DEVELOPMENT OF CONTROL SYSTEM FOR CRITICAL PARAMETERS OF MEDICAL DEVICE STERIZATION AT AN ELECTRON ACCELERATOR

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The hard- and software interfaces that provide on-line control and archiving of the basic parameters of the medical device sterilization (electron energy, beam current, width and shape of the beam scan, the conveyor speed and the absorbed dose in the treated products) have been developed at a radiation-industrial installation LU-10 of NSC KIPT. The main primary sensor of the control system is a stack-type monitor-absorber of the beam located behind the line of movement of the processed objects. Continuous monitoring of the processing parameters is performed by measuring and analyzing the currents from the plates of the monitor in a mode of "radiation shadow" created by irradiated objects. The structure of the control system, how it works and the calibration procedures for measuring channels are described.

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INTRODUCTION

Nowadays, more than 50% of disposable health care products are sterilized by radiation with the use of γ-rays, bremsstrahlung (X-rays), and electron beams [1]. In the latter case the particle energy is generally in the range 5 to 10 MeV.

International standard ISO 11137-1: 2006 (Sterilization of health care products – Radiation – Part1: Requirements for development, validation and routine control of a sterilization process for medical devices) specifies, that all procedures qualification, of processing, metrological performance, and other elements that affect the sterilization process must be properly ensured and documented.

One of the main conditions of the treatment is the transfer of absorbed dose of the radiation to a product within specified limits. The dose distribution in the treated product depends on the electron energy, linear density of the flux on the surface of the irradiated object, and the speed of the object in the irradiation zone (conveyor speed). Therefore, monitoring of critical parameters should be the carried out with special attention.

The standard does not specify the structure and implementation of the control system of processing conditions. It denotes only, that any reliable system providing complete monitoring and control of critical parameters, and ones, that can be correlated with them, can be used.

The report describes the hardware and software developed and implemented in "Accelerator" Sc&Res Est of NSC KIPT at an industrial radiation plant with an electron accelerator LU-10 to control the main parameters of the sterilization process [2].

1. STRUCTURE OF CONTROL SYSTEM

The control system of radiation processing consists of the following elements (Fig. 1):

• automated operator workstation;
• database server;
• server of the accelerator LU-10 parameters;
• local network.

The main tasks of the system are:

• control and monitoring of the sterilization parameters;
• control of equipment of the systems;
• acquisition of monitored and settable parameters at the database server.

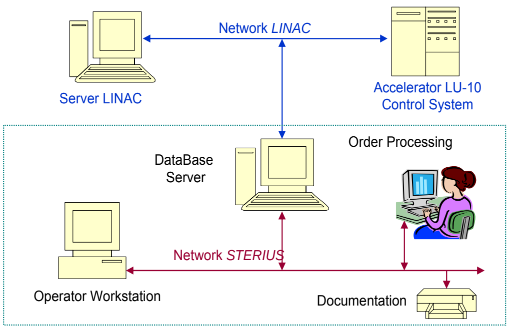

Fig. 1. Block diagram of control system

2. OPERATOR WORKSTATION

An operator workstation is a hardware and software system to measure and control a product processing regime in real time. The workstation is built on the basis of PC and a modular-crate CAMAC system with the measuring channels (Fig. 2).

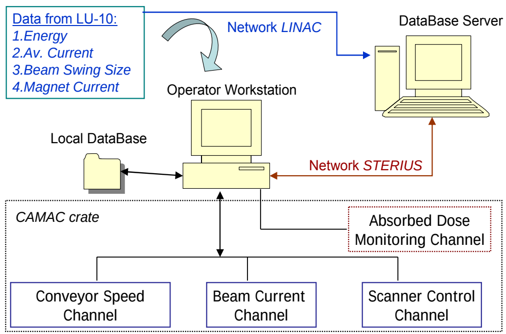

Fig. 2. Block diagram of automated operator workplace

The control and monitoring of parameters of the radiation processing are carried out using a set of measuring channels with readers located at the operator workplace and in control room of the accelerator. In the latter case, the process parameters are sent to the operator workstation via the network "LINAC".

3. MEASURING CHANNELS

The structure of automated operator workplace includes:

• control channel of the scanner electromagnet;

- measuring channel of the average beam current;
- measuring channel of the conveyor speed;
- monitoring channel of the electron energy and absorbed dose.

3.1. CONTROL CHANNEL OF SCANNER ELECTROMAGNET

The structure of the channel includes:

- module of digital-to-analog converter (DAC);
- controlled power supply of scanner electromagnet (+/- 25A);
- interlock system.

The digital-to-analog converter DAC-002 performed in the CAMAC standard represents an original design unit. It is intended to generate voltage pulses of arbitrary shape with amplitude -3 to + 3 V and repetition rate from a few to hundreds Hz.

The key characteristics of DAC are:

- resolution, bit – 14;
- RAM size, kB – 2×32;
- output voltage range, V – + 3 / -3;
- RAM scanning frequency, Hz – 1-1000000.

A feature of this DAC is presence of the two independent pages in RAM. This gives the possibility of updating the data on one page of RAM, while other page is scanned. As a result, the change of the DAC output parameters (amplitude, frequency, offset) is carried out without interrupting its signal.

The scanner power supply corresponds a current generator controlled by the input voltage. The maximum amplitude of the current in the magnet coil at its impedance of ~2.8 Ohm and scanning frequency of 3 Hz is ~25 A.

The interlock system is intended to lock off the accelerator beam in the absence of the an AC component in the current of the scanner electromagnet or when its amplitude is less than a predetermined threshold value.

3.2. MEASURING CHANNEL OF AVERAGE BEAM CURRENT

The structure of the channel includes:

- gated current integrator;
- analog-to-digital converter (ADC);

The analog-to-digital converter FK4226 is 8 bit ADC with memory (RAM) 1 kB. The maximum frequency of ADC is 20 MHz.

The pulse signal of beam current from a built-in nonintercepting magnetic induction sensor of the LU-10 Linac is fed to the input of the current integrator. Then it is supplied to the input of ADC, converted into digital code and stored in the memory. After that it is uploaded into PC. Measurement of average beam current is carried out once per second by averaging over the 100 beam pulses.

Calibration scheme of measuring channel of the average beam current consists of a controlling generator and an output register (module 350) performed in the CAMAC standard. The output of the generator is terminated via coaxial cable with the calibration winding of the beam current sensor (MIT).

The controlling generator forms the current pulses with predetermined amplitude at a duration of 4 us and repetition rate of 300 Hz. The current amplitude is set either manually (by setting the switches on the front panel), or programmatically through the output register (5 bit TTL level signals).

Calibration of the beam current sensor is executed automatically. The program changes subsequently the pulse current amplitude from 0 to maximum and measures the average current delivered from the sensor MIT. Then, the least squares fit of dependence of the sensor signal amplitude versus the amplitude of the pulse generator by a linear function in the form $Y=A*X+B$ is performed with the obtained data, and the coefficients A and B are determined (Fig. 3). Those coefficients are stored in a file and used to determine the average beam current of the LU-10 machine.

A working standard based on a vacuum Faraday Cup is used also for calibration of the measuring channel of the average beam current [2].

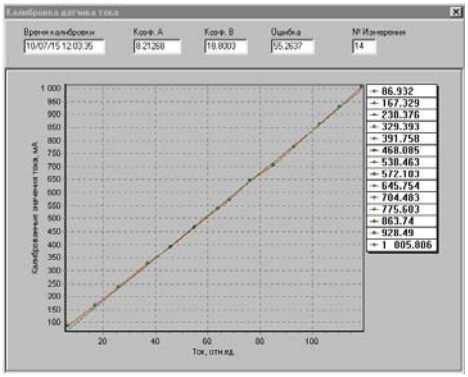

Fig.3. Calibration of beam current measuring channel with the reference generator

3.3. MEASURING CHANNEL OF CONVEYOR SPEED

Fig. 4 shows a schematic diagram of measuring channel that determines the velocity of the processed product transfer through the irradiation zone (the conveyor speed). A measuring apparatus has four independent 16-bit counters performed under the CAMAC standard. To measure the speed, the output signal of the built-in tachometer of the conveyor is used. The signal corresponds a sequence of rectangular pulses, which repetition rate is proportional to the speed of the conveyor.

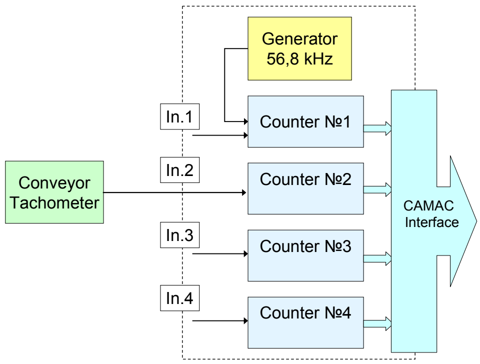

Fig. 4. Functional diagram of measuring channel of the conveyor speed

The pulses from the output of the conveyor tachometer send on input of the counter № 2. Pulses from a quartz oscillator with frequency 56.8 kHz are sent on the counter №1. The counters data are read out into PC every second. The conveyor speed is determined using the following expression

V=A*B*C2/C1, where A = 0.0062 – the coefficient for converting angular velocity of the conveyor drive to its linear velocity (cm/s), B=56786 – the number of pulses on the counter №1 for 1 s, C1 – number of pulses on counter №1, C2 – number of pulses on the counter № 2 for time of measurement.

The obtained value of the conveyor speed is displayed every second in digital form at the operator workstation and is stored through predetermined time interval into database to archiving the processing regime.

3.4. MONITORING CHANNEL OF ELECTRON ENERGY AND ABSORBED DOSE

Continuous monitoring of electron beam energy and absorbed dose in the irradiated objects is one of the main requirements of the standard ISO 11137-1: 2006. For this purpose, the measuring channel has been developed (Fig. 5), which consists of:

- stack monitor-absorber (SM)of electron radiation;
- integrator block;
- software.

Stack monitor-absorber is a sandwich composing 10 insulated aluminum plates and measuring 122×75×17 cm (X, Y, Z). The horizontal axis Z coincides with the axis of the accelerator, the X axis is directed vertically upwards, and the axis Y - horizontally. Thickness of each from the two outer plates is 5 mm and each from the internal 8 plates is 2 mm. Between the plates there the are air gaps 16 mm wide. The center of the monitor is on the axis Z. The monitor is located in the air downstream the irradiated object at a distance of 223 cm from the exit window of the accelerator.

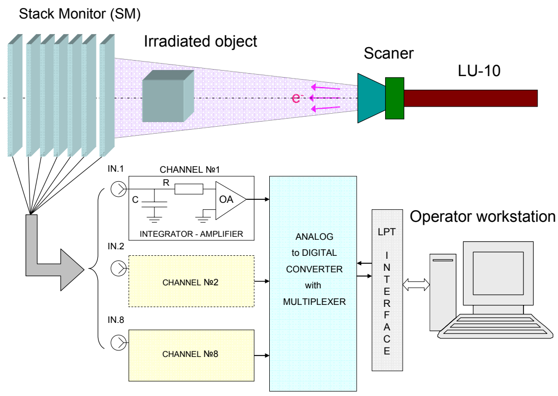

Fig. 5. Block diagram of monitoring channel of the electron energy and absorbed dose

The signals from the SM plates are fed to the inputs of the integrator by coaxial cables (see Fig. 5). The capacitors (C) with rated capacity 15 uF are used the an integrators. The discharge circuit includes a resistor R and an input impedance of the operational amplifier (OA). The integration time is ~150 ms.

An operational amplifier is used as a current-to-voltage converter with gain 1. The output of each integrator channel is connected to the switch of the analog signal. For the measurement, the channel number is set by a control program through the computer's parallel port (LPT-interface). The output of the switch is connected to the input of the analog-to-digital converter of the AD7895 type. The signals from the output of ADC are converted into a binary 12-bit code and read out by the control program. The ratio of the currents from the plates allows to determine the electron energy. In its turn, the ratio of total current from SM to the beam current allows to determine the amount of absorbed radiation energy (average dose) in an irradiated object [3].

The routine dosimeters Harwell Red 4034 and film B3 are used for direct measurement of the dose. Their on-site calibration as well as calibration of dose monitoring channel on the basis of SM is performed using the reference calorimetric RISO dosimeters and specially designed phantoms. The measuring channel of electron energy is calibration using a built-in accelerator's is magnetic analyzer.

3.5. ARCHIVING PARAMETERS

The following parameters are stored at regular intervals in the database server during radiation treatment (in brackets is the parameter source):

- beam energy of LU-10 (server LINAC);
- average beam current (server LINAC);
- current in the coil of the magnet scanner (server LINAC);
- amplitude of scan and offset value of the beam current (server LINAC);
- average beam current (operator workstation);
- conveyor speed (operator workstation);
- absorbed dose (operator workstation);
- scanner settings (operator workstation).

4. DATA BASE SERVER

A dedicated computer with the running Windows XP is used as a database server. It performs the following functions (Fig. 6):

- storage of database files and control of access to them;
- backup of database files on the schedule;
- monitoring the status and parameters of radiation processing obtained from other computers of local networks «Sterius» and «Linac».

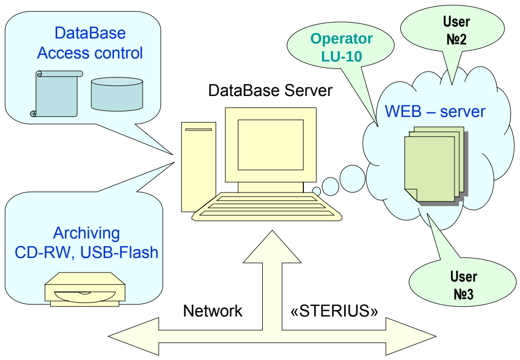

Fig. 6. Main functions of the database server

Currently, the database of type MS Access is used. For users of the «Sterius» network the appropriate access rights to the database are set.

The operation of the backup archive system is ensured by scheduled execution of the special command files, which are specially designed for those purposes. Data archiving is done by copying the database files to the external storage media: a flash memory (USB), and an optical rewritable disc (CD-RW).

5. WEB-SERVER

A web-server is designed for efficient monitoring and displaying the radiation treatment parameters. It is based on the Apache software using the scripts written in PHP5. The web server allows viewing in real-time the critical parameters of processing (the average beam current, the electron energy, the current of scanner magnet, the conveyor speed, etc.) from any computer on the local networks «Sterius» or «Linac» with a standard Internet browser (Fig. 7). The ability to view the processing parameters from the archive database by date and time of the processing is included also. It provides independent control of the treatment mode.

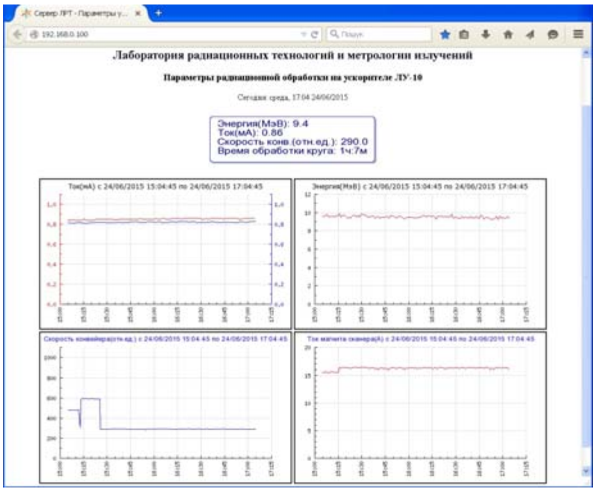

Fig. 7. Web-server page with operational informati on on processing parameters

6. SOFTWARE

6.1. GRAPHICAL USER INTERFACE OF PROCESSING REGIME

The operator workstation displays the following parameters in the text and graphic form (Fig. 8):

- Information about a processed product and parameters of its processing:
  - number of the order;
  - customer;
  - type of the product;
  - package type and quantity;
  - set dose and its limits;
  - height of the irradiated object;
  - time of the treatment start.
- Beam parameters:
  - energy;
  - average beam current;
- Set and measured parameters of the scan:
  - width (amplitude of scanning);
  - offset;
  - current of scanner magnet;
- Speed of the conveyor;
- Average absorbed dose by an object.

6.2. GRAPHICAL USER INTERFACE OF THE BEAM SCANNING MODE

A designed graphical user interface allows the operator to set the amplitude, offset and form of the beam scan on the processed object (Fig. 9).

6.3. SOFTWARE FOR THE MONITORING THE CHANNEL OF THE ABSORBED DOSE

A graphical interface designed to display the currents from SM and to monitor the electron energy and the absorbed dose in the processed object is presented in Fig. 10.

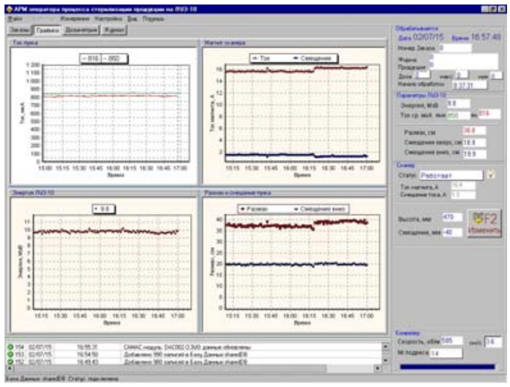

Fig. 8. Operator workstation screen

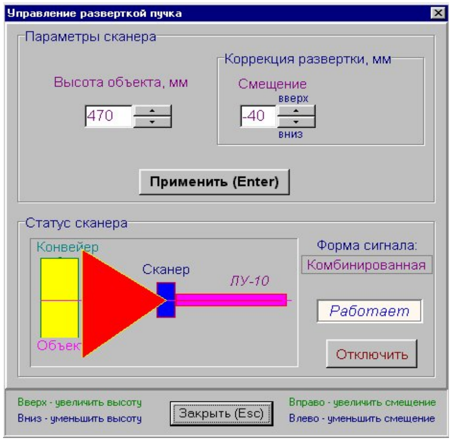

Fig. 9. Graphical user interface of workstation operator to control parameters of scanning beam

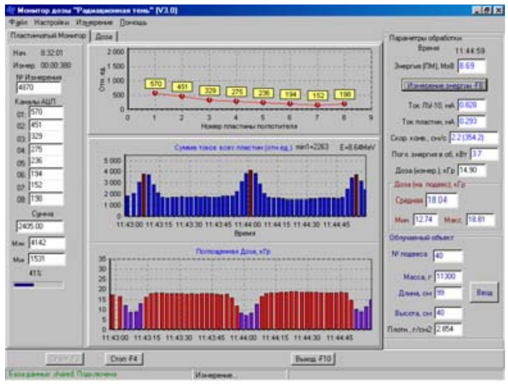

Fig. 10. Graphical user interface for on-line monitoring of absorbed dose

In the main window, there are:

- panel of the processing parameters and the object characteristics;
- panel with measured value of the beam current;
- graphs displaying the distribution of currents from the SM plates, the distribution of the sum of all currents from the plates by the time, the absorbed dose distribution in the object along the length of the transport container.

If necessary, a specially designed program "DozaCalc" is used to determine the absorbed dose in the object in the off-line mode. Fig. 11 shows its GUI. The program acquires the radiation treatment parameters from the database "Sterius" for a requested period and calculates the mean absorbed dose in the object. The processing parameters, the values of the current from the SM plates and the calculated dose are displayed in the numerical and graphical form.

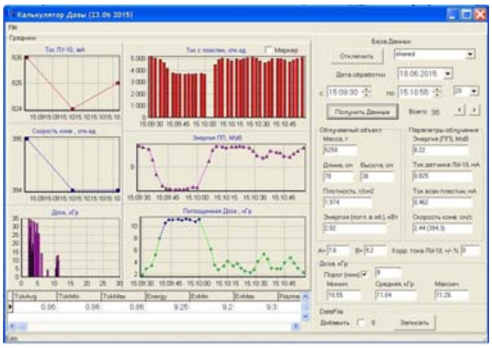

Fig. 11. Graphical user interface of program for determination of absorbed dose in off-line mode

CONCLUSIONS

The control system of the sterilization process parameters developed at the industrial electron Linac LU-10 in "Accelerator" Sc & Res Est of NSC KIPT meets the requirements of the standard ISO 11137-1: 2006. That is confirmed also by obtaining the certificate for quality management system under the standard ISO 13485: 2003 "Medical devices – Quality management systems – Requirements for regulation".

The use of the CAMAC interface has allowed to create an open-type hardware providing the ability to add the additional measuring channels and their updating.

The presence of the beam scanner under control of PC together with a set of codes designed for simulating beam interaction with processed object enables optimization of a processing mode in relation to uniformity of the dose distribution, as well as metrological study of devices for the radiation measurements [4, 5].

REFERENCES

1. Trends in Radiation Sterilization of Heals Care Products // *IAEA- STI/PUB/1313*. 2008.
2. V.N. Boriskin, S.A. Vanzha, V.N. Vereshchaka, et al. Development of Radiation Technologies and Tests in “Accelerator” Sc & R Est, NSC KIPT // *Problems of Atomic Science and Technology. Series “Nuclear Physics Investigations”*. 2008, № 5, p. 150-154.
3. S.A. Vanzha, V.I. Nikiforov, R.I. Pomatsalyuk, et al. Development of “Radiation Shadow” Technique for Monitoring Regime of Product Sterilization by Electron Beam // *Problems of Atomic Science and Technology. Series “Nuclear Physics Investigations”*. 2010, № 2, p. 150-153.
4. V.I. Nikiforov, N.M. Pelikhatyi, R.I. Pomatsalyuk, et al. Development and Validation of Software for Simulation of Product Processing Regimes at an Electron Accelerator // *Problems of Atomic Science and Technology. Series “Nuclear Physics Investigations”*. 2013, № 6, p.156-160.
5. A.A. Zakharchenko, V.I. Nikiforov, R.I. Pomatsalyuk, et al. Analysis and Optimization of a Mode of Product Industrial Processing at an Electron Accelerator // *Problems of Atomic Science and Technology. Series “Nuclear Physics Investigations”*. 2015, №6, p. 90-94.

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РАЗРАБОТКА СИСТЕМЫ КОНТРОЛЯ КРИТИЧЕСКИХ ПАРАМЕТРОВ СТЕРИЛИЗАЦИИ ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ НА УСКОРИТЕЛЕ ЭЛЕКТРОНОВ

Р.И. Помацалюк, В.А. Шевченко, И.Н. Шляхов, А.Э. Тенишев, В.Л. Уваров

Для системы управления радиационно-технологической установки ЛУ-10 ННЦ ХФТИ разработаны приборный и программный интерфейсы, обеспечивающие on-line контроль и архивирование основных параметров процесса стерилизации изделий медицинского назначения – энергии электронов, тока пучка, ширины и формы его развертки, а также скорости конвейера и поглощенной дозы в обрабатываемых изделиях. Основным первичным преобразователем системы контроля является пластинчатый монитор-поглотитель пучка, размещенный за линией перемещения обрабатываемых объектов. Непрерывный мониторинг параметров обработки производится путем анализа токов с пластин монитора в режиме создаваемой объектами «радиационной тени». Описаны структура системы контроля, принцип ее работы и процедура калибровки измерительных каналов.

РОЗРОБКА СИСТЕМИ КОНТРОЛЮ КРИТИЧНИХ ПАРАМЕРІВ СТЕРИЛІЗАЦІЇ ВИРОБІВ МЕДИЧНОГО ПРИЗНАЧЕННЯ НА ПРИСКОРЮВАЧІ ЕЛЕКТРОНІВ

Р.І. Помацалюк, В.А. Шевченко, І.М. Шляхов, А.Е. Тєнішев, В.Л. Уваров

Для системи управління радіаційно-технологічною установкою ЛУ-10 ННЦ ХФТИ розроблені приладовий і програмний інтерфейси, що забезпечують on-line контроль і архівацію основних параметрів процесу стерилізації продукції медичного призначення – енергії електронів, струму пучка, ширини і форми його розгортки, а також швидкості конвеєра і поглинутої дози в оброблюваних виробах. Основним первинним перетворювачем системи контролю є пластинчатий монітор-поглинач пучка, розміщений за лінією переміщення оброблюваних об'єктів. Безперервний моніторинг параметрів обробки проводиться шляхом вимірювання і аналізу струмів з пластин монітора в режимі створюваної об'єктами «радіаційної тіні». Описано структуру системи контролю, принцип її роботи і процедуру калібрування вимірювальних каналів.