DIN 1946-4

ICS 91.040.10; 91.140.30

Supersedes
DIN 1946-4:2018-06

Ventilation and air conditioning – Part 4: Ventilation in buildings and rooms of health care, English translation of DIN 1946-4:2018-09

Raumlufttechnik –
Teil 4: Raumlufttechnische Anlagen in Gebäuden und Räumen des Gesundheitswesens, Englische Übersetzung von DIN 1946-4:2018-09

Ventilation et conditionnement d'air –
Partie 4: Ventilation dans les bâtiments et l'endroit du système de santé publique, Traduction anglaise de DIN 1946-4:2018-09

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A comma is used as the decimal marker.

Contents

Foreword

This document has been prepared by Working Committee NA 041-02-53 AA of *DIN-Normenausschuss Heiz- und Raumlufttechnik sowie deren Sicherheit* (DIN Standards Committee Heating and Ventilation Technology and their Safety) with the participation of the relevant experts and regulators.

If, for public health or medical reasons, any additional stipulations are to be placed on the technical features, dimensions, and design of ventilation systems, these stipulations shall only be set down by the relevant health authorities on the basis of existing health regulations.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. DIN shall not be held responsible for identifying any or all such patent rights.

Amendments

This standard differs from DIN 1946-4:2008-12 as follows:

a) requirements regarding infection prevention and control, medical device safety, and relevant occupational health and safety provisions are now taken into consideration;

b) design criteria have been modified, as have the necessary methods for qualifying systems for technical and hygiene acceptance and requalification testing;

c) the qualification of operating rooms on the basis of the current International Standards series on cleanrooms and associated controlled environments, DIN EN ISO 14644, is now specified;

d) filter classification terms and definitions have been brought in line with the new filter classification as laid down in DIN EN ISO 16890-1;

e) a check list for planning, designing and operating system components has been added in the form of a Supplement to this standard.

The following corrections have been made to DIN 1946-4:2018-06:

a) in 6.5.7.1 the requirement regarding Eurovent energy efficiency class A has been deleted.

Previous editions

DIN 1946-4: 1963-05, 1978-04, 1989-12, 1999-03, 2008-12, 2018-06
DIN 4799: 1990-06

1 Scope

This standard applies to the planning, construction, acceptance and operation of ventilation and air conditioning (VAC) systems in buildings and rooms used in the health sector and which are used for medical examinations, treatments and operations on humans, as well as in any rooms directly connected to such rooms via doors, corridors/hallways, etc. , and in logistics facilities, e.g. in:

— hospitals;

— outpatient clinics;

— treatment rooms in doctor's offices/surgeries;

— operating rooms in outpatient facilities;

— dialysis centres;

— internal and external (service) units used for manufacturing medicinal products or for preparing medical devices (previously referred to as “sterilization facilities”).

This standard applies to the operation of VAC systems only when they have been designed, constructed and accepted on this basis of this standard. Additional requirements regarding the planning of special treatment facilities (e.g. for treating highly infectious, deadly diseases) shall be taken into consideration.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

DIN 4108-2, *Thermal insulation and energy economy in buildings — Part 2: Minimum requirements to thermal insulation*

DIN 4109 (all parts), *Sound insulation in buildings*

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

DIN EN 1822 (all parts), *High efficiency air filters (EPA, HEPA and ULPA)*

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

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

DIN EN 12599, *Ventilation for buildings — Test procedures and measurement methods to hand over air conditioning and ventilation systems*

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

DIN EN 16798-3, *Energy performance of buildings — Ventilation for buildings — Part 3: For non-residential buildings — Performance requirements for ventilation and room-conditioning systems (Modules M5-1, M5-4)*

DIN EN ISO 7730, *Ergonomics of the thermal environment — Analytical determination and interpretation of thermal comfort using calculation of the PMV and PPD indices and local thermal comfort criteria*

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

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

DIN EN ISO 14698-1, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles*

DIN EN ISO 14698-2, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

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

VDI 2047, *Cooling towers; terms and definitions*

VDI 2089 Part 1, *Building Services in swimming baths — Indoor pools*

VDI 3803 Part 1, *Air-conditioning — Central air-conditioning systems — Structural and technical principles (VDI ventilation code of practice)*

VDI 6022 Part 1, *Ventilation and indoor-air quality — Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)*

VDI/VDE 3512 Part 2, *Temperature measurement for building automation — Temperature sensors, temperature sensing elements and their measurement parameters*

VDMA 24186-1, *Program of services for the maintenance of technical systems and equipment in buildings — Part 1: Air handling devices and systems*

AMEV RLT-*Anlagenbau* 2011, *Hinweise zur Planung und Ausführung von Raumlufttechnischen Anlagen für öffentliche Gebäude* (Information on designing and installing ventilation systems in public buildings)[1)]

AMEV *Wartung* 2014, *Wartung 2014 — Wartung, Inspektion und damit verbundene kleine Instandsetzungsarbeiten von technischen Anlagen und Einrichtungen in öffentlichen Gebäuden* (Maintenance, inspection and associated minor maintenance works of services and facilities in public buildings)[2)]

AMEV *Bedien RLT* 2008, *Bedienen von raumlufttechnischen Anlagen in öffentlichen Gebäuden* (Operation of ventilation and air-conditioning equipment in public buildings)[2)]

IfSG, *Gesetz zur Neuordnung seuchenrechtlicher Vorschriften (Seuchenrechtsneuordnungsgesetz — SeuchRNeuG)* (Law on the reorganisation of animal health provisions) — *Article 1: Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz — IfSG)* (Law on prevention and control of infectious diseases in humans (Protection against Infectious Diseases Act — IfSG)

Technische Regeln für Arbeitsstätten — Lüftung, ASR A3.6 (Technical rules for workplaces — Ventilation, AS A3.6) January 2012 amended GMBl 2013, p. 359

TRGS 525, *Technische Regeln für Gefahrstoffe — Gefahrstoffe in Einrichtungen der medizinischen Versorgung* (Technical rules for hazardous substances — Hazardous substances in medical care facilities)

GefStoffV, *Verordnung zur Anpassung der Gefahrstoffverordnung an die EG-Richtlinie 98/24/EG und andere EG-Richtlinien (Verordnung zum Schutz vor gefährlichen Stoffen) (Gefahrstoffverordnung — GefstoffV)* (Regulation adapting the German Hazardous Substances Ordinance to EC Directive 98/24/EC and other EC

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1) Registered in the DITR database of *DIN Software GmbH*, obtainable from: *Bernhard GmbH*, Postfach 1265, 42905 Wermelskirchen, Germany.

2) Obtainable from: *Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit* (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety), Krausenstraße 17 – 20, 10117 Berlin, Germany.

Directives (Ordinance on protection against dangerous substances) (German Hazardous Substances Ordinance)

TRBA 250, *Technische Regeln für Biologische Arbeitsstoffe — Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege* (Technical rules for biological working substances — Biological substances in the fields of medical hygiene and welfare work)

3 Terms and definitions, and abbreviated terms

3.1 Terms and definitions

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

3.1.1
system qualification
general acceptance of a VAC system carried out in a succession of steps to qualify the installations, its functions and its performance, where each step does not begin until the preceding step has been successfully completed

Note 1 to entry: See also DIN EN ISO 14644-4.

3.1.2
surgical smoke plume
mixture of diverse gaseous, vaporous, liquid and solid substances released interoperatively during electro-surgical and laser procedures which pose diverse localized, systemic, reversible and irreversible hazards to persons

Note 1 to entry: Due to the thermal decomposition of tissue, not only are pyrolytic products such as carbon monoxide, formaldehyde and hydrocyanic acid released, but fine and ultra-fine particulates and biologically active components (vital (tumour) cells, cellular remnants, viruses, etc.) are also released. Also referred to as “surgical smoke” or “surgical plume”.

3.1.3
invasive, surgical procedure
invasive operative procedure classed according to the extent of the procedure and the degree of risk

Note 1 to entry: According to the recommendation *Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen* (Hygiene requirements during operations and other invasive procedures) issued by the Commission for Hospital Hygiene and Infection Prevention of the Robert Koch Institute (RKI), invasive, surgical procedures are classified according to the extent of the procedure and the degree of risk, as follows: *Operationen* (operations), *kleinere invasive Eingriffe* (minor interventions), and *invasive Untersuchungen und vergleichbare Maßnahmen* (invasive diagnostics and other similar procedures).

3.1.4
functional qualification
further tests and measurements carried out to verify the correct functioning of all VAC system components, carried out after the successful completion of the installation qualification of that system

3.1.5
hybrid operating room
a Room Class I operating room/surgical theatre which contains large medical imaging equipment

3.1.6
hygiene engineer
(for the purposes of this standard) engineer who is independent of the planner and builder, and has special expertise in ventilation technology, and special knowledge and experience in the field of medical hygiene