SLOVENSKI STANDARD
SIST-TS CEN/TS 16244:2018

01-julij-2018

Prezračevanje bolnišnic - Usklajena nivojska struktura, skupni pojmi in definicije za standard za prezračevanje v bolnišnicah

Ventilation for 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

Ventilation des hôpitaux - Structure hiérarchique cohérente et termes et définitions usuels pour une norme relatives à la ventilation dans les hôpitaux

Ta slovenski standard je istoveten z: **CEN/TS 16244:2018**

ICS:

11.140	Oprema bolnišnic	Hospital equipment
91.140.30	Prezračevalni in klimatski sistemi	Ventilation and air-conditioning systems

SIST-TS CEN/TS 16244:2018 **en,de**

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 16244

April 2018

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

Ventilation des hôpitaux - Structure hiérarchique cohérente et termes et définitions usuels pour une norme relatives à la ventilation dans les hôpitaux

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

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Ref. No. CEN/TS 16244:2018 E

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European foreword

This document (CEN/TS 16244:2018) has been prepared by Technical Committee CEN/TC 156/WG 18 “Ventilation in Hospitals”, the secretariat of which is held by NEN.

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Introduction

The aim of CEN/TC 156 working group 18 is to establish a standard for all aspects of ventilation in hospitals. This Technical Specification (TS) is work item 00156231 of CEN/TC 156 and gives a framework and structure for the parts of the standard "Ventilation in Hospitals". Based on this framework the standard will be developed. The TS also provides preliminary definitions to be used in the standard and gives an overview of the scope.

The standard "Ventilation in hospitals" could be applied to all healthcare premises whether located in a hospital, clinic or other premises where healthcare services are delivered. It will include the specific high risk areas and covers the aspects of construction and ventilation that provide defined levels of air quality/cleanliness for classification of these areas. The standard will deal with the design, classification, operation and maintenance phase of a project. The standard will not consider the general ventilation aspects covered by other standards or the medical implications.

The resulting standard is intended for healthcare managers, design, construction and commissioning engineers, estates managers and operations managers.

When drafting the parts of the standard for ventilation in hospitals, at least the following standards will be taken into account for normative references:

EN 308, *Heat exchangers — Test procedures for establishing the performance of air to air and flue gases heat recovery devices*

EN 1506, *Ventilation for buildings — Sheet metal air ducts and fittings with circular cross-section — Dimensions*

EN 1507, *Ventilation for buildings — Sheet metal air ducts with rectangular section — Requirements for strength and leakage*

EN 1751, *Ventilation for buildings — Air terminal devices — Aerodynamic testing of dampers and valves*

EN 1822 series, *High efficiency air filters (EPA, HEPA and ULPA)*

EN 1886, *Ventilation for buildings — Air handling units — Mechanical performance*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 12097, *Ventilation for buildings — Ductwork — Requirements for ductwork components to facilitate maintenance of ductwork systems*

EN 12792, *Ventilation for buildings — Symbols, terminology and graphical symbols*

EN 12237, *Ventilation for buildings — Ductwork — Strength and leakage of circular sheet metal ducts*

EN 12599, *Ventilation for buildings — Test procedures and measuring methods for handing over installed ventilation and air conditioning systems*

EN 13030, *Ventilation for buildings - Terminals. Performance testing of louvres subjected to simulated rain*

EN 13053, *Ventilation for buildings — Air handling units — Rating and performance for units, components and sections*

EN 13779, *Ventilation for non-residential buildings — Performance requirements for ventilation and room-conditioning systems*

EN 15780, *Ventilation for buildings — Ductwork — Cleanliness of ventilation systems*

EN 16032, *Acoustics — Measurement of sound pressure level from service equipment in buildings*

EN 60068-2-11, *Environmental testing — Part 2: Tests — Test Ka: Salt mist (IEC 60068-2-11)*

EN ISO 9000, *Quality management systems — Fundamentals and vocabulary (ISO 9000)*

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

EN ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3)*

EN ISO 16890 series, *Air filters for general ventilation — Part 1: Technical specifications, requirements and classification system based upon particulate matter efficiency (ePM)*

For the consistency in the standard on ventilation in hospitals, the preliminary terms, definitions and abbreviated terms defined in Clauses 3 and 4 will be used. Part 1, the general part, will repeat (possibly with improvement) the terms that are necessary for all parts of the standard. If additional definitions or adaption of the given definitions are necessary they will be defined in the specific part of the standard.

1 Scope

This Technical Specification sets out the framework and structure for the standard related to ventilation in hospitals. It gives the requirements for the drafting of the parts of the standard, including preliminary terms and definitions.

The standard for ventilation in hospitals is intended for all healthcare premises where healthcare services are delivered. It is applicable for healthcare services located in a hospital, clinic or other premises. This includes general and specific risk areas, within healthcare and provides defined levels of air quality/cleanliness for classification of these areas. The standard addresses the minimum requirements for ventilation systems. It specifies the design, installation, operation, qualification process and maintenance of the ventilation systems.

The standard describes the following hygienic issues related to the ventilation system:

a) air quality (e.g. cleanliness levels, temperature, humidity, air quantity);

b) the protection of patients, staff and visitors against harmful agents;

c) reducing the growth of microorganisms (e.g. clean-ability, accessibility, wet surfaces, accumulation of particles);

d) control of the airflow direction (e.g. tightness of systems and constructions, pressure difference).

The standard describes a structured approaches for all phases from design up to and including maintenance and requalification and gives minimum requirements for the ventilation systems:

a) minimum user requirement specification (URS);

b) functional design requirements (FD);

c) requirements for components in the detailed design (DD).

This standard is intended for healthcare ventilation system project managers, designers, construction and commissioning engineers, estates managers and operations/facilities managers.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
active sampling of air
sampling of *air* by a sampling tube or probe using a pump and collection of microbial particles on to an agar surface or filter surface to determine the microbial load (CFU/m^3)

3.2
air lock
enclosed space having two doors, situated between two environments with different air conditions, making it possible to pass from one environment to the other without significant disturbance to either

[SOURCE: ISO 6707-1]

3.3
air handling unit
factory made encased assembly consisting of sections containing a fan or fans and other necessary equipment to perform one or more of the following functions: circulating, filtrating, heating, cooling, heat recovery, humidifying, dehumidifying and mixing air

[SOURCE: EN 13053]

3.4
air terminal
device through which the supply air is distributed into ventilated space or exhaust air is extracted from the ventilated space

Note 1 to entry: Air terminals can also include other functions, such as air flow control, heating, cooling, filtration or room air circulation and treatment.

3.5
alarm
signal of system malfunction or critical situation that can cause malfunction of the system resulting in a situation that is not in accordance with the required (system) performances or break down of system components

Note 1 to entry: As-built condition where the installation is complete with all services connected and functioning but with no production equipment (e.g. operating lamps, operating table, anaesthesia equipment), materials or personnel present [EN ISO 14644-1].

3.6
at-rest
condition where the installation is complete with equipment (e.g. operating lamps, operating table, anaesthesia equipment) installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present

[SOURCE: EN ISO 14644-1]

3.7
certification body
organization that meets the requirements of EN ISO/IEC 17024 for third-party certification bodies and issues a certificate of conformity

[SOURCE: ISO 18436-1]

3.8
colony forming unit
CFU
bacteria carrying particle which gives rise to a colony on a culture plate

3.9
controlled humidity
actively controlled humidity of the air by dehumidification and humidification to realize a certain dew point

3.10
corrosion-resistant
sustainable way of protection against corrosion by means of the materials used

[SOURCE: EN 60068-2-11]

3.11
critical zone
dedicated space in the operating room which covers the critical areas, including tables with the sterile instruments in which the concentration of contamination (including microbiological, gaseous and particulate) is controlled and that is constructed and used in a manner to minimize the introduction and maximize recovery of contamination inside the area

Note 1 to entry: The size of the critical zone is usually marked permanently on the floor based on the worst-case conditions (maximum space).

3.12
customer
organization, or the agent thereof, responsible for specifying the requirements of an operating room/suite

[SOURCE: EN ISO 14644-1]

3.13
detail design
DD
drawings, data, calculations and specifications from which constructed works, components and assemblies can be constructed

Note 1 to entry: By the end of the detailed design process, the design should be dimensionally correct and coordinated, describing all the main components of the system and how they fit together. A detailed design will provide sufficient information for applications for statutory approval to be made.

[SOURCE: ISO 15686-3]

3.14
design verification
DQ
documented evidence that the proposed design of the facilities, systems and equipment is suitable for the intended use

[SOURCE: EN ISO 13408-6]

3.15
dilution mixing system
system that creates air cleanliness by dilution of the airborne contaminants by mixing and diluting with supplied clean air and removing the diluted air

3.16
functional design
FD
specification of the functions of the components of a system and of the working relationships among them

Note 1 to entry: At the end of the functional design all the functional specifications of the ventilation system are defined.

[SOURCE: ISO/IEC 2382]

3.17
installation
operating room one or more operating rooms, together with all associated structures, air-treatment systems, services, and utilities

[SOURCE: EN ISO 14644-1]

3.18
installation verification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[SOURCE: ISO/TS 11139]

3.19
lay-up preparation room
lay-up preparation area
room or area where sterile packs are opened, checked and arranged on the trollies

3.20
lint (fluff) separator
fine-mesh net or perforated plate installed in the exhaust channel to protect the exhaust ducts from fibres

[SIS/TS 39]

3.21
maintenance
servicing any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition

[SOURCE: EN ISO 22716]

3.22
medical location
premises where any examination, treatment, or other act having preventive, diagnostic therapeutic or rehabilitative aims and which is carried out by a health care provider

3.23
microbiological testing
active or passive microbiological tests are carried out to determine and evaluate the extent of the airborne microbial load

3.24
occupancy state
state for which prescribed requirements and according tests refer to, as one or more of four of them, viz. “as-built”, “at-rest”, setback or “operational”

Note 1 to entry: It should be recognized that the “as-built” state is applicable to newly completed or newly modified operating rooms. Once testing in the “as-built” state is completed, further testing for compliance will be performed in the “at-rest” or the “operational” state, or both.

[SOURCE: EN ISO 14644-1]

3.25
operating suite
collection of rooms e.a. lay-up room, operating room, corridors, staff rest room, air locks

3.26
operating room
room especially equipped for the performance of surgical operations, and is constructed and used in a manner to minimize the introduction, generation, and retention of contamination and where temperature, humidity, and pressure are controlled as necessary

3.27
operational
condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon

[SOURCE: EN ISO 14644-1]

3.28
operational verification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO/TS 11139]

3.29
passive sampling
sedimentation of microbial particles on to an agar surface to determine the microbial load (CFU/cm^2, CFU/dm^2 or CFU/m^2)

3.30
particle
solid, liquid or microbial object which, for purposes of classification of air cleanliness, falls within a cumulative distribution that is based upon a threshold (lower limit) size

[SOURCE: EN ISO 14644-1]

3.31
particle concentration
number of individual particles per unit volume of air (particles/m^3)

[SOURCE: EN ISO 14644-1]