# Republic of Cuba

## Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

**Second National Report**

**2020**

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# SECTION A. INTRODUCTION

## A.1. General Information

The Republic of Cuba submitted the instrument of adhesion to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 3 July 2017, and it has been in force in the country since October 1st of the same year.

This is the second National Report of the Republic of Cuba to be assessed at the Seventh Review Meeting of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, hereinafter referred to as the Joint Convention. This report is prepared in accordance with the Guidelines on the form and structure of national reports (INFCIRC/604/ Rev.3 of 18 December 2014).

This National Report has been prepared by the Division of Nuclear Safety (DSN) of the Office for Environmental Regulation and Safety (ORSA) attached to the Ministry of Science, Technology and Environment (CITMA), as a regulatory body responsible for safety and radiation protection and safe management of radioactive waste, with the participation of the Center for Radiation Protection and Hygiene (CPHR), under the Agency for Nuclear Energy and Advanced Technologies (AENTA) from the Ministry of Science, Technology and Environment (CITMA), as the operating organization of the national facility for the centralized management and storage of radioactive waste and disused radioactive sources.

The use and application of nuclear energy began in Cuba in the 1940s, with the application of radioactive sources in medical practice. Nevertheless, nuclear sciences and technologies really began to be assimilated in our country after 1959.

Since 1979, with the creation of the Cuban Atomic Energy Commission (CEAC) and the Executive Secretariat for Nuclear Affairs (SEAN), legal rules have been issued for the regulation and control of the nuclear energy use in Cuba, in accordance with the development and prospects of the Cuban nuclear program, taking as a reference the experience accumulated in the country and international practice, which is the basis of the current Cuban nuclear legislation.

The use of ionizing radiation in Cuba is associated with its applications in medicine, industry, teaching and research, so the types of radioactive wastes generated are low- and intermediate-level waste. In addition, disused sealed radioactive sources arise from these applications. There are no facilities related to the nuclear fuel cycle, only a Sub-Critical Assembly that has 160 fuel elements of Natural Uranium enriched to 0.72%, moderated with light water, which is used for educational purposes.

In order to ensure that practices with sources, including radioactive waste management, are carried out safely and that people and the environment are protected against the harmful effects of ionizing radiations, the Cuban State has adopted the necessary provisions to create a regulatory body and a national infrastructure comprising the appropriate legal and regulatory framework, where responsibilities related to safety are clearly and unequivocally assigned.

## A.2. Structure

Section A shows the scope of the applications of nuclear energy in Cuba and the measures taken by the Cuban State to ensure that these applications are safely carried out. The structure of the report is described, and the actions carried out since the First National Report, presented to the Sixth Review

Meeting.

Section B shows the current situation with regard to the National Policy and Strategy for radioactive waste management, as well as a description of the practices generating radioactive waste, the criteria to classify them and possible management options.

Section C refers to the scope of application of the Joint Convention for the Republic of Cuba in relation to radioactive waste.

Section D describes the facilities for radioactive waste management in the country and the inventory of radioactive waste.

Section E develops the legislative and regulatory framework, as well as all aspects related to the regulatory body, highlighting the implementation of safety measures and provisions.

Section F establishes the obligations of the license holder, human and financial resources, quality assurance, operational radiation protection, radiological emergencies and the decommissioning of facilities.

Section G is not developed because there is no spent fuel in Cuba.

Section H details the degree of compliance with the obligations provided for radioactive waste management in the following topics:

- General safety requirements
- Existing facilities and past practices
- Siting of proposed facilities
- Design and construction of facilities
- Safety assessment of the facilities
- Operation of the facilities
- Institutional measures after closure

Section I deals with the obligations under Article 27 of the Joint Convention regarding transboundary movements.

Section J deals with disused sealed sources, as provided in Article 28 of the Joint Convention.

Section K mentions the actions in relation to planned measures to improve safety identified at the Sixth Review Meeting.

Section L shows Annexes to the Report.

In addition, the overview matrix of the country is included according to point 11 of INFCIRC/604/Rev.3, and bibliographic references.

## A.3. Actions carried out after the First National Report

The main changes regarding the First National Report presented to the Sixth Review Meeting of the Contracting Parties are mentioned below and are developed in each corresponding section or sub-section.

- Approval of the Decree Law No. 10 “On the National Regulatory Authorities”. The Decree Law designates the Office for Environmental Regulation and Safety as the national regulatory authority in nuclear and radiation safety, among other subjects, and approves its functions. This is developed in sub-sections E.2 and E.3.
- Characterization of solid waste packages contaminated with Cs-137, and liquid waste; and approval of a national project for the treatment of aqueous liquid waste. This is developed in sub-section B.2.3.
- Change in the inventories of solid radioactive waste and disused sealed sources. This is developed in sub-section D.2 and Section L.
- Renewal of the operating license of the management facility, safety reassessment. This is developed in sub-section H.5.
- Modifications in the Radioactive Waste Management Facility of the CPHR. This is developed in sub-section H.2.1.
- Actions developed in relation to the Safety Culture. This is developed in sub-section E.3.6.

# SECTION B. POLICIES AND PRACTICES

## B.1. Policy for radioactive waste management

As a result of the work carried out to update the draft Policy and Strategy, it was identified that the recent changes in the structure of the State and the Government derived from the approval of a new Constitution of the Republic in April 2019, demand the updating, elaboration and implementation of other policies that require greater urgency, in accordance with the national procedure established for that purpose. For this reason, it was decided to prioritize updating the draft Strategy for the management of radioactive waste until the year 2030, which establishes the criteria, objectives and goals for the safe management of radioactive waste, taking as reference the recommendations of the International Atomic Energy Agency (IAEA) and an assessment of national realities.

The document "Strategy for the management of radioactive waste in Cuba 2020-2030" was finalized, currently it is under review for approval. Most of the elements of the Policy have their expression in the national legislative and regulatory framework.

The collection, treatment, conditioning and interim storage of radioactive waste in the country is carried out on a centralized basis by the Centre for Radiation Protection and Hygiene (CPHR). This institution has the required facilities for this purpose: a Radioactive Waste and Disused Sources Treatment and Conditioning Plant (RWTP) and an Interim Storage Facility. The radioactive waste in this facility is retrievable in order to meet, in due course, the acceptance criteria for the future disposal facility.

The main elements of the policy established in the legislative framework are the following:

Law No. 81 "On the Environment" of July 11, 1997. [1]

- The import of hazardous and radioactive waste requires the prior and express authorization of the Ministry of Science, Technology and Environment (CITMA), which shall demand the import to be carried out in accordance with international recommendations and current national regulations. It also has to be socially justified.
- Environmental actions for sustainable development are based on requirements for the economic and social development of the country and on the following principles:
    a. The public knowledge of environmental actions and decisions and the consultation of the opinion of the citizens shall be ensured in the best possible way; but in any case, with ineludible character.
    b. The State establishes and provides the necessary means and guarantees the adequate and timely protection of the right to have a healthy environment.
    c. Every person shall have adequate access, as legally established in this regard, to available environmental information held by state bodies and agencies.
    d. Environmental management is integral and involves several sectors. State's bodies and agencies, other institutions and organizations, society and citizens in general participate in it, according to their respective competences and abilities.
    e. The role of the community is essential for the purposes of this law. It participates effectively in decision-making and the development of self-management processes aimed at protecting the environment and raising the quality of life of the people.

Decree-Law No. 207 "On the Use of Nuclear Energy" of February 14, 2000. [2]

- CITMA is the Ministry in charge of directing, implementing and controlling the State and Government policy in relation to the use of nuclear energy and is responsible for the regulation and control of the safe use of nuclear energy, as well as for the system of accounting for and control of nuclear materials through the National Center for Nuclear Safety
- The regulatory and control activities carried out by the National Center for Nuclear Safety have an effective autonomy and independence from those related to the promotion and development of nuclear energy and have sufficient economic and human resources to carry out their functions.
- The radioactive waste management will be carried out so that:
    - it ensures the protection of human health and the environment;
    - predictable impacts on the health of future generations are not greater than those currently permitted;
    - it does not impose undue burdens on future generations; and
    - the potential effects on human health and the environment beyond national borders are not greater than those acceptable in the country.
- Authorization holders shall be responsible for the management of radioactive waste generated as a result of their activity during their operating lifetime, as well as for the closure or decommissioning of facilities. Therefore, they shall plan from the outset the financial resources necessary to defray the respective costs. This responsibility may be transferred to a specialized facility.
- Licensees and registrants that generate radioactive waste shall make economic contributions to a fund intended for the disposal. This fund will be created, administered and controlled by the State Council of the Republic of Cuba.

CITMA Resolution No.35/2003, Regulation "On the safe management of radioactive waste" of March 7, 2003 [3].

- License holders from waste generators, in order to ensure that the generation of radioactive waste, environmental impact, and cost of management are kept to a minimum, shall:

    - prevent unnecessary contamination of materials;
    - use minimal amounts of radioactive material;
    - use short lived radionuclides insofar as it is possible;
    - avoid unnecessary use of toxic and hazardous materials; and
    - implement appropriate procedures for all operations.

- The license holder importing a sealed source shall make the reasonable and necessary efforts to re-export it to the supplier once it is considered disused, and for such purposes, a contractual agreement between the parties at the time of acquisition should be negotiated.
- All waste generators and the radioactive waste management facility shall have the corresponding authorization from the regulatory body, as established in the current legislation, and they shall be subject to periodic inspections by the regulatory body inspectors.
- Radioactive waste is defined as: material that contains or is contaminated with radionuclides at concentrations or activities greater than clearance levels as established by the regulatory body and for which no further use is foreseen.
- Sources, including substances, materials and objects used in practice that meet clearance

levels may be released from regulatory control in accordance with the procedures established for this purpose by the regulatory body.

- The disposal of radioactive waste shall be carried out in a way that ensures the safety and radiation protection of people and the environment during all stages of the facilities, for which the regulatory body shall establish the safety objectives of the facility.

## B.2. Radioactive waste management practices

Radioactive wastes generated in Cuba arise from the use of radioactive materials in medicine, industry, research and teaching. They are classified according to their characteristics and management option [3]. In correspondence with existing practices and those planned for the coming years, high-level radioactive waste is not anticipated that will be generated in the country. When the waste complies with the clearance criteria and levels stipulated in the current regulation [4], radioactive materials are released from regulatory control in accordance with the established procedures and controls.

The current legislation [3] states that all radioactive waste should be controlled and their generation should be kept to the minimum practicable. Prior to the construction of a facility with the potential for generating radioactive waste, from the design phase, and throughout its operating lifetime, the necessary measures are required to be implemented in order to control the generation of radioactive waste, in terms of both its volume and radioactivity content. This should be taken into account in the selection of building materials, the radioactive materials to be used and the processes and equipment, as well as in the procedures for operation and decommissioning.

Waste generators (as part of management) carry out in their own facilities the characterization, segregation and interim storage of the generated waste. Waste generators are not authorized to carry out any kind of treatment or conditioning of radioactive waste and disused sealed sources, only their safe interim storage in their facilities until the clearance levels and criteria are met or the radioactive waste are transferred to the CPHR, as the centralized waste operator.

The processing of radioactive wastes and disused sealed sources is carried out in the CPHR's Radioactive Waste and Disused Sources Treatment and Conditioning Plant (RWTP), in such a way as to guarantee safety under normal operating conditions. Measures are taken to prevent incidents or accidents and provisions are made to mitigate the consequences in the event of an accident.

### B.2.1. Criteria used to define and classify radioactive waste

Radioactive waste are those materials that contain or are contaminated with radionuclides at concentrations or activities greater than clearance levels established by the regulatory body [3, 4] and for which no further use is foreseen.

Radioactive wastes are classified in accordance with current regulations [3], as shown in Table No. 1. This classification is based on radioactive waste management options.

| Type of waste | Description | Management options |
|---|---|---|
| Low and intermediate level and very short lived waste | Radioactive waste containing radionuclides with short half-life (less than 100 days) which, after a period of interim storage, will decay to clearance levels. | Interim storage in waste generators or in management facilities until reaching clearance levels |
| Low and intermediate level and short lived waste | Radioactive waste containing radionuclides with activities above the clearance levels established by the regulatory body, with half-life higher than 100 days and less than 30 years and that does not generate residual heat above 2 kW/$m^3$ | Treatment, conditioning and interim storage in the management facility and near surface disposal. (the decision is pending) |
| Low and intermediate level and long lived waste | Radioactive waste containing radionuclides with activities above the clearance levels established by the regulatory body, with half-life higher than 30 years and that does not generate residual heat above 2 kW/$m^3$ | Treatment, conditioning and interim storage in the management facility and disposal. (the decision is pending) |

Table No.1 Classification of radioactive waste according to management options.

The radioactive waste received at the CPHR management facility are classified and segregated according to their characteristics and the methods provided for their treatment and conditioning. Liquid wastes are segregated into aqueous or organic. The treatment of solid waste is not currently planned, so there is no criterion for its segregation.

Disused sealed sources are classified into five risk-based categories [5]. This is in line with the IAEA's recommendations.

The planned modification of the Waste Regulation will assume the classification of radioactive waste from the IAEA Document, GSG-1 Classification of Radioactive Waste of 2015.

### B.2.2. Origin of radioactive waste

As mentioned above, the radioactive wastes generated in Cuba arise from the application of ionizing radiation in medicine, industry, research and teaching. Most of the inventory corresponds to disused radioactive sources, which cannot be returned to suppliers and shall be managed in the country. Generated solid and liquid radioactive wastes are low and intermediate level, and are included in the three (3) types described in Table No.1.

There have been no changes in the types of radioactive wastes generated in the country, since the previous Report. Most of these wastes are contaminated with very short lived radionuclides ($T_{1/2}$< 100 days) belonging to the first group, according to the classification shown in Table No.1.

As described in the previous report radioactive waste containing radionuclides with half-life greater

than 100 days and less than 30 years (second group in Table No.1) were generated in past practices. During the 1980s, research related to the treatment and conditioning of radioactive waste, was carried out at the former Nuclear Research Institute (ININ). The above mentioned waste was supposed to be generated at the Juragua NPP (which was then under construction). As a result of these studies solid and liquid radioactive waste mainly contaminated with Cs-137, Co-60, Sr-90, Eu-152, among others, was generated. Some of the waste was immobilized and conditioned in 210 l drums and the other was stored in the interim storage facility from the CPHR, without treatment or conditioning.

Other research activities, mainly in the field of medicine and biology generated solid and liquid wastes contaminated with H-3 and C-14. No waste of this type is currently generated.

The largest volume of solid waste stored in the facility arises from dismantling and decontamination of two medical facilities, that were contaminated one with Cs-137 and the other with Ra-226. These wastes are mostly debris and contaminated soil. According to the classification shown in Table No.1 and depending on the radionuclides contained in the wastes, these are included in the second group (Cs-137) or in the third group (Ra-226) of the mentioned Table.

This group of long-lived waste (third group) includes some chemical compounds (Uranium, Thorium), which were used in non-nuclear applications (assessment of catalytic processes and quality control of processes in the sugar industry), as well as scrap metal contaminated with natural radionuclides, which have been detected at the radiological surveillance points for scrap metal.

Disused sealed sources have been generated in all spheres of application, although most come from industry, where they were used in nuclear gauges (level, density, humidity, thicknesses, etc.), non-destructive testing, etc. Another important group comes from medicine, most used in radiotherapy treatments. The radionuclides contained in radioactive sources and their activities are varied and include the five source classification categories.

### B.2.3. Management options for radioactive waste and disused sealed sources

At present, only very short lived (T1/2<100 days) solid and liquid radioactive wastes continue to be generated. The management option for this type of waste is temporary storage in the facilities where they are generated until decay below the clearance levels. These wastes could be transferred to the CPHR if the generator institution does not have enough storage capacity. After meeting clearance levels, these materials are released from regulatory control and managed as conventional waste, provided they are not considered hazardous wastes, according to other national regulations. The CPHR has developed a Practical Guide for the management of radioactive waste from medical and research facilities. The Guide contains recommendations to waste generators for the management of this type of waste in order to minimize volumes and optimize their management and control. In this sense, recommendations on the collection, characterization, segregation and interim storage of this type of waste are provided.

Although inventories of radionuclides stored in the facility are available, there are short- and long-lived radioactive wastes that have not been treated or conditioned yet, since their chemical and radiological composition is not known. A detailed characterization of these radioactive wastes is required.

In recent years, progress has been made in characterizing radioactive waste. A facility for gamma spectrometric measurement of solid waste packages containing Cs-137 was put into operation. It

was designed and constructed at the CPHR, with the advice of an IAEA expert. The characterization facility comprises: a mechanical system that allows the controlled rotation of the packages and the vertical displacement of the detector; a detection system composed of a NaI (Tl) detector and the necessary shields and collimators and the system for spectra acquisition and analysis. The radioactive waste packages containing Cs-137 were measured at this facility. This method of measurement is now under validation. Other waste packages containing mixtures of radionuclides cannot be measured due to the low resolution of this type of detector. A means of financing is sought to acquire a hyperpure Germanium detector.

A characterization of the liquid waste was carried out to determine: colour, clarity, suspended solids, pH and phase (aqueous, organic). In addition, the users were contacted to investigate the origin of the waste, mostly from research practices.

After completing the characterization, the waste whose activity concentration is below the clearance levels established in current regulations [4] will be released from regulatory control.

The treatment and conditioning for interim storage, until the final disposal is defined and implemented, is planned for the radioactive waste that cannot be released from regulatory control. The options envisaged for the management of this radioactive waste will be, where appropriate, the following:

- Aqueous liquid waste: The national Project: “Removal of Cs-137 from liquid radioactive waste using nanoparticles with superparamagnetic and adsorbent properties” started in 2020. The objective of the project is to design, synthesize and characterize multifunctional nanostructured materials with superparamagnetic properties and active sites to selectively remove Cesium from aqueous solutions [6]. Once their effectiveness has been proven, these compounds will be used for the treatment of liquid radioactive waste, to reduce the Cs-137 concentration below the clearance level so that the liquids can be discharged into the environment. The activity of the other radionuclides contained in liquid waste (Co-60, Eu-152) has practically decayed below the clearance levels. If the treatment is not effective (the specific activity does not decrease below the authorized clearance levels) liquids shall be immobilized by cementation. Some preparatory work will be necessary, to experimentally determine appropriate formulations consisting of cement and any additives (zeolite is recommended), and their relative amounts to produce solid cement blocks having adequate mechanical strength and leach resistance [7].

- Organic liquid wastes: pre-treatment with clay or an emulsifying agent shall be carried out. The obtained product shall be immobilized in cement matrix. It is necessary to perform previous experiments to determine the appropriate formulations consisting of cement and any additives, and their relative amounts to produce solid cement blocks having adequate mechanical strength and leach resistance [7].
- Solid waste: Solid radioactive waste shall be immobilized in cement matrices, in 210 l drums.
- Waste conditioned in the past (historical waste): most of these waste packages are damaged, so if they do not meet the clearance criteria shall be reconditioned in 400 l cylindrical containers.

The disused sealed sources have been divided into 2 groups for their management, based on the safety criteria to be followed to handle them:

- Category 1-2 radioactive sources
- Category 3-5 radioactive sources

Disused radioactive sources of categories 1-2 remain in storage facility inside their devices (irradiators, teletherapy heads). Conditioning of these sources could not be carried out. An IAEA expert mission is planned to evaluate one of the hot cells of the Center for the Production of Isotopes (CENTIS) and to recommend the necessary modifications to this hot cell, in order to use it for the conditioning of Category 1 and 2 sources. In addition, capsules and containers are required to place the recovered sources, as they are not currently available.

Category 3-5 disused radioactive sources continue to be conditioned for temporary storage at the facility. A total of 619 sources, recovered from radioactive lightning conductors, were conditioned in the last two years (2019-2020).

Most of devices (nuclear gauges, lightning conductors, etc.) containing the sources of categories 3-5 are damaged (corroded), because they were exposed to severe environmental conditions in the industries where they were used. Besides, they were manufactured more than 30 years ago.

The conditioning process consists of removing the sources from the devices where they are contained, characterizing the sources (verification of the radionuclide, dose rate measurements, activity estimation and leak testing by smear samples) and placing in stainless steel capsules. The conditioning plan is previously prepared, containing the devices to be dismantled and the sources to be placed in each capsule, depending on the radionuclide, activity and dimensions of the sources, as well as the limits established in the safety assessment.

Once completed, the capsule is sealed by welding the lid. After checking that the capsule is leaktight, it is stored in a suitable container. Conditioned capsules can be retrieved in the future and transferred to a borehole, if this is the option selected for the final disposal.

The dismantling of devices to remove the radioactive sources and their subsequent conditioning in stainless steel capsules are included among the operations authorized by the regulatory body in the current license for the radioactive waste management practice. This conditioning methodology is based on the latest IAEA recommendations [8].

## SECTION C. SCOPE OF APPLICATION

In the Republic of Cuba, the Joint Convention applies to safety in the management of low- and intermediate- level radioactive waste. The above mentioned wastes are generated in practices related to medicine, research, industry and teaching, including disused sealed sources that are not returned to the manufacturer or supplier. Other practices generating other types of waste are not conducted nor anticipated to be developed in the near future.

In Cuba, there are no facilities related to the nuclear fuel cycle, nor planned in the near future. There are 160 fuel elements in a subcritical reactor used for teaching purposes.

Natural occurring radioactive materials (NORM) are not considered in this report.

# SECTION D. INVENTORIES AND LISTS

## D.1. Facilities

In Cuba, there is only one centralized facility for the management of radioactive waste and disused sealed sources. This facility includes:

i. Interim Storage Facility
ii. Radioactive Waste and Disused Sources Treatment and Conditioning Plant (RWTP)

## D.2. Radioactive Waste Inventory

No significant changes have occurred in recent years in the applications of ionizing radiations that generate radioactive waste in Cuba. The CPHR continues to collect the radioactive waste and disused radioactive sources at the generator's facilities throughout the country.

Disused sealed sources and very short lived solid and liquid radioactive wastes ($T_{1/2}$ < 100 days) were mainly generated in this period (since the previous report). Very short lived wastes are not included in the inventory presented in this report. As it was mentioned before, most of these wastes are managed at the generator facilities.

The inventory of radioactive waste contaminated with radionuclides with half-lives greater than 100 days was increased with nuclear material reagents (Uranium, Thorium), which were received from universities and research centers. The total volume of these wastes was approximately 200 $dm^3$. In addition, several metal parts (pipes, valves, etc.) contaminated with natural radionuclides were received in the facility. These contaminated metal parts were detected at the scrap metal radiological surveillance points. They are now stored at the Treatment and Conditioning Plant, waiting for characterization and to assess the possibility of decontamination and clearance, so they have not been included yet in the inventory of radioactive solid waste.

The volume of liquid radioactive waste was not increased in this period.

The inventory of disused radioactive sources was increased in this period (since the previous National Report), with:

- neutron sources used for teaching,
- disused Co-60 sources from a research irradiator, from the Center for Technological Applications and Nuclear Development (CEADEN),
- soil moisture/density gauges, containing Am-Be and Cs-137 radioactive sources,
- various nuclear density gauges, containing Cs-137 sources, from industry,
- radioactive lightning conductors containing Am-241 and C-14 sources,
- ionization smoke detectors containing Am-241 and Kr-85 radioactive sources, and
- calibration sources of various radionuclides.

Thirty four (34) Ir-192 brachytherapy sources that were stored in the facility were returned to the supplier.

The inventory of radioactive waste and disused radioactive sources stored at the CPHR Waste Management Facility is presented in the Section L of this report.

Annex L.1 shows the estimated volume of radioactive waste stored at the CPHR waste management facility. Annex L.2 presents a summary of the inventory of stored disused sealed sources.

The largest number of disused sealed sources continues to be the Am-241 sources from ionic smoke detectors. While the highest activity corresponds to Co-60 sources, many of them are of category 1 or 2 (irradiators and teletherapy heads), followed by Cs-137 sources from old teletherapy heads and nuclear gauges. Among them, the 24 disused radioactive sources from the research irradiator from the Center for Technological Applications and Nuclear Development (CEADEN), which were transferred to a container, transported and safely stored in the temporary waste storage facility.

The conditioning of the disused sealed radioactive sources, following the methodology recommended by the IAEA, began in 2007, with the Ra-226 sources [9]. The conditioning of other disused radioactive sources of categories 3-5, by re-encapsulation in stainless steel capsules continued in 2015 [8]. Forty four (44) neutron sources and seventy four (74) Cs-137 radioactive sources were conditioned between 2015 and 2016. These sources were removed from nuclear gauges, calibration and teaching devices. Neutron sources were placed in 8 stainless steel capsules and the Cs-137 sources in 3 capsules. One hundred eighty eight (188) radioactive lightning conductors, 183 of them containing Am-241 sources and 5 containing C-14 sources, were dismantled in the last two years. The 570 sources of Am-241 removed from these lightning conductors (estimated number, since some sources were broken) were conditioned in 10 stainless steel capsules, while the 49 C-14 sources were placed in one capsule.

The inventory of disused radioactive sources conditioned and stored at the CPHR Waste Management Facility is presented in the annex L.3.

The conditioned capsules are stored in containers, guarantying adequate shielding and safety. The data of the waste packages (containers), as well as the capsules and the sources they contain are properly recorded. The conditioned capsules constitute new radioactive sources, although in Annex L.2 of this report, the initial individual sources are reported.

The disused radioactive sources from the irradiator of the Food Irradiation Plant, belonging to the Food Industry Research Institute still remain stored in the user facility. A container for the transport and storage of these sources has been acquired through an IAEA TC project. The Institute, with the advice of the CPHR, is applying for the authorization from the regulatory body for removal of the disused sources from the reserve pit (where they are stored), transfer them to this container and transport to the Radioactive Waste Storage Facility.

The Annex L.4 in Section L of this report shows the inventory of disused sealed sources of the Food Irradiation Plant.

# SECTION E. LEGISLATIVE AND REGULATORY SYSTEM

## E.1. Implementation of measures

Cuba has established and implemented a national legislative and regulatory framework with all necessary measures to ensure the safety of workers, the public and the environment during the use of ionizing radiation sources including the management of radioactive waste and disused sealed sources.

Since 2007, the regulatory body adopted a Policy for the establishment of the legislative and regulatory framework for the use of nuclear energy and began to develop the "Strategy for the preparation, revision and modification of regulatory documents in the nuclear field", which is reviewed and updated every 3 years. This Strategy takes into account the analysis of the national and international environment, which includes: the development and future projection of practices associated with the use of ionizing radiation in the country, the building-up of experiences in implementing the legislative and regulatory framework, changes in State organizational structures and the national legislation, as well as the adoption of new international commitments and the new standards on safety and protection, promoted by the IAEA.

The Strategy also encompasses a Program for its implementation, which contemplates the general actions identified to be carried out in the current strategic cycle, which allows the annual planning of specific tasks for the preparation, review and modification of regulatory documents, as well as for the adoption of commitments derived from international legal instruments and safety standards.

## E.2. Legislative and regulatory framework

The legislative and regulatory framework in force in Cuba establishes the objectives, criteria and principles for carrying out the safe management of radioactive waste, which is expressed in the following legal regulations:

- Law No. 81 "On the Environment" of July 11, 1997 [1]. CITMA is the body responsible for proposing environmental policy and directing and controlling its implementation based on coordination and control of the country's environmental management.

- Decree-Law No. 207 “On the use of Nuclear Energy" of February 14, 2000, hereinafter Decree-Law 207. [2]. CITMA is the body in charge of directing, implementing and controlling the State and Government policy in relation to the use of nuclear energy and is responsible for the regulation and control of the safe use of nuclear energy, as well as for the system of accounting for and control of nuclear materials through the National Center for Nuclear Safety.

- CITMA-MINSAP Joint Resolution, Regulation “Basic Safety Standards" of November 30, 2001, hereinafter BSS. [7]. It establishes the basic requirements for the protection of individuals against exposure to ionizing radiation and for the safety of radiation sources.

- CITMA Resolution No. 35/2003, Regulation "For the safe management of radioactive waste" of March 7, 2003, hereinafter “Waste Regulation” [3]. It establishes the general rules governing the requirements for the safe management of radioactive waste, in order to ensure the protection of people, property and the environment from the harmful effects of

ionizing radiation, now and in the future, without imposing undue burdens on future generations.

- CITMA-MINSAP Joint Resolution, "Regulations for the Selection, Training and Authorization of the Staff Performing Practices Associated with the Use of Ionizing Radiation" of December 19, 2003, hereinafter referred to as "Staff Regulation". [11]. It establishes the provisions governing the basic requirements for the selection, training and authorization of the staff engaged in practices associated with the use of ionizing radiation, so that enough qualified personnel are available to ensure the safety of practices and the protection of workers, the public and the environment.

- CITMA Resolution No. 121/2000, "Regulations for the Safe Transport of Radioactive Materials" of December 14, 2000, hereinafter "Transport Regulation" [12]. It establishes the technical and administrative requirements to be met during the transport of radioactive materials to protect people, property and the environment from the harmful effects of ionizing radiations.

- CITMA Resolution No. 58/2003, of April 15, 2003 [13]. It states the prohibition of importing and acquiring radioactive lightning conductors throughout the country. It provided a period of 10 years (until July 2013) to dismantle the installed radioactive lightning conductors and manage them as radioactive wastes, including those stored.

- CITMA Resolution No. 96/2003, of July 10, 2003. [14] It establishes requirements for holders of ionization-type smoke detectors, regarding the notification of their possession and management as radioactive waste when they are disused.

- CITMA Resolution No. 103/2004, "Regulation of State Inspection of Environmental Regulatory Activity" of June 10, 2008 [15]. It regulates State Inspection of the Environmental Regulatory Activity, carried out by CITMA.

- CITMA Resolution No. 334/2011, "Regulation on Notification and Authorization of Practices and Activities Associated with the Use of Ionizing Radiation Sources", of December 29, 2011, hereinafter "Authorization Regulation" [5]. It establishes technical and administrative requirements governing the process of notification and authorization of practices and activities associated with the use of ionizing radiation sources.

- CNSN Resolution No. 1/2004, "Guidance on clearance levels" of January 9, 2004, [4] It states the clearance levels for solids, and the authorized release limits for liquids and gases to the environment.

- CNSN Resolution No. 17/2012, Guide "Safety Assessment of Practices and Activities Associated with the Use of Ionizing Radiation Sources" of December 24, 2012. [16]. It sets out the general criteria for a safety assessment to be consistent with the current legislation.

- CNSN Resolution No. 18/2012, "Guide for preparedness and response to radiological emergencies" of December 25, 2012, hereinafter "Emergency Guide". [17]. It establishes the requirements to ensure an adequate level of preparedness and response in cases of radiological emergencies and to prepare the Radiological Emergency Plan (REP) of the institutions involved.

- CNSN Resolution No. 6/2015, “Safety Guide for the Control of Surface Contamination" of January 28, 2016. [18]. It sets the limits for the control of surface contamination in normal operation.

Currently, most of these legal regulations are under revision and modification , with the aim of updating and harmonizing them, taking into account the structural and institutional changes in the country, as well as the approval and implementation of new policies such as: Environmental Policy and the Policy on National Regulatory Authorities, to which is added the experience of several years of implementation, as well as international advances and recommendations.

It should be highlighted that as part of the implementation process of the Policy on National Regulatory Authorities, on April 16, 2020, Decree Law 10 On National Regulatory Authorities was approved by the State Council establishing the process for creating these authorities, harmonizing their operation and organization, as well as the determination of their hierarchy, which reinforces and ratifies various aspects established in the specific nuclear legislation. These aspects are addressed throughout this Report.

### E.2.1. Licensing system

Activities related to radioactive waste management as well as all practices and activities using ionizing radiation sources are subject to the notification and approval process by the regulatory body, according to the current legislation [5]. This legislation states different authorization modalities (licensing, registration and permission) taking into account the dangerousness of the sources associated with practices and activities and the complexity of the operating procedures.

Under this criterion, radioactive waste management facilities conducting treatment, conditioning and interim storage of radioactive waste and disused sealed sources require a license to carry out activities subject to regulatory control. This license is granted for the stages of construction, operation and decommissioning of the facilities.

In the case of waste generators, the licensing process for assessing safety in the radioactive waste management is authorized within the framework of the authorization process for the specific practice being carried out.

Likewise, the staff working in the waste generators and radioactive waste management facilities is subject to the licensing process, which shall meet, among others, the following requirements: basic and specialized training, previous experience, psychic and physical aptitude, age, and the training required to fulfill job duties. [11].

The authorizations for the management facilities, as well as for the staff working in them, are valid for 5 years. After this period, they have to be renewed to continue its operation.

When changes are to be made to the authorized practices, they should be informed to the regulatory body for their evaluation and, if appropriate, amendments to the authorizations are made.

In the case of the disposal facility for radioactive waste; under the provisions of Law No. 81 [1], new projects of facilities used for handling, transporting, storing, treating and disposing of hazardous wastes shall be submitted to the Environmental Impact Assessment (EIA) process. This EIA process includes the application for an Environmental License.

As established in CITMA Resolution No. 132/2009, "Regulation for the Process of Environmental Impact Assessment" [19] all environmental license applications for the implementation of construction projects or activities in nuclear and radioactive facilities as well as those related to other practices associated with the use of nuclear energy and nuclear and radiation safety, are submitted to the regulatory body for its consideration. Within the matters of its competence, the regulatory body is the authority responsible for assessing and ruling on the environmental license applications.

All documentation related to EIA process is public. In order to ensure an effective implementation of the EIA process, the regulatory body shall, inter alia, take the following actions:

- To adopt the necessary measures to ensure an adequate flow of information to guarantee an efficient processing.
- To conduct environmental inspections and take appropriate measures against detected infringements, in accordance with current legislation.
- To implement verification and monitoring mechanisms, and others designed to systematically enforce environmental controls either on ongoing works and activities or in full operation; the control mechanisms can include the granting of environmental licenses for specific phases or stages of the project, after their evaluation.
- To take the necessary measures to ensure that the interests and concerns of citizens, related to the area in which a work or activity is projected, are considered in the EIA process.

The EIA process for radioactive waste disposal facilities is also governed by specific legislation and regulations. In this sense the Waste Regulation [3] states that the site for the disposal of radioactive waste should be previously authorized by the regulatory body. The regulatory body's technical opinion is binding to grant or deny the environmental license.

### E.2.2. Prohibition to operate without a license

All waste generators and waste management facilities shall have the authorization granted by the regulatory body pursuant to the provisions of Decree Law 207 [2], the Waste Regulation and the Authorization Regulation in force [3, 5] and in this regard no natural or legal entity shall generate, store or manage radioactive waste beyond that stipulated by the mentioned authorization.

The fact of commissioning or operating a facility in which radioactive substances or other sources of ionizing radiation are used without due authorization constitutes a crime foreseen and sanctioned in article 186 of the Penal Code [21].

### E.2.3. Control System

In order to verify compliance with the existing legislative and regulatory framework in the country regarding ionizing radiation sources, the regulatory body has established a control system that includes analysis and evaluation during the authorization and inspection processes. In case of non-compliance, the regulatory body requires that corrective actions be taken. Non-implementation of these actions may lead to the application of coercive measures provided for in the legislative and regulatory framework in force.

### E.2.3.1. Documentation and reports

During the licensing process, applicants shall submit to the regulatory body the documentation related to radiation safety and protection. The documentation to be submitted covers the following aspects:

i. Safety case including, among other things, the following:
    a. description of practice and facility
    b. safety assessment
    c. radiation safety and protection program.
ii. Results of the acceptance and commissioning tests of the equipment and components.
iii. Aspects related to the facility staff.
iv. Security and fire safety certificates granted by the corresponding competent authority.
v. Radiological emergency plan.

The detail of the information required by the regulatory body is established in the current Authorization Regulation [5].

In the case of the radioactive waste management facility, in addition to the documentation required during the licensing process, the license granted establishes, among other specific conditions, those relating to the submission to the regulatory body of reports related to safety and radiation protection, including:

- Occurrence of radiation incidents and emergencies
- List of disused sealed sources and radioactive waste annually collected
- Estimated volume of radioactive waste stored in the facility
- Overexposure of any worker of the facility
- Total activity stored per radionuclide in the facility
- Discharges of radionuclides to the environment
- Any other relevant information considered by the regulatory body.

Regarding waste generators, the requirements and conditions of the authorization, relating to reports, are established according to the risk of practice.

### E.2.3.2. Inspection

Decree Law 207 [2] empowers inspectors of the regulatory body to carry out inspections to verify compliance with the requirements established in the current legislation, the requirements imposed in the authorizations granted and the state of radiation safety in practice.

The regulatory body may also carry out inspections during the licensing process, when radiological events occur, to verify compliance with previous inspection measures, in response to complaints and allegations of misuse of ionizing radiation, among other causes [15].

The frequency of planned inspections is set out in a graded approach and taking into account the risk groups that have been defined on the basis of hazard and risk of sources associated with the practices and at each particular facility.

According to these criteria and based on the inventory of radioactive material and the operations carried out in both the RWTP and the interim storage facility, the inspection frequency for the radioactive waste management facility is twice a year.

Once inspections are conducted, the regulatory body issues an Inspection Report detailing the findings detected during inspections, those findings which are non-compliances with the regulations or license conditions are remarked as deficiencies. In addition, written warnings are included, as well as the deadline for compliance.

In order to remedy deficiencies detected during inspections, facilities should draw up a plan of measures, indicating the committed violations, the measures proposed to eradicate them, the schedule of compliance, and people responsible.

The results of inspections and compliance with the requirements imposed during inspections are monitored by the regulatory body.

In this regard, the new Decree Law 10/2020, of the National Regulatory Authorities, establishes in its article 17.1. that the National Regulatory Authorities carry out planned inspections of the natural and legal persons under their regulatory control to verify if the regulatory requirements and the conditions specified in the authorization granted to the inspected subject are met. In addition to the planned inspections, the regulatory body may carry out other inspections for complaints, to follow up on the requirements indicated in the planned inspections or for the investigation of accidents or other incidents.

The aforementioned Decree-Law, in its article 18 establishes that the National Regulatory Authorities, as a result of the inspection, prepare a report where they expose the results of compliance with the legal and regulatory provisions within the scope of their competence.

### E.2.4. Enforcement

The regulatory body´s enforcement actions are implemented as per the legislative framework in force, which offers the possibility of imposing several administrative measures, according to the nature, gravity and significance of the safety breach.

Decree Law 207 [2] establishes the general rules for the suspension and revocation of authorizations, as well as the faculty of inspectors to impose the following measures:

- suspend or halt the execution of operations and activities
- secure, retain or confiscate radioactive sources
- temporarily or partially shut down premises and facilities

On the other hand, the Authorization Regulation [5] complements the stipulations of Decree Law 207 [2], regarding the suspension and revocation of authorizations, and establishes the basis, as well as the terms and conditions to lodge an appeal against these measures.

Decree-Law 200 [20], although only applicable in the event of detecting violations related to breaches of inspection measures, empowers the inspectors to impose the following measures:

- Fine
- Warning
- Obligation to do whatever it is necessary to halt the continuity of the misconduct or

infringement.

Law No. 62, which is the Cuban Penal Code [21], dated December 29th, 1987, includes criminal conducts in relation to this topic, in its Articles 185 and 186 and consequently establishes its sanctions.

The updated Decree-Law No. 207 will take into account several recommended aspects related to enforcement and will include key policy elements for enforcement actions.

### E.2.5. Clear assignment of responsibilities

The current legislative framework clearly establishes the responsibilities of each party involved in radioactive waste management.

Decree Law 207 [2] lays down that authorization holders shall be responsible for the management of radioactive wastes generated as a result of their activity during their operating lifetime, as well as the closure or decommissioning of the facilities, for which the necessary financial resources to cover the corresponding costs shall be provided.

Waste regulation [3] states that waste generators may temporarily store low- and medium-level and very short lived wastes, until decay below the clearance levels and then release to the environment. Other types of waste shall be transferred to the CPHR as the organization in charge of the centralized management of radioactive waste.

## E.3. Regulatory Body

By the end of 1990, the growing development of nuclear activity in the country led to the creation of the National Center for Nuclear Safety (CNSN), as an independent regulatory body, through Resolution No. 27 dated November 30, 1990 of the head of the Executive Secretariat for Nuclear Affairs (SEAN), to address safety aspects in relation to the use of nuclear energy in the country. In 1994, through Decree-Law No. 147 "On the Reorganization of the State Central Administration Bodies", CITMA was created, and the Institutions related to nuclear matters, were attached to this Ministry, since then and so far, the regulatory body is part of CITMA.

Decree Law 207 [2] establishes that the regulatory and control activities carried out by the regulatory body, have an effective autonomy and independence from those related to the promotion and development of nuclear energy. Furthermore, the regulatory body has its own economic and human resources sufficient to carry out its duties.

In 2002, CNSN joined the Office of Environmental Regulation and Nuclear Safety (ORASEN) created by CITMA to achieve higher levels of integration and effectiveness of regulatory functions in the chemical, biological, environmental and nuclear matters.

By the end of 2018, as a result of CITMA reorganization process, the organizational structure and name of the Office of Environmental Regulation and Nuclear Safety (ORASEN) changed, which included the National Center for Nuclear Safety. For this reason, the referred Office is currently called the Office for Environmental Regulation and Safety (ORSA) and CNSN has become one Division of this Office, called the Division of Nuclear Safety (DSN).

In April 2020, as mentioned above, Decree Law 10/2020 is approved, which establishes that ORSA is an independent legal person attached to CITMA that fulfills functions as a National

Regulatory Authority in biological, chemical, nuclear and radiological safety as well as environmental protection against pollution.

Currently, the DSN is the organizational unit of ORSA in charge of regulation and control of nuclear and radiation safety in the country.

### E.3.1. Duties and Faculties of the Regulatory Body

As established in the legal framework and regulations specific to nuclear matter, the functions and faculties of the regulatory body are to:

1. Carry out review and assessment of documents and reports on safety submitted by applicants or authorization holders;

2. Grant, amend, renew, suspend or revoke authorizations for practices related to the use of radiation sources based on its technical opinions;

3. Grant, amend, renew, suspend or revoke individual licenses for personnel that is involved in practices related to the use of radiation sources.

4. Grant the recognition of competence of radiological protection service providers and dictate their termination when appropriate.

5. Organize and carry out inspections of facilities, as well as other institutions engaged in nuclear energy activities, in order to verify compliance with the existing legal, technical or procedural provisions as well as the conditions established in authorizations;

6. Apply enforcement actions for non-compliance of the existing legal framework, technical or procedural provisions on nuclear and radiation safety.

In addition, Decree Law 10/2020 establishes in its article 7.1. that National Regulatory Authorities have the following functions within their scope of competence:

1. Prepare and propose to the corresponding authority the applicable legal provisions for the protection of health, safety, the environment and other areas identified by the Government in the field of technology.

2. Issue specific provisions, procedures and regulations, in their field of regulation, and supervise, require, control and monitor their compliance.

3. Supervise compliance with the established regulatory requirements.

4. Impose appropriate enforcement actions, in accordance with current legislation, when detecting any infraction within the scope of its competence.

5. Grant, modify, suspend, revoke or renew, authorizations granted to natural or legal persons subject to regulations in the scope of their competence.

6. Conduct inspections to natural and/or legal persons to verify compliance with current legal framework.

7. Establish and implement procedures in order to provide official opinions:

    a) On matters within its scope of competence, ex officio or at request of an interested party;

    b) in case of conflict situations; and

    c) the need to establish or modify regulations and technical provisions.

8. Establish:

    a) Procedures for systematically reviewing regulations and evaluating their impact, in order to determine if they meet the objectives that were set, effectively and efficiently;

    a) cooperation with the National Office for Standardization to assure the use of Cuban technical standards within the scope of its competence; and

    b) If required, cooperation agreements or exchanges with their international counterparts or other national authorities for the harmonization and verification of the pertinent matters.

9. Obtain, safeguard and manage the required information, within the scope of its competence.

10. Require authorized parties, in case of an unwanted event or accident, to carry out an investigation to determine its causes and establish preventive actions.

11. Participate in investigations independently or with other state bodies, in the case of serious accidents or emergency situations.

12. Prepare, propose and be part of the collaboration actions for the training and development of its assets, either with counterparts abroad or with international organizations and also be part of other collaboration actions.

13. Call upon natural or legal persons, as needed, as advisers of its activities.

14. Prepare and propose to the Minister of the State Administration Body to which it is attached the budget proposal necessary for the performance of its functions.

These institutions may also have other functions that do not interfere or conflict with those listed above, and are assigned by the relationship they have with their field of regulation, such as:

1. Implement, within the scope of its competence:

    a) International legal instruments in force for the Republic of Cuba; and

    b) systems for accounting and control of internationally regulated materials or substances, known as safeguards systems.

2. Respond to emergency situations.

3. Participate in programs of instruction and communication to the population on aspects of interest in their field of competence.

4. Promote and manage:

    a) Research programs; and

    b) scientific and technical projects and services.

5. Advise the courts, the attorney general of the republic, competent criminal investigation bodies and the Comptroller General of the Republic, as well as participate with them in the processes or matters in which it is required.

6. Encourage the introduction of risk analysis and assessment techniques.

7. Participate in national education and training programs in matters within its competence.

8. Establish measures for conducting analyzes aimed at achieving experiences in regulatory matters, their dissemination and their implementation by authorized parties, the national regulatory authority itself, and other relevant authorities.

9. Sign, when appropriate, the corresponding agreements with counterparts from other countries; account for the different international obligations contracted and required to ensure the protection of health, the environment and other areas determined by the Government.

10. Manage the assigned resources effectively, in correspondence with the risks associated with their area of competence.

11. Assure that their independence in decision-making is not compromised.

12. Others associated with its field of regulation that are assigned by the Government.

In addition, the article 8 establishes that National Regulatory Authorities must be accountable through reports that are issued to the Council of Ministers, directly or through the minister of the State Administration Body where they are attached when appropriate.

### E.3.2. Organization chart

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

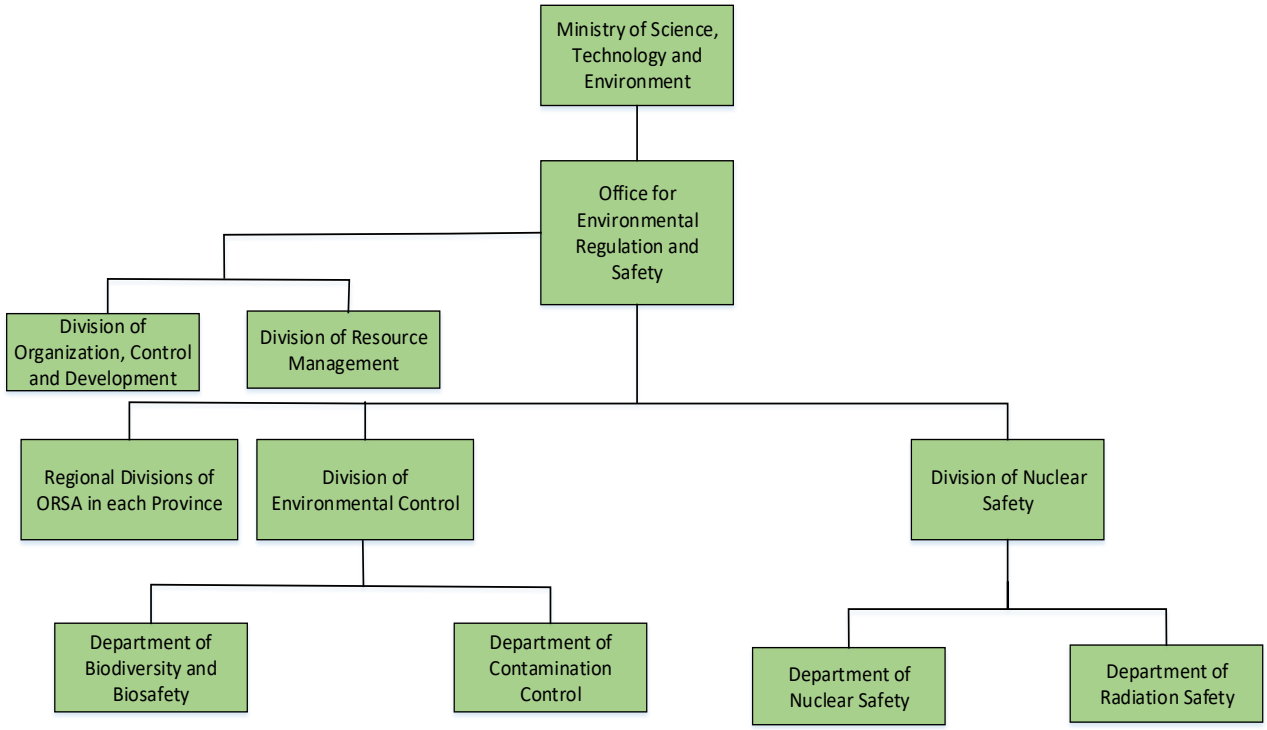



Figure No. 1: ORSA organizational chart.

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.

### E.3.3. Human and financial resources

The regulatory body has 23 professionals and 3 administrative staff (August 2020). Out of professionals, 35% are women. The 25% of professionals have completed Master's degrees. The 79% of the specialists are accredited to perform the functions of nuclear and radiation safety inspectors.

The regulatory body has qualified personnel with vast experience in radiation safety; 75% of the specialists have more than 15 years of experience in this activity, and have participated in both national and international training programs, and as IAEA experts.

Financial resources are assigned by the State through ORSA budget and guarantee 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, which includes training, and the acquisition of computer programs for safety assessments.

Decree Law 10/2020 establishes in article 9.1 that the National Regulatory Authorities receive the financing required for their operation and sustainability directly from the State Budget and for that purpose, the State Administration Bodies to which they are attached guarantee that the proposed budget is considered as part of its annual planning process, differentiating the part of the resources that correspond to the National Regulatory Authority. It also establishes that these Authorities may receive financial resources for their development from other authorized sources such as from

projects with organizations of the United Nations System or others, as well as from cooperation agreements and their own income.

### E.3.4. Staff training

The regulatory body has implemented a Training and Development Plan for all its employees for them to comply with the competences required to perform their duties and keep the staff well-trained throughout their working life. This is a systemic and continuous process carried out in correspondence with the future projections of the institution.

In the 2018-2020 period, specialists of the regulatory body have participated in different training modalities such as: seminars, workshops, courses, trainings, technical meetings and international conferences. A significant number of training activities have been received through Technical Cooperation Projects with the IAEA.

Specifically, in radioactive waste management, our specialists participated in several training activities as part of the Interregional Project INT9182 "Sustaining Cradle-to-Grave Control of Radioactive Sources" and the Regional Project RLA9084 "Strengthening of the regulatory and radiological safety infrastructure", both with the IAEA.

### E.3.5. Management system

Since the end of the 1990s, the regulatory body implemented a Quality Management System (QMS) based on the principles of the ISO 9001 international standard, which has evolved over 20 years, along with the changes that have been made in successive revisions of the mentioned standard.

During this time, the system has incorporated IAEA's recommendations, with an acceptable level of integration, which has resulted in a Safety and Quality Management System (MS). At present, work is being done to achieve a higher level of integration between the safety requirements included in the new IAEA recommendations [22] and those of NC ISO 9001: 2015 Quality Management System, Requirements. [23].

The MS of the regulatory body is structured in processes and sub-processes that are interrelated and duly documented.

The documentary basis of the MS of the DSN is a subset within the documentary system of the QMS of ORSA.

Currently, within the MS, the Quality Policy and the Safety Policy are independently kept, 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 has been prepared and is in the approval process.

The MS establishes an Annual Internal Audit Program, which periodically assesses the performance, effectiveness and capacity of the internal processes of the DSN to assure quality, safety and leadership for safety.

This Program is complemented with the audits carried out by ORSA during the year, and with other third-party audits carried out by CITMA and other Central State Administration Bodies.

The Heads of the regulatory body review the MS once a year, to ensure its suitability, adequacy, effectiveness and continuous alignment with the strategic guidance of the organization. This is the most important control event carried out by the top management of the organization.

Throughout the year and as a complement to the Management Review, a 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 the top management and those responsible for the processes.

In this regard, Decree Law 10/2020 establishes in article 13 that the National Regulatory Authorities are responsible for implementing a quality management system appropriate to their objectives, which assures reliable and transparent processes, and for this:

1. They promote a culture of safety and excellence in society, by increasing and strengthening leadership, knowledge, as well as attitudes, commitments and ethical behavior at the individual and collective level with respect to the activity they carry out.

2. They ensure that codes of good practice, international guides or guidelines, and internationally accepted practices are implemented.

3. They demonstrate their competence through the international peer review carried out by international organizations related to their field of regulation.

4. They support their decisions on tests and evidence that have demonstrated competence through an accreditation process.

### E.3.6. Safety culture

The regulatory body continues to develop actions and initiatives as part of the National Program for Promotion and Development of Safety Culture. The Cuban regulatory program focuses on two areas: the promotion and regulatory supervision of the safety culture of users, and the promotion and development of the internal regulatory safety culture.

The Cuban regulatory body has implemented a management system and a national program to promote and develop a safety culture as separate but closely related regulatory activities. The management system must ensure the promotion of a sound safety culture, but at the same time the safety culture must contribute to an effective management system.

Safety culture is recognized as an intrinsic value within the regulatory body's management system. During the management system review process, it was decided to add a new sub-process to the Process Map. This new sub-process is part of the "Monitoring and continuous improvement" process and will take into account the activities and procedures required or resulting from the safety culture program. The process map and performance indicators for this sub-process are currently being developed.

This year, a version of the Integrated Management Policy was prepared, which integrates the Safety Policy and the Quality Policy, which is in the approval process, as already mentioned. In addition, a follow-up assessment of the Safety Culture is being prepared in the regulatory body.

In October 2018, the XVII Annual Regulatory Conference was held with the theme “Communication with the public on radiological protection”. Representatives of the regulatory body and the national

media discussed transparency and dissemination of safety and regulatory information, the role of regulatory spokespersons and the media in the proper understanding of safety issues by the public. The management of radioactive waste was an issue addressed.

The regulatory body continues efforts to encourage users to implement Resolution 3/2015 "Expectation of the regulatory body on the safety culture in organizations involved in activities with ionizing radiation sources." This resolution intends that users carry out a self-assessment of their level of Safety Culture in order to establish an Action Plan and correct the findings. These regulatory efforts include holding workshops and conferences with users. Despite the activities carried out, the level of implementation of this Resolution by users is still low. In this sense, it has been decided to incorporate a requirement on safety culture as part of the license conditions.

On the other hand, the System for Analysis, Dissemination and Learning from Radiological Events and Incidents (ADASIR) designed with the aim of promoting a culture of organizational learning at the national level, both in the regulatory body and in users will be strengthened, with the implementation of two new systems for the notification, presentation and analysis of safety issues on incidents and near misses:

- Official radiation incident reporting system.
- Anonymous system for reports of radiological incidents.

The design and procedures for these two systems have been completed. The software support is being developed.

The Regulatory Body has continued to share its experience in the field of safety culture with other countries through regional projects in Latin America sponsored by Ibero-American Foro of Radiological and Nuclear Regulatory Agencies (FORO) and the IAEA. The FORO Guidelines on Safety Culture in Organizations, Facilities and Activities with Ionizing Radiation Sources is scheduled to be published as an IAEA TECDOC.

### E.3.7. Relationship with other bodies and organizations

In order to fulfill its duties, the regulatory body establishes relationships with other State institutions, bodies and agencies. These relationships are aimed at cooperating with other national regulatory authorities, which according to their competence, are also engaged in issues related to the use of ionizing radiation in the country. Among them: The Ministry of the Interior, in charge of security and fire protection, the National Civil Defense General Staff, regarding the preparedness and response to radiological emergencies and the Ministry of Public Health for the coordination of regulation and control of the use of X-rays for medical and dental diagnosis.

The regulatory body also works together with the General Customs of the Republic of Cuba and the Ministry of Foreign Trade and Foreign Investment, to strengthen border control mechanisms during the import and export of radiation sources and nuclear materials.

Likewise, the regulatory body has established formal relationships with the Ministry of Foreign Affairs in relation to the fulfilment of the international commitments assumed by Cuba in connection to the use of nuclear energy.

Besides, there are work relationships between the regulatory body and other national groups, scientific societies and professional organizations, mainly in the medical area; and with the Agency for Nuclear Energy and Advanced Technologies (AENTA) regarding the promotion and application

of nuclear techniques.

Relationships are generally formalized through cooperation or work agreements signed by the interested parties and periodically reviewed to check its efficiency and to be updated.

The regulatory body has also relations with institutions devoted to staff training and education, which has resulted in important human resource contributions in the country. In this regard, the Higher Institute of Applied Sciences and Technologies (INSTEC) of the University of Havana is the major contributor.

In the international arena, the regulatory body advices CITMA, on Conventions, Agreements and International Treaties related to the nuclear field, as well as on the implementation of actions resulting from the commitments made by the Cuban State in the field of Radiation and Nuclear Safety and Safeguards.

In this sense, the regulatory body is the national contact for the implementation of the Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency and the Convention on Early Notification of a Nuclear Accident, as well as for the implementation of Guidelines for the Import and Export of Radioactive Sources. The regulatory body also represents Cuba in conferences and technical meetings, and its director has participated in the IAEA General Conference, as a member of the Cuban Delegation to this important event.

During these years, the regulatory body has kept a broad and important relationship with the IAEA, which has enabled it to train its professionals and contribute to the training of professionals in the region, through the organization of different regional courses in the country and expert missions.

The regulatory body, as member of the FORO, maintains an active participation in projects of the technical program, which allows training and exchange of experiences among specialists.

# SECTION F. OTHER GENERAL SAFETY PROVISIONS

## F.1. Responsibilities of the license holder

The responsibilities of the authorization holder are established in the current legal framework.

The primary responsibility for ensuring protection and safety of sources used in practice rests with the authorization holder, who has to comply with the legal framework, technical or procedural regulations in force, as well as the conditions established in the authorization. This responsibility could not be delegated under any circumstances.

The authorization holders, considering the risk associated with the practice may designate the person directly responsible for the safe and reliable operation of the source and the facility, who will be empowered and provided with the necessary resources so that the actions and tasks related to the responsibility of the holder could be carried out. This designation shall be a license condition.

The holders of authorizations from organizations that generate or manage radioactive waste are responsible for the management of radioactive waste generated during the operational life of the facilities, as well as for the decommissioning or closure of the facilities. The necessary financial resources to cover the costs associated to these activities should be allocated from the beginning.

Depending on the complexity of the operations and the magnitude of the hazards associated to the facility or activities concerned and in accordance with the graded approach, the holders of authorizations from organizations that generate or manage radioactive waste shall:

- Minimize the generation of radioactive waste through appropriate design, operation and decommissioning of their facilities or practices by using the appropriate procedures;
- Carry out safety assessments at regular intervals, as established by the regulatory body;
- Demonstrate the protection of the environment through an environmental radiological impact assessment for those facilities that, due to their impact, it is required by the regulatory body;
- Determine the operational limits, conditions and controls, including waste acceptance criteria, to guarantee that the waste management facility performs its operations in accordance with the authorization;
- Ensure that staff are trained and have the necessary qualifications and competence and, where relevant, hold the required license from the regulatory body;
- Establish and implement a management system for all stages of radioactive waste management;
- Keep the records and reports required by the regulatory body, including those necessary to guarantee the traceability of radioactive waste at all stages of radioactive waste management;
- Prepare the Radiological Emergency Plan that includes preparedness and response measures, conduct exercises and drills;
- Implement measures to ensure an appropriate security level;
- Guarantee that the management of radioactive waste generated is not unnecessarily delayed and ensure interdependency between all steps in radioactive waste generation and management;
- Undertake research and development according to the operational needs in radioactive waste management and implement its results.

## F.2. Human and financial resources for radioactive waste management

The financial resources for radioactive waste management activities (including collection, transport, characterization, treatment, conditioning and interim storage) are mainly provided by waste generators, which, as set forth by Decree Law 207 [2], have to pay the costs associated with the management of radioactive waste generated. The State allocates financial resources to CPHR as operator of the centralized facility for radioactive waste management.

The CPHR has sufficient and well-trained human resources, and in this regard, a strategy is developed to raise and maintain the training of its entire group of professionals. The centralized facility is operated by three professionals and a technician, trained to safely manage the radioactive waste and disused sealed radioactive sources. These staff has, on average, 15 years of experience in the activity, maintaining a continuous training program under the supervision of the regulatory body. One of the specialists is recently hired (2 years) and is in the process of training in order to obtain the individual license from the regulatory body.

Other areas of the CPHR provide support for the proper implementation of the radioactive waste management practice, for example the Environmental Radiological Surveillance Laboratory in the characterization of radioactive waste, the Secondary Standard Dosimetry Laboratory (SSDL) in the calibration and verification of the radiation protection equipment, as well as the External and Internal Dosimetry Laboratories, among other services. The Logistic Division provides support for the transportation of radioactive waste and disused radioactive sources and for the maintenance of the facilities. The support provided by the workshop is essential for the operations related with the dismantling of devices to remove and condition the associated radioactive sources.

Figure 2 shows the organizational structure of the CPHR.

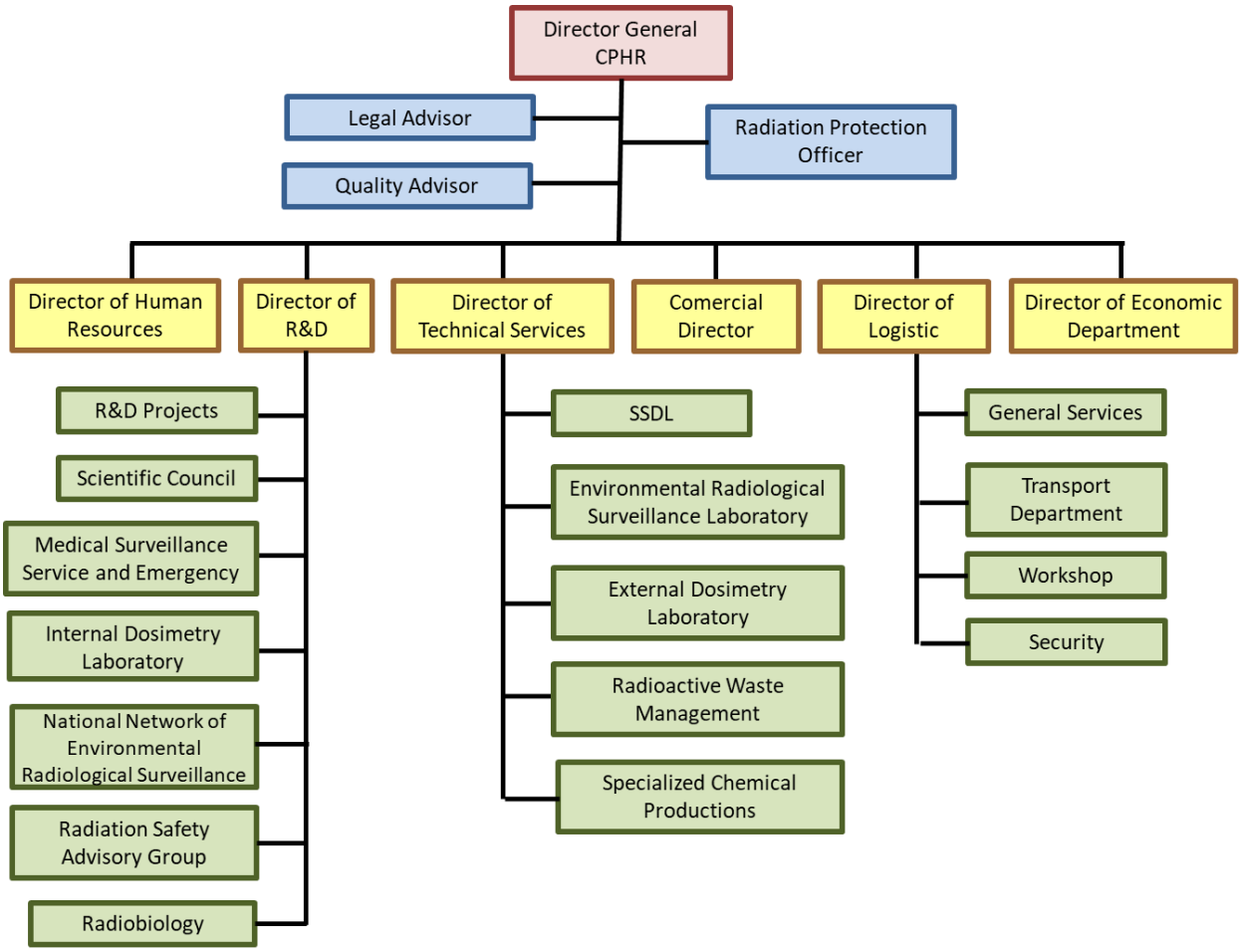



Figure No. 2: Organizational structure of the CPHR.

Staff training.

The initial and continuous training of each CPHR worker is an established and documented process, which includes the identification of training needs, the preparation of the training and development program and the impact evaluation of the actions carried out.

The description of each job position has been established and each worker has a job competency matrix, in which the knowledge that must be accredited for labor competence certification is reflected.

In terms of radiation protection and radioactive waste management, the required knowledge has been identified and must be accredited by each worker.

The accreditation of general job competencies in Radiation Protection certifies the initial training of the occupationally exposed worker, and re-trainings are carried out annually. Re-training programs are developed by the manager of the practice and the RPO, considering factors such as:

- Modifications in the practice (changes in procedures, modification of the scope, etc.);
- New national regulations affecting the practice;
- Renewal of authorizations;
- Needs identified internally for certain jobs, or due to the occurrence of abnormal situations;
- Safety culture;
- Emergency preparedness.

Trainings are carried out through internal seminars, national or international courses, fellowships, etc. A significant number of training activities have been received through the IAEA Technical Cooperation Projects.

## F.3. Quality Management System

The CPHR has implemented a process-based Management System, according to the NC/ISO 9001:2008 standard, "Quality management system, Requirements", which covers all the activities, including the radioactive waste management. This system makes feasible to safely implement the activities and to have an adequate control of radioactive waste and disused sources received in the facility. An adequate record system ensures the traceability of radioactive waste and disused sources at all stages. The CPHR is currently executing a project for the transition to the new NC/ISO 9001:2015 Standard, which should conclude this year 2020. The procedures have been adapted in order to comply with the requirements of the new Standard. The management of risks has been established at the CPHR and they are evaluated in the annual management reviews.

The operations that are carried out, including radioactive waste management, are documented in procedures that are systematically reviewed. Management review and internal audits (by the CPHR's internal auditors) are carried out annually.

## F.4. Operational radiation protection

The BSS [10] establish the requirements to authorize a practice on the basis of the general principles of radiation protection: justification, application of dose limits and optimization of protection.

For radioactive waste management, the justification principle is applied to the practice that generates the radioactive waste.

The dose limits [10] are set for both Occupationally Exposed Workers (OEW) and the public. The following dose limits are established for OEW:

a. an effective dose of 20 mSv per year averaged over five consecutive years;
b. an effective dose of 50 mSv in any single year;
c. an equivalent dose to the lens of the eye of 150 mSv in a year;
d. an equivalent dose to the extremities (hands and feet) or to the skin (average dose over $1cm^2$ of the most highly irradiated area of the skin) of 500 mSv in a year.

For public exposure, the dose limits are:

a. an effective dose of 1 mSv in a year;
b. in special circumstances, an effective dose up to 5mSv in a single year, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
c. an equivalent dose to the lens of the eye of 15 mSv in a year;
d. an equivalent dose to the skin of 50 mSv in a year.

For the radioactive waste management practice, the regulatory body establishes, as a license condition, that:

- The effective doses for OEW should be kept below 10 mSv per year and 0.5 mSv per year for the public.

- For authorized practitioners or trainees, participating in operations carried out by the CPHR, the effective doses should be kept below 5 mSv taking into account the time spent in the practice.

Control of occupational exposure.

The operators of the radioactive waste management facility are subject to individual radiological monitoring and are required to wear whole body TLD dosimeters to assess effective dose and TLD finger ring dosimeters to assess equivalent dose to hands. In very specific operations, such as the conditioning of disused radioactive sources, TLD dosimeters have been used to evaluate the equivalent dose to the lens of the eyes. All these services are provided by the External Dosimetry Laboratory. In addition, electronic personal alarm dosimeters are used in these operations.

The control of internal contamination is performed through direct measurements (whole body and thyroid) and indirect (measurement of samples). These services are provided by the Internal Dosimetry Laboratory, in accordance with the individual radiological monitoring program in the CPHR.

Access of visitors and non-occupationally exposed workers to the facilities is always subject to assess, on a case-by-case basis, to determine whether or not the use of dosimeters is necessary.

Radiological control of areas and workplaces is performed at the RWTP and the Interim Storage, according to the established procedure. This procedure includes measurements of dose rates and surface contaminations, as well as sampling of airborne activity.

For non-routine operations, such as the dismantling of devices for removal and conditioning of the radioactive sources, specific radiological monitoring points (dose rates and surface contaminations) are established according to the work to be performed.

Depending on the operations being performed, the following personal protective equipment is used: overalls or long-sleeve laboratory coats, disposable overalls (Tyvek), gloves, shoe covers, caps and respiratory protective equipment (dust filters and masks).

In addition, other actions are implemented to keep doses as low as reasonably achievable (ALARA), for example:

- the planning of operations, including the prior estimation of operator's doses;
- the design of workplaces where the radioactive sources are handled with adequate shielding, including a lead glass window, and with air extraction when handling leaking sources (for example the radioactive sources from lightning conductors);
- the use of tweezers and other remote handling tools.

Control of public exposure

The control of public exposure is mainly based on:

a) Placing appropriate area classification signs, as established in national regulations;
b) Access control to the facilities;
c) Information to members of the public who, for justified and authorized reasons, have to access to the facilities;
d) Radiation monitoring program of the facilities (including points outside the facilities);
e) Compliance with the dose rate levels established in the perimeter of the facilities, through

adequate structural design and correct distribution of the inventory of radioactive materials;

f) Control of liquid effluents generated in the Waste Treatment and Conditioning Plant, the forklift truck control area and the radiological changeroom facility;
g) Compliance with the levels of clearance and release of materials with low radioactivity content, as established in the current national regulation;
h) Control of radioactive material inventories.

All these actions are carried out in accordance with the established procedures and are reported in the corresponding records.

The radiation monitoring program includes dose rate measurements (with a monthly frequency) outside the Waste Treatment and Conditioning Plant and the Storage Facility, including the areas around the retention tanks for the collection and control of liquid effluents. These actions allow controlling compliance with the dose rate constraints established by the regulatory body around the facilities.

Doses received by the operators of the Radioactive Waste Management Facility

In the period from 2017 to 2019, the annual individual effective doses of CPHR staff, operating the radioactive waste management facility remained below 0.3 mSv, a value well below the dose constrains established for the practice.

Discharge limits. Measures to mitigate an unplanned release

As a result of normal operation, liquid effluents that may be contaminated with radioactive material are generated in the RWTP, the forklift truck control area and the radiological changeroom facility. Canalization systems with retention tanks for the collection and control of these effluents are installed in these facilities. The collected liquids are discharged once it has been verified that the activity concentration is below the clearance levels established in the current legislation [4]. The liquid released from the retention tank of the RWTP does not go directly to the environment, and to a septic tank and afterwards to an absorption pit system. Consequently, direct public exposure is highly unlikely in the event of an unplanned release above the authorized levels.

The RWTP and the Interim Storage have ventilation (extraction) systems. No filters for the exhaust air are installed at the outlet.

## F.5. Emergencies preparedness

### F.5.1 Preparedness and response

The National Civil Defense General Staff is the national authority in Cuba in charge of organizing, leading, executing and controlling the implementation of State and Government policy for the reduction of the effects of any kind of disaster, and for that is technically advised by different specialized institutions.

Authorization holders are responsible for the organization and preparation of Radiological Emergency Plans (REP) to be developed within the limits of their facilities, or during transportation, taking as reference the results of safety assessments. The Radiological Emergency Plans establish the measures to ensure an effective and efficient response to a radiological emergency or to radiological events.

The Radiological Emergency Plan is one of the documents that have to be presented to the

regulatory body to apply for the authorization, as established in the current Authorization Regulation [5].

The REP is harmonized with the Disaster Reduction Plan of the territory where the facility is located and establishes the cooperation with external institutions to ensure the participation of emergency response organizations in case of a radiological event or emergency.

The practical verification of the effectiveness of the REP is carried out in accordance with the requirements and procedures established by CITMA, in coordination with the National Civil Defense. For this purpose, the facilities must plan annual drills, a partial exercise every two years, and a general exercise every four years.

CPHR has a REP approved by the regulatory body, where all practices with ionizing radiations that are carried out in the institution are incorporated, including the radioactive waste management. This plan is the basis for planning activities so, should any radiological event occur, the consequences can be mitigated, in order to protect site personnel, the public and the environment. Possible participants (internal and external), as well as the actions to be taken for each postulated event, are defined in the REP. The REP of the facility is in line with the requirements established in the Emergency Guide [17]. It is updated at least every two years and whenever any circumstance occurs that modifies some of the aspects that served as the basis for its preparation or as a result of past experiences of radiological events or emergencies.

Since the previous Review Meeting, an Emergency Preparedness Review Mission (EPREV) was undertaken in Cuba by the IAEA. The objective of the EPREV Mission was to assess the preparedness for nuclear or radiological emergencies and the capability to respond to such situations. The results of the Mission were positive, recognizing the good practices, some areas in which improvements were needed, as well as recommendations and suggestions. Regarding the Requirement 15: “Managing radioactive waste in an emergency”, it was noted that there is no formal national strategy for the safe management of radioactive waste, including radioactive waste arising in a nuclear or radiological emergency or human and animal remains with contamination as a result of an emergency. Compliance with this requirement was considered in the draft national strategy.

### F.5.2. International Agreements

In order to strengthen international response in the event of a nuclear accident or radiological emergency, on September 26th, 1986, Cuba signed the Convention on Early Notification of Nuclear Accidents and the Convention on Assistance in Case of Nuclear Accident or Radiological Emergency. Both were ratified on January 8th, 1991.

## F.6. Decommissioning

The legislation in force [5] states that when a practice is intended to cease and decontamination and dismantling activities are required, the facility should apply for a Decommissioning License, and for this purpose, the following documents must be submitted to the regulatory body:

1. Dismantling plan of the facility that includes: stages, responsibilities, and implementation schedule.
2. Procedures for decommissioning operations, including decontamination and dismantling techniques and processes.
3. Waste management plan, including the estimation of waste volumes and definition of options and criteria for the management of radioactive waste and disused sealed sources arising

during decommissioning.

4. Assessment of operational and potential doses resulting from the decommissioning. Individual radiological monitoring. Measures to reduce occupational exposure.
5. List of workers who will participate in the decommissioning activities, accreditation of psychophysical aptitude and competences to perform their assigned work.
6. Measures proposed to prevent radiological accidents during decommissioning or mitigate their consequences.

The regulatory body conducts regulatory inspections during decommissioning, in order to dictate on the release of the facility from regulatory control, once compliance with the radiation safety requirements established for the facility at this particular stage have been duly verified.

The authorization holders are responsible for the management of radioactive waste generated during the operational life of the facilities, as well as for the decommissioning or closure of the facilities. The necessary financial resources to cover the costs associated to these activities should be allocated from the beginning [2].

## SECTION G. SAFETY OF SPENT FUEL MANAGEMENT

As stated in Section A and in the scope of this National Report, this Section does not apply to Cuba.

# SECTION H. SAFETY OF RADIOACTIVE WASTE MANAGEMENT

## H.1. General safety requirements

The management of radioactive waste is carried out complying with the following principles:

- Human health and the environment should be protected from the possible harmful effects of radioactive waste.
- The expected health impact on future generations is not greater than the currently acceptable.
- Undue burdens are not imposed on future generations.
- Potential effects on human health and the environment beyond national borders are not greater than those acceptable in the country.
- It is carried out in accordance with an appropriate national legal framework.
- The radioactive waste generation is kept at the lowest possible level.
- Proper safety must be ensured during the operating life of radioactive waste management facilities.
- There is a reciprocal dependency between the generation stage and all subsequent stages of radioactive waste management.

The establishment of authorizations and limits, conditions and controls for pre-disposal management of radioactive waste is the result of close work relations between waste generators, CPHR as operator of the radioactive waste management facility and the regulatory body.

### H.1.1. Criticality and Removal of Residual Heat Generated during Radioactive Waste Management

Due to the radiological characteristics of radioactive wastes generated in Cuba (half-lives, energies and activity concentrations), these are classified as low and intermediate level, as shown in Table No. 1, Section B.2.1. of this report, so no special measures are required to address either criticality or residual heat removal.

### H.1.2. Minimization of radioactive waste generation

In Cuba the minimization of radioactive waste generation has the following objectives:

- Reduce environmental impact
- Reduce management cost

Appropriate measures are taken, such as: prevention of unnecessary contamination of materials; the use of minimum quantities of radioactive material; the use, as far as possible, of short-lived radionuclides; avoiding the unnecessary use of toxic and hazardous materials; as well as the use of appropriate procedures for all operations carried out during radioactive waste management. [3]

### H.1.3. Interdependence between the different stages of radioactive waste management

The Waste Regulation [3] sets out the general requirements for both generating entities and the radioactive waste management facility, in order to take into account, the interdependence between the different stages of radioactive waste management.

The license holder of the radioactive waste management facility establishes the acceptance criteria

that must be met by the authorization holders of waste generators in order to guarantee the adequate management of radioactive waste, including the correct segregation and collection of wastes according to their physical and radiological characteristics as well as how these radioactive wastes should be prepared to be collected, taking into account the interdependence between the different management stages.

Disused radioactive sources are being conditioned in stainless steel capsules and safely stored. These conditioned capsules may be recovered in the future, if it is decided or needed, and placed in the disposal facility, once it is in operation.

### H.1.4. Effective protection of people, society and the environment

The legal and regulatory framework in force in the country establishes requirements relating to the protection of individuals, society and the environment. Waste Regulation [3] sets out the requirements for the safe management of radioactive waste, in order to ensure the protection of people, property and the environment from the harmful effects of ionizing radiation, now and in the future without imposing undue burdens on future generations. In this sense, the regulatory body verifies that authorization holders comply with the clearance levels and the authorized discharge limits.

### H.1.5. Biological, chemical and other risks associated with radioactive waste management

The Waste Regulation [3] states that other non-radiological characteristics of radioactive wastes should be taken into account during the stages of radioactive waste management and the possibility that they may also be classified as hazardous wastes.

It is further established that facilities that manage radioactive waste with these characteristics must also comply with the national existing environmental regulations applicable to other hazardous wastes. In this regard, the compatibility of safety requirements for the management of radioactive waste and the management of hazardous wastes should be ensured.

### H.1.6. Impact on future generations

At present, the radioactive waste management facility operates in compliance with the limits, controls and operational conditions that have been assessed and accepted by the regulatory body in the authorization process, which is verified during the inspection process. In particular, it ensures compliance with the values of dose restrictions, clearance levels and discharge limits of liquids and gases to the environment.

In Cuba the disposal option of radioactive waste and disused sources has not been defined yet. After deciding the disposal variant and the construction of the future facility, the regulatory body will require that safety assessments be carried out to demonstrate that the expected health impact on future generations is not greater than the currently acceptable.

### H.1.7. Undue burdens on future generations

Decree Law 207 [2] establishes that authorization holders shall be responsible for the management of radioactive waste generated as a result of their activity during their operating life, as well as for the decommissioning of facilities. Consequently, the necessary financial resources will be planned from the start, as management cannot be deferred over time in order not to impose undue burdens on future generations.

Operations carried out in the CPHR management facility take into account long-term solutions, avoiding, as far as possible, undue burdens on future generations. These operations consider, inter alia, the following aspects:

- Conditioning of radioactive sources in capsules allowing the retrievability.
- Minimization of waste volumes through the implementation of clearance and the dismantling of devices and the recovery of associated radioactive sources.

## H.2. Existing Facilities and Past Practices

### H.2.1. Existing facilities

As mentioned above, there is only one radioactive waste management facility in Cuba.

This facility has a 5-year operating license which must be subject to renewal before its expiry term. To that end, the facility must submit, as required by the current legislation [5], a safety reassessment which takes into account the current state of safety systems and technological elements. The current operating license is valid until October 2023.

The management facility is subject to inspections twice a year by the regulatory body, in order to verify compliance with the established safety requirements.

As mentioned in the previous report, in 2009, after almost 20 years of operation of the facility, due to the degradation of important safety systems, it was necessary to carry out a project to repair the structural building of the store. In 2013 constructive repair was carried out on the facility, as well as on the ventilation system, which was damaged. The ventilation system is tested every 4 years and it assures a rate of seven (7) air changes per hour in the storage rooms.

In this period (since the previous report) two new capabilities were constructed, a radiological changeroom facility located next to the interim store, and a platform for radiological monitoring and control of the forklift and its decontamination if necessary, at the storage room exit. The radiological changeroom facility has a “clean area”, where personal protective equipment and other devices and materials used for working in the storage rooms are located and a “dirty area”, with the necessary provisions for radiological control of stuffs and personnel and their decontamination if required.

The effluents generated in the forklift control area and in the dirty area of the radiological changeroom facility are collected in a retention tank. Periodically, according to established procedures, samples of the liquid contained in the retention tank are taken for analysis. If the activity concentration is below the clearance levels, they are released to the site's general sewer system.

The repair and improvement of the flood protection system was carried out in 2020. This system was built around the site and takes into account the unevenness of the land to ensure that rainwater runs to the system, preventing its entry into the facilities. Due to the heavy rains that occurred in recent years, several slabs of the channel fell inside obstructing it. These slabs were replaced and reinforced. In addition, a sidewalk was built along the channel to prevent the dragging of soil into it.

### H.2.2. Past practices

Since the 1940s, in Cuba, sources of ionizing radiation began to be used, mostly in medical

practice. Before the existence of the interim storage for radioactive wastes and disused sources, some premises of the National Institute of Oncology and Radiobiology (INOR) were used to store disused sources from the brachytherapy practice that was performed there, mostly Ra-226 sources.

Some INOR premises were used to store disused sources from various institutions, including Ra-226 and Cs-137.

With the time, some sources stored at the INOR became leaking and it resulted in the contamination of some of the premises. This situation motivated that, at the end of the 90's, the decision was taken to remove the sources from those premises and to transfer them to CPHR centralized interim storage.

Between 1999 and 2004, dismantling and decontamination of those premises was carried out, including the removal of contaminated materials: floor slabs, wall debris, floor fillings and garden soil. All these works were authorized by a license granted by the regulatory body, which established the permissible levels of contamination that had to be reached to release these facilities from regulatory control. Finally, and after inspections carried out by the regulatory body to verify compliance with the conditions of the authorization, the premises in question were released from regulatory control without restrictions for their use.

## H.3. Siting of proposed facilities

To date, Cuba is not planning to build any new radioactive waste management facility. Neither is planning to enlarge or modify the existing one.

## H.4. Design and construction of facilities

The design and construction of the CPHR's radioactive waste management facility ensures to limit possible radiological consequences for humans and the environment through the provision of adequate safety measures and systems.

As before mentioned, the waste management facility consists of a radioactive waste and disused sealed source interim storage and a RWTP. Within the boundaries of the site there are other facilities devoted to the production of pesticides and other chemicals as well as the administrative building.

An overview of the site can be found in Annex L.5 of this Report.

### H.4.1 Interim Storage Facility of Radioactive Waste and Disused Radioactive Sources

The interim storage facility is a surface construction over a 1-meter thick zeolite-filled material and composed of two interconnected premises of 6 x 21 x 4.5 meters each and a ventilation room located adjacent to the storage area.

Annex L.6. of this Report shows a sketch of the premises of the radioactive waste interim storage facility. As mentioned in H.2.1, a radiological changeroom facility, a platform for radiological control of the forklift and a retention tank for the collection and control of the effluents generated in these two facilities, are located next to the store. Prefabricated structural elements (roof, walls and floor) were used in the construction of the storage facility. Afterwards, these elements were covered with additional high quality concrete and steel structural elements (layers) for greater protection.

The thickness of the walls is 55 cm and the roof are 90 cm and it was initially covered with polyethylene sheets and a layer of vegetal soil, which was removed as part of a remodeling process as described in Section H.2.1. The walls of the ventilation room are of 30 cm-thickness. There is a 12.8 m high chimney (measured from the ground level) on the roof slab of the ventilation room. The storage facility doors are made of 3 and 5 mm thick steel sheets. The floor of the two storage rooms is covered with epoxy paint.

The construction company that carried out the store repair, assured the integrity and quality of the construction materials for a 10-years period, Consequently, after the aforementioned period, it will be necessary to make a reassessment of the structural conditions of the storage facility to determine if it is feasible to continue its use as an interim storage facility, or to determine if any other structural repair work or other necessary actions are required.

The purpose of this facility is the interim storage of radioactive waste and disused sources, generated by national users of ionizing radiation. The storage capacity, per project, is 192 drums of 210 l per premise, placed in two rows and at three levels, with enough space in between to enable the use of the forklift truck, as well as the visual inspection and monitoring of the stored drums. This provides an estimated volume of 40 $m^3$ of stored wastes in each of the premises. In the interim storage facility, the transfer of radioactive materials is limited to: the reception of new radioactive wastes and disused sources, transfer to the RWTP of disused radioactive sources to be conditioned and to the reorganization and visual inspection of the materials already in the store.

In the period, the perimeter security fence that should delimit the interim storage facility within the site where the management facility is located, could not be installed due to lack of financing. This aspect is included in the budget for 2021. The interim storage facility has intrusion alarm systems and fire detection systems installed.

Approximately 75% of the planned storage capacity of the facility is currently being used. At present there is no plan to build a new facility for the storage of existing waste. According to estimates that have been made, the available storage capacity is sufficient for the amount of wastes that will be generated in the country in the coming years.

As mentioned above, currently according to the practices carried out in the country, only very short lived waste, which can be cleared after a period of 1-2 years, and disused sources that have not been returned to providers are being generated. Besides, the quantity of sealed sources in use is decreasing. In addition, disused sources of categories 3-5 are being removed from the devices where they are contained and conditioned. These operations reduce the number of containers and packages stored in the facility, and therefore free up storage capacity.

### H.4.2. Radioactive Waste Treatment and Conditioning Plant

The RWTP is located in a building that was previously used as radioisotope storage by the Ministry of Public Health. This structural building was remodeled and adapted to carry out radioactive waste management operations.

A sketch of the RWTP is showed in annex L.7. of this Report.

This facility has the following areas:

- A technological area of approximately 100 $m^2$, an area devoted to carry out part of the treatment and conditioning operations of radioactive waste and disused sources, and to control and transfer of the conditioned packages to the interim storage facility,

- A laboratory of 22 $m^2$, where tasks related to source conditioning that involve greater risks, such as the dispersion of radioactive materials, exposure to the highest dose rates, etc., are carried out. Likewise, the decontamination of tools and small objects is carried out there, and for that a sink is available. In this place there are two fume hoods with their own exhaust systems.
- An area for the reception and segregation of radioactive waste and disused sealed sources and for the dismantling of devices to recover the associated sources, for further conditioning. If required, the decontamination of vehicles used for the transportation of wastes, as well as the containers for reuse could also be carried out in this area. Therefore, there is a slope towards a central channel that evacuates to the retention tank, which is part of the effluent control system of the RWTP,
- Area for the storage of radioactive waste waiting treatment,
- Radioactive waste decay area prior to their clearance;
- Office, and
- Change room.

The retention tank is located outside the RWTP, with its own perimeter security fence around. This is part of the control system of liquid effluents that are generated in the facility.

In addition, nearby to the facility, there is a premise for the storage of non-radioactive materials, such as empty drums, containers, etc.

In all areas, except the office and personal access area, the floor and working surfaces are covered with epoxy paint. The walls are washable.

The RWTP has a ventilation system, with connections to the extraction at points where there is a greater probability of dispersion of radioactive materials.

### H.4.3. Important safety elements, systems and components

The management facility has several elements, systems and components important for safety, among which, are the following:

- Shielding and confinement.
- Containers for storage of radioactive waste
- Lifting equipment and remote handling tools
- Ventilation systems (extraction)
- Fume hoods at the RWTP
- Conditioned waste packages
- Liquid effluent control systems
- Fire detection and intrusion alarm systems at the interim storage facility
- Flood protection system
- Radiation protection equipment.
- Fire extinguishing systems.
- Power supply system.

- Aerosol collection equipment.
- Facility for the characterization of solid radioactive waste packages.
- Changeroom facilities.
- Water supply system.

The facility carries out a preventive and corrective maintenance program for all elements, systems and components important for safety, including periodic monitoring, inspection and testing. In addition, there is a procedure to investigate, in case of deviation of the parameters of operation of equipment or systems related to protection and safety. All this is included in the operation, repair and maintenance record of relevant safety systems.

## H.5. Assessment of safety of facilities

The safety assessment of practices and activities involving the use of ionizing radiations in the country, including the management of radioactive waste and disused sources, is one of the requirements to obtain the Operating License [5]. The safety assessment is part of the safety case, and should describe the following aspects:

1. Estimation of expected doses under normal operating conditions for both occupationally exposed workers and the public.
2. Estimation of potential doses for emergencies, accidents or radiological events for both occupationally exposed workers and the public.
3. Identification of accident initiating events.
4. Estimation of the frequency of occurrence of such events.
5. Analysis of the magnitude of the consequences associated with each initiating event.
6. Defense analysis.
7. Quantitative or qualitative risk assessment associated with each accidental sequence.
8. Management and reduction of risk. For those accidental sequences that have an unacceptable risk, the necessary actions to reduce risks must be assessed and proposed.

As a result of the renewal of the operation license for the Radioactive Waste Management Facility in 2018, a review and update of the safety case was carried out, including the safety assessment.

The radiological risks associated with this practice are:

- external exposure,
- radioactive contamination (both external and internal).

The Safety Assessment included the estimation of expected doses for occupationally exposed workers (OEW) of the facility and the public, under conditions of normal operation and of radiological accident. The possible initiating events of accidental sequences were identified for each stage of radioactive waste management. The consequences of the initiating events from the radiological viewpoint, as well as the safety barriers to prevent and mitigate accident situations were also described. The risk was qualitatively estimated for each of the accidental sequences modeled.

The expected doses under normal operating conditions were estimated from the working procedures for each of the processes, considering both the expected workloads and conservative scenarios. The values of existing dose rates at the facilities, the time length of operations

measured under real conditions, as well as the effective doses received by the OEW in specific operations were taken as reference values. As a result, an OEW that performs all operations will receive an annual effective dose of about 5.4 mSv, thus complying with the 10mSv restriction per year for the practice of Radioactive Waste Management.

The doses for the public (workers of the Managua site not involved in the practice and the personnel of the Security and Protection Agency) were estimated. The dose rates outside the facilities (considering the historical results of the radiological controls) and the exposure times were taken into account. It was obtained that a member of the public could receive a maximum dose of 0.22 mSv/year, which is in line with the restriction imposed for the practice of 0.5mSv/year.

Initiating events of accidental sequences were identified for each operational stage of the management of radioactive waste and disused sources for which authorization is requested. These initiating events are basically related to human errors, device and equipment failures, leaking or broken sources, sources stuck inside device, incorrect information about the radioactive sources contained in the devices, drop of sources, capsules containing sources, packages or containers, blackouts, natural disasters, fires, spillage of radioactive material (waste), and unauthorized access to facilities.

The individuals affected (OEW or public), the frequency of occurrence, the safety barriers in place and the probability of failure of the set of barriers were identified for each initiating event, and the consequences were assessed from a radiological viewpoint. All the above allowed to qualitatively assess risk in each case.

Out of a total of 28 identified initiating events, 13 accidental sequences have a medium level risk and 15 have low level risk. The facility has an acceptable risk, as result of evaluation.

## H.6. Operation of facilities

As already mentioned, the radioactive waste management facility in Cuba has an operating license granted by the regulatory body, in force until October 2023, which covers the following operations:

- Reception and segregation of radioactive waste.
- Interim storage of radioactive waste and disused sealed sources.
- Interim storage of sealed sources in use in exceptional cases.
- Clearance of waste.
- Dismantling of devices and recovery of associated radioactive sources.
- Conditioning of category 3, 4 and 5 disused radioactive sources.
- Radiological characterization and decontamination of facilities and equipment of institutions using ionizing radiation sources in the country.

In order to carry out these operations, procedures and records have been developed and implemented, which are integrated to the Management System of the facility.

These procedures are reviewed and updated considering the operational experience and international practice.

The operating license establishes limits and mandatory conditions for the license holder. These conditions are verified during the internal audits to the facility, the periodic reviews by the Radiation Protection Officer and during regulatory body inspections.

The technical services necessary to carry out the operations, such as calibration and verification of

equipment, individual radiological monitoring (internal and external dosimetry), monitoring of gases and aerosols, among others, are performed by the CPHR.

## H.7. Institutional measures after closure

The disposal option of radioactive wastes and disused sources has not been defined yet.

According to current legislation [3], the design of facilities for the disposal of radioactive waste must ensure the safety and radiation protection of people and the environment during all phases over the lifetime of the facility.

# SECTION I. TRANSBOUNDARY MOVEMENT

## I.1. Transboundary movement

The current legislation [1] establishes that any import of radioactive waste must be subject to an authorization issued by CITMA through the regulatory body, in accordance with international recommendations. Until now, no import of radioactive waste into the country has been assessed or authorized.

In the case of disused sealed sources, which are returned to the supplier or country of origin, the Export is authorized through an Export Permit issued by the regulatory body and with the prior consent of the State of destination, according to the provisions of the Guidelines for the Import and Export of Radioactive Sources [24], supplementary to the Code of Conduct [25].

# SECTION J. DISUSED SEALED SOURCES

## J.1. Disused sealed sources

The current legislation [3] establishes that anyone who imports a sealed source will make the necessary reasonable efforts to re-export it to the supplier once it is disused, and to that end, this specification must be contractually agreed between the parties at the time of acquisition. If this is not possible, and if the source reaches the end of its lifetime or it is leaking, it is transferred to the CPHR's radioactive waste management facility.

In addition, if the authorization holder has sealed radioactive sources suitable for use and does not intend to continue using them, these sources may be transferred to another duly authorized holder or to the management facility.

Initially in the management facility, the radioactive sources containing radionuclides of short half-life ($T_{1/2}$ <30 years) were conditioned by emplacement of the devices containing the radioactive sources into concrete lined drums, ensuring the compliance with the acceptance criteria previously defined and approved by the regulatory body. The fact that most of these devices were manufactured more than 30 years ago, together with the environmental conditions they were exposed to during their service lifetime (mostly in industries), has resulted in the corrosion and deterioration of the majority of devices.

Consequently, devices containing category 3-5 sources as for instance nuclear gauges, radioactive lightning conductors, ionization smoke detectors, brachytherapy devices, etc., are nowadays being dismantled in order to recover the associated radioactive sources, for their characterization and conditioning in stainless steel capsules. Capsules with conditioned sources are safely stored in the facility. Following this methodology, Ra-226 radioactive sources, neutron radioactive sources (such as Am-Be, Pu-Be and Ra-Be), sources of C-14 and Am-241 recovered from radioactive lightning conductors, and some Cs-137 sources have been conditioned.

Category 1-2 sources are stored in the facility within their devices (teletherapy heads and irradiators). In the coming years, it is planned to assess the feasibility of conditioning of these sources.

## SECTION K. ACTIVITIES FOR IMPROVING SAFETY

A number of activities are carried out on an ongoing basis at radioactive waste management facilities in order to improve safety, for instance:

- Actions drawn from practice described in the radiation protection and safety program.
- Quality management system, which includes periodic review of operational procedures and the entire management system, as well as management reviews and internal audits conducted on an annual basis.
- Periodic reviews by the Radiation Protection Officer.
- Inspections by the regulatory body.
- Visual inspection of packages and containers of radioactive waste and disused sources.
- Conditioning of disused radioactive sources.
- Training programs for the staff that operate the facilities and provide support services.
- Maintenance programs of facilities and equipment.

As mentioned in sub-section H.2.1., the construction of two new premises adjacent to the temporary storage facility was completed: a radiological changeroom facility and a premise for radiological control and decontamination of the forklift truck, as well as a retention tank for the collection and control of the effluents generated during the operation.

Additionally, the repair and improvement of the flood control channel was carried out in 2020.

As described in sub-section B.2.3., the conditioning of categories 3-5 sources continues at present, in order to remove the sources from their devices that are deteriorated, and to guarantee their adequate storage. A total of 619 sources were conditioned in recent years, recovered from 188 radioactive lightning conductors.

The actions carried out since the previous Review Meeting in relation to Safety Culture are described in sub-section E.3.6.

# SECTION L. ANNEXES

## Annex L.1. Estimated volume of radioactive waste stored in the CPHR Management Facility

(March 2020)

| Type of waste | Main features | Estimated volume, $dm^3$ | Remarks |
|---|---|---|---|
| Liquids | Cs-137, Co-60, Eu-152, H-3, C-14 | 3 000 | |
| Solids | Compressed waste | 3 000 | Processed in the nineties |
| Solids | No processed waste (as generated) | 38 000 | Wastes generated from dismantling and decontamination of radioactive facilities are included |
| Solids | Conditioned waste (immobilized in a solid matrix) Cs-137, Co-60, Eu-152 | 6 200 | Historical waste (conditioned in the eighties) |

## Annex L.2. Disused radioactive sources stored in the CPHR Management Facility

(March 2020)

| Radionuclide | Number of sources | Estimated total activity, Bq |
|---|---|---|
| Am-241 | 28778 | 1.28E+11 |
| Am-241/Sr-90 | 2 | 1.00E+05 |
| Am-Be | 38 | 1.90E+12 |
| Ba-133 | 9 | 1.53E+07 |
| Bi-207 | 1 | 3,00E+04 |
| C-14 | 75 | 2.87E+07 |
| Cf-252 | 7 | 6.26E+08 |
| Co-60 | 743 | 1.23E+14 |
| Cs-137 | 1234 | 4.95E+13 |
| Eu-152 | 3 | 1.66E+05 |
| Eu-154 | 3 | 1.16E+08 |
| Eu-155 | 1 | 3.21E+03 |
| H-3 | 101 | 9.73E+09 |
| Hg-203 | 6 | 2.22E+06 |
| I-129 | 3 | 6.52E+05 |

| Radionuclide | Number of sources | Estimated total activity, Bq |
|---|---|---|
| Ir-192 | 48 | 1.64E+04 |
| Kr-85 | 4908 | 2.92E+09 |
| Ni-63 | 35 | 5.77E+09 |
| Pb-210 | 90 | 8.22E+05 |
| Pu-238 | 20 | 1.22E+10 |
| Pu-239 | 43 | 1.86E+07 |
| $Pu^{238}$-Be | 8 | 8.04E+11 |
| $Pu^{239}$-Be | 5 | 1.33E+12 |
| $Ra^{226}$-Be | 1 | 1.06E+09 |
| Pu (smoke detectors) | 1000 | 1.85E+10 |
| Ra-226 | 1092 | 1,79E+11 |
| Sr-90 | 1866 | 6.22E+11 |
| Th | 1 | 3.70E+08 |
| U-238 | 8 | 7.40E+08 |

## Annex L.3. Conditioned radioactive sources in the CPHR Management Facility

(March 2020)

| Radionuclide | Type of sources or devices from where the DSRS were recovered | Number of conditioned sources | Number of conditioned capsules | Total Activity | |
|---|---|---|---|---|---|
| | | | | GBq | Ci |
| Ra-226 | 1009 brachytherapy needles and tubes, the others are sources used for calibration and teaching | 1071 | 84 | 188.5 | 5.09 |
| Am-Be | Nuclear gauges and calibration sources | 32 | 6 | 1594 | 43.0 |
| Pu-Be | | 11 | 2 | 2109 | 57.0 |
| Ra-Be | | 1 | | 1.06 | 0.03 |
| Cs-137 | Nuclear gauges, calibration and teaching devices | 74 | 3 | 2248 | 60.8 |
| Am-241 | 183 lightning conductors | 570* | 10 | 18.8 | 0.5 |
| C-14 | 5 lightning conductors | 49 | 1 | 0.13 | 0.003 |

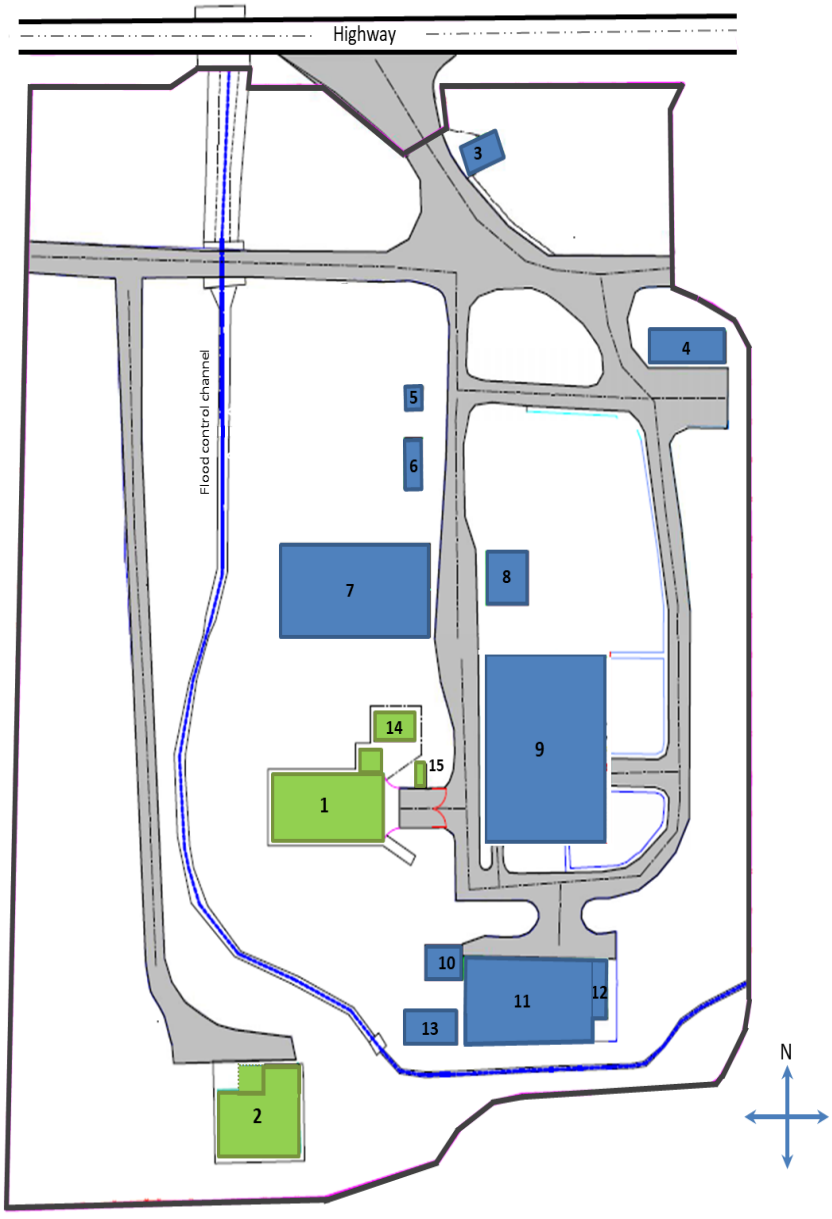
* The number of sources is estimated, as some of them were broken

## Annex L.4. Disused sources stored at the users' facilities

### Disused Radioactive Sources from the irradiator at the Food Irradiation Plant

| Number of sources | Initial unit activity (Bq) | Initial total activity (Bq) | Reference date month/year | Unit activity in 2020 (Bq) | Total activity in 2020 (Bq) |
|---|---|---|---|---|---|
| 52 | 4.81E+13 | 2.50E+15 | 05/1986 | 5.60E+11 | 2.91E+13 |

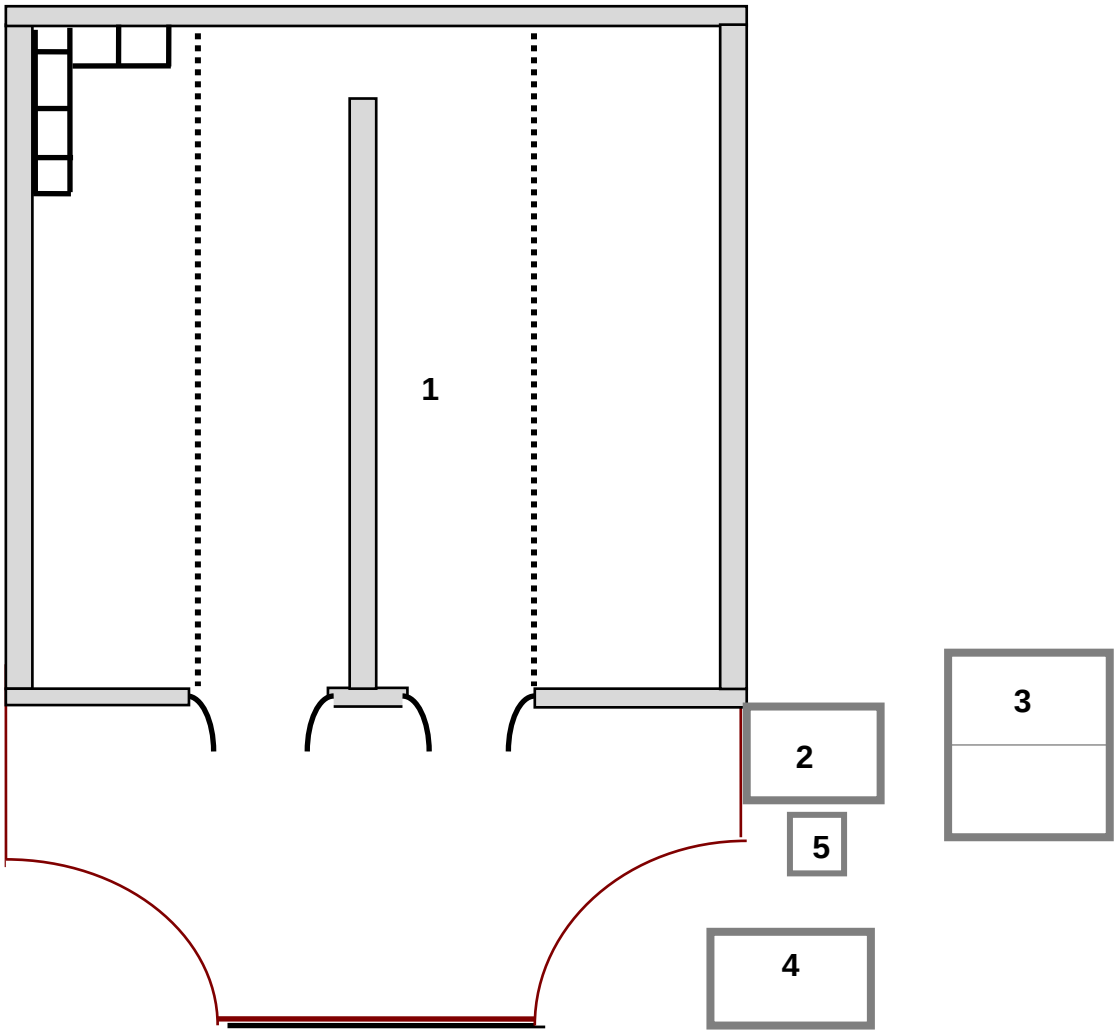
## Annex L.5 View of Managua Site, where the CPHR Waste Management Facility is located




**Legend**

1. Storage facility
2. Radioactive Waste Treatment and Conditioning Plant (RWTP)
3. Security checkpoint
4. Administrative building
5. Room for laundry and gardening services
6. Workshop
7. Pesticide storage
8. Solvent storage
9. Technological building
10. Compressor room and Abatex production plant
11. Pesticide plant
12. Electric power generator
13. Cistern
14. Radiological changeroom facility
15. Forklift truck control area

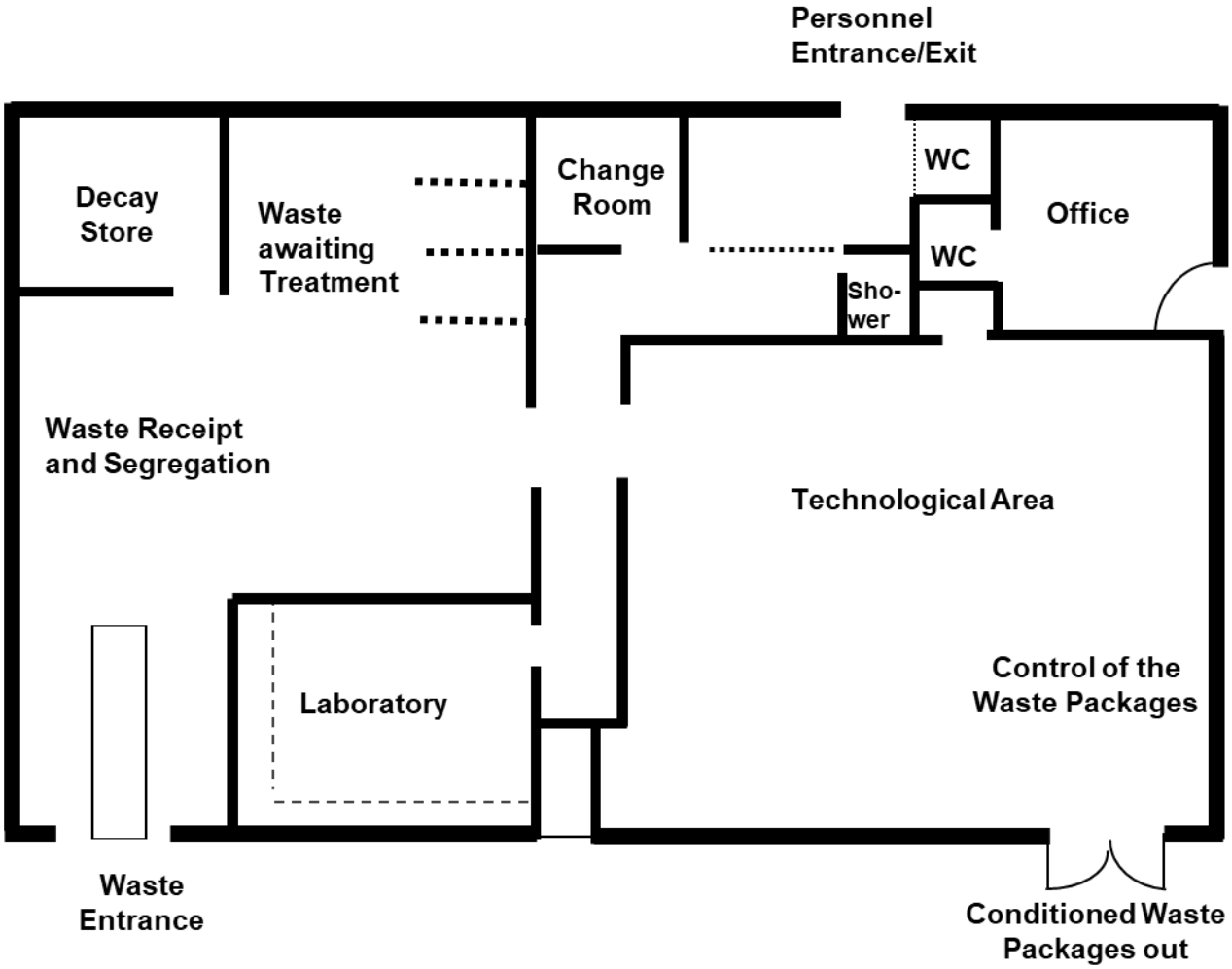
## Annex L.6. Scheme of the Centralized Store for Radioactive Waste and Disused Radioactive Sources




**Legend**

1. Store
2. Ventilation room
3. Radiological changeroom facility
4. Forklift truck control area
5. Retention tank

## Annex L.7. Scheme of the RWTP



## OVERWIEV MATRIX

| Type of Liability | Long-Term Management Policy | Funding of Liabilities | Current Practice/ Facilities | Planned Facilities |
|---|---|---|---|---|
| **Spent Fuel** | NA | NA | NA | NA |
| **Nuclear Fuel Cycle Wastes** | NA | NA | NA | NA |
| **Application Wastes** | Treatment, conditioning and interim storage facility (Centralized) | Waste generators pay for waste management.<br><br>Financial contribution is also received from the Government. | Clearance<br><br>Interim storage in waste generators until clearance<br><br>Treatment, conditioning and interim storage in the centralized management facility | None |
| **Decommissioning** | Decommissioning services provided by the CPHR. RW generated from D&D transferred to CPHR for treatment, conditioning and interim storage (Centralized) | Users pay for decommissioning services and management of generated RW.<br><br>Financial contribution is also received from the Government. | None | None |
| **Disused Sealed Sources** | Return to supplier.<br><br>Conditioning and interim storage (Centralized) | Authorization holders pay for DSS management in Cuba or return to supplier. | Transferred to the centralized management facility for conditioning and storage.<br><br>Return to supplier. | None |

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