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Climatized module as the basic unit of high-tech medicine. Problems of development and application

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Abstract. In this article a study of climatized module application as a product for clean rooms complex formation in different technological schemes was made. The problems of clean rooms modular formation as well as its all advantages and disadvantages are considered. The clean rooms classification was analyzed. The scheme of climatized module classification has been derived. The problems of modern rules and regulations in sphere of clean rooms organization in Russian Federation was revealed and assumptions for improving of this situation were made. The following issues are considered: ensuring a high level of clean rooms equipping and execution; development of modular construction in medicine, pharmaceutical production, production of microelectronics and other fields on the climatized module basis; the possibility of upgrading obsolete technological solutions; creation of a structural classification of the climatized module for both medical technology and for various areas of possible application. The conclusions on the research were made.

Key words: clean rooms, complex, prefabricated building, medical climatized module, particle concentration, hermetically sealed.

1. Introduction

In the development of modern high-tech production clean rooms (hereinafter CR) construction and application occupies an important place [1].

In the usual premises of industrial or medical processes air purity is estimated by the mass concentration of pollutions in the air. Unlike them, CR are characterized by a countable concentration of particles, that means their number per air volume unit. The main factor in CR concept determining is that these rooms are characterized precisely by the countable concentration of particles, i.e. the number of particles per air volume unit as well as the size of these particles (0.1, 0.3, 0.5 microns and etc.). Therefore the peculiarities of maintenance and determination of purity indicators, specific requirements for control devices, air particle counters, interior finishings, general climate support system, etc. 2].

The purpose of this study is to improve the medical services level through the competent climatized module (hereinafter MK) use in the clean room complex (hereinafter CRC) organization and the creation of better conditions for high-tech industries (pharmaceuticals, microelectronics, military industry, etc.).



This goal determines the following objectives: 1) ensuring a high level of equipment and execution of CR; 2) development of modular construction on the CM basis; 3) the possibility of obsolete technological solutions upgrading; 4) the creation of CM structural classification for both medical technology and various areas of possible application. The study was carried out by the method of morphological analysis of information and its synthesis.

2. State of the field

The idea of using CM in high-tech medicine is not the new one (fig. 1). Throughout the entire world, the creation of hermetic, multi-profile, antibacterial reusable rooms with the possibility of high factory availability has proved its superiority over traditional interior finishes. In several countries the CRC development is standardized by regulatory documents. For example, in USA special rules for CR interior finishing by definite kinds of materials, that have proved themselves well enough over the past 30 years, and certain norms for air exchange and equipping such premises has been adopted. In Russia CM implementation for CRC is insufficiently explored theme and it has limited application because of inadequate compliance of regulatory documents with modern realities, as well as the high cost materials for CM. However, CM development is changing and some companies actively engaged in CM development and application for CRC aims [3].

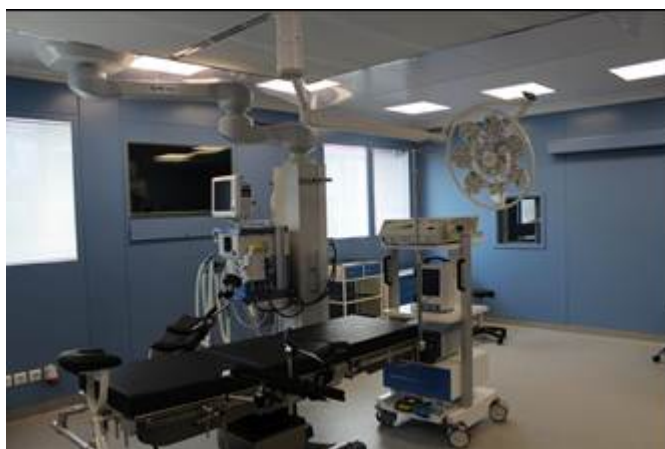


Figure 1. Application example of CR on CM basis for operating room.

3. CM design features

CM is a separately designed, multifunctional and reusable module for the organization of special cleanliness classes rooms. CM is a fast-erectable construction (prefabricated building), which has a huge number of advantages over the traditional finishing in the field of CRC formation in pharmaceutical production, micro-electronics production, the formation of special cleanliness classes premises in medical technology, etc.

Its main features are followings: 1) premises air-tightness and high-tech antibacterial finishing with increased wear resistance; 2) CM is a full-fledged integrated solution that includes engineering systems solutions such as ventilation, automation engineering, water treatment and water disposal, electrical engineering, equipping with necessary technologies, etc.; 3) increased factory readiness and an individual project for further CRC servicing and reorganization development; 4) the possibility of multiple use of the CM (dismountable technology) as a prefabricated building (hereinafter PFB); 5) the possibility of complex technological units formation, when using CM as PFB or stand-alone self-supporting modules [4].

The CM development in our country and all around the world has made it possible to reduce the undesirable consequences of the post-operation period, as well as to form full-fledged technological processes without violating the purity of air exchange, cleanliness classes, and the room mismatch in the process performed in this unit. It should be noted that the execution and development of the CM

must be carried out by high-quality specialists with extensive experience in this field, understanding of technological processes, the ability to differentiate technologies (for example, medicine from pharmaceutical production and etc.), and also be able to verify the products quality standards [5, 6].

However, despite all the advantages of CM for CRC, they have a number of disadvantages that limit the CM development in Russia and their mass use. Such shortcomings include: 1) the lack of a strict regulatory and legal framework for the design, use and implementation of CM in CR. Nowadays, there are a number of regulatory documents that describe the principle of constructions and implementing of the CRC in Russia. They consider the air cleanliness classes, finishing materials quality, air-tightness, chemical treatment and resistance to it and other aspects. But at the same time, in that documents there is no clear explanation of how the CRC should look in the general constructive and technological execution. Nowhere is it said about the possibility of CM use for the CRC organization as medical equipment. This disadvantage leads to unfounded freedom of choice, which encourages irrational solutions, as well as the design decisions complication; 2) the high cost of the full complex for the CR organization on the CM basis (from the project development to the CM commissioning). It is worth to mention the high price is determined by final products high quality characteristics, as well as by the uniqueness of each manufactured unit. Perhaps the creation of a universal modules series, as well as design solutions that can be laid out as separate parts in modern technology, with all the previously worked out and calculated engineering loads and equipment, will lead to a price reduction in both in production and in designing. After all it is necessary to remember that the CRC organization with the help of CM is the development of high-tech medicine, and, consequently, the improvement of the public health quality [7, 8].

4. CM specific features

CM is a module that is directly related to PFB [9]. According to its structural base it is a metal frame, which can be executed in several forms [10]. The most used and popular ones are: 1) stand-alone modules inside a common room. These modules have a frame, which is covered with enclosing panels. All necessary engineering systems are located under the floor and (or) in the thickness of the wall structures. Air purity maintenance systems (air exchange and air conditioning systems) are located on floors and places specially designated for them, or on the module itself. 2) The module that is installed in the finished premises. This module is a metal frame inside the room with hanging panels. All engineering systems are behind the panels. 3) The module, which is the PBF itself. This stand-alone module can be used to form buildings by combining several elements. A good example of this use of CM may be feldsher-midwife station (hereinafter FMS), which are built in hard-to-reach areas or in areas with different emergencies [11].

Enclosure structure is a composite panels made of various materials with special covering, which must withstand a large number of chemical treatment cycles. Such panels can be plaster-metal, panels made of HPL plastics, stainless steel filled with gypsum wall board and etc. The ceiling is made using the clip-in system, for the possibility of constant control over the ceiling space and engineering systems [12].

The main feature of the whole CM is that it is hermetically sealed. Floor covering, ceiling structures hairline joints, joints of wall fences, doors, glass blocks - all these elements are carried out hermetically with the help of sealing rubber, shapes, sealants and etc [13-15]. For example, in the company LLC «NPO StroyMedService» a unique system of fixing and sealing HPL panels in the CM was developed. Their method allows fixing and sealing the panels with the possibility of their further «hot» replacement, or completing reorganization.

The special design, the structure air tightness, the sustainable development, the modern technologies use and the multifunctional performance are defined CM as modern medical equipment, which should and can improve the level of CRC execution, the level of public health, and increase the implementation level of various production facilities where CR is needed.

5. CR classification

As it was mentioned earlier, the CM for CRC has a number of design features that depend on the CR classification.

An important CR characteristic is the definition of its class. The CR is characterized by a classification number that determines the allowable concentration of micro-particles in 1 cube meter of air. In the CR, several clean zones can be organized. Each clean zone should be in a laminar airflow, which allows to create local clean zones, such as a laminar flow unit. The nature of the air flow in the CR largely depends on the features of the construction of both the CM and the climate systems.

In table. 1 the CR classification according with interstate standard GOST ISO 14644-1 «Clean-rooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration» is illustrated.

Table 1. Cleanliness classes according to GOST ISO 14644-1.

Cleanline ss class	The maximum permissible number of particles in 1 cube meter of air with dimensions equal to or greater than, μm					
	0,1	0,2	0,3	0,5	1,0	5,0
1 ISO	10	2				
2 ISO	100	24	10	4		
3 ISO	1000	237	102	35	8	
4 ISO	10000	2370	1020	352	83	
5 ISO	100000	23700	10200	3520	832	29
6 ISO	1000000	237000	102000	35200	8320	293
7 ISO				352000	83200	2930
8 ISO				3252000	832000	29300
9 ISO				35200000	8320000	293000

In table 2 there is a more detailed CR classification according with different standards.

Table 2. CR classification according with different standards.

GOST ISO 14644-1	GOST R 50766-95	USA standard 209 E	USA standard 209 D
1 ISO	R1	-	-
2 ISO	R2	-	-
3 ISO	R3 (1)	M 1.5	1
4 ISO	R4 (10)	M 2.5	10
5 ISO	R5 (100)	M 3.5	100
6 ISO	R6 (1000)	M 4.5	1000
7 ISO	R7 (10000)	M 5.5	10000
8 ISO	R8 (100000)	M 6.5	100000
9 ISO	R9 (1000000)	-	-

The air purity requirements during CRC design process are usually determined by technical conditions, technological assignment, technological regulations (processes), etc.

6. Micro-pollutions sources

The ambient air contains a huge amount of micro-particles, which directly or indirectly affect the process in the CRC. Micro-pollution of air is allocated by personnel, enclosing structures, equipment, penetrate into the CR from the environment. In the clean rooms 70-80% of pollution comes from human activities, 15-20% from the work of specialized equipment, 5-10% of pollution comes from the environment [16].

These indicators show that the CM for the CPC must be hermetically sealed and equipped with an air exchange system set.

A clean room is an artificially created environment. There are no such conditions of purity on the Earth. For example, ISO class 5 corresponds to air purity in the atmosphere at an altitude of more than four kilometers. Maintaining a given cleanliness class is a constant struggle with possible pollution sources, maintaining a permanent barrier between them and an external natural and polluted environment.

NASA conducted a study on the relationship between the particles number and the number of microorganisms in the air. This was necessary to simplify classifications and calculations, as well as standardization and licensing of CR. Calculation of microorganisms in the air is a long and costly research, and the micro-particles calculation is carried out quickly and accurately enough. The NASA standard NHB 5340 was developed, which established a clear dependence between the number of particles and microorganisms. This dependence is illustrated in Table. 3.

Table 3. Dependence between the particles number and the number of microorganisms according with NASA standard NHB 5340.

Cleanliness class according USA standard 209 D	Particles		Microorganisms	
	Diameter, μm	Quantity in $1 \text{ ft}^3 \text{ (L.)}$	Suspended in $1 \text{ ft}^3 \text{ (L.)}$	Precipitate d per 1 ft^2 per week (1 sq. m. per week)
100	> 0,5	<100	<0,1	1200
		(<3,5)	(<0,0035)	(12900)
10000	> 0,5	<10000	<0,5	6000
		(<350)	(<0,0176)	(64600)
	> 5,0	<65		
100000	> 0,5	<100000	<2,5	30000
		(<3500)	(<0,0884)	(323000)
	> 5,0	<700		
		(<25)		

The development of that standard promoted the development of various classifications, including the Russian one. GOST ISO 14644-1 was created with reference to the American scientists developments and researchers of scientists from around the world.

7. CM classification for CRC

Based on the above facts, a morphological analysis of the information was performed and an intrinsic model of the CM classification was determined.

The main idea of classification is to designate CM as equipment that allows producing better CR quality. The use of CM will allow reducing the time and resources for the CRC technology development. The classifier creation will allow the most accurate and fast formation of technical requirements for CM equipping.

From the research, the following main parameters when choosing CM can be determined: 1) the main point of the classifier is the premises purpose. This parameter means its technological belonging. From this point it is possible to get an extensive premises list (medicine, pharmaceutical production, microelectronics, military industry, laboratories of different directions, etc.). Having determined the premises purpose, it becomes possible to determine the area of these premises, their overall dimensions, as well as necessary equipment. This item will allow to immediately get a necessary equipment list, its load on all engineering systems and the frame as a whole; 2) The second important point is the cleanliness class (Table 1). Taking into account this classification, it is possible to distinguish the cleanliness class parameter in the future room. Moreover, based on this characteristic, it is possible to single out air distribution and climate systems. This is the equipment selection for capacity, dimensions, power consumption, the class of filter elements, etc. The equipment data must correspond to the cleanliness class (Table 1). Having obtained this data, it becomes possible to immediately determine the necessary characteristics of the equipment; 3) The next item is chosen according with points 1 and 2 of the classification/ This is the engineering systems choice. In this paragraph, the need for water and sewerage, their location in the module is determined. The necessity in providing with electricity, its costs an demanding capacities for equipment and the connection points number are also determined. Based on point 1, important secondary engineering systems are identified (for example, medical gas supply systems); 4) CM design features. At this point the construction scheme is selected: the frame (depending on the equipment weight, its attachment, etc.), enclosing structures (choice of wall panels, ceiling panels, door types, etc.), choice of lighting, choice of floor covering; 5) the last item of the classifier - additional systems. This point is the most extensive, because it includes systems that, based on item 1, differ for each technology. These are such systems as automation and dispatching system, smart lighting system, emergency prevention systems, air quality control systems, etc.

If to develop this classifier and take into account all aspects and problems in the formation of tasks for the CM production, it will be possible to shorten the project production time, and also allow the customer to get the most extensive product view and find out more about the necessary product characteristics.

The main problem for today is the lack of a full understanding of all the CM advantages over the traditional finishing, as well as the lack of strict control of the CM compliance and equipment with all the necessary technological processes characteristics in which this CM will be used. The development of the classifier will allow to avoid annoying and sometimes critical errors in the CRC formation, as well as additional costs that, in the case of organizing high-tech production, can be quite critical [17].

8. Conclusion

After conducting this research, conclusions were drawn on the following issues: 1) ensuring a high level of equipment and execution of clean rooms. The use of CM is the logical and most rational way to organize a clean room complex in different technological schemes. CM is a high-tech product that allows to reduce the problems that arise in the formation of complex technological processes; 2) development of modular construction on the basis of CM. Use CM in modular construction is the most rational technological scheme. Simplicity of constructive solutions in combination with high technologies, as well as increased factory readiness allow to install the building ready for operation in the shortest possible time, without huge labor costs; 3) the possibility of upgrading obsolete technological solutions. CM is a flexible unit that has huge potential for application in the finished architecture and can be located in the working technological scheme, which will allow increasing the level of techno-

logical production, as well as reducing the costs of reconstruction and major repairs; 4) creation of CM structural classification. Criteria analysis for classification will create a full-fledged and voluminous CM classifier that will simplify the development elements and decision-making on the introduction of CM into the high-tech production technological scheme.

This study made it possible to determine all the advantageous CM characteristics, to define the classification of these modules and to designate the MC as an integral part of the high-tech production progress.

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