TOWARDS ZERO INFECTIONS

Update on coming EU standard for hospital ventilation

17 August 2018, Virum (DK), Peter Højerback

AVIDICARE

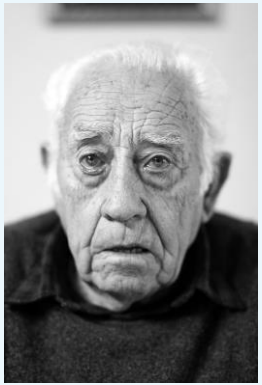
Innovation company – yet proven for 10 years

- 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

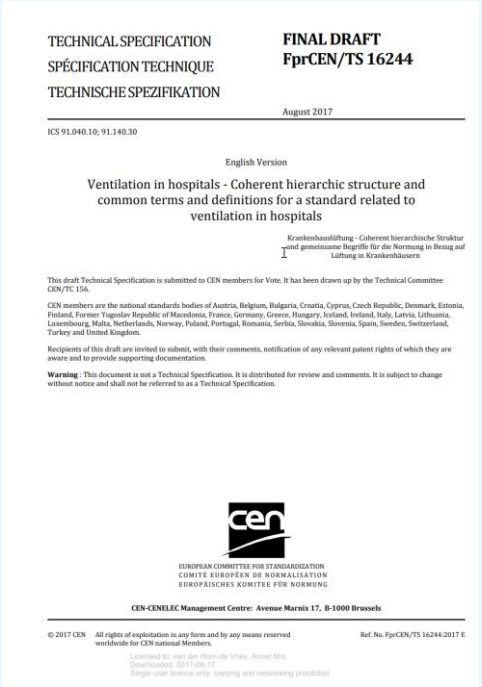
- Defined as <10 CFU/m^3
- Based on studies by Lidwell
- Required for infection sensitive ORs
- Some use ultra-clean air in all ORs (future-proofing)
- Driven by northern/western Europe
- Written into coming EU standard for OR ventilation

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 defintions
- Defines design, construction and operation process and requirements



TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

FINAL DRAFT
FprCEN/TS 16244

August 2017

ICS 91.040.10; 91.140.30

English Version

Ventilation in hospitals - Coherent hierarchic structure and common terms and definitions for a standard related to ventilation in hospitals

Krankenhauslüftung - Coherent hierarchische Struktur und gemeinsame Begriffe für die Normung in Bezug auf Lüftung in Krankenhäusern

This draft Technical Specification is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 156.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a Technical Specification. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a Technical Specification.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. FprCEN/TS 16244:2017 E

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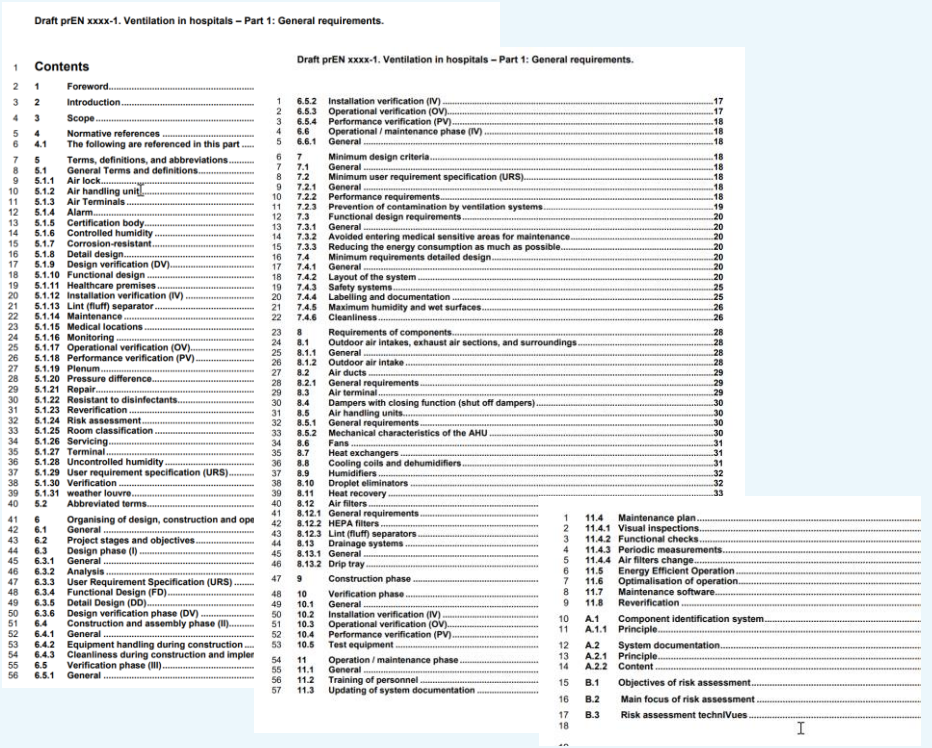
Part 1 – General Requirements (final review)

- Terms, definitions and abbreviations
- Organising of design, construction and operations incl maintenance
  - Specifications
  - Verifications
- Minimum design criteria
- Requirements of components
- Project phases

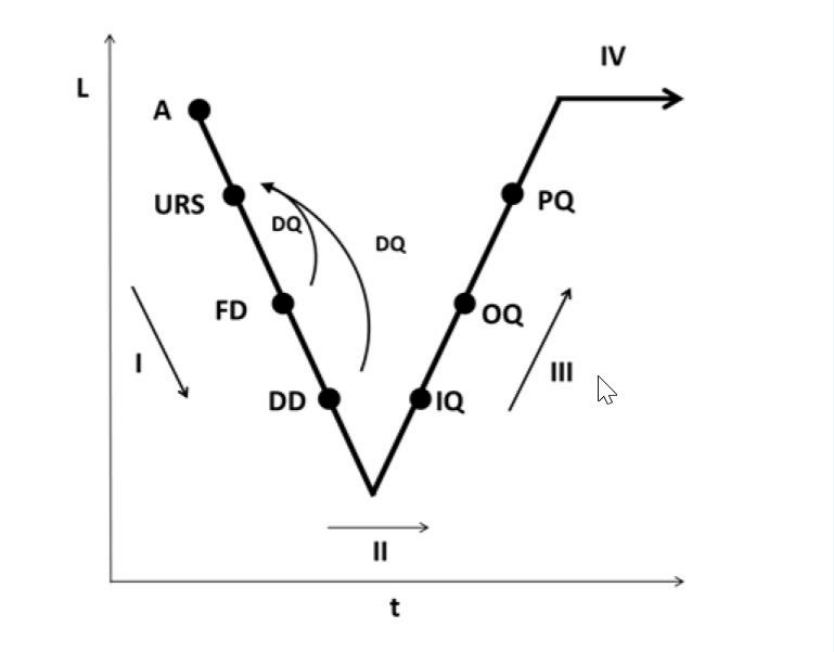


Draft prEN xxxx-1. Ventilation in hospitals – Part 1: General requirements.

Contents

Draft prEN xxxx-1. Ventilation in hospitals – Part 1: General requirements.

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

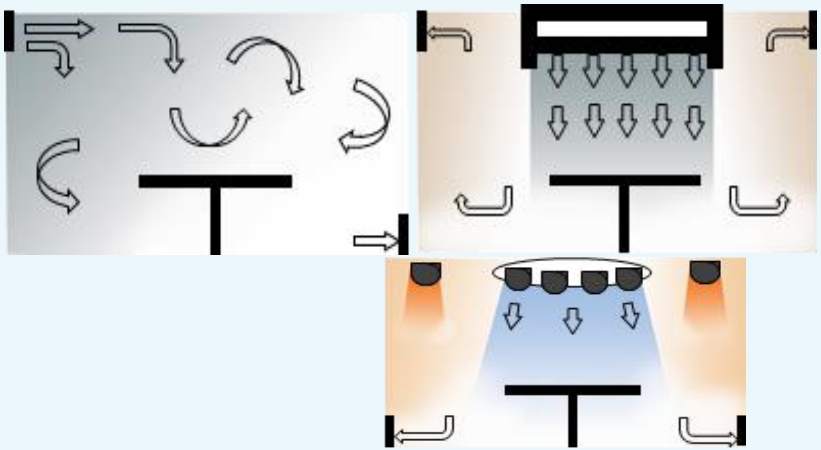
Part 2 – Operating Suites (discussions remain)

- 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)

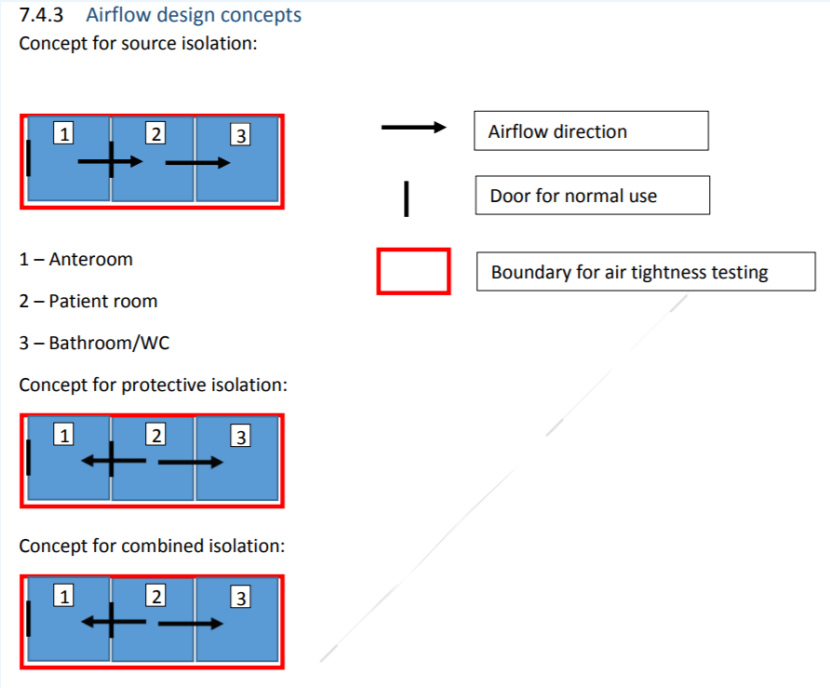
Part 2 – Operating Suites (discussions remain)

- 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



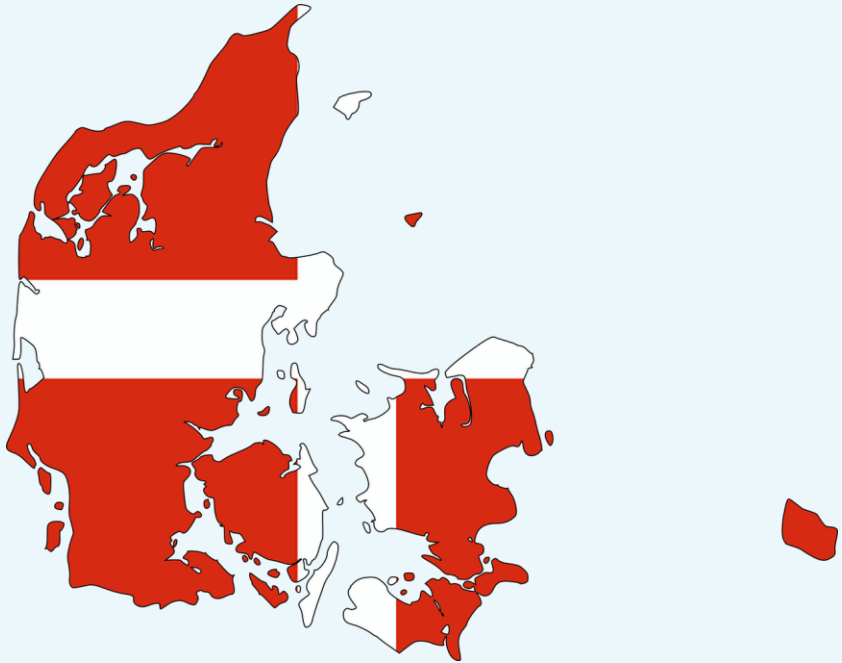
Part 3 – Isolation units (final review)

- 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



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