THE CONTROL SYSTEM FOR RADIATION STERILIZATION OF HEALTH-CARE PRODUCTS AT THE ACCELERATOR LU-10

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The regulatory documents for the technological process of sterilization (DSTU ISO 11 137:2003 and others) set requirements on monitoring, maintaining and archiving the basic parameters of the process. To meet the requirements, an automated control system was created at the LU-10. It includes a PC-controlled beam scanner, technological measuring channels (TMC), and also a set of working standards to calibrate the channels. The CAMAC standard was used as an interface. The software of the complex provides the real-time processing of information on the beam parameters, their control, archiving, and also the information exchange within the local-area technological network. The presence of the Customer Database comprising the characteristics of incoming products makes it possible to optimize the process conditions for the products by the computer simulation method.

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1. INTRODUCTION

1.1. The radiation treatment of end products and raw materials is the part of many present-day technologies. Thus, several radiation programs are being carried out at the East-Ukrainian Radiation-Technological Facility (RTF) based on the electron linac LU-10 of the R&D Prod. Est. "Accelerator" under NSC KIPT. Among them are the sterilization of health-care products, pharmaceutical raw materials and stock forms, etc. [1]. The regulatory documents for a number of technological processes demand a continuous control and archiving of radiation treatment conditions [2,3]. To meet the requirements, an automated control system (Fig.1) was created at the LU-10.

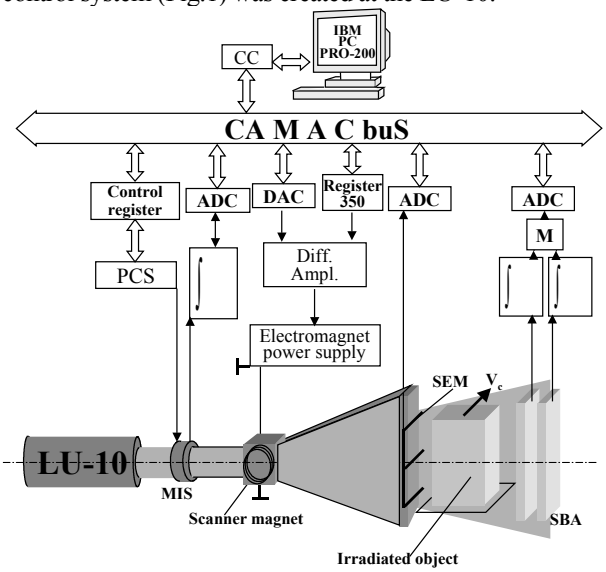

Fig. 1. Block diagram of the radiation-treatment control system (RTCS)

The control system includes:

- the radiation field shaping complex (scanner);
- technological measuring channels (TMC) to measure the main parameters of the radiation field;
- a set of working standards (WS);
- the TMC calibration system;
- the interlock system;
- the system of process conditions documentation.

1.2. At present-day dynamic market conditions, products of different size and mass are coming for radiation treatment. This necessitates a quick correction of irradiation conditions, first of all, of the width of beam scanning zone on the object. For this purpose, a PC-assisted scanner control complex with the CAMAC interface has been created at the LU-10.

The complex provides a programmed control of the beam scanning zone width within 20…60 cm, with an automatic setting of the zone center in the middle of the object under treatment. The complex control unit also provides the means for correcting the position of the beam scan center in order to compensate the angle of beam entry into the scanner electromagnet.

2. TECHNOLOGICAL MEASURING CHANNELS

All the TMC are operating in the real-time mode and provide monitoring of the main radiation field parameters.

The energy (most probable value), width and center position of the beam scan at the exit window of the accelerator are measured by means of the secondary-emission monitor (SEM) [4].

A nonperturbing monitoring of the beam current (pulsed value) is conducted with the use of a magnetic-induction sensor (MIS). To measure the average beam current, an output unit is used, which comprises a peak detector, an average current integrator and a gate-pulse generator.

The TMC with a probe device in the form of a sectionalized beam absorber (SBA) (free-air Faraday cup) is used to monitor the absorbed dose in the object under treatment, and also the electron energy (average value). The space distributions of the absorbed dose in the irradiated objects (minimum and maximum values) are measured with dacryl 2M detectors (DRD 4/40). For preliminary estimation of the dose distribution, and also, for optimization of the process conditions, a computer simulation with the program package "DOSE" is used. The package has been prepared on the basis of the

PENELOPE system and received metrological certificate.

The velocity sensor, arranged on the conveyor electric actuator, controlled the conveyor speed $\mathbf{V}_c$.

3. WORKING STANDARDS

The electron flux and energy (average value) calibration of TMC is performed with the WS on the basis of the combined charge-calorimetric probe (CCP) [5]. The electron energy spectrum is measured by a built-in magnet analyzer.

The calibration in the energy flux (power) of the scanned beam is performed with the WS using a primary detector, e.g., a continuous flow calorimeter of absorbed power [6].

The calibration in the pulsed current and average current is made automatically before each switching-on of the beam with the use of the built-in pulsed current standard (PCS).

The WS, based on the magnetostrictive line [7], is used to calibrate the channel measuring the width and center position of the scan zone.

The dosimeters were calibrated using the working standard ERC-3 [8].

4. DOCUMENTARY MAINTENANCE

4.1. The architecture of the documentary maintenance system (DMS) for radiation treatment (sterilization) of products is shown in Fig.2. The DMS is a subsystem of the laboratory network "LINAC" that connects the computers of the R & D Complex "Accelerator" and comprises three main components:

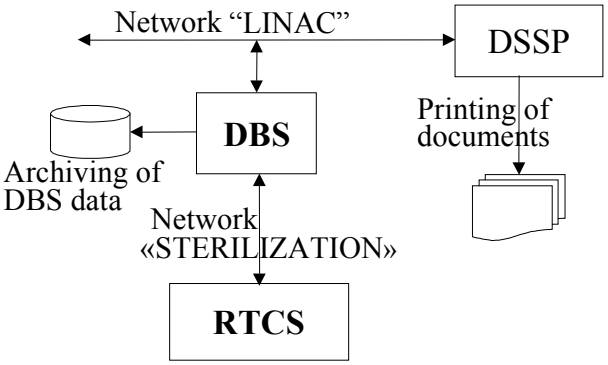

Fig. 2. Block-diagram of sterilization document maintenance system

- radiation treatment control system (RTCS);
- database server (DBS) of the sterilization process;
- documentation server of the sterilization process (DSSP).

All DMS components are communicated with each other through the network. In this case the RTCS and the DBS form a separate internal network "STERILIZATION" to exclude the influence of the external network "LINAC" on the operation of RTCS and DBS. The DBS deals with the following tasks:

- data acquisition from the RTCS;
- data storage;
- archiving of data on the orders for products treatment (interface program "Orders");
- processing of external queries (from DSSP and RTCS).

The DSSP tasks are as follows:

- acquisition of data on the process parameters from the DBS;
- preparation and editing of documents;
- storage and archiving of documents;
- data printing.

In setting up the order for product treatment, the following parameters are introduced into the database:

1. order number;
2. ordering company;
3. type of products;
4. quantity of products;
5. type of packaging;
6. minimum irradiation dose;
7. maximum irradiation dose;
8. type of irradiation (two-sided, one-sided);
9. date of delivery;
10. date of processing.

All the parameters are introduced into the corresponding table of the database by means of the interface program "Orders".

5. CONCLUSION

The available capacity of the RTF LU-10 and the continuous work on upgrading the control of technological processes offer the prospect of meeting in the nearest years the growing demands of the Ukrainian market for radiation sterilization services.

REFERENCES

1. K.I. Antipov, M.I. Ayzatsky, Yu.I. Akchurin et al. Electron Linacs in NSC KIPT:R&D and Application // *Problems of Atomic Science and Technology. Series: Nuclear Physics Investigations*. 2001, №1(37), p.40-47.
2. *Standard ANSI/AAMI/ISO 11137-1994.* Sterilization of Health-Care Products – Requirements for Validation and Routine Control – Radiation Sterilization.
3. *Sterilization Validation & Routine Operation Handbook (by Anne F. Booth)*. Technomic Publishing Co., Inc., Lancaster, USA, p.157.
4. V.N. Boriskin, V.A. Gurin, V.A. Popenko et al. Monitoring Channel of the Technological Linac Beam Cross-Section // *Problems of Atomic Science and Technology. Series: Nuclear Physics Investigations*. 2001, №5(39), p.147-149.
5. V.L. Uvarov, V.N. Boriskin, V.A. Gurin et al. *Calibration of Electron Beam Measuring Channels in Technological Linacs*. Proc. of the 7th Int. Conf. on Accelerator and Large Experimental Physics Control Systems ICALEPCS'99. 1999, Italy, Trieste, p. 220-222.
6. V.L. Uvarov, S.P. Karasyov, V.I. Nikiforov et al. *Beam-Power Calibration System for Industrial Electron Accelerators.* Proc. of EPAC 2004, Lucerne. 2004, p.2167-2169.
7. V.N. Boriskin, S.P. Karasyov, R.I. Pomatsalyuk et al. *Development of methods and means for non-*

perturbing diagnostics of the scanned electron beam. Proc. of the 10th International Meeting on the Use of Charged Particle Accelerators in Industry and Medicine. 2001, Russia, St. Petersburg, p.295-298 (in Russian).
8. S.P. Karasyov, V.L. Uvarov, I.I. Tsvetkov. A system of metrological maintenance of radiation technologies with the use of electron radiation and bremsstrahlung // *Problems of Atomic Science and Technology. Series: Nuclear Physics Investigations.* 1997, № 2,3 (29,30), p.54-56.

СИСТЕМА КОНТРОЛЯ РАДИАЦИОННОЙ СТЕРИЛИЗАЦИИ ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ НА УСКОРИТЕЛЕ ЛУ-10

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Нормативные документы на технологический процесс стерилизации (ДСТУ ISO 11 137:2003 и др.) устанавливают требования мониторирования, поддержания и архивирования основных параметров процесса. Для удовлетворения этим требованиям на ЛУ-10 создана автоматизированная система контроля. В ее состав входит управляемый РС сканер пучка, технологические измерительные каналы, а также набор рабочих эталонов для калибровки каналов. В качестве интерфейса использован стандарт КАМАК. Программное обеспечение комплекса дает возможность в режиме реального времени производить обработку информации о параметрах пучка, управлять ими, их архивировать, а также обмениваться информацией в пределах локальной технологической сети. Наличие базы данных «Заказчик» с характеристиками поступающей продукции позволяет оптимизировать режим ее обработки методом компьютерного моделирования.

СИСТЕМА КОНТРОЛЮ РАДІАЦІЙНОЇ СТЕРИЛІЗАЦІЇ ВИРОБІВ МЕДИЧНОГО ПРИЗНАЧЕННЯ НА ПРИСКОРЮВАЧІ ЛП-10

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Нормативні документи на технологічний процес стерилізації (ДСТУ ISO 11 137:2003 та інші) установлюють вимоги моніторування, підтримки і архивування основних параметрів процесу. Для задоволення цим вимогам на ЛП-10 створена автоматизована система контролю. У її склад входить керований РС сканер пучка, технологічні вимірювальні канали, а також набір робочих еталонів для калібрування каналів. Як інтерфейс використаний стандарт КАМАК. Програмне забезпечення комплексу дає можливість у режимі реального часу робити обробку інформації про параметри пучка, керувати ними, архивувати їх, а також обмінюватися інформацією в межах локальної технологічної мережі. Наявність бази даних «Замовник» з характеристиками продукції, що надходить, дозволяє оптимізувати режим її обробки методом комп'ютерного моделювання.