

Analysis of the necessary radioprotection procedures in manufacture of iodine-125 sources used in brachytherapy: A preliminary study

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ABSTRACT

The estimates for the year 2009 predict that 466,730 new cancer cases would occur in Brazil. Prostate cancer is the second most incident in our country, with almost 50,000 new cases in 2009. Brachytherapy, a type of radiotherapy, with iodine-125 sources is an important form of treatment for this kind of cancer. The “Instituto de Pesquisas Energéticas e Nucleares” (Institute for Nuclear and Energy Research – IPEN) created a project to produce a national prototype of these sources and develop a facility for local production. Manufacturing seeds locally will diminish the overall treatment cost making such treatment available to a larger number of patients. While the laboratory is under development, the IPEN imports and distributes seeds. This work aims to present and evaluate the radiological protection procedures applied to imported sources in order to assist in the setup of the new laboratory. Although iodine-125 presents low energy photons, around 29 keV, local and personal dosimeters are used during the separation and distribution process of seeds as described in CNEN NN 3.01 standard “Diretrizes Básicas de Proteção Radiológica” (Radiological Protection Basic Guidelines). All testing has demonstrated that there is no area contamination and very low exposure, suggesting that the application of the standards outlined in CNEN NN 3.01 has been effective. As a result of this work, a new dosimeter should be installed and evaluated in a future study.

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1. Introduction

1.1. Cancer in Brazil

Malignant tumors are responsible for a high rate of deaths throughout the world population. In 2007, out of a total of 58 million deaths worldwide, cancer was responsible for 7.6 million. The incidences of cancer with the highest mortality rates were lung (1.3 million), stomach (about 1 million), liver (662 thousand), colon (655 thousand), prostate (543 thousand) and breast (502 thousand) (INCA, 2008).

In Brazil, the frequency of deaths from cancer was 13.7% (Medicina Geriátrica, 2003) in 2004. It is an intermediary level

between developed and developing countries. Demographic studies indicate an increase in the elderly population of Brazil for years to come. Therefore, an increase in cancer mortality requires a more active prevention policy (Salvajoli et al., 1999).

The study of the disease in Brazil began in 1934, with the creation of the Brazilian Society of Oncology. In 1953, the Hospital Antonio Candido de Camargo was founded, focused on treating people with cancer. Since then, several hospitals dedicated to oncology emerged all over the country. The National Cancer Registry was created with the purpose of carrying out epidemiological studies with regional and national data (INCA, 2008).

Estimates for the year 2009 indicated that there would be 466,730 new cases of cancer in Brazil. The most frequent incidents, as it occurs in the world (except skin cancer of the nonmelanoma) are, among men, prostate and lung cancers, while breast and cervical cancer are predominates in females.

The Southern and Southeastern regions, in general, have the highest rates, while the Northern and Northeastern show the lowest rates. The rates in the Midwest are showed to be in the middle. Table 1 presents cancer estimates of the INCA – National Cancer Institute (Salvajoli et al., 1999).

Abbreviations: CNEN, “Comissão Nacional de Energia Nuclear” – National Nuclear Energy Commission; IPEN, “Instituto de Pesquisas Energéticas e Nucleares” – Institute for Nuclear and Energy Research; INCA, “Instituto Nacional do Câncer” – National Cancer Institute.

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Table 1
Brazilian cancer estimates for the year 2009 in men and women.

Type of malignancy	Estimated new cases	
	Men	Women
Prostate	49,530	–
Female breast	–	49,400
Cervical	–	18,680
Trachea, stomach and lung	17,810	9460
Stomach	14,080	7720
Colon and rectum	12,490	14,500
Oral cavity	10,380	3780
Esophagus	7900	2650
Leukemia	5220	4320
Skin melanoma	2950	2,970
Other locations	55,610	62,270
Subtotal	175,970	175,750
Skin nonmelanoma	55,890	59,120
All neoplasms	231,860	234,870

Source: (INCA, 2008).

In 2008/2009 around 49,000 cases of prostate cancer were estimated, a disease that, with early diagnosis, can be treated with brachytherapy sources of iodine-125. In one treatment, about 100 units of seeds are used. They are imported with the minimum price of \$30.00 a unit, preventing public treatment at large. In 2008, IPEN distributed approximately 33,413 seeds to 19 clinics in Brazil (Rostelato et al., 2008).

1.2. Brachytherapy with iodine-125

Brachytherapy is the radiotherapy modality in which the source is placed in contact or within a patient tumor. The dose is continually received, during a short period of time (temporary implants) or during the decay of the source (permanent implants). The brachytherapy iodine-125 sources are classified as interstitial, LDR – low dose rate, sealed and permanent (Salvajoli et al., 1999; Podgorsak, 2005). Some aspects of the Iodine sources production are reported in the literature. Mathew et al. investigated a method for iodine-125 adsorption on palladium coated silver wires (Mathew et al., 2002). Manolkar et al. presented studies on two different types of source core preparation, one based on electrodeposition of iodine-125 on a silver wire and another by physical adsorption on alumina microspheres (Manolkar et al., 2003). Cieszykowska et al. showed the deposition of iodine-125 on a silver support in an electrochemical process (Cieszykowska et al., 2005). Mielcarski et al. examined a method for electrodeposition for the same radioactive isotope on a silver electrode (Mielcarski and Puchalska, 2002). Saxena et al. described a method for iodine-125 adsorption on palladium coated silver wires (Saxena et al., 2006).

For prostate cancer, the seeds can be used in strand or loose form. Before treatment, the oncologist outlines the regions of interest, the medical physicist studies the case and stipulates the quantity of seeds that will be used. At the date of the implant, the medical physicist re-plans the procedure due to changes of volume in the organ. The doctor inserts the needle with the seeds into the patient guided by transrectal ultrasound. Those procedures assure the correct dose distribution in the target. In addition to that, the low energy released by iodine-125 is absorbed primarily within the volume of interest, saving surrounding healthy tissues, such as the rectum and the urethra (Souza, 2009). If there is a leakage in the seed releasing iodine-125 into the blood stream, the isotope will migrate in to the thyroid gland (Chen and Blair, 2004).

Iodine-125 seeds deposited in the prostate do not cause future complications for the patient. The seeds are constructed of an inert material, coated with titanium. After two years the seeds emit very little radiation, been considered radiation-free. The action of the photons emitted by the iodine-125 nucleus will eliminate tumor

cells typically resulting in disease control at levels of 85%–95% (Cavalcanti, 2009; Langley and Laing, 2004).

1.3. Radiation protection remarks

Undesirable biological effects caused by the use of ionizing radiation for medical purposes were observed since the beginning of practice. Therefore in 1928, during the Second International Congress, the International Commission on Radiological Protection was created, so that a multidisciplinary group could study and publish surveys in the area. The standards of the National Nuclear Energy Commission (CNEN) of Brazil are based on the ICRP publications to establish its own rules in the field (ICRP 1, 1958; ICRP 2, 1959).

In 1958 the ICRP established a program to protect the human race and its environment by introducing recommendations to obey a system of radiation doses restrictions. In 1973, the ICRP presented the maximum dose allowable: an effective dose of 50 mSv/year to workers on a condition that the dose does not exceed 1 Sv in 50 years (ICRP 1, 1958; ICRP 2, 1959; ICRP 26, 1977).

The control of doses has to be performed taking into account: local and individual monitoring, classification of workers and work area, and establishment of reference levels (ICRP 26, 1977; ICRP 35, 1982; IAEA SS 9, 1982).

The monitoring of workplaces and workers involved must be performed and their analysis is the responsibility of the radiation protection team. The dose levels of registration, investigation and intervention should be established. Moreover, everyone involved should be aware of the results of the work environments monitoring and outcomes of their own personal monitoring (ICRP 26, 1977).

Currently, in order to optimize the process, the ICRP has established that the control should be done in five years and must not exceed 100 mSv, resulting in an average annual dose of 20 mSv (ICRP 60, 1991).

This work will use the monitoring values of the workers and the areas involved to create a radiological protection policy that will be employed at the facility that will produce these sources to be used in brachytherapy.

Radiation monitoring is conducted by observation of parameters, leading to a comparison with the exposure readings in order to ensure safety and prevent accidents. In the handling of imported sources, there is the monitoring of packaging, the environment and workers involved (IAEA SS 115, 1984; ICRP 75, 1997).

The national standard requires that areas are classified so that access is restricted to specially trained personnel and previously authorized. The open or free areas represent areas without control, such as hallways and bathrooms. The maximum dose in this location is the maximum limit for the public, 1 mSv/year. The supervised areas are monitored sites kept under supervision, but are usually not required specific radiation protection procedures. In controlled areas specific measures of protection and security have to be adopted. Requirements such as optimization, dose limitation, special training programs and policies to reduce accidents are mandatory. All areas must be identified as regard to their classification (CNEN NN 3.01, 2005).

1.4. Iodine-125 laboratory in IPEN – Brazil

A multidisciplinary team was established at the Institute for Energy and Nuclear Research – Center for Radiation Technology (IPEN-CTR/SP) to develop an iodine-125 source and deploy a national facility for local production. Seeds produced in Brazil will lower costs making treatment viable for most patients.

For this reason, Rostelato developed the doctoral thesis “Study and Development of a New Method for Production iodine-125 seeds for application in brachytherapy”, in 2005. The project aimed to produce

an extensive body of knowledge that would enable the development of a prototype for the local production, shown in Fig. 1. Because it is new technology, the country is free from the payment of royalties. The study considered several issues that had been addressed by other researchers of the team, in various publications (Rostelato, 2005).

The process of welding the seed studied by Feher in “Development of Procedure Using Plasma Welding Process for Preparation of iodine-125 seeds” was published (Feher, 2007). The same researcher is developing another method of welding, using a solid-state laser. The automation of welding is being developed by Somessari (2010).

The seed dosimetry studied by Zeituni in “Dosimetry of iodine-125 Sources in Applied Brachytherapy” was published (Zeituni, 2008). This work developed a methodology for the dosimetric procedures, which should be performed at least once a year.

The quality control was developed by Moura in “Study and Methodology Development for Quality Control in the Production Process of iodine-125 Radioactive Sealed Sources applied to Brachytherapy”. He studied the different leakage test methods applied to radioactive seeds.

As the group prepares the laboratory, the radiation protection team has performed a preliminary study of:

- the doses received by workers in the areas involved with the handling of imported sources;
- local control of the doses present in air;
- the necessary conditions for the new laboratory safety.

This study will enable the establishment of a safe process in accordance with Brazilian standards.

2. Objectives

The objectives of this work are:

- To analyze existing data in order to implement area control dosimeters in the new iodine-125 sources laboratory;
- To evaluate the doses received by workers in the group who studied the manufacture of these sources;

With the purpose of:

- Assisting the radiation protection team in control of doses;
- Serving as reference for a future work.

3. Methodology and experimental procedure

The methodology used in this work was the evaluation of the laboratory radioprotection system, in accordance with the rule CNEN NN 3.01 “Diretrizes Básicas de Proteção Radiológica”

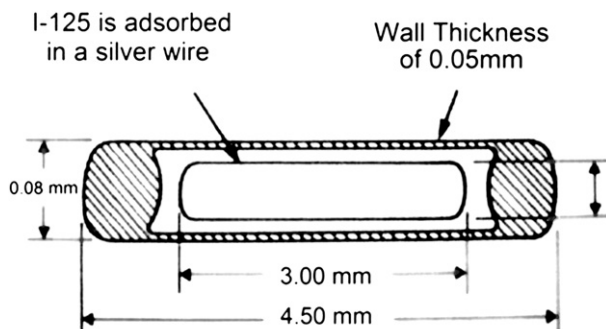


Fig. 1. Iodine-125 seeds schematic diagram.

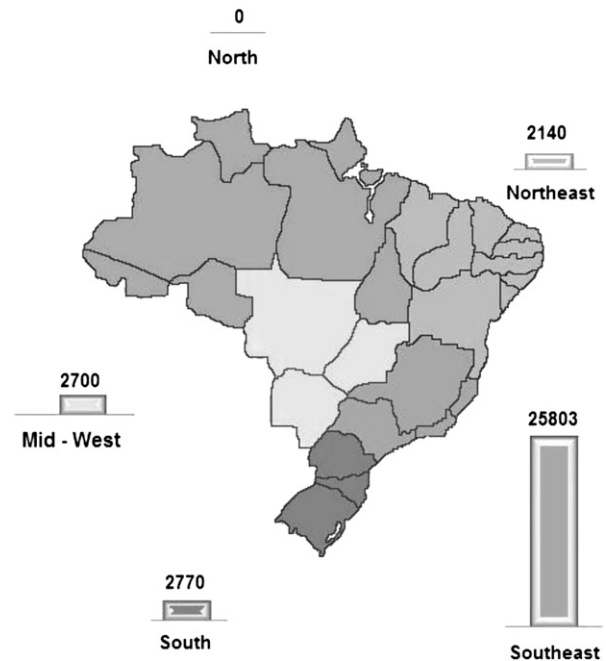


Fig. 2. Seeds distribution by region in Brazil (2008).

(Radiological Protection Basic Guidelines), set by the “Comissão Nacional de Energia Nuclear” (National Nuclear Energy Commission – CNEN). The following topics will be presented:

- Characteristics of the seeds distributed by the IPEN;
- Location of the main monitoring point;
- Characteristics of the groups of workers and personal dosimetry results.

3.1. Characteristics of iodine-125 seeds

The process of radionuclide production in nuclear reactors is based on the capture of thermal neutrons (i.e., neutrons with low kinetic energy, in the order of 0.025 eV) for atoms of a given element (Kaplan, 1978). Iodine-125 is produced in nuclear reactor, from xenon-124, which is only 0.1% natural xenon. The daughter nucleus, metastable xenon-125, decays by isomeric transition (100%) with a half-life of 57 s to xenon-125, which also decays by electron capture (99.3%) and positron emission (0.7%), with a half-life of 16.9 h, generating iodine-125.

Iodine-125 decays by electron capture (100%) to tellurium-125. The decay of iodine-125 is accompanied by the emission of photons of 27 keV, 31 keV and 35 keV. Due to the low average energy of emission, such photons have little penetrating power. Iodine-125 has a half-life of 59.408 days. The titanium capsule absorbs electrons and X-rays with energies below 5 keV. The type of seed observed in this work emits two additional photons of energy of 22.1 keV and 25.2 keV. These photons are characteristic X-rays produced by the interaction of photons of iodine-125 with the silver wire (Zeituni, 2008).

Iodine-125 seeds demand in Brazil amounts to 40,000 seeds/year. Approximately 33,413 ONCURA/GE Healthcare seeds were purchased in 2008 and distributed by IPEN to 19 clinics (Fig. 2), most of them located in the southeastern region (Souza, 2009).

3.2. Description of installation and activities

A laboratory for production of iodine-125 seeds is currently under development (room 48 Fig. 3). The process of seeds

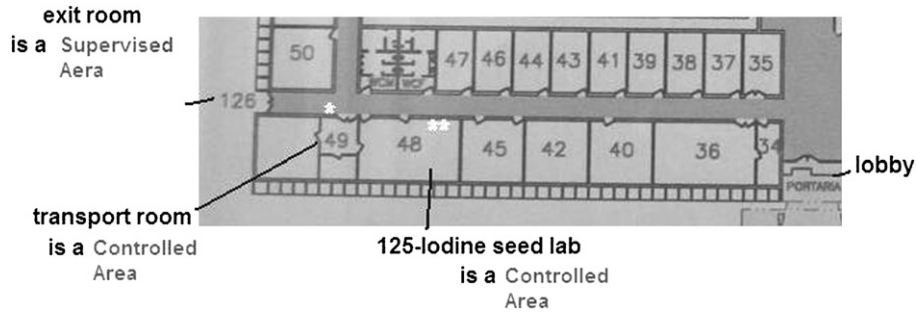


Fig. 3. Research Center scheme with classification of areas, location of rooms and dosimeter. Source: building layout by Botelho/CTR-IPEN.

production is divided into three main parts: adsorption of iodine on silver wire (production cell 1), seed sealing (production cell 2) and quality control (production cell 3), as shown in Fig. 4. Pressure and exhaustion are controlled in each of the production cells. To date, some trials have been made conducted in each of the three phases, and currently a plan for radioprotection and production automation is being developed.

The first part of the process is the adsorption of iodine-125 on silver wire (clusters). After surface treatment is completed, the deposition process is carried out with a sodium iodide (NaI^{125}) solution.

The seed coat is made of titanium. This material is used extensively for medical and dental implants because it is biocompatible with the human body. It is completely inert and immune to corrosion by all fluids and tissues of the body. Welding of the titanium capsule is the second part of the process and is carried out by using a solid-state laser.

The third part of the process is quality control, in agreement with the international standard ISO-9978 (the International Organization for Standardization), Radiation protection – Sealed radioactive sources – Leakage test methods, 15 February 1992 (INTERNATIONAL STANDARD ORGANIZATION, 1992; Souza, 2009).

In accordance with the Brazilian legislation, the radioprotection team studies the implementation of the following forms of monitoring: occupational, personal (visitor), environmental, and local area. The occupational control will be made with personal TLD dosimeters. The visitor dose control will use a pen dosimeter. Environmental detectors will control the dose-output of air and water. The area TLD dosimeters will be placed in areas that need to have a careful dose control. A warning detector will be positioned in the laboratory ceiling (local dosimetry).

3.3. Existing dosimeters (evaluated in this work)

Thermoluminescent dosimeters (TLD) are used in personal and area monitoring. The thermoluminescence is a luminescence phenomenon thermally stimulated. It is a process composed of two stages. In the first stage, the material is exposed to an external radiation source, going from a state of thermodynamic equilibrium to a metastable state (energy storage). In the second stage, the material is heated and undergoes to a thermostimulated relaxation (return to equilibrium, releasing energy) (Cameron et al., 1968; Knoll, 1989).

Luminescence is a widely known phenomenon that can be observed in solids, liquids or gases. When providing energy to

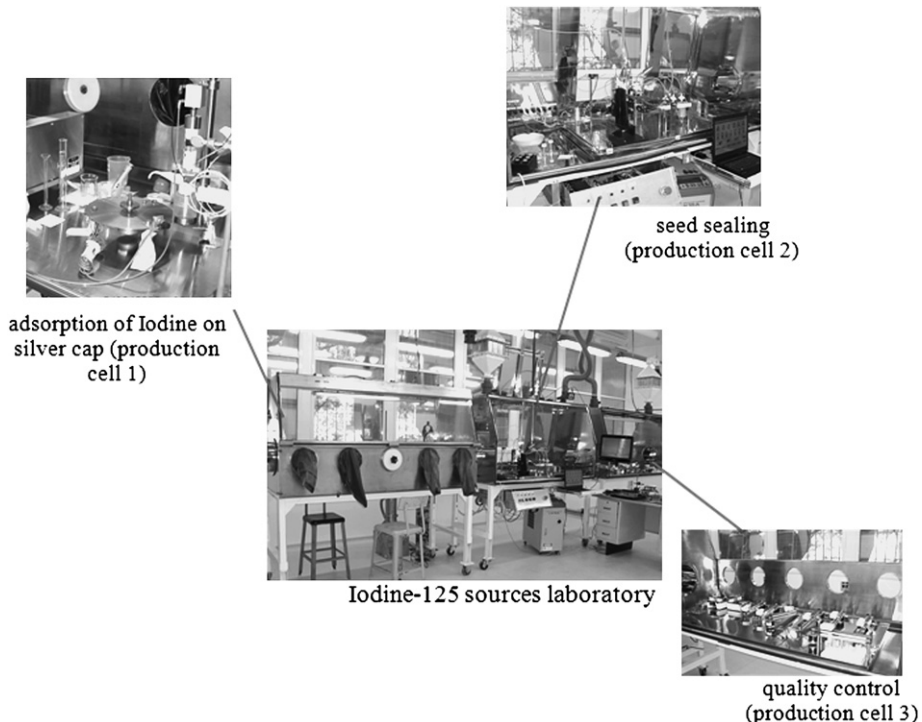


Fig. 4. Iodine-125 sources laboratory.

Table 2
Results of the measures in $\mu\text{C}/\text{kg}$ converted to mSv.

	$X(\mu\text{C}/\text{kg})$	$D_{\text{AR}}(\text{mSv})$
2005	34.6	1.48
2006	29.7	1.27
2007	30.6	1.30
2008	31.6	1.35

a material, part of that can be absorbed or re-emitted in the form of luminescence. The energy is emitted in the form of light. To perform a measurement, a previously irradiated thermoluminescent material is heated results in luminescence emission that is measured by a TLD reader machine (Cameron et al., 1968; Knoll, 1989).

In this study, the dosimeters are made with $\text{CaSO}_4 \cdot \text{Dy}$ with Teflon®. The dosimeters are prepared by using the method of evaporation in a sealed system. The $\text{CaSO}_4 \cdot \text{Dy}$ crystal, after being crushed with grain size between 85 and 185 μm , is mixed with Teflon®. The pellets are cooled pressed and sintered at 380 °C in air for 1 h. Before irradiation, the pellets pass through a heat treatment at 300 °C for 1 h in a muffle oven.

The main physical characteristics of the TLD from home are:

- Limit of detection: 0.05 mSv with 5% uncertainty;
- total weight of the pellet: 50 mg
- dimensions of the pellets: 6 mm in diameter and 0.6 thick;
- detector wrap: made of plastic with $3.8 \times 6.0 \times 0.8$ cm containing three filters made by plastic, lead and lead with a hole.

The dosimeters readings are made by a TLD reader Harshaw NE Technology, Model 5500 Automatic made by Bicon.

Two tips of dosimeters were evaluated.

- Area control – A-15

A TLD dosimeter is used for area control. It is positioned on the wall, where the radioactive material leaves for transport (* outside room 49, in Fig. 3). This room, which is isolated by two doors, is considered a supervised area because it is the local output of radioactive product. Products move from the package room (room 49, in Fig. 3) to the transport room (room 126, in Fig. 3). The dosimeters are evaluated quarterly.

- Occupational control

All individuals have a personal dosimeter to enter controlled or supervised areas. The classification of the assessment locals is showw in Fig. 3.

4. Results and discussion

4.1. Area dosimeters

4.1.1. Area dosimeter – Localization at point A-15

The 4-year results of A-15 dosimeter readings are presented in Table 2. The background exposition was discounted in each datum

Table 3
Percentage of exposure per year compared with the annual ceiling of permissible 20 mSv.

Year	Percentage of 20 mSv
2005	7.40
2006	6.35
2007	6.50
2008	6.75

by subtracting the natural exposure value, obtained by a dosimeter for environmental control.

To quantify the exposure, assuming that a worker has received all the exposure that the dosimeter has received (extremely conservative position), the following calculation was made (Table 2), in accordance with the equation presented below (Sanchez, 2002):

$$D_{\text{AR}}(\text{Sv}) = 33.7 \cdot X(\text{C}/\text{kg}) \cdot 1.27 \text{ (converting factor Gy} \rightarrow \text{Sv)} \quad (1)$$

D_{AR} (Sv) = Absorbed dose in air, measured in Sievert (Sv). It represents the amount of energy that the radiation deposits in the medium.

X = Exposure, measured in Coulombs per kilogram (C/kg). It represents the amount of charges ionized in air by the radiation per unit of mass (ICRP 60, 1991).

Considering the annual ceiling permissible per year to be 20 mSv (CNEN 3.01, 2005), Table 3 shows the percentages of the total doses in the four years inventoried.

Since the dosimeter is in a supervised area (as shown in Fig. 3), the values presented in Table 2 are low when compared with the annual ceiling indicated by the standard CNEN 3.01 (2005). A worker, who receives the same exposure as that of the dosimeter, does not exceed permissible limits. This work is part of a radio-protection team plan to conduct periodic research, keeping data under constant surveillance. When production starts, the outflow of material is expected to triple. The classification of the room will be reviewed and security enhanced.

4.2. Occupational exposure

Table 4 shows the results of the monitoring of individuals involved in handling and distribution of sources over 3 years.

Based on personal dosimeter reports, the acceptable levels of dose are presented in Table 5:

From the data presented it can be seen that no individual has reached the limits in Table 5. Many individuals were below the method levels of log-dose. In 2006, individuals I 03 and I 06 were directly involved with the new studies with iodine-125. I 02, I 04 and I 06 also receive little radiation dose during these three years. At the time, they were involved in descontamination of the material used in seed manufacture tests. New dosimeters assessments will be made when the laboratory starts full operation, in 2010.

4.3. Laboratory adaptation

To comply with radiation protection rules, the iodine-125 will arrive in shielded containers that are monitored by a radiation protection supervisor. The material will be handled with lead gloves and within production cells, reinforced with aluminum. The team studies the possibility of placing a new TLD area dosimeter in the corridor outside the laboratory. The warning detector is being installed in the laboratory ceiling (at location **48, showed in Fig. 3). The major challenge now is how to measure the activity in the

Table 4
Results of 3 years of personal dosimeters of individuals involved with iodine-125 sources handling and transport.

Year/mSv	I 01	I 02	I 03	I 04	I 05	I 06	I 07	I 08
2005	0	0.4	–	0.51	0	–	–	–
2006	0	0	2.67	0	0	4.84	–	–
2007	0	0	0	0	0	0.41	–	0

I: Individual, –: Individual did not work in the IPEN.

Table 5
IPEN reference levels.*

Restriction of dose levels: 10 mSv/year
Registration of dose levels: 0.20 mSv/month
Investigation levels:
Effective dose: 6 mSv/year
Dose equivalent: skin/hands and feet: 150 mSv/year
Dose equivalent: crystalline: 50 mSv/year

* These values are set by IPEN radiation protection team based on CNEN NN 3.01 guideline.

air that comes out of the cells. The values established in the standard CNEN NE 6.05 “Gerência de Rejeitos Radioativos em Instalações Radiativas” (Radioactive Waste Management in Radiation Facilities) (CNEN NE 6.05, 1985) is 3 Bq/m³. The issue of measuring this value for a low energy (29 KeV) is being discussed by the researcher’s team. The result will be presented in a future work.

4.4. Radiological implications

It’s very difficult to correlate the administrated dose with response or the damage caused by nuclear radiation. In living beings, primarily in humans, is very difficult to detect changes caused by low radiation. Even among the survivors of Hiroshima and Nagasaki the occurrence of radiation-induced mutations has not been satisfactorily demonstrated (Yoshimoto et al., 1990).

Unquestionably, ionizing radiation is a mutagen agent, a conclusion valid for animal and plant species, based on results obtained over six decades of experimentation. There is evidence that genetic effects of radiation are a linear phenomenon. Because of this, the radiation protection scientists always assumed some degree of damage, when the population is exposed to small amounts of radiation (Hall and Giaccia, 2005).

Within a laboratory manipulation of radioactive products any accident must be anticipated and avoided. The literature of radioactive iodine incorporation in the production field is scarce. In the article “Contamination During a Brachytherapy Procedure” Caldwell et al. describe an unusual contamination incident that occurred during the treatment of a prostate cancer patient with seeds containing iodine-125. The authors assert that the iodine leaked outside the patient’s prostate gland is housed in thyroid gland (Caldwell et al., 2007).

At IPEN laboratory, the greater contamination probability is in the production of sources. If there is a radiation leak in the production cell, the operator can incorporate iodine, which is highly volatile. For control, will be installed in a laboratory detector alarm and the results of workers “in vivo” dosimetry (whole body and thyroid) will be kept under surveillance. In addition, the classification as controlled areas and the magnetic locks installed should prevent unauthorized individuals.

According to the team responsible for radioprotection an incident with imported sources was never recorded. They come packaged inside the country only shields that are open in hospitals.

5. Conclusion

This work presented the preliminary radiation protection study with imported iodine-125 sources used in brachytherapy. This analysis will help researchers to develop the system to be employed in the new laboratory to produce these sources in Brazil.

Readings over the past 4 years have indicated that the area dosimeter receives little exposure. This is due to the fact that the radioprotection team conducts periodical reviews, constant monitoring, and the work of a well-trained staff.

The evaluation of occupational exposures shows that low or no exposure was received by the workers during the 3 years surveyed. Since production costs in Brazil will make the treatment more accessible, the tendency is to increase the flow of materials for transport. The radiation protection team will maintain the A-15 dosimeter under careful supervision. Future evaluations will be made and published.

The laboratory is undergoing several changes to fit Brazilian and international rules. Worker protection and process safety are the fundamental and main concern of the radiation protection team. We have faced several difficulties, such as to measure 3 Bq/m³ for a low energy of 29 KeV.

Given to the new reality in focus, an area monitoring detector (at location **48, shown in Fig. 3), with a visual and sounding alarm, should be installed in the room. It will help detect contaminants during the seeds production process. This work will continue throughout the laboratory construction.

Future study in the radioactive waste management is under development and will be published soon.

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