R³ Nordic Guideline for Hospital Ventilation

General Requirements, Operating Suites, and Isolation Rooms

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FOREWORD

This guideline is written by the group of Nordic experts from Denmark, Finland, Norway, and Sweden having tens of years international experience within the field. For several years there has been a mutual understanding by authors of this document about the solid basis for Hospital Ventilation design that have now been published in this common guideline for the Nordic countries.

This design guide provides guidance and solid basis for design as well as for verification of the technical performance of ventilation systems. It also gives guidance for the users to assess the realization of the critical indoor parameters as well as life-cycle quality assurance of the systems performance.

This guideline outlines basic requirements for proper design of ventilation systems for hospital applications. The guideline expresses what is perceived to be best practice in the field at the point of publication. The published guideline is under continuous maintenance by R3 guidelines section to make them living documents being able to include new advancements and feedback from the field.

Feedback to content and comments for new areas to be covered may be sent by e-mail to chair of the Guideline Section: hagstrom.kim@gmail.com.

It is important for R3 Nordic to stress that the publication is a best practice document and as such the R3 Nordic is not liable for any issues arising from using the guidance presented the report. The advice is general and points to proper and safe use of ventilation systems in hospitals, however, any application and installation made must be validated according to the user specifications to prove the actual performance.

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INTRODUCTION

This guideline covers aspects of ventilation in medical locations. The aim is to create a common baseline for the definitions and requirements of ventilation systems in medical locations whether located in a hospital, clinic, or other premises where healthcare services are delivered.

This guideline provides defined levels of air quality/cleanliness and comfort for these areas and addresses the requirements for ventilation systems. It deals with the specific requirements for the design, installation, operation, verification process, maintenance, and reverification of the ventilation systems.

This guideline describes requirements and hygienic issues for the ventilation systems:

- user requirement specification and verification of result
- functional design requirements and requirements for components
- air quality (e.g., cleanliness levels, temperature, humidity, air quantity)
- the protection of patients, staff, and visitors against harmful agents
- reducing the growth of microorganisms (e.g., clean-ability, accessibility, avoidance of wet surfaces, accumulation of particles)
- control of the airflow direction (e.g., tightness of systems and constructions, pressure difference)
- maintenance and reverification to ensure that the conditions are met during lifecycle.

This guideline is intended for design, construction and commissioning engineers, healthcare managers, estates managers as well as operational and maintenance managers.

This guideline aims to establish a continuous dialogue between the stakeholders of various professions involved in the implementation and use of controlled environment zones. This guideline therefore concerns all zones in which a risk assessment reveals the need to implement an organizational and/or technical process to control the indoor environment of the activity.

CONTENT

TERMS, DEFINITIONS, AND ABBREVIATIONS

Active Sampling of Air sampling of air by a sampling tube or probe using a pump and collection of microbial particles on to an agar surface or filter surface to determine the microbial load (CFU/m^3).

Airborne isolation isolation against contaminants transferred by the airborne route.

Air lock a space situated between two environments with different air conditions, making it possible to pass from one environment to the other without significant disturbance to either. Typically, an enclosed space having a minimum of two means of doors.

Air handling unit factory made encased assembly consisting of sections containing a fan or fans and other necessary equipment to perform one or more of the following functions: circulating, filtrating, heating, cooling, heat recovery, humidifying, dehumidifying and mixing air (EN 13053)

Air Terminals device through which the supply air is distributed into ventilated space or exhaust air is extracted from the ventilated space. Air terminal may also include other functions, such as air flow control, heating, cooling, filtration or room air circulation and treatment.

Alarm the signal of system malfunction or critical situation that can cause malfunction of the system resulting in a situation that is not in accordance with the required (system) performances or break down of system components.

At-Rest condition where the clean room or clean zone is complete with equipment installed and operating in a manner agreed upon, but with no personnel present (ISO 14644-1)

Certification body organization that meets the requirements of ISO/IEC 17024 for third-party certification bodies and issues a certificate of conformity (ISO 18436-1)

Classification method of assessing level of cleanliness against specification for a cleanroom or clean zone

Note 1: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air. (ISO 14644-1)

Cleanroom room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed, and operated in a manner to control the introduction, generation, and retention of particles inside the room.

Note 1: The class of airborne particle concentration is specified.

Note 2: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3: Other relevant physical parameters might also be controlled as required, e.g., temperature, humidity, pressure, vibration and electrostatic. (ISO 14644-1:2015)

Clean zone defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation, and retention of contaminants in the space.
Note 1: The class of airborne particle concentration is specified.
Note 2: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.
Note 3: A clean zone can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.
Note 4: Other relevant physical parameters might also be controlled as required, e.g., temperature, humidity, pressure, vibration and electrostatic. (ISO 14644-1)
Note 5: A clean zone can be a protected zone.

Controlled humidity humidity of the air is actively controlled by dehumidification and humidification to realize a certain dew point interval.

Colony forming unit (CFU) microorganism carrying particle which gives rise to a colony on a culture plate.

Combined isolation isolation for immune-compromised patients who are also a source for airborne contaminants.

Contaminant any particle, chemical or biological entity that can adversely affect the patient and staff, product, or process.

Contact isolation isolation against contaminants transferred by contact.

Contaminant removal effectiveness (CRE) ratio of particle concentration measured in the exhaust/return to the average of particle concentration in the room, when particles entering from filtered supply air are ignored (SOURCE: REHVA Guidebook No. 2).

Corrosion-resistant sustainable way of protection against corrosion by means of the materials used, (i.e., EN 60068-2-11 describes a test for salt mist).

Critical zone zone where the defined cleanness criteria are to be met. Critical areas can be used for example to define the protected zone(s) within an operating room.

Explanation: There can be and typically are several critical zones in a room. The same applies to Operating room, where critical zones are typically wound area and different instrument tables (for storing or preparation). In a room you may have several critical zone’s, which are individually protected.

Dilution factor number to describe to what extent the contaminants are diluted in the air by the ventilation system.

Dilution mixing airflow (DMF) air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction.

Detailed Design drawings, data, calculations, and specifications from which constructed works, components and assemblies can be constructed (ISO 15686-3)

NOTE By the end of the detailed design process, the design should be dimensionally correct and coordinated, describing all the main components of the system and how they fit together. A detailed design should provide sufficient information for applications for statutory approval to be made.

Design verification (DV) documented evidence that the proposed design of the facilities, systems and equipment is suitable for the intended use (ISO 13408-6)

Functional design specification of the functions of the components of a system and of the working relationships among them (ISO 2382)

NOTE At the end of the functional design all the functional specifications of the ventilation system are defined.

Healthcare premises premises where healthcare services are delivered.

Installation hardware of the ventilation system

Installation verification (IV) process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification (ISO 11139)

Isolation unit unit consisting of one airlock, one patient room and one bathroom.

Lay-up room/area clean room or one or more clean zones where sterile packs are opened, checked, and arranged on the instrument tables and mayo stands**.**

Lint separator fine-mesh net or perforated plate installed in the exhaust channel to protect the exhaust ducts from fibers**.**

Maintenance any periodic, planned, or unplanned work on a ventilation system, support and verification operations designed carried out to keep the system in proper working condition.

Medical locations premises where any examination, treatment, or other act having preventive, diagnostic therapeutic or rehabilitative aims and which is carried out by a health care provider.

Monitoring observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation. This information may be used to detect trends in operational state and to provide process support. (ISO 14644-2)

Multi patient isolation room an isolation room, where multiple patients carrying the same infectious disease are treated in a common patient room.

Operating department collection of rooms, e.g., lay-up room, operating room, corridor, staff rest room, air locks.

Operating room cleanroom especially equipped for the performance of surgical operations/ - interventions and is constructed and used in a manner to minimize the introduction, generation, and retention of contaminants.

Operational agreed condition where the cleanroom or clean zone is functioning in the specified manner, with equipment operating and with the specified number of personnel present (ISO 14644-1).

Operational verification (OV) process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures (ISO 11139).

Particle minute piece of matter with defined physical boundaries (ISO 14644-1).

Particle concentration number of individual particles per unit volume of air (ISO 14644-1:2015.)

Periphery area an area in the operating room around the critical zone which allows the supporting operating team to move freely including the anesthetist, the anesthetic and accommodating the equipment.

NOTE For proper air circulation it has been found that for vertical UDF systems there is need for a horizontal distance between clean (protected) zone and the walls of minimum 1.5 m.

Performance verification (PV) process of proving and documenting the system, as installed and operates in accordance with the operational procedures, performs in accordance with predetermined criteria.

Plenum compartment or chamber to which one or more air ducts are connected and that forms part of the air distribution system. A plenum can also be used as a pressure chamber to allow the even distribution of air through a filter supplying air into the room or exhaust air outlet from the room to the ducting system.

Positioning analysis determining the necessary (horizontal) size of the critical zone, based on the maximum possible set-ups for all operations intended to be carried out in the operating room, including the positioning/placing of the operating table, size and number of operating positions, tables for sterile instruments/ materials/(sample) implants and transplants, medical equipment (e.g. C-arms and other hybrid operation components), operating team wearing sterile clothing, etc.

Pressure difference difference between the pressure inside an enclosure and outside the enclosure.

Process Verification (PrV) The last stage in the commissioning, where the end users should demonstrate that the total functionality in the URS will be achieved.

Protective isolation (sterile care) means for microbiological airborne protection of immune-compromised patients with an elevated risk of infection.

Protected zone defined space or zone protected by an UDF**.**

Recovery test a test performed to determine whether the room or zone can return to a specified cleanliness level within a finite time, after being exposed briefly to a source of airborne particulate challenge. Recovery test is the time to achieve a 100:1 or 10:1 reduction of the ≥ 0.3 µm or ≥ 0.5 µm particles**.**

Repair activities performed to restore the function of a system that fall outside the definition of maintenance.

Resistant to disinfectants ventilation and air-conditioning components and products are resistant to disinfectants if they are materials able to withstand a long-term application of disinfectants and disinfecting methods.

Reverification process of demonstrating the system is fit for purpose fulfilling specified requirements.

Risk assessment structured process comprising hazard identification, estimation of risks including a judgment if objectives have been achieved**.**

Servicing See maintenance**.**

Setback condition where the system is operating at reduced capacity or switched off e.g., for energy saving when no medical activity is being undertaken.

Should means a recommended value, property, or action etc. by this guideline. The recommendation may be made mandatory by a user or in an individual project by referring to this guideline and stating that it is guidance shall be followed.

Source isolation means for protecting the environment against airborne microbiological contamination from patients with infection.

System Room or building cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services, and utilities.

Terminal device through which the supply air is distributed into ventilated space or air is extracted from the ventilated space.

NOTE a terminal may also include other functions, such as air flow control, heating, cooling, filtration or room air circulation and treatment.

Unidirectional airflow (UDF) controlled airflow through the entire cross-section of cleanroom or clean zone with a steady velocity and approximately parallel streamlines. This type of airflow results in a directed transport of particles from the cleanroom or clean zone. (ISO 14644-4).

User requirement specification (URS) approved document that records the specification for the system as well as functional, operational and/or technical aspects of the system required to realize the desired air quality.

Verification process of proving and documenting that the system is in accordance with predetermined criteria.

Weather louver device intended to allow the passage of supply or exhaust air while minimizing the ingress of rain, snow, etcetera, louvers can have either fixed or adjustable blades, (EN 13030).

ABBREVATIONS

AHU	Air handling unit
ALARA	As low as reasonably achievable
BMS	Building Management System
CFU	Colony forming unit
DD	Detailed Design
DMF	Dilution mixing airflow
DV	Design verification
EHA	Exhaust air
ETA	Extract air
FD	Functional Design
HEPA	High Efficiency Particulate Air filter, air filter group in accordance with EN ISO 294
HCW	Health Care Worker
IP code	International Protection Rating code
IV	Installation verification
LEV	Local Exhaust Ventilation
LSAPC	Light scattering airborne particle counter
NA	Not applicable
ODA	Outdoor air quality
OR	Operating room
OV	Operational verification
P&ID	Piping and instrumentation diagram
PV	Performance verification
QM	Quality management
REC	Recirculation air
RH	Relative humidity in %
SEC	Secondary air
SUP	Supply air quality
UDF	Uni Directional Air Flow
URS	User requirement specification
VAC	Ventilation and air-conditioning (system)

PART 1 GENERAL MEDICAL AREAS

1 PROJECT PROCESS

1.1 General

The project process is very important to ensure the right quality of the systems. It should be a structured process, with collaboration between representatives from the client, design team and the contractor. Special attention should be paid to risk assessment and systematic verification during the entire process.

The process can be structured in 5 main steps as illustrated in Figure 1.

Figure 1. Project process.

To ensure the systematic verification, this process should be followed by the parallel one for verification as shown in Figure 2.

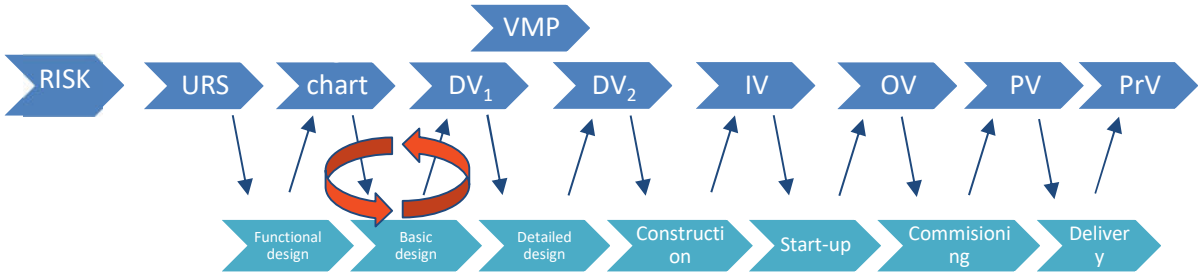

Figure 2. Integrated process of projecting and verification.

1.2 Establishing the basis

The main scope with this stage is to provide a solid and reconciled basis for the design stage. The initial needs for the medical areas should be defined. Based on the initial decisions for establishing the project, the main functional and quantified requirements should be carried out. This would be the basis for the first risk assessment in the project, to see which elements should be implemented in the user requirement specification (URS) and which organizational measures are necessary. The URS again should be further developed together with the basic layout, corresponding flow charts for personnel, patients, material and waste, and the detailed program (per room).

The first risk assessment should be performed with all the relevant stakeholders, i.e., end users/subject matter experts, senior management, safety representative, technical support and representatives from the design team. It is important to investigate so many threats as possible and

be sure the necessary measures are taken. It may be technical measures, which should be implemented in the URS, or organizational measures, which should be taken care of by the hospital.

NOTE Further information about the risk assessment can be found in "Säkerställd renhet i vårdens lokaler".

Establishing the basis will then consist of the following documents:

- URS
- layout
- flow charts
- room program

The URS is a key document in this process, as the delivery will be verified according to the requirements in this document. It should be owned by the hospital (senior management or other end user representatives), but other experts should contribute to put in all relevant perspectives. The URS should describe the areas to be covered, which relevant regulations/standards/guidelines to consider and which performance to reach in each area. All requirements should be based on the main goal, to protect patients, staff and visitors against harmful agents and minimize the risk of growth of microorganisms.

For each area there should be a list of all the prerequisites for the system:

- area and volume of the rooms
- hygienic level
- comfort level (temperature and humidity)
- number of people
- thermal load from equipment

The required functionality should also be described, such as:

- air quality
- normal functionality
- functionality in failure situations (e.g., fire alarm, fan failure)

For specific areas, like operation theatres or isolation rooms, more specific prerequisites and functionality requirements should be added, see sections 2 and 3.

1.3 Design

The scope for the design stage is to provide a verified basis for the construction stage.
The design stage consists of several steps, according to the complexity in the project. In large, complex projects the design phase could be divided into three main steps – functional, basic, and detailed design, whereas for smaller projects the whole design stage could be seen as one.

In functional design, the goal is to translate the URS into a specification of the functions needed.

This early stage in the process is also the time for setting the project goals related to sustainability. Ventilation systems in medical areas may be very energy consuming, so every project needs to take a close look to the possibilities for:

a) reducing the amount of air
b) reducing the energy needed to climatize and circulate the air
c) re-use of materials and components
d) other project-specific elements

In basic design, the layout and all the different systems should be designed. Based on the functional design, all the required systems should be described with P&ID and a description. Further, the intersections between the systems should be identified and clarified. The layout should be coordinated with the different flows (material, personnel, waste etc.) and all the necessary areas for the technical systems.

In exceptionally large and time-consuming projects, the design verification should be carried out in two steps, DV1 and DV2.

The DV1 should be a verification of the basic design according to the URS, to see that all the crucial elements are identified and considered in the initial project budget. This phase can also include simulations or mockup installations to ensure the performance.
In detailed design, the detailed specifications, calculations, and drawings should be carried out.

The official design verification (DV2) should be performed after the detailed design is accomplished.

1.4 Construction

The construction stage is the one where all the planning and design will be realized. This stage will end with the status "mechanical complete". Concurrent documentation should be part of the construction and should be summarized in the installation verification (IV).

1.5 Commissioning

After "mechanical complete" and installation verification, the systems may be turned on and verified one by one. This first step is the operational verification (OV).
When all the different systems are verified, they should be evaluated together to see that the total functionality is according to the URS. This is the performance verification (PV).

The last step in the commissioning stage is the process verification (PrV), where the end users should demonstrate that their routines will work together with the new facility, and the total functionality in the URS will be achieved.
NOTE Further information about the verification process can be found in Annex A.

1.6 Operation and maintenance

When all these steps are verified and documented, the facility may be operated as intended. The facility and the systems will need systematic maintenance and re-verification throughout the lifetime.

2 DESIGN CRITERIA

2.1 General

All performance requirements must be defined in the design phase. The requirements must be clear and ensure that it is possible to verify the requirements during the verification phase.

The purpose of the User Requirements Definition (URS) for healthcare facilities is to implement indoor air quality that:
1) protects patients, staff, and visitors in such a way that the concentration of harmful substances is low
2) the result is a pleasant indoor environment, which is defined by the amount of fresh air, temperature, relative humidity (RH), quality of incoming air, draft, direction of air flow and sound level
3) also consider sustainability factors and energy efficiency

2.2 Requirements for Indoor Environment Quality

Supply air quality in a hospital should meet at least SUP 1 according to EN 16798-3.

Recirculation of air between rooms or different zones is not allowed. Use of additional secondary air (SEC, EN 16798-3) of equal air quality may be used within a room. Overflow of air may be used within a unit with functionally associated rooms, such as air lock serving patient room.

Extract air (ETA, EN 16798-3) from healthcare premises is defined as ETA 2: Extract air with moderate pollution level, or a higher pollution level.

SUP, SEC and extract (ETA) air in ventilation systems shall be designed, controlled, operated and maintained such that unacceptable contamination e.g., by inorganic or organic substances, harmful gases within the system, are controlled.

The room types are divided to ventilation classes and should meet the requirements given in Table 1. Additional requirements for rooms with special treatments or processes should be identified in URS.

Table 1 Ventilation classes

Ventilation Class	Flow direction	Sound level of the ventilation system** dB(A)	Room type
CL1	Outward flow from clean to less clean	≤45	Operating rooms, additional terminal filtration of ISO 35H or better is required*
CL2		≤45	
CL3		≤40	Other rooms in OR department
CL4	N.A.	≤ 40	Treatment/consultation room, staff meeting room etc.
CL5	N.A.	≤30**)	Patient ward
CL6	Outward or inward flow**)	≤30	Isolation Room ***)

* Detailed performance specifications in Part 2.
** With minimum airflow rate, when patient only is present.
*** Detailed performance specifications in Part 3.

2.3 General performance requirements

The ventilation system for the general room types should be designed to meet comfort conditions in accordance with the URS having Table 2 as baseline.

Table 2 Requirements for indoor environment for general room types

Room Type	Ventilation class	Amount of outdoor air (ODA)*	Relative Humidity***	Temperature
			%	*°C*
Patient room with occupancy of permanent nature **	CL5	0,010 m^3/s,patient and 0,001 $m^3/s,m^2$ ****	Air humidification is not required	Heating season: **20-24** Cooling season: **23-26**
Rooms for Staff, and other general areas**	CL4	0,007 m^3/ s,person and 0,000,7 $m^3/s,m^2$ *****	Air humidification is not required	Heating season: **20-22** Cooling season: **23-26**

* Additional ventilation may be required by local regulations or for microbiological and chemical dilution and heat gains and losses etc.
** Visitors and staff should be taken into account separately based on variable usages. There may be elevated airborne exposure risk in close contact with the patient, Kalliomäki et al (2020)
***Condensation of moisture on components or surfaces is not allowed. If humidification is needed for specific purpose, it should be defined in URS.
**** Category I and low polluting building according to EN16798-1
***** Category II and Low polluting building according to EN16798-1
Note 1: Bold indicates the range over which the parameter may float.

2.4 General system requirements

The ventilation system should be designed and built safe and easy to maintain and clean in such a way that need to access patient areas for inspection or maintenance (e.g., filter change, fan maintenance) is reduced, while they are in medical use.

While considering the location of components with the need of maintenance they should be easily accessible and maintainable without causing occupational health risk to maintenance personnel, for example in such a way that maintenance and cleaning can be easily performed from outside.

Wet surfaces in ventilation system are not allowed in patient or medical sensitive areas and only dry cooling should be used.

Sustainable design practices should be applied to minimize energy usage. Demand based operation of the ventilation system enables energy saving opportunities also in hospitals. However, when implementing such operation user activity and medical process and its variation needs to be understood and taken in into account in design and implementation of the control system. This should be considered in URS.

Building management system, Controls and Alarms

Building management system (BMS) is an essential tool for the operation of large and/or complex buildings.
The control system design should cover both normal operation and safe operation/reaction in the case of failure. The individual control systems (e.g., for rooms, functional units, zones) should be able to continue their function independently even, when the connection to BMS is lost.

All motorized and control components should be connected to BMS and easily accessible for maintenance, and their location should be shown in the user documentation.

The pressure-controlled rooms should be equipped with differential pressure indicators.

Also, visual or acoustic signal and manual or automatic reset should be enabled close to room in question, if required in URS.

The BMS should provide at least the following alarms:

a) frost protection
b) supply air temperature and air humidity out of range
c) pressure differential across important filter section
d) functioning of each fan (air flow rate or pressure)
e) fault status of dampers

Adjustment and calibration of the sensors dealing with critical process parameters should ~~be~~ to the maintenance plan.

Facility management system (FMS)

The hospital's main goals for the management and implementation of property maintenance activities are: Effective maintenance work, ensuring conditions, managing risks and developing operations. To achieve these goals, the hospital must have a Facility management system (FMS), the preparation of which must be integrated as part of the design, implementation and warranty period maintenance processes. The FMS system must form a clear overview of the property's condition and future measures, and it must be possible to report historical information.

FMS systems functionalities:

a) Property maintenance management
b) Maintenance manual / Calendar
c) Service requests
d) Maintenance plan
e) Maintenance management
f) Long-term plans
g) Energy management monitoring and optimization
h) Integration capabilities to other supporting systems (energy, equipment, finance etc.)
i) Dynamic reporting

Documentation

The documentation attached to the FMS must support the maintenance functions. These include e.g., equipment manufacturers' maintenance instructions and construction information, building technology, maintenance reports and location drawings.

Humidity and condensation

Wet surfaces and water (condensate) in the system should be avoided because they cause corrosion and growth of microorganisms. The humidity in the system is an important indicator of the risk for condensation in the system. Humidity at the air filters of more than 90% often cause problems even if they are of a short duration.

If wet surfaces are to be expected, such units should be in the technical room where they can periodically be checked, cleaned and maintained.

It should be ensured as early as the design stage (of AHUs) that temperatures below the dewpoint are avoided within the area of the air filters, especially during standstill of the system.

It should be ensured that no uncontrolled condensation in the system can occur during all normal operating conditions, or during failure, if that can be simply prevented by a safety function.

a) if a humidifier is installed, the control system should keep the humidity in the ducting after the humidifier to a maximum of 70%
b) If the humidity exceeds this limit (70%) or there is no air flow, the humidification should be stopped.

Cleanliness

The key issue is to design, build and maintain the whole ventilation system so that it can be kept. clean enough during the whole lifetime of the installation. A clean system is the base for sustainable correct functioning of the system and preventing the growth of microorganisms and malfunctioning of filters.

The following requirements apply to the ductwork, components, air handling units (according to EN 13053) and entire systems (see EN 16798-3, Annex A).

All components should be in accordance with EN 15780 qualified for the cleanliness quality class HIGH and the EN 13053.

All components should be produced, delivered and installed in a clean condition and be protected against contamination and damage in accordance with EN 15780.The design and installation issues should include (as a minimum):

a) cleanliness criteria and measurement method
b) production of the system components
c) delivery to site
d) site storage
e) installation
f) protection of components after installation

Cleanliness (covering construction, storage, installation and usage) should be planned, inspected and documented in accordance with EN 15780. Required inspection intervals during operation should be in accordance with EN 15780 cleanliness quality class HIGH.

In addition to EN 15780, disinfection may be needed as additional concerning patient infections, and this is typically implemented after the system has been cleaned. System materials should be selected to tolerate disinfection method to be applied.

For special contaminated rooms (such as isolation rooms or patient or operative areas after patients with drug resistant microbes) it may be necessary to decontaminate such room first before cleaning to protect the staff from microbial exposure.

Surfaces and materials within the air flow

Only devices and system components should be used which do not release any harmful substances, fibers, and odors into the air flow or the rooms, respectively, and do not stimulate the growth of microorganisms.

Surfaces which are in contact with the transported air should be designed and manufactured smooth and cleanable so that a deposit of dirt is not promoted.

Glass and mineral fiber mats used for insulation or sound attenuation should not be in direct contact with the air e.g., unsealed attenuators and internal insulation.

Any porous linings within the air flow should be covered with suitable abrasion-proof material (e.g., glass silk cover).

Seals and sealants should be smooth, have closed pores, should not absorb any moisture nor form a nutrient substrate for micro-organisms. The use of injectable joint sealants on site should be avoided and expanding foams should not be used.

Local conditions should be considered when choosing construction and materials for plant and external ductwork and components e.g., coastal areas.

2.6 General requirements for components

This chapter give guidance and requirements to ventilation system components for hospital environments that exceed the minimum standards.

Outdoor air intake
The intake of air should be directly from the outside environment.

The filters should be protected against getting wet or getting blocked by freezing.

If there is a risk of freezing of the weather grille, net or filter, suitable solutions must be provided:

a) After the fresh air grille, there must be a fresh air chamber at least 500 mm long, which is equipped with a floor well
b) In areas where the supply air may contain subcooled water or heavy snowdrifts, heating of the outdoor grille may be necessary.

Outdoor air shut-off dampers

Dampers must be designed and installed in the system so that during downtime or maintenance work, air cannot flow in the wrong direction.

Outdoor air dampers should be placed to the outdoor air duct, before the filter and after the outlet weather grille. The airtightness of the dampers in both supply and exhaust ducts should be minimum EN1751: Class 3.

AHU

The construction of the components of AHU should meet the requirements of EN 1886 and EN 13053.

Mechanical characteristics of AHU's should meet following requirements according to EN 1886 and 13053:

a) mechanical stability at least class D2
b) air tightness of an AHU should comply with Table 4, EN 1886 at least class L2
c) filter bypass leakage should comply with Table 7, EN 1886 for the first and second filter stages for at least ISO EPm1 (>=80%) filtration
d) thermal insulation of the equipment enclosure should comply with to EN 1886 for at least class T3
e) the thermal bridging factor should be at least TB4 according to EN 1886. If the temperatures inside the outside air handling unit falls to below -7°C or in case of weatherproof construction a thermal bridging factor of TB3 should be maintained
f) The used materials should be resistant to sterilization agents and not emitting contaminants
g) it is recommended that all penetrations in the AHU should be pre-installed at the factory.

In addition, the AHU should meet the following requirements:

a) the internal surfaces of the AHU should be smooth, easy and safe to be cleaned,
b) the seals used should not absorb any moisture and should not form a nutrient substrate for micro-organisms
c) the internal components of the AHU should be accessible or extractable for cleaning, sanitation and maintenance
d) for humidifiers, coils, upstream and downstream should be accessible or extractable for cleaning, sanitation and maintenance

The AHU should have indicators to assess the status of the internal components. The components to be assessed are at least: filters, humidifiers and fans. Filter, cooling coil and humidifier sections should be equipped with windows and lighting for inspection and maintenance.

Heat recovery

The ventilation system of healthcare facilities is a significant energy consumer. Whenever possible, heat recovery systems should be connected to the system to reduce the energy consumption of the premises.

Heat recovery units should comply with EN 308 and EN 13053.
The regenerative heat exchanger (class III according to standards EN 13053 and EN 308) should not be used in medical facilities. In less critical areas, it can be considered based on a risk assessment.

To avoid the risk of contaminant transfer, completely heat recovery systems with an intermediate heat transfer medium should be applied, category II according to EN 13053.
Heat recovery systems should be protected by at least a class ISOePM1 60% air filter on both the supply- and extract-airsides.

Ductwork

Ductwork should be made tight, easily cleanable and all the components needing maintenance should be accessible. To achieve these following preconditions should be in place:

- Ducts and components used should be according to EN 1506, EN 1507 and EN 12097
- The ductwork leakage should comply with and be tested to ATC-2 as EN 16798-3
- For sustainability and cleanability reasons the ductwork should be as short and straight as possible
- flexible air ducts (if allowed by local legislation) are not recommended and are permitted only for the connection of air supply and extract devices and only up to a stretched length of 1000 mm. They should be safely installed so that a disconnection is prevented, connections with only tape are not allowed. Cleaning possibilities must be ensured.

Inspection openings should be installed at least for following ducted components:

a) Air filters except terminal HEPA filters
b) Coolers
c) heaters
d) Humidifiers

Filters

All ventilation systems serving healthcare medical locations should be provided with a two-stage supply air filtration to meet EN 16798-3, Indoor Climate class SUP 1 requirement. The 2nd filter stage should comply with ISO ePM1 >80% (EN ISO 16890).
In areas where the outside air is polluted and defined as ODA 3 (e.g., inner city zones, industrial zones) adding complementary gas phase filtration should be considered (according to EN 16798-3).
1st and 2nd filter stages should be equipped with pressure difference indicator for monitoring.

HEPA filters

HEPA final filters should meet at least class ISO 35H (H13: EN 1822) according to ISO 29463. For proof of s HEPA, the filter efficiency an individual test certificate should be provided with the filter.

HEPA filters should be placed in the air supply/exhaust device or as close to the room air terminal as possible. Disregard to location of the HEPA filter it should be possible to integrity test by scan testing (according to EN ISO 14644-3) To facilitate testing

- a tightly closable test aerosol supply connection must be arranged before each HEPA filter
- a representative concentration measurement point should be provided upstream of the filter accessible from the room side

Filter integrity test according to ISO-14644-3 should be performed at the first and every new filter installation, or as per reverification program (typically every 2. Year), to demonstrate the integrity of the installation.

Air terminals

Supply terminals have a significant effect on the indoor air quality, thermal comfort conditions and the efficiency of the ventilation (distribution of air) within a ventilated space. The location, type and adjustment of the supply air terminal should be designed to produce optimal indoor climate conditions considering the URS, the activity, the room air conditioning strategy within the space and the layout of the system.

Air terminals should be easily accessible for inspection, cleaning and maintenance and the construction should be openable without special tools to enable throughout cleaning by wiping of the internal parts and surfaces of the terminal.

The materials and all surfaces should tolerate appropriate cleaning, and disinfection, if necessary, methods and agents defined in URS.

Exhaust air terminals may in some applications have major influence on the efficiency of the ventilation and local conditions.

Type of the exhaust air terminal influences the dust and impurities build-up into the terminal itself or into ductwork. Clogging of exhaust terminals or other components downstream of the terminal have also major effect on the pressure and flow conditions and it should be prevented. The design of the exhaust terminal should allow easy visual inspection and if needed may be equipped with a filter at room level.

Shut off dampers

Shut off damper closing leakage should meet EN 1751: class 4, and casing leakage should meet the requirement for ductwork. Damper should be equipped with visible indication of the control position. Need for failsafe operation of the damper during system failure, shutdown or maintenance should be considered in URS, e.g., powerless closure.

Heat exchangers

Heat exchangers should be designed according to EN 13053 for hygienic purposes so that they can be easily cleaned.

For finned heat exchangers, corrosion-resistant materials should be used depending on the specific conditions.

Cooling coils and dehumidifiers

Wet surfaces and water (condensate) in the system should be avoided.

If cooling coils are wet, draining systems are required. It should be prevented that uncontrolled air from the environment (e.g., technical area) can enter the system (e.g., by under pressure).

Wet air-cooling coils e.g., dehumidifiers should have a limiting face velocity maximum 2 m/s and be provided with removable droplet eliminators.

Humidifiers

In situations where a controlled humidity is necessary (URS) humidifiers should be used. Wet surfaces and water (condensate) in the system can cause corrosion and growth of microorganisms and should always be avoided.

If humidification is necessary, steam humidifiers in accordance with standard EN 13053, humidifier class E, should be used.

Droplet eliminators

If the average air speed exceeds > 2 m/s, droplet eliminators can be used to avoid water droplets entering the system and causing wet surfaces supporting corrosion and growth of microorganisms.

For hygienic reasons droplet eliminators should be according to EN 13053 and have the following attributes:

a) all components should be easy to access and remove through service doors for and inspection and cleaning
b) measures should be taken to prevent microbial growth
c) draining system

Drainage systems

Wet surfaces and water (condensate) in the system can cause corrosion and growth of microorganisms and should be avoided.

If draining systems are required it should be made sure that the tray will be drained completely, it should be prevented that uncontrolled air from the environment (e.g., technical area) can enter the system (e.g., by under pressure).

A drainage system should fulfil the following requirements:

a) a drainage tray big enough to collect the condensate produced
b) the drainage tray should be made by corrosion-resistant materials, stainless steel or an aluminum-based alloy
c) it should have a clear and transparent trap/siphon lasting for at least 5 years e.g., glass trap
d) the trap should have a means for filling and incorporate couplings to facilitate removal for cleaning
e) the trap should be located in an easily visible position where it will not be subject to casual knocks

3 CONSTRUCTION PHASE

Before starting the construction phase, a clean build protocol should be established. Guidance for the protocol can be found e.g., from EN ISO 14644-4. The cleanliness level should be inspected and documented according to INSTA 800.

4 OPERATION / MAINTENANCE PHASE

4.1 General requirements

There are four main topics for the maintenance phase, which should be included in the end user's quality system:

- training of personnel for maintenance of the ventilation system
- documentation system
- maintenance plan
- procedures for reverification

Training of personnel

All personnel working on the ventilation systems should have documented training record.

Documentation system

The end user should have a documentation system with all relevant information about the ventilation systems and their components. This system should be updated at any time.

Maintenance plan

Maintenance of ventilation systems for medical locations should be risk based. The initial risk assessments should be followed with updated ones during maintenance phase. This risk-based maintenance plan should be communicated to and approved by the senior management.

The maintenance plan should comply with national guidelines for maintenance.
Guidance for visual inspections can be found in EN 15780, EN 12097 and EN 16798.

Reverification

Performance reverification should be done periodically and recorded. The detailed test procedures should be based on the documentation from the verification process, and the frequency should be determined from the risk assessment.

PART 2 OPERATION ROOMS

5 INTRODUCTION AND SCIENTIFIC BACKGROUND

The main purpose of ventilation within operating room is to ensure patient and HCW safety during operation. Minimizing the infection risk the room, air cleanliness should be controlled during operation. Based on research recommended CFU/m^3 levels are given, which are based on the scientific evidence provided below and in the scientific references of this document.

Charnley (1972) summarized results from 5 800 total hip replacements between 1960 and the beginning of 1970. The infection rate fell from 7 to 9 per cent to less than 1 per cent purely as a result of measures taken to prevent exogenous infection in the operating room. Prophylactic antibiotics were purposely avoided in this study.

It was believed that of all precautions taken against infection in the operating room, the most important was clean air, but this measure alone did not reduce the infection rate below about 1.5 %. The further reduction from 1.5 % to 0.5 % level was believed to be due to measures taken to avoid penetration of bacteria through the textile of the surgeon´s operating gown by using body-exhaust suits, and due also to improved methods of wound closure.

Lidwell et al (1982) reported a multicenter study in which nineteen hospitals took part and over 8 000 operations for the replacement of the hip or knee joint had been recorded. Each surgeon was allocated at random between conventional and ultraclean operating rooms. The results showed that ultraclean air in operating rooms reduced the incidence of deep sepsis after total joint replacement operations and that this reduction was enhanced when the operating team wore special suits, i.e., whole body-exhaust suites. It should be noted that the multicenter study by Lidwell et al (1982) confirmed Charnley´s results; that there is a correlation between air contamination and the infection rate, with better protection against infection in the case of UDF compared to DMF. According to analyses of Whyte et al. (1983) the most important and consistent route of wound contamination is airborne and Whyte and Lytsy (2019) suggested that ultraclean air at the wound in the operating room, on average, should contain no more than 10 CFU per m3. Today this value is internationally accepted for surgery susceptible to infections, e.g., orthopedic and trauma surgery.

While all surgeries do not need ultraclean air conditions it is up to hospital and project to assess the strategy to be used for operating rooms. Whether all the operating rooms are fit for ultraclean operations or are there dedicated rooms for ultraclean and clean operations. Additionally, for the sustainability to consider in the first case applying different operation modes for different operations (cleanliness, # of personnel etc., infection operation) and to verify the safe operation of the selected system in various modes.

Additionally, there are issues on occupational health and safety and wellbeing to pay attention to. These include use of diathermic surgery that contain ultrafine particles and gaseous contaminants generated by burnt body tissue and anesthetic gas emissions evacuation of which local extract arrangement is recommended to be used. Also, thermal comfort is an issue within operating room. As operating staff has different activity levels and clothing depending on their roles.

6 DESIGN REQUIREMENTS

6.1 General air quality requirements for operating suites

In addition to general requirements, the thermal environment and ventilation airflow rate for air quality in different room types in the operating suite should meet the requirements given in Table 3.

Table 3 Thermal, ventilation and air quality requirements for operating suites

Room Type	Ventilation Class (See Table 2)	Amount of outdoor air (ODA)	Relative Humidity	Temperature
			%	*°C*
Operating room	CL1, CL2	≥0,275 m^3/s *) **)	**<60** (at 21 °C) Air humidification is not required	**18-26**
Instrument lay-up room	As associated operating room	0,007m^3/s,person and 0,0007 $m^3/s,m^2$	**<60** (at 21 °C) Air humidification is not required	
Other rooms	CL3			

*Additional ventilation may be required by local regulations or for microbiological and chemical dilution and heat gains and losses etc. The maximum number of people in the OR should be decided by the client.
** Minimum total value per room
Note 1: The presented minimum ventilation airflow rate is based on a situation where operating rooms are equipped with local exhaust systems for anesthetic gases and surgical smoke. If this is not the case, it is recommended to use higher airflow rate.
Note 2: Bold indicates the range over which the parameter may float.
Note 3: Patient temperature control is taken care of by medical thermal devices.

It is recommended to have an adjustable temperature set point within the operating room to accommodate the thermal comfort of the staff.

A stability of temperature control in the operating room and reliable temperature reference point in critical area, are important especially, if the ventilation system performance is dependent on the temperature difference between supply and room air. Thus, an accuracy of ± 1°C in the room is recommended.

In general, there is no medical reason for continuous humidity control beyond general requirements for staff comfort and condensation prevention. (Except for a few operation types, where temperature span, should take the special requirement in to design criteria) Excursion of the room conditions. beyond above requirements for some period in extreme climate conditions may be allowed. (Note, sterile equipment needs to be maintained <70RH%)

Operating room should be maintained in over pressure ≥ 10 [Pa] to ensure outward flow to adjacent spaces. If a separate lay-up room is used next to operating room the flow direction should be towards the layup room. (Pressure direction Operation room -> layup room -> airlock -> corridor)
A ceiling void above false ceiling should be in negative pressure to the room.

6.2 Air cleanliness levels and ventilation principles

Two levels for operational air microbial cleanliness, CL1 and CL2 are defined. Both cleanliness levels can be achieved by applying two different ventilation principles: the protected zone principle or the dilution mixing principle.

However, caution is to be used, if protected zone principle is used for CL2, because the lower airflow rate used for CL2 may not be sufficient to provide protected zone, but the room airflow rate pattern become in practice dilution mixed as shown in Figure 5. At least two situations may be recognized;

1) CL1 protected zone system is used to provide CL2 condition – the discharge velocity falls too low to maintain protected zone
2) Protected zone principle is designed for CL2 room – airflow rate is too low to provide sufficiently sized protected zone.

In practice, in both cases excess airflow would be needed to maintain protected zone. However, protected zone principle may be applied for local protection of a single zone, i.e., in lay-up area.

The protected zone principle is based upon a UDF airflow to the critical zone in such a way it is protected by the sweeping action of the clean air against contaminants from within as well as from the periphery of the critical zone. The positioning of protected zone in relation to identified critical zone is illustrated in Figure 3.

The dilution mixing principle is based on a DMF airflow. The expectation is that the cleanliness level is to be met in the whole operating room without any dedicated protected zone or periphery area with dilution mixing principle. However, it is worth to identify critical zone to ensure that it will be properly ventilated as illustrated in Figure 4.

Dedicated performance requirements At-Rest, are set for each ventilation principle for projecting in order to ensure that operational cleanliness may be met. Figure 5 gives guidance for selection of the ventilation principle for different performance levels.

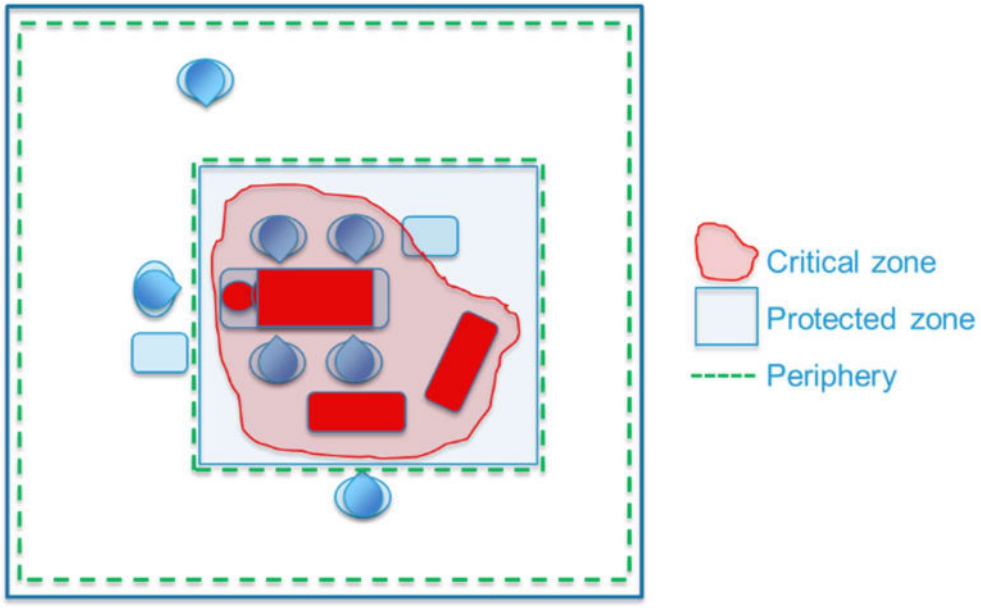

Figure 3. OR with Protected Zone principle

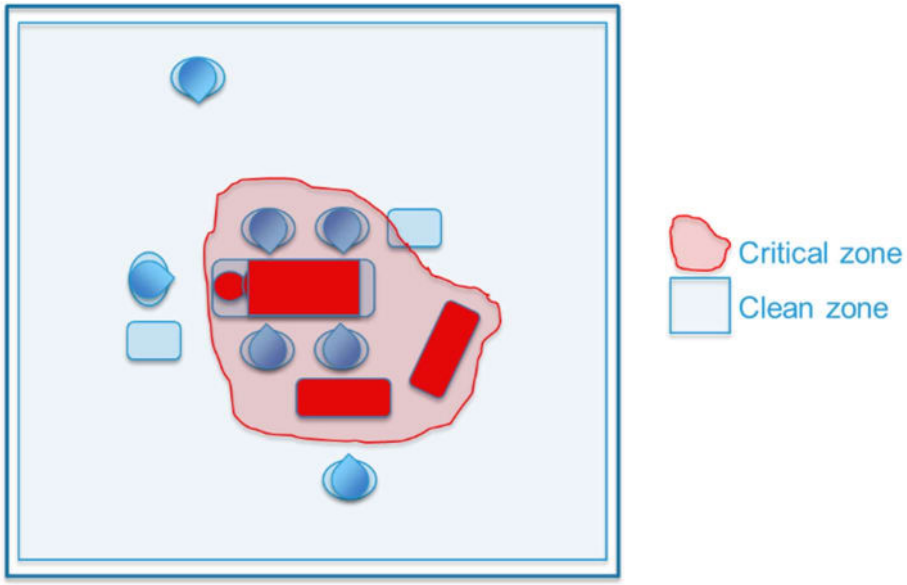

Figure 4 OR with Dilution mixing principle.

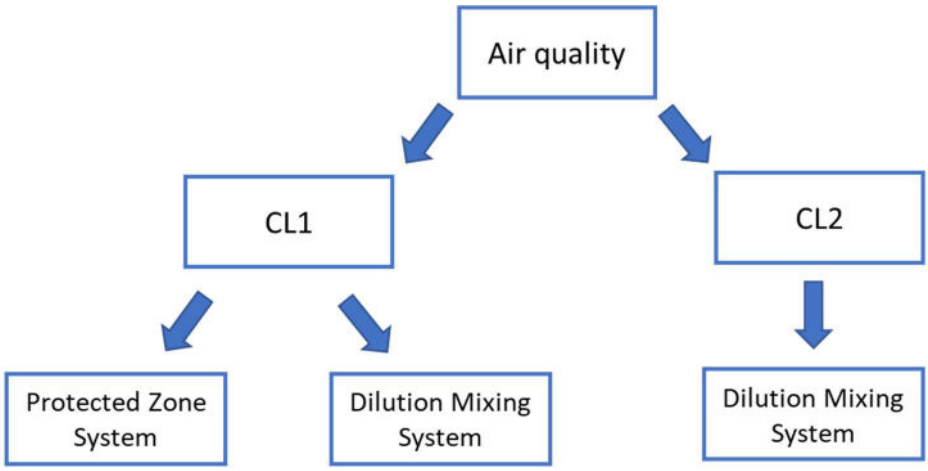

Figure 5. Flowchart: guidance for performance level, risk class and, system principle

6.3 Requirements for ventilation performance at-rest

Ventilation performance requirements for at-rest conditions given in Table 4 are used as acceptance criteria for ventilation system. During life cycle they may also be used to verify that the ventilation system is ready for operational activities.

Table 4.Performance requirements for operating room ventilation *At-Rest*

	Specification	CL 1*		CL2
		UDF	DMF	DMF
Particle concentration	ISO 14644-1 0.5 micron	ISO 5 Periphery ISO 6	ISO 5	ISO 7
Segregation test	Annex C	10^{-4} or better		
Recovery test	Annex D	100:1	≤ 10 min	≤ 20 min
Microbiological test (active air sampling) CFU/m³ *	Annex B EN 17141	<1 No fungi	<1 No fungi	<1 No fungi

*This measurement is to ensure that initial cleanliness is reached prior the room is taken in use.
** CL1 also applicable for the separate instrument lay-up room

At-Rest requirement is not applicable for operational conditions.

For energy saving purposes Set-back operation mode is recommended during non/operating periods. But after switching to the operational state the at-rest requirements should be reached within a predefined time (maximum 30 minutes).

6.4 Requirements for operational air cleanliness

Ventilation is an important contributor for operational cleanliness. However, air cleanliness levels during operational activity depend on multiple factors including users/staff clothing, medical procedures, behavior, equipment, and consumables, used during operation. Thus, operational cleanliness may not be used as an acceptance criterion for ventilation only. but for the total of all processes in the room.

End users may however use operational verification and given cleanliness levels to ensure safe operational conditions after system handover, during life cycle and even for pre-verification during design stage. Operational verification is conducted during ongoing operation, which may also be simulated operation without a patient. Guidance for operational verification is given later in the text.

Table 5 Requirements for *Operational* air cleanliness for Operating room ventilation

Test	Specification	CL 1**		CL2
		UDF	DMF	DMF
Microbiological test (active air sampling) CFU/m³	Annex B EN 17141	Protected zone ≤10 Periphery ≤30	≤10	≤50
Fungi's			< 1 CFU/m3 (no growth)	

*Mean value during one operation: max value for single measurement 3 times the mean value. The results of this measurement are not only dependent of the ventilation system but is also depending on the (medical)process e.g., number of staff, clothing systems
** CL1 also applicable for the separate instrument lay-up room

6.5 Performance requirements for supporting rooms in the operating department

A wide variety of supporting rooms, and pass through hatches, may be present in operating department either connected to individual operating room or for the whole department depending on the actual design. As a rule the whole operating department should be an independent clean zone, separated from the rest of the hospital and the airflow direction should always be from operating rooms/lay-up rooms towards supporting rooms and further to the general hospital areas.

Depending on the specific usage of the supporting rooms and risk assessment, the performance requirements and need for additional zoning or terminal HEPA filtration should be defined.

6.6 System requirements for operating suites and lay-up rooms

Factors and loads to be considered in ventilation system selection/design

The choice of the ventilation principle (protective zone or dilution mixing) to be used and design of ventilation and auxiliary systems should be based upon a risk acknowledgement of infection sensitive areas (definition of critical zone) and loads and their positioning in relation to critical zone and their influence on the airflow pattern.

When defining critical zone, at least following aspects are considered:
- The positioning of the patient
- The number and position of instrument tables and equipment

The loads and their (microbial, particles, surgical smoke, heat, undesirable gases)
- The number of personnel and their location
- Type of protective clothing of personnel
- Type and position of the lamps and other major medical devices (load, size)

For multipurpose operating rooms it is not sufficient to use only one operational layout, but variety of operational layouts and loads should be considered, when defining the performance requirements for ventilation and loads to be used as a basis of design.

Protected zone system

A protected zone system can be based on the UDF concept. The minimum required footprint of the protected zone created by UDF should be based on the position analysis to cover all critical zones. Protected zone should also be marked on the floor in the operating room and tested and documented.

The protected zone typically should provide larger area of the unidirectional airflow than the working area of the protected zone, as edge of UDF downflow is mixed with general room air.

The amount of supply airflow must be calculated based on the required strength of the sweeping action of the air to surpass any disturbances in the protected zone, on the level of general cleanness, particles, the microbiological load, other contamination sources, surgical smoke, and heat load. The highest calculated airflow must be chosen for the design.

Parameters to be defined and documented in UDF design:
- Dimension and shape of UDF supply surface
- Air velocity and velocity profile, if not uniform
- Supply air- and air temperature zones and their differential temperature to be maintained during operation, including the minimum temperature difference to be used.
- Location of exhaust low and high and re-circulating return air paths
- Type and height of the side screens around the perimeters of the UDF

Dilution mixing system

The amount of supply airflow should be calculated based on particle load, microbiological load, heat load other contamination sources and required recovery time. The highest calculated airflow needed must be chosen for the design.

Minimum air flow rate should be based on calculation of the resulting microbial cleanliness level, CFU/m^3, by dilution of the total source strength. Annex E gives guidance for the calculation of the necessary airflow.

For the design, the following additional aspects should be considered and documented:

- Supply air- and room air temperature and their differential temperatures range and capability to maintain safe airflow pattern.
- Location and type of supply and exhaust equipment, to achieve the required ventilation effectiveness and achieve required recovery time throughout the whole operating room, securing proper dilution mixing.

Room pressure / Flow direction

The operating room should be kept in overpressure and flow direction at the boundaries of the operating department should be directed towards the general hospital areas to prevent intrusion of infectious particles by airflow.

The operating room construction should be tight to ensure controlled flow from cleaner areas to less clean. The construction tightness should be defined in the design documents and should it be tested during verification. Recommended tightness of the structures is 0,4l/s,m^2 at 50 Pa.

Door test may be used to verify the tightness. The doors should be sealed and not impair the general room tightness – for example class C – air leakage < 9 m^3/h m^2 100Pa (EN 12207:2016).

If a sealed false ceiling is used that constitutes the space boundary. Otherwise, the ceiling void is included into the room volume and it's ceiling and walls should have the required permeability likewise. Unsealed ceiling void and eventual inside hollow walls should be in negative pressure towards the operating room. Pressure difference should be >10 Pa and corresponding to the chosen pressure cascade.

At the facade, the pressure difference is time to time very high and may cause undesired airflows due to natural forces (wind, temperature). Additional wall construction that separates the operating room wall from the facade creating a ‘box in box’ configuration can be used to remove the facade. effect.

Operating of infectious patients

When infectious patients are operated the primary concern is to minimize the exposure for operating staff. For this reason, it is recommended that they should be treated in ultra clean operation conditions (CL 1) with maximum airflow rate. The operating room should also be thoroughly cleaned and decontaminated after an infectious operation.

Set-back

During set-back the operating room conditions may drift from At-Rest requirements and the ventilation system may be used in reduced mode (i.e., by reducing the outdoor-air and/or recirculated-air volume flow rate(s) and to switch off the cooling and humidification systems where applicable)

Positive pressure within the operating room should be maintained in setback to prevent ingress of uncleaned air. Ingress of unfiltered air through the outdoor-air and return air ducting due to changed flow conditions should be prevented.

Safety aspects

It should be ensured that no air is supplied to the operating room that has not passed the HEPA filters, even in case of a malfunction of the ventilation or recirculation system including backflow prevention.

The use of air-cooling coils in recirculation air should be designed dry and the condensation should be prevented and controlled.

Local extraction systems

Local extraction systems are strongly recommended for removal of Diathermic smoke and Anesthetics gases. The extracted air should be either exhausted outdoors or properly filtered to remove both particles and gases.
It should be ensured that extraction systems and return air do not have negative effect on the air cleanliness. The systems should also be included into regular maintenance schedule.

6.7 Additional product requirements for operating suites

Supply air terminal

Supply air terminal devices (laminators, diffusers, grills, e.g.) should tolerate manual cleaning and disinfection and they should be designed to be easily removable.

Exhaust air terminal

Positioning of exhaust air terminals have impact on the efficiency of contaminant removal, and this should be considered in the ventilation design.

The extract terminal device should contain a system to prevent large objects entering the exhaust system e.g., perforated plate / mesh / coarse filter, and be easily accessible and openable for cleaning purposes.

Due to a pollution of the extract air with harmful gases (e.g., from disinfectants, preservatives, surgical smoke), viruses and cytotoxic there may be hygienic and/or toxicological concerns regarding the use of secondary air. To ensure sufficient contaminant removal local exhaust should be used together with sufficient make-up ventilation rate.

Secondary air, fans, and sound attenuators

Only extract air from the room itself may be used as secondary air for the room.

Secondary air fans should be speed adjustable and directly driven.

Sound attenuating materials should be hygienically safe and positioned up stream of the air filters.

Overflow device

Overflow openings and ducting (flexible duct is not permissible) should be smooth and resistant to disinfectants and easily fully cleanable during routine cleaning.

In rooms where X-rays or any other (laser) rays are used overflow openings and ducting should be designed to prevent radiation leakage to surroundings. And follow local safety requirements.

Space heating systems and chilled ceilings

In the operating room, floor, wall, and ceiling heating surfaces can be used. These surfaces should be smooth and closed as well as cleanable and resistant to disinfectants.

Convective space heating and cooling devices should not be used within operating rooms.

Floor heating systems or heat generated in rooms situated below of operating rooms can adversely influence on the airflow pattern in operating rooms.

Doors and leakage

The doors should be kept closed, when not used and door openings should be minimized when operational. Open doors can cause high airflow exchanges through the door opening caused by movement or temperature difference between adjacent rooms.

Sliding doors are recommended to be used instead of a revolving door as revolving doors create a disturbance airflow pattern when turning. Sliding doors should be fitted with a wide and a small opening position and the widest position should be used only during transport of the patient or major equipment.

Equipment for lighting and services

Any operating lamps, media-pendants, media-bridges, or large medical devices in air stream may disturb airflow pattern. It is recommended to use devices that are shaped to facilitate the airstream to flow around and/or through openings in it.

The installation of operating lamps, media-pendants, media- bridges etc. should be airtight to avoid any uncontrolled leakage.

Medical equipment affecting air cleanliness

Any devices circulating air within operating room (e.g., forced air patient warmer) may pose a risk of negative effect on the air cleanliness around the patient and sterile instruments. They should be equipped with sufficient filtration and positioned in such a way that the negative effect is minimized.

These devices should be used during the operational performance verification.

7 CONSTRUCTION PHASE, VERIFICATION MEASURES

Before executing the performance tests during operation or At-Rest, the system should be in a controlled state and commissioned including testing and documented reporting in accordance with the design.

The following tests need to be performed and documented during the finalizing the commissioning.

7.1 Installation verification (IV)

Addition to verification described in general part the IV in operating room should at least contain following specific tests:

- The air tightness of the complete construction should be tested before starting the ventilation system. Overflow openings should be tightly sealed during the permeability test.
- Verification of proper installation of HEPA terminal filters and their integrity test

7.2 Operational verification (OV)

The test activities and its reports should refer to specified values in the design documents.

1. Air balancing
2. Air velocity test (UDF systems only)
3. Air flow pattern test/visualization
4. Functional test of controls (T & RV)
5. Alarm tests
6. Room flow/pressure cascade tests

After a system is completed and commissioned the Performance test At-Rest should be performed.

The goal of this test is to determine the reduction of air borne risk factors (contamination), therefore different methods of testing are necessary for different types of ventilation principles and contaminants. These methods can be used for acceptance tests and periodical testing and reverification.

When these tests are passed the operating suite can be used and operational performance tests can be planned and performed.

Performance test of a Protected zone system at-rest

A protected zone system performance can be verified to meet the design and requirements in table 5 by employing the segregation test according to Annex C.

Performance test of a Dilution mixing system at-rest

A Dilution mixing system performance can be verified to meet the design and requirements in table 5 by employing the recovery test according to Annex D.

Clean-up time test from set-back to at-rest

If setback is used, time from setback to at-rest should be determined according to Annex F.

7.3 Performance verification (PV)

Performance test during medical activities

After completion and successful operational verification At-Rest, the performance during medical activities may be verified and compared to requirements in Table 6.

Performance testing during medical activities is intended to establish the performance of the ventilation concept designed and implemented according to the user requirement specification in combination with all operational parameters such as heat load, number-, location-, clothing- and behavior of personnel, and equipment. During these tests, the parameters of the ventilation system should be according to design and documented accordingly.

Performance testing comprises counting colony forming units (CFU) in air by active air sampling. The realization of measurement is guided in Annex B.

8 OPERATION / MAINTENANCE PHASE

The minimum requirements in part 1 should be followed.

8.1 Monitoring of technical parameters in operating department

For the technical parameter monitoring the critical technical performance parameters of the designed airflow concept should be determined and monitored for all critical room's. The critical parameters for operating room are presented in Table 6.

When the monitoring system detects out of alarm range values, appropriate warnings, and alarms as well as corrective actions should be implemented.

Table 6 Critical parameters to monitor in operating room.

Aspect of test	Protected zone system	Dilution mixing system
Air volume	Yes	Yes
Temperature difference supply / periphery	As per design	Yes
Pressure/ flow cascade	Yes	Yes

8.2 Operational Performance monitoring of operating rooms

Periodic operational performance verification is recommended to. These tests can be performed at a specified interval, it is recommended once/year as a minimum. It is also recommended to repeat the verification after major changes (i.e., the clothing system is changed, the number of people in the OR is increased beyond the design conditions, etc. change of large equipment. changes made on airflow or volume) or after infection outbreaks.

The user should conduct good practice and precaution because the operational performance results are significantly influenced by the activities of the user.

When the results of the periodic verification show an excursion from the normal range of results further investigation on the cause of the excursion should be made. When possible, the results of the investigation should be evaluated, and improvements considered.

8.3 Reverification

Reverification of operating rooms and lay-up rooms

System performance can be considered constant when the technical system is kept in good shape and functioning on the designed working points. Thus, when the initial performance has proven to be according to the specifications there is no need to re-qualify the complete systems performance according to Table 4.

The recommended periodic verification tests are presented in Table 7. These are sufficient indicators of the possible malfunction of the system/construction.

Table 7. Periodic verification tests in operating room and lay-up rooms

Aspect of test	Maximal interval
Air volume	≤2 years
HEPA filter integrity test	≤2 years
Clean-up test (when set back is used (see informative annex F)	≤2 years
Pressure/ flow cascade	≤1 years

In case of major changes in airflow balancing, constructional lay-out, or in the air handling system, the system should be commissioned and re-verified to demonstrate to perform according to Table 4. This is not applicable in the event of a like for like component change in the system (i.e., HEPA-filter change).

PART 3 ISOLATION ROOMS

9 INTRODUCTION AND DESIGN PRINCIPLES

Guidance and minimum requirements given in part 1 form the basis for designing, constructing, and operating isolation rooms. Part 3 provides additional guidance and requirements that are specific for rooms used for isolation of patients from the environment. It gives recommendations for dimensioning as well as advice how the ventilation system can be designed and verified.

Isolation rooms are divided into source isolation and protective isolation. Covid outbreak created an additional need for isolated environments with multiple patients having the same infection. Realization of such environments, e.g., intensive care units with airborne isolation is also described in the guide.

To design an appropriate isolation unit, it is essential to define which type of isolation is needed by medical staff. This guideline covers only isolation units for airborne isolation for the typical usage in most hospitals. Contact isolation is covered by normal single patient rooms and gives no additional requirements for ventilation systems.

The different types of airborne isolation covered by this guide are:

- Source isolation (of single/multiple infected patients)
  - Isolation level S_A - Normal/Typical risk
  - Isolation level S_B - High/unknown/hidden risk
- Protective isolation (of patients with elevated infection risk)
- Combined isolation

Some specific types of isolation may have additional requirements for indoor environment (e.g., burn patients). Also, in every country there may be few rooms for patients with exceptional risks that may have special design.

The design of isolation room is based on following principles:

- Isolation unit is consisting of different linked rooms; patient room, airlock, bathroom/toilet etc.
- Air leakage from / to the whole isolation unit towards environment should be minimized – this is to be made by tight construction barrier that should be maintained and verified both as built and during life cycle.
- Airflow direction within the isolation unit between the rooms should reflect the specific isolation usage (source, protective, combined)
- The airflow rate dimensioning should be based on the targeted protection degree (dilution of the microbial contaminant concentration) ventilation efficiency, and nursing process.
- Influence of the nursing process:
  - Patient room; as the patient remain continuously in patient room it can be considered that the source strength and thus also necessary dilution by ventilation may be treated as a steady state situation. The size of the patient room does not influence the necessary ventilation rate.
  - Exposure risk: recent research evidence Kalliomäki et al (2020) clearly show a highly increased exposure risk of nursing personnel, while in close contact with a patient (and vice versa) with traditional ventilation arrangements. In the guideline it has been addressed that this “worst case” situation should be addressed and verified.
  - Air lock: the most critical usage situation is, when nursing personnel exit from infection isolation. This takes place in limited time, only few minutes, and the airflow rate should during that period be sufficient to provide necessary dilution before leaving the airlock.
- Multi-patient room may be designed according to above principles given for individual isolation.

10 DESIGN REQUIREMENTS

The design of isolation room ventilation is based on the dilution. Patients with various diseases are treated in isolation rooms and the microbes cause different risk levels to users both in severity and their infectiveness. For this reason, it is not meaningful to design rooms for any particular disease, but this guideline proposes two different risk levels (S_A ,S_B) and targeted dilution factors depending on the severity. The recommended dilution factor, i.e., the number describing the extent the contaminants are diluted in the air by the ventilation system, is given in Table 8.

The contamination concentration from an infected patient's outbreath to HCW is used as the basis for dilution factor. For protected isolation, it is recommended to use corresponding airflow rates.

Table 8 Recommended dilution factors for different isolation risk levels

	Dilution Factor	
	S_A	S_B
Patient room (w/o bathroom) *	$1:10^3$	$1:2*10^3$
Airlock**	1:10	1:50
(Total)	$1:10^4$	$1:10^5$

* Steady state
** Dynamic

For a patient room a steady-state contamination (continuous contaminant source from a patient) is assumed. In the airlock the situation is dynamic as the contaminant leaks between rooms during passage and HCW stays a limited time in the airlock, while dressing/undressing the protective clothing.

For the treatment of infectious diseases in situations where there is a need to treat large number of patients with carrying the same infectious disease (such as a pandemic situation), it may be necessary to treat them in the common patient room. Such multiple patient room should be ventilated by applying the principles given in this document in following way:

The total patient room ventilation rate should be dimensioned applying given ventilation airflow rate per patient multiplied by number of patient locations. For example, the total patient room ventilation airflow rate for a multiple patient source isolation room for 4 patients is 4 times the ventilation rate defined for 1 patient isolation room.

The total patient room ventilation airflow rate can be made adjustable in multi-patient isolation to save energy in such case that all the patient beds are not in use. However, a precondition for this is that the room air distribution is realized in such a manner that the required recovery time will be met in the proximity of the patient also with reduced airflow situation.

10.1 Indoor environment requirements for isolation rooms

Table 9. Requirements for indoor environment for Isolation rooms

Room Type	Ventilation Class (See table 2)	Amount of outdoor air (ODA)	Relative Humidity***	Temperature
			%	*°C*
Isolation Room	CL6*)	See Table 10	Air humidification is not required, can be applicable for special application	Cooling/Heating season: **22-26****
Air Lock	CL6*)	See Table 10	Air humidification is not required	

* For Protective and Combined isolation ISO 35H or better terminal filter should be used.
** The comfort temperature for patient is typically within the range of 23-24 °C
Note 1: Bold indicates the range over which the set point may be selected.

11 DIMENSIONING OF AIR FLOW

The necessary airflow rates for patient room and airlock can be calculated based on recommended dilution factors using below equations and given physical characteristics.

For a patient room a steady-state contamination (continuous contaminant source from a patient) is assumed.

$$Q_{isolation} = F_{dilution} * q_{breathing} / F_{ventilation\ efficiency}$$

$Q_{isolation}$ is the required amount of supply air, in $m^3\ s^{-1}$
$F_{dilution}$ is the dilution factor
$q_{breathing}$ is the amount of exhausted breathing air by the patient, $m^3\ s^{-1}$
$F_{ventilation\ efficiency}$ is the ventilation efficiency in the room

- For a normal person, the amount of air breathed out, $\mathbf{q_{breathing}}$, is typically 0.15 dm^3/s (0.54 m^3/h).
- Ventilation efficiency of the used air diffusion $\mathbf{F_{ventilation\ efficiency}}$, in the isolation room. For Table 12 a value of 75% is used. Actual value may be used if it is determined by tests.

For airlocks unsteady-state usage situation is expected as explained earlier and the required air exchange rate may be calculated by using logarithmic equation:

$$ACH_{airlock} = ln\ (dilution\ factor) / t_{residency}\ [h]$$

$ACH_{airlock}$ *is air exchange rate in hour at the airlock*
ln (dilution factor) is a natural logarithm of the required dilution factor from Table 10
$t_{residency}$ *[h] is the residency time within the airlock between doors openings*

The required residence time for contaminant dilution is set to avoid escape of contamination outside the unit. Due to different changing procedures in the different isolation levels a different time interval is set for different levels. In isolation level S_B the staff normally stays longer due to more complex changing routines. The residency time interval (waiting time) used for the calculation of the values in Table 10 (due to high airflow rate complete dilution is assumed):

- S_A: 3 minutes
- S_B: 5 minutes

The calculated airflow design requirements are given in Table 10. Correspondingly the same equations are used for verification 100:1 recovery time calculation.

Table 10. Airflow design requirements (URS) for isolation units

Type of isolation unit	Source isolation Level S_A	Source isolation Level S_B	Protective isolation	Combined isolation
Air flow rate Patient room (/bed)* Airlock	 200 l/s Upon recovery time	 400 l/s Upon recovery time	 200 l/s Upon recovery time	 200 l/s Upon recovery time
Recovery time (100:1) Patient room, 60m³ Airlock	 < 24 min < 6 min	 < 12, min < 6 min	 < 24 min < 6 min	 < 24 min < 6 min
Waiting time in the airlock**	>3 min	>5 min	>3 min	>3 min
Typical ACH** Patient room, 60m³ Airlock WC	 12 ACH 46 ACH -	 24 ACH 46 ACH -	 12 ACH 46 ACH -	 12 ACH 46 ACH -

* Supply air is 100% outside air.
**Typical number of air changes in the rooms based on the dilution factors. The Isolation room is in steady-state condition and the ai change rate depends on the room volume, whereas the decay of contamination in the air lock is a dynamic (intermittent) process and should be met during residency.

12 SYSTEM REQUIREMENTS FOR ISOLATION ROOMS

Specific system requirements for isolation rooms are given in Table 11.

Table 11. System requirements for isolation units

Type of isolation unit	Source isolation Level S_A	Source isolation Level S_B	Protective isolation	Combined isolation
Exhaust filtration	ISO 35H or better	ISO 35H or better		ISO 35H or better
Supply filtration			ISO 35H or better	ISO 35H or better
Air tightness of the isolation unit at 50 Pa*	0.2 l/s m²	0.1 l/s m²	0.4 l/s m²	0.2 l/s m² **

* Air tightness should be tested on the inner unit surface, including doors, windows and pass-through cabinets, see Figures 6 and 7.
** Depending on isolation level for source isolation

12.1 Airflow principle

The airborne protection in isolation room is based on the minimization of the flow through the isolation unit boundary surfaces covering all the individual rooms (patient room, air lock(s), Bathroom/Toilet) within. Depending on the type of the isolation room the airflow direction between the individual rooms varies. The airflow principles for different types of isolation are presented in below drawings.

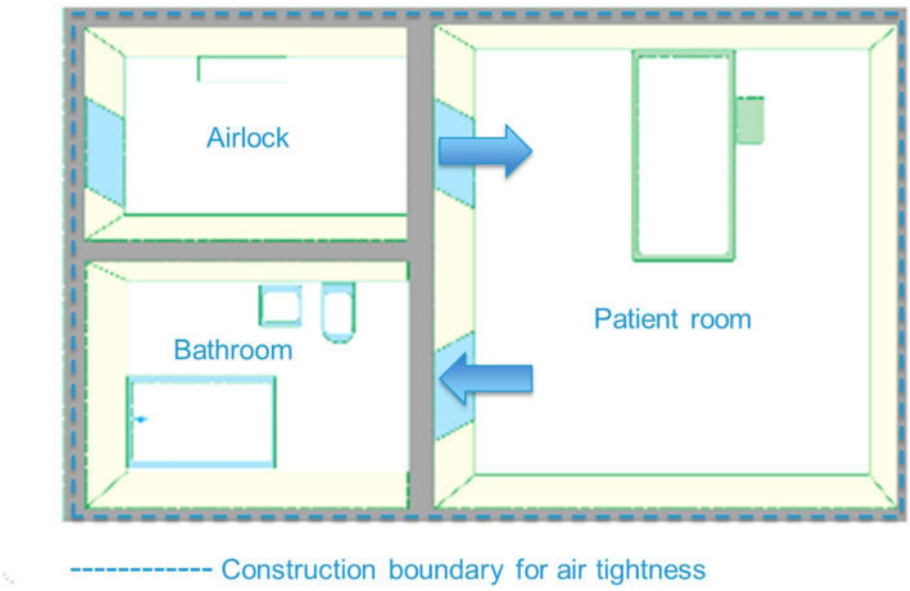

Figure 6. Airflow principle for source isolation

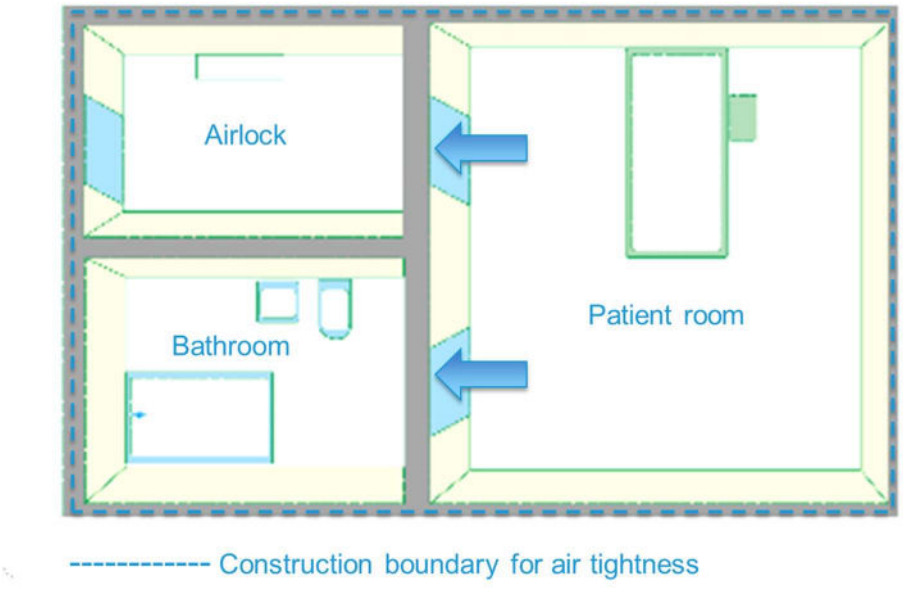

Figure 7. Airflow principle for protective and combined isolation

12.2 Design requirements

System risk assessment

As the main goals in isolation unit are to minimize the concentration of airborne contaminants in the air and prevent their escape to surrounding areas, it is important to conduct a risk assessment considering safety of patient, staff, visitors and surroundings. The risk assessment should cover fault situations and preparedness on those, such as the acceptable time for system unavailability, need for redundant and/or separate air handling systems, secure power supply and necessary alarms.

Emergency power should be supplied for the ventilation and control system for the isolation unit.

System, components, and materials should be designed to enable vaporization of the isolation unit. (i.e., each Isolation unit should be equipped with tight shut-off dampers on both supply and exhaust)

Building construction requirements

The building construction around the isolation unit should meet the requirements for air tightness given in Table 14 – also when an isolation unit has contact with the façade. The façade effect may be solved by building the isolation unit as a "box-in-box"-construction.

Windows should be closed and sealed, and for Level S_B they should be fixed. For Level S_A, P_A and P_B they may be opened with special tools, only for cleaning purposes.

Both sliding doors (effect on the airflows between rooms) or swinging doors (cleanability an issue) may be used as they both have their pros and cons. It is important to ensure that the used door construction is sufficiently rigid to tolerate continuous pressure difference.

Any door to the airlock should be interlocked to ensure sufficient residence time according to the measured recovery time in the airlock before the next door may be opened. The door to corridor should be equipped with automatic door closer. It should be possible to override he interlock for emergency situations (e.g., fire alarm of immediate life-threat) and bed transportation. Shut-off of the interlock should be indicated by a door alarm.

There should not be any other openings to the surroundings, or they should be equipped with pass through arrangement.

Room surfaces should meet with infection control requirements (i.e., smooth, impermeable, durable) and be compatible with the chosen cleaning and disinfection methods.

Construction layout, materials, equipment, and furniture should be designed to enable vaporization of the isolation unit. It is recommended that false (non-tight or non-sealed) ceilings would be avoided for Level S_B to better enable disinfection of ceiling installations.

Vaporization

Isolation units, in particular level S_B, should be possible to disinfect by vaporization. The vaporization should always be performed for the whole isolation unit, which means that the doors within the isolation unit should be open during vaporization. The isolation unit should be kept in under pressure during vaporization, if possible, and monitored by the pressure indicator between the isolation unit and the surroundings. The planning of the vaporization must be part of the design and the vaporization method need to be verified to ensure its efficiency in disinfecting the whole unit.

Alternate usage

Alternate usage is not recommended and primarily isolation rooms should be dedicated to either infection of protective isolation only. However, if alternate usage will be applied following safety precautions are required for multipurpose isolation rooms that are used for both source and protective isolation:

- Isolation level S_B isolation rooms should not be used as multipurpose isolation rooms.
- The isolation room ventilation system should be built based on the requirements of Combined isolation with additional functionality for source isolation.
- The room construction should be proven airtight both with over and under pressure.
- The isolation room should be completely vaporized before using it for protective isolation.

Set-back/ Patient room mode

Isolation room is a major energy consumer. Depending on the hospital and patient situation the usage rate of isolation rooms may vary.

Thus, the isolation unit ventilation system should be equipped with a set-back room mode for energy saving purposes to enable use in reduced capacity when there is no need for airborne isolation. Such a set-back mode should enable the use of the room for normal patient use to facilitate efficient usage of the rooms.

During operational qualification, the correct operation of different operation modes and the changeover situations should be tested.

Operating mode selection

During usage the selection of the actual operation mode (i.e., isolation/set back) is made by medical staff based on the actual patient isolation need and this should be easily enabled from the nursing station.

Exhaust arrangements

The exhaust ductwork for source isolation should be kept in under pressure. This should be considered, when designing exhaust fan arrangement.

Heat recovery

For the ventilation heat recovery made only intermediary heat transfer medium system should be used, according to class 2, EN308.

Filters

HEPA-filters may be installed in the ductwork, separate for each unit or inside the isolation unit. Irrespective of the strategy for where to install them, the following should be defined:

- How to integrity test/qualify them
- Enable safe change Vaporization/bag-in-bag-out/disposal

When a HEPA-filter is used in the exhaust, it should be possible to requalify and change without any danger for the staff. This can be done by safe-change filter-housing or in-room vaporization before filter change.

Ductwork

For the safety of maintenance personnel, the exhaust ducts should be marked with biological signs until HEPA-filter (or until exhaust, in case of no HEPA-filter is installed)

Air terminals and airflow pattern

Supply and exhaust terminals should be positioned, and airflow pattern designed, to reduce the exposure of the staff, visitors, and patients as much as possible. The efficiency is to be tested during verification as described later in the text.

Dampers

Automatically closing motor actuated airtight shut-off dampers should be installed in the supply air and extract air ducts of isolation unit to prevent backflow and cross-contamination in case of system failure (i.e., in the event of a system standstill or an interruption in the energy supply).

The shut-off dampers should be installed closest possible to the isolation units, but still accessible for maintenance, and at least upstream of the 3rd filtration stage and downstream of the 1st exhaust filter stage.

Indicators and alarms

There should be a visual indicator outside the access door of the isolation unit to indicate pressure between the isolation unit and the surroundings. If operation mode control is used, it should also be indicated. There should also be at least visual alarm in case of critical error (i.e., system failure, open door). I also acoustic alarm is used; it should be possible to be temporarily muted.

Additionally, there should be a technical alarm to BMS in case of ventilation system failure.

The critical alarms and indicators should also be shown at the nursing station in the nurse's office.

13 CONSTRUCTION PHASE, VERIFICATION MEASURES

The verification measures mentioned in general part should be realized before specific verification measures described in this chapter.

13.1 Air tightness test

The isolation unit leakage rate should meet the requirement from Table 14.
The air tightness should be tested according to EN ISO 9972 with the exception that the unit door is part of the tested structure.

For the test, he room construction should be equipped with a separate test connection through which the air is supplied/exhausted for pressurization. The connection should be closed and sealed after testing.

The test airflow and the pressure difference between the isolation unit and the surroundings should be documented and used for comparison during reverification to understand influence of changes in construction on the system performance.

13.2 Recovery test

The recovery test should be performed according to ISO-EN 14644-3.
Recovery test should be carried out after completing the installation in the At-Rest condition, with equipment and furniture installed and fully functional.
If new, untested terminal/airflow pattern is designed it would be advisable to verify its performance before installation of the system.

Selection of measuring points

Minimum of two measuring points should be used in the Patient room, for the Air lock one measuring point is sufficient:

- Patient room:
  - In the working plane at the bed (1,5 m above floor level) 50cm from the head end
  - Near the main exhaust or overflow opening.
- Air lock: In the working plane (1,5 m above floor level) in the middle of the Air lock.
-

For multi-patient isolation rooms, the number of the measurement points is maximum number of the patient beds plus one. This meaning that in 4 patient isolation room the number of measurement points is 5 of which 4 should be in the working plane at each bed and one close to exhaust.

Realization of the recovery test

Before testing, calculate the concentration required to carry out the 100:1 recovery test based on a steady state concentration. Care should be taken to avoid coincidence error and potential contamination of the LSAPC optics.

Testing procedure:

a) the particle size used in this test is 0,5 µm.
b) the Patient room / Airlock air should be contaminated with an aerosol while the ventilation and control systems are fully functional
c) raise the initial particle concentration to more than 100 times depending on the target cleanliness level
d) commence measurements at not more than 1 min intervals and record time and concentration

13.3 System performance, Functional test

A comprehensive functional test should be done for the isolation room control system ensuring that the functional targets are met in each operating mode.

14 OPERATION / MAINTENANCE PHASE, REVERIFICATION MEASURES

The following system parameters should be measured annually:

- Pressure difference between the isolation unit and the surroundings
- Ventilation airflow rate
- Airflow direction between the rooms within the isolation unit

All these values should be compared to the initial values of initial verification and, if any differences occur, measures should be taken. (i.e., drop in pressure difference or increase in airflow rate may both indicate increased leakage of the isolation unit and may pose need for sealing measures)

Re-verification of the system is recommended to be scheduled with the integrity test of HEPA-filter, typically every second year at least, or HEPA filter change.

This is not applicable in the event of a like for like only is sufficient.

If continuous monitoring of above parameters is implemented into the control system, it can be utilized for re-verification and the interval between independent re-verification measures may be extended.

When initial performance has proven to be according to the specifications there is no need to re-qualify the complete systems performance regularly.

In case of major changes (i.e., airflow balancing changes, constructional lay-out changes or changes in the air handling system design), the system should be commissioned and verified according to chapter 17. to demonstrate the performance according to specification. This is not applicable in the event of a like for like only is sufficient (i.e., replacing a HEPA filter or actuator).

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ANNEX A VERIFICATION

General

Verification is a continuous process from design to performance and operational level, to be sure the ventilation system will meet the requirements in the URS.

Design verification (DV)

DV should be performed on all material intended for the construction, e.g., layout, technical drawings, BIM, details, P&IDs, technical leaflet, datasheets and other kind of basis for construction. All relevant material should be inspected, to see whether it complies with the requirements in the URS or not. And all elements described in the URS should be verified before construction.

Installation verification (IV)

In IV, all requirements in the URS should be physically inspected and verified, to see that they meet the relevant requirements. IV should include elements from EN 12599, but also other relevant requirements from the URS. It should be proven and documented that the delivery is in accordance with the contract, the design material and the URS.

Typical steps to perform IV is to mark out on P&IDs and technical drawings, physical investigation of the construction details and tightness test of the ducts.

Operational verification (OV)

OV should be performed after the systems are powered up and set into normal operation. It should include elements from EN 12599, but also other relevant requirements from the URS. It should be proven and documented that the delivery is in accordance with the contract, the design material and the URS.

Typical steps to perform OV is to verify the amount of air in each room (both in normal and standby mode), the required airflow direction or pressure differences between rooms, testing of critical components like fire dampers or HEPA-filters (if present), and verify that sound level, temperature and relative humidity are within the required ranges. All these functionality checks should be performed at rest. When all these (and other relevant) parameters are verified, the cleanliness of the room and areas should be demonstrated.
When all inspections and functional tests are completed, they should be documented and signed, and lead to a complete OV report.

Performance verification (PV)

PV should verify the total functionality of the ventilation systems together with all the intersections to other systems and parts of the building.
Typical tests in PV could be:

- normal start and shutdown of the system
- fan failure situations
- neighbor systems shutting on and off, to see how they influence on each other
- verify alarms and communication to the BMS
- functionality tests in operation (with persons and equipment running)

When all the relevant functionality described in the URS is verified, the final cleanliness should be demonstrated in operation. It should be defined in the contract whether the demonstration of final cleanliness is part of the delivery of the ventilation system or the responsibility of the owner.

When all inspections and performance tests are completed, they should be documented and signed, and lead to a complete PV report. A successful PV should be the basis for the operational stage. Maintenance plans, operating procedures, training, and reverification should be planned according to the PV. To ensure this, it is recommended to invite different stakeholders to observe relevant parts of the PV.

ANNEX B ACTIVE SAMPLING OF AIR

Principle

Two methods (filtration and impaction) are recommended, which is in accordance with EN17141 Cleanrooms and associated controlled environments – Biocontamination control
General principles and methods. Airborne microbe-carrying particles (colony forming units (CFU)) are trapped via filtration using membrane filters or via impaction on an agar plate. Particles of ≥2µm should be trapped in both cases.

Examples of measuring instruments are given below. Alternative sampling methods may be used, if they cover the same properties and that the results have been demonstrated as being in accordance with the sampling methods specified below.

General

At least 4 but preferably 6 samples of 10 minutes should be taken during ongoing surgery to ensure that most of the time between incision and suturing is covered. Each set of samples should e.g., have information identifying the operating room, type of surgery, number of people present, their clothing system and number of door openings.

Select sampling locations at working height around 1.2m above floor level in accordance with the instructions, e.g., ≤0.8m away from the surgical site, on the instrument trolley or in the periphery of the room. Use a flow of around 100l/minute and a sampling time of 10 minutes, i.e., a sampling volume of around 1m^3.

One unexposed plate (reference plate) from the same media batch per sampling set should be incubated for the same time as the sampling plates. Agar plates should be labelled on the bottom or on the edge (not on the lid).

Incubation recommendations: Blood agar plates should be incubated aerobically for at least two days at 35°C ±2.5°C. TSA plates should be incubated aerobically for at least three days at 32°C ±2.5°C, and for at least two further days at 22°C ±2.5°C to detect molds and yeasts.

The total number of colonies (CFU) per plate should be counted and from this result the concentration should be given as number of CFU/m^3. The mean value and min/max values for each operation should be documented. The mean value should be used for rating the microbial cleanness level. In addition, any of the measured values should not be higher than 3 times the class limit. The microorganisms detected should be identified to relevant level if required. The sample set should be deemed invalid if the reference plate shows growth.

Examples of sampling and evaluation documentation are given in the ‘Example of measuring records for air sampling’ with active air sampling in operating room for infection-prone surgery’ below.

Further guidance on active air sampling:

1) Filtration
   a) Sampling material Membrane filters, pore size ≤3µm.
   b) Sampling Allow the agar plates to reach room temperature prior to sampling to avoid condensation on the plate.
   c) Sampling Allow the agar plates to reach room temperature prior to sampling to avoid condensation on the plate. Exposed membrane filters must be transferred aseptically to the agar plate.

Note: Plates with gelatin membrane filters should be incubated with the exposed side of the filter facing upwards.

2) Impaction
   a) Sampling material Sieve or slit-to-agar sampler with d_{50} ≤2µm. TSA or Blood agar are suggested~~,~~ size and agar fill in accordance with the specification given by the manufacturer of the sampling instrument.
   b) Sampling Allow the agar plates to reach room temperature prior to sampling to avoid condensation on the plate.

Recommended threshold's limits for ultraclean operating room:
Average per operation 10CFU/m^3 and highest individual value 30 CFU/m^3

Example of measuring records for air sampling

		Air flow m^3/min
Filter manufacturer Batch no		Culture plate media Batch no
Date		Sampling operator responsible
Operating room no		Type of operation
Incision start	Suturing start	Clothing system

No	Start Time	End Time	No of door open-ings	No of people pre-sent	Sample remarks	Reading remarks	Total no of CFU per plate	Read date Signa-ture
Reference plate								
Sample 1								
Sample 2								
Sample 3								
Sample 4								
Sample 5								
Sample 6								
Mean value								
Highest value								
Remarks (species detected)								
CFU/refere nce plate								
Presence of molds								

ANNEX C SEGREGATION TEST (LR METHOD IN UDF OPERATING ROOM)

The purpose is to measure the extent of the protection efficiency against the entrainment of room air into the clean zone by challenging the area outside the clean zone with airborne particles. Dispersion routes within the clean zone may also be taken into consideration.

C.1 General

The LR method (Method for Limitation of Risks) describes a reliable method for the systematic evaluation of potential microbiological risks caused by the entrainment of room air into a clean area or 'clean zone'. The method has been published by Ljungqvist and Reinmüller (1993, 1995 and 2002). The LR method consists of three parts: an initial visualization of air movements, followed by a particle challenge test with the simultaneous measurement of particles in the clean zone. A risk factor is calculated based on the maximum value measured in the clean zone.

C.2 Measuring conditions

The LR method is not dependent on the size of the clean zone or the operating room. Ventilation and lighting must be operated normally. Operating lamps must be turned on and positioned in their normal position and the operating table and instrument tables must be in their usual positions. If not otherwise specified, the lamp positions should be like shown in Figures C1 or C2. The positions of the operating table, instrument table and operating lamps should be documented.

The measuring probe of the particle counter must face vertically upwards and be positioned in the middle of the operating table at around 1.0 – 1.1m above floor level. The evaluation should normally be carried out in an empty room without the operating personnel present. Further information can be obtained by performing the test under simulated surgical operations.

C.3 Method

The three steps of the LR method:
First step: The main air movements are visualized (with the aid of smoke, e.g., using Air Current Test Tubes or smoke generator), and any vortices or stagnation areas are identified. With this it is possible to ensure that air supply from UDF is working properly. With this it is also possible to define the boundary of the protected zone.

The second step consists of the particle challenge test, which identifies potential risk situations. The particle challenge test with simultaneous particle measurement is performed with the measuring probe of the particle counter facing upwards and placed in the center of the operating table (if appropriate also in the center of the instrument table) 1.0 – 1.1m above floor level at the same time as particles are generated along the lower periphery of the clean zone. Particles should be generated until the measured local concentration exceeding 10^7particles/m^3 equal to or larger than 0.5 µm is reached.

In the third step a risk factor is calculated. The risk factor is defined as the ratio between the maximum measured concentration (number of particles ≥0.5 µm/m^3) in the clean area and the particle challenge level. Due to insufficient measuring accuracy at high concentrations, the value of 10^7particles/m^3 must be used as the particle challenge level when calculating the risk factor.

C.4 Equipment

Appropriate particle source for the local generation of particles (≥0.5 µm) to a concentration of more than 300,000 per cubic foot (e.g., Air Current Test Tubes or smoke generator).

Appropriate light source for observation of air movements. Particle counter for the calculation and size determination of airborne particles ≥0.5 µm. The sampling flow must be 28,3 l/min. The measuring probe must be of an aerodynamic design and the sampling tubing between the instrument and measuring probe must be as short as possible.

C.5 Procedure

Position the measuring probe of the particle counter facing upwards in the center of the operating table around 1.0 – 1.1 m above floor level. Start the continuous measurement of particles in measurement cycles of one minute each. The zero value must be recorded before each particle challenge position.

If necessary, the measuring probe may be positioned facing upwards in the middle of the instrument table 1.0 – 1.1 m above floor level. Start the continuous measurement of particles in measurement cycles of one minute each. The zero value must be recorded before each particle challenge position.

C.5.1 Rectangular clean zones

Generate particles in four places immediately outside the boundary; in the center of each side, immediately outside the boundary of the clean zone in an area approximately 0.5 m wide and between 0.1 m and 1.2 m above floor level during at least three consecutive documented particle recordings one minute apart. If necessary, or where agreed, a particle challenge may also be imposed in the corners of the clean zone and measurements carried out in the same way.

C.5.2 Circular clean zones

Generate particles in four places; evenly distributed around the outer perimeter of the clean zone, immediately outside the boundary of the clean zone in an area approximately 0.5 m wide and between 0.1m and 1.2 m above floor level during at least three consecutive documented particle registrations one minute apart.

C.5.3 Calculation of risk factor

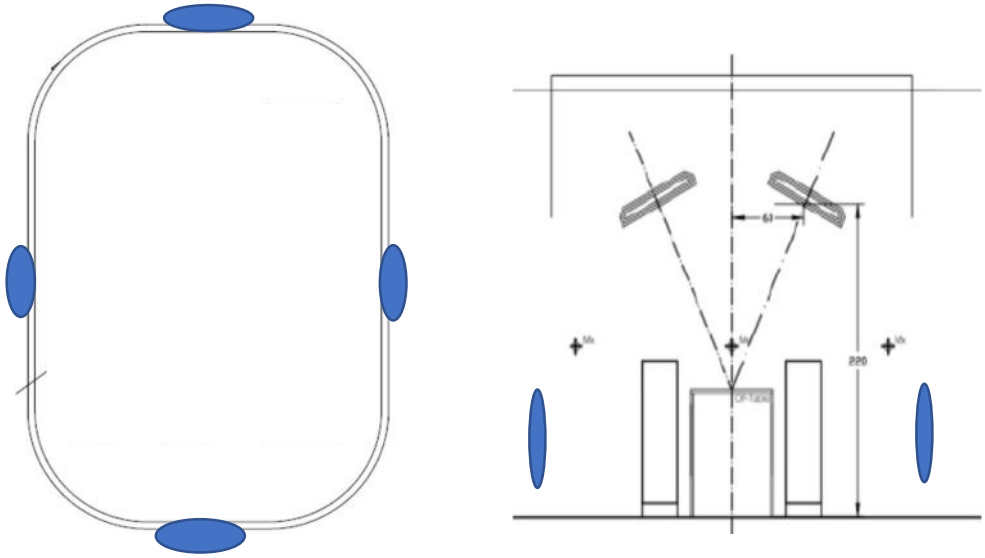
The maximum number of particles recorded, ≥0.5 µm/m^3 at the test location (center of the operating table), is divided by the load level of 10^7particles/m^3 ≥0.5 µm/m^3. This ratio constitutes the risk factor.

C.6 Evaluation

When the risk factor is equivalent to or less than 10-4 (≤0.01%) during the load test, it can be established that no entrainment of room air will take place under normal conditions and that a clean zone exists.

When the risk factor is greater than 10^{-4} (>0.01%) during the challenge test, it can be established that entrainment of room air may occur under normal conditions. Therefore, the entire room can be considered as having the same air cleanliness and, thus, the recovery test should be conducted according to Annex D.

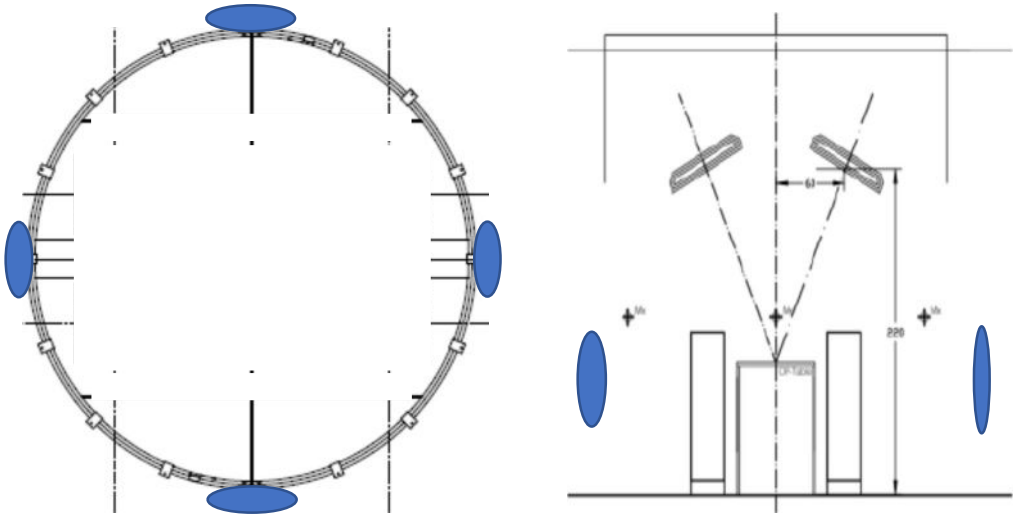
Rectangular clean zone



Areas of particle load discharge

Figure C.1 Schematic standard arrangement (LR-method) Rectangular zone.

Circular clean zone



Areas of particle load discharge

Figure C.2 Schematic standard arrangement (LR-method) Circular clean zone.

ANNEX D RECOVERY TEST IN DILUTION-MIXING VENTILATED OPERATING ROOMS

General

The recovery test should be performed according to ISO-EN 14644-3.

This test should be carried out upon an installation in the At-Rest condition, with equipment and furniture installed.

D.1 Selection of measuring points

Place the LSAPC probe in the working plane, typically 1,1–1,2 meter, at appropriate location(s) (which can include critical locations or suspected worst-case locations). The measuring points, minimum number of points are according to ISO-EN 14644-3 and representative to whole room, but instead of standard grid part of the measurement points should be positioned to critical points identified in positioning analysis (such as operating table, locations of instrument tables).
Operating lights shall be positioned as shown in Annex C for segregation test, if not otherwise specified.

D.2 Test method

Care should be taken to avoid high airborne concentrations of particles that can cause coincidence error and contamination of the LSAPC optics. Before testing, calculate the concentration required to carry out the recovery test. If the concentration exceeds the maximum concentration of the LSAPC, where particle coincidence will occur, use a dilution system.
Testing procedure:

a) set up the particle counter in accordance with the manufacturer's instructions and the apparatus calibration certificate
b) the particle size used in this test should be 0,5µm. It is recommended that the size channel used by the LSAPC corresponds to that of the maximum number concentration of the aerosol
c) the cleanroom area to be examined should be contaminated with an aerosol while the air-handling units are in operation
d) raise the initial particle concentration to more than 100 times depending on the target cleanliness level (see Note 1)
   It is important to ensure a homogeneous distribution of the particle concentration.
e) commence measurements at not more than 1 min intervals and record time and concentration.
f) The results of the decay of the logarithm of the particle concentration should be plotted against time to ensure that the results used are where the decay is exponential, i.e. the decay line is straight, and not at the beginning where the decay has not been established, or at the end where the background count in the cleanroom reduces the decay rate.

NoteThe target cleanliness level can be either the design cleanliness level, the level established by testing according to ISO 14644-1 at the at-rest condition, or an alternative agreed cleanliness level, assuming that the level is at a point on the decay graph where the decay is exponential.

D.3 Evaluation by 100:1 recovery time

Evaluation procedure:

a) note the time when the particle concentration reaches the 100× target concentration threshold (t100n);
b) note the time when the particle concentration reaches the target cleanliness level, tn;
c) the 100:1 recovery time is represented by t0,01 = (tn − t100n)
d) If the recovery time of all measurement points is less than equal to required recovery time the test is passed. If not, the ACH should be increased/ ventilation adjusted and retested until the requirement is passed.

ANNEX E AIRFLOW DESIGN BASED ON MICROBIAL SOURCE STRENGTH

In an operating room the operational personnel are the principal source contributing to microbial load. When the source strength of the persons is known the minimum airflow rate to reach the targeted cleanliness level (microbial load) may be calculated for ventilation systems using dilution mixing principle using below equation:

$$Q = \frac{n \cdot q_S}{C \cdot Cr} \quad \text{(E.1)}$$

where Q = minimum total air flow rate for dilution mixing ventilation (m^3/s)
n = number of people (number)
q_s = source strength per person (CFU/s)
C = concentration (CFU/m^3)
Cr = contamination removal efficiency

Contaminant removal efficiency (*Cr*) is the ratio of average contaminant concentration in the air flow leaving the clean room and maxim concentration inside the cleanroom. This ratio depends on the type of the ventilation system and its efficiency to dilute the ventilated space. In a perfect mixing situation *Cr* would have value 1.

Microbiological source strength (q_s) is defined as the average number of CFU released per second from one person wearing a specific clothing system. The microbial source strength (CFU/s) for one person wearing a defined clothing systems (clean air suit) could be used to estimate the total microbial load in operating rooms and the minimum air flow (m^3/s) necessary +to dilute the microbial load to designated level (CFU/m^3).

The source strength may be determined in a test chamber or during ongoing surgery, which may also be a simulated.

In a test chamber the source strength is calculated using test subjects performing a series of standardized movements in a test chamber and the measured concentrations of particles released (Reinmüller et al 2003, Ljungqvist et al 2014a).

During ongoing surgery, the source strength may be estimated by measuring the CFU in the operating room air in cases where the airflow, the clothing system used and the number of people in the room are known. When this method is used the average source strength by a person may be calculated by number of people (excluding patient).

Clean Air Suits give an average source strength of ≤1,5 CFU/s and ordinary scrub suits give an average source strength up to 5 CFU/s when measured in operating rooms during ongoing orthopedic surgery (Tammelin et al 2000, 2012, Ljungqvist et al 2013 and 2014b).

In the test chamber the activity levels of the test subjects are often higher than those of the operating team during ongoing surgery. This results in source strength values for clothing systems evaluated in a test chamber that are mostly higher than those estimated in operating rooms. It should be noted that the source strength mean value of a specific clothing system from measurements during ongoing orthopedic surgery seems to be slightly less than half the mean value received from test chamber measurements (Ljungqvist et al 2014a, 2014b).

The effect of clothing systems on microbiological airborne contamination

Clean air suits are medical devices indented to reduce the dispersal of bacteria-carrying particles from personnel to the air of the operating room (Tammelin et al 2000). Clean air suits are manufactured from materials with low particle permeability and have special cuffs around the arms and legs. Shirts must be tucked into trousers if the clean air suit has a shirt/trouser arrangement. Helmets/hoods must be tucked into the shirt. All persons in the operating room are required to wear a clean air suit if low airborne bacteria levels are to be maintained in the room.

The standard EN 13795 regulates surgical gowns, drapes, and clean air suits. This standard currently contains mainly requirements regarding the materials used in the finished product. A microbiological cleanliness of <100 CFU/dm^2 is required for all textiles upon use or prior to sterilization. The cleanliness requirement applies up until the critical zone for both disposable and reusable materials. Work is under way about the specification of requirements for the design of the products.

Sterile surgical gowns are intended to prevent contact contamination between patients and personnel, and do not affect the airborne contamination in the operating room unless worn gowns are discarded in the room, thereby releasing bacteria-carrying particles into the room.

Scrub suits stands for work surgical clothing made from more permeable material. Such work clothing is not considered to be a medical device and should not be used in operating rooms where a high degree of cleanliness is required.

Airflow rate calculation of UDF systems and comparison to DMF

UDF system is a common ventilation system to provide a protected zone. Typical UDF supply outlet is a canopy type air supply device from which the air is supplied with a specified velocity. The total airflow rate of a single uniform flow UDF outlet may be calculated from below equation:

$$Q_{UDF} = A \times v \qquad \text{(E.2)}$$

Where Q_{UDF} = total air flow (m^3/s) for unidirectional flow
A = the area of supply surface (m^2)
v = the supply velocity (m^3/s) at surface

As an example, a 3,2 m by 3,2 m outlet with discharge velocity of 0,32 m/s would need total airflow rate of 3,3 m^3/s. A comparison is given in Figure E.1 between such UDF and minimum airflow rate of dilution mixing airflow with various numbers of operating persons and their source strength.

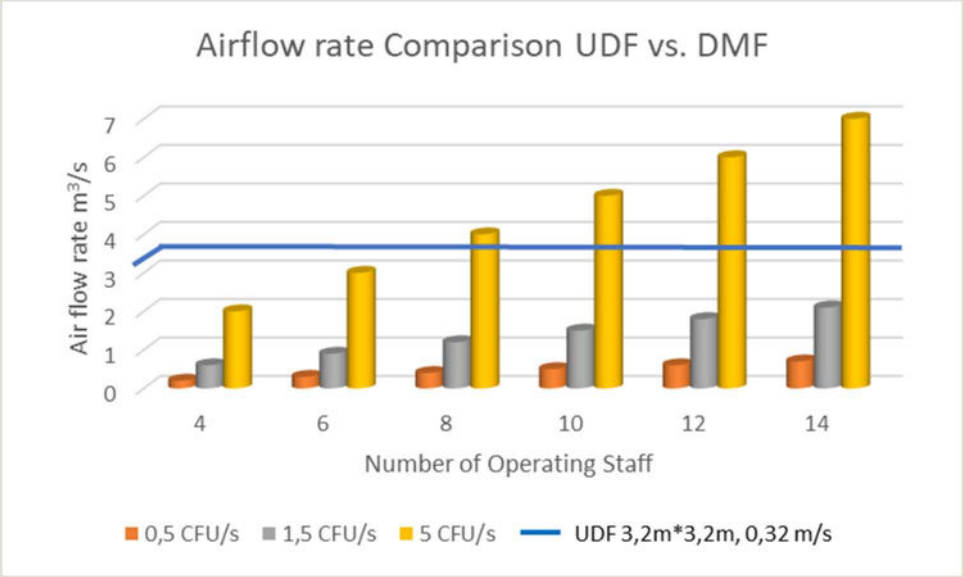


Figure E.1. Comparison of the calculated supply air volume Q between an UDF size 3,2 m by 3,2 m and 0,32 m/s discharge velocity and DMF systems (*Cr*=1) with different levels of microbial source strength and amount of operating personnel for cleanliness level *C* ≤ 10 CFU/m³

Note from the comparison

- To provide protective zone the UDF airflow rate is constant for the size and type of the unit regardless of the microbial loading in the room.
- The needed minimum airflow rate for DMF is highly dependent on the microbial source, both clothing level and amount or persons. It is worth noting that depending on the type of DMS system and its contaminant removal efficiency the airflow rate may need to be adjusted.
- When the source strength is 5 CFU/s for one person, a DMF with 6-8 persons require approximately the same supply air volume as a UDF in the example.

It is worth noting that indifferent of the chosen ventilation principle, both systems require proper gowning, discipline, and cleaning.

ANNEX F CLEAN-UP TIME TEST FROM SETBACK TO AT-REST

Purpose of the test is to ensure that the At-Rest conditions are reached in defined time (clean-up time of 15 minutes) before the operational activity is started after the system has been run at Setback.

TEST SCOPE

The test is conducted by using particle counter. Particle concentrations are tracked at one measurement point in an operating room or lay-up room while the OR ventilation system operation is changed from setback to operational state. The clean-up time is the time, when the At-Rest conditions are reached after the change of the system operating state.

- Dilution Mixing system, the particle concentration is measured from the center of the operating room.
- Protected Zone system, the particle concentration is measured at the border of the protected zone.

A. At the handover stage of the new system (when the ventilation system of the whole OR suite is At Rest tested and running)
B. Periodical verification according to definitions of this guideline.

VERIFICATION TEST PROCEDURE

1. The system is driven to set back in the afternoon of day one.
2. The particle measurements are started in the morning of day two and continued until the At-Rest particle concentration has been stabilized.
3. The system is driven to operational state.
4. The clean-up time is calculated and documented.
5. If the defined clean-up time is not reached a problem-solving procedure should be conducted.
6. In case the defined clean-up time is not reached at the end, the measured clean-up time should be used as the criteria for system operation.