Mikrobiologisk renhet i operationsrum – Förebyggande av luftburen smitta – Vägledning och grundläggande krav

Microbiological cleanliness in the operating room – Preventing airborne contamination – Guidance and fundamental requirements
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# Content

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Post-operative wound infections/Surgical site infections</td>
<td>4</td>
</tr>
<tr>
<td>Endogenous infection</td>
<td>4</td>
</tr>
<tr>
<td>Exogenous infection</td>
<td>4</td>
</tr>
<tr>
<td>Microbiological requirements for air in operating rooms</td>
<td>4</td>
</tr>
<tr>
<td>Ventilation</td>
<td>5</td>
</tr>
<tr>
<td>Preventing the flow of microorganisms from and to adjacent rooms</td>
<td>6</td>
</tr>
<tr>
<td>Clean-up time of the air following an operation</td>
<td>6</td>
</tr>
<tr>
<td>The effect of clothing systems on airborne contamination</td>
<td>6</td>
</tr>
<tr>
<td>1 Scope</td>
<td>7</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>7</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>7</td>
</tr>
<tr>
<td>4 Microbiological requirements</td>
<td>10</td>
</tr>
<tr>
<td>4.1 General</td>
<td>10</td>
</tr>
<tr>
<td>4.2 Infection-prone clean surgery</td>
<td>11</td>
</tr>
<tr>
<td>4.3 Other surgery</td>
<td>13</td>
</tr>
<tr>
<td>4.4 Set-up rooms</td>
<td>14</td>
</tr>
<tr>
<td>4.5 Rooms with direct connection to an operating room intended for infection-prone clean surgery</td>
<td>15</td>
</tr>
<tr>
<td>5 Technical building requirements</td>
<td>15</td>
</tr>
<tr>
<td>5.1 General</td>
<td>15</td>
</tr>
<tr>
<td>5.2 Design</td>
<td>16</td>
</tr>
<tr>
<td>5.3 Air tightness requirements</td>
<td>16</td>
</tr>
<tr>
<td>5.4 Floors</td>
<td>16</td>
</tr>
<tr>
<td>5.5 Ceilings</td>
<td>16</td>
</tr>
<tr>
<td>5.6 Ceiling-mounted equipment</td>
<td>16</td>
</tr>
<tr>
<td>5.7 Walls</td>
<td>16</td>
</tr>
<tr>
<td>5.8 Fixtures and loose interior fittings</td>
<td>17</td>
</tr>
<tr>
<td>5.9 Doors</td>
<td>17</td>
</tr>
<tr>
<td>5.10 Windows</td>
<td>17</td>
</tr>
<tr>
<td>6 Technical ventilation requirements</td>
<td>17</td>
</tr>
<tr>
<td>6.1 General</td>
<td>17</td>
</tr>
<tr>
<td>6.2 Total air flow</td>
<td>17</td>
</tr>
<tr>
<td>6.3 Air supply principles</td>
<td>19</td>
</tr>
<tr>
<td>6.4 Outdoor air flow</td>
<td>20</td>
</tr>
<tr>
<td>6.5 Recirculated air flow</td>
<td>20</td>
</tr>
<tr>
<td>6.6 Pressure differences</td>
<td>20</td>
</tr>
<tr>
<td>6.7 Air filters</td>
<td>21</td>
</tr>
<tr>
<td>6.8 Air humidity</td>
<td>21</td>
</tr>
<tr>
<td>6.9 Room temperature</td>
<td>21</td>
</tr>
<tr>
<td>6.10 Noise level</td>
<td>22</td>
</tr>
<tr>
<td>6.11 Static electricity</td>
<td>22</td>
</tr>
<tr>
<td>6.12 Operating rooms</td>
<td>22</td>
</tr>
<tr>
<td>6.13 Set-up rooms</td>
<td>23</td>
</tr>
<tr>
<td>6.14 Corridors of operating suites</td>
<td>23</td>
</tr>
<tr>
<td>7 Functional tests</td>
<td>23</td>
</tr>
<tr>
<td>7.1 Air flow tests</td>
<td>23</td>
</tr>
<tr>
<td>7.2 Pressure difference</td>
<td>23</td>
</tr>
<tr>
<td>7.3 Leakage tests</td>
<td>24</td>
</tr>
</tbody>
</table>
7.4 Air movement studies ................................................................. 24
7.5 Entrainment of airborne particles into clean zones .................. 24
7.6 Recovery time .......................................................................... 24
8 Measuring equipment and calibration ........................................ 26
8.1 General requirements .............................................................. 26
9 Design and quality of clothing .................................................... 26
10 Logistics ................................................................................... 27
11 Cleaning of operating rooms and set-up rooms ....................... 27
12 Operation and maintenance of ventilation systems ................. 28
13 Documentation of the ventilation system .................................. 29
14 Risk analysis and deviation management .................................. 29
Annex A (informative) Microbiological measuring methods ........ 30
A.1 Active air sampling ............................................................... 30
A.2 Passive air sampling ............................................................. 31
A.3 Example of measuring records for air sampling .................... 33
A.4 Example of report .................................................................. 34
Annex B (informative) Assessment of protection efficiency of air in clean zones LR method in the operating room .................................................. 35
B.1 General .................................................................................. 35
B.2 Measuring conditions ............................................................ 35
B.3 Method .................................................................................. 35
B.4 Equipment ........................................................................... 35
B.5 Procedure ............................................................................. 36
B.6 Evaluation ............................................................................ 36
Annex C (informative) Air flows, air change, concentration and recovery time ................................................................. 37
C.1 Air change ............................................................................. 37
C.2 Concentration ........................................................................ 37
C.3 Recovery time ........................................................................ 37
Annex D (informative) History ...................................................... 41
D.1 Airborne contamination ........................................................ 41
D.2 Ventilation of operating rooms ............................................. 41
D.3 Preventing the inflow of microorganisms from adjacent rooms 42
D.4 Architecture of operating suites .......................................... 42
Annex E (informative) The working group for this publication .......... 43
REGULATIONS AND STANDARDS ..................................................... 44
LITERATURE AND REFERENCES ..................................................... 45
Introduction

Swedish legislation (Swedish Code of Statutes, Health and Medical Services Act, SFS 1982:763) clearly states that health-care must be of good quality with a good standard of hygiene.

This technical specification describes measures which can create an environment with controlled microbiological cleanliness in the operating room. Emphasis is placed on preventing airborne contamination of the surgical field and of medical devices.

Post-operative wound infections/Surgical site infections

Post-operative wound infections occur with approximately 7% of all operations, and are the third most frequently occurring health-care associated infections in Sweden. In so-called 'clean operations', i.e. operations in bacteria-free tissue, the risk of infection is 1-3% (Att förebygga vårdrelaterade infektioner 2006. (Preventing health-care associated infections)). Most post-operative wound infections are caused by contamination of the tissue with bacteria during the actual operation. Once the wound has been closed, the infection risk is low. Bacterial contamination may originate from the patient himself, endogenous source of bacteria, or the surroundings, known as exogenous source of bacteria.

Endogenous infection

In clean operations, the patient's own skin is the main endogenous source of infection. In most cases, the bacteria from the normal skin flora only cause infections in infection-prone clean surgery, such as the implantation of material that is foreign to the body. *Staphylococcus aureus*, which is present in the skin flora in approx. 10% of healthy people, can however cause infection in all types of surgery. In operations on organs which normally contain bacteria, such as the gastro-intestinal tract, the surrounding tissue becomes contaminated with large quantities of bacteria able to cause infection in this type of surgery.

Exogenous infection

Contamination from the environment can reach the surgical site via the air, airborne contamination, or through contact with, for example, instruments and fluids which become contaminated during the operation.

The skin is the most important source of airborne contamination in the operating room. A person releases approximately 10⁷ skin particles when walking and approximately 10% of these carry bacteria. There is considerable individual variation. The skin fragments vary in size from approx. 5 to 60 µm (Noble 1975). An average sedimentation rate of 0.3 m/min can be assumed if the particles are allowed to settle undisturbed, i.e. when unaffected by ventilation (Noble 1963). Anaerobic bacteria in the skin flora also disperse into the air from the skin and survive long enough to constitute an infection risk (Benediktsdóttir 1982). Activity and friction against the skin, e.g. from clothing, increase the dispersal. When skin scales pass through relatively impermeable clothing, they can also become fragmented, with the result that more than 50% of the bacteria-carrying particles may be less than 5 µm (Noble 1963, Mackintosh 1978, Reinmüller 2003, Ljungqvist 2006).

People with skin problems or infections can also disperse large quantities of *S. aureus*, and other potentially pathogenic bacteria, such as group A streptococci, into the air. Ventilation and clean air suits do not reduce this infection risk adequately. Infection control recommendations clarify how the presence of such people in the operating room must be limited (Att förebygga vårdrelaterade infektioner 2006 (Preventing health-care associated infections)).

Microbiological requirements for air in operating rooms

Recent developments in new surgical methods indicate that operations where foreign material is inserted into the body will become more frequent, thereby increasing the need for operating rooms for clean surgery.
This technical specification is linked to the requirements concerning the microbiological cleanliness of the air in operating rooms, as set out in BOV 2010 (Byggenskap och Vårdhygien 2010 (Construction and infection control)). The recommendations are based on a combination of results from past studies (Annex D History) and what can be achieved by combining ventilation and the use of clean air suits.

**Ventilation**

Operating rooms are ventilated to provide a safe and comfortable environment for patients and personnel working in the room. This technical specification primarily concerns aspects of ventilation that are of significance in preventing airborne infection. The principal tasks of ventilation are to maintain a low level of airborne microorganisms during operation, to minimise the risk of inflow of airborne microorganisms from the surroundings and to clean up the air after surgery. Ventilation systems must operate 24 hours a day, but the flow rate may be reduced when the room is not in use.

Air flow is specified as the number of air changes per hour or the volume of supply air per unit of time, normally in m\(^3\)/s.

To calculate the number of air changes, it is necessary to know the air flow and the volume of the room. The volume of the room is of no practical importance for the stationary contamination level. This is determined by the total flow of supply air. However, the volume of the room is of significance to how fast decay (clean-up) occurs.

In Sweden, two main principles of ventilation systems are currently (2014) used in operating rooms. One is based on turbulent mixed air and normally involves supply air devices in the ceiling and exhaust air devices close to the floor. The reverse arrangement is also used and the system is then known as 'displacement ventilation'. The outdoor air flow rate is approx. 0.6 m\(^3\)/s. In the case of turbulent mixed air, the number of bacteria-carrying particles in the air is reduced by dilution.

The other principle is based on parallel air flow, where the air is distributed into the room through so-called parallel air flow ceilings with a total supply air flow of >2.5 m\(^3\)/s. With a parallel flow above the operating table, the intention is to transport the bacteria-carrying particles out of the operating area by a sweeping action. However, during operation, the parallel flow is disturbed by movements and heat generation of the operating team and by the location and heat generation of operating lamps, so that the air movements here also can be turbulent mixed. For both ventilation principles a first estimation of the supply air flow needed could be based on the dilution principle (see also 6.3) (Nordenadler 2010).

**Preventing the flow of microorganisms from and to adjacent rooms**

When a door to an operating room is opened, air may flow into the room and cause a risk of inflow of bacteria-carrying particles when there is a temperature difference between the adjacent room and the operating room. Theoretical calculations indicate that this is of low significance to the cleanliness of the air in operating rooms with conventional turbulent air distribution if the bacteria content is above 50 cfu/m\(^3\) (Nordenadler 2010). A far more important source of contamination is introduced if another person enters the room. The relative additional contribution to the airborne bacteria-carrying particles by opening of a door is greater in operating rooms where a very low level of contaminants is necessary. To reduce the inward flow of bacteria-carrying particles from rooms immediately adjacent to an operating room for infection-prone clean surgery, these rooms should have a defined air cleanliness (Ljungqvist et al 2009, Nordenadler 2010).

The operating room should be at positive pressure relative to the adjacent rooms. Changing air flow directions should be avoided.

Airborne contamination can be dispersed from the infected patient to adjacent rooms in some cases. Examples of such infections are tuberculosis, varicella and measles. Patients with extensive burn injuries disperse large quantities of bacteria-carrying particles into the air, thereby contaminating the entire environment in the operating room. Hospitals with an infectious disease department or a burns department should have an operating room which can be accessed from a corridor outside the operating suite. To enable equipment to be taken into the room, the entrance from the operating suite to the room should include an air-lock. The air-lock should have negative pressure in relation to this operating room and to the corridor. The clean-up time should be observed before the next patient is brought in for surgery. At 20 air changes/hour, the contamination is lowered to one hundredth in about 15 minutes (theoretical value, see Annex C).
Clean-up time of the air following an operation

The clean-up time is dependent on the air change rate. The clean-up time after a surgical procedure begins when no new contamination is added, i.e. the operating team (and the cleaners) have left the room and closed the door. With 18 air changes/hour (an air flow of around 0.5 m³/s in a 35 m² operating room with a ceiling height of 3 m), a 90% reduction in airborne contaminants is achieved after approx. 8 min. Once the patient and the operating team have left the room, the room is usually prepared for the next operation by one or two people, which gives a low level of airborne contamination. The number of bacteria-carrying particles redispersed to the air from the floor surface during cleaning is \(<10^{-3}\) (<1 in 1000) (Hambraeus 1978). Once the operating room has been cleaned after an operation, very little airborne contamination from the previous patient and operating team will remain.

The effect of clothing systems on airborne contamination

Clean air suits are clothing which reduces the dispersion of bacteria-carrying skin particles from the staff into the air of the operating room. SS-EN 13795 gives minimum requirements for materials that are suitable for use in surgical clothing. Design is also an important factor as regards function, but will be specified in future standards. For clean air suits to have an effect on the number of airborne bacteria-carrying particles in the operating room, they must be worn by everyone in the room.
1 Scope

The intention behind this technical specification is to provide guidance concerning the way in which the airborne contamination of surgical sites and medical devices can be minimised in operating rooms and adjacent rooms. The aim is to prevent post-operative infections caused by airborne microorganisms. The technical specification gives functional requirements, guidance concerning the technical design of ventilation systems and describes methods for evaluating the capacity of ventilation systems to remove microorganisms from the air. The interaction between clothing systems and air flow is also described. Other important measures to ensure cleanliness in operating rooms are cleaning/preparation of the room before and after an operation, working methods and traffic flow for patients and staff. These areas are considered but are outside the actual framework of the technical specification.

Fire risks are not addressed in the specification.

2 Normative references

This technical specification refers to the following documents, which are indispensible for the application of the specification. For dated references, only the specified edition applies. For undated references, the latest edition of the standard or document (including amendments) applies.

NOTE In connection with procurement the year of the document being cited should be stated.

SS-EN 779, Particulate air filters for general ventilation – Determination of the filtration performance

SS-EN 1822-1, High efficiency air filters (EPA, HEPA and ULPA) – Part 1: Classification, performance testing, marking

SS-EN ISO 14644-1, Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness

SS-EN ISO 14644-3, Cleanrooms and associated controlled environments – Part 3: Test methods

3 Terms and definitions

For application of this document, the terms and definitions that are specified in the document and those which follow below shall apply.

3.1 aerobic bacteria
bacteria which require access to free oxygen in order to live and grow

3.2 active air sampling
collection of bacteria-carrying particles from a specified volume of air through collection on a filter or impaction on an agar surface

3.3 air change
the ratio between the air flow into or out of a room and the volume of the room

Note 1 to entry: Usually expressed in number of air changes per hour.

3.4 air flow
volume of air transported per unit of time

Note 1 to entry: Specified in the unit m³/s, l/s or m³/h.

3.5 air humidity
relative humidity ratio between the current moisture content of the air and the saturated value at the relevant temperature
Note 1 to entry:  Relative humidity is usually abbreviated to RH (Relative Humidity) and is specified as a percentage (%).

3.6
air velocity
the velocity of flowing air

Note 1 to entry: Here expressed in metres per second (m/s).

3.7
anaerobic bacteria
bacteria that can survive and grow without access to free oxygen

3.8
at rest
condition where the installation is complete with equipment installed and operational, but with no personnel present

3.9
cfu (colony forming unit)
bacteria-carrying particle which gives rise to a colony on a culture plate

3.10
circulated air
air that circulates inside a room or exhaust air which is returned to the room from the same room

3.11
clean air suit
suit shown to minimize contamination of the operating room air from skin scales originating on the skin of persons and carrying infective agents

Note 1 to entry: Clean air suits are medical devices giving a documented source strength of less than or equal to 1.5 cfu/s and person (mean) when measured in an operating room.

3.12
clean surgery, clean operations
surgical operation in bacteria-free tissue

3.13
clean zone
a defined area which has a higher air cleanliness than other parts of the room

Note 1 to entry: Cf. sterile zone. Clean zones and sterile zones can, but do not need to, coincide.

3.14
cleaning
method where surfaces are mechanically worked to remove dirt, dust and other impurities, so that the surfaces become visibly clean

3.15
differential pressure
difference in air pressure between rooms

Note 1 to entry: Specified in Pa.

3.16
disinfection
reduction of microorganisms to a level which does not involve a risk of infection or the transfer of infection
3.17 dispersal chamber (body-box)
test chamber with HEPA-filtered supply air and with exhaust air in which the concentration of the total number of particles and bacteria-carrying particles from test subjects is measured in order to calculate the source strength

3.18 endogenous infection
infection from the patient him- or herself

3.19 exhaust air
air that is transported out of a room

3.20 exogenous infection
infection of the patient from other people or the surroundings

3.21 final filter
air filter used to separate particles and microorganisms in the final filtration stage

3.22 HEPA filter
High Efficiency Particulate Air filter in accordance with SS-EN 1822-1

3.23 lint (fluff) separator
fine-mesh net or perforated plate installed in the exhaust channel to protect the exhaust ducts from fibres.

3.24 operating room
room which is primarily intended for surgical operations

3.25 ordinary scrub suit
working garment for operating room staff, made from more permeable materials and not intended to prevent airborne dispersal from staff

Note 1 to entry: Ordinary scrub suit is not a medical device.

3.26 outdoor air
air in or from the outdoors
cf. indoor air

3.27 passive air sampling
collection of bacteria-carrying particles from air over a specified period of time through sedimentation on an agar plate

3.28 pre-filter
air filter used to separate particles and microorganisms installed before the final filter in the direction of flow

3.29 recirculated air
proportion of the exhaust air which is returned to the room (normally after filtration)