



LEGISLATIVE POWER  
LAW NO. 5.169

ESTABLISHING THE NUCLEAR AND RADIOLOGICAL REGULATORY AUTHORITY.

THE CONGRESS OF THE PARAGUAYAN NATION ENACTS WITH FORCE  
OF LAW

Single Title

**Radiological and Nuclear Regulatory**

**Authority General objective**

**Article 1°.** - The objectives of this law are:

- a) To allow the peaceful and beneficial use of ionizing radiation.
- b) To take measures for the protection of people, both for present and future generations, and the environment against the harmful effects of ionizing radiation, to take measures for the technological and physical safety of radiation sources and radioactive waste.
- c) Provide a mechanism by which these objectives are achieved through the establishment of an appropriate system of regulatory control.

**Article 2°.**- Definitions in order to clarify all the technical concepts mentioned in the law; it is understood by:

- a) Authorization: Permission granted in a document by the Regulatory Authority to a legal person who has submitted an application to carry out a practice or any other.
- b) Emergency: (Nuclear or Radiological): A non-routine situation or event that requires prompt action primarily to mitigate a hazard or adverse consequences to human health and safety, quality of life, property or the environment.
- c) Exclusion: Outside the scope of application of the law or regulations.
- d) Exemption: Administrative act by which it is declared that a certain material or source is not subject to the controls and precepts required by law or its regulations.
- e) Exposure: The act or situation of being subjected to irradiation. Exposure may be external (irradiation caused by sources outside the human body) or internal (irradiation caused by sources inside the human body);
- f) Radioactive waste: Matter, in whatever physical form, which is left as

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g) (a) Release from further regulatory control by the Regulatory Authority of radioactive material or radioactive objects that have been **involved in** authorized practices.

h) Dose (of radiation): A measure of the radiation received or 'absorbed' by a target.

i) Source, radiation source, radioactive source: Anything that can cause radiation exposure, either by emitting ionizing radiation or by releasing radioactive substances or materials.

j) Sealed sources: Radioactive material that is permanently enclosed in a capsule or tightly wrapped in a solid form.

k) Licence : Authorisation granted by the regulatory authority on the basis of a safety assessment and supplemented by specific requirements and conditions to be met by the licensee.

l) Nuclear material: Material containing significant amounts of fissile or fertile nuclides.

m) Radioactive material: Any material containing substances that emit ionizing radiation.

n) Physical protection: Measures taken at nuclear or radioactive facilities that are applied to prevent or deter the theft of nuclear material during use, storage and transport, and to prevent sabotage of nuclear or radiological facilities.

o) Practice : Any human activity which introduces additional sources of exposure or exposure pathways or extends exposure to more persons or modifies the overall exposure pathways due to existing sources in such a way as to increase the exposure or the likelihood of exposure of persons or the number of persons exposed.

p) Ionizing radiation: For the purposes of radiation protection, radiation capable of producing ion pairs in biological material.

q) Physical security: A set of measures aimed at preventing unauthorized access to or damage to radioactive sources, and the loss, theft or unauthorized removal of such sources.

r) Technological safety: Measures and measures to control exposures as well as to prevent accidents and mitigate their consequences should they occur.

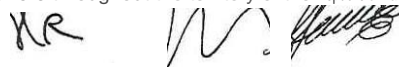
c. s) Occupationally exposed worker: Any person who is employed on a full-time, part-time or temporary basis by an employer and who has recognized rights and duties with regard to occupational radiation protection.



Chapter I Creation,  
Juridical Nature

con las Article 3 - The Radiation and Nuclear Regulatory Authority, hereinafter identified by the acronym Autoridad Reguladora Radiológica y Nuclear (ARRN), is hereby created as an autonomous State body, with legal personality under public law and its own assets, under the jurisdiction of the Executive Branch, whose functional and administrative organization shall be governed by this Act.

Article 4 - The Radiation and Nuclear Regulatory Authority (ARRN) shall have full legal capacity to act in the public and private sphere throughout the territory of the Republic of Paraguay.



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**Objectives, functions and duties**

**Article 5** - The objectives of the Radiological and Nuclear Regulatory Authority (ARRN) are as follows

a) To establish standards, technical regulations, guidelines, codes of practice and regulatory safety codes for activities involving nuclear technology and all sources of radiation existing in the country, and to update them periodically in accordance with technological developments and the recommendations of the International Atomic Energy Agency (IAEA).

b) To regulate and control the activities or practices that are carried out in the national territory, with radiation sources, including nuclear, physical security and the use of radioactive minerals, as appropriate.

c) To verify that nuclear activities are not diverted to unauthorized purposes and that they are carried out subject to the international commitments assumed by the Republic of Paraguay.

d) To control and regulate source security measures to deter, detect and delay unauthorized access, theft, loss or unauthorized use or disposal of radioactive sources during all phases of their management, in order to ensure that this is done in accordance with the provisions of this law and the international commitments assumed by the Republic of Paraguay.

e) To establish criteria and standards to prevent the commission of intentional acts that could lead to severe radiological consequences or to the unauthorized removal of nuclear material or other material, sources or equipment subject to regulation and control under the provisions of this Act or other regulatory documents.

f) To ensure the safe management of radioactive waste, disused sealed sources.

**Article 6** - Scope of Application.

The scope of application of the present law extends to all events or acts that generate present or potential, certain or probable exposure to ionizing radiation from medical, industrial, agricultural, research, educational, nuclear or electrical activities or practices.

This also applies to the generation of radioactive wastes from these practices or to the generation of radioactive wastes from these practices.

The following are excepted: events or acts excluded by regulation by the Radiation and Radioactive Regulatory Authority (RRA). Exceptions are made for events or acts excluded by regulation by the Radiological and Radio Regulatory Authority (ARRN).

**Article 7**.- Regulated events.

Without the prior approval of the Radiation and Nuclear Regulatory Authority (RNRA), no policy shall be adopted or introduced, carried out, discontinued or ceased and no source shall, as appropriate, be designed, manufactured, constructed or assembled, procured, imported or used in any other way, and no source shall, as appropriate, be used in any other way.

To be lent or hired out, to be owned, to be established, to be set up, to be fitted out.  
(a) to be installed or operated, maintained or repaired, transferred or dismantled, dismantled, dismantled, The use, carriage, storage, or disposal of such substances is prohibited, unless the exposure caused by such practices or substances is excluded or exempted from the scope of this Act or its regulations.

**Article 8** - The Radiological Regulatory Authority shall have the following responsibilities  
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**a)** To issue standards, technical regulations, guidelines and 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 the transport of nuclear materials, and to update them periodically in accordance with technological developments and the recommendations of the International Atomic Energy Agency (IAEA).

**b)** To promote and disseminate to users and society in general the standards relating to radiation protection and safety and the actions of the Radiation and Nuclear Regulatory Authority (ARRN) carried out within the framework of its competences and powers.

**c)** 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 the activities set forth in article 5 of the present law with respect to radioactive sources or equipment generating ionizing radiation, nuclear materials and nuclear facilities, in accordance with the regulations in force. The authorisation of nuclear power plants, their  
The siting, operation and closure shall, in all cases, require the prior binding authorization of the Executive Power.

**e)** To regulate the conditions of radiological protection and to grant specific authorizations for the Occupationally Exposed Worker (OEW) to carry out the function: according to international requirements, regulations and radiological and nuclear safety standards; especially for those persons exposed in research. According to international requirements, regulations and norms of radiological and nuclear safety, especially for those persons exposed in research, construction, installation, operation and operation of nuclear power plants: construction; installation; operation; maintenance; extraction of radioactive minerals; handling; decommissioning; disabling and others that may be appropriate, of equipment and facilities exposed to radioactive material or generators of ionizing radiation, cyclotrons, facilities for the management of radioactive waste or residues, disused radioactive sources and spent fuels, who will have to prove to the Radiation and Nuclear Regulatory Authority (ARRN) that they are sufficiently qualified to operate in such activities. Compliance with these regulations shall be a prerequisite for evaluation in requests for licences and permits, and their respective validity shall be conditional on compliance, which shall be subject to inspection.

**f)** Make available to the worker occupationally exposed to ionizing radiation information on the annual dose values, including, if applicable, their integrated value, if he/she works in more than one institution exposed to ionizing radiation. If the worker performs duties in more than one institution exposed to ionizing radiation, the integrated value shall be made available.

**g)** Classify the types of authorisations required for each of the listed activities subject to authorisation.

**h)** Establish a national inventory that records the types of sources and equipment that generate ionizing radiation.

**i)** To monitor, through inspections previously instructed by the Radiation and Nuclear Regulatory Authority (ARRN), compliance with the regulations established in the present law, its regulations and in the international conventions ratified by the Republic of Paraguay, of any activity that might involve ionizing radiation.

**j)** To impose sanctions in case of infringements to the provisions of the present law, its regulations in force or other laws of which the Radiation and Nuclear Regulatory Authority (ARRN) is the enforcement authority.

**k)** To regulate and control compliance with the services provided by third parties related to the application of ionizing, nuclear or nuclear-electric radiation.

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**m)** To monitor and control the management and safe storage of disused radioactive sources and of any radioactive waste that might be generated as a result of the different authorised practices.

**n)** Require those who practice with radioactive materials to take out sufficient insurance to cover the safe management of radioactive waste and disused sealed sources, as well as any damage that may be caused to people and the environment.

**(ii)** With the prior approval of the Ministry of Foreign Affairs, to enter into agreements with regulatory bodies of other countries and related international organizations for the purpose of transferring technology or know-how in the form of multilateral or bilateral cooperation.

**o)** Promote and ensure compliance with the specifications established in national and international regulations approved and ratified by the Republic of Paraguay.

**p)** Establish appropriate mechanisms to inform the public and users of the regulatory framework and mandatory safety measures to be implemented in the event of radioactive exposures regulated by the Radiation and Nuclear Regulatory Authority (RNRA).

**q)** Authorize the import, export and transport of radioactive sources or equipment generating long-lasting radiations in accordance with the regulations in force.

**r)** To provide technical assistance and carry out the necessary inspections in cases of radiological and nuclear emergencies.

**s)** To be the official liaison and focal point for relations with the International Atomic Energy Agency (IAEA); the International Nuclear Information System (INIS); the Regional Nuclear Information Network (RRIN); and other international organizations and national regulatory authorities in the area of its competence.

**t)** It is a partner in regulatory infrastructure projects supported by the International Atomic Energy Agency (IAEA) or by other national or international institutions.

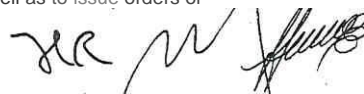
**u)** To advise the Executive Power on matters within its competence and other governmental authorities and organizations on matters within the competence of the Radiological and Nuclear Regulatory Authority (ARRN) and, in particular, the Executive Power on matters concerning the International Conventions to which the State is a party and also on safeguards agreements.

**v)** To promote and carry out research on ionizing, nuclear or nuclear-electric radiation safety matters and to adapt existing regulations to the technological advances made by States with a longer tradition in this field.

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

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

**y)** Promote civil and criminal actions before the competent courts against subjects who fail to comply with licenses; permits or avoid submitting to the licensing process, in accordance with the provisions of this law and its regulations; as well as to issue orders of



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The Committee may also request the assistance of the public forces when necessary for the proper exercise of the powers granted by this Act.

z) Guarantee the confidentiality of the restricted information brought to its knowledge, in order to ensure the due protection of technological, commercial or industrial secrets and the adequate application of physical protection measures.

(aa) Require the preparation of the Environmental Impact Statement issued by the Secretary of the Environment as a mandatory prerequisite for the granting of permits or authorizations for all activities that generate ionizing radiation, and others identified in the regulations that could have significant environmental effects.

(bb) To submit to the Executive Branch periodic technical reports containing recommendations on necessary or advisable measures to be adopted in the public interest.

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

(dd) To issue well-founded and timely recommendations to the Executive Branch regarding the possible impact of any activity involving the use of materials that could generate ionizing radiation, including those of nuclear or nuclear-electric origin, carried out or to be carried out in the territory of foreign countries, whose actions could generate transboundary effects.

(ee) To establish mechanisms aimed at preventing illicit trafficking in radioactive materials and, in particular, to sign cooperation agreements with the National Customs Directorate that will allow access to timely controls on the identification of radioactive sources entering the country and enable compliance with regulatory obligations to be verified.

ff) Evaluate: manage and measure the risks and potential risks generated by ionizing radiation, including those of nuclear or nuclear-electrical origin.

(gg) to take any other action aimed at giving effect to the purposes of this Act

Article 9°.- Any person authorized to carry out any activity?

a) He/she shall have primary responsibility for the physical safety and technological security of the activity or practice. -He/she shall have primary responsibility for the safety and technological performance of the activity or practice, including the management of radioactive waste and for ensuring compliance with this Code and all applicable regulations relating to such activity or practice. The following shall apply to such activity or practice

b) It shall be responsible for ensuring that adequate arrangements are made for the safe and ultimate disposal of radioactive waste, including sealed radioactive residues produced in that activity or practice.

c) It shall be responsible for ensuring that appropriate measures are taken to dismantle in a safe manner, both from the viability and safety point of view, any facility in which the activity is already practised or can be carried out.

Article 10.- The Nuclear and Radio Regulatory Authority (ARRN), through its duly accredited inspectors, shall have access to verify any activity that could be a radioactive source or uses radioactive equipment or sources, in order to determine if it is a radioactive source or uses radioactive equipment or sources, with the purpose of obtaining information about the radiation level and safety level of the installation and to verify the

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Article 11.- The Radiation and Nuclear Regulatory Authority (ARRN) shall establish permanent mechanisms for coordinated management with other authorities such as: the Authorities of the National Customs Directorate; the Ministry of Public Health and Social Welfare; the Secretariat of the Environment, the National University and other institutions that have authority and competence or functions over products, services, facilities or activities that could be of use to the Radiation and Nuclear Regulatory Authority (ARRN) with respect to its regulatory and control functions.

**Chapter III  
Organizational Structure**

Article 12.- The Radiation and Nuclear Regulatory Authority (ARRN) shall be managed by a Board of Directors composed of five Members: an Executive Secretary and four Directors. In the event of vacancy of the Executive Secretary or temporary absence of the Executive Secretary without delegation of office, the Directors shall appoint an acting Executive Secretary. The Executive Secretary, or acting Executive Secretary, shall have a double vote in the event of a tie.

The Executive Secretary and the Directors shall receive the remuneration provided for in the annual budget of the Radiation and Nuclear Regulatory Authority (ARRN).

The Board of Directors of the Radiological and Nuclear Regulatory Authority (ARRN) shall approve the organization chart and internal regulations for the operation of the Radiological and Nuclear Regulatory Authority (ARRN), at the proposal of the Executive Secretary. They shall meet in ordinary session once a week, on the day and at the time indicated in the internal regulations, and the Executive Secretary may convene an extraordinary session as often as he/she deems convenient or necessary.

The Board of Directors shall form a quorum with the presence of three members and shall be chaired by the Executive Secretary or his substitute. Its resolutions shall be adopted by simple majority.

In case of vacancy of the Executive Secretary or temporary absence of the Executive Secretary, without delegation of the office, the Directors shall appoint an interim. The Executive Secretary, or whoever takes his place, shall have a double vote in the event of a tie. Resolutions shall be adopted by the concurring vote of at least three of its members.

The profile of the head of the Executive Secretariat and of the members of the Board of Directors shall be subject to the provisions of Article 14 of Law No. 1.626/00 "DE LA FUNCION PUBLICA", with the exception of paragraph b), in the sense that he/she shall be at least thirty five years old and at most sixty five years old. The head of the Executive Secretariat and the members of the Board of Directors of the Radiological and Nuclear Regulatory Authority (ARRN) shall have exclusive dedication, and shall be subject to the incompatibilities for public officials provided for by the legislation in force. The following may not be appointed as members of the Board of Directors of the Regulatory Authority (ARRN) who is the holder of an authorisation governed by this Act or who has a direct interest in such matter.

The Executive Secretary-President will exercise the legal representation and will be appointed by the Executive Branch and the four members of the Board of Directors will be appointed by the following institutions:

A representative of the Ministry of the Interior;  
A representative of the Ministry of Foreign Affairs;  
A representative of the Ministry of National Defense;  
and, A representative of the Secretary of the Environment.

The members of the Directorate of the Radiation and Nuclear Regulatory Authority (RNARA) shall remain in office for five years and may be appointed for up to five years.



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two terms of office. The term of office of the Executive Secretary shall coincide with that of the President of the Republic.

Article 17.- To be a member of the Board of Directors of the Radiological *and* Nuclear Regulatory Authority (ARRN), the following is required:

- a) Have Paraguayan nationality.
- b) To be a professional of great authority *and* technical *and* moral solvency in matters related to radiological *and* nuclear safety and its field of application.
- c) Not having had any particular interest in the exploration, exploitation, industrialization *and* commercialization of nuclear *and* radiological materials and supplies for five years prior to the nomination of his or her candidacy.

Article 18.- The Members of the Board of Directors shall remain in office for the following terms:

- a) Expiration of the term of appointment;
- b) Resignation submitted to the Executive Peder;
- c) Serious misconduct duly proven, after administrative summary, *and*,
- d) Death or total or relative incapacity.

Article 19.- The functions of the Board of Directors are:

- a) Apply and oversee compliance with the legal and regulatory standards governing the activity of the authority, as well as ensure compliance with international treaties signed and ratified by the Republic;
- b) To dictate the rules of operation of the Board of Directors;
- c) To deal with all matters relating to the personnel of the Authority;
- d) Cooperate with the Executive Secretary in the formulation of the annual budget and calculation of resources to be submitted, through the Executive Director, to the Honorable National Congress for its approval together with the General Budget of the Nation, including the quota as a member state of the International Atomic Energy Agency (IAEA); *and*,
- e) In general, any other action aimed at the better performance of its functions *and* the purposes of this Act *and* its implementing regulations.

### Chapter IV Assets and Sources of Resources

The following State institution shall become part of the Radiological and Nuclear Regulatory Authority (ARRN):

- From the Ministry of Public Health and Social Welfare:

(a) The Radiation Protection Department; *and*,

b) The J.c ldf (the ; #a

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Article 21.- The department mentioned in the preceding article shall transfer its assets to the Radiological and Nuclear Regulatory Authority (ARRN), for all the corresponding legal and patrimonial effects. The active assets shall be transferred by the aforementioned departments, after the intervention of the General Comptroller of the Republic, the Department of Fiscal Patrimony of the Ministry of Finance and the Office of the Chief Clerk of the Government, within ninety days from the promulgation of the present law.

For the purpose of determining the active assets of each department, an inventory shall be made of the capital assets acquired in the framework of the execution of the General Budget of the Nation, at least as of the last three years prior to the enactment of this law.

Article 22.- The assets and resources of the Radiation and Nuclear Regulatory Authority (ARRN) shall constitute its patrimony and shall be its source of resources:

- a) Amounts received from the application of fees and the imposition of fines;
- b) Subsidies; inheritances; legacies; donations and transfers received in any form;
- c) The profits resulting from the management of its own funds;
- d) The funds provided for in the General Budget of the Nation; and,
- e) Such other funds, property or resources as may be allocated to it by virtue of applicable laws and regulations.

Capitulo V  
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Article 23. - The Radiological and Nuclear Regulatory Authority (ARRN) may fix fees and collect charges and other services related to the activities regulated by the laws of which it is the Authority of Application.

Article 24.- The Radiological and Nuclear Regulatory Authority (ARRN) shall establish the schedule of fees and other services related to the activities regulated in the laws within its competence; and shall determine the mechanisms for transferring these resources to special ARRN accounts. The fee shall be established by the Executive Power.

The Radiation and Nuclear Regulatory Authority (ARRN) shall publish annually the table of values of fees, rates and other services rendered, which may be adjusted in accordance with the variation of the Consumer Price Index published by the Central Bank of Paraguay.

Article 26 - The Radiological and Nuclear Regulatory Authority (ARRN) may, by means of a well-founded resolution, exceptionally exempt the payment of fees, rates and other services, in view of the social purpose of the project, work, activity or its public convenience.

Chapter VI  
Infracciones and penalties

Article 27.- The Radiological and Nuclear Regulatory Authority (ARRN) shall establish by regulation the conducts that shall constitute infringements to the laws and regulations of which it is the Authority of Application, within the framework of its competences and attributions, and shall classify them according to the seriousness of the damage that they could represent on the health of living beings, the  
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**Article 28.-** The Argentine Radiation and Nuclear Regulatory Authority (ARRN) is empowered to apply sanctions in case of proven infringements or transgressions to the laws and regulations of which it is the Authority of Application.

**Article 29.-** Any sanction shall be applied, prior compliance with the procedures established for this purpose by the Radiation and Nuclear Regulatory Authority (ARRN), in the exercise of its powers, guaranteeing the principle of due process and respect for the guarantees established in Article 17 of the National Constitution.

**Article 30.-** The penalties shall be graduated according to the seriousness of the infraction and the present or potential damage generated and shall consist of:

- a) The imposition of fines, whose maximum amount shall be thirty thousand minimum wages for various unspecified activities, and shall be determined proportionally to the severity of the infraction and according to the seriousness of the damage produced and potential.
- b) the suspension of an authorisation, licence, registration or permit, or its definitive revocation.
- c) The confiscation of nuclear or radioactive materials.
- d) The preventive or definitive closure of facilities subject to the regulation of the Radiation and Nuclear Regulatory Authority (ARRN), when they are operated without due authorisation or in the event of the detection of serious breaches of the regulations and standards for radiation and nuclear safety and the protection of personnel and facilities.
- e) Warning.
- f) Penalties may be imposed cumulatively, where appropriate.

### Chapter VII Final and Transitional Provisions

**Article 31.-** The budgetary balances relating to programmes and sub-programmes approved by the General Budget Law of the Nation for the fiscal year of the year in which the present law is enacted and the budget of the National Atomic Energy Commission and the departments of the Ministry of Public Health and Social Welfare indicated in Article 31, The budgetary balances of the National Atomic Energy Commission and of the departments of the Ministry of Public Health and Social Welfare indicated in article 20 of the present law, shall become part of the initial budget of the Radiological and Nuclear Regulatory Authority (ARRN), for its execution.

**Article 32.-** The personnel of each of the divisions indicated in Article 20 of the present law, which at the date of its promulgation is part of the Personnel Annex, shall become part of the initial payroll of the Radiological and Nuclear Regulatory Authority (ARRN) and shall enjoy the same privileges as regards seniority and retirement regime. The personnel linked under the contractual linkage regime for a specific position shall also become part of the Radiological and Nuclear Regulatory Authority (ARRN), as long as they are affected by the budget of the succeeding departments.

**Article 33.-** All provisions contrary to the present law are hereby repealed and specifically:

- a) Articles 2, subparagraphs g), h), i) and k); and 6 of Law No. 1.081/6 5 "Q UE CR EA LA

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b) Article 2, paragraphs g), i), j), k), l) of Law No. 140/91 "APPROVING WITH AMENDMENTS DECREE-LAW No. 11 OF FEBRUARY 15, 1990, AMENDING ARTICLES 2 AND 3 OF LAW No. 1.081 OF AUGUST 30, 1965 "CREATING THE NATIONAL COMMISSION ON ATOMIC ENERGY".

c) Articles 246, 247 and 248 of Law N° 836/80 "C6 SANITARY DICO".

Article 34.- The National Atomic Energy Commission (CNEA) of the National University of Asuncion shall retain the functions of promoting the peaceful use of nuclear technology, of training specialized human resources, of research on the subject regulated by the present law and shall continue to provide services within the scope of its competence, exercised within the scope of the functions of the National Atomic Energy Commission (CNEA).

The National Atomic Energy Commission (CNEA) shall cooperate with and assist the Radiological and Nuclear Regulatory Authority (ARRN) in the steps required for the fulfilment of its purposes.

Article 35.- The Executive Branch shall regulate the present law within one hundred and eighty days of its promulgation.

Article 36.- Communicate to the Executive Power.

Approved the Draft Law, promulgable the month of December of the year two thousand and the tenth day of the month of December of the year two thousand and sixteen, of the month of April of the year two thousand and sixteen, in accordance with the provisions of article 2 of the Constitution of the Republic of Paraguay.

Juan Bartolomé Ramírez Brizuela
Presidente
H. Cámara de Diputados

Juho César Velázquez Tilleria
Presidente
H. Cámara de Senadores

Hugo L. ...
Parliamentary Secretary

Patricia Alfaro de Franco
Secretaria Parlamentaria

Asuncion, 7 May 2014.

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Minister of National Defense

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