Journal of Physical Science and Application 3 (6) (2013) 380-386

Automation System for Quality Control in Manufacture of Iodine-125 Sealed Sources Used in Brachytherapy

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Received: May 01, 2013 / Accepted: June 06, 2013 / Published: June 15, 2013.

Abstract: The objective of this work is to develop an automation system for quality control (QC) in the production of Iodine-125 sealed sources, after undergoing the process of laser beam welding (LBW). These sources, also known as Iodine-125 seeds are used, successfully, in the treatment of cancer by brachytherapy, with low-dose rates. Each small seed is composed of a welded titanium capsule with 0.8 mm diameter and 4.5 mm in length, containing Iodine-125 adsorbed on an internal silver wire. The seeds are implanted in the human prostate to irradiate the tumor and treat the cancerous cells. The technology to automate the quality control system in the manufacture of Iodine-125 seeds consists in developing and associate mechanical parts, electronic components and pneumatic circuits to control machines and processes. The automation technology for Iodine-125 seed production developed in this work employs programmable logic controller (PLC), step motors, drivers of control, electrical-electronic interfaces, photoelectric sensors, interfaces of communication and software development. Industrial automation plays an important role in the production of Iodine-125 seeds, with higher productivity and high standard of quality, facilitating the implementation and operation of processes with good manufacturing practices (GMP). Nowadays, the Radiation Technology Centre at IPEN-CNEN/SP imports and distributes 36,000 Iodine-125 seeds per year for clinics and hospitals in the whole country. However, the Brazilian potential market is of 8,000 Iodine-125 seeds per month. Therefore, the local production of these radioactive seeds has become a priority for the Institute, aiming to reduce the price and increase the supply to the population in Brazil.

Keywords: Iodine-125 seeds, quality control, brachytherapy, automation system, (Nd:YAG) laser welding,automation system.

1.Introduction

Prostate cancer occurs when cells within the prostate grow uncontrollably, creating small tumors. The term "cancer" refers to a condition in which the regulation of cell growth is lost and cells grow uncontrollably. Most cells in the body are constantly dividing, maturing and then dying in a tightly controlled process. Unlike normal cells, the growth of cancer cells is no longer well-regulated.Instead of dying as they should; cancer cells outlive normal cells and continue to form new, abnormal cells [1]. Abnormal cell growths are called tumors. The term "primary tumor" refers to the original tumor; secondary tumors are caused when the original cancer spreads to other locations in the body. Prostate cancer typically is comprised of multiple very small, primary tumors within the prostate. At this stage, the disease is often curable (rates of 90% or better) with standard interventions such as surgery or radiation that aim to remove or kill all cancerous cells in the prostate. Unfortunately, at this stage the cancer produces few or no symptoms, and can be difficult to detect [1].

With low dose rate (LDR) brachtherapy treatment, tiny little metal pellets containing radioactive Iodine-125 or Palladium-103 are inserted into the prostate via needles that enter through the skin behind the testicles. As with 3D conformal radiation therapy, careful and precise maps are used to ensure that the

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seeds are placed in the proper locations. Over the course of several months, the seeds give off radiation to the immediate surrounding area, killing the prostate cancer cells. By the end of the year, the radioactive material degrades, and the seeds that remain are harmless. Compared with external radiation therapy, brachytherapy is less commonly used, but it is rapidly gaining ground, primarily because it does not require daily visits to the treatment center.

The Iodine-125 seeds are implanted into the human prostate to irradiate the tumor for cancer treatment. Nowadays, the Radiation Technology Centre, at IPEN-CNEN/SP imports and distributes 36,000 Iodine-125 seeds per year, for the clinics and hospitals in the whole country. However, the Brazilian market potential is now over 8,000 Iodine-125 seeds per month. The local production of these Iodine-125 radioactive sources became a priority for the Institute, in order to reduce the prince and the problems of prostate cancer management. It will permit to spread their use to a larger number of patients in Brazil. On the other hand, the industrial automation plays an important role for Iodine-125 seeds in order to increase the productivity, with high quality and assurance, avoiding human factors, implementing and operating with good manufacturing practices (GMP).

In the Radiation Technology Centre, IPEN-CNEN/SP developed a methodology for quality control in production process sealed sources of Iodine-125 for use in brachytherapy, which objective of this work and automate this process [2, 3].

2. Materials and Methods

The seed consists of a sealed tube of titanium (biocompatible material to human tissue) measuring 0.8 mm external diameter and 4.5 mm in length, containing a silver wire with Iodine-125 adsorbed. The sealing of the titanium tube is made, at both ends, by welding process using electric arc or laser [4, 5].

Take into account (Nd:YAG) laser welding, this sealing should be watertight, free from cracks, avoiding the Iodine-125 deposited in a silver wire to escape and spread through the human body [6-8].

To ensure this does not occur, rigorous quality control (QC) leakage tests should be applied according to the standard procedures ISO 9978: Radiation protection, sealed radioactive sources, leakage test methods. Several procedures are described in the ISO 9978 standard and choice must be done using the Table “Selection of leakage test methods related to manufacturing technology” [6].

After sealing of the titanium tube is made by (Nd:YAG) laser welding, the seeds are sent to the last glove box, where they undergo the process of quality, having their surfaces cleaned and tested. If a leak is found in any seeds, they are tested separately in order to identify the fault and consider whether they should be disposed as radioactive waste. The main objective of automation is to simplify and streamline the process of quality control in the manufacture of Iodine-125 seeds.

The flowchart of automated process for Iodine-125 seed testing sealing is shown in Fig. 1 [2].

2.1 Automation

Automation is the use of control systems (numerical control, programmable logic control and other industrial control systems), in concert with other applications of information technology, such as, computer-aided technologies (CAD, CAM, CAx) to control industrialmachinery and processes, reducing the need of human intervention. In the scope of industrialization, automation is a step beyond mechanization. Whereas mechanization provided human operators with machinery to assist them with the physical requirements of work, automation greatly reduces the need for human sensory and mental requirements as well.

Processes and systems can also be automated. Automation plays an increasingly important role in the global economy and in daily experience. Engineers

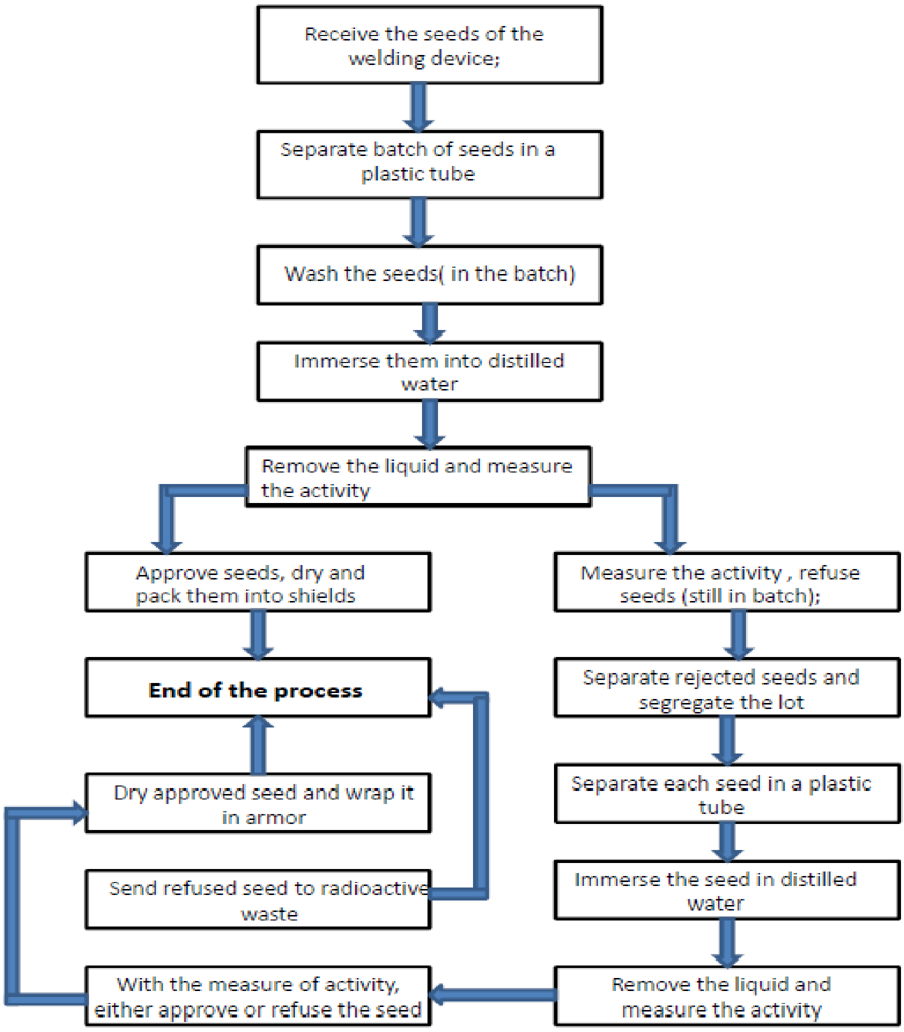

Fig. 1 Flowchart of automated process for Iodine-125 seed testing sealing.

strive to combine automated devices with mathematical and organizational tools to create complex systems for a rapidly expanding range of applications and human activities. Many roles for humans in industrial processes presently lie beyond the scope of automation. Human-level pattern recognition, language recognition, and language production ability are well beyond the capabilities of modern mechanical and computer systems.

Tasks requiring subjective assessment or synthesis of complex sensory data, such as scents and sounds, as well as high-level tasks such as strategic planning, currently require human expertise. In many cases, the use of humans is more cost-effective than mechanical approaches even where automation of industrial tasks is possible. Specialized hardened computers, referred to as programmable logic controllers (PLCs) are frequently used to synchronize the flow of inputs from (physical) sensors and events with the flow of outputs to actuators and events. This leads to precisely controlled actions that permit a tight control of almost any industrial process.

Human-machine interfaces (HMI) or computer human interfaces (CHI), formerly known as man-machine interfaces, are usually employed to communicate with PLCs and other computers, such as entering and monitoring temperatures or pressures for further automated control or emergency response.

Service personnel who monitor and control these interfaces are often referred to as stationary engineers [9].

An automation system is a precisely planned change in a physical or administrative task utilizing a new process, method or machine that increases productivity, quality, and profit while providing methodological control and analysis. The value of system automation is in its ability to improve efficiency, reduce wasted resources associated with rejects or errors, increase consistency, quality and customer satisfaction, and maximize profit [9].

2.2 Programmable Logic Controllers

Control engineering has evolved over time. In the past humans were the main methods for controlling a system. More recently electricity has been used for control and early electrical control was based on relays. These relays allow power to be switched on and off without a mechanical switch. It is common to use relays to make simple logical control decisions. The development of low cost computer has brought the most recent revolution, the programmable logic controller (PLC). The advent of the PLC began in the 1970s, and has become the most common choice for manufacturing controls. Programmable logic controllers (PLCs) have been gaining popularity on the factory floor and will probably remain predominant for some time. Most of this is because of the advantages they offer, as well as:

- Cost effective for controlling complex systems;
- Flexible and can be reapplied to control other systems quickly and easily;
- Computational abilities allow more sophisticated control;
- Trouble shooting aids make programming easier and reduce downtime.

2.3 Ladder Logic

Ladder logic is the main programming method used for Programmable Logic Controllers (PLCs). As mentioned before, ladder logic has been developed to mimic relay logic. The decision to use the relay logic diagrams was a strategic one. By selecting ladder logic as the main programming method, the amount of retraining needed for engineers and trades people were greatly reduced.

2.4 Stepper Motor and Driver

A stepper motor is a brushless, synchronous electric motor that can divide a full rotation into a large number of steps. The motor’s position can be controlled precisely, without any feedback mechanism. Stepper motors are similar to switched reluctance motors, which are very large stepping motors with a reduced pole count, and generally are closed-loop commuted [10].

Driver is an electrical circuit or other electronic component used to control another circuit or other component, such as a high-power transistor. The term is used for a specialized computer chip that controls the high-power transistors in DC-to-DC voltage converters. An amplifier can also be considered the driver for loudspeakers or a constant voltage circuit that keeps an attached component operating within a broad range of input voltages [11].

2.5 Supervisory and Data Controls

SCADA stands for supervisory control and data acquisition. It generally refers to an industrial control system (computer system monitoring and controlling a process). The process can be industrial infrastructure or facility. Industrial processes include those of manufacturing, production, power generation, fabrication and refining, and may run in continuous, batch, repetitive or discrete modes. Infrastructure processes may be public or private, and include water treatment and distribution, wastewater collection and treatment, oil and gas pipelines, electrical power transmission and distribution, civil defense siren systems, and large communication systems. Facility processes occur both in public facilities and private ones, including buildings, airports, ships, and even spaceship stations. They monitor and control heating ventilation and air conditioning (HVAC), access, and energy consumption [12].

3. Automation Process

The automation system technology for Iodine-125 seeds production developed in this work was mainly assembled employing:

- Electro-electronic and mechanical components;
- Programmable Logic Controller (PLC);
- Stepper motors and drives;
- Microcomputer, supervisory and interfaces;
- Photoelectric and optical sensors;
- Distribution systems seeds Iodine-125.

3.1 Integrate Hardware and Software

On the automation system for quality control of Iodine-125 seed production developed in this R&D work was necessary to integrate:

- Electro-electronic and mechanical parts and pneumatic components (Fig. 2);
- In Fig. 3, it is shown the software arrangement screen InduSoft Web Studio 6.1 supervisory, which offers real-time process visualization, concerning valves (vacuum and pressure) and sensors (laser and microswitch) operations, and all peripherals installed on the system, therefore having a high performance monitoring of automated processes, offering a complete view of the operation during Iodine-125 seeds quality controls [13];
- In Fig. 4, it is shown the software arrangement screen control of Siemens PLC Step S7 200, which is an electronic device with digital hardware and software design MicroWIN 4.0 by Siemens. It uses PLC to control all process, performing specific functions such as logic, sequencing, timing, counting and arithmetic, through inputs and outputs modules, turn valves (vacuum and pressure), sensors (laser and microswitch), stepper motor drivers and other peripherals on/off [14];
- In Fig. 5, it is shown Siemens Programmable Logic Controller (PLC Step S7 200), stepper motor drivers (Applied Motion) and other components to control machines and processes for Iodine-125 seeds qualitycontrols;
- In Fig. 6, it is shown software arrangement screen control of Applied Motion stepper motor driver, used in the process. Through the program is possible to control pulse width modulation to realize microsteps and velocity, obtaining a higher resolution and accuracy positioning [15].

The statistical repeatability of correctly Iodine-125 brachytherapy seed encapsulated by (Nd:YAG) laser welding with the automation system developed in IPEN-CNEN/SP is greater than 95%.

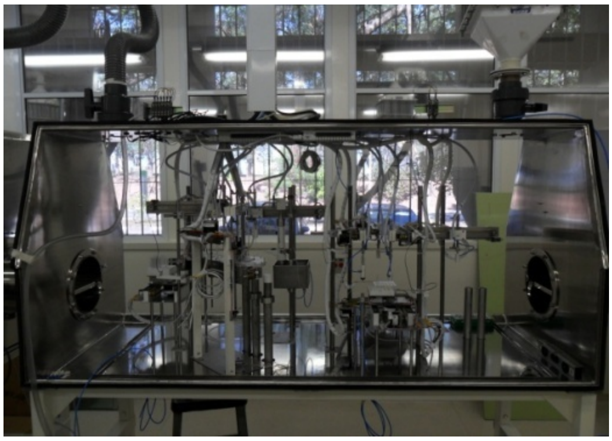

Fig. 2 Automation system for quality control of Iodine-125 seed production, with pneumatic components, electro-electronic and mechanical parts.

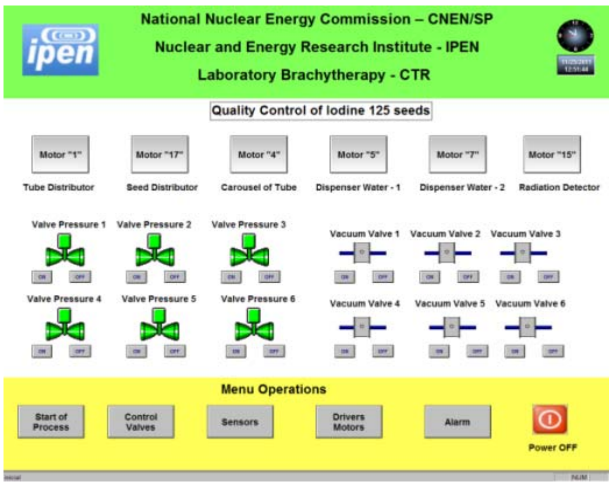

Fig. 3 Softwarearrangement screen InduSoft Web Studio6.1 supervisory.

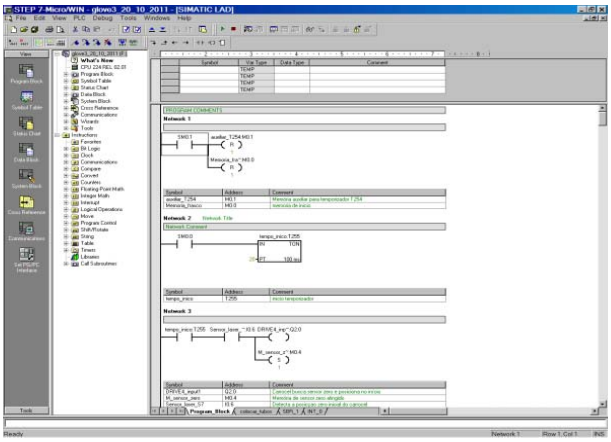

Fig. 4 Software arrangement screen control of Siemens PLC Step S7 200 MicroWin.

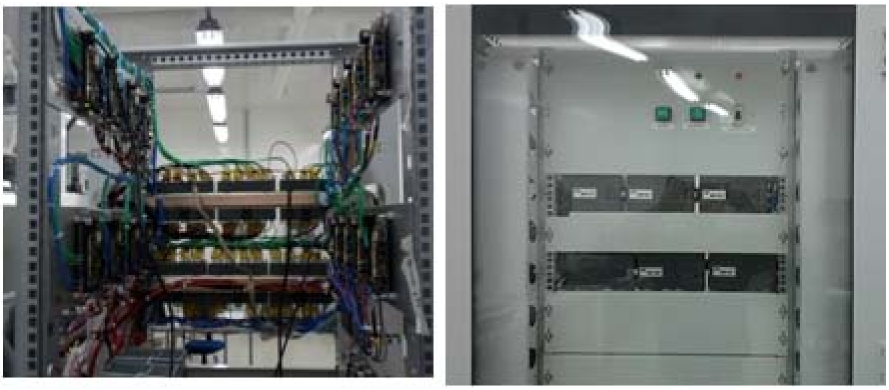

Fig. 5 Siemens Programmable Logic Controller (PLC) and stepper motor drivers to control machines and processes for Iodine-125 seeds quality controls.

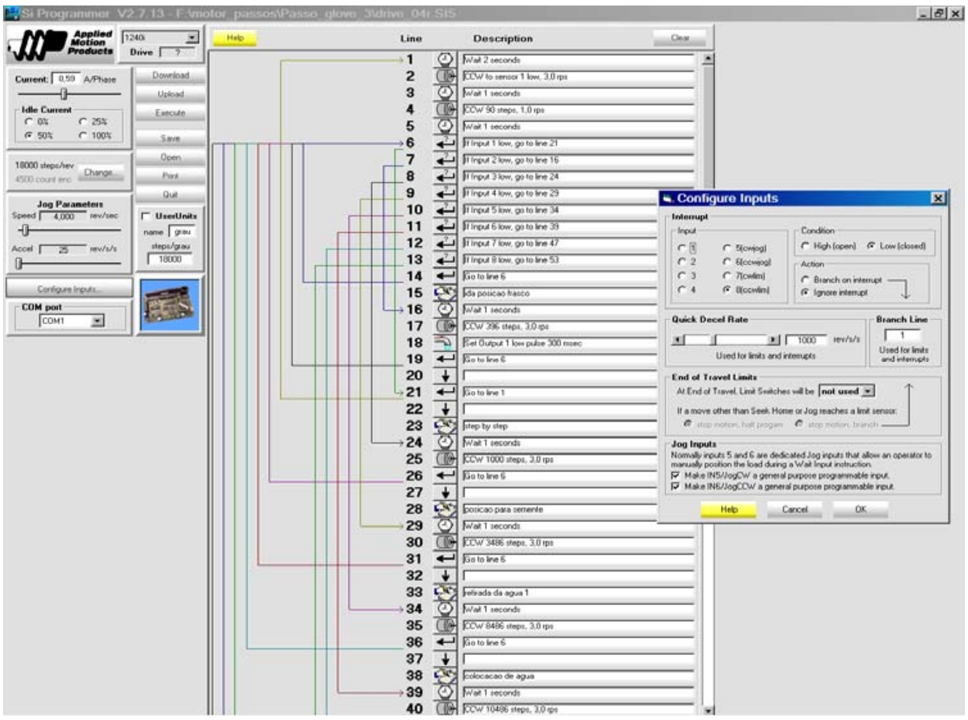

Fig. 6 Software arrangement screen control of Applied Motion stepper motor driver.

4. Conclusions

The Iodine-125 seeds are implanted into the human prostate to irradiate the tumor for cancer treatment. These types of sealed sources may be used to treat superficial, intra-abdominal and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, eyes and prostate (early stages) are commonly treated. The main advantage of brachytherapy application in cancer diseases treatment compared with external radiation therapy (teletherapy) is precise targeting of the radiation with sparing of healthy tissues, what boost success of therapy. Leak tests were made to detect any leakage of radioactive material from inside the iodine-125 seeds applied in brachytherapy. In the quality control routine, during seed production, leak tests are performed according to the International Standard Organization, radiation protection, sealed radioactive sources, ISO-9978 standard.

The main objective of automation is to simplify and streamline the process of quality control in the manufacture of Iodine-125 seeds. On the other hand, the industrial automation increases the productivity and flexibility, with high quality and assurance, decreasing costs, avoiding human factors, implementing and operating with good manufacturing practices (GMP).

Acknowledgments

The authors gratefully acknowledge the State of Sao Paulo Research Foundation (FAPESP) for its financial support and the scientific and technological support during this R&D Project from IPEN-CNEN/SP, without which it would be impossible to carry out this work.

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