Peculiarities of organizing the construction of nuclear medicine facilities and the transportation of radionuclide

Valeriy Telichenko¹, Galina Malykha¹ and Igor Dorogan¹

¹Moscow State University of Civil Engineering, 129337, 26, Yaroslavskoye Shosse, Moscow, Russia

E-mail: malykha@mail.ru

Abstract. The article is devoted to the organization of construction of nuclear medicine facilities in Russia. The article describes the main methods of nuclear medical diagnostics, as well as the peculiarities of nuclear medicine facilities that determine the need for application of specific methods for organizing and managing the construction, methods of requirements management in the organization of construction of nuclear medicine facilities. Sustainable development of the transport of radioactive isotopes from the place of production to places of consumption is very important for the safety of the population. The requirements management system is an important and necessary component in organizing the construction of complex facilities, such as nuclear medicine facilities. The author developed and proposed a requirements management system for the design, construction and operation of a nuclear medicine facility, which provides for a cyclic sequence of actions. This system allows reducing the consumption of resources including material and energy during construction and operation of complex objects.

1. Introduction

The term "nuclear medicine" refers to the medical specialty associated with the use of radioactive substances and ionizing radiation for the diagnosis and treatment of diseases [1]. Scientific studies [2-5] showed that the construction of buildings for nuclear medicine is a very complicated and important task. The main methods of nuclear medical diagnostics are:

- scintigraphy - scanning of the body with radionuclides;
- single photon emission computed tomography (SPECT);
- Positron emission tomography (PET), etc.

Radioisotope diagnostics uses radioactive isotopes involved in the metabolism and work of internal organs— isotopes of carbon \(^{11}\)C, fluorine \(^{18}\)F, copper \(^{64}\)Cu, gallium \(^{68}\)Ga, zirconium \(^{89}\)Zr, technetium \(^{99}\)Tc, iodine \(^{123}\)I, \(^{125}\)I and \(^{131}\)I, indium \(^{111}\)In, xenon \(^{133}\)Xe, etc. As a rule, isotopes with a short half-life are used to reduce the radiation load on the body.

Nuclear medicine facilities are highly technological and multifunctional. A large medical center that uses nuclear medicine methods can have a very complex organizational and technological structure, and can be located in buildings having various purposes [6]. Such centers carry out simultaneously clinical, scientific research, educational, and advisory activity.

For example, when the cyclotron is outside the medical institution it is necessary to transport radioactive substances on the city. The sustainable development of the transport of radioactive isotopes from the place of production to places of consumption is very important for the safety of the population.
Very important for safety are the pre-project and project stages of the life cycle, since it is at these stages that the main technical solutions affecting the safety of the nuclear medicine facility are being formed. During the construction phase, the main task is to comply with the adopted safety measures and eliminate emerging deviations, implement effective design and technological solutions.

Construction of a complex facility, such as a nuclear medicine facility, should be organized using the project management theory. In most cases, the focus is on managing the timing, cost, project resources, etc. However, in this case, the most important tasks of management are the tasks related to ensuring security, i.e. management of risks, requirements, project configuration.

2. Materials and methods

Nuclear medicine facilities have the features of both civil and industrial capital construction facilities, as they are equipped with a large number of complex medical equipment.

Therefore, for nuclear medicine facilities related to increased danger, the list of documents necessary for the construction of the facility (regardless of funding sources) should contain the documents of the following stages:

- pre-investment phase;
- design and ordering of equipment;
- construction and transportation of equipment;
- testing and commissioning;
- operation and transportation of isotopes and wastes;
- decommissioning and disposal.

After the approval of the investment program and the start of financing, technical requirements for the first level nuclear medicine facility (TR-1) should be compiled, which contain:

- medical and technological task;
- a list of regulatory and/or technical documents regulating the operation of the facility;
- urban development plan of the land plot where the capital construction project is planned to be located (land plots if several variants of the capital construction project are proposed), or a land use plan.

Based on preliminary data, the feasibility study (FS) as special kind of design documentation must be developed. However, to substantiate the necessity of the object, in this case it is not necessary, as it is the social object.

The feasibility study is the documentation containing the description of the investment project, including the main characteristics, terms and stages of the construction and location of the capital construction facility, the main architectural, technological, structural and volumetric planning, engineering and other solutions to create a capital construction facility, information on the main technological equipment, taking into account the TR-1, the compliance of these solutions with the current level of development of technology, modern building materials and equipment used in construction, as well as the estimated cost of the capital construction facility, the provision on the possibility (impossibility) of using the effective design documentation for the re-use of the capital construction facility, similar in designation, design capacity, natural and other conditions of the territory where the construction is planned.

The feasibility study consists of the following sections:

a) an explanatory note;
b) a scheme of planning organization of the land plot;
c) basic architectural solutions;
d) basic technological solutions;
e) basic design and volumetric-planning solutions;
f) information about the basic technological equipment, engineering equipment, on the networks of engineering and technical support and on engineering and technical solutions;
g) construction design;
h) the solution for organization of demolition or dismantling of existing capital construction facilities (if necessary);
i) a list of environmental protection measures;  
j) a list of measures to ensure fire safety;  
k) a list of measures to ensure compliance with the requirements of energy efficiency and the equipment of buildings, structures and facilities with energy metering devices;  
l) justification of the proposed (marginal) cost of construction;  
m) a draft design task.

The requirements for the content of the FS sections are set out in Part III of the Appendix to the Regulation on Technological and Price Auditing of the Justification of Investments Involved in Investment Projects for the Creation of Capital Construction Facilities, for which it is planned to conclude contracts, the task of which is simultaneously the design, construction and commissioning of capital construction facilities approved by the Decree of the Government of the Russian Federation No.563 dated May 12, 2017.

Based on the fundamental technological, constructive, architectural, engineering and technical solutions, Technical requirements of the second level (TR-2) are formed, which should be included in the draft design task. The development of TR-2 involves medical workers, architects, engineers, radiation protection specialists, and representatives of equipment suppliers.

A technological and price audit is advisable for expert assessment of solutions included in the FS. Such an audit is mandatory in case of budget financing. During the audit, the expert organization will hold a public discussion of the FS. The positive conclusion of the technological and price audit of the FS is the basis for continuing the implementation of the investment project. To reduce the implementation time and reduce the costs of the investment project, it is advisable to conclude a contract, the subject of which is simultaneously the execution of work on the design, construction, and commissioning of capital construction facilities. For budgetary organizations, the procedure for concluding such contracts is established by Decree No.563 of the Government of the Russian Federation dated May 12, 2017 "On the procedure and on the grounds for concluding contracts, the subject of which is simultaneously the execution of work on the design, construction, and commissioning of capital construction facilities, and on amending certain acts of the Government of the Russian Federation."

In this case, at the design stage, specific equipment brands, the requirements for its placement, the technology of performing the work, and the specific nomenclature of the materials used can be determined. Based on this, Requirements for working documentation will be formed, which will be the Technical requirements of the third level (TR-3), mainly addressed to suppliers of materials, equipment, subcontracting construction, installation, and adjustment organizations.

When constructing a complex facility, such as a nuclear medicine facility, great attention should be paid to managing the timing, cost, project resources, etc. In this case, the most important are the management tasks, which are directly related to ensuring security, i.e. management of risks, requirements, project configuration. Let's consider the use of the requirements management system when organizing the construction of nuclear medicine facilities. A requirement is a formalized representation of the expected characteristic of the projected facility. The basic set of requirements is formulated in the medical and technical design assignment. The building owner must clearly formulate all the requirements concerning productivity, efficiency and other properties of the future facility, otherwise the facility will not satisfy the building owner, or forced alterations will require additional investment. However, during design, as well as at other stages of the life cycle, requirements can be added and changed. Therefore, the project management system can include a requirements management system as management of the processes of formation and fulfillment of requirements at all stages of the life cycle.

Nuclear medicine facilities are classified as especially dangerous facilities according to Article 49 of the Urban Planning Code [7]. The requirements for the nuclear medicine facility can be divided based on who establishes these requirements. This feature allows distinguishing the requirements of regulatory documents, the building owner, local authorities, other bodies authorizing the operation of the facility.

The transportation of radioactive cargoes requires design of the route and careful preparation. According to the requirements of the police, the transportation route should not pass near major cities, as well as medical institutions. However, the radiopharmaceuticals must be transported just from
hospitals in the major cities. The transport vehicle must have the shipping certificate. Workers, engaged in loading, unloading and transport, must pass a special training. The vehicle for the carriage of radioactive cargo should have special colouring, warning signs and information plates.

When transporting by car it is not allowed longitudinal acceleration (braking) more than 2 g, lateral acceleration exceeding 1 g. Transport can be accompanied by a police car, other emergency vehicle needs to be ready. In the event an emergency situation should be developed emergency map events to ensure a quick handling of the incident and its consequences.

Mandatory requirements [8] have to be follow if you have exceeded the critical amount of radionuclide. For xenon $^{133}$Xe the limit of activity is 0.01 MBq, for gallium $^{68}$Ga – 0.1 MBq, for carbon $^{11}$C, fluorine $^{18}$F, copper $^{64}$Cu, iodine $^{122}$I and $^{131}$I – 1 MBq, for technetium $^{99}$Tc, iodine $^{123}$I - 10 MBq.

The Urban Planning Code [7] specifies the requirements for compliance with which the constructed facility is checked when issuing a permit for commissioning. These include the requirements of technical regulations, urban planning of the land plot, project documentation, technical conditions of organizations operating engineering and maintenance networks. The requirements of energy efficiency and equipment of the facility with devices for accounting for energy resources, the requirement to transfer information to the information system for ensuring urban development are particularly specified. Compliance with regulatory requirements for the construction facility is verified at the design stage by the General Board of State Expert Review of Russia, at the construction stage - by the state construction supervision authorities, Federal Environmental, Engineering & Nuclear Supervision Agency, construction supervision by the project owner and contractor, architectural supervision by the project organization, at the stage of authorization for operation - by the organizations licensing medical activities, using ionizing radiation sources and appropriate surveillance. Thus, it is necessary to improve the system verification of requirements for the construction facility. Special difficulties are caused by reconstruction at health facilities [9], when during the construction and installation work, it may be necessary to change the solutions made earlier. Requirements management is an important part of the project management. In the field of construction organization, this part is just beginning to be applied. The requirements management system can be represented as the following scheme (Figure 1).

In the projects of nuclear medicine facilities, the requirements management system can be implemented in the form of an independent or built-in information system that allows creating, changing, and saving requirements in a form of a database. This allows tracking the history of the appearance and compliance with requirements, document the process, transfer knowledge to other project participants. Requirements can be represented as a hierarchy (tree), each branch of which represents a particular group or subgroup. In particular, the requirements to a facility can be divided into the following groups:

![Figure 1. General presentation of the requirements management system](image-url)
– requirements of the authorities and the public (environmental protection, social efficiency, architectural expressiveness);
– user requirements (performance, durability, adaptability, maintainability, etc.);
– investor requirements (economic efficiency, payback);
– requirements for supervision (compliance with standards);
– requirements of the contractor (manufacturability, labor protection).

The processing of requirements consists of research, analysis, formulation and approval of requirements with subsequent tracking of their implementation in the project, on the construction site and in the period of operation. When developing a project or when constructing a facility, the list of requirements serves for setting tasks by the customer, solving them by the designer, and implementing the solutions by builders and erecting personnel. At the research stage, identification of the requirements that were not originally established, their discussion and specification are carried out. At the analysis stage, the possibility of complying with the requirements and costs for this process is evaluated. After the analysis, a new or changed requirement is formulated; calculations and design work are carried out, if necessary. The changed design solution, if necessary, is examined and approved by the customer. An example of dynamic requirements management in the process of reconstruction may be the selection of equipment elements in technological systems. For example, when designing a reconstruction project or even when purchasing new equipment, it becomes clear that a previously installed element of a technological system is no longer manufactured and cannot be delivered. In the process of equipment replacement, the requirements management system should prompt that another element will change the pressure and fluid supply in the system, the required drive power, which may lead to the replacement of the power distribution and protection system. In addition, dimensions and mass of equipment become different, which changes the requirements for building structures.

It is advisable to automate the verification of requirements; however, at the current stage of the development of information technologies, complete automation of the verification processes is impossible. For this purpose, it is necessary to solve many problems of compatibility of software products, formats and databases, data transmission and recognition. At present, to check the requirements, it is necessary to involve experts in the areas under consideration. To manage requirements for the design, construction and operation of a nuclear medicine facility, it can be implemented using Excel spreadsheets, or Access databases, as the domestic system for such purpose has not been developed yet. The requirements management system provides the following cyclical sequence of actions.

1. Specialists of the technical project owner and the designer handle the array of requirements of the first, then second and third levels. The requirements are formalized and entered into the table in accordance with the hierarchical principle. It is recommended to observe the hierarchy of the elements of equipment and structures, technological systems, facilities, offices and buildings of the nuclear medicine facility.

2. The head of the requirements management system sets the milestones for verifying requirements and forms expert teams for each milestone. The same or different experts may be involved at various inspection milestones.

3. At each inspection milestone, experts verify the requirements and record the results in the database, put the date of verification and their name (electronic signature). The list of requirements that were not met at the time of verification is reported to the project management.

4. The project manager takes measures to fulfill the specified requirements using available resources. In exceptional cases, the request itself can be changed by the decision of the customer or based on the application of special technical conditions.

3. Results
Verification of the requirements is carried out at the design, construction, and commissioning stages. According to the decision of the requirements system manager, additional requirements verification can be assigned, for example, during the period of operation.
The requirements table is filled during the development of technical requirements (TR-1, TR-2, TR-3) at the pre-project stage, at the design and construction stages. The rows of the table have hierarchical subordination. The table contains a request and information about the source of the requirement: regulations, requirement of the customer, etc. The requirement value can be numeric, logical or verbal, and in the form of a date. For a numerical requirement, the conditions "equal", "less", "less than or equal to", "more", etc. may be used.

The note can specify a method for calculating the numerical value of a requirement or a reference to a document containing such a method. The database table can also contain a reference to a document that confirms the fulfillment of the requirement. During verification, the expert who is entrusted with the verification of the requirements shall indicate in the "Completion" column the value to which the requirement corresponds. When entering a value, at which the specified condition is satisfied, the corresponding table cell automatically turns red, otherwise it is green (the original cell color is white). If the values for the entire group of requirements are the same, then the group's header line also turns green. Since the number of requirements of different levels can be several thousand, the rows of the database should be filtered and sorted, as well as the "routes" - interrelations of various requirements. However, even without these capabilities, the requirements verification table is a full-fledged document that allows significantly improving the quality of design and construction and installation works, speed up the process of commissioning the facility.

This system allows reducing the consumption of resources including material and energy during construction and operation of complex objects.

4. Conclusion

The conducted research established that the revealed features of nuclear medicine facilities determine the necessity of applying modern methods of project management. It has been established that the requirements management system was an important and necessary component in organizing the construction of complex facilities, such as nuclear medicine facilities. Automation of the requirements verification process could greatly simplify the work of experts. However, today, due to a large number of unresolved problems regarding the compatibility of software products, formats and databases, data transfer and recognition, it is not possible to completely automate the process of verifying requirements. However, with the further development of information technology, it will be possible to connect data sources for automatic verification of requirements, and to use automated generation of output documentation based on templates. At the same time, the automatic transfer of data from other programs (terminals) generates a new problem - the reliability of the transmitted data, which must be confirmed by parallel communication channels and in some cases re-checked.

References

[1] Korsunsky V N, Kodina G E and Bruskin A B 2007 Yadernaya meditsina. Sovremennoe sostoyanie i perspektivy razvitiya (Nuclear medicine. Current status and development prospects). Nuclear Strategy XXI 4 pp 4-6
[2] Budinger T.F., Jones T. 2014 History of Nuclear Medicine and Molecular Imaging. Comprehensive Biomedical Physics, pp 1-37
[3] Lee J., Kim B.-I., Johnson A.L., Lee K. 2014 The nuclear medicine production and delivery problem. European Journal of Operational Research, 236(2), pp. 461-472
[4] Wang S. 2015 Chinese Medical Sciences Journal, 24(2) pp. 85.
[5] Merschbrock C., Munkvold B.E. 2015 Computers in Industry, 73, pp. 1-7.
[6] Russian State Standard SP 158.13330.2014
[7] Russian State Law 190-FZ 2004 Urban Development Code of the Russian Federation
[8] 2004 Safety rules during transportation of radioactive materials. NP-053-04 (Moscow: The Federal service for ecological, technological and nuclear supervision) 103 p
[9] Malykha G G, Guseva O B, Petrunin V V and Tesler N D 2012 Vestnik of Moscow State University of Civil Engineering 9 pp 214-220