Coordinamento scientifico
Mario Lombardo
A.Re.S.S., Responsabile Area Organizzazione e Programmazione
Maurizio Salvatico
A.S.L. CN1, Responsabile Risk Management;
Referente di Progetto A.Re.S.S.
Fabrizio De Miti
A.Re.S.S., Coordinatore dei Progetti di Edilizia
Sanitaria e Tecnologie
Paola Armeodo
A.O. S. Croce e Carle di Cuneo, Direttore del Dipartimento
Tecnico-Logistico
Pier Angelo Argentero
A.S.L. TO3, Responsabile Unità Prevenzione Infezioni
Ospedalieri, CO.RR. Rivoli
Marco Masero
Politecnico di Torino, Dipartimento di Energetica
Carla Zotti
Università degli Studi di Torino,
Dipartimento di Sanità Pubblica e di Microbiologia
Carla Jachino
A.Re.S.S., Area Organizzazione e Programmazione

Coordinamento organizzativo
Maurizio Salvatico
Carla Jachino
Illaria Matta
Ilaria Perino
Giuseppe Calèca
Stefania Feruglio

A.Re.S.S. · Area Organizzazione e Programmazione
Corso Palestro, 3 - 10122 Torino
www.aress.piemonte.it

1 Aprile 2011
Centro Incontri
Regione Piemonte
C.so Stati Uniti, 23 - Torino

Programma (provvisorio)
9:00 – 9:30 Registrazione partecipanti
Presidenza della Regione Piemonte, Roberto Cola
Assessore alla Tutela della Salute e Sanità, Caterina Ferrero
Assessore agli Affari istituzionali, Rapporti con il Consiglio
regionale, Controllo di gestione, Polizia locale e Società
partecipate, Elena Maccanti
Commissario Straordinario A.Re.S.S., Claudio Zanon

Indicazioni generali per la gestione delle sale operatorie
Moderatore: Responsabile Area Organizzazione e Programmazione
A.Re.S.S., Dott. Mario Lombardo
10:00 – 10:30
Istituto Clinico Humanitas, Dott. Norberto Silvestri
Management e costi delle sale operatorie

II^ Sessione
Esperienze internazionali sul trattamento dell’aria in sala operatoria
Moderatore: Politecnico di Torino, Dipartimento di Energetica,
Prof. Marco Masero
14:00 – 14:30
Brunner Haustechnik AG, Ing. Arnold Brunner
New opportunities and chances for an innovative
organization of operating theatres with the new German
and Swiss Hospital Guidelines for Ventilation

III^ Sessione
La situazione attuale delle sale operatorie
nella Regione Piemonte
Moderatore: Associazione Uffici Tecnici Ospedalieri del Piemonte,
Arch. Ferruccio Bianco
14:30 – 14:50
The new German standard DIN 1946-4: Ventilation in hospitals

In our contribution the german standard DIN 1946-4 "Ventilation and air conditioning - Part 4: Ventilation in hospitals" will be introduced to the audience. This document has already been published in December 2008. The innovations within will be explained and compared to former guidelines from Germany and Switzerland.

The new DIN is a completely revised version of the edition from 03-1999 and considers the recommendations of the Commission for Hospital hygiene and infections prevention of the Robert Koch-Institute. Accordingly it describes the latest state of the technology. The new DIN also contains measurement-technology requirements for the evaluation of the construction of ventilation and air-conditioning systems (HVAC systems) in operating rooms and therefore replaces the previously valid DIN 4799 from 06-1990.

The main contents of the new set of guidelines are structured as follows:

- Classification of rooms and requirements for ventilation and air-conditioning
- Components for ventilation and air-conditioning
- Qualification and acceptance tests for HVAC-systems

The area of applications covers the construction and acceptance for HVAC systems for rooms that are used for medical examinations, treatments and interventions on humans, as well as adjacent rooms, if they are part of the same air-compound. These standards do not apply for the operating of HVAC systems, if they have not been constructed and accepted according to these guidelines (existing facilities).

The guidelines for planning, construction and operating (4.2.) already refer to the necessity of a complete replicability of every decision of the process, in particular the determination of binding standards for the user, such as to keep a journal of project-performance specifications (Appendix A).

According to these guidelines, medically used rooms are differentiated into rooms of classification I and II, provided the existence of specific requirements for a low germ level. Operating rooms are classified as room-class I. The classification and therefore the design of operating rooms (Ia or Ib) are based on the intended use on a long-term basis with the highest requirements for a low germ level. This determination can only be made by the authorized hygienist (5.2.1).

The room classification Ia has also been allocated for operation rooms with the highest requirements for a low germ level. This requires a ventilation system with a local, unidirectional airflow. However, the recommended protection area in the operating room should amount to approximately 9,0 m² and only be reduced according to specific user-requirements. The protection area should cover the operating table, the steriley dressed operating staff and the openly standing tables for the instruments. The protection area can also be used for the preparation of the instruments, if there is no appropriate possibility for this within the sterile area.

Operating rooms with lower requirements regarding a low airborne germ level are classified as Ib and can be equipped with a mixed/non-unidirectional airflow.

In addition to the ventilation system of operating units and both classifications for operating rooms, the guidelines also specify interpretation data and fundamental requirements, such for outer airflow (at least 1'200 m³/h), the temperature level of the supply airflow, the overflow to adjacent rooms, as well as the sound pressure level (5.4).

The requirements for the space heating are limited to the relevant aspects regarding air hygiene.

Chart 1 also contains «Concepts and interpretation measures» that are applicable for rooms of the classification II. The room-concepts for isolation-care are distinguished by the kind of infection hazard in «infection rooms» designated for infectious patients and isolation rooms for patients who are exposed to an infection hazard («Isolation room», Chart 1).
The new guidelines extensively cover the requirements for the components of ventilation and air-conditioning that refer to surfaces, implementations and acceptance data. They contain statements about air pipes, service hatches, claps and appliances. Chapter 6.5.7 et seq. covers the requirements for air filtration. Generally it requires a two-stage filtering of the outdoor air using F9 terminal filters. Furthermore, rooms of the classification I require a terminal 3rd filtration step of at least class H13. A filtration of the extract-air also provides protection against particle exposure (F5) for the components.

The guidelines contain extensive chapters about qualification of facilities, acceptance tests and recurring examinations. The qualification of facilities (7.) is structured into the qualification of installation, performance and capacity. The acceptance tests are divided into technical and hygienic acceptance, just as described in the former guidelines. An extensive chart (N° 2) contains data about the minimal extent of the technical qualifications, divided into test subject, test parameter and test type. The hygienic acceptance (7.4) can only be conducted after successful conclusion of the technical acceptance and starts with the «hygienic inspection» of the entire HVAC system. Initially, an examination of the necessary airflow directions has to be accomplished in rooms of the room classification I. In rooms with unidirectional ventilation the designated outpouring of the unidirectional airflow within the protected area must be visualized by a smokestudy. Another examination is conducted with the distinct overflow of the installed operating room lights.

The committee for the guidelines did not come to an agreement upon a test procedure regarding the quantitative qualification of the protection impact of the protection area. As a result, the parties involved in planning and construction have to agree at an early stage upon a so called «measurement of the degree of protection» or the «measurement of the degree of turbulence». The measurement of the degree of protection is conducted with a measurement of particles on patches of the operating table as indicated by the user. In this process, the room is charged with a source of particles used as a reference, as well as a construction within the protection area (see figure 1) that contains a minimum of exemplary charges to measure relevant airflow and heat aspects (Appendix C). The minimal protection impact has to be agreed upon already in the planning stage and serves now as the target value. This target value is the result of the quotient between the measured concentration of particles in the protection area in proportion to the concentration of the reference material.

In measuring the degree of turbulence there are no charges in the protection area. The guidelines only demand that the upper limits for the turbulence standards in the protection area and under the operation room lights are complied with.

The guidelines also introduce the necessity of a microbiological monitoring during the first operation after the successful conclusion of a technical and hygienic acceptance. In this process, germ measurements within the protection area and in the background of the room are compared with limit values that are determined by the authorized hygienist. The cause for a noncompliance of the limit values can be found with the room user as well as with the HVAC systems. However, a reconsideration of the HVAC system should only be conducted with the previously described technical and hygienic acceptance methods.

Ultimately, the guidelines provide information regarding the extent and frequency of recurring tests and their documentation. Appendix E informatively contains the accomplishment of exemplary tests for operating rooms. The so called system test is useful in connection with complex room geometry and operating equipment in order to improve the security in planning and executing.

Figure 1: Standard-load test set-up to test the effect of protection against load entry from outside exemplary arrangement; deviating set-ups are subject to agreement.
New opportunities and chances for an innovative organisation of operating theatres

The new DIN 1946-4 ”ventilation and air conditioning - part 4: ventilation in hospitals” opens up new ways for the layout and the design of operating theatres. New approaches will be explained and discussed on the basis of an already existing project. Innovative measures for streamlining the workflow will be discussed as well.

The GZO – Gesundheitsversorgung Zürcher Oberland / Health Care Zurich Oberland – has been formed in the course of the abolition of several local hospitals. Thus, the Hospital Wetzikon turned into the only central and specified clinic in the region of Zurich Oberland. The catalog of benefits includes:

- Medicine,
- surgery with visceral surgery/ orthopedics/ENT
- traumatology,
- gynecology and obstetrics,
- medical radiology,
- an emergency departement,
- diagnostic and therapeutic service as well as a rescue organisation.

The numbers of cases indicate the relevance of this hospital for the region: In 2002 there were 6’500 stationary patients, 1’200 partly stationary patients, 11’000 emergency cases and 54’000 outpatient treatments. In 2007 there were already 8’700 stationary patients, as well as 12’000 emergency cases and 89’000 outpatient treatments - with unchanged infrastructure and despite a shortage of staff. The budget 2009 now calculates 9’700 stationary patients.

The rebuilt operation and emergency wing of the GZO-Hospital Wetzikon opened in may 2003. It had already been systematically planned according to the Swiss Hospital Guideline. Essential guidelines have now also been included into the new norm DIN 1946-4 “Ventilation and air conditioning – Part 4: Ventilation in hospitals”.

The renovation and reorganisation of the Hospital Wetzikon had been an intensive project in terms of planning, as almost every department has been effected by it. This called for temporary solutions and arrangements, smooth operations had to be defined and logistics ensured. A complete provisional arrangement has been created for the entire time of the reconstruction.

Implementation of the Hospital Guideline

The Swiss Hospital Guideline (SWKI 99-3) has been substantially benchmarking for the HVAC systems, among others in the field of the classification of operating rooms and other hospital rooms, which is based upon evaluation of the infection risk. All operating rooms have been categorized for the highest hygiene class and are equipped with ULF supply-air diffuser (Unilateral flow supply-air diffuser) of the measurements 3,0 m x 3,0 m. Due to these ULF-diffuser it is possible to perform any operation in each of the operating rooms.

The dynamic shielding with ULF supply-air diffuser of the protection area in the operating rooms allows the hygienically justifiable possibility of a simple convenient air conditioning in all anterooms of the operating theatres that also reduces expenses. The protective effect of the ULF supply-air diffuser depends on the size, form, apron length, tissue distributor (in order to achieve a laminar air flow), speed of the outpouring, air temperature, position of the passages for the return air, as well as factors of the surrounding area (as cold walls and windows). All of these factors have to be considered already in the planning in order to ensure an impeccable performance of the outlet. The sterile supply air flows over the patient, the operating team as well
as the tables for material and instruments, then it gets heated by the internal heat load and flows back to the return air grill. In this process the aprons prevent the mixture between clean and charged air.

The new layout – only made possible by the new hospital guideline – has been converted for the renovation of the operation and emergency wing of the GZO-Hospital Wetzikon as follows:

- Clear separation of the areas between emergency, operating section and awakening. However, it is possible to use the operating section as extended emergency in case of a disaster.
- Replacement of the supply rooms that had been previously allocated to single operating rooms with an open transfer area.
- Generation of a continuous supply corridor for sterile material, which should be delivered from a central sterilization area underneath the corridor and allows the quickest possible disposal.
- Generation of “green caps” with ULF supply-air diffuser, aprons and medium supply bridges in the operating rooms.
- Zones for provisioning with double-sided lifting doors and sterile supply air enables the staff to set the sterile instruments on the open tables during work continues in the operating rooms.
- Conception of the ventilation according to the overflow-principle and protection pressure. The pressure drop corresponds to the hygiene descent (steril preparation -> operating room -> transfer corridor -> awakening / change of bed). Simultaneously this prevents a cross-contamination between the operating rooms.
- The patients are prepared in berths that are open towards the transfer corridor. These berths are as well equipped with medium supply bridges, e.g. for the anaesthesia equipment. The same berths also serve – if necessary – for the awakening.

This innovative concept has numerous advantages: Instead of the previously four, the hospital now possesses five plus an extra spare operating space. The single rooms are divided with easily installable and light walls which would easily allow the generation of one big operating room (with three operating places). Patients and operating rooms are flexible to assign. The new arrangement requires a lot less space, which made it possible to place an additional daily clinic with eight berths on the ground floor without any substantial area extension. The ULF supply-air diffuser with their relatively low aprons accomplish the highest possible sterility. The sterile zone for provisioning also enhances the air quality and significantly reduces the non-productive change and intermission times. The amount of operations can be considerably raised with the same size of staff and better working conditions.

New kind of air conditioning system – better operational safety with lower cost

The concept for the HVAC system has been adapted from the high level biosafety technology and adjusted to the conditions of the hospital. Circulation air – sterile air – diffuser (ULF) have been installed in the operating rooms. The ventilators that are integrated into the ULF supply-air diffuser extract the air from the operating room and deliver it to the cooler (dry cooling) and from there via the HEPA-filter and the tissue distributor back to the operating room. Instead of different single and smaller ventilation-units, two equivalent, high quality units for the preparation of the outside air (per OP 800 m³/h) have been installed in the plant room. Both constructions can be operated by the use of a sophisticated steering control and regulation as well as achieve the necessary capacity alone or together. This may require a stronger effort for steering control, but this results, among others, in the following advantages:

- Redundancy always exists. For financial reasons, the smaller installations are not double featured in other hospital facilities, but here, all climate zones possess a backup in case
of a breakdown of the air conditioning. This is of vital importance for an operating and emergency facility.

- In case of breakdown or revision of one facility, the other one is working one hundred percent. Zones without vital priority are switched off or served with a reduced level. Thus, a revision of the facilities is also possible during normal activities.
- The reduction of the number of VAC-Systems enables a high-quality in equipment and material but still reduces the total costs.

This concept can only be realized, if the protection effect of the ULF supply-air diffuser is actually working. In order to guarantee this, a new test for the evaluation of the protection level has been developed and established in the new hospital guideline.
New opportunities and chances for an innovative organisation of operating theatres with the new German and Swiss Hospital Guidelines for Ventilation

Dipl. Ing. Arnold Brunner
Revision of the Swiss hospital guideline

• Start January 22nd, 1997
• Target: End in 1998
• essential Hospital-organisations participate
  – Hospital hygiene
  – Technical and maintenance service
  – Building services engineering
• 1st draft with official consultation January 2001
• final draft December 2002 (2nd official consultation)
DEUTSCHE NORM

Raumlufttechnik — Teil 4: Raumlufttechnische Anlagen in Gebäuden und Räumen des Gesundheitswesens
VDI-Lüftungsregel

Vorwort

Diese Norm wurde vom Normenausschuss Heiz- und Raumlufttechnik (NHRS) unter Beteiligung der betroffenen Fachkreise und Regelsetzer erarbeitet. Die grundlegende Überarbeitung dieser Norm erfolgte unter Berücksichtigung der aktuellen hygienerelevanten Regelwerke VDI 6022 Blatt 1, ÖNORM H 6020 und SWKI 99-3.


Publication in November 2008

Torino, 1 Aprile 2011

Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Guide for planning, construction and operation

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Project performance specifications

- Project definition, Intended use description
- Project organisation and quality management (QM-Masterplan)
- Testing concept (system qualification)
- Energy control and measurement concept
- Fire protection concept (fire compartments, escape routes, smoke extraction, evacuation)
- Time schedule, cost estimate
Project performance specifications

Room definitions (room data sheet) listing at least:

- hygiene classification
- protective-overpressure concept
- electrical safety classification
- room-climate requirements
  (temperature, humidity, sound pressure level)
- materials to be used (walls, floor, ceilings, etc.)
- operational facilities, equipments (internal loads)
Project performance specifications

• Prepared by the orderer / customer in cooperation with experts
• The target definition phase will be concluded when the performance specification of the project is approved by all parties involved in target definition.
• This serves as a basis for planning.
Air hygiene in operating rooms

Operating rooms are distinguished into:

- Operating rooms with ventilation systems of unilateral flow (ULF) for attaining a protected area in which the operation takes place and where the instruments tables are positioned (room class 1A);
- Operating rooms with ventilation systems of mixed or turbulent displacement flow (room class 1B).
New operating room class 1A

• vertical displacement flow
• minimum size of the ULF diffuser 9,0 m²
• terminal, manufacturer inspected, high efficiency particulate air (HEPA) filters H13
• surrounding airflow aprons down to the height of the doors (approx. 2,1 m above floor level)
• supply air volume flow > 8‘000 m³/h
• outdoor air supply (800 –) 1200 m³/h
Integral OP acceptance tests (qualification)

Two acceptance tests:

**Technical acceptance test**
performance parameter of the HVAC system

**Hygienic acceptance test**
sufficient protective effect against load entry from outside

sufficient protective effect against load entry from inside
OP-Room acceptance test (outer load entry)
OP-Room acceptance test (inner load entry)
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Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
hospital-hygiene conclusion

State-of-the-art operating rooms

Minimum requirement:

For the entire protected area a protective effect

> 4 (without operating lamps) or
> 2 (with operating lamps)

respectively, shall be demonstrated.
These examinations shall be carried out in the form of averaged double determinations above the test positions (n = 17 in accordance with Figure D.2 projected onto the floor below the LTF outlet) marked by black, orange and white self-adhesive dots.

Figure D.2: 17 test positions in the measuring grid projected onto the floor below the ULF outlet.
The new Sergical Ward at the Hospital Wetzikon (GZO)
The old layout-concept
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
The new concept
The new philosophy
Supply Corridor
Sterile store
Transfer Area
Disposal
Anaesthesia Induction Area

Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
functional principle of the ULF ceiling outlet
Overflow prinzip / Pressure regime
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie
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Con il Patrocinio di

Le nuove raccomandazioni regionali sul trattamento dell’aria nelle sale operatorie

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Outside-air

Material Preparation

Operation

HEPA-Filter H13
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arnold.brunner@bht.ch