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COMPARATIVE ANALYSIS OF EUROPEAN AND RUSSIAN STANDARDS FOR VENTILATION OF OPERATING ROOMS IN HOSPITALS

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Abstract

Hospital is a building in which a lot of attention should be paid to the indoor climate. The most important part of the indoor climate is air. It must be properly cleaned and prepared for the good condition of the building. The quality of air in hospitals should be strictly regulated. At present, Russia and European countries have their own rules and standards for ventilation in hospitals. In addition there are some international documents. The only way answer to the question which is better and is there any difference is to make a comparative analysis of standards.

The main idea of this Barchelor's Thesis is to compare the current requirements, guidelines and standards for clean rooms in Russia and in other countries. In this Barchelor's Thesis ventilation in operating rooms of hospitals will be considered.

Monitoring the air quality in hospitals is very important. Any damage in the ventilation system can cause the spread of infection. That is why in hospital are used different ventilation system than in offices or in other buildings.

In this Barchelor's Thesis ventilation requirements of operating rooms in different countries will be reviewed.

Subject headings, (keywords)

Ventilation system, clean room, thermal conditions, air movement, air quality, hospital air, operating theater

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CONTENTS

LIST OF TERMS

Air recirculation - reusing the same volume of air in a closed air supply system with its repeated processing (filtration, dehydration or moisture etc.). In health care facilities allowed closed recirculation (local) in a single room.

Air exchange rate - defined as the number of air changes per unit time, equal to the volume ratio supplied air per unit time to the volume of the space where it is served.

AHU – Air Handling Unit - equipment for the preparation and distribution of clean air in order to achieve certain environmental parameters.

Airlock – room, separating clean areas from dirty areas.

Clean room - a room in which the concentration of airborne particles is controlled. This room is constructed and used to minimize the flow, the allocation and retention of the particles inside the room and allows to control other parameters such as temperature, humidity and pressure.

Clean zone – a space in which the concentration of airborne particles is controlled. This space is constructed and used to minimize the flow, the allocation and retention of the particles inside the room and allows controlling other parameters such as temperature, humidity and pressure.

Contaminant – any substance (particles, molecular and biological structures), which may adversely affect the product or process or people (patients).

Decontaminzation – reducing the concentration of harmful substances to the desired level.

Hospital-acquired infection (nosocomial infection) - any symptomatic disease of microbial origin, affecting the patient as a result of his hospitalization or a visit to a medical institution for treatment, as well as the hospital staff because of their activity,

regardless of when patient feels the symptoms of the disease (during the whereabouts of persons in the hospital or not).

Health care facilities - specialized health care institutions where people with certain diseases have full range of medical services: diagnosis, treatment and rehabilitation after illness.

HEPA/ULPA filters - High Efficient Particulate Air filter and Ultra Low Penetration Air filter

Laminar flow (unidirectional airflow) - controllable air flow with a constant speed and approximately parallel stream lines along the entire cross section of the clean area.

Operation theater (operating room (OR) or operating suite) - part of health facility which has the operative interventions. Structurally, operation block consists of operating rooms, preoperative, storage facilities for equipment, recreation staff facilities.

Particle – the smallest part of matter with defined physical boundaries.

Supply airflow rate - the amount of air supplied to the clean room (clean area) through a final filter or air ducts per time unit.

Turbulent flow (non-unidirectional airflow) - the air flow with air swirls having various directions and speeds.

CFU - colony forming units - is an estimate of viable bacterial or fungal numbers.

Changing room - space where staff can put on or take off their clothes for a clean room.

1 INTRODUCTION

Clean room is a space where the amount of particles (dust, bacteria) of a certain size per cubic meter are controlled. Air temperature, humidity, pressure and noise levels should be also regulated. Nowadays clean rooms have proliferated, and they are used in many industries. This type of rooms are used in pharmacology and in medicine to prevent infection in the patient's body, in microelectronics in the production of electronic equipment, etc.

The most important of them are clean rooms in hospitals, because they affect people's lives. There is a risk of nosocomial infections (hospital-acquired infection) and postoperative infectious complications. The health and work of doctors also depend on the purity of the air. That is why it is very important to be careful in the design of ventilation in hospitals. “Everything which is to come into contact with the wound has been made sterile, except the air, which is in contact with everything”/1/.

There are several classes of clean rooms, depending on the class of normalized Colony Forming Units (CFU). Selecting of proper indoor and ventilation systems can help not to exceed this amount. The highest classes of clean rooms in hospitals are operating theaters. The absolute cleanliness must be ensured in them, a low level of contamination by microorganisms, to prevent the entering of various types of pollution in the open wound of man.

2 AIMS AND METHODS

2.1 Aims

The main aim in this Bachelor’s Thesis is to identify the difference between European and Russian standards, identify advantages and disadvantages.

Nowadays a group of scientists in Europe works to create a common standard for cleanroom ventilation in hospitals. However, a general agreement has not been achieved. The main difference and a satisfactory alternative for a common standard will be found in this Bachelor's Thesis.

2.2 Methods

Two methods are identified in compliance with the aims in this Bachelor's Thesis. The first method is to familiarize with ventilation in hospitals and methods to ensure clean air. This method include the study of the literature on a given topic i.e. various books and guides for specialized ventilation in buildings, like hospitals.

The second method is to compare the rules and regulations of Russia with the rules and regulations of Europe in the field of ventilation of clean rooms in hospitals. The standards of different countries will be considered in general, and part of the standards of operating theaters.

During the study documentation on this topic, special attention was paid to the different values for the indoor climate. The values of these parameters was compared:

1) Velocity of air in the operating theater, m/s
2) Type of air flow in the operating theater, laminar or turbulent
3) The air temperature, ^{o}C
4) Number of CFU, $1m^3$ of air
5) Humidity, %
6) Noize level, dB

3 HEALTH CARE FACILITIES

3.1 Types of health care facilities

There are different types of health care facilities to ensure that people do not infect each other. They are divided by professional orientation. In Russia, there are the following groups of health care facilities: therapeutic (health care facilities for people over 15, different doctors in one building), pediatric (health care facilities for children, accept patients under 15 years), surgery (health care facilities for patients who need surgical intervention), special health care facilities (ambulance, blood transfusion station), maternity hospitals, radiology.

Other countries have different classifications. Health care facilities may be classified: hospital (health care facilities for inpatient care), health care center (first aid centers), medical nursing home (health care facilities with living areas providing both general and special treatment), pharmacies and drug stores (trade in medicinal preparations, and different goods for health), medical laboratory and research conducting various tests in various fields of medicine for discovering new ways to treat).

3.2 Different rooms in health care facilities

The hospital in the broadest sense is a complex of blocks where each one has its own purpose. It is very important to understand and classify different rooms. According to Russian standard SanPin 2.1.3.2630-10 “Sanitary and epidemiological requirements to organizations engaged in medical activities”, there are four classes of cleanliness rooms in health care facilities. This is a class A – “especially clean”, Class B – “clean”, Class C – “conditionally clean”; D – “dirty”.

The first class, class A, is for operating rooms, delivery rooms, aseptic boxes for hematology, burned patients, wards for premature babies, aseptic pharmacy unit, sterilization (clean half), boxes of bacteriological laboratories /2/. Destruction of bacteria, microbes and biological contamination should not be less than 99%. Uses supply air duct ventilation. Most often, in some places (over the operating table and over the chamber of the patient) there are used laminar flow with cross-sectional area of 9 m^2.

The second class, class B, the procedural, dressings, preoperative, chambers and halls of intensive care, children's wards, rooms of milk collection and pasteurization, packaging and assistant pharmacy, rooms for bacteriological and clinical laboratories designed for research /2/. Allowed air purification from microorganisms not less than 95%.

The third class (Class C, conditionally clean rooms) include chamber surgical wards, corridors, adjacent to the operating room, maternity halls, observation, boxes and infectious chamber units, doctors' lounge, material, storage of clean linen. Allowed air purification from microorganisms not less than 95% /2/.

The last one, the fourth class with the corridors and rooms of office buildings, stairways diagnostic and treatment buildings, sanitary rooms, toilets, facilities for the temporary storage of dirty linen and temporary storage of waste /2/.

It must be taken into account that the premises belonging to the class A can have a different purpose and a different area. For example, operation rooms can be cardiovascular, burn, transplant, the abdominal cavity - they use a laminar flow with 9 m^2 area, in standard, in small operation rooms it is not required.

Another classification is given in the international standard ISO 14644-1. The premises are divided into 9 classes of purity. Class 1 - the cleanest and the class 9 is dirtiest. Class clean room on this classification depends on the amount of particles of different sizes (0.1 to 5.0 microns) in a cubic meter of air.

A simple operating theater consists of an anesthetic room, airlock, preoperative room. Operating theaters can include rooms for change of clothes and for washing. It is very important that these rooms have different classes of cleanliness. Change of clothes and washing making are for preventing dirt entering with doctors.

4 HOSPITAL-ACQUIRED INFECTION

Hospitals have many patients at the same time. Of course, the aim is to divide them into groups of diseases, but at first, diseases of one group can be quite different. Secondly, there is the probability of error when a doctor gives a diagnosis, and not the fact that the patient has a disease that the doctor said in a preliminary diagnosis and thirdly the patient can have even more diseases except the diagnosis.

There is such a thing as a hospital-acquired infection. Hospital-acquired infection is any type of microbiological disease, patient or the hospital staff got directly being in it. Hospital-acquired infection (HAI) can be transmitted through food, water, medical apparatus and instruments, dust, insects (mosquitoes, flies) and animals (rats). Ways of transmission of nosocomial infections can be very different. HAI can be transmitted by contact, droplet and airborne dust. There are also some factors that promote development and spread of HAI:

- Outdated equipment and instruments
- Disruption of schedule of the cleaning and disinfection
- Noncompliance patients and staff rules of personal hygiene
- Poor condition of eating places
- Problems with water supply
- Lack of properly-functioning ventilation systems

Methicillin-resistant Staphylococcus aureus (MRSA) reached a record in 2008 and it still caused a nation-wide problem. It is a serious threat to Finnish health care. In Finland, hospital infections annually cause an estimated 1 500 deaths and the management of 195–492 million euros in additional costs. /3, p.137./

In Finland the rate was estimated to be 8.5% of patients in 2005 /4/. Hospital-wide surveillance enables the calculation of some indicators that are specific to intensive care. There are numerous differences in the surveillance protocols, particularly concerning the type of infection documented, the case definitions used (particularly for pneumonia), the population studied (for example, all patients or only those who have spent more than 48 hours in an intensive care unit), the definition of one day use of a device (for example, inclusion or not of noninvasive mechanically assisted ventilation, 24 hours exposure or less, two central lines per patient counting for ‰ one or two days), the type of surveillance provided (denominator data collected by unit or by patient), and the risk factors collected for each patient. /5./

Of course, it is easier to prevent disease than to fight it. That is why complex measures are used in hospitals to prevent the spread of HAI. They are:

1) Sterilization is a process of purification. In this process, in contrast to disinfection, all kind of microorganisms are killed on the surfaces of devices. The aim of disinfection is to clean the pathogen infection. Sterilization cleans everything. It can be chemical, thermal, radiation, filtration methods.
2) Separation of one from other areas to prevent transfer of infections.
3) Compliance with the basic rules of hygiene
4) Surface disinfection helps to avoid accumulation of infections
5) Wearing of protective clothing (bathrobes, aprons)
6) Compliance with the established schedule cleaning of hospital rooms

7) Properly installed ventilation

5 VENTILATION

To provide sufficient air quality in the operating room there must be properly working ventilation. Air Handling Unit (AHU) for operating rooms is not connected with the ventilation system hospital. Air passes through several stages of purification filters with various purity types before entering into the operating room. Two filters are installed in the AHU and the final cleaning filter is installed into a laminar flow ceiling. Figure 1 showed that laminar flow ceiling can be round, square or polygonal.

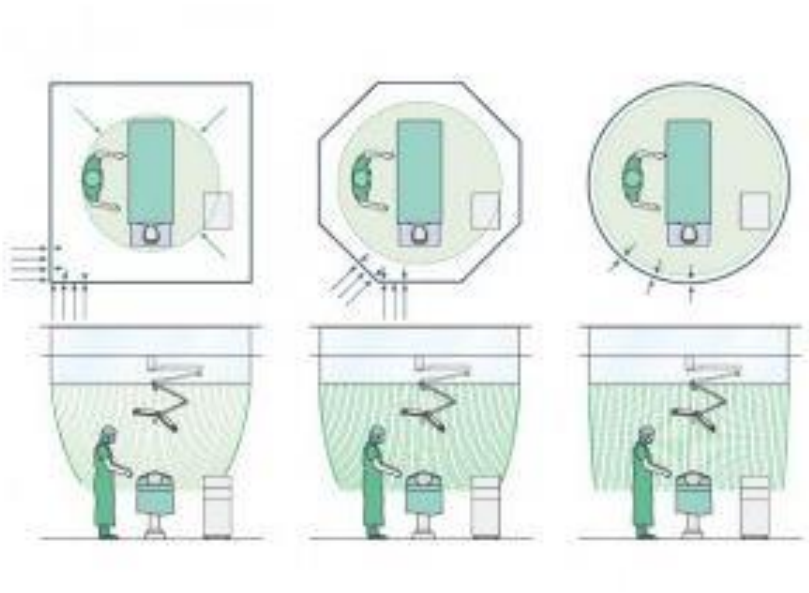


FIGURE 1. Different forms of laminar ceiling./6/

Because laminar flow supplies a huge amount of air, and spends a lot of energy, you need to think about the economy. In operation can be utilised local recycling, air is taken from the operating room than it is passed through a filter and fed back into the room. The volume of recirculated air should not exceed 80%.

Air is removed from the operating room with extract devices located in different corners of the room and from the two zones, top and bottom. From the bottom 60% of the air is and from the upper 40% /7/.

Typical AHU showed on the Figure 5. This air supply system for the operating theater includes filters (1 – filter of second stage of treatment, 3 – return air filter, 12 – filter of first stage of treatment), fans (2 – supply air fan), dampers (4 – isolation dampers), humidifier (5), Steam distributor/humidification path (6), condenser (7), evaporator (8), electrical module (9), machine module (10), exhaust air fan (11), silencers /8/.

FIGURE 2. AHU for operating theaters./8/

In the operating room, the air passes a three-stage cleaning system, for these levels of treatment different classes of filters. According to the international classification, the smaller particles are trapped filter, the higher is class of purification. There are four classes of coarse filters (G1-G4), five classes of fine filters (F5-F9), four classes of high-purity filters (HEPA, H10-H14) and three classes ultra-fine air purification (ULPA, U15-U17). Usually in the operating room H13 as last filter is used. HEPA at the figure 3.

FIGURE 3. HEPA filters /9/.

Fans are one of the main parts in the mechanical ventilation, since they make the movement of air. Two criteria are worth paying attention when selecting the fan, productivity (the amount of air that it moves) and pressure. For operating rooms also important is the size of the fan and the noise it produces. Centrifugal fans from figure 4 are used in ventilation for operating room.

FIGURE 4. Centrifugal fan /10/.

To reduce the noise from the fans there are special devices - silencers. The most common models is pipe and plate. Plate silencers are at the figure 5. There is a rectangular box made of thin sheet metal, divided along the inside of the plate, tiled with sound absorbing material (glass wool, felt, etc.). Plate silencers are used in ducts of large cross section. Pipe silencers at are made on a different principle. They consist of two pipes with different diameters. One tube is placed in the other and the space between them is filled with insulation. Pipe silencer is at figure 6.

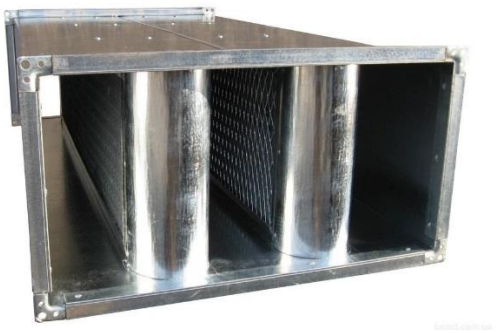


FIGURE 5. Plate silencer /11/.

FIGURE 6. Pipe silencer /12/

Two types of heat exchanger are used in the air supply for operating room. At the initial stage, the air is heated (or cooled) by water heater, and before to let him into the operating room electric heater brings it up to the desired temperature (this is done for better accuracy).

Air cooler is not only for decreasing the air temperature, also it is for drying. Therefore, it provides in a section with tray for collecting and draining condensed water. Air coolers are water or coolant as a heat transfer medium (freon). Water cooling coil has a similar structure to the water heater.

6 STANDARDS OF DIFFERENT COUNTRIES

Many countries have standards, norms, building codes, which are clearly regulating the temperature, humidity, pressure, air flows in clean rooms, such as operating theaters. These parameters are possible to control when a special ventilation system is created.

First operating room, which was a prototype room, which still existing, was constructed in 1961 in England. It was the invention of sr. John Charnley and he called it “greenhouse”. John Charnley installed in the greenhouse the air flow, which aimed downward with a velocity not exceeding 0.3 m/s. It gave sound result: he reduced infections after such operations from 9% to 1.3% /13, p 177/. Cleanroom development and related standards started from this point.

6.1 Austria

In Austria, the regulatory standard is ÖNORM H 6020 Ventilation and air conditioning plants for locations for medical use - Design, construction, operation, maintenance, technical and hygienic inspections. New Austrian ÖNORM H 6020:2007 standard replaces the previous ÖNORM H 1999 6020-1 (Ventilation systems in hospitals - Design, construction and control) and H ÖNORM 2001 6020-2 (Ventilation systems in hospitals - Operation, maintenance, technical and sanitary control)

The new standard ÖNORM H 6020:2007 establishes a classification of spaces for their purity /14/:

- Area class H1: Operation protection area
    1) Area class H1a: Operation protection area in an operating theatre e.g. surgeries on bones and big joints with implementation of foreign material (e.g. artificial hip), neuro-surgical operations on central nervous system (e.g. on the spine), open thorax surgery (opening of the sternum).
    2) Area class H1b: Operation protection area in an operating theatre for other operational surgeries (e.g. abdominal surgery, ophthalmic operation, urological surgeries)
- Area class H2: protective insulation
    1) Area class H2a: clean areas (protection area) in burn units
    2) Area class H2b: clean areas (protection area) in bedrooms for special treatment (e.g. bone marrow transplantation)
- Area class H3: source insulation
- Area class H4: other rooms. All remaining hygienic relevant rooms which do not belong to class H1, H2 andH3. For example:
    - inpatient room

- surgical dressing room
- intensive care unit

Rooms classes H1, H2, H3 are necessarily provided with a mechanical ventilation system. Three-stage filters cleaning uses in the rooms of class H1, H2. Two stages of cleaning uses in classes H3 and H4. In the premises of all classes it is necessary to put a filter on the exhaust air.

Velocity cannot be more than 0.45 m/s in areas with low turbulent flow. The design speed in the laminar flow is 0.3 m/s. Average rate should be 0.24 m/s, and single measurement cannot be less than 0,22 m/s.

According to the Austrian Standard, it is allowed to switch off the air-conditioning system if the system is not used, and the room is empty, but before using it must be enabled previously (running no less than 30 minutes). The protection zone over the operating table must cover the work area up to 1.2 meters, as well as to protect the staff and instruments of the operation. Supply air temperature should be above room temperature to a maximum of 3 degrees. HEPA-filters must be installed of at least class H13. Turbulence does not exceed 10%.

Certain requirements is also applied in a system of laminar flow with recirculation: adjustable speed fans, symmetrical arrangement of recirculation units, the lack of roughness in the silencers, silencer should be put before the filter, the use of a filter class F7 as a pre-treatment.

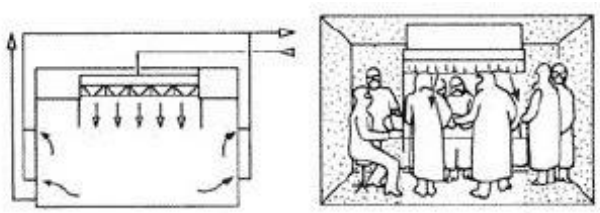
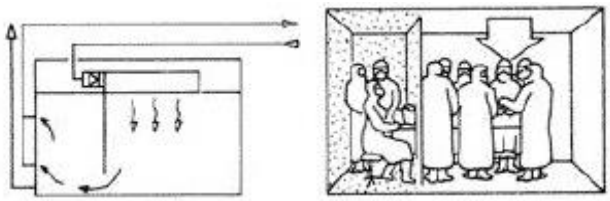
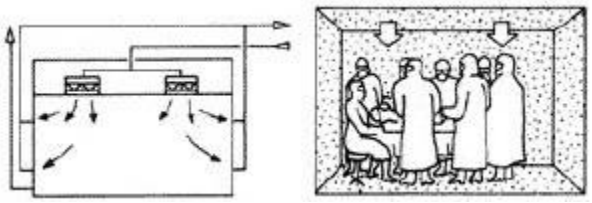
6.2 Switzerland

For the first time in Switzerland a document regulating air quality in operating rooms was adopted in 1975. Swiss Guideline SKI Bulletin 4 based on the German standard DIN 1946, Part 4 (Ventilation in hospitals. 1963). /15./

This standard was developed in the Institute of Health and medical facilities (SKI - Schweizerisches Institut fur Gesundheits- und Krankenhauswesen). The next step was a standard "Guidelines for the construction operation and maintenance of air treatment systems in hospitals" – SKI, Band 35 «Richtlinien fur Bau, Betrieb und Uberwachung

von raumlufttechnischen Anlagen in Spitalern». The standard establishes several groups of rooms by the number of particles in them.

TABLE 1. Groups of rooms by Swiss standards /16/

Types of work	Groups of rooms	The number of CFU in $1m^3$ of air	The supply flow rate, m^3/h
	I	< 10	10 000
	II	< 50	2000-3000
	III	< 200	2000-3000

Next step, the development of a new standard for hospitals started in 1997. The new standard was adopted in 2003, this guide is updated and adopted as new standards for ventilation in hospitals SWKI 99-"Heating, ventilation and air conditioning systems in hospitals (design, construction and operation)". The big change was the abandonment of traditional methods for assessing air quality. The new recommendations pointed that it's necessary to assess air quality by the concentration of particles. In this way Switzerland stopped to evaluate cleanliness by microbiologically contaminated (CFU).

SWKI is making huge research efforts in the field of clean room and ventilation. On the Table 2 the recommendations of the organization on the quality and quantity of filters for different groups of rooms are showed.

TABLE 2. Recommendation of SWKI /16/

Cleanliness class	1 stage of purification	2 stage of purification	3 stage of purification	4 stage of purification
ISO 2	G4 70-85%	F7 90-95%	H12 99,5%	U17 99,999995%
ISO 3	G3 50-70%	F6 85-90%	H11 95%	U16 99,99995%
ISO 4	G2 30-50%	F5 70-85%	H10 85%	U15 99,9995%
ISO 5	F5 70-85%	F9 98-99%	H14 99,995%	-
ISO 6	F5 70-85%	F8 95-98%	H13 99,95%	-
ISO 7	G4 70-85%	F7 90-95%	H12 99,5%	-
ISO 8	G3 50-70%	F6 85-90%	H11 95%	-
ISO 9	G2 30-50%	F5 70-85%	H10 85%	-

Swiss standard divides operating rooms into two types: with a laminar flow, and without it (mixed, low turbulent). The maximum allowed noise level in operating room is 48 dB. The air temperature must be regulated and vary within 19-26 C.

In the operating rooms with laminar flow, surface area of laminar ceiling shall not be less than 9 m^2, air passes through three stages of cleaning filters different effectiveness. The surrounding laminar ceiling aprons must end at a height of a door or at 2.1 meter from the floor. Supply air velocity in laminar air flow should be in the interval 0,23-0,25 m/s.

To control the situation of clean rooms in Switzerland there is organization SRRT: Swiss Society for Technology Cleanroom (Schweizerische Gesellschafit fur Reinraumtechnik)

6.3 Germany

There are two organizations engaged in production standards in Germany. Organization of DIN and VDI actively cooperate with each other. The Commission on Air Pollution Prevention of VDI and DIN (KRdL) was founded in March 1990.

Deutsches Institut für Normung (Standardisation Committee of German Industry) began its work in 1917 with the title Normenausschuss der deutschen Industrie (German Standardisation Committee). Later in 1926 the name was changed to «Deutscher Normenausschuß» (German Standardisation Committee), and in 1975 it was changed again to the one what they use now. German Institute for Standardization located in Berlin, Germany. DIN is a member of ISO. There are several types of DIN standards and their designations. Usual standard DIN, without additional letters is an internal standard in Germany. Standard DIN EN denotes species translation of European standards into German. DIN ISO means standard of ISO translated into German.

Verein Deutscher Ingenieure (The Association of German Engineers) has existed for 157 years. Office is located in Dusseldorf, Germany. The main difference between the DIN and VDI is that VDI is not an organization but rather a union of engineers. All work in VDI is on a voluntary basis.

6.3.1 Standard DIN 1946

Germany has released a standard DIN 1946 in 1963, Part 4 (Ventilation in hospitals). Standard was revised in 1989. Part four of the standard is about clean rooms - «Cleanroom technology. System to ensure air purity hospitals» – DIN 1946, Teil 4. Raumlufttechik. Raumlufttechishe Anlagen in Krankenhausern, Dezember, 1989. Rooms were divided into two groups according to the purity of air:

1) room class 1 (operating) with high and very high purity requirements of indoor air;

2) room class 2 (all other areas), the usual requirements for the concentration of substances.

Currently, there is a new standard of DIN 2008. It provides indicators for mechanical purity of pollution (particles) and for microbial contamination and prescribed classes of premises. They can be IA, IB and II. The class IA includes aseptic operating room with laminar flow of air for protecting area with operation table, and the class IB includes all other operating rooms with a ventilation system of turbulent flow.

According to the standard DIN 1946-4-2008 class of the clean room can be determined by /17/:

- The quality of filtration (number of purification steps and the quality of the filters)
- Flow type of supply air
- The purpose for which the facilities will be used

There are two classes of cleanrooms, I class and II class. Class I is subdivided into Ib “high level of air cleanliness” and Ia "very high level of air cleanliness." They differ from each other by different types of air flow. In rooms of class Ia use laminar or low turbulent air flow is used, in areas of class Ib turbulent use.

For ventilation in rooms of class II (with the exception of special facilities, such as laboratories, kitchens and pharmacies) is installed two-stage air purification. The first filter should be at least F5-F7 to protect the air conditioner, the second F9 is to prevent air pollution particles (stops particles with large diameter $\geq 5{,}0$ μm).

6.3.2 Standard VDI 2167

Another one is the German standard VDI 2167, “Building equipment in hospitals. Part 1. Heating, ventilation and air-conditioning”. The standard is made accordingly the Swiss SWKI 99-3 and has no fundamental differences with it. In difference from SWKI 99-3, this standard does not contain the information about ventilation and heating in pharmaceutical manufacture. Scope of VDI 2167 is the all hospital buildings, clinics, rooms for surgery, room for burn patients and so on /18/. On the Tables 4 and 5 the comparison between two German standards are showed:

TABLE 3. DIV and VDI standards /19/.

Operating Class Ia	Standard DIN	Standard VID
Supply: laminar zone with curtains	3,2x3,2 m^2 size of the zone	3,2x3,2 m^2 Minimum area = 9 $м^2$
Inflow of supply air	1200 m^3/h	800-1200 m^3/h
Average air velocity	≥ 0,23 m/s	0,24 – 0,30 m/s
Location of exhaust vents	No indications	Near the floor
Placing the air conditioner inside the room Class I	Unacceptable	No indications
Temperature of supply air	19-26 ºC	Only with the use of air conditioning
Inside temperature during the operation	Regulated lower limit	Regulated lower limit
Sound pressure level	≤ 45 dB	≤ 48 dB
Room heating	From the heated wall	Heating devices acting mainly due to radiation of heat, easy to clean.

TABLE 4. DIN and VDI standards /19/.

Operating Class Ib	Standard DIN	Standard VID
Flow type of indoor air	Mixed flow or displacement	Mixed or flow from laminar zone
Airlock	Need an airlock	No indications

Inflow of supply air	1200 m^3/h	800 - 1200 m^3/h
Location of exhaust vents	Top and bottom	No indications
Placing the air conditioner inside the room Class I	unacceptable	No indications
Sound pressure level	≤ 45 dB	No indications
Room heating	From the heated wall	Heating devices acting mainly due to radiation of heat, easy to clean.

GAA-RR of DIN/VDI: "Society of clean room technology" (Gemeinschaftsarbeit ausschluSS Reinraumtechnik) is engaged in the development of standards and the monitoring of situations related to the clean rooms in Germany. GAA-RR is the part of the Organizations of DIN and VDI.

6.4 France

NF S 90-351 is the French standard for clean rooms. The name of it "Health care – Zones of environment control - Requirements for the control of air pollution" (Établissements de santé - Zones à environnement maîtrisé - Exigences relatives à la maîtrise de la contamination aéroportée), it was adopted in 2003 and updated in 2013. Table 6 showed to us the difference between old and new standards with some comments.

French standard divide rooms for 4 zones. Zone 1 is the area with the minimum risk, in zone 4 - the risk is highest. All the rooms are divided into groups:

Zone 1 (minimum class of risk) - administrative offices, technical rooms, office space.

Zone 2 (medium class of risk) - elevators, hallways, restrooms, pharmacies, waiting rooms, consultation rooms.

Zone 3 (high class of risk) - reanimation, maternity boxes, surgical department, pediatrics, laboratory.

Zone 4 (very high class of risk) - operational, transplantation, neonatal units, burn centers.

According to the French standard, air should pass three-stage cleaning. The chain of filters shall consist of F6-F7-H13. The old standard humidity level was 45% -65%, but the new version does not have any requirements for the humidity in operating rooms. Pressure difference between rooms with different classes of cleanliness should be 15±5 Pa. When the pressure difference more than 20 Pa there are some troubles with door opening. The temperature during working time must be from 19 to 26 °C.

The classification of areas for microbiological indicator can be seen on the Table 5.

TABLE 5. Classes for microbiological contamination

Class on micro-organisms	CFU/m^2
M 1	≤ 1
M 10	≤ 10
M 100	≤ 100

Table 6. Comparative table of new and old French standards. /20/

Name of parameter	Parameter	Target value		Comments
		2013	2003	
Particles	Class of air cleanliness	ISO 5 ISO 7 ISO 8	ISO 5 ISO7 ISO 8	Identical (revision of ISO 14644-1 in the process)
	Kinetic removal of particles (0,5 µm)	CP 5 ≤ 5 min CP 10 ≤ 10 min CP 20 ≤ 20 min	CP 5 ≤ 5 min CP 10 ≤ 10 min CP 20 ≤ 20 min CP 40 ≤ 40 min CP > 40 > 40 min	- Class 2 removed - The terminology has changed
Microorganisms	Class of microbiological contamination	M1 : ≤ 1 CFU/m^3 M10 : ≤ 10 CFU/m^3 M100 : ≤ 100 CFU/m^3	B1 : ≤ 1 CFU/m^3 B5 : ≤ 5 CFU/m^3 B10 : ≤ 10 CFU/m^3 B100 : ≤ 100 CFU/m^3	- Class 1 removed - The terminology has changed
Ventilation	Temperature	19°C - 26°C (operating temperature) 15°C - 30°C (standby time)	19°C - 26°C	Increased temperature range in standby time
	Humidity	Without regulation	45 % - 65 %	
	Velocity	0,25 - 0,35 m/s (4 class of risk)	Without regulation	Operating rooms: a high range, wards: a low range
	Air change rate	≥ 15 V/h (3 class of risk) ≥ 10 V/h (2 class of risk)	50 h^{-1} (zone 4) 30 - 40 h^{-1} (zone 3) 15 - 20 h^{-1} (zone 2)	
	Pressure difference	15 Pa ± 5 Pa	Not less than 15 Pa	Δp between rooms with different classes of cleanliness
Noise level	Maximum level of noise	Operation room: 48 dB Laboratory:48 dB Sterile:40 dB	Zone 4 : 48 dB (A) Zone 3 : 45 dB(A) Zone 2 : 40 dB(A)	Approximate values for the acoustic characteristics

In France, there is an organization ASPEC: The Association for the Prevention and Control of Pollution (Association pour la Prevention et l'Etude de la Contamination), and it deals with the control of air quality.

6.5 Finland

At this moment Finland doesn't have single standard of ventilation in hospitals. Finland has only guidelines for some hospitals (they have done it by themselves). In Europe CEN-working group is going on the work to have EN standard "Ventilation in Hospitals", but there is still a lot of work in progress. Below in the Table 8 is a summary of the latest public guidance that is published in the Association of the Finnish Hospital Engineering (AFHE) /21/.

Operating areas for clean surgery (orthopedics, transplantation, eye etc.) must have ISO class 5 of cleanliness. Operating staff regulate the air temperature in range +/-3 and regulate relative humidity. Vertical low turbulent flow are used in this operating areas. Operating room has 15 Pa overpressure to surrounding spaces, airflow direction to less clean environments.

Operating areas for general surgery must have ISO class 5 of cleanliness. Operating stuff regulate the air temperature (+/-3) and relative humidity. Vertical partial low turbulent flow (perforated diffuser) are used in this operating areas. Operating room has 10-15 Pa overpressure to surrounding spaces, airflow direction to less clean environments.

Areas for outpatient and infection surgery must have ISO class 7 of cleanliness.
Operating stuff regulate the air temperature (+/-3) and relative humidity. Vertical partial low turbulent flow (perforated diffuser) are used in this operating areas. Infection surgery areas must be at neutral or slight under pressure (10 Pa), outpatient surgery must has overpressure. Organization R^3 Nordic: Contamination Control and Cleanroom (Renhetsteknik och Rena Rum) oversees the situation in clean rooms in Denmark, Finland, Norway, Sweden.

Table 7. Example of requirements for hospital in Finland /21/.

Space	Supply airflow (dm^3/s)/ person	Supply airflow (dm^3/s)/m^2	Exhaust airflow (dm^3/s)/m^2	Air exchange rate 1/h	Air speed	Relative Humidity %	Temperature winter/ summer	Filtration class F/H	Sound level dB/A	Pressure condition
OP & Matern. Ward										
-orthopedics.		14-22	14-22	17	>0,2	45-55	22+/-1	12	28	Pos.
-gen.surgery		14-22	14-22	17	>0,2	45-55	22+/-1	10	28	Pos.
-outpatient & infection		14-22	14-22	17	>0,2	45-55	22	10	28	Pos./Neg
Recovery ward	15	6	6				23/25	8	28	
Maternity ward	15	8	8			30-65	24/25	8	28	
Isolationrooms										
- leukemia protection	25	4	4			50	22+/-1	10	28	Pos.
-Burn 2-direct.isol.	30	6	6			20-25	28-32	10	28	Pos./Neg
-premature & infant	19	3	3			30-50	25+/-1	10	28	Pos.
-Infection isol.	25	4	4	3-10		30-40	22-24	8	28	Neg.

6.6 Russia

In Russia ventilation for clean rooms regulate different standards: SNIP 41-01-2003 "Heating, Ventilation and Air Conditioning", GOST 52539-2006 "Air quality in hospitals', SanPin 2.1.3.2630-10 "Sanitary - epidemiological requirements for organizations engaged in medical activities", SanPin 2.1.6.1032-01 "Hygienic requirements to ensure the quality of ambient air in populated areas", SanPin 2.1.3.1375-03 "Hygienic requirements for the placement, installation, equipment and operation of hospitals, nursing homes and other health care hospitals", GOST 51251-99 "Air cleaning filters. Classification. marking ", SNIP 06-31-2009 "Public buildings and facilities»

In addition, information about the requirements for operating theaters can be found in third-party standards, such as the values for the maximum noise level can be taken from GOST 12.1.036-81 «Noise. Admissible levels of noise in houses and public buildings». Non-profit organization that monitors standards in the field of clean air in the cleanrooms is the Association of Engineers for Microcontamination Control.

6.6.1 SanPin 2.1.3.2630-10

Document SanPin 2.1.3.1375-03, published in 2003 and replaced in 2010 by SanPin 2.1.3.2630-10. This document contained rather strange instructions for indoor climate in hospitals. For example, there were the words "To the cleanroom air should be supplied by laminar or slightly turbulent streams (air velocity less than 0,15 m/s)." But laminar flow can be made at a speed more than 0.2 m/s, when the boundary line is less than 0.15 m / s air flow does not become a weak turbulent, it becomes strong turbulence because it’s just not enough speed. The number of CFU per 1 m^2 in the operating room and before the start of work should be not more than 200. It is the same in the old edition and kept the same in the new document. For comparison, in France, the same number should be not more than 5.

New sanitary-epidemiological rules and norms 2.1.3.26.30-10 establish rules for placement design and operation of health care facilities, as well as establish standards for working conditions the staff of health facilities.

6.6.2 GOST R 52539 – 2006

GOST R 52539 - 2006 «Air quality in hospitals» establishes more appropriate requirements to the air in the clean room. According to it, there are 5 groups of rooms. They are divided by the number of maximum allowable airborne particles (according to International Standard 14644-1) and the maximum permissible number of CFU per 1 m^2 of air /22/.

Group 1 (ISO 5, SO 6) - the latter include operating. The cross sectional area of unidirectional airflow should be less than 9 m^2. The air flow velocity is in the range 0,24 -0,3 m/s. Allowed recirculation of indoor air. Laminar flow area must be equipped with vertical lamels, length of it must be not less than 0.1 m and the distance from the floor to the lower edge of it at least 2.1 m. The maximum number of CFU per 1 m^2 of air equal to 5 for the zone of the operating table and 20 for the area surrounding it.

Group 2 (ISO 5, ISO 6) - Requirements for group 2 are similar to the requirements of the first group. However, the second group is the room with the patients. There must be airlocks (protected environments in which dust, dirt particles, and other contaminants are excluded partially by maintaining the room at a higher pressure than the surroundings).

Group 3 (ISO 8) - In these areas recommended to install a unidirectional flow with a smaller cross-section (4,3 m^2). The air must pass a three-stage filtration, including HEPA filter on the output. It is recommended that facilities in accordance with the requirements for Group 1. The maximum number of CFU per 1 m^2 of air is 100.

Group 4 - Emergency room, waiting room. These spaces are generally using natural ventilation. Separate waiting rooms for patients with infectious diseases should be provide in the design. The maximum number of CFU per 1 m^2 of air is 500.

Group 5 (ISO 8) - Insulators. Separate ventilation system is required for these areas with minimal air change rate 12 h^{-1} and the presence of the airlock. Air recirculation is not allowed and maximum number of CFU per 1 m^2 of air is 100.

The document also provides recommendations for air change rate. Table 8 shows the ventilation rates rooms of various classes.

TABLE 8. Requirements to the air flow rate. /22/

Groups of rooms	Air change rate
1-3	Not less than 100 m^3/ h (28 l/s) per one person
4	According to regulatory documents
5	According to regulatory documents
The premises in which the anesthetic agents used	Not less than 800 m^3 / h (222 l/s) per one anesthesia machine
Rooms for smoking patients	Not less than 72 m^3 / h (20 l/s), per one person (assuming that smoking will be all in the room)

6.7 Wales

Welsh standard Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises consists of two parts: Part A. Design and validation; Part B. Operational management and performance verification. This document replaced "HTM 2025 - Ventilation in healthcare systems 1994". Rooms in Health Technical Memorandum are divided into sterile (preparation room, operating room, scrub bay), clean (sterile pack bulk store, anesthetic room, scrub room), transitional (recovery room, clean corridor, general access corridor, changing rooms, plaster room) and dirty (service corridor, disposal) /23/.

Welsh standard allows a local recirculation with using HEPA-filters. Amount of CFU in one cubic meter depends on the amount of people in a operating room, special staff clothing and type of ventilation system. HTM 03-01 specifies that the amount of bacteria in the air should not exceed 10 CFU/m^3. Velocity in the operating room at one meter from the floor must be within 0,2 - 0,3 m/s, and the relative humidity within 35-60%.

7 INTERNATIONAL STANDARDS

International Organization for Standardization, ISO, was founded in 1946. It is engaged in the development of standards. Standards of the organization are not obligatory for execution. English, French and Russian are the official languages of the organization. Nowadays as part of the ISO are 163 countries, 113 of them is a full member, 46 corresponding members, 4 subscribing members. /24/. Full members are involved in the development of standards, corresponding members have observer status, and subscribers will not take part in the activities of the ISO, but receive information about new products. Location of countries and their status is shown in the Figure 3.

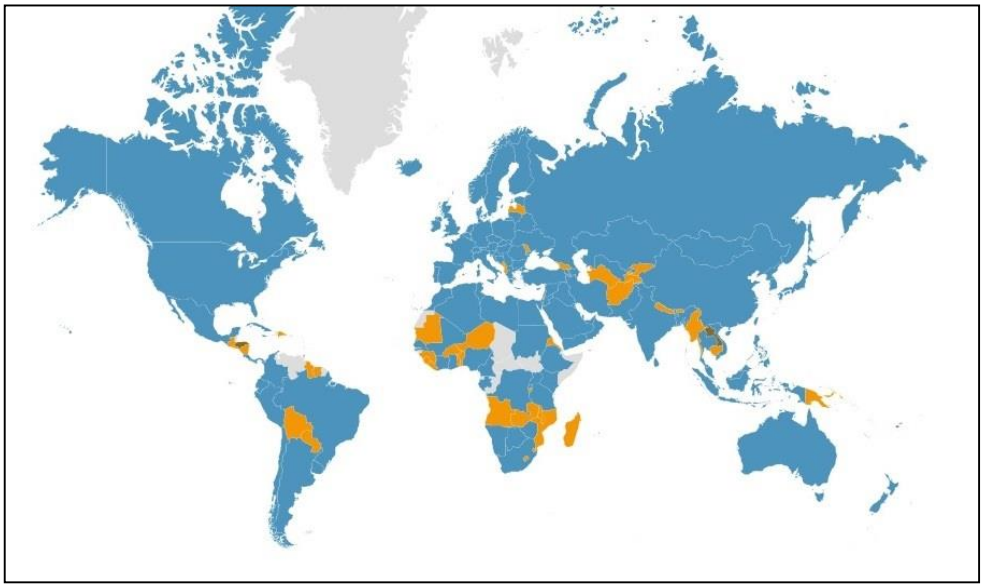


FIGURE 3. ISO members. /24/

There is a theory stating that organization received its name from the Greek word isos (ἴσος, meaning equal). However, Willy Kuert, one of the founders of the organization, disproved this information /25/.

7.1 Standard ISO 14644

The international organization ISO, which has already been mentioned earlier, in 2003, released the new standard ISO 14644 Cleanrooms and Associated Controlled Environments, which is considered international. The standard consists of 8 parts.

Part 1: Classification of air cleanliness. This part contains cleanliness classes for rooms and corresponding maximum concentration of particles with different sizes. It is also prescribed methods for the determination of purity and guidance on the calculation of particle concentrations. Provides guidelines for measuring and calculation of particles. ISO 14644-1 gives to as classification of clean rooms and amount of particles in it. Table 9 showed this information:

TABLE 9. Classification of clean rooms and amount of particles in it /26/

The cleanliness classes № ISO	The maximum allowable concentration of particles in one m^3, with dimensions equal to or greater than the following values. μm					
	0,1	0,2	0,3	0,5	1,0	5,0
ISO class 1	10	2	-	-	-	-
ISO class 2	100	24	10	4	-	-
ISO class 3	1000	237	102	35	8	-
ISO class 4	10000	2370	1020	352	83	-
ISO class 5	100000	23700	10200	3520	832	29
ISO class 6	1000000	237000	102000	35200	8320	293
ISO class 7	-	-	-	352000	83200	2930
ISO class 8	-	-	-	3520000	832000	29300
ISO class 9	-	-	-	35200000	8320000	293000

Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1. Part 3: Test methods. The listing and brief description of test methods applicable to the premises to determine its condition and correct work, guide to their location, the materials used and up to the certification of the clean rooms. Part 4: Design, construction and start-up. This part of standard identified the basic rules for the design and construction of the clean room.

In cleanroom ISO class 1-5 typically used unidirectional flow of air, and for the Class 6-9 ISO - non-unidirectional. Typical sound pressure level for the cleanroom should be 50 to 65 dB. In some cases, you may need to reduce the level of noise or excess of permitted limits. Sound pressure levels are measured in accordance with ISO 3746 «Noise of machines. Determination of power levels of noise sources using sound

pressure. Survey method using an enveloping measurement surface over a reflecting plane»

According to Standard 14644-4 there are some ways to prevent air mixing between rooms with different class of cleanliness: the principle of displacement air flow (air has to go from a clean to less clean room and have a speed of at least 0,2 m/s at the joints of premises), the principle of differential pressure (to prevent the penetration of air, pressure difference should be less than 10 Pa. Pressure difference of more than 20 Pa will prevent the door opening), the principle of a physical barrier /27/.

The other parts are: Part 5: Operation, Part 6: Terms and definitions, Part 7: Separative enclosures (clean air hoods, gloveboxes, isolator, minienvironments), Part 8: Molecular contamination.

7.2 Standard ISO 14698

Standard ISO 14698 «Cleanrooms and Associated Controlled Environments-Biocontamination Control» divided into two parts:

1) General principles and methods.
2) Evaluation and interpretation of biocontamination data.

In the first part of the standard biocontamination control system is regarded. Recommendations are given for the device, plan, frequency and sampling points. Considered processing of the results. The second part describes the analysis and data collection. It is recommended to use different methods of analysis and appropriate corrective action (received error detection). These standards translated into the languages of the countries that participated in the design and available for national organizations participating countries ISO.

8 ANALYSIS OF THE RESULT

Stringent rules should be applied to clean the air in operating theaters stringent rules should be applied. Comparison of the results obtained allege that there are not too many

differences. The standards are almost identical in some countries (German-speaking countries). In addition, in the other countries differences are not so great. However, it is important to understand that difference is not big, but significant.

Table 10 shows the values for comparison. Humidity values range from a minimum 30% to maximum 65%. Harmful microorganisms cannot form in this interval. However, the moisture can cause serious inconvenience staff. Too low value will dry the skin, mucous membranes or cause electric shock (if the floor is not an anti-static).

The temperature has different values. Low temperatures can cause hypothermia for the patient, and too high temperature may cause increase uncomfortable conditions for the operating staff. Therefore, for example, a temperature below 21 ^{o}C can cause hypothermia in the patient. It is about inadvertent hypothermia because hypothermia sometimes is used to reduce the oxygen demand of the patient in certain types of operations. It was proved that the temperature is above 23 ^{o}C interferes surgical staff work. /28, p. 84./

The big difference was found among the levels of noise. Although the noise level is not determining indicator of indoor climate quality, temperature and humidity are more important for cleanliness, specific requirements apply to level of noise. The maximum value 48 dB corresponds to the noise that does not cause discomfort, such as a conversation medium volume. The minimum value 28 dB corresponds to the whisperings of the person or the ticking of clocks. Recent studies have found a correlation between the level of noise in the operating room and post-operative recovery period. Noise higher than 43,7 dB may cause complications after surgery. Scientists describe the level of 25 dB safest /29/. But it’s impossible to make this level of noise with recirculation fans.

The number of purification steps and filters does not observe the difference. Ceiling diffuser area also not so different. It is essential that the area ceiling diffuser allowed to cover not only the operating table, but the table with tools, equipment and all staff.

Table 10. Comparative table for different countries

Country	Type of flow	CFU in $1m^3$ of air	Velocity of air, m/s	Pressure difference, Pa	Filters	Humidity %, RH	Temperature, ^oC	Noise, dB	Clean area m^2
Austria	Unidirectional	-	0,22-0,45	Slight overpressure in the operating theatre compared to side rooms	Three stage. Last H13	35-45	20-24	45 (35 for Clean areas of burn units)	At least 8 m^2 Or from 6 m^2 to 8 m^2
Germany	Unidirectional	-	≥ 0,23	-	Three stage. Last H13	30-50	19-26	45	3,2x3,2 m^2
	Low turbulent		0,24 –0,30	-	Three stage. Last H13	30-50	20-25	48	3,2x3,2 m^2
Switzerland	Unidirectional	-	0,23-0,25	-	Three stage. Last H13	30	19-26	48	At least 9 m^2
Wales	Unidirectional	10	0,2-0,3	25	Three stage. Last H13	35-65	18-25**	40	2,8x2,8 m^2
France	Unidirectional	10	0,25 - 0,35	15 ± 5	Three stage. Last H13	-	19-26	48	
Finland	Low turbulent	-	>0,2	15	Three stage. Last H12	45-55	21-23	28	-
Russia	Unidirectional	5-20*	0,24 –0,30	10-15 between rooms with different classes of cleanliness	Three stage. Last H13	30-50	21-24	35	At least 9 m^2

*- different zones: 1) over the operating table, 2) around the operating table

**-indicates the range over which the temperature should be capable of being contr

9 CONCLUSION

The standards of different countries have been compared in the field of ventilation in the operating room in this Bachelor's Thesis. It is difficult to determine the ideal values for temperature, air velocity, pressure, humidity, because different standards have different values. Some standards do not regulate all parameters of indoor climate.

The standards are updated approximately every 7-10 years. It's quite a long time, because the technology does not stand still. Materials and devices used in medicine are constantly improving. Standards must keep situation under control revised twice as often.

However, it is too hard to accept a single standard in the field of clean rooms for a few countries. Each country is notable for its own climate, therefore, the requirements for the processing and purification of air in each country will be at least a little bit different. Architecture of building is too much different and different locations of buildings, their orientation relative to the sun, the wind rose, the climate zone. All of this points to the fact that the country should have their own, even though slightly different rules.

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