Contents

Chapter 1 Introduction 1 ................................................................. 3
  Preamble ................................................................................. 3
Statutory requirements ................................................................. 3
  Plants installed in units manufacturing medicinal products .......... 4
  Design and validation process .................................................. 4
Chapter 2 Provision of ventilation in healthcare buildings ................. 4
  Specialised ventilation ............................................................ 4
  Recirculation systems ............................................................ 5
  Dilution ventilation and clean air-flow paths ............................. 5
  Mechanical ventilation systems ................................................. 5
Chapter 3 Assessment of service requirement .................................. 5
  Air purity ................................................................................ 6
  Plantroom size and location ...................................................... 6
  Inlet and discharge sizing and location ........................................ 6
Chapter 4 Air-handling unit design and specification guidance ............ 6
  General requirements ............................................................ 6
  Location and access ................................................................ 6
  Technical requirements .......................................................... 6
  Provision of dampers ............................................................... 7
  Fans ....................................................................................... 7
  Filtration ................................................................................ 7
  Combustion ............................................................................. 7
  Definition of filter terms .......................................................... 7
  Primary and secondary filter selection ........................................ 7
  Energy recovery ...................................................................... 8
Chapter 5 Air distribution system ..................................................... 9
  Cleaning and access door locations .......................................... 9
  Diffuser and grille selection and sizing ...................................... 9
  Transfer grille’s and Pressure stabilisers .................................... 9
Chapter 6 Automatic controls ......................................................... 9
  General requirements ............................................................. 9
Chapter 7 Specialised ventilation systems ................................................................. 10
  General information .............................................................................................. 10
  Air-movement control .......................................................................................... 10
  Operating department ventilation systems ......................................................... 10
  Air terminals and air distribution within rooms .................................................. 10

Ventilation of operating department ancillary areas ............................................ 11
  Sterile pack bulk store ....................................................................................... 11
  Recovery .............................................................................................................. 11

Ultra-clean ventilation systems ............................................................................. 11
  General requirements ......................................................................................... 11
  Types of UCV system ......................................................................................... 11
  Remote plant systems ........................................................................................ 12
  Vertical-flow UCV systems ................................................................................ 12
  UCV Filters ........................................................................................................ 13
  Controls and instrumentation ............................................................................. 14
  Noise level’s ....................................................................................................... 14
  Controls and instrumentation ............................................................................. 14

Chapter 8 Validation of specialised ventilation systems ...................................... 14
  Location of dampers and test holes ................................................................... 14
  Commissioning personnel .................................................................................. 15
  Cleanliness of installation ................................................................................. 15
  Filters .................................................................................................................. 15
  Fire dampers ..................................................................................................... 16
  Dynamic commissioning .................................................................................... 16

Air-handling and distribution system .................................................................... 16
  Room-air distribution .......................................................................................... 16
  Noise levels – general ....................................................................................... 16
  Filter challenge .................................................................................................. 17
  HEPA-Filters ........................................................................................................ 17

Ventilation system commissioning/validation report ............................................ 18
  Validation of UCV operating suites .................................................................... 18
  General ............................................................................................................... 18
  UCV unit validation procedure .......................................................................... 19
  Test grid – vertical units ..................................................................................... 19
  UCV terminal challenge tests (vertical and horizontal systems) ....................... 19
Chapter 1 Introduction 1

Preamble

“1.4 Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – Ventilation in healthcare premises.”

Expand on the withdrawal of HTM 03-01:2007 to prevent the prolonged use within contractual agreements. As with HTM 2025 – this is still being asked for today. Make a clear statement that the 03-01:2007 no longer applies in anyway other than for historic reference purposes and any system that is designed, installed, operated in line with previous versions of HTM need to be assessed inline with new guidance only.

Although published as guidance the HTMs are increasingly being used as a legal document. Further clarity required on its intended purpose and the use of the guidance in everyday working practices. I.E what should happen if an end user decides not to follow this guidance. There is also a clear cross over with COSHH regulations and many HVAC systems incorporating extract could fall into the LEV bracket. (As an example Recovery areas, Anaesthetic areas, potentially even the UCV theatre?).

Statutory requirements

“Statutory requirements

Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established. Plants serving a conventional operating department, for instance, will be required to ensure the separation of areas within the suite by maintaining a specific direction of air flow between rooms, even when doors are opened. They will also maintain the selected operating department’s environmental conditions regardless of changes in outside air conditions or activities within the space. In addition, ultra-clean ventilation systems (which are designed to provide a zone around the patient that is effectively free of bacteria-carrying airborne particles while the operation is in progress) have been shown to significantly reduce surgical site infection in patients undergoing large joint replacement surgery. Their use for other forms of surgery may well be indicated.”
Linked to operating theatre departments only. Needs broadening out. Now it should also detail the many related links between IEQ/IAQ and patient wellbeing and recovery time. Sick building syndrome and the like. Also more recent studies on the effectiveness of UCV systems in general.

1.13 Fire regulations

The positioning of BS 9999 “not applicable to hospital’s” requires clarification – maybe

Plants installed in units manufacturing medicinal products

The crossover of EU GMP/MHRA graded/audited area needs further description on the reasonability’s for each aspect. Many of these areas are managed by the end user and although the validation of the area(s) are undertaken as per auditory requirements the condition of the AHU system in line with the HTM is often overlooked.

Design and validation process

To include outdoor relation to indoor air within the assessment.

“Note: 1. When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure”

Enforce this comment. This is a statutory requirement. Words such as “should” replaced with “must” and the like.

1.25 “Specialised ventilation” is referred to as critical ventilation in other sections. – Standardise use of terminology.

**Chapter 2 Provision of ventilation in healthcare buildings**

Specialised ventilation

Local exhaust ventilation

Clear description needed to clarify types of LEV in healthcare settings.

Ventilation for general areas – Clarification on “general areas”.

Specialised ventilation, critical ventilation, non-critical, general areas.

Needs a reparable way of identifying/classifying a list form is not future proof and the description is too open to interpterion whereby almost every system could be defined as “critical”.
Recirculation systems

Localised air scrubbers to fixed/portable lay-up benches are increasing. Use of portable HEPA-Filtration equipment needs guidance they can be a useful tool if used correctly.

Dilution ventilation and clean air-flow paths

“2.54 The exposure of staff to casual spillages of substances such as medical gases in anaesthetic rooms should in the first instance be dealt with by establishing a clean air-flow path. Air should be supplied at high level and extracted at low level directly behind the anaesthetic equipment position.

The philosophy of establishing a clean air-flow path – from the air-supply point, to the staff, on to the patient, and out via a low-level extract – would also apply in recovery rooms and birthing rooms. A suitable air-change rate will provide background dilution ventilation as an additional safeguard. This approach ensures that “all reasonable steps are taken to prevent or control exposure (of staff) to the hazardous substance” as required by COSHH.”

Low level extract(s). If this is insisted then let’s insist. (Enforce). Most Recovery and anaesthetic areas have high level Extract’s installed. – Clearly this is not being enforced. Action plan for new and existing facilities that don’t meet this criteria.

Mechanical ventilation systems

Should be size restrictions applied to the design of specialist ventilation plant I.E number of spaces/terminals. Difficulties in re-verification of the “whole system” on an annual basis should be discussed. Some AHU’s are serving a mixture of critical and general areas. The annual verification process is then made very expensive and could argue meaningless to test the performance of the “whole system”. This should be considered at design stage as to the total cost of ownership.

Very impractical to re-balance, re-commission correct any air movement issues on these systems once in operation. Some systems are found to be serving 30% of the hospital >200 grilles. Should be limited or operational restrictions made more clear at design stage.

There is also limited - no discussion on N+1 – Perhaps this should be added into this section?

Chapter 3 Assessment of service requirement

Modular and mobile healthcare solutions needs to be included within the guidance.

A Clear statement that notwithstanding the mobile nature of these systems that the ventilation system and the clinical space should meet the necessary minimum requirements.
Air purity

“3.13 Given that almost all viable particles originate from the occupants of a space and not from the incoming air, dilution is the more important factor aerobiologically. Therefore, for general areas a G4 filter is suitable. More critical areas will require an F7 filter. High-efficiency particulate air (HEPA) filters are required only in ultra-clean systems (information on filter grades is given in Chapter 4).”

Clause no longer relevant – should be removed and/or re-written to include acceptable levels of IAQ/IEQ references. See also air filtration section.

Plantroom size and location

External located AHU systems should have increased warnings such as being placed undercover.

Inlet and discharge sizing and location

Air protections screens are an increasing installation on the exterior of AHU plant. No guidance exists on these systems within HTM 03-01 – Opportunity to document guidance on these products.

Chapter 4 Air-handling unit design and specification guidance

General requirements

“None combustible”. – Needs further clarity. How can this be commissioned and signed off at point without detailed certification and information from product manufacturers.

Location and access

Location of ventilation plant outdoors should include a more detailed section on acceptability of equipment and the effects of positioning outside. If needs to be located outside the area should be well lit, the flooring should prevent slip hazards in winter months. There should be consideration for all AHU units to be covered.

Technical requirements

AHU drainage system – Outdoor AHU’s very rarely trace heated. More elaboration on this and Layout of AHU – More examples. The example used in HTM is only one type. Many following inspection (Appendix 1 HTM 03-01 Part B question around one type of system).

More clarity is required for drainage on energy recuperations systems such as plate heat exchangers.
More information on energy recovery systems in general. More information required on thermal wheels for example.

Provision of dampers
Location and access provisions are to be enforced.

Fans
New types of fans to be incorporated.

Filtration

“4.118 Neither the filter media nor any material used in the construction of the filters should be capable of sustaining combustion. The filter media should be such that particles of it do not detach and become carried away by the air flow.”

Combustion

The current clauses within the HTM document concerning this area are ambiguous and causes a lot of confusion surrounding what is actually deemed to be acceptable:

- There is no guidance as to what certification or standard the filters should be tested to
- If certain materials of construction (such as synthetic medias) are deemed completely unacceptable, maybe these materials need to be listed in the HTM to provide further clarity?
- If there is a preferred solution (such as glass media bag/metal frame in pre and secondary stage to meet a combined efficiency) then this example should be given in the HTM with a back-up option where this is not achievable due to AHU limitations?

Definition of filter terms

Clauses 4.122 through to 4.127 inclusive of tables 3, 4 & 5 is now outdated and needs completely re-writing to reference new BS & ISO standards.

Primary and secondary filter selection

All clauses 4.128 through to 4.145 are now outdated and need completely re-writing to reference the below items (this is not exhaustive)

The air filtration for a hospital should not just be specified based on the perceived risk of infection spread, but it also be specified to ensure the indoor environment air quality is sufficient to protect both the patients and employees from air pollution associated health problems. This is more about protecting the employees who spend their whole working lives in these environments.

With the above statement in mind, not only does the particulate filtration need to be specified accordingly, but, particularly in urban areas, serious consideration needs to be given to whether carbon/molecular solutions need to be utilised to protect from the risks of molecular contaminants such as NO₂ etc.
Filtration efficiencies specified in the HTM document need to fall in line with those given in the latest standards such as EN16798 (important to note that this document is being updated at present to reference ISO16890 classifications, currently references EN779:2012). Guidance on classifications can be found in the Eurovent 4-23 document and discussions I’ve had with Tobias Zimmer, suggest that the amended version of EN16798 will reflect the Eurovent document in terms on required combined final efficiency classifications, which are given as ISO16890 classifications.

HTM also needs to focus more on a final combined efficiency as provided in documents such as the Eurovent document rather than dictating pre and secondary efficiencies as in the now obsolete EN13779 standard. This provides greater flexibility to hospitals and filter companies to ensure the most cost effective solution is utilised.

It is the combined efficiency that is crucial rather than the individual efficiencies.

In all instances, filter specifications should be based on outdoor air quality (ODA), again EN16798 provides this.

To facilitate the above and provide clarity, a reference table in the new HTM should be provided that details the SUP class for each area of the hospital and required final combined filter efficiency based on the ODA for the hospital in question.

ISO16890

Any references to filter classifications need to be as per ISO16890, all references to EN779 need to be removed.

Energy Efficiency

With energy being big focus for the new HTM. There needs to a clause in the HTM regarding air filtration and associated energy costs. As we know, filter selection can have a huge impact on this and needs to be highlighted. Going back to a point earlier in this email, maybe preferred solutions should be included that detail filter types by location and minimum specifications for certain products regarding energy and a reference to the new Eurovent energy class. A requirement that filters have to have a minimum eurovent energy classification will go some way to helping hospitals use the most energy efficient products. This will also stop non-Eurovent tested products being acceptable in this industry.

Energy recovery

“4.150 Whichever energy-recovery device is chosen, the extract side will need to be protected by a G3 filter and provided with a drainage system (as described above) to remove condensate.”

Clause is now outdated and requires updating.
Chapter 5 Air distribution system

Cleaning and access door locations

Section should now incorporate and/or refer to current British standards and TR19 industry best practice guidance.

Diffuser and grille selection and sizing.

“Clause 7.71 The diffuser equipment chosen should not cause “dumping”, and it should provide a velocity 1 m above floor level at the operating position of between 0.2 m/s and 0.3 m/s.”

A suitable test method is required to undertake this measurement to enable accurate and repeatable readings. – This is often overlooked and if essential should be compulsory and measured during commissioning and verification procedures. (As with UCV termianl velocity).

“5.58 As they operate on the jet principle, the use of sidewall and linear grilles is restricted to areas where air-change rates are fewer than ten per hour.”

Perforated rectangular diffusers can provide acceptable conditions within the occupied zone at up to 15 air changes per hour. In areas where a higher air-change rate is required, square or circular ceiling-mounted diffusers should be used.

Many square rectangular perforated diffusers are positioned together and utilised as a laminar flow type operating theatre. – Review comment.

More information also required for new types of terminal diffusers – such as swirl diffusers.

Transfer grille’s and Pressure stabilisers

Commissioning of pressure stabilisers is very rarely undertaken. Nor any maintenance.

They should be commissioned in-situ and records issued and kept. Including location, creating of negative effects on any air movement schemes and maximum velocities through apertures.

Chapter 6 Automatic controls

General requirements

“6.7 Alarms should be provided to show “filter fault” and “low air flow”. The “filter fault” alarm should be initiated by a predetermined increase of pressure differentials across the filter. The “low air flow” alarm should be initiated when the supply-air quantity falls to 80% of the design value.”

This comment needs reviewing in light of 75% rule. I.e 75% would create low air flow alarm.
Alarms and indication

Shared area’s / spaces need to be discussed with regards to control.
I.E locking a system to prevent air into shared spaces being reduced when one system is in setback. (Shared prep room’s as an example).

Theatre control panel section needs reviewing.

Chapter 7 Specialised ventilation systems

General information

- Specialised ventilation as referred to within Part A
- Critical ventilation as referred to within Part B.
- Non -critical / general areas.

The above categories need a concise and future proof way of identifying/classifying the ventilation plant into the above or other categories.

The Definition of a critical system’s available within Part B is no longer adequate for emerging clinical spaces and procedures. A matrix approach as appose to a list would future proof the categorisation of specialist/critical ventilation systems.

Air-movement control

This section should include more guidance on shared clinical spaces.

Operating department ventilation systems

Again, more guidance on shared clinical spaces should be given.

Air terminals and air distribution within rooms

“7.71 The diffuser equipment chosen should not cause “dumping”, and it should provide a velocity 1m above floor level at the operating position of between 0.2 m/s and 0.3 m/s.”

Should this be validated and verified? If so how, - test method required.
Ventilation of operating department ancillary areas

Sterile pack bulk store

Most of the times the terminal grilles are inaccessible to measure due to bulk pack stores shelving etc.. Terminal grilles in all areas should be mandatory to access.

Recovery

Same as above due to curtain rails.
Room pressure differential schemes need clarifying for recovery area’s when they back out onto other areas as appose to corridor’s etc..
Doors and open areas within recovery need further clarity. Single doors, double doors, sliding doors, open areas etc.. etc..

Ultra-clean ventilation systems

General requirements

The inner and outer temperatures of UCV systems (the +1°C phenomenon) requires more emphasise/ clarity. Its rarely documented in the test measurement procedures.

Increased section on our learnings of switching off the UCV system, setback and the verification and commissioning/balancing to be completed in “all optional settings”.

This is inclusive of shared AHU plant supplying multiple theatres, Conventional / UCV, 2 UCV etc.. etc.. All possible modes of operation should be checked.

I.E UCV Operational, UCV Standby, Vic Aversa, both operational & both standby. 4 – possible modes of operation. These should be verified over a shutdown period and not on a case by case basis.
It is importance the end user is aware of the added shut down time implications to this design of system.

The negative pressure of ductwork in UCV systems. The HVAC supply system and design of ductwork needing to be sufficient to provide a positive pressure as far up the ducting as possible.

Types of UCV system

“7.105 There is no aerobiological reason why two or more UCV systems should not be installed in a common area as long as adequate spacing is provided. This type of arrangement is known as a “barn theatre ” and requires special design considerations and operational discipline. “

Increased guidance required on Barn Theatre’s.
Remote plant systems

“7.108 This arrangement is the preferred option for new installations as it has the following advantages:

• recirculation fans are located outside the theatre, thus reducing noise. Multiple recirculation fans can be replaced by a single fan unit with its drive out of the air stream;
• casual heat gains from recirculation fan(s), canopy lights, equipment and people within the theatre can be removed by a chiller battery in the return air stream. This will prevent heat build-up in the theatre;
• return-air filters can be changed without needing access to the theatre, making routine maintenance more feasible;
• the opportunity exists to locate HEPA filters in the primary supply duct rather than the theatre terminal. This will reduce the number of filters required and allow them to be changed without entering the theatre.”

Consider reviewing the comment remote systems are preferred. They are clearly in the minority of installs and have several negative factors also.

Vertical-flow UCV systems

“7.113 Because of the large volume of air being moved in a relatively small space, the siting of the return-air grilles can cause short-circuiting of the air discharged through the UCV terminal. If the return-air grilles are positioned at high level, partial walls should be provided to control short-circuiting. For a 2.8 m × 2.8 m terminal, the partial walls should be not less than 1 m from the operating room walls. The clearance should be increased proportionally for larger terminals (that is, 1.15 m for 3.2 m × 3.2 m units; and 1.25 m for 3.5 m × 3.5 m units). In all cases, the side walls should terminate at 2 m above floor level.”

Above section needs reviewing in light of screenless UCV systems. Also additional guidance required on screenless systems.

Inclusive of note: “The use of lines on the floor delineating the extent of the clean zone and hatching or colour-coding the “noentry” zone between the air diffuser and patient will serve to prompt staff and are therefore essential.” – This is further enhanced with screenless and flush mounted systems.

“7.120 For all vertical UCV systems, the design discharge velocities will be as follows:
Air velocity 2 m above floor level:

• partial-wall system = 0.38 m/s average;
• full-wall system = 0.30 m/s average.”

Consider maximum velocity especially for 2 metres whereby many UCV designs are increased to velocity averages way in excess of design just to achieve 1 metre velocity profiles. This is usually a UCV design issue and the HTM should not allow this to happen. – Maximum will also reduce energy running costs, and TCO etc.. The limit is normally derived by maximum noise level however this just gets overlooked to achieve velocities.
“7.121 In order to ensure that the terminal quadrants are in balance, the average air velocity for each quadrant should not exceed ±6% of the measured average velocity for the terminal. Air velocity 1 m above floor level:
* all systems = 0.2 m/s minimum within the operating zone.”

Consider some form of tolerance on the above?

What to do in the event of failure – (Linked to escalation policy). I.E should an existing theatre be closed if one reading is 0.19m/s etc..

• For example a more detailed measuring sample than 10 seconds for those low readings?
• A maximum number of positions allowed within tolerance that can achieve below 0.20m/s. etc...

Also added comments to incorporate testing on Screenless systems and how velocity from linier slot can effect readings if not tested correctly.

**UCV Filters**

“7.129 Terminal filters should be provided within the air-flow terminal or in the air supply to it. HEPA filters grade H10 (as specified in BS EN 1822) should be installed. There is no aerobiological benefit in fitting filters of a higher grade than this, although for practical reasons most UCV manufacturers recommend the fitting of H12-grade filters.”

Now section needs updating to fall in line with current EN1822. Also needs to document Gel systems and recent failings.

“7.132 Where UCV units are constructed in sections, a means of measuring the pressure drop across the terminal filters in each section should be provided. The pressure test-points should be located outside of the partial wall, capped to prevent air leakage and accessible within the theatre without the need of measuring the pressure drop across the terminal filters in each section should be provided. The pressure test-points should be located outside of the partial wall, capped to prevent air leakage and accessible within the theatre without the need to open the unit’s inspection panels. Alternatively, direct-reading pressure gauges should be fitted.”

These are very rarely installed. – If this is the preference the comment should be further enforced or perhaps a gauge per UCV quadrant/section?

“7.133 The UCV system will require a return-air filter to capture the relatively coarse particles that would otherwise significantly reduce the life of the final filter. This should be at least a G3 grade to BS EN779. In remote recirculation systems, there may be advantages in fitting a higher grade return-air filter as it will reduce the load on the terminal HEPA filters and extend their life.”

Now needs revising with current BS/ISO standards.

Air filter assessments. – Should be considered as part of the annual validation. All correct level of information should be provided to the customer at handover. Type efficiency, size, initial differential pressure. Filter should be adequately labelled.
HTM 03-01 Comments Part A -

HTM 03-01 Part A in chapter 4, Air-handling unit design and specification guidance, Technical Requirements states in 4.12 “The plant and its distribution system must not contain any material or substance that could cause or support combustion.” This makes it clear that the system not just the plant must not contain any material or substance that could cause or support combustion. Filters within the UCV clearly come into this clause yet many UCV systems are installed with fire attenuation, card framed pre-filters – and many other plastic components.

Combustion – the HTM clause used the “whole system” – As the UCV is a part of the system anything within the UCV should also conform to this clause.

Controls and instrumentation

Section needs to now incorporate new eTCP panels and new technology.
Table 6 Indicator-light logic table - As above.

Noise level’s – More accurate repeatable test method or SOP for measuring noise level readings. Standardise the unit of measurement. NR and dB(A)

Controls and instrumentation

eTCPs – Theatre control panels. The current “RAG” rating section on theatre and UCV control panels is now outdated and/or irrelevant with emerging technology. This needs to be revised to include new technologies and simplify for the end user.

Chapter 8 Validation of specialised ventilation systems

As with the initial validation. This should be mandatory for a provider to test the system as a whole not left to individual organisations to commission their part only.

“8.14 On completion, the system should be operated by the contractor as a whole and subject to performance tests in accordance with the contract requirements. For critical systems, these should include independent validation of the system performance on behalf of the client.”

Again – words such as “should” need to be delivered stronger.

In many cases the only time the system is considered as a whole is during the first annual verification some 12 months after install.

Location of dampers and test holes

Test points. – Need designing them into a system. – More information is required to enhance this. Many systems have no accessible test points for accurate measurement of duct velocity.
Commissioning personnel

“Clause 8.8 It is unlikely that one particular individual will have all of the required commissioning skills; a commissioning team is therefore usually needed. The objective of commissioning is to ensure that the necessary performance and safety requirements are met.”

Also applies for annual re-verification and delivery of verification process model.

- Commissioning brief
- Pre-commissioning checks
- Standard of installation

“8.19 During the installation of the system, the following must be witnessed by either the client or his representative:”

Many of the items included within this section are very rarely witnessed.
If witnessed, maybe a standard way of recording this should be provided and enforced. I.E IQ/OQ/PQ.

Validation of new system and/or refurbishment should have a documented standard procedure and validation protocol with detailed Functional requirements. IQ/OQ/PQ type protocols as an Example.

Enforcement of Clerk of works?
AE/AP role very rarely present to witness any test and performance measurements of new installations.

Cleanliness of installation

Section needs revising to document up to date publication(s) and standards such as TR19.

Filters

“8.26 The quality of filter housing and, in particular, seals is a critical factor in maintaining the efficacy of the filtration system by ensuring that air does not bypass the filter panels. Therefore, the following checks should be made:

• filter seals should be fitted and in good condition;
• filters should be installed correctly with respect to air flow;
• bag filters should be installed so that the bags are vertical and their pockets free;
• HEPA filters should be installed in a sealed housing and their seals tested to DIN 1946 if specified;”

Why DIN 1946? – Terminal housing’s tested in line with ISO 14644. – DIN filter gaskets are entirely different and rarely purchased in UK.

Nothing on the efficiency?, type of filter? Labelling etc..? Some vital information missing from this check list.
Fire dampers

“8.28 The following must be witnessed, and proving tests should be carried out as detailed:
• the operation of all fire dampers;
• access provided to enable the dampers to be visually inspected and/or re-set should be sufficient for the purpose;
• indication should be provided of the dampers’ position (open/tripped);
• indication of the fire dampers’ location should be provided both on the ductwork and at a visible point on the building fabric if the ductwork is concealed.”

Again words such as “should” – need to be enforced more thoroughly. Also, section should refer to current guidance and BS on installed fire damper tests.

Dynamic commissioning

More emphasis for design and commissioning of pressure regimes. HVAC commissioning engineers only commission the flowrates in some cases and/or use the supply and extract to achieve the room pressure differentials – add description that this is not acceptable.

Validation – Pressure regime clauses need clarifying. Maximum pressure adding for health and safety reasons. The importance of the individual pressure value needs explanation as contradictory text throughout the document stating that individual pressures are not important providing they are going in the correct direction. – Also suggest that they should not be less than 75% etc.. - Requires clarifying. Also – How can you have 75% of a zero target pressure?

Air-handling and distribution system

Correction factors. – Clarification on requirement and what to do in reality when all access is restricted. ceilings are solid and within a live hospital. Statement to clarify use.

Room-air distribution

“8.36 Pressure-relief dampers and pressure stabilisers should be set to achieve the specified rooms static pressures and should be locked. The grille’s direction-control vanes and diffuser cones must be set to give the specified air-movement pattern. Visualisation techniques may need to be employed in order to prove that the required air-flow pattern is being achieved.”

Section needs to enforce accurate and repeatable measurement of this.

Noise levels – general

Noise levels, - NR & dB – why not standardise to dB? A well-documented test method for measurement of noise levels would be a positive move.
Filter challenge

*General ventilation filters* 8.52 – Again, words like “should” etc... need to be enhanced.

**HEPA-Filters**

Section 8.53 – 8.58

All sections need revising.

- use a discrete particle counter (DPC) to detect leaks. (In order to obtain a sufficient challenge, it may be necessary to temporarily remove the supply AHU’s secondary filters.)

This contradicts the above statement in 8.53. Not in line with ISO 14644.

8.56 – Penetration is not always 0.01%. – Depends on the area – this contradicts pharmacy aseptic guidance & also is not possible with an E10 filter.

8.57 – A SOP needs developing. “The filter face, its seal and housing are then scanned, and if a significant number of particles at or above this size are detected, there is deemed to be a leak at or near the test position.”

Significant number is open to interpretation and not thorough enough.

“8.58 Should the HEPA filter fail this test, it must be replaced. Should the filter mounting seal or housing fail this test, it may be repaired and the test repeated.” – Repair onsite – what level is permitted. Allowed? Elaborate.

In-situ HEPA-Filter testing needs its own sections including but not limited to;

- The pros and cons of DOP testing and alternative testing using a DPC.
- If DPC testing is preferred then a more accurate and repeatable test method needs designing agreeing and documenting as the current ISO 14644 methodology is not suitable neither is the current HTM method.

Also more guidance could be provided for;

- What to do in the event of a leak.
- What section of site repairs is considered acceptable.
- Use and control of silicone grease and other forms of silicone sealant to make good housings and frame work.

Possible to consider DOP for first installation and then DPC thereafter unless filtration is replaced then default to DOP test due to accuracy and clear pass/fail criteria.
Considerations need to be enforced at the design stage of the “testability” of the ventilation system with regards to HEPA-Filter installation leak testing (DOP). – Example In-line AHU HEPA filtration with no scanning and/or volumetric facility.

DOP The risks associated with outgassing and using an aerosol within vulnerable patients present.

Testing risks when changing filter is a neutropenic ward for example when all isolation rooms share a common ventilation plant.

Shared ventilation plant for isolation rooms. – Some systems very difficult to DOP test once in operation without complete shutdown and evacuation of area.

**Ventilation system commissioning/validation report**

More emphasis on the legal requirement for end users / operators to retain accurate records of design and commissioning and initial appraisal information.

Validation of specialised ventilation systems broadened beyond operating theatres. (Very operating theatre heavy).

**Validation of UCV operating suites**

**General**

"**8.71 In order to avoid preloading the UCV terminal's recirculation ducts and HEPA filters, the operating suite should be free of any obvious dust and at least ‘builders clean’ before the recirculation fans are set to work (see also paragraph 8.16).**"

A minimum area cleanliness & PPE “tick list” should be provided prior to installation of HEPA filters. Incorporating Gel systems.

Validation of AHU plant serving twin theatres, I.E UCV + UCV. UCV + Conventional etc.. needs to be elaborated. The commissioning and validation process should be documented to include the system as a whole and validation of the performance characteristics in all possible modes of operation inclusive of peripheral areas.

Barn Theatre’s – Design, Commissioning, Validation and re-verification thereafter needs its own section., The adjustment of one UCV setpoint can have a huge effect on the performance of another UCV within the same space as seen during commissioning of previously installed barn theatres.

Provisions for guidance on screenless and flush mounted UCV systems and the associated testing inclusive but not limited to revised entrainment test method.
UCV unit validation procedure

Test grid – vertical units

Clearly corrections required in the documented test grid.

UCV terminal challenge tests (vertical and horizontal systems)


**“8.96 A leak is defined as a significant rise above the background level.”**

This is not clear enough in its description of a leak – to open to opinion.

UCV terminal air velocity test

Tolerance on 1 metre velocities. Is it viable for the end user organisation to close an operating theatre due to a single 1 metre velocity falling below 0.20m/s.

What do we do for system’s designed and commissioned to a previous HTM 2025 for example whereby the +/-6% was not included.

Tolerance on 2 metre velocities. Is it viable for the end user to close an operating theatre due to a 0.37m/s average velocity or a marginal sectional balance disparity.

UCV entrainment test

Entrainment test method – further enhancement of test method is required to remove ambiguity. Escalation procedure for if the entrainment test should fail. In some cases there is not always a clear reason as to why this is and what can be done to eradicate this failure.

UCV noise level

**“UCV noise level**

8.147 An industrial-grade Type 2 sound-level meter fitted with a muff should be used to check the noise level. The instrument should be calibrated using a matched sound source prior to each set of readings.”

No allowance be provided for future increase in fan speeds due to filter soiling? Many UCV systems meeting 55dBA on commissioning. – 1 year later over noise level.

UCV control system checks

Password protections on systems – should be provided by suppliers and retained by customers. – For longevity of use of equipment and to protect customer against supplier going into administration etc..
UCV theatre microbiological tests

Some establishments requesting for particle counting to be undertaken to ISO 14644 under UCV. Maybe a good opportunity to discuss this and the pro’s and con’s of undertaking such a test under UCV systems “at rest” and linking to a cleanroom standard.

Appendix 1 Use and function of typical equipment used in ventilation systems

Filter

“**A1.10** Filters may be fitted to extract systems to protect energy-recovery devices. They are also fitted to remove biological, radiation or chemical hazards. They are often contained in a “safe change” facility in order to protect those carrying out maintenance.”

The term “safe change” is now not considered correct - replaced with BIBO Bag in Bag out.

Appendix 2 Recommended air-change rates

An extended appendix 2 – (Re-named – and expanded). Stating the room, a brief of its application and any typical design characteristics. Similar to existing but greatly extended, as discussed in the meeting the ASHRE standard has some 70 room area’s documented.

This could incorporate all HBN criteria in the same format. Also incorporate shared areas.

The above could also be used to clarify the “treatment room”, “minor ops”, and further clarify some of the HIS guidance on minimal access interventions. (“Such as some procedures can be undertaken in a room with an open window”).

Endoscopy area’s needs to be re-structured and consider other forms of endo type procedures such as Bronchoscopy on infected patients etc...

This is extended to “Day Case” Theatre’s, and also Theatre sluices/disposal and dirty utility ambiguity.

Removal of standardised approach to air filtration specification. This can be a minimum level of air filtration but must be equal to or better than current BS and ISO standards and also make reference to the outdoor air pollution level and what level of supply air is required within the space.

Appendix 3 Hierarchy of cleanliness

“**Notes:** a. Nominal room pressures are given to facilitate setting up of pressure-relief dampers, the calculation process, and the sizing of transfer devices. In practice, the resultant pressures are not critical, provided the desired air-flow rates and movement are achieved.”

Statement should be clarified. – Incorporate tolerance/maximum etc.?

Further Clarification required for pressure differential’s from area to area. (I.E not just nominal room pressures. Elaborate to include pressure differentials.)
Appendix 7 Operating suites standard design solutions

Include other clinical areas as examples. (Such as endoscopy).

Shared areas. More guidance on design of shared spaces.