Quality Assurance Procedure Development in Iodine-125 Seeds Production

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ABSTRACT

Brachytherapy using iodine-125 seeds had been used in prostate cancer treatment. In the quality control routine during seed production, leak tests are made to detect any leakage of radioactive material from inside the titanium shield. Leak tests are made according to International Standard Organization- Radiation protection – sealed radioactive sources - ISO 9978 standard, and require liquid transfer between recipients. If any leakage happens, there will be contamination of liquid and tubing. This study it was to establishing decontamination routines for tubing, allowing its using again after that, in the automated assay process.

Keywords: brachytherapy, iodine seeds, leak test, sealed radioactive sources

INTRODUCTION

Iodine-125 seeds had been used in Brazil in private clinics and hospitals to treat the prostate cancer. Each prostate implant needs between 80 and 120 seeds[1]. The annual demand in the country is estimated to be 8000 seeds per month[2]. It is in the installation phase at IPEN – Nuclear and Energetic Research Institute, a division of CNEN – SP (Nuclear Energy National Commission), a laboratory to produce the iodine-125 seeds. Iodine-125 have a half life of 59,4 days and emits gamma radiation with average energy of 29 KeV and short penetration[3]. These seeds are made by a silver rod (0.5mm diameter x 3mm length) with the iodine-125 adsorbed, inside a titanium welded capsule (0.8mm diameter x 4.5mm length). Titanium´s choice was made because its biocompatibility. The shape and dimensions of this seed are coincident with the most common iodine seeds in the Brazilian market, making easy its acceptance. FIGURE nº 1 shows a schematic drawing of iodine-125 seed to be produced at IPEN.

The production of iodine seeds must have a quality control system to verify the accordance of the product. The general standards for quality control system NBR ISO 9000 (Associação Brasileira de Normas Técnicas – NBR ISO 9000)[4] will be used as guide for the quality system. The final step in the production of the seeds is the welding of titanium capsule, made using a laser welding system. This operation enclosures the radioisotope and its substrate, isolating it from the external environment. Due to this characteristic, iodine seeds are classified as sealed radioactive sources, according to the International Standard Organization. Radiation Protection – sealed radioactive sources – General Requirements and classification ISO 2919[5] .

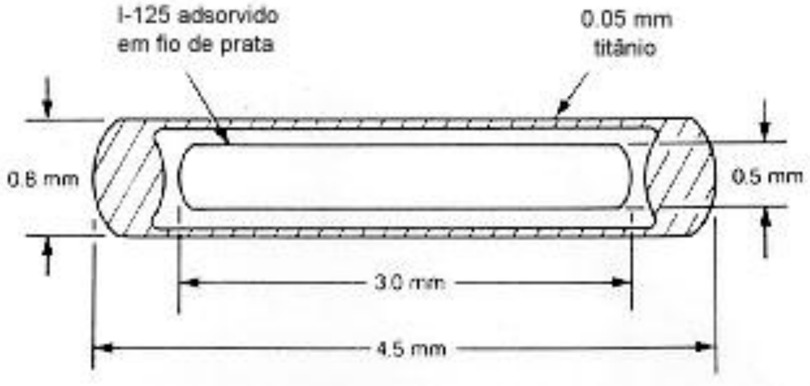

FIGURE nº 1: Iodine – 125 seed.

The titanium shielding makes possible γ ray energy to pass, preventing any radioactive material leakage. That condition will be checked through leakage tests made according to the International Standard Organization. Radiation protection – leakage test methods - ISO 9978 Standard[6]. This standard establishes conditions and procedures to make leakage tests in the sealed radioactive sources, showing different methods to do that. In the annex "A" there is a guide for the choice of test method, according to the characteristics of the sealed source. Iodine-125 seeds require the immersion method for leakage tests. Seeds must be immersed in distilled water during a time and after that the activity of the water will be measured. The limit value to be approved is 185Bq (5nCi). If the result is above that, sealed source is considered to have leakage. In this case, the water and tubing of automated system will be contaminated, needing decontamination to allow process to continue. This study consisted in simulate liquid transfer tubing contamination, passing iodine-131 (sodium iodine) solution through the tubes. After that, decontamination was tested making clean water transference (washing). Some parameters were changed (total washing water volume and the number of washing cycles). Two different types of plastic tubes where used in the assay, varying internal diameter and construction material. Two different pumping systems where also used to transfer the liquid. Results allow determining engineering specification for the automatic quality control system, to be implemented in the radioactive seeds production process.

MATERIALS AND METHODS

Two pumping devices where used, peristaltic pump model Perista-Mini Pump, ATTO Corporation and Vacum pump Edwards model EM2. Two different tubes where tested, silicon rubber tube, Ø internal 2mm and PTFE (Teflon) tube, Ø internal 1mm. To measure the activity where used both Ionization chamber, CAPINTEC CRC 15W and sodium iodine well detector, CAPINTEC. The Peristaltic transfer system arrangement is showed in FIGURE n° 1.

The vacuum transfer system used in the essay n° 5 is showed in FIGURE n° 2.

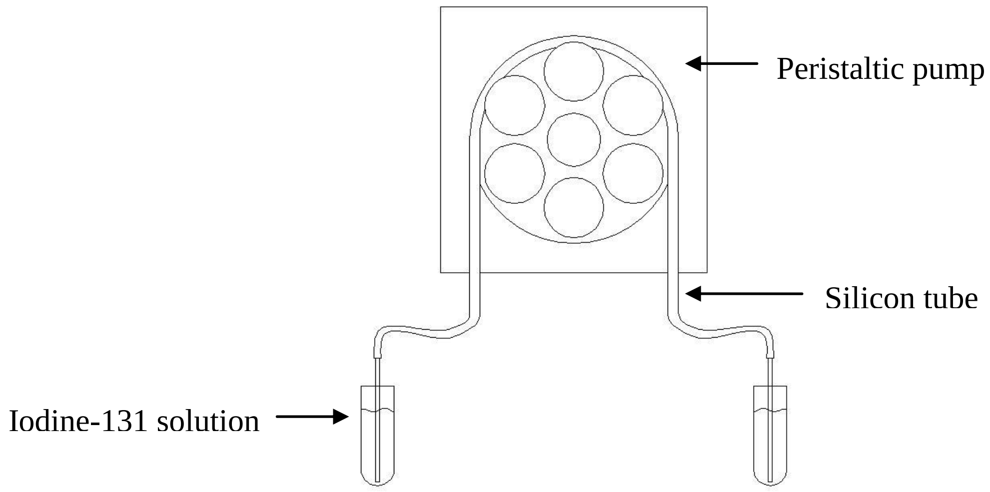

FIGURE n° 1: Peristaltic transfer system.

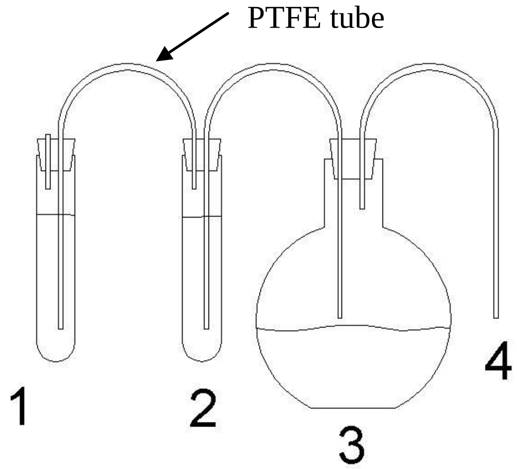

FIGURE n° 2: Vacuum transfer system used in the essay n° 5.

1. Recipient with radioactive material
2. Intermediary recipient
3. radioactive liquid container
4. Vacuum suction

Essay nº 1

Tube contamination with 37 MBq (1 mCi)of iodine-131, added to 2 mL distilled water. After that was transferred 2 mL of distilled water (washing) and its activity measured. Last step was repeated until activity value stabilized. Transfer speed 3,3 mL/minute. It where made 2 series of 30 cycles.

Essay nº2

Tube contamination with iodine-131 (1 mCi) added to 2 mL distilled water. After that was transferred 50 mL of distilled water (washing) and segregated. After that was transferred 2 mL of distilled water and its activity measured.Transfer speed 3,3 mL/minute.

Essay nº3

Same as the essay number 2 with higher transfer speed (9 mL/minute).

Essay nº4

Same as the essay number 3 with higher washing water volume (75 mL).

Essay nº 5

Tube contamination with iodine-131 (1 mCi) added to 2 mL distilled water. After that was transferred 75 mL of distilled water (washing) and segregated. After that was transferred 2 mL of distilled water and its activity measured. Transfer speed 45 mL/minute.

RESULTS AND DISCUSSION

The results of essay number 1 are showed in FIGURE n° 3, below.

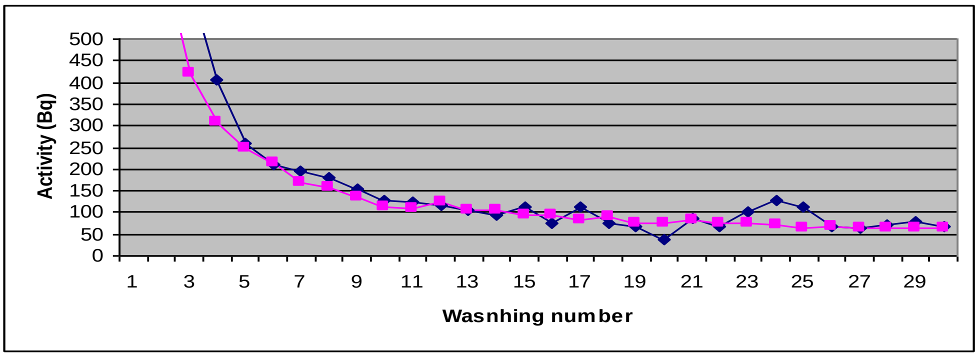

FIGURE n° 3: Results of the essay number 1.

The washing method used in this essay had no efficiency, needing a lot of washing cycles to reach the minimum activity value (around 60 Bq).

The results of essay number 2 are showed in FIGURE n° 4, below.

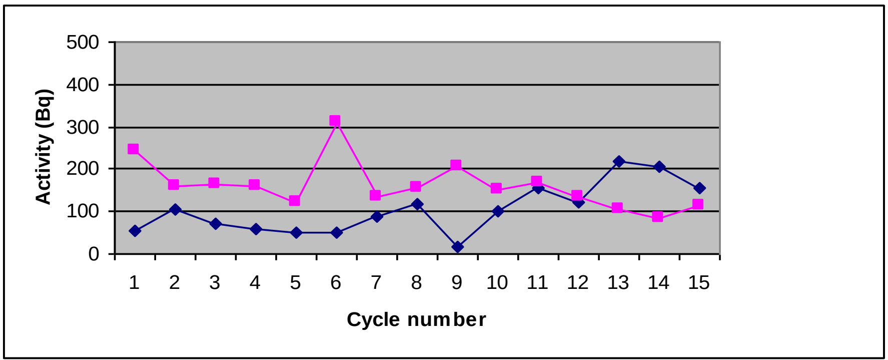

FIGURE n° 4: Results of the essay number 2.

The result of essay number 3 is showed in FIGURE n° 5, below.

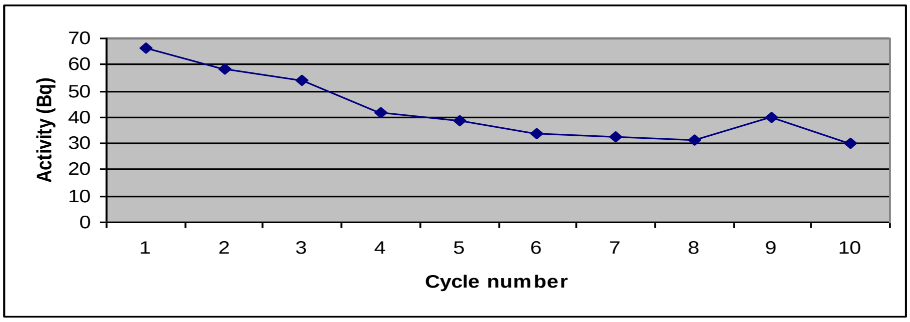

FIGURE n° 5: Result of essay number 3.

The result of essay number 4 is showed in FIGURE n° 6, below:

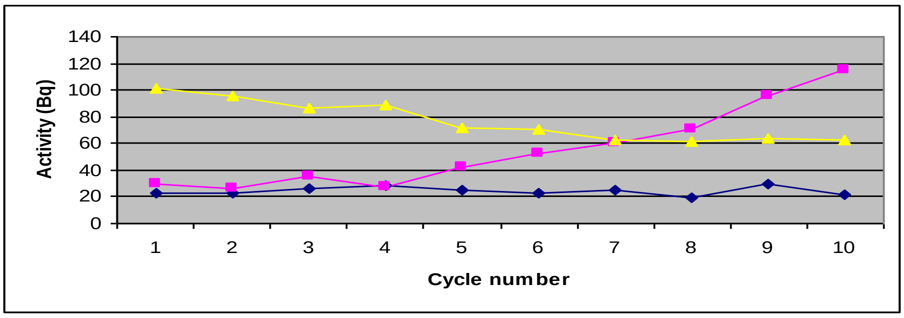

FIGURE n° 6: Results of essay number 4.

These results show initially a good low activity values, but there was a tendency to increase these values. After an inspection in the system it was found a high activity value in the silicon tube. This activity did not decrease after several washing cycles with distilled water.

The result of essay number 6 is showed in FIGURE n° 7, below.

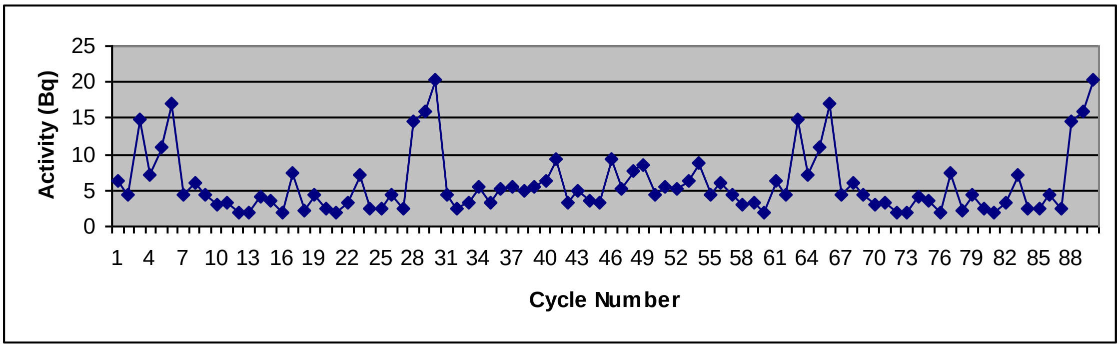

FIGURE n° 7: Result of essay number 6

After 90 cycles this method showed the best result with low activity values in the water after washing the system, repeatability and no residual activity in the PTFE tube. The material of the tube had good influence in the result, as the increased transfer speed.

CONCLUSIONS

In the iodine-125 seeds production, the automated control quality system will perform leak tests. Serial production needs the system is always clean for the next test. It is necessary to guarantee decontamination at low enough activity values of the tubing used to transfer liquids, in the case of radioactive material leakage. The choice of the tubes, including different material and shape evaluation was performed and this result will be applied to engineering specifications.

PTFE (Teflon) tubes will be used to transfer liquids in the system. The suction will be provided by installing a vacuum pump with properly filtration and particles retention, preventing environmental contamination. The high speed of the liquid inside the tubing help to carry radioactive material and to maintain activity values low enough to permit reutilization of the hydraulic circuit. The automation system will manage the position of tubes and recipients to change the font and destination of the materials in each leak test phase.

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