EXPERIENCE OF ELECTRON BEAM TREATMENT FOR STERILIZATION OF DISPOSAL MEDICAL GOODS AND IN OTHER MEDICAL AND BIOLOGICAL APPLICATIONS

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Abstract

The installation for sterilization of disposal medical goods based on the ILU electron accelerators Are described. The industrial installation is running where the syringes are sterilized in consumer packs directly by the electron beam having energy of 2.6 MeV. The different irradiation technologies for immobilization of enzymes, production of medical preparations and gels for medical and technical applications are described.

1 INTRODUCTION

During last years the electron beam treatment is more and more widely used for the sterilization of various medical devices and preparations. The electron beam sterilization of disposal syringes is now a norm. But not only syringes, but the single use devices for blood exchange, gynecologic endings, gloves, disposal cloths for operations, etc., are now sterilized by electron beam [1]. The machines with electron energy of 10 MeV are usually used for these purposes. These machines are rather complicated and expensive.

We have designed and elaborated the irradiation technologies permitting to perform sterilization of majority of the medical products on our machines having energy range 2-4 MeV. The lower working energy of electrons and less dimensions of machine leads to more simple and cheap design of irradiation hall thus making the sterilization facilities easier in construction and cheaper.

2 INDUSTRIAL STERILISATION FACILITIES

The Budker Institute for Nuclear Physics has designed and supplied irradiation facilities operating in many countries. One of our last supplies is the automated installation for sterilization of single-use syringes working in the city of Izhevsk, Russia [2].

The technology for sterilization of syringes permitting to use the electron beam with energy of 2.5-4 MeV was suggested and elaborated in our Institute. This sterilization technology is approved by Ministry of Health Care of Russian Federation. The syringes are irradiated from two sides inside the consumer packs containing 250 syringes vertically posed in one layer.

One of the main technological problems of electron beam sterilization of syringes is the achievement of maximum possible homogeneity of dose distribution. The high dose inhomogeneity leads to low quality of sterilization, as the lower dose limit 25 kGy is determined by the resistivity of microbes, and the greater dose leads to sufficient degradation of mechanical properties of plastic syringes.

The electrons with energy of 2.6 MeV have low penetration ability and so were not still used for sterilization of medical goods for in case of traditional irradiation (perpendicular to the axis of syringe) the dose distribution is very inhomogeneous even using bilateral irradiation. So the first non-trivial problem to be solved was the proper choice of the position of the syringes during the treatment to obtain the minimum inhomogeneity of dose distribution .

Our experiments have shown that the most homogeneous distribution of resulting dose is achieved when the syringes in the consumer pack (250 2 ml or 5 ml syringes together with needles in the cartoon box with dimensions 420*210*120 mm) are oriented vertically (height 120 mm) in the process of electron beam treatment (more precisely, parallel to the direction of electron beam fall). The test bilateral irradiation of the syringes have shown the ratio of maximal absorbed dose to minimal of 1.4.

The sterilization installation designed for the city of Izhevsk is based on the electron accelerator ILU-6. It is the single resonator RF machine [3] operating at energy of 2.6 MeV and average beam power of up to 20 kW. The pulse nature of the beam current and automatic control system permit to vary the absorbed dose in great range. Electron energy, beam current, pulse repetition rate, beam position in the extracted window and transportation of the treated products are computer controlled.

The main problem to be solved in design of the technological line for irradiation is the input of the goods to be treated into the irradiation zone and their output. The special conveyor system performs this work. Its design assures the radiation safety due to the special protecting metal sheets.

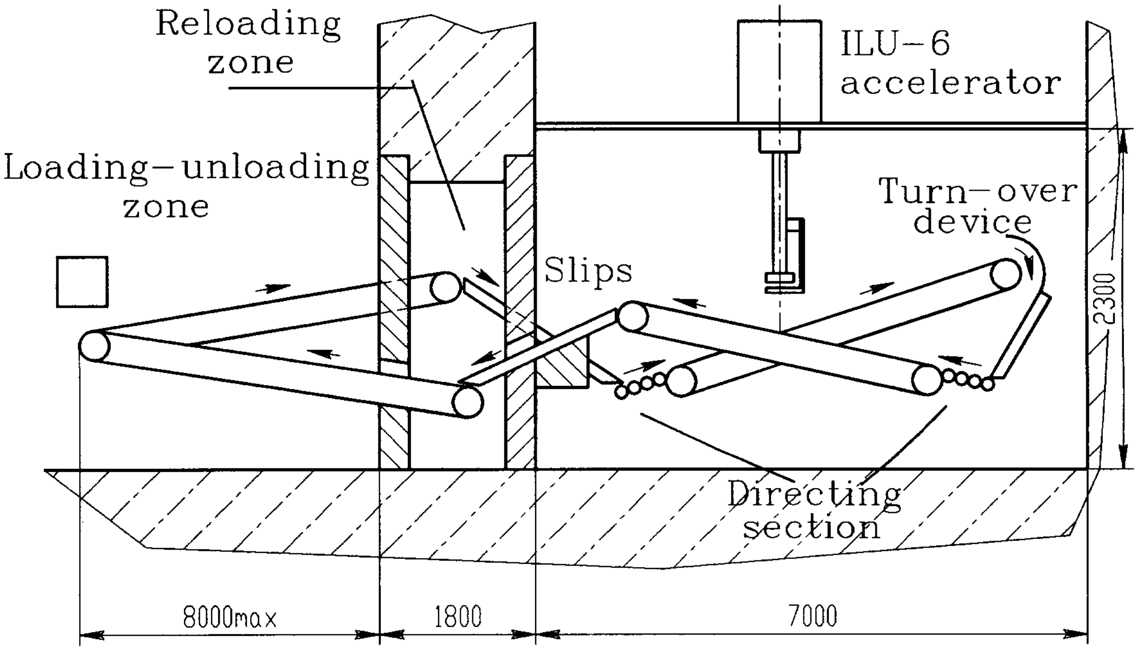

Figure 1. Organization of irradiation process.

Figure 1 represents a simplified view of the radiation hall with the accelerator ILU-6 and the special conveyor system designed to work in the conditions of constant irradiation. The conveyor system consists of the three independent conveyors. Their belts are made of the stainless steel netting.

The feeding conveyor passes from the store of the non-treated products to the irradiation zone through the opening in the shielding. The slope of this conveyor is about 15°. The last metal drum of this conveyor provides the additional radiation shielding. The packs from the feeding conveyor are slipping along the metal slip and are passing on the underbeam conveyor.

The underbeam conveyor is transporting the packs under the beam, turning them over and transporting again under the beam realizing the two-sided (bilateral) irradiation scheme. The underbeam conveyor has two belts (made of the stainless steel netting) driven by one motor through the common drive. The coefficient of filling can be controlled, but it is usually close to 1.0 to have the maximum efficiency.

The first belt of underbeam conveyor has a slope of about 10°. It transports the packs first time under the beam. At the end of the belt the packs are falling down on the second belt with simultaneous turning over under influence of their own weight. The turn-over device is supplied with air-cushion. The second conveyor belt transports the turned-over packs again under the beam to the exit opening of the shielding. This belt also has a slope of about 10°. The packs are passing under the beam on the equal distance from the foil of the beam extraction device on the both belts of the underbeam conveyor.

The packs from this second belt of the underbeam conveyor are slipping along the metal slip with the help of air flux. Then the packs are passing on the directing rollers of the third discharge conveyor belt which transports them to the store of ready products. All conveyors are fully controlled by computer.

The productive rate of the installation is no less 100000 syringes per hour. The installation is certified by the Ministry of Health Care of Russian Federation.

The same irradiation technology is used on the other installation with ILU-6 machine operating in Kiev, Ukraine. We have now the orders for such sterilization facilities, and they are in the state of design. ILU-10 machine with energy of up to 4 MeV is purposed now, and it will permit to widen the range of the products which can be treated as electron energy is greater.

The technologies for sterilization of blood exchange systems, sawing materials for surgery, disposal gynecological endings, gloves, catheters, etc., are elaborated on the accelerators ILU-6 and ILU-10. The other related problem worked out on the same accelerators is the production of the sterile disposal surgery cloths and medical cloths made from special tissues and not-tissue materials.

3. BIOTECHNOLOGICAL AND MEDICAL APPLICATIONS OF ELECTRON BEAM

Sterilization or pasteurization of packed preparations of various biologically active substances, medical products and preparations, packed herbal forms (mixtures) can be easily realized using ILU-6 and ILU-10 machines. The other application field of electron beam is the low temperature chemical synthesis going due to the free radical binding. For example, the water solution of polyethylenoxide (PEO) after the irradiation becomes the gel, and the absorbed dose determines the consistence of gel. The PEO gels are widely used as carriers in medicine, cosmetic products, production of tooth pastes, contact media for ultrasonic diagnostics, etc.

The free radical binding can be used for the linking of the great molecules with the other molecules to impart them qualitatively new properties. One of the possible variants is so called immobilization of the enzymes on the various carriers - polymers having some spatial structure [4]. We have acquired the experience in the usage of the ILU machines in radiation-induced immobilization of various biologically active substances on polymer matrices as well as in radiation-induced linking of low molecular polyethylenoxides in aqueous solutions at the stage of gel formation.

The preparations of immobilized enzymes on the basis of polymer carrier are used in analytical chemistry, biotechnology, medicine and environmental applications. They can be produced by known methods of radiation immobilization with the help of various sources of irradiation [4, 5 & 6]. The specific activity of immobilized enzymes depends on initial activity of enzyme and mode of irradiation. Our immobilization method permits to preserve from 40 to 60% of initial enzyme activity. The use of radiation technology for immobilization of enzymes with polymer matrices made it possible to produce various medical and veterinary preparations and components, various cleaning means, active components for wool washing agents and for the processes of softening and unhairing of cattle, swine and sheep hides.

Complex of bacterial proteases in water solution of polymer under irradiation creates free-radical links forming mycellium-like enzyme-polymer structures. The radiation immobilization of proteolytic enzymes on polymer matrix imparted them qualitatively new properties - the time of specific action of enzymes increases in some ten times, while specific properties of product remain the same. The obtained enzyme complex retains its high level of specific activity across a wide range of pH (6.0-11.5) and temperature (18-80°C).

Usage of immobilized enzymes permits to remove the hair from hide and to obtain undamaged and clean wool with the increase of ecological safety due to reduction of water and chemical agents consumption. Duration of unhairing process is for sheep hides 1-3 hours, for cattle hides - 6-8 hours. The yield of dried clean wool is 320-360 grams from cattle hide and 1000-1500 grams from sheep hide. Enzymatic soaking permits to realize production cycle without hide bating.

Components of washing solution "Biosib" are forming two-phase liquid system containing immobilized enzymes. Its main components are more safe after use than widely used sulphonates, sodium phosphate, ferro- and polyphosphates and water glass. The used washing solution is transferred into separating column where it separates rapidly into three layers. The top layer contains large quantity of lanolin which can be extracted for use in cosmetic industry. The middle layer (about 85% of total volume) is pure washing solution ready for use. The bottom layer contains particulate matter removed from the raw wool. This matter can be used as good fertilizer.

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