NEW WORK ITEM PROPOSAL	
Closing date for voting 8 June 2017	Reference number (to be given by the Secretariat) ……..
Date of circulation 27 April 2017	**CEN/TC 156/ N 1605**
Secretariat BSI	**CENELEC/TC / SC** (Sec)…

IMPORTANT NOTE: Incomplete proposals risk rejection or referral to originator.

☒ The proposer has considered the guidance given in Annexes 1 and 2 during the preparation of the NWIP

Proposal (to be completed by the proposer)

Title of the proposed deliverable
(in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title **Ventilation for Hospitals - part 3 - Requirements for ventilation and air-conditioning in isolation rooms.**

French and German title (if available)

Scope of the proposed deliverable

This third part of the standard on ventilation for hospitals is to be applied to all isolation rooms, whether located in a hospital, clinic or other premises where healthcare services are delivered. It includes specific 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, installation, operation and maintenance and the process of qualification/validation of the ventilation systems.

This third part of the standard on ventilation for hospitals is additional and complementary to the minimal general requirements set out in the first part.

The scope of this third part describes all additional requirements needed for isolation rooms. This includes minimum user requirement specification (URS), functional design requirements (FD) and requirements for components in the detailed design (DD) for the air treatment processes that are to be designed, installed, operated and maintained at healthcare premises delivering isolation services.

Other specific rooms, like operating suites, sterilization rooms or psychiatric isolation room (padded cells) are outside the scope of this part about the isolation rooms.

Purpose and justification of the proposal

The existing standards on ventilation in buildings can result in a good indoor climate. But for isolation rooms in healthcare premises additional requirements are needed, because of the vulnerability of patients and risk for infection for third parties. Ensuring continuity of hygiene and safety is essential.

The main hygienic and safety issues are:

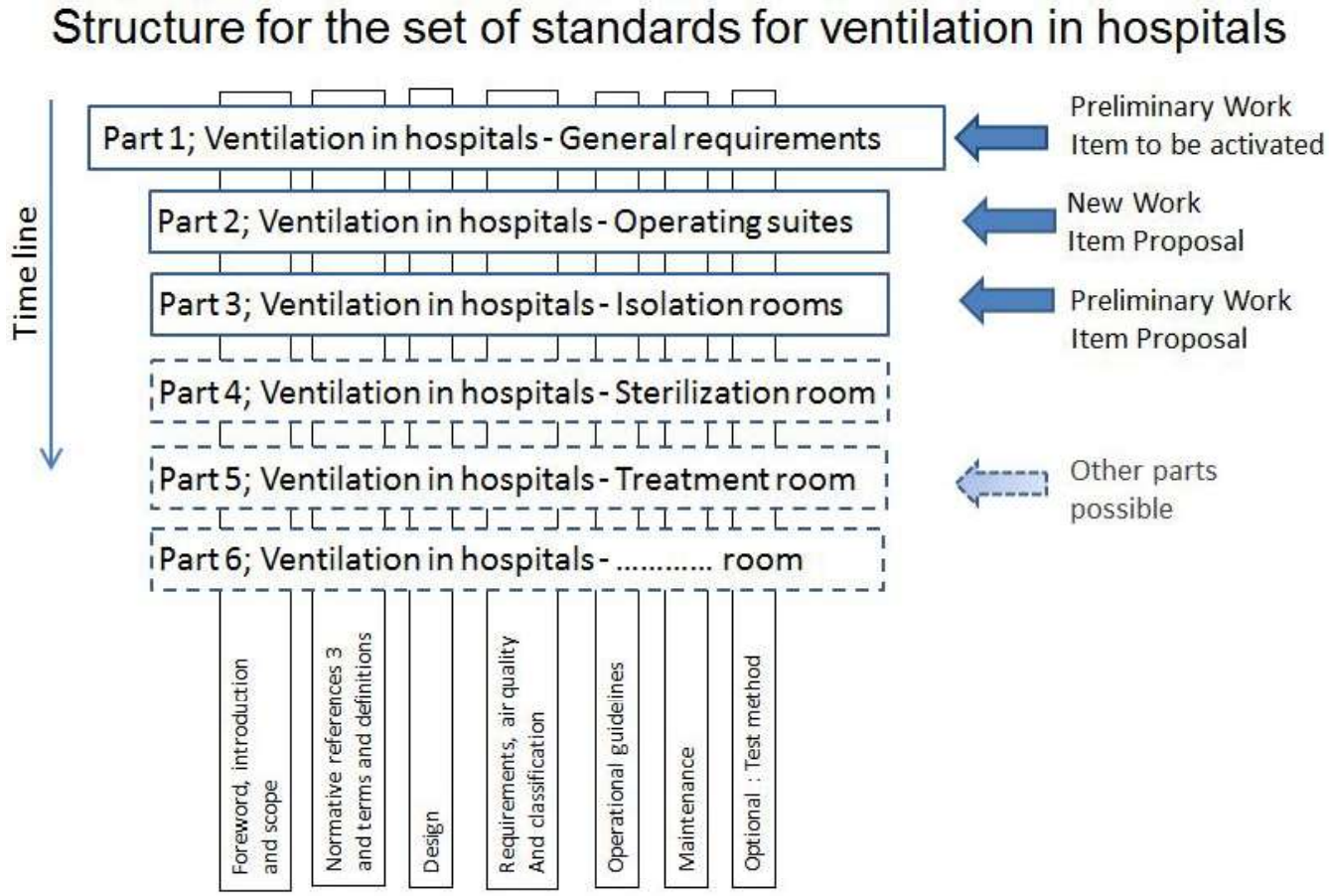
- The protection of patients, staff and visitors against harmful agents
- reducing the growth of microorganisms (e.g. clean-ability, accessibility, wet surfaces, accumulation of particles),
- control of the airflow direction (e.g. tightness of systems and constructions, pressure difference)
- air quality (e.g. cleanliness levels, temperature, humidity, air quantity)
- safety measures for maintenance (e.g. safe-change filters, air tight valves)

Long standing experience in this field shows that just setting requirements is not enough. A good management system is needed to ensure the quality of the ventilation and air quality system throughout the process of design, installation, testing, operation and maintenance. Therefore, all parts of the standard for ventilation in hospitals are structured using general project steps:

0. Analysis
1. User requirements specification (URS)
2. Functional design (FD)
3. Detailed design (DD)
4. Design qualification (DQ)
5. Realisation
6. Installation qualification (IQ)
7. Operational qualification (OQ)
8. Performance qualification (PQ)
9. Operation and maintenance
10. Requalification

NB: these steps are not a requirement; it is just a way to structure the standard.

This results in a coherent structure that is explained in the figure below:



This standard is aimed at healthcare management, design, construction and commissioning engineers, estates managers and operations managers.

Is the proposal actively or probably in support of European regulation / legislation or established public policy?

☐ **Yes** ☒ **No**

If Yes, indicate if the proposal is

- **in relation to EC mandate(s): ……..(which one(s))**
- **in relation to EC Directive(s)/Regulation(s): ……..(which one(s))**
- **in relation to other legislation or established public policy: ……..(give details)**

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal.

☒ European Standard ☐ Harmonization Document* ☐ Technical Specification ☐ Technical Report

* for CENELEC only

Envisaged track

☒ Enquiry and vote (see 11.2.3 of IR Part 2) ☐ UAP (see 11.2.5 of IR Part 2)

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached ☐ An existing document to serve as initial basis

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

If a draft is attached to this proposal,:

Please select from one of the following options (note that if no option is selected, the default will be the second option):

☒ Draft document will be registered as a preliminary project in the committee's work programme (stage 00.60)
☐ Draft document will be registered as a new project in the committee's work programme (stage 20.00)
☐ Draft document can be submitted to UAP (FprEN – stage 50.20)

Known patented items

☐ **Yes** ☒ **No** **If "Yes", see CEN-CENELEC Guide 8 and provide full information in an annex**

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CEN, CENELEC, ISO and IEC deliverables. The proposer should explain how the work differs from any apparently similar work, or explain how duplication and conflict will be minimized.

The hygienic aspects for ventilation in hospitals are different from other buildings.

A listing of relevant existing documents at the international, regional and national levels.

ISO 14644 Cleanrooms and associated controlled environments:

- Part 1: Classification of air cleanliness

- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

- Part 3: Test methods

- Part 4: Design, construction and start-up

— Part 5: Operations

HTM03: Heating and ventilation systems Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises; Part A and Part B

SAS TS39

DIN 1946: Heating, ventilation and air conditioning; HVAC systems in hospitals.

FR S 90-351 - Controlled environment areas - Requirements for airborne

contamination requirements

Liaisons: **A listing of relevant external European or international organizations or internal parties (other CEN, CENELEC, ISO and/or IEC committees) to which a liaison should be established (in case of ISO and IEC committees via Vienna and Dresden Agreements).** ISO/TC 205 Building environment design	**Joint/parallel work:** **Possible joint/parallel work with:** ☐ CEN (please specify committee ID) ☐ CENELEC (please specify committee ID) ☒ ISO (please specify committee ID) 205 ☐ IEC (please specify committee ID) ☐ Other (please specify)

Candidate for European – International cooperation?
Vienna Agreement (ISO-CEN Agreement):

☐ **Yes** ☒ **No ('Yes' meaning joint ISO-CEN development)**

Dresden Agreement (IEC-CENELEC Agreement):

☐ **Yes** ☒ **No ('Yes' meaning that the NWI, if approved, is to be offered to IEC for taking up)**

Name of the Proposer *(include contact details)* *Annet van der Horn, NEN* *annet.vanderhorn@nen.nl*	**Proposed Project Leader** *(include contact details)* *Roberto Traversari, TNO* *roberto.traversari@tno.nl*

Supplementary information relating to the proposal

☒ This proposal relates to a new document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

☐ This proposal relates to a research project outcome

Members already known to support the proposal and willing to participate to the activities:… *[Note: The proposal cannot usually be approved without a minimum of 5 national Members]*

Annex(es) are included with this proposal (give details)

☒ **Informative Annex 1 "Principal categories of market needs"**
Informative Annex 2 "Principal categories of stakeholders"

Informative Annex 1 "Principal categories of market needs"

- Consumer protection and welfare
- Environment
- Innovation
- Support to:
  -public policy
- Market access/barriers to trade, i.e. enhancing the free movement of:
  - services
  - goods
- Interoperability
- Health/Safety
- Terminology

Informative Annex 2 "Principal categories of stakeholders"

- Industry and commerce,
  where particularly appropriate, to be identified separately as
  - Large enterprises (those employing 250 staff or more)
  - Small and medium sized enterprises (SME), (those employing 250 staff or fewer)
- Government
- Consumers
  including those organizations representing interests of specific societal groups, e.g. people with disabilities or those needing other particular consideration)
- Academic and research bodies
- Non-governmental organisations (NGO),
  including organizations representing broad or specific environmental interests
- Standards application business (e.g. testing laboratories, certification bodies)

The immediate affected stakeholders from industry and commerce in terms of their position in a product value chain, are:
- Supplier (of ventilation systems)
- Manufacturer (of ventilation systems)
- Intermediary (e.g. warehousing, transport, sales)
- Service provider (construction and commissioning engineers,, design)
- User of the product or service (hospitals, healthcare organizations, healthcare management, estates managers and operations managers)
- Maintenance / disposal (of ventilation systems)

1 CEN/TC 156/WG 18 'Ventilation in hospitals'

2 prCEN/Std 16244-3 2017 Part 3 Ventilation of isolation units rev 0.7_1-May -2018

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2 # Table of contents

1 Foreword

This document has been prepared by Technical Committee CEN/TC 156 “Ventilation for buildings”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by XXXXX, and conflicting national standards shall be withdrawn at the latest by XXXXXX.

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

This European Standard is a part of a series of standards for ventilation systems in healthcare premises where healthcare services are delivered.

It considers the requirements of ventilation systems, air handling units as a whole, the requirements and performance of specific, critical components and sections of air handling units including hygiene requirements.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Or other standard text of TC 156.

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2 Introduction (to be revised)

This part of EN 16244 was developed in response to the demand for equal European requirements for hospital ventilation. Different member states have different technical guidelines and national standards to deal with ventilation in healthcare premises whether located in a hospital, clinic or other premises where healthcare services are delivered. These differences are caused by historical developments and the adaption and response to new insights. The aim of this set of standards is to create a common baseline for the definitions and requirements of ventilation systems in healthcare premises whether located in a hospital, clinic or other premises where healthcare services are delivered.

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This standard consists of the following parts:

Part 1: Ventilation in hospitals – General requirements
Part 2: Ventilation in hospitals – Operating suites
Part 3: Ventilation in hospitals – Isolation units

The following parts are under preparation:
Part 4: Ventilation in hospitals – Sterilisation room.

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3 Scope

This standard applies to all kinds of isolation units where healthcare services are delivered. It is applicable for healthcare services located in a hospital, clinic or other premises. The standard addresses the minimum requirements for ventilation systems. It specifies the design, installation, operation, qualification process and maintenance of the ventilation systems for isolation units.
Additional requirements are needed for isolation units because of the vulnerability of patients and risk for infection for third parties. Ensuring continuity of hygiene and safety is essential.

The main hygienic and safety issues are:

- The protection of patients, staff and visitors against harmful agents
- reducing the growth of microorganisms (e.g. cleanability, accessibility, wet surfaces, accumulation of particles)
- control of the airflow direction (e.g. tightness of systems and constructions, pressure difference)
- air quality (e.g. cleanliness levels, temperature, humidity, air quantity)
- safety measures for maintenance (e.g. safe-change filters, air tight valves)

This standard describes all minimum requirements for the ventilation systems:

- minimum user requirement specification (URS),
- functional design requirements (FD)
- requirements for components in the detailed design (DD)
- requirements for commissioning and qualification
- requirements for the operation and maintenance

Everything covered in part 1 is also relevant for isolation units. This part 3 is covering additional requirements for ventilation in isolation units.

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

4 Normative references

The following are referenced in this document:

[1] EN 16244-1 *Ventilation in hospitals* Part 1 *General requirements*

[2] EN 1822-1 *High efficiency air filters (EPA, HEPA and ULPA)*

[3] EN ISO 14644-3:2005 *Cleanrooms and associated controlled environments* — Part 3: *Test methods*

[4] EN ISO 14644-1:2015 *Cleanrooms and associated controlled environments* — Part 1: *Classification of air cleanliness*

[5] EN308:2011 *Heat exchangers — Test methods for determining the power criteria of air/air and an air/exhaust gas mixture heat recovery devices*

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EN 779, *Particulate air filters for general ventilation — Determination of the filtration performance*¶
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*¶

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~~EN 779, *Particulate air filters for general ventilation — Determination of the filtration performance*~~¶
~~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 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 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 13053, *Ventilation for buildings — Air handling units — Rating and performance for units, components and sections*~~¶

5 Terms, Definitions and abbreviations

Contact isolation – isolation against contaminants transferred by contact

Airborne isolation – isolation against contaminants transferred by the airborne route

Source isolation - technical means for taking care of patients with infection

Protective isolation / sterile care - technical means for taking care of immune-compromised patients with an elevated risk of infection

Combined isolation - isolation for immune-compromised patients who are also a source for airborne contaminants.

Isolation unit – a unit consisting of one airlock, one patient room and one bathroom

6 Organisation of design, construction and operation

See part 1, chapter 6.

7 Design

7.1 General

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To design an appropriate isolation unit, it is essential to define which type of isolation is needed. This is a medical decision and should be written down in the URS. The different types of isolation are listed below:

- Contact isolation
- Airborne isolation
    - Source isolation
        - Isolation level S_A – (BSL 2+/3-)
        - Isolation level S_B - High/unknown/hidden risk (BSL 3)
    - Protective isolation
    - Combined isolation

Contact isolation is covered by normal single patient rooms and gives no additional requirements for ventilation systems. This standard will only cover isolation units for airborne isolation.

7.2 Analysis

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The determination of the actual condition and the resulting establishment of a need for ventilation measures will be different for the different types of isolation units and should be individually considered in the URS.

At least the following items shall be considered:

a) description of functions, activities;

b) description of processes;

c) relevant regulations, standards, guidelines;

d) resources;

e) selection of site of installation, dimensions, infrastructure;

f) future prospects (legislation, standards, changes in medical treatment procedures);

g) definition of the medical tasks and strategic planning for future treatments and equipment requirements.

7.3 Minimum user requirements specification (URS)

Type of isolation unit	**Source isolation Level S_A**	**Source isolation Level S_B**	**Protective isolation**	**Combined isolation**
Recovery time (100:1) Patient room Airlock	 < 25 min < 6 min	 < 15 min < 8 min	 < 25 min < 6 min	 < 25 min < 6 min
Waiting time in the airlock*	>3 min	>5 min	>3 min	>3 min
Typical nr of air changes** Patient room Airlock WC	 >12 ACH >46 ACH -	 >20 ACH >36 ACH -	 >12 ACH >46 ACH -	 >12 ACH >46 ACH -
Supply air quality (Supply air is 100% outdoor air)	SUP 1 (part 1, 8.12.1)	SUP 1 (part 1, 8.12.1)	SUP 1 + H13 terminal filter	SUP 1 + H13 terminal filter
Exhaust air (EN13779)				
Exhaust filtration	Minimum F9 (ePM1 85%)	Minimum H13		Depending on isolation level for source isolation
Supply filtration			Minimum H13	Minimum H13
Shut-off dampers	Class 4 (according to EN 1751)	Gas tight (<0,0028 l/s*m2 at 2000 Pa)	Class 4 (according to EN 1751)	Depending on isolation level for source isolation
Air tightness of the isolation unit	0.2 l/s m^2 *** at 50 Pa	0.1 l/s m^2*** at 50 Pa (underpressure during fumigation)	0.4 l/s m^2*** at 50 Pa	Depending on isolation level for source isolation
Duct tightness Supply ducts Extract ducts	(part 1) Class C Class C before the fan Class D after the fan****	 Class C Class D before exhaust HEPA-filter Class C after exhaust HEPA-filter	 Class C Class C	 Depending on isolation level for source isolation

Table 1 Input values to URS for isolation units

*To shorten the waiting time in the airlock, the airflow rate in the airlock shall be increased to ensure shorter recovery time.

**Typical nr of air changes by ideal dilution in the rooms based on the dilution factors, see Annex NN.

***air tightness should be tested on the inner unit surface, including doors, windows and pass-through cabinets, see Figure 1 and 2

****If a HEPA-filter is installed, no special requirements apply to the ductwork (see Level S_B)

7.4 Functional design

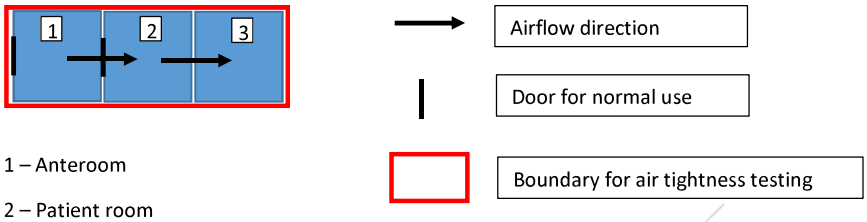
7.4.1 Introduction

7.4.2 Functional design of isolation units

Planning of the fumigation system shall be part of the functional design, with respect to at least technical and construction materials, equipment, furniture and system layout.

7.4.3 Airflow design concepts

Concept for source isolation:

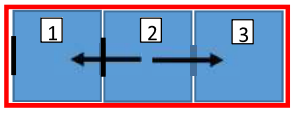


1 – Anteroom

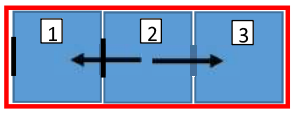
2 – Patient room

3 – Bathroom/WC

Concept for protective isolation:



Concept for combined isolation:



7.4.4 Functional and safety aspects

The main functionality shall be to minimize the concentration of airborne contaminants in the air. The recovery time shall be in accordance to Table 1.

A risk assessment regarding safety for patient, staff, visitors and surroundings shall be carried out, where at least the following aspects shall be addressed:

- The acceptable time for unavailability
- Redundant and/or separate air handling systems
- Secure power supply
- Alarms

The ventilation and control system for the isolation unit shall be supplied by emergency power.

The doors shall be interlocked with automatic door closer, at least on the outer door.

7.4.5 Heat recovery

The recovery system should be completely separated (with intermediary heat transfer medium, class 2 according to EN308).

7.4.6 Set-back mode

For the patient comfort and energy saving purposes the isolation unit ventilation system shall be equipped with a set-back mode to enable use in reduced capacity when there is no need for airborne isolation. The selection of the operation mode shall be made by medical staff responsible for patient care.

During operational qualification, the correct operation of different operation modes and the changeover shall be tested.

7.5 Detailed design

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7.5.1 General

7.5.2 Layout of the system

The exhaust fan arrangement for source isolation should be placed as far out in the building as possible, to ensure the exhaust ductwork is kept in underpressure.

7.5.3 Filters

Filters are to be installed in supply and exhaust ducts according to Table 1.

If a HEPA-filter is used in the exhaust, it shall be possible to requalify and change without any danger for the staff [2].

(NOTE – this can be done by safe-change filter-housing or in-house fumigation)

HEPA-filters may be installed in the ductwork, separate for each unit or common for several units with redundancy, or inside the unit. Depending on the strategy for where to install them, the following should be defined:

- How to test/qualify them [3]
- Re-qualification intervals (refer to part 1) [4]
- Fumigation/bag-in-bag-out/disposal

Both supply and exhaust HEPA-filters should be tested according to part 1.

7.5.4 Ductwork

Supply and exhaust ductwork are to be installed with tightness class according to Table 1.

The ducts should be marked with biological signs until exhaust HEPA-filter (or until exhaust, in case of no HEPA-filter installed)

7.5.5 Air terminals

Supply and exhaust terminals shall be positioned, and airflow pattern designed, to reduce the exposure of the staff, visitors and patients as much as possible.

7.5.6 Dampers

Dampers with closing function are to be installed in supply and exhaust ducts according to Table 1. The dampers should be installed closest possible to the isolation units, but still accessible for maintenance.

Fail-safe dampers, see part 1.

Dampers for increased tightness requirements (airtight dampers) should be installed to prevent backflow and cross-contamination between the units in case of system failure.

Airtight dampers upstream of the ducted 3rd filtration stage shall meet the requirements of at least class 4 as in EN 1751.

Motor actuated airtight dampers which close automatically in the event of a system standstill or an interruption in the energy supply shall be installed in the supply air and extract air channels:

- for systems supplying rooms of different room classes, at the interfaces between the different room class areas;
- at the boundaries of areas of the same room class where an air-side separation is to be ensured even in the case of a system standstill;
- in the supply air and extract air ducts of VAC systems supplying areas for which different hygienic requirements apply, at a location between the connected rooms and the air handling unit.

Airtight dampers upstream of the 3rd filtration stage are required only if the system cannot be shut down for filter replacement.

Gas tight dampers should meet the requirement of a maximum leakage rate of 10 l/h m2 at Δp=2000 Pa.

7.5.7 Building construction

The building construction around the isolation unit should meet the requirements for air tightness given in Table 1. It is not allowed to have openings to the surroundings.

False ceilings should be avoided for Level S_B, where the installations should be open for disinfection, and the surfaces should be resistant against fumigation.

Windows should be normally closed, and for Level S_B not possible to open (fixed glazing). For Level S_A, P_A and P_B they may be opened with special tools, only for cleaning purposes.

When an isolation unit has contact with the façade, the façade has to meet the tightness requirement in Table 1.

NOTE - This may be solved by building the isolation unit as a “box-in-box”-construction.

The doors to the airlock and patient room could be of two types:

- sliding doors
- swinging doors

Sliding doors are preferable from a ventilation perspective as they cause less disturbance to the air distribution. On the other hand, a swinging door is easier to clean. If sliding doors are used, the cleanability should be considered.

The doors to the airlock shall be interlocked. There shall be a defined waiting time before the next door may be opened. This waiting time shall be set according to the measured recovery time.

The interlock shall be possible to shut off for emergency (e.g fire alarm) and bed transportation. Any shut-off of the interlock should be indicated by a door alarm.

7.5.8 Indicators

There shall be a pressure indicator between the isolation unit and the surroundings. The indicator should be visible outside the access door of the isolation unit.

7.5.9 Fumigation

Isolation units in level S_B shall be able to fumigate. The fumigation shall always be performed for the whole isolation unit, which means that the doors within the isolation unit should be open during fumigation. The isolation unit shall be kept in underpressure during fumigation, monitored by the pressure indicator between the isolation unit and the surroundings. The planning of the complete system for fumigation has to be part of the design.

7.5.10 Alarms

There shall be a technical alarm by ventilation system failure.

An additional indicator shall be installed outside the access door of the isolation unit. It shall be visible, and if acoustic, it shall be able to be temporarily muted.

For Level S_B there shall also be an indicator at the nursing station.

7.5.11 Operating mode control

Selection of different operation modes (i.e. isolation/set back) shall be made by nursing staff from the nursing station based on the actual patient isolation need.

8 Testing, commissioning, documentation

8.1 Technical tests during IQ

All tests described in part 1 and the following test shall be performed.

8.1.1 Air tightness testing of the isolation unit

The air tightness shall be tested according to ISO 9972. BEUTH.de

The leakage rate should be in accordance to Table 1.

8.2 Technical test during OQ

All tests described in part 1 and the following test shall be performed.

The value of the airflow and the pressure difference between the isolation unit and the surroundings shall be documented.

8.2.1 Recovery test

General

The recovery test shall be performed according to ISO-EN 14644-3.
This test shall be carried out upon an installation in the at rest condition state, with equipment and furniture installed.

Selection of measuring points

Use minimum two measuring points in the Patient- and Anteroom.
In Patient room: Place the DPC probe in the working plane at the bed (ca 1,5 m above floor level) near to the patient's head and near the main exhaust or overflow opening.
In Airlock: Place the DPC probe in the working plane in the middle of the room and near the main exhaust or overflow opening.

Procedure for recovery test

Before testing, calculate the concentration required to carry out the recovery test based on a steady state concentration. Care should be taken to avoid coincidence error and potential contamination of the DPC optics.

Testing procedure:

a) set up the particle counter in accordance with the manufacturer's instructions and the apparatus calibration certificate;
b) the particle size used in this test should be not greater than 0,5 µm. It is recommended that the size channel used by the DPC corresponds to that of the maximum number concentration of the aerosol;
c) the Patient and Airlock area to be examined should be contaminated with an aerosol while the air-handling units are in operation;
d) raise the initial particle concentration to more than 100 times depending on the target cleanliness level (see note1). If the initial concentration exceeds the maximum capability of the DPC such that coincidence occurs, use the dilution system;
e) commence measurements at not more than 1 min intervals and record time and concentration.

NOTE The target cleanliness level is the design cleanliness level at-rest conditions.

Evaluation by 100:1 recovery time

Evaluation procedure:
a) note the time when the particle concentration reaches the 100 × target concentration threshold (t100n);

b) note the time and concentration when the particle concentration reaches the target cleanliness level, (tn);
c) the 100:1 recovery time is represented by t0,01 = (tn - t100n).
d) the value of both measurement points shall be recorded, and the highest one shall be used to determine the recovery time

Test reports
The following information and data should be recorded.
a) type designations of each measuring apparatus used and its calibration status;
b) number and location of measuring points;
c) result of measurement.

8.3 Performance Testing PQ

All tests described in part 1 shall be performed.

8.4 Re-verification

Re-verification of the system is recommended combined with the HEPA-filter testing.

The air volume and airflow direction between the rooms within the isolation unit shall be tested annually.

The pressure difference between the isolation unit and the surroundings shall be measured annually.

All these values shall be compared to the initial values of OQ. If any differences occur, measures shall be taken.

When initially performance has proven to be according to the specifications there is no need to re-qualify the complete systems performance.

8.5 Documentation

The installations should be documented as described in part 1, chapter 7.4.4.

8.6 Maintenance

The maintenance procedures should cover the risk for the staff, when servicing the system. Personal protecting equipment shall be considered, e.g. gloves, P3-masks, safety glasses, clothing.

The pressure indicator shall be calibrated annually.

9 Informative section

Annex NN

Dilution factor: A number to describe to what extent the contaminants are diluted in the air by the ventilation system.

The calculations of dilution factors are based on the number of contaminants from a patient. A dilution factor of 100:1 is used as a basis in the calculations.

Calculation:

- For a normal person, the amount of air breathed out is typically 54 m3/h. We assume as a worst-case scenario that all the air is contaminated
- The ventilation efficiency in the isolation room is typically about 70%
- Dilution factor of 100:1
- The airflow volume needed will be 77 m3/h pr patient

The microbes have different nature and they represent different risk levels. There will therefore be different needs of dilution factors for the different classes of isolation units.

The dilution time is set according to normal procedures in the patient rooms and the airlocks.

For patient rooms, the required dilution time is set to 10 minutes. The dilution factor however, varies according to the risk level.

For level S_A: Dilution factor 10:1 in less than 10 minutes → 100:1 in less than 20 minutes → 12 air changes

For level S_B: Dilution factor 20:1 in less than 10 minutes → 100:1 in less than 14 minutes → 20 air changes

For airlocks, the required dilution time is set to 3 or 5 minutes to avoid escape of contamination outside the unit, due to different changing procedures in the different levels. In class S_B the staff normally stays longer due to more complex changing routines.

The dilution factor however, varies according to the risk level.

For level S_A: Dilution factor 10:1 in less than 3 minutes → 100:1 in less than 6 minutes → 46 air changes

For level S_B: Dilution factor 50:1 in less than 5 minutes → 100:1 in less than 7 minutes → 36 air changes

All these figures are based on ideal dilution in the room by supply air.