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Обзор российской нормативной документации по организации и функционированию кабинетов и отделений магнитно-резонансной томографии

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АННОТАЦИЯ

Диагностические исследования, проводимые с использованием какого-либо медицинского оборудования, нуждаются во всестороннем контроле, который обеспечивается рядом нормативных документов. Особенное внимание уделено рентгеновским методам визуализации, но в области магнитно-резонансной томографии можно заметить как недостаточность этого внимания, так и разнонаправленность усилий по нормированию.

Это объяснимо: в основе данного диагностического метода не используются источники ионизирующего излучения, а магнитные поля хоть и оказывают некоторое воздействие на здоровье человека, особенно на персонал, который работает в кабинетах магнитно-резонансной томографии постоянно, но являются относительно безопасными для пациентов, которые приходят на диагностическую процедуру время от времени и не имеют в своём теле инородных металлических (стальные имплантаты) или электронных (кардиостимуляторы, нейростимуляторы) изделий.

Тем не менее незнание и несоблюдение требований, которые носят как рекомендательный, так и обязательный характер, может значительно повысить риск причинения вреда пациентам или персоналу, а также привести к снижению качества визуализации и диагностики. Отдельная особенность сферы регулирования магнитно-резонансной томографии состоит в том, что за последние десятилетия было вновь издано либо пересмотрено более десятка различных стандартов, санитарных норм, правил, писем и рекомендаций, значительная часть которых дополняет или дублирует друг друга, либо противоречит другим документам. В результате сложно обеспечить соответствие кабинета магнитно-резонансной томографии требованиям нормативных документов.

В данной работе проведён обзор действующей на территории России нормативной документации, относящейся к организации и функционированию кабинета магнитно-резонансной томографии, выделены аспекты, наиболее важные с точки зрения безопасной и качественной эксплуатации, и сформулированы шаги, необходимые для модернизации системы как с точки зрения качества диагностики, так и безопасности диагностических исследований с применением ядерно-магнитного резонанса.

Ключевые слова: магнитно-резонансная томография; нормативы; медицинская организация; организация здравоохранения.

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The Russian regulatory documents on the organization and functioning of offices and departments of magnetic resonance imaging

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ABSTRACT

Diagnostic studies that are conducted using any medical equipment require comprehensive control, which is provided by several regulatory documents. Particular attention is paid to X-ray imaging methods, but in the field of magnetic resonance imaging, one can notice both the lack of attention and the multidirectional efforts for its normalization.

Understandably, this diagnostic method is not based on the use of ionizing radiation, and magnetic fields have some effect on human health, especially on personnel who work in magnetic resonance imaging rooms at all times. They are safe for patients who come to the diagnostic procedure from time to time and those without foreign metal (steel implants) or electronic (pacemakers and neurostimulators) objects in their bodies.

However, ignorance and non-compliance with both advisory and mandatory requirements can significantly increase the risk of harm to patients or staff, as well as lead to a decreased quality of imaging and diagnostics. A separate feature of the field of magnetic resonance imaging regulation in the past decades includes more than a dozen of different standards, sanitary norms, rules, letters, and recommendations that have been published or revised, of which a significant part complement or duplicate each other, or completely contradict each other. Therefore, the need to ensure the compliance of the magnetic resonance imaging room/department with the requirements of regulatory documents is greatly complicated.

This study provides an overview of the regulatory documentation in force in Russia related to the organization and functioning of a magnetic resonance imaging room/department, highlights the aspects that are most important from the point of view of the safe and high-quality operation, and formulates the steps necessary to modernize the system, both from the point of view of the quality of diagnostics and the safety of magnetic resonance imaging studies.

Keywords: magnetic resonance imaging; magnetic resonance imaging; organization and administration; practice guidelines as a topic.

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审查俄罗斯关于磁共振成像室和部门的组织和运作的监管文件

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简评

使用任何医疗设备进行的诊断研究都需要全面控制，这由许多监管文件提供。 特别关注X射线成像方法，但在磁共振成像领域，人们可以注意到缺乏这种关注和多方向的努力来规范化。

这是可以理解的：这种诊断方法的基础没有使用电离辐射源，虽然磁场对人体健康有一定的影响，尤其是对一直在磁共振成像室工作的工作人员，但对于那些在不时进行诊断程序，并且他们的体内没有外来金属（钢植入物）或电子产品（起搏器、神经刺激器）。

但是，无知和不遵守建议和强制性要求会显着增加对患者或工作人员造成伤害的风险，并降低成像和诊断的质量。 磁共振成像监管领域的另一个特点是，在过去几十年中，重新发布或修订了十多个不同的标准、卫生规范、规则、信函和建议，其中很大一部分相互补充或重复，或与其他文件相矛盾。因此，很难确保MRI室符合监管要求。

在本文中，我们回顾了俄罗斯现行的与磁共振成像室的组织和运作相关的监管文件，从安全和高质量操作的角度强调了最重要的方面，并制定了必要的步骤在诊断质量和使用核磁共振的诊断研究的安全性方面对系统进行现代化改造。

关键词：磁共振成像； 标准； 医疗机构； 医疗保健组织。

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INTRODUCTION

Instrumental diagnostics, involving the examination of patients using certain medical equipment, requires careful comprehensive control that must be specified in regulatory documents. To date, the requirements for X-ray imaging methods are the most complete. While in the field of magnetic resonance imaging (MRI), the requirements established are incomplete and inconsistent.

Unlike general radiography, computed tomography, mammography, and other methods involving the use of ionizing radiation, MRI is obtained due to exposure to magnetic fields, which does not induce obvious negative consequences to the human body. Thus, in our opinion, the regulatory system in this field has significant omissions, and the current regulations are based on the requirements for X-ray methods. Additionally, some documents are only advisory, leading to their complete disregard in practice. Failure to comply with certain mandatory conditions significantly increases the risk of harm to the health of patients or staff and decreases the quality of imaging and diagnostics.

Studies on some aspects within the life cycle of equipment, such as quality control, have been previously published [1]. Furthermore, methodological recommendations were developed based on the best international practices and related to the design [2] and operation of MRI rooms [3] and the labor protection of the medical personnel working there [4]; however, some significant steps were neglected.

Considering the recent adoption of several regulatory documents related to MRI, conveying information to medical organizations and proposing to introduce the standards into their activities are considered extremely important.

This study presents an overview of the regulatory documentation in Russia related to the organization and functioning of MRI rooms; emphasizes the aspects most important from the viewpoint of safe and high-quality operation; and develops the steps required to modernize the quality assurance system.

CURRENT REGULATORY BASE: CODE OF REQUIREMENTS FOR EQUIPMENT, ROOM, AND BUILDING

Apparatus selection

The application of the current regulatory framework can help choose an MRI unit. There are three state standards (i.e., GOST R 56310-2014 [5], GOST R 56320-2014 [6], and GOST R 56610-2015 [7]), which establish general requirements for preparing and executing technical specifications for state and municipal procurement of MRI units. These standards apply to MRI units with a constant magnetic field with a magnetic field induction B_0 of less than 0.75 T (GOST R 56320-2014) and superconducting coils B_0 of greater than 1 T (GOST R 56310-2014) for the entire body and less than 0.75 T and greater than 0.15 T for the limbs (GOST R 56610-2015). These documents, similar to other standards, are advisory and not binding.

Moreover, the classification and characteristics of some models of MRI units (mostly outdated at the moment) are given in the Information and Methodological Letter of the Federal Service for Supervision of Consumer Rights Protection and Human Welfare of 08/01/2007 N 9-05/122-486 (hereinafter Letter) [8].

Planning of MRI unit arrangement

After generating a medical and technical assignment at the stage of working with a potential supplier, one of the first tasks for medical organizations is most often the choice of a room to place the equipment. Simultaneously, depending on the functioning characteristics of a particular medical organization, the MRI room can be allocated as a separate structural unit or part of the Radiology Department (which is permitted by the Letter). The issue of the choice of premises is regulated by several regulatory documents.

Thus, according to cl. 4.3 of the Territorial Estimated Standards (TES) 31-313-98 of Moscow [9] and cl. 4.1.6 of the Sanitary Rules (SR) 2.1.3678-2020 [10], which were enforced on January 1, 2021, the building where the MRI room is planned to be located should not be residential or have a nonmedical purpose. Article (c) of cl. D.2.11 of Appendix D of SR 118.13330.2012 [11] and the section "Requirements for location and organization of work" of the Letter limit the choice of floor for the MRI room to the first floor, underground, or basement, while allowing its placement in an extension or a building specially constructed for this. In turn, according to the Letter and cl. 6.3.5a of SR 158.13330.2014 [12], considering the bearing capacity of floors is advisable when placing heavy equipment (in some cases, the weight of an MRI machine with all additional modules can reach tens of tons); therefore, these documents provide arguments for placing the MRI room in the basement/semibasement floor or on the first floor.

The intention and equipment of adjacent premises are the equally important selection factors. Clause 4.19.3 of SR 2.1.3678-2020 clearly prohibits the neighboring arrangement of an MRI room with wards for pregnant women, children, and cardiological patients and with 24-hour wards for patients. In adjacent premises, built in or attached transformer substations can never be located (cl. 7.7.1.5.3 of SR 158.13330.2014).

To avoid leaks, according to cl. 6.2.8 of the same rules (SR 158.13330.2014), choosing a room for an MRI unit under showers, lavatory, washing rooms, and other "wet places" is not recommended without additional waterproofing, and cl. 6.2.6 warns about the possibility of disruption of the equipment operation in the functional diagnostics rooms adjacent to the MRI room.

The control room (often referred to as the console room) should be located outside the controlled access area (cl. 4.19.5 of SR 2.1.3678-2020), which will be discussed in more detail in the "Physical factors" section. It must necessarily be a separate room with natural light, according to the "Requirements for location and organization of work" section of the Letter and cl. 71 of the rules for labor protection in medical organizations [13]. Simultaneously, cl. 4.6.2 in section SR 2.1.3678-2020 indicates that an MRI procedure room and a control room can be located in an area without sources of natural light, assuming that normalized microclimate indicators are provided, i.e., this set of rules contradicts itself.

According to the latest document, the appointment of patients in the control room is also forbidden; however, the procedure room (scanning room), according to cl. 5.14 of TES 31-313-98, should not have natural lighting.

Perhaps the least attention, in terms of layout, is given to the technical room of the MRI premises, which comprises the auxiliary equipment. According to the Letter, it should not be placed adjacent to the control room, the doctor's office, or patient wards. However, note that from the viewpoint of physical factors considered below, the requirements for these premises can be expressed more strictly.

Design (creation of an engineering project for an MRI room)

An engineering project is a document that describes the arrangement of equipment and the sequence of technological processes associated with its operation in the structure of a building under construction or in operation. However, in relation to MRI, most participants in the design and operation processes often have disagreements regarding the need to develop an engineering project.

Let us consider the current state of this issue.

The MRI room is part of a medical organization; therefore, its design must consider the requirements of the relevant rules of SR 158.13330.2014 regarding space-planning solutions for buildings (cl. 6.2.6), ventilation and air conditioning (cl. 7.2.3.3), minimum footage of premises (Table C.7), the degree of protection of lamps for general lighting of medical premises (Table P.1), and other aspects.

In contrast, according to cl. 3 of the Order of the Ministry of Health No. 560 dated June 9, 2020 [14], an MRI study is an X-ray examination; therefore, it must comply with the requirements of SanPiN 2.6.1.1192-03 [15]. Appendix 7 of these rules states that when the room commissioning agreed with the regional radiological department, a technological project must be submitted. Additionally, cl. 3.10 prohibits the use of the manufacturer's design proposal as a technological project, limiting the use of this document only to the choice of premises and their area.

The need for approval of the project for the MRI room was noted, among other things, in the Letter.

Composition and area of the MRI room

In addition to a careful approach to the placement of equipment to most effectively fulfill the target task of the MRI room, the functioning of such a structural unit involves several additional technological processes. These include preparing the patient for the study, inserting a catheter and performing other ancillary operations, reviewing the results of previous studies and completing a description of what has been performed, and communicating (questionnaire) with patients and their accompanying persons. However, during the interaction with the supplier in terms of preparing a floor plan for a technological project, the specifics of the work of a particular medical organization are often not considered.

The most effective approach for optimizing the space organization can be a clear description of the medical and technical assignment of all operations to be performed in the MRI room. In this case, the proposal for equipment arrangement and, thus, the project documentation, in addition to the established requirements of the equipment manufacturer, will meet the needs of the medical organization.

Furthermore, the current regulatory documentation introduced certain restrictions on the composition and area of the MRI room, while it is referred to both mandatory (i.e., SR 2.1.3678-2020, SR 158.13330.2014, and TES 31-313-98) and recommendatory (Letter) documents. A set of requirements for the composition and minimum area is presented in Table 1.

Note that the medical and technical assignment and technical documentation of the manufacturer may impose additional requirements on the minimum floor space relative to a particular MRI model.

Interior decoration of the MRI room

There are no special requirements for the MRI room in the regulatory documents in terms of interior decoration. The same provisions apply here that are relevant for all medical and diagnostic rooms with a dry regime and are presented in SR 158.13330.2014. Clause 6.4.2 states that the walls and ceilings are finished with acrylic or silicate water-soluble paints or other materials that allow wet cleaning and disinfection. The equipment attachment points, if it is placed on plasterboard walls or light partitions, should be further strengthened. This is consistent with the requirements of "SanPiN" 2.6.1.1192-03 (cl. 3.16).

Nevertheless, cl. 6.4.7 of SR 158.13330.2014 contains special instructions for radiation and radionuclide diagnostics and radiation therapy rooms regarding the floor, as it must consist of antistatic materials with a minimum number of joints between individual sheets of coating, or a jointless coating based on deactivated hardening compositions is permissible.

It is also appropriate to quote TES 31-313-98 of Moscow: "The interior decoration of the premises must be made of materials approved by the authorities and institutions of the Department of State Committee for Sanitary and

Table 1. Requirements of regulatory documentation for the composition and minimum area of the premises of the magnetic resonance imaging room

MRI room	Minimum area, m^2			
	SR 2.1.3678-2020	TES 31-313-98	SR 158.13330.2014	Letter
Procedure Diagnostic room	Manufacturer's sp.	42	25	40–46* (but not less than 12)
Control (console) room	8	20	10	14–17
Technical (apparatus) room	-	20*	20	20–24
Doctor's office	-	12	-	12
Preparatory room	4	10	12	-
Dressing room	-	-	-	Availability
Toilets for staff and visitors	-	-	-	3 × 2**
Photolaboratory (photo) room	-	10	-	10**
Engineer's room	-	10	-	-
Staff room	-	-	-	12

Note. *Area subject to change; **if necessary, can be displaced from the MRI room. MRI–magnetic resonance imaging; Sp–specifications; SR–sanitary rules; TES–Territorial Estimated Standards.

Epidemiological Oversight of the Ministry of Health of the Russian Federation, and correspond to their functional purpose" (cl. 5.16).

Physical factors

Most requirements in the current regulatory documentation are imposed on working conditions and physical factors affecting staff and patients, both in general terms and directly in relation to MRI. Harmful factors in the MRI room can include a constant magnetic field (directly at the device when laying the patient and working with radiofrequency coils), the risk of infection transmission, a high level of workload and intensity, insufficient illumination, and pulsation of the light flux. Simultaneously, according to SanPiN 1.2.3685-21 [16], the compliance of the microclimate parameters with the hygienic standards of physical factors in the workplace should be assessed. In the current regulatory documentation, the requirements for these parameters are presented separately.

The operation of MRI assumes the presence of magnetic fields that are constant and variable in time and space (GOST R IEC 60601-2-33-2013), whereas, in the most common version, an MRI unit with a superconducting magnet, a constant magnetic field is not deactivated unless an emergency occurs, and variable fields are used only when performing a scan and obtaining an image. To reduce the negative impact on personnel, SanPiN 1.2.3685-21 establishes the maximum permissible levels of constant magnetic fields (Table 5.8) and electromagnetic fields of industrial frequency (Table 5.41). Similarly, the Letter introduced the intensity of a constant magnetic field at workplaces (Table 2) and the electromagnetic field of a personal electronic computer at workplaces (Table 3) [8].

GOST R of the International Electrotechnical Commission (IEC) 60601-2-33-2013 (cl. 201.7.9.3.101) introduces the concept of a controlled access area limited by an induction isoline of a constant magnetic field corresponding to 0.5 mT, whereas the level of the electromagnetic field inside the controlled access area must comply with GOST IEC 60601-1-2-2014. The control room should be located outside the controlled access area; however, if the zone of the line of the controlled access area extends to areas of adjacent premises, strict control and restriction of access of patients and personnel with pacemakers and other types of implanted electronic stimulators is required (cl. 4.19.5, 4.19. 7 SR 2.1.3678-2020). According to the rules for labor protection in a medical organization (cl. 70), as well as cl. 4.19.4 of SR 2.1.3678-2020, both the controlled access area and the MRI room are supposed to be marked with warning signs.

The procedure, control, and preparatory rooms and the doctor's office, which are part of the MRI room, belong to the premises for the performance of work and, therefore, are subject to the requirements of SR 2.1.3678-2020 in terms of microclimate and ventilation. So, according to cl. 4.5.16, the premises of the MRI room must be equipped with supply and exhaust ventilation, and Appendix 3 introduces the requirements for the cleanliness class, temperature, and air exchange, while natural air exchange is not allowed (this requirement is duplicated in clause 7.2.3.3 of the SR 158.13330.2014).

Additionally, the Letter regulates the temperature, air velocity and relative humidity, the rate of air exchange for supply and exhaust, the category of cleanliness, and the rate of exhaust during natural air exchange [8].

Therefore, the requirements of different documents differ to some extent. Their summary is presented in Table 2.

Note that the temperature and humidity in the procedure and technical rooms are critical parameters for ensuring the normal functioning of the equipment. Thus, manufacturers accompany the installation of a ventilation

Table 2. Requirements for the microclimate and ventilation of the premises of the magnetic resonance imaging room

Requirements	SR 2.1.3678-2020	SR 158.13330.2014	Letter
Procedure (diagnostic) room			
Cleanliness class (category)	V	G	Ch
Temperature, °C	20–23	-	22
Air exchange (supply/exhaust), %	100/100 Oxygen content ⩾18%	3/4	2/2
Control (console) room			
Cleanliness class (category)	G	G	Ch
Temperature, °C	18	-	20
Air exchange rate (supply/exhaust)	3/4	3/4	-/1
Technical (apparatus) room			
Cleanliness class	-	-	-
Temperature, °C	-	-	-
Air exchange rate (supply/exhaust)	-	-	-
Doctor's office			
Cleanliness class	G	-	Ch
Temperature, °C	20	-	20
Air exchange rate (supply/exhaust)	60 m^3 per person	Supply	-/1
Preparatory (dressing) room			
Cleanliness class	G	-	-
Temperature, °C	20	-	-
Air exchange rate (supply/exhaust)	From corridor/1	3/-	-
Toilet			
Cleanliness class	G	D	G
Temperature, °C	20	20–27	20
Air exchange rate (supply/exhaust)	Exhaust	Exhaust	Exhaust
Staff room			
Cleanliness class	G	-	Ch
Temperature, °C	20	-	20
Air exchange rate (supply/exhaust)	From corridor/1	-/1	-/1

and air conditioning system with additional requirements for the microclimate.

To ensure comfortable work (especially when precise manipulations are required), all cabinet rooms must have high-quality artificial lighting, while both the illumination itself and the pulsation coefficient are normalized. The set of requirements of SanPiN 1.2.3685-21 (Table 5.54) and the Letter (Table 8) is presented in Table 3.

During the operation of an MRI unit, a sufficiently high level of acoustic noise is created. Simultaneously, as mentioned above, the most common MRI units with a superconducting magnet always work (to maintain superconductivity), and additional modules (gradient coils, radiofrequency coils, etc.) are activated during scanning, which increases the noise level. The maximum sound pressure level largely depends on the model and conditions of use of the MRI and, in some cases, can exceed 100 dBA. Thus, to ensure normal working conditions, soundproofing should be provided in the MRI room and adjacent premises.

The maximum permissible noise levels in the office premises are presented in Table 5.35 of SanPiN 1.2.3685-21 and Tables 4–7 of the Letter. The requirements in these documents are identical, except for the discrepancies in classifying a particular room as one or another category (e.g., in terms of areas where medical activities are performed).

Additionally, these regulatory documents impose requirements on sound pressure levels in octave frequency bands and a general limit on the noise produced by the equipment (140 dB relative to the level of 20 μPa according to cl. 201.9.6.2.1 GOST R IEC 60601-2-33-2013 [17]).

Electrical and fire safety

Considering the inclusion of MRI in the list of X-ray examinations, the equipment located in the office is subject to SanPiN 2.6.1.1192-03, according to which the power supply of the MRI unit must be implemented through a separate feeder (cl. 10.9), and grounding is performed along

Table 3. Requirements for illumination in the rooms of the magnetic resonance imaging unit.

Premises	Working plane and height above the floor*, m		Artificial illumination			
			Illumination under general lighting, lx		Ripple coefficient, %	
	SanPiN 1.2.3685-21	Letter	SanPiN 1.2.3685-21	Letter	SanPiN 1.2.3685-21	Letter
Procedure room	H-0.8	H-0.8	300 (**500)	500***	15 (**10)	10
Control room	H-0.8	-	300	-	15	-
Patient preparatory room	H-0.8	-	75	-	-	-
Dressing room	H-0.0	-	200	-	-	-
Doctor's office	H-0.8	-	300	-	15	-
Staff room	H-0.8	-	300	-	15	-
Toilets	H-0.0	H-0.0	75	50	-	-

Note. *H–horizontal; **during intravenous manipulations; ***in this section, requirements are made for the procedure and diagnostic rooms (what is meant by the latter is unclear).

an autonomous circuit with a bus with a cross-section of at least 4 × 25 mm (cl. 10.5).

According to GOST R 50571.28-2006 [18], the MRI room can be assigned to the safety group 1, and therefore, using a backup power source and signal notification of switching to it becomes necessary. Note that an uninterruptible power supply source is a mandatory component of the MRI unit with a superconducting magnet.

Fire safety requirements are established in GOST 12.1.004-91 [19], according to which, in relation to the MRI room, the level of fire safety should be determined (Appendix 2), the probability of fire and explosion should be determined (Appendix 3), and the economic efficiency of the fire safety systems should be assessed (Appendix 4). Moreover, note that the installation of fire alarms and fire extinguishing systems in the procedure room is difficult, and therefore, smoke and gas sensors are installed on the exhaust ventilation. Fire extinguishing equipment must be MRI compatible [4].

Operation

As a medical product, an MRI unit must undergo mandatory maintenance and technical condition control. According to the Letter of the Ministry of Health of the Russian Federation No. 293-22/233 dated October 27, 2003 [20], the list of works within the maintenance is established by the methodological recommendations "Maintenance of medical equipment" and includes installation and adjustment, monitoring of the technical condition, periodic and current maintenance, and repair of medical equipment.

In turn, GOST R 56606-2015 [21] defines a list of tests performed within the technical condition control, namely, acceptance and periodic tests and tests for the constancy of parameters. Test methods and the requirements for equipment and conditions for their implementation are presented in GOST R 59092-2020 [22].

Additionally, there are local provisions; for example, in Moscow, the order of the Moscow Health Department No. 564 of August 17, 2018 was approved [23], which regulates the storage, installation, use, operation, maintenance, repair, and disposal of medical equipment.

The requirements for ensuring the safety of personnel while working in the MRI room are set in Section IX of the Rules for Occupational Safety in a Medical Organization [13]. First, its requirements limit the exposure time of personnel to magnetic fields. Simultaneously, rather ambiguous requirements have been introduced; that is, the laying of the electromagnet power cable is regulated and the duty of the staff to check the connection of the ground loop and the prohibition of leaving the MRI unit turned on unattended.

FACTORS HINDERING THE USE OF THE REGULATORY FRAMEWORK

Thus, we are faced with a whole list of regulatory legal acts in terms of the use of MRI, approved over the past decades. Unfortunately, a significant part of them was formulated based on similar documents for medical ionizing radiation equipment or introduced point limitations, often taken from international sources. Therefore, the procedure for ensuring the compliance of the MRI room with the requirements of regulatory documents and standards is complicated by the inconsistency, incompleteness, and sometimes contradiction of the information provided.

The obvious factors complicating the use of the existing regulatory framework include the lack of a systematic approach and unified terminology, duplication (often with amendments) of requirements for the same parameters, and, most importantly, "white spots" covering a significant part of the equipment commissioning and operation stages. Certainly, a qualified reader can easily compare the "diagnostic room" and "procedure room" or determine the intention of the "computer room" and "photolaboratory" in the MRI room. However, industry or sanitary standard formats suppose a slightly different approach.

The discrepancy not only in the ranges of permissible values but also in the list of requirements presented in the

regulatory documentation, on the one hand, and the technical documentation of manufacturers or recommendations from specialized professional communities, on the other hand, are also noteworthy.

Let us consider the measurement of the air exchange rate in the procedure room of the MRI premises as an example. So, in the documentation, when rationing the air supply and exhaust, the oxygen content, and the frequency of monitoring these parameters, the fact that the market offers no MRI compatible devices that allow such functions is completely not considered. In most cases, the efficiency of the ventilation system primarily affects the equipment performance; therefore, taking care of the comfort of patients in the presence of a malfunction is only senseless, and the equipment operation should be stopped. Simultaneously, the regulatory documentation almost completely ignores the emergency ventilation system, which directly affects the safety of MRI operation.

The requirements governing the placement of the control room outside the controlled access area are not often feasible (its boundaries can only be determined at the final stage of putting the MRI unit into operation after the measured contour map has been created).

A more general problem arises at the office design stage. Unfortunately, practice has revealed the complete failure of the developed medical and technical assignment and the engineering project created on their basis. Thus, the analysis of the documentation for some already functioning MRI rooms has shown that ignoring the obvious requirements for patient flow and equipment loading and the descriptions of technological processes in the medical and technical assignment with a design based only on the manufacturer's suggestion for arranging the equipment and the most general layout of the room significantly decreases the efficiency of the department and the complete impossibility of performing part of the manipulations.

The requirements for arranging a room for performing the interview, anthropometry, and examination of patients for the presence of metal and shifting of bedridden patients from a standard to an MRI-compatible couch or chair are not regulated in any way. This leads to the fact that these actions are performed in a common corridor where patients are awaiting their appointment, and anthropometry and detection are not performed at all.

Therefore, important security requirements, such as restricting access, are not executable. Staff may experience difficulty in transporting sedentary patients and be forced to ignore important, from the viewpoint of safety, stages of preparation for the study.

Discussing about ensuring the safety and quality of MRI, we must state the complete unsystematic nature of the requirements. Although attempts are being made to develop methodological recommendations and educational programs, only a few points are found in the regulatory documentation. Moreover, the attempts of a medical organization to directly fulfill the contradictory requirements are reminiscent of the attempts to squeeze into the "needle eye."

CONCLUSION

The efficient and safe operation of MRI rooms requires careful and consistent work in extensive cooperation with the medical community, equipment manufacturers, regulatory authorities, and metrological institutions. Simultaneously, standardization and unification and systematization and widespread implementation of the procedure for monitoring the implementation of the requirements introduced should be the priority fields of interaction.

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