Improving Processes of Design and Construction of Nuclear Medicine Facilities

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Abstract The article describes the organisation of the design and construction processes for nuclear medicine facilities in Russia. One of the key problems in this field has to do with the need to use custom-designed equipment whose specifications must be tailored to specific design solutions early on in the design process. However, this factor is ignored by the design-in-stages approach and by the legislation that regulates this area in Russia. Based on our vast experience drafting and analysing regulations, we have come up with a solution to this problem. The idea is to include a preliminary pre-design stage in the process. This preliminary stage would comprise a preliminary assessment of the safety of the healthcare facility, a feasibility study, a selection of the manufacturer to produce the required custom equipment and a draft sketch of the equipment. This would eliminate problems and errors at the later design and construction stages, eliminating non-conformances and the need to make amendments to existing documentation. At the same time, the proposed solution would not increase the time needed for design and construction.

1 Introduction

Acceleration complexes, radiation scalpels, X-ray, MRT, single-photo and positron tomography (PET-centres), radionuclide therapy centres, proton and ion therapy centres, neutron-collision and neutron-capture therapy centres allow doctors and medical physics to achieve unprecedented results when it comes to diagnosing and treating a broad variety of medical conditions. [1] Nuclear medicine is a high tech sector that relies on unique and highly complex equipment, a lot of which is imported. Manufacture of this kind of equipment requires research and experiments, which take time and money.

A decision about whether design documentation is needed for custom-based and unique equipment must be made in advance to ensure optimal planning and layout solutions for all the treatment and diagnostics processes that utilize ionizing radiation and to ensure radioactive safety. [2] However, when such projects are financed by the state, the preliminary stage usually gets curtailed with the technical customer being made responsible for developing a specification for the required equipment.

Terms of Reference for equipment development should be elaborated by the customer with the participation of the design company's specialists. At the same time, the design company

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should obtain initial data for designing including dimensional specifications, static and dynamic loads of the equipment, power consumption, ventilation, lighting and biological protection requirements. This data may be supplied by the equipment manufacturer only, while the equipment manufacturers' data varies widely.

At the same time, the Technical Client may not specify a specific equipment manufacturer in the Terms of Reference prior to finishing equipment supply bidding (tender) procedures. Likewise, the designer may not specify a specific equipment brand in the documentation. In addition, the bidding for a contract to deliver production equipment may not be announced before determining the maximum initial contract price (MICP), which is usually determined during the project documentation elaboration.

Thus one of the main problems with organizing the design and construction of nuclear medicine facilities in Russia has to do with the fact that it is often impossible to develop equipment specifications needed for a specific project in advance before actual design work is commenced, especially when the project is financed by the state. One corollary of this is frequent design errors that then have to be corrected at high cost and that result in delays in construction.

2 Methods

In order to find a solution to this problem we need to identify what happens before work starts on a project in earnest and how that preliminary work can ensure successful multi-level relations between the design firm, the customer, suppliers and equipment manufacturers [3], as well as determine how this approach to organizing the design efforts impacts on the overall project implementation timeframe.

For the nuclear medicine facilities related to increased risk it is proposed to create a list of documents required for the pre-design stage regardless of the source of funds. When elaborating technical specifications, it is possible to use preparatory materials for the land-use planning scheme. [4] They reflect the basic medical institution profile, suggested volume and scope of medical services, planned number of patients, planned number of attending and attracted physicians, the approximate number of beds in the departments (for the hospital). [5] The requirements should be drawn up by the Technical Client and are subject to the state and local government customer approval in case budget financing, or invest or approval - in the case of private-venture funding.

For the preliminary safety issue resolution it is advisable to draw a sketch of the facility, including medical equipment selected, and elaborate a Preliminary Medical Facility Safety Justification (PMFSJ). The PMFSJ endorsement and approval procedure should be statutorily prescribed. Based on the practical experience, the authors suggest submitting a PMFSJ report for approval to the Federal Service for Supervision of Consumer Rights Protection and Human Well-Being (Rospotrebnadzor), Federal Service for Ecological, Technological and Nuclear Supervision (Rostekhnadzor), as well as to local authorities responsible for the sitting of hazardous facilities.

According to the author, PMFSJ may comprise:

1. General description of the medical facility (list and the scope of services, floor area and types of premises, etc.);
2. Characteristics of the facility location (preliminary surveying results, health and sanitary conditions);
3. General design approaches;
4. Ensuring radiological safety (radiation dose, normal operation limits, and biological protection);
5. Requirements for custom-made medical equipment;
6. Ensuring the fire safety and escape routes;

7. Preliminary decisions on the facility civil defence;
8. Ventilation, air conditioning, heating, water supply, sewerage, and electricity supply systems requirements;
9. Ensuring counter-terrorist security.

It is also suggested to make the PMFSJ a mandatory information element for obtaining a land plot development plan (LPDP).Such a procedure will later facilitate obtaining construction permits and medical facility commissioning.

Simultaneously with elaborating the PMFSJ, the Technical Client may carry out a bidding procedure for designing and manufacturing custom-made medical equipment. Based on the bidding results, a contract could be awarded to a manufacturer. Part 16, Article 34 of the Federal Law No. 44-FZ 1 provides for a life cycle contract (LCC) including facility designing, development, construction and repairs, as well as maintenance and disposal, if required. However, medical facilities are not included among such facilities [2].Therefore, the full-scale use of such a contract in the area of health requires amendments to the legislation.

However, even without amendments to the legislation, it is possible to provide for the phased implementation of the awarded contract by the manufacturer .In this case, the custom-made equipment development-and-supply contract should require the equipment data delivery by the contractor (manufacturer) upon the completion of conceptual and contract design, as well as working documentation, so that the designer could include them in the project in a timely manner.

Based on the preliminary data of equipment configuration and building arrangement, it is suggested to elaborate a special type of pre-design documentation –Technical and Economic Calculation (TEC).It differs from the Feasibility Study in that the economic feasibility of the construction of a medical facility need not be proved, because it is a social entity and it was shown to be necessary at the pre-investment stage during the investment programme preparation.

In the Technical and Economic Calculation, a comparison of building arrangement options is made, the number of stories, building ground location and departments' locations are determined and technological and design concepts are compared. Proposals for the organisation and building technology, especially for the reconstruction cases are made out.

The customer uses the results of technical and economic calculations to obtain technical specifications (TS),plan the elaboration of special technical specifications (STS), select a land plot, and prepare and obtain the land plot development plan (LPDP).This work is still anyway performed by the customer; however, the designer's role in relevant data preparation is not clearly circumscribed as yet.

The offered scheme of the pre-design stage is shown in Table 1. Under such an arrangement, the processes and results thereof (documents) are taking on some features of the life cycle, which is characteristic of the industrial facilities, and in case of a medical facility leads to project quality improvement.

Table 1. Pre-design stage arrangement

Term	Technical Client	Designer	Manufacturing facility
1 month	Start of financing;Working out design requirements	Offers for pre-design work, site investigations	Offers for equipment development and supply
2 months	Bidding procedures for pre-design work and equipment development	Working out sketches PMFSJ, EIA	Conceptual equipment design
3 months	PMFSJ approval; MTA preparation; obtaining TS, STS, LPDP	Working out TEC; engineering survey	Engineering equipment design

1 month	Bidding procedures for design work; project planning	Offers for design work	

As the diagram indicates, additional work is performed at the pre-design stage that was not previously envisaged. It seems that the period of design work performance and the project as a whole should have been extended. However, when looking closer, it becomes clear that this would not happen. In fact, the Technical Client, prior to issuing a design assignment, still spends several months obtaining technical requirements for connection of utilities systems and technical support network, as well as for technological connection to power networks. In case of custom-made equipment, it takes some time to search for a manufacturer and carry outbidding procedures.

Therefore, with proper work management, the total project time is practically not extended, and some gaining in terms of duration and project documentation implementation property may be expected at the design stage.

At the end of the pre-design stage a medical and technical assignment (MTA) is prepared according to [3]. It almost replaces the design engineering assignment and provides Technical Specifications for a medical facility.

Table 2 shows the proposed design stage and initial construction stage arrangement taking into account coordination of business processes of the Technical Client, design company, manufacturers and contractors.

Table 2. Design and construction stage arrangement

Term	**Technical Client**	**Designer**	**Manufacturing facility**
4 to 8 months	Design and survey work monitoring; bidding procedures for working documentation; Equipment manufacture monitoring	Design documentation	Working documentation for equipment
2 to 3 months	Working documentation and survey results monitoring; obtaining construction permits; bidding procedures for contract work; acceptance of the preparatory stage working documentation	Working documentation of the preparatory construction stage	Manufacture of equipment
4 to 6 months	Equipment and working documentation acceptance; handing over of equipment for installation; acceptance of construction and assembly operations results	Working documentation; field supervision	Equipment manufacture and supply

Discussion

As can be seen from the schemes given above, custom-made equipment development and manufacture should be coordinated with the facility design and construction. Thus, data of the technical project for the custom-made equipment are used to elaborate the design documentation (DD).When preparing the design documentation, designers develop working documentation, and manufacturing facility may start equipment manufacture, since its technical requirements have been obtained on the basis of TEC results.

Carrying out a bidding procedure for design and survey work is also an important issue for the medical facilities designing. Regulatory documents [4] set specific requirements for the designer only in terms of technological solutions and special sections of the documentation where medical facilities are not explicitly set out (requirements for the latter are set for the installation contractors only).It is advisable that the work type list should

include the work regarding preparation of design documentation, for which CRO's approval is required, work for preparing architectural and technological solutions related to medical facilities or for nuclear medicine only.

In addition, in some cases the design work and equipment manufacture may be performed by a very limited range of specialists, often by a sole supplier. However, this work is not included into the statutory list of work and services provided by a sole supplier. It is suggested to complete the above list of work with medical facilities design and special technological equipment supply work.

Conclusions

The study has confirmed the advisability of having a preliminary stage in the design of nuclear medicine facilities, during which the design firm, the technical customer and the manufacturer of custom-designed equipment work together on specifications.

The study also identified the steps that need to be completed during the preliminary design stage.

Analysis of the construction process of nuclear medicine facilities using the proposed approach has shown that the time needed for design and construction does not increase in this case, while the expenses and labor that usually get spent on making amendments to the design are reduced.

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