Renhets TEKNIK

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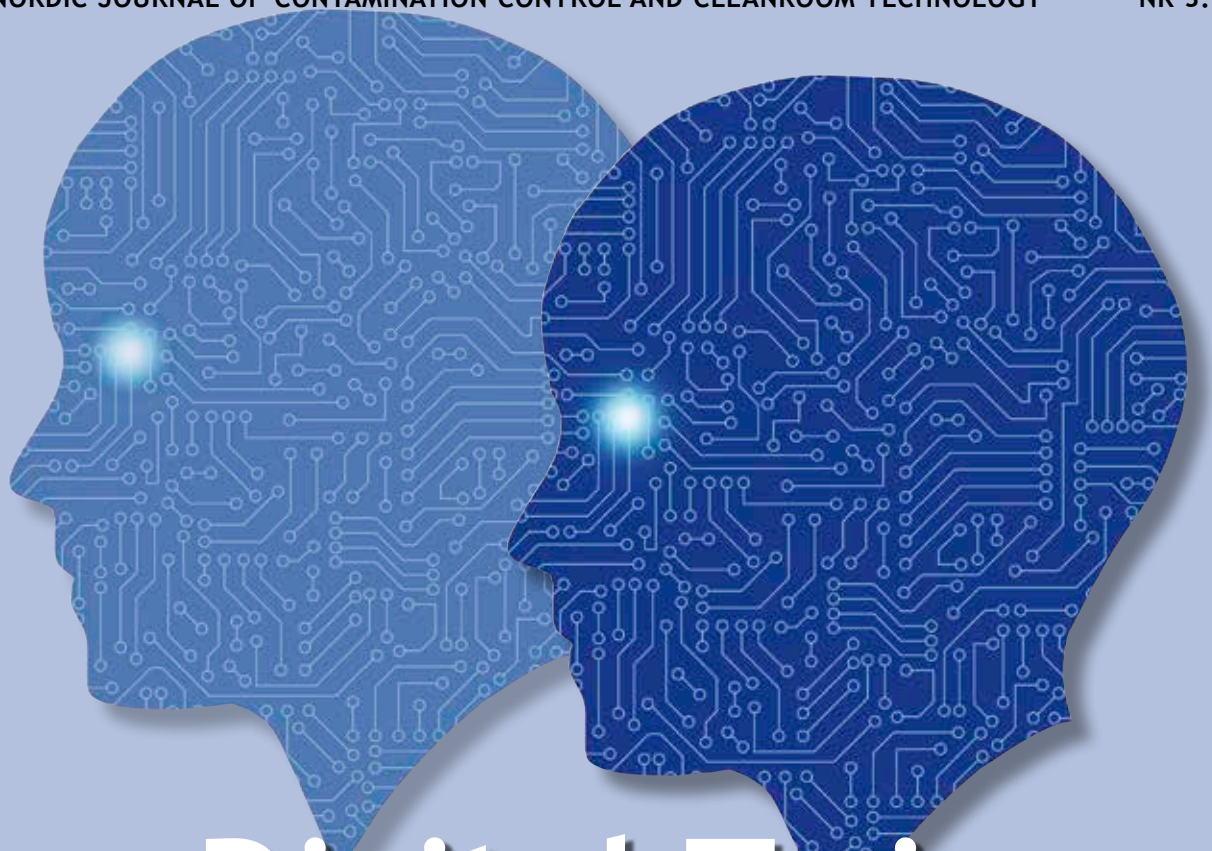

Digital Twins

and three other presentations from Webinair 2020

WEBINAIR

- SYMPOSIUM 2022 • CALL FOR PAPERS
- SOME OBSERVATIONS REGARDING SURGICAL CLOTHING SYSTEMS
- RELEASER & NYHETER

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INNEHÅLL

6-9 Four presentations from R³ Nordic Webinair 2021

18-19 Inbjudan till 2022 års symposium i Nådendal, Finland.

23-27 Some observations on protective efficacy of surgical clothing system...

AMENDMENT

There is an erratum in the article “Room air distribution strategies in hospital isolation rooms” i.e. the caption of Figure 1 in that article is missing. The corrected version of the article with caption is found on the R³ Nordic’s homepage. The caption is as follows: Figure 1: Basic room air distribution strategies (Hagström et al., 2000)

For those of you who would like further information in English about the magazine, articles, advertising or others, please contact the editor Alan Friis; alfr@force.dk

OMSLAGSBILD / COVER: ILLUSTRATION DIGITAL TWINS
ILLUSTRATION: A J CONSULTING · STOCK PHOTOS / INGIMAGE

ORDFÖRANDE HAR ORDET

Kære medlem

Så er efteråret 2021 så småt kommet til os. Et efterår som ser langt lysere ud end sidste efterår, om end der stadig nok er nogen tid til al alt bliver som før.

-Men i hvert fald er vi på vej og i gang og forhåbentlig med en masse ny viden og nyt syn på mange hverdagsting. –"Sjældent er noget så skidt at det ikke er godt for noget", siger et gammelt ordsprog.

-Og mon ikke vi med de sidste par års erfaringer i bagagen har fået dannet grundlag for bedre vaner og dermed også forståelse for vores verden, der jo netop handler om renhed, hygiejne og mikrobiologi ...

Med håb herom ønsker jeg rigtig god læselyst
Bedste hilsner

Lene Blicher Olesen, ordförande

JUKKA VASARA - NY STYRELSELEDAMOT

Jukka Vasara, ledamot (vice ordförande)

I am Jukka Vasara from Finland. I work at Granlund Group as Vice President. My background is master of science in HVAC engineering and my role at Granlund is to manage and develop the hospital and clean room design business.

I have been a member of R³ Nordic for more than twenty years and been a member of the last programme committees of Finnish R³-symposums and a member of the Board since May.

Granlund Group is leading HVAC and Electrical design and consulting company in Finland. We have over 1000 experts working in 23 cities in Finland. We have also offices in Sweden, Britain, Dubai and Shanghai. I started Cleanroom design 30 years ago when we created the cleanroom design scopes to Granlund Group. After that we have done several Cleanroom projects in Finland and also in UK, Russia, China and India. At this moment we are designing big hospital projects in Helsinki, Oulu, Kuopio, Tampere and Rovaniemi. Granlund has made hospital design over 60 years and more than two million square metres of designed hospital space.

I am member of ISO/TC209 working group which updates the ISO 14644-4 design standard. I have worked also about 10 years creating european standard or Technical specification to Hospital ventilation CEN/TC156WG18.

I live with my wife in Helsinki, but we also have another home in the countriside in Kuopio, eastern part of Finland. We have two children who have lived on their own for several years.

KALENDER

2021

Okt

12-13 CTCB-I certifiering, Associate level, Göteborg

12-14 CTCB-I certifiering, Professional level, Göteborg

18-19 Grunnkurs i renhetsteknikk Skjetten, Norge

26-28 EHEDG Advanced Course, Force Technology, Brøndby, Danmark

Nov

- Sjukhusdagar, Akademiska Sjukhuset Uppsala, Sverige

2022

May

10-11 R³ Nordic Symposium 2022

Nästa nummer

beräknas utkomma den 16 december

Manusstopp / Annonsbokning:

16 november

Företag och medlem som vill delta med artikel eller release, skall sända detta i god tid före manusstopp till redaktör Alan Friis.

REDAKTÖRENS SPALT

Dear R³ member

The current issue of RenhetsTeknik (RT) we continue the thematic issues, where we have focused the on-line webinar to be held on May 19th and 26th 2021. The editorial board of RT will continue it's gratitude to the many speakers from the online webinar who have already submitted a paper for publishing in our journal. The papers all pertain to cleanroom technology and are divided in two batches the first addressing hospital applications and the second on pharmaceutical industries.

HYGIENIC PERFORMANCE AND QUALITY

Although we have a minor delay it is still our intention publish a series of publication of papers related to hygienic performance and quality of product contact surfaces. The idea is to bring one or two papers per issue depending on available content and interest to publish such papers in RT. Papers may focus on engineered surface properties, relationship between topography and cleaning efficiency, anti-microbial surfaces, material composition, manufacturing technologies etc. We will also take a deeper look at some of the commercial products available on the market and set up a small panel of experts to assist in a fact finding mission on the topic of surfaces and materials that claim to have improved hygiene features.

As usual we have collected relevant company news as wells as news and highlights from international work, new guidelines as well as information on relevant training courses.

JOIN THE EDITORIAL GROUP

We still have an open invitation for members of R³ to join the RT editorial board. The RT editorial board seeks new members to join us to make RT even better. Mainly we need more ideas about papers or themes for future issues, but all ideas are welcome. Your contribution need not be large, and you can decide yourself how much time you spend on this aside from our four short meetings.

FINALLY,

I hope you enjoyed the summer and that the autumn will allow us to open up slightly with precaution of course.

ALAN FRIIS
REDAKTÖR

Ventilator Renrum erbjuder service av renrum.

Vi är experter inom renrumsteknologi och erbjuder byggnation, konsultation samt produkter för renrum. Vi har hög kompetens och mångårig erfarenhet av renhetsteknik och byggnation av renrum inom bl.a. läkemedels- och elektronikindustrin. Konsultation/byggnation av kontrollerade miljöer. Besök oss på **ventilator.se**

Regelbunden tillsyn och service ökar renrummets livslängd, ser till att rätt funktion och kvalitet bibehålls och ger en god driftsekonomi. Våra serviceingenjörer har mångårig erfarenhet av kontrollerade miljöer.

Genom att regelbundet mäta renhetsgrad, utföra kalibrering och funktionskontroll hos olika komponenter som fläktar och filter med mera får vi en ökad driftsäkerhet.

I dag arbetar vi med både avtalskunder som enstaka uppdrag. Självklart har vi kundanpassade serviceavtal för nya som befintliga anläggningar.

Efter utfört serviceuppdrag överlämnar vi alltid dokumentation, utbildar användarna och ger tips och råd. Med oss som partner får ni full kontroll över er anläggning. **Välkommen!**

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WEBINAIR

Digital Twins: What is the Value Behind All the Hype?

FRANCISCO FORNS-SAMSO, GRANLUND OY

The Digital Twin concept is an emerging trend in the built environment. Essentially meaning the coupling of the physical system with its digital representation. The idea is that the digital information duplicates the information embedded from the physical systems, it is linked and maintained throughout its lifecycle. Digital twins are essentially used for visualization, simulation, monitoring, analytics and reporting. In practice, it is still unclear how digital twins create tangible value in the industry considering the complexity and diversity of buildings and stakeholders. Within this context, it is logical to think that a building might have several digital twins that serve specific functions or purposes. The aim of this article is to demonstrate in a real case study how an ecosystem digital twins can untap the real value in its use during in the operational phase of buildings. The key aspects of this paper include: 1) the application of platform ecosystems to manage and operate building assets, 2) how multiple digital twins can enable integration of existing and new information for improved analysis and visualization, 3) how we can reuse existing information for supporting different use cases and 4) how the integration of information enables the creation of new information to better understand the building behaviour and improve decision-making process.

PLATFORMS AND PLATFORM ECOSYSTEMS

In order to understand the value of digital twins for the built environment it is very important to firstly understand about platforms and platform ecosystems. The term *platform* is used to describe a management phenomenon at the level of individual products, product systems, industry supply chains, markets, industries and even constellation of industries (Gawer, 2009). Business models based on multilateral platforms are the ones that connect producers and consumers to exchange goods, services, money or information (Harlan et al. 2020). In the platform model, information and interactions between the participants are the main assets. With the increase of number of participants, the value of the platform increases proportionately, a phenomenon known as "network effect". As a result, a platform is a structure that creates value by allowing direct interaction between at least two distinct types of actors. Technology has reshaped the concept of platforms and has accelerated the entry of producers with clear examples such as Amazon or Uber. Platform ecosystems are defined as a hubs or central points of control within a technology-based business system (Jacobides et al. 2018). Alstyne et al. (2016), in their article "Pipelines, Platforms, and the New Rules of Strategy" present the idea that platforms are ecosystems formed by four actors: (i) owners (in charge of the governance of the platform), (ii) suppliers (setters of the platform interface with its participants), (iii) producers (suppliers of product or service in the platform) and (iv) consumers (users of the products or services offered by ecosystem). In the real estate industry digital platforms have been mainly developed to make transactions between buyers or sellers of properties or offer accommodation services such as Airbnb. Less focus has been put in developing platforms to manage and operate real estate assets. In this paper we present the BIMLIFE platform design to operate building assets and generate value for the different stakeholders.

BIMLIFE: A PLATFORM FOR DIGITAL TWINS

Even tough, digital twins have gained a high level of interest in the recent years in the built environment, the concept is not new. Many scholars attribute the initial ideas to Grieves (2005) in his work related to Product Lifecycle Management (PLM). Digital Twins can be defined as *"An integrated software solution to manage static and dynamic information of a built asset across its lifecycle phases. It usually provides a realistic digital representation of the physical asset, generated by enriching the geometric or graphical data with support from building automation systems (BAS), sensors, internet of things (IoT) components, and other feedback systems informing about the asset, its occupants, or its environment".* (Camposano, 2021)

The BIMLIFE platform represents an ecosystem of digital twins that aim at creating value through value network effects between different actors in the process. Different actors operate at different levels, namely those levels are strategic, managerial and operational. One of the main challenges for digital twins is to develop a system that operates at those different levels and information is accessible, linked and integrated. In the BIMLIFE project we have acknowledged that an ecosystem of digital twins with a common data environment structure is a way to approach this challenge. Figure 1 shows the architecture of the BIMLIFE platform ecosystem where it is important to highlight the 1) owners of the platform, 2) suppliers which are the existing systems, 3) producers and 4) consumers. In this project a stronger emphasis has been put in the producer side and the interactions in the consumer side.

PROJECT PILOTING

The project has been piloted in the Hervanta Campus at the Tampere Technical University.

PORTFOLIO BECHMARKING TOOL

At a strategic level, the Portfolio Benchmarking is a decision support system for property managers of both real estate investments and corporate facilities. The introduction of benchmarking data enables a) a cross-analysis for anomaly detection that includes not only the time variable, but additionally design, usage and environmental variables; and b) the prioritization of development projects within defined strategic portfolios. To achieve this, the decision support system is flexible to changes due to variations of KPIs needs a long the life cycle of the real estate portfolio and the differences among organization's domain needs. Additionally, the user interface is interactive and dynamic to help managers identify potentials areas for further root cause problem analysis. The scope of the solution includes two common financial instruments utilized in the strategy level within the industry: OPEX (Figure 2) and CAPEX. In addition, this development sets the basis for further research in the existing correlations between the financial figures and other aspects such us property service consumption and user satisfaction. In this case study, the strategic goal is to reduce the Operations & Maintenance (O&M) costs for the one of the buildings in the portfolio.

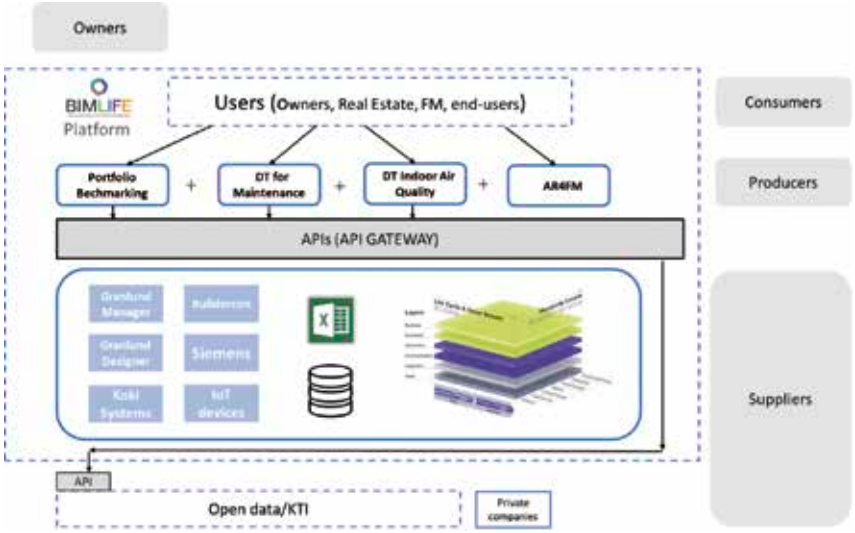

Figure 1: Platform Architecture BIMLIFE project

DIGITAL TWIN FOR BUILDING MAINTENANCE

The next step at managerial level is to utilize the digital twin for maintenance. The maintenance digital twin aims at improving the operational efficiency of the teams performing operations and maintenance work along with improving the efficiency of the technical systems. The tool is developed for the use of technical facility managers and operations personnel to have an integrated interface for accessing of information about the technical systems like heating, cooling, ventilation, water, gas, fire and safety. Those systems are represented digitally using building information models (BIM) modelled during the design stages and later integrated with the use of open standards (IFC file format), coupled with static and dynamic data. Static data can be for instance: information from the design stages, IFC product information, equipment manufacturers information, maintenance tasks, maintenance notes and maintenance his-

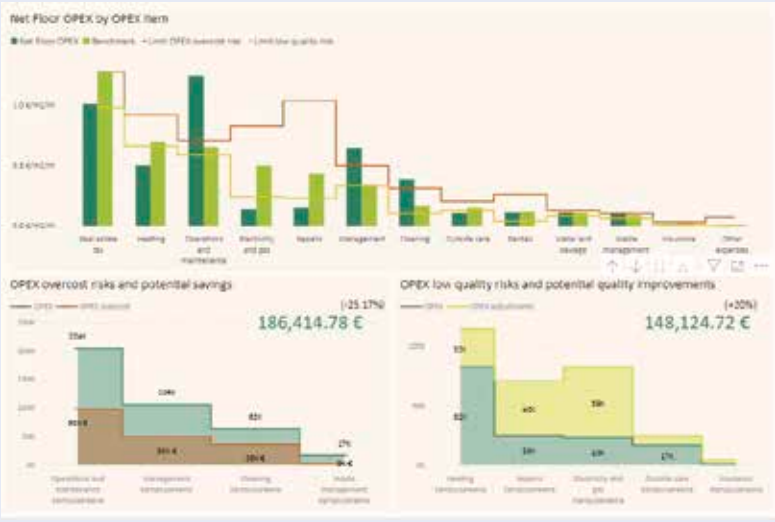

Figure 2: OPEX control of the main cost items and potential areas of improvement

Figure 3: Digital Twin for Maintenance

tory. Having all the maintenance data in single repository enables to better plan maintenance activities and find root causes to a maintenance issue. The Digital Twin for maintenance also visualizes the different air handling unit or cleaning zones (Figure 3). The services requests are also visible and categorized which enables better planning for the different teams. Additionally, dynamic data can include information retrieved from the building automation systems such as temperatures, pressures, air flows, etc., sensor information from IoT devices. With available data the building digital twin in the future can employ machine learning algorithms to predict system malfunctions utilizing automated fault detection and diagnosis methods.

DIGITAL TWIN FOR INDOOR AIR QUALITY

A second managerial tool is in using digital twin for improving the indoor conditions using real-time sensor data. The tool has the option that the building end-users can interact with the building by providing feedback about the conditions of the building at room, floor or building level. The feedback can be related to any aspect that impacts the end-user wellness and satisfaction such as indoor air quality, noise, light, odour, ambience, design, quality of the furniture, etc. Secondly, by collecting real-time data from the IoT devices or BAS systems the tool provides graphical information about the indoor air quality conditions such as temperature, CO2, humidity, lux levels, etc. All these measures, which has a strong impact to end-users wellbeing and productivity. A color-coded heat map quickly shows what rooms are within, below or above predetermined targets. In such a way, in the case it is an office building with no seats assigned the users can select the area where those indoor conditions are more suitable for their workday. Another feature of the tool is the monitoring the occupancy at building, floor and room levels. Such information helps to understand space usage and plan post-Covid measures for employees returning back to the office. The tool additionally provides historical information to represent the trends in different measures and one overall indoor condition score to monitor the quality of the building over time related to indoor conditions.

AUGMENTED REALITY FOR MAINTENANCE

The augmented reality (AR) tool is developed to support maintenance personnel in the field to make reactive and preventive maintenance routines for efficient (Figure 4). The tool main feature is to visualize in real setting the technical systems that are commonly not visible and provide different static and dynamic information related to that equipment. The tool also enables indoor navigation to guide maintenance personnel to plan the work and maintenance routes to increase the efficiency in the maintenance activities. The tool enables component related design information from the IFC file, dynamic information from the building automation systems and linkage to maintenance plans, actions and history for the technical systems. Such information enables to reduce time searching for information while it is in a single solution. The tool can be launched using common mobile devices such as tablets and smart phones.

Figure 4: Augmented reality (AR) for facility management to support personnel in the field of operations & maintenance

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WEBINAIR

Practical Safety Ventilation in Ultraclean Air Operating Rooms

PEDRO GANDRA, CONSIDERO TEKNIKKONSULT

THIS ARTICLE IS BASED ON A PARTIAL, SHORT VERSION OF MY THESIS FOR THE DEGREE OF LICENTIATE OF ENGINEERING, PRESENTED AT CHALMERS UNIVERSITY OF TECHNOLOGY.

When planning new ultraclean air operating rooms, often the firsts questions are which is the preferred room air distribution system and what system is the best to meet the requirements of microbiological air cleanliness. Today, in Sweden, the requirement is a target level of 5 CFU/m³ during the design phase, in order to ensure that the level of ≤10 CFU/m³ during infection prone surgery is maintained.

This study is based mainly on the analysis of published scientific reports and other documentation. The focus is to compare the main principles for room air distribution systems, mixing and displacement principle and to see whether the requirements of microbial air cleanliness can be fulfilled during ongoing surgery. Three different distribution systems available in Sweden have been compared.

The room air distribution systems studied are:

- *Mixing airflow/partly displacement*
- *Unidirectional airflow (UDF/UDAF)*
- *"Temperature controlled airflow (TcAF)"A specific Swedish room air distribution system.*

The result of the comparison shows that in operating rooms for infection prone surgery all three studied room air distribution systems could achieve the target level of 5 CFU/m³ when the air volume flows are above 2 m³/s provided that the total microbiological source strength does not exceed 10 CFU/s. The total microbiological source strength depends upon the number of people in the operating room, their chosen surgical clothing system, and their activity level.

SUMMARY

For decades, the displacement air systems based on the UDAF concept have been considered superior to dilution mixing air systems for ultra- clean air operating rooms. However, recently it has been shown, see CHOPIN Project, that during activity about the same grade of air cleanliness in the critical zone can be achieved by dilution mixing (non-unidirectional) airflow principles when used total air volume flow is in the same level as used in today's conventional sized UDF systems (low velocity systems <0.3 m/s with airflow ≤3m³/s). For UDF-systems with large filter areas and high airflows (≥4 m³/s) other parameters might also be of importance.

Independently of the preferred system, physical obstacles in the air stream, movements of people, and equipment generate local disturbances can increase the concentration of contaminants. The increased concentration could be a potential source of wound infection. Limitations in assessment methods, both air sampling and CFD-simulations, have not been able to quantify the effect of these disorders. The existence of disturbances has long been known from smoke visualization studies of air movements.

The discussed room air distribution systems have their advantages and disadvantages as it has been shown in this thesis. The reason is that surgical procedures are challenging, complex, and the airflow tends to become unstable in the critical zone (surgical site). Actually, more or less non-unidirectional airflows occur frequently in the critical zone of the operating room, independently of the chosen room air distribution system.

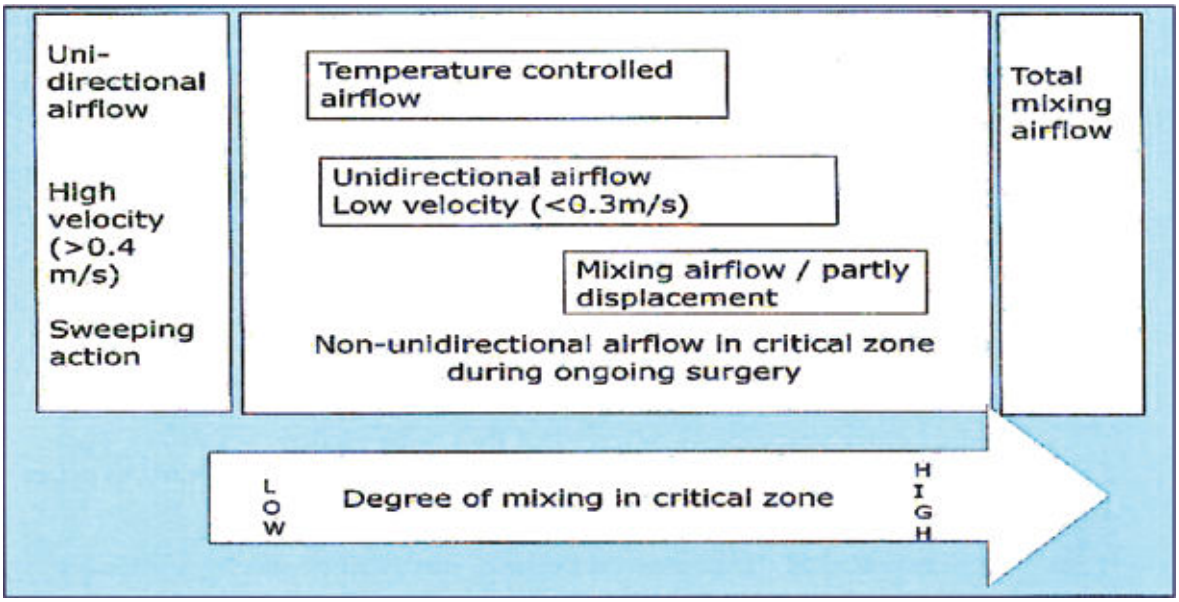

Figure 1.
Principles of room air distribution systems in ultraclean air operating rooms.

To sum up, the principles of discussed room air distribution systems are shown in the Figure 1.

This figure is based on a drawing published by Fläkt Review No 71, 1987 and shows the degree of mixing that varies within the three systems; temperature-controlled airflow, unidirectional airflow with low velocities, and mixing airflow/partly displacement. This depends on, e.g., disturbances of obstacles in the airflow, presence of heat sources, and the activity level of the staff.

There are little differences in CFU levels in the critical zone during ongoing surgery among the different room air distribution principles, when the air volume flows are in the same range. Other parameters, such as clothing system, number of people and their activity level have a greater impact.

INTRODUCTION

In this study, as a part of required content, there is chapter reviewing earlier studies and literature, which relatively extensive in this case. Although the majority of the references have been cited and reviewed in studies like this, one of my findings is relatively unknown and especially interesting. Scientific or, at least, ambitious comparisons of different room air distribution systems for operating room are tricky to make for several reasons and are therefore rare. However, as early as in 1967, one of this field´s prominent researchers, Owen M. Lidwell et. al, managed to build two twin rooms equipped with three different ventilation solutions in order to measure and compare them. The three air distribution solutions were:

1. *Downward displacement, 6 diffusers evenly placed in the roof*
2. *Moderate velocity turbulence, 3 grilles from one side of the ceiling*
3. *Low velocity turbulence, from the other side of the ceiling*

The results were surprising: 1. No significant differences could be detected between the three distribution systems regarding the contaminant levels. 2. Varying the supply air volume flow, was "by far the most important" for controlling the level of airborne contamination. (Lidwell et.al 1967)

At this time, research on this field was increasingly driven by the new cleanroom industry with both much higher demand of cleanliness and essentially different conditions for work environment and work process priorities. That explains why the principle of downward displacement and what was incorrectly called Laminar Air Flow (LAF) was preferred, and the common and down-to-earth principle of contaminant dilution was more less abandoned and even condemned for use in ultra clean air operating rooms.

Every ventilation solution has its disadvantages, LAF/UDAF roof ventilation in surgery can, for example, generate work environmental issues but even patient hypothermia. At least in Sweden this has led to gradual, uncontrolled, reduction of the inlet airflow velocity without reported increased frequency in post-operative wound infections. That motivated Johan Nordenadler to travel to different OR´s in Sweden and measure the contaminant level other parameters during ongoing surgery and 2010 in his PhD-thesis he could describe, among other conclusions, that

OR´s ventilated by low velocity LAF/UDAF systems were cleaning up the room air and meeting the requirements for infection prone surgery but by dilution and not by displacement of the contaminants! (Nordenadler, 2010)

The finding led to the design of new high air volume flow dilution solutions, that since at least 2016 are used daily at the New Karolinska Hospital in Stockholm and in an increasing number of OR´s in several places in Sweden.

My research contribution followed this trail and my thesis was divided in two parts:

1. Calculation and analysis of data from published measurements by other authors. This part will not be further described in this article other than in the final conclusions.
2. Description with comments of a mock-up based investigation in which I participated called "The CHOPIN study". This investigation aimed to comparing three room air ventilation solutions available on the Swedish market. To my knowledge, the CHOPIN study is the only published study that compares, at that time, new high volume airflow dilution system with a conventional Austrian LAF/UDF in use in a Swedish OR and a Swedish room air ventilation system combining both the dilution and the displacement principles in its design.

Although the CHOPIN-study was neither designed nor led by scientific researchers, it was indeed a quite ambitious project. It´s aim was simply to, in a couple of months, help the Stockholm Council to choose the "best ventilation solution" for near one hundred OR´s to be build!

The same number of persons wearing the same surgical clothing system, (almost the same individuals actually), carried out three simulated operations with the same grade of activity, in three different rooms ventilated with one of the three solutions in study but all three with the same levels of high air volume flow, here defined as ≥ 1,5 m^3/h (1500 l/s), in identical conditions and same source strength. Air samples were identically taken and analyzed, and showed the requirements of ≤ 10 CFU/m^3 (Whyte et.al. 1983) were met with no significant difference in achieved cleanliness. Furthermore, we could see that the higher the air volume flow, the lower the concentration of contaminants i.e. identical observations than those made by Lidwell and co-workers almost fifty years earlier! (Tell & Cederlund, 2015).

This indicates that, contrary to what has been believed for decades, the dilution principle of ventilation can be used in ultraclean air operating rooms for the most air quality demanding procedures like prosthetic surgery. This solution offers pros and cons compared to others but meets the requirements of microbiological air quality and should be considered in both remodeling and newbuilding OR projects.

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WEBINAIR

The Proposed Changes to Annex 1 draft February 2020: Review of impacts on the requirements for Cleaning and Disinfection

MATT COKELY, SENIOR GLOBAL TECHNICAL CONSULTANT MANAGER, ECOLAB LIFE SCIENCES.

RELEVANCE OF ANNEX 1 BEYOND THE EU

As stated in the EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use – Introduction: *"The pharmaceutical industry of the European Union maintains high standards of Quality Management in the development, manufacture and control of medicinal products...Manufacturing authorisations are required by all pharmaceutical manufacturers in the European Union whether the products are sold within or outside of the Union."*

Pharmaceutical manufacturers within the EU, or manufacturers supplying products to the EU are therefore required to conform to EU GMPs.

EudraLex Vol.4 Annex 1 is common to the member states of the EU, but also the participating authorities of (PIC/S). As of June 2018, 48 countries have acceded as state members of PIC/S.

Updates or revisions therefore have significant and wide-reaching consequences.

HOW THE DRAFT ANNEX EVOLVED

On December 20th, 2017 the European Commission produced a draft of a revised Annex 1.

The draft revision had attempted to reflect many of the advances in sterile manufacturing technology that had occurred in the preceding 10 years since the Annex had been updated, particularly with regards to RABS, isolators and single use technologies. There was an acceptance and alignment with ICH Q9 (Quality Risk Management - QRM) and ICH Q10 (Pharmaceutical Quality System - PQS) and the new draft implicitly encouraged using the principles of QRM, with numerous references to QRM made throughout the document.

THE IMPACT OF THE ANNEX 1 UPDATE ON CLEANING AND DISINFECTION

Of the many changes in the draft Annex, this article will look particularly at the impact the draft had on the requirements for cleaning and disinfection, and whether the latest version (Annex 1 v.12 February 2020) has changed the guidance significantly in this respect.

It would be considered prudent for sterile manufacturers to compare the proposed changes in the draft to the procedures and practices at their own sites to determine if adjustments to site CCS will be needed to remain compliant.

CLEANING VERSUS DISINFECTION AND THE FOCUS ON DISINFECTANT RESIDUES

4.36 The disinfection of cleanrooms is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme. For disinfection to be effective, prior cleaning to remove surface contamination should be performed... Cleaning programs should effectively remove disinfectant residues.

It has been accepted for some time that the terms 'cleaning' and 'disinfection' should be considered as two distinct terms, and it can often be helpful to consider them as two distinctly different processes within cleanroom environments.

The Annex 1 section previously called 'Sanitation' had already been renamed 'Disinfection' and been expanded in the Annex draft issued in 2017, indicating that this was an area of increased focus.

The separation of these two processes is now clearly stated.

The process of cleaning is to remove physical dirt, soiling or disinfectant residues from a surface which could otherwise present a risk of physical, chemical or particulate contamination to the cleanroom area or products being manufactured within it. The presence of dirt, soil or residues on a surface could also present a physical barrier impeding the contact of any disinfectants that may be applied to a surface or to any microorganisms present, potentially impacting on the disinfectant efficacy.

By contrast, disinfection refers to the application of a chemical with a known antimicrobial activity or effect, for a specific contact time to reduce any bioburden present to an acceptable level.

The presence of visible residues has often been seen in the past as an indication that a cleaning and disinfection process is not fully in-control, as the activity itself is leaving a 'contaminant' on the surface. The Annex draft now goes further, raising the concern that the residues themselves can have some hidden effects.

ROTATION AND USE OF DISINFECTION AGENTS

4.36 The disinfection of cleanrooms is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme... More than one type of disinfecting agent should be employed to ensure that where they have different modes of action and their combined usage is effective against all bacteria and fungi. Disinfection should include the periodic use of a sporicidal agent. Monitoring should be undertaken regularly in order to assess the effectiveness of the disinfection program and to detect changes in types of microbial flora (e.g. organisms resistant to the disinfection regime currently in use).

4.38 Disinfectants and detergents used in Grade A zone and Grade B areas should be sterile prior to use (disinfectants used in Grade C and D may also be required to be sterile). Where the disinfectants and detergents are made up by the sterile product manufacturer, they should be monitored for microbial contamination. Dilutions should be kept in previously cleaned containers and should only be stored for defined periods. If the disinfectants and detergents are supplied "ready-made" then results from certificates of analysis or conformance can be accepted subject to successful completion of the appropriate vendor qualification.

Disinfectants are usually divided into broad-spectrum disinfectants or sporicides (usually more aggressive, oxidising chemistries capable of penetrating and killing bacterial endospores).

Whilst the requirement to rotate a broad-spectrum disinfectant with a sporicide 'in accordance with a written programme' (i.e. not using sporicides only reactively) remains, the Annex draft v.12 issued in February 2020 has changed slightly. It now appears to imply the use of two different (possibly broad spectrum) disinfectants with different modes of action in addition to the periodic use of a sporicidal agent, however this needs clarification.

Whilst this practice is sometimes seen, there may be little value in rotating two broad spectrum disinfectants that are exerting an effect on a similar spectrum of organisms. Having two broad spectrum disinfectants that need to be rotated can also increase complexity in terms of

SOPs, and procedures, and increases the burden of validation and control of materials on site.

The Annex draft v.12, perhaps disappointingly, continues to reference organisms 'resistant' to the disinfection regime. The concept of acquired rather than innate resistance occurring at a site has been a contentious point for years, with little evidence of this phenomena forthcoming.

The requirement for disinfectants and detergents used in Grade A zone and Grade B areas to be sterile prior to use (termed Grades A and B areas in Annex 1 2008 and in the 2017 draft) and for solutions to be monitored for microbial contamination, remains in place.

Interestingly, Annex 1 daft v.12 highlights that disinfectants used in Grade C and D may also be required to be sterile. This is again an indication that QRM principles must be applied. The use of sterile products in lower grade areas should not be ruled out if a contaminant present in a disinfectant could detrimentally impact on a production area and/or the products being manufactured within that area.

IN HOUSE PREPARATION OF DISINFECTANT FROM CONCENTRATES

4.38 ... Where the disinfectants and detergents are made up by the sterile product manufacturer, they should be monitored for microbial contamination. Dilutions should be kept in previously cleaned containers and should only be stored for defined periods. If the disinfectants and detergents are supplied "ready-made" then results from certificates of analysis or conformance can be accepted subject to successful completion of the appropriate vendor qualification.

Concentrate versions of disinfectants have long been used and are considered by many to be a practical and cost-effective means of producing large volumes of disinfectant for use. However, the Annex 1 draft issued in 2017 made it clear that there were increased considerations that impact on disinfectants being prepared and filtered into sterile areas.

VALIDATION OF DISINFECTANT EFFICACY AND IN USE EXPIRY PERIODS

4.37 The disinfection process should be validated. Validation studies should demonstrate the suitability and effectiveness of disinfectants in the specific manner in which they are used and should support the in-use expiry periods of prepared solutions.

The Annex is clear that the effectiveness (efficacy) of disinfectants should be validated, and that the validation should be representative of the specific way they are used. This reinforces that end users of disinfectants should carefully consider the contact times, surface materials and methodology used to validate disinfectants.

It also requires that the 'in-use expiry' or hold time of a disinfectant solution is demonstrated through validation. This may represent a further increased burden on users preparing detergent or disinfectant products from concentrate rather than using "ready-made" or ready-to-use products. Here the Annex draft concedes that certificates of analysis or conformance from approved vendors may be sufficient, negating the need to validate.

CONCLUSION:

The revised version 12 of the Annex 1 draft issued February 2020 retains much of the 'direction of travel' of the 2017 draft with regards the guidance for cleaning and disinfection as an integral part of a Contamination Control Strategy (CCS).

The final version of the Annex will invariably still contain some text that may be open to interpretation and will of course never be able to be a perfect guide for all readers. Further targeted consultation with a select number of relevant industry groups and organisations is complete, and suggest clarifications and amendments submitted to the to the Annex1 Inspectors Working Group (IWG) .

It is hoped that this process will now result in a final version of Annex 1 in Q3 2021.

New developments in cleanroom design

WEBINAIR

(ISO 14644-4 revision)

IR. FRANS SAURWALT, KROPMAN CONTAMINATION CONTROL

Frans Saurwalt is the chairman of ICCCS, convener of ISO TC209 WG4, Expert in WG3, Secretary of CEN TC156 WG18 Hospital ventilation, President of EHEDG-NL, chair of VCCN project group 4, member of the VCCN events and symposia committee, VCCN distinguished and honorary member.

The current version of ISO 14644-4 dates back to 2001. Within ISO Technical Committee (TC) 209 working group (WG) 4 has been assigned the task to review and update this part of the 14644 and 14698 set of standards. With the Committee Draft internal ISO balloting of 14644-4 being passed with comments twice, an overview of the relevant developments and addressed topics of modern cleanroom design will be given and the highlights discussed. This presentation will not present the current content of the revised standard but will give information on the new developments that are considered and discussed. It will also link to the recent ISO 14644-16 on Energy Management as well as parallels to work within CEN TC156 WG18.

INTRODUCTION

During the successful development and introduction of ISO-14644-1 on classification of cleanrooms in 1999 the ISO Technical Committee 209 (TC209) was in parallel developing work on other parts of the series of standards. This included the work on and completion (year) of :

- ISO 14644-2 (2000) Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- ISO-14644-3 (2005) Test methods
- ISO-14644-4 (2001) Design, Construction and Start-Up of cleanrooms.
- ISO-14644-5 (2004) Operations
- SO-14644-6 (2007) Vocabulary
- ISO-14644-7 (2004) Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
- ISO 14698-1 (2003) Biocontamination control: Part 1 General Principles and methods
- ISO 14698-2 (2003) Biocontamination control: Part 2 Evaluation and interpretation of biocontamination data

Parts 1, 2, and 3 in ISO-14644 have recently been updated. Part 6 has been withdrawn. Other parts of the ISO 14644-series have been added to the score.

Together with the contents of the ISO 14698 standards, they address additional cleanliness attributes as well as being considered both in air as well as on surfaces.

As the scope of contamination control and cleanrooms have developed over the years, in 2015 the New Work Item Proposal for a revision of the ISO-14644-4 Design, Construction and Start-up, was accepted and the work in the associated working group 4 (WG4) started.

WORKING GROUP APPROACH

The working group set out to review the current 2001 version in order to align it with standards published or revised after 2001: ISO 14644-part 1, 2, 3, 7, 8, 9, 10, 12, 14, 15, 16, 17 and FDIS part 11.

In the initial phase of the revision work the following questions were addressed by the experts:

- What of the current version is outdated and should be deleted and/or replaced?
- What of the current content should remain and possibly be edited to be more clear?
- What new established knowledge needs to be added?
- What document structure would suit the new version best?

During this initial stage the document was agreed to be re-arranged all over, following the logical steps of a project process. This included aligning the informative sections as guidance to the consequent normative chapters. This also allowed to split the exiting checklist, that was deemed very valuable, likewise over the informative sections. The chapters and distinguished process steps are:

- Requirements; sectioned in: general, cleanroom requirements, other requirements and documentation
- Design; sectioned in: general, conceptual design, basic design, detail design and change management
- Construction; sectioned in: general, construction plan, construction verification and documentation
- Start-up; sectioned in general, commissioning, training, handover and documentation.

IMPORTANT CHANGES

A couple of important changes can be identified:

Cleanliness attributes in air and on surfaces

Other cleanliness attributes to consider than particles in air as per part 1 include: viables, chemicals and nano-scale particles. And all cleanliness attributes can be considered in the air as well as on surfaces.

Although not completely absent the latest additions to the series of 14644 standards include chemicals, nanoscale and addresses cleanliness of surfaces according to the developments over the years past 2001.

This means that references to other attributes are made for the monitoring of application specific levels.

Sequenced buildup of documentation

The sequence of buildup of documentation from requirements to hand over has been clarified as a process of development and evaluation/verification throughout the process. The part on documentation contained in the 2001 version has been worked over and distributed over the various applicable phases. This enables the user to align and develop the documentation while accordingly including approved design and construction changes.

Dedicated chapter on construction

Introduction of the important aspects of construction in a construction plan, a quality plans as well as the clean build protocol emphasis the aspects that are cleanroom specific to a construction process.

Dedicated chapter on Start-up

The start-up phase covers all phases of the installation after mechanical completion till hand over to be operated and maintained.

As this is a significant aspect of a cleanroom project and requires adequate organization, execution and documentation this chapter is a closing piece of the previous stages.

Guidance on design

Although all informative annexes have been extensively dealt with the following items stand out to be specially addressed.

In the annex as guidance on design there is great emphasis on the importance of engineering controls to be able to establish control over the operation and to demonstrate control during operation.

In the revision many of the figures have been deleted. Over the years they have been misinterpreted and misused. Only the essential conceptual figures remain: on the box in box structure and conceptual logistics, on the three principles of segregation: physical barrier, physical barrier with overflow and aerodynamic segregation and on Unidirectional Airflow (UDAF) and Non-Unidirectional Airflow.

Calculations and CFD as design tools

A very important change is the approach towards airflow design. Over many years the method of design has been stuck with ranges of air changes per hour as basis for the airflow design of Non-UDAF cleanrooms. These air changes have shown a tremendous range and quite an over kill in many occasions. Although understandable when no other insight and tools are available this way of designing is not ade-

quate anymore. Current design work addresses the various 'sources' and loads of contaminants to be designed for and evaluates the required air volume by equations. Already for some years values to assess the source loads of personnel and their typical cleanroom garments are becoming more and more available. Also, the recent work on ISO-14644-11 'Assessment of suitability of equipment and materials for cleanrooms' help to provide better design development and evaluation inputs. In these equations complex factors need to be included that value how effective the ventilation and contaminant removal efficiency at the relevant locations are. As assessments on existing facilities, based upon the approach of ISO 14644-16 'Energy efficiency in cleanrooms and separative devices', can provide better insight in the overall 'source strength' and practical ventilation efficiency values, this promises to be a very useful source of design information in the near future.

On the other hand, have the developments of computational fluid dynamics (CFD) simulations significantly improved the usefulness. These simulations can be very well exploited in the design phase for both UDAF as NON-UDAF configurations. Of course the chosen turbulence-model, input- and boundary conditions as well as many factors like the software settings, cell types e.g. greatly influence the predicted flows and particle concentrations. Special care needs to be taken for the different types of outlets that Non-UDAF cleanrooms may be based on.

Construction process

The guidance on construction places emphasis on the proper construction procedures to safeguard the best construction during the various stages of cleanliness until ready to start-up.

This includes material and site management, clean build protocol, and addresses adequate instruction to personnel as well as the applicable verifications to be carried out during construction.

Start-Up

The guidance on start-up helps to understand and organize the required series of activities planned, organized and executed in a logical order to take the installation from the fully built and constructed or assembled state into operation. Identifying commissioning activities as well as verification activities and tests this section supports the user of the document to understand and implement the required steps for a project.

Status and planning of the revised standard

The current status of the draft is in process of being delivered to the ISO organization for editorial processing and translation to be issued as a DIS (Draft International Standard) for a ballot. The outcome of the Ballot will be either: Approved or Disapproved. Additional with the ballot outcome there can be comments accompanying the Disapproved votes, providing the aspect of disapproval as well as comments alongside Approval votes. When the DIS is accepted, only the comments need to be addressed and the DIS will be developed in a FDIS (Final Draft International Standard) that either can be finally Approved or Disapproved.

The current document that is developed into the DIS, has passed a Committee Draft balloting and commenting phase twice, so in total 750 comments of which 70% editorial and 30% technical, have been discussed and processed. The working group was very happy to receive so many comments during these initial stages, while there are no significant objections to the new structure and contents document. All received comments and the discussion on those, helped to improve the document.

Depending on the processing of the DIS and the outcome of the ballot, a final version can be expected no earlier than end of 2022.

The 51st R³Nordic Symposium & exhibition has been postponed to

May 9-11, 2022 at Naantali Spa, Finland

The 51st R³ Nordic Symposium takes place on 10th-11th of May 2022

The venue of the event is Naantali Spa in the sunshine town Naantali on the south-west coast of Finland. The President of the Republic of Finland stays in the presidential summer residence Kultaranta during the summer and for that reason Naantali is considered the holiday capital of Finland.

We are allowed to use photos from Naantali Spa's image gallery. (www.naantalispa.fi)

THE 51ST SYMPOSIUM & EXHIBITION

A draft of the renewed symposium programme will be published in next issue of RenhetsTeknik. Abstracts available at publishing time are included in either RT 4:21 or RT 1:22.

In case You are working with cleanroom technology and contamination control in hospitals and pharmaceutical, food and biotech industries, we urge You to send in an abstract to the Chairperson Leila Kakko at leila.kakko@tuni.fi.

The deadline for abstract submission is 15th of October 2021. The members in the Programme Committee will approve abstracts suiting the programme. There will also be invited speakers in the programme, which will be avaiable on **www.r3nordic.org/symposium-2022** from the end om January 2022 onwards.

SPECIAL OFFER "GO 3 PAY FOR 2"

Our early-bird special offer "Go 3 Pay for 2" for industrial delegates is valid before 1st of April 2022. Please, note that prices will raise from that date onwards. The participant fee for persons coming from hospitals, educational institutions etc. is also available and those prices can be found in the column under "Public & Municipal"in the registration form, which you will find in RT 4:21 and on the homepage. The form is avaiable from mid-December 2021 onwards.

Pågående standardiserings-arbeten

RAPPORT BERIT REINMÜLLER

MEDICAL DEVICE SYMBOL

The international standard for the application of medical device symbols on labels, ISO 15223-1, has been amended and the 4th Edition will replace ISO 15223-1:2016. This amendment is multifaceted and will introduce many new changes to the symbol requirements that medical device organizations around the world will be expected to follow.

SIS TK333 OPERATIONSTEXTILER

EN 13795:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits kommer att översättas till svenska och en arbetsgrupp är tillsatt. Arbetet med en vägledning på svenska till 13795-2 är i det närmaste färdigt.

En översyn av termer som är gemensamma i t ex SS-EN 13795, vägledningen till SS-EN 13795 och SIS TS-39 har påbörjats.

ISO/TC 209 WG11

WG 11 Cleanroom and associated controlled environments – Part 18: Assessment of suitability of consumables had several virtual meetings this year and the latest meeting was in August. Comments to the earlier presented text were discussed. The document gives guidance to the requirements of consumables, e.g., cleanroom garments both disposables and reusables. The garments are presently discussed in the ISO 14644-5 Operations. When 14644-5 is going to be revised the question where garments will probably be discussed again. The aim of this working group is to present a CD in October.

SIS TK 527 RENHET I OP-RUM

En revidering av SIS TS 39 har gjorts och kommer att skickas ut på remiss under hösten.

Minnesord Göran Olsson

Under sommaren kom beskedet om att Göran Olsson gått bort, endast 75 år gammal.

Göran kom med i föreningens aktiva arbete 1993 och redan året efter valdes han till ordförande i Nordiska R^3-föreningen efter professor Bengt Ljungqvist. Han höll stadigt i ordförandeklubban fram till år 2000 och under sina sex år som ordförande drev han bl a igenom utgivningen av den tidning du håller i handen, RenhetsTeknik. Det var år 1995 som Leif Månsson och undertecknad fick i uppdrag att producera en populärvetenskaplig tidskrift med fokus på R3-teknik, för medlemmar och branschen. Under sin tid som ordförande var han också initiativtagare till IKL (Internationella kontakter Läkemedel).

Efter militär utbildning inledde Göran sin civila karriär. Det var under hans tid som VD för företaget Mätforum som han kom i kontakt med R^3 Nordic. Efter alla år som säljare, produkchef och VD, drev han eget företag och under mer än två decennier var han ordförande i styrelsen för Enköpings Sparbank.

Göran var intresserad av idrott, dels aktivt, dels som funktionär, domare och styrelseordförande. Det var också genom handboll på 80-talet som Göran och undertecknad träffades och som ledde fram till många kontakter och samarbeten under åren.

I mitten av 2000-talet flyttade Göran och Birgitta till hennes föräldrars gård norr om Uppsala. Göran blev skogsbonde och var så fram tills sin död i juni.

Våra tankar går till Birgitta samt barnen Fredrik och Kristin.

Anders Jarl

PDA continues with virtual conferences. From the PDA 75 Annual Meeting, information about the meeting and the awards winners can be found in the PDA Letter archives.

Five new technical reports and guidance documents have been published during 2021, one is "Points to consider in remote and hybrid GMP/GDP inspections", and another is PDA Technical Report 83 (TR 83), Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response. This TR describes the proven, successful principles used and measures that can be taken to mitigate the risk of contamination by viruses. It also provides guidance in effective preparation and response should such an event occur in manufacturing processes using in vitro mammalian or other eukaryotic cell cultures to produce biopharmaceutical products.

PDA Journal of Pharmaceutical Science and Technology July/August 2021; Volume 75, Issue 4 contains among other articles a commentary: *Risk-Based Selection of Environmental Classifications for Biopharmaceutical Operations* by Nick Bevan, Tim Corbidge, David Estape, Lars Hovmand Lyster and Jorgen Magnus

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After the virtual PHSS Sterile Product Manufacture Conference four new issues of PHSS "Clarity of GMP Guidance Notes" were published.

No.2 -Assuring Sterility Of Indirect Product Contact Parts

Revised issue to cover: New and Existing Filling lines. Container Closure Vibrating. Feeder Bowls and Hoppers.

This guidance article is prepared by industry subject matter experts and sterile product manufacturing specialists to facilitate understanding and interpretation of aspects of GMP Regulatory (Health Authority) requirements for aseptic manufacturing of sterile medicinal products.

No.3 Qualification Of No-Touch-Transfer: NTT
The focus of this PHSS guidance is:

- NTT Qualification part A: Container manufacture qualification of containers and packaging to be suitable for NTT process application including sterility assurance through the supply chain.
- NTT Qualification part B: Qualification of contamination control measures in transfer of RTU containers via an NTT process applied to a filling line Barrier system defined within a Contamination Control Strategy (CCS).

Cleanroom Airflow Definitions

Cleanroom Airflow Definitions: Aligning Uni-Directional Airflow (UDAF), Localised Uni Directional airflow (L-UDAF) and Grade A Air Supply

Uni-directional airflow (UDAF) where airflow vectors move in the same direction from a HEPA filtered source is one of the main environmental airborne contamination control attributes in pharmaceutical manufacturing (together with pressure differentials between clean areas). UDAF in Pharmaceutical applications is sometimes referred to as LAF (Laminar airflow) where scientifically airflow vectors would be straight and parallel.

Pharmaceutical Isolator Leak Integrity Classes

Background to development of PHSS Guidance on Barrier Isolator technology Leak integrity classes and leak rates/acceptance criteria for qualification and routine monitoring. Covered in the document:

- Implementing Pharmaceutical Isolator integrity testing
- Qualification and routine monitoring of Pharmaceutical Isolator barrier leak integrity
- PHSS Classification classes for Pharmaceutical Isolators including larger complex Aseptic processing Filling Isolators
- Test pressures
- Test Duration
- Positive operating pressure pharmaceutical isolators
- Negative pressure operation isolators
- Integrated process machine integrity
- Qualification and routine monitoring leak integrity testing
- Leak integrity test automation and records

The first document earlier published in the series is - *Assurance of Sterility for container closure in-direct product contact surfaces in Aseptic process filing*

These comprehensive guidance documents are free of charge to PHSS Members, and there is a small charge for non-members.

Latest issue of European Journal of Parenteral & Pharmaceutical Sciences, Vol 26, issue 2 presents one peer-reviewed paper, three opinion papers, editorial comments and PHSS news, and the monthly update by Malcolm Holmes (EJPPS Online). The paper on fungi isolated from pharmaceutical cleanrooms is very interesting.

Peer Review Papers

- Comparative Evaluation of Amorphous Polymers in Solubility and Bioavailability Enhancement of Famotidine Through Solid Dispersion by Ankit Mishra, Priyanka Chaturvedi, Pranali Mishra, MS Sudheesh

Opinion Papers

- Study of fungi isolated from pharmaceutical cleanrooms: Types and origins by Tim Sandle
- The future of medicine - cell and gene therapy by Adam Bird
- A practical methodology to assess VHP cycle effectiveness during routine qualification by Ian Aled Jones*, Will Edwards, Madeline George-Olapade, Leanne Jones

Regulatory Update by Malcolm Holmes. Editorial.

- A Permanent Remote World?
- PHSS News

Styrelsen för R³ Nordic 2021

Förutom nye ledamoten Jukka Vasara, som presenterades på sid 3, ingår följande fyra personer i styrelsen för R³ Nordic.

Lene Blicher Olesen, ordförande

Jeg har været formand i et år, hvilket jeg er meget taknemmelig for. Til daglig er jeg ansat hos AlfaNordic A/S. Jeg er egentlig uddannet kemiingeniør, men har gennem mere end 20 år, altid arbejdet med noget der har med rene rum, mikrobiologi og aseptik at gøre. Arbejdet indenfor renrumsområdet, har langt overvejende været i forbindelse med pharmaproduktion, men jeg har også været involveret en smule i renrumproblematikker på operationsstuer. De fagfelter jeg har beskæftiget mig rigtig meget med, er områder som renrums klassificering, airflow pattern studies, recoverytesting, HEPA-filtertest, samt discipliner indenfor aseptic processing, isolator teknologi & H2O2 dekontaminering, environmental monitoring, mikrobiologiske testmetoder og identifkation af mikroorganismer.

Jeg har de seneste 15 år været aktivt medlem i den danske renrumsgruppe i Dansk Standard, de sidste 10 år som formand. Her arbejder vi internationalt med på standarderne indenfor renrumsområdet, og personligt har jeg selv været med på arbejdet indenfor ISO 14644-1, -2 & -3 samt EN17141. Desuden har jeg arbejdet en del sammen med vores kollegaer i PHSS, dels som en del af review board, dels som nyt medlem i PHSS fokus gruppe på Environmental monitoring. Fritiden bruger jeg gerne sammen med mine børn, familien, venner og gerne i naturen sammen med vores hund. Desuden er jeg en passioneret fritidsmusiker, der bruger et par aftener om ugen på at spille saxofon og klarinet sammen med andre glade musikere.
Jeg kan fanges på: leneblicherolesen@gmail.com, LBI@alfanordic.com eller +45 22 23 92 82.

Lennart Hultberg, skattmästare

Jag har arbetat inom renhetsområdet i mer än 30 år, huvudsakligen inom läkemedelsbranschen. Där har jag själv arbetat i, designat och byggt renrum i ISO klass 5-8.
Sedan 2017 driver jag en egen konsult och utbildningsfirman vid namn Processhygien och Kontrollerade miljöer i Norden AB. Jag utbildar inom området renhet och kvalitet för Teknisk högskola, Yrkeshögskola samt håller grundkurser och sjukhusdagar för Nordiska R3 föreningen.

Jag är gift med Janet och vi har två barn Julia och Adam samt hunden Yessie och våra katter Nike och Puma. Jag har varit trogen föreningen sedan 1988 och även varit dess ordförande i två omgångar. 2019 blev jag hedersmedlem i vår förening. Ni kan nå mig på: Lennart@processhygien.com, www.processhygien.com telefon +46 760 399500

Geir Valen Pattersen , ledamot

Etter noen år i det militære, tok jeg radiografutdanningen i Oslo og arbeidet deretter som radiograf i Kristiansand i 5 år. Deretter tok jeg en videreutdanning i stråleterapi og arbeidet som stråleterapeut ved Radiumhospitalet og i Kristiansand. Siden arbeidet jeg som høgskolelærer for radiografer og stråleterapeuter og studerte fysikk ved Universitetet i Oslo.
I 2010 startet jeg som syklotronoperatør ved Norsk medisinsk syklotronsenter as (NMS), ved siden av studiene. Dette var primært nattarbeid. Deretter arbeidet jeg ett år på nukleærmedisinsk avdeling, til jeg begynte hos NMS på fulltid som produksjonsingeniør i 2012. Fra 1 september går jeg over i en ny stilling som hms-leder. Jeg har dock fortsatt ansvar for all steril opplæring for arbeid inne på renrom og i tillegg hjelper jeg av og til på mobil PET med å skanne pasienter i samarbeide med Alliance. I tillegg til min jobb i produksjonen og arbeid med renrom, er jeg også HMS ansvarlig. Dette innebærer blant annet oppfølging av alle HMS relaterte saker som avvik, opplæring med mer.
Jeg er også Sikkerhetsrådgiver og har ansvaret for all transport av farlig gods (ADR transport), noe som innebærer transport av radioaktivt materiale.
Fra 2018 er jeg valgt som leder for den lokale R³ gruppen i Norge (LAU Norge).

Alan Friis , ledamot

Jeg har været med i styrelsen i seks år og har været redaktør for renhetsTeknik sedan 2020.
Jeg arbejder som specialist i hygiejnisk design hos FORCE Technology, hvilket indbefatter at være leder af et EHEDG og DANAK akkrediteret testlaboratorium. Jeg har i forskellige sammenhænge beskæftiget mig med hygiejnisk design af fødevareprocesser i mere end 25 år. I den periode har jeg dels arbejdet på Danmarks Tekniske Universitet (DTU), været selvstændig og er nu ansat på FORCE Technology.
Jeg har i flere omgange været med i aktiviteterne både R³ Nordic og European Hygienic Engineering and Design Group (EHEDG). På DTU deltog jeg i en række forsknings- og udviklingsprojekter med industrideltagelse, både nationale, nordiske og EU-projekter. Mens jeg var selvstændig havde jeg fornøjelsen af, at lede flere industridrevne projekter om udnyttelse hygiejnisk design til at forbedre fødevaresikkerhed generelt. Jeg har desuden undervist i hygiejnisk design på DTU og som efteruddannelse for industrien og er i dag EHEDG Authorised Trainer.
Jeg deltager i standardiseringsarbejde omkring harmoniserede EU-standarder for fødevaremaskiner via Dansk Standards komite S-246. Desuden sidder jeg i forskellige arbejdsgrupper i EHEDG blandt andet Testing and Certification og Training and Education og jeg er medforfatter til en guideline om Hygienic Systems Integration og sidder yderligere med i revision af guidelines om testmetoder og åbneprocessystemer.

WITH KIND PERMISSION FROM PHSS

Some observations on protective efficacy of surgical clothing systems with additional clothing components concerning airborne bacteria-carrying particles measured during ongoing surgery

BENGT LJUNGQVIST AND BERIT REINMÜLLER · BUILDING SERVICES ENGINEERING, CHALMERS, GÖTEBORG, SWEDEN

The main source of airborne bacteria-carrying particles is the staff and the patient. In order to reduce airborne bacteria-carrying particles from the staff, it is important that the surgical team wears a functional clothing system. This paper compares results from measurement studies of the protective efficacy, i.e., source strength, of a surgical clothing system with different additional clothing components. The studies were performed during ongoing surgery. The results show that the use of disposable hood or textile hood and the use of knee-length textile boots have considerable influence on the source strength, i.e., microbial air cleanliness in the operating room.

INTRODUCTION

The number of airborne bacteria-carrying particles, colony-forming units (CFUs), in the operating room is considered as an indicator of the risk of infections to the patient undergoing surgery susceptible to infections. To reduce surgical site infections, it is desirable to keep the bacteria-carrying particles at a low number in the operating room air, especially during orthopaedic prosthetic surgery.

Whyte et al (1) suggested that the air in the wound area should, on average contain no more that 10CFU/m^3 for surgery susceptible to infections. This level (≤10CFU/m^3) is nowadays international accepted and often called ultraclean air. A technical specification, SIS-TS 39:2015 (2), published by the Swedish Standard Institute SIS, suggests half as large CFU-values as above.

The main source of airborne bacteria-carrying particles in an operating room is usually the personnel and patient, why the protective efficacy of the surgical clothing system concerning bacteria-carrying particles plays an important role on the microbial air cleanliness.

Measurements of airborne bacteria-carrying particles (aerobic CFUs) were performed in operating rooms during ongoing surgery to evaluate the protective efficacy, source strength, of a clothing system with various additional clothing components, such as disposable hood, textile hood, shoes without and with textile knee-length boots.

MATERIAL AND METHODS

Apparatus

Airborne viable particles were collected using a filter sampler (Sartorius MD8®) and gelatine filters and a slit-to-agar sampler (FH3®). The gelatine filters had a pore size of less than 3µm. The impaction STA-sampler had a d_{50}-value of less than 2µm.

Each sampling period both instruments was 10 minutes. The sampling volumes were 1m^3 for the filter sampler and 0.5 m^3 for the STA sampler. Both samplers were operated according to the manufactures' instructions.

The microbial growth-medium used, incubation time and locations are described by Ljungqvist et al (3), where also a comparative study of the two measuring methods of collecting airborne viable particles is discussed.

The measurements of the comparative study (Ljungqvist et al (3)) were performed in operating rooms during ongoing orthopaedic surgery. The results show that the two measuring methods, filter method and impaction with the STA-sampler gave values (CFU/m^3) in the same range. It was established with Mann-Whitney's U-test that there was no significant difference between the two measuring methods. These two methods with their difference in agar and incubation time are described as accepted methods in SIS-TS 39:2015 (2).

Operating rooms

The measurements were performed in operating rooms at hospitals in the Stockholm area. The tests were performed during ongoing orthopaedic surgery in two operating rooms, where the air movements could be characterised as dilution mixing, i.e., the dilution principle is applicable. The supply air was HEPA-filtered with air volume flows in the two operating rooms of 0.62m^3/s and 0.71m^3/s, respectively, which for the two cases give about 18 air changes per hour.

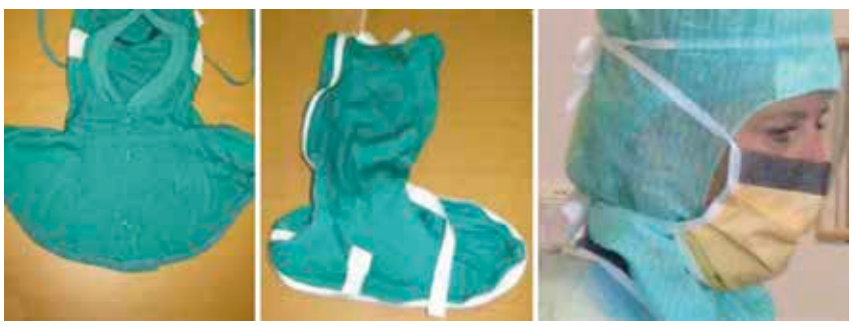
Clothing systems

The surgical clothing systems used were Olefin clothing system with three variations of additional clothing components. The fabric Olefin consists of 98% olefin and 2% carbon fibre. The blouse with cuffs at arms and neck and trousers with cuffs at the wrists were laundered about 20 times, but not antimicrobial treated. The weight is 125g/m^2. Disposable facemasks, sterile disinfected gloves, two types of headcovers and two different footwear were also worn.

The two types of head covering were common disposable hoods and textile hoods with cuffs at the face and pushbutton below the chin (laundered about 20 times). One footwear system had clean socks of cotton and disinfected plastic shoes, the other had textile knee-length boots over the shoes. The textile knee-length boots with zip at the back of the leg were laundered approximately 10 times. Photos of the different clothing components are shown in Fig 1 and 2.

Figure 1
Olefin surgical clothing system, blouse and trousers.

Figure 2 Olefin surgical clothing system, textile hood and textile knee-length boots, and the disposable hood.



The tests have been performed with the following three variations of clothing components:

1 Olefin clothing system with disposable hood and plastic shoes
2 Olefin clothing system with textile hood and plastic shoes
3 Olefin clothing system with textile hood and textile knee-length boots.

Source strength

With the assumption of no leakage into the operating room and the HEPA-filters having efficiency close to 100%, the simplest possible expression, which is applied on the dilution principle, describe the source strength, protective efficiency of surgical clothing system (outward particle flow):

$$q_s = c \times Q/n \qquad (1)$$

where q_s = *source strength, bacteria-carrying particles (CFU/s)*
c = *concentration, bacteria-carrying particles (CFU/m^3)*
Q = *total air flow (m^3/s)*
n = *number of persons (number)*

The source strength is here described as the mean value of the number of aerobic CFUs per second emitted from one person. Data are given as mean values based on several persons dressed in specific clothing systems. The source strength is a valuable tool in describing the protective efficacy of clothing systems against bacteria-carrying particles, e.g. a lower source strength gives a higher indication of a more suitable clothing system, (Ljungqvist et al (4, 5)).

RESULTS

Data from measurements with the filter sampler (Sartorius MD8) performed by Blomfeldt (6) are described by Kasina et al (7) during ongoing hip-joint operations in an operating room with dilution mixing air and an airflow of 0.62m^3/s. The surgical team (6-8 persons) was dressed in Olefin clothing system with disposable hood and plastic shoes.

In Table 1 concentrations of aerobic CFU are given from eight relevant operations and estimation of the source strength mean values is described with aid of Equation (1).

Table 1 gives that the source strength mean value for Olefin clothing system with disposable hood and plastic shoes is 1.85CFU/s. This value

should be compared to values less than and equal to 1.5CFU/s, which is the source strength level for clean air suits according to SIS-TS 39:2015 (2). To improve the source strength value for the Olefin system additional clothing components should be used.

Ullmann et al (8) described measurements with the STA sampler when the surgical team (5-6 persons) had Olefin clothing system with textile hood and plastic shoes without and with textile knee-length boots over the shoes during ongoing orthopaedic surgery with high activity in an operating rooms with dilution mixing air and an airflow of 0.71m^3/s. Concentrations of aerobic CFUs and estimated source strength with aid of Equation (1) are for the two cases shown in Table 2 and Table 3, respectively.

Measurement with clothing system described in Table 2 and Table 3 have also been performed in a dispersal chamber and the source strength mean values without and with boots become 2.3CFU/s and 1.0CFU/s, respectively, (Ullmann et al (8), Ljungqvist Reinmüller (9)).

The source strength mean value of a specific clothing system from operating room measurements during orthopaedic surgery with high activity (hip joint) seems to be about half the mean value obtained in dispersal chamber tests, see Ljungqvist et al(10, 5), Ullmann et al (8) and Gandra (11). This gives, as a first approximation, an expected source strength mean value of 1.15CFU/s for the system without boots and a mean value of 0.5CFU/s for the system with textile boots.

These two values should be compared to the source strength mean values given in Table 2 and Table 3. It should be noted that these values fulfil the source strength level for clean air suits according to SIS-TS 39:2015 (2).

Table 2 and Table 3 show that the reduction of the number of aerobic CFUs with boots compared to without boots is about two third. Even if the number of measurements during ongoing surgery is limited, the results indicate that the reduction during ongoing surgery is in the range as in the dispersal chamber tests.

Figure 3 (next page) shows exposed agar plates used in the measurements of airborne bacteria-carrying particles with the Olefin clothing system described in Tables 2 and 3. The upper four plates are showing the results from measurements with knee-length boots and the plates below are the results without knee-length boots.

Table 1
Concentration of aerobic CFUs and estimated source strength during ongoing orthopaedic surgery with high activity (hip-joint) in an operating room with dilution mixing air and an airflow of 0.62m^3/s. The surgical team was dressed in Olefin clothing systems with disposable hood and plastic shoes. Measurements were performed with the gelatine filter sampler (Sartorius MD8).

Operation number	Number of persons	CFU concentration		Source strength* (CFU/s)
		Mean value (CFU/m^3)	Mean - Max (CFU/m^3)	
1	6	37.0	20-57	3.82
2	6	2.7	0-6	0.28
3	6	20.7	1-40	2.14
4	6	7.3	1-18	0.75
5	8	35.2	22-48	2.73
6	8	24.5	14-40	1.90
7	8	8.0	2-16	0.62
8	6	25.0	10-46	2.58
Grand mean value	6.75	20.05	–	1.85
Source strength values are given with two decimal places.				

Table 2
Concentration of aerobic CFUs and estimated source strength during ongoing orthopaedic surgery with high activity. in an operating room with dilution mixing air and an airflow of 0.71m^3/s. The surgical team was dressed in Olefin clothing systems with textile hood and plastic shoes. Measurements were performed with the STA sampler (FH3) with the sampling time of airborne CFUs for 10 minutes per sample.

Air sample number	Number of persons	Concentration (CFU/m^3)	Source strength* (CFU/s)
1	6	4	0.47
2	6	10	1.18
3	6	10	1.18
4	6	14	1.66
5	5	12	1.70
Mean value	5.8	10	1.24
Source strength values are given with two decimal places.			

Table 3
Concentration of aerobic CFUs and estimated source strength during ongoing orthopaedic surgery with high activity. in an operating room with dilution mixing air and an airflow of 0.71m^3/s. The surgical team was dressed in Olefin clothing systems with textile hood and with textile knee-length boots. Measurements were performed with the STA sampler (FH3) with the sampling time of airborne CFUs for 10 minutes per sample.

Air sample number	Number of persons	Concentration (CFU/m^3)	Source strength* (CFU/s)
1	5	<2	<0,28
2	5	<2	<0,28
3	5	2	0,28
4	5	6	0,85
Mean value	5	<3	<0,42
Source strength values are given with two decimal places.			

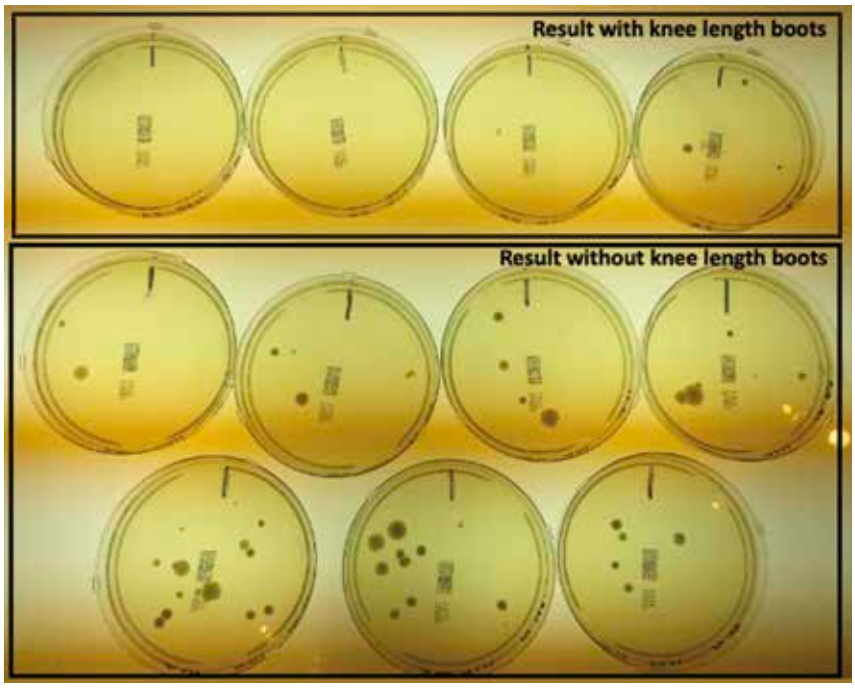


Figure 3
Agar plates used in the measurements of airborne bacteria-carrying particles in the operating room when the personnel are wearing the Olefin clothing system with textile hood and with and without textile knee-length boots (from Ullmann (12)).

Figure 4
Disposable hood (left) and textile hood (right) seen under microscope with the same magnification

Table 4
Estimation of mean value concentrations of aerobic CFUs during ongoing surgery with high activity in three operating rooms with dilution mixing air and airflows of 0.6m³/s, 1,5m³/s, and 2.5m³/s, respectively. The surgical team (6 persons) were dressed in Olefin clothing system with different additional clothing components, see example.

Olefin clothing system	Source strength* (CFU/s)	Mean value CFU concentration* (CFU/m³)		
		Airflow 0,6m³/s	Airflow 1,5m³/s	Airflow 2,5m³/s
Disposable hood and plastic shoes	1.9	19	7.6	4.6
Textile hood and plastic shoes	1.2	12	4.8	2.9
Textile hood and textile knee-length boots	0.4	4	1.6	1

** Source strength values and mean value concentrations are given to one decimal place.*

DISCUSSION AND CONCLUSION

Tables 1-3 show that the reduction of the number of aerobic CFUs is one third when the Olefin clothing system is used with textile hood instead of disposable hood and the total reduction becomes almost 80% when both textile hood and knee-length boots are used.

The difference in protective efficacy (source strength) between disposable hood and textile hood depends on how occlusive the fabrics are. The difference in poor size of the two fabrics are shown with microscopic photos in Figure 4.

It should be noted that the effect of knee-length boots is established in the pharmaceutical industry. Reinmüller (13) describes tests in an aseptic filling room for aseptic production of sterile products, where the operators were dressed in cleanroom coveralls and hoods, face masks and sterile gloves. The effect of knee-length textile boots compared to without knee-length boots was evaluated. When knee-length boots were used a reduction of airborne particles and aerobic CFUs of about 90% was achieved. The high reduction with cleanroom clothing might depend on that the cleanroom operator being better covered than the surgical staff within an operating room.

The theoretical mean value concentration of bacteria-carrying particles in an operating room can be calculated, when the dilution principle is applicable, if the total airflow, the number of people and their source strength are known. In this case, the Equation (1) becomes:

$$c = n \times q_s / Q \qquad (2)$$

In the following example, some estimations are given with Equation (2).

Example:

Calculate the mean value concentrations of bacteria-carrying particles (aerobic CFUs) during ongoing orthopaedic surgery with high activity in three different operating rooms with dilution mixing air and airflows of 0.6m³/s, 1,5m³/s, and 2.5m³/s, respectively. The surgical team was six persons dressed in Olefin clothing system with different additional clothing components, three cases.

Case 1 Olefin clothing system with disposable hood and plastic shoes (Table 1).

Case 2 Olefin clothing system with textile hood and plastic shoes (Table 2).

Case 3 Olefin clothing system with textile hood and textile knee-length boots (3)

The calculations are performed with Equation (2) and the numbers are given with one decimal place. The results are shown in Table 4.

The results in Table 4 show that use of additional clothing components can considerably improve the microbial air cleanliness in operating rooms during ongoing surgery.

It should be noted that the European Standard EN 13795-2:2019 (14) states that to manufacture a functional clean air suit, design shall also be considered. Arms and feet openings shall therefore be closed. A barrier hood should be worn, tucked into the gap at the neckline. If the clean air suit consists of blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting waist. In addition, it could be mentioned that the Swedish Standard SS 8760164:2020 (15) contains the construction pattern for all three parts (hood, blouse, trousers) of the clean air suit.

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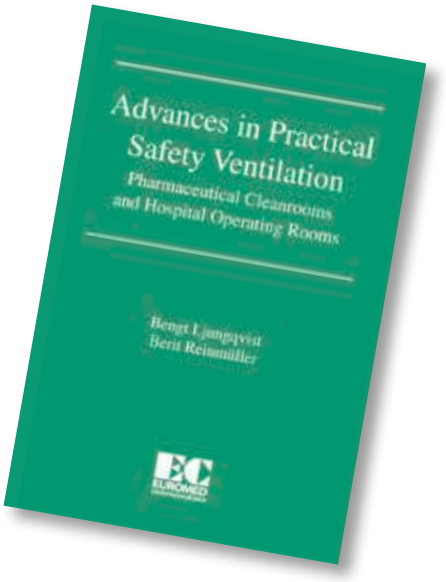


Book review:

Advances in Practical Safety Ventilation

TOR GRÅBERG, M.SC. PHARM., HEAD OF OPERATIONS QUALITY COMPLIANCE AND EXTERNAL AFFAIRS, ASTRAZENECA
FORMER HEAD OF THE DRUG INSPECTORATE, MEDICAL PRODUCTS AGENCY, SWEDEN

Anyone with an interest in ventilation issues will have a great opportunity to learn and understand much more about different applications of safety ventilation after reading this anthology. This book is a collection of 36 scientific peer-reviewed papers written by Professor Emeritus Bengt Ljungqvist and Assoc. Professor Berit Reinmüller.

The book covers research previously publicized during a period of almost 30 years (from 1991 until 2019) and focusses on airborne contamination control in pharmaceutical cleanrooms and hospital operating rooms.

The book is clearly divided into seven sections:

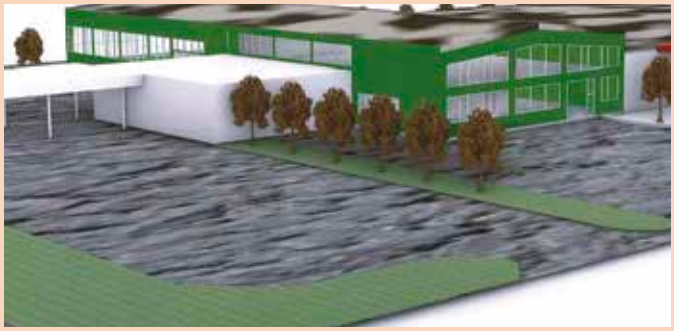
Section 1 – Air movements and dispersion of contaminants
Section 2 – Microbiological environmental monitoring, Measuring equipment
Section 3 – The LR-method and its application
Section 4 – Airflows through openings, Freeze-dryers and autoclaves
Section 5 – Pharmaceutical Blow-Fill-Seal environments
Section 6 – Cleanroom clothing systems
Section 7 – Hospital operating rooms

Some highlights from the book: A. The method "Limitation of risks" (LR-method) offers a consistent procedure for evaluating potential microbiological risks of airborne contamination in clean zones in a structured and systematic way. This method is easy to use and consists of three steps – visualize – particle challenge test – calculating the risk factor. By using this approach, the LR-method presents an effective way for the limitation of potential risks. Examples of the use of the LR-method are described in section 3. B. The behavior of airflow through doorways is an important area to understand e.g. when opening autoclaves and freeze-dryers and to mitigate unwanted airflow patterns by installation of HEPA filter units above the opening to provide clean air and hence protect the opening. Different aspects of this are described in section 4. C. In section 5 you will be able to learn more about the airborne particle generation and contaminant dispersion routes within a Blow-Fill-Seal (BFS) machine and hence how to reduce particle concentrations. The BFS technique is used to manufacture e.g. aseptically filled small volume parenterals and therefore it is important to understand the relationship between airborne particle concentrations and the particle concentrations in filled plastic ampoules. D. In section 6 the focus is cleanroom clothing systems. How to protect the product and the environment from airborne particles generated from the human skin. Clothing system should be designed to fully cover a person and the clothing itself needs to be tested with regards to material properties such as particle generation, particle filtration and robustness to resist damage.

I would highly recommend this book. It can be used for educational purposes as well as a reference for practical applications. Each paper is richly illustrated with graphs, equations and pictures which gives the reader a broader understanding of the topics and how to use the knowledge in an applied way.

During my years as a Chief Pharmaceutical Inspector at the Medical Products Agency in Sweden, I saw numerous examples in the pharmaceutical industry across the globe of uncertainty and a lack of understanding of ventilation issues. It is my sincere hope that this book will bring back the interest and willingness to understand safety ventilation as an important factor to achieve the airborne contamination control quality required during pharmaceutical manufacturing as well as to accomplish the cleanliness needed in hospital operating rooms.

Camfil invest in the Technical Center in Trosa



Stockholm, Sweden, 17th June 2021

Camfil Group is expanding its ultramodern technical center in Trosa, Sweden and the work is planned to complete by the end of 2021. The new expansion unit will spread over 2300 square meters in area and intends to meet the growing demands of Camfil's filtration solutions. The rising demand for energy-efficient, sustainable clean air products will help protect people's health along with the reduced impact on the environment. The long-term contribution of the energy savings filtration solutions will create a revolutionary impact as clean air and its importance are part of the global agenda. The significantly larger research and development area will also be used for test and learn practices that will enhance the customer experience at the Tech Center. Another part of the area will be dedicated to machinery upgrade and process development that includes research and development of raw material that can deliver products with even higher performance. With advanced material science, Camfil will develop innovative materials and machinery for the next generation of sustainable high-performance air filters.

The Tech Center in Trosa has five laboratories that contribute towards research and innovation in particle filtration, HEPA technology, molecular filtration, indoor air quality (IAQ) and the gas turbine industry. The new area is built to increase the research capacity, especially within molecular contamination control, filtration for power generation, and energy-efficient and sustainable raw materials. Due to current global trends as energy saving, sustainability, and health awareness, Camfil expects the intensity of research and development to increase significantly over the next few years. The increased efforts in R&D will provide ultra-modern energy-efficient and sustainable clean air filtration solutions. The laboratory has ISO 9001 international standard for a quality management system. Additionally, the research and development team is preparing to be ISO/IEC 17025 standard accredited with the new laboratory.

"The expansion of the Tech Center facility will greatly increase our R&D and process development capacity. The timing is working in the best interest as we foresee a strong trend for increased awareness about the importance of clean air. The clean air trend has become even more evident during the pandemic as removal of harmful pathogens from the indoor air is high on the agenda. The demand for highly efficient and sustainable air filters is constantly growing, globally. This fact and advances in process technology and material science render new opportunities. Camfil's team is dedicated to providing high-tech solutions that protect people and the business." says Anders Sundvik, Vice President R&D at Camfil

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X-ray imaging enables fast analysis of prefilled syringes

Full Story at: Bioprocess Online

Prefilled syringes are both container closure systems and delivery devices, and the process for assessing syringe integrity is more complex than for glass vials because syringes have more sealing areas, writes pharmaceutical industry consultant Tim Sandle. X-ray microtomographic imaging is a nondestructive option for analyzing syringe integrity and is potentially faster and more accurate than other tests, Sandle writes.

Phages a tool against Salmonella

Bethan at New Food, news@emails.newfoodmagazine.com>

A collaborative research project by AB Agri and the University of Leicester found that Salmonella colonisation in broiler chickens could be tackled by bacteriophage – the natural viruses of bacteria – in animal feed.

Tests demonstrate a low dose of phage reduced the Salmonella count to below detection limits – a result that could have far-reaching impact in poultry production and food hygiene.

"The results highlight phages as a promising tool to target bacterial infections in poultry," said Martha R J Clokie, Professor of Microbiology at the University of Leicester.

25 nya symboler för medicintekniska produkter

De nya symbolerna i standarden ISO 15223-1 är ett krav enligt de nya regelverken för medicintekniska produkter, MDR, och medicintekniska produkter för in vitro-diagnostik, IVDR.

Mer information finns på www.medtechmagazine.se

R³ NORDIC INVITES TO

EHEDG Advanced Course in Hygienic Engineering & Contamination Control

26th - 28th of October 2021

FORCE Technology, Park Allé, Brøndby, Denmark

AIM

The advanced course gives knowledge and insight in hygienic design of process equipment, lines and facilities in food, biotech and pharma industry as well as their suppliers. Investment in hygienic design can when optimally used give optimal product safety and constant product quality as well as lead to diminished down time, maintenance costs, cleaning costs and environmental impact. It deals with how to fulfil present legislation and standards and anticipate future changes.

PARTICIPANTS

The advanced course is originally targeted for service producers in food, biotech and pharma industry e.g. mechanical engineers. It is also meant for managers and supervisors, constructors, project managers as well as sales engineers, who are active in using, building or servicing equipment for industries relying on hygienic or aseptic processing. The advanced course is excellent for the technical and quality assurance staff, who needs knowledge in hygienic engineering, in these industries.

CONTENT

The course is given in English from a practical point of view. The theoretical fundamentals of the different subjects are given in a concise way, continuously relating these to practice through pictures or examples. Design guidelines are dealt with in terms of the basic properties experimental evidence. The course gives you tools to solve hygienic problems within your own organization.

The course is interactive due to training in small groups. On the last course day, there will be an Exam (course material allowed). EHEDG certificate will be mailed to approved participants attending the full course.

REGISTRATION

The course fee is 1950 €/participants. Company members get 10% reduction on the fee. The fee comprises course material, course certificate (posted to approved participants attending the whole course), coffee/tea, lunches and dinners mentioned in the programme.

The prices are excl. VAT.

REGISTRATIONS AT LATEST ON 11TH OF MAY 2021

Please, contact Gun Wirtanen for further information and/or registration by e-mail guliwi@luukku.com. At registration, we need:

1) Name of participant
2) Company
3) Contact address (incl. e-mail)
4) Invoicing address (incl. e-mail)
5) Information on e.g. food allergies, diets.

CANCELLATION POLICY

Cancellations must be sent in writing by mail to Gun Wirtanen at guliwi@luukku.com. Participation in this training course can be cancelled free-of-charge at latest four weeks prior to the event except for an administration fee of 100 €.

Cancellations thereafter, we will charge 50 % of the participation fee. We charge the full participation fee for late cancellations made two weeks before the event start or thereafter (a colleague can take a paid course place at late cancellations).

THE COURSE TRAINERS ARE

Alan Fris, Ferdinand Schwabe and Gun Wirtanen.

Day 1

08.45 – 09.15	Registration with Coffee/Tea and Presentation
09.15 – 09.45	Introduction to Hygienic Design - Motivation
09.45 –11.15	Legal requirements
11.15 – 12.00	Lunch
12.00 – 13.15	Hygienic design criteria
13.15 – 13.30	Coffee/Tea -break
13.30 – 15.00	Hazards in hygienic processing
15.00 – 15.15	Coffee/Tea -break
15.15 – 16.30	Construction materials
16.30 – 17.00	Video - Verification of hygienic design & EHEDG test methods and certification
17.00 – 17.45	Welding stainless steel
18.30 – 21.00	Dinner

Day 2

08.30 – 10.00	Static seals and couplings
10.00 – 10.15	Coffee/Tea -break
10.15 – 11.30	Cleaning & Disinfection
11.30 – 12.15	Lunch
12.15 – 13.30	Valves & Pumps
13.30 – 14.15	Demo on process flows / traceability system
14.15 – 14.30	Coffee/Tea –break
14.30 – 16.30	Equipment exercises with coffee/tea available
16.30 – 17.00	Lubricants
17.30 – 20.00	Dinner

Day 3

08.30 – 10.15	Building and process layout
10.15 – 10.30	Coffee/Tea -break
10.30 – 11.30	Installation & maintenance
11.30 – 12.15	Lunch
12.15 – 13.30	EHEDG Advanced Course exam (1 h)
13.30 – 13.45	Coffee/Tea -break
13.45 – 14.45	Group work (4-6 participants/group) on design pictures
14.45 – 15.30	Presentation of EHEDG
15.30 – 15.45	Exam results

R³ NORDIC, CTCB-I OCH CHALMERS INVITE TO

Cleanroom Testing & Certification

12-14 Oktober 2021

Installationsteknik, Chalmers, Göteborg

The course material is intended for self-study prior to attending the lectures.
The content of the course notes, written in English, forms the basis for the lectures.
The course notes will be delivered after payment of a registration fee, at latest one month before the start of the course.
Candidates can apply for either of two levels of certification; Professional or Associate. As proof of the certification, a diploma will be issued to each participant who completes the course and passes the examination.

ASSOCIATE LEVEL

For people who are either familiar with some aspects of cleanroom testing, and wish to gain knowledge about the subject (purchasers and evaluators of clean room testing), or have been working less than two years as a cleanroom tester, but wish to use the certification course as a basis of training and working towards professional status. If you apply for the associate course, and have suitable qualifications, you will be required to:

- study the self-study course notes that will be sent to you, attend a lecture course, and then pass a written examination on cleanroom testing
- attend a demonstration exercise on practical aspects of cleanroom testing.

PROFESSIONAL LEVEL

For people whose profession is cleanroom testing, and who routinely carries out all aspects of cleanroom testing. At the time of their exam they should have a minimum of two years' experience. If you apply for, and have suitable qualifications, you will be required to:

- study the self-study course notes that will be sent to you, attend a lecture course, and then pass a written examination on cleanroom testing
- pass a practical exam by showing a high level of competence in (a) filter integrity testing and (b) measuring air velocities and volumes
- Complete a particle counting exercise.
  Note that certificates on Professional Level are valid for five (5) years. Recertification is required in order to maintain certification on Professional Level beyond five years.

COURSE FEES 2021

CTCB Associate Level - 2 days in Gothenburg
Included: Course notes, lecture notes, written exam, practical demonstration and lunch both days.
Registration fee: SEK 3 950
Course and exam fee: SEK 11 250

CTCB Professional Level - 3 days in Gothenburg
Included: Course notes, lecture notes, written and practical exams and lunch day 1 and 2.
Registration fee: SEK 3 950
Course and exam fee: SEK 14 500

Exam Re-sit and Upgrading from Associate to Professional Level - 1 day in Gothenburg
Candidates who do not pass a practical exam (filter leak testing and/or air velocity) can "re-sit" the exam within one year. Candidates who wish to upgrade their certificate from associate to professional level can complement with the practical exam within one year.
Registration fee: SEK 2 950
Practical exams fee: SEK 3 500 *(per exam)*

Recertification CTCB Professional Level - 3 days in Gothenburg
Included: Course notes, lecture notes, practical demonstration, written and practical exams.
Registration fee: SEK 3 950
Course and exam fee: SEK 12 500

Note 1: Candidates who are not already members of R³ Nordic or another ICCCS affiliated society will also be charged the cost of one year's individual membership - currently SEK 650,- in R³ Nordic.

Note 2: VAT will be added to all prices given above.

Note 3: Any costs required for accommodation are the responsibility of the candidate.

Further information is available at www.safetyventilation.com
Questions and application form: Lars Ekberg,
ctcb-gothenburg@cit.chalmers.se /+46 (0)703 15 11 55

The number of seats is limited. ***Apply no later than August 10, 2021.***

R³ NORDIC LAU NORGE INBJUDER TILL

Grunnkurs i renhetsteknikk

18-19 oktober 2021

Olavsgaard Hotel, Skjetten

BEGRENSET 35 DELTAGERE

PROGRAM - 18. oktober 2021

09.00-09.30	Registrering
09.30-10.00	Åpning, introduksjon. Presentasjon.
10.00-10.45	Standarder i renrom (KS)
10.45-11.30	Ventilasjon og luftbevegelse (KS)
11.30-12.30	Lunsj
12.30-13.30	Ventilasjon og luftbevegelse fort. (KS)
13.30-13.45	Kaffepause
13.45-14.30	Konstruksjon av renrom. Kvalifisering av renrom (KS)
14.30-15.30	Ulike type benker. Testing av ulike type benker (KS)
15.30-15.45	Kaffepause
15.45-17.00	Kontaminasjonsbegrepet. Levende og døde partikler (BR)

PROGRAM - 19. oktober 2021

08.30-10.30	Mennesket i det rene rom, arbeidsteknikk og påkledning (BR)
10.45-11.30	Mikrobiologi i renrom (KA)
11.30-12.15	Lunsj
12.15-13.00	Mikrobiologiske testmetoder (KA)
13.00-13.20	Kaffepause
13.20-14.45	Klær, vask og rengjøring (BR)
14.45-15.30	Case - gruppeoppgave
16.00	Avslutning, kursevaluering, deltakerbevis

Kursavgift

NOK 7 980 (R³-medlem 7 330)

Inkl felles middag, lunsj, kaffe, te, frukt, lunsj, kjeks, softis, o.l.

Påmeldingsfrist: 14.09.2021

Meld deg inn i R³ Nordic før påmelding for å få medlemspris

r3nordic.org/shop/medlemskap/ansok-om-medlemskap/

Påmelding inkl felles middag 18. oktober (inkludert)

mail til r3nordic.no@gmail.com eller kontakt Barbro Reiersøl på mobil 95 13 19 45.

Overnatting på Olavsgaard hotel

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Tlf. til hotellet: +47 63 84 77 00

Arrangør: Norske LAU R³ Nordic
Eli Bjørnson, Serviceproduksjon,
Barbro Reiersøl, AET AS,
Phuong Huynh, Sykehusapoteket i Drammen og
Geir Valen Pettersen, Norsk Med. Syklotronsenter
Hong Thanh Thi Nguyen, IFE, Kjeller

Kurslærere:
Barbro Reisersol, AET (BR)
Kari Solem Aune, COWI (KS)
Kjersti Aulie, GE Healthcare (KA)

R³ NORDIC INBJUDER TILL

Sjukhusdagar

Prel Nov 2021

Akademiska Sjukhuset

TEMA LÖF

”LÖF, Regionernas Ömsesidiga Försäkringsbolag, har som ett av sina viktiga uppdrag att arbeta för ökad patientsäkerhet. Detta sker bland annat genom att presentera olika expertdokument.

I samverkan med R³ Nordic, presenteras nu skriften ”Krav att beakta i projektprocessen för att uppnå optimal lokalfunktion med avseende på renhet”. Denna lägger fokus på renhet, mikrobiologisk, visuell och partikulär, i vårdens lokaler. Detta ska ske i projektprocessens alla skeden; från utrednings- och programarbeten, under projekteringsprocessens olika delar, under byggnation samt under driftskedets olika faser.

Arbetet syftar till att verksamhetens behov och rutiner får ett genomslag i utformningen av lokaler och tekniska försörjningssystem. Detta sker genom att stärka en aktiv medverkan från verksamheten i utrednings- och programarbete. Detta tydliggörs genom att redovisa arbetsmetodik, förväntade person- och materielflöden och definiera erforderliga renhetsnivåer.

En metod för riskbedömning presenteras och exempel på tillämpning exemplifieras. Denna ska kunna användas i projektprocessens alla skeden. Resultatet, förändrade förutsättningar och eventuella avvikelser och konsekvenser ska redovisas för verksamhetens representanter. Riskbedömningen blir således ett verktyg för att säkerställa att uppställda krav uppfylles.

Projektledare för arbetet har varit Lennart Hultberg.”

Prof Jan Gustén, Chalmers Tekniska Högskola

Intressenmälan på mail till Lennart Hultberg
lennart@processhygien.com

Anmälan till alla våra kurser ska vara skriftliga och är bindande. Avbokning ska ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, ska återbetalas. Vid avbokning senare, minst 14 arbetsdagar före kursstart, återbetalas halva kursavgiften. Vid avbokning senare än 14 arbetsdagar före kursstart sker ingen återbetalning. Ersättare kan registreras fram till och med första kursdagen. R³ Nordic förbehåller sig rätten att ändra kursinnehåll och föreläsare utan att meddela deltagare eller att ställa in kursen. Föreningen ansvarar inte för merkostnader i samband med kursens inställelse. Vid inställelse återbetalas kursavgiften i sin helhet.

MARKNADSGUIDE

FÖRETAGS- & BRANSCHREGISTER ÖVER STÖDJANDE MEDLEMMAR I R³ NORDIC

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FÖRBRUKNINGSMATERIAL FÖRPACKNING PROCESS

AET ARBEIDSMILJØ OG ENERGITEKNIKK AS (NO)
Ing.firma, prosjektering, produkter for renrom.
Tel 23 06 73 30 / info@aet.no

INREM AB (SE)
Pincetter, kläder, torkdukar, svabbar, handskar, klibbmattor, renrumspapper, skor, stolar mm
Tel 08-59080720 / info@inrem.se

INSTRUMENT ÖVERVAKNING VALIDERING KALIBRERING

MY AIR AB (SE)
Kontroll och validering för att minimera luftburen smitta och säkerställa processer
Tel 072-503 84 59 / lars.jansson@myair.se

NINOLAB, AB (SE)
Partikelräknare, automatisk övervakning. Bänkar. LAF-tak, luftduschar. Niklas Nordin.
Tel 08-59096200 / info@ninolab.se

PARTICLE MEASURING SYSTEMS (DK)
Partikelräknare, sensorer och system.
Lars Peter Kristensen, Tel: 25 21 82 88
lpkristensen@pmeasuring.com

PSIDAC (SE)
Gain control and safer healthcare environments - CPS 6000 Monitor System
Björn Österlund / www.psidac.com

MIKROBIOLOGI STERILISTERING

GETINGE FINLAND OY (FI)
Peter Holmberg
Tel 040 900 4620 / peter.holmberg@getinge.fi

MICLEV AB (SE)
Biologiska indikatorer, färdigberedd media, sterilisering, luftprovare, mikroorganismer.
Tel 040-365400 / info@miclev.se

NINOLAB, AB (SE)
Inkubatorer, värmeskåp, class100 sterilasatorer. Autoklaver - diskmaskiner. Niklas Nordin.
Tel 08-59096200 / info@ninolab.se

CRC CLEAN ROOM CONTROL AB (SE)
Kvalificering av renrum, LAF, säk-bänkar och skyddsventilation. Mikrobiologiska tester. Rök.
info@cr-control.se / www.cr-control.se

KONSULTER PROJEKTERING

CIT ENERGY MANAGEMENT AB (SE)
Teknisk utveckling, validering och funktions-kontroll inom luftrenhet, klimat och energi.
031-772 11 51 / stefan.aronson@cit.chalmers.se

COWI AB (SE)
Teknikutveckling, miljöteknik och projektledning
Torbjörn Lång / trla@cowi.com

CRC CLEAN ROOM CONTROL AB (SE)
Rådgivningar, förstudier och projektering. Utbildning. Tel 018-246460 / 070-5926604.
info@cr-control.se / www.cr-control.se

VENTILATOR RENRUM, INDUSTRI AB (SE)
Renrum, säkerhets- och sterilbänkar. Lufttak. Projekt ventilation, entreprenader, utrustning.
Tel 070-9711454 / bjarne.osterberg@ventilator.se

RENRUM OP-RUM LAF INREDNING BÄNKAR TAK

AET ARBEIDSMILJØ OG ENERGITEKNIKK (NO)
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Tel 23 06 73 30 / info@aet.no

CRC MEDICAL AB (SE)
Kundunika renluftslösningar för miljöer med mycket höga krav i sjukhus och sterilcentraler
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anders.lofgren@menardifilters.com

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Tel 08-59096200 / info@ninolab.se

INREM AB (SE)
LAF-enheter, moduler, säkerhetsbänkar etc
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Tel 070-9711454 / bjarne.osterberg@ventilator.se

RENGÖRING STÄDNING

PHARMACLEAN AB (SE)
Konsultation, lokalvårdsutbildning och lokalvård för renrum. Regina Björnsson.
Tel 0708-986428 / www.pharmaclean.se

PIMA AB, SERVICEFÖRETAGE (SE)
Bemanning - Entreprenad - Konsultation
www.pima.se
Tel 08-55424610 \ kontakt@pima.se

RENRUMSKLÄDER TEXTILIER TVÄTTNING

DFD CLEAN ROOM (DK)
De Forenede Dampvaskerier A/S
V. Henriksens Vej 6, 4930 Maribo
Tel 5476 0509 / crmar@dfd.dk

BERENDSEN TEXTIL SERVICE AB (ELIS) (SE)
Renrumstvätteri. Renrumskläder.
Tel 020-740116 / goran.nilsson@elis.com

NINOLAB AB (SE)
Säkerhets- sterilbänkar. LAF-tak o luftduschar (ScanLaf), Thermo Partikelräknare (MetONE)
Tel 08-59096200 / info@ninolab.se

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Tel 070-9711454 / bjarne.osterberg@ventilator.se

VENTILATION FILTER

CAMFIL SVENSKA AB (SE)
Renluftslösningar. HEPA-, ULPA och gasfilter. Till- och frånluftsdon. www.camfil.se
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