Quality Assurance Procedure Development in Iodine-125 Seeds Production

J.A.Moura* E.S.Moura, F.E.Sprenger, H.R.Nagatomi, C.A.Zeituni, A.Feher, J.E.Manzoli, M.E.C.M.Rostelato

Instituto de Pesquisas Energéticas e Nucleares-IPEN-CNEN. Centro de Tecnologia das Radiações-CTR. São Paulo. Brasil.
**Email:jmoura31@yahoo.com.br*

ABSTRACT

Brachytherapy using Iodine-125 seeds has 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 the 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 the liquid and tubing. This study aims to establish decontamination routines for tubing, allowing its repeated use, in the automated assay process.

Key words: *brachytherapy, Iodine seeds, leak test, sealed radioactive sources*

INTRODUCTION

Iodine-125 seeds have been used in Brazil in private clinics and hospitals to treat the prostate cancer. Each prostate implant needs, at least, 80 seeds(1). The annual demand in the country is estimated, to be 8000 seeds per month(2). A laboratory to produce the Iodine-125 seeds is in installation phase at IPEN – Nuclear and Energetic Research Institute, a division of CNEN – SP (Nuclear Energy National Commission). Iodine-125 has a half life of 59.4 days and emits gamma radiation with an average energy of 29 KeV(3). These seeds are made of 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). The Titanium choice was made because of its biocompatibility. The shape and dimensions of this seed are coincident with most common Iodine seeds in the Brazilian market, making its acceptance easy. FIGURE n^{o} 1 shows a schematic drawing of the Iodine-125 seed to be produced by IPEN.

The production of iodine seeds must have a quality control system. The general standards for quality control system (Associação Brasileira de Normas Técnicas – NBR ISO 9000)(4) will be used. The final step in the production of the seeds is the welding of the Titanium capsule, 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).

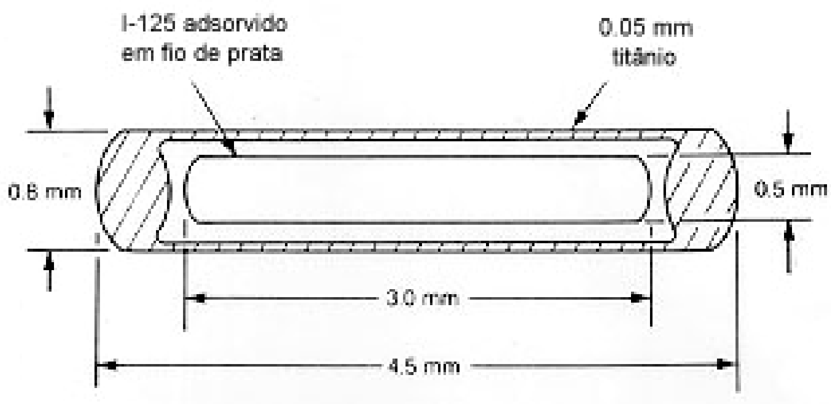

FIGURE nº 1: Iodine – 125 seed.

The 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 perform them. There is a guide for the choice of the test method, according to the characteristics of the sealed source, in the annex “A”. Iodine-125 seeds require the immersion method for leakage tests. Seeds must be immersed in distilled water for some time and then the water activity is measured. The limit value to be approved is 185Bq (5nCi). If the result is above that, the sealed source is considered to have leakage. In this case, the automated system water and tubing will be contaminated, needing decontamination to allow the process to continue. This study consisted of simulating transfer tubing liquid contamination, pouring Iodine-131 (sodium iodine) solution through the tubes. After that, the 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 were used in the assay, varying internal diameter and construction material. Two different pumping systems were 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 were used, peristaltic pump model Perista-Mini Pump, ATTO Corporation and Vacum pump Edwards model EM2. Two different tubes were tested, silicon rubber tube, Ø internal 2mm and PTFE (Teflon) tube, Ø internal 1mm. To measure the activity, both Ionization chamber, CAPINTEC CRC 15W and Sodium Iodine well detector CAPINTEC were used. The Peristaltic transfer system arrangement is showed in FIGURE n° 2. The vacuum transfer system used in the essay n° 5 is showed in FIGURE n° 3.

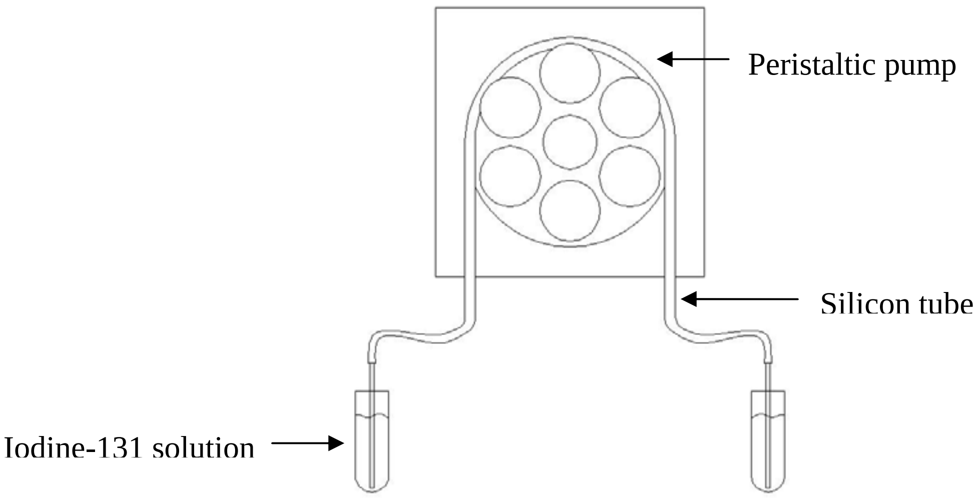

FIGURE n° 2: Peristaltic transfer system.

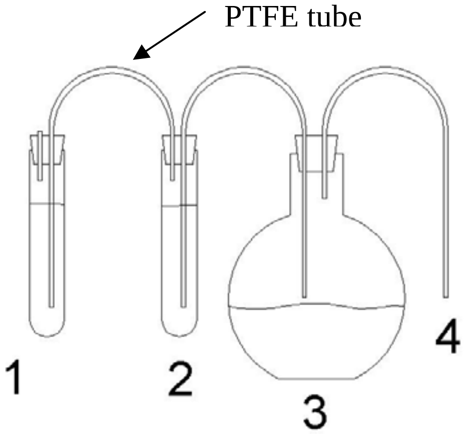

FIGURE n° 3: Vacuum transfer system used in the essay n° 5.

1. Recipient with radioactive material
2. Intermediary recipient
3. Radioactive waste container
4. Vacum suction

Essay n° 1. Tube contamination with 37 MBq (1 mCi) of Iiodine-131, added to 2 mL distilled water. Then, 2 mL of distilled water were transferred (washing) and the activity was measured. The last step was repeated until the activity value stabilized. The transfer speed was 3.3 mL/minute. Two series of 30 cycles were made.

Essay nº2. Tube contamination with Iodine-131 (1 mCi) was added to 2 mL distilled water. Then, 50 mL of distilled water were transferred (washing) and segregated. After that, 2 mL of distilled water were transferred and the activity was measured. Transfer speed was 3.3 mL/minute.

Essay nº3. The same as essay n^o 2, with higher transfer speed (9 mL/minute).

Essay nº4. The same as essay n^o 3, with higher washing water volume (75 mL).

Essay nº 5. Tube contamination with Iodine-131 (1 mCi) added to 2 mL distilled water. Then, 75 mL of distilled water were transferred (washing) and segregated. After that, 2 mL of distilled water were transferred and the activity was measured. The transfer speed was 45 mL/minute.

RESULTS AND DISCUSSION

The results of essay n^o 1 are showed in FIGURE n° 4, below.

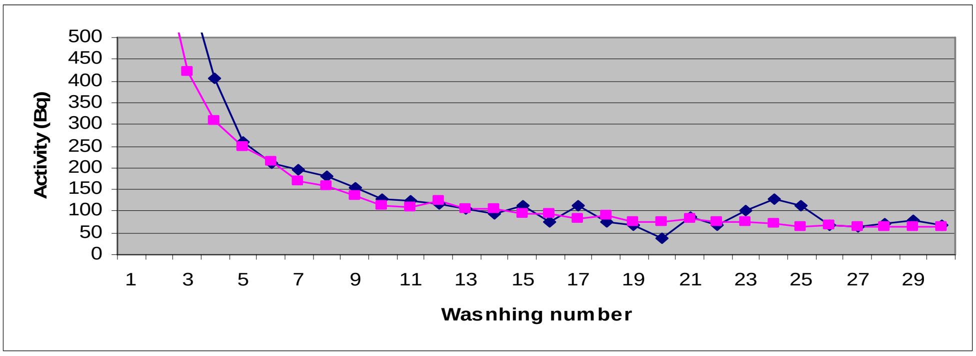

FIGURE n° 4: Results of essay n^o 1.

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). This minimum activity value reached has, also, to be lowered in order to allow the use of the same transfer tubing system for another leak test in the automated process.

The results of essay n^o 2 are showed in FIGURE n° 5, below.

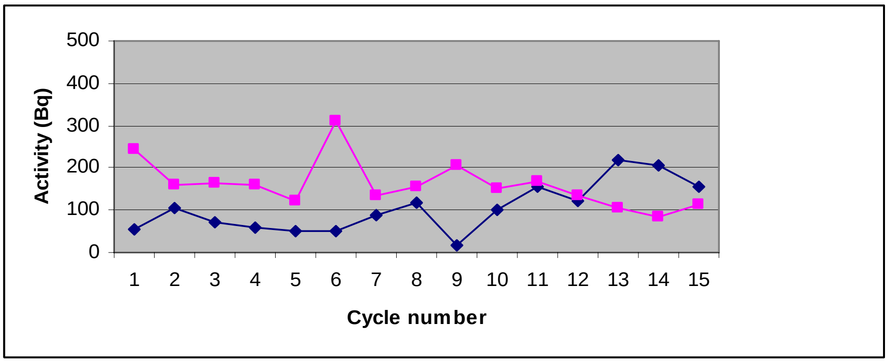

FIGURE n° 5: Results of the essay n° 2.

This washing method was not efficient either. The minimum activity value reached is not low enough for the automated test system.

The result of essay n° 3 is showed in FIGURE n° 6, below.

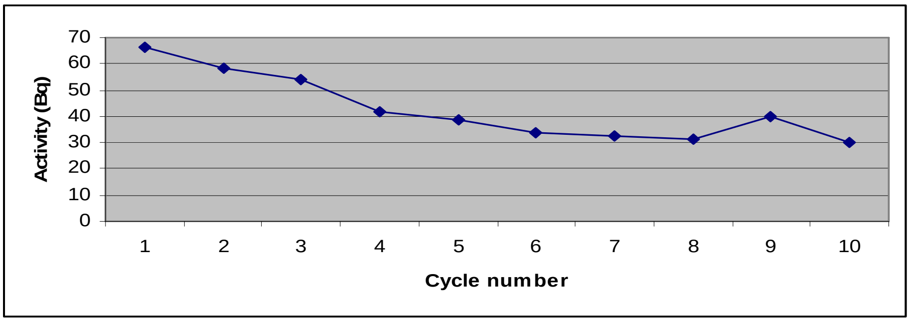

FIGURE n° 6: Result of essay n° 3.

The result of essay n° 4 is showed in FIGURE n° 7, below.

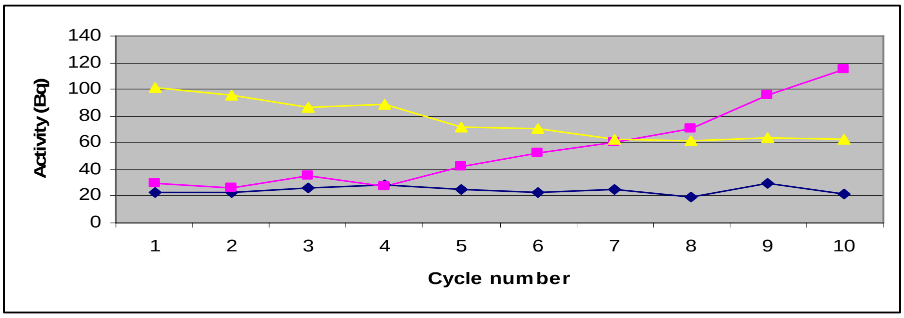

FIGURE n° 7: Results of essay no 4.

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

The result of essay n° 5 is showed in FIGURE n° 8, below.

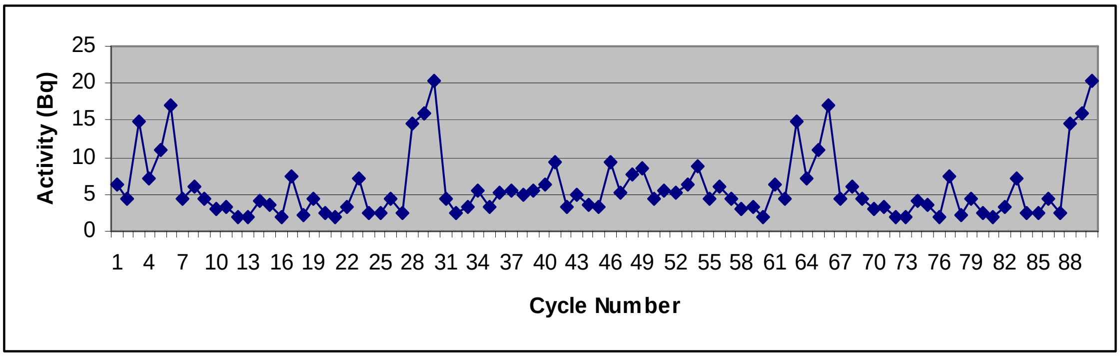

FIGURE n° 8: Result of essay n° 5

After 90 cycles, this method showed a good 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 it increased the transfer speed.

CONCLUSIONS

In the Iodine-125 seeds production, the automated control quality system will perform leak tests. Serial production needs the system to be always clean for the next test. It is necessary to guarantee decontamination at low activity values of the tubing used to transfer liquids, in case there is radioactive material leakage. The choice of the tubes, including different materials 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 proper filtration and particles retention, preventing environmental contamination. The high speed of the liquid inside the tubing helps 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 source and destination of the materials, in each leak test phase.

ACKNOWLEDGMENTS

The authors are grateful to Fundação de Amparo à Pesquisa do Estado de São Paulo – FAPESP for financial support to the Project.

REFERENCES

1) (1) S. B. Strum, M. C. Scholz. Implantation of prostate cancer with radioactive isotope – brachytherapy. USA: 1996.

2) (1) M. E. C. M. Rostelato,. Estudo e desenvolvimento de uma metodologia para confecção de sementes de iodo-125 para aplicação em braquiterapia. 2005. Tese (Doutorado). Instituto de Pesquisas Energéticas e Nucleares. São Paulo.
3) (1) A.S. Meigoni. Dosimetric Characterization of Low Energy Brachytherapy Sources: Measurements. In: World Congress on Medical Physics and Biomedical Engeneering, july, 23-28, 2000, Chicago.
4) (1) Associação Brasileira de Normas Técnicas. Coletânea de normas de sistemas da qualidade. Rio de Janeiro: 1995.
5) (1) International Standard Organization. Radiation protection – sealed radioactive sources – General Requirements and Classification. Mar. 08, 1995. (ISO 2919).
6) (1) International Standard Organization. Radiation protection – sealed radioactive sources – leakage test methods. Feb. 15. 1992. (ISO 9978).