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Ensuring Cleanliness in Operating Theatres

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High cleanliness of a hospital environment is necessary to ensure safe working conditions for the medical staff, a correct process of hospitalization and to protect hospital visitors, an aspect rarely mentioned. A supply of air cleaned in highly-effective air filters to hospital wards with air conditioning systems and exhaust of infected air will help in maintaining the required standards of cleanliness. This article presents information on recommended classes of air and surface cleanliness, with special focus on operating theatres and suites.

air cleanliness surface cleanliness operating room hospital

1. INTRODUCTION

Maintaining adequate cleanliness in a hospital environment is extremely important as it affects the well-being of patients and medical staff. Patients in hospital wards have a weakened immune system and are highly prone to infections, which can be caused by medical equipment and instruments infected with micro-organisms, equipment or structural partitions in the ward, indoor air and other people present in the hospital.

Also medical staff, who come into contact with numerous ill patients on a daily basis, run a risk of infection. Absenteeism due to illnesses among the medical staff in the USA is 40% higher than in other occupations. Nurses are the most vulnerable group in hospitals, especially regarding infections caused by pathogens transported by blood and other body fluids. They account for 63% of health care workers who fall ill, while doctors account for 24% only [1]. Despite information about this kind of risk run by the medical personnel in hospitals and health care centres, there are only scarce data and standards on protecting those occupational groups against infections. Both in Poland and in other countries the acceptable levels of biological indoor air cleanliness in hospital rooms, with special focus on operating rooms, have been determined with special regard to creating proper conditions for patients. That is why existing documents say that due to an invasive character of the procedures performed in the operating theatres and possible post-operative infections, it is absolutely necessary to meet the highest cleanliness standards in the operating theatre and in the other rooms of the operating suite, where patients are put [1]. This problem concerns not only medical equipment and the hygiene of the staff—issues often raised by epidemiologists—but also indoor air and surfaces in rooms.

However, the acceptable concentration of pollution in a hospital environment would not be satisfactory in case of an environmental emergency, with regard to patients, medical staff and visitors.

At present there are no common standards used for interpreting the quantitative and qualitative results of microbiological tests of a hospital environment, e.g., of indoor air and surfaces. Since Austrian, German and French scientific-technical associations have long been working on standardization procedures to formulate a joint opinion concerning acceptable levels of micro-organisms in indoor air in health care institutions, this unsatisfactory situation is likely to change in the near future.

To illustrate the problem of classification of hospital rooms in terms of the presence

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of micro-organisms and dust particles, this article will present the latest and most popular recommendations set out in standards and guidelines. Special attention will be paid to operating theatres.

2. MICROBIOLOGICAL CLEANLINESS OF INDOOR AIR

Micro-organisms—basic components of the air environment—essentially do not multiply in the air; they constitute only an incidental factor borne by the air current on dust particles or dried secretion such as droplets of mucus. They can contribute to the spread of hospital infections, being air- and droplet-borne or air- and dust-particle-borne [2]. Therefore, it is very important to determine acceptable concentrations of micro-organisms in the hospital environment, both in indoor air and on surfaces. The rooms for which such values have to be determined include operating theatres and other clean zones of operating suites, which are some of the high risk zones.

2.1. Poland

Unfortunately, to date Poland has had no guidelines for acceptable levels of microbiological pollution in health care institutions, which would be on par with state-of-the-art knowledge and the progress of technologies used in hospitals. The only source of information on acceptable micro-organism concentration is Kruczkowski's [3] publication implemented in 1984 by the Ministry of Health and Social Welfare as an auxiliary source for the design of new hospitals and recommended in the modernization and refurbishment of existing ones. Hospital rooms are divided into three groups, depending on the acceptable level of bacteria in the air: (a) cleanliness class I (minimum level of bacteria) with acceptable bacteria concentration of up to 70 bacteria/m^3 of air, (b) cleanliness class II (low level of bacteria) with acceptable bacteria concentration up to 300 bacteria/m^3 of air and (c) cleanliness class III (normal level of bacteria) with acceptable bacteria concentration up to 700 bacteria/m^3 of air.

Cleanliness class I rooms include highly aseptic operating theatres (for transplantations, heart operations, treatment of severe burns, brain operations), sterile boxes, infusion liquids laboratories, the filling box and special wards (for patients with burns).

Cleanliness class II rooms include aseptic operating theatres, septic operating theatres, plaster rooms in operating suites, intensive care units and wards, postoperative rooms, premature infant wards, patient preparation rooms (next to operating theatres) and surgeon preparation rooms, "clean" and "dirty" corridors, and sterilization rooms in operating suites.

Cleanliness class III rooms include, among others, delivery rooms, treatment rooms (operating theatres and plaster rooms in emergency wards), "clean" and "dirty" parts of central sterilization rooms, endoscopy rooms, light-treatment rooms, electrotreatment rooms, X-ray rooms, X-ray control rooms, blood drawing rooms in blood donation centres, photographic laboratories, diagnostic laboratories and apparatus rooms.

Depending on the character of an operating theatre (or rather on the kinds of performed operations), operating theatres fall into cleanliness class I or II. The other rooms of the operating tract are cleanliness class II rooms. In the case of operating theatres the cleanliness class determines the concentration of contamination in the area of the operating field; therefore, it is acceptable to allow slightly higher contamination concentration outside this field, not exceeding, however, the parameters of the next cleanliness class [3].

Unfortunately, since to date there have not been other Polish guidelines for microbiological cleanliness in hospital rooms, Kruczkowski's [3] guidelines are very often applied by designers of air-conditioning systems.

2.2. Other Countries

To compare Polish requirements with those currently applied abroad, basic information on the acceptable micro-organism concentration in indoor air in operating theatres is given in this section.

TABLE 1. Selected Microbiological Cleanliness Requirements for Hospital Rooms [9, 10]

Poland [3]		Switzerland [4]		Germany [5]			Finland [11]		France [8]		USA*	
Class	CFU/m^3	Class	CFU/m^3	Class	Acceptable Value (CFU/m^3)	Limit Value (CFU/m^3)	Risk Level	Limit Value (CFU/m^3)	Class	CFU/m^3	Class	CFU/m^3
I	70	I	<10				high	<10	B5	5	1	35
II	300	IIb	50	I	4	10			B20	20	5	175
		II	200				normal	100	B100	100		
III	700	III	500								20	700

Notes. *—guidelines published by the American Academy of Orthopaedic Surgeons in 1976, CFU—colony-forming unit.

The most commonly known guidelines for indoor air microbiological cleanliness in hospitals, applied not only in their country of origin, were developed in Switzerland [4], Germany (Standards No. DIN 1946-4:1999 [5] and DIN 1946-4:2005 [6]), Austria [7], France [8] and the USA[1] (Table 1).

According to the Swiss classification, hospital rooms are divided into the following microbiological cleanliness classes [12]: I (a very low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of ≤10 CFU/m^3 (colony forming unit per cubic metre) of air, IIb (a low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of 50 CFU/m^3 of air, II (a low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of 200 CFU/m^3 of air and III (a normal level of microbiological contamination) with the acceptable quantity of micro-organism colonies 200 CFU/m^3 of air.

Swiss guidelines classify rooms as follows [13]: (a) class I, operating theatres used for transplantology, orthopaedics, cardiosurgery; intensive care units for patients undergoing immunosuppressive therapy after bone marrow transplantation; rooms for patients with extensive burns; and specialist laboratories (serum production, preparation of transfusion fluids); (b) class II, operating theatres of lower requirements, also at emergency wards; preoperative rooms; corridors in operating suites; premature infant wards and delivery rooms; intensive care units for surgery and internal departments; and rooms for patients with less severe burns and (c) class III, intensive care units for patients with coronary diseases, delivery rooms and children's wards, central sterilization rooms, surgeries and wards, changing rooms, X-ray rooms and control rooms, gym halls, central bed stations, sterile storerooms, laboratories, corridors, kitchens and laundry rooms.

In Standard No. DIN 1946-4:1999 [5] hospital rooms are divided in terms of the required microbiological cleanliness of indoor air. The standard also presents related recommendations for the design of air-conditioning or ventilation systems. With regard to hospital areas, the standard specifies two kinds of rooms: class I, high, possibly particularly high requirements concerning low content of micro-organisms in indoor air; and class II, normal requirements concerning low content of micro-organisms in indoor air.

Following are German recommendations for concentration of contamination in rooms of a low-turbulence flow of air (air-conditioned operating theatres and other rooms where a very high degree of air cleanliness is required, equipped with an operating theatre laminar flow ceiling with a HEPA filter) [14]: (a) dust contamination: recommended acceptable concentration of particles >0.5 μm: 4000 particles/m^3 of air; limit concentration of particles >0.5 μm: 10000 particles/m^3 of air; (b) microbiological contamination: recommended acceptable con-

[1] Guidelines published by the American Academy of Orthopaedic Surgeons in 1976.

centration of colonies of micro-organisms suspended in the air: 4 CFU/m^3 of air and limit concentration of colonies of micro-organisms suspended in the air: 10 CFU/m^3 of air. Those recommended values were formulated for an operating theatre which has been disinfected and in which operations are not performed during cleanliness inspection.

3. MICROBIOLOGICAL CLEANLINESS OF SURFACES

Survival of micro-organisms on surfaces in a medical environment is a factor which contributes to their spreading and can be responsible for spreading infections. Some reports have shown that pathogenic strains resistant to medicines survive longer on surfaces than sensitive strains [15].

ASPEC (Association pour la protection et l'étude de la contamination) has presented guidelines for microbiological cleanliness in operating theatres, after disinfection, for high- and very-high-risk-zones and three reference levels, operation, alarm and target [16] (Table 2).

4. CLASSIFICATION OF INDOOR AIR DUST CLEANLINESS

Since operating theatres require high cleanliness of indoor air, they are classified as clean rooms on the basis of the quantitative concentration of airborne dust particles and micro-organisms. This section discusses essential information which can help in classifyng operating theatres and other rooms of the operating suite in terms of dust contamination [17]. The reader will also find other information on how clean rooms can be classified in accordance with Standard No. 209e [18], commonly known and quoted in Poland (although the USA has replaced it with Standard No. EN ISO 14644-1:1999) [19].

The Polish Committee for Standardization approved Standard No. PN EN ISO 14644-1:2004 in 2005 [17]. It is a translation (without amendments) of the English-language version

TABLE 2. ASPEC's Guidelines for Microbiological Cleanliness (in CFU/plate) in Operating Theatres [16]

	High Risk Zone		Very High Risk Zone	
Level	**Bacteria**	**Moulds**	**Bacteria**	**Moulds**
Operation	25	1	10	1
Alarm	10	1	5	1
Target	5	<1	<1	<1

Notes. ASPEC—Association pour la protection et l'étude de la contamination, CFU—colony-forming unit.

TABLE 3. Classification of Clean Rooms and Zones in Terms of the Content of Dust Contamination in the Air in Accordance With Standard PN EN ISO 14644-1:2004 [17]

	Maximum Concentration Limits* for Particles Equal to and Larger Than the Considered Sizes Shown Below					
ISO Classification No.	**0.1 µm**	**0.2 µm**	**0.3 µm**	**0.5 µm**	**1 µm**	**5 µm**
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

Notes. *—concentration limits (particles/m^3 of air) are calculated in accordance with Equation 1 in the standard.

TABLE 4. Comparison of Classes of Dust Cleanliness in Accordance With Standards No. 209 of 1988 and 1992 [18] and PN EN ISO 14644-1:2004 [17; 9]

Standard	USA	USA	Poland
Year of publication	1992	1988	2004
Class	—	—	ISO Class 1
	—	—	ISO Class 2
	M1.5	1	ISO Class 3
	M2.5	10	ISO Class 4
	M3.5	100	ISO Class 5
	M4.5	1 000	ISO Class 6
	M5.5	10 000	ISO Class 7
	M6.5	100 000	ISO Class 8
	—	—	ISO Class 9

Notes. Grey indicates ISO classes that apply to rooms in an operating suite depending on specific requirements.

of Standard No. EN 14644-1:1999, which is an introduction (without any amendments) to Standard No. ISO 14644-1:1999 [20]. Table 3 shows a classification of clean rooms in accordance with the said standard. Like Standard No. 209e [18], this standard takes into account the stage at which the clean room is utilized: (a) when installations have been completed, they are connected and operational, but the rooms have no production units, materials or staff yet; (b) when installations have been completed, devices/units have been installed and are operating in accordance with the agreement between the client and the supplier; however, service is not provided yet and (c) when installations operate correctly, staff work in the room in accordance with agreed recommendations. Table 4 compares those classes of dust cleanliness in rooms.

5. LEGAL FRAMEWORK IN POLAND

An amended Regulation of the Health Minister of November 10, 2006, on the professional and sanitary requirements for the rooms and devices installed in health care institutions came into force on December 9, 2006 [21]. The new version of this document contains many regulations which managers of health care institutions approve of. Many detailed regulations which did not live up to modern solutions were deleted and many other detailed terms were replaced with more general ones. In many cases no requirements were defined if a given problem was regulated in other acts, e.g., the building act. Such general regulations offer greater freedom to designers and contractors [22].

According to the regulation, (a) in operating suites, isolation wards and rooms for patients with a weakened immune system, a supply-exhaust ventilation should be used as well as an air-conditioning system, which will ensure that the parameters of air quality are appropriate to the function of the room; (b) in operating theatres and other rooms where nitrous oxide is used, 20% of the air should be blown in and out under the ceiling and 80% above the floor. The location of blow points must not force the air flow from the side of the patient's head across the operating field and (c) installations and devices of mechanical ventilation and air conditioning should be cleaned at least every 24 months. Cleaning should be documented [21].

6. CONCLUSIONS

- The problem of maintaining a high degree of air cleanliness in operating theatres and in other clean zones in operating suites is extremely important for patients with debilitated immune systems, who are prone to infections, as well as for medical personnel.

- Poland's legal framework on the cleanliness of indoor air and surfaces in hospitals does not live up to the real needs resulting from the risk of hospital infections.
- Since no Polish requirements concerning classes of acceptable cleanliness for indoor air and surfaces in hospitals have been defined, we can only consult the requirements from other countries, which are better suited to the current needs of the hospital environment.

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