected. The QC results were checked and compared to the requirements. However, the inspectors appeared to have insufficient understanding of concepts such as TAR (tissue-air-ratio) or measurements such as verifying the isocentre. One point check was made to test collimator rotation. Inspectors did not notice during a test carried out on the isocentre that the couch height display showed 4 mm deviance when the tolerance limit is 2 mm.

Because the accelerator beam is pulsed beam, a proportional counter is not suitable for survey measurements (a pressurized ionization chamber should be used). However, survey measurements were done in previous inspections using a proportional counter and a point check at the door was carried out on this occasion. The hospital also used a similar type of meter and the measurement results were inspected.

**Medical Facility Site Visit 2:**

An inspection at the Instituto Nacional de Enfermedades Neoplasicas was carried out by one inspector, observed by IRRS reviewers. Nuclear medicine practice was inspected using a checklist. There was no entrance meeting. The Radiation Protection Officer (RPO) was a medical physicist.

Individual staff licences and their personal dosimetry records were inspected. Calibration and quality control measures of two activity meters were inspected. The

inspector noticed that the calibration of the measurement equipment needs to be updated. From quality control records of three SPECT cameras only weekly intrinsic uniformity tests were inspected, but not, for example, resolution or centre of rotation tests. The usage of nuclides was inspected and compared to the licensed amounts of activities. The waste storage room was inspected. Tc-99m waste was kept in the storage room for three days and other waste for three months. Both solid and liquid waste was stored. Security of the storage was not inspected.

Contamination measurements were done in the laboratory and a patient room by using a general proportional counter. However, the meter was moved around fast so that the counter may not have shown the correct dose rates. The inspector did not bring a contamination meter although such a meter is available in OTAN. The inspector noticed that contamination of the rooms is checked after the departure of the patients but not formally recorded.

Tc-99m is delivered daily to the hospital from the IPEN laboratory. Purity checks of Tc-99m were not inspected. The function of the ventilation box was not inspected. The purity of radio pharmaceuticals was not inspected.

There are no Peruvian safety requirements for nuclear medicine laboratory construction (for example for floor materials). The laboratory was not constructed to be easily decontaminated.

There was no exit meeting. However, there was a brief informal debriefing between the inspector and the RPO, without any written report or notes. The inspector said that she will send a report of the inspection in due course.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:**

GS-R-1 5.12-17 states: *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. 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. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements.*

*5.13. The main purposes of regulatory inspection and enforcement are to ensure that:*

*(1) facilities, equipment and work performance meet all necessary requirements;*

*(2) relevant documents and instructions are valid and are being complied with;*

*(3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;*

*(4) deficiencies and deviations are identified and are corrected or justified without undue delay;*

*(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and*

*(6) the operator is managing safety in a proper manner.*

*Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out.*

*Inspection*

*5.14. The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.*

*5.15. Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity. If the regulatory body uses the services of consultants for the inspections, then it shall have the responsibility for taking any actions on the basis of these inspections.*

*5.16. In addition to routine inspection activities, the regulatory body shall carry out inspections at short notice if an abnormal occurrence warrants immediate investigation. Such regulatory inspection shall not diminish the responsibility of the operator to investigate any such occurrence immediately.*

*5.17. Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process".*

**R36. Recommendation:**
Inspections should be more focused on safety assessment of the practice, including patient safety.

**R37. Recommendation:**
More training is required for inspectors, especially focusing on radiation therapy dosimetry and QC to build up competence to inspect radiation therapy practice.

**S11. Suggestion:**

- Management should make a gap analysis of knowledge and establish a training programme with a realistic time schedule.
- Regulations and guides for medical practices should be developed and revised.
- IAEA assistance is needed for assessing and reviewing the system of licensing and inspection completely including the supervision of inspection in the field.

### *4.4.4 Enforcement*

Enforcement of regulatory provisions is mainly initiated through inspection. The "Inspection Act" is a form filled out at the end of each inspection and used as declaration of findings to the operator. This form may or may not include the measures requested by IPEN/OTAN on non-compliance. In any case, findings and regulatory requirements, including a timeframe for fulfilling the requirements, are confirmed to the operator by a letter.

There are sanctions in place for various non-compliances in Rule of Law Nº 28028, graded according to the non-compliance. Very severe offences are sanctioned either by closure of the facility or revoking of the authorisation.

In accordance with Article 124 of the Radiation Safety Regulation, inspectors are authorised to request emergency measures to be taken if a severe situation arises. However, IPEN/OTAN does not have the same authority explicitly written in regulations for enforcing immediate measures upon the operator.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 5.20 states: "*If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgement of the regulatory body pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail activities and to take any further action necessary to restore an adequate level of safety*."

**R38. Recommendation:** Provisions should be made in legislation that gives explicit authority to IPEN to enforce immediate actions if safety of facilities or activities has severely deteriorated or been violated.

### 4.4.5 Enforcement at Research Reactors

There is an informal agreement between the licensee and OTAN regarding the addressing of safety issues on a daily basis, however, in 2008 OTAN had cause to suspend the operating licence at the RP-10 facility for a couple of weeks. Since this time, only provisional licences for operation have been granted with provisional requirements. Such requirements have to be fulfilled during the time period imposed by the provisional licences in order for the full operating licence to be restored. This cascade of provisional licences is used by OTAN to regulate the RP10 facility, but this is an unusual practice in the light of international experience.

# 5. OCCUPATIONAL RADIATION EXPOSURE

## 5.1 REQUIREMENTS FOR RADIATION PROTECTION

Requirements for occupational radiation protection are established in Law N°28028, in Rule of Law 28028, in the Radiological Safety Regulations and in TUPA. Also conditions and limits are included in licences issued to users.

### *5.1.1 Responsibilities for Registrants, Licensees and Employers*

Supreme Decree N° 009-97-EM, Article 19 and Law 28028 ('Law to Regulate the Use of Ionizing Radiation Sources') Article 6(r) and (t) establish that the authorization holder and the employer are jointly responsible for worker protection and radiation safety.

The measures taken to define responsibilities for occupational exposure are defined in the terms and the conditions of the licence for the facility, activity or practice. The measures are different, depending on the nature of the activity or practice and the risk.

OTAN has written procedures including proformas with instructions to enable consistent processing of applications for authorization, with specific instructions depending on the practice.

Radiation protection principles (justification, optimization and limitation) are contained in Supreme Decree N° 009-97-EM, in particular, optimization is in Article 12 (c) Title II, Chapter I, Occupational Exposure.

Some types of records are required and maintained according to Supreme Decree N° 009-97-EM but other records are required only by the terms and conditions of authorizations.

There is no specific requirement in regulations for employers, registrants and licensees to ensure that decisions regarding measures for occupational protection and safety are recorded. For all practices, all requirements are provided in the conditions of the licence.

All licences are made available so that workers are able to read the conditions.

Some records are required to be submitted to IPEN in accordance with the terms and conditions of authorization and they must also be available for the inspectors during inspection.

In case of modification of these records, changes have to be notified to the regulatory body.

Supreme Decree N° 009-97-EM, Article 112 requires employers, registrants and licensees to ensure that policies, procedures and organizational arrangements for protection and safety be established for implementing the relevant regulatory requirements. Also, some of these management requirements are established in the conditions and limits of the licences.

Supreme Decree N° 009-97-EM requires:

- that employers and licensees implement all means and measures for safety and protection, and;

- that employers and licensees ensure that suitable and adequate facilities, equipment and services for protection and safety are provided.

The requirements given in TUPA are more stringent for relevant facilities classified in Category A and B as defined in Rule of Law 28028.

There are specific requirements for radiotherapy given in Norm (IR.001.01) approved by IPEN and for dental radiology in Norm (IR.011.96). For industrial radiography, requirements are given in an old standard which is still in draft form.

**Conclusions:**

The regulations set up clear requisites about the responsibility of holders and employers for worker protection.

Article 33 of Supreme Decree N° 009-97-EM requires employers, licensees and registrants to ensure that necessary health surveillance is provided to workers.

Articles 26, 28 and 32 of Supreme Decree N° 009-97-EM require employers and licensees to ensure that appropriate protective devices and monitoring equipment are provided and arrangements made for their proper use.

There are also specific requirements in TUPA and also in the conditions and limits of licences, depending on the practice.

The regulations do not require employers and licensees to ensure that arrangements are made to facilitate consultation and co-operation with workers, with regard to all measures necessary to achieve the effective implementation of the regulations.

Article 15 of Supreme Decree N° 009-97-EM requires employers, registrants and licensees to ensure the necessary conditions to promote a safety culture are provided.

Article 18 of the Supreme decree N° 009-97-EM makes provisions for having enough, qualified, trained and experienced personnel.

Article 33 of Rule of Law 28028 requires that each worker involved in a practice using ionising radiations must be trained and must have an individual licence granted by IPEN following an examination. The registrant and licensee must employ only radiation workers with this individual licence.

Training service providers include IPEN and other private companies. The IPEN training programme is published on their webpage.

The conditions of licences require that licensees ensure a minimum time period of training in protection and safety be provided, but there is no specification of the content of the training programme. The quantity of training required depends on the risks associated with practices. Special radiation safety training is required for industrial radiography.

Article 34 of Rule of Law 28028 requires periodic retraining to revalidate a radiation worker's individual licence.

#### *5.1.2 Responsibilities for workers*

Regulations do not clearly require licensees and employers to ensure that workers follow any applicable rules and procedures for protection and safety specified by the employer or licensee.

Article 60.3 of Rule of Law 28028 requires an individual licence for radiation protection officers at nuclear installations. This allows them to perform radiological safety and protection tasks in a nuclear facility however; the tasks and the role of this officer are not described in the regulations.

The regulations do not clearly require the licensee and employer to ensure that workers use monitoring devices and that appropriate protective equipment and clothing be provided.

The regulations do not require that workers should cooperate with the employer or the licensee with regard to protection and safety.

Regulations do not require the licensee to ensure that workers cooperate with the operation of radiological health surveillance and dose assessment programmes. OTAN foresees the improvement of conditions of licences to include this obligation.

The regulations do not require from the licensee or employer that workers provide information on their past and current work to ensure their effective radiation protection.

The IRRS team was informed that many workers do not have dose records from previous relevant employers because some of them were not provided with dosimetry and others did not keep this information.

The regulations do not require the licensee to ensure that workers abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the regulations.

The regulations do not require the licensee to ensure that workers accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the regulations.

The regulations do not require the licensee to ensure that workers report to the employer, registrant or licensee if for any reason they are able to identify circumstances that could adversely affect compliance with the regulations.

Article 21 of Supreme Decree N° 009-97-EM requires that female workers on becoming aware that they are pregnant notify their employer in order that their working conditions may be modified if necessary.

The regulations do not include requirements to ensure the safety of workers engaged in work that involves or could involve a source not under the control of their employer or the licensee responsible for the source.

**Conclusions:**

There is no clear requirement in regulations concerning the responsibilities of workers.

### *5.1.3 Radiation protection programmes*

Article 73 of Supreme Decree N° 009-97-EM requires that an accounting system which indicates the location and description the source, the activity and form of radioactive substance is the responsibility of the registrant or licensee.

Article 26 of Supreme Decree N° 009-97-EM requires that licensees shall designate controlled areas which fulfil requirements, especially occupational protection and safety measures including procedures and appropriate rules.

Article 27 of Supreme Decree N° 009-97-EM requires that licensees shall designate supervised areas which fulfil specific conditions.

Article 71 of Supreme Decree N° 009-97-EM requires that, in the operation or use of radiation sources, clear indications shall be established, commensurate with the risk, about the organization and responsibilities for safety and protection, requirements of safety assessment, evaluation of consequences, operating procedures and their periodic review, accident notification, maintenance activities, tests and inspections.

Article 26 of Supreme Decree N° 009-97-EM requires that equipment and means for individual protection at entrances and exits of designated controlled areas shall be provided. There are no requirements that this equipment meets defined standards or specifications.

Article 30 of Supreme Decree N° 009-97-EM requires that the workers performing routine or occasional work in controlled areas and likely to incur significant occupational exposure, shall use individual radiological surveillance through accredited systems consistent with the specific provisions of the Regulatory Body.

Article 31 of Supreme Decree N° 009-97-EM requires that when the worker performs his usual activities in supervised areas, or occasionally enters a controlled area, individual radiation surveillance shall not be obligatory, but occupational exposure shall be evaluated, being based on the results of the radiological surveillance of the work place, or by individual surveillance.

Article 28 of Supreme Decree N° 009-97-EM requires that a program of radiological surveillance shall be implemented in sites and workstations commensurate with the magnitude of normal and potential exposures.

The regulations do not include maintenance and review of this programme to be under the supervision of a qualified expert and a radiation protection officer.

For radiotherapy, there is a specific requirement given in Norm (IR.001.01) that the monitoring of the workplace must be done by the radiation protection officer designated by the licensee. A similar requirement for industrial radiography is included in a draft Norm still to be published.

Article 117 of Supreme Decree N° 009-97-EM requires that registrants and licensees keep records about the exposure of workers.

Article 25 of Supreme Decree N° 009-97-EM says that planned exposures caused by special circumstances shall be justified only if other technical alternatives not involving such an exposure are not available. In this case, both the task and the dose which may be incurred shall be previously authorized by the Regulatory Body. Also, all reasonable efforts should be made to reduce the doses to the lowest level possible, without exceeding the annual dose limits.

The regulations do not specifically require that users have a management system in place that, amongst other things, ensures the effectiveness of all monitoring (including for QA purposes).

#### *5.1.4 Intervention in emergencies*

Articles 86, 87, 88 and 89 of Supreme Decree N° 009-97-EM require that each registrant or licensee responsible for sources for which prompt intervention may be required, ensures that an emergency plan exists defining on-site responsibilities and

taking account of off-site responsibilities appropriate for the source and providing for implementation of each form of protective action

### *5.1.5 Monitoring programme*

Articles 8, 22 and 28 of Rule of Law 28028 require authorization for providers of services relating to the use of sources of ionizing radiation. External and internal dosimetry services are classified as Category E authorizations as defined in Rule of Law 28028. IPEN provides the authorizations which are processed and signed by OTAN. Specific requirements are given in TUPA. The current, but old Norm (PR.003:94) referring to dosimetry services and approved by IPEN, is currently under review.

IPEN has the capacity to do external dosimetry measurements and they do so for one operator. There are two commercial companies providing external dosimetry services, both of which are authorized by IPEN.

Dosimetry types used are TLD and In-Light systems. These services are required to be tested by the Secondary Standard Dosimetry Laboratory of IPEN. They are adequate for current requirements.

There is no internal dosimetry service (anthropo-radiometry or bioassays).

Articles 8, 22 and 28 of Rule of Law 28028 require authorization of service providers supplying monitoring services related to use of ionizing radiations sources.

Monitoring services require Category E authorization as defined in Rule of Law 28028.

IPEN provides the authorizations which are processed and signed by OTAN. There are specific requirements in TUPA.

The registrant or licensee makes their own workplace measurements, and measurements are made during inspections by OTAN as verification.

There is no external company currently seeking authorization to provide monitoring services.

Articles 32 of Supreme Decree N° 009-97-EM requires that radiological monitoring be made by means of equipment appropriate to the type of exposure or contamination, and calibrated at a frequency determined specifically by a calibration laboratory authorized or recognized by the Regulatory Body.

IPEN has a secondary standard dosimetry laboratory which provides calibration services.

Norm PR.003:94 relates to dosimetry services, and is currently under review. It sets the periodicity of dosimetry at every 4 weeks, and reference levels to notify the regulatory body, and the periodicity for reporting results.

Articles 8, 22 and 28 of Rule of Law 28028 require authorization of service providers supplying services relevant to the use of sources of ionizing radiations.

Individual dosimetry services are Category E authorizations as defined in Rule of Law 28028.

IPEN provides the authorizations which are processed and signed by OTAN.

Article 117 of Rule of Law 28028 requires that registrants and licensees keep records about the exposure of workers, as well as the results of operational and environmental monitoring, according to a method and extent specifically established by IPEN.

Norm PR.003:94 relating to dosimetry services requires that such services must keep dose records in compliance with regulations.

There is no requirement in the regulations to have a national dose register, but OTAN has its own national register of the doses of workers reported by dosimetry services.

There is no requirement in the regulations that personnel training services shall be approved by the appropriate competent authority.

The regulations do not require that appropriate investigations are made to identify whether or not exposures to natural sources of radiation should be considered as occupational, except in the case of radon.

Article 62 of Supreme Decree N° 009-97-EM requires that in regard to radon in housing and workplaces, the action levels should be those indicated in Annex IV of that document.

There is no requirement for dosimetry for aircrew.

There are no provisions in the regulations concerning monitoring of exposures to natural radioactivity, except radon at workplaces and in dwellings.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** RS-G-1.1 § 2.34(e)

**R39. Recommendation:** IPEN should update :

- Norm IR.011.96 for dental radiology
- Norm PR.003:94 for individual dosimetry services, including detailed requirements on appropriate facilities, equipment and personnel with adequate knowledge and skills.

**2. BASIS:** RS-G-1.1 § 5.32 (a), BSS para I.26 (e) states: "*employers, registrants and licensees shall, in consultation with workers, through their representatives if appropriate, when required by the Regulatory Authority, designate a Radiation Protection Officer.*"

**R40. Recommendation**: IPEN should include in their regulations requirements for the existence of a Radiation Protection Officer, its role and tasks and indicating the criteria to determine whether the RPO is internal or external to the licensee installation.

**S12. Suggestion:** IPEN should include in their regulations a requirement for the RPO to have a designated deputy when necessary.

**3. BASIS:** RS-G-1.1 § 2.36 (c), BSS para I.10

**R41. Recommendation:** Regulations should require that workers :

- cooperate with the employer or licensee with regard to protection and safety;

- cooperate with the operation of radiological health surveillance and dose assessment programmes;
- abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the regulations;
- accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the regulations;
- report to the employer, registrant or licensee if for any reason they are able to identify circumstances that could adversely affect compliance with the regulations.

**4. BASIS:** RS-G-1.1 § 2.40, BSS para I.30 states: "*if workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall cooperate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions"*

**R42. Recommendation: R**egulations should be developed to ensure the safety of workers engaged in work that involves or could involve a source not under the control of their employer or the licensee responsible for the source.

**5. BASIS:** RS-G-1.1 § 5.35(a), BSS para I.28(a) states: "*employers, registrants and licensees shall ensure that workers be provided with suitable and adequate personal protective equipment which meets any relevant standards or specifications."*

**R43. Recommendation:** Regulations should be developed to require that licensees provide workers with suitable and adequate personal protective equipment which meets any relevant standards or specifications.

**6. BASIS:** RS-G-1.1 § 5.101

**R44. Recommendation:** Extend Article 32 of Supreme Decree N° 009-97-EM requiring that quality management systems, to ensure the effectiveness of all monitoring, are in place and operational.

**7. BASIS:** RS-G-1.3 § 3.9, § 3.10

**R45. Recommendation:** Rule of Law 28028 should be amended to include the requirements that :

- individual dosimetry services have appropriate facilities, equipment and personnel with adequate knowledge and skills;
- workplace monitoring services have appropriate facilities, and the required personnel.

**8. BASIS:** RS-G-1.3 § 3.9, § 3.10

**9. BASIS:** RS-G-1.1 § 5.55

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
| --- |
| **R46. Recommendation:** To be in compliance with Articles 30 and 32 of Supreme Decree N° 009-97-EM, the government should have an internal dosimetry capability.<br>**S13. Suggestion:** The government should consider whether an internal dosimetry service should be established nationally or through contracting with a regional internal dosimetry service. |
| **10. BASIS:** RS-G-1.3 § 9.17<br><br>**11. BASIS:** RS-G-1.1 § 5.84 |
| **S14. Suggestion:** Regulations should include a requirement for a national individual exposure register. |
| **12. BASIS:** RS-G-1.1 § 2.34 (h)<br><br>**S15. Suggestion:** When reviewing radiation protection regulations, a requirement should be included that radiation protection training services be approved by the appropriate competent authority.<br>**13. BASIS:** RS-G-1.1 § 2.16, 2.25<br><br>**R47. Recommendation:** Regulations should include a requirement to conduct appropriate investigations to identify whether exposures to natural sources of radiation are to be subject to the requirements for practices, for example in NORM industries and aircraft. |

# 6. CONTROL OF MEDICAL EXPOSURES

## 6.1 REGULATIONS

In addition to Law 28028 and its associated regulation there are also Norm IR.001.01 for teletherapy and Norm IR.011.96 for dental radiology, both issued by IPEN. TUPA also contains some clauses relating to medical exposures.

Law 28028 and Rule of Law 28028 require administrative mechanisms for the authorization of all practices with ionization radiation. The Radiation Safety Regulation lays down the criteria for radiation protection aspects of medical exposure. TUPA states administrative requirements for medical practice. Also there are 'Norms' for teletherapy and dental radiology. However, for radiology and for nuclear medicine regulations and guides have yet to be developed and existing 'Norms' should be revised to be consistent with international requirements and guidance.

### *6.1.1 Responsibilities for Medical Exposure*

Radiological Safety Regulation Article 49 requires that medical exposures are prescribed by medical practitioners.

Norm IR.001.01 paragraph 804 assigns medical practitioners the primary task and obligation of ensuring overall patient protection and safety but only in radiation therapy. There is no requirement in the regulations for this or other medical practices.

Article 50 of the Radiological Safety Regulation requires medical personnel to be health professionals or other properly qualified and trained people, who are specifically authorized by the Regulatory Body.

For radiation therapy medical personnel are required to be available according to Norm IR.001.01 paragraph 804. For other medical practices there are no requirements.

For teletherapy, Norm IR.001.01 Annex III establishes the responsibilities for staff, including the medical physicist, who has responsibility for calibration, dosimetry, and quality assurance in the medical physical aspects. Qualified experts are not defined but in practice this is interpreted to be medical physicists.

Regulations do not require registrants and licensees to ensure that for diagnostic uses of radiation, the imaging and quality assurance requirements of the BSS are fulfilled with the advice of a qualified expert, in either radio-diagnostic physics or nuclear medicine physics, as appropriate.

There is a requirement in Rule of Law 28028 Article 26 that quality control has to be performed before using any equipment and then at a frequency given in the licence conditions. For x-ray equipment the ARCAL or Spanish Protocols, and for nuclear medicine, the IAEA recommendations and NEMA Standards are recommended in the licence conditions. However, use of them is not verified during inspection.

The regulations do not require in either radiology or in nuclear medicine that the legal person submits in their application for an authorization the details of named medical practitioners and their qualifications in radiation protection. Neither do they require the alternative: that only medical practitioners with qualifications in radiation protection will be permitted to prescribe medical exposure by means of the authorized source.

IPEN has not specified (or approved) training criteria in radiation protection in consultation with relevant professional bodies, for persons who have responsibilities or assigned tasks in the conduct of medical exposures. However, Rule of Law 28028 requires that all persons operating sources of ionizing radiation must have an individual licence, except for the cases of bone densitometry and radioimmunoassay.

Norm IR.001.01 Annex II provides criteria to determine if a given person is a medical physicist in radiotherapy. However, there is no formal recognition of medical physicists in the country. There are no such criteria for other medical practices.

The regulations do not require that medical practitioners should promptly inform the licensee of any deficiencies regarding compliance with the standards (BSS) with respect to protection and safety of patients. OTAN has participated in the IAEA training course "Preventing Accidents and Incidents in Radiation Therapy" where the importance of clinical reporting systems was highlighted. The learning gained from this useful course has yet to be implemented.

The regulations do not require that medical practitioners, having informed the licensee of a deficiency in safety, shall take appropriate actions to ensure the protection and safety of patients.

**Conclusion:**

Responsibilities for medical exposure are mostly defined only in teletherapy practice. Regulations and guides for radiology and nuclear medicine are needed and 'Norms' for teletherapy and dental radiology should be revised.

### *6.1.2 Justification of Medical Exposures*

Justification of medical exposure is specifically required in Article 35 of the Radiological Safety Regulation. However, assignment of direct responsibility to both the referrer and the practitioner to consider justification of patient exposure is not required by legislation.

BSS II.5

There is no guidance on applying justification. However, there is some advice in Article 35 of the Radiological Safety Regulation.

Radiological Safety Regulation Article 36 requires that any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

Radiological Safety Regulation Article 37 states that mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including radiation detriment. The IRRS team was informed that the current health screening programmes are prepared by the Ministry of Health and they have their own criteria for justification. Currently there is a programme for screening breast cancer using mammography.

Radiological Safety Regulation Article 38 requires that the exposure of humans for medical research is deemed to be not justified unless it is in accordance with the provisions of the Helsinki Declaration and follows the guidelines for its application prepared by CIOMS and WHO; and subject to the advice of an Ethical Review Committee (or any other institutional body assigned similar functions by national authorities) and to applicable national and local regulations. No guide for applying the requirement exists.

**Conclusion:**

Justification of medical exposure appears to be regulated according to international standards. However, there is no guide for applying the principle of justification.

### *6.1.3 Optimization of Protection for Medical Exposures*

Article 40 of the Radiological Safety Regulation requires optimization of doses to patients in a general manner. Although guidance levels are required by Article 45 of the Radiological Safety Regulation, they do not exist in Peru for protection of the patient for medical exposures. However, dose to the patient is assessed for some common conventional examinations (thorax and spine) during quality control of equipment. The requirements are detailed for radiation therapy in Norm IR.011.01, but there are no guides for nuclear medicine and radiology.

There is no regulation to require that equipment to be used in medical exposures has been so designed that failure of one element of the system is promptly detectable, hence minimizing unintended medical exposure of patients. In general it is required in Article 40 of the Radiological Safety Regulation that equipment to be used in medical exposures should be designed so that the incidence of human error in delivery of unintended medical exposure is minimized. It is also generally required that registrants and licensees take preventive steps to minimize the probability and magnitude of incidents (unintended exposures and accidental exposures). This is implemented only through quality control. Diagnostic and therapeutic equipment should be calibrated according to Radiological Safety Regulation Article 43. Licensees are not required to make analyses of potential risks or consequences of errors and failures. Training in radiation protection is required for an individual authorization.

There is no special requirement for radiation protection of paediatric patients.

There are general requirements in the Radiological Safety Regulation for the design and performance of equipment consisting of radiation generators and that containing sealed sources used for medical exposure. There are only specific requirements for radiation therapy in Norm IR.011.01. There is no requirement to translate the operating manuals into Spanish.

Radiological Safety Regulation Article 39 requires that registrants and licensees ensure particular attention is given to optimization of medical exposures of pregnant women.

Radiological Safety Regulation Article 43 requires that the equipment and sources used for medical exposure shall be subjected to periodic calibrations of the beam or activity, through a calibration laboratory accredited by the National Authority, and under specific established conditions. Norm IR.011.01 paragraph 815 requires that calibration of radiotherapy equipment is traceable to a Standard laboratory. For

radiation therapy IAEA calibration protocols are recommended in the conditions of a licence. Although there is no requirement to verify the calibration of brachytherapy sources by measurements, in practice well chamber measurements are performed for Ir-192 sources.

The regulatory body verifies compliance with these calibration requirements through inspections by checking calibration certificates. However, there is not enough competence to verify dosimetry protocols used in practice and the relevance of the results.

Regulations do not specify clearly requirements for clinical dosimetry. For radiation therapy there is a requirement in Norm IR.011.01 paragraph 815 for determining dose to target volume but not a requirement to specify the definition of the target volume. There is no requirement to determine absorbed dose to relevant organs of healthy tissue.

Radiological Safety Regulation Article 44 states that a programme of quality assurance appropriate in scope and extent for medical exposure shall be implemented to assure that physical and clinical parameters, as well as procedures, are appropriate for diagnosis or treatment of patients. A medical physicist is required to conduct QA in radiation therapy in accordance with Norm IR.011.01 paragraph 403. The QA programmes for radiation therapy and radiology take into account the principles established by WHO and PAHO. For nuclear medicine there are no requirements. Quality audit reviews are not required but participation in the dosimetry audit of IAEA is required for radiation therapy clinics.

Peru has not established guidance levels for x-ray diagnostics and nuclear medicine. However, patient doses are measured in quality control of x-ray equipment.

There is no requirement that an Ethical Review Committee, or other institutional body assigned similar functions on the subject by national authorities, should specify dose constraints to be applied on a case by case basis in the optimization of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual.

The Radiological Safety Regulation states in Annex I that exposure of people providing voluntary assistance to patients and not being employees or occupational exposed workers, should be constrained so it is unlikely that his or her dose exceeds 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have incorporated radioactive substances shall be constrained to less than 1 mSv, during the period of diagnosis or treatment of the patient.

**Conclusion:**

Regulations include most of the criteria and conditions for optimization of medical exposures, but only for radiation therapy. Some significant omissions are:

- a requirement to have instruction manuals in Spanish;
- a requirement for self assessment of potential risks in radiation therapy;
- guides for nuclear medicine and radiology that ensure special attention is paid to optimization of paediatric doses.

### 6.1.4 Maximum Activity for Patients in Therapy on Discharge of Hospital

Conditions for patient discharge are set in Article 47 of the Radiological Safety Regulation: i.e. patients shall remain in the hospital until activity decays to less than 1100 MBq. Licence conditions require that a hospital gives instructions concerning contact with other persons and relevant precautions for radiation protection.

**Conclusion:**
Discharge of patients is carried out in accordance with BSS 115. Guides should be developed for nuclear medicine that should also implement the principles of ICRP 94 and 103 for release of patients from hospitals after therapy.

### 6.1.5 Investigation of Accidental Medical Exposures

Article 48 of the Radiological Safety Regulation requires investigation of all incidents involving substantially incorrect exposures. It does not clearly specify that the licensee should undertake the investigation. Compliance with the requirement is verified during inspection only if the incident is reported to the regulatory body.

IR.011.01 Chapters 8.5 and 12 specify the actions that registrants and licensees must perform following an accidental medical exposure in radiation therapy. There is no requirement for a specific period within which the licensee should report to the regulatory body. Information about an incident has to be given to the patient as required in the Radiological Safety Regulation Article 48 and also to the physician of the patient as required in the IR.011.01. There is a licence condition for licences in radiology that incidents causing an effective dose of 20 mSv or more for “people” should be reported. This dose reporting value should not be applied to patients. The high dose reporting value has complicated the investigation of unexpectedly high staff doses.

There are adequate requirements relating to the duty of the holder of authorizations to investigate incidents in radiation therapy.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** BSS II.

**R48. Recommendation:** Regulations and guides for radiology and nuclear medicine should be developed and revised as required, in consultation with relevant professional bodies.

# 7. PUBLIC EXPOSURE INCLUDING RADIOACTIVE WASTE MANAGEMENT

## 7.1 GENERAL

Activities and facilities in Peru having significance with regard to public exposure are the following: the research reactor RP-10, the Radioisotopes Production Plant and nuclear medicine.

80% of nuclear medicine practice occurs in Lima. Tc-99 and I-131 are the most common radionuclides. Regarding I-131, 25% of the practices are for treatment (use of higher I-131 activities) and 75% for diagnosis.

The total amount of I-131 used in the country could reach a maximum value of 3 Ci/week. There are two main nuclear medicine departments using 80% of the I-131 being applied in Peru: namely INEN and Almenara Hospitals (both in Lima). These Hospitals use an activity of I-131 within the range of 300 to 1000 mCi/week each.

The waste management method is, basically, storage for decay (e.g., after 10 semi-periods, 100 days) and subsequent discharge to sewage or, in the case of solids, disposal as hospital conventional solid waste.

There is no sewage treatment plant in the hospitals having nuclear medicine facilities. There is no central sewage treatment plant in Lima and sewage goes directly into the sea.

Other unsealed sources are used occasionally for hydrology studies, and in some laboratories for research purposes. These practices, some very sporadic, are under regulatory control and do not constitute a significant source of exposure to public.

The research reactor and the radioisotopes production plant also have liquid waste treatment capabilities with retention, storage for decay and finally authorized discharges. Wastes which cannot be discharged are managed as low level radioactive waste and, in some cases, as intermediate level waste (resins).

The fuel elements in the research reactors are still not considered to be radioactive waste, but the grade of burn up is high.

Peru has a national inventory of radioactive waste which is currently maintained by the Radioactive Waste Management Programme (PGRR) division of IPEN. PGRR is identified as the organization in Peru responsible for the management of radioactive waste. PGRR has a storage facility in El Huarangal for low and intermediate level radioactive waste.

PGRR has some predisposal activities (e.g. on-site conditioning of waste, transport, conditioning in El Huarangal before storage) but there are no disposal activities in Peru.

Most disused sealed sources are stored in the PGRR storage facility in el Huarangal. Obligations to transfer disused sealed sources to PGRR storage facility are included in licence conditions and in Rule of Law 28028, Article 73. However, some disused sealed sources are still stored at facilities, some already being radioactive waste and others awaiting a decision by the users. The most important cases are radium sources for brachytherapy and two cobalt 60 Category 1 sources from teletherapy units. Sr-90 sources for ophthalmologic beta-therapy are also stored in some hospitals. About 60 radioactive lightning rods are currently under the control of IPEN in the radioactive

waste storage facility at El Huarangal. However an undetermined number of lightning rods are still in use in Peru. The use of radium sources and radioactive lightning rods are still permitted practices, however these sources can no longer be imported, as stated in Article 7 of Rule of Law 27757. This prohibition also includes Cs 137 teletherapy sources.

There have been attempts to organize campaigns to collect disused radium sources and transfer them to the national waste storage facility in El Huarangal for conditioning and storage, however without success. In the light of international experience, the situation of radium sources in Peru constitutes a safety issue (e.g., broken sources due to radon gas pressure, leading to leaks of radium and extensive contaminations of large areas have been found in many other countries).

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** BSS II

**S16. Suggestion:** IPEN should develop a programme to assess the situation of disused radium sources in Peru. The aim being to collect, condition and store them in a safe manner. IPEN should consider prohibiting the use of radium sources by mean of a regulation.

Article 73 of Rule of Law 28028 establishes a policy of devolution of sources to the provider, wherever possible. This practice is currently applied in industrial gammagraphy. The Article requires that authorized users having disused radioactive sources for which any further use is not foreseen, must re-export them to the country of origin or send them to the IPEN radioactive waste management plant within a period not greater that ninety days following their becoming surplus to requirements.

A draft National Policy and Strategy was developed by IPEN with the assistance of IAEA Regional Technical Cooperation Projects RLA9055/062. It is being analyzed by OTAN and presentation for approval is pending.

Peru signed the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. However, ratification is still pending.

### *7.1.1 Regulatory Framework and Requirements for the Control of Public Exposure*

Articles 53 to 58 of the Radiological Safety Regulation establish the technical conditions and requirements on radiation safety for protection of the public against radiation exposure. This rule is entirely based on IAEA SS 115 (1996) and also incorporates national experience in the field of radiation protection.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115

**G4. Good Practice:** The Radiological Safety Regulation is based both on International Standards and national feedback in the field of radiation safety.

Article 15 of the Radiological Safety Regulation requires licensees and registrants to establish, implement and maintain radiation safety policies, procedures and organizational arrangements to control public exposure.

Articles 12 to 14 of the Radiological Safety Regulation require licensees and registrants establish, implement and maintain radiation protection optimization and limitation of public exposures associated with normal use of sources under their responsibility.

Articles 64 to 66 of the Radiological Safety Regulation require that licensees and registrants shall establish, implement and maintain measures for ensuring safety of sources, in order that the likelihood of public exposure is controlled.

Article 67 of the Radiological Safety Regulation requires that licensees and registrants shall establish, implement and maintain suitable and adequate facilities, equipment and services for protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the exposure.

Articles 26 to 29 of the Radiological Safety Regulation mention classification of areas for workers, but do not include provisions for the control of visitors.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115, par. III.5 states that:

*"Registrants and licensees, in co-operation with employers when appropriate, shall:*

*(a) ensure that visitors be accompanied in any controlled area by a person knowledgeable about the protection and safety measures for that area;*

*(b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions; and*

*(c) ensure that adequate control over entry of visitors to a supervised area be maintained and that appropriate signs be posted in such areas."*

**R49. Recommendation:** IPEN should develop regulations including requirements to registrants and licensees to take measures, in cooperation with employers when appropriate, for control of visitors' exposure in controlled or supervised areas.

The following regulations require registrants and licensees responsible for safety in practices and facilities to have adequate (according to the associated risks) emergency preparedness and response arrangements:

- The Radiological Safety (Regulation (Supreme Decree N° 009-97-EM)
- Rule of Law N° 28028 (Supreme Decree N° 039-2008-EM), Title IV, Chapter IV Art 46, item c (only refers to the on-site aspects and the provision of assistance to the off-site responsible organizations).
- The Unique Text for Administrative Procedures (TUPA, Supreme Decree N° 020-2005-EM) (for different practices according to risk).

Specific requirements to registrants and licensees with regard to management of radioactive waste resulting from accidental situations (including predisposal and disposal), are not included in the regulations.

**Conclusion:**

In case of a nuclear or radiological accident generating radioactive waste the responsibilities regarding their management are not clearly allocated.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** SS 115 par. III.2h states that:

*"Registrants and licensees shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:*

*(h) emergency plans or procedures, commensurate with the nature and magnitude of the risk involved…"*

WS-R-1 par. 9.7

*"The operator shall establish procedures for prescribed actions in the event of:*

*(a) emergencies or non-routine occurrences;*

*(b) receipt of waste which is found not to conform to the waste acceptance requirements.*

*The procedures shall specify when reports should be made to the regulatory body."*

GS-R-2, par. 4.86.

*"Radioactive waste and contamination shall be appropriately managed".*

GS-R-2, par. 4.92.

*"Arrangements shall be made for the safe and effective management of radioactive waste in accordance with international standards67. These arrangements shall include: criteria for categorizing waste; a plan for monitoring and sampling to characterize the contamination and the waste; measurable criteria in terms of dose reduction for use in assessing the effectiveness of decontamination efforts; a method of testing decontamination methods before their general use; a method of duly minimizing the amount of material declared as waste and avoiding the unnecessary mixing of different waste types; a method of*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*determining appropriate methods of storage, predisposal management and disposal; and a plan for the long term management of waste.*

GS-R-2, par. 5.18.

*"Emergency plans shall include, as appropriate:*

*(a) allocation of responsibilities for performing the functions specified in Section 4 in GS-R-2;"*

**R50. Recommendation:** IPEN should produce regulations including requirements, with provisions to allocate responsibilities to registrants or licensees respect to waste arising from accidental situations.

Responsibilities regarding decommissioning and remediation activities are allocated in Rule of Law N° 28028, Articles 39, 43, 46 and 56.

Articles 86 to 100 of the Radiological Safety Regulation require that emergency plans address arrangements for prompt identification of abnormal conditions and for provision of effective on-site and off-site response within adequate timescales.

The provisions for preparation of emergency response plans are indicated in TUPA whereby the authorization process requires facilities and practices to prepare a suitable Safety Report including an emergency plan which takes into account the risk of the practice.

Articles 56 to 57 of the Radiological Safety Regulation include provisions to ensure that consumer products capable of causing exposure to radiation are controlled so they can not be supplied to the public unless the products meet exemption requirements specified in table V.1 of the Radiological Safety Regulation.

Law 27757 establishes in Article 3 that the Ministry of Economy and Finance shall elaborate a list of consumer products with radioactive materials requiring authorization by IPEN. Article 8 in Rule of the Law 27757 includes the list of consumer products requiring authorization. Item N° 9026.10.19.00 in this list covers any consumer product containing radioactive material.

There are provisions in regulations to require suppliers of non-exempt consumer products to ensure that such products comply with radiation safety requirements. In particular, those aspects of their design and construction that could affect the exposure of people during normal handling and use, as well as in the event of mishandling, misuse, accident or disposal.

These provisions are described in:

- The Radiological Safety Regulation (Articles 56, 57 and 58)
- TUPA

TUPA establishes the authorization process required for suppliers of non-exempted consumer products.

In the above-mentioned regulations there are no provisions for suppliers of consumer products to ensure adequate labelling and instructions regarding correct installation,

use, maintenance, servicing and repair, radionuclides involved, related dose rates and recommended disposal procedures.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115, par. III.16 states that:

*"Suppliers of consumer products shall ensure that:*

*(a) where practicable, a legible label be firmly affixed to a visible surface of each consumer product stating that:*

*(i) the product contains radioactive material; and*

*(ii) the sale of the product to the public has been authorized by the relevant*

*Regulatory Authority; and*

*(b) the information specified in (a) be also displayed legibly on each package in which a consumer product is supplied."*

SS 115, par. III.17

*"Suppliers of consumer products shall provide clear and appropriate information and instructions with each consumer product on:*

*(a) the correct installation, use and maintenance of the product;*

*(b) servicing and repair;*

*(c) the radionuclides involved and their activities at a specified date;*

*(d) radiation dose rates during normal operation and during servicing and repair operations; and*

*(e) recommended disposal procedures".*

**R51. Recommendation:** IPEN should issue regulations, including requirements for suppliers of consumer products using radioactive sources, to ensure adequate labelling and instructions regarding correct installation, use, maintenance, servicing and repair, radionuclides involved, related dose rates and recommended disposal procedures.

Article 107 of the Radiological Safety Regulation indicates that it is not permitted to import or transport radioactive wastes from another country into or through the national territory.

Rule of Law N° 28028 (Articles 21 to 25 and 27) and the Radiological Safety Regulation (Articles 64 to 65) establish conditions for decommissioning of a facility. The safety requirements for decommissioning activities are similar to those considered during the exercise of practice, including the requirement for an authorization, safety assessment and the consideration of normal and other potential circumstances.

Article 18 of the Radiological Safety Regulation requires that personnel for operation, safety and protection in all practices, be appropriately qualified to enable them to

perform their duties correctly. This is also required in TUPA where the authorization process requires appropriate training and retraining of such personnel.

Article 10 of the Radiological Safety Regulation and Articles 21 to 25 of Rule of Law N° 28028 require that the licence holder define the technical skills, qualifications and experience necessary for all personnel performing safety related duties. TUPA requires a certificate of a training course in radiation protection to obtain an individual licence. These training courses are provided by IPEN for specific practices. OTAN agrees with the contents of the course. Individual personnel licences are delivered by IPEN after an examination of their knowledge about the contents of the training course conducted by OTAN.

There are no requirements in regulations that topics related to control of exposures of the public (e.g., dose limitation, dose restriction, optimization, control of discharges, environmental monitoring, etc) be included in the contents of courses from IPEN as necessary (e.g., nuclear medicine, research reactor).

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115 par. III.2e states that:

*"Registrants and licensees shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:*

*(e) appropriate protection and safety training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as required, in order to ensure the necessary level of competence"*

WS-R-5 par. 8.4;

*"In order to provide an adequate level of safety, the operating organization shall, inter alia, prepare and implement appropriate safety procedures; apply good engineering practice; ensure that staff are properly trained and qualified and are competent; and keep and submit records and reports as required by the regulatory body."*

NS-R-2 par. 3.1;

*"The operating organization shall define the qualifications and experience necessary for personnel performing duties that may affect safety. These qualifications and experience shall be approved by the regulatory body if so required. Suitably qualified personnel shall be selected and given the necessary training and instruction to enable them to perform their duties correctly for the different operational states of the plant and in the event of an accident, in accordance with the appropriate operating or emergency procedures. Persons performing certain functions important to safety shall be required to hold a formal authorization; this may be issued or acknowledged by the regulatory body in accordance with national requirements."*

WS-R-5 par. 3.8

*The responsibilities of the operating organization include:*

- *Establishing a decommissioning strategy and preparing and maintaining a decommissioning plan throughout the lifetime of the facility;*
- *Establishing a quality assurance programme as part of the management*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*system;*

- *Notifying the regulatory body prior to shutting down the facility permanently or terminating the activity;*
- *Managing the decommissioning project and performing the decommissioning activities;*
- *Identifying an acceptable destination for all waste arising from decommissioning;*
- *Performing safety assessments and environmental impact assessments related to decommissioning;*
- *Preparing and implementing appropriate safety procedures, including emergency preparedness, and applying good engineering practices;*
- *Ensuring that properly trained, qualified and competent staff are available for the decommissioning project;*
- *Performing appropriate radiological surveys in support of decommissioning;*
- *Ensuring that end state criteria have been met by performing a final survey;*
- *Keeping records and submitting reports as required by the regulator y body."*

**R52. Recommendation:** IPEN should review and, if necessary, revise the content of IPEN courses to include, where necessary, the following topics: public protection, environmental monitoring of practices, control of foodstuffs and/or selected commodities, management of radioactive waste, waste storage, waste disposal, decommissioning and remediation.

Article 8 of Law No. 28028, Articles 21 to 27 of Rule of Law N° 28028, Article 65 of the Radiological Safety Regulation and TUPA all require that if a source of external irradiation can cause exposure to the public prior to commissioning and during operation, necessary safety measures will be applied by registrants and licensees.

### *7.1.2 Control of Radioactive Discharges*

The Radiological Safety Regulation (Articles 103 to 106), Law No. 28028 (Article 8) and Rule of Law N° 28028 (Article 73) establish specific requirements for the control of radioactive discharges.

These specific requirements include limits for authorized discharges, review of applications to discharge radioactive materials to the environment, approval or rejection mechanisms of these applications and the granting of authorizations, periodic inspections to verify compliance, enforcement against any violations of regulations, standards and licence conditions (Articles 74 to 83).

Article 13 of the Radiological Safety Regulation empowers IPEN to establish dose constraints for discharges satisfying requirements established by SS 115. The value of

the dose constraint is fixed as a licence condition in some installations (e.g., research reactor).

Article 106 in the Radiological Safety Regulation establishes the requirement to implement a radiological environmental surveillance programme in case of authorized discharges of radioactive materials to the environment and the need for recording and reporting the results to the Regulatory Body.

Environmental monitoring activities are performed by IPEN to assess the impact of El Huarangal Atomic Center releases (up to 10km) and compliance with the established limits of discharges. IPEN also carries out an environmental monitoring programme at the national level for other purposes, including radioecology.

The results of these monitoring programmes are reported to OTAN. While the results of the monitoring related to El Huarangal Atomic Center are regularly submitted to the regulatory body, problems with the environmental monitoring programme at the national level have been detected by the IAEA Team. For instance in recent years IPEN did not perform the annual environmental monitoring campaign due to budgetary problems.

Article 106 of the Radiological Safety Regulation is of a general character and OTAN has no independent capability to conduct any type of environmental monitoring activity. Therefore, it is not clear how IPEN controls independently the effectiveness of environmental programmes carried out by IPEN. Also it is not clear in the regulations, how OTAN ensures the quality of the monitoring programmes in place, analyzes the results or identifies which regulatory actions should be applied in cases of non-compliance.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** SS 115 para. III.11b states that:

*"Registrants and licensees, during the operational stages of sources under their responsibility, shall:*

*(b) monitor the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of critical groups;(c) record the monitoring results and estimated exposures;(d) report the monitoring results to the Regulatory Authority at approved intervals; and (e) report promptly to the Regulatory Authority any discharges exceeding the authorized discharge limits in accordance with reporting criteria established by the Regulatory Authority."*

**R53. Recommendation:** IPEN should develop detailed regulations on the characteristics of the environmental monitoring programmes being run by IPEN in Peru and considerations on the use of the results (e.g., verification of compliance of discharge limits, validation of assumptions used in the safety assessment, dose assessment). These regulations should have provisions for the enforcement.

**2. BASIS:** RS-G-1.8, para 3.5, 3.6. states that: "*With regard to specific responsibilities in the area of monitoring, the regulatory body:*

*(a) Should establish technical requirements for monitoring arrangements, including arrangements for emergency monitoring and quality assurance, and*

*should regularly review them;*

*(b) Should check the monitoring data provided by operators;*

(*c) Should provide evidence that can satisfy the public that authorized sources of exposure are being suitably monitored and controlled.*

On this basis, the allocation of responsibilities for the regulatory body should be along the following lines*:*

*(a) Although the licensees should be generally responsible for source and environmental monitoring, in some cases (such as major practices or sources) the regulatory body may carry out a limited confirmatory programme of environmental measurements to verify the quality of the results provided by the licensee and to confirm that the doses to members* of the public are maintained below the constraints established in the licence."

**S17. Suggestion:** IPEN should have a programme to assess independently the suitability of the environmental monitoring programme carried out by IPEN, including the analysis of results and trends. Moreover, IPEN should have capability to conduct limited confirmatory measurements. IPEN should make formal arrangements with institutions or laboratories in Peru where some environmental samples collected under control of the Regulatory Body could be analyzed.

Article 105 of the Radiological Safety Regulation requires that operators be authorized by the Regulatory Body to release radioactive materials to the environment in compliance with specific relevant requirements established in the authorization.

In Peru there are no situations of discharge of radioactive substances to the environment that can cause exposure to members of the public in another country and this situation is not considered in the national regulations.

Regulations in Peru do not include provisions to ensure that management options involving authorized discharge, where implemented, take due account of non-radiological hazards.

**NOTE:** The Norm for Safe Waste Management PR.002.95 from 1995 was not considered by OTAN when preparing the IRRS Self-Assessment Questionnaire but was analyzed during the IRRS mission. This Norm requires the consideration of non-radiological risks in Article 4.11. However, this Norm is based on IAEA Standards which have been superseded. It is outdated and not fully consistent with current IAEA recommendations.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-2 para. 5.8 states that: *"Authorized discharge, authorized use and clearance of materials from regulatory control, if necessary after an appropriate treatment and/or a sufficiently long storage period, can be effective in reducing the volume and amount of radioactive material that requires further processing. However, it shall be ensured that these management options, if implemented, are in compliance with the conditions and criteria established by the national regulatory body. In the application of such options, the regulatory body shall ensure that due account is given to non-radiological hazards."*

**R54. Recommendation:** IPEN should develop regulations to require that licensees consider non-radiological hazards during safety assessment of facilities and activities.

Article 106 of the Radiological Safety Regulation requires the reporting of environmental monitoring data to the regulatory body but does not make provision for special reporting when detecting increases in contamination. However Article 120 of the Radiological Safety Regulation establishes that persons and entities are obligated to report to the Regulatory Body any identified accidental situation.

There are no regulations requiring licensees to verify the adequacy of assumptions made for prior assessment of radiological consequences of discharges by means, for instance, of the results of environmental monitoring programmes.

There are no regulations requiring licensees to ensure that corrective measures are undertaken in cases of unplanned or uncontrolled releases.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115 para III.13 e, g. states that: *"Registrants and licensees shall, if appropriate:*

*(e) report promptly to the Regulatory Authority any significant increase in environmental radiation fields or contamination that could be attributed to the radiation or radioactive discharges emitted by sources under their responsibility;"*

*(g) verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges.*

**R55. Recommendation:** IPEN should establish provisions in regulations requiring the licensee to promptly report any significant increase in environmental radiation**.**

**R56. Recommendation:** IPEN should require the licensee to verify with the results of an environmental monitoring programme, assumptions made for assessing the radiological consequences of discharges.

Article 55 in the Radiological Safety Regulation requires that licensees implement a programme of radiological and operational surveillance in correspondence with the magnitude of the source to ensure fulfilment of conditions set in authorizations. However, there is no requirement for assessing public exposure from the source, or to make use of environmental monitoring results to validate assumptions made to establish discharge limits.

Article 117 of the Radiological Safety Regulation requires that licensees keep records of results of radiological environmental and operational surveillance programmes.

Article 121 of the Radiological Safety Regulation requires that licensees report to the Regulatory Body any data relevant to safety and protection related to sources under their responsibility.

For the case of operating IPEN's research reactor, the requirements for recording and reporting the results of the monitoring programme are included in the conditions of the issued authorization. In the case of nuclear medicine services it is required only that licensees record the result of measurements prior to release of materials.

However, there are no detailed provisions regarding the use of monitoring programmes data to validate assumptions and assess exposures.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** SS 115 par. III.13 a, b, g states that:

*"Registrants and licensees shall, if appropriate,*

*(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards regarding public exposure to sources of external irradiation be satisfied and to assess such exposure;*

*(b) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards for discharges of radioactive substances to the environment and the requirements established by the Regulatory Authority in granting the discharge authorization be satisfied and that the conditions assumed in deriving the authorized discharge limits remain valid and sufficient to enable the exposures to critical groups to be estimated;*

(*g) verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges."*

SS 115 par. III. 2f,

*"Registrants and licensees shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:*

*(f) appropriate monitoring equipment and surveillance programmes to assess public exposure to the satisfaction of the Regulatory Authority;"*

RS-G-1.8 par. 2.9,

*"The type of monitoring programme, as well as its scale and extent, should be commensurate with the source characteristics at the expected or current discharge rates, the radionuclide composition, the comparative significance of different exposure pathways, and the magnitudes of expected and potential doses to individuals. Some practices and sources (e.g. hospitals or research institutes using short lived radionuclides) may not require a monitoring programme for the environment; some (e.g. small nuclear installations or nuclear medicine departments using radionuclides for diagnostic purposes) may require routine monitoring at the source but only occasional checks on environmental levels; and others (e.g. most nuclear installations, large nuclear medicine departments) require continuous and comprehensive monitoring of both source and environment. Every facility should be prepared to conduct emergency monitoring at an appropriate level."*

RS-G-1.8 par 5.7

*"The nature of the monitoring programme will change at different stages of operation of a facility. At the pre-operational stage, environmental monitoring is designed to establish existing activity concentrations and radiation dose rates in the environment. At this stage it is necessary to investigate local factors (e.g. meteorology, hydrology, hydrobiological characteristics in the aquatic environment, population distribution, consumption rates of foodstuffs, occupancy factors and land use) that might affect the doses received by individuals in the population. The monitoring network and the environmental sampling regime*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*should be established on the basis of this information."*

SS 115 par. III.2g,

*"Registrants and licensees shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:*

*(g) adequate records of the surveillance and monitoring as required by the Standards;"*

SS 115 par III.13a – III.13d

*"Registrants and licensees shall, if appropriate:*

*(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards regarding public exposure to sources of external irradiation be satisfied and to assess such exposure;*

*(b) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards for discharges of radioactive substances to the environment and the requirements established by the Regulatory Authority in granting the discharge authorization be satisfied and that the conditions assumed in deriving the authorized discharge limits remain valid and sufficient to enable the exposures to critical groups to be estimated;*

*(c) keep appropriate records of the results of the monitoring programmes;*

*(d) report a summary of the monitoring results to the Regulatory Authority at approved intervals;*

*(e) report promptly to the Regulatory Authority any significant increase in environmental radiation fields or contamination that could be attributed to the radiation or radioactive discharges emitted by sources under their responsibility;*

*(f) establish and maintain a capability to carry out emergency monitoring, in case of unexpected increases in radiation fields or radioactive contamination due to accidental or other unusual events affecting sources under their responsibility; and*

*(g) verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges."*

**R57. Recommendation:** Regulations should require verification of the adequacy of assumptions made in safety assessments to establish discharge limits for facilities and activities by means of use of results of environmental monitoring programmes, when applicable and accordingly to the risk involved.

**R58. Recommendation:** IPEN should require that the licensee uses the results of source and environmental monitoring as the basis to assess doses being received by the population.

### *7.1.3 Control of Foodstuffs and Selected Commodities*

A system of action levels has been established in the Radiological Safety Regulation (Table II.3 in Annex III) for foodstuffs. A formal regular programme for controlling

the levels of radioactivity in foodstuffs and commodities doesn't exist but IPEN has the capability of carrying out radiation monitoring of foodstuffs and commodities on demand. This control is done only for certificates for trading of food and commodities and not as a monitoring programme.

#### *7.1.4 Control of Chronic Exposures (radon, NORM and past practices) and Remediation*

There are known NORM situations in Peru (e.g. in pipes used in the oil industry). Due to the geological characteristics of the country, other situations of NORM are expected (e.g. uranium series in soils).

While there are no past practices needing remediation, some activities related to exploration for uranium have been recently conducted. IPEN is dealing with the management of the related radioactive waste (very small volumes of radioactive materials coming from prospecting studies). However there is no detailed regulatory framework related to management of wastes coming for uranium mining and milling activities, in case they should occur.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** SS 115 App. VI par. VI.1 states that:

*"It is presumed that the State will have determined the allocation of responsibilities for the management of interventions in chronic exposure situations between the Regulatory Authority, national and local Intervening Organizations and registrants or licensees."*

**R59. <u>Recommendation</u>:** IPEN should conduct an investigation regarding chronic exposures situations related to NORM (including oil and gas industries and ores and uranium mining). The aim being to establish, when appropriate, the necessary regulations and means of regulatory control.

Articles 81 to 85 of the Radiological Safety Regulation assign responsibilities to authorized persons and the Regulatory Body regarding interventions.

Articles 59 to 63 of the Radiological Safety Regulation provide decision making considerations regarding chronic exposure remedial actions (mandatory or advisory). For the specific case of radon the considerations are made in Articles 62 and 63.

Article 60 of the Radiological Safety Regulation establish the need to justify and optimize remedial actions taking into account projected doses, associated risks and the social and financial costs of remediation.

There is no national strategy or legal framework for remediation (See Section 7.1.4 on national policy and strategy)

Article 85 of the Radiological Safety Regulation establishes that in cases where an intervention is needed, the licensee responsible for the source that caused the situation shall cover the costs of intervention actions. However, it is not clearly stated who is responsible for the cost of remediation actions needed in chronic exposure situations from different origins.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** WS-R-3 para 4.9 states that: *"The regulatory body shall establish safety criteria for the remediation of contaminated areas, including conditions on the end points of remediation. The responsibilities of the regulatory body shall include, among other things, the following*:

*(a) To investigate potentially contaminated areas and to designate as contaminated areas those areas requiring remediation;*

*(b) To review and approve the strategies and remediation programmes submitted by the organization responsible for implementing the remedial measures;*

*(c) To develop criteria and methods for assessing the implementation of remedial measures;*

*(d) To issue any authorization or licence necessary for taking the approved remedial measures;*

*(e) To review work procedures, monitoring programmes and records during the implementation of measures for remediation and for post remediation;*

*(f) To provide and maintain control mechanisms for the future use of lands, structures or resources affected by contamination and by the ensuing remediation;*

*(g) To review and approve significant changes in procedures or equipment that may have an environmental impact or may alter the exposure conditions for public or occupational exposure;*

*(h) To receive and assess reports of abnormal occurrences;*

*(i) To carry out regular inspections and to take enforcement actions as necessary;*

*(j) To ensure compliance with the legal and regulatory requirements,*

*including the criteria for waste management and discharges established for the remediation programmes."*

**2. BASIS:** WS-R-3 para 6.1 states that: *"During the implementation of remedial measures, consideration shall be given to radiation safety, transport safety and waste safety, so as to minimize hazardous impacts, and to the potential for prolonged exposure after the termination of remediation operations [4, 7, 8, 18, 19]. Consideration shall also be given to general health and safety issues and environmental issues."*

**3. BASIS:** WS-R-3 para 6.3 states that: *"The area shall be monitored and surveyed regularly during remediation so as to verify the levels of contamination and to ensure compliance with the requirements for waste management. Regular surveillance will also enable the organization responsible for the remediation to detect any unexpected levels of radiation and to modify the remediation plan accordingly. Revisions to the remediation plan shall be subject to the approval of the regulatory body. There may need to be several iterations of review and revision of the remediation plan."*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**R60. Recommendation:** IPEN should make provision in regulations to ensure funding for remediation actions takes into account the various possible situations (e.g., past practices, contaminations not attributable to a user or legal person, exceptional scenarios such as accidents in neighbouring countries, contamination resulting from orphan sources or malevolent acts, etc).

Articles 80, 83 and 84 of the Radiological Safety Regulation establish requirements regarding safety criteria for remediation of the contaminated area, e.g., that decisions on intervention shall be based on justification of the intervention and consideration of optimization of the protection principle. Exposure control criteria shall be established by the Regulatory Body, taking into account established intervention and action levels.

Regarding means to ensure detection of potential situations needing remediation, Articles 74 and 75 of the Radiological Safety Regulation require that licensees investigate the causes of incidents and report to the Regulatory Body.

### *7.1.5 National Waste Management Policy and Strategy*

There is no a national waste management policy and strategy to address protection of individuals, society and the environment now and in the future, including beyond national borders and establishing, among other provisions, that radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

A draft National Policy and Strategy has been developed by IPEN. IPEN participated in the IAEA Regional Technical Cooperation Project RLA9055/062 which includes assistance for preparation of a national policy and strategy for radioactive waste management. The above-mentioned draft was presented in March 2009 by the IPEN Director of Services to OTAN's Director (Memorandum Nr 068-09-SERV). This proposal is being analyzed and reviewed for comments by OTAN. Afterward, OTAN will present this draft to the President of IPEN for approval or submission to the appropriate governmental level.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 par 3.4 states 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*:

*(1) environmental protection;*

*(4) radioactive waste management (including determination of national policy);"*

WS-R-2 par. 5.3

*"When it is proposed to store radioactive waste or to defer decommissioning for an extended period of time, consideration shall be given to the principle that*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*"radioactive waste shall be managed in such a way that will not impose undue burdens on future generations".*

**R61. Recommendation:** IPEN should develop a national waste management policy and strategy in agreement with IAEA standards and obtain approval at the relevant governmental level.

**S18. Suggestion:** IPEN should review existing regulations in order to identify elements which may be basis for national policy and strategy (e.g., the identification of the national institution responsible of radioactive waste management in Peru, the users' responsibilities regarding generation and management of waste, etc).

**S19. Suggestion:** IPEN could use the framework of IAEA Project RLA0955/62 to facilitate drafting of the national waste management policy.

Although there is no national waste management policy and strategy, some elements exist in the current regulatory framework. For instance Article 104 of the Radiological Safety Regulation requires that operators reduce to a minimum the activity and volume of wastes produced and arrange that appropriate management is given.

Similarly, Articles 43g, and 46j, in Rule of Law N° 28028 require applicants for a licence for nuclear facilities to include in the licensing documentation, the financial provisions to cover the costs of decommissioning and waste management including disposal.

Other elements of national policy and strategy could be found in the Norm for Safe Waste Management PR.002.95, including options for waste management (Article 4.4), classification of wastes from the operational point of view (under Title V and VI) and the identification of the national centralized storage facility. However, this standard is based on IAEA Standards which have been superseded. It is now outdated and inconsistent with current IAEA recommendations.

#### *7.1.6 General Safety Provisions for Radioactive Waste and Decommissioning*

Though there are no specific regulations for radioactive waste management. The existing provisions regarding protection and safety and optimization (already mentioned in section 7.1.1) are applicable to radioactive waste management activities.

As already mentioned above, Article 104 of the Radiological Safety Regulation requires that the activity and volume of originated wastes are reduced to a minimum.

There are no provisions in the regulations to ensure that potential effects of the management of radioactive waste beyond national borders are taken into account.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-2 par. 2.2 states that: *"In considering options in the predisposal management of radioactive waste, due consideration shall be given to the protection of workers and the public and to the protection of the environment. Protection shall also be provided beyond national borders. Such considerations shall include radiological and non-radiological hazards, including conventional health and safety aspects, and the potential impact and burden on future generations from extended periods of storage of radioactive waste or delayed decommissioning of nuclear facilities."*

**R62. Recommendation:** Regulations should include the requirement to consider the potential effects of the management of radioactive waste beyond the national borders of Peru.

The regulatory framework does not provide for the establishment of requirements for environmental protection associated with predisposal waste management or take into consideration all potential environmental impacts that can reasonably be expected.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-2 par. 2.7 states that: *"Requirements for environmental protection associated with predisposal management of radioactive waste shall be established by the national regulatory body, taking into consideration all potential environmental impacts that can reasonably be expected."*

**R63. Recommendation:** IPEN should include in the regulatory framework, requirements for environmental protection associated with predisposal waste management taking into consideration all potential environmental impacts that can reasonably be expected.

There are no specific regulations to ensure the operator identifies an acceptable destination for the transport of the radioactive waste and that radioactive waste is transported to its destination safely and in accordance with international transport requirements. However some relevant elements for safe transport of radioactive materials are included in Articles 101 and 102 of the Radiological Safety Regulation (see Section 10.)

Waste management activities are considered as 'practices' and regulations for the radiation protection of workers involved in the management of radioactive waste are addressed in the relevant articles of Chapter III in the Radiological Safety Regulation.

WS-R-2 par. 3.5

There are no provisions in regulations to ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations.

A classification from the operational point of view is included in the Norm for Safe Waste Management PR.002.95. However, this standard is outdated and inconsistent with current IAEA recommendations.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-2 par. 3.5 states that: "*To facilitate effective and safe predisposal management of radioactive waste, the regulatory body shall ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations*"

**R64. Recommendation:** IPEN should include provisions in regulations to ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations

**S20. Suggestion:** When preparing new or revised regulations, IPEN should make reference to the recently published IAEA Standard on Radioactive Waste classification.

Articles 73 and 121 of the Radiological Safety Regulation provide for the accountability of sources and reporting to the Regulatory Body respectively.

The requirement for maintaining a safety culture within practices is mentioned in Article 15 of the Radiological Safety Regulation. Although there are not specific for waste management, this Article of the regulations could be applied.

However, there are no details on this subject and means to implement or to evaluate its effectiveness were not observed during the present revision.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-5 par. 2.4 states that: *"A safety culture shall be fostered and maintained in both the operating organization and the regulatory body in order to encourage a questioning and learning attitude to safety and to discourage complacency. Individuals responsible for decommissioning activities shall be trained to appropriate levels of awareness of health, safety and environmental matters."*

**R65. Recommendation:** IPEN should develop a detailed regulation on safety culture, including provisions to ensure that a safety culture is fostered and maintained in both the operating organizations and IPEN.

There are no specific regulations or environmental radiation protection requirements for all waste management, remediation and decommissioning activities, in particular for those cases when a facility is released with restrictions on future use.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-5 par. 2.5 states that: "*Environmental radiation protection, consistent with that for a practice, shall be maintained during the entire decommissioning process and beyond if a facility is released with restrictions on future use. If there are no such restrictions, the site and the facility shall meet the pertinent regulatory end point criteria.*"

WS-R-3, par. 7.3 states that:

*"If necessary, specific restrictions shall be established for the following purposes:*

*(a) To control the removal of radioactive material from contaminated areas or the use of such material, including its use in commodities;*

*(b) To control access to contaminated areas;*

(*c) To control the future uses of contaminated areas, including use for the production of foodstuffs and water use, and to control the consumption of foodstuffs from contaminated areas."*

WS-R-3, par. 7.6 states that:

*"A mechanism shall be established for periodically reviewing the conditions in remediated areas and amending or removing any restrictions imposed. If surveillance and maintenance are required after remediation is completed, a surveillance and maintenance plan shall be prepared which shall be periodically reviewed. The plan shall be subject to the approval of the regulatory body."*

**R66. <u>Recommendation</u>:** IPEN should complement existing regulations on environmental radiation protection requirements, in particular for those cases where after a decommissioning or remediation programme a facility is released with restrictions on future use.

### *7.1.7 Control of Radioactivity in Materials for Clearance or Recycling*

In accordance with Article 116 of the Radiological Safety Regulation and Article 20 of Rule of Law N° 28028, IPEN has established criteria for clearance of materials from regulatory control.

There are no specific regulations requiring that due consideration be given to non-radiological hazards at the various stages in predisposal management of radioactive waste. Article 4.11 of the Standard for Safe Waste Management PR.002.95 requires consideration of non-radiological risks. However, this Standard is based on IAEA Standards which have been superseded and it is thus outdated and inconsistent with existing IAEA recommendations

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-2, para 5.8 states that: *"Authorized discharge, authorized use and clearance of materials from regulatory control, if necessary after an appropriate treatment and/or a sufficiently long storage period, can be effective in reducing the volume and amount of radioactive material that requires further processing. However, it shall be ensured that these management options, if implemented, are in compliance with the conditions and criteria established by the national regulatory body. In the application of such options, the regulatory body shall ensure that due account is given to non-radiological hazards."*

**R67. Recommendation:** IPEN should develop specific regulations requiring that due consideration is given to non-radiological hazards at the various stages in predisposal management of radioactive waste.

Article 73 of Rule of Law N° 28028 establishes some requirements for re-use of radioactive materials.

#### *7.1.8 Safety Requirements for Predisposal Management of Radioactive Waste (Clearance and Storage Dealt in Separate Sections)*

Regulations do not establish an appropriate waste classification system. Licensees and registrants have their own classification systems as part of their management procedures. A classification from the operational point of view is included in the Norm for Safe Waste Management PR.002.95. However, this Norm is outdated and inconsistent with current IAEA recommendations.

A recommendation to develop a waste classification scheme is included in Section 7.1.6.

Articles 103 to 106 of the Radiological Safety Regulation and Article 73 of Rule of Law N° 28028 establish regulatory requirements for predisposal management of waste.

Article 65 in the Radiological Safety Regulation requires preparation and submission of a safety assessment for activities and facilities, including predisposal facilities.

IPEN has not established a system for siting and design of predisposal waste management facilities in order to provide reasonable assurance of safety for the anticipated operational period and for its decommissioning. However, Articles 69 and 70 of the Radiological Safety Regulation provide elements related to siting and design of facilities in general.

#### *7.1.9 Safety Requirements for Storage of Radioactive Waste*

IPEN has not established specific requirements for the design and construction of radioactive waste storage facilities. However, Articles 69 and 70 of the Radiological Safety Regulation require that licensees having large inventories of sources (as is the case of the waste storage facility in Peru) consider all the features that could affect the

radiological safety of sources, as well as the need for implementing a system of multiple barriers commensurate with the associated risks.

Articles 109 of Radiological Safety Regulation and 14 of Rule of Law N° 28028 require licensees to revalidate licences. Chapter V in Title II of Rule of Law N° 28028 establishes the conditions to modify licences when needed.

Articles 64 and 65 of the Radiological Safety Regulation require licensees to comply with the requirements of regulations in all the phases of the lifetime of facilities and to carry out safety assessments for all these phases according to specific requirements issued by the Regulatory Body. There are no requirements regarding retrievability of waste.

Articles 105 of the Radiological Safety Regulation and Article 73 of Rule of Law N° 28028 establish that licensees can release radioactive materials only if they have been cleared or if these releases have been authorized by the Regulatory Body. For the case of reuse of material contaminated with radionuclides, an authorization is required.

#### *7.1.10 Safety Requirements for Disposal of Radioactive Waste*

A national radioactive waste disposal strategy has not yet been defined. Criteria and solutions to be implemented have not been decided. Therefore there are no specific regulations on these issues.

#### *7.1.11 Safety Requirements for Decommissioning of Nuclear and other Facilities Containing Radioactive Material*

Article 56 of Rule of Law N° 28028 in subsection a.3, requires that applicants for a decommissioning licence submit to IPEN, as part of the licensing documentation, a safety assessment with an identification and evaluation of risks. Subsection i of the same Article establishes the need to present the financial provisions for the decommissioning project.

Chapter VII in Title IV of Rule of Law N° 28028 establishes the relevant requirements for decommissioning of facilities.

The regulatory framework for decommissioning has been established in Rule of Law N° 28028. Responsibilities have been allocated in Title II of this document, whereas regulations within Chapter VII in Title IV of the document require that applicants for a licence for decommissioning of a facility prepare and submit to the Regulatory Body, documentation containing among other elements, the safety assessment, operational rules, radiation protection manual, emergency plan, waste management provisions and financial provisions.

Chapter VII in Title IV of Rule of Law N° 28028 requires that persons intending to carry out decommissioning of a facility apply for an authorization. As part of the licensing documentation applicants must submit for approval by the Regulatory Body, a plan for the management of waste (Article 56, subsection g). Article 27 of the same document requires that applicants consider the management of all resulting waste.

According to a procedure described in Article 27 of Rule of Law N° 28028 the Regulatory Body receives the applications for a decommissioning authorization and issues the authorization within a 20 day term if the applications fulfil the established requirements. At the end of the decommissioning process the Regulatory Body

verifies compliance with technical conditions and issues a resolution relieving the licensee of further responsibilities. Title VI in the same document establishes the inspection and enforcement responsibilities of the Regulatory Body for all authorized practices, including decommissioning activities.

Article 54 of Rule of Law N° 28028 establishes that the licensee must inform the Regulatory Body of his intentions to decommission a facility with six months in advance. Once the Regulatory Body declares the end of operational activities it must establish the conditions to be fulfilled by the licensee of the facility until the decommissioning licence is issued.

According to Articles 43 (subsection g) and 46 (subsection j) of Rule of Law N° 28028, provisions for decommissioning should be submitted by users to the Regulatory Body as part of the licensing documentation in the phases on construction and operation of the facility.

For new facilities regulations does not require that operators consider eventual decommissioning activities in the design of the facility, including features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to prevent the spread of contamination.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-5, para 5.4 states that: *"For new facilities, consideration of decommissioning shall begin early in the design stage and shall continue through to the termination of the practice or the final release of the facility from regulatory control. The regulatory body shall ensure that operators take into account eventual decommissioning activities in the design, construction and operation of the facility, including features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to prevent the spread of contamination."*

**R68. Recommendation:** IPEN should establish regulations requiring that for new facilities the operators shall consider eventual decommissioning activities in the design of the facility, including features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to prevent the spread of contamination.

IPEN does not require a suitable decommissioning plan to be prepared by licensees as soon as possible in existing facilities where a decommissioning plan does not yet exist, once requirements and guidance are provided.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-5, para 5.5 states that: *"For existing facilities where a decommissioning plan does not yet exist, a suitable plan for decommissioning shall be prepared as soon as possible, once the regulatory body has provided requirements and guidance, and shall be periodically updated."*

**R69. Recommendation:** IPEN should establish a programme to review the existing practices in Peru which could need to develop a decommissioning plan and make formal requirements for doing this, together with providing the necessary criteria and guidance to develop this plan.

Chapter VII in Title IV of Rule of Law N° 28028 requires applicants for a licence for decommissioning of a facility to prepare and submit to the Regulatory Body documentation containing, among other elements, the safety assessment, operational rules, radiation protection manual, emergency plan, waste management provisions, financial provisions, etc.

Articles 43 (subsection g), 46 (subsection j) and 56 (subsection i) of Rule of Law N° 28028 set the responsibilities of licensees with respect to financial provisions for decommissioning.

Article 56 of Rule of Law N° 28028, item I, requires that as a condition of obtaining a licence for closure and the closure statement, an economic study of the dismantling process and funding foresights to face it must be presented for approval by the regulatory body. However, funding provisions are not clear for the case that the decommissioned facility is released with restrictions on its future use.

Article 54 in Rule of Law N° 28028 establishes that the licensee must inform the Regulatory Body of his intentions to decommission a facility with six months in advance. However, a term for submitting the decommissioning plan to the Regulatory Body has not been set in regulations.

The regulations do not require that the operator develops an adequate maintenance and surveillance programme in the case of deferred dismantling for its review and approval.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** WS-R-5, para 6.5 states that: "*If the decommissioned facility is released with restrictions on its future use, financial assurance that is adequate to ensure that all necessary controls remain effective shall be obtained before authorization is terminated.*"

WS-R-5, para 8.2;

*"The operating organization shall inform the regulatory body prior to shutting down the facility permanently. If a facility is shut down and no longer used for its intended purpose, a final decommissioning plan5 shall be submitted for approval within two years of the cessation of the authorized activities, unless an alternative*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*schedule for the submission of the final decommissioning plan is specifically authorized by the regulatory body. The operating organization shall not implement the decommissioning plan until the regulatory body has approved it. Any amendments to this plan shall also be submitted to the regulatory body for approval. The operating organization shall ensure that the facility is maintained in a safe configuration until the approval of the decommissioning plan."*

WS-R-5, para 8.3

*"In the case of deferred dismantling, the operating organization shall ensure that the facility has been placed, and will be maintained, in a safe configuration and will be appropriately decommissioned in the future. An adequate maintenance and surveillance programme, which shall be subject to the approval of the regulatory body, shall be developed to ensure safety during the period of deferment."*

**R70. <u>Recommendation</u>:** IPEN should establish in the regulations provisions to consider:

- funding considerations for the case that the decommissioned facility is released with restrictions on its future use;
- a term for submitting the decommissioning plan to IPEN;
- an adequate maintenance and surveillance programme in the case of deferred dismantling for its review and approval.

Article 59 of Rule of Law N° 28028 states that, once decommissioning activities have finished, and after the verification by the Regulatory Body of compliance with the end point criteria, the Regulatory Body issues a decommissioning resolution and, according to Article 27 in the same document, relieves the operator from further responsibility.

# 8. EMERGENCY PREPAREDNESS

## 8.1 GENERAL

Peru has established a general legislative and statutory framework in order to prepare for and manage any consequences of natural and technological disasters. Decree 19338, 'Law on the Civil Defence System' (CDS) is the legal document of the highest level in this matter and creates the Civil Defence System as part of the National Defence with the aim of protecting the public against any disaster or contingency regardless of its origin. The core of the CDS is the National Civil Defence Institute (INDECI) and it is in charge of the coordination and control of all activities of civil defence.

Also, there is a National Plan for Preventing and Attending Disasters which was approved by Supreme Decree No. 001-A-2004-DE/SG. The main purpose of this Plan is presenting directives, objectives, strategies and programmes to guide activities at inter-regional and inter-institutional levels in order to prevent the adverse impact of disasters.

In addition, Supreme Decree No. 062-2005-EM approves the Organizational Structure and the Rules and Duties of the Peruvian Institute of Nuclear Energy (IPEN). According to the afore-mentioned document the Technical Office of the National Authority (OTAN) should act as a coordinator for emergency preparedness and response for nuclear or radiological emergencies occurring in the country. It is understood that IPEN is a member of the Scientific and Technological Consultant Committee of INDECI.

## 8.2 BASIC RESPONSIBILITIES

A legislative and statutory framework has been established in order to prepare for and manage any contingency. The consequences of a nuclear or radiological emergency in the public domain have not been properly included in the National Plan for Preventing and Attending Disasters (there are only general comments regarding radioactive contamination of the environment). There are no clear provisions for the case of a nuclear or radiological emergency occurring beyond national borders. Also, there are no arrangements or agreements with bordering States to act in case of a radiological emergency.

Provisions are established in the Radiological Safety Regulation, Title IV Chapter II for all users of ionizing radiation sources subject to regulatory control to prepare Emergency Plans to be submitted to the OTAN when applying for an authorization.

IPEN has the authority to issue, promote and/or adopt specific radiation emergency preparedness and response regulations and guides. But there are no guides for users to prepare emergency plans.

The legislative framework has established and identified the National Civil Defence Institute, an existing governmental body, to act as the national coordinating authority for any contingency, either of natural origin or man-induced, whose function, among

others, is to coordinate the assessment of threats and the resolution of differences and incompatible arrangements between the various response organizations.

There is no clear statement in regulations or other documents through which an existing governmental body or organization is established or identified to act as a national coordinating authority with functions for coordinating emergency preparedness and response for nuclear or radiological events and neither IPEN nor OTAN are mentioned in this respect. The main functions among others, of such an authority were it identified, would be to coordinate threat assessment within the State and to ensure that the functions and responsibilities of operators and response organizations are clearly assigned and understood by all response organizations. Examples of appropriate functions for such an authority are:

(GS-R-2 EPR The method & EMERCON Manual)

- The ability to coordinate the response preparations for all national organizations with roles in preparation for, or response to, nuclear or radiological emergencies, conventional emergencies or criminal activities (e.g. terrorist attacks or threats).
- Ensuring that the functions and responsibilities of operators and other response organizations are clearly assigned and understood by all concerned.
- Ensuring that the responsibilities for preparedness and response to a radiation emergency are clearly allocated.
- Resolving differences and incompatible arrangements between the various participating parties.
- Coordinating the assessment of threats within the State.
- Developing an integrated national radiation emergency plan (NREP).
- Coordinating the development of plans and procedures within and between each level (national, local and operator).
- Guiding the planning process.
- Ensuring that a review is conducted periodically in order to identify any new practice or event that could necessitate an emergency response.
- Fostering the implementation by other States, of measures designed to fulfil the relevant international obligations in accordance with the Safety Requirements of the IAEA.
- Acting as the focal point for international cooperation including projects undertaken under the Notification and Assistance Conventions and IAEA assistance projects.

Legislation assigns general responsibilities relevant to any type of emergency but does not clearly allocate the responsibilities for preparedness and response to a nuclear or radiological emergency to the Regulatory Body. In particular, there are no clearly established responsibilities for IPEN or OTAN in relation to response operations at a national or local level.

At the level of licensees, IPEN establishes a regulatory and inspection system that provides reasonable assurance that emergency preparedness and response arrangements are in place for all facilities and activities. The authorization process

requires facilities and activities to have suitable emergency plans which are verified through inspections.

**Conclusion:**

There is a comprehensive legislative framework for preparedness and response to any contingency within the basic responsibilities of the governmental agencies of the Civil Defence System. The National Civil Defence Institute is the core institution of the system. Provisions for emergency preparedness and response to a nuclear or radiological emergency are not properly integrated with the arrangements and capabilities of the country to deal with conventional emergencies. Some co-ordinations were undertaken in the past but a sustainable process was not assured.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS:** GS-R-2 para. 3.1 states: "*Adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to [nuclear or radiological] emergencies.*"

**R71. Recommendation**:

The INDECI, in close collaboration with IPEN should include in the 'National Plan for Preventing and Attending Disasters' appropriate provisions for nuclear and radiological emergencies to assure that adequate preparations are established and maintained at local and national levels and if appropriate with bordering countries.

**2. BASIS** GS-R-2 para. 3.1 states: *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process. [The State] shall ensure that [the regulatory body and response organizations] have the necessary resources and that they make preparations and arrangements to deal with any consequences of [a nuclear or radiological emergency] in the public domain, whether the [nuclear or radiological emergency] occurs within or beyond national [borders]. These preparations shall include the actions to be taken both in and after an emergency."*

**R72. Recommendation:**

IPEN (and response organizations) should have the necessary resources to deal with any reasonably foreseeable consequences of a nuclear or radiological emergency in the country.

**3. BASIS:** GS-R-2 para. 3.4 states: "…*Legislation shall be adopted to allocate clearly the responsibilities for preparedness and response for a nuclear or radiological emergency and for meeting the requirements established in this Safety Requirement publication. This shall include establishing or identifying an existing governmental body or organization to act as a national co-ordinating authority whose function, among others, is to co-ordinate the assessment of the threats within the State (see paras 3.13–3.20) and to co-ordinate the resolution of differences and incompatible arrangements between the various response organizations. This authority shall ensure that the functions and responsibilities of operators and response organizations as specified in these requirements are clearly assigned and*

*are understood by all response organizations, and that arrangements are in place for achieving and enforcing compliance with the requirements."*

**R73. Recommendation:**

A coordinating committee should be created. IPEN and INDECI should work in close cooperation in order to propose to the appropriate governmental authority that a coordinating authority for nuclear emergencies is designated. Also, that a standing committee is created composed of themselves, as the core of the coordinating authority, and other relevant response organizations able to fulfil the appropriate functions.

**4. BASIS:** GS-R-2 para. 3.9 states: "*In fulfilling its statutory obligations, the regulatory body… shall establish, promote or adopt regulations and guides upon which its regulatory actions are based"*

**5. BASIS:** GS-R-2 para. 4.56 states: "*Arrangements shall be made to protect emergency workers, in accordance with international standards*."

**6. BASIS:** GS-R-2 para. 4.56 states: *National guidance that is in accordance with international standards shall be adopted for managing, controlling and recording the doses received by emergency workers. This guidance shall include default operational levels of dose for emergency workers for different types of response activities, which are set in quantities that can be directly monitored during the performance of these activities (such as the integrated dose from external penetrating radiation). In setting the default operational levels of dose for emergency workers the contribution to doses via all exposure pathways shall be taken into account.*

**7. BASIS:** GS-R-2 para. 4.72 states: *"In addition, arrangements shall be made for promptly assessing the results of environmental monitoring and monitoring for contamination on people in order to decide on or to adapt urgent protective actions to protect workers and the public, including the application of operational intervention levels (OILs) with arrangements to revise the OILs as appropriate to take into account the conditions prevailing during the emergency"*

**R74. Recommendation**:

IPEN should issue national guidance for:

- The operators to prepare their Emergency Response Plans.
- Establishing the provisions for managing, controlling and recording the doses received by emergency workers in accordance with the international standards.
- Establishing the OILs (Operational Intervention Levels) with arrangements to revise them as appropriate to take into account the conditions prevailing during the emergency.
- Managing and controlling the safe and effective management of radioactive waste during and after an emergency.

## 8.3 ASSESSMENT OF THREAT

Radiological threat assessment is performed at the national level in order to identify any event that could give raise to a radiation emergency and necessitate an emergency response. This radiological threat assessment has been carried out by the Regulatory Body as part of coordination undertaken (but not yet completed) to prepare the country's Integrated Plan. The assessment took into account existing practices and radiation sources in the country and other unexpected sources which could appear.

The radiological threat assessment was prepared by OTAN using data on characteristics of radiation sources existing in the country. The assessment was not formally revised although it was presented to National Institute for Civil Defence. The report is dated on June 2004 and it has not been updated. The following elements should be taken into consideration when revising the report:

- To locate on a map the urgent protective action zone for the research reactors.
- To identify operators of dangerous mobile sources (threat category IV in Table I of the GS-R-2) that can result in emergencies anywhere in the State.
- To address the locations at which there is significant probability of encountering a dangerous source that has been lost, abandoned, stolen or illicitly transported. This should include scrap metal processing facilities and national border crossings.
- To consider combination of the assessment with conventional emergencies. For instance, earthquakes could initiate a radiological emergency.
- To explain the meaning of the threat categories existing in the country.

Radiological threats have been categorized in accordance with the five threat categories in Table I of GS-R-2.

Radiological threat assessments do not take into consideration their occurring in combination with conventional emergencies (such as an earthquake, for example).

IPEN does not adequately ensure that the nature and extent of emergency arrangements are commensurate with the potential magnitude and nature of the hazard associated with a facility or practice. There are some provisions at the user level; emergency plans are required according to the magnitude of the radiation source, as established in Article 86 of Radiological Safety Regulation (D.S. N° 009-97-EM).

**Conclusions:**

An assessment of threats was carried out in 2004. The provisions of the IAEA's standards and methodologies were applied. This assessment did not consider the combination of nuclear or radiological emergencies with conventional emergencies and other elements in relation to mobile sources and locations at which there is a significant probability of encountering a dangerous source that has been lost, abandoned, stolen or illicitly transported, for instance, scrap metal processing facilities and national border crossings.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para. 3.16 states: *Operators, the national co-ordinating authority (see para. 3.4) and other appropriate organizations shall periodically conduct a review in order to ensure that all practices or situations that could necessitate an emergency intervention are identified, and shall ensure that an assessment of the threat is conducted for such practices or situations. This review shall be undertaken periodically to take into account any changes to the threats within the State and beyond its borders, and the experience and lessons from research, operating experience and emergency exercises.*

**R75. Recommendation**:

IPEN should revise and update the report on the assessment of radiological threats considering the latest improvements of the IAEA's methodologies/standards and the national experience of the INDECI management. Stakeholders among operators, response organizations, and other appropriate institutions of the Civil Defence System and local authorities should be involved in this process. The process could be coordinated by the Civil Defence Institute with the close support of IPEN.

## 8.4 LEGAL BASIS AND RESPONSIBILITIES

### *8.4.1 Establishing Emergency Management and Operations*

Since it is notified in case of an accident (as established in licence conditions) IPEN has a *de facto* responsibility for activation of the response at the national level. Coordination of the response at this level needs to be implemented. Mechanisms for this are not yet in place because the integrated plan has not been prepared.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para.4.10 states: *Arrangements shall be made for the implementation of a command and control system for the response to a nuclear or radiological emergency. This shall include arrangements for co-ordinating activities, for developing strategies and for resolving disputes between the response organizations concerning functions, responsibilities, authorizing the allocation of resources and priorities*

**R76. Recommendation:**

IPEN should define clearly its role and functions and its role in the command and control system during radiological emergency response operations and be aware of the response strategies commensurate with the threat assessment.

### *8.4.2 Identifying, notifying and activating*

IPEN acts as a National Contact Point on a 24-hour basis, for receiving emergency notifications of an actual or potential nuclear or radiological emergency. IPEN, as the regulatory body, is the national contact for receiving notifications of actual or potential nuclear or radiological emergencies. The few notifications received each year are for events of loss and missing or found radiation sources, some scrap processors and some false alarms.

Currently users send notifications but notifications may also be received from the public or other organizations. Notifications are received by telephone through a central station or sometimes at OTAN. There are no formally implemented arrangements for duty response teams with appropriate resources to be activated where necessary. Two intervention teams have been created formerly, but they are not presently operational.

IPEN acts as a National Contact Point on a 24-hour basis, for sending to the IAEA emergency notifications of an actual or potential nuclear or radiological emergency as required. Any type of emergency notification can be sent to the IAEA IEC, however, the IRRS Review Team was informed there has been no cause to make such a notification. Notifications would be sent by fax. There are no procedures formally approved for this process.

IPEN is nominated as National Warning Point for provisions of the Convention on Early Notification of a Nuclear Accident and it is the National Competent Authority for cross-border, overseas and domestic emergencies. The role is to receive and send emergency notifications and to participate in emergency exercises. There are no IPEN procedures in place for this role. Actuation is based on IAEA EPR documents.

IPEN acts as the National Competent Authority in relation to the provisions of the IAEA's Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. The role of the Regulatory Body is to collect information from responsible organizations and to request assistance from IAEA as necessary. The provisions for requesting assistance from IAEA will be included in IPEN emergency plan.

Attention should be paid to the training and use of the ENAC web page.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para. 4.16 states*: "Notification points shall be established that are responsible for receiving emergency notifications of an actual or potential nuclear or radiological emergency. The notification points shall be continuously available to receive any notification or request for assistance and to respond promptly or to initiate an off-site response".*

**R77. Recommendation**:

IPEN should make the necessary arrangements to be provided with the resources and ability to promptly activate itself and other appropriate response organizations

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

in case of being notified of an event that could warrant urgent protective action in an unforeseeable location (threats of category IV).

**S21. Suggestion:** Existing capabilities could be used for this purpose (operations centres already available in the Civil Defence System could be trained to work out in case of a nuclear or radiological emergency)

**2. BASIS:** GS-R-2 para. 4.14 states: "*Appropriate emergency response actions shall be initiated promptly upon the receipt of a notification from another State or information from the IAEA of a notification relating to an actual or potential transnational emergency that could affect the State or its nationals".*

**R78. Recommendation**:

IPEN as the National Warning Point for the Notification Convention should have what it needs to fulfil with the ENATON Manual.

**S22. Suggestion:** Special attention should be paid to train people with the ENAC web site.

### *8.4.3 Taking Mitigatory Action*

The Regulation for the Organization and Duties of IPEN (D.S. N° 062-2005-EM) establishes legal responsibilities to participate in activities for implementing institutional and national emergency plans, which includes the provision of expertise and services in radiation protection to first responders, local officials and national officials in case of a nuclear or a radiation emergency.

Arrangements to provide technical expertise for facilities or practices in threat categories II, III or IV are under consideration in the IPEN Institutional Plan for Emergencies. At the present there are no formally available and trained response teams to be deployed promptly to the scene of an accident. It should be mentioned that it is not currently possible to support first responders where the accident site is located away from Lima. The resources for rapid mobilization of a specialized team from IPEN are insufficient. Also, the regime of "a specialist on duty" is not properly implemented.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para. 4.35 states *"Arrangements shall be made to provide expertise and services in radiation protection promptly to local officials and first responders responding to actual or potential emergencies involving practices in threat category IV. This shall include arrangements for on-call advice and arrangements to dispatch to the scene an emergency team that includes radiation specialists capable of assessing threats involving radioactive or fissile material, assessing radiological conditions, mitigating the radiological consequences and managing the exposure of responders".*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**R79. Recommendation**:

IPEN should organise response teams able to be dispatched promptly to the scene of an accident to support the first responders or make arrangements for "on-call" advice. These teams should be trained in recovery operations such as recovering dangerous sources, managing radiological response at the scene, etc. Also, the IPEN should coordinate the provision of expertise and services in radiation protection to local officials where needed.

### *8.4.4 Taking Urgent Protective Action*

National intervention levels for taking urgent protective actions (sheltering, evacuation and iodine prophylaxis) have been adopted and approved in Radiological Safety Regulation (D.S. N° 009-97-EM), specifically Annex II.

Emergency planning zones have not been adopted in legislation for facilities in threat category II. The IPEN Institutional Plan for Emergencies under preparation will adopt the urgent protective action planning zone just for the 10MW research reactor, as there are no facilities in category I.

IPEN is responsible for formulation of recommendations for urgent protective actions off-site. IPEN/OTAN also has responsibility for formulating criteria and recommendations for off-site urgent protective actions. The Radiological Safety Regulation includes provisions for urgent protective actions. This responsibility agrees with the Third Complementary Provision of Law 28028. Furthermore, the General Criteria Plan from the National Institute for Civil Defence (INDECI) establishes that IPEN is a consultant for disasters.

During an emergency it is foreseen that IPEN will be part of adviser group to the local or national Director of Emergency, as appropriate.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para. 4.48 item (ii) states: "*An urgent protective action planning zone, for facilities in threat category I or II, for which arrangements shall be made for urgent protective action to be taken promptly, in order to avert doses off the site in accordance with international standards"*

**R80. Recommendation**:

IPEN should enforce the implementation, if necessary, of an urgent protective action planning zone in the emergency plans (on-site and off-site) for the 10 MW research reactor.

**2. BASIS:** NS-R-4 para 7.76 states*: The emergency response team shall include persons with up to date knowledge of the operations of the research reactor, and it should normally be led by the reactor manager or a delegate. All personnel involved in responding to the emergency shall be instructed, trained and retrained periodically as necessary in the performance of their duties in an emergency. All persons on the site shall receive instruction on the steps to take in an emergency.*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*Instructions shall be prominently displayed.*

**R81. Recommendation**: IPEN should explicitly require the Licensee and enforce as appropriate that the emergency response team include persons with up to date knowledge of the operations of the research reactor and it should normally be led by the reactor manager or a delegate.

### *8.4.5 Protecting Emergency Workers*

Dose levels for emergency workers have been adopted in the legislation for the various types of response activities. The Radiological Safety Regulation (D.S. N° 009-9-EM) has established in Articles 95, 96 and 97, dose levels for emergency workers in case of saving life or preventing serious injury or actions intended to avert large collective doses or for preventing the development of catastrophic situations. These levels are not in accordance with international standards and should be revised and updated according to the latest IAEA standards.

IPEN has not been designated in legislation as the responsible organization for managing doses received by emergency workers in intervention. However, if a category IV accident of the threat assessment occurs (lost or abandoned sources and/or sources recovery operations in the public domain) IPEN would *de facto* assume this responsibility. Dosimetry service suppliers currently record the occupational and emergency doses. There is no national guidance for managing, controlling and recording the doses received by the emergency workers.

### *8.4.6 Assessing the Initial Phase*

IPEN should provide support to first responders during the initial phase of a radiological emergency at facilities in threat category IV. The Regulatory Body is notified first so it must support the first responders during the initial response operations.

Also, according to the Institutional Emergency Plan under review, radiation specialists and radiological monitoring teams are provided by IPEN to assess the radiation levels and radioactive contamination in emergencies of threat category II. The Unit of Radiation Monitoring (Direction of Services) which will be included in the Institutional Emergency Plan is responsible for monitoring the radioactive contamination in the affected area around the 10 MW research reactor, the only facility in threat category II.

### *8.4.7 Keeping the Public Informed*

IPEN has no legal responsibilities to provide useful, timely, truthful, consistent and appropriate information to the public in a radiation emergency. This is under consideration in the Integrated Emergency Plan. The legal responsibility will be defined when this Plan is approved. Currently IPEN makes statements and provides information about any emergency.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para. 4.83 states : "*Arrangements shall be made for: providing useful, timely, truthful, consistent and appropriate information to the public in the event of a nuclear or radiological emergency; responding to incorrect information and rumours; and responding to requests for information from the public and from the news and information media"*

**S23. Suggestion**:

IPEN might use existing capabilities and programmes of public information on the Civil Defence System framework to integrate public information in case of nuclear or radiological emergency

### *8.4.8 Taking Long-term Protective Actions*

IPEN has legal responsibilities in formulating recommendations for long term protective actions. The Radiation Safety Regulation (Art. 93 and Annex II) has provisions for long term protective actions. The responsibility of IPEN is specified in its Regulation for Organization and Duties. The recommendations are foreseen to be achieved through notification of agricultural countermeasures, restrictions and control of food or agriculture to the Ministry of Agriculture.

Default OILs for environmental measurements are not established. It is foreseen to include them in the Integrated Radiological Emergency Plan.

Default OILs for food concentrations are established. These values are established in Radiological Safety Regulation (D.S. N° 009-97-EM). In general foods: 1 kBq/kg for gamma emitters; 0,1 kBq/kg for beta emitters and 0,01 kBq/kg for alpha emitters. There are also OILs for milk, baby foods and drinking water. The responsible organization for establishing and revising these OILs for food concentrations is IPEN as the Technical Office for the National Authority.

IPEN *de facto* supports national officials with environmental radioactivity monitoring in the post-accident phase. Environmental radioactivity monitoring is performed by the Laboratory for Environmental Control, which depends on the Direction of Services from IPEN. In the case of an accident requiring environmental monitoring, IPEN will support national officials or other organizations involved in the response.

IPEN is responsible for implementing the programme of environmental radioactivity monitoring post-accident.

IPEN has *de facto* responsibilities for controlling the safe and effective management of radioactive waste during and after an emergency. The Radiological Safety Regulation enables IPEN to control the safe and effective management of radioactive wastes from any origin. This is achieved by inspecting the activities for radioactive wastes management.

## 8.5 CAPABILITIES OF EMERGENCY RESPONSE ARRANGEMENT

### *8.5.1 Organization.*

IPEN acts as an adviser to government, private institutions, and other competent authorities in connection with the use of nuclear energy according to the Regulation for Organization and Duties of IPEN. It is foreseen within the Integrated Radiological Emergency Plan that IPEN will act as an adviser to government and authorities in nuclear safety and radiation protection matters in planning for and in the event of emergencies.

The main role, besides that of adviser, is to support the coordination of the planning process to respond to a nuclear or radiological emergency. The role of coordination is provided by Law 28028.

### *8.5.2 Plans and Procedures*

OTAN does not have its own emergency plan. It is under preparation to be included into the IPEN Institutional Radiological Emergency Plan.

OTAN has assigned legal responsibilities for control of the emergency plans of operators, for facilities and practices in threat categories I, II, III or IV. The Radiological Safety Regulation establishes in Articles 87 and 88, provisions for general responsibilities in controlling radiological emergencies which include these categories. IPEN is in charge of verifying the provisions of the Regulation including those related to the emergency plans of operators.

Responsibility for preparing and implementing the emergency plans of operators, facilities and practices for categories II, III or IV are established in the Radiation Safety Regulation (Article 88°) and these emergency plans are required when applying for an authorization. Emergency plans are prepared and approved by the applicant and submitted to OTAN as part of the technical information for the authorization process. OTAN reviews and approves the operator's emergency plans.

There are no:

- Integrated Plans at the national level for responding to nuclear or radiological accidents;
- provisions in IPEN's plans or conventional response organizations to deal with a nuclear or radiological emergency;
- provisions in local authorities plans to deal with nuclear or radiological emergencies.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para 5.13 states :.*"Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies. These arrangements for a co-ordinated national response shall specify the organization responsible for the development and maintenance of the arrangements; shall describe the responsibilities of the operators and other response organizations; and shall describe the co-ordination*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

*affected between these arrangements and the arrangements for response to a conventional emergency…."*

**2. BASIS:** GS-R-2 para 5.14 states: *Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions*

**R82. <u>Recommendation</u>**:

IPEN should prepare its own emergency plan in close cooperation with the INDECI and other relevant response organizations and local authorities.

### *8.5.3 Logistical Support and Facilities*

OTAN has some tools, instruments and equipment for performing its assigned response functions. The available tools, instruments and equipment are only just adequate to support the first response of small situations.

The tools, instruments and equipment which are used for performing the assigned response functions are: a gamma and beta monitor, surface contamination monitors, personal radiation detectors, a radioisotope identification detector, emergency kit, small shielding and a vehicle.

For emergency purposes there are insufficient instruments for the following functional aspects: portable radionuclide identification, telescopic detection for monitoring dangerous sources, air sampling and alpha surface contamination measurements Nor is there a set of check sources or means for the monitoring of neutron sources. Where necessary, two instruments for portable radionuclide identification more usually used for inspections, could be used in case of emergency.

OTAN has limited essential supplies (protective clothing, decontamination materials, etc) for performing its assigned response functions. More resources would be provided by IPEN if required in emergencies.

OTAN has inadequate communication systems for performing its assigned response functions. Communication is achieved by private mobile cell-phones and non-dedicated telephones.

OTAN has inadequate facilities for performing its assigned response functions. Facilities are the same as for the normal operations of the institution, except for a small room for equipment and tools.

OTAN has inadequate documentation for performing its assigned response functions. There are some draft procedures and instructions not yet formally approved. These procedures include some functions to be performed in a radiological emergency.

OTAN has no appropriate arrangements for maintaining infrastructural elements (tools, instruments, equipment, communication systems, facilities) in proper condition during an emergency.

OTAN has in place essential arrangements for obtaining logistical support during an emergency. Once an emergency has been notified to IPEN, logistical support is

achieved as requested depending on the magnitude of the emergency. The administrative office of IPEN is tasked to provide all of necessary resources and financial support to the response teams according to Directive No. 03-99-IPEN/PR "National Radiological Emergency Situations" of IPEN.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para 5.25 states: *" Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions specified in Section 478. These items and facilities shall be selected or designed to be operational under the postulated conditions (such as the radiological, working and environmental conditions) that may be encountered in the emergency response, and to be compatible with other procedures and equipment for the response (such as the communication frequencies of other response organizations), as appropriate. These support items shall be located or provided in a manner that allows their effective use under postulated emergency conditions."*

**R83. Recommendation**:

IPEN should define the appropriate tools, instruments, supplies, equipment and documentation that should be kept by their emergency teams and make arrangements for having them in advance. Monitoring instruments should be enough to cover the probable situations that could come out according to the threats assessment.

### *8.5.4 Quality Assurance Programme*

IPEN has not established a quality assurance programme to ensure a high degree of availability and reliability of all supplies, equipment, communication systems and facilities necessary to perform assigned response functions. These issues will be taken into account in the proposed Regulatory Body plan as well as the Integrated Emergency Plan.

## 8.6 EMERGENCY EXERCISE PROGRAMME

### *8.6.1 Training, Drill and Exercise*

OTAN has no arrangements in place for ongoing initial and refresher training on an appropriate schedule, nor arrangements for ensuring that personnel (other than Regulatory Body staff) assigned to positions in the national emergency organizations undergo specific training for nuclear or radiological emergencies. Training arrangements are in place only for the operators of the nuclear research reactors. For other personnel, training arrangements will be included as part of proposed Integrated Emergency Plan.

OTAN has no training or exercise programme for its own staff related to fulfilling their role in an emergency. These programmes will be prepared and included into the Regulatory Body emergency plan.

Members of the Regulatory Body have attended some of regional courses organized by IAEA and also some national courses. The management of training needs is not systematic. Some workshops have been carried out to exercise the response for criminal threats.

OTAN participates as observer in research reactor emergency exercises. A national exercise has not been performed because the integrated plan has not been yet developed. Also, Peru has not taken part in international CONVEX exercises. The IRRS Review Team understands the reason for this is the lack of the integrated plan.

Regulatory Body staff have some experience in local exercises (research reactor drills and simulations). There is no experience at the national or international level.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para 5.31 states:*" The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 4. The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training"*

**R84. Recommendation**:

IPEN in close cooperation with the INDECI should prepare and approve a comprehensive training programme based on an analysis of needs on emergency preparedness and response matters in accordance with the functions assigned to each response organisation.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-2 para 5.33 states :*." 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 and the national level programmes for threat category IV or V are tested at suitable intervals84, 85. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body."*

**R85. Recommendation**:

IPEN should assist the INDECI to prepare and approve a comprehensive national programme of exercises (under the umbrella of Civil Defence management system)

to train all response organizations acting in case of a nuclear of radiological emergency.

**R86. <u>Recommendation</u>**:

IPEN should be assigned responsibility in law for organising the evaluation of exercises included in the programme.

# 9. CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES

## 9.1 GENERAL

The government of Peru has sent a signed commitment to the IAEA to work toward full implementation of the Code of Conduct (Code of Conduct on the Safety and Security of Radioactive Sources). This is demonstrated by the letter dated 16 March 2007 from Sr Conrado Seminario Arce (President of IPEN) to Dr M. El Baradei at the IAEA. The government has also committed to implementation of the additional guidance in support of the Code of Conduct, entitled 'Guidance on the Import and Export of Radioactive Sources'.

### *9.1.1 Basic Principles (7 to 17)*

A significant range of measures have been established to ensure the safety of sealed sources during their lifecycle, such as creation of laws and regulations, an authorization system, an inspection regime and enforcement systems.

Apart from some IPEN training courses, on-going communication between the Regulatory Body and users is limited to inspection activities during compliance assessment. For this and other reasons, there is as yet a limited radiation safety culture in Peru and a limited security culture. The latter can be characterized as being at the levels required by the BSS. The Code of Conduct on the Safety and Security of Radioactive Sources now urges States to consider whether a more graded approach to security, commensurate with the range of hazards in the country, is needed.

With some important exceptions (highlighted later) an effective national legislative and regulatory system of control over the management and protection of sealed radioactive sources is in place in the country.

Taken together, measures set out in legislation (009-97-EM, Article 5, (71) and authorizations (Licence Conditions 6 and 7) placing prime responsibility for safe management and security of radioactive sources on licensees, contribute significantly towards minimizing the likelihood of a loss of control of sealed radioactive sources.

In the event that a user, or anyone else, finds an orphaned radioactive source OTAN will normally be notified. This is a condition of the user's licence (Condition 28). The mechanisms for this are not clearly set out however.

In the case of source discovery in places other than users' premises, notification of OTAN is not fully planned. However, the IPEN website includes an emergency telephone number and information for anyone finding a source bearing the radiation trefoil to be able to contact IPEN. The webpage includes a picture of the radiation warning trefoil. However, in the absence of a National Response Plan, the awareness of people not normally working with radiation is likely to be low. This includes relevant governmental and non-governmental organizations (such as the police) that may have no prior knowledge of the significance of the trefoil, and the actions that such a find should initiate. This means that the probability of OTAN being alerted is low in practice.

The IRRS Team understands that once OTAN is notified, they will respond immediately. The IRRS Team was also informed that included in OTAN's response

role is the capability to make an orphan source safe and to transport it to the IPEN disposal facility at no charge. It was not clear how many staff of OTAN have the competences for this and what equipment is available to accomplish the task.

However, there is a possible unintended consequences faced by any government that provides such a free disposal service for orphan sources. It has been recognized by OTAN that it is possible that falsely reporting the loss of a source may be cheaper to the user than paying for proper disposal. Until July 2008, this was the case. The sanction was less than the commercial fee for source disposal. However, OTAN have successfully influenced the amendment of Law 28028 made in July 2008. Since then, the standard sanction tariff for loss of a source has been increased so as to be comparable with the cost of disposal. Both the influencing process (of legislation in draft) and the eventual outcome (of raising the sanction tariff of loss of a source to a more realistic level), represent good practice.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources 15 to 20(a) and 20(m)

**G5. Good Practice:** The role of IPEN in influencing the improvement of legislation, and ensuring that sanctions are set at levels which are proportionate to the costs of compliance are both good practices.

It should be noted that immediate response arrangements and free disposal service for orphaned sources represents a key element of a proposed National Response Plan; components of such a plan have already been drafted and will be built upon. Elements that still need to be developed include planning to enable searches to be organized for significant lost sources, and in particular the preparedness of, and coordination with other relevant organizations.

The IRRS review team was informed that OTAN would respond in an *ad hoc* fashion.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources para 8 states:

*"Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should:*
*[ ……]*
*(c) include national strategies for gaining or regaining control over orphan sources;*
*(d) provide for rapid response for the purpose of regaining control over orphan sources"*

**R87. Recommendation:** The Government of Peru should develop a national strategy for the detection of and response to, incidents involving radioactive

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

sources that have been lost from regulatory control.

**S24. Suggestion:** A plan should be developed from the national strategy and be integrated, as appropriate with other national emergency response plans. It should include clear assignment of responsibilities and listing of the capabilities of all parts of government that may need to be involved. The plan should include arrangements for its dissemination to other relevant organizations, and a mechanism for ensuring that all copies, wherever they are held are managed so as to be kept up to date.

At present, measures to reduce the likelihood of malicious acts are limited, for example due to the lack of direct liaison between IPEN and other parts of government that are able to make a meaningful threat assessment. The first stage in setting up measures to prevent malicious acts is to know what needs to be protected and this is done by the use of the country's national register of sealed sources. The next stage is to understand what the threat is. However, this is not the role of the Regulatory Body. Internal security services and the local intelligence community should be approached by IPEN for specialized information and expertise.

The IRRS Team was informed that there is an intention to develop regulation of source security, if the capability to do so can be acquired. The outcome of such work would be effective measures to reduce the likelihood of malicious acts, including sabotage, consistent with the threat defined by the State.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources para 7 states that**: "***Every State should, in order to protect individuals, society and the environment, take the appropriate measures necessary to ensure: [ ]*
*(b) the promotion of safety culture and of security culture with respect to radioactive sources;*
*8(e) Every State should [have a system to] foster ongoing communication between the regulatory body and users".*

**R88. Recommendation:** IPEN should review ways to promote both a safety and a security culture within the country and implement the feasible option(s).

**S25 Suggestion:** Promotion options may include regular newssheets from IPEN to the authorised users, enhancement of information available to users on the IPEN web-pages, periodic (e.g. annual) meetings to enable informal liaison between IPEN and Radiation Protection Officers, or collaboration with others such as a university to increase association between radiation safety practitioners.

**2. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources para 19 (g) states that: *the State should put in place legislation and/or regulations that provide requirements for security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of*

*radioactive sources during all stages of management*;

**3. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources para 19 (g) states that: *the State should put in place legislation and/or regulations that provide requirements for security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources during all stages of management*

**R89. Recommendation:** The Government of Peru should review its domestic threat, existing security requirements and international good practice as provided by IAEA Security Guide No. 11 and consider what improvements are appropriate. In particular, the authority of IPEN to liaise directly with other relevant governmental bodies should be reviewed.

Some but not all the of the appropriate facilities and services needed for radiation protection, safety and security are available to, and used by, persons authorized to manage radioactive sources. It is clear there would be a search for missing sources and that found sources are likely to be secured. In a similar *ad hoc* way, a response would be made to intervene in the event of an accident or malicious act involving a radioactive source. The country is also able to call on personal dosimetry and environmental monitoring services as well as those for the calibration of radiation monitoring equipment.

The licence issued to users includes requirements on the user to report abnormal events to IPEN (Condition 28). In addition, the public (and other parts of government) can locate, if they should search for it, the emergency contact number for IPEN, part of which includes the Servicio National de Attencion a Emergencias – SENAER. It is good practice to have single point of contact, (as long as it is also effective). However in the absence of a National Plan, and any other significant awareness raising mechanisms on orphan source issues, it seems there is a low probability that a finder, the police or any other organization finding a source would know what to do, or even where to search for initial advice.

The country has in place a comprehensive national inventory of sealed radioactive sources that includes not only the minimum of IAEA Categories 1 and 2 sealed sources, but all sealed sources known to exist within the State. This is good practice. The sources listed number about 2,440 at the time of writing. In this respect, it complies with and exceeds the requirements of Code of Conduct on the Safety and Security of Radioactive Sources paragraph 11.

IPEN may wish to consider if it would be beneficial to add a data field to the national inventory that relates to the IAEA Category of the source. This would enhance the ability of the regulatory body to report on Category 1 and Category 2 sealed sources within the inventory.

OTAN may choose to implement the study it has already made of the IAEA's RAIS system. This could save on effort insofar as the system is already built and available for implementation by States, but the population of data would remain a resourcing challenge.

IPEN may wish to consider the following alternatives:

- it may be beneficial to add a data field to the national inventory that relates to the IAEA Category of the source. This would enhance the ability of the regulatory body to report on Category 1 and Category 2 sealed sources within the inventory. The work required to populate the database into the new field would be significant, or
- OTAN may choose to implement the study it has already made of the IAEA's RAIS system. This could save on effort in so far as the system is already built and available for implementation by States, but the population of data would be a resourcing challenge.

The Code of Conduct on the Safety and Security of Radioactive Sources also states in paragraph 11 that, for the purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavour to harmonize the formats of their registers. The country has not put in place arrangements to share its data with other States, but as the database is built in MS Access, this would be straightforward to do if required.

In addition to programmes on Nuclear Applications and Non-Destructive Testing (NDT), IPEN provides a number of Radiation Protection training programmes annually to a wide range of user-groups. These include for example: Industrial Gauges, Industrial Radiography, and General Safety of Radioactive Sources.

These training courses are an important contribution to the safety culture of the country in the absence of other supporting measures. TUPA and Article 34 of 28028 require that refresher training of RP Officers occurs at least once in the 5 year life-span of an individual authorization. Some of these courses should provide some awareness among industry, health professionals and to some extent government bodies of the safety and security hazards associated with orphan sources.

IPEN also provide some limited awareness-raising opportunities for members of the public, who are attracted by email and web-based announcements. It would be useful to review the content of such courses to ensure that suitable opportunities are taken to ensure that the issues of orphan sources are suitably represented.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**1. BASIS**: Code of Conduct on the Safety and Security of Radioactive Sources 13 states: "*Every State should*

*(a) promote awareness among industry, health professionals, the public, and government bodies of the safety and security hazards associated with orphan sources; and*

*(b) encourage bodies and persons likely to encounter orphan sources during the course of their operations(such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources*".

**R90. <u>Recommendation</u>**: As part of the development of its national strategy for dealing with orphan sources, IPEN should review the current material on the safety issues of IPEN courses for both safety practitioners relevant training provided to industrial and medical users, and implement any enhancements that may be

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

appropriate.

**R91. Recommendation:** Having gained authority to liaise directly with other parts of government, IPEN should liaise with customs colleagues and border guards and seek every opportunity to encourage them to collaborate in the implementation of appropriate monitoring programmes to detect such sources.

Some regular refresher training on the less technical aspects of inspection would be beneficial. Observations at two site inspections made by OTAN staff suggested that there may be a need for operational awareness training so as to take a more critical approach to information provided by users and Radiation Protection Officers. The aim should be to equip the Inspector with the critical skills needed to test any information provided by a user to establish its reliability / trustworthiness.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources 10 states: *"Every State should ensure that adequate arrangements are in place for the appropriate training of the staff of its regulatory body, its law enforcement agencies and its emergency services organizations".*

**S26. Suggestion:** IPEN could consider the benefits of establishing an inspection skills course for Inspectors to develop their critical analysis of information provided by users.

The IRRS Team was informed that OTAN has worked with the company 'Aceros Arequipa' (who manufacture steel and trade in scrap metal) to train staff in the need for and the use of portal monitors at their site in Lima. This occurred a few years ago, but OTAN still wish to have similar discussions with other relevant companies.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources 13 states: "*Every State should:*

*(a) promote awareness among industry, health professionals, the public, and government bodies of the safety and security hazards associated with orphan sources; and*

(*b) encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources".*

**R92. Recommendation:** IPEN should work with customs officers and border guard organizations in order to encourage them to be aware of, and respond to

orphan sources during the course of their operations.

### 9.1.2 Legislation and Regulations

Legislation and regulations provide for governmental responsibilities regarding safety of sources, as established by Law Nº 28028 and Supreme Decree 009-97-EM.

The government has not yet reviewed the domestic security threat to sealed radioactive sources in the context of paragraph 18 (d) of the Code of Conduct on the Safety and Security of Radioactive Sources or reviewed the comprehensiveness of its regulations on this matter, the training available to IPEN on nuclear security and the security and reputational benefits that could result from such a review.

The extent to which Peruvian legislation and regulations require security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources during all stages of management have not yet been reviewed in the context of paragraph 19 (g) of Code of Conduct on the Safety and Security of Radioactive Sources.

### 9.1.3 Regulatory Body

IPEN is authorised to issue guidance. The IRRS Team was informed that a Norm on Industrial Radiography was in development and had been consulted on publicly.

There is no requirement in legislation or licences for a security plan to be submitted to the Regulatory Body as part of applications for authorizations. This should be considered as part of the review of security requirements recommended above.

Regulatory Body liaison with other relevant government departments and agencies depends on extended line management chains. International experience shows that direct liaison between different parts of government is the most efficient and effective arrangement. The ability of the country to respond to information and intelligence gleaned by other parts of government or indeed to share this type of information is currently limited in Peru.

The government has established a sound basis for the control of the import and export of Category 1 and Category 2 sealed radioactive sources.

The Regulatory Body has not yet reviewed the security of its critical records, both in terms of denying access to such information by persons intending to undertake malicious act, and also with the aim of ensuring effective business continuity management. It may be beneficial to review the security of electronic and paper records held at OTAN in order to have a higher level of confidence that they will be protected from threats including alteration (22c), theft (para 17 of the Code of Conduct on the Safety and Security of Radioactive Sources), fire, flooding and earthquake (19 h, 22 c).

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources 7 (a)states: *" Every State should in order to protect individuals, society and the environment, take the appropriate measures necessary to ensure:*

*(a) that the radioactive sources within its territory, or under its jurisdiction are safely managed and securely protected during their (useful lives and at the end of their useful lives.*

*22 c; Every State should ensure that its regulatory body*

*( c) maintains appropriate records……These records should be properly secured against unauthorised access or alteration, and back-up copies should be made.*

*17; Each State should take appropriate measures consistent with its national law to protect the confidentiality of any information that it receives in confidence under this Code of Conduct on the Safety and Security of Radioactive Sources form another State or through participation in an activity carried out for the implementation of this Code of Conduct on the Safety and Security of Radioactive Sources.*

*19 h; (Such) legislation and / or regulations should provide for, in particular:*

*(h) requirements relating to the verification of the safety and security of radioactive sources, through…..the maintenance of appropriate records".*

**R93. <u>Recommendation</u>:** IPEN should review the physical protection of its critical records, including authorization files, copies of licences and the national inventory of sources and implement appropriate measures to ensure both business continuity and protection of sensitive information in accordance with the national code.

**Code of Conduct on the Safety and Security of Radioactive Sources Regulatory Body, paras 20 to 22**

A Radiation Protection Officer (RPO) is required by law for selected practices (Article 61.3 of 28028 and Procedure 4 of TUPA) and this requirement is reflected in relevant authorizations. Underpinning this requirement is a structured approach to defining the qualifications and experience expected of RPOs which is defined in TUPA Procedure 4.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** *Code of Conduct on the Safety and Security of Radioactive Sources paragraph 19 (g) states: " … the state should put in place legislation and/or regulations that provide requirements for security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources during all stages of management".*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**2. BASIS:** *Code of Conduct on the Safety and Security of Radioactive Sources paragraph 20 (m) states: "Every State should ensure that the regulatory body established by its legislation has the authority to liaise and co-ordinate with other governmental bodies and with relevant non-governmental bodies in all areas relating to the safety and security of radioactive sources*"

**R94. Recommendation:** The Government of Peru should review the domestic threat, existing security requirements and international good practice (as provided by IAEA Security Guide No.11) and consider what improvements are appropriate.

The Code of Conduct on the Safety and Security of Radioactive Sources (8.(h)) expects Regulatory Bodies to have arrangements in place for continuous improvement. Considerable work has been done in OTAN recently to improve standards and to develop performance indicators for the inspection and evaluation departments, however, there is neither a structured programme nor a mechanism for true continuous improvement.

Law 28028 (First Transitional Provision) provides for making financial provision (as defined by IPEN) for the end-of-life disposal of radioactive sources. In practice this is a little used provision. It is difficult for IPEN to estimate the quantum of provision that should be made and to be certain that users have genuinely made adequate financial provision. It would be appropriate to review these arrangements and to work towards extending the competence of IPEN in this regard.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** .Code of Conduct on the Safety and Security of Radioactive Sources 22 (b): 22.states*: "Every State should ensure that its regulatory body:*

*(a) establishes procedures for dealing with applications for authorization;*

*(b) ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused".*

**S27. Suggestion:** It is suggested that IPEN develops a relationship with suitable legal and financial experts who can support them in developing arrangements to ensure that reliable Financial Provisions for end-of-life disposal of orphan sources are established**.**

The IRRS Team was informed that traceability of sources is assured by the requirement for sources and devices to be marked with their serial number and other relevant details. As would be expected, older sources or devices are occasionally found where the unique identifier has been obscured or was never present. The regulator demands that users apply their own marking in these circumstances, using an internal IPEN procedure.

The frequency of verification (by the user) that sources are present is determined by risk, according to practice. The IRRS Team was told that verification is at three monthly intervals for well-logging and industrial radiography sources. Accountancy and verification checks are part of the transport authorisation process. The impression gained by the IRRS Team is that by emphasis, for higher risk practices such as mobile uses of sources, undue reliance has been placed on paperwork, rather than using an instrument to verify that a source has not been lost. It is recommended that IPEN reviews its procedures relating to the requirement it places on users to verify the actual presence of sources.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** *Code of Conduct on the Safety and Security of Radioactive Sources 18 (b); Code of Conduct on the Safety and Security of Radioactive Sources 19 (h)*

**R95. Recommendation:** IPEN should review its requirements relating to the expectations of users on the verification of sources and ensure that a suitable balance is struck between reliance on administrative measures, and direct measurement.

#### *9.1.4 Import and Export*

Radioactive sealed sources are not exported from the country, except in so far as spent sources are returned to the manufacturer. IPEN is contacted by the Regulatory Body of any country from which imports are initiated, to check that an authorisation is in place. All imports are authorised by IPEN and the integration of authorisation of import and export, users and radiation protection officers in a single department is good practice.

The requirement for signage of sources and devices, and areas where sources are used is provided by Supreme Decree 009-97-EM, as well as being a condition of licences. The standard of signage is provided by law.

# 10. TRANSPORT OF RADIOACTIVE MATERIAL

## 10.1 GENERAL

The provisions in Article 70° of Rule of Law 28028 and Articles 101° and 102° of the Radiological Safety Regulation establish specific requirements to be fulfilled for the transport of radioactive material.

## 10.2 TRANSPORT SAFETY

### *10.2.1 Emergency Response*

The IAEA Regulations for the Safe Transport of Radioactive Material have been adopted through the Article 102° of the Radiological Safety Regulation.

Procedure Nº 10 of R.M. 033-2008-MEM/DM requests submission of an emergency plan for transport of radioactive material having more than 7.4 TBq.

Article 9° of Law N° 28256 (Law for Terrestrial Transport of Hazardous Material) and also in Rule of Law 28256 (D.S. N° 021-2008-MTC) both require an emergency plan for road and train transport of hazardous material.

Arrangements to respond in case of transport incidents or accidents involving radioactive materials at the national or local level are not specifically agreed.

The consideration of risk due to a combination of radioactive materials with other dangerous substance is not addressed in specific guidance related to transport safety, as it is requested in the IAEA standards for transport.

### *10.2.2 Compliance assurance*

IPEN is responsible for verification and ensuring compliance with regulations on radiological protection and safety matters, including during transport.

Appropriate means to accomplish this responsibility, such as the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers and to provide evidence that the provisions of these Regulations, are not formally implemented. Transport of some radioactive materials (for instance, for distribution of nuclear medicine radionuclides) must be authorized. The applications are assessed by OTAN and random inspections are conducted.

The basic means for assuring compliance with regulations include inspection of some packages and transports. Also the design of packages of Type A are assessed and inspected.

OTAN has no provisions for periodic assessments of radiation doses to all persons involved in transport of radioactive material operations. Assessment of doses is performed by the holders of authorizations. For instance, the holder of an authorization for industrial radiography performs a global dose assessment but nothing particular to transport operations.

### *10.2.3 Special arrangements*

Consignments for which conformity with provisions set out in TS-R-1 is impracticable are prohibited to be transported except under special arrangement. Such special arrangements are dealt with as stated in the IAEA Regulation for Safe Transport, as this standard was adopted by the Radiological Safety Regulation.

### *10.2.4 Training*

IPEN requires training for workers involved in transport of radioactive material concerning radiation protection, including the precautions to be observed in order to restrict their occupational exposure and the exposure of other persons who might be affected by their actions. The training for all workers involved with ionizing radiation exposure, including transport, is requested according to the risk of the practice.

Workers are trained by means of periodic national courses.

IPEN does not require that persons engaged in the transport of radioactive material receive training on the contents of the transport regulations, commensurate with their responsibilities. There are no specific provisions on the kind of training according to responsibilities. The current content of training courses is quite general and applicable to all persons engaged in safety aspects of the transport of radioactive materials.

**Conclusion:**

TS-R-1 Regulations for the Safe Transport of Radioactive Material has been adopted in the country. An Action Plan for the implementation of the Regulations has not been prepared. Special attention should be paid to the assurance of compliance.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-1 para 2.2 states :*"There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States:*

*(7) Adequate infrastructural arrangements shall be made for the safe transport of radioactive material."*

**2. BASIS:** GS-R-1 para 2.2 states: *"3.4. 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:*

*(9) safety in the transport of dangerous goods".*

**R96. <u>Recommendation</u>**:

IPEN should prepare an Action Plan to implement the requirements of TS-R-1.

# 11. EDUCATION AND TRAINING

## 11.1 GENERAL

OTAN does not use consultants for any of the activities it is in charge.

IPEN has no formal training programme for its staff, although they participate in international courses, workshops and meetings. After attending a meeting, a short report is made by the participant.

Inspectors do not follow a specific training for becoming inspector. The inspectors do not receive an individual licence of work.

OTAN assesses the competency of its staff only through the evaluation of the work done: each task is controlled by a manager. There are no formal procedures for assessing periodically competence of technical staff.

In 2008 an informal questionnaire was circulated among inspectors and evaluators to determine their previous education and training, the courses they had attended and their wishes about courses/training to be followed.

Training activities have been recorded for the years 2003 to 2008. Of nine staff members there were three persons without any recorded training. Most training was participation in international training courses or congresses; six training events were organized in Peru. The total number of training events was 15. One person had participated in seven congresses, others 1 to 3 training courses. Seven of the training events were on radiation protection of sources and practices. Two training events were on transport of radioactive material and one on detecting sources. Five training courses were on radiation protection in medical practices although one was a congress of medical physics and another was a coordination meeting of the IAEA ARCAL project. Only one course was on patient protection: IAEA regional training course of preventing accidents and incidents in radiation therapy.

The Superior Centre of Nuclear Studies (CSEN), depending on IPEN, provides education in collaboration with the public university: including a Masters programme on nuclear energy, medical physics, nuclear physics and nuclear chemistry courses, a postgraduate course in nuclear medicine, professional specialization on radiation protection, courses for technicians, teachers and users. These courses are not given every year, but depending on the demand for such trained persons. These courses include information on radioactive waste and transport activities.

These courses are given by IPEN people and teachers from the university.

There is an internal IPEN document reporting on education programmes and the number of people having attended courses during previous years.

IPEN, through TUPA, requires that operators recruit personnel having the requisite knowledge and skills to perform their assigned functions. Workers must be individually licensed by IPEN. The term of the individual licence is different depending on the practice, but not the programme of the course. A training course, which may be validated by an examination where appropriate, is necessary for individual licence renewal. Training for renewal is usually charged by the licensees in the case of industrial practices, but not in the medical ones.

OTAN has a database providing all individual licences delivered by OTAN.

During the authorisation process OTAN checks that an applicant employs individually licensed workers and provides the list of them in the authorization file.

During inspection, inspectors check the list of workers and their individual licences.

IPEN does not require that operators and response organizations make appropriate arrangements for ongoing refresher training for personnel in positions with responsibilities for emergency response.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
| --- |
| **1. BASIS:** *GS-R-1 para 4.8 states: "The primary responsibility for optimization lies with the management. Commitment to an effective protection and safety policy is essential at all levels of management, particularly at the senior level. The management commitment should be demonstrated by written policy statements that make radiation protection criteria an integral part of the decision process, and by clear and demonstrable support for those persons with direct responsibility for radiation protection in the workplace and the environment".*<br><br>**R97. Recommendation**: IPEN should develop a continuous training programme for its staff including individual plans and based on different training methods such as classroom based training, on the job training, mentoring and distance learning.<br><br>**2. BASIS:** *GS-R-1 para 4.8 states: "The primary responsibility for optimization lies with the management. Commitment to an effective protection and safety policy is essential at all levels of management, particularly at the senior level. The management commitment should be demonstrated by written policy statements that make radiation protection criteria an integral part of the decision process, and by clear and demonstrable support for those persons with direct responsibility for radiation protection in the workplace and the environment".*<br><br>**R98. Recommendation:** A process of regular, formal assessment of the competence of evaluators and inspectors should be devised.<br><br>**3. BASIS:** *GS-R-1 para 4.8 states: "The primary responsibility for optimization lies with the management. Commitment to an effective protection and safety policy is essential at all levels of management, particularly at the senior level. The management commitment should be demonstrated by written policy statements that make radiation protection criteria an integral part of the decision process, and by clear and demonstrable support for those persons with direct responsibility for radiation protection in the workplace and the environment".* |
| **R99. Recommendation:** IPEN should set up a training programme for new evaluators and inspectors. |

# 12. MANAGEMENT SYSTEM

## 12.1 GENERAL

### *12.1.1 Introduction*

The IRRS Review Team assessed the regulatory framework dealing with management system aspects against GS-R-3. Neither IPEN nor OTAN has a proper management system in place. Following a national request for all administrations to implement a formal management system, IPEN has nominated a committee for quality management. Currently, OTAN management activities are performed using a few procedures and manuals for certain activities that could be considered part of a Management System.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**1. BASIS:** GS-R-3 para 2.1 states: "*A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:*

- *Bringing together in a coherent manner all the requirements for managing the organization;*
- *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;*

Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety".

**R100. Recommendation:** OTAN should establish its own management system independently from IPEN and in accordance with GS-R-3.

## 13. APPENDIX I – LIST OF PARTICIPANTS

| | | |
|---|---|---|
| **INTERNATIONAL EXPERTS:** | | |
| 1. Manuel **RODRIGUEZ** | Nuclear Safety Commission, Spain (CSN) | mrm@csn.es |
| 2. Serhat **ALTEN** | Turkish Atomic Energy Agency (TAEC) | salten@taek.gov.tr |
| 3. Chris **ENGLEFIELD** | UK Environmental Agency | christo.englefield@btinternet.com |
| 4. Ritva **BLY** | Radiation and Nuclear Safety Authority, Finland (STUK) | Ritva.bly@stuk.fi |
| 5. Marie-Line **PERRIN** | Nuclear Safety Authority, France (ASN) | Marie-line.perrin@asn.fr |
| 6. Pablo **VEGUERIA** | National Centre for Nuclear Safety, Cuba (CNSN) | Pablo@orasen.co.cu |
| 7. Ricardo **WALDMAN** | Nuclear Regulatory Authority, Argentina (ARN) | rwaldman@sede.arn.gov.ar |
| 8. Diego **TELLERIA** | IAEA | d.telleria@iaea.org |
| **IAEA STAFF MEMBERS** | | |
| 1. Stephen **EVANS** | Division of Radiation, Transport and Waste Safety | s.evans@iaea.org |
| 2. Stéphane **CALPENA** | Division of Nuclear Installation Safety | s.calpena@iaea.org |
| 3. Sarah **PULIMOOD** | Division of Radiation, Transport and Waste Safety | s.pulimood@iaea.org |
| **OFFICIAL OTAN LIAISON OFFICER:** | | |
| 1. Renan Ramirez | OTAN | rramirez@IPEN.GOB.PE |

## 14. APPENDIX II – MISSION PROGRAMME

**Peru IRRS Daily Programme**

| | | | | | |
|---|---|---|---|---|---|
| **19-Apr-09** | **IRRS Team Briefing** (Hotel) | | | | |
| **20-Apr-09** | *Serhat Alten (LGI & PI)*<br>*Manuel Rodriguez(LGI & PI)*<br>Carlos Ampuero (LGI & PI)<br>Renan Ramirez (LGI & PI) | *Riva Bly (Medical)*<br>Ruben Bruna (Medical)<br>Yuri Ravello (Medical) | *Pablo Vegueria (EPR and Transport)*<br>Julio Villanueva (EPR)<br>Miguel Ticllacuri (Transport) | *Marie-line Perrin (Occ. Exp)*<br>Maria Diaz (Occ. Exp)<br>German Caceres (Occ. Exp) | *Chris Englefield (Industrial & Code of Conduct on the Safety and Security of Radioactive Sources)*<br>Miguel Ticllacuri |
| **21-Apr-09** | *Marie-line Perrin (Occ. Exp)*<br>German Caceres (Occ. Exp)<br>Riva Bly (Medical)<br>Yuri Ravello (Medical)<br>Ruben Bruna (am: Medical) | *Serhat Alten (LGI & PI)*<br>*Manuel Rodriguez(LGI & PI)*<br>Carlos Ampuero (LGI & PI)<br>Renan Ramirez (LGI & PI)<br><br>**Policy Discussions** | *Ricardo Waldman (RR)*<br>Gerardo Lazaro (RR)<br>*Chris Englefield (Code of Conduct on the Safety and Security of Radioactive Sources)*<br>Miguel Ticllacuri (Code of Conduct on the Safety and Security of Radioactive Sources) | *Diego Telleria (Waste)*<br>Maria Diaz (Waste) | *Pablo Vegueria (EPR)*<br>Julio Villanueva (EPR) |
| **22-Apr-09** | *Marie-line Perrin (Occ. Exp)*<br>German Caceres (Occ. Exp)<br>Riva Bly (Medical)<br>Yuri Ravello (Medical)<br>Ruben Bruna (am: Medical) | *Serhat Alten (LGI & PI)*<br>*Manuel Rodriguez(LGI & PI)*<br>Carlos Ampuero (LGI & PI)<br>Renan Ramirez (LGI & PI) | *Ricardo Waldman (RR)*<br>Gerardo Lazaro (RR)<br>*Chris Englefield (Code of Conduct on the Safety and Security of Radioactive Sources)*<br>Miguel Ticllacuri (Code of Conduct on the Safety and Security of Radioactive Sources) | *Diego Telleria (Waste)*<br>Maria Diaz (Waste) | *Pablo Vegueria (EPR)*<br>Julio Villanueva (EPR) |
| **23-Apr-09** | *Chris Englefield (Code of Conduct on the Safety and Security of Radioactive Sources)*<br>Miguel Ticllacuri | **Visit to El Huarangal Atomic Centre:**<br>*Marie-line Perrin, Diego Telleria, Ricardo Waldman, Serhat Alten, Manuel Rodriguez, Stéphane Calpéna*<br><br>**Visit to Clinica San Pablo (Radiotherapy):** | | | *Pablo Vegueria (EPR)*<br>Yuri Ravello (am - EPR)<br>Julio Villanueva (pm - EPR) |

| Peru IRRS Daily Programme | | | | | |
|---|---|---|---|---|---|
| | | *Ritva Bly, Nguyen Loan* | | | |
| **24-Apr-09** | *Serhat Alten (LGI & PI)*<br>*Manuel Rodriguez(LGI & PI)*<br>Carlos Ampuero (LGI & PI)<br>Renan Ramirez (LGI & PI)<br><br>**Policy Discussions** | *Ricardo Waldman (RR)*<br>Gerardo Lazaro (RR) | **Visit to SENASA (Gamma Irradiator):**<br>*Chris Englefield*<br><br>**Visit to Centro de Medicina Nuclear:**<br>*Ritva Bly, Nguyen Loan* | | *Pablo Vegueria (EPR)*<br>Julio Villanueva (EPR) |
| **25-Apr-09** | | | | | |
| **26-Apr-09** | | | | | |
| **27 Apr 09 (am)** | *Marie-line Perrin (Training)*<br>*Riva Bly (Training)*<br>*Eduardo Medina (Training)* | *Serhat Alten (LGI & PI)*<br>*Manuel Rodriguez(LGI & PI)*<br>Carlos Ampuero (LGI & PI)<br>Renan Ramirez (LGI & PI) | *Ricardo Waldman (Mgt System)*<br>Eduardo Medina (Mgt System) | *Diego Telleria (Waste)*<br>*Maria Diaz (Waste)*<br><br>*Pablo Vegueria (EPR)*<br>*Julio Villanueva (EPR)* | **Meeting (am):**<br>**President of IPEN**<br>**(Policy Discussions)**<br><br>*Manuel Rodriguez, Serhat Alten*<br>*S Evans, S Calpéna* |
| **27 Apr 09 (pm)** | **Report Preparation** | | | | |
| **28-Apr-09** | Full Team and Peru Liaison Officer<br><br>**Report Preparation** | | | | **Meeting (pm):**<br>**Vice Minister of Energy**<br>**(Policy Discussions)**<br><br>*Manuel Rodriguez*<br>*Stéphane Calpéna* |
| **29-Apr-09** | *Full Team and Peru Liaison Officer*<br>**Report Preparation** | | | | |
| **30-Apr-09** | **EXIT MEETING** | | | | |

## 15. APPENDIX III – SITE VISITS

| | |
|---|---|
| **1.** | **IPEN Dosimetry Service**<br>IPEN Dosimetry Service is a Secondary Standard Dosimetry Laboratory for calibration of dosimetry instruments, radio-diagnostic and teletherapy equipment. Their tasks include the following :<br>• Participation in international dosimetry inter-comparison tests for external dosimetry<br>• Organisation of annual external dosimetry inter-comparisons at the national level for the two national private dosimetry services.<br>• Acting on the request of the competent authority, providing information on new equipment, qualifications and calibration.<br>• Calibrating sources.<br>• Providing an individual external dosimetry services to the enterprise in charge of the industrial irradiator. (IPEN and OTAN individual dosimetry is provided by private dosimetry services).<br>• Providing a thyroid external dosimetry for workers at the IPEN radioisotopes production plant: as required by the Authority in the conditions of the licence of the plant, one thyroid counting is performed each week on the worker involved in iodine production. The thyroid counter is calibrated with a phantom, after participation in international inter-comparison tests. Internal equivalent dose to the thyroid is then assessed.<br>• Involvement in the emergency plan of the site for external dose assessment, thyroid counting and thyroid equivalent dose assessment, dose assessment to the population, environmental surface contamination.<br>• Performing dosimetric impact assessment of population sites as part of environmental monitoring. |

| | |
|---|---|
| **2.** | **Radioisotope Production Facility**<br>A visit to the plant for radioisotope production was performed. It is located in a building annex to the reactor building. It has its own radiation protection control centre provided with radiation monitoring instruments and radiation protection tools. The plant receives material irradiated at the reactor through a hot corridor provided with filtered air exhausting system (HEPA and active carbon) and with environment radiation monitors. The irradiated materials can be delivered to different hot cells, depending on the radioisotopes to be produced. Currently there are four operating cells to produce I-125, Mo-99 and Sm-153 for medical uses as well as Ir-192 for industrial (gammagraphy) and medical (brachytherapy wires) uses.<br>Currently a new hot cell is being built to produce I-125 in compliance with the sanitary requirements of the health authorities.<br>Irradiation takes place one day per week. Preparation of short half-lived radioisotopes for nuclear medicine facilities (mainly Mo-99) is carried out daily; Ir-192 sealed sources are manufactured only on demand.<br>Hot cells are provided with a drain system for liquid radioactive wastes which are collected in a tank for decay prior to release.<br>The facility also has laboratories to prepare fractions for medical and research uses and quality control laboratories.<br>A separated zone is provided to prepare packages for transport, shielding boxes, packages, labelling and all documents to comply with transport regulations were available. The operator informed that transportation, mainly internal to Peru provinces, is performed by air. |

| | |
|---|---|
| **3.** | **IPEN National Waste Storage Facility**<br><br>The facility is located in el Huarangal Atomic Center, northeast of Lima. This facility is the national centralized waste storage facility and, as required in the regulations, all disused sealed sources were send for long term storage, once declared waste. Additionally, some solid waste from the use of long living radionuclides in research are also brought into this storage facility, this constituting a minor volume. The installation has convenient security provisions like, perimeter fence, security cameras, alarms, control of access. The facility has a database with the inventory of all the wastes. The operator of the facility is IPEN and is under regulatory control by OTAN. Waste are classified and segregated and conditioned for long term storage.<br><br>The operator also provides services of collection and, when required, dismantling and/or conditioning of radioactive wastes. The facility has conditions to accept radioactive waste, which are informed to generators at the moment of agreement for transference. These conditions are still not in a regulatory guideline. In some cases existing transport regulations are applicable. The facility does some predisposal activities, like conditioning for long term storage and is considering some more complex conditioning activities, like dismantle of sources in lighting rod to reduce volumes of wastes, but this practice is still not authorized. The storage facility is fully operational, with enough space to keep on receiving wastes. However, there are no estimates of the waste which could be needed to be stored in the future (e.g,. radium medical sources, lighting rods, etc). |

| | |
|---|---|
| **4.** | **The Saint Pablo Hospital:**<br>An inspection to The Saint Pablo Hospital was carried out by two inspectors. Radiation therapy practice with one linear accelerator was inspected using a checklist. There was a brief entrance meeting without introducing the inspection plan. Radiation protection officer (RPO) was a medical physicist. Additionally there were present an oncologist, two dosimetrists and a technologist.<br>Individual licences were inspected. Calibration of the beam was inspected from the IAEA worksheets of TRS 398. It was not noticed that the used reference ionization chamber for photon beam calibrations was a small thimble chamber (PTW 31003) with PMMA walls. According to TRS 398 graphite walled ionization chambers usually have better long term stability and more uniform response than plastic walled chambers; however, the latter are more robust and therefore more suitable for routine measurements. The calibration of the chamber was too old according to the requirement, because the IPEM SSDL was not able to provide the calibration (SSDL's letter dated 9 Oct 2008). Previous calibration (February 2007) was done there using TRS 374.<br>QC of the accelerator was inspected. The QC results were checked and compared to the requirements. However, it came out that there was not enough understanding of the basic concepts like TAR (tissue-air-ratio) or basic measurements like verifying the isocentre. One point check was made to test the collimator rotation. Inspectors did not notice during the test which was carried out in the isocentre that the height display of the couch showed 4 mm deviance when the tolerance limit is 2 mm.<br>Because the accelerator beam is pulsed beam, a proportional counter is not suitable meter for survey measurements, but instead pressurized ionization chamber should be used. However, the survey measurements were done in previous inspections using proportional counter and a point check at the door was carried out this time. The hospital used also the similar type of meter and the measurement results were inspected. OTAN has seven pressurized ionization chambers that are recommended to be used in future.<br>More training is needed for inspectors especially focusing on radiation therapy dosimetry and QC to build up competence to inspect radiation therapy practice. |

| | |
|---|---|
| **5.** | **Instituto Nacional de Enfermedades Neoplasicas:**<br><br>An inspection to to Instituto Nacional de Enfermedades Neoplasicas was carried out by one inspector. A nuclear medicine practice was inspected using a checklist. There was no entrance meeting. The Radiation Protection Officer (RPO) was a medical physicist.<br><br>Individual staff licences and their personal dosimetry were inspected. Calibration of two activity calibrators was inspected and also the QC of it. The inspector notified that the calibration of the measurement equipment has to be updated. From QC of three SPECT cameras only weekly intrinsic uniformity tests were inspected, not for example resolution or centre of rotation tests. The use of nuclides was inspected and compared to the licensed amounts of activities. The storage room of waste was inspected. Tc-99m waste was kept in the storage for three days and other waste for three months. Both solid and liquid waste was stored. Security of the storage was not inspected.<br><br>Contamination measurements were done in the laboratory and a patient room by using general proportional counter. It was used moving the meter too fast around so that the counter can not show correct dose rates. The inspector did not have a contamination meter with her although that would have been available in OTAN. The inspector notified that the contamination of the rooms is checked after the departure of the patients without any register.<br><br>Tc-99m came daily to the hospital from IPEM laboratory. The purity checks of Tc-99m were not inspected. The function of the ventilation box was not inspected. The purity of radio pharmaceuticals was not inspected.<br><br>There are no safety requirements of the nuclear medicine laboratory constructions for example for floor materials. The laboratory was not built up to be easily decontaminated.<br><br>There was no exit meeting. However, there was a very quick informal debriefing between the inspector and the RPO, without any written report or notes. The inspector said that she will send a report of the inspection later on. |

## 16. APPENDIX IV – MISSION COUNTERPARTS

| Module | Subject Area | IRRS Experts | Lead Counterparts |
|---|---|---|---|
| 1 | LEGAL AND GOVERNMENTAL INFRASTRUCTURE FOR NUCLEAR AND RADIATION SAFETY | Manuel Rodriguez<br>Serhat Alten | Renan Ramirez<br>Carlos Ampuero<br>Eduardo Medina |
| 2 | RESEARCH REACTOR | Ricardo Waldman<br>Serhat Alten | Gerardo Lazaro |
| 3 | INDUSTRIAL USES OF IONISING RADIATION | Christopher Englefield | Miguel Ticllacuri |
| 4 | OCCUPATIONAL RADIATION EXPOSURE | Marie-Line Perrin | Gérman Caceres |
| 5 | CONTROL OF MEDICAL EXPOSURE | Ritva Bly | Yuri Ravello<br>Ruben Bruna |
| 6 | PUBLIC EXPOSURE, INCLUDING WASTE MANAGEMENT | Diego Telleria | María Diaz |
| 7 | EDUCATION AND TRAINING | Marie-Line Perrin | Ruben Bruna |

| Module | Subject Area | IRRS Experts | Lead Counterparts |
|---|---|---|---|
| 8 | TRANSPORT | Pablo Vegueria | Miguel Ticllacuri |
| 9 | EMERGENCY PLANNING AND PREPAREDNESS | Pablo Vegueria | Julio Villanueva |
| 10 | MANAGEMENT SYSTEM OF THE REGULATORY BODY | Christopher Englefield<br>Ricardo Waldman | Eduardo Medina |
| 11 | CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIAOACTIVE SOURCES | Christopher Englefield | Miguel Ticllacuri |

## 17. APPENDIX V – RECOMMENDATIONS / SUGGESTIONS / GOOD PRACTICES

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| I | **Legal and Governmental Responsibilities** | **R1** | An amendment to legislation should be implemented requiring the effective separation of regulatory activities from promotion and operation. |
| | | **R2** | A national policy on nuclear and radioactive waste management should be developed. |
| | | **R3** | Regulations on transport of dangerous materials, including nuclear and radioactive material by air and sea should be developed. |
| | | **R4** | The national emergency plan should be amended to include nuclear and radiological emergencies, as appropriate. |
| | | **R5** | The Government should consider action, in accordance with Article 24 of Law Decree 21875 to provide IPEN with sufficient financial and human resources to effectively accomplish its assigned functions and tasks as regulatory body. |
| | | **R6** | Safety principles for nuclear installations should be included in the statutory framework, rather than only addressed in the licensing conditions for the RP10 reactor. |
| | | **S1** | Legal provisions should be prepared requiring financial indemnification of third parties in the event of a nuclear or radiation accidents. |
| II | **Responsibilities and Functions of the Regulatory Body** | **R7** | IPEN should define and implement a programme for regulatory guidance development and issuance to help licensees to:<br>• comply with safety and radiation protection requirements included in high level regulations;<br>• develop and present safety assessments or any other required safety related information necessary to obtain authorizations and;<br>• prepare documents to be submitted in support of applications for all authorizations included in Rule of Law 28028 with adequate format and content. |
| | | **R8** | Requirements related to discharge limits and radioactive waste conditioning should be included in facilities´ authorisations. |
| | | **R9** | IPEN should ensure a systematic approach to collection, analysis and dissemination of operating experience among licensees. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R10** | IPEN should establish cooperation agreements and national systematic communications with other relevant competent authorities. |
| | | **S2** | IPEN should establish the full range of information to be submitted periodically by operators on safety matters to better accomplish its function on control of facilities and activities. Requirement for submission of such periodic information should be included in regulations or authorizations. |
| | | **S3** | In addition to the existing generic regulations for record-keeping, IPEN should detail their requirements relating to safety, including retention periods. |
| | | **G1** | Most procedures to be followed in licensing processes, including necessary documents, information and other requirements, are compiled in an administrative regulation called 'TUPA' available on the IPEN Website. |
| | | **R11** | Human resources, in terms of numbers and skills, should be sufficient to enable IPEN to fully implement its regulatory programme in accordance with its functions and responsibilities. |
| III | **Organisation of the Regulatory Body** | **S4** | A recruitment plan should be developed by IPEN, including the necessary qualifications, experience and expertise, to achieve numbers of staffing having the proper competences to adequately perform regulatory duties. |
| | | **S5** | IPEN should seek to enhance existing good relations with operators in order to promote safety culture. |
| IV | **Activities of the Regulatory Body** | **R12** | IPEN should develop and make public through regulations (and guides as appropriate) clearance criteria to be applied for radioactive substance to be released from regulatory control in compliance with Article 20 of Rule of Law 28028. |
| | | **R13** | Taking into account human–machine interface and human factors for all stages and in the associated development of operational requirements, the Regulatory Body should explicitly require the licensee and enforce that:<br>• minimization of human actions that may jeopardize safety be considered;<br>• independent verification and the application of ergonomic principles be performed. |
| | | **R14** | The Regulatory Body should explicitly require through regulations and enforce the use of independent verification and the application of ergonomic principles. |
| | | **R15** | OTAN should explicitly require through regulations and enforce that periodic reviews be conducted and that a programme be established for the collection and analysis of operating experience taking into account other similar reactors. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R16** | The Regulatory Body should explicitly require the applicant, as part of its authorisation submission, to conduct a comprehensive safety assessment and obtain an independent verification. |
| | | **R17** | The Regulatory Body should explicitly require through regulations and enforce the licensee's responsibility to report any new information which may concern safety at the research reactors and/or any changes to information previously submitted. |
| | | **R18** | The Regulatory Body should explicitly require and enforce that licensees develop programmes to foster a positive safety culture. |
| | | **R19** | OTAN should require of the Licensee and enforce as appropriate, the establishment of a management system including in order of priority:<br>• a performance based quality assurance, internal audits and an independent assessment process;<br>• a tracking system to monitor changes for regulatory documents dealing with research reactors;<br>• records of non-compliance and the corrective measures;<br>• administrative procedures for the generation, collection, retention and archiving of records and reports, and that information entries in logbooks, checklists and other appropriate records which are properly dated and signed;<br>• a graded approach;<br>• the safety committee of the licensee independent from the manager of the RP-10 reactor and reporting above the reactor manager. Such safety committee should set up meetings on regular basis and as often as necessary to deal with safety issues. (Suggestion minimum should be once a year);<br>• inspections; corrective maintenance of systems or items important to safety and in-service inspections. |
| | | **R20** | OTAN should explicitly require and enforce as appropriate that the Licensee maintains a written strategy for dealing with transport and final or intermediate storage of the RP-10 reactor's spent fuel. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R21** | OTAN should explicitly require the Licensee and enforce as appropriate that:<br>• the licensee's responsibilities for safety related topics be fulfilled;<br>• the reactor manager reviews periodically the operation of the research reactor, including experiments.<br>• provision be made for additional technical personnel such as training officers, safety officers and reactor chemists.<br>• provision be arranged to seek assistance with contractors. |
| | | **R22** | OTAN should explicitly require the Licensee and enforce as appropriate that procedures be put in place for validation of training to verify its effectiveness and the qualifications of staff. |
| | | **R23** | OTAN should explicitly require the Licensee and enforce as appropriate that requirements be established for the frequency and scope of inspection of all SSCs and any item important to safety to ensure compliance with safety system settings, reliability and limiting conditions for safe operation including periodic testing, maintenance and feedback experience. |
| | | **R24** | The Regulatory Body should explicitly require (and enforce as appropriate) that Licensee OLCs include actions to be taken by operating staff within an allowed time if a limiting condition for safe operation is violated. |
| | | **R25** | The Regulatory Body should check if existing licensee's documents address all safety topics dealt with in the licence conditions and the Safety analysis report. |
| | | **R26** | The Regulatory Body should explicitly require and enforce that the Licensee, as appropriate:<br>• establishes operating procedures for abnormal conditions;<br>• uses the licensee's permit process for inspection and periodic checking of procedures before and after the conduct of the work;<br>• has a clearly defined structure of review and approval for the performance of the periodic testing and maintenance work. |
| | | **R27** | The Regulatory Body should explicitly require the Licensee and enforce as appropriate that OLCs be established and procedures be prepared for dealing with failures of fuel elements and control rods so as to minimize the amounts of radioactive products released. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R28** | OTAN should explicitly require and enforce as appropriate, that the Licensee conduct:<br>• periodic fire and explosion hazards analyses for safety (the RP-10 fire fighting system will have to be upgraded and maintained as appropriate);<br>• hazard analyses dealing with flammable gases, liquids and combustible materials that could produce or contribute to explosive mixtures and be kept to minimum necessary amounts and be stored in adequate facilities to keep reacting substances segregated. |
| | | **R29** | The Regulatory Body should enforce that where confinement is dependent on the efficiency of filters, provisions be made as appropriate for in situ periodic testing of the efficiency of the filters. |
| | | **R30** | The Regulatory Body should explicitly require and enforce as appropriate that the Licensee:<br>• performs a safety analysis for each experimental device, including an analysis of the damage that would be caused to the experimental device by postulated initiating events of the reactor and OLCs;<br>• reactor manager establishes a procedure for the review and approval of proposals for experiments and modifications and for the control of their performance and that this procedure should take into account all relevant information. |
| | | **R31** | The Regulatory Body should explicitly require and enforce as appropriate, that the Licensee establishes a programme for the management of ageing including in-service inspection. |
| | | **R32** | The Regulatory Body should explicitly require the Licensee and enforce as appropriate that the possibility of bypassing interlocks and trips of the reactor protection system be carefully evaluated and appropriate means of protecting interlocks and trips that are important to safety from being inadvertently bypassed be incorporated into the reactor protection system. |
| | | **R33** | The Regulatory Body should explicitly require and enforce as appropriate that the Licensee become familiar with decommissioning projects at similar research reactors to facilitate the assessment of the complexity and costs of the ultimate decommissioning of its own reactor. Furthermore, before the end of the operational stage IPEN should explicitly require and enforce as appropriate that the licensee has established a decommissioning programme which includes the consideration written in this report. |
| | | **S7** | The Regulatory Body may wish to consider an advisory or other mission(s), including SCART to promote and reinforce safety culture at research reactors. |
| | | **S6** | IPEN should take actions to publicise the notification requirement of Article 7 of Rule of Law 28028. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **S8** | Authorisation procedures should be scrutinized to determine if they could be further simplified. More emphasis might be given to the comprehensive evaluation of applications. Evaluation should strictly implement the procedure. |
| | | **S9** | For research reactors as well as complex or new technology radioactive facilities, IPEN should prepare a programme for safety review and assessment of licensees' submissions. |
| | | **G2** | IPEN requires that the potential for slope instability (such as landslides, rock slides taking into account past experience of the Nino) that could affect the safety of the research reactor be evaluated for the site and its vicinity and launch remediate actions. The Licensee has erected an embankment to protect the site against landslides. |
| | | **G3** | OTAN written procedures; "Authorization of Installations" and "Authorization of Individual Licences" include useful flow charts of the processes. |
| V | **Development of Regulations and Guides** | **R34** | IPEN should identify all topics still requiring the development of regulations. A programme and necessary actions to issue these new regulations should be defined with establishing priorities and timescales. |
| VI | **Inspection and Enforcement** | **R35** | OTAN should include radiation protection as a main topic in the annual inspection programme for the RP-10 facility. |
| | | **R36** | Inspections should be more focused on safety assessment of the practice, including patient safety. |
| | | **R37** | More training is required for inspectors, especially focusing on radiation therapy dosimetry and QC to build up competence to inspect radiation therapy practice. |
| | | **R38** | Provisions should be made in legislation that gives explicit authority to IPEN to enforce immediate actions if safety of facilities or activities has severely deteriorated or been violated. |
| | | **S10** | The capacity for effective regulatory oversight for research reactors should be reinforced with additional inspectors. |
| | **Thematic Area: Occupational Radiation Protection** | **R39** | IPEN should update :<br>• Norm IR.011.96 for dental radiology<br>• Norm PR.003:94 for individual dosimetry services, including detailed requirements on appropriate facilities, equipment and personnel with adequate knowledge and skills. |
| | | **R40** | IPEN should include in their regulations requirements for the existence of a Radiation Protection Officer, its role and tasks and indicating the criteria to determine whether the RPO is internal or external to the licensee installation. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R41** | Regulations should require that workers :<br>• cooperate with the employer or licensee with regard to protection and safety;<br>• cooperate with the operation of radiological health surveillance and dose assessment programmes;<br>• abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the regulations;<br>• accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the regulations;<br>• report to the employer, registrant or licensee if for any reason they are able to identify circumstances that could adversely affect compliance with the regulations. |
| | | **R42** | Regulations should include Requirements to ensure the safety of workers engaged in work that involves or could involve a source not under the control of their employer or the licensee responsible for the source. |
| | | **R43** | Regulations stating that licensees should provide workers with suitable and adequate personal protective equipment, should also require that this equipment meet any relevant standards or specifications. |
| | | **R44** | Extend Article 32 of Supreme Decree N° 009-97-EM requiring that quality management systems, to ensure the effectiveness of all monitoring, are in place and operational. |
| | | **R45** | Rule of Law 28028 should be amended to include the requirements that :<br>• individual dosimetry services have appropriate facilities, equipment and personnel with adequate knowledge and skills;<br>• workplace monitoring services have appropriate facilities, and the required personnel. |
| | | **R46** | To be in compliance with Articles 30 and 32 of Supreme Decree N° 009-97-EM, the government should have an internal dosimetry capability. |
| | | **R47** | Regulations should include a requirement to conduct appropriate investigations to identify whether exposures to natural sources of radiation are to be subject to the requirements for practices, for example in NORM industries and aircraft |
| | | **S12** | IPEN should include in their regulations a requirement for the RPO to have a designated deputy when necessary. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **S13** | The government should consider whether an internal dosimetry service should be established nationally or through contracting with a regional internal dosimetry service. |
| | | **S14** | Regulations could include a requirement for a national individual exposure register. |
| | | **S15** | When reviewing radiation protection regulations, a requirement should be included that radiation protection training services be approved by the appropriate competent authority. |
| | **Thematic Area: Control of Medical Exposures** | **R48** | Regulations and guides for radiology and nuclear medicine should be developed and revised as required, in consultation with relevant professional bodies. |
| | **Thematic Area: Public Exposure and Radioactive Waste Management** | **R49** | IPEN should develop regulations including requirements to registrants and licensees to take measures, in cooperation with employers when appropriate, for control of visitors' exposure in controlled or supervised areas. |
| | | **R50** | IPEN should produce regulations including requirements, with provisions to allocate responsibilities to registrants or licensees respect to waste arising from accidental situations. |
| | | **R51** | IPEN should issue regulations, including requirements for suppliers of consumer products using radioactive sources, to ensure adequate labelling and instructions regarding correct installation, use, maintenance, servicing and repair, radionuclides involved, related dose rates and recommended disposal procedures. |
| | | **R52** | IPEN should review and, if necessary, revise the content of IPEN courses to include, where necessary, the following topics: public protection, environmental monitoring of practices, control of foodstuffs and/or selected commodities, management of radioactive waste, waste storage, waste disposal, decommissioning and remediation. |
| | | **R53** | IPEN should develop detailed regulations on the characteristics of the environmental monitoring programmes being run by IPEN in Peru and considerations on the use of the results (e.g., verification of compliance of discharge limits, validation of assumptions used in the safety assessment, dose assessment). These regulations should have provisions for the enforcement. |
| | | **R54** | IPEN should develop regulations to require that licensees consider non-radiological hazards during safety assessment of facilities and activities. |
| | | **R55** | IPEN should establish provisions in regulations requiring the licensee to promptly report any significant increase in environmental radiation**.** |
| | | **R56** | IPEN should require the licensee to verify with the results of an environmental monitoring programme, assumptions made for assessing the radiological consequences of discharges. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R57** | Regulations should require verification of the adequacy of assumptions made in safety assessments to establish discharge limits for facilities and activities by means of use of results of environmental monitoring programmes, when applicable and accordingly to the risk involved. |
| | | **R58** | IPEN should require that the licensee uses the results of source and environmental monitoring as the basis to assess doses being received by the population. |
| | | **R59** | IPEN should conduct an investigation regarding chronic exposures situations related to NORM (including oil and gas industries and ores and uranium mining). The aim being to establish, when appropriate, the necessary regulations and means of regulatory control. |
| | | **R60** | IPEN should make provision in regulations to ensure funding for remediation actions takes into account the various possible situations (e.g., past practices, contaminations not attributable to a user or legal person, exceptional scenarios such as accidents in neighbouring countries, contamination resulting from orphan sources or malevolent acts, etc). |
| | | **R61** | IPEN should develop a national waste management policy and strategy in agreement with IAEA standards and obtain approval at the relevant governmental level. |
| | | **R62** | Regulations should include the requirement to consider the potential effects of the management of radioactive waste beyond the national borders of Peru. |
| | | **R63** | IPEN should include in the regulatory framework, requirements for environmental protection associated with predisposal waste management taking into consideration all potential environmental impacts that can reasonably be expected. |
| | | **R64** | IPEN should include provisions in regulations to ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations. |
| | | **R65** | IPEN should develop a detailed regulation on safety culture, including provisions to ensure that a safety culture is fostered and maintained in both the operating organizations and IPEN. |
| | | **R66** | IPEN should complement existing regulations on environmental radiation protection requirements, in particular for those cases where after a decommissioning or remediation programme a facility is released with restrictions on future use. |
| | | **R67** | IPEN should develop specific regulations requiring that due consideration is given to non-radiological hazards at the various stages in predisposal management of radioactive waste. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R68** | IPEN should establish regulations requiring that for new facilities the operators shall consider eventual decommissioning activities in the design of the facility, including features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to prevent the spread of contamination. |
| | | **R69** | IPEN should establish a programme to review the existing practices in Peru which could need to develop a decommissioning plan and make formal requirements for doing this, together with providing the necessary criteria and guidance to develop this plan. |
| | | **R70** | IPEN should establish in the regulations provisions to consider:<br>• funding considerations for the case that the decommissioned facility is released with restrictions on its future use;<br>• a term for submitting the decommissioning plan to IPEN;<br>• an adequate maintenance and surveillance programme in the case of deferred dismantling for its review and approval. |
| | | **S16** | IPEN should develop a programme to assess the situation of disused radium sources in Peru. The aim being to collect condition and store them in a safe manner. IPEN should consider prohibiting the use of radium sources by mean of a regulation. |
| | | **S17** | IPEN should have a programme to assess independently the suitability of the environmental monitoring programme carried out by IPEN, including the analysis of results and trends. Moreover, IPEN should have capability to conduct limited confirmatory measurements. IPEN should make formal arrangements with institutions or laboratories in Peru where some environmental samples collected under control of Regulatory Body could be analyzed. |
| | | **S18** | IPEN should review existing regulations in order to identify elements which may be basis for national policy and strategy (e.g., the identification of the national institution responsible of radioactive waste management in Peru, the users' responsibilities regarding generation and management of waste, etc). |
| | | **S19** | IPEN could use the framework of IAEA Project RLA0955/62 to facilitate drafting of the national waste management policy. |
| | | **S20** | When preparing new or revised regulations, IPEN should make reference to the recently published IAEA Standard on Radioactive Waste classification. |
| | | **G4** | The Radiological Safety Regulation is based both on International Standards and national feedback in the field of radiation safety. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | **Thematic Area: Emergency Preparedness** | **R71** | The INDECI, in close collaboration with IPEN should include in the 'National Plan for Preventing and Attending Disasters' appropriate provisions for nuclear and radiological emergencies to assure that adequate preparations are established and maintained at local and national levels and if appropriate with bordering countries. |
| | | **R72** | IPEN (and response organizations) should have the necessary resources to deal with any reasonably foreseeable consequences of a nuclear or radiological emergency in the country. |
| | | **R73** | A coordinating committee should be created. IPEN and INDECI should work in close cooperation in order to propose to the appropriate governmental authority that a coordinating authority for nuclear emergencies is designated. Also, that a standing committee is created composed of themselves, as the core of the coordinating authority, and other relevant response organizations able to fulfil the appropriate functions. |
| | | **R74** | IPEN should issue national guidance for:<br>• The operators to prepare their Emergency Response Plans.<br>• Establishing the provisions for managing, controlling and recording the doses received by emergency workers in accordance with the international standards.<br>• Establishing the OILs (Operational Intervention Levels) with arrangements to revise them as appropriate to take into account the conditions prevailing during the emergency.<br>Managing and controlling the safe and effective management of radioactive waste during and after an emergency. |
| | | **R75** | IPEN should revise and update the report on the assessment of radiological threats considering the latest improvements of the IAEA's methodologies/standards and the national experience of the INDECI management. Stakeholders among operators, response organizations, and other appropriate institutions of the Civil Defence System and local authorities should be involved in this process. The process could be coordinated by the Civil Defence Institute with the close support of IPEN. |
| | | **R76** | IPEN should define clearly its role and functions and its role in the command and control system during radiological emergency response operations and be aware of the response strategies commensurate with the threat assessment. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R77** | IPEN should make the necessary arrangements to be provided with the resources and ability to promptly activate itself and other appropriate response organizations in case of being notified of an event that could warrant urgent protective action in an unforeseeable location (threats of category IV). |
| | | **R78** | IPEN as the National Warning Point for the Notification Convention should have what it needs to fulfil with the ENATON Manual. |
| | | **S21** | Existing capabilities could be used for this purpose (operation centres already available in the Civil Defence System could be trained to work out in case of a nuclear or radiological emergency) |
| | | **S22** | Special attention should be paid to train people with the ENAC web site |
| | | **R79** | IPEN should organise response teams able to be dispatched promptly to the scene of an accident to support the first responders or make arrangements for "on-call" advice. These teams should be trained in recovery operations such as recovering dangerous sources, managing radiological response at the scene, etc. Also, IPEN should coordinate the provision of expertise and services in radiation protection to local officials where needed. |
| | | **R80** | IPEN should enforce the implementation, if necessary, of an urgent protective action planning zone in the emergency plans (on-site and off-site) for the 10 MW research reactor. |
| | | **R81** | IPEN should explicitly require the Licensee and enforce as appropriate that the emergency response team include persons with up to date knowledge of the operations of the research reactor and it should normally be led by the reactor manager or a delegate. |
| | | **S23** | IPEN might use existing capabilities and programmes of public information on the Civil Defence System framework to integrate public information in case of nuclear or radiological emergency. |
| | | **R82** | IPEN should prepare its own emergency plan in close cooperation with the INDECI and other relevant response organizations and local authorities. |
| | | **R83** | IPEN should define the appropriate tools, instruments, supplies, equipment and documentation that should be kept by their emergency teams and make arrangements for having them in advance. Monitoring instruments should be enough to cover the probable situations that could come out according to the threats assessment. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R84** | IPEN in close cooperation with the INDECI should prepare and approve a comprehensive training programme based on an analysis of needs on emergency preparedness and response matters in accordance with the functions assigned to each response organisation. |
| | | **R85** | IPEN should assist the INDECI to prepare and approve a comprehensive national programme of exercises (under the umbrella of Civil Defence management system) to train all response organizations acting in case of a nuclear of radiological emergency. |
| | | **R86** | IPEN should be assigned responsibility in law for organising the evaluation of exercises included in the programme. |
| | **Thematic Area: Safety and Security of Radioactive Sources (Code of Conduct)** | **R87** | The Government of Peru should develop a national strategy for the detection of and response to, incidents involving radioactive sources that have been lost from regulatory control. |
| | | **S24** | A plan should be developed from the national strategy and be integrated, as appropriate with other national emergency response plans. It should include clear assignment of responsibilities and listing of the capabilities of all parts of government that may need to be involved. The plan should include arrangements for its dissemination to other relevant organizations, and a mechanism for ensuring that all copies, wherever they are held are managed so as to be kept up to date. |
| | | **G5** | The role of IPEN in influencing the improvement of legislation, and ensuring that sanctions are set at levels which are proportionate to the costs of compliance are both good practices. |
| | | **R88** | IPEN should review ways to promote both a safety and a security culture within the country and implement the feasible option(s). |
| | | **S25** | Options for promoting both safety and security culture may include regular newssheets from IPEN to the authorised users, enhancement of information available to users on the IPEN web-pages, periodic (e.g. annual) meetings to enable informal liaison between IPEN and Radiation Protection Officers, or collaboration with others such as a university to increase association between radiation safety practitioners. |
| | | **R89** | The Government of Peru should review its domestic threat, existing security requirements and international good practice as provided by IAEA SECURITY GUIDE NO.11 and consider what improvements are appropriate. In particular, the authority of IPEN to liaise directly with other relevant governmental bodies should be reviewed. |
| | | **R90** | As part of the development of its national strategy for dealing with orphan sources, IPEN should review the current material on the safety issues of IPEN courses for both safety practitioners relevant training provided to industrial and medical users, and implement any enhancements that may be appropriate. |

| | Areas | IAEA Comment No<br>R: Recommendations,<br>S: Suggestions,<br>G: Good practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | **R91** | Having gained authority to liaise directly with other parts of government, IPEN should liaise with customs colleagues and border guards and seek every opportunity to encourage them to collaborate in the implementation of appropriate monitoring programmes to detect such sources. |
| | | **S26** | IPEN could consider the benefits of establishing an inspection skills course for Inspectors to develop their critical analysis of information provided by users. |
| | | **R92** | IPEN should work with customs officers and border guard organizations in order to encourage them to be aware of, and respond to orphan sources during the course of their operations. |
| | | **R93** | IPEN should review the physical protection of its critical records, including authorization files, copies of licences and the national inventory of sources and implement appropriate measures to ensure both business continuity and protection of sensitive information in accordance with the national code. |
| | | **R94** | The Government of Peru should review the domestic threat, existing security requirements and international good practice (as provided by the IAEA Security Guide No.11) and consider what improvements are appropriate. |
| | | **S27** | It is suggested that IPEN develop a relationship with suitable legal and financial experts who can support them in developing arrangements to ensure that reliable Financial Provisions for end-of-life disposal of orphan sources are established**.** |
| | | **R95** | IPEN should review its requirements relating to the expectations of users on the verification of sources and ensure that a suitable balance is struck between reliance on administrative measures, and direct measurement**.** |
| | **Thematic Area: Transport of Radioactive Material** | **R96** | IPEN should prepare an Action Plan to implement the requirements of TS-R-1. |
| | **Thematic Area: Education and Training** | **R97** | IPEN should develop a continuous training programme for its staff including individual plans and based on different training methods such as classroom based training, on the job training, mentoring and distance learning. |
| | | **R98** | A process of regular, formal assessment of the competence of evaluators and inspectors should be devised. |
| | | **R99** | IPEN should set up a training programme for new evaluators and inspectors. |
| VII | **Management System** | **R100** | OTAN should establish its own management system independently from IPEN and in accordance with GS-R-3. |

# 18. APPENDIX VI – REFERENCE MATERIAL PROVIDED BY IPEN /OTAN

**LAWS – Top level (Approved by Legislative Power)**

1. Decreto Ley N° 21875, "Ley Orgánica del Instituto Peruano de Energía Nuclear" (1977)
2. Ley N° 27757, "Ley de Prohibición de la Importación de Bienes, Maquinaria y Equipos Usados que Utilicen Fuentes Radiactivas" (2002)
3. Ley N° 28028, "Ley de Regulación del Uso de las Fuentes de Radiación Ionizante" (2003)

**RULES OF LAW – Second Level (Approved by Supreme Decree)**

1. Decreto Supremo N° 009-97-EM, "Reglamento de Seguridad Radiológica."
2. Decreto Supremo N° 014-2002-EM, "Reglamento de Protección Física de los Materiales e Instalaciones Nucleares"
3. Decreto Supremo N° 039-2008-EM, "Reglamento de la Ley 28028, Ley de Regulación del Uso de Fuentes de Radiación Ionizante".

**OTHER REGULATORY DOCUMENTS – Third level (IPEN's approval)**

1) Norma PR.001.91 "Requisitos para la Vigilancia Radiológica Individual". Approved by Resolution of President of IPEN (R.P.N ° 062-91-IPEN/AN)
2) Norma PR.003.94 "Requisitos Técnico-Administrativos para los Servicios de Dosimetría Personal de Radiación". Approved by Resolution of President of IPEN (R.P.N ° 005-94-IPEN/AN)
3) Norma PR.002.95 "Disposiciones para el manejo Seguro de los Desechos Radiactivos". Approved by Resolution of President of IPEN (R.P.N ° 009-95-IPEN/AN)
4) Norma IR.011.96 "Aspectos Técnicos y Administrativos para obtener la Licencia de Instalación de Radiología Dental". Approved by Resolution of President of IPEN (R.P.N ° 015-96-IPEN/AN)
5) Norma IR.012.98 "Requisitos Técnicos de Seguridad Radiológica para Irradiadores Gamma Panorámicos de Categoría II y IV". Approved by Resolution of President of IPEN (R.P.N ° 008-98-IPEN/AN)
6) Norma IR.013.98 "Requisitos Técnicos de Seguridad Radiológica para el Uso de Irradiadores Gamma Autoblindados de Categoría I". Approved by Resolution of President of IPEN (R.P.N ° 009-98-IPEN/AN)
7) Norma IR.001.01 "Requisitos de Seguridad Radiológica en Teleterapia". Approved by Resolution of President of IPEN (R.P.N ° 007-01-IPEN/AUNA)

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


**[1.]** **IAEA SAFETY STANDARDS SERIES GS-R-1 -** *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*

**[2.]** **IAEA SAFETY STANDARDS SERIES GS-G-1.1 -** *Organization and Staffing of the Regulatory Body for Nuclear Facilities*

**[3.]** **IAEA SAFETY STANDARDS SERIES GS-G-1.2 -** *Review and Assessment of Nuclear Facilities by the Regulatory Body*

**[4.]** **IAEA SAFETY STANDARDS SERIES GS-G-1.3 -** *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*

**[5.]** **IAEA SAFETY STANDARDS SERIES GS-G-1.4 -** *Documentation for use in Regulation of Nuclear Facilities*

**[6.]** **IAEA SAFETY STANDARDS SERIES GS-G-1.5 -** *Regulatory Control of Radiation Sources*

**[7.]** **IAEA SAFETY STANDARDS SERIES GS-R-2 -** *Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*

**[8.]** **IAEA SAFETY STANDARDS SERIES GS-R-3 -** *Management System for Facilities and Activities*

**[9.]** **IAEA SAFETY STANDARDS SERIES NS-R-1 -** *Safety of Nuclear Power Plants: Design Safety Requirements*

**[10.]** **IAEA SAFETY STANDARDS SERIES NS-R-2 -** *Safety of Nuclear Power Plants: Operation Safety Requirements*

**[11.]** **IAEA SAFETY STANDARDS SERIES NS-R-4 -** *Safety of Research Reactors*

**[12.]** **IAEA SAFETY STANDARDS SERIES NS-G-4.1 -** *Commissioning of Research Reactors*

**[13.]** **IAEA SAFETY STANDARDS SERIES SS115 -** *International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*

**[14.]** **IAEA SAFETY STANDARDS SERIES TS-R-1 -** *Regulations for the Safe Transport of Radioactive Material*

**[15.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.1 -** *Decommissioning of Nuclear Power Plants and Research Reactors*

**[16.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.2 -** *Decommissioning of Medical, Industrial and Research Reactors*

**[17.]** **IAEA SAFETY STANDARDS SERIES WS-R-1 -** *Near Surface Disposal of Radioactive Waste*

**[18.]** **IAEA SAFETY STANDARDS SERIES WS-R-2 -** *Predisposal Management of Radioactive Waste including Decommissioning*

**[19.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.3 -** *Regulatory Control of Radioactive Discharges to the Environment*

**[20.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.4 -** *Decommission of Nuclear Fuel Cycle Facilities*

**[21.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.5 -** *Predisposal Management of Low and Intermediate Level Radioactive Waste*

**[22.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.6 -** *Predisposal Management of High Level Radioactive Waste*

**[23.]** **IAEA SAFETY STANDARDS SERIES WS-G-2.7 -** *Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*

**[24.]** **IAEA SAFETY STANDARDS SERIES WS-R-3 -** *Remediation of areas contaminated by past activities and accidents*

**[25.]** **IAEA SAFETY STANDARDS SERIES WS-R-5 -** *Decommissioning of facilities using Radioactive Material*

**[26.]** **IAEA SAFETY STANDARDS SERIES WS-G-6.1 -** *Storage of Radioactive Waste*

**[27.]** **IAEA SAFETY STANDARDS SERIES RS-G-1.7 -** *Application of the Concepts of Exclusion, Exemption and Clearance*

**[28.]** **IAEA SAFETY STANDARDS SERIES RS-G-1.8 -** *Environmental and Source monitoring for Purpose of Radiation Protection*

**[29.]** **IAEA SAFETY STANDARDS SERIES RS-G-1.9 –** *Categorization of Radioactive Sources,*

**[30.]** **IAEA CODE OF CONDUCT** *on the Safety and Security of Radioactive Sources*

**[31.]** **IAEA CODE OF CONDUCT** *on the Safety of Research Reactors*

**[32.]** **IAEA GUIDANCE** *on the Import and Export of Radioactive Sources*

**[33.]** **IAEA SAFETY SERIES NO. 111-G-1.1** - *Classification of Radioactive Waste*

**[34.]** **SAFETY SERIES NO. 35 – G2 -** *Safety in the Utilization and Modification of Research Reactors*

**[35.]** **IAEA TECDOC 1388 -** *Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies*

**[36.]** **INSAG SERIES NO. 17 -** *Independence in Regulatory Decision Making*

**[37.]** **INSAG SERIES NO. 20 -** *Stakeholder Involvement in Nuclear Issues*

**[38.]** **INSAG SERIES NO. 21 -** *Strengthening the Global Nuclear Safety Regime*

**[39.]** **IAEA LEGAL SERIES NO.14** - *Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency Adopted on 26 September 1986 at the 18th 1986 plenary meeting*

## 20. APPENDIX VIII - IPEN / OTAN ORGANISATIONAL CHART