# 'ISO 14644-4, "Content and use of the standard"
## *highlights on the importance of energy management in the design*

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Consultant / Technical Manager

# About me

- Active in the Contamination control community
- Active in standards and guidelines development



**ISO TC209**
**ISO 14644-3 Expert**
**ISO 14644-4 Convener**
**ISO 14644-7 Expert**

**CEN TC156**
**WG18 Secretary**

**Technical Committee Chair**

**PG-04 Chair**
**Committee member L&C**
**Distinguished member**
**Honorary member**

**Regional chair**
**EHEDG-NL**

# About me

**KROPMAN**
CONTAMINATION CONTROL

Technical manager contamination control

35+ years consultancy, design, construction, commissioning, qualification/validation-support

GMP, biosafety, healthcare, medical devices, mircro-electronics, radiopharmaceutical food, facility and process projects.

**Skid-mounted systems**

**Cleanrooms and labs**

**Process installations**

**Services**

# Take home message

- Phasing project development
- All cleanliness attributes (where applicable)
- Flow/pressure cascade ← 'room pressure'
- Calculations: Source strength + airflow ← Air Change Rates
- Clean built protocol

*More sustainable: Design, Construction, Start-up* ➔ *Operation!*

# History

ISO TC209 WG4 :

Revision of ISO 14644-4 2001 'Design, construction, start-up"

- ▶ Start 2015
- ▶ CD1 2019
- ▶ CD2 2020
- ▶ DIS  2021
- ▶ FDIS 2022 (Ballot closed 13-Oct: approved)
- ▶ Final editing in progress

# Content

1. Scope
2. Normative references
3. Terms and definitions
4. Abbreviated terms
5. General
6. Requirements
7. Design
8. Construction
9. Start-up
(guidance on)
Annex A requirements
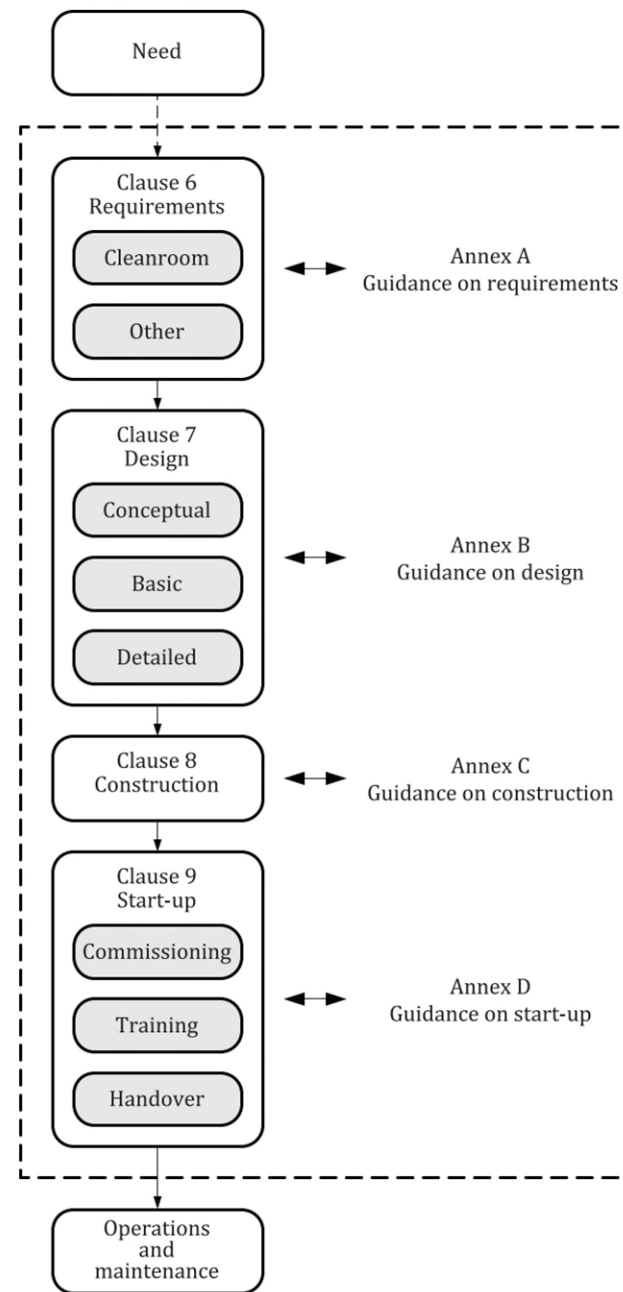Annex B design
Annex C construction
Annex D start-up
Bibliography



Figure 1 — Flowchart: from requirements to design, construction and start-up

## Project Phasing

**Idea**

↓

**Requirements**

↓

**Design**

↓

**Construction**

↓

**Start-up**

↓

**Operation**

## Aspects

- Review/Approval per phase
- Information development and documentation
- Quality plan
- Clean build protocol

Informative annexes:
- Checklist per phase
- Explanatory text

# Requirements

Effective contamination control achieved by:
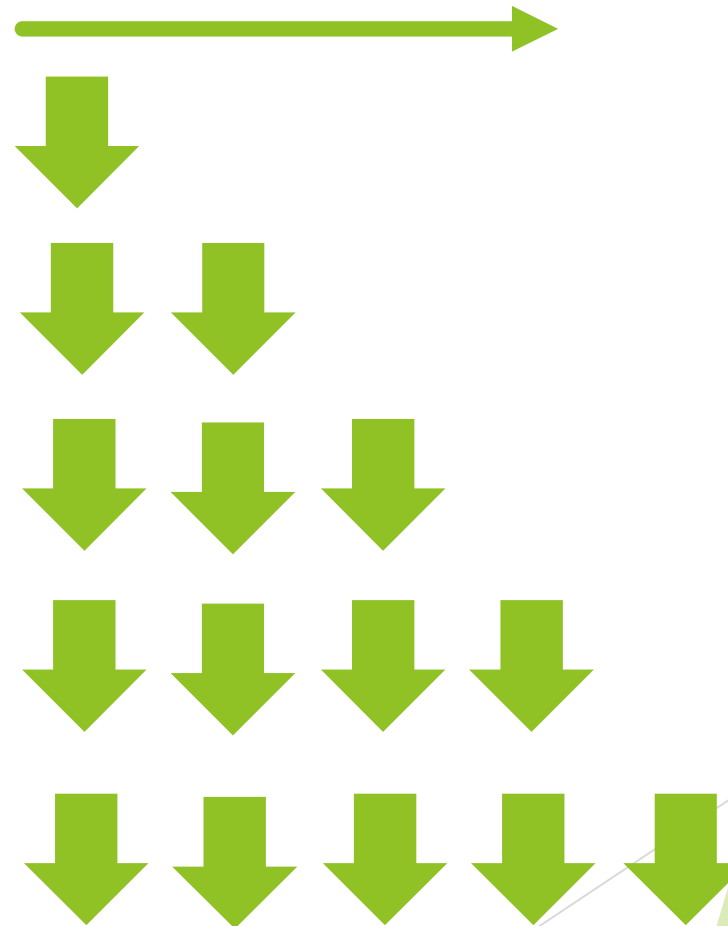
a) the amount of contamination brought into the cleanroom should be minimized;

b) the generation and transmission of contamination should also be minimized;

c) contamination that is generated should be quickly removed from the cleanroom or contained so as not to deposit and gather on surfaces;

d) the environmental conditions of the cleanroom should be controlled through an effective air-handling system and surface-cleaning program.

# Other Contaminants, in Air, on Surfaces

| | | |
|---|---|---|
| **Particles** | **In Air** | **On surfaces** |
| Viables (micro-organisms) | In Air | On surfaces |
| Chemicals | In Air | On surfaces |
| Nano particles | In Air | On surfaces |
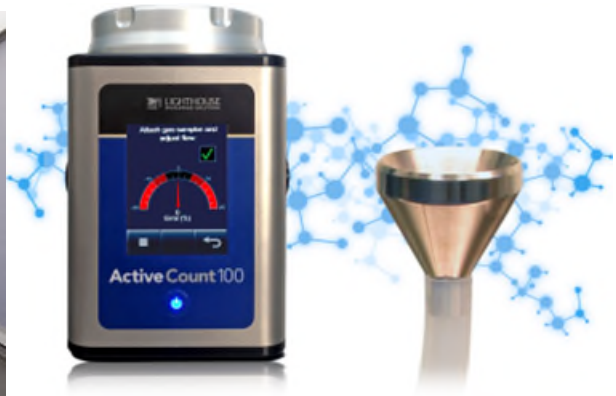
# Design

Effective contamination control strategy:

a) engineering controls, i.e. the facility and environmental controls;

b) personnel and material controls, i.e. gowning and behaviour as part of procedures and a quality management system; (ISO 14644-5)

c) cleaning, including disinfection if required. (ISO 14644-5)

# Design

Focus on understanding:
- Activities and risks of process
- Sources of contamination
- Critical control points
- Limits/levels
- Risk elimination/mitigation by
- Isolation, segregation, separation containment e.g.
- limiting 'sources' inside.
- Keeping 'contamination' out
- Using adequate airflow design
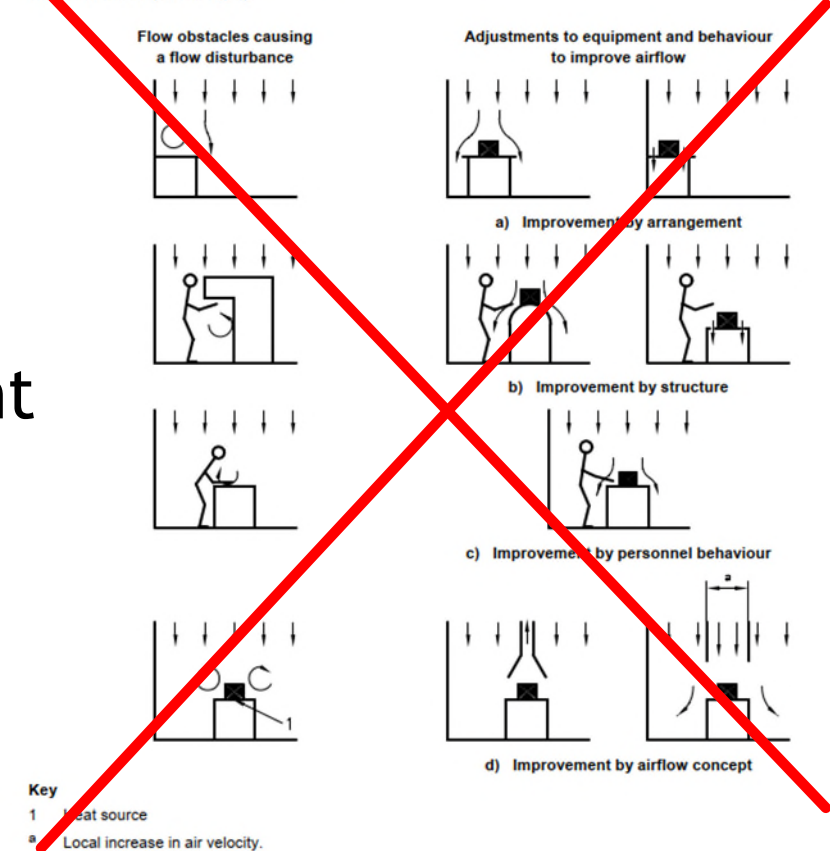- Monitoring



Figure A.3 — Influence of personnel and objects on unidirectional airflow
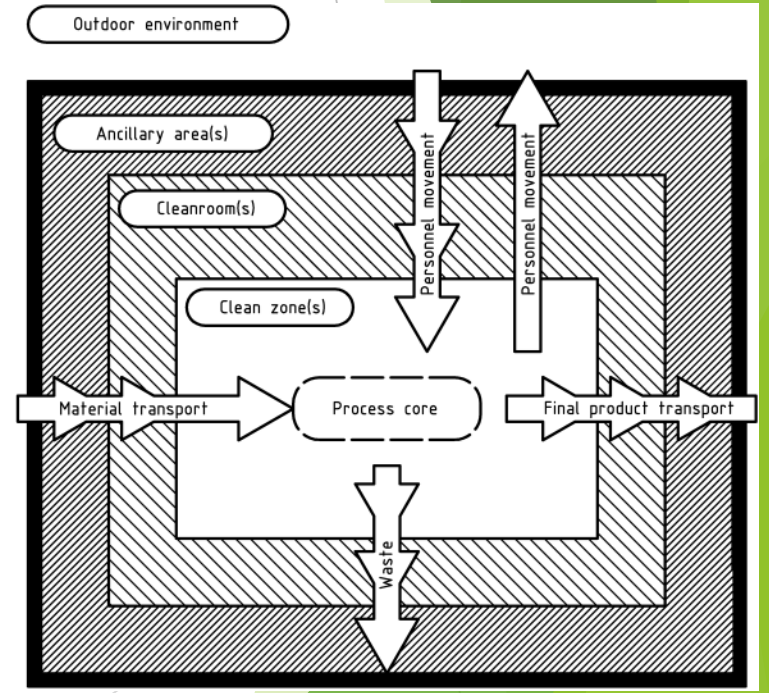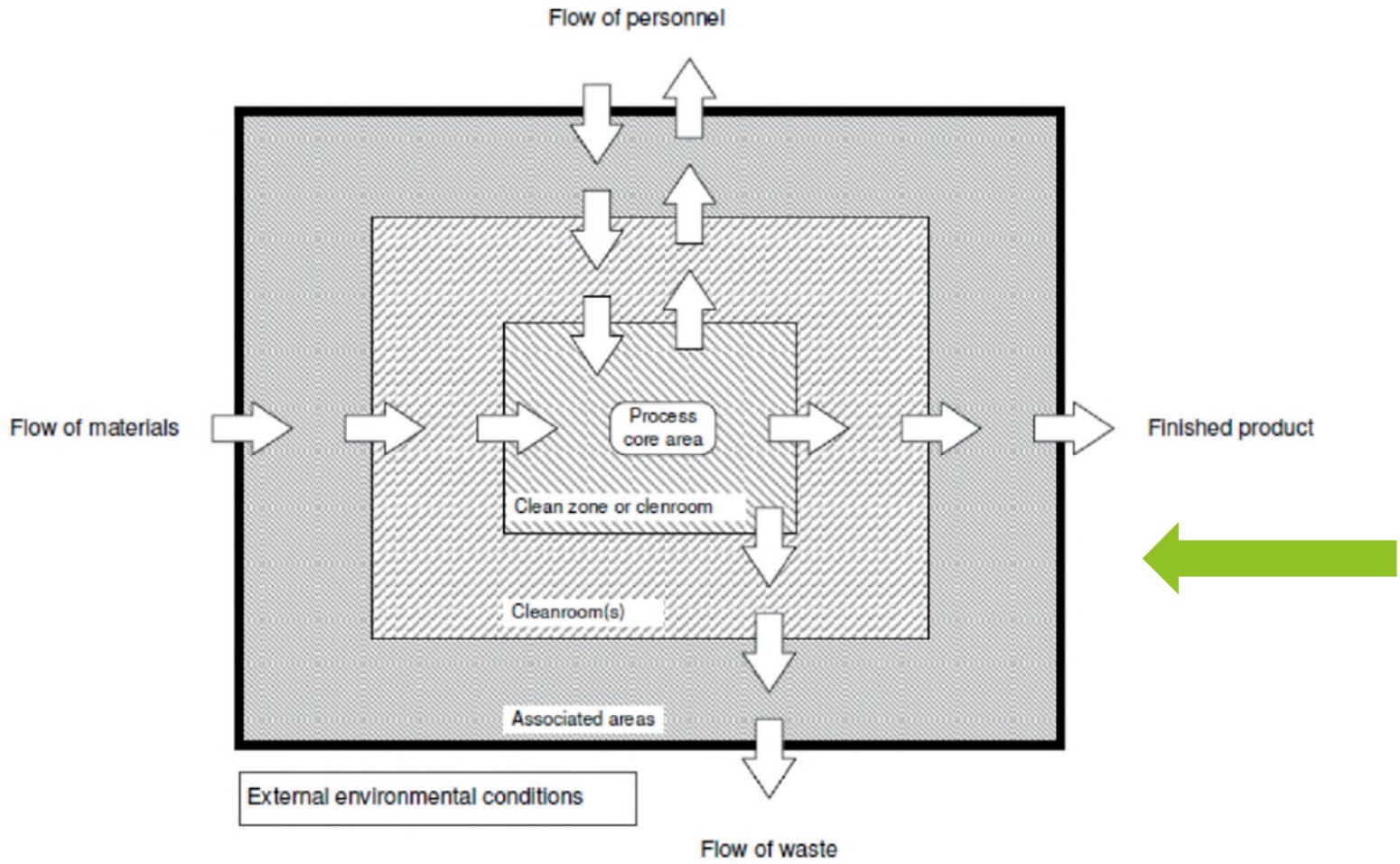
# Design Concepts
## Zoning



Figure A.1 of ISO 14644-4  2001

# Design Concepts

## Segregation

Protecting against outside
Containing inside
Combination of both


Flow ←→ Pressure relation
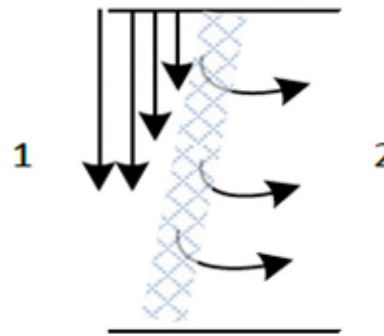
Flow Cascade leading to 'pressure differentials'

Relation with 'offset' :   difference between supply and return airflow volume

- **Physical barrier**
  (rigid/flexible screens,
  wall's including leakage
  and overflow devices)
  ISO 14644-3:
  - Air pressure difference test
  - Containment leak test



- **Aerodynamic segregation**
  ISO 14644-3:
  - Segregation test
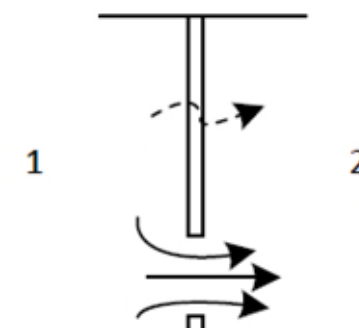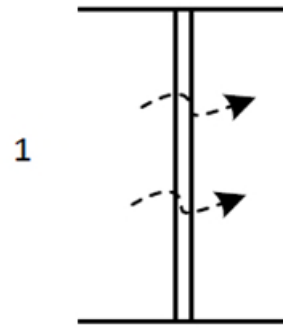
# Design Concepts
## Airflow concepts

**Unidirectional**



Ventilation mechanism:
Displacement

UDF-velocity
x
UDF Surface
=
Airflow Rate

**Non-unidirectional**



Ventilation mechanism:
Dilution

Room volume
x
*'Air Change Rate'*
=
Airflow Rate

Cleanliness need
Sources

Airflow Rate
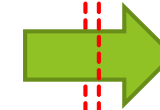
# Design Concepts

ISPE HVAC good practice guide:

6 to 20 AC/hr for CNC, EU Grade D) spaces

20 to 40 AC/hr for Grade 8 (EU Grade C) spaces

40 to 60 AC/hr for Grade 7 (EU Grade B) spaces
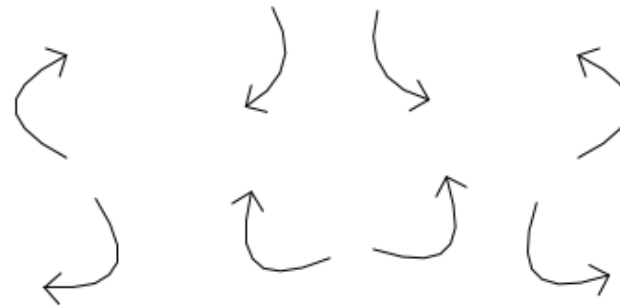
Grade 5 (EU Grade A) spaces operational

| ISO | ACR$^d$ | ACR/h |
|-----|---------|-------|
| 6 | 70-150 | 23,3 - 53,3 |
| 7 | 30-70 | 10 - 23,3 |
| 8 | 10 - 20 | 3,3 - 6,6 |

$ACR = ACR^d / 3$

**History**

Table B.2 — Examples for microelectronic cleanrooms

| Air cleanliness class$^a$ (ISO Class) in operation | Airflow type$^b$ | Average, airflow velocity$^c$ | Air changes per hour$^d$ m³/m² · h | Examples of applications |
|---|---|---|---|---|
| 2 | U | 0,3 to 0,5 | na | Photolithography, semiconductor processing zone$^e$ |
| 3 | U | | na | Work zones, semiconductor processing zone |
| 4 | | 0,3 to 0,5 | na | Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones |
| 5 | U | 0,2 to 0,5 | na | Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones |
| 6 | N or M$^f$ | na | 70 to 160 | Utility zones, multilayer processing, semiconductor service zones |
| 7 | N or M | na | 30 to 70 | Service zones, surface treatment |
| 8 | N or M | na | 10 to 20 | Service zones |

NOTE    na = not applicable

a    Occupancy states associated with the ISO Class should be defined and agreed in advance of establishing optimum design conditions.

b    When airflow type is listed, it represents the airflow characteristics for cleanrooms of that class: U = unidirectional; N = non-unidirectional; M = mixed (combination of U and N).

c    Average airflow velocity is the way that unidirectional airflow in cleanrooms usually is specified. The requirement on unidirectional airflow velocity will depend on local parameters such as geometry and thermals. It is not necessarily the filter face velocity.

d    Air changes per hour is the way that non-unidirectional and mixed airflow is specified. The suggested air changes are related to a room height of 3,0 meter.

e    Impervious barrier techniques should be considered.

f    With effective separation between contamination source and zones to be protected. Could be a physical or airflow barrier.

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# Design Concepts

$$Q = \frac{S}{\varepsilon \cdot C}$$

(for HEPA filtered supply air)

Q = air supply volume rate (m³/s)
S = total contamination units dispersion rate $n$/s (source)
ε = air change effectiveness index
C= required concentration ($n$/m³)

*Discussions are the values of S and ε and their accuracy.*
S depending on equipment, gowning, materials, cleaning
C values: target values during operation
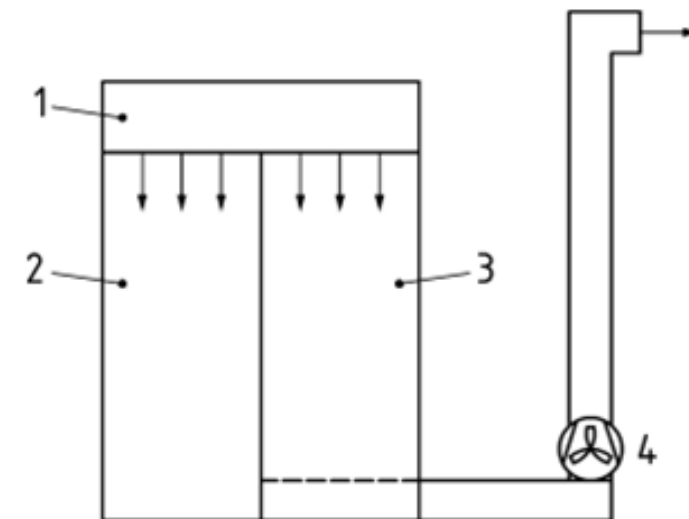
**S-values are hard to get and vary:**
Personel:
'body box' values ≠ 'operational values'

**ε- values complex to predict accurately**
*0,2 - 0,8*

**Key**

1  HEPA filter
2  changing area
3  body box
4  exhaust fan

# Design Concepts

$$Q = \frac{S}{\varepsilon \cdot C} - \boldsymbol{\beta \cdot Q_D - V_D \cdot A}$$

(for HEPA filtered supply air)

Q = air supply volume rate (m³/s)
S = total contamination units dispersion rate *n*/s   (source)
ε = air change effectiveness index
C= required concentration (*n*/m³)

*B   = the ventilation efficiency coefficient of the device (dimensionless)*
*$Q_D$ = the supply air volume flow rate of device (m3·s⁻¹);*
*$V_D$ = the particle deposition velocity (m·s⁻¹), which can be 0,0037 m·s⁻¹ for particles ≥ 5 µm*
    *and 0,0073 m·s⁻¹ for MCPs;*
*A   = the horizontal surface deposition area (normally the same as the floor) (m2).*

# Design Concepts

Studies ongoing and getting reported:
**More data as input to source strength!**

**Figure 4** *Particle concentration of different sizes for walking*

**Table 4** *Particle concentration emitted by human body in cleanrooms*

| Ref | Author | 0.5 µm | 5 µm | 0.5 µm/5 µm |
|---|---|---|---|---|
| [22] | Kurzeder et al. | 106 | 4 | 26.5 |
| [24] | Dastex et al. | 182 | 8 | 22.8 |
| [21] | Yang et al. | 7916 | 583 | 13.6 |
| [14] | Romano et al. | 5940 | 360 | 16.5 |
| [25] | Whyte et al. | 1020000 | 37300 | 27.3 |
| This study | Zhang et al. | 7051 | 695 | 10.2 |

Zhang F, Shiue A, Fan Y, Liu J, Meng H, Zhang J, Leggett G,
Dynamic emission rates of human activity in biological cleanrooms,
Building and Environment (2022), doi: https://doi.org/10.1016/j.buildenv.2022.109777.



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OCTOBER 11-13
ANTALYA / TURKIYE - 2022

**CLEANROOM DESIGN BY EQUATIONS ON SOURCE STRENGTH**

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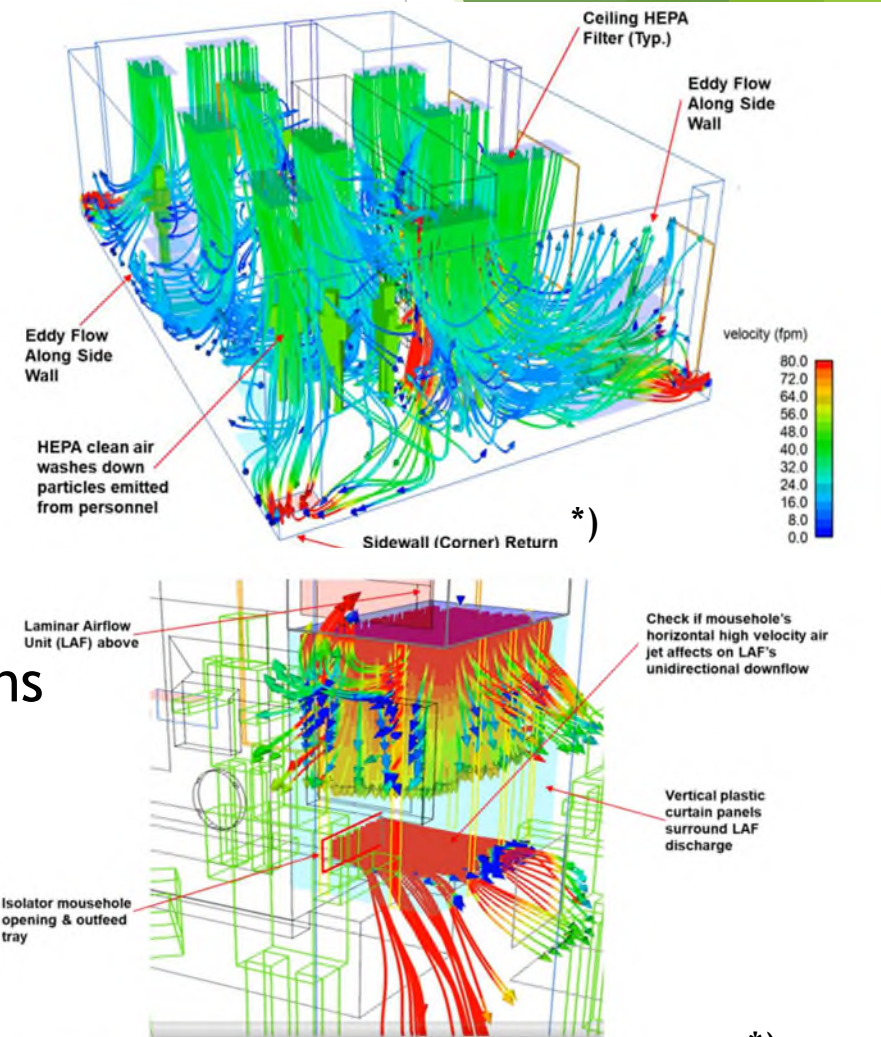
# Design Concepts

1. NON-UDF:

HVAC calculations:
- Heat dissipation, extracts, overflow, leakage
- Source strength based evaluation
- CFD supported

2. UDF:

- Good practice design: velocity, $\delta T$, flow guidance screens
- CFD supported

*) PDA "Cleanroom Contamination Prevention & Control"



Ceiling HEPA Filter (Typ.)

Eddy Flow Along Side Wall

velocity (fpm)
80.0
72.0
64.0
56.0
48.0
40.0
32.0
24.0
16.0
8.0
0.0

Eddy Flow Along Side Wall

HEPA clean air washes down particles emitted from personnel

Sidewall (Corner) Return        *)



Laminar Airflow Unit (LAF) above

Check if mousehole's horizontal high velocity air jet affects on LAF's unidirectional downflow

Vertical plastic curtain panels surround LAF discharge

Isolator mousehole opening & outfeed tray

*)

Figure 3 - Interaction between LAF Vertical Air Stream and Mousehole Horizontal Air Stream

# Design

Selection of materials:
    suitable, cleanable, resistant (abrasion/impact, chemical e.g.)
    repair, maintenance
    <span style="color:green">end of life recycling</span>

Layout

    Specific guidance:
    Air locks
    Changing rooms
    Workstation arrangement

# Sustainability

Emphasis on correct requirements:
- Do not over specify
- Do design accordingly
- Use current energy directive requirements
- Consider energy efficiency measures: (ISO-14644-16)
- End of life recycling

'First time right' by project phasing and reviews

# Sustainability

- Energy efficiency: (ISO-14644-16)
    - Turn-down
    - Tunability

Based upon actual operational levels
- Feedback for 'total source strength'
- Feedback to tune

Possibility:
Direct control based upon concentration e.g. LSAPC.

# Construction

Planned and organized
- Quality
- Clean build protocol
- Verifications
- Documentation

# Clean built protocol



Cleanliness and cleaning during construction to start-up:
Considering
- Construction related activities
- Material that enters the site from the outside environment
- Material that proliferates due to inadequate cleaning practices and waste removal

Clean Build Protocol Development

Clean Build Protocol Implementation

# Start-up

Setting to work

Functional and performance verifications

Training

Handover

Documentation (additional to design & construction as-built documents)
    commissioning
    instructions on performance monitoring
    maintenance instructions

# Take home message

- Phasing project development
- All cleanliness attributes (if applicable)
- Flow/pressure cascade ← 'room pressure'
- Calculations:
   Source strength + airflow ← 'Air Change Rates'
- Clean built protocol

*More sustainable: Design, Construction, Start-up ➔ Operation!*

Aknowledgments:

The ISO TC209 WG4 experts team!!