

# Formation of regulatory documents data to ensure the information system operation in the production process

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**Abstract**—The use of radionuclide materials for animal treating is one of the new directions of veterinary medicine. A new technological process for obtaining Lutetium trichloride-177 has been developed for medical purposes, with the use of registration information system, documentation and the life cycle maintenance, at the Reactor Materials Institute. A separate problem for the functioning of the information system is the formation of informational data of regulatory documents, governing the production process. This study presents a methodology for developing the structure and type of data to ensure the operation of an information system based on the use of a general matrix model.

**Keywords**—digitalization, digital economy, information system, informational data.

## I. INTRODUCTION

The cyberspace creation and development assume the complete digitalization of information that accompanies products at all stages of the life cycle. The digitalization stage precedes the digital economy and is the start for the necessary transformations [1, 2]. Digital economy is the result of the transformational effects of innovative general technologies in the information and communication technologies field, and the digital economy implementation is possible only with the deep integration of information and telecommunication technologies with the real economy processes of any country, with abundance of global norms, rules and standards [3]. If you reconsider this statement from the macroeconomic level to the microeconomic level and a particular enterprise, you will get the following: integration into the digital economy of a particular enterprise is possible only if the information and communication technologies are deeply integrated into specific technological processes with abundance of the regulatory documents requirements of the enterprise.

## II. RELEVANCE

The need for a transition to the digital economy in Russia is now realized, but there is the main question that concerns all levels of interaction between participants in economic processes and the production stage in particular: where should we start? Moreover, the problems of uncertainty while entering the path of digitization, in our opinion, are more relevant for a particular enterprise, a specific technological process.

The experience of acquiring some software on the market, completing training and starting using it at their enterprise turned out to be negative for the individual Russian manufacturers. All the leading risk researchers of the world unanimously consider the implementation of turnkey solutions, related to information technology support of various processes, as the riskiest of them all. The information technology support should be developed for those industries where the implementations are planned to be applied. Attempts to introduce information technology support, simply by repeating current business processes in a digital environment, bring the companies expenses, but not economic benefits [4]. Therefore, each enterprise will have to make their own way at the digitalization stage.

So far one thing is indisputable: a successful start and any start in general everything should be digitalized: initial product, process and personnel requirements, as well as all accompanying documentation [5, 6]. In other words, it is required to form a complete, up-to-date and constantly updated library of requirements, and then establish the links between these requirements, the ways to monitor them, if necessary, the methods of effective intervention, as well as prompt updating and modernization of these requirements [6, 7].

## III. RESEARCH OBJECTIVE

Radiation therapy of malignant tumors has been used in humane medicine for over a hundred years. During this time, this method of treatment has won a worthy place in anticancer therapy, along with surgical removal of the tumor and chemotherapy. The radiation therapy is used as an independent method, as well as an element of complex treatment of oncological diseases. Radioactive isotopes and radiation are the fundamentally new methods in the veterinary medicine; it opens great opportunities in the study of life processes, the disease pathogenesis, diagnosis and therapy of animals [8].

One of the treatments used in radiotherapy is the radionuclide  $^{177}\text{Lu}$ , which is characterized as the most promising  $\beta$ -emitting radionuclide for radionuclide therapy due to its nuclear-physical properties [9, 10, 11].

A new technological process for the production of  $^{177}\text{Lu}$  has been developed at the Reactor Materials Institute. The

technological process is based on <sup>177</sup>Lu activation obtaining method by nuclear reactor neutron irradiation of initial material containing <sup>177</sup>Lu. A registration information system has been developed for recording the process parameters, verifying and maintaining the life cycle to control and document all stages of production [9].

It is necessary to provide up-to-date regulatory documentation for implementation of the technological process and ensuring the operation of this information system, which is an independent and rather a difficult task.

#### IV. METHODS AND RESULTS

Standardization at any level of interaction combine patterns, principles, methods and forms to achieve optimal level of order, by wide and multifaceted use of established regulations and requirements, to solve existing, planned and potential economic and social issues [12].

At the first stage of the information preparation, the task is formulated as follows: the information must be necessary and sufficient. Then comes the most difficult stage: identifying the structure and type of information.

One of the methods used by German specialists in the field of digital control is the general matrix method [13].

The matrix in its general form is a rectangular table of some numbers or elements, which are determined by a large number of simultaneously and collectively acting factors. The requirements of a particular technological process, which is used to manufacture a special device, can serve as elements of the matrix. The matrix is being used in a general form for predicting economic phenomena, when the problem of studying the dependence of one variable on several explanatory variables is solved using a multiple regression analysis [14]. It is advisable to use the matrix notation for the inclusion of new explanatory variables in the regression model.

The direct matrix method considers the system technical parameters and evaluates those aspects that determine the effective functioning of the system, and also determines the points of conformity assessment [13]. Any technical system is a group of interconnected and interacting elements, united by a common goal, and considered in a specific context as a whole.

The direct matrix model presented in Figure 1 represents the kind of information required in such cases. The direct matrix method considers the system technical parameters in the general case and assesses those aspects that determine the effective functioning of the system, as well as determines the points of conformity assessment [15]. The general matrix model forms a regression model, which is a function of an independent variable and parameters with the addition of a random variable [16].

Using the model of the general matrix in such conditions will help to reveal:

- Do not confuse “imply” and “infer”. the missing product, process and personnel competencies requirements;
- lack of formalized types of documents that provides the process of manufacturing products and preparing forward documentation for the final products that

form a digital model of the product and which can be used for electronic product documents.

For a specific process of manufacturing an original device at the consumer request in Expert Methodological Center conditions, it is necessary to construct process algorithms that characterize it discretely, definitely, efficiently and massively with the prospect of applying these algorithms to a whole class of problems.

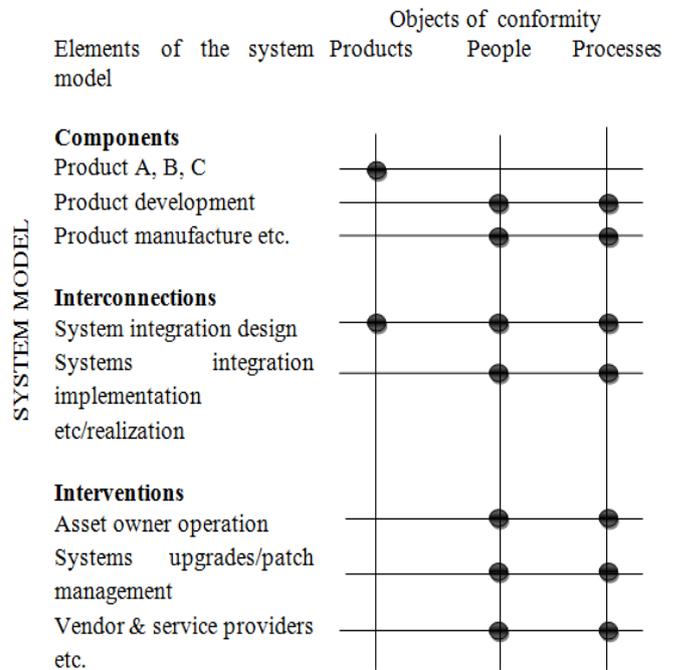


Fig. 1. The general matrix model

Then it is necessary to analyze the received information, which means a continuous, cyclic process that starts with determining the information needs of people responsible for making decisions, and ends with the provision of the information that meets these needs. Such an analysis will allow achieving the goal set at the first stage, namely, to identify the missing requirements to each component of the conformity assessment, as well as missing formalized forms of documents through which information can be exchanged, process control and the formation of a digital model of the product manufactured.

In order to somewhat simplify the direct matrix model, we consider it only at the production stage and for the time being we exclude the product development stages, management system modernizations, update management, and interrelation of production and design. In this case, we obtain a simplified version of the general matrix model presented in Fig. 2.

A simple model of the general matrix allows selecting the necessary information data for the implementation process. These data are combined and generate a specific architectural form, containing binding fragments of the structure: raw materials, quality control, personnel, etc. (Fig. 3). Regulatory documentation defining requirements for a specific architectural system form that includes the State standard “R 52249-2009 Rules of production and quality control of medicines. Good Manufacturing Practice for Medicinal Products (GMP)” [17].

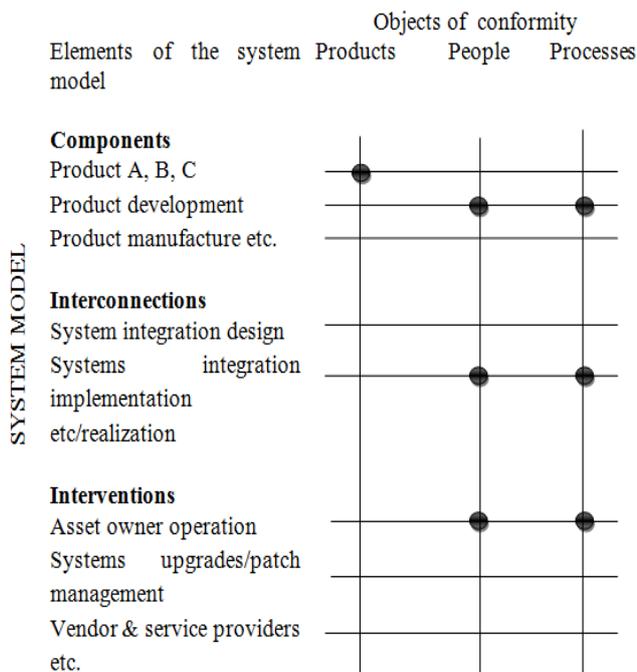
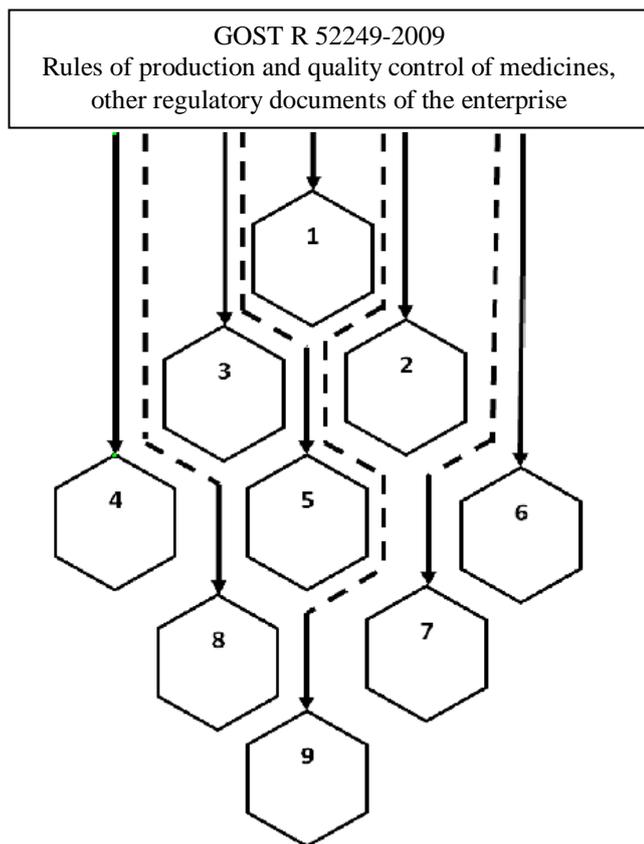


Fig. 2. The general matrix simple model



1 – facilities, utility networks; 2 – raw materials; 3 – workplaces; 4 – personnel; 5 – technological operations; 6 – quality control; 7 – documentation; 8 – technological equipment; 9 – final products

Fig. 3. Information system architecture with binding fragments

This standard is an identical translation of the European Union’s GMP (EU GMP) “Good Manufacturing Practice for Medicinal Products”. In addition to this standard,

information of various regulatory documents of the enterprise is needed.

The general matrix simple model allows you to create a portfolio of regulatory documents data necessary to fill the information system on compliance components. For this information system, data on the three compliance components: products, personnel competence and processes, must be provided.

Production – the fragments of the information system: raw materials and products; quality control; technological operations; documentation; finished products.

Personnel competence – the fragments of the information system: facilities, engineering systems; workplaces; personnel; technological operations; technological equipment; documentation.

Processes – the fragments of the information system: facilities, engineering systems; workplaces; technological operations; technological equipment; documentation; final products.

In the process of documentation analysis, the documents were assessed for compliance with the requirements of electronic document circulation using the following criteria: an adequate (i.e. complies with the requirements of electronic document management) and an outdated (i.e. requiring modification for use in electronic document management) forms. At the same time, it was necessary to check the information accuracy to fill in the electronic product form (EPF) in accordance with the State standard “2.216-2011” [18] and the electronic product dossier (EPD) in accordance with the State standard “R 54089-2018” [19].

The developed system approach to the formation of this information will allow us to provide information about all fragments of the information system in a uniform way. This circumstance will allow in the future to use the information system not only at the production stage, but also to ensure cooperation with the design stages, technological process modernization and product sales.

#### V. CONCLUSION

1. The use of radioactive isotopes and radiation are the new methods in the veterinary medicine, which open great opportunities in the study of life processes, the pathogenesis of diseases, diagnosis and animal therapy.

2. A new technological process for the production of lutetium trichloride -177 has been developed using an information system for recording the parameters of the technological process, documentation and maintenance of the production life cycle.

3. In order to implement the process and ensure the operation of this information system, it is necessary to provide up-to-date regulatory documentation, which is an independent and rather difficult task.

4. Development of digital economics and implementation of digital technologies require digitization of the regulation documents at all management levels.

5. In terms of corporate standard system it is important to develop the structure with clear division of the standardization objects into products and processes.

6. With the help of the general matrix simple model, the structure of informational data is emphasized and formed for the implementation of the technological process.

7. The developed system approach to the data formation will allow us to provide data about all fragments of the information system in a uniform way. This will allow future application of the information system not only at the production stage, but also to ensure cooperation with the design stages, technological process modernization and product sales.

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