The impact of Cleanroom Operation on Contamination Risk

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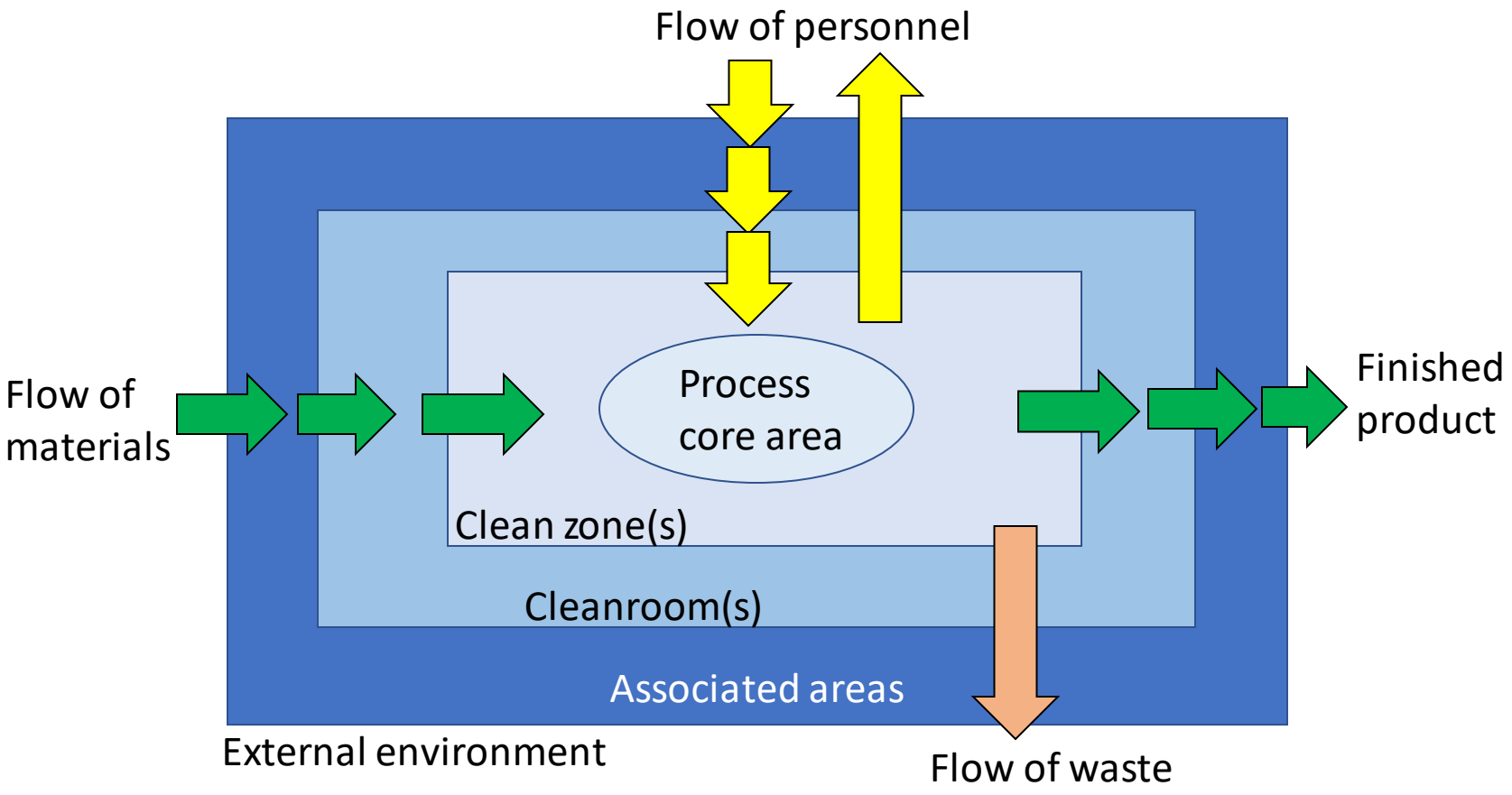
Contamination control requirements

- Risk assessment
  - Potential harm by amount, size, type of contamination
  - Means and moment of transfer by deposition and contact
- Contaminants
  - **Particles**
  - Chemical
  - Micro-organisms
- Requirements for
  - **Air cleanliness**
  - **Surface cleanliness**
  - Materials
- Measurement method(s)
  - Verification
  - Monitoring

Contamination control concept



Establish control

- Facilities for intended use:
  - Number of people
  - Process equipment
- Cleanroom installation:
  - Air cleanliness level
- Operational procedures:
  - Particle deposition rate:
    - Entry and exit of people, materials and equipment
    - Cleaning program
    - Working methods
- Verification.

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Operations by people

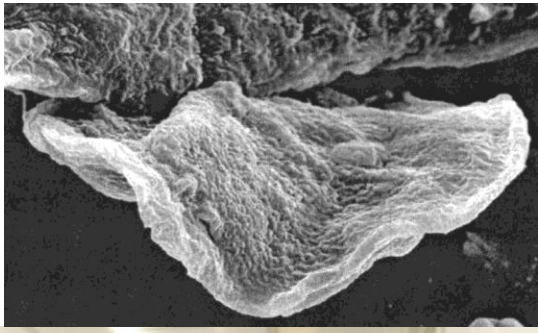
- People are needed in a cleanroom to:
  - execute complicated activities
  - perform logistic activities
  - observe processes
  - make decisions
  - check quality
  - perform activities that cannot be automated
  - or executed by a robotic system economically

- Need for operational procedures.

Contamination by people

People:

- generate particles (and micro-organisms)
- eject saliva droplets
- carry particles (and chemicals)
- distribute particles
- make contact various surfaces
- cause cross contamination.



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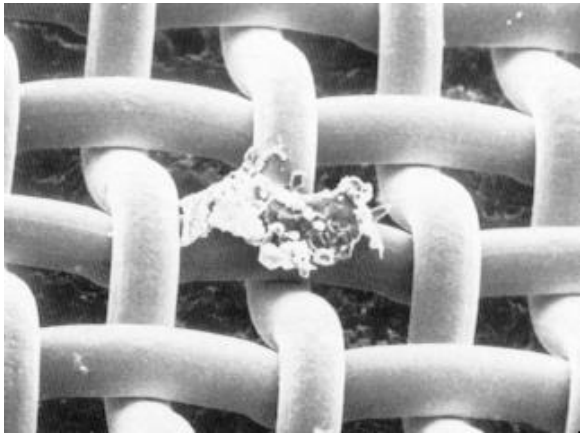
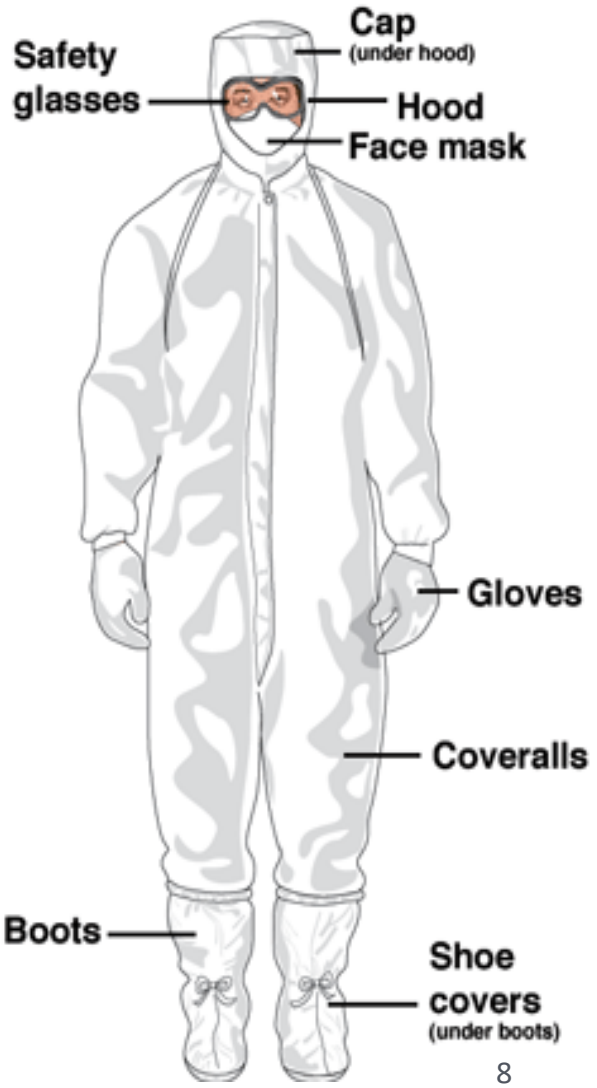
Garments

- Type of garments
- **Changing procedure** into and out of cleanroom
- **Cleanliness changing room**
- Number of people using changing room
- Cleaning
- Packing
- Logistics
- Frequency of use





Estimated particle emission from a person

Estimated emission of particles by people

Person	Emission of particles per minute			Particle deposition per minute		
	0.5	1	5	25	50	100
in street clothes	10 000 000	5 000 000	1 000 000	200 000	100 000	50 000
in cleanroom coat + shoe/head cover	2 000 000	1 000 000	200 000	20 000	10 000	1 000
in coverall	500 000	250 000	100 000	1 000	100	20
in under garment, coverall + googles	100 000	50 000	5 000	50	5	2
Control by	**Removal by dilution and air flow**			**Removal by cleaning**		
Example in 5m x 5m x 4m room	10 air changes ->		100 -> ISO 6 (class 1 000) particles ≥5µm	Particle Deposition Rate of particles ≥ 50 µm/m^2/hr		240

Establishing control for ISO class can still give problems because of high Particle Deposition Rate!

Changing procedure

- Dress from top to bottom (no touching the floor – no touching outside garment).
- Taking off garments is as important as putting them on when re-used.
- Separation incoming and outgoing personal.
- The changing room should be cleaned more frequent than the cleanroom.
- Difference between cleanrooms for technical products or services and cleanrooms for the control of microbiological contamination:

Technical	Mirco biological
Re-use of garments	Single use of garments
Shoe covers and hair covers used under garment	Cleanroom under garments sometimes used
No gloves used when changing	Gloves used for changing
Sometimes face mask used and no goggles are used	Face mask and goggles used

Cleaning to keep surface cleanliness within limits

- Contamination mechanisms are:
  - Particle deposition rate (affected by air and surface cleanliness),
  - Particle transfer by contact (affected by surface cleanliness).
- The cleanroom installation removes the airborne particles (≤ 5 µm and partly < 25 µm).
- By cleaning particles ≥ 5 µm can be removed.
- A cleaning program consists of a program executed by
  - the cleaners and
  - the people working in the cleanroom.
- The total number of particles on all surfaces have an impact on the contamination of products (-> source).

Operational procedures

- Entrance and exit procedure for people:
  - Type of garments and accessories
  - Re-use of garments
  - Changing procedure
  - Lay out of changing room.

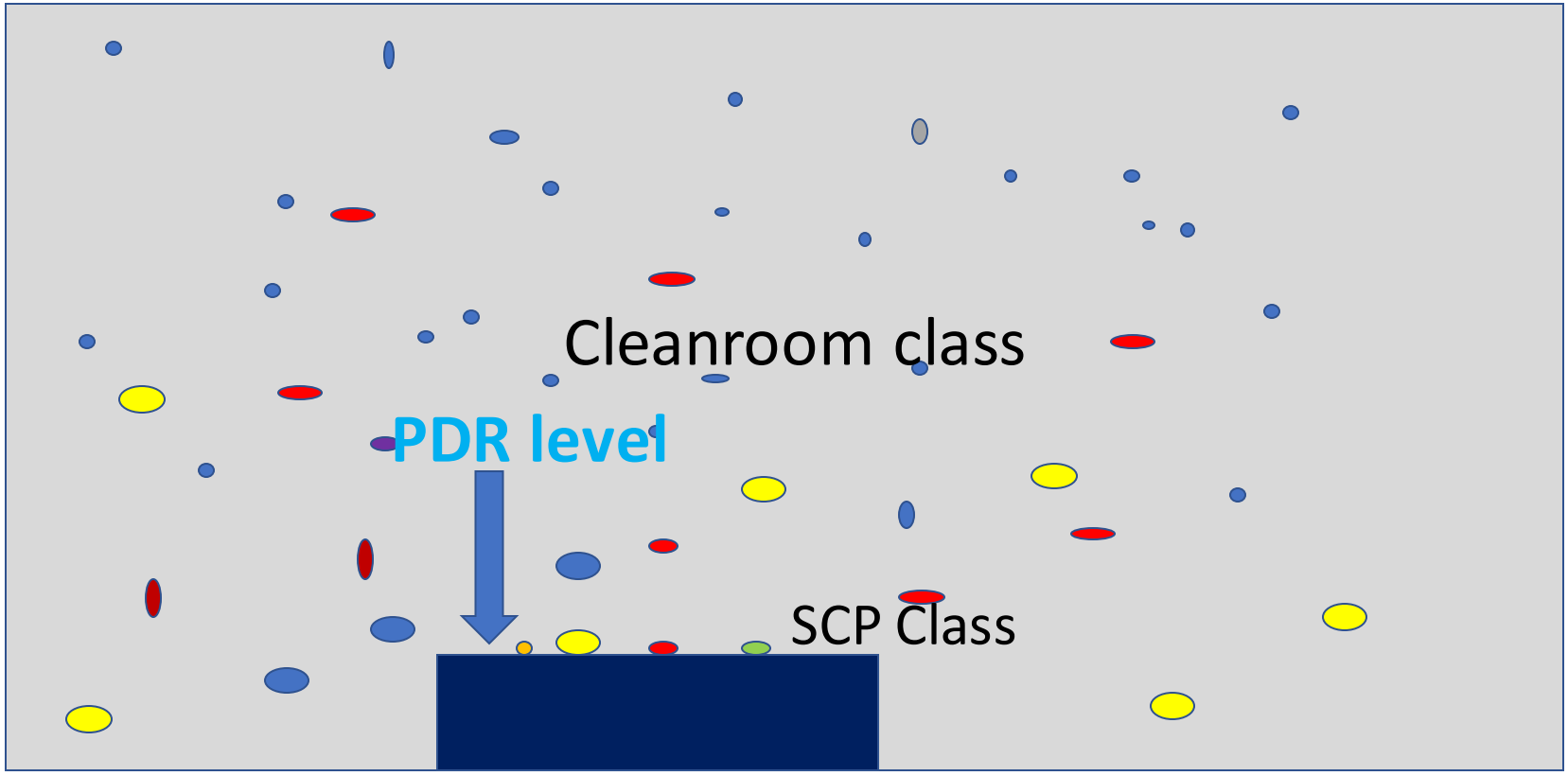
- Entrance and exit procedure for goods
  - Lay out of goods transfer room (2 or 3 stage).
- Working procedure
  - Lay out of cleanroom and production process.
- Cleaning program by cleaners and operator
  - Logistics and facilities for cleaning.

Cleanroom behavior

Operator impact on the operational quality and thereby the contamination risk

- Training
- Motivation
- Personal hygiene
- Execution changing procedure
- Execution of transfer procedures
- Execution working procedures
- Gathering in neighborhood of vulnerable product surfaces
- Movements (careful walking, arm and hand movement)
- Position opposite vulnerable product surface (arm movements, talking, coughing etc.).

Relation between Air and Surface cleanliness



ISO Cleanroom Class: Air Cleanliness by Particle concentration
SCP: ISO Surface Cleanliness by Particle concentration Class
PDR: Particle Deposition Rate Level

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Air Cleanliness and Surface Cleanliness

- Cleanroom installation
  - To meet required cleanroom class (ISO 14644-1 or Federal Standard 209:1999) for particles ≥ 0.5 µm.
- Operational procedures to meet required:
  - Air cleanliness (ISO 14644-2) and
  - Particle Fall Out limit (IEST STD CC1246E) and/or
  - Particle Deposition Rate Limit (future ISO14644-17)
    - Procedures for incoming flow of people and materials
    - Cleaning program
    - Working methods
  - Surface cleanliness according to IEST STD CC1246E or ISO 14644-9.

Demonstrate control by monitoring

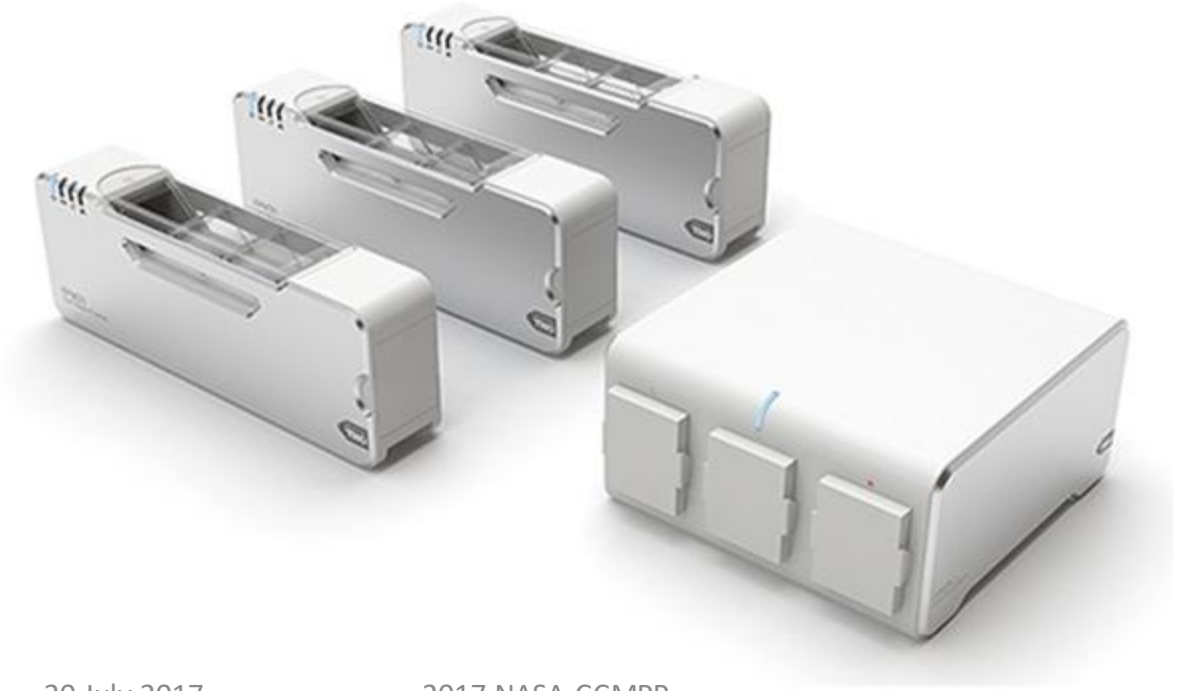
At critical locations:

- Monitor airborne particle concentration of particles ≥ 5 µm with a light scattering airborne particle counter to demonstrate the efficiency of the cleanroom installation during operation.
- **Monitoring deposition of macroparticles > 10 or 20 µm** to gather information on both air and surface cleanliness and the risk of product contamination (by particles).
- **Real-time monitoring of the particle deposition rate provides details on the operational quality of a cleanroom.**
- Monitoring of surface cleanliness demonstrates the effectiveness of the cleaning methods and frequencies.

Real-time particle deposition rate monitoring

Sensors (in situ and real time)

- APMON (obscuration, counting and sizing)
  - See also presentation Jan Gerbrands (Technology of Sense)



Real time particle obscuration monitor

- Image analysis of holographic image differences per time interval gives:
  - Number of particles
  - Size of particles
  - Particle area's (largest horizontal cross section of particle)
- These data provide:
  - Overview of deposition events
    - Coverage per period
    - Cumulative coverage and POR
    - Number of particles > 15 µm per period
    - PDR
  - Differential particle size distribution
  - Cumulative particle size distribution

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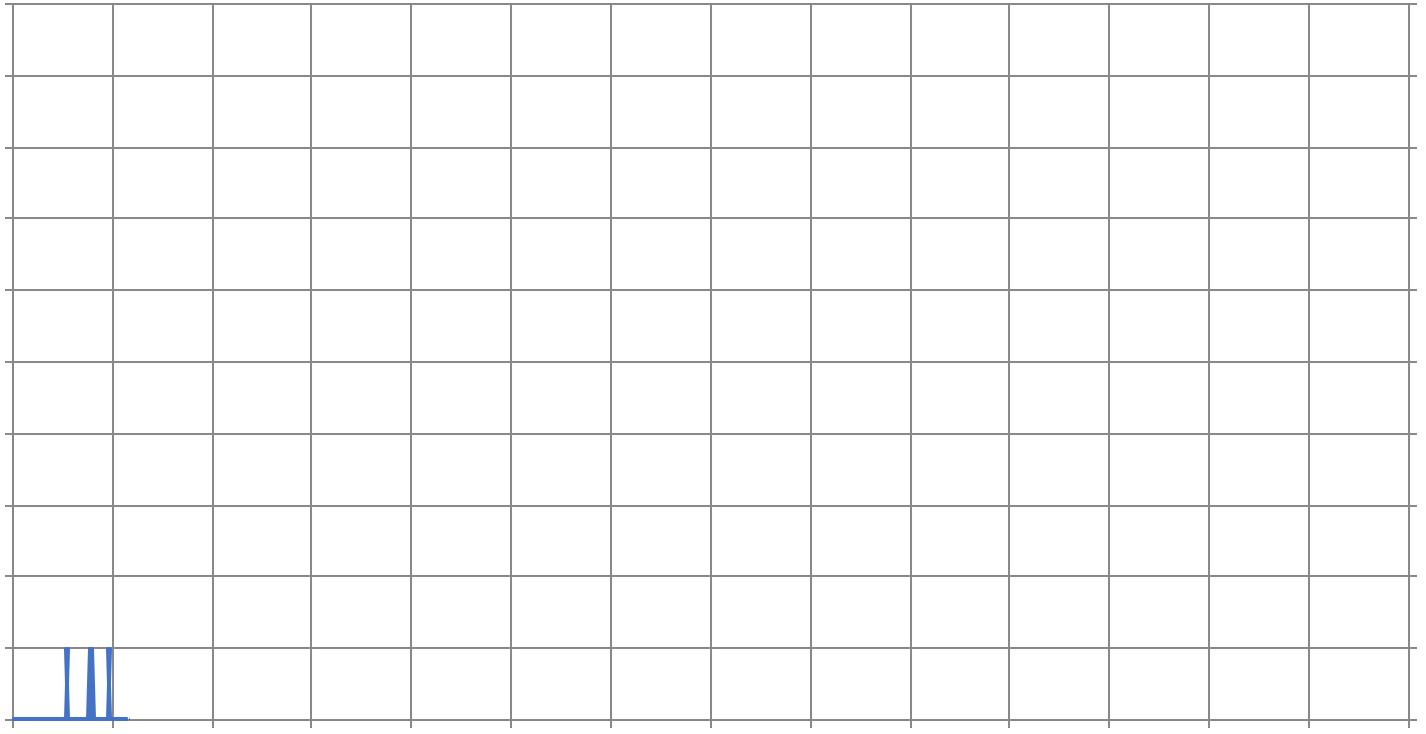
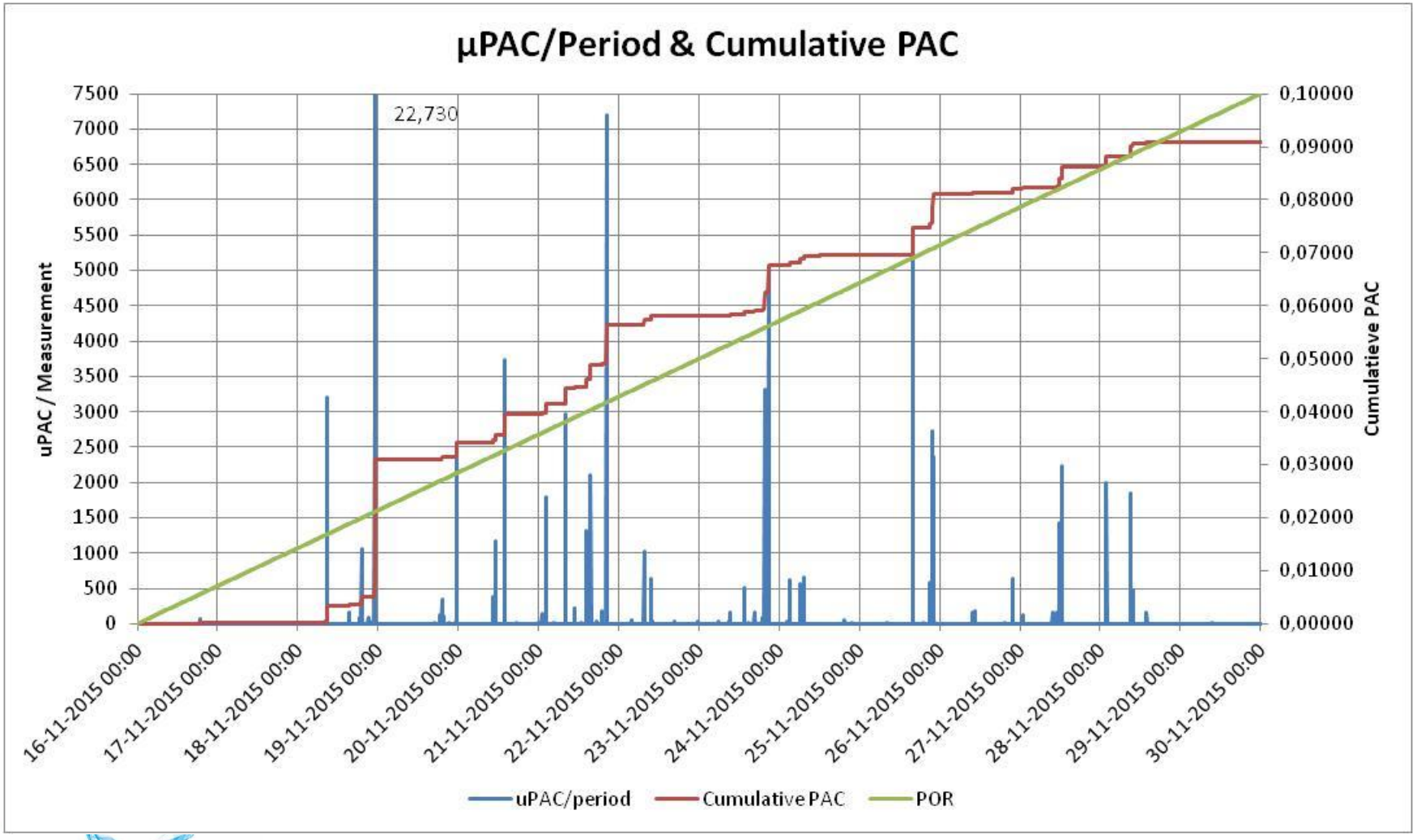
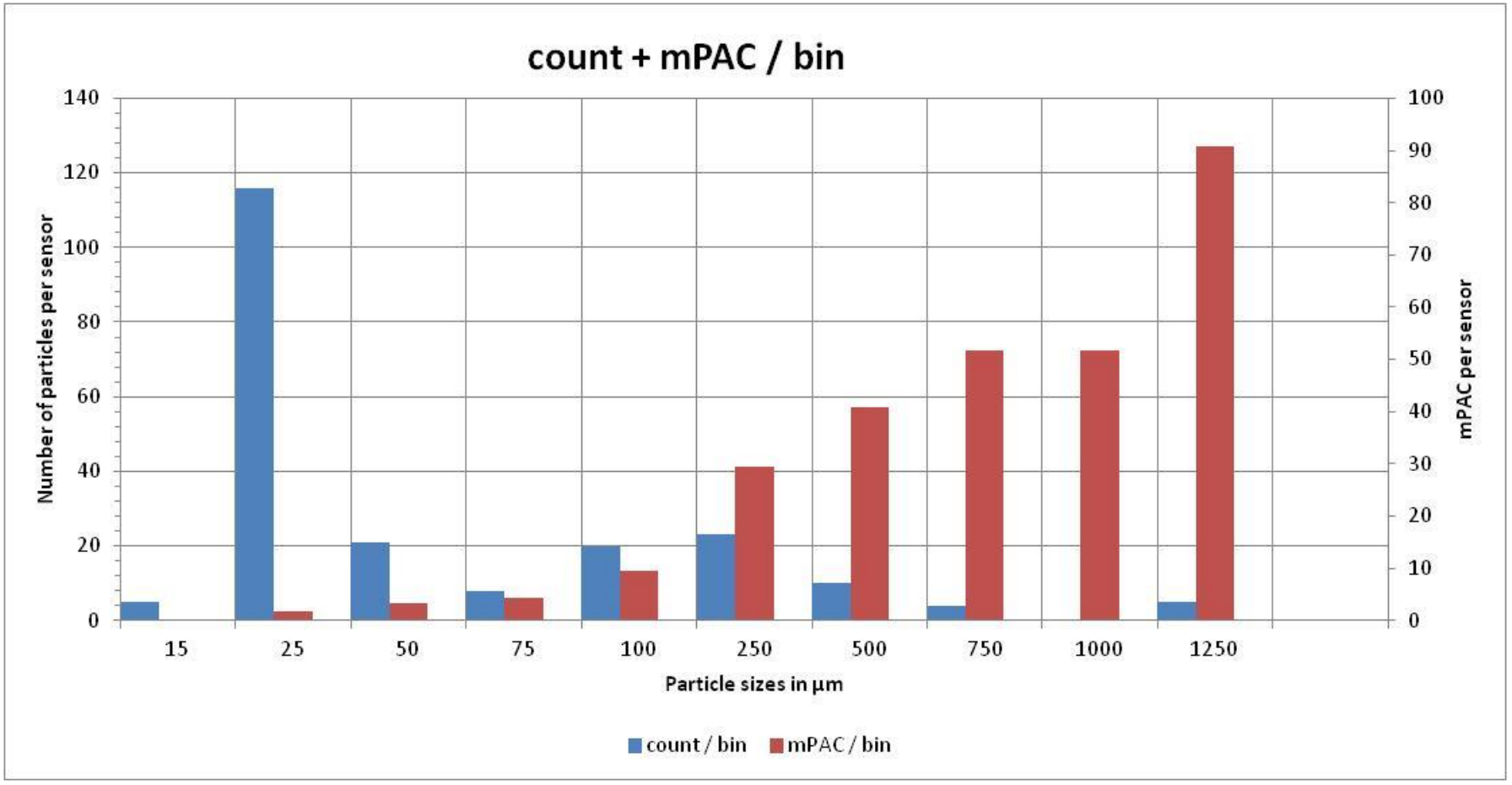
Real-time particle deposition



Real-time obscuration



Differential particle and obscuration distribution on sensor



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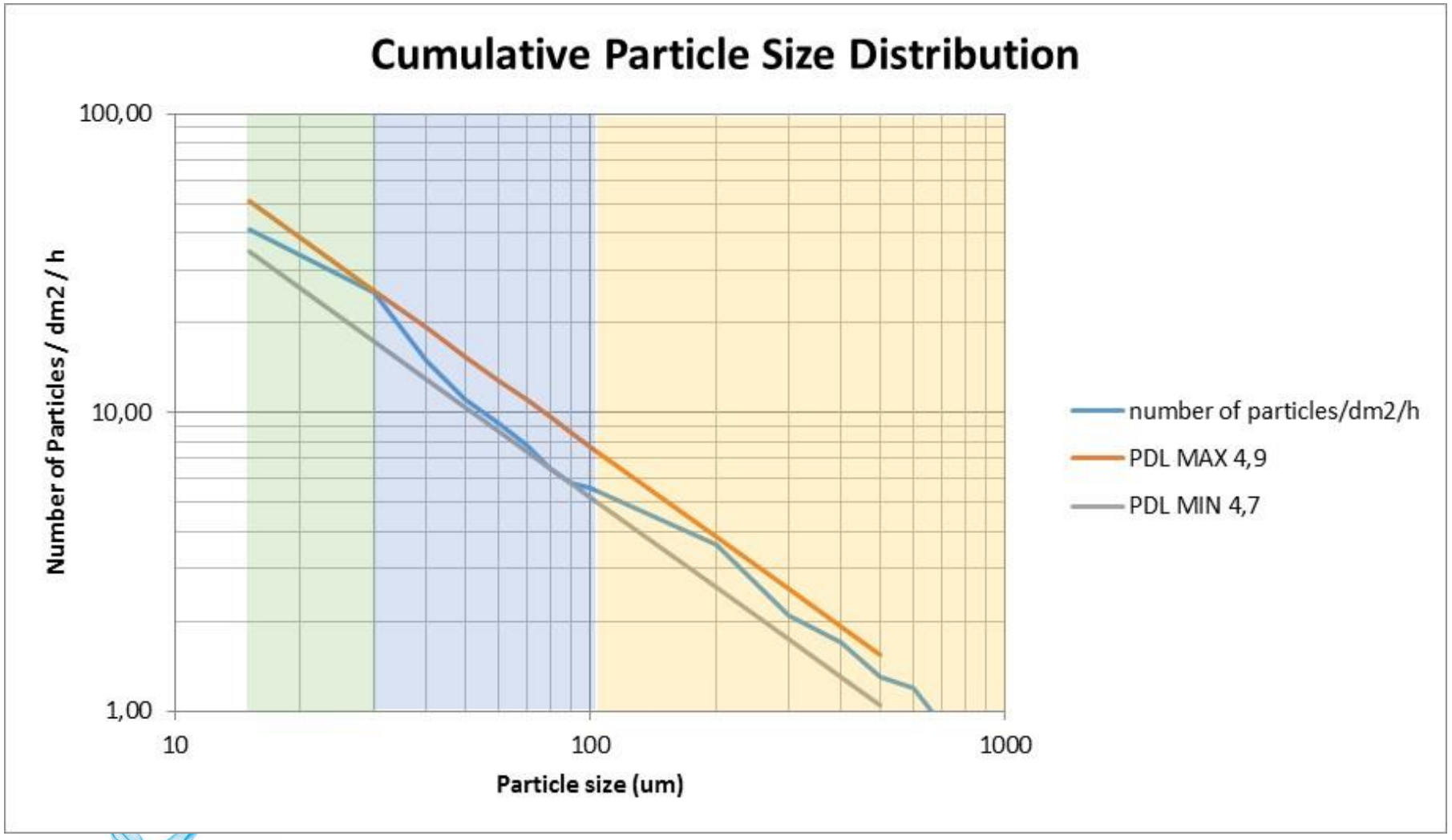
Cumulative particle size distribution



Monitoring Surface Cleanliness

- The MOSC of Technology of Sense is a sensor that measures the surface cleanliness directly
- MOSC details are:
  - Area 9 cm^2
  - Particles ≥ 20 µm
  - UV fluorescent particles only
  - Wireless
- Indirectly by pickup rubber
  - Measurement by particle microscope

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Operational quality of a cleanroom

The operational quality of a cleanroom location determines the risk of product contamination

- Cleanroom installation removes airborne particles.
- People cause deposition of macro-particles on all surfaces.
- The Particle Deposition Rate can be reduced by improvement of:
  - Discipline
  - Cleaning of large surfaces;
  - Cleaning of work benches, equipment and tools.
- The impact of the operational quality can be measured by:
  - Airborne particle counters (particles ≥ 5 µm);
  - Particle Deposition Rate monitors (particles > 10 µm);
  - Particle Obscuration Monitor (in ppm area coverage);
  - Surface cleanliness monitor

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