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Current status of the Radiation Technology and Quality Control for Radiation Processing in Latin America.

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ABSTRACT

The use of the Radiation Technology has gained acceptance in various regions of the world, where studies estimated that the installed capacity increases at a rate of 6 % per year and Latin America is part of this increase, due the advantages of this process when it is employed for the food preservation, sterilization of medical-pharmaceutical material and to control the insect pests.
This paper shows the art state of the application of Radiation Technology in Latin America, as well as the technological characteristics of the most gamma irradiation facilities and minor number the electron beam accelerator facilities, the types of irradiated products, state of the Quality Management System and the Dosimetric Systems used in the Radiation Processing Control in the Region.

1. INTRODUCTION

There is great interest in most of the countries of Latin America and the Caribbean to increase or develop activities of the radiation processing (gamma and electron technologies) with different applications such as sterilization of disposable medical devices, decontamination of pharmaceutical products and medicinal herbs, food ingredients, blood, biological tissue, food preservation, processing of fruits and vegetables with quarantine purposes, for the preservation of the environment, crosslinking of polymer (electrical conductor insulation, improvement of physical and chemical properties, plastic foam "PE", vulcanization of rubber and latex), among others.
Due to the production and marketing capacity in the region are increasing, it is necessary to harmonize the quality control methods of the radiation processing to ensure the marketing of products that have been irradiated by means of safe and reliable processes.
The paper shows the compiled information of the radiation technology state and the standards used in the process control in the countries of the Region, through technical reports, exchange of experiences and knowledge of the coordinators participants and experts in meetings and reports of the First, Middle and Final Meeting of Coordinators, during execution of Project ARCAL RLA 8046 "Establishment of Quality Control of the Industrial Irradiation Processing" (2009-2012) [1, 2, 3, 4], sponsored by the International Atomic Energy Agency (IAEA) in the Latin America Region and the support of the government of the participating countries. It should be noted that this material is the result not only of the execution of project but the all experience for more than four decades of application of this technology in the Latin America countries, the data provided in most part are of governmental institutions and the data belong to the private institutions are presented slightly due to the limited nature of the information. The countries participating in this project were: Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Mexico, Peru, Dominican Republic, Uruguay and Venezuela.

2. RADIATION TECHNOLOGY STATE IN LATIN AMERICA

2.1 Argentina

Argentina is one of the countries in the region with a significant development in the application of this technology at industrial scale. It has laboratory irradiators and an industrial facility, also in the Ezeiza Atomic Center is found a High Dose Laboratory traceable to the National Physical Laboratory (NPL) of United Kingdom.

2.1.1 Irradiation Facilities.

1964 – Laboratory self-contained irradiator (^{60}Co), CNEA.
1970- Semi-industrial irradiation facility (^{60}Co), (PISI), Ezeiza Atomic Center, CNEA (Multi-porpuse).
1971 –Movile irradiator, IMO (^{60}Co), CNEA.
1988- Industrial irradiation facility (^{60}Co) – IONICS (multi-purpose).
1991 – Movile irradiator IMCO-20 (^{60}Co),
EMI 9-Modulate irradiator.
Irradiator Gammacell 220.
Electron beam facilities.

2.1.2 Main Applications

Sterilization of biological tissue for implant, disposable medical devices, pharmaceutical products, laboratory material, food irradiation, quarantine treatment, decontamination of beekeeping material (beehives, stamped wax), inputs for laboratory animal (food, chip), food for mascots, cosmetics and containers, detection of irradiated foods, among others.

2.1.3 Quality Management System

In the PISI is used as reference for the irradiation of any products the Standards ISO 11137, supplemented with other standards and applicable regulations. It also has an Integrated Management System, which not only contemplates quality aspects but also of security, environment, social responsibility, etc.
On the other hand the IONCS irradiation facility is certified under the Standards ISO 9001/2008 from January of 2010.

2.2 Brazil

Brazil has shown to be the country of the Region with a bigger application from this technology to commercial and industrial scale, as much in gamma facilities as in accelerators of electrons. It has an own technology in the design and construction of facilities gamma.
This country started the use of radiation technology in the seventies on crosslinking polyethylene for insulation of wire and electronic cables and sterilization of medical care devices. The present status of industrial applications of radiation shows that the use of this technology is increasing according to the economical development and the necessity to become the products manufactured in the local industries competitive in quality and price for internal and external market.

2.2.1 Irradiation Facilities

To support the research and development of the research institution and the industry of the country there are installed in Radiation Technology Centre (CTR) at IPEN-CNEN/SP two industrial EBA facilities, three gamma facilities (industrial, panoramic and Gammacell) and a High Dose Dosimetry Laboratory that is used for the measurements of the irradiations performed in CTR's irradiators and to calibrate the routine dosimeters used by contract service companies of the country. The rest of the facilities belong to the private sector.

Table 1. Status of gamma irradiators in Brazil.

Company	**Capacity (kCi)**	**City/State**	**Installation**
Johnson & Johnson	2000	Sao Jose dos Campos/SP	1978
CBE-EMBRARAD	2000-3000	Cotia/SP	1981-1999
CBE-EMBRARAD	5000	Jarinu/SP	1999
IPEN-CNEN/SP	2000	Sao Paulo/SP	2005
CDTN-CNEN/MG	60	Belo Horizonte/SI	2004
Tech-Ion	3000	Manaus/AM	2000
CENA/USP	2000	Piracicaba/SP	2012

Table 2. Industrial electron beam accelerators with energy from 200 keV to 10 MeV operating in Brazil.

Company	**Manufacturer**	**Model**	**Energy (keV)**	**Current (mA)**	**Applications**
IPEN-CNEN/SP and Cofibam	Radiation Dynamics, Inc.	JOB 188 JOB 307	1,500	25 60	R&D and Crosslinking of wire and electric cables
Antilhas Embalagens	Energy Sciences, Inc.	EZCure I	110	500	Curing
Bridgestone-Firestone	Energy Sciences, Inc.	EC/300 -1 and 2	300	500	Crosslinking
Cryovac Brasil	Cryovac	ECLU - 1,2,3 and 4	500	30	Crosslinking
Unipac Embalagens	Energy Sciences, Inc.	CB200/060/070	210	168	Curing
Curwood Itap	RPC Industries	Broad Beam - 1 and 2	300	600	Curing

Acome do Brasil	Acome/ Radiation Dynamics, Inc.	DPC 1000	550	66	Crosslinking of wire and electric cables
Prysmian	Radiation Dynamics Inc.	JOB 308	1,500	60	Crosslinking of wire and electric cables
Aceletron	Titan Corporation/ EL Surebeam	LINAC - 1 and 2	10,000	1.8	Food irradiation, gemstone enhancement, radiosterilization of medical disables, cosmetics, polymer modification

2.2.1 Main Applications.

Radiation sterilization of disposable medical products, materials modification (wire and cable insulation crosslinking used in electric home appliances, computers, cars, motors, communication cables, heat shrinkable products (tubing, film, tape, and sheet), polyethylene foam, pre-vulcanization of rubber tires components, food irradiation, decontamination such as spice, dehydrated fruits and grains, agribusiness improvements, tissue banking, cultural heritage preservation, electronics devices and degradation of PTFE (Teflon).
Other applications: In the area of grafting curing induced by radiation studies are being done on development of carbon fibers composites, membranes for electrolyte fuel cell, nanotechnology materials, In order give a better management for the industrial and radiotherapy radioactive spent of the country a prototype of gamma irradiator for blood banking is being developed and to attend the increase demand of services on gem stone irradiation a dedicated gamma irradiator is being designed in order to reduce the cost of the facility.

2.2.3 Quality Management System

Implementation of relevant standards in governmental and private institutions, such as, ISO 9001:2008, ISO 11137:2006, ISO 13485:2004, ISO/IEC 17025 and CNEN-NN-1.16 (IAEA SSG-8) at IPEN-CNEN/SP, CDTN-CNEN/MG and CBE-EMBRARAD and irradiated wire and electric cable manufacturers COFIBAM and ACOME have implemented ISO 9001:2008 in Brazil.

2.3 Chile

Another country of the region that has reached satisfactory results with the employment of this Technology is Chile, where the Multi- purpose Irradiation Plant (PIM) operates from the year 1978, which is located in the Center of Nuclear Studies of The Aguirre belonging to the Chilean Commission of Nuclear Energy (CCHEN).
The facility was designed as unit pilot and multi-purpose, that which allows the realization of different processes, allowing to make applications of the intense sources of radiation, in such

areas as the sterilization of medical material and food irradiation. Both applications can be carried out indistinctly in some of their irradiation systems, continuous or semi-continuo.

2.3.1 Irradiation Facilities.

The PIM is an installation that has a capacity of shielding of 1 MCi. The storage of the sources is of type pool, depth 4,5 meters, the ^{60}Co source had an activity of 330.000 Ci in June of the 2012.
Other laboratory facilities are the Irradiator Gammacell 220 and the Irradiator of ^{137}Cs type BPCDI N'3 located in the Section Health and Foods of the Department of Nuclear Applications of the CCHEN.

2.3.2 Main Applications.

The radiosterilization of medical material and the food irradiation, decontamination of frozen or dehydrated foods, irradiation of raw material for the Food and Pharmaceutical Industry.

2.3.3 Quality Management System

The PIM has the Certification of Quality for ISO 9001:2008, granted by Veritas Bureau and the Authorization of the sanitary authority to process foods.

2.4 Colombia

At the present time, Colombia has an irradiation facility, this belong to the Colombian Geologic Service, entity attributed to Mines and Energy Ministry. In this installation the irradiation service is offered to users of different industrial sectors. Although exists the interest of the private sector of building an industrial multi-purpose installation.

2.4.1 Irradiation facilities.

The irradiation facility is of category IV, with a nominal activity of 100 kCi and at the present time of 8,45 kCi, with batch irradiation system, with a capacity of production of a 1 meter cubic.
They have in perspective a project for the recharge of the installation up to 100 kCi, the modernization of the transport system as well as of the increase of shielding.

2.4.2 Main Applications.

In this facility the irradiation service is offered to semi- industrial scale due to its capacity and low activity of the irradiation source to products that require low dose of users of different industrial sectors as the pharmaceutical, medical, cosmetic and researches.

2.4.3 Quality Management System

It has a guide for the implementation of a Quality System in the Industrial Irradiation Processes, what will be of great benefit for the implementation and harmonization of the quality criterion in the region.

2.5 Costa Rica

The commercialization of irradiated products in Costa Rica is very little, the irradiation facilities and electron accelerators existent are guided to irradiate medical devices of transnational companies that take place in Costa Rica and that they export these products to diverse markets. It reduces the possibility to carry out experimental tests guided to the irradiation of food products in the existent industrial irradiators.
Due to the limitations that the country presents with relationship to the application of this technology like are: few qualified and certificates human resources, the perception of the people with relationship to the installation of irradiation centers and the consumption of irradiated products, the absence of resources to develop investigation and development projects, all make of the scarce development of the technology in the country.

2.5.1 Irradiation Facilities.

It has two facilities of high technology dedicated to the sterilization of medical products. One of this is an electron accelerator of 7.5 MeV of Baxter Company and the other one belongs to the BeamOne Company, it is an accelerator of electrons of 10 MeV, this it is a company specialized in selling the industrial irradiation services and it offers services in Costa Rica to companies like Hospira, Boston Scientific, ArthroCare, etc.
On the other hand, the country has two irradiators Gammacell 220, one is in the Regional International Organism of Animal Sanity (OIRSA), which one has come using to irradiate diverse species that are used in research projects that execute diverse entities. The other one is in the Costa Rica University and that it has served at the moment from support to diverse projects that it executes this University, it is out of service.
The Technological Institute of Costa Rica carries out diverse actions guided to build in short-half- term an industrial multi-purpose irradiator with the objective of satisfying the future demand of the tissue bank project that develops the Center of Investigations in Biotechnology of the Technological Institute of Costa Rica

2.5.2 Main Applications.

The application in the private companies is the irradiation of medical material and in the state sector it is directed to the investigation of the agricultural sector, as the production of varieties of rice, using mutations induced with irradiation gamma, resistant to pest, participation in the regional program of eradication of the fruit fly and generation of promissory varieties of beans resistant to the pest.

2.5.3 Quality Management System

In the government sector a Quality Management System is not implemented and of the private sector does not have the information.

2.6 Cuba

The Irradiation Technology has its beginnings in Cuba in the year 1958, with a laboratory irradiator, Canadian, type Knopp Cobalt Source, for the treatment of biological tissue for implant. Being Cuba the first country of Latin America in applying this technology for implants. At the present time this irradiator is dismantled.

Our country has been able to assimilate the irradiation technology appropriately and it has passed from the technological assimilation phase to the commercial consolidation phase. Significant results have been reported in the control of processes (high dose dosimetry), the establishment of sterilizing dose (implementation of the ISO11137) and in the search of engineering solutions like they are studies of the irradiation geometry, innovations in the systems of transportation of the products, development of special containers, use of coolant pills, etc., to offer specialized services of irradiation.

2.6.1 Irradiation Facilities.

In the decade of the 70 the Nuclear Technical Department is created in the National Center of Scientific Researches (CNIC), where the investigations are begun to carry out in the Canadian Laboratory self-contained irradiator on the food irradiation and later an integral assimilation of this technology is achieved as well as of the dosimetric systems for the calibration and control of the irradiation process.
In the year 1971 is settle a laboratory self-contained irradiator, Russian, type MPX-γ-25 M, with an initial activity of 10,0 kCi. At the present time it is dismantled.
In the year 1986 another laboratory self-contained irradiator is established, Canadian, type Gammacell 500-01, capacity of 80 liters and an initial activity of 35 kCi, located in the National Center of Agricultural Sanity (CENSA). At the present time it is also dismantled. And a Food Irradiation Facility (PIA), russian, for the treatment of potatoes and onions, with an initial activity of 67,5 kCi located in the Institute of Investigations for the Food Industry (IIIA). At the moment, it is in remodeling process, with the modification of the transport mechanism and the recharge of the source up to 100 kCi.
In the year 1994 is settled another laboratory self-contained irradiator, russian, type MP-γ – 30, capacity of 4 liters and an initial activity of 10,45 kCi, in the CEADEN, for the development of the irradiation technologies and to offer added value high services, which is working at the moment but with a dose rate very low.
In the 2012, in the own CEADEN, it settled a laboratory self-contained irradiator, hungarian, initial activity of 10,5 kCi, with its which a new growth of the application of this Technology together to the works of remodeling of the irradiation facility is appreciated.

2.6.2 Main Applications.

The application of this irradiation Technology has a wide number of specialized services in a commercial scale in the national context, of which we can point out for different spheres: food irradiation, radioesterilization of medical and pharmaceutical material, medicinal herbs, nutritional supplements, biological products, among other applications.
They have also been carried out investigations in the field of the mutation breeding in different varieties of crop, as rice, tomato, sugar cane, yucca, corn, avocado, banana, grains and citric.
Other products have also been irradiated like movies film, heritage preservation, pustules of borer of the sugar cane and tetuan of the sweet potato, shampoo, cream children, among others.
The last researches related with this technology have been made in the modification of polymeric matrix for the preparation of hydrogel membranes and the development of detection methods of irradiated foods by means of the comet assay.

2.6.3 Quality Management System

The Irradiation Service of the two facilities, which are working at the moment, has implemented its Quality Management System in correspondence with the Standards NC ISO 9001: 2008.
This Service is regularly audited for internal authorities and it continues working for its certification for the Normalization National Office. Also cuban Standards exist for the regulation of biological and food irradiated products (NC 680:2009 Food Irradiation).
Besides, there is a series of Standards related with the employment of different dosimetric systems, which are employed in the irradiation process control.

2.7 Ecuador

In Ecuador the employment of the Irradiation Technology has its beginnings in the year 1981 in a facility with cobalt 60 sources, which it is in the Nuclear Sciences Department (DCN), of the National Polytechnic School, in Quito. This unit began its service assisting to the investigation and requirements of the users in some areas, as the medicine, agriculture, and pharmacist. Later in the same Institution it was put an accelerator of electrons in the year 1982.

2.7.1 Irradiation Facilities.

The irradiator, french manufacturer, has a design capacity of 150 kCi, the first charge was of 20 kCi in the year 1981 and it was recharged with 40 kCi, in february of 1991, the current activity is smaller to the 4 kCi.
The electron accelerator, soviet manufacturer, has a power is of 5 - 10 MeV, its installation delayed some years, because the beam design was changed.

2.7.2 Main Applications.

At the present time the use of the irradiator, mainly is for the investigation, although it is continued giving limited services for sterilization of medical products, medicines, decrease of microbial load in spices, dry fruits, vegetables and processed foods.
The accelerator is used in sterilization of medical products, as decrease of microbial load of processed foods, as well as the investigation.
In a general the country confronts difficulties with the good acting of this technology, on one hand in the irradiator the manipulation of the product is made manually, what diminishes the efficiency of the process, the volume of the irradiation room is insufficient to allow an improvement in the efficiency and the low activity of the source, among other reasons. On the other hand, the electron accelerator presents the following difficulties: the old instrumentation for the calibration of the electron beam, the old control dosimetric system and the calibration certificate of the equipment doesn't exist.

2.7.3 Quality Management System

The country doesn't have implemented Quality Management System in the Process of Irradiation.

2.8 El Salvador

El Salvador had an installation with an industrial irradiator (gamma sterilizer model JS6300), designed, manufactured and installed by Atomic Energy of Canada Limited. The maximum capacity of the cobalt 60 sources were from 9.25 to 18.5 PBq (250 to 500 kCi), with an initial charge of 4.0 PBq (108 kCi). The facility was built in 1974 and the irradiator was installed and commissioning in 1975. The source was never recharged and it suffered an accident in February of 1989. To the moment of the accident the activity of the source was of 0.66 PBq (18 kCi). The irradiator was designed for a relatively small quantity of products. The irradiation facility was property of a company that manufactured intravenous solutions and kit for blood products. At the present time the facility is closed.

2.9 México

Mexico is another of the countries of the region with a development in ascent in the employment of the gamma irradiation, where it is more and more well-known and used by its advantages on other alternatives. A diversity of dehydrated products for human and animal consumption are processed, also, products for the pharmaceutical industry and the health sector, and the polymers are treated to improve its physical-chemical properties. In the year 2000, it settled a new gamma irradiation plant with private capital (of Griffith Micro Science and Sterigenics) that at the moment it is property of the company Sterigenics, and it is located in Tepeji of the River, Hidalgo. It is a multi-purpose unit that has the capacity to assist fresh or dehydrated products. In 2008 it began the treatment of fresh fruit dedicated to the export markets, guava and in 2009, mango and citric. Another semi-industrial irradiator that operates with less than 100kCi, it is in operation in the Autonomous University of Mexico (UNAM). Its use supports the investigation and the formation of human resources. Partially, it processes cosmetics, ingredients for the production of articles of personal use and dehydrated condiments.
The last year, began operations another installation in Matehuala, San Luis Potosí, dedicated mainly to the treatment of fruits and fresh vegetables as pest control for export to North America, as well as, for mobilization in the national territory.

2.9.1 Irradiation Facilities.

Different irradiation facilities exist belonging so much to the state sector as private.
The installation located in the National Institute of Nuclear Investigations (ININ) it is equipped with an irradiator JS6500 (designed and manufactured by MDS NORDION) category IV, of humid storage with shielding design for 1 MCi, setting in operation March 1, 1980 and a current activity of 621.862 Ci, it also possesses three self-shielding irradiators: a Gammacell 220 with current activity of 72.99 Ci, an irradiator VickRad with current activity of 2.61 Ci and an irradiator Transelektro LGI-01 of hungarian production with current activity of 1997.84 Ci.
The Sterigenics facility. - Designed for the company NORDION, it was inaugurated April 7, 2000. It is a multi-purpose facility of continuous process with transporter of totes box, its irradiator is category IV and the shielding design supports up to 5 MCi. It offers services of irradiation of fruits and fresh vegetables.
The Phytosan/Benebión facility. – This facility is employed to control the insect pest, it had a recharge of 200 kCi of cobalt 60 in May of 2011 and it began its operation in July of 2011. It was located strategically in the frontier of the pest control region to be able to assist the shipments of fruits and fresh vegetables that cross this division. Some of its technical

characteristics are: Irradiator MDS NORDION, double wing of sources, maximum activity for the shielding design until 1.5 MCi, entrance system and exit of the bunker with transportation band.
Irradiator type GAMMABEAM 651 - PT of high intensity is located in the Nuclear Sciences Institute of the UNAM, is used to carry out research works, as well as irradiations of industrial material, the last recharge was carried out in 2007, with 25 kCi.

2.9.2 Main Applications.

Dehydrated foods and herbalists, cosmetics, medical products, irradiation of fruits and fresh vegetables.

2.9.3 Quality Management System

The installation of the ININ obtained the certificate of Quality ISO 9001: 2008 in 2009.
The Sterigenics Plant has the certification ISO 9001: 2000 for DNV and it also operates under the Standard ISO 11137.

2.10 Perú

The Peruvian Institute of Nuclear Energy - IPEN is a Decentralized Public Institution of the Sector Energy and Mines; it takes the responsibility to promote and to develop the nuclear energy and its multiple applications, controlling the sure use of the same ones. The IPEN has technical personnel qualified in the areas of irradiation technologies and to evaluate and to make the control of quality to all the irradiation facilities that are working in the Peru.
Three entities that applying the irradiation technology: Peruvian Institute of Nuclear Energy (IPEN), it operates an irradiator category I, Service of Agricultural Sanity (SENASA), it has an irradiator category II and three irradiators category I and the association in participation IPEN - IMMUNE, it operates the irradiation multi-use facility (PIMU) with an irradiator category IV.

2.10.1 Irradiation Facilities.

The Peru has an irradiation multi-use facility (PIMU) from April of 1996, russian technology, category IV. The permissible maximum activity of cobalt-60 source in the design is of 500,000 Ci, being its initial charge of 100,00 Ci. The facility can work in the batch or continuous regimen.
An irradiator Gammacell 220 Excel, at the moment it is working, it is inside the facilities National Center of Radiological Protection and Medical Services. The initial total activity August 15 the 2003 was of 23,984 Ci.
In the National Service of Agricultural Sanity - SENASA are:
-Irradiator Gammabeam 127 (GB-127); it is classified as a dry panoramic irradiator of category II, it is of canadian production (International Nordion Inc.).
-2 Self-shielding irradiators, category I, type JLSHEPHERD & ASSOCIATES, Model 109-68 S.N.
-Horizontal irradiator of Cs-137; it possesses sources of Cs-137, the dose rate March 31 1992 was of 1.5525 kGy/h.

2.10.2 Main Applications.

Irradiation of medicinal herbs, condiments and spices, dehydrated products, coloring organic, biological and medical products, dressings and cosmetics.

2.10.3 Quality Management System.

The country has implemented and improved a quality management system; with manuals, procedures and instructions, in according the Standard ISO 17025 and the Peruvian Technical Standards related with the application of the irradiation technology.

2.11 Dominican Republic

The Dominican Republic has two industrial Irradiators for electron beam inside the Fenwal International Company.
A project exists in evaluation for the installation of a multi-purpose irradiator of mixed capital (the government and agro-industrial managers).
It is had a good collection of studies and researches on the effect of the radiation in the plastic materials, but these they are confidential and they belong to the Fenwal International Company.
One of the main situations that have the country is the lack of divulgation of the irradiation technology for the food preservation. This makes that the productive sectors feel rejection to the technology or don't show interest.

2.11.1 Irradiation Facilities.

The existent industrial irradiators differ basically for their applications and energy.
a) High Energy (10 MeV). SureBeam, dedicated to the irradiation of medical devices, installed in 1999, capacity of 60,000 cubic meters / year, densities among 0.08 g/cc to 0.35 g/cc.
b) Irradiator of Sterile Connection. Installed in 2008, half energy (650 keV). Design System Baxter Accelerator Varian, control system Surebeam (L3), irradiation area 10 cm x 10 cm.

2.11.2 Main Applications.

It only provides irradiation services to manufacturing companies of medical devices.
Irradiated Product 100 % for export.

2.11.3 Quality Management System.

It has certification for the ISO 13485-2003, ISO 11137-2006 (2007).
Implemented the new version of the ISO/ASTM 51261-2011- Calibration of Routine Dosimetry Systems for Radiation Processing and the new version of the ISO-11137-2:2012 Radiation Sterilization, Dose establishment.

2.12 Uruguay

The first irradiator at pilot scale was inaugurated in the country in the 2010. A Modulate facility, argentinean manufacturer, with an initial activity of cobalt 60 sources and design of 80.000 Ci, that allows to treat volumes to pilot scale through a container of 23 liters of

capacity. Located in the Technological Laboratory of the Uruguay - LATU - an Organization dedicated to the technological advice of the national companies.

2.12.1 Irradiation Facilities.

Modulate Irradiator, Model EMI 9 “CNEA-FIS-60-03 ", with cobalt 60 source, initial activity of 80.000 Ci. The EMI-9, argentinean manufacturer, licensed by the CNEA Argentina was bought to Sinercom SA-Technological Advice SA.
Other irradiators are:
-Irradiator Gammacell 220, in the Tissue National Bank (Hospital of Clinical).
-Irradiator Gammacell 220, in the CIN, Sciences Faculty (University of the Republic).

2.12.2 Main Applications.

The test first in the mark of the activities of pre feasibility in the 2003 were carried out with samples of honey, alfajores, spices, mushrooms, dressings, honey products, nitrofurazona and fresh fruits.

2.12.3 Quality Management System.

Quality management system implemented for the irradiation process control (ISO 9001).

2.13 Venezuela

From the 2004 the country has an Industrial Sterilization Plant with gamma rays (PEGAMMA), with capacity to process 14 cubic meters of products, with ^{60}Co sources, current activity of 90000 Ci, located in the underground Facilities of the Reactor RV-1
It has a Laboratory where it is carried out the Dosimetric control of the irradiation plant.
In the 2005 a mini irradiator of 2 cubic meters doesn't operate more to modify its design and security system, at the moment in reactivation process.

2.13.1 Irradiation Facilities.

The Industrial Sterilization Plant is located in the Venezuelan Institute of Scientific Investigations (IVIC). The irradiator was designed by MDS Nordion Inc., model JS 9500 (HD). With a shielding maximum capacity of 111.000 TBq (3 MCi), and for the rack of 37.000 TBq (1 MCi) of cobalt-60. The irradiator is endowed with totes box, with a capacity of 0,273 cubic meters.
At the moment, the PEGAMMA has 19 pencils of cobalt 60, for an activity of 53.011 kCi.
The mini-irradiator will be a facility with a maximum activity of 1.850 TBq (50 kCi). The rack of the source is cylindrical, with modules of three levels of height. This facility will be used to carry out the investigation works and qualification of products.

2.13.2 Main Applications.

Irradiation of plastics, disposable medical clothes, natural products, spices, medical sutures, animal foods, pharmaceutical products.

2.13.3 Quality Management System.

A Quality Management System is established on the Standards ISO.

3. CONCLUSIONS

Exist one upgraded inventory of the type and operative state of the irradiation facilities in the region and in consequence of their limitations and capacities.
The incorporation of the public and private sector in the implementation of the Radiation Technology, together to the efforts of accompaniment of the OIEA, they are decisive to strengthen the industrial applications of economic, environmental and social interest in the Region.
It was proven that the Region has a professional human capital that can contribute to the economic and social growth in a competitive and advantageous way.
A better understanding exists regarding the use and application of the specific international standards for the use of the industrial irradiation for such applications as: conservation and wholesome of foods, sterilization of products and medical-surgical devices.
It was determined during the execution of the Project that the application of the radiation processing in Latin America by percent is the following one:
Modification of materials: 4 %
Treatment of pharmaceutical products: 13 %
Sterilization of medical products: 30 %
Treatment of foods: 35 %
Other Products: 18 % (serum, raw material, nutritional supplement, medicinal herbs, blood, research).
Where, the biggest percent of treated products are the foods, with a bigger contribution of Chile, Mexico and Peru. The sterilization of medical products continues and in a smaller scale the modification of materials, inside this aspect the biggest application is from Brazil.
The exchanged of experiences in the implementation of the Quality Management Systems (QMS) in attention to the requirements of the Standards ISO/ASTM, it has helped to reduce the technological breaches and times of answer in the application efforts at to develop the procedures and applicable instructions necessary in each installation.
At the end of the Project was obtained that only four countries have QMS for the irradiation services [Gamma (IG) or electron beam (EB)] certified by external entity, these are: Chile (IG, CCHEN), Brazil (private companies, IG and EB), Mexico (IG, ININ, Sterigenics) and Dominican Republic (private company, EB). Countries like Argentina (Ezeiza), Brazil (IPEN), Cuba, Peru, Uruguay and Venezuela have implanted QSM non certificates. Lastly Colombia, Costa Rica (state sector) and Ecuador not yet have implemented QSM.
It is essential to strengthen the Quality Assurance and Quality Control Systems (QA/QC) for the radiation processing on the base of international standard, including Dosimetric intercomparison in the region.
The High Dose Dosimetry has been strengthened by means of the application of the Standards ISO/ASTM. In the routine dosimetric control are employed a variety of dosimetric systems, although we should point out that those most used are the PMMA.
The process of calibration of the dosimeters mostly is executed in the own facilities, these are calibrated annually or for batch.
All the countries have gamma facilities of different manufacturer and four of them (Brazil, Costa Rica, Ecuador and Dominican Republic) have accelerators of electrons.

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