



Republic of Cuba

Convention on Nuclear Safety

First National Report

2019

LISTS OF ABBREVIATIONS AND ACRONYMS

ADASIR	Sistema de Análisis, Diseminación y Aprendizaje de Sucesos e Incidentes Radiológicos (System for Analysis, Dissemination of, and Learning from, Radiological Events and Incidents)
AENTA	Agencia de Energía Nuclear y Tecnologías de Avanzada (Nuclear Energy and Advanced Technologies Agency)
CEAC	Comisión de Energía Atómica de Cuba (Atomic Energy Commission of Cuba)
CEADEN	Centro de Aplicaciones Tecnológicas y Desarrollo Nuclear (Centre for Technologic Applications and Nuclear Development)
CEN	Central Electronuclear (Nuclear Power Plant)
CIAC	Centro de Ingeniería Ambiental de Camagüey (Centre for Environmental Engineering of Camagüey)
CISAT	Centro de Investigaciones y Servicios Ambientales de Holguín (Centre for Environmental Research and Services of Holguín)
CITMA	Ministerio de Ciencia Tecnología y Medio Ambiente (Ministry of Science, Technology and Environment)
CNSN	Centro Nacional de Seguridad Nuclear (National Centre for Nuclear Safety)
CPHR	Centro de Protección e Higiene de las Radiaciones (Center for Radiation Protection and Hygiene)
DSN	Dirección de Seguridad Nuclear (Division of Nuclear Safety)
EIA	Evaluación de Impacto Ambiental (Environmental Impact Assessment)
EMNDC	Estado Mayor Nacional de la Defensa Civil (Civil-Defence Joint Chiefs of Staff)
FORO	Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares (Ibero-American Forum of Nuclear and Radiological Regulatory Agencies)
IEP	Inspector Estatal Principal (Senior State Inspector)
MINCEX	Ministerio de Comercio Exterior y la Inversión Extranjera (Ministry of Foreign Trade and Investment)
MINSAP	Ministerio de Salud Pública (Ministry of Public Health)
NBSR	Joint Resolution CITMA-MINSAP, Regulation; "Radiological Basic Safety Standards", of November 30 th , 2001, published in Gaceta Oficial Ordinaria No. 1, of January 4 th , 2002
OACE	Organismos de la Administración Central del Estado (Bodies of the Central Administration of the State)
IAEA	International Atomic Energy Agency
ORASEN	Oficina de Regulación Ambiental y Seguridad Nuclear (Office for Environmental and Nuclear Safety Regulation)
ORSA	Oficina de Regulación y Seguridad Ambiental (Office for Environmental Regulation and Safety)
SEAN	Secretaría Ejecutiva para Asuntos Nucleares (Executive Secretariat for Nuclear Affairs)
SG	Sistema de Gestión (Management System)
SNCCMN	Sistema Nacional de Contabilidad y Control de los Materiales Nucleares (State System for Accounting for and Control of Nuclear Materials)

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A. INTRODUCTION

General

This is the first National Report of the Republic of Cuba to be evaluated at the 8th Review Meeting of the Contracting Parties of the Convention on Nuclear Safety (CNS), from here on; the Convention. This report was drafted in accordance with the Guidelines regarding National Reports under the Convention on Nuclear Safety (INFCIRC/572/Rev.6 of January 19th, 2018).

This National Report has been prepared by the Division of Nuclear Safety (DSN) of the Office for Environmental Regulation and Safety (ORSA); the National Regulatory Authority in radiological and nuclear safety, amongst other matters, attached to the Ministry of Science, Technology and Environment (CITMA).

The uses and applications of nuclear energy begin in Cuba in the 1940's, with the use of radioactive sources in the medical practice, these had their juridical and institutional expression through Decree No. 4054, in 1947, which created the National Commission for Application of Atomic Energy to Civil Uses having the main goal of promoting the use of nuclear energy in the national territory, impelling investigations in the fields of health care. This Commission was dissolved in 1955, giving pass to the Commission of Nuclear Energy of Cuba, with similar goals, but adding the possibility for installing reactors in the country and for the control and inspection of these activities.

Nonetheless, the most feasible steps towards assimilation of nuclear science and technology in Cuba were taken after 1959. The National Commission for Peaceful Uses of Atomic Energy was created in 1974, later called Commission of Atomic Energy of Cuba (CEAC), by issuance of Decree No. 52 of October 24th, 1979, this Commission had the duties of coordinating and controlling the national efforts by the Bodies involved in these fields, as well as of advising the Government on the related policies to adopt. The Executive Secretariat for Nuclear Affairs (SEAN) was created under the umbrella of this Decree, aimed at supporting the functions of the Commission, implementing the defined policies.

In the following years there was progress in the implementation of nuclear technologies, and a set of juridical norms were issued in accordance with the development and perspectives of the Cuban Nuclear Programme, which had its peak with the start of the construction of the *Juraguá* Nuclear Power Plant Project in 1982. This Project was sited in *Abreus* Municipality, *Cienfuegos* Province, by the Centre – South of the Island of Cuba, on the littoral to the Caribbean Sea, 220 Km to the South-East of Havana City, and 8 Km to the North-West of Cienfuegos City. There was also a project for construction of a Nuclear Research Centre that would involve a research reactor.

Installation of two energy blocks, with common auxiliary buildings, was foreseen for *Juraguá* NPP, at least, in a first stage. Each block with a power generation of 417 MWe. Each unit would be provided with a pressurized water reactor WWER-440 / B-318, and two turbo-generators type K-210-44/3600, of Soviet design and manufacture.

Decree-law No. 56 "For the Regulation of the Peaceful Uses of Nuclear Energy", entered into force in 1982, among other aspects established:

- a) The definition of the activities subject to License (for realization of any act of import,

procurement, use, operation, processing, transport, transfer, evacuation, storage or export of radioactive substances or other sources of ionizing radiations and of nuclear materials) and the general conditions for granting the License.

- b) The institutions and the mechanisms for regulation and control of the activities involving the peaceful uses of nuclear energy (System of Regulatory Measures):
 - ✓ State System for Accounting for and Control of Nuclear Materials.
 - ✓ System of Physical Protection of the Nuclear Materials, Radioactive Substances and other Sources of Ionizing Radiations.
 - ✓ System for the Safety of Nuclear Facilities.
 - ✓ National System for Radiation Protection.
- c) The administrative measures in case of infractions of licenses' conditions.
 - ✓ Suspension of the license for a term of up to 6 months.
 - ✓ Revocation of the license.

From the beginnings of the Cuban nuclear programme a special attention was placed on the aspects related to safety. On the establishment of a technical and organizational infrastructure, as well as on personnel's preparation for their involvement in the safety topics of the nuclear facilities. From the entry into force of Decree-law No.56, other juridical norms were issued, allowing development and implementation of a legal framework for the nuclear field in the country, such as:

- a) Decree No. 137 "Rules for the safe transport of radioactive substances", of March 10th, 1987.
- b) Joint Resolution CEAC-MINSAP, "Rules for the medical surveillance of workers occupationally exposed", of May 4th, 1987.
- c) Decree-law No.98 "On the State Supervision of the Safety at Nuclear Facilities, of December 11th, 1987.
- d) Decree No. 142 "Rules for work with radioactive substances and other sources of ionizing radiations", of April 30th, 1988.

In particular, Decree-law No. 98 generated a significant change in the system of state inspection in the country, when creating a System for State Supervision of the Nuclear Facilities, comprising several spheres of the state supervision that included the involvement of State Bodies and Organisms with the following competences:

- a) SEAN, on nuclear safety and radiation protection matters;
- b) State Committee for Labour and Social Welfare, on *technical safety* matters;
- c) Ministry of Construction, on civil construction matters;
- d) Ministry of the Interior, on physical protection and prevention and extinction of fires, and
- e) Ministry of Public Health, on matters of hygienic-sanitary inspection.

For each sphere of the state supervision it was resolved to designate, by the Council of Ministries, a Senior State Inspector (IEP), as the maximum authority in the sphere of their competences, in charge of directing the group of state inspectors appointed by each one of the organisms. Among

the attributions of the IEP the following were established:

- a) suspend or withdraw specific authorizations and permits granted, when it is considered that safety measures and requirements are not being complied with;
- b) establish the order and scope of the inspection works on systems, equipment and components subject to state supervision;
- c) grant permits for installation, operation, repair and maintenance of systems, equipment and components of the nuclear facilities under state supervision, and when appropriate, delegate this attribution to the state inspectors in their respective fields of competence.

This Decree-law assigned SEAN the responsibility of organizing, coordinating and controlling the work of these Bodies. For discharging this responsibility, SEAN created the Council of Organs of State Supervision, which had, among other, the functions of planning and methodological direction of the work of state supervision, the approval of the drafts of safety regulations and the evaluation of the actions to take with the entities subject to state supervision.

As a consequence of the development of the state supervision and of the nuclear activity in Cuba, there was a need for having an independent Centre, competent in nuclear safety. Therefore, on November 30th, 1990, by means of SEAN's Resolution No. 27, the National Centre for Nuclear Safety was created, in order to assist the activities of the state supervision and the evaluation of the safety conditions at nuclear facilities; as the entity in charge with the regulation and control of the use of nuclear energy in the country.

In 1992, under the economic difficulties of the country, the construction of the NPP was temporarily shut down, and in 1993, based on the provisions issued by the regulatory body the operating organization elaborated the 'Integral Work Plan for the Stage of Temporary Shutdown', where in the following general aspects were contemplated:

- a) Ensure preservation of the works, in a way such that allowed resumption, if the economic conditions turned up allowing this, in a feasible term.
- b) Corroborate the safety level of Juraguá NPP, by conducting safety evaluations.

The Integral Work Plan for the stage of Temporary Shutdown ended up completed in its entirety, and it was subjected to systematic verifications on the part of the regulatory body.

In 1994, by means of Decree-law No.147 "On the reorganization of the Bodies of the Central Administration of the State", the Ministry of Science, Technology and Environment (CITMA), was created, and the institutions in charge of the nuclear field in the country, SEAN and CEAC, were ascribed to CITMA, which since then is the organism in charge of directing, executing and controlling the policies of the State and of the Government in connection with the use of the nuclear energy.

By the mid 90's, the regulatory body, besides assuming its duties; began a programme of improvements with a view to perfecting its functions, maintaining its technical capacities and upgrading the legal and regulatory framework, taking into account the lessons learned in the nuclear field, the structural changes, the new conditions in the country as well as the new technical concepts and the international recommendations, which turned out in the development of the legal framework in force.

In 2002 the projects of construction of the NPP and of the Centre of Nuclear Research were shut down, therefore, since then, the use of nuclear technologies in Cuba is associated to the applications of ionizing radiations in industry, medicine, education and investigations. There are not facilities associated with nuclear fuel cycle, only a Subcritical Assembly having 160 fuel elements of Natural Uranium with an enrichment of 0.72%, moderated by light water, which is used with educational purposes.

B. SUMMARY

This is the first national report submitted by the Republic of Cuba for examination by the Parties of the Convention on Nuclear Safety, therefore, there is no need to present up-to-date "information on the questions that have evolved from the previous" national report, as provided in the informative Circular INFCIRC/572/Rev.6 "Guidelines regarding National Reports under the Convention on Nuclear Safety".

C. REPORTING ARTICLE BY ARTICLE

Article 7: Legislative and regulatory framework.

Article 7 1) Establishing and maintaining a legislative and regulatory framework.

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

Decree-law No. 207 "On the Use of the Nuclear Energy" [1] dictated by the Council of State, February 14th, 2000, is the fundamental norm with regard to nuclear safety in Cuba. This Decree-law repealed most of the legal norms referred to nuclear matters that were passed in the 80's and establishes the general precepts that regulate the use of nuclear energy in the country, embracing the following aspects:

- a) Objectives, Scope and Principles
- b) Institutional Framework
- c) Authorizations for the use of nuclear energy
- d) Inspections
- e) Radioactive Ores
- f) Accounting and Control of nuclear materials
- g) Radioactive wastes management

The scope of application of this legal norm, established in its Article 2, includes all the possible subjects, and defines the group of activities involving the use of the nuclear energy, including nuclear facilities, because when putting in force this legal norm, the construction projects of Juraguá NPP, and of the Centre of Nuclear Research, had not yet been shut down.

Therefore, the Decree-law provides on the whole scope of activities susceptible of control, including:

- a) design, production, imports, exports, distribution, sales, reception, possession, use, exploitation, maintenance, repair, transfer, disassembly, transportation, storage and evacuation of sources of ionizing radiations, as well as any activity where these intervene;
- b) siting, design, construction, commissioning, operation, and decommissioning; of nuclear and radioactive facilities

c) radioactive wastes management

Article 3 establishes the general principles that govern the use of nuclear energy in Cuba, most of them constitute the basis of the relevant legal framework, among these principles the following stand out:

- a) nuclear energy is used for peaceful goals in benefit of the economic and social development of the country;
- b) social and economic benefits derived from the use of the nuclear energy are subordinate to the protection of life, health, goods and of the environment;
- c) for the execution of activities related with the use of the nuclear energy authorizations are required;
- d) the use of the nuclear energy is based on fulfilment with the basic principles of radiological protection;
- e) the necessary safety measures are established in order to ensure protection of the life, health, goods and of the environment and their implementation is mandatory with upmost priority, over the social and economic benefits;
- f) the activities related with the use of the nuclear energy have quality assurance systems for their realization;
- g) the use of the nuclear energy shall be accompanied by the necessary information to the public on its possibilities, benefits, risks and safety measures, including the introduction of its theoretical and practical foundations in the programmes of the National System of Education.

The Institutional Framework defined in the Chapter II, establishes the functions of the Ministry of Science, Technology and Environment (CITMA), as the Body of the State in charge of:

- a) Directing, executing and controlling the Policy of the State and Government in connection with the use of nuclear energy.
- b) Regulating and controlling; the use of nuclear energy; and the nuclear safeguards through the National Centre for Nuclear Safety (CNSN) (currently; Division of Nuclear Safety).
- c) Promoting the use of the nuclear energy through its Agency of Nuclear Energy (currently; Nuclear Energy and Advanced Technologies Agency).
- d) Supervising the regulation and control activities realized by the Ministry of Public Health (MINSAP).

CITMA, as the Ruling Organism in the nuclear field has duties of promotion of the use of the nuclear energy, as well as duties for its regulation and control, therefore, the respective, separate, entities that would discharge those different duties were directly appointed, in a way such that the decisions in safety matters (by CNSN; currently DSN) would be free from undue interference from the entities appointed for promotion and development of nuclear energy (Agency of Nuclear Energy, currently; Nuclear Energy and Advanced Technologies Agency), that is a precept, through Article 5, in the following way: *The regulation and control activities realized by CNSN (currently DSN) shall have effective autonomy and independence from those related with the promotion and development of nuclear energy, CNSN (currently DSN) shall be provided with enough economic and human resources for the exercise of its functions.*

Chapters III and IV of this Decree-law 207 establish the general aspects referred to the authorizations for the use of the nuclear energy and to the authorizations for personnel, respectively.

Chapter III, under the principle enunciated in Article 3, relative to authorization prerequisite prior to conducting activities involving the use of the nuclear energy, gathers, in its Second Section, the applicants' and license holders' obligations and responsibilities. These are detailed in this Report in the section on the fulfilment with the provisions of Article 9.

The Third Section and last one of Chapter II, denominated "On the suspension and revocation" (Articles 19 to 21), establishes the general precepts referred to these administrative sanctions. In this regard, Article 19 defines a usual cause for suspension and revocation of authorizations (if the holder incurs in behaviours that affect fulfilment with the established safety requirements).

Article 20 refers to distinctive features of both, given by the period of execution and their effects in time, which in the event of suspension are temporary (it is possible to re-establish validity the authorization suspended, if the holder demonstrates that the violations that led to the suspension have been corrected), and in the event of revocation; suspension is definitive (in order to resume works, the holder must complete all the formalities and demands required to the effects of the application for a new authorization, again).

Chapter IV dedicated to the authorizations to personnel, establishes the requirement for authorization to personnel; involved in tasks that have a direct impact on safety, during the conduction of activities involving the use of nuclear energy; aimed at the acknowledgment of the psychophysical fitness, the educational level, the experience, and the practical knowledge and skills required for appropriate fulfilment of the responsibilities and duties inherent to their job position.

Chapter V, "On Inspections", establishes basic aspects such as: authorities empowered, objectives of inspections, obligations of the inspected subject, state inspectors' accreditation by CITMA, and inspectors' obligations. These precepts regulate the essential elements that govern all the systems of state inspection in Cuba, specifying the relative particularities to the nuclear field. As a distinctive aspect stands out the stated in Article 29, referred to the empowerment of the state inspectors in this field for transacting, ordering or executing one or several measures, in the event violations are detected, with a potential for leading to situations of danger or imminent risk to life, health, goods and to the environment.

Chapter VI, "On Radioactive Ores", requires coordination between the extinct Ministry of Basic Industry, today Ministry of Energy and Mines and CITMA for regulation and control the mining activity, in connection with the radioactive ores, as well as for the rational use of these, supplementing the precepts established in Law No.76, "Law of Mines", of December 20th, 1994, taking into account that in its Article 2nd makes reference to more specific legislation as for the regulation of the radioactive ores.

Chapter VII "On accounting and control of nuclear materials" (Articles 35 to 37), establishes the general precepts referred to the State System for Accounting for and Control of Nuclear Materials (SNCCMN), in line with the international commitments assumed by the Cuban State with regard to nuclear safeguards.

Chapter VIII "On the management of radioactive wastes and spent fuel" is based on the main provisions of the international instrument on the subject, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management even when Cuba was not a Contracting Party at the time of issuance of the Decree-law.

Article 38 establishes the definition of radioactive waste management specifying the content and scope of this term, which includes the set of managerial and operational activities involving, manipulation, previous treatment, treatment, conditioning, transportation, storage and disposal of radioactive wastes, and Article 39 establishes that such activities shall be carried out in a way such:

- a) to ensure protection of the human health and of the environment;
- b) that the repercussions foreseen for the future generations are not worse than those acceptable at present;
- c) that undue burden is not posed on future generations; and
- d) that the possible effects on human health and on the environment beyond the national borders are not worse than those acceptable in the country.

Other aspects such as the responsibility for the management of radioactive wastes and of spent fuel, as well as for prevision of related financial resources are established in Articles 41 and 42; since it is a responsibility, of the license holders, to manage the radioactive wastes and the spent fuel generated as a result of their activities, as well as to foresee, from the very beginning, the financial resources that would be needed for covering the costs of such management.

Decree-law No.186/1998 "On the Security Systems", of June 17th, 1998 [2], establishes the Competent Authority in the country with regard to Security and Physical Protection, in its Article 3 establishes that the State exercises the regulatory, inspection and control functions through the Ministry of the Interior. Also, Article 40 defines the scope of the System of Security and Protection, which includes the protective measures against fires and the physical protection of the radioactive substances and other sources of ionizing radiations.

Law No. 62, Penal Code of Cuba, of December 29th, 1987 [3], foresees the behaviours constitutive of crime with regard to these topics, in its Title III. Crimes against the collective security, in Chapter IV, Infraction of the relevant norms applicable in the use and safekeeping of radioactive substances and other sources of ionizing radiation – in Articles 185 and 186 -; and consequently the Law establishes sanctions to the effect.

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

The Republic of Cuba is a Contracting Party of all the international juridical instruments referred to nuclear safety, as shown below:

- a) Convention on Early Notification of a Nuclear Accident. Ratification; January 8th, 1991.
- b) Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. Ratification; January 8th, 1991.
- c) Convention on Nuclear Safety. Signed: September 20th, 1994. Ratification; July 3rd 2017.
- d) Joint Convention on the Safe Management of Spent Fuel and on the Safe Management of Radioactive Wastes. Adhesion; July 3rd, 2017.

Cuba expressed commitment for adoption of; the Code of Conduct on Safety and Security of radioactive sources; of the supplementary Guidelines on Import and Export of radioactive sources and; of the Orientations on the management of disused radioactive sources.

Article 7 2) i) National safety requirements and regulations

Overview of the secondary legislation for nuclear safety (ordinances, decrees, etc.).

In accordance with the general principles and provisions established in Decree-law No. 207 "On the Use of the Nuclear Energy", the complementary legislation on nuclear safety has been passed.

Among these complementary norms stand out a group of regulations on safety approved by CITMA or together with other competent organisms, like MINSAP, which regulate in a specific way the activities, behaviours and processes associated to the safe and peaceful use of nuclear energy in Cuba, in consonance with the good international practices and recommendations, referred to the following topics:

- a) Safe transport of radioactive material. (*Resolución No. 121 /2000 del CITMA, "Reglamento para el transporte Seguro de Materiales Radiactivos", de 14 de diciembre del 2000*) [4]. (Resolution No. 121/2000 by CITMA; "Rules for the safe transport of radioactive materials" of December 14th, 2000, published in Gaceta Oficial Ordinaria No. 93, of December 15th, 2000).
- b) Accounting and control of nuclear material. (*Resolución No. 62/96 del CITMA, "Reglamento para la contabilidad y control de los materiales nucleares", de fecha 12 de julio de 1996*) [5]. (Resolution No. 62/96 by CITMA; "Rules for accounting and control of nuclear materials", of July 12th, 1996).
- c) Basic radiation safety standards. (*Resolución Conjunta CITMA-MINSAP Reglamento, "Normas Básicas de Seguridad Radiológica", de 30 de noviembre de 2001*) [6]. (Joint Resolution CITMA-MINSAP, Regulation; "Radiological Basic Safety Standards", of November 30th, 2001, published in Gaceta Oficial Ordinaria No. 1, of January 4th, 2002).
- d) Management of radioactive waste. (*Resolución No. 35/2003 del CITMA, "Reglamento para la gestión segura de desechos radiactivos", de 7 de marzo de 2003*) [7]. (Resolution No. 35/2003 by CITMA, Rules "For the safe management of radioactive wastes", of March 7th, 2003, published in Gaceta Oficial Ordinaria No. 20, of March 10th, 2003).
- e) Selection, training and authorization of personnel involved in practices with ionizing radiation sources. (*Resolución Conjunta CITMA-MINSAP "Reglamento para la selección, capacitación y autorización del personal que realiza prácticas asociadas al empleo de las radiaciones ionizantes" de 19 de diciembre de 2003*) [8]. (Joint Resolution CITMA-MINSAP, "Rules for selection, training and authorization of personnel involved in practices using ionizing radiations", of December 19th, 2003, published in Gaceta Oficial Ordinaria No. 13, of March 24th, 2004).
- f) Competence of radiation protection service providers. (*Resolución No. 6/2004 del CITMA, "Reglamento para el reconocimiento de la competencia de los servicios para la seguridad radiológica", de 13 de enero de 2004*) [9]. (Resolution No. 6/2004 by CITMA, "Rules for recognition of competence of services in radiological safety", of January 13th, 2004, published in Gaceta Oficial Ordinaria No. 22, of April 23rd, 2004).
- g) Inspection. (*Resolución No. 103/2008 del CITMA, "Reglamento de la Inspección Estatal de la Actividad Reguladora Ambiental" [10]*). (Resolution No. 103/2008, by CITMA; "Rules for the State Inspection in Environmental Regulatory Matters", published in Gaceta Oficial Ordinaria No.41, of July 2nd, 2008).

- h) Notification and authorization of practices and activities. (Resolución No. 334/2011 del CITMA, "Reglamento sobre Notificación y Autorización de prácticas y actividades asociadas al Empleo de Fuentes de Radiaciones Ionizantes", de 29 de diciembre de 2011) [11]. (Resolution No. 334/2011, by CITMA, "Rules for Notification and Authorization of practices and activities involving the use of sources of ionizing radiations", of December 29th, 2011, published in Gaceta Oficial Ordinaria No. 11, of March 28th, 2011).

In addition to the Rules already mentioned, other legal provisions have been passed, establishing the regulatory position of the country, sustained in all cases by safety principles and fundamentals, such as:

- a) Joint Resolution CITMA - MINCEX, of April 29th, 2002; which establishes the obligation for radiological control during exports and imports, or use of scrap metal, or in the national territory; and
- b) Resolution No. 58/2003 by CITMA, of April 15th, 2003, which prohibited import, procurement and installation of new radioactive lightning rods in the country, and established a 10-year term (until 2013) for dismantling and substitution of these radioactive lightning rods for conventional lightning rods.

Overview of regulations and guides issued by the regulatory body.

The regulatory body passes dispositions and Guides (mandatory and recommendatory) that supplement the technical and procedural requirements established in the Rules, in order to facilitate their implementation by the users. At present 14 Guides and a disposition are in force, as shown below:

- a) Resolution No. 2/2004 by CNSN "Guide for implementation of the Rules for the safe transport of radioactive materials" of January 15th, 2004.
- b) Resolution No. 1/2004 by CNSN "Guide on the levels for unconditional clearance of solid materials with very low radioactive content and on discharges of liquids and gases to the environment", of January 9th, 2004.
- c) Resolution No. 40/2011 by CNSN "Safety Guide for the practice of nuclear medicine" of April 28th, 2011.
- d) Resolution No. 41/2011 by CNSN "Safety Guide for the practice of radiotherapy" of April 28th, 2011.
- e) Resolution No. 42/2011 by CNSN "Guide for radiological surveillance of Scrap" of April 28th, 2011.
- f) Resolution No. 18/2012 by CNSN; "Guides for preparedness and response to Radiological Emergencies", of December 26th, 2012.
- g) Resolution No. 15/2012 by CNSN "Safety Guide for the practice of Nuclear Gauges", of October 25th, 2012.
- h) Resolution No. 19/2012 by CNSN, "Guide for recognition of competence in the service of Courses on Radiological Protection", of December 26th, 2012.
- i) Resolution No. 17/2012 by CNSN "Guide on safety assessment for practices and activities associated with the use of sources of ionizing radiations" of December 24th, 2012.
- j) Resolution No. 3 /2013 by CNSN "Guide for recognition of competence in the service of Individual Radiological Surveillance".

- k) Resolution No. 4/2013 by CNSN "Safety Guide for the use of unsealed sources",
- l) Resolution No. 7/2015 by CNSN "Safety Guide for the implementation of the safety rules on the practice of industrial radiography" of December 28th, 2015.
- m) Resolution No. 3/2015 by CNSN, Guide: "Expectations of the regulatory body on the Safety Culture in Organizations that perform Activities with Sources of Ionizing Radiations", of March 16th, 2015.
- n) Resolution No. 5/2015 by CNSN, which establishes the recognition of competence of the Services of radiological surveillance at borders, carried out by the General Customs of the Republic, of October 9th, 2015.
- o) Resolution No. 6/2015 by CNSN, "Safety Guide for control of surface contamination", of December, 28th, 2015.

Since 2007, the regulatory body adopted a Policy for the establishment of the legal and regulatory framework, for the use of nuclear energy and began to develop the "Strategy for preparation, revision and modification of regulatory documents in the nuclear field" which is revised and updated every 3 years and is implemented by means of an annual Plan.

This Strategy takes into account the analysis of the national and international environment, which includes: the development and future projections of the practices associated to the use of ionizing radiations in the country, the experience accumulated in the implementation of the legal and regulatory framework, the changes of structures of the State, and the national legislation, as well as the adoption of new international commitments and the new normative documents impelled by the OIEA with regard to safety and security.

The Strategy involves a Programme for its implementation that contemplates the general actions identified in each strategic cycle, what allows the annual planning of the specific tasks for the preparation, revision and modification of regulatory documents, as well as for the adoption of; the commitments derived from the International Juridical Instruments; and of Technical Norms. For these ends, according to the implementation Programme the corresponding annual plans are elaborated.

Among the actions included in the Strategy, stand out those in connection with the implementation of the legal norms in force, such as seminars, notification, and free distribution to the interested parties, as well as the systematic evaluation of the implementation status, which allows to identify the aspects that require to be modified or clarified.

The revision frequency is established in accordance with the juridical hierarchy of the document, every 10 years for documents passed by the Organisms of the State and Government, and every 5 years for documents passed by the Regulatory Body.

The regulatory body has a procedure for the preparation and revision of national regulatory documents, which establishes the circulation of the drafts to the interested parties and the conciliation of observations, with a view to their participation in this process.

The implementation of the Strategy has derived in the identification of the revision and modification of the legislation for the nuclear field, and has allowed detection of deficiencies and preparation of the modified drafts, as well as derogations needed, and the need for approval of new legal norms.

The regulatory body currently works in the preparation of modification drafts for a set of legal norms, such as:

- a) Decree-law No. 207 "On the Use of the Nuclear Energy" [1]
- b) Resolution No. 121/2000 by CITMA; "Rules for the safe transport of radioactive materials" of December 14th, 2000, in order to update it in accordance with the norm of specific safety requirements IAEA SSR-6 (Rev. 1).
- c) Joint Resolution CITMA-MINSAP, Rules; "Radiological Basic Safety Standards", of November 30th, 2001, in order to update it in accordance with the norm of general safety requirements IAEA GSR Part 3

Article 7 2) ii) System of licensing

Overview of the licensing system and processes including types of licensed activity and, where appropriate, the procedure for relicensing.

Cuba has a system for Notification and Authorization of practices and activities that involve sources of ionizing radiations, established by Resolution No. 334/2011 by CITMA, "Rules for Notification and Authorization of practices and activities involving the use of sources of ionizing radiations" of December 29th, 2011. This implies that all the practices and activities that use sources of ionizing radiations, are subject to the notification and authorization process with the Regulatory Body, in accordance with the requirements in this rules.

Different authorization modalities are established (Licenses, Registration and Permits) based on the risks associated to the sources involved in the practices and activities, and on the complexity of the operational procedures.

Under this approach, License is required for; the execution of practices involving sources of highest risks and also where the operational procedures are the most complex; also for technical service providers in connection with the sources. License is required for the stages of construction, operation and decommissioning of facilities.

The following practices are subject to License: (Article 25 of Resolution No. 334/2011 by CITMA; "Rules for Notification and Authorization of practices and activities involving the use of sources of ionizing radiations").

- a) Treatment, conditioning, long storage and disposal of radioactive wastes and disused sealed sources.
- b) Production of radioisotopes.
- c) Design and production of radioactive sources and radiation-emitting devices.
- d) Industrial and research irradiators.
- e) Industrial radiography, including radiation generating equipment and sealed radiation sources.
- f) Well logging.
- g) Mobile nuclear gauges.
- h) Fixed nuclear gauges with sources of Categories 1, 2 and 3, as defined in Annex No. 3 of

these Rules¹.

- i) Radiotherapy including teletherapy, therapy with X-rays and brachytherapy.
- j) Nuclear medicine including "in vivo" techniques and metabolic therapy.
- k) Systematic terrestrial transport of radioactive packages.
- l) Use of radioactive tracers in industry and research.
- m) Use of particle accelerators, such as; microtron, cyclotron, neutron generators, customs control devices and the like.
- n) Use of mobile X-ray equipment.
- o) Operation of subcritical assemblies.
- p) Use of ionizing radiation sources for calibration of measuring instruments.
- q) Use of sealed and unsealed sources, not specified in the previous items, that belong to Categories 1, 2 and 3, as defined in Annex No. 3 of these Rules.

Likewise, personnel are subject to the process of individual licensing, for that must comply with requirements such as: basic formation, previous experience, psychic and physical fitness, age, and the instruction and training required to discharge the duties of their job post.

Operation License and Individual License have a five-year term validity, once elapsed must be renovated to continue operation.

When changes are intended in the scope of practices already authorized, must be notified to the regulatory body, for evaluation, and if appropriate, amendments will be issued to the existing authorizations.

Under the provisions of Law No. 81 "On the Environment" [12], the new projects of nuclear power plants and other nuclear reactors, including the research facilities for production and transformation of fissile materials, and the areas and facilities for disposal of related wastes, must be subjected to Environmental Impact Assessment (EIA) process through CITMA. This process includes application for an Environmental License.

As prescribed in Resolution No. 132 /2009 by CITMA, "Rules on the Environmental Impact Assessment process" [13], all applications for Environmental License for execution of projects or activities at nuclear or radioactive facilities, or for other practices involving; the use of nuclear energy; and nuclear and radiological safety, must be submitted for evaluation by CNSN (currently DSN), which is the responsible authority for evaluating and resolving on the relevant Environmental License Applications, in the matters of its competence.

Involvement of the public and interested parties within the Contracting Party.

All the documentation referred to the EIA process is public. Likewise, for ensuring effective implementation of the EIA process, the regulatory body must implement measures, such as:

- a) The necessary measures for ensuring an appropriate flow of information for an efficient process proceeding.

¹ This Annex implements the source classification as per IAEA Safety Guide No. RS-G-1.9.

- b) Conduct environmental inspections and adopt appropriate measures against the violations detected, in conformance with the current legislation.
- c) Implement verification and monitoring mechanisms, and others, designed to systematically exercise, the environmental controls on works or activities that are in progress or in operation; the control mechanisms may include the grant of environmental licenses for specific phases or stages of the project, after proper evaluation.
- d) Measures for taking into account the interests and concerns of the population with regard to the projected work or activity, throughout the whole EIA process.

The EIA process in the case of nuclear facilities, is also governed by the specific legislation and regulations. The technical verdict of the regulatory body would prevail for granting or denying the environmental license.

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

Decree-law 207/2000 empowers the inspectors of the regulatory body to conduct inspections to license holders or applicants, to relevant contractors, and to any other party presumed to conduct activities related with the use of the nuclear energy; with the purpose of verifying that:

- a) authorization applicants and holders, as well as contractors, have the necessary competence for effective discharge of their duties;
- b) authorization conditions are complied with;
- c) the juridical, technical, or procedural safety provisions are complied with.; and
- d) there is fulfilment with the terms established for compliance with the regulatory instructions and requirements resulting from the inspections.

The particularities of the inspection process established in Resolution No. 103/2008 by CITMA, "Rules for the State Inspection in Environmental Regulatory Matters" [10].

The frequency of the planned inspections is established using a graded approach and taking into account the groups of risks that have been defined based on the danger and the risk of the sources associated to the practices and in each installation in particular.

The criteria established by the regulatory body to define the frequency of inspections are the following, to:

- a) The entities/practices of Risk Group 1 or Very High: 2 times per year.
- b) The entities/practices of Risk Group 2 or High: 1 time per year.
- c) The entities/practices of Risk Group 3 or Medium: 1 time every 2 years.
- d) The entities/practices of Risk Group 4 or Low: 1 time every 3 years.
- e) The entities/practices of Risk Group 5 or Very Low: 1 time every 4 years.
- f) The entities that systematically import radioactive material and ionizing radiation generating equipment: 1 time every 2 years. The entities that carry out these imports in a non-systematic way, would be included in the Annual Plan whenever it is determined a need for inspection.
- g) The entities that provide Technical Services to equipment with sources of ionizing radiation: 1 time every two years.
- h) The entities that provide support Services in Radiological Safety: 1 time every 3 years.

Once inspections are completed, an inspection report is issued by the regulatory body, detailing the deficiencies found, matched to the applicable legal precepts of the non-compliance, and to the remedial or corrective measures imposed, as well as to the term for their implementation.

The inspected entities, must prepare an action plan for solving the deficiencies found, indicating the violations and their corresponding remedial or corrective actions proposed, the due date for completion, and the responsible for implementation.

The results of the inspections and the fulfilment with the requirements imposed are subject to follow-up by the regulatory body.

Article 7 (2) iv) Enforcement of applicable regulations and terms of licences.

The regulatory body exercises enforcement under the provisions of the legal framework in force, which gives powers for imposing different administrative measures, commensurate with the nature, severity and transcendence of the safety infraction.

Decree-law 207/2000, establishes the general precepts for suspension and revocation of authorizations, as well as gives power to inspectors for imposing the following measures:

- a) to suspend or stop the execution of operations and activities;
- b) to secure, retain or impound radioactive sources; and
- c) to close, temporarily or partially, locals and facilities.

On the other hand, the Rules for Authorizations [11], supplement the provisions in Decree-law 207/2000, regarding the suspension and the revocation of authorizations, and establish the causals, as well as the terms and conditions for interposing the appeal resource against these measures.

Decree-law 200/99, "On the Contraventions in Environmental matters" [14], is applied when detecting contraventions involving non-compliance with inspection requirements and measures, and empowers the inspectors of the regulatory body for imposing the following administrative measures:

- a) Fines
- b) Admonitions
- c) Obligation to do what would impede continuity of the infringing behaviour.

Article 8: Regulatory Body.

Article 8 1) Establishment of the regulatory body.

Legal foundations and statute of the regulatory body.

As mentioned in the Introduction to this Report, the regulatory body was created in 1990 through Resolution No. 27 of the Executive Secretary of the SEAN, dated November 30, to address state supervision activities and the safety assessment of nuclear facilities.

It is important to highlight as background that in 1985 the Centre for Radiation Protection and Hygiene (CPHR) was created by SEAN, and there was assigned, among other functions, the state supervision of radiation safety. When the works of the Cuban Nuclear Programme, led by

the construction of the CEN, had achieved significant progress, it was decided to create the Nuclear Safety Group, which would later become a Department within this Centre, whose main function would be to organize and execute the state supervision of nuclear safety in the country.

In 1990, the advances achieved in the works at CEN, as well as the scope and dimension of the activity of the Department of Nuclear Safety, demonstrated the need to separate from the CPHR the regulatory functions of nuclear safety and to establish an independent regulatory body specifically aimed at this activity (the National Centre for Nuclear Safety), which in 1992 was assigned with the state supervision of radiation safety as well.

In 1994, with the reorganization of the Bodies of the Central Administration of the State (OACE), through the Decree-Law No. 147 "On the Reorganization of the Central State Administration Organizations", CITMA was created, and the institutions in charge of the nuclear area, SEAN and CEAC, were included in this Ministry, so that since that moment the regulatory body became part of that Ministry.

Afterwards, in 2002, the regulatory body joined the Office for Environmental Regulation and Nuclear Safety (ORASEN) created by CITMA through the Resolution No. 6/2002 of CITMA to achieve higher levels of integration and effectiveness of regulatory functions in chemical, biological and nuclear safety as well as environmental protection.

On November 28th, 2018, through Resolution No. 247/2018 of CITMA, the change of name and structure of the Office for Environmental Regulation and Nuclear Safety (ORASEN) and its organizational units was approved, which included the National Centre for Nuclear Safety. For this reason, the aforementioned Office is now called the Office for Environmental Regulation and Safety (ORSA) and the National Centre for Nuclear Safety is renamed the Division of Nuclear Safety (DSN).

Authorities and responsibilities.

As it is established in the current legislation and regulations, the regulatory body has the following essential functions and responsibilities:

- a) To develop and propose for approval to the appropriate authorities, the legal, technical or procedural regulations in nuclear and radiation safety, and in relation to the accounting for and control of nuclear materials system.
- b) To organize and conduct review and assessment of the application for authorization or any other document required to authorization holders, related to radiation safety.
- c) To grant, modify, renew, suspend or revoke authorizations for carrying out activities related to the use of nuclear energy based on the technical opinions issued.
- d) To grant, renew, suspend and revoke individual licenses to individuals who carry out practices associated with the use of ionizing radiation.
- e) To recognize the competence of Radiation Protection Services Providers or issue their termination when applicable.
- f) To organize and carry out inspections of facilities, as well as legal entities where activities related to the use of nuclear energy is carried out, with the objective of verifying compliance with the legal, technical or procedural requirements in force, regarding nuclear and radiation safety, as well as the authorization conditions.
- g) To impose or recommend the imposition of coercive measures, due to violations of legal, technical or procedural provisions in force regarding safety.

- h) To verify compliance with requirements established by virtue of international safeguards commitments with the peaceful use of nuclear energy.
- i) To technically advise organizations involved in response to radiological emergencies and being involved in response operations as well as recommend protective actions in terms of protection and safety, as appropriate.

Organizational structure of the regulatory body.

The organizational chart of ORSA is presented in the Figure No. 1.

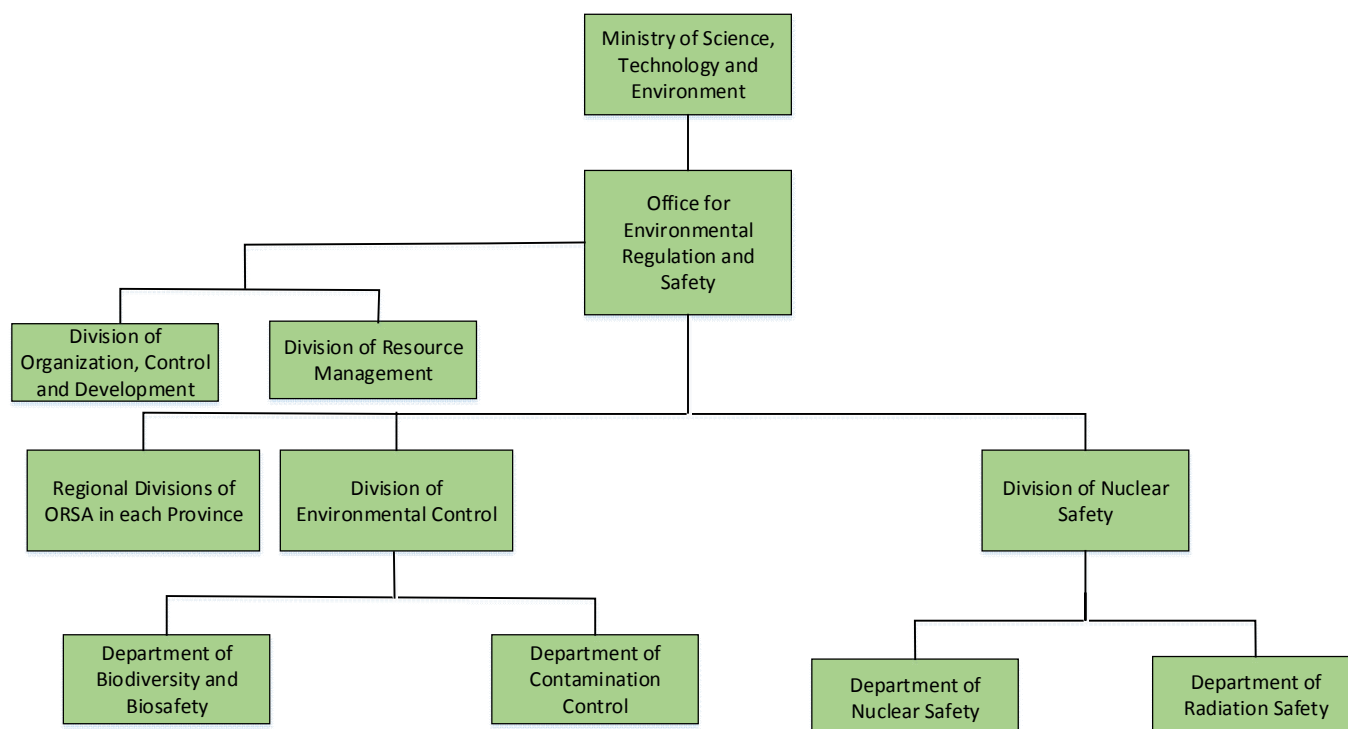


Figure No. 1: ORSA organizational chart.

The Division of Nuclear Safety is supported, for fulfilling its functions nationwide, by specialists in the Regional Divisions of ORSA in the provinces of Cienfuegos and Holguín.

Development and maintenance of human resources over the past three years.

The regulatory body staff includes 24 professionals and 3 administrative (May 2019). Thirty-three percent (33%) of the total of professionals are women and twenty-five (25%) percent have completed Master’s degree.

Seventy-nine percent (79%) of specialists are accredited to conduct inspections for nuclear and radiation safety.

The regulatory body staff is a qualified personnel with vast experience in radiation safety. Seventy-five percent (75%) of specialists have more than 15 years of experience in their functions, and have participated in both national and international training programmes, and as IAEA experts.

Measures to develop and maintain competence.

The specialists of the regulatory body are mostly engineers and nuclear physicists graduated from the University of Havana and the Moscow Energy Institute. Currently the young professionals who enter the institution are graduates in the mentioned careers at the University of Havana.

The regulatory body has implemented a training programme whose objective is to achieve the specialization of personnel, according to the competencies required for the performance of their functions and tasks in the field of Nuclear Safety, Radiation Protection and Nuclear Safeguards.

The training programme is implemented through an internal procedure of the regulatory body that covers the stages of organization of the activity, detection of training needs, preparation of the individual training plan for newly incorporated personnel and the individual training plan for each worker in order to reach the skills required for performing their duties and keep them throughout the entire working life. This process is carried out systematically, in correspondence with the future projections of the regulatory body.

Periodically a process of evaluation of the levels of knowledge, skills and aptitudes associated with the tasks performed by the specialists of the regulatory body is carried out. This work requires strategic planning of the training and training activities of the staff that takes into account at least the following elements:

- a) Initial training (within the framework of the management system of the regulatory body) with a systematic approach to the detection of training needs and management of training.
- b) Specific training for the job (with human resources of the regulatory body or external).
- c) On the job training.
- d) Continuous training oriented to the development and maintenance of specific skills.

This training and development plan is linked to the knowledge management actions of the regulatory body, in order to maintain the competencies of the organization.

In the 2016-2018 period, specialists from the regulatory body have participated in different training modalities such as: seminars, workshops, courses, trainings, technical meetings and international conferences.

The regulatory body has maintained a broad and important relationship with the IAEA, which has allowed training of its professionals and to contribute to the training of professionals in the region, by organizing different regional courses in the country and expert missions.

To date, the regulatory body has signed two Cooperation Agreements, the first with the National Commission for Nuclear Safety and Safeguards of Mexico (CNSNS), in May 1996 and the second with the Nuclear Safety Council (CSN) of Spain, in March 1999. These Agreements allowed a large number of CNSN (currently DSN) specialists to participate in training activities, for several years.

Likewise, the regulatory body is one of the founders of the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO). In this association, the specialists participate actively in the projects developed through its technical programme.

Statement of adequacy of resources.

The regulatory body is considered to have human resources enough to carry out its functions. The financial resources are allocated by the State through the ORSA annual budget which guarantees the performance of its functions. However, given the limitations of the national economy, this budget is not enough to cover some specific needs such as: cooperation activities with other foreign regulatory bodies with greater experience and development, including training, and the acquisition of specific software for safety assessments.

Management system of the regulatory body.

Since the end of the 90's, the regulatory body implemented a quality management system (SGC) based on the principles of the international standard ISO 9001, which evolved over 20 years along with the changes in the successive revisions of aforementioned standard.

Throughout these years, the system progressively incorporated the IAEA recommendations developed through its safety standards. Nowadays, the system has evolved as a management system (MS) that incorporates quality and safety requirements with an acceptable level of integration. At this moment, the working needed to achieve a higher level of integration between the safety requirements recommended in the IAEA GSR Part 2 and those of the ISO 9001: 2015 quality standard, is being done.

The MS of the regulatory body is structured in 19 processes and 10 interrelated sub-processes.

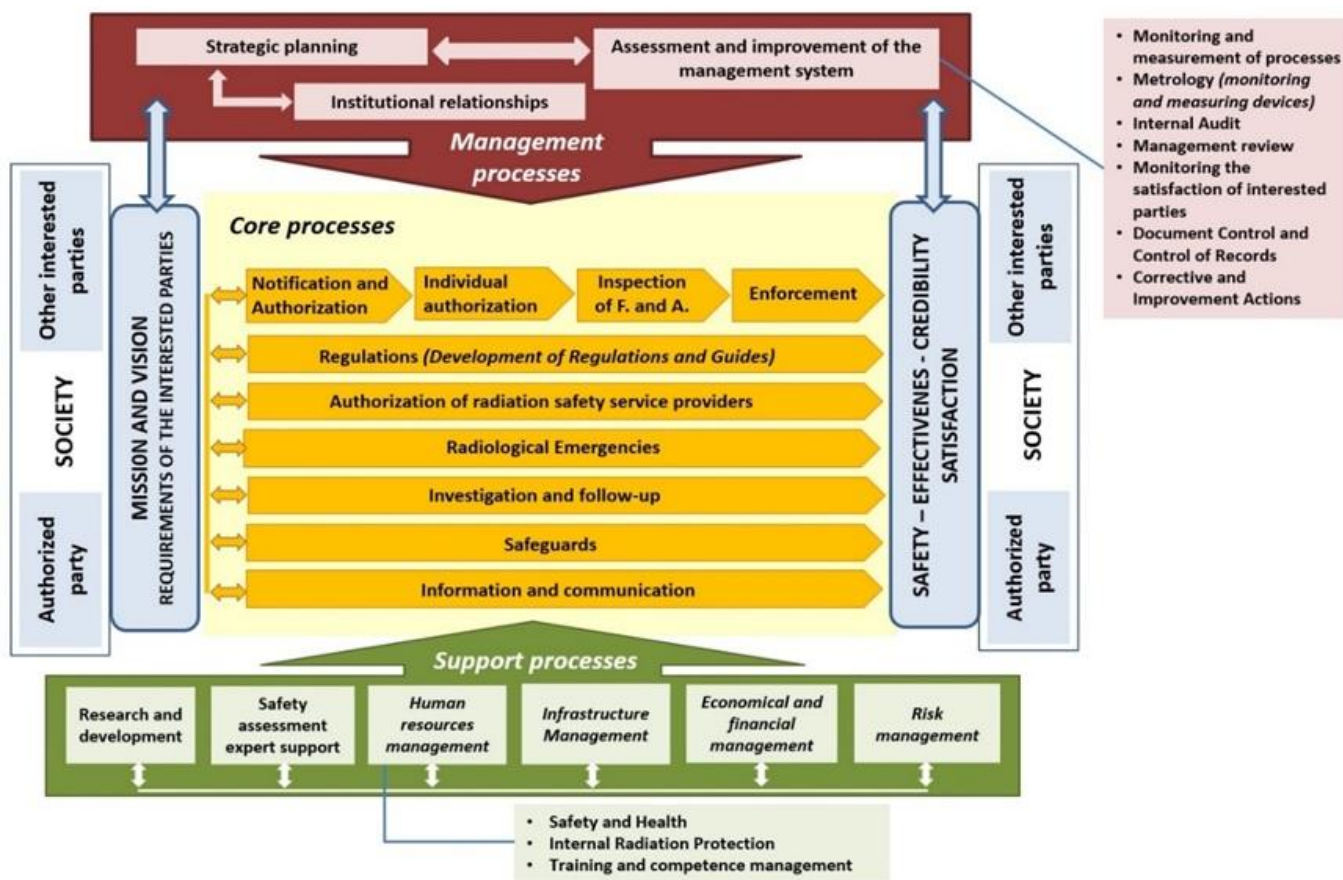


Figure No. 2: Process map of the management system of the regulatory body

All processes are documented, as well as the interfaces between them. Currently, within the MS the Quality Policy and the Safety Policy are declared, which have many common elements that contribute to the same objectives and goals of the organization. For this reason, an integrative version of both governing documents was prepared, which is in the process of approval.

The SG establishes an Annual Internal Audit Programme, which periodically evaluates the performance, effectiveness and capacity of the internal processes of the regulatory body to ensure safety and leadership for safety and quality. This Programme is complemented by external audits.

The management team of the regulatory body reviews the SG once a year to ensure its suitability, adequacy, effectiveness and continuous alignment with the strategic direction of the organization. Management Review is the most important control event that Senior Management of the organization performs. One of the most significant results of this process is the Improvement Programme of the regulatory body, which is regularly updated and monitored.

Throughout the year and as a complement to the Management Review, the qualitative and quantitative evaluation of the processes is carried out through a system of 47 performance indicators. This evaluation method allows the analysis of results and decision making for improvement by senior management and those responsible for the processes.

Openness and transparency of regulatory activities including measures taken to improve transparency and communication with the public.

Decree Law No. 207 “On the Use of Nuclear Energy” establishes in its Article 3, subparagraph i), that “the use of nuclear energy must be accompanied by the necessary information to the population of its possibilities, benefits, risks and safety measures, including the introduction of its theoretical and practical basis in the programmes of the National Education System”.

As a public servant, the regulatory body is obliged to follow the official communication procedures established by CITMA. In this regard, it assumes the responsibility of providing information to all interested parties, especially to authorization holders, the public and the media.

Through the ORSA, by its own means, the Division of Nuclear Safety maintains secure communication channels that convey clear and verifiable information regarding its areas of competence. Among others are: email correspondence, oral communication, meetings, information on the Web, quarterly electronic newsletter, reports and other public documents, and opinion polls.

External technical support.

Although external technical support is generally not required, the regulatory body has identified a group of experts in the country that could be involved in the authorization / inspection processes in the following matters:

- a) Physical aspects of radiotherapy, nuclear medicine and the use of x-rays for medical imaging purposes.
- b) Technological aspects in industrial irradiators, nuclear gauges and industrial radiography.

- c) Scientific technical aspects of dosimetric calibration, analytical techniques / sealed research sources, biological effects of ionizing radiation, health surveillance and radioactive waste management.
- d) Technological aspects of the materials used in shielding construction.
- e) Radiological protection of the environment.

In the country there are several institutions recognized by the regulatory body to perform as radiation safety support services that can be required as external technical support of the regulatory body, such as:

- a) Centre for Radiation Protection and Hygiene (CPHR),
- b) Centre for Technology Applications and Nuclear Development (CEADEN);
- c) Centre for Environmental Studies of Cienfuegos;
- d) Centre for Environmental Engineering of Camagüey (CIAC); y
- e) Centre for Environmental Research and Services (CISAT).

It is worth highlighting the Centre for Radiation Protection and Hygiene (CPHR) which hosts the National Dosimetric Bank; emergency preparedness and response assets and capabilities; an individual dosimetry service, a secondary calibration laboratory and a lab for environmental radioactivity monitoring. CPHR also, carries out studies on existing exposures and provides support to DSN with the metrological assurance (verification and calibration) of the measuring instruments and the measurement of environmental samples, among others.

Article 8 2) Status of the regulatory body.

Place of the regulatory body in the governmental structure.

As referred in the previous section entitled “Organizational structure of the regulatory body”, corresponding to the compliance with Article 8 1) of this Report, the regulatory functions for nuclear and radiation safety are performed by the Division of Nuclear Safety of ORSA, which is attached to CITMA. This subordination does not prevent the effective exercise of its regulatory functions independently and without conflict of interest.

Reporting obligations (to parliament, government, specific ministries).

In order to show the state of nuclear and radiation safety in the country, the Division of Nuclear Safety prepares and submits to CITMA, through ORSA, annual reports on its activity. Those reports also include the performance of the regulatory body by fulfilling its main tasks for ensuring that the use of nuclear energy is carried out without risks to life, health, property and the environment.

Means by which effective separation is ensured between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy, and means by which independence of the regulatory body in making its safety-related decisions is assured.

In correspondence with what is stated in this Report, regarding compliance with Article 7 1), Decree-Law No. 207 “On the use of Nuclear Energy” empowers CITMA as the governing body in the nuclear field, both for the functions of promotion of the use of nuclear energy, and the regulation and control. Decree-Law No. 207 itself states, the bodies through which these functions are exercised, so that decisions on safety (CNSN, currently DSN) are free from

interference from bodies dedicated to the development or promotion of nuclear energy (Nuclear Energy and Advanced Technologies Agency, AENTA). Article 5 prescribes the following: “The regulation and control activities carried out by the CNSN (currently DSN) have an effective autonomy and independence from those related to the promotion and development of the nuclear energy and has sufficient economic and human resources for the exercise of its functions”.

Functional independence is also covered by the rest of the complementary regulations related to the processes or activities, either managed by the regulatory body such as: authorization and inspection or oversights by it: practices with ionizing radiation sources, transport of radioactive material, radioactive waste management, etc.

The director of the regulatory body is the authority empowered in the country to grant, amend or renew authorizations and order enforcement actions such as suspension and revocation of authorizations. (CITMA Resolution No. 334/2011).

In the administrative order, independence is guaranteed so that the functions and decisions of the regulatory body are not hindered. The DSN is integrated into an independent Office subordinated to CITMA (Office of Regulation and Environmental Safety) and which only exercises regulatory functions.

Article 9: Responsibility of the License Holder.

Decree Law 207, on its Article 15, clearly states the responsibility of the license holders to “guarantee the safety of activities related to the use of nuclear energy, so that its execution does not entail undue risks to life, health, goods and the environment”.

Additionally, the following fundamental obligations are included:

- a) to comply with the requirements established in the legal, technical or procedural provisions in force regarding nuclear and radiation safety;
- b) to comply with the conditions imposed in the authorizations, as well as comply, within the established deadlines, with the warnings issued as a result of the regulatory inspections;
- c) to guarantee a safe accomplishment of works and with an increased quality;
- d) to ensure that the staff complies with the qualification requirements established for each job, guaranteeing the continuous education and training of the staff;
- e) to facilitate access to all the information and documentation required for performing the regulation and control functions;
- f) to facilitate the operation service, the means, equipment, instruments, laboratory analysis data, the sampling to perform the necessary analyses and checks, to demonstrate or guarantee safety during inspections, audits, verifications or examinations made by inspectors;
- g) to guarantee security and fire protection; for this purpose, install security and fire protection systems in accordance with the current legal requirements;
- h) to inform the regulatory body about the occurrence of any unusual event during operation or execution of activities, understanding as an event, any unintentional occurrence, including operating errors, equipment failures or other mishaps, whose actual or potential consequences cannot be ignored from the safety point of view; and
- i) to elaborate, organize and prepare radiological emergency plans to be implemented within the limits of the facility, or during transport, as well as guaranteeing the practical verification of the effectiveness of the emergency plans in correspondence with the

requirements and procedures established by the Ministry of Science, Technology and Environment, in coordination with the Civil-Defence Joint Chiefs of Staff.

In addition to the main obligations of the license holder, the regulations, referred to in the report on compliance with Article 7 2) i) *National safety requirements and regulations*, establish specific responsibilities related to technical or safety management aspects.

Article 10 Priority to Safety.

Overview of the arrangements and regulatory requirements regarding policies and programmes to be used by the license holder to prioritize safety in activities for design, construction and operation of facilities.

Legal provisions on priority to safety

The Article 3 of the Decree Law No. 207, subsection d) defines clearly the priority to safety as one of the general principles that govern the use of nuclear energy in Cuba, requiring that:

“the necessary safety measures are to be established in order to guarantee the protection of life, health, property and the environment and its compliance is required, which has the highest priority over social and economic benefits”;

The same article, in the subsection f, states:

“the use of nuclear energy is based on compliance with the basic principles of radiological protection”;

Safety Culture

Overview

The Regulatory Body has developed a set of actions and initiatives for Safety Culture fostering and developing both at Regulatory Body and in facilities involved in the use of sources of ionizing radiation, being a pioneer organization in this field and gathering vast experience which allowed it to collaborate with regional initiatives in Latin America in the frameworks of Iberian-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) and International Atomic Energy Agency (IAEA)

Safety Culture of Regulatory Body

As early as 1995, being the National Centre for Nuclear Safety (CNSN) the regulatory body, the first steps to foster and develop safety culture in regulatory activities were taken. The actions performed are summarized below:

1995. First national survey on safety culture in nuclear activities in Cuba

A questionnaire, based on new published IAEA documents on Safety Culture and adapted to regulatory body as organization was conducted throughout the country, in different practices, entities and organizations. The questionnaire included topics such as the understanding of regulatory roles and purposes, the responsibility for safety, knowledge and clarity of regulatory requirements, communication and interaction with the regulatory body, its presence and

interference in the entities, access to its safety information and the appreciation of regulatory professionalism and work. As a result of this survey, 10 recommendations to improve safety culture of the regulatory body were formulated.

1998. Safety Policy Statement of Regulatory Body.

This Policy, implemented by Resolution 11/98 of CNSN Director, publicly defines the regulatory body commitment to achieve high safety levels during the use of sources of ionizing radiation and establishes the framework which will govern its performance as organization, and also the managers' and personnel behaviours to fulfil this commitment.

The Safety Policy, structured in 7 topics, namely, Commitment to safety, Management commitment, Personnel commitment, Ethics and professionalism, Interactions with institutions using nuclear energy, Commitment with the Public and International communication, is the base of its Internal Safety Culture

2000-Annual Regulatory Conferences

According to its Safety Policy and in response to recommendations of the first national survey, Annual Regulatory Conferences were implemented to encourage the exchange between regulatory body and entities, at a top management level. At the same time, this kind of action contributes to entities management leadership and commitment through safety information and awareness they achieve in these meetings. In its 17 editions of this annual event a wide variety of topics on safety and radiation protection in the country have been discussed, as it is shown below:

2000	<i>Safety status of facilities in Cuba based on lessons learned from licensing, inspections and radiological incidents.</i>
2001	<i>Control of sources of ionizing radiation.</i>
2002	<i>Current status of radiological safety in medical practices in Cuba</i>
2003	<i>Current status of radiological safety in industrial practices in Cuba</i>
2004	<i>Current status of radioactive waste management in Cuba</i>
2005	<i>Role of OACE (Organizations of the Central State Administration) and OPP (People's Power Bodies) in radiological safety control of subordinated entities.</i>
2006	<i>Cuban regulatory framework in the field of import and export of sources of ionizing radiation and radioactive materials.</i>
2007	<i>Safety recommendations for radiotherapy facilities based on operational experience (lessons learned) and the results of Probabilistic Safety Analysis (PSA)</i>
2009	<i>Regulatory control of medical diagnostic radiology in Cuba</i>
2010	<i>10 years fostering safety culture in Cuba</i>
2011	<i>New regulations and other topics on radiological safety</i>
2012	<i>Current status of safety and radiation protection in Cuba: Advances, Difficulties and Challenges</i>
2013	<i>Radiation protection of patients in Cuba</i>
2014	<i>Occupational Dosimetry</i>
2015	<i>Regulatory Body expectative on safety culture in organizations involved in activities with sources of ionizing radiation (CNSN Resolution 1/2015)</i>

2016	<i>Safety in radiology with emphasis on paediatric radiology.</i>
2018	<i>Communication on Radiation Protection with the Public</i>

2002-National Programme for Safety Culture fostering and development in Organizations involved in the work with sources of ionizing radiation (PSC-IRS)

The regulatory body established a national programme with the aim at assessing safety culture in the activities with sources of ionizing radiation in order to formulate an Action Plan to achieve higher and validated levels of Safety Culture in the country. The Programme included safety culture of Regulatory Body, Operators and Technical Supporting Organizations.

2002-Diagnostic study on Safety Policy effectiveness

A 15-questions survey was conducted among regulatory personnel to assess the safety policy effectiveness and to determine the improvement required, summarized in 7 recommendations.

2002-Second national follow-up survey on safety culture of regulatory body.

A follow-up survey was conducted among regulatory personnel throughout the country which included 24 topics on regulatory activities. Results were classified in four levels: Good, Acceptable, Questionable and Critical. The topics included are listed below:

- a) Understanding of the Safety Culture concept
- b) National legal framework
- c) Regulatory Body independence
- d) Regulatory Model
- e) Resources for Regulatory Activities
- f) Communication channels
- g) Regulatory documents
- h) Regulatory Body relations with Licensed entities
- i) Regulatory Body interferences
- j) Dealing with regulatory issues by Licensed entities
- k) Presence of regulatory personnel in the Licensed entities
- l) Internal process oversight in operating organizations
- m) Regulatory body publications on safety issues.
- n) Lessons learned from radiological events.
- o) Professionalism of Regulatory Body personnel
- p) Impact of the Regulatory activity
- q) International Exchange on Safety
- r) Promotion of safety research
- s) Regulatory body managers
- t) Qualification and training of regulatory personnel
- u) Corporative Self-control
- v) Radiation protection of regulatory personnel
- w) Code of Conduct

The survey included a questionnaire distributed among personnel from legal entities under regulatory control in order to get their perspective in regard to safety culture of the Regulatory Body.

As a result, a Plan for Improvement of Safety Culture of Regulatory Body was prepared, including 53 actions.

Safety Culture of Users of Sources of Ionizing Radiation.

2001-Regulatory requirement on Safety Culture.

The Joint Resolution between CITMA (Ministry for Science, Technology and Environment) and MINSAP (Ministry for Public Healthcare) about Regulation “Basic Standards on Radiological Safety” establishes, in article No. 12, the requirement to Licence Holders of implementing actions to foster and sustain the Safety Culture

2004- Safety Culture pilot assessment in users of sources of ionizing radiation.

As part of the National Programme for Safety Culture fostering and development (PSC-IRS) a methodology for safety culture assessment, based on IAEA documents on Nuclear Safety Culture, was adapted and developed. The methodology was implemented in two hospitals with radiotherapy and nuclear medicine practices and in an industrial facility for radioisotopes production.

As a result of such assessments safety culture problems were identified and an Improvement Actions Plan on Safety Culture was prepared, with emphasis on 4 main areas: Management Safety Leadership and Commitment, Safety Priority, Personnel Involvement on safety issues and organizational Learning on safety.

2019-System for Analysis, Dissemination and Learning from Radiological Events and Incidents (ADASIR)

With the purpose of fostering an Organizational learning culture at national level, both in the regulatory body and in operating organizations, the ADASIR System was implemented with focus on prevention of radiological events in the country and to increase the radiological safety culture levels, in general.

The ADASIR System guides the analysis process of radiological events reported at national level and worldwide. It also assures dissemination and learning from lessons and experiences resulted from those events and it verifies the facilities and country preparedness to prevent a similar event through existence and availability of those barriers and controls which failed in the studied event.

This system provides a learning loop allowing the improvements of regulatory activities effectiveness, the robustness of the Operators radiation protection programmes and the involvements of other stakeholders in the strengthening of country radiological safety.

2015-CNSN Resolution 3/2015 “Regulatory Body expectative on Safety Culture in Organizations involved in activities with sources of ionizing radiation”

Taking into account the importance of having an auto-generated process of Safety Culture development in operating organizations instead of an imposed or mandatory one, a new strategy was adopted the Regulatory Body adopting a resolution, which is recommendatory and encourages entities to perform a self-assessment of their Safety Culture level y to establish an

Improvement Actions Plan. This document defines Safety Culture as follows:

“the assemble of characteristics and attitudes in an Organization, its leaders and individuals, based on shared values and behaviours patterns, which make safety during the work with sources of ionizing radiation an overriding priority and a shared commitment”

The Resolution also defines 10 Basic Elements to characterize the Operator’s Safety Culture which are listed below:

- a) Priority of Safety: Safety is considered a core value and a priority with regard to other Organization interests related to costs, deadlines, contractual, production, commercial, political issues and other ones of this kind.
- b) Visible Top management safety leadership and commitment: The Safety leadership and commitment of Top and other organizational level managers is visible and recognized as key elements for Safety Culture fostering and development
- c) Proper identification and solution of safety problems: The issues with potential impact on safety are quickly identified, comprehensively assessed and immediately addressed and solved in the Organization.
- d) Permanent focus on Safety: Processes are planned, controlled and modified in the organization, as required, assuring that required safety level is kept.
- e) Individual responsibility, involvement and behaviour in regard to safety: Safety is perceived inside the Organization as a responsibility of all personnel, with permanent focus on doses optimization, radiological accident or loss of source control prevention through a questioning attitude, a rigorous and prudent approach and an active personnel involvement in safety issues, which are patterns of individual behaviour in regard to safety.
- f) Communication culture on safety: An informed culture exists which allows the open and free communication on safety issues, both horizontally and vertically, inside the whole Organization looking for a personnel involvement on safety and an excellent level of safety.
- g) Reporting culture: A reporting culture exists in the Organization, assuring that personnel feel free to raise concerns on safety and report any failure, human error, incident or near-miss without any fear of retaliation.
- h) Just Culture in regard to individual behaviours: A fair culture prevails in the Organizations during the accidents, incidents and near-misses analysis and investigation and also in regard to unsafe acts, behaviours and conditions. These analysis and investigations are focused on the identification of organizational, systemic and root causes of those events and never on blame.
- i) Culture of Continuous learning: A culture for learning exists in the Organization, based on assimilation of lessons learned from incidents and accidents occurrences in this sector as well as on pair comparison and the implementation of best engineering and management practices oriented to continuous improvement of safety of Organization processes and activities.
- j) Collective behaviours in regards to safety: A collaborative, respectful and trusting environment exists in the Organization in benefit of safety.

International collaboration on Safety Culture

The Regulatory Body has shared its experience in the field of Safety Culture fostering and developing with other countries through regional projects in Latin America sponsored by the FORO and the IAEA. The most relevant are:

- a) 2012-2015 Development of Guidelines on Safety Culture in Organizations, Facilities and Activities with sources of ionizing radiation, FORO
- b) 2017-2019 Pilot study on the methodology of Safety Culture assessment in industrial gammagraphy, FORO
- c) 2012-2019 Regional training activities and Regional survey on Safety Culture in activities involved in the use of sources of ionizing radiation.

Measures taken by license holders to implement arrangements for the priority of safety, such as those above and any other voluntary activities, examples of Good Practices and safety culture achievements.

Although the CNSN Resolution No. 3/2015 is not a mandatory document, it has been implemented only in two medical facilities which use sources of ionizing radiation, showing then, that safety is based on rules and regulations to reflect that the lowest level of safety culture is the dominant level in the entities.

Some License holders have implemented Safety Management System, as part of which, policies on Priority of Safety have been adopted. Other actions like organization learning through peers comparison, blame free environment, involvement of patients in their treatment safety through novel initiatives and participation in regional pilot project on Safety Culture self-assessment have been implemented by some Licence Holders.

Regulatory processes for monitoring and oversight of arrangements used by the licence holders to prioritize safety.

Through the system of Licensing, inspection and regulatory assessment referred in this report in regard to the fulfilment of Article 7, The Regulatory Body monitors and oversights how the Licence holder prioritize safety of his process and operations.

Means used by the regulatory body to prioritize safety in its own activities.

The Regulatory Body has a Safety Policy which defines its commitment to safety. This policy is currently being reviewed as part of the Regulatory Body Safety Management System

The Regulatory Body has its own Radiation Protection Programme and a Management System, described in this report in regard to the fulfilment of Article 8, which assure the priority of safety in its own activities. The actions described on the efforts to foster and develop its internal safety culture is another indicator of the means it uses. The Radiation Protection Programme includes the exposure control, the health vigilance and proper training of regulatory personnel involved in inspections and emergency situations, the control of available sources of ionizing radiation for verification of measurement equipment and the use of Individual Protection devices.

In 2004 Cuba received an IAEA Radiation Safety Infrastructure Appraisal mission. Starting from the mission recommendations a set of actions have been implemented which allowed the improvement of Regulatory Body work among which the following are worth mentioning:

- a) Design and implementation of the Strategy for preparation, review and modification of regulatory documents in the nuclear field, which allows to follow the state-of-the-art international safety regulations
- b) Review of legal and regulatory framework
- c) The approval and implementation of a new Regulation on notification and authorization of

practices and activities involved with the use of sources of ionizing radiation (CITMA Resolution No. 334/2001)

- d) Improvement of the Regulatory Body Management System, with emphasis on authorization, inspection and enforcement processes, with a graduated approach.
- e) Completion and functionality of sources inventory.
- f) Creation and functioning of the Technical Standardization Committee 119: Radiation Protection

According to this report, in relation to the fulfilment of Article 7.2.i, the Regulatory Body has been developing, since several years ago, an “Strategy for preparation, revision and modification of regulatory documents in the nuclear field” with an implementation plan for a period of 3 years. The preparation of this Strategy has been based on the following issues:

- a) Assessment of the implementation level of the current legal and regulatory framework on radiation protection and safety of sources of ionizing radiation as well as the international legal instruments in which Cuba is a part.
- b) Review of publications of IAEA Safety Standards issued in the last 3 years
- c) Technologies and uses of ionizing radiation which are planned to be introduced in the country in the short term
- d) Changes in the national legal framework which could have a relation with the current safety legal and regulatory framework
- e) Projections of the Technical Standardization Committee on Radiation Protection.

Based on the results of those analyses, strategic projections for review and updating of current regulation are made as well as definitions of new regulation needed. This strategy allows to follow the international state-of-the-art safety regulations and to define guidelines and actions to be taken by the Regulatory Body in order to keep the legal and regulatory framework updated and in continuous improvement.

In 2016 an IAEA EDuTA (Education and Training Appraisal in Radiation Protection and the Safety of Radiation Sources) Mission was received. The recommendation to Regulatory Body was oriented to review the legal and regulatory framework with the purpose to develop provisions to the qualified expert, specifying its duties and responsibilities in regard to Radiation Protection Officer in a way that is consistent with IAEA Safety Standards. These provisions will be included in the projects for modification of the CITMA-MINSAP Join Resolution about the Regulation “Basic Standard on Radiation Protection” from November 30th, 2001 and CITMA Resolution No. 6/2004 “Regulation for competence recognition of Radiation Safety Services”.

Article 15. Radiation protection.

Overview of the provisions and regulatory requirements of the Contracting Party relating to radiation protection in nuclear facilities, including applicable laws not mentioned in Article 7.

The general technical and management requirements for radiation protection and safety of radiation sources are set forth in the Joint Resolution CITMA-MINSAP Regulation "Basic Radiological Safety Standards", *NBSR*, of November 30, 2001. This Regulation provides the requirements of the IAEA Safety Series No. 115 “International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources” and establishes the following aspects related to radiation protection:

- a) Responsibilities of the license holders related to occupational exposure and public exposure, including the requirements applicable to natural sources exposure.

- b) General technical criteria for exemptions and clearances.
- c) Requirements for justification, the optimization of safety and protection, and the limitation of the individual dose to occupationally exposed workers and the member of the public.
- d) Provisions for adequate workers' health surveillance.
- e) Requirements for the control of occupational and the public exposure.

There are other regulations that establish specific radiation protection requirements in their fields of application, which are the following:

- 1) CITMA Resolution No. 121/2000, "Regulations for the Safe Transport of Radioactive Materials," of December 14, 2000".
 - a) Establishment of radiation protection programmes for the transport of radioactive materials.
 - b) Optimization of the safety and protection during transport.
 - c) Perform periodic assessments of the radiation doses to persons due to the transport of radioactive material.
 - d) Dose limits for the public exposure due to activities associated with the transport of radioactive material.
 - e) Maximum radiation levels for:
 - i) any point at any external surface of a package or overpack.
 - ii) any point at any external surface of a package and from the vehicle, or at a certain distance, during transport under exclusive use.
 - iii) the external surface of the means of transport and at the distance of 2 m away from the external surface of the means of transport.
 - iv) At the distance of 3 m away from unshielded radioactive materials for packages of low dispersion radioactive materials.
 - v) the design of type B (U) and C packages after they are tested.
 - f) Requirements for non-fixed contamination on the external surfaces of a package.
 - g) Limits to non-fixed contamination on external and internal surfaces of overpacks, containers, cisterns and intermediate containers for bulk cargo.

- 2) CITMA Resolution No. 35/2003, "Regulation for the safe management of radioactive waste", of March 7, 2003.
 - a) Radiation protection criteria for solid low-level radioactive waste clearance.
 - b) Requirements to discharge radioactive liquids and gases to the environment. The limits authorized by the CNSN (currently DSN) for the discharge of radioactive liquids and gases to the environment are established in Resolution No. 1/2004 CNSN "Guide on the levels of unconditional clearance of solid very low-level radioactive waste and the discharge of radioactive liquids and gases to the environment", of January 9, 2004. The discharge of radioactive liquids and gases to the environment in activities' concentrations exceeding the CNSN's (currently DSN) prescribed limits be previously authorized and for this, the license holders must:
 - i) Determine the characteristics and activity of the radioactive liquid or gas that will be discharged and, the methods and potential discharge points;
 - ii) Determine, from an appropriate pre-operational study, all significant routes of exposure through which the radioactive liquids and gases discharged can result in exposure to the public;
 - iii) Evaluate the doses of critical groups due to planned discharges; and
 - iv) Justify by carrying out appropriate optimization studies that the optimal release control option has been chosen.

The specific authorization of radioactive liquids and gases discharges to the environment is included as a condition in the facility's license for operation.

Regulatory expectations regarding the licensee's processes aimed at optimizing radiation doses and applying the principle of "as low as reasonably achievable" (ALARA).

Safety and protection optimization requirements are set out in articles 58 to 61 of the *NBSR*. In particular, the article 58 establishes that "... protection and safety will be optimized so that the magnitude of the individual doses, the number of individuals exposed and the likelihood to undergoing exposures are as low as reasonably achievable, with economic, societal and environmental factors taken into account, under condition that the doses shall be subject to restrictions".

The regulatory body establishes the dose restrictions for workers and the member of the public, by practices and sources assigned to them, and in particular for the control measures optimization of radioactive substances discharged to the environment. These restrictions are relative to the radiation source; apply to the individual dose caused by the sources and serve as a limit to optimize the protection and safety of the radiation source at the design stage. In the operation stage these restrictions are used to ensure compliance with dose limits. The license holders must notify the cumulative doses that at any time of the year exceed the dose restriction established for the practice and submit to the regulatory body a report with cause analysis and the measures taken.

Additionally, in correspondence with the provisions of article 13 b) of the *NBSR*, the license holders must "have quality control mechanisms and procedures to examine the overall effectiveness of protection and safety measures". On the other hand, according to articles 72 and 74 of this regulation, the actual protection and safety conditions in the controlled and supervised areas must be examined periodically in order to determine the need for additional measures or to modify existing ones.

For all the above, the license holders are expected to systematically review the safety conditions in which the facilities are operated. In particular, the operational procedures and implemented dose controls in order to implement measures to ensure ALARA principle achievement. In accordance with the provisions of article 53 of the CITMA Resolution No. 35/2003, the license holders, which ought to dump radioactive material to the environment, must:

- a) Keep all radioactive liquids and gases discharges below to authorized limits, and as low as reasonably possible;
- b) Monitoring and recording the discharge of radioactive liquids and gases with sufficient detail and precision in order to demonstrate authorized limits compliance and to allow an estimate of the exposure of any critical population group.

In this regard, the license holders should include systematically evaluations and implementation of appropriate measures to optimize the dose to the public resulting from these discharges.

For authorization's renewal, the license holders must submit a report with an assessment of its practice's implementation, including the effective doses trends. Through this report, licensee presents to the regulatory body its systematic safety review results, the occupational experience gained and the implemented measures to optimize the safety, in particular by the application of the ALARA principle.

Implementation of the radiation protection programmes by the license holders.

The license holders are accountable by:

- 1) Set the protection and safety objectives in accordance with applicable requirements to activities or facilities for which they are responsible;
- 2) Establish and execute a protection and safety programme that is in correspondence with the nature and magnitude of the risks inherent in the practices carried out and is sufficient to guarantee compliance with these requirements. The licensee must:
 - a) determine the measures and resources necessary to achieve the protection and safety objectives, ensure that the resources are allocated and the measures are correctly executed;
 - b) keep a continuous review of the measures and resources, and verify, with the necessary regularity, the achievement of the protection and safety objectives;
 - c) detect possible faults or deficiencies in the measures and resources for protection and safety, and to act to correct them and avoid their repetition;
 - d) establish consultative mechanisms to facilitate the protection and safety and cooperation among stakeholders;
 - e) keep appropriately recording the accountabilities fulfilment.

With regard to radiation protection elements, the programme should provide the following:

- a) Occupationally exposed worker's obligations.
- b) Obligations of the licensee holders to adopt the protection and safety measures guarantying adequate working conditions and accomplishment of the radiological protection requirements.
- c) Classification of areas.
- d) Establishment in local rules and procedures guarantying adequate level of protection and safety, as well as their supervision.
- e) Use of personal protective equipment.
- f) Evaluation of occupational exposure and individual radiological surveillance.
- g) Monitoring of the workplace.
- h) Workers' health surveillance.
- i) Compulsory record keeping of occupational exposure.
- j) Training.

The licensee holders must verify compliance with dose limits. In accordance with the regulatory guides and authorizations conditions, the following requirements must be met:

- a) investigate and record any monthly dose higher than 1/10 value of the dose limit;
- b) notify any monthly dose higher than 3/10 value of the dose limit or the dose authorized limit for the practice, and to submit a pertinent investigative report;
- c) notify the cumulative doses that at any time of the year exceed the dose restriction established and submit to the regulatory body a report with cause analysis and the measures taken.

For member of the public is established that the estimated average doses for the relevant critical groups, which are attributable to the practices, will not exceed an effective dose of 1 mSv per year; a dose equivalent for lens of 15 mSv per year and a dose equivalent for skin of 50 mSv per year.

For protecting the members of the public, the license holders shall guarantee an adequate facility's design. In order to restrict public exposure, licensees are obliged to establish procedures

for access control (visitors) and to make available sufficient shielding and other optimized protection measures. They shall carry out a safe radioactive waste management programme and shall guarantee optimized control measures for radioactive substances discharge to the environment, complying with the dose restrictions established by the regulatory body. Licensees shall establish and execute a programme for radiological surveillance of public exposure, maintain appropriate records, and submit to the regulatory body a summary of the outcomes, including prompt information of any significant increase in environmental radiation/ pollution levels. In case of accidents or other radiological events in their premises, resulting in unexpected increases of radiation or contamination levels, they shall carry out emergencies radiological surveillance activities and to promptly notify of it to regulatory body.

Regulatory examination and control activities.

The main regulatory examination and control activities are carried out through administrative processes of authorization and inspection, including assessment of licensee's compliance reports established by the regulatory body.

Cuba has no nuclear facility under Convention's scope. The radioisotope production facilities (including cyclotron), radiotherapy services, industrial irradiators, and the radioactive waste management facility are considered complex installations. In such cases, a license is required for the *construction* (which includes the assessment of the site, design, construction and assembly, as well as the acceptance tests and commissioning of the equipment and systems of the installation), *operation* and *closure* stages. During facility's life cycle, the applicants must submit a safety assessment as established in the regulation.

In the safety assessment, which is thoroughly assessed by the regulatory body, the applicant must demonstrate that the applicable regulatory requirements have been properly complied with and that the operations will be carried out in safety conditions complying with the established limits and conditions.

The holder of an operation license of a facility that requires a license for closure must apply for a closure license and submit the following documentation to the regulatory body:

- a) Plan for dismantling the installation that includes: stages, managers, and execution schedule.
- b) Procedures for carrying out the closing works that include the techniques and processes of decontamination and dismantling.
- c) Management of radioactive waste and disused sealed sources including the estimation of the volume of waste and determination of the routes and criteria to be used for the management of radioactive waste and disused sealed sources.
- d) Evaluation of the possible occupational and potential doses derived from the closure work. Individual radiological surveillance. Measures aimed at reducing occupational exposure.
- e) List of workers who will participate in the closing work, accreditation of psychophysical aptitude and training for the execution of the works.
- f) Proposed measures to prevent and mitigate radiological accidents during closing work.

Once the work is completed at the closing stage, the regulatory body decides on the release of the regulatory control of the installation, when the compliance with the radiological safety requirements established for this stage has been verified.

For certain installations, the delivery of periodic reports such as emissions of radioactive

substances to the atmosphere or sewage system or results of environmental monitoring, results of operational monitoring, etc. are included as license conditions. These reports are also thoroughly assessed by the regulatory body and as a result an opinion is issued.

The license renewal process is a time when the licensee must make the following information available to the regulatory body:

- 1) Updated security file that reflects the changes made in the performance of the practice during the period of validity of the authorization. This file must contain an updated security assessment, in the case of an operating license, which takes into account the current status of security systems and technological elements.
- 2) Report containing an assessment of the practice during the period of validity of the expiring authorization, in which the following aspects are developed:
 - a) Analysis of the behaviour of the doses received by the workers, including: compliance with the values of dose restrictions and dose limits.
 - b) Analysis of the operational incidents that occurred in relation to the elements, components and systems important for safety.
 - c) Measures taken to ensure the optimization of the practice.
 - d) Analysis of the results of radiological surveillance of areas and workplaces.

All this information is evaluated by the regulatory body; the results of the evaluation are set out in a technical opinion that concludes adopting the decision to grant or deny the renewal application. If it is verified that the practice has been carried out and will continue to be carried out under acceptable safety conditions, a new authorization is issued.

As referred to in this Report, in the report on compliance with Article 7, the regulatory body has implemented an inspection system in accordance with an annual plan in which the gradual approach is applied establishing an inspection frequency to the practices that are going 2 times a year for the most complex facilities and activities once every 5 years for those of less complexity and danger. The inspections' types are:

- a) Routine or planned.
- b) By denunciation of any natural or legal person.
- c) Due to radiological event occurred.
- d) Follow-up.
- e) In the process of evaluating an authorization request (including renewal).

Article 16: Emergency preparedness.

Article 16 1) Emergency plans and programmes.

Overview of the Contracting Party's arrangements and regulatory requirements for onsite (including multi-unit nuclear installations and/or multi-facility sites) and off-site emergency preparedness, including applicable laws not mentioned under Article 7.

There are legal norms in Cuba that define the institutional framework and responsibilities of the regulatory body, response organizations and the measures to be implemented in exceptional situations.

The Constitution of the Republic of Cuba in its Title X National Defence and Security, Chapter IV Exceptional and Disaster Situations", establishes the general principles related to Emergencies

and in the Article 128 subsection “k”, establishes the authority of the President of the Republic to declare the State of Emergency and the Disaster Situation.

The Law 75 "On National Defence" of December 21, 1994 [15], Article 114 defines the Civil-Defence Joint Chiefs of Staff (EMNDC) as the national authority responsible for organizing, directing, executing and controlling the application of the State and Government policy for the risk-reduction-cycle of any kind of disaster and in its CHAPTER XIV “ON THE CIVIL DEFENSE” (Art. 11,13) the EMNDC’s authorities are established.

The Directive No. 1 “For the Disaster Risk Reduction” of the President of the National Defence Council, among others, the following aspects are established: the general hazard assessment of disasters in Cuba; the phases for response to disasters; the general system of emergency classification and documents required to be prepared for response to emergencies. The main planning documents are the Disaster Risk Reduction Plans at different levels: national, provincial, municipal; plans of governmental bodies (Ministries and other governmental and public entities) and operator plans. Under this document, the following outstanding plans have been developed:

- a) Annex to the National Disaster Reduction Plan for action in case of radiological emergencies at the national level.
- b) Plan of CITMA for response to Radiological Emergencies.
- c) Plan of MINSAP for the medical response to a radiological emergency.

Furthermore, the elements related to the implementation of responsibilities of governmental organizations in case of a nuclear or radiological emergency have been developed in their plans.

The Joint Resolution CITMA-MINSAP “Basic Radiation Safety Standards” of November 30, 2001 establishes the radiological protection requirements to be applied in emergency exposure situations when the implementation of protective actions to reduce or avoid exposures is required. Also, this Resolution establishes specific requirements to be fulfilled for preparing the emergency plans of operators and response organizations.

The Resolution No. 18/2012 of DSN “Guide for Preparedness and Response to Radiological Emergencies of December 26, 2012, establishes requirements for operators to assure an adequate level of preparedness for response to radiological emergencies and also for preparing the Radiation Emergency Plan on site. This plan is part of the Disaster Risk Reduction Plan of the licensee.

At the request of the Government, an IAEA Emergency Preparedness Review Service (EPREV) mission was carried out in November 2018. The team that carried out this mission prepared a report with recommendations and suggestions to improve the system of preparedness and response to nuclear and radiological emergencies. The team also identified good practices that will serve to share the experience internationally.

Overview and implementation of main elements of national plan.

The essential elements contained in the national plan are the following:

- a) An introduction that includes, the legal basis, the planning bases, objectives, scope, basics to activate the plan, relationship with other plans of governmental agencies, international coordination, international notification and request for international assistance.
- b) Hazard assessment and classification.

- c) The response organization including the responsibilities of the OACE that participate in the response, the classification of the emergency, the activation, chains of command, phases of the response, etc.
- d) Actions for preparedness that address aspects related to the revision of the plan, training and exercises.
- e) Logistic support.
- f) Public communications.
- g) Response measures.

Regulatory review and control activities.

The fundamental activities of regulatory examination and control are:

- a) Review and assessment of the operator's response plans before granting a license for starting up the operation and during the license renewal process.
- b) Verification of the operator's provisions for response to an emergency during inspections.
- c) Independent evaluation of exercises and drills carried out by the operator.

Article 16 2) Information of the public and neighbouring States.

Considering that there are no nuclear installations within the scope of the Convention in the country, there are no provisions to inform the public in the vicinity of nuclear facilities about emergency planning and emergency situations or to inform to neighbouring states.

Article 16 3) Emergency preparedness for Contracting Parties without nuclear installations.

Measures for the preparation and testing of emergency plans that cover the activities to be carried out on the national territory whether it is likely to be affected by an emergency at a nuclear installation in another country.

As it has been mentioned in this report, the Republic of Cuba does not have nuclear power plants in its territory. However, the national plan for response to nuclear and radiological emergencies provides for response actions in case of severe nuclear accidents at the nuclear power plants: Turkey Point and St Lucie located in the Florida Peninsula, USA, and Laguna Verde located in the State from Veracruz in Mexico. (See the figures in the annex).

Although an assessment of the radiological impact on the national territory of a severe nuclear accident in the aforementioned nuclear installations has not been made, it is presumed that; under atmospheric conditions that favours the dispersion of radioactive contamination in direction to the national territory; levels of radioactive contamination above the background levels are expected to occur and might require the adoption of protective measures, mainly food control/restrictions.

The main actions anticipated in the plans for these accidents are:

- a) Receipt and analysis of the information received from the IAEA regarding the accident and its escalation. Request for additional information to the IAEA if necessary.
- b) Monitoring of media, websites and social networks to obtain information that may be useful.
- c) Use of prediction models of contamination dispersion or request from the World Meteorological Organization predictions of atmospheric dispersion of radioactive material.
- d) Maintain an adequate programme of public information.

- e) Activation of the Environmental Radiological Surveillance Network and deployment of environmental sampling and monitoring teams to areas of interest.
- f) Make predictions of the possible radiological impact on the national territory.
- g) Setting capabilities for monitoring goods, ships and aircraft coming from areas potentially affected by the accident, as well as their passengers, crews and belongings.
- h) Sampling and monitoring of sources of drinking water supply and areas for the production of food where contamination can be found.

In 2008, as part of the International Emergency Response Exercise ConvEx-3 (2008) that simulated a nuclear accident at the Laguna Verde Nuclear Power Plant a National Table Exercise was planned whose general objectives were to:

- a) Test whether the emergency management in a nuclear emergency is efficient and appropriate.
- b) Test whether during an emergency the information is exchanged efficiently and in a timely manner.
- c) Test the effectiveness of the coordination for international assistance.
- d) Test that media releases are appropriate, coordinated and timely and check the level of consistency of the information transmitted to the public.
- e) Compare and check the consistency of response actions/protective measures between countries in Zone 1 (less than 1000 km from the State where the accident occurred) and between countries in Zone 2 (more than 1000 km from the State where the accident occurred).

In addition, specific objectives for the national exercise were considered aimed at verifying plans for public information, existing capacities for radiological impact assessment, verifying methods for adopting countermeasures in agriculture and food control if necessary, identify methods to assess the impact on the export and import industry as well as the economic, psychological and social impact and test the procedures for requesting and offering assistance to other countries in the framework of the exercise.

International arrangements, including those with neighbouring States, as necessary.

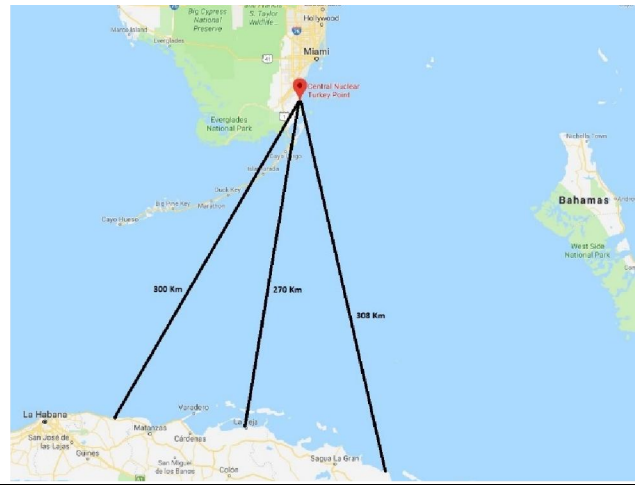
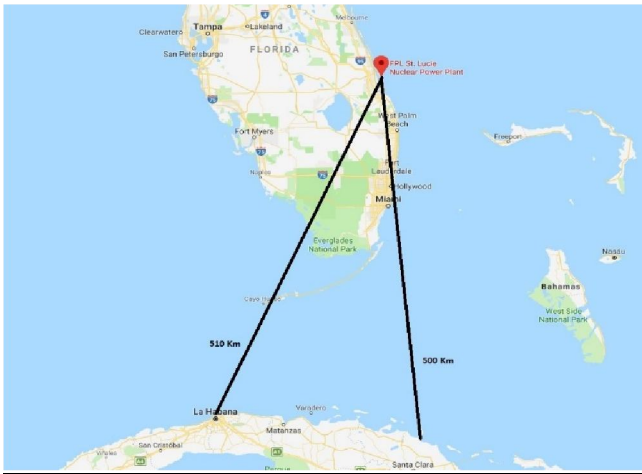
In order to strengthen the international response in the event of a nuclear accident or radiological emergency, on September 26, 1986, Cuba signed the Convention on Prompt Notification of a Nuclear Accident and the Convention on Assistance in the Event of a Nuclear Accident or Radiological Emergency, both were ratified on January 8, 1991, as referred to in the report on compliance with Article 7 in this Report.

International agreements.

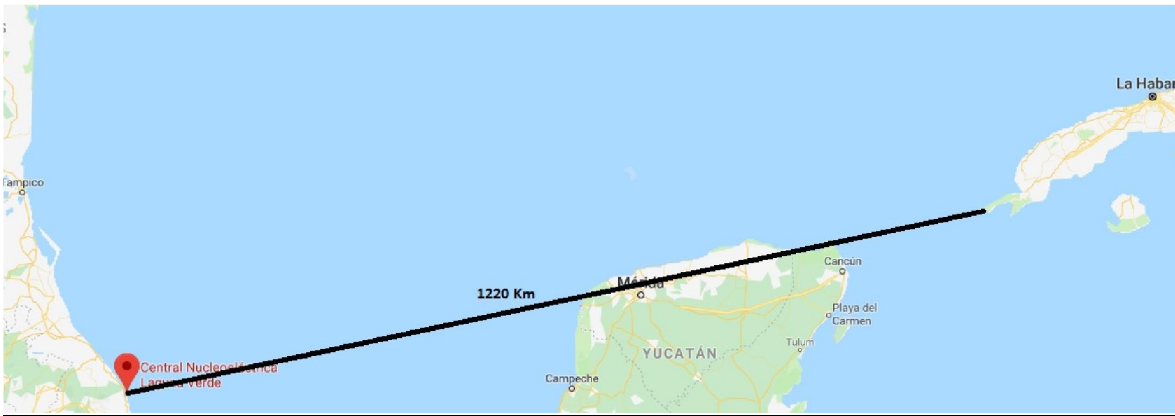
Until now, Cuba does not have agreements with neighbouring states for response to a severe nuclear accident.

ANNEX.

Maps showing the location of the Nuclear Power Plants in the Florida Peninsula



Map showing the location of the Nuclear Power Plant in Mexico



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