FIRST NATIONAL REPORT OF THE REPUBLIC OF PARAGUAY TO THE CONVENTION ON NUCLEAR SAFETY

7. existing legislative and regulatory framework

7.1. Establishing and Maintaining a legislative and regulatory framework

In Paraguay on August 30, 1965 the Law No. 1081/65 which creates the National Atomic Energy Commission (CNEA in Spanish), aiming to be the institution responsible for promoting and regulating the peaceful uses of nuclear energy was approved. This institution was created under the Ministry of Foreign Affairs. In 199, due to a legislative modification, it became dependent on the National University of Asuncion

The National Atomic Energy Commission was, for many years, the institution responsible for regulating the activities of the radiological and nuclear field in the areas of industry, research and teaching.

On the other hand, Law No. 836/80, or ¨Health Code of the Ministry of Public Health and Social Welfare¨ (Ministerio de Salud Pública y Bienestar Social) established that this public institution had the responsibility of carrying out the regulations in the field of medical uses of ionizing radiation

As of May 8, 2014 it was approved by the Legislature and promulgated by the Executive Branch, the Law No. 5169/14 which created the Regulatory Authority Radiological and Nuclear (ARRN in Spanish nomenclature) as a unique and independent authority under the jurisdiction of the Executive.

Currently the ARRN is the only institution in the country, responsible for carrying out the regulations in all areas of radiological and nuclear applications. It has its own budget since January 2016.

Overview of the primary legislative framework for nuclear safety, including interfacing national legislation

The law No 5169, which created the Regulatory Authority Radiological and Nuclear, supports the legislative framework at national level for everything related to the peaceful use of nuclear energy. This law provides in Article 8 the functions and duties of the ARRN;

Article 8:. The Regulatory Authority Radiological and Nuclear (ARRN) shall have the following functions, powers and duties:

a) Enact standards, technical regulations; guides; codes of practice relating to regulatory and nuclear safety, physical protection, and control of the use of radioactive or nuclear materials, licensing and control of nuclear and radiological facilities, international safeguards and transport of nuclear materials must update them regularly and in accordance with the technological developments and the recommendations of the International Atomic Energy Agency (IAEA).

b) To promote and disseminate to users and society in general rules concerning the protection and radiation safety and the actions of the Regulatory Authority Radiological and Nuclear (ARRN) implemented within the framework of its powers and functions.

c) To define the practices and radioactive materials that are exempt from regulatory control.

d) To authorize, suspend or revoke the authorizations granted for the performance of all activities set forth in article 5 of this law regarding radioactive sources or equipment generating ionizing radiation, nuclear materials and nuclear facilities in accordance with current regulations . The authorization of nuclear power plants, its location, operation and decommissioning require the prior authorization of the Executive binding in all cases.

e) Regulate the conditions of radiation protection and enabling grant specific authorizations to perform the function Workers Occupationally Exposed (TOE); according to international requirements, regulations and standards on radiation and nuclear safety; especially those exposed in the investigation; construction; installation; operation; maintenance; extraction of radioactive minerals; handling; forfeiture; disablement and others that were convenient, equipment and installations exposed to radioactive materials or generating ionizing radiation, cyclotrons, facilities for waste management or radioactive waste, disused radioactive sources and spent fuel, who must prove to the Regulatory Authority Radiological and nuclear (ARRN) sufficient to operate in such activities suitability. Compliance with these regulations will be budget assessment in applications for permits and licenses and their respective validity is conditional on compliance, which will be subject to audit.

f) Make available to the workers occupationally exposed to ionizing radiation, information on annual dose values, including, if the case, its integrated value, if exercised functions in more than one institution exposed to ionizing radiation.

g) Sort the types of authorizations required for each of the activities listed under authorization.

h) Establish a national inventory to record the types of sources and ionizing radiation generating equipment.

i) Oversee, through inspections previously instructed by the Regulatory Authority Radiological and Nuclear (ARRN), compliance with the regulations set forth in this law, its regulations and international conventions ratified by the Republic of Paraguay, of any activity could involve ionizing radiation.

j) Impose sanctions in case of infringements of the provisions of this law are checked, their existing regulations or other laws of which the Regulatory Authority Radiological and Nuclear (ARRN) outside enforcement authority.

k) Regulate and monitor compliance of the services provided by third parties that relate to the applications of ionizing radiation, nuclear or nuclear radiation.

l) Create and manage the National Dose Registry.

m) To monitor and control the management and safe storage of radioactive sources and radioactive waste that could be generated as a result of the different authorized practices.

n) Require those who carry out practices with radioactive materials hiring policies sufficient insurance to cover the safe management of radioactive waste and disused sealed sources; as well as damages that may arise to people and the environment.

ñ) Previous intervention of the Ministry of Foreign Affairs, enter into agreements with regulators in other countries and related international organizations whose object was the transfer of technology or knowledge in the form of multilateral or bilateral cooperation.

o) To promote and ensure compliance with the specifications set out in national and international regulations approved and ratified by the Republic of Paraguay.

p) To establish appropriate mechanisms to inform the public and users the regulatory framework and mandatory measures to be implemented in case of radioactive exposures regulated by the Regulatory Authority Radiological and Nuclear (ARRN) produced safety.

q) To authorize the import, export and transport of radioactive sources or ionizing radiation generating equipment in accordance with the regulations.

r) Providing technical assistance and conduct audits as necessary in cases of radiological and nuclear emergency.

s) To be official link and focal point in relations with the International Atomic Energy Agency (IAEA); World Nuclear Information System (INIS); Regional Information Network in the Nuclear Area (RRIAN); and other international organizations and national regulatory authorities in the area of competence.

t) Being counterpart regulatory projects related to infrastructure supported by the International Atomic Energy Agency (IAEA) or other national or international institutions.

u) To advise the Executive on matters within its jurisdiction and other authorities and governmental organizations on matters pertaining to the Regulatory Authority Radiological and Nuclear (ARRN), and in particular the executive branch with regard to International Conventions which the State is party and also safeguards agreements.

v) To promote and conduct research on security and safety issues of ionizing radiation, nuclear or electric nuclear regulations and adapt to technological progress made by States with the greatest tradition in the field.

w) Cooperate with official intelligence agencies aimed at preventing possible attacks with nuclear or radioactive material.

x) Controlling entry into the country of unauthorized nuclear and radioactive materials or other equipment subject to regulation and control.

y) Promote civil and criminal proceedings in the competent courts against individuals who violate licenses; permits, or do submit to the licensing process, as provided in this Act and its regulations; as well as seek search warrants and require the assistance of the police when this is necessary for the proper exercise of the powers conferred by this law.

z) To guarantee the confidentiality of restricted information made knowledge, in order to ensure proper safeguarding of technological, commercial or industrial secrets and appropriate application of physical protection measures.

aa) Require the submission of the Environmental Impact Statement issued by the Ministry of Environment as a prerequisite for granting compulsory licenses or

permits all activities that generate ionizing radiation, and other identified regulations that could have significant environmental effects.

bb) Submit to the Executive Branch periodic technical reports containing recommendations on necessary or convenient to be taken for the benefit of the public interest.

cc) Request information from all authorized regarding the status and conditions of activities subject to regulation are subject.

dd) issue founded and appropriate recommendations to the Executive about the impact that could have any activity, involving use of materials that may generate ionizing radiation, including those of nuclear or nuclear power source, carried out or to be carried in the territory of foreign countries, whose actions could generate transboundary effects.

ee) Establish mechanisms to prevent illicit trafficking in radioactive materials and especially enter into cooperation agreements with the National Customs that provide access to appropriate checks on the identification of radioactive sources entering and leaving the country and allow verifying compliance with regulatory obligations.

ff) Assess; manage and measure the potential and risks generated by ionizing radiation present, also considering the nuclear or nuclear origin.

gg) Perform any other action to comply with the purposes of this Act.

Ratification of international conventions and legal instruments related to nuclear safety.

Paraguay has signed and ratified several international conventions and agreements in the nuclear field are listed below:

• Convention on the Physical Protection of Nuclear Material"

Location: Vienna, AUSTRIA

Date: March 3, 1980

Ratification: November 21, 1984 - LAW No. 1086

• "Constitutive Statute of the International Atomic Energy Agency (IAEA)"

Location: New York

DATE: October 26, 1956

RATIFICATION: September 3, 1957 - Law No. 467

• "Regional Cooperation Agreements for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean - ARCAL"

Location: Vienna

DATE: September 24, 1998

RATIFICATION: No

• Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

SIGNATURE: October 2, 1986

RATIFICATION: No

• Convention on Early Notification of a Nuclear Accident.

SIGNATURE: October 2, 1986

RATIFICATION: No

• Convention on Nuclear Safety

SIGNATURE: April 10, 2014

• Amendment to the Convention on the Physical Protection of Nuclear Materials

SIGNATURE: December 15, 2015

Article 7 (2) (i) National safety requirements and regulations

Overview of the nuclear safety for secondary legislation (Ordinances, Decrees, etc)

As for the regulatory aspect, in 2000, an important milestone was achieved by the approval of Decree No 10754/2000 of the Presidency of the Republic, the "National Safety Regulations for the Protection against \Ionizing Radiation and for the Safety of Radiation Sources, ",, at that moment, the only regulation at national level implemented by both regulatory authorities of the time.

However, as of February 11, 2016 the ARRN approved by Resolution D-ARRN-006/16 a regulation called the "Basic Regulation of Radiation Protection and Safety of Ionizing Radiation Sources" (hereafter referred to as the Basic Regulation) . This Regulation is based on the new recommendations of the International Atomic Energy Agency, the GSR Part 3

Scope of application:

The Basic Regulation of Radiation Protection and Safety of Ionizing Radiation Sources, provides in Art. 25, that any natural or legal person who proposes to make any kind of practice with ionizing radiation or other activity that involves exposure to them, contained in the extensive list of the Arts. 3 and 4 of that legal body, shall notify the ARRN, and request authorization if the respective practice or activity requires so. Until the authorization is granted, the solicitor may not perform any of those actions.

The Art 3 referred, reads;

“”The practices to which this Regulation applies are;

> *a) The acquisition, sale, rent, loan, transfer, entry and exit of the country, production, distribution, assembly, processing, packaging, disarmament, transportation, possession, use, donation and disposal of radioactive materials and equipment generating ionizing radiation industrial purposes, medical, veterinary, agricultural, research or teaching, and any other activity that may involve natural sources of ionizing radiation;*
>
> *b) Those involving exposure to natural sources of radiation, as specified in these regulations; and,*
>
> *c) \Any other practice specified by the relevant provisions.”*

Then, article 4 also referred reads:

".*Exposures to which these regulations apply are: occupational exposure, medical exposure or public exposure due to any practice or source; including both normal exposures and potential. For the purposes of establishing physical practical requirements of radiation protection and safety, this regulation considers three types of exposure situations: planned, emergency and existing exposures*".

It is also worth mentioning the "Principle of justification of practice", inserted on Art. 7, that establishes:

'Justification of practices: Any practice or source of ionizing radiation that is not properly justified and produce a positive net benefit to the exposed individuals to society shall not be authorized."

Licensing System

The Licensing System for the operators of installations that use sources of ionizing radiation in the country is divided in the form of licenses, registrations and specific authorizations.

Practices in turn, are categorized on a sliding scale, consisting in categories 1 to 5 from higher to lower risk practice, following the recommendations of the IAEA. The Scale, contained in Appendix 6 of the Basic Regulation is as follows:

Practice	**Risk**	**Inspection Period**	**Type of Authorization to be provided**	**Effective Term of Authorization**	**Single Authorization**
CATEGORY 1					
Irradiators,(Sterilisation and Food Preservation. Irradiation of Blood Tissues. Auto armored)	**Very High**	**1 year**	**LICENSE**	**2 years**	**5 years**
Teletherapy: (Multiple Beams o Gammaknife, Accelerators Cobalt Therapy)	**Very High**	**1 year**	**LICENSE**	**2 years**	**5 years**
Ciclotron	**Very**	**1 year**	**LICENS**	**2 years**	**5 years**

	High		E		
CATEGORY 2					
Brachytherapy medium and high dose rate	High	1 year	LICENSE	2 years	5 years
Industrial Radiography.	High	1 year	LICENSE	2 years	3 years
CATEGORÍA 3					
Nuclear Medicine: 1.Teraphy; 2. Diagnosis in vivo; 3. Diagnosis in vitro (Depending on inventory radionuclides used) ; 4.Positron Emission Tomography (PET)	MIDDLE	1 year	LICENSE	2 years	5 años
Temporary Storage of Radioactive Waste..	MIDDLE	2 years	LICENSE	2 years	5 años
Mobile Equipment for Scanning Containers with RX Source	MIDDLE	2 years	LICENSE	2 years	5 años
Nuclear Gauges: 1. Level; 2.Used in Dredges; 3.Used in Conveyors Belts;	MIDDLE	2 years	LICENSE	2 years	5 años
Oil Wells Probes (Profiling)	MIDDLE	2 years	LICENSE	2 years	5 años
Radioactive Tracers	MIDDLE	2 años	LICENSE	2 years	5 años
Fluoroscopy	MIDDLE	2 years	LICENSE	5 years	5 años
CATEGORÍA 4					
Nuclear Gauges: 1.Level; 2.Thickness; 3. Dust Monitors; 4. Dust particles on air; 5. Weight; 6. Snuff Density; 7. Portable Meters Moisture/ Density.	LOW	3 years	REGISTRATION	5 years	NA
Radioimmunoassay.	LOW	3 years	REGISTRATION	5 years	NA

Bone Densitometers.	LOW	3 years	REGISTRATION	5 years	NA
RX Equipment for medical diagnosis (except Dental)	MIDDLE	2 years	LICENSE	5 years	5 años
Low Dose Rate Brachytherapy Dose	MIDDLE	1 year	LICENSE	2 years	5 años
CATEGORÍA 5					
X-Rays used in control of packages.	VERY LOW	3 years	REGISTRATION	5 years	NA
Low Dose Rate Brachytherapy dose using ophthalmic applicators and permanent implants	VERY LOW	5 years	REGISTRATION	5 years	NA
X-Rays in Dental Diagnosis.	VERY LOW	5 years	REGISTRATION	5 years	NA
X-Rays Clinics used in Dental Diagnosis	VERY LOW	2 years	REGISTRATION	5 years	NA
X-Rays used in Veterinary Diagnosis .	VERY LOW	5 years	REGISTRATION	5 years	NA
X-Rays used for metal detection in meat and bone in cold stores	VERY LOW	5 years	REGISTRATION	5 years	NA
Electronics capture devices (Chromatographs types).	MUY BAJO	5 years	REGISTRATION	5 years	NA
X-Rays fluorescence.	VERY LOW	5 años	REGISTRATION	5 years	NA
Use of radioactive sources and material in Research and Teaching	VERY LOW	5 years	REGISTRATION	5 years	NA

Source: IAEA TECDOC 1526. REG 017, Categorization of Radioactive and practices in which they are employed (based on the IAEA TECDOC 1344) sources. BSS / 115.

Licenses are granted to all installations using supplies or equipment generating ionizing radiation of Category 1, 2 and 3. For practices in categories 1, 2 and 3 ,in addition to an operating license, it is also required a construction License. Requirements for granting them are set out in the Basic Regulation, Art 36 for the construction license and the Art.37 and 38 for operating licenses.

For practices in Categories 4 and 5, the Basic Regulation provides in Art. 28 that authorization is required, as set out in Appendix VI of the Basic Regulation for registration. The requirements for granting authorizations for registration are set out in Art.40 of the Basic Regulation.

Besides, the basic Regulation provides specific authorizations for the following cases:

• Authorizations for Companies that perform import or export of sources of ionizing radiation.

• Authorizations for Companies that perform maintenance and repair of equipment generating ionizing radiation.

• Authorization for the safe transport of radioactive sources.

• Authorization for institutions conducting Courses of Radiological Protection

• Authorization for import of radioactive sources

• Authorization for companies that provide services of Personal Dosimetry

• Individual Authorization for Radiation Protection Officers (RPO) and occupationally exposed workers (TOEs).

The validity of each of the Authorizations (licenses, registrations or specific authorization) is also stipulated in the Basic Regulation, in Appendix VI

Procedure for relicensing:

The Regulatory Authority Radiological and Nuclear (ARRN) grants authorizations after the process of analysis of the documentation submitted by the Authorization Holders, and in some cases, after inspection the renewal of authorizations according to the category to which it relates

The Basic Regulation also provides that to the renewal of the different types of authorizations (licenses, registrations and specific authorizations released). The requirements necessary to grant the corresponding renewals are set out in Art. 46 of the Basic Regulation of radiation protection and safety of ionizing radiation sources

Article 7 (2) (iii) System of regulatory inspection and assessment

Law 5169 of May 8, 2014, in Art. 8 paragraph i), authorizes the ARRN to monitor, by conducting inspections, all facilities \that work with or use sources of ionizing radiation in the country. Inspections are set out in Chapter XVI of the Basic Regulation on Radiation Protection and Safety of Ionizing Radiation Sources, from 174 to 182 Art.

The ARRN also has the Inspection Regulation, approved by Resolution D-ARRN No 020/2016, in which is established everything related to inspections, ie:

General disposition

Authority responsible for the Inspection

Inspectors, requirements and responsibilities

Installations subject to inspection

And finally everything related to the inspection itself, ie, classification, organization and development, Report of the inspections, and claims record

Periodic inspections are made, based on a schedule established by the Department of Inspection and Control of the ARRN. This schedule is produced at the beginning of the year and approved by the Board of Radiological and Nuclear Regulatory Authority

Enforcement of applicable regulations and terms of licenses

Sanctioning power:

The sanctions to be applied to authorization holders are stipulated by Law 5169/14, specifically Articles ranging from 27 to 30, empowering the ARRN to apply sanctions in case of infringements or violations of the laws or regulations of which it is the implementing authority. So in the Basic Regulation they are listed in Chapter XVII. Penalties for violations of the Basic Regulation.

The relevant articles stipulate:

Art.28:

> *“The Regulatory Authority Radiological and Nuclear (ARRN) is empowered to impose sanctions if proven the commission of offenses or violations of the laws and regulations of which is Enforcement Authority”.*

Art.30:

> *“Penalties shall be graded according to the seriousness of the offense and present or potential harm generated and consist of:*
>
> *a) The imposition of fines, the maximum amount is thirty thousand minimum wages for various unspecified activities, and shall be determined in proportion to the severity of the offense and depending on the severity of the damage and potential.*
>
> *b) The suspension of an authorization, license, registration or permit, or final revocation.*
>
> *c) Confiscation of nuclear or radioactive materials.*
>
> *d) Preventive or permanent installations subject to regulation by the Regulatory Authority Radiological and Nuclear (ARRN), when developing without proper authorization or to the detection of serious breaches of regulations and standards on radiation and nuclear safety closure and protection of personnel and facilities.*
>
> *e) Warning.*

f) Sanctions may be imposed cumulatively when proceed."

The Regulatory Authority Radiological and Nuclear has not yet applied sanctions on Authorization Holders considering that inspections have recently begun in the current year. There should be noted as it was mentioned before in this report, that although the creation dates from 2014, is only on 2016 that the budget for the Authority was approved.

Article 8 (1) Establishment of the regulatory body

The Institution that carries out the task of regulation of the use and application of ionizing radiation in Paraguay is the Regulatory Authority Radiological and Nuclear (ARRN).

The structure organizes the Authority is composed of an Executive Secretary with the rank of minister and 4 Board members

- Chap. III. Organic Structure

- Art. 12 and Art. 16

Executive Secretary and 4 directors representing

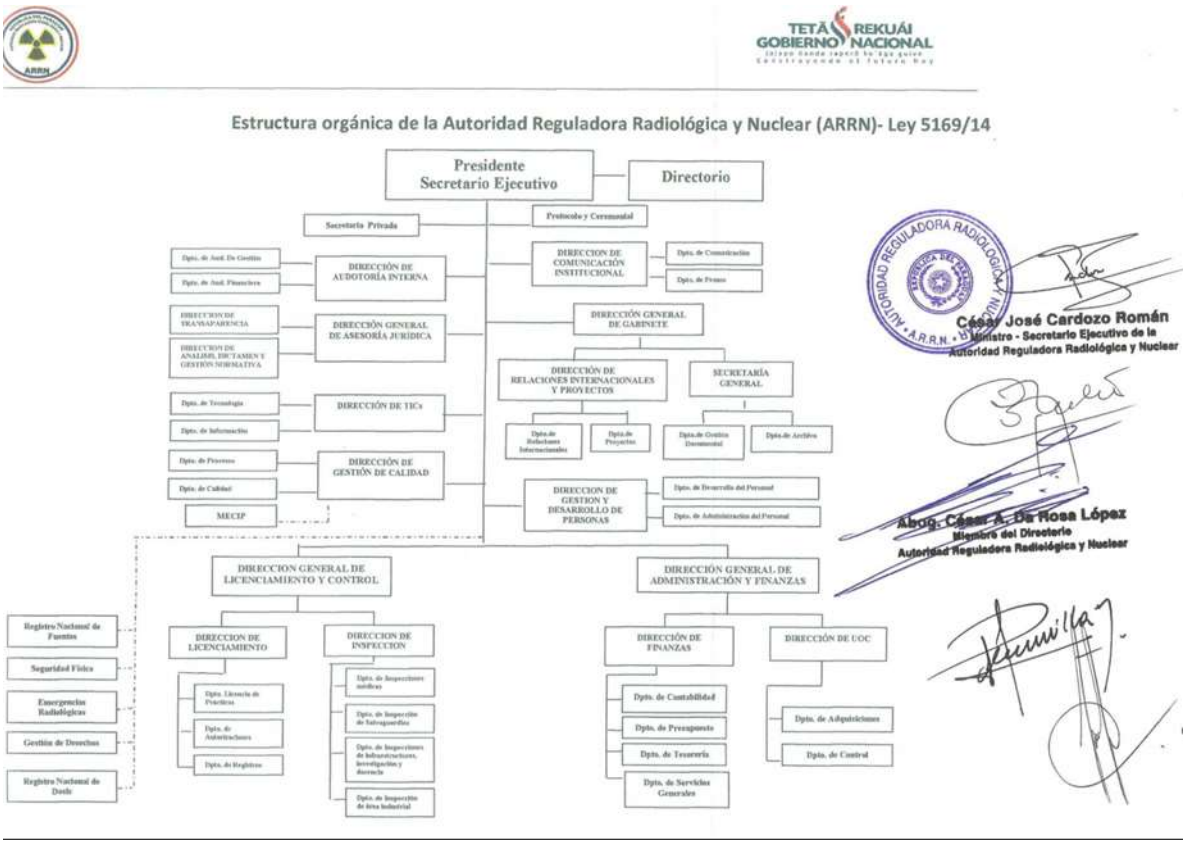
-Ministry of Interior,

-Ministry of Foreign Affairs,

-Ministry of National Defense

Environmental -Secretariat

Organizational structure of the regulatory body



Development and maintenance of human resources over the past three years

The Paraguay has benefited from the strengthening and training of human resources through scholarships, training courses, workshops and scientific visits, organized by the International Atomic Energy Agency through projects in different areas of application (regulation, medicine, industry, agriculture among others)

Regarding the Regulatory Authority Radiological and nuclear, it has a staff of qualified people in the area, and new human resources were recently added and are in stage of training to develop their skills in the different\areas of expertise. In the organizational structure of the Regulatory Authority Radiological and Nuclear it is provided a Quality Management Department.

The Regulatory Authority Radiological and Nuclear has its own budget since January 2016 and has started its activities in full form from February. However recently in July it has already begun with the involvement of all its employees in the quality process, by performing introductory courses in Quality Management System.

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Article 8 (2) Status of the regulatory body:

The Regulatory Authority, Radiological and Nuclear ARRN,I s an entity with absolute independence from organizations dedicated to the promotion and peaceful use of nuclear energy, as well as institutions or companies using nuclear technology or working with ionizing radiation, and those of those service institutions. This situation, fully meets the requirements and recommendations emanating from the international Atomic Energy Agency with regard to an Independent Regulatory Authority.

The Nuclear Regulatory Authority Radiological and Nuclear was created under the executive branch but with characteristics of autonomy for dictate their own regulations in nuclear matter, and budget independence. The Executive Secretary with the rank of minister is appointed by the President and the Board members are appointed by the ministries it represents, Ministry of Interior, Ministry of Defense, Ministry of Environment and the Ministry of Foreign Affairs. None of these ministries are themselves users of Nuclear Technology in the country, so there is no conflict of interest.

Place of the regulatory body in the governmental structure

As previously mentioned, the ARRN is a regulator, and an independent and autonomous body under the jurisdiction of the executive, not depending therefore on any other intermediate governmental or private entity.

Article 16 Emergency Preparedness

Paraguay is a country that currently has no nuclear facilities, but with radioactive installations of relevance.

The most important facilities are in the area of medical applications, with three centers of radiotherapy with linear accelerators, and two centwers of brachytherapy with high dose rate. It also has a cyclotron, two temporary storage deposits of disused sources and a small neutron generator with sources AmBe. These facilities have their physical security systems and have developed their security plans.

The country has a Plan Response in Emergencies, called RER Plan. It is a document that is in force since February 20, 2007 and was approved by Resolution No. 143 of the Ministry of National Defense. We are currently working on a draft for

updating the Plan prepared in accordance with the IAEA document called EPR-Method 2003 "Method for Developing Arrangements for nuclear or radiological emergencies"

International drills regarding this plan were executed in the past by the National Atomic Energy Commission (CNEA), with similar institutions of Argentina and Mexico, but the ARRN will start its new drills at national level, until next November. International drills are in consideration for the future.

There are also a National Commission on Prevention and Response to Biological Emergencies called CONAPREB, whose functions is to prevent and to respond to emergencies arising from biological, chemical, radiological agents or other weapons of mass destruction, accidental or caused by terrorist acts. This Commission was established by Decree No 20997 of April 30, 2003.

The CONAPREB is composed of different state institutions relevant to the prevention and response in case of accidents. Currently it up

Ministry of Defense

Ministry of Interior

National Directorate of Civil Aviation (DINAC)

National Atomic Energy Commission (CNEA)

Regulatory Authority Radiological and Nuclear (ARRN)

National Customs

Ministry of Public Works and Communications MOPC through the Highway Police

Emergency Medical Services SEME the Ministry of Public Health and Social Welfare

The Volunteer Fire Departments Paraguay

End of the Report.