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TECHNICAL SPECIFICATION DEVELOPMENT - VENTILATION IN MEDICAL LOCATIONS

CEN TC 156 / WORKING GROUP 18 |

DR. ROBERTO TRAVERSARI

DISCLOSURE

Dr. Roberto Traversari

- I have the following potential conflicts of interest to report:

- ❑ Consulting
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)
- ✓ I do not have any potential conflict of interest

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A TECHNICAL SPECIFICATION (TS) FOR HOSPITAL VENTILATION

Disclaimer:

All information provided is preliminary and under development within the working group.

No agreement within the working group is reached yet

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VENTILATION IN HOSPITALS

- Convener: Roberto Traversari (working at the Netherlands Organization for Applied Scientific Research, Department of Building Physics and Systems, Delft, The Netherlands)
- Secretary: Frans Saurwalt (working at Kropman, Nijmegen, The Netherlands)
- Support: Annet van der Horn (NEN the Royal Netherlands Standardization Institute, Delft, the Netherlands), funded by the VCCN (society for contamination control Netherlands) member of ICCCS (International Confederation of Contamination Control Societies)
- National Experts: 27 active experts from 16 member states (a total of 46 experts are involved)

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BACKGROUND

PROBLEM

- European countries have different national standards and guidelines
- Due to historic development guidelines and standards differ a lot
- Some member states don’t have guidelines or standards
- There is an need for a more harmonised approach

Active since December 2019

Result of voting

(National Members having abstained are not counted in this vote.)

Approved by National Members

National Members approving: 15
National Members disapproving: 2
Number of Members approving: 88.235 % (requirement >= 55 %)
Weighted percentage of Population approving: 75.325 % (requirement >= 65 %)

WORK ITEM
GIVES MANDATE TO WORKING GROUP 18

Scope of the proposed deliverable (technical specification)

- It applies to all healthcare premises where healthcare services are delivered
- It provides defined levels of air quality/cleanliness and comfort for these areas and addresses the requirements for ventilation systems
- It specifies the design, installation, operation, verification, process, maintenance and reverification of the ventilation systems
- The document describes the following hygienic issues related to the ventilation system:
  - a) protection of patients, staff and visitors against biological and other harmful agents
  - b) reducing the growth of microorganisms (e.g. clean-ability, accessibility, wet surfaces, accumulation of particles)
  - c) air quality (e.g. cleanliness levels, temperature, humidity, air quantity, thermal comfort)
  - d) control of the airflow direction (e.g. tightness of systems and constructions, pressure difference)
- This TS is intended for project managers, designers, construction and commissioning engineers, estates managers and operations/facilities managers

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TECHNICAL SPECIFICATION

WHAT IS A TECHNICAL SPECIFICATION

CEN introduced the Technical Specification to provide an 'appropriate' consensus/transparency solution to a market need where there is *no immediate need* for *national implementation* and *withdrawal of conflicting national standards*.

- A Technical Specification can act as a pre-standard, but it can also be accepted that the 'appropriate consensus' represented by the Technical Specification could continue to meet a market need **without eventual conversion into an EN**

- A Technical Specification may be established with a view to serving for instance the purpose of:
  - publishing aspects of a subject which may support the development and progress of the European market but where a European Standard is not feasible or not yet feasible
  - giving guidance to the market on or by specifications and related test methods
  - providing specifications in experimental circumstances and/or evolving technologies

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GUIDING PRINCIPLES

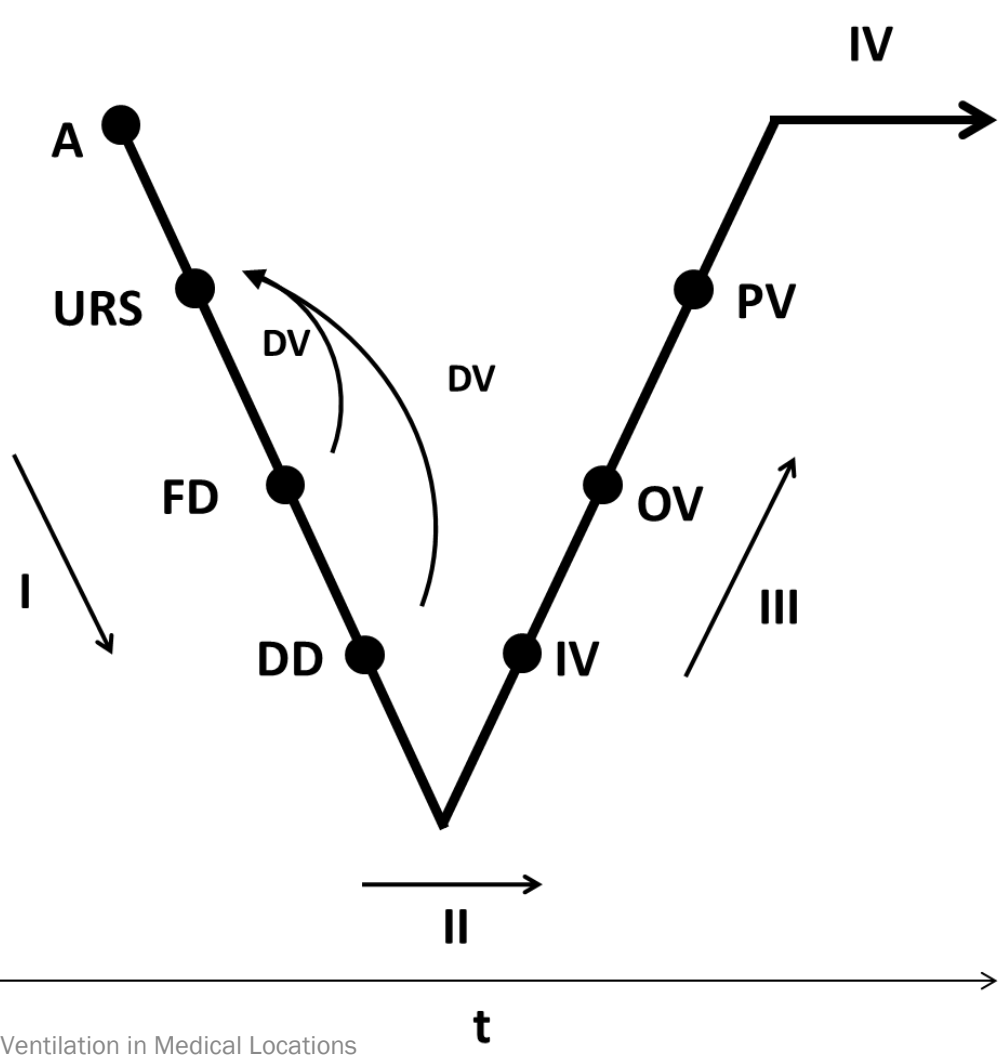
THE 5 MAIN QUESTIONS DURING THE PROCESS

- Is this specific for hospitals or already covered by other EN's (Protection of patients, visitors and staff)
- Is it scientifically/evidence based
- Is it formulated as a minimum performance (not as one technical solution)
- Is it dealing with ventilation or the boundary conditions for correct functioning of the system.
- Can it be accepted by the different European countries

DESIGN PROCESS IS IMPORTANT

GENERAL PRINCIPLED FOR GOOD DESIGN

I	Design phase
II	Construction phase
III	Qualification phase
IV	Operational phase
A	Analyses
URS	User requirement specification
FD	Functional design
DD	Detailed design
DV	Design verification
IV	Installation verification
OV	Operational verification
PV	Performance verification



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REQUIREMENTS

MORE BASED ON PERFORMANCE THAN ON TECHNICAL SOLUTIONS

- Different ventilation classes with different performance requirements:
  - CL-1a: operating rooms based on UDAF
  - CL-1b: operating rooms based on DMAF

  } e.g. for infection-prone clean surgery
  - CL-2: operating rooms e.g. for other surgery
  - CL-3: e.g. other rooms in OR department
  - CL-4: e.g. treatment room
  - CL-5: e.g. patient ward
  - CL-IR: Isolation rooms

- It is up to the European countries to decide the ventilation classes for specific room types

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REQUIREMENTS

GENERAL PERFORMANCE IS BASED ON

- Supply air quality (filter grade)
- Minimum amount of outdoor air (ODA)
- Flow direction
- Sound level of the ventilation system

- Performance of the system (at rest)
  - Number of particles (ISI 14644)
  - Recovery time (100:1)
  - OR-lamp wake Recovery test
  - Segregation if applicable

  } Test often used to prove compliance with technical requirements for handing over the system

- Operational performance (including te process e.g. surgery)
  - Microbiological test: Level of CFU/m^3 or CFU/dm^2.s

  } Test to prove the microbiologic compliance (system and process)

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REQUIREMENTS

SPECIFIC PERFORMANCE REQUIREMENTS FOR

- Cleanliness
- Tightness of ducting dampers
- Lay-up of the system, filter arrangement, fan locations
- Viewing port and draining systems
- Safety systems, setback mode
- Building management systems
- Heat recovery
- Labeling an documentation
- Maximum humidity and wet surfaces
- Surfaces and materials within the air flow

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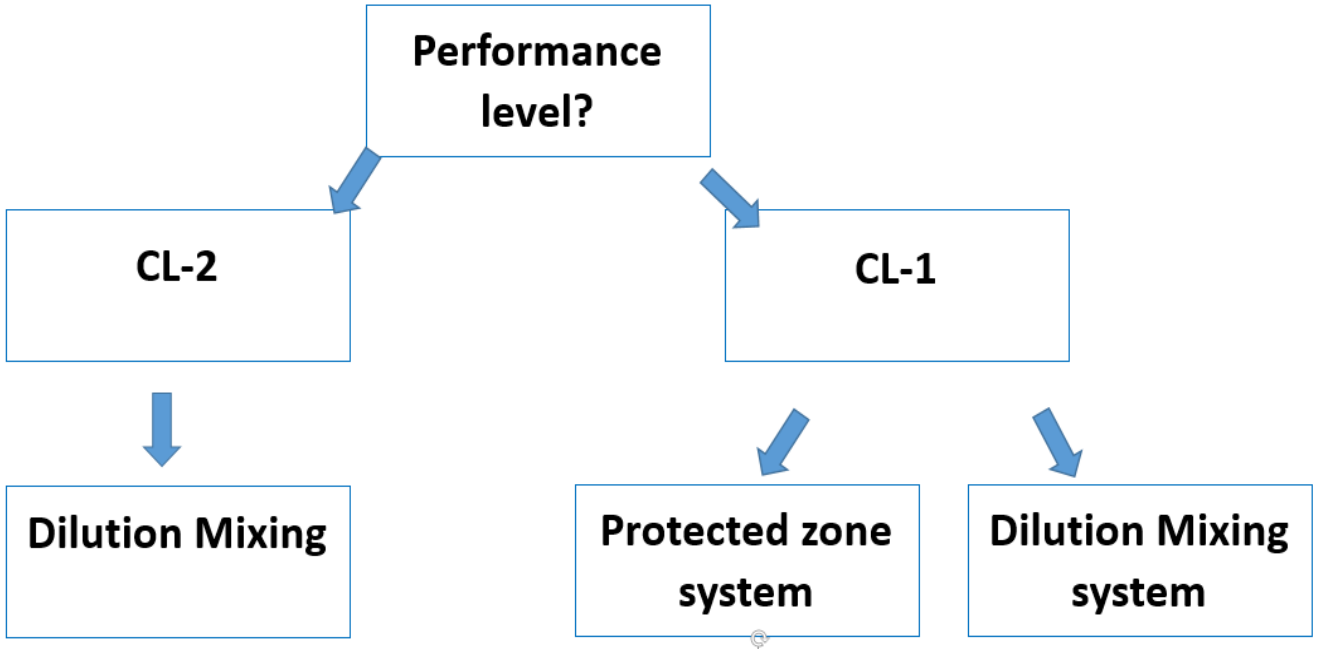
OPERATING ROOMS
SPECIFIC PERFORMANCE REQUIREMENTS



Both systems can fulfil the requirements for CL-1 (infection-prone clean surgery)

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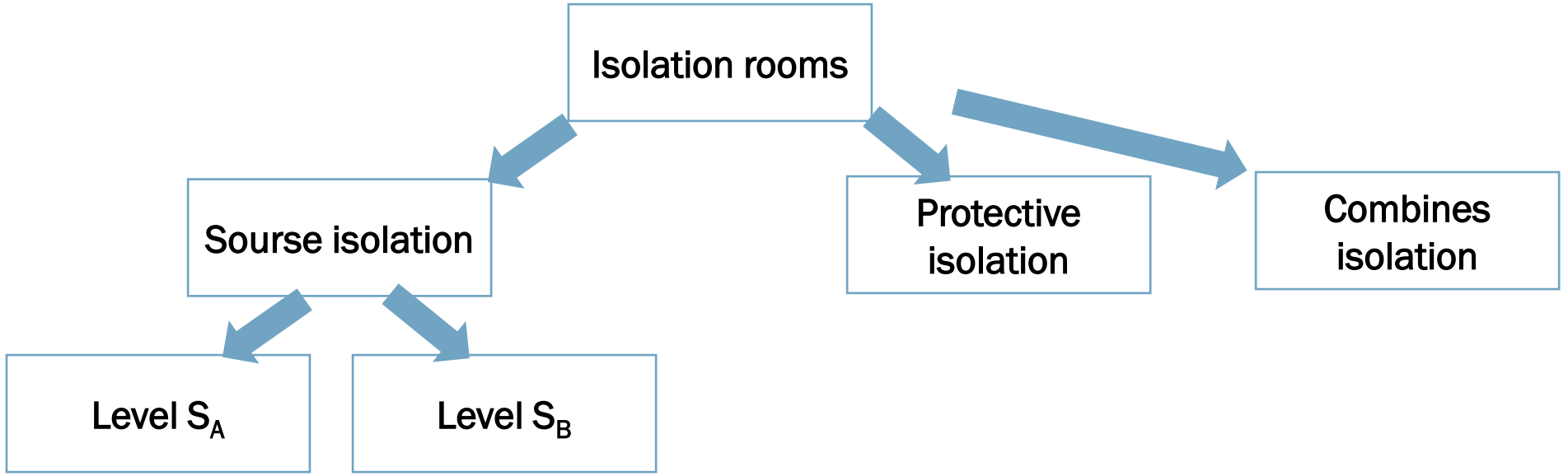
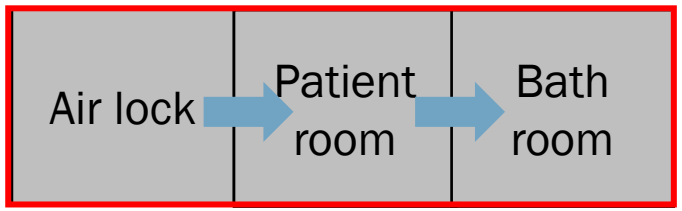
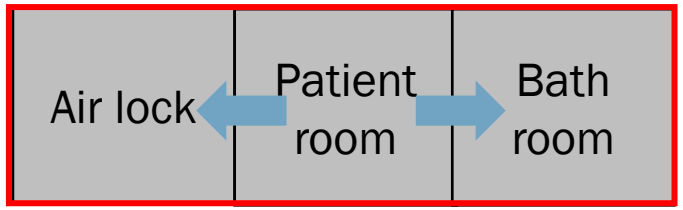
ISOLATION ROOMS
SPECIFIC PERFORMANCE REQUIREMENTS







Recovery time in the air lock and patient room is the main requirement.
Recovery time in the air lock is based on a waiting time in the air lock

SOME EXAPLES OF POSSIBLE CHOICES ON NATIONAL LEVEL

VENTILATION CLASS AND TYPE OF PROCEDURE

The given procedures below are examples and are intended to help understand the meaning of the choice. Procedures can be added, changed, or deleted.)

Ventilation class	Type of procedure(s)
CL-1a[1)]	OR for infection-prone clean and other surgery
CL-1a	Lay-up room for infection-prone clean and other surgery
CL-1b[1)]	OR for infection-prone clean and other surgery
CL-1b	Lay-up room for infection-prone clean and other surgery
CL-2[1)]	For other (non infection-prone) surgery and lay-up room for other surgery
CL-2	Rooms with a direct connection (without a door) to an operating room for infection-prone clean surgery
CL-3	Other areas
CL-4	Other areas
CL-5	Other areas
.....	.....
1)	Size of the critical area shall be sufficient to contain the surgical site, surgical team and surgical instruments.

SOME EXAPLES OF POSSIBLE CHOICES ON NATIONAL LEVEL
HUMIDITY AND TEMPERATURE

Minimum relative humidity

Room type	Minimum relative humidity
General room types	☐ 30% ☐ No minimum requirement
Operating room/lay-up room	☐ 30% ☐ No minimum requirement

Temperature range

Room type	Temperature range
Room air temperature operating room/lay-up room	☐ 18-24°C ☐ 20-24°C ☐ 18-26°C

SOME EXAPLES OF POSSIBLE CHOICES ON NATIONAL LEVEL
TEST METHOD FOR SEGREGATION TEST. ONLY FOR UDAF

Applicable test methods

Type of test	Test method
Segregation test	☐ SIS-TS39:2015/ table 7, LR-method ☐ HTM03 ☐ VCCN guideline 7 ☐ DIN 1946-4 ☐ ÖNORM H6020 ☐ SWKI VA105-01

THANK YOU FOR
YOUR TIME

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