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Realising Potential.

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RECOGIZER
Self-Learning Building Solutions

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CENTRE of EXCELLENCE
HEALTHCARE & LIFE SCIENCES

DBCA Dutch Building Commissioning Association

vccn

CTCB-I

ICCCS Accredited Education

ISO

Introduction

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- State of affairs regarding ISO TC 209 WG 15 Airborne particle sampling techniques

- What do we aim to achieve?
  - Guidance to good practise
  - Classification versus Monitoring
  - Collecting samples
  - Application examples

- Why have a Technical Report in the first place?

Cleanrooms and associated controlled environments

ISO 14644 series

Part 1, Class. of air clean. by particles
Part 2, Continued compliance with part 1
Part 3, Test methods
Part 4, Design, construction and start-up
Part 5, Operations
Part 6, Vocabulary
Part 7, Separative devices
Part 8, Assessment. of air clean. by chemicals
Part 9, Assessment of surface clean. by particles
Part 10, Class. of surface clean. by chemicals
Part 12, Nanoparticles
Part 13, Cleaning of surfaces
Part 14, Assessment of suitability for use of equipm. by airb. particle conc.
Part 15, Assessment of suitability for use of equipm. and materials by airb. chemical conc.
Part 16, Energy efficiency
Part 17, Particle deposition

Setting the scene
What defines a cleanroom

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3.1.1

cleanroom

room within which the number concentration of **airborne particles** is **controlled** and **classified**, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room.

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

Setting the scene
Where we don't want to be

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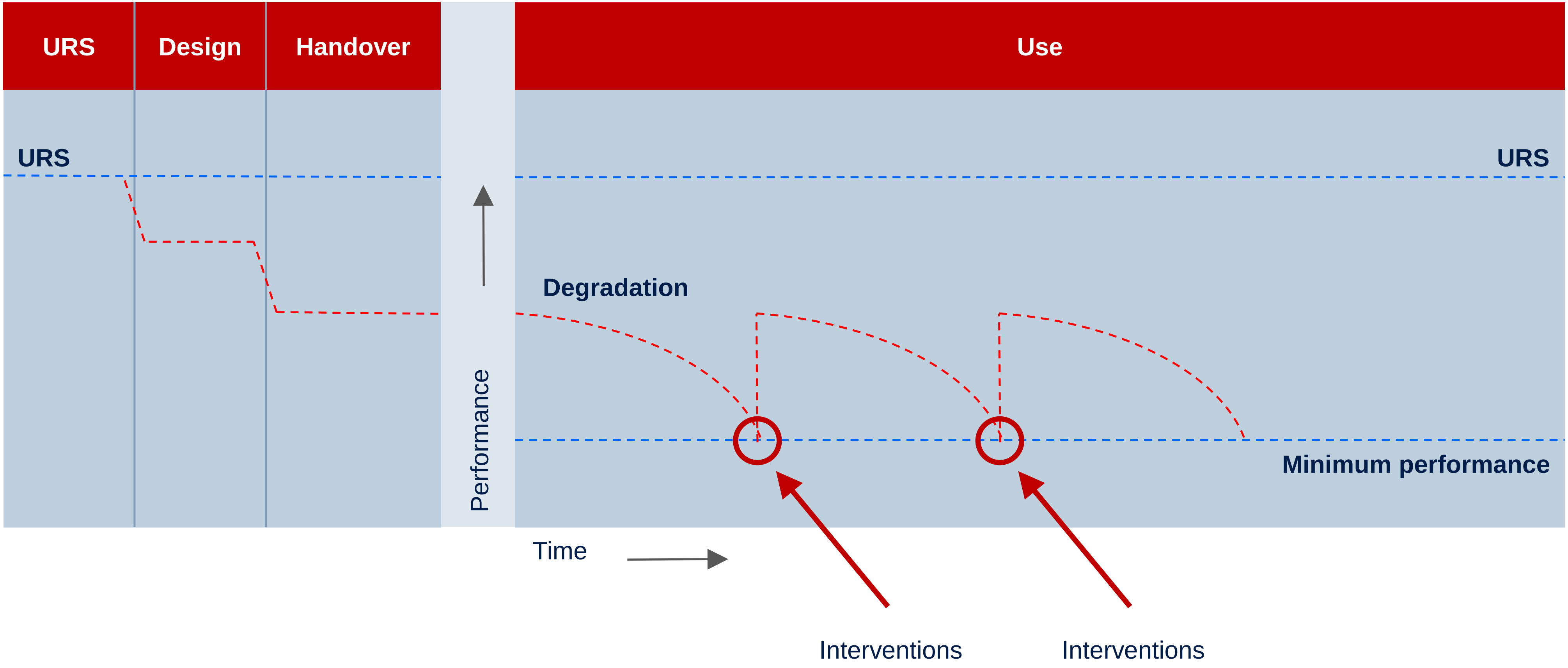
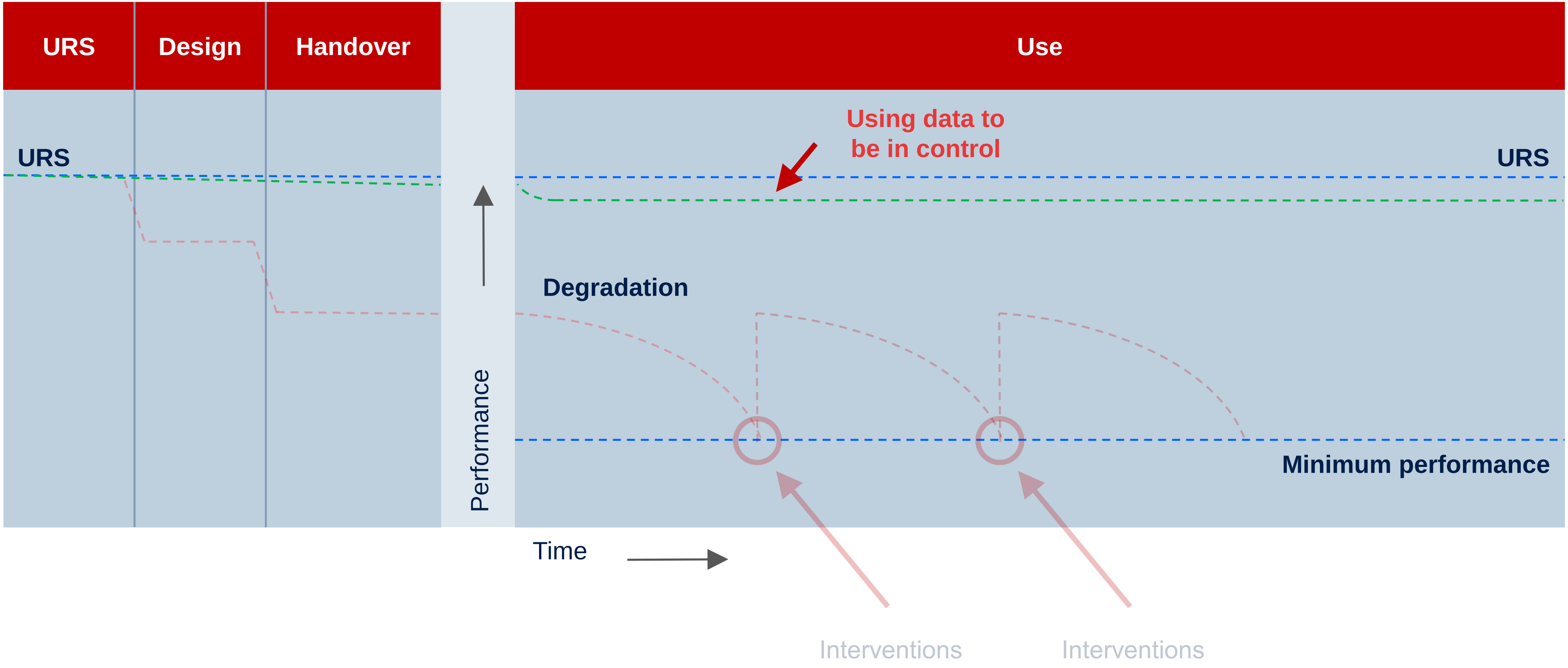


Setting the scene
Where we would like to be



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Ensuring it can work

Demonstrating it actually works

Classification

Monitoring

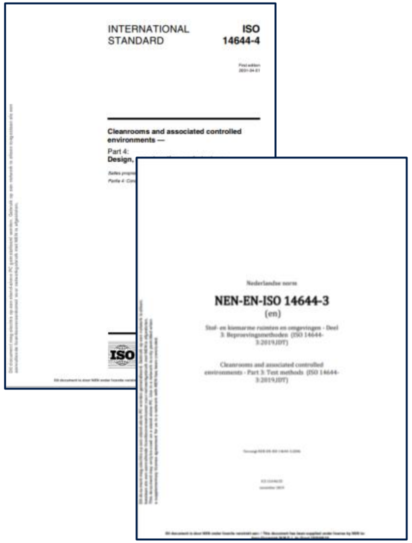
Commissioning
- Building
- Mechanical Systems
- Electrical Systems
- Plumbing Systems

Performance Testing
- Indoor environmental performance
- Energy performance

Establishing control

Demonstrating control

ISO TC 209 WG 15
Classification vs Monitoring



Classification

(Quality of sample)

Occupancy states

As built

At rest

Operational

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (*N*)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below[a]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	*10*[b]	d	d	d	d	e
2	100	*24*[b]	*10*[b]	d	d	e
3	1 000	237	102	*35*[b]	d	e
4	10 000	2 370	1 020	352	*83*[b]	e
5	100 000	23 700	10 200	3 520	832	d, e, f
6	1 000 000	237 000	102 000	35 200	8 320	293
7	c	c	c	352 000	83 200	2 930
8	c	c	c	3 520 000	832 000	29 300
9[g]	c	c	c	35 200 000	8 320 000	293 000

[a] All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.

[b] These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see Annex D.

[c] Concentration limits are not applicable in this region of the table due to very high particle concentration.

[d] Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

[e] Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

[f] In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See C.7.)

[g] This class is only applicable for the in-operation state.

Sample volume

$$V_s = \frac{20}{C_{n.m}} \cdot 1.000$$

Table A.1 — Sampling locations related to cleanroom area

Area of cleanroom (m²) less than or equal to	Minimum number of sampling locations to be tested (N_L)
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21
232	22
276	23
352	24
436	25
636	26
1 000	27
> 1 000	See Formula (A.1)

NOTE 1 If the considered area falls between two values in the table, the greater of the two should be selected.

NOTE 2 In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the horizontal plan area of the cleanroom or clean zone.

ISO TC 209 WG 15
Classification vs Monitoring

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Classification


Nederlandse norm

NEN-EN-ISO 14644-1
(en)

Stof- en kiemarme ruimten en omgevingen - Deel 1: Indeling van luchtreinheid door het concentreren van deeltjes (ISO 14644-1:2015,IDT)

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015,IDT)

Vervangt NEN-EN-ISO 14644-1:1999; NEN-EN-ISO 14644-1:2010 Ontw.

ICS 13.040.35
januari 2016

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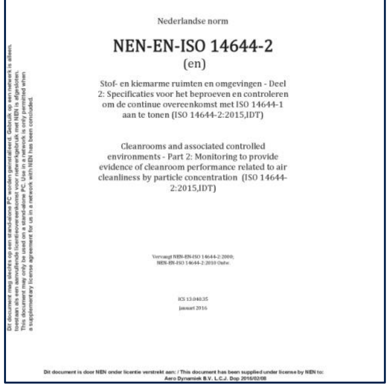
(Quality of sample)

Monitoring


Nederlandse norm

NEN-EN-ISO 14644-2
(en)

Stof- en kiemarme ruimten en omgevingen - Deel 2: Specificaties voor het beproeven en controleren om de continue overeenkomst met ISO 14644-1 aan te tonen (ISO 14644-2:2015,IDT)

Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015,IDT)

Vervangt NEN-EN-ISO 14644-2:2000; NEN-EN-ISO 14644-2:2010 Ontw.

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(Quality of data)

- Monitoring plan
- Matters to consider when developing a monitoring plan
- Considerations for setting alert and action levels

3.2

Monitoring

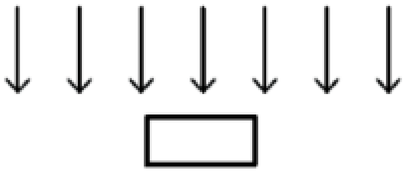
observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation

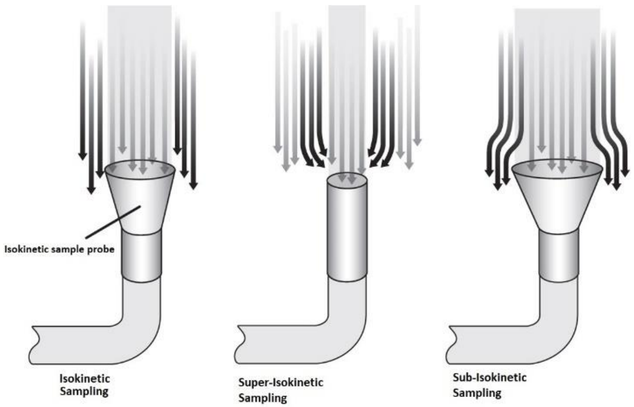
Note 1 to entry: Monitoring may be continuous, sequential or periodic and if periodic, the frequency shall be specified.

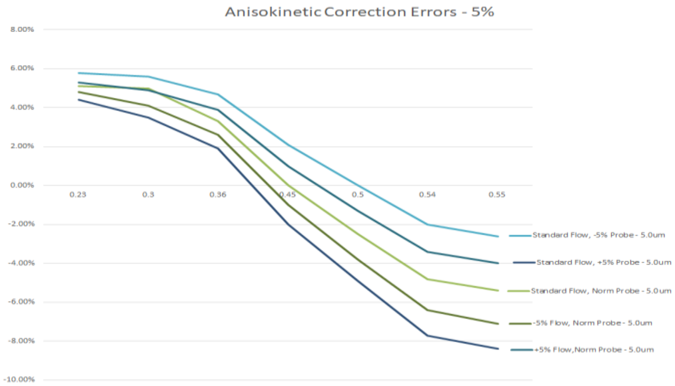
Note 2 to entry: This information may be used to **detect trends** in operational state and to provide process support.

ISO TC 209 WG 15
Collecting samples – isokinetic sampling

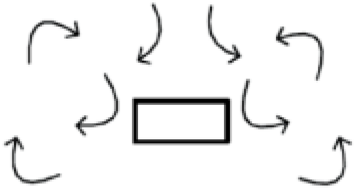
Unidirectional





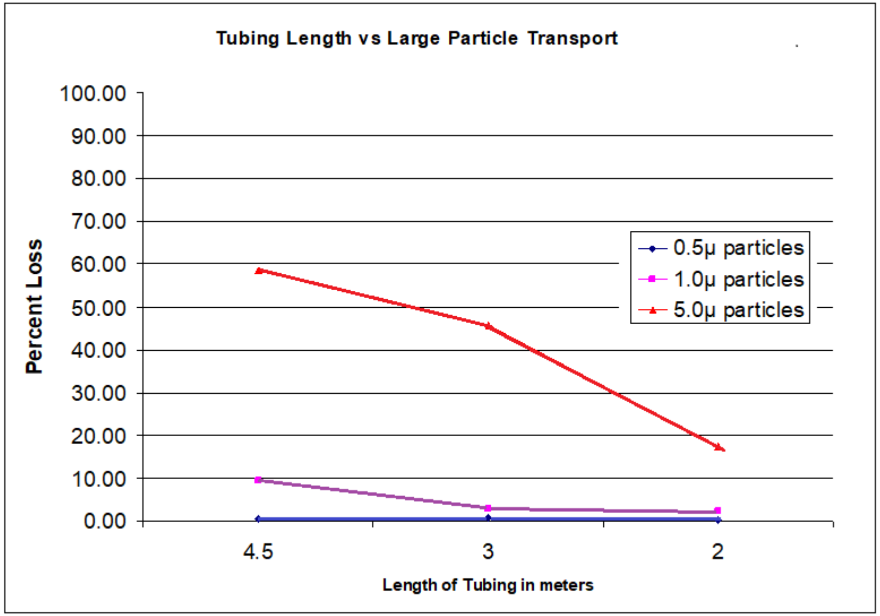


Non-unidirectional



ISO TC 209 WG 15
Collecting samples – sample tubing

- Tubing length
  - As short as possible
  - Turbulent flow inside
- Tubing bends
  - As little as possible
  - As wide as possible
- Tubing material
  - As smooth as possible
- Other considerations
  - Fittings
  - Valves



Collecting samples – guidance

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Probe orientation

Unidirectional airflow

Non-unidirectional airflow

Tubing length

Sampling particles > 5.0 µm

< 1 m length

< 2 m length

Tubing bends

< 2 bends (r ≥ 150 mm)

< 3 bends (r ≥ 150 mm)

No assessment necessary
Connect ISP to LSAPC with or without tubing

Additional assessment recommended
Evaluate potential losses with attaching ISP to LSAPC with tubing

Additional assessment required
Evaluate and assess impact of particle loss in tubing

ISO TC 209 WG 15
Collecting samples – guidance

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Additional assessment recommended
Evaluate potential losses with attaching ISP to LSAPC with tubing

- Less impactful installation
- Review transit loses
- Review alert and action thresholds
- Review historical data
- Use of rigid type conduit
- Consider installation tools
- Consider larger diameter tubing excessive number of bends exist.
- Consider maintaining and cleaning tubing

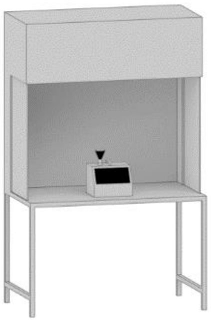
Additional assessment required
Evaluate and assess impact of particle loss in tubing

- Less impactful installation
- Review transit loses
- Perform transit loss testing if documented review is considered excessive (>20%)
- Review alert and action thresholds
- Review historical data
- Use of rigid type conduit
- Consider installation tools
- Consider larger diameter tubing where excessive number of bends exist.
- Consider maintaining, cleaning or renewing tubing
- Perform particle loss engineering studies

Application examples

Situation 1

Direct measurement

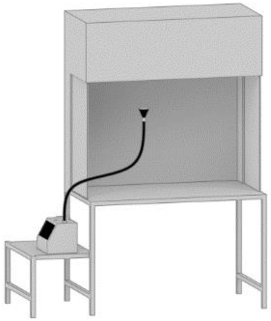


No assessment necessary

Situation 2

Limited tube length

Limited bends

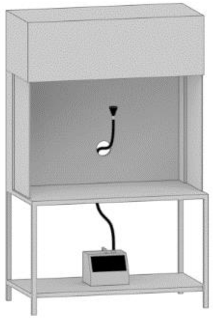


Additional assessment recommended

Situation 3

Considerable tube length

Multiple bends



Additional assessment required

ISO TC 209 WG 15
Special thanks to...

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