

New guidelines for hospitals in Switzerland and in Germany



SWKI-Guideline 99-3: Heating, ventilation and air-conditioning systems in hospitals

VDI 2167, Part 1:
Building services in hospitals – Heating, ventilation and air-conditioning

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This article gives an overview over the Guideline VDI 2167 'Building services in hospitals – Heating, ventilation and air-conditioning' which is based on the Swiss Guideline 'Heating, ventilation and air-conditioning systems in hospitals (Planning, construction, operation)' of the SWKI 'Schweizerischen Verein von Wärme- und Klima-Ingenieuren'. Other than editorial changes which were carried out when adopting the Guideline, the content of both Guidelines is identical.

The structure of the VDI Guideline, the scope, the newly defined hygiene classes, the new HVAC (heating, ventilation, air-conditioning) concepts as well as the qualification of new operating rooms are dealt with in particular. Assessments of existing sterile air diffuser or existing operating rooms are discussed. The interpretation of the results as regards hospital hygiene is explained from the Guideline committee's point of view.

Introduction

The 'Guideline for the construction, operation and monitoring of ventilation and air-conditioning systems in hospitals' published in 1987 in Switzerland has demonstrated its effectiveness, but after 13 years of use needed to be amended for technological advances as well as new insights in the field of hospital-hygiene. The Guideline was implemented in May 2003. In Germany, DIN 1946-4 Ventilation and air conditioning - Part 4: Ventilation in hospitals' was revised in 1999, i.e. in some parts merely an editorially revision was merely carried out. Technical statements remained essentially unchanged. (The now initiated revision does also not make any headway.) This unsatisfactory situation led to a publication from the view point of leading German hygiene organisations.

In 2000, the 'Robert Koch-Institute' published the new guidelines on hygiene ('Requirements on hygiene for operations and other invasive surgery'; Bundesgesundheitsblatt 43, 2000, 644-648). The following requirements, among others, are made for HVAC systems in operating rooms:

- Unidirectional airflow ventilation is essential for aseptic interventions with high risk of infection.
- The size of the ceiling panel has to conform to the type of surgical intervention. As a rule, the operating table and the instrument tables shall be protected.

- A room class I (DIN1946-4) shall be installed only in the operating room.

The 'Deutsche Gesellschaft für Krankenhaushygiene' (DGKH) published 'Hospital hygiene guidelines for the design and operation of heating, ventilation and air-conditioning systems (HVAC systems) in hospitals' in the periodical Hygiene und Medizin 2002, 27, 106-113 together with their partner organisations 'Schweizerische Gesellschaft für Spitalhygiene' (SGSH) and 'Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin' (ÖGHMP). To ensure protection of the operating table and instrument table among others, a protected area measuring around 2,8 m by 2,8 m is defined. In order to achieve this, the following requirements are laid down:

- unidirectional airflow
- primary degree of turbulence < 5%
- size: 3,2 m x 3,2 m with aprons measuring at least 5 - 50 cm in length
- filter class H 14

The corridors used for the sterile goods supply for the operating rooms shall be endowed with static positive pressure and the hospital hygiene expert must decide whether particulate air filters shall be fitted as terminal filters. Furthermore – provided that HVAC equipment is in operation in the operating rooms – merely a basic 'comfort ventilation' shall be in place in all rooms adjacent to the surgical department.

Given that the SWKI-Guideline was compiled in close collaboration with the Societies for Hospital Hygiene and largely meets their requirements, the VDI (Verein Deutscher Ing. – The Association of German Engineers) decided to adopt the SWKI document into the VDI guidelines catalogue. The draft was published in December 2004. In consequence 'DIN1946-4' will be removed from the VDI manual 'Building services – Volume 2 HVAC Ventilation'.

Structure of the VDI Guideline for hospitals

The new Guideline VDI 2167 – identical in content to the SWKI-Guideline – is orientated at the standard ISO 14644-4 'Cleanrooms and associated controlled environments - Part 4: Design, construction and start up'. VDI 2167 is divided into a normative (first) section and an informative Annex. The Guideline leads clearly structured from clause 5 'Analyses' to clause 13 'Requalification and optimisation' through the entire life cycle of an installation. Individual modules may also be integrated into tasks as described in the HOAI.

The structure of the Guideline VDI 2167 'Building services in hospitals – Heating, ventilation and air-conditioning':

1. Scope
2. Terms, organizations, abbreviations
3. General
4. Classification of rooms
5. Analyses
6. Determination of the protective effect
7. Analysis
8. Planning
9. Realisation
10. System qualification
11. Acceptance
12. Operation
13. Requalification and optimisation

Bibliography

Annex Examples HVAC concepts (informative)

The guide – as described in clauses 5 to 10 – leads all parties involved through a project in a process-orientated way and enables them to use a common language. The guide lists all required documents and may therefore be used as a checklist.

As usual in the hospital field, it is essential for an interdisciplinary project that the individual steps of planning and decision-making follow a rigid structure and are appropriately documented. Each stage described in the guide is therefore a self-contained module that should be start with the required documents. These documents shall clearly indicate the fields of competence and responsibilities of each party involved. Before concluding a module, its objective(s) which were defined when starting the module should also be checked, i.e. each module should be concluded with a conscious position-fixing process before the next module is started.

Improvements in the hospital Guideline

Apart from the well-defined process orientation, significant technical and hygienic aspects have been revised. The most important areas will be considered below.

Hygiene classes

The classification of rooms, described in the former Guidelines, based on the concentration of airborne germs (CFUs per cubic metre of air) which should not be exceeded during surgical interventions, is more or less arbitrary. Sound clinical studies, unambiguously proving the relation between the concentration of airborne germs and the infection of surgical wounds, are not available. Orthopaedic implant surgery is an exception (Lidwell Study). For this reason, the airborne germ concentration was no longer used as a criterion for assessing the quality of the HVAC systems in operating rooms. Microbiological measurements are therefore also not required for acceptance tests and routine checks of operating rooms.

It has been proven that a high airborne germ level results in a high sedimentation rate. It is further assumed that an increased germ sedimentation may potentially lead to an increased rate of infections, if no measures are otherwise taken. To devise a quality assessment for ventilation and air-conditioning systems from this, doesn't do justice to the task of 'reduction of infection rate'. Ventilation and air-conditioning systems play a limited role in the prevention of infections, other means of contamination and also their prevention are far more essential.

In order to define the necessary technical hygienic measures in the Guideline, functions to be performed in a room are now summarized in hygienically relevant groups. Each hygiene group was examined to its hospital-specific requirements. Thus, three hygienic grades were developed

- operating rooms and other rooms for surgical interventions,
- rooms with increased hygienic requirements,
- hygienically relevant rooms

each with their own ventilation and air-conditioning requirements. Where no hospital-relevant requirements are identified - for example in secondary anterooms – the usual ventilation and air-conditioning design provisions are applied (see also EN 13779 // Ventilation for buildings - Performance requirements for ventilation and air-conditioning systems).

Operating rooms and other rooms for surgical interventions

All protective measures taken in connection with surgical interventions aim to reduce the risk of post-operative infections. This risk varies to a large degree, and depends on the type of surgical intervention. Most post-operative infections are caused by the patient's own flora (on the skin, or in other

naturally contaminated organs such as the intestinal tract). In this situation, the quality of the air in the operating environment is rather secondary. However, sterility of the instruments and the avoidance of airborne contamination of the instruments are standard requirements met by modern surgery even in intestinal interventions.

Rooms with increased hygienic requirements

These include rooms where patients are hospitalised or medicated, whose general state of health increases their risk of contracting an infectious disease that is communicable via the air. Higher hygienic requirements must also be met by rooms where diagnostic or therapeutic procedures involve a risk of releasing micro-organisms, exposing the personnel to the risk of infection. In addition, higher hygienic requirements must be met by sterile-goods storerooms and sterile corridors.

Hygienically relevant rooms

As a matter of principle, any room in a medical institute, where patients are treated or nursed, or where material for use on patients is kept or stored, is hygienically relevant. This also includes the hospital kitchen and the disposal section.

Hygiene requirements for ventilation and air-conditioning systems

It is assumed that also the non-hospital specific ventilation and air-conditioning guidelines are adhered to. Therefore it is only logical to assume that Guideline VDI 6022 "Hygienic requirements for ventilation and air-conditioning systems – Comfort areas" serves as basic knowledge.

Project-performance specification

In Germany, a 'performance specification' is often prepared during the process of planning and realisation according to VDI/VDE 3694 for the compilation of all requirements of the orderer and for the performance of the contractor regarding the scope of supply and services. In the hospital guideline, differing from the VDI Guideline, a 'project-performance specification' is now compulsory for all parties involved for the duration of the entire project according to EN ISO 14644-4 'Cleanrooms and associated controlled environments – Design, construction and start up'. The most important points are briefly listed below:

„The performance specification of the project, prepared by the orderer in cooperation with experts, provides project-specific information on the following areas :

- Project definition
- Project organization and quality management (QM master plan)
- Intended use
- Room definitions (room data sheet)
- Performance definitions
- Energy and measurement concepts

- Safety and environmental protection manual
- Testing concept (system qualification)
- Fire protection concept (fire compartments, escape routes, smoke extraction, evacuation)
- Disposal concept
- Approvals
- Schedule
- Cost estimate

A room data sheet should at least list the following information:

- hygiene classification
- protective-overpressure concept
- electrical safety classification
- air-conditioning requirements
 - min./max. temperature
 - min./max. humidity
 - max. sound pressure level
- materials to be used (walls, floor, ceilings, equipment, etc.)
- operational facilities

At the conclusion of the target definition stage, the Guideline states that 'The target definition phase is concluded when the performance specification of the project is approved by all parties involved in target definition. This serves as a basis for planning.'

The Guideline experiences its official recognition through the reference of the orderer in case of assignment, i.e. the orderer makes the Guideline an integral part of the contract. However, the Guideline only becomes fully effective through the joint target definition process – as given in the performance specification. The Guideline allows a certain leeway for deviating arrangements which have to be controlled through in the performance specification. However, this shall be approved by all parties involved in the project, i.e. a common project definition has to be agreed in the target definition process. In the case of a surgical department, for example, parties involved in the project may take up the following positions or be their holders:

- Investor (authorities, hospital management, responsible bodies, etc.)
- User (surgeons, anaesthetist, specialists, nursing service, OR-organization, etc.)
- Hospital hygiene (hospital-hygiene experts, cleaning personnel, etc.)
- Purchaser (operating room equipment, media supply system, IT-equipment, etc.)
- Maintenance personnel (technical service, external maintenance service, energy suppliers) Planer (architects, building services engineering, medical service planning, etc.)
- Consultants (organizational and financial consultants)
- Further parties involved in the project

In the case of a contract, the explicit approval of all suppliers and contractors shall also be secured, i.e. the performance specification has to be attached as an integral part of the contract.

Ventilation and air-conditioning concepts

Ventilation and air-conditioning in hygienically-relevant rooms

Rooms such as patient's room, delivery room, room for caesarean sections, emergency and recovery observation rooms as well as waiting rooms fall into this hygiene class. The danger of transmitting unidentified pathogens makes it necessary to provide efficiently ventilated waiting rooms for patients. The Guideline specifies now an exhaust-air rate in excess of 75 m³/h per person for these rooms and that separate waiting rooms shall be available for patients undergoing immunosuppression.

Ventilation and air-conditioning in rooms with increased hygienic requirements

The following rooms or groups of rooms fall into this hygiene class:

- sterile-goods storage/sterile corridor
- angiography, heart catheter laboratory, surgical angiography with implantation of foreign material
- minor surgery, dermatology, wound care
- sterile care, room for transplant recipients after surgery, isolation rooms
- intensive care unit, including neonatology
- endoscopic diagnosis

Such rooms shall be ventilated with an increased ambient air flow rate of > 100 m³/h per person. Cleanliness of the supply air is defined inasmuch that it is compulsory to filter this air with filters of class F9 (according to EN 779). The concept 'turbulent mixed flow' is intended for the supply of air into the room.

Special case – isolation rooms

Isolation rooms are closed rooms for patients with infectious diseases communicable via the air (such as TB, varicella, etc.). Special ventilation and air-conditioning measures are therefore necessary. A supply-air rate per room of ≥ 500 m³/h (or an air-exchange rate of 12) shall be ensured. The room shall be maintained at negative pressure with respect to adjoining rooms and shall be provided with a so-called active airlock to protect the environment. Applying the overflow principle, the airlock supply air can be used as supply air for the room. If possible, the doors shall be interlocked. Doors standing open at the same time shall always be signalled acoustically. Negative pressure in the patient's room shall be monitored by means of measurements, if required.

In order to avoid contamination of the duct system and the rooms connected to it, and to protect the maintenance personnel, the exhaust air shall be filtered (particulate air filter, class H13 according to EN 1822) before entering the exhaust-air network. The supply-air rate can be reduced by using a mobile recirculated-air unit (filter F9 according to EN 779).

Basic concept(s) of ventilation and air-conditioning in surgical departments

Today, securing the physiological and occupational medical conditions is the most important requirement for ventilation and air-conditioning systems in hospitals. Considering all possibilities leading to infections, the air-conditioning measures currently taken outside the operating rooms in order to reduce the airborne germ concentration in the room appear inappropriate in many cases. This is particularly true for the investment and consequential costs. Far greater attention should be paid to the

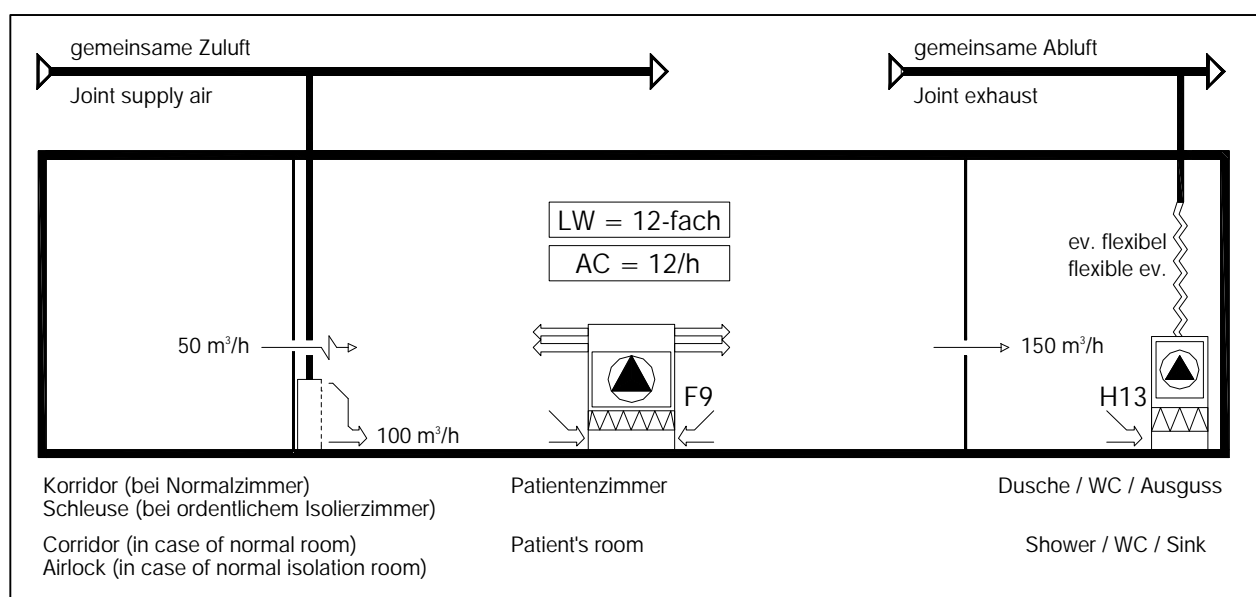


Figure Isolation room: Possible solution for isolation rooms in a normal patient's rooms requiring an air-exchange rate of 12 with a mobile recirculated-air unit and attachable exhaust filter unit protecting the duct network and sustaining the static negative pressure.

accompanying measures (e.g. protective clothing of the personnel, effective patient's draping, etc.).

Technical measures for operating rooms and other rooms for surgical interventions conform with the aim of protection as newly defined by the hospital hygiene namely to reduce to the highest possible degree the entry of germs into surgical wounds during operation. The air supplied to operating rooms and other rooms for surgical interventions shall be filtered by means of terminal particulate air filters, i.e. via an efficient air filtration. With a strong degree of turbulence, the protected area is flooded with a vertical displacement flow to dynamically protect the area against incoming contamination. By means of a directed airflow, a fast and efficient removal of contamination originated in a critical area away from the protected area also takes also place. A fault-tolerant protection system is the aim. A minimum size of the unidirectional airflow diffuser of approximately 9,0 m² should be maintained (smaller diffusers are possible in special cases).

A sufficiently large protected area is therewith achieved with optimal air flow guidance and with the support of surrounding aprons guiding flows down to the height of doors (lower edge approximately up to 2,1 m above floor level). It is now accepted that the air is recirculated and cooled within the room. Dry cooling systems shall be guaranteed.

Multifunctional surgical departments

The basic concept of operating room ventilation as specified in the new hospital guideline is relies on the experience that in many hospitals a wide range of interventions is carried out – from urological interventions with less important ventilation to implantations of artificial joints with highly sophisticated ventilation. The working group was convinced that only a large unidirectional airflow diffuser area of excellent screening effect is suitable for complex interventions.

This dynamic protection concept with unidirectional airflow ceilings in operating rooms allows that all hygienically relevant operations (sterile work) with critical interventions (operations) shall be conducted in this protection area, i.e. the exposure and preparation of the sterile instruments and materials, all sterile operations as well as the intervention itself including wound care. As soon as the wound has been dealt with, a reduced air-hygiene standard may be accepted such as that which prevails in a doctor's surgery or in a patient's room. This concept is also easily conveyed and at this stage is accepted practice in surgical departments. Hence, no special ventilation requirements result for the remaining operating areas and even for the environment of the unidirectional airflow area. Providing that the unidirectional airflow diffuser complies with the expected protective effect in the operating room, as regards air hygiene, a cost-effective ventilation system for air renewal may consequentially be realised

in the adjoining rooms of the operating rooms, if needs be, combined with building element tempering or other thermo-active elements.

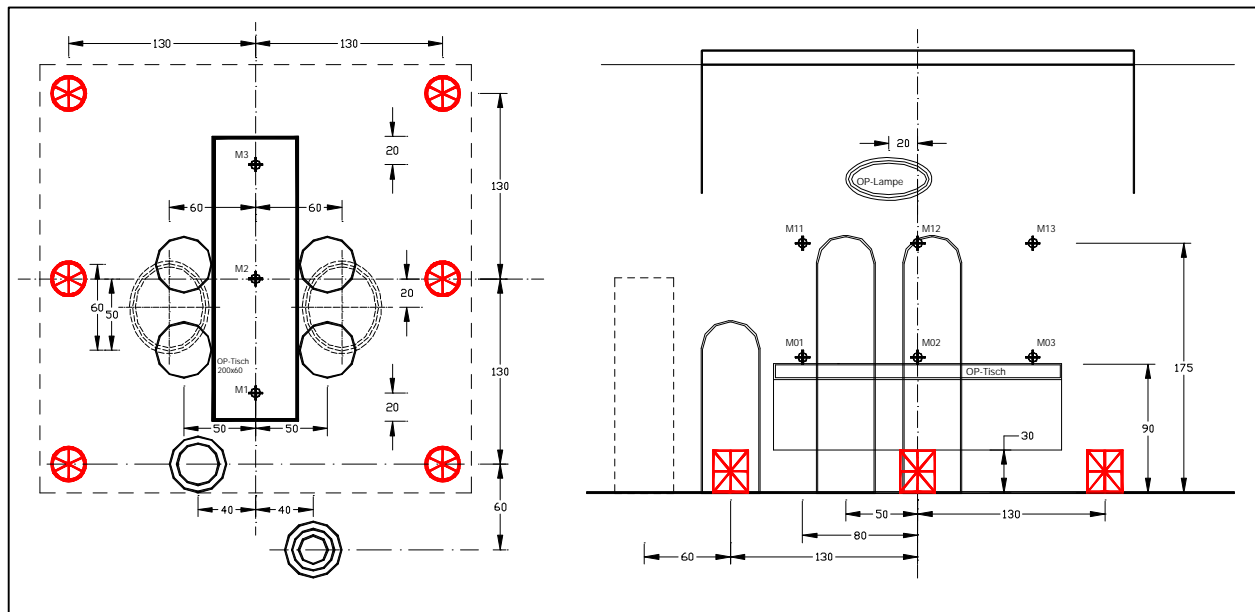
The risk of a post-operative infection of the wound depends to a large degree on the type of surgery. The significance of microorganisms carried into the wound by the air differs greatly for different types of operations. Surgery where foreign material (e.g. artificial joints and cardiac valves) is implanted is much more critical with respect to the risk of infection than operations in anatomical areas which already contain a physiological contamination, as already minute contaminations with germs can give rise to an infection in the area of the artificial implant in endoprosthetic operations. Hence it can be deduced that for operations where foreign material is implanted greater protective efforts are required from the unidirectional airflow diffuser than for, e.g. operations of the gastro-intestinal tract.

Even at the planning stage of new operating rooms, it is not the intention that surgical interventions compulsory require a larger unidirectional airflow area, the versatility of a larger area should be seen as an advantage, considering the long-term use of such rooms. If, over the years, specific types of surgery gain more importance, operating rooms with large unidirectional airflow areas are better prepared in order to cover the amended requirements. A further and more significant advantage can be found in the organisational area. The allocation of patients is significantly easier through identical qualitatively high equipment in operating rooms which leads to a reduction of waiting times and thus to an improvement of productivity. In addition, substantial investment costs in the remaining infrastructure may be saved through the realisation of the dynamic protection concept 'sterile bell-shaped airflow'. It is also possible to switch off the operating rooms unidirectional airflow systems outside the operating hours by using a suitable ventilation and air-conditioning concept – this would lead to a substantial reduction of operating costs.

In specialised clinics (e.g. hand surgery, ophthalmic (eye) surgery, or ENT-surgery) where always the same types of interventions are performed, standard dimensions of the sterile air diffuser may deviate. Smaller diffusers may be provided if for certain types of surgical interventions which do not require operation of a large sterile air diffuser.

Acceptance test of operating rooms

Considering the increased requirements with respect to room-air quality, the acceptance of operating rooms is divided into a technical section (performance parameters of the system) and a hygienic section (proof of protective effect). Determination (measurement) and interpretation (assessment) of the results shall thereby be strictly separated in the Guideline. It shall be the responsibility of



Schematic of standard measurement arrangement – outside load. (Protection against load entry from outside). The measurement arrangement of the operating room is displayed. 'Diffusers', shown in red, emit the aerosol flow (reference load) with low momentum and isothermally at the specified locations into the operating room. Deviating arrangements are subject to agreement within the performance specification.

the hospital-hygiene expert to assess the results obtained from measurements and to recommend any possibly required hygiene measures internally or to initiate them.

The technical and hygienic acceptance tests are performed using a reference load test set-up. The acceptance certificate shall be conducted and recorded by a body independent of the planner, supplier, manufacturer of the system and from the evaluating hygiene expert in charge.

Technical acceptance

The technical acceptance in operating rooms concerns the qualification of the ventilation and air-conditioning systems. Hence the following system parameters will be checked under nominal load:

- Seal-tight and leakage tests of filters
- Volume flows of supply air, exhaust air and overflow air
- Direction of overflow air at the doors of the operating room
- Direction of overflow air towards the plenum of the suspended ceiling distribution of supply-air velocity and temperature at the air-terminal device
- Mean values of supply-air and exhaust-air temperatures
temperature deficit of supply air with respect to the room-air temperature
- Surface temperatures of room boundary surfaces
- Comfort parameters (1,75 m above floor level):
airflow velocity, degree of turbulence, air temperature, sound pressure level, relative humidity

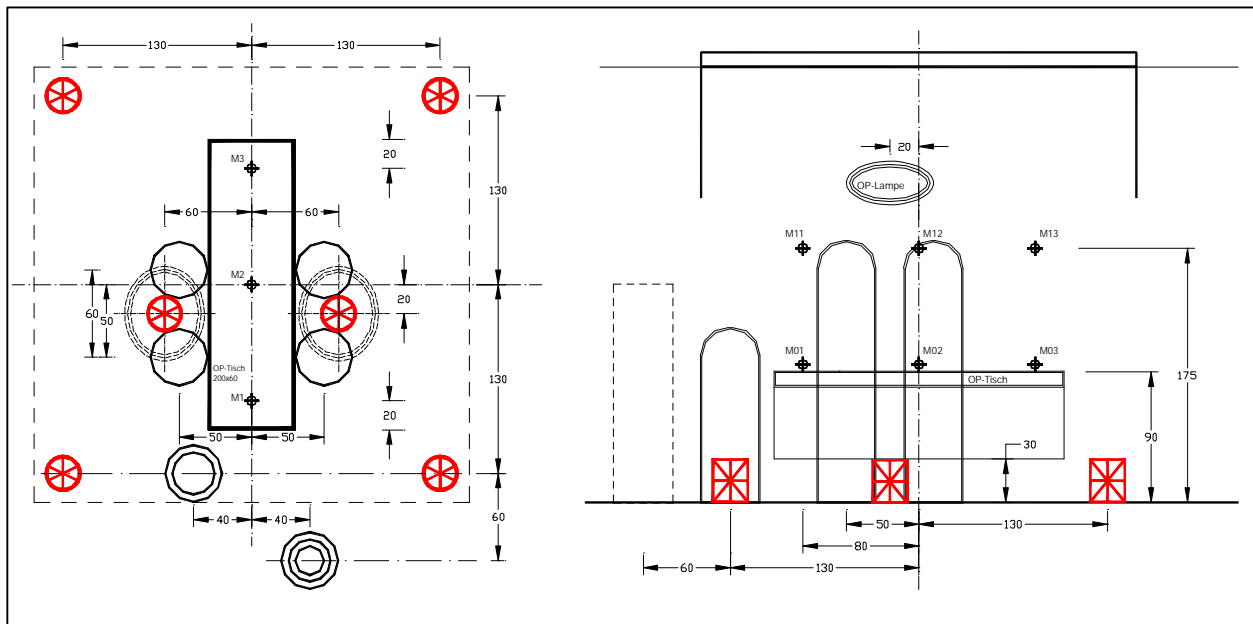
Unless limits have been specified in the performance specification, the following minimum and maxi-

imum values shall be observed (at nominal supply-air volume flow rate of 100 %):

- Filters leak-free as per EN ISO 14644-3 or SWKI 96-4
- Seal-tight test as per EN ISO 14644-3
- Supply-air temperature: 18 to 24 °C (setpoint user-adjustable)
- Minimum mean supply-air velocity: 0,24 m/s (four measurements per square metre of surface area of the supply-air terminal device)
- Minimum supply-air velocity: 0,20 m/s
- Maximum deviation of local supply-air temperatures from the mean: $\pm 1,0$ K (four measure-



Reference load set-up: Qualification of an operating room GZO-Hospital Wetzikon. A distributor for the reference load is visible underneath the operating table. The sample of air is taken from this distributor for the measurement of particle concentration. In front, the measurement of air velocity for the determination of the volume flow is obvious. This photograph was taken as part of a dissertation. The influence of different diffuser sizes on the degree of protection was aimed to be determined.



Schematic of standard measurement arrangement – inside load. (Protection against load entry from inside).

The measurement arrangement of the operating room is displayed. 'Diffusers' are shown in red. The measuring points M1 – M3 serve the determination of the local protection class, measuring points M11 – M13 serve the determination of comfort parameters.

- ments per square metre of surface area of the supply-air terminal device)
- Temperature deficit of supply air with respect to the room (mean of supply-air temperatures compared to mean from four measurements taken outside the supply-air terminal device; distance to wall at least 0,5 m)
- Comfort parameters as per VDI 2083-5 "Clean-room technology - Thermal comfort", (met: 1,2/ clo: 1,2)
- The system running at full load with the product-specific nominal air flow rate, the sound pressure level measured in the centre of the area at 1,75 m above floor level shall not exceed 48 db(A) (for a reference load test set-up)

Seal-tight and leakage tests shall be repeated at least every other year and after any intervention concerning the terminal filter stage.



GZO-Hospital Wetzikon (Switzerland) Reference load set-up for the qualification of an operating room

Hygienic acceptance

The qualification procedure as proposed in the Guideline orientates itself among others at the ISO family of standards 14644 and was compiled by an interdisciplinary committee in a long-standing development. The procedure was developed step-by-step starting with an extensive literature study followed by dissertations and diploma theses at various national and international universities and various simulation studies at the ETH Zurich and at the HTA Lucerne then extensively tested in different operating rooms in Switzerland. All these efforts served the purpose of defining and subsequently verifying the measurement method.

The reference load test set-ups as specified in this Guideline were initially chosen based on practical considerations; now, however, they have become a self-standing model, serving solely to ensure reproducible and comparable conditions for all measurements. The variation between the objects to be measured calls for a defined measurement set-up so as to allow comparison of the objects measured. Regretably, in some cases this modelling no longer exactly depicts the reality of the situation.

For the 'proof of sufficient protective effect' the metrological challenges to be faced are, essentially:

- Internal thermal loads have a considerable impact on the flow pattern of the air in the room and must be simulated during the measurement.
- A sufficient concentration of ambient airborne particles must be generated in a suitable manner and proved by measurements.
- The measurement set-up shall be suitable for practical use and must yield comparable and reproducible results.
- The measurement is to allow statements on the entire operating room and, in particular, on the air quality in the area to be protected.

The test with the simulated internal loads now specified does not only check ventilation components but also works integrally, i.e. the test is a complete overall view of the operating room as regards the protective effect of the directed air flow. Both the planning and test work is far more complex as this test reproduces the utilisation more effectively: it inspects not only of the components of the individual suppliers but also their interaction.

Particle-reference load

The protective effect is determined by measuring the particle concentration in the protected area while the operating room is loaded with a reference particle load which has the same intensity (source strength) throughout all measurements. The reference particle load consists of an aerosol flow that is constant in time, emitted into the room at six specified locations. Specifying a constant source strength opens up the possibility to obtain a cha-

racteristic reference quantity for the assessment of the results of the hygiene test, which is the same for all situations.

For this purpose, a reference operating room was defined which has a supply-air volume flow of 3,0 m³/s. A reference particle concentration of $C_{Ref} = 10^6$ P/ft³ shall be generated therein by means of a reference load at the background of the room. Even at lowest concentrations in the protected area (e.g. $C_x = 10$ P/ft³), a particle reduction rate analogous to that obtained by disinfection (10^{-5}) may be statistically determined. The following required reference source strength results – due to the dilution effect of the supply air – for the reference operating room:

$$Q_{Ref} = C_{Ref} \cdot V_{Ref}$$

$$Q_{Ref} = 10^6 \cdot 3 \cdot 35,3 \cdot 60 = 6,3 \cdot 10^9$$

$$P/min = P/ft^3 \cdot m^3/s \cdot ft^3/m^3 \cdot s/min$$

The source strength (Q_{Ref}) shall be adjusted to a constant value $6,3 \cdot 10^9$ P/min for all measurements. The reference source strength cannot be measured directly, but is determined as the product of the aerosol concentration (C_{Aer}) times the total aerosol volume flow (V_{Aer}). It is essential in this case that the aerosol flow is emitted at the specified locations, the emission having low momentum and being isothermal. The interpretation of the particle measurements can be based on the minimum size of particles for which no significant filter penetration occurs any more during the filter leakage test. The minimum size shall be determined during the technical acceptance.

The load imposed on operating rooms being independent of the size of the ceiling supply-air diffusers and their ventilation mode under practical conditions, the specification of a constant source strength (reference load) is consistent. If, on the other hand, a constant particle concentration at the background of the room were specified, the source strength would depend on the supply-air volume flow of the operating room under test and thus the virtual room load in the operating room would not be the same, i.e. measurements from different objects would not be comparable.

Proof of sufficient protection

The acceptance 'proof of sufficient protection' of the operating room is a two-step procedure. First, proof shall be furnished that the aseptic area is sufficiently protected from its environment by means of the unidirectional airflow (protective effect against load entry from outside). A standard arrangement and further details are depicted in the following diagram.

For the sake of more intuitive understanding and more straightforward interpretation, the calculation of the protection class (SG) is recommended over stating particle concentrations measured in the protected area. It is defined as:

SG_X = -log (C_X/C_{Ref})

C_X: particle concentration at measuring point X [P/ft³]
 C_{Ref}: reference particle concentration = 10⁶ P/ft³

Referring to the (constant) reference particle concentration ensures that a change in value of the protection class can be traced to a change in counter readout.

The least favourable of the local protection classes (the smallest numerical value) is used to characterise the actual protective effect of the operating room compared to the required protective effect against load entry from outside and inside.

The second partial test, using a modified arrangement of the reference-load source is performed to detect any upward flow of contaminated room air from the floor into the protected area (protection against load entry from inside).

The task of the testing body is complete when the protective effects against load entry from outside and inside have been determined and when a complete inspection report has been drafted. The interpretation, in terms of hygiene, of the measured individual protection classes as well as of the overall protective effect and the recommendation of any additional measures for controlling the emission of germs by the operating-room personnel during certain operations is the sole responsibility of the hospital hygiene expert.

Range of values of the protective effect and protection classes

The protective effect against load entry from outside and inside characterises an operating room taking into consideration all of its flow-affecting ventilation, heating and medical installations and fittings. Operations where foreign material is implanted require higher protective effects than, e. g., operations of the gastro-intestinal tract. The achievable protective effect is affected significantly by the quality of the ventilation equipment, but also by that of the medical installations. This quality can be assessed using the test set-up described above.

Using this test set-up, operating rooms for operations involving the implanting of foreign material shall have a protective effect of 4. Operating rooms used mainly or solely for operations on already contaminated areas may, in principle, have lower protective effects of the ventilation, unless logistical reasons demand that they be suitable for all types of operations.

A protective effect of '4' (SG = -log(C_X/C_{Ref}) = -log(100/10⁶) = 4) is equivalent to a particle concentration of 100 P/ft³ measured, for example, at one measuring point. State-of-the-art operating rooms may achieve a protective effect of 5. This is considered to be excellent, but probably can only be achieved without the influence of conventional

operating room lights and with surrounding long aprons guiding flow.

Protective effect 4 should be achieved at nominal air volume flow in newly constructed operating rooms. These newly constructed operating rooms shall still have a protective effect of at least 3 when a reduced air volume flow is used for certain operations (e. g. interventions in the area of the gastrointestinal tract).

Achieving a protective effect of 4 with respect to the ventilation of the operating room will not relieve the user of the operating room from his duty to take the appropriate preventive measures considering the situation and technical and scientific progress.

Any measurements of germ numbers carried out during clinical use are to be performed by the hospital-hygiene expert. They are, however, not a criterion for the assessment of the heating, ventilating and air-conditioning systems.

Assessment of existing operating rooms

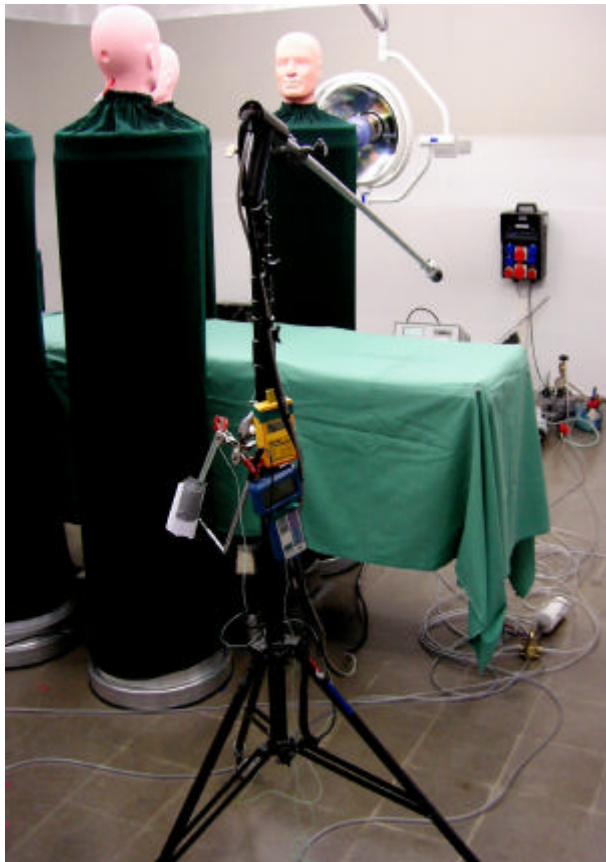
The new Guideline cannot be applied to existing operating rooms with older ventilation and air-conditioning systems which do not feature the current local protection concepts. For these systems the requirement to keep the risk of infection as low as possible also applies. Inductive flows which may introduce micro-organisms into the operating environment (or onto the sterile instruments) shall be effectively prevented.

Interpretation of the measurement results for existing operating rooms

If the measurements in existing operating rooms with air-supply ceilings not designed in accordance with this guideline show a protective effect of 1 or less, the ventilation of the operating room concerned shall be renovated. Older operating rooms where endoprosthetic operations or operations with a similar infection hazard are carried out, require a protective effect of at least 2. Interpretation of the measurement results in cooperation with a hospital-hygiene expert who is experienced in ventilation technology is recommended.

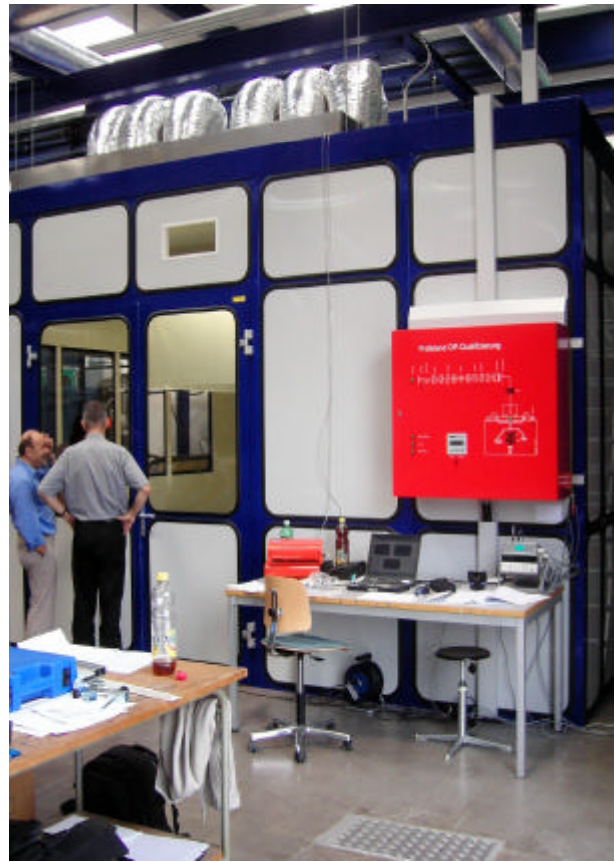
Taking into consideration the type of surgery to be performed in the operating room it may be necessary to carry out a risk analysis. The results may possibly require further investigations. Depending on what the results are, it may be possible that, by taking minor measures, surgery in older operating rooms can continue, provided that the minimum hospital-hygiene requirements (to be used only for specified interventions) are fulfilled. Possible measures may include improved protective clothing, underpressured ventilated systems for the operating personnel, structural measures such as a germ-stopping partition, modified routing of air flow or partial replacement of ventilation and air-condi-

tioning components, etc. Following risk analysis, the coordination of the measures to be taken shall be agreed upon with the hospital-hygiene expert in consultation with all parties involved in the project.



Experimental set-up in the laboratory operating room at the HTA School of Engineering + Architecture in Lucerne

tion Promotion Agency which is part of the Federal Office for Professional Education and Technology (OPET), in cooperation with leading institutes (e.g. TFH Berlin).



Exterior view of the laboratory operating room at the HTA School of Engineering + Architecture in Lucerne

Summary and future prospects

As the first Guideline, the Swiss Guideline SWKI 99-3 'Heating, ventilation and air-conditioning systems in hospitals' contains exact specifications regarding the technical and hygienic qualification of operating rooms. It may be expected that the results obtained by this measurement arrangement lead to distinct quality characteristics and permit selective, i.e. optimised cost-benefit improvement measures. This Guideline will now be adopted into the VDI guidelines catalogue (draft VDI 2167 - December 2004).

The objective is to compile a European Guideline on the basis of SWKI/VDI. The first steps towards a CEN standard have been taken (the last meeting was scheduled in November 2004 in Milano). Also, research and development shall be promoted. A laboratory operating room has been constructed and equipped at the HTA School of Engineering + Architecture in Lucerne. Within this laboratory operating room, research in the field of particulate and biological contamination in operating rooms as well as the development of advanced ventilation components and medical-technological components shall be promoted with support of CTI, the Inno-

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Abbreviations

CEN	Comité Européen de Normalisation
DGKH	Deutsche Gesellschaft für Krankenhaushygiene / German Society for Hospital Hygiene
DIN	Deutsches Institut für Normung / German Institute for Standardization
ISO	International Organization for Standardization
KTI/CTI	Förderagentur für Innovation / Innovation Promotion Agency
ÖGHMP	Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin / Austrian Society for Hygiene, Microbiology and Preventive Medicine
OPET	Bundesamt für Berufsbildung und Technologie / Federal Office for Professional Education and Technology
SGSH	Schweizerische Gesellschaft für Spitalhygiene / Swiss Society for Hospital Hygiene
SUVA	Schweizerische Unfallversicherungsanstalt
SWKI	Schweizerischen Verein von Wärme- und Klima-Ingenieuren
VDI	Verein Deutscher Ingenieure / The Association of German Engineers