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SAFE OPERATION OF INDUSTRIAL GAMMA RADIATION FACILITY – ROMANIAN SVST CO 60

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Rezumat. *În zilele noastre, tratamentul produselor cu radiații gamma este o tehnologie bine stabilită, care a atins o utilizare comercială încă din anii 1960. Este folosită pe scară largă în aproape toate domeniile, în special pentru sterilizare în industria medicală și farmaceutică, pentru conservarea și decontaminarea alimentelor, pentru modificarea caracteristicilor materialelor plastice și chiar pentru conservarea patrimoniului cultural. Această lucrare analizează noile caracteristici și îmbunătățirile aduse procesului de operare în siguranță a iradiatorului și evaluează rezultatele extrase din funcționare. Analiza constă în evaluarea noilor componente tehnice, programul PLC-ului, inclusiv rapoartele, erorile, alarmele generate, stocarea datelor etc. și controlul accesului personalului operator.*

Abstract. *Nowadays, radiation processing with gamma rays is a well established technology, reaching a commercial use since the 1960s. It is widely used in almost every domain, mainly for sterilization in the medical and pharmaceutical industry, preservation and decontamination of food, treatment of plastic materials and even in cultural heritage preservation. This paper analyses the new features and improvements made for safety operations and assesses the results from its operation. The analysis consists in evaluating the new technical components, the PLC software including reports, errors, alarms, data storage etc. and control access to the operation processes.*

Keywords: safe operation, industrial irradiator, process automation, PLC.

1. Introduction

Nowadays, radiation technologies are systems with very high scientific and technical standard [1]. It is widely used in almost every domain, mainly for sterilization in the medical and pharmaceutical industry, preservation and decontamination of food, treatment of plastic materials and even in cultural heritage preservation [2].

Romania has 17 years of experience with radiation treatment when SVST Co-60 gamma industrial irradiator was commissioned at IFIN-HH in the year 2000; it complied with the latest safety no. 107 series edited by IAEA in 1982. If not managed properly, operation, control and maintenance, the use of radioactive materials, in this case Co 60, represents a real danger, first for human life and second for the environment.

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Another potential danger is represented by the fact that industrial irradiation facilities use high activity sources. SVST Co-60 gamma industrial irradiator is designed to work with 2 million Curies.

Taking into account the characteristics and danger when operating this kind of facilities, safety operation is a mandatory requirement by the national regulatory body in Romania, CNCAN and also by international organization, IAEA.

This is a strong reason for continuous up-dates and improvements of these facilities.

In 2013, the command and control system was completely changed from PC operated software to an industrial PLC and HMI produced by Siemens, leader in this domain; it also complied with the latest IAEA specific safety guide "Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities", no. SSG - 8, edited in 2010.

This paper analyses the new features and improvements made for safety operations and assesses the results from its operation.

The analysis consists in evaluating the new technical components, the PLC software including reports, errors, alarms, data storage etc. and control access to the operation processes.

In addition, the system is capable in switching between operation systems (the PC operated and PLC operated), so, if the new system needs interventions or repairs, the old system can be used for continuous operation.

Currently, the new build command and control system reaches the current expectations for safety operation of industrial gamma irradiation facilities and also improves and eases the processes workflow.

2. IRASM radiation processing centre

IRASM Center is a part of IFIN-HH (National Institute of Physics and Nuclear Engineering – Horia Hulubei) an R&D nuclear institute in Romania. At IRASM it is located the only industrial irradiator in Romania, operating since 2000, a result of a technical cooperation project between IAEA and Romanian Government, under the name "Multipurpose Irradiation Facility".

IRASM Center is both R&D and client oriented, offering industrial radiation services, consulting, analyses, training and research in radiation processing. The end-users can benefit not only from radiation treatment but also pre-radiation and post-radiation microbiological tests and product radiation qualification.

Radiation services refer to sterilization and decontamination process for different products.

Sterilization service is a well-established and highly standardized method for sterilization of single use medical supplies (syringes, catheters, needles, cotton gauzes, dental implants, Petri dishes etc.), sterilization for primary packaging materials (bottles, dispensers, gelatin capsules, sterile drugs etc.) and pharmaceutical products. In addition to radiation sterilization, customers can benefit from a certified service for radiation sterilization validation.

Decontamination process is required in any domain in which the products have regulatory limits for microbial load (bio-burden). In this case, gamma irradiation can be used for bio-burden reduction. It can be applied for final products but also for raw materials, packages and other additives.

When talking about irradiation dose, decontamination requires lower doses than sterilization. The control of bio-burden is used to a wide range of materials like primary products for pharmaceutical industry (titan oxide, magnesium lactate etc.), foodstuff for animals, organic support for micro and micro-organisms, dry herbs (tea), dietary supplement (capsules, tablets) and packaging products (cups, bottles, foils etc.). High volume and complex devices can be processed for disinfection (water purification equipment, cleaning and protection equipment, beehives etc.).

This service addresses customers from medical, pharmaceutical and cosmetic domains, food industry, dietary supplements manufacturers, packaging domain and any other industry where microbiological safety is a requirement.

Regarding R&D activities, IFIN-HH-IRASM is involved in cultural heritage preservation using gamma rays for materials like: paper, wood, textile, leather and parchment. Large quantities were treated, during and after each R&D project.

Also, there were treated over 150 cubic meters of books, religious books and archives from Romanian Parliament, hospital and city halls documents, National Theatre of Bucharest etc.

IFIN-HH-IRASM is certified according to the following standards, which allows customers to get the CE mark and market license for the radiation sterilized products:

- ISO 9001:2008: Quality management system: Requirements;
- ISO 13885: Medical devices - Quality management systems - Requirements for regulatory purposes;
- ISO 15378: Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP);
- ISO 11137: Sterilization of health care products – Radiation.

3. Description of SVST Co 60 industrial irradiator

For SVST Co-60 is a large facility where different products are processed with radiation at a large scale. In a radiation process, the product is intentionally irradiated by placing the product in the vicinity of a radiation source for a fixed period of time whereby the product is exposed to radiation.

The irradiator is category IV gamma with panoramic wet source storage in which the radioactive sources are stored and fully shielded in a pool of water when not in use (fig. 1).

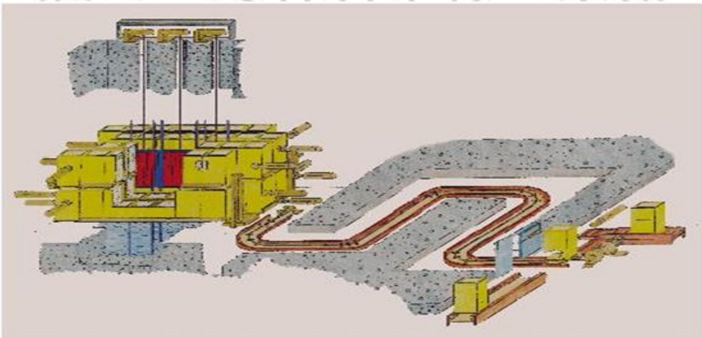

Fig. 1. Schematic diagram of SVST Co-60 industrial irradiator.

The product transport system is tote-box type with 2 levels (fig. 2) and 2 passes each side of the source (fig. 3). The boxes are pushed by pneumatic cylinders and the transfer to/from the irradiation room is done by a carriage on rails.

Fig. 2. SVST Co-60 transport system.

Fig. 3. A typical cobalt source rack.

The process is taking place inside the irradiation room, a place where the products are loaded and where the radioactive material is stored and used. In order to keep the surrounding safe for people and personnel, the irradiation room has 2 meter thick concrete walls and a maze shape. The basic principle of radiation treatment is rather simple. The first step is to load the products into containers of 480x480x900 (mm) and send it inside the irradiation room with a system of automatic carriage on a 2 level/ 2 sided conveyor.

The maximum capacity is around 10 cubic meters that fit into 52 containers fully loaded (fig 4). The second step consists in raising the racks loaded with radioactive materials and start moving the containers around it using pneumatic cylinders. Each movement has set a certain amount of time in order for each container to receive the same dose. After the total time has elapsed, the containers are moved out by the same carriage and on the same path but with respect not to mix the processed products with the un-processed ones.

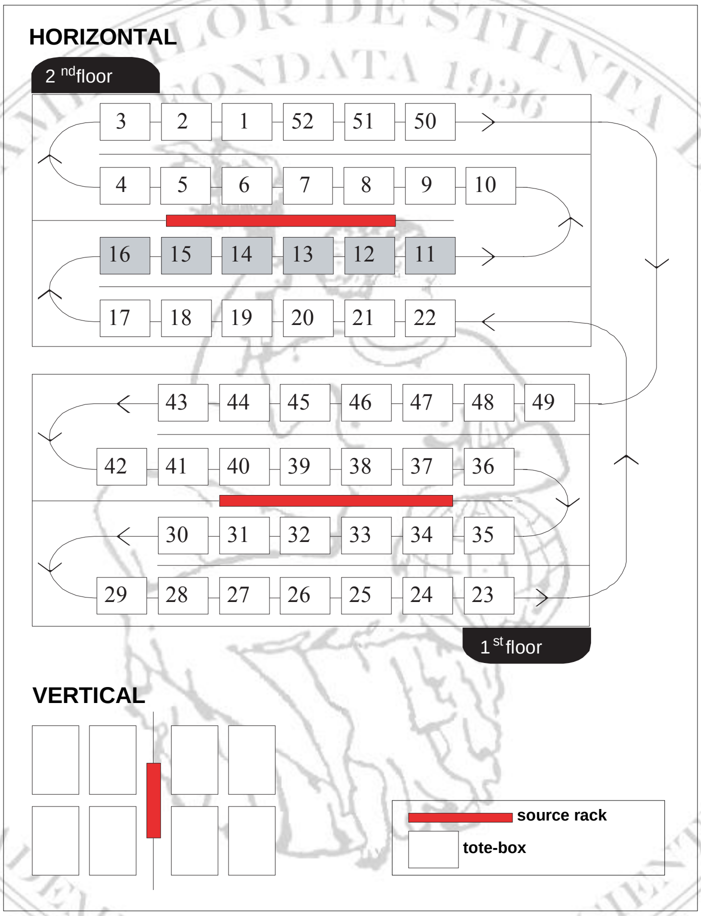

Fig. 4. Irradiation arrangements and movements of tote-boxes.

4. Safety features of SVST Co 60 irradiator

In 2013, the irradiator was up-graded with a new safety and control system in 2013 in order to comply with the new requirements of Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities, IAEA Safety Standards Series No. SSG-8 (2010) and is licensed for operation by CNCAN (License no SM 1299/2011).

The role of safety systems is to prevent a radiological incident which may affect, in the first place the personnel and then the environment and the products.

Incidents involving over-irradiation of personnel are reported mainly by IAEA. They describe the context in which such events occur and what caused it.

A general conclusion can be stated that the reason of such accidents was not following the procedure of operation and by-passing the safety devices and not by technical failures. Starting from this, the safety operation issue is divided in two:

1. Maintenance and correct use of safety devices: it is imperative to perform scheduled verifications and maintenance of safety devices in order to have a high safe operation.

2. Personnel training and following the rules: the safety devices play the role of preventing errors due to human mistakes but they are not able to stop a deliberate act of buy-passing it. So, in this case, training of personnel plays an important role so they realize the danger and follow protocol.

Siemens PLC is operated using a HMI touch screen (fig. 5).

Fig. 5. HMI operated PLC

The operation menu is composed of 2 screens: main screen and start screen. The main screen holds information of irradiator's sub-systems status. The most important are the following:

- safety system: incorporates data about different devices used in radioprotection and safe operation (fig. 6);
- source pass mechanism: shows the current status of pneumatic pistons who move the containers inside the irradiation room; it also monitors the sequence of moving in order to respect the correct arrangement of containers after each cycle;
- *toate* box car system: gives information on container carriage who transports the products inside the irradiation room;
- storage transportation system: represents the external conveyor where the products are loaded and un-loaded from containers;
- water treatment system: shows the status of different devices who monitors the correct functioning of this sub-system;
- ventilation system: indicates when it is safe for operators to enter the irradiation room regarding the ozone gas. It keeps the personnel door looked for a determined period of time necessary to eliminate the ozone.

Fig 6: Information provided by safety system menu

The safety system is composed of several devices that provide information to the user about their current state of functioning:

1. Emergency buttons have the role of stopping immediately the irradiator's mechanical movements and descending the radioactive source in the shielding position. They are placed in different positions in order to offer a fast response and minimize the potential dangers.

Two of these emergency buttons are placed inside the irradiation room and connected with wires across the concrete wall so they are accessible from any position. Their purpose is mainly to stop raising the radioactive source when personnel are inside. Another characteristic is defined under the term “fail safe” meaning that in the event of a specific type of failure, it responds in a way that will cause no harm or at least a minimum of harm, to other devices or to personnel.

2. Safety relays: there are a number of 3 safety relays who work independently from the PLC and receive independent signals from the safety devices i. e. emergency buttons. Their main role is to avoid a PLC state of error and bring the radioactive source into shielding position. Safety relay no. 1 manages the source hoisting system, safety relay no. 2 enables the power supply to the personnel door lock: it checks out-puts received from the source rack sensors and radiation monitors and if conditions are met enables the personnel door to un-lock. Safety relay no. 3 ensures immediate and direct (without PLC) interaction if any of the emergency buttons are pushed. The system can be put back on normal functioning using a special key that confirms the errors and re-check if the problem was solved.

3. Personnel door: has several safety functions that prevents opening it during process or raise the sources while it is opened. The safety functions are redundant so if one fails, the system will keep its safe operation. One improvement consists in the installation of a pneumatic valve which will release the air from the source hoist system when the door is opened. This practically disables the system from raising the sources in to working position, accidentally or intentionally. Also, the door cannot be opened if there is no person logged in into the system.

4. Radiation detectors: the system was up-graded with 3 new radiation detectors which are mounted inside irradiation room, in different positions. If they detect radiation above a certain value, the personnel door will remain locked. They also operate.

The system was also optimized by introducing separate windows for 3 main parts of the irradiator:

Storage transport system: represents the area were the containers are loaded and un-loaded of products (fig. 7);

2. *Toate* box car system: represents the automatic carriage that transports the container into the irradiation room;

3. Source pass mechanism: represents the internal conveyor on which the containers are moved around the radiation source.

All of these parts are continuous and monitored in real time using sensors mounted on different mechanical parts. In this way, the errors are easily identified and promptly repaired. Another new operation safety feature is represented by including a „Master key" which, if removed, makes impossible all commands on HMI excluding, off course, the emergency buttons. The process control was improved by adding access levels for the operating personnel. The system was designed on 3 levels of control:

- operator: start and stop the process and acknowledge basic operation errors;
- service operator: access important functions like the possibility to move individual mechanical components like pistons, carriage or simple operating sequences; it also has the possibility to acknowledge important errors and re-start the process;
- supervisor: access systems' settings and it is able to modify it;
- administrator: establishes the level of access for personnel and assigns passwords.

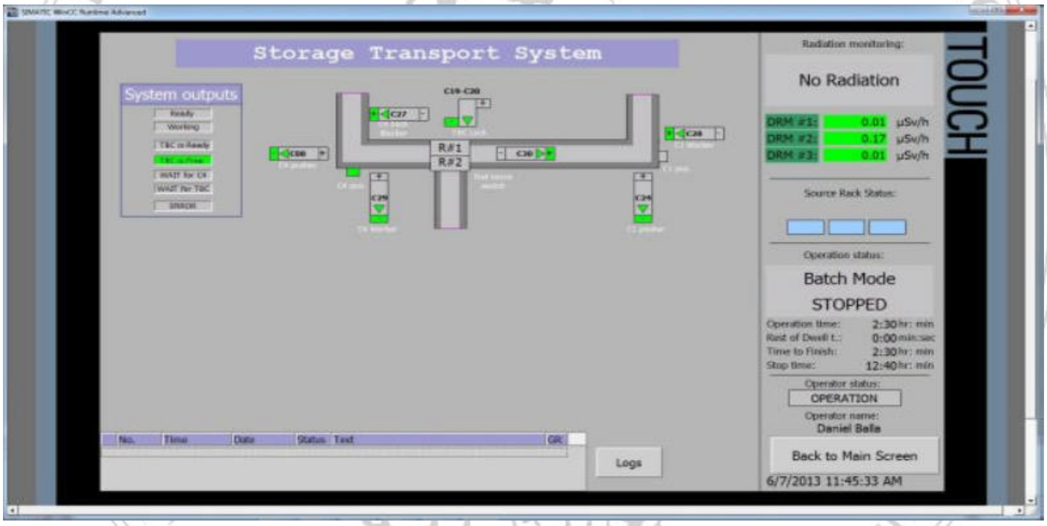

Fig. 7. Representation of storage transport system on HMI.

Thus, depending on competences the system can be accessed and used excluding errors made accidentally or by the lack of knowledge and experience. When talking about electronic records, the system is able to record and divide all processes into 3 categories:

- operator log: records all log-ins and log-outs for every level of access mentioning the time and date;
- process and operation log: records relevant data about the processes and assigns an unique number for every one;
- alarm log: registers all errors received from different devices.

A very important thing is that, regardless of access level, the records cannot be modified or deleted! This ensures traceability and data for all system events.

Process monitoring was up-graded by introduction of a back-up timer which monitors the time per every cycle. This device works independently from PLC and counts the time for a irradiation time cycle (Fig. 8). This device assures that, in a case of PLC failure, the products cannot be over-irradiated and the radiation sources will descend automatically into the storage position.

Fig. 8. Back-up timer device

Conclusions

Radiation treatment using industrial irradiators is a well-established technology with over 50 years of practice. Its advantages were recognized on different domains from pharmaceutical and material engineering industry to food and cultural heritage domains. Romania SVST Co-60 industrial irradiator has over 15 years of continuous functioning and served on research project as well as economic purposes. During this period it was up-graded from PC-operated system installed in 2000 to a modern PLC operated control and safety system, functioning from 2013. Improvements consisted on various changes in process approach and complied with the latest AIEA Safety Guide SSG-8. Basically, the safety, control and monitoring were improved by:

- continuous and real time monitoring of safety systems and irradiator systems;
- continuous and independent monitoring of relay systems and radiation monitoring;
- access of authorized personnel on level of competences;
- 3 levels of records – electronically (PLC and USB) and printed;
- information stored on PLC cannot be modified or deleted regardless of level of access, for better traceability of process.

R E F E R E N C E S

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