TOWARDS ZERO INFECTIONS

Update on coming EU standard for hospital ventilation

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Innovation company – yet proven for 10 years

• Towards zero infections
• Minimizing surgical infections while creating a pleasant work environment that saves energy
• Opragon™ product line
• Market leader in Sweden
• The Netherlands, Germany, Switzerland, Denmark, Norway, US, Ukraine, India
• Headquarters and advanced lab in Lund, Sweden
• Strong owners
Why standards?

• Standards facilitate everyday life
• One market in EU
  – Larger market benefits consumers and companies
• Increasing safety by promoting quality of care
• Sharing of best practise
• Ensuring compatible and interoperable systems
Why a hospital ventilation standard?
Europe demands ultra-clean air

- Defined as <10 CFU/m³
- Based on studies by Lidwell
- Required for infection sensitive ORs
- Some use ultra-clean air in all ORs (future-proofing)
- Driven by northern/western Europe
- Written into coming EU standard for OR ventilation
New EU Standard - Ventilation in Hospitals (CEN/TC 156 - WG18)

• Design, classification, operation and maintenance of ventilation systems for hospitals
• Adds to general ventilation standards
• Will replace any national standards
• Contents
  – Technical Specification (approved)
    • prCEN/TS 16244
  – Part 1 – General Requirements
  – Part 2 – Operating Suites
  – Part 3 – Isolation Rooms
Part 0 - Technical Specification

- Approved
- Sets scope for standard work
- Sets preliminary definitions
- Defines design, construction and operation process and requirements
Part 1 – General Requirements (final review)

- Terms, definitions and abbreviations
- Organising of design, construction and operations incl maintenance
  - Specifications
  - Verifications
- Minimum design criteria
- Requirements of components
- Project phases
Part 1 – Same process for all projects

- URS – User Requirement Specification
- FD – Functional Design
- DD – Detailed Design
- IQ – Installation Verification (main components)
- OQ – Operational Verification (air quality)
- PQ – Performance Verification (human safety)
- Note: IQ, OQ, PQ will become IV, OV, PV
Part 2 – Operating Suites (discussions remain)

- Main goal to minimize infections by having less than 10 cfu/m3
- Working comfort
- Energy conservation

- Two air cleanliness levels
  - Ultra-clean (<10 cfu/m3)
  - Clean (<100 cfu/m3)
Part 2 – Operating Suites (discussions remain)

- Two systems
  - Tubulent Mixing
  - Protected Zone
- Different verification for each type of system
  - TM: Recovery text (<10 min)
  - PZ: Segregation test
  - Note: Bacteria measurement an alternative
    - TS39 (SIS)
  - May need National Annexes
Part 3 – Isolation units (final review)

- URS
  - Recovery time, Waiting time in airlocks, ACH, Supply Air Quality, Exhaust Filtration, Dampers, Air tightness of isolation unit, Duct tightness
- Functional Design
- Detailed Design
- Testing, commissioning, documentation
- Annex: Dilution factors
Denmark is welcome

• Access to working documents only to members of the WG
• Denmark may join via Dansk Standard
  – Option to join via SIS (Sweden) that has an active group
• Important – remember why it is needed!
  – Less infections
  – Working comfort
  – Energy