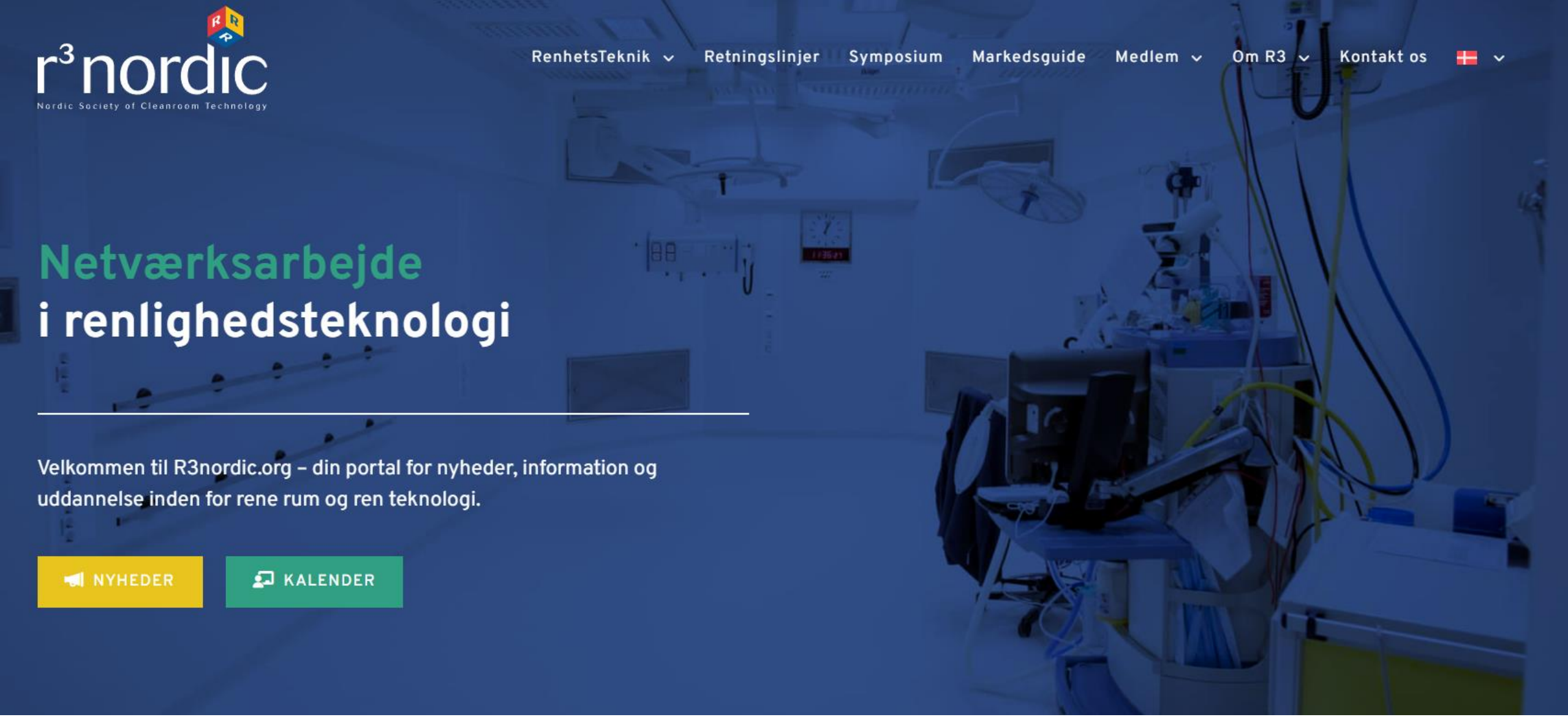

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Vejledningen som har været gældende siden 2014

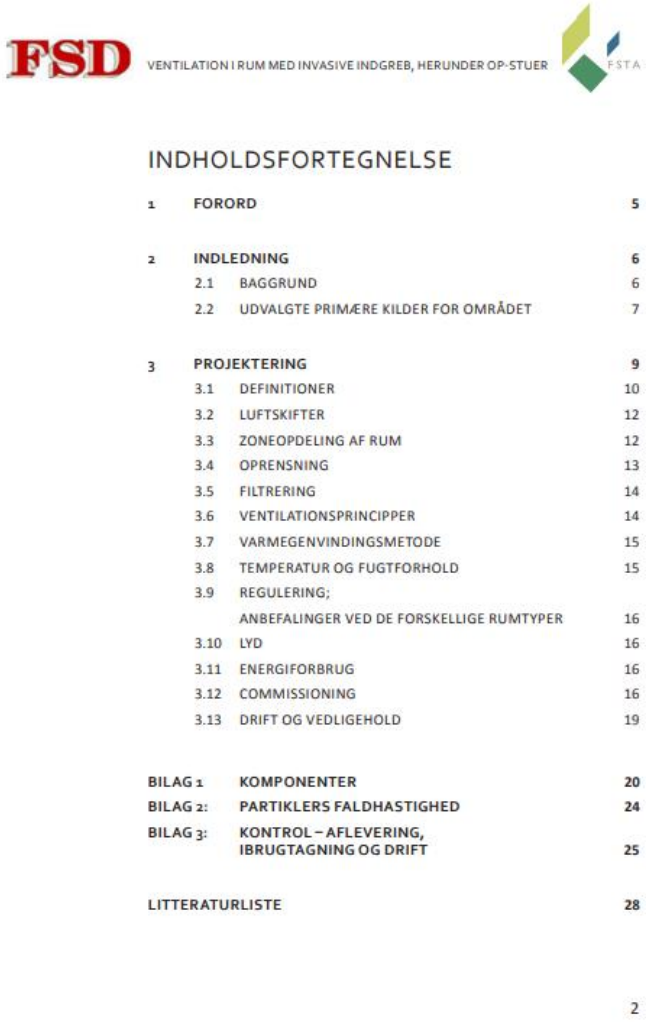
- Denne Vejledning er en opdateret og revideret udgave af vejledningen fra **1998 "Ventilation i Operationsstuer"** udarbejdet af
- FSD.

FSD

VEJLEDENDE RETNINGSLINJER FOR

VENTILATION I RUM MED INVASIVE INDGREB, HERUNDER OP-STUER

VERSION 1.0, AF 1. SEPTEMBER 2014



FSD VENTILATION I RUM MED INVASIVE INDGREB, HERUNDER OP-STUER

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2

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2 INDLEDNING

I ventilationsmæssig sammenhæng skal operationsstuer ses både som rum med høje hygiejnekrav i forbindelse med invasive indgreb, ligesom krav til et godt arbejdsmiljø i arbejdsrum i henhold til regelsæt i Bygningsreglement og Arbejdstilsynets bestemmelser skal overholdes.

Det er således både komfortkrav og hygiejnekrav, der er bestemmende for luftkvaliteten i forbindelse med installation af ventilationsanlæg som betjener rum med invasive indgreb.

Denne vejledning indeholder forslag og anbefalinger til forhold, der i særlig grad bør være i fokus i forløbet med projektering, etablering, commissioning forud for klinisk ibrugtagning såvel som den efterfølgende drift og vedligehold af ventilationsanlæg, som betjener et rum hvor der foretages invasive indgreb. Vejledningen kan anvendes såvel ved nyetablering som ved renovering af operationsstuer og undersøgelsesrum etc.

Det kan ofte være en kompleks og omfattende opgave at skulle opfylde krav til hygiejne og komfort samt indfri lokale forventninger ved etablering af ventilationsanlæg og -systemer til sådanne rum.Denne vejledning kan derfor heller ikke betragtes som komplet dækkende for emnet. Vejledningen skal alene ses som et supplement til gældende standarder, regler og anvisninger, som i forvejen foreligger fra relevante myndigheder.

Målgruppen omfatter bredt alle interessenter med opgaver i og omkring operationsstuer, herunder hygiejneorganisationen, bygherre, rådgiver, leverandør, driftsorganisation for teknisk drift såvel som det kliniske driftspersonale. Vejledningen skal således understøtte forståelsen af det komplekse system, som påvirkes af såvel tekniske forhold som personalets adfærd.

Med vejledningen ønsker FSD/FSTA, at krav til og design af ventilation til Operationsstuer og rum. hvor der sker invasive indgreb. bliver lettere tilgængeligt for de personer der planlægningsmæssigt, projekteringsmæssigt og driftsmæssigt arbejder med etablering og drift af operationsstuer.

Vejledningen er desuden udarbejdet med emner, der i dagligdagen kan være til gavn for de personalegrupper, som har deres arbejde i de respektive områder.

FSD VENTILATION I RUM MED INVASIVE INDGREB, HERUNDER OP-STUER FSTA

FØLGENDE PERSONER HAR DELTAGET I UDARBEJDELSEN AF VEJLEDNINGEN:

Kaj Hyldgaard	Teknisk koordinator	Nyt Aalborg Universitetshospital
Lars Sloth	Maskinmester	Aalborg Universitetshospital
Pernille Ripadal	Hygiejnesygeplejerske	Region Nordjylland
Hans Hagelkvist Bloch	Maskinmester	Aarhus Universitetshospital
Claus Berntsen	Bygningschef	Slagelse-Næstved Sygehuse
Elsebeth Tvenstrup Jensen	Overlæge, Mikrobiologi & Infektionskontrol	Statens Serum Institut
Dorthe Bechmann	Civilingeniør, Chefkonsulent energi	Region Hovedstaden
Henning Pedersen	Maskinmester	Privat konsulent
Hans Theil	Civilingeniør, HVAC hospitaler	Søren Jensen
Johnny Nielsen	Projektchef	Fournais Energi
Jan W. Holsøe	Civilingeniør, VVS & ventilation, afdelingsleder	Balslev
Lars Nielsen	HVAC-ingeniør	Søren Jensen
Jørgen Pedersen	Civilingeniør, specialist ventilation og renrum	NNE Pharmaplan
Carsten Rasmussen	Ingeniør	Rambøll
Thøger Haugstrup	Projektleder, diplomingeniør	Alectia
Anders Kobbelgaard	Civilingeniør, Energi og indeklima	Midtconsult
Bjørn Barbré Pedersen	Seniorrådgiver Sundhed	Midtconsult

Rigtig gode forklaringer på forskellige principper og baggrunden for det.

3.6 VENTILATIONSPRINCIPPER

Opblandingsventilation:
Luften tilføres ved loft (udenfor opholdszonen) med en relativ høj hastighed, typisk 4 m/s. Den høje hastighed medfører at der medrives rumluft, hvorved der sker en opblanding. Dermed opnår man en nogenlunde ensartet fordeling af forurening og temperatur i rummet. Udsugning sker normalt ved gulv og loft.

Fortrængningsventilation (anvendes normalt ikke i denne type rum):
Her tilføres luften ved gulv med lav hastighed, typisk 0,4 m/s, og en undertemperatur. Med udsugning placeret ved loft forstærkes de opadgående luftstrømme forårsaget af termisk påvirkning fra lamper, mennesker og andet.

UDF – Uni Directional Flow – også kaldet LAF (Laminar Air Flow):
Her tilføres luften med lav hastighed over en stor flade – typisk en del af loftet. Indblæsningshastigheden vil typisk være ca. 0,3 - 0,5 m/s. Den tilførte luft er HEPA-filtreret og dermed vil rumluften have en meget stor renhed så længe der ikke er tilført forurening til området. Ønsket er, at alle forureninger fanges af luftstrømmen og transporteres bort fra den kritiske zone, som holdes beskyttet af den rene luft.

Den nødvendige hastighed af den tilførte luft vil være afhængig af mange faktorer:

- Afstand fra filter til det kritiske område
- Varmekilder i luftstrømmen
- Fysiske hindringer i luftens bane

Lufttilførslen kan ske vertikal eller horisontalt. Typisk dog vertikal, da horisontalt flow kan være vanskelig at indarbejde i et lokale med mange personer. Det er afgørende. at der ikke er væsentlige hindringer i luftens bane eller tilførsel af forurening før luften når det område, som skal beskyttes.

Der kan med fordel gennemføres CFD-simulering under projektering for at optimere forholdene. Den nødvendige lufthastighed skal verificeres f.eks, med røgstudier under simulerede operationer. Dokumentation af luftflow foretages i form af videooptagelser.

Punktsug
Der etableres punktsug på alle operationsstuer. Disse bør føres direkte til det fri, med afkast over tag, da luften kan indeholde skadelige partikler og gasser fra operationsprocesser.

Type Infektionsfølsomhed Samlet vurdering af infektionsrisiko ved indgrebet.		1 Minimal	2 Mellem	3 Mellem	4 Høj	5 Høj
Klassifikation af operation		Småkirurgi ("Chirurgia minor")	Minimal invasiv udenfor opera-tionsafdeling	Større minimal	Ultraren uden LAF	Ultraren med LAF
Vejledende EU renrumsklasse		CNC – (Controlled Not	D	C	B	B
Dimensionsgivende krav til arbejdsmiljø og indeklima				5-15 personer	5-20 personer	5-20 personer
Maksimalt kimtal, middelværdi under operation i kritisk zone			200 CFU/m³	100 CFU/m³	10 CFU/m³ (1)	10 CFU/m³ (1)
Kontrolgrænse for antal partikler >0,5 µm pr. m³	Rummet rengjort og uden personbelastning		3.520.000	352.000	3.520	3.520
	Under operation			3.520.000	352.000	352.000
Mindste volumenstrøm total (nettoarealer)			8,3 l/s/m²	12,5 l/s/m²	16,7 l/s/m²	16,7 l/s/m² Eksklusiv LAF
Mindste volumenstrøm udeluft (nettoarealer)			5,6 l/s pr. m² dog mindst 333 l/s	5,6 l/s pr. m² dog mindst 333 l/s	5,6 l/s pr. m² dog mindst 333 l/s	5,6 l/s pr. m² dog mindst 333 l/s
Anbefalet nettoareal af OP-stue			40 m²	60 m²	80 m²	80 m²
Overtryk i forhold til mindre rene områder				10-15 Pa	10-15 Pa	10-15 Pa
Anbefalet slutfilter iht. DS/EN 779 og DS/EN 1822		F7	F9	H14	H14	H14

Tabel 1, Vejledende projekteringsforudsætninger (skal læses sammen med efterfølgende definitionsark)

Påklædning = kildestyrke

I projektet: Hvilke værdier har man valgt og hvordan er det dokumenteret værende iorden

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FSD vejledningen er rigtig god til at give forståelse for helheden og hensigten med de forskellige elementer, som er forudsætningen for en velfungerende operationsafdeling.

-Men ikke præcis nok til et udbuds materiale.

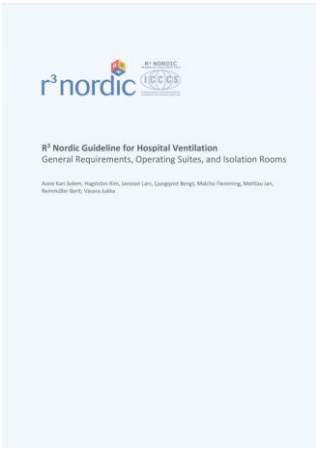
Og det har muligvis aldrig være hensigten med vejledningen

FSD VENTILATION I RUM MED INVASIVE INDGREB, HERUNDER OP-STUER FSTA

Spørgsmål i ventilations gruppen:

- Revidere, 10 år gammel FSD/FSTA vejledning, - eller er det tid til en ny ?

- Ny Nordisk Hospitals guideline, netop på vej, som er et fælles europæisk CEN samarbejde, som blev til et nordisk samarbejde.



FSTA har sagt ja til at tilslutte os Nordisk Hospitals guideline.

Hvis der følger et dansk annex med, omhandlende de særlige Danske forhold. (Forklarende mellem gammel og ny vejledning)

- Så det er vores nye virkelighed

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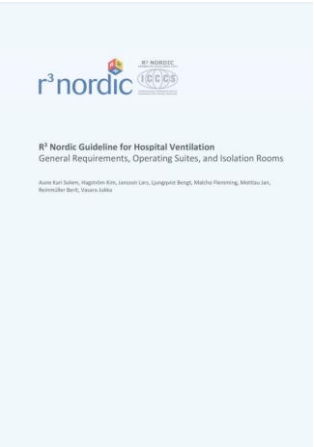

Hvad sker der fremadrettet, i Ventilations gruppen:

- Et udvalg arbejder med det ”Danske annex til guidelinen”
- Et udvalg arbejder med ”drift og vedligehold af Op-områder og høj-isolations områder”

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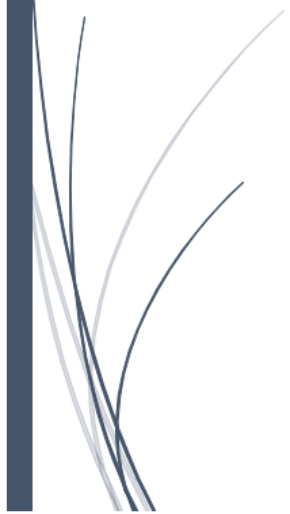
Draft startet 15-05-2024/JAMO

15-05-2024

Annex DK

Nordic hospital guideline



FSTA Ventilations gruppe 2024

Indhold

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Formål: 2
Målgruppen for dette annex 2
Operationsstuer 3
Klasser af operationsstuer 3
Parametre med betydning for renheden på operationstuen. 4
Påklædning 4
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Renovering af gamle operationsstuer 9
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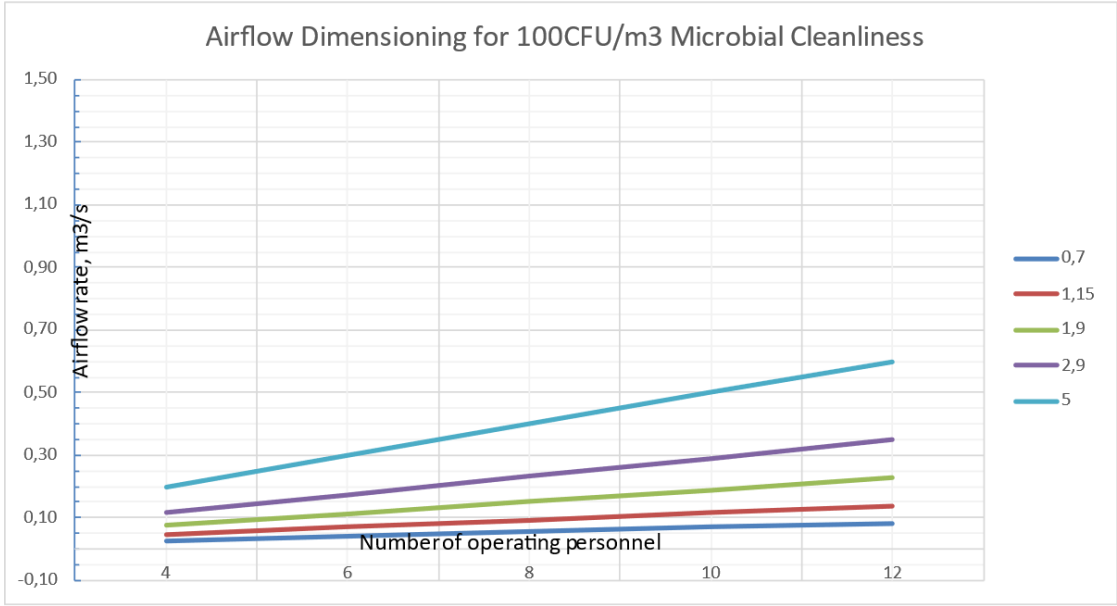
Eksempel fra Annex:
på antal personer, påklædning, luftmængde 100 CFU

Eksempel med <100 CFU

Target air cleanliness CFU/m3:	100	Persons				
		4	6	8	10	12
Source strenght / CFU/s	0,7	0,03	0,04	0,06	0,07	0,08
	1,15	0,05	0,07	0,09	0,12	0,14
	1,9	0,08	0,11	0,15	0,19	0,23
	2,9	0,12	0,17	0,23	0,29	0,35
	5	0,20	0,30	0,40	0,50	0,60

- surgical clothing system, cleanroom quality, 99 % polyester, 1 % carbon fibre =>	qs= 0,7 CFU/s
- single-use surgical clothing system, 100 % polypropylene =>	qs= 1,15 CFU/s
- common surgical clothing system, 50 % cotton, 50 % polyester =>	qs= 1,9 CFU/s
- surgical clothing system, 99 % polyester, 1 % carbon fibre =>	qs= 2,9 CFU/s
- common surgical clothing system, 69 % cotton, 30 % polyester, 1 % carbon fibre =>	qs= 5,0 CFU/s



Klassificering af barrieretøj

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Eksempel fra Annex:
Nye måde at definere operations stue tøj på

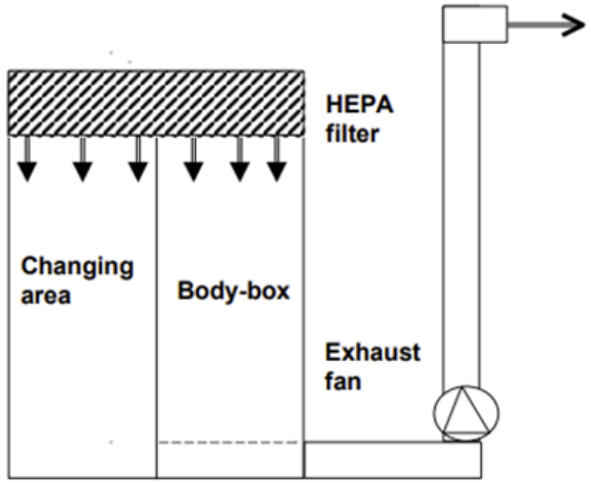

Figure 2.7 Surgical clothing system of 99.5% polyester and 0.5% carbon fiber, textile hood, blouse and trousers.

Relationship between clothing system and source strength

Describe the relationship between materials and testing values (chamber and operating room)
The protection efficiency, source strength, of the surgical clothing systems

Typical sourcestrength values

Stress that source strength are mean values that vary in operation

- surgical clothing system, cleanroom quality, 99 % polyester, 1 % carbon fibre =>	qs= 0,7 CFU/s
- single-use surgical clothing system, 100 % polypropylene =>	qs= 1,15 CFU/s
- common surgical clothing system, 50 % cotton, 50 % polyester =>	qs= 1,9 CFU/s
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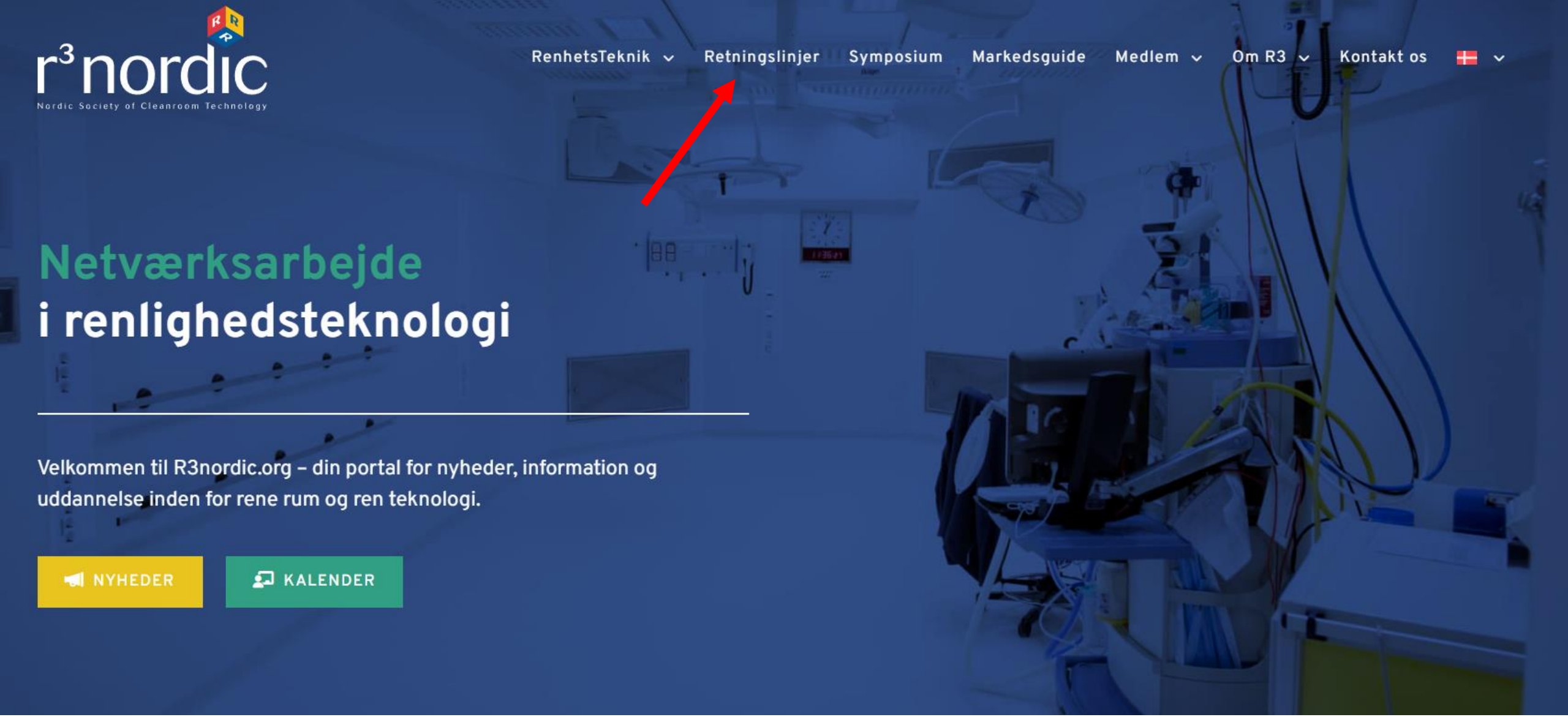

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Vejledning om hospitalsventilation

R3 Nordic er stolte af at kunne annoncere udgivelsen af en ny guideline om hospitalsventilation.

Guidelinen er skrevet af en gruppe nordiske eksperter fra Danmark, Finland, Norge og Sverige, som har årtiers international erfaring på området. Forfatterne til dette dokument har i flere år haft en fælles forståelse af det solide fundament for design af hospitalsventilation, som nu er blevet offentliggjort i denne fælles retningslinje for de nordiske lande.

Denne designguide giver råd og et solidt grundlag for design og verifikation af ventilationssystemers tekniske ydeevne. Den giver også brugerne råd til at vurdere realiseringen af vigtige indendørs parametre og kvalitetssikring af systemets ydeevne i hele dets livscyklus. Vejledningen beskriver grundlæggende krav til korrekt design af ventilationssystemer til hospitalsbrug og udtrykker, hvad der betragtes som bedste praksis på området på udgivelsestidspunktet.

Den offentliggjorte retningslinje vedligeholdes løbende af R3-retningslinjesektionen for at gøre dem til levende dokumenter, der kan inkludere nye udviklinger og feedback fra feltet.

Vi vil gerne takke bidragydere fra Danmark; @Flemming Malcho, @Jan Mottlau, Finland; @Kim Hagström, @Jukka Vasara, Norge; @Kari Solem Aune og Sverige; @Bengt Ljungqvist, @Berit Reinmüller.

Det fulde dokument kan downloades gratis fra følgende link: https://r3nordic.org/wp-content/uploads/2023/09/R3-Nordic-Guideline-for-Hospital-Ventilation_20092023.pdf. 20. september 2023.

R^3 nordic and the guideline section

Population: 28 million people
Geographical area > 1150 000 km²

Guideline section:

- Kim Hagström, chair (FI)
- Berit Reinmüller (SW)
- Bengt Ljungqvist (SW)
- Jan Mottlau (DK, IS)
- Flemming Malcho (DK)
- Jukka Vasara (FI)
- Kari Solem Aune (NO)

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R³ Nordic Guideline – an overview

- **Project process and verification**

- **General medical locations**
  - Functional performance requirements and their verification
  - Systems and components requirements

- **Additional requirements for specific areas**
  - Operating rooms
  - Isolation rooms

Commissioning er en kvalitetsstyrings proces, der verificerer, dokumenterer og tester, at et byggeri opfylder de specificerede krav.

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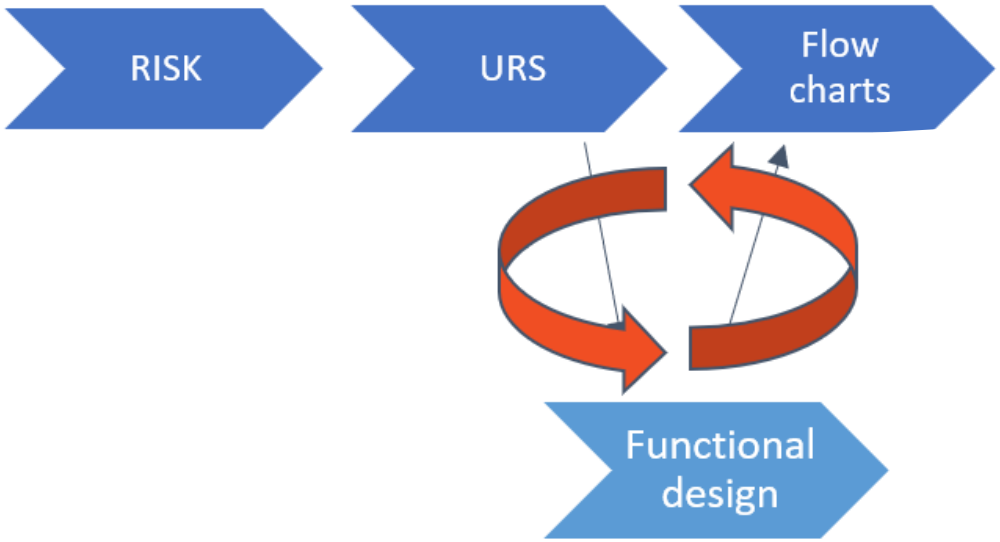
Establishing the basis



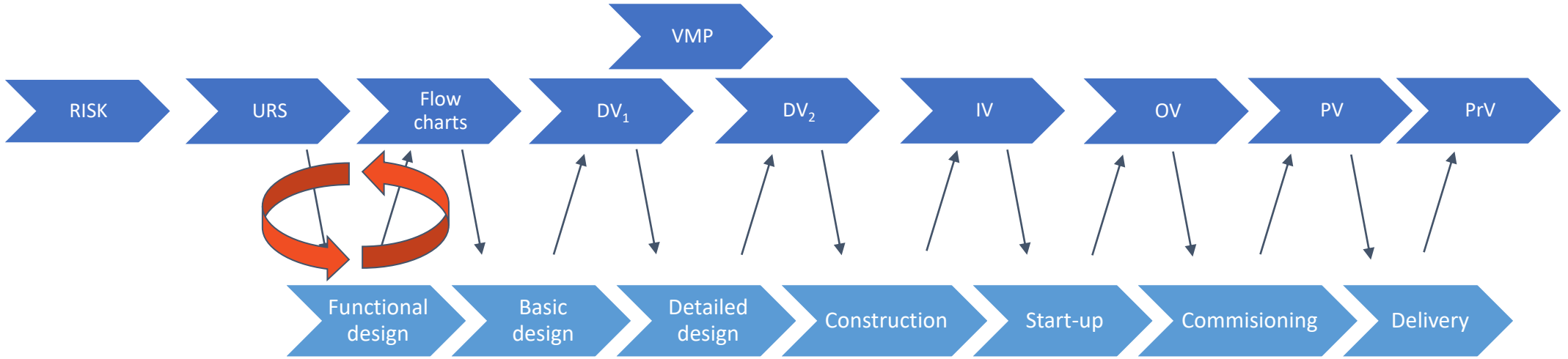
Goal:

to provide a solid and reconciled basis for the design stage

Result documents:

- URS (User reguirement specification)
- Layout
- Flow charts (People, materials)
- Room program

Project process and verification



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Defining the needs/risks for medical areas

Area A

- Functional requirements
- Quantities

→ Risk assessment Area A

Area B

- Functional requirements
- Quantities

→ Risk assessment Area B

Area C

- Functional requirements
- Quantities

→ Risk assessment Area C

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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 Specification (URS) is to ensure:

1) **Protection of patients, staff, and visitors**
2) **Safe and pleasant indoor environment**
3) **Considering sustainability factors and energy efficiency**

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.

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Design

2.2 Requerments 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.**

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Design

2.2 Requerments for indoor Environment quality

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.

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Design criteria
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
			%	℃
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.

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Design criteria
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.

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2.4.2 General performance requirements

Facility management system (FMS)

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.

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

2.6 General requirements for components

Component type	Requierments ultra brief
Outdoor air intake	Recommendation –wet, -snow, -blocked by freezing nor referment to standard, (Thus Denmark DS447 is requiered)
Outdoor air shut-off dampers	Least EN1751: Class 3 airtightness
AHU	EN 13053, least class D2, EN 1886 and Table 4 least class L2, comply with Table 7, east ISO EPm1 (>=80%) filtration, least class T3,t least TB4, weatherproof TB3, Hygenic design
Heat recovery	EN 308 and EN 13053 for hygienic purpose
Ductwork	EN 1506, EN 1507 and EN 12097. Comply with ATC-2 as EN 16798-3
Filters	EN ISO 16890 ePM1 >80% , EN16798-3 SUP1 (prev. 13779)
HEPA filters	ISO 29463 least 35H class, test ISO14644-3
Air terminals	Comfort, cleanability
Shut off dampers	EN 1751: class 4
Cooling coils and dehumidifiers	Wet surfaces and water (condensate) in the system should be avoided, face velocity < 2 m/s
Humidifiers	EN 13053, humidifier class E, should be used.
Droplet eliminators	EN 13053 hygenic effect. , (> 2 m/s for demister effect)
Drainage systems	Wet surfaces and water (condensate) in the system can cause corrosion and growth of microorganisms and should be avoided.

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2.6 General requirements for components

HEPA filters

- HEPA final filters should meet at least class ISO 35H according to ISO 29463 (H13: EN 1822) .
- For proof of 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.

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3 Construction fase

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.

ISO 14644-4 start up.

D.4 Start-up documentation

The reports of the start-up, including pre-commissioning, commissioning and verifications, should be documented and approved. The documentation should include:

a) supplier's commissioning and test documentation;

b) calibration certificates of instrumentation used;

c) relevant as-installed drawings and details;

d) all commissioning and verification results;

e) witnessed verification of conformity with design specification;

f) test report information as specified in ISO 14644-1, ISO 14644-3, ISO 14644-8, ISO 14644-9, ISO 14644-10 and ISO 14644-17.

D.5 Checklists regarding start-up

The points listed in Table D.1 should be reviewed for their relevance to the project or process in the start-up phase.

Table D.1 — Start-up checklist

No.	Item	Description specified
1	Preparing for commissioning	
1.1	Documentation	The following supporting documentation should be available: — drawings — schematics — agreed commissioning format or reporting template — clean build protocol (at the appropriate stage) — approved completed construction verification — system start-up, shutdown and turn-down procedures
1.2	Construction completeness	The following should be confirmed as completed: — construction integrity — ductwork pressure testing — supporting utilities connected — ductwork cleaning — cleanroom cleaned

Den nordiske INSTA 800-serie er en standard serie, der angiver et system til fastlæggelse og bedømmelse af rengøringskvalitet. Den reviderede udgave af den nordiske INSTA 800-serie blev udgivet i foråret 2018

4 Operation / Maintenance Phase

4.1 General requerments

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

4 Operation / Maintenance Phase

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.

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

4 Operation / Maintenance Phase

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.

Re-verification

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.

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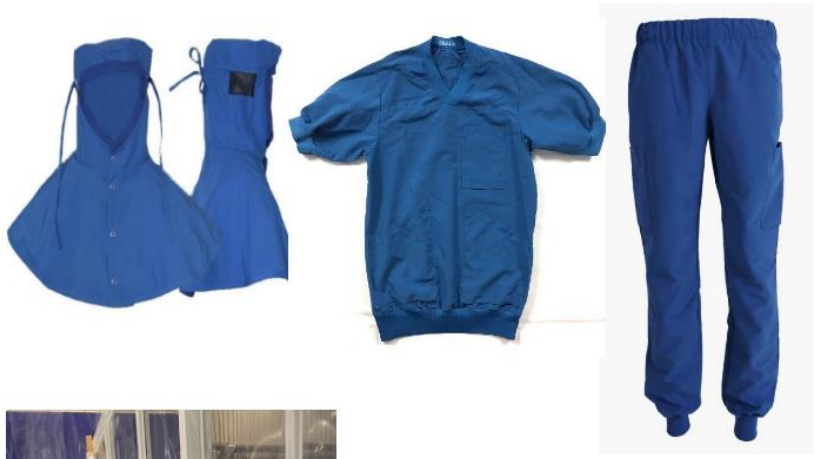
Part 2: Operating rooms

Operating rooms



What to consider, be aware of contamination from:

- Number of people
- Clothing
- Behavior
- Door openings
- Cleanliness outside
- Logistics – for example of sterile goods
- Pollution sources (anesthesia gases, surgical smoke, etc.)
- System operating parameters (dT, v)

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Nye måde at definere operations stue tøj på

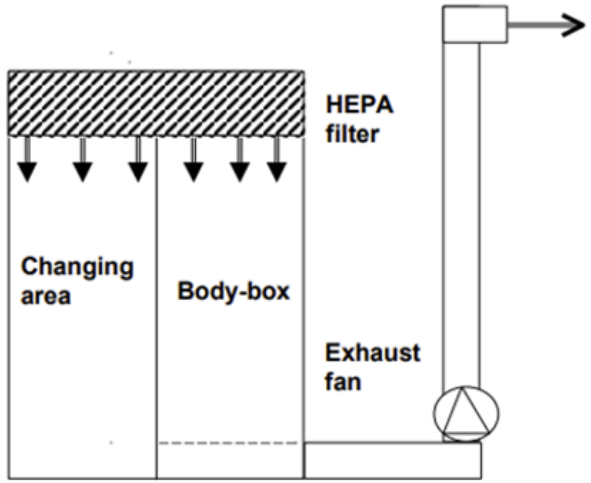

Figure 2.7 Surgical clothing system of 99.5% polyester and 0.5% carbon fiber, textile hood, blouse and trousers.

Relationship between clothing system and source strength

Describe the relationship between materials and testing values (chamber and operating room)
The protection efficiency, source strength, of the surgical clothing systems

Typical sourcestrength values

Stress that source strength are mean values that vary in operation

- surgical clothing system, cleanroom quality, 99 % polyester, 1 % carbon fibre =>	qs= 0,7 CFU/s
- single-use surgical clothing system, 100 % polypropylene =>	qs= 1,15 CFU/s
- common surgical clothing system, 50 % cotton, 50 % polyester =>	qs= 1,9 CFU/s
- surgical clothing system, 99 % polyester, 1 % carbon fibre =>	qs= 2,9 CFU/s
- common surgical clothing system, 69 % cotton, 30 % polyester, 1 % carbon fibre =>	qs= 5,0 CFU/s

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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
  - Dilution mixing principle.

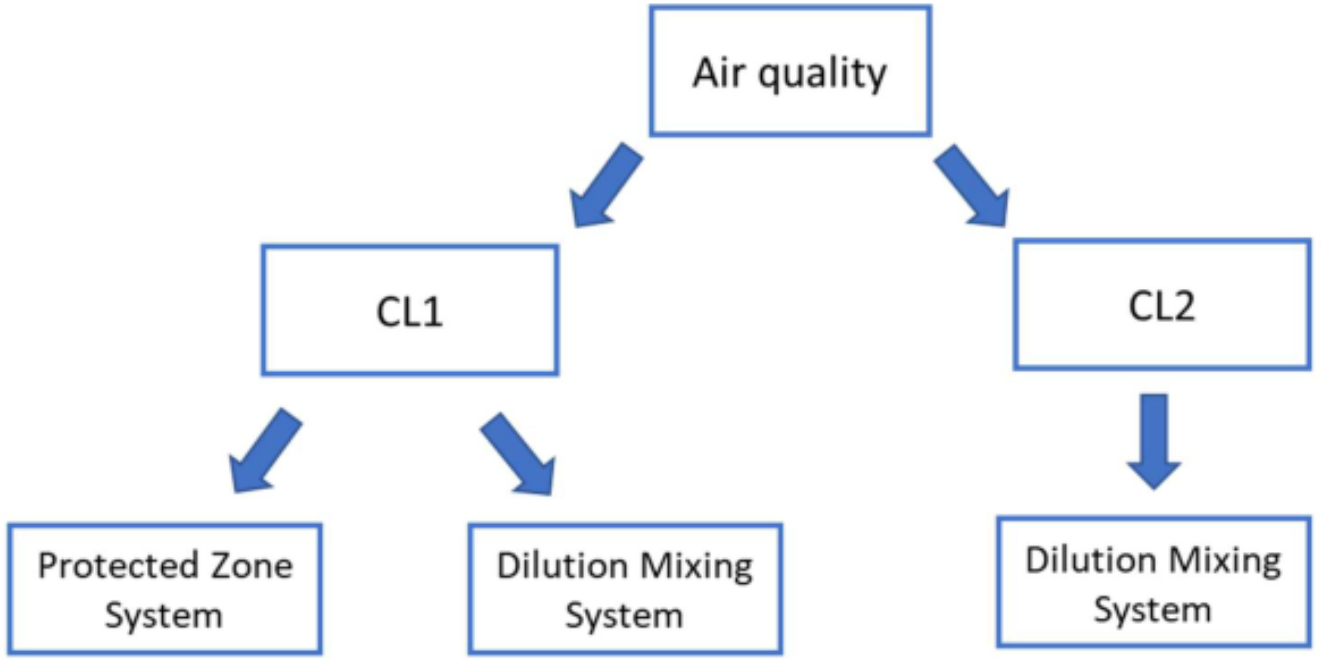
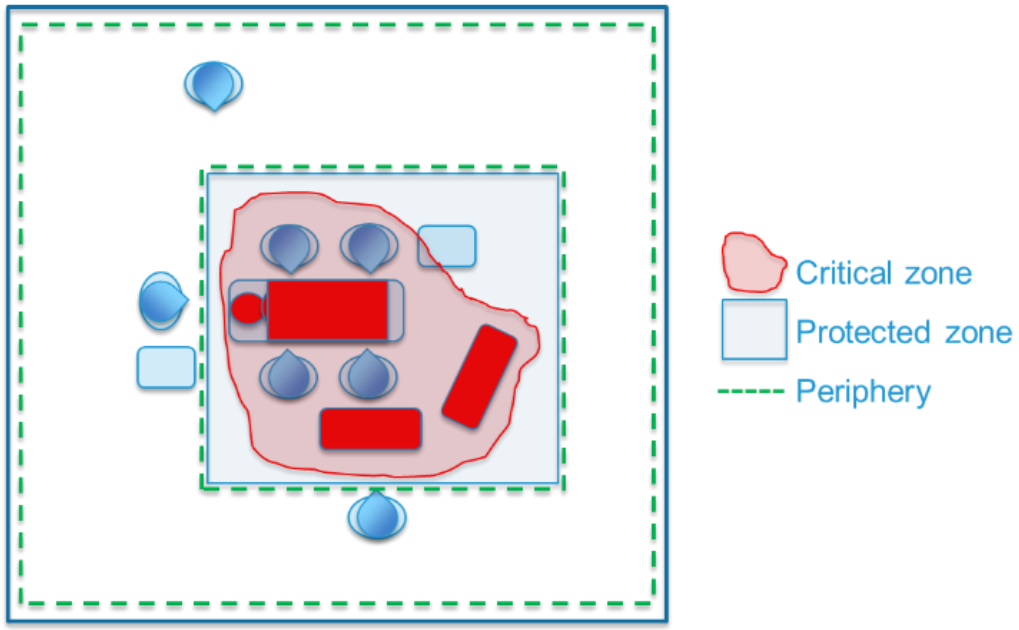


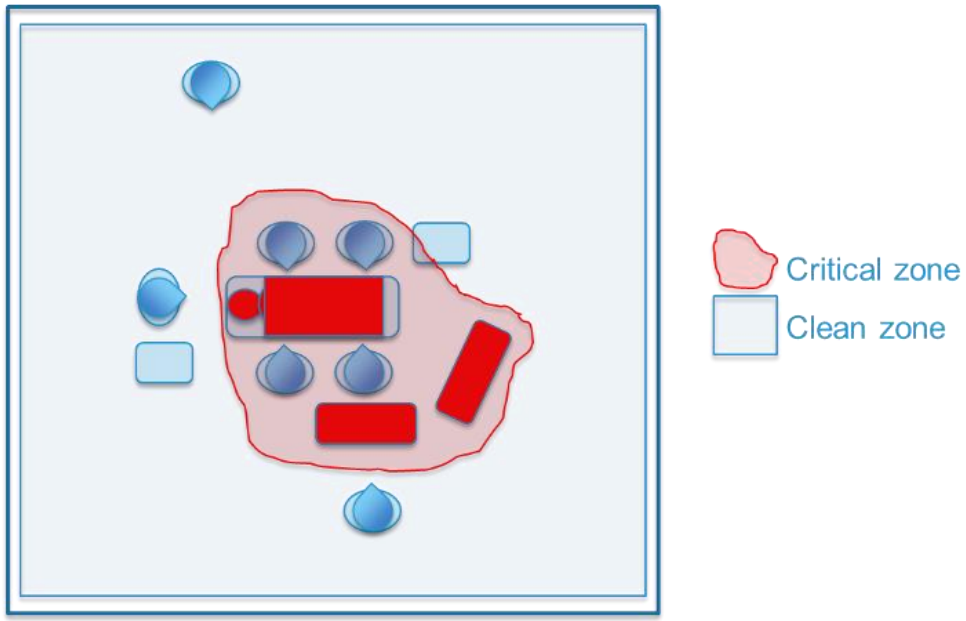
Figure 5. Flowchart: guidance for performance level, risk class and, system principle

OR Ventilation Concepts, Requirements

ZONING LAF



DILUTION/ TAF



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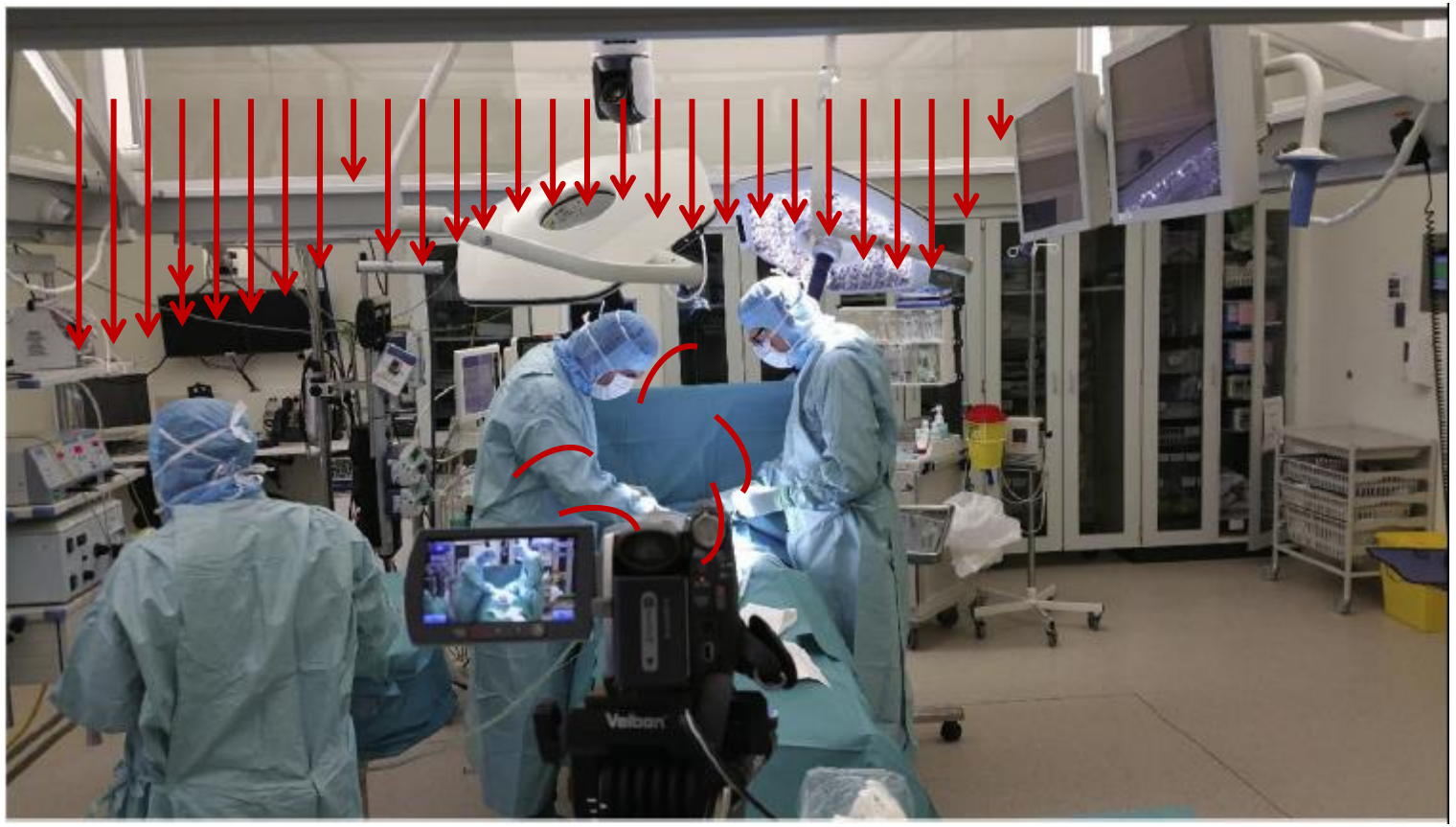
OR Ventilation performance, "At Rest" vs. "In Operation"



Illustrasjon: Windsor

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Requirements for Operating Room
Environment

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.

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Requirements At-Rest

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

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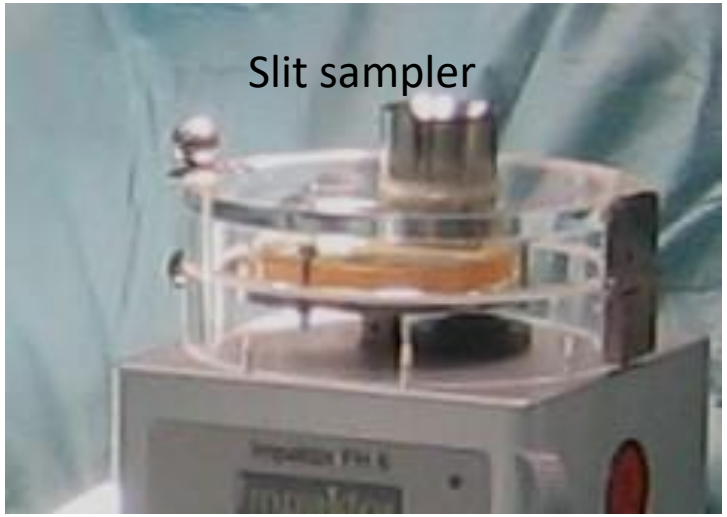
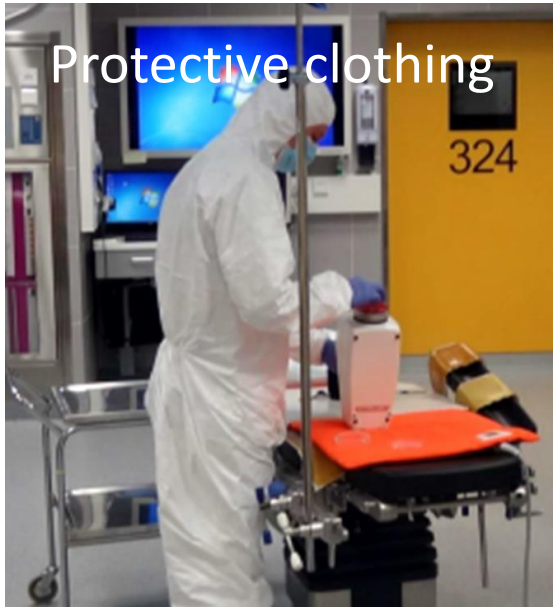
Sampling of air At Rest





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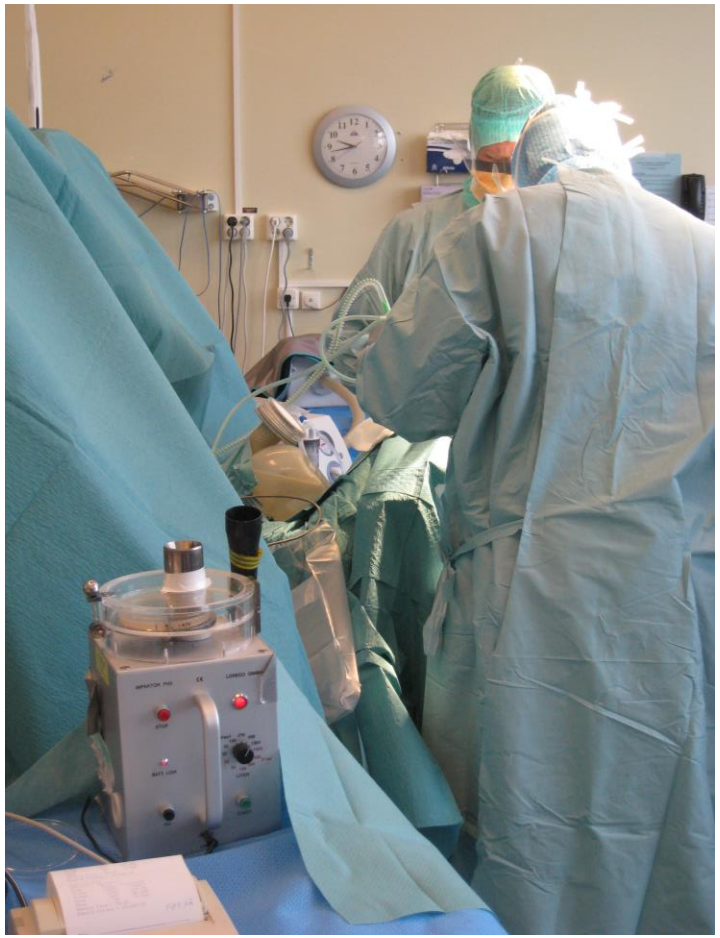
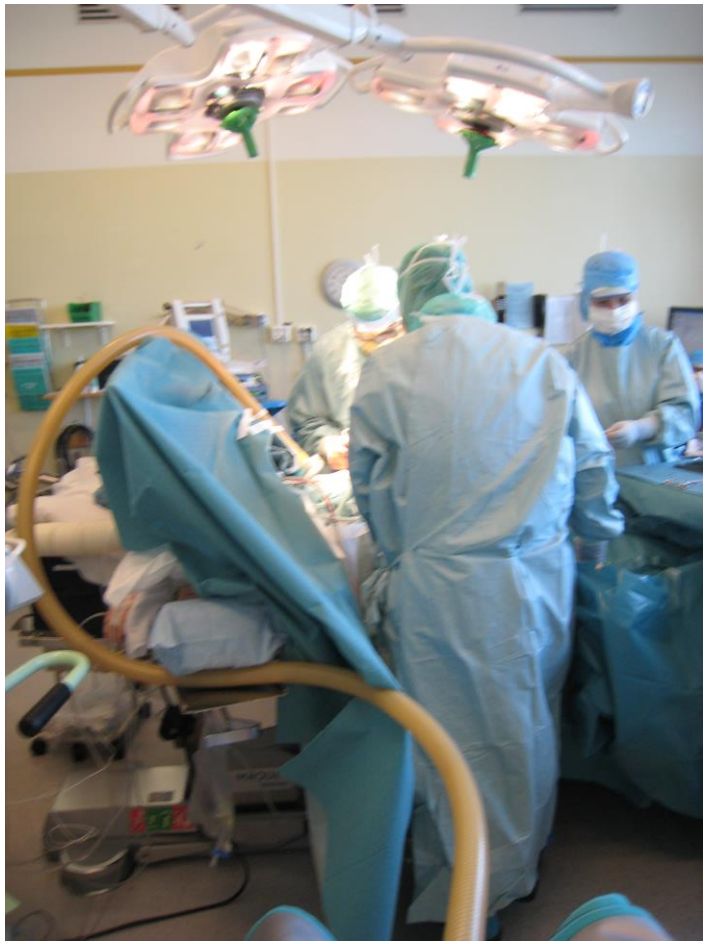
Annex B: Sampling during ongoing operation





- Measurement at a representative location
- As close to critical areas as possible
- Must not disturb the operation
- Protective clothing worn by the measuring person

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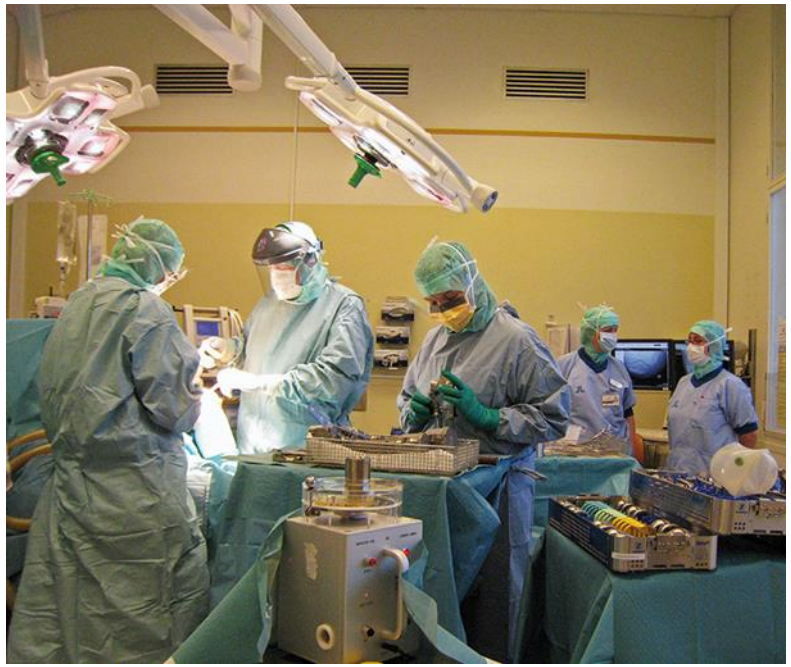
Requirements During surgery

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



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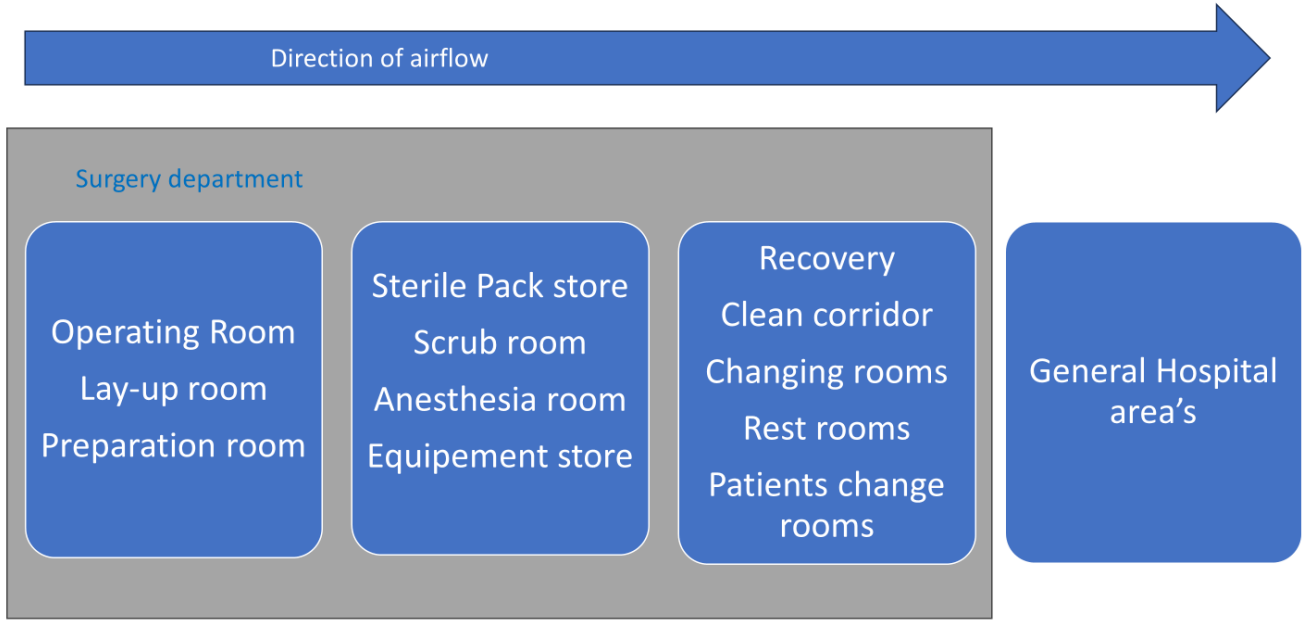
Room pressure / Flow direction

The operating room should be kept in overpressure towards surrounding areas.

- 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
- Recommended tightness of the structures is 0,4l/s,m2 at 50 Pa.
- The doors should be sealed and not impair the general room tightness – for example tightness class C – air leakage < 9 m3/h m2 100Pa (EN 12207:2016).



Operating of infectious patients

Target to minimize the exposure for operating staff

- *Operation of infectious patients:*
  - Ultra clean operation conditions (CL 1)
  - Maximum airflow rate
  - Cleaning and decontamination after surgery

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Set-back

When the operating room is not in use, the ventilation can be used at reduced mode

- Overpressure must always be maintained
- Air cleanliness must be maintained
- It must be ensured that unfiltered air cannot enter to the system, for example, through the exhaust duct
- Temperature and humidity requirements do not need to be met

Part 3: ISOLATION ROOMS

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Airborne Isolation

Guideline covers only isolation units for airborne isolation.

- 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 (for infected patients having simultaneously elevated infection risk)

- 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.

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Contamination in the patient room

Breathing frequency at rest: 12-15 pr min

Breathing volume: 450-600 ml pr breath

Breathing volume pr hour: 0,54 m^3/h (0,15 l/s)

→ Person breathing volume is used as contaminant source strength to be diluted

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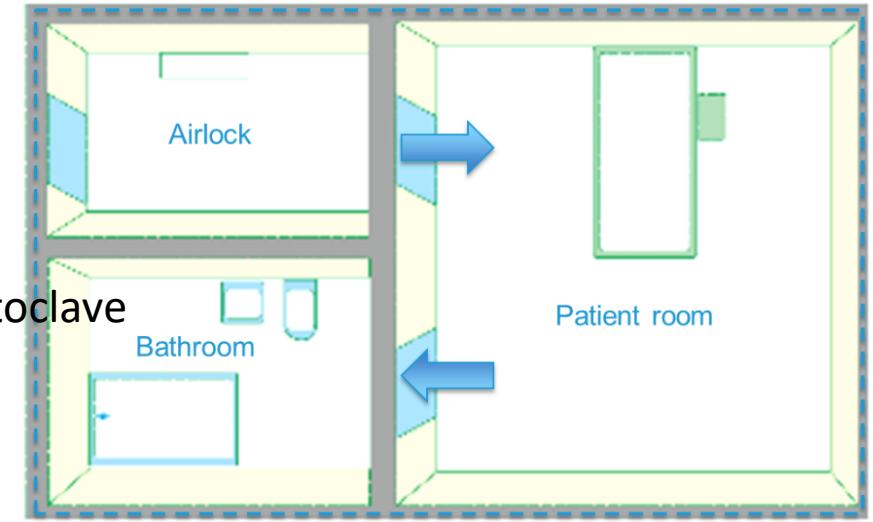
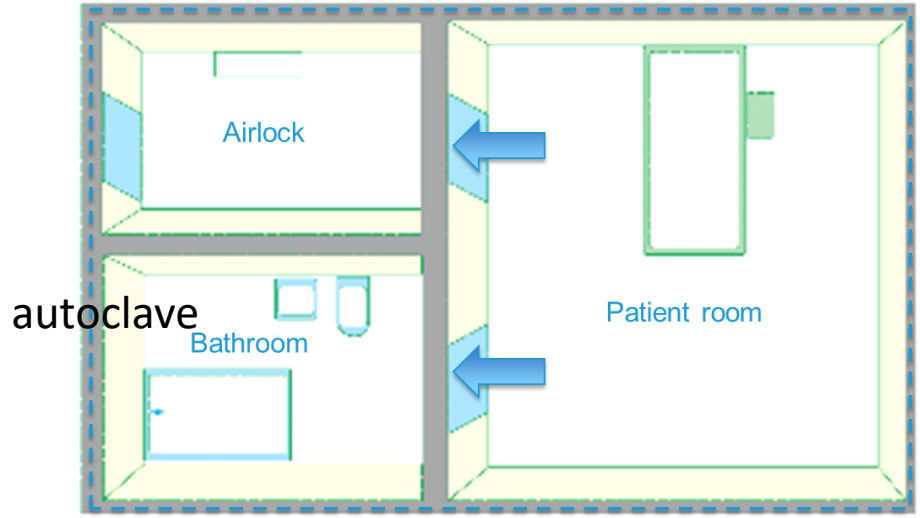
Isolation rooms - airflow principles

source isolation, 2 different risk levels



protective isolation



Leakage rate through the construction boundary should be minimized – tightness requirement given in guideline.

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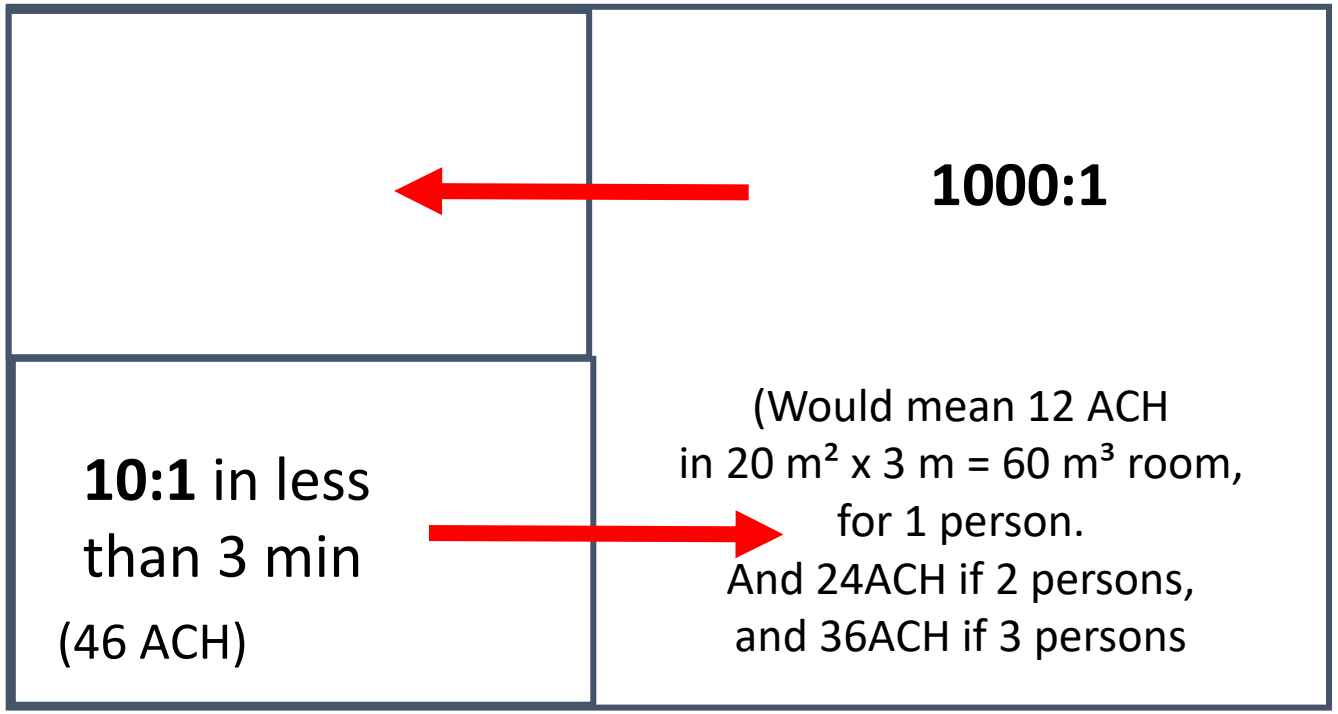
Technical requirements, level S_A

Dilution factor target:

10 000:1 in total

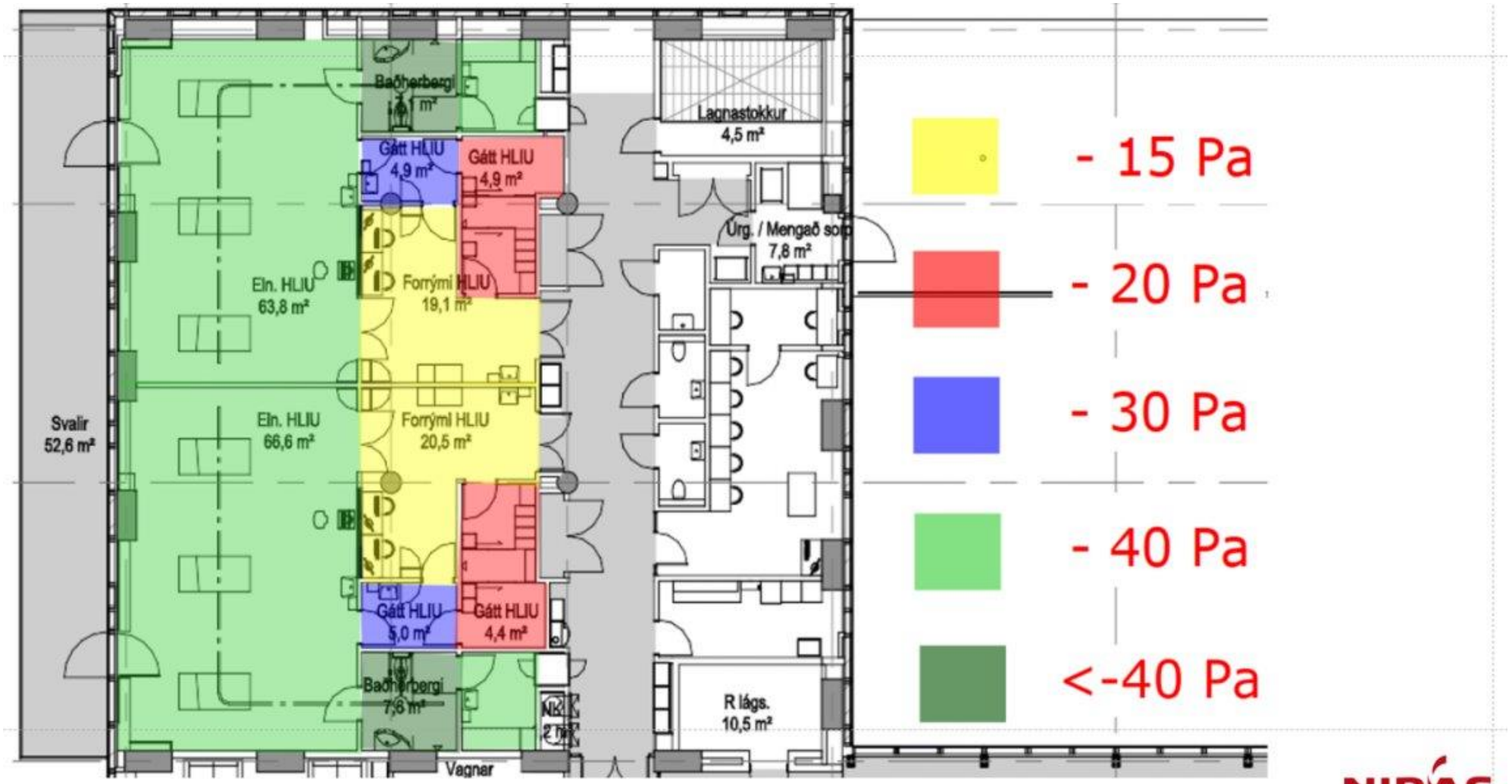
(Isolation room to public area)

- Patient Room Steady state
- Airlock dynamic situation



Insert l/s per person and not ACH as it will vary depending of room size and no of persons

HLIU department pressure cascade set up.



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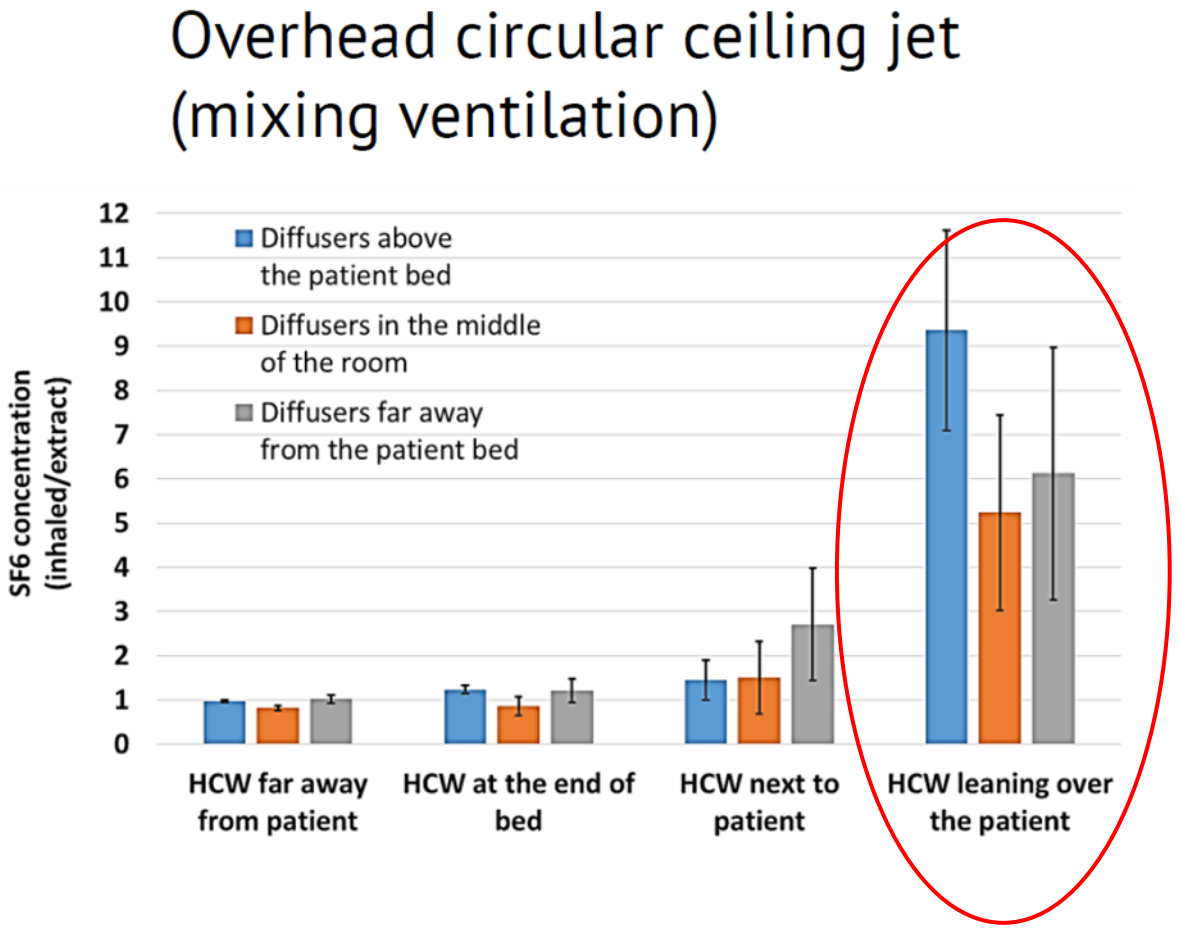
Ventilation Efficiency, HCW Exposure risk close to patient



Kalliomäki P., Koskela H, Protective Airflow in Hospital isolation rooms (In Finnish), TuAMK Report 244, 66p. 2018.

Airflow, Design requirements

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

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Verification

- Air tightness test
  - Documentation of tightness, and pressure/airflow difference
  - (ex. Blowerdoor test)
- Recovery test
  - Measurement points
  - Guidance for (100:1) test realization
- System performance, functional test

OPERATION / MAINTENANCE PHASE, REVERIFICATION MEASURES

- The following system parameters should be monitored / measured annually:
  - Integrity of HEPA filter installation (Every 2nd year)
  - Pressure difference between the isolation unit and the surroundings (Every year)
  - Ventilation airflow rate (Every year)
  - Airflow direction between the rooms within the isolation unit (Every year)

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)

Future Steps - Training

- Guideline group is developing a training program of the guideline
  - Approximately 1 day training
  - Content, material and presenters from the R3 Guideline group

- A training concept proposed to allow easy, low-cost access:
  - Training to be held regionally and hosted by a University Hospital ?

Future Steps – Maintenance of the Guideline

The guideline group aims to:

Regularly update the guideline based on received comments and questions

- The schedule for the 1st update is targeted for 10/24 – comments by 5/24
- E.g. Danish FSTA have in practice adopted the document for their use and is reviewing the content.

Considering widening the scope of the guideline based on received feedback

- E.g. sterilization department has been initially discussed.

The Guideline group is also open for new active members willing to dedicate their own time for common work.

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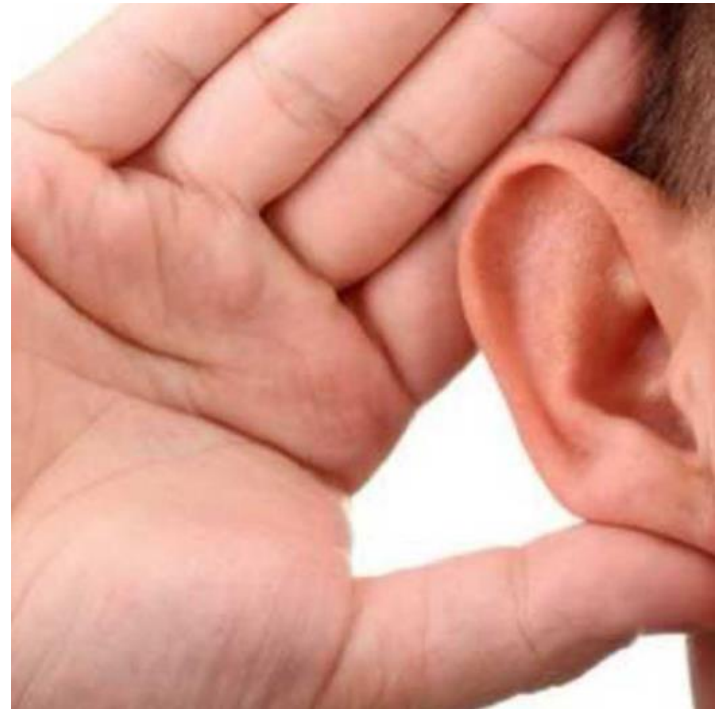
Thank you for listening ☺

The full document may be downloaded for free from the following link:
https://r3nordic.org/guidelines/



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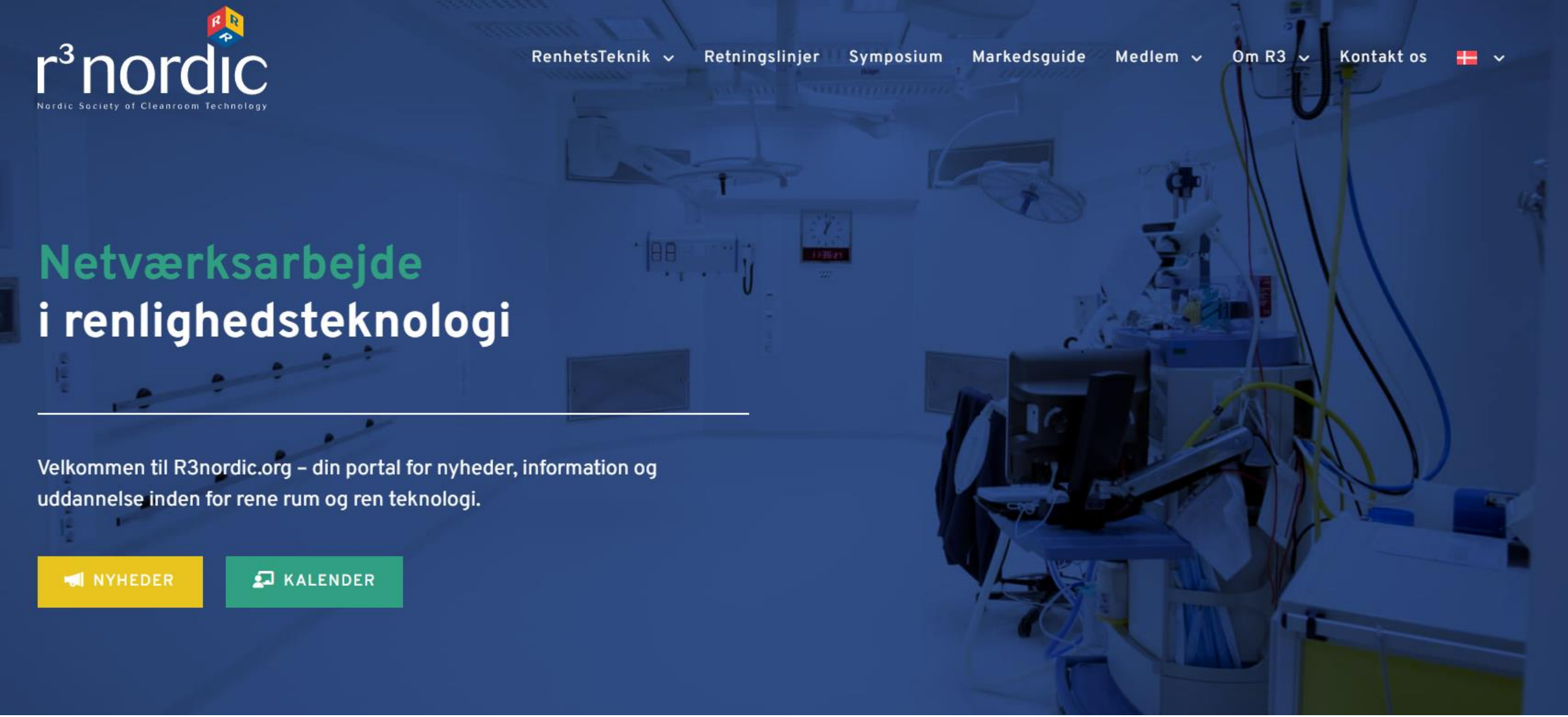

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