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APIS GUIDE 01 · HEALTHCARE

Hospital ventilation & *classified areas.*

A specification and validation guide for operating theatres, intensive care and clean areas — written for hospital owners, technical services managers and project teams across the Western Balkans.

APIS · HVAC-R DIVISION

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ABOUT THIS GUIDE

What is inside, and *who it is for.*

Hospital ventilation projects rarely fail because the wrong air handling unit was bought. They fail because nobody wrote down, room by room, what the classified areas had to achieve — and the omission only becomes visible at validation, when there is no agreed acceptance criterion and no programme left to negotiate one.

This guide sets out what a healthcare ventilation specification must contain to be buildable, priceable and verifiable. It covers the four classification frameworks in common use across the region, the four parameters that must be fixed for every classified room, the filtration and air handling unit requirements that follow, and the commissioning and validation sequence that closes the project out. It ends with a forty-point checklist you can take straight into your own tender documents.

Who this is written for

- Hospital directors and heads of technical services planning a new build, an extension or a theatre refurbishment
- Public-sector and ministry procurement teams preparing healthcare tender documentation
- Healthcare developers, PPP sponsors and their technical advisers
- Main contractors and MEP consultants pricing or reviewing healthcare ventilation scope

What this guide is not

It is not a design document, and it does not replace a qualified ventilation designer, a hygiene specialist or a competent validation body. It does not set the room classification for your facility — that is a clinical and infection-control decision taken by the operator, which this guide will help you record correctly once it has been taken. Nothing here should be read as legal or regulatory advice on the requirements applicable to healthcare premises in any particular jurisdiction.

> A NOTE ON STANDARDS
>
> Standards are cited by number throughout so that you can find and read them yourself. Editions are revised periodically. Before a citation is written into a contract document, confirm the current edition and, where relevant, the national adoption applicable at the project location. Where this guide describes typical or commonly applied values, they are identified as such — they are a starting point for discussion with your designer, not a substitute for design.

Contents

How to use it

The guide follows the order in which the decisions have to be taken. If you are drafting a specification, work through it from Section 02 forward and complete the room data sheet in Section 03 as you go. If you are reviewing a bid or a set of tender documents you did not write, start at the checklist in Section 09 and work backwards to the sections that explain the items you cannot tick.

> THREE QUESTIONS WORTH ASKING BEFORE YOU READ FURTHER
>
> 1. Does your specification name **one** governing framework, or several?
> 2. Can you produce, today, a table giving the class, occupancy state, air change rate and pressure differential for every classified room in the project?
> 3. Does the contract say who performs the classification testing, and who pays for the retest if a room fails?

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SECTION 01

Why hospital ventilation fails *at handover.*

The problem is almost never the equipment. It is that the acceptance criteria were never written down, and by the time anyone notices, the contract is already signed.

Ventilation in a hospital does two jobs at once. It makes rooms comfortable, which is an engineering problem with well-understood answers. And it controls the airborne contamination that reaches a patient with an open surgical site or a suppressed immune system, which is a very different problem — one where the required performance is a clinical decision, and the engineering follows from it.

Almost every difficult healthcare ventilation project we have seen went wrong at the junction between those two things. Someone had to state what the classified rooms must achieve, and no one did.

Three symptoms you will recognise

1 · The specification names standards but sets no values

A tender document lists ISO 14644-1, DIN 1946-4, EU GMP Annex 1, ASHRAE 170 and VDI 6022 in its opening clause and then never returns to them. No room is assigned a class. No air change rate is stated. No pressure differential is given. Each of those documents describes a different framework, written for a different purpose, and several of them cannot sensibly be applied to the same room simultaneously.

The effect on pricing is immediate. Tenderers must guess, and they guess differently. One bidder prices a laminar-flow ceiling over the operating table; another prices turbulent mixed flow. The difference can be a factor of two on the theatre package. The evaluation then compares two numbers that are not describing the same building.

> THE COMMERCIAL CONSEQUENCE
>
> An unspecified classified area is not a saving. It is a variation waiting to happen, priced later, without competition, at the moment the client has least leverage — after the ductwork is installed and the ceiling is closed.

2 · Filtration is specified by name, not by classification

“HEPA filters to be provided” is not a specification. HEPA is a band containing two classes — H13 and H14 under EN 1822-1 — separated by a factor of ten in penetration, and the standard also covers the adjacent EPA and ULPA bands. Where the filter sits matters as much as its class: a terminal filter in the room ceiling and a filter in the air handling unit protect against different failure modes, and specifying one does not deliver the other.

The related failure is documentary. A filter arrives on site with a hygiene certificate, or a manufacturer’s declaration of conformity, or a factory test report — and the project team files it as evidence of classification. It is not. Section 04 sets out what each document actually proves.

3 · Validation has no defined pass mark

The commissioning engineer measures particle counts, air change rates and pressure differentials, and then has to compare them against something. If the contract fixed no criterion, one of three things happens: the criterion is invented at the point of testing, usually by the contractor; the operator imposes a stricter criterion than was priced; or the room is accepted with the question unresolved and re-emerges as a defect years later.

None of these is a good outcome, and all three are avoidable at the cost of a single well-drafted table in the tender documents.

> *A hospital ventilation system that cannot be shown to meet a stated criterion has not been commissioned. It has merely been switched on.*

Why this happens more often in healthcare than anywhere else

Three structural reasons, none of them anyone's fault:

1. **The decision belongs to someone who is not in the room.** Room classification follows from infection-control policy and the clinical procedures intended for each space. The people who hold that knowledge — infection control, surgical leads, the hospital hygienist — are rarely involved when the technical specification is drafted.
2. **Four frameworks compete for the same room.** A European hospital project can plausibly cite ISO 14644-1, DIN 1946-4, EU GMP Annex 1 and ASHRAE 170. They were written for cleanrooms in general, for German healthcare buildings, for sterile pharmaceutical manufacture, and for US healthcare facilities respectively. Choosing between them is a real decision, and it is easier to cite all four.
3. **The consequence is deferred.** An unpriced classified area causes no problem at tender, none at award, and none during first fix. It surfaces at validation, which is the last activity before handover, when there is no float left.

What this guide does about it

The remainder of this document works through the decision in the order it has to be taken. Section 02 helps you choose one governing framework and record why. Section 03 fixes the four parameters that must be stated for every classified room. Sections 04 to 06 cover what those parameters demand of the filters, the air handling units and the pressure regime. Section 07 sets out the validation sequence and who signs what. Section 08 tells you what the decision will cost to run for the next fifteen years — which is usually the moment the specification gets sensible.

SECTION 02

Choosing the *classification framework.*

Four systems, written for four different purposes. Pick one to govern, use the others for reference, and write down which is which.

The first substantive decision in any healthcare ventilation specification is which framework governs. This is not a technical preference. Each framework defines performance differently, tests differently and accepts differently, and mixing them produces requirements that cannot all be satisfied at once.

The four frameworks, and what each is actually for

TABLE 2.1 — FRAMEWORK SELECTION

Framework	Written for	How it defines performance
ISO 14644-1	Cleanrooms and associated controlled environments, any industry	Airborne particle concentration only, by class ISO 1 to ISO 9, at stated particle sizes. Says nothing about air change rates, pressure or temperature.
DIN 1946-4	Ventilation and air conditioning in healthcare buildings	Room classes based on the protective effect achieved in the room, tested by a defined protection-degree method. Prescribes filtration stages and air handling requirements.
EU GMP Annex 1	Manufacture of sterile medicinal products	Grades A to D, each mapped to particle limits at rest and in operation, with microbiological monitoring limits. A regulatory, not an engineering, framework.
ASHRAE 170	Ventilation of health care facilities (US practice)	Prescriptive minimum air change rates, outdoor-air fractions, pressure relationships, filtration and design conditions, tabulated by room function.

> THE DISTINCTION THAT MATTERS MOST
>
> **ISO 14644-1 is a measurement result. ASHRAE 170 is a design input.** ISO 14644-1 tells you what the air in the finished room must contain. ASHRAE 170 tells you what to build in order to have a reasonable chance of achieving it. A specification that gives you only one of the two is incomplete — and the two are not interchangeable, because a room can meet a prescribed air change rate and still fail a particle count.

How to decide

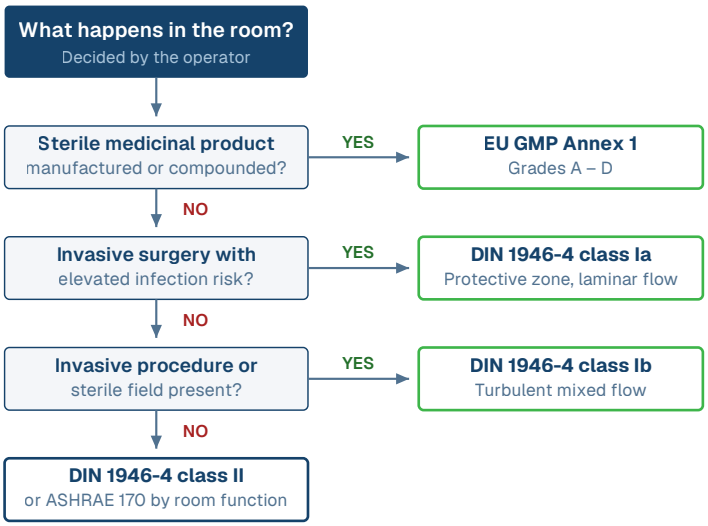
In practice the choice across the Western Balkans falls out along these lines. This is a starting position for discussion with the operator and the designer, not a rule.

TABLE 2.2 — TYPICAL GOVERNING FRAMEWORK BY AREA

Area	Usually governed by	Reference frameworks
Operating theatres, general and orthopaedic	DIN 1946-4 room class	ISO 14644-1 for particle verification; ASHRAE 170 for air change and pressure cross-check
Intensive care and high-dependency	ASHRAE 170 or national healthcare guidance	DIN 1946-4 class II
Protective isolation (immunosuppressed patients)	ASHRAE 170 protective environment	ISO 14644-1 for filter integrity verification
Airborne infection isolation	ASHRAE 170 or national guidance	Containment verified by pressure and direction, not by particle class
Central sterile services, packing and sterile store	DIN 1946-4 or ISO 14644-1	Operator's infection-control policy
Hospital pharmacy, aseptic preparation and compounding	EU GMP Annex 1 grades	ISO 14644-1 classification is embedded in the grades
Endoscopy, delivery rooms, treatment rooms	National healthcare guidance	DIN 1946-4 class II as a floor

A COMMON AND EXPENSIVE ERROR

Applying EU GMP Annex 1 grades to operating theatres. Annex 1 governs the manufacture of sterile medicinal products. Its grades carry continuous environmental monitoring, microbiological limits and a qualification regime built for a pharmaceutical facility operating under a manufacturing authorisation. Imposing them on a theatre suite adds substantial capital and recurring cost without addressing the risk the theatre actually faces. Annex 1 belongs in the hospital pharmacy, not in surgery.



IN EVERY CASE

Then add, for each room:

1 · ISO 14644-1 class for verification
2 · Occupancy state — at rest / in operation
3 · Air change rate, total and outdoor
4 · Pressure differential and direction
5 · Filtration stages and classes
6 · Temperature and humidity range

RECORD ALSO

Governing framework and edition
Who took the classification decision
Date of the infection-control sign-off

Figure 2.1 — Classification decision sequence. The left column selects the governing framework; the right column lists what must be recorded for every classified room regardless of which branch was taken.

The particle classes, in one table

Whichever framework governs, particle verification will almost always be expressed through ISO 14644-1. The classes below are the ones that appear in healthcare work. The full standard covers ISO 1 to ISO 9 and additional particle sizes.

TABLE 2.3 — ISO 14644-1 LIMITS AT THE SIZES USED IN HEALTHCARE

Class	≥0.5 µm per m³	≥1.0 µm per m³	Typical healthcare use
ISO 5	3 520	832	Laminar-flow protective zone over the operating table; GMP grade A and B at rest
ISO 6	35 200	8 320	Intermediate, occasionally specified for high-risk implant surgery peripheries
ISO 7	352 000	83 200	Theatre periphery; GMP grade B in operation and grade C at rest
ISO 8	3 520 000	832 000	Preparation and support rooms; GMP grade C in operation and grade D at rest

> AT REST, OR IN OPERATION — THE QUESTION THAT MUST BE ANSWERED
>
> ISO 14644-1 defines three occupancy states: **as-built** (complete, no equipment, no people), **at rest** (equipment installed and running, no people) and **in operation** (equipment running, people present, process under way). The same room can be two classes apart between at-rest and in-operation.
>
> A specification that states “ISO 7” without naming the occupancy state has not stated a requirement. Name the class and the state, for every classified room, and state the number of people and the equipment load assumed for the in-operation test.

The DIN 1946-4 room classes

DIN 1946-4 does not classify by particle count. It classifies by the protective effect the ventilation achieves in the room, verified by a defined test method. Broadly:

TABLE 2.4 — DIN 1946-4 ROOM CLASSES IN OUTLINE

Class	Air distribution	Applied to
Ia	Low-turbulence displacement flow over a defined protective zone — a laminar-flow ceiling above the operating table and instrument tables	Operating theatres for procedures with elevated infection risk, notably implant and joint replacement surgery
Ib	Turbulent mixed flow, three filter stages, defined air volumes	Operating theatres for procedures without elevated risk; many treatment and intervention rooms
II	Conventional supply with defined filtration; no protective-zone requirement	Support, recovery, preparation and general clinical areas within the department

The engineering consequence of class Ia is large. A laminar-flow ceiling covering the protective zone, sized to the surgical field and the instrument tables, drives supply air volumes, plant room space, duct sizing, ceiling

coordination and terminal filter area far beyond a class Ib room. Where the standard specifies a minimum dimension for the protective zone, that dimension governs the ceiling size — confirm the figure against the current edition before it is written into a tender, because it fixes a substantial part of the theatre cost.

> **RECORD THE DECISION, NOT JUST THE OUTCOME**
>
> Whichever framework you adopt, write a short classification statement into the tender documents: the governing framework and its edition, the class or grade for each room, the occupancy state at which it is verified, and who took the decision. Two paragraphs at the front of the specification will prevent more disputes than any other two paragraphs in the document.

SECTION 03

The four parameters a specification *must fix.*

Air change rate, pressure regime, filtration and thermal conditions. Every classified room needs all four, stated as numbers, in a table.

Once the governing framework is chosen, the specification has to translate it into values a contractor can price and a commissioning engineer can test. Four parameters do most of that work. A room data sheet carrying all four, for every classified room, is the single most valuable document in a healthcare ventilation tender.

Parameter 1 — Air change rate

State two figures, not one: **total air changes per hour**, which governs dilution and particle removal, and **minimum outdoor air changes per hour**, which governs the removal of gaseous contaminants including anaesthetic agents. A system can meet a high total air change rate almost entirely on recirculated air and still fail to control what recirculation does not remove.

Prescriptive tables such as those in ASHRAE 170 give minimum values by room function. Confirm the values against the current edition of whichever document you adopt; they are revised, and a value quoted from memory or from an older project is a common source of error. Where the room is a class Ia protective zone, the air volume is set by the displacement flow velocity across the protective area rather than by an air change rate, and the resulting figure is normally far higher than any tabulated minimum.

> AIR CHANGE RATE IS NOT A PROXY FOR CLEANLINESS
>
> Raising the air change rate improves dilution and shortens recovery time, but it does not compensate for a poor air distribution pattern, a leaking terminal filter frame or an uncontrolled pressure regime. Specifications that respond to an uncertain requirement by inflating the air change rate buy running cost, noise and plant space without buying the protection they were seeking.

Parameter 2 — Pressure differential and direction

State the differential in pascals, the sign, and the reference space. “Positive pressure” alone is not testable — positive with respect to what? Section 06 covers the cascade in detail. What the specification must contain is a number, a direction and a named neighbour for every classified room, together with the door and airlock arrangement assumed to achieve it.

Parameter 3 — Filtration stages and classes

State the number of stages, the classification of each, and the position of each in the system. Section 04 sets out what each classification means and which document proves it. Healthcare specifications commonly require three stages for class I rooms — two within the air handling unit and a terminal stage at or near the room — but the requirement follows from the governing framework and must be taken from it rather than assumed.

Parameter 4 — Temperature and relative humidity

State a range, not a set point, and state who may adjust it. Operating theatres typically require a range that surgical staff can vary within defined limits, because thermal comfort under surgical clothing and lighting is a genuine clinical concern. Relative humidity has both a lower bound, associated with electrostatic discharge and mucosal drying, and an upper bound associated with microbial growth and condensation. The bounds drive the

humidification and dehumidification plant, which is frequently the largest single energy consumer in a theatre suite.

ALSO FIX, IN THE SAME TABLE

- **Noise limit** — a value in dB(A) at a stated position. Theatre teams work in these rooms for hours; ventilation noise is a recurring complaint that cannot be corrected after installation without significant cost.
- **Recovery time** — where the governing framework requires it, state the required recovery performance and the test method. This is what tells you the room returns to class after a contamination event.
- **Air distribution pattern** — displacement, low-turbulence displacement over a protective zone, or turbulent mixed flow. This is a design decision with a large cost consequence and it must not be left to the tenderer.
- **Operating hours and setback** — whether the room may be set back outside operating hours, to what condition, and how long it must take to return to full specification. See Section 08.

The room data sheet

Reproduce this table in your tender documents with one row per classified room. It takes an afternoon to complete with the operator and it removes most of the ambiguity that Section 01 described.

TABLE 3.1 — ROOM DATA SHEET TEMPLATE

Room	Class / grade	State	Total ACH	Outdoor ACH	Pressure	Filtration	°C / % rh
OT-01	–	–	–	–	–	–	–
OT-02	–	–	–	–	–	–	–
Prep / scrub	–	–	–	–	–	–	–
Sterile store	–	–	–	–	–	–	–
Recovery	–	–	–	–	–	–	–
Corridor	–	–	–	–	–	–	–
Isolation	–	–	–	–	–	–	–

Two rules make the table work. First, every cell must contain a value or an explicit “not applicable” — a blank cell is read by a tenderer as an absence of requirement. Second, the pressure column must name the reference space, not merely a sign, so that the cascade in Section 06 can be checked for consistency across the whole department.

A caution on transcription. Values quoted in this guide are illustrative of the structure a specification needs, not recommended design values for any specific project. Take every number from the governing framework in its current edition, applied to your rooms by a qualified designer, and confirmed with the operator’s infection-control function.

SECTION 04

Filtration, and what a certificate *actually proves.*

Two classification systems, three stages, and four documents that are routinely mistaken for one another.

Filtration is where healthcare ventilation specifications are most often loose and most often audited. Two European standards classify filters, and they are not alternatives — they cover different performance ranges and a healthcare system normally uses both.

The two classification systems

TABLE 4.1 — WHICH STANDARD CLASSIFIES WHICH FILTER

Standard	Covers	Expresses performance as
EN ISO 16890 series	General ventilation air filters — the coarse, pre-filter and secondary stages	Efficiency against a particulate mass fraction: ePM1, ePM2.5, ePM10, or ISO Coarse where the filter is too weak to qualify in the ePM groups
EN 1822 series	EPA, HEPA and ULPA filters — the terminal and high-efficiency stages	Efficiency at the most penetrating particle size, by class from E10 to U17

ISO 16890 replaced the older EN 779 classification, in which filters carried G and F designations such as G4, F7 and F9. Those designations still appear in older project documents, in some product literature and in the habits of most of the industry. **They are not equivalent**, and no exact conversion exists, because the two standards measure against different particle distributions. Where a legacy specification says “F7”, the correct response is to ask the designer what ePM class is required, not to look up a conversion table.

> DO NOT CARRY FORWARD G AND F DESIGNATIONS
>
> A tender that specifies “F9 secondary filtration” in 2026 is asking for a product that is no longer classified that way. Bidders will each substitute a different ePM class, and the difference between ePM1 60% and ePM1 80% is real — in both filtration performance and in the fan energy required to push air through it for the next ten years.

The EN 1822 classes

EN 1822 classifies by efficiency at the **most penetrating particle size**, or MPPS — the particle diameter at which a given filter medium performs worst, which for typical glass-fibre HEPA media falls in the region of 0.1 to 0.3 µm. Testing at MPPS rather than at a convenient large particle size is what makes the classification meaningful: it reports the filter at its weakest point.

TABLE 4.2 — EN 1822 CLASSES ENCOUNTERED IN HEALTHCARE

Class	Group	Overall efficiency at MPPS	Where it is used
E11	EPA	≥ 95 %	Occasionally as a final stage in lower-classification areas
E12	EPA	≥ 99.5 %	Secondary or final stage in class II areas
H13	HEPA	≥ 99.95 %	The common terminal filter in operating theatres and clean areas
H14	HEPA	≥ 99.995 %	Specified where the governing framework or the operator requires it, notably in protective isolation and some class Ia protective zones
U15	ULPA	≥ 99.9995 %	Rare in healthcare; belongs to semiconductor and high-grade pharmaceutical work

The step from H13 to H14 is a factor of ten in penetration. It is also a step in pressure drop, in filter cost and in the energy required to move air through the filter for its whole service life. Specify H14 where the requirement genuinely calls for it, not as a margin of comfort against an unstated criterion.

For the HEPA and ULPA classes the standard also defines a **local** efficiency value, tested by scanning the filter face and frame. This matters more than the overall figure, because it is what detects a pinhole, a media fold defect or a bad seal between media and frame — the failure modes that an averaged overall efficiency will hide.

The four documents, and what each one proves

TABLE 4.3 — FILTER DOCUMENTATION

Document	What it proves	What it does not prove
EN 1822 individual test certificate	That this specific filter, identified by serial number, was scan-tested at the factory and met its class	That it is still intact after transport and installation, or that it is sealed into its housing
Type test report	That the filter model was tested and achieves the class	Anything about the individual unit delivered to your site
Hygiene certificate	That the product or the air handling unit was assessed against a hygiene requirement, commonly VDI 6022	Any filtration classification whatsoever. A hygiene certificate is not a filter class certificate.
Installed leak test report	That the filter, its frame and its seal, as installed on your project, pass a scan test in place	Nothing — this is the document that matters, and it is the one most often missing

THE SINGLE MOST COMMON GAP IN A HEALTHCARE SUBMITTAL

Terminal HEPA filters arrive with a factory certificate, are installed, and are never leak-tested in place. A filter that passed a scan test in a factory in another country can still leak on your ceiling — through a damaged media pleat, a compressed or displaced gasket, a distorted frame, or a housing that was never designed to seal. Require an installed leak test to a named method, on every terminal filter, as a hold point before the ceiling is closed.

Filter stages and where they sit

A healthcare system normally carries three filtration stages, though the requirement must be taken from the governing framework rather than assumed:

1. **First stage, in the air handling unit, upstream of everything.** Its job is to protect the coils, the heat recovery device and the downstream filters from coarse dust and insects. Cheap to replace, and the stage that determines how long the expensive stages last.
2. **Second stage, in the air handling unit, downstream of the fan and coils.** A higher ePM class. This is the stage that does most of the work and it should sit downstream of any component capable of shedding contamination.
3. **Third stage, terminal, at or immediately before the room.** An EN 1822 class filter in a housing designed to be leak-tested in place. Terminal position is what protects the room against contamination picked up in the ductwork between the plant and the ceiling.

> DESIGN POINTS THAT DECIDE WHETHER THE FILTERS ACTUALLY WORK
>
> - Every stage needs a **differential pressure gauge or transmitter**, with the clean and dirty set points recorded. Without it, replacement is scheduled by the calendar rather than by condition, which is both wasteful and unsafe.
> - Terminal housings should be specified as **scan-testable**, with an upstream injection point and a downstream scanning access. Retro-fitting this after the ceiling is built is expensive and frequently impossible.
> - **Gel-seal housings** give a more reliable and more repeatable seal than gasket-and-clamp arrangements, and they tolerate repeated filter changes better. The cost difference is small against the cost of a failed classification test.
> - Filter changes in classified areas are a **controlled activity**, not routine maintenance. Specify the access route, the containment method and the retest requirement at design stage — see Section 08.

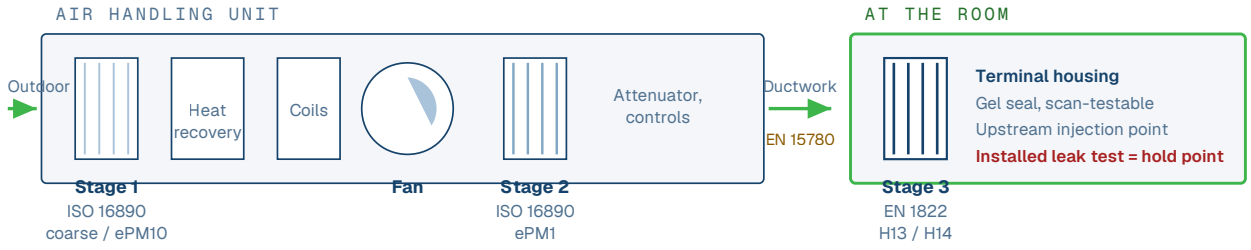


Figure 4.1 — Three-stage filtration and the position of each stage. The terminal stage is the only one that protects against contamination introduced downstream of the air handling unit, and the only one whose in-place seal must be proved on site.

SECTION 05

Hygienic air handling *unit design.*

A hygienic unit is one that can be inspected, cleaned and dried. Almost every requirement follows from those three verbs.

An air handling unit serving a classified area has to do more than condition air. It has to be constructible in a way that prevents it from becoming a contamination source itself — and, critically, it has to remain inspectable and cleanable for the twenty years it will operate. VDI 6022 is the reference most commonly cited across the region for these hygiene requirements, and manufacturers offer hygienic executions assessed against it.

What a hygienic execution actually requires

TABLE 5.1 — HYGIENIC DESIGN REQUIREMENTS AND WHY EACH EXISTS

Requirement	Reason
Fully drainable condensate trays, sloped to the outlet, in stainless steel	Standing water in a cooling section is the most reliable microbial breeding site in the entire system
Correctly sized traps, matched to the fan pressure at that point	An undersized trap on the suction side is pulled dry and admits unfiltered air; on the discharge side it blows through. Both are common and both defeat the drainage design
Smooth, corrosion-resistant, cleanable internal surfaces with no exposed insulation	Exposed fibrous insulation cannot be cleaned and can shed into the air stream
Inspection doors, internal lighting and viewing ports at every section	A section that cannot be seen will not be inspected, and a component that cannot be reached will not be cleaned
Differential pressure measurement across every filter stage	Condition-based filter replacement, and evidence that the stage is present and loaded as expected
Sufficient spacing to withdraw coils and filters without dismantling the unit	Maintainability is a design decision taken at plant room layout stage, not a site problem
Casing performance classified to EN 1886 — mechanical strength, casing leakage, filter bypass leakage, thermal transmittance and thermal bridging	A leaking casing on the suction side draws unfiltered plant room air directly past the filters. Bypass leakage around a filter frame defeats the filter entirely

SPECIFY THE EN 1886 CLASSES, NOT JUST “HYGIENIC”

EN 1886 classifies air handling unit casings for mechanical strength, casing air leakage, filter bypass leakage, thermal transmittance and thermal bridging. State the required class for each of these in the specification. “Hygienic execution to VDI 6022” describes the hygiene concept; the EN 1886 classes are what make the casing performance measurable and comparable between tenderers. Confirm the current edition and the designations it uses before drafting.

Heat recovery and recirculation

Heat recovery is where energy performance and infection control meet, and the meeting is not always comfortable. The question in every case is whether any path exists by which extract air can reach the supply air stream.

- **Plate heat exchangers** keep the two streams physically separate, with leakage limited to the exchanger's own construction. This is the conservative choice for classified areas.
- **Run-around coil systems** have no air path at all between streams, at the cost of lower recovery efficiency and additional pumping energy.
- **Rotary heat exchangers** recover more energy but carry an inherent carry-over of extract air into the supply stream. Purge sectors and correct fan positioning reduce it. Whether the residual carry-over is acceptable in a classified area is a decision for the operator's infection-control function, and it must be documented, not assumed.

The same question governs recirculation. Where the governing framework or the operator restricts recirculation in classified areas, the restriction must be written into the specification, because a system designed on the assumption of recirculation cannot be converted to full fresh air afterwards without replacing the plant.

The ductwork is part of the hygiene system

A terminal filter protects the room from the duct. Nothing protects the duct from itself. Three requirements belong in every healthcare specification:

1. **Cleanliness class at handover.** EN 15780 defines cleanliness classes for ventilation systems and the methods for assessing and cleaning them. State the required class, and require it to be demonstrated before handover — not merely promised.
2. **Air-tightness class.** Duct construction and air-tightness are governed by EN 1507 for rectangular sheet metal ductwork and EN 12237 for circular. Both define air-tightness classes. **A specification citing the standard without naming a class has specified nothing**, because the standard's lowest class permits leakage that a classified area cannot tolerate. Name the class, and require a pressure test on a defined sample.
3. **Access for cleaning.** Access doors at defined intervals and at every component that collects dirt — dampers, attenuators, coils, bends. Position them at design stage and show them on the drawings; access doors added on site are placed where the ceiling grid allowed rather than where the cleaning needs them.

> PROTECT THE DUCTWORK DURING CONSTRUCTION
>
> Duct installed on a live construction site and left open collects plaster dust, insulation fibre and rainwater. Require ends to be capped as installed, require the protection to be maintained, and make it an inspectable item. Post-installation cleaning of a whole hospital duct system is a substantial cost and a programme risk near handover — exactly the point at which there is no time for it.

Plant room and intake

- **Intake position** — away from exhaust discharges, cooling towers, road traffic, service yards, ambulance standing and helicopter operations. Check the prevailing wind and the position of every discharge on the roof, including those belonging to other trades.
- **Intake height and screening** — above ground contamination, screened against birds, insects and driven rain.
- **Plant room condition** — the plant room must be clean and sealed. In a unit with any negative-pressure section, the plant room air is part of the system whether the design intended it or not.

- **Standby capacity and resilience** — decide, and state, what happens to each classified area on the failure of a fan, a unit or the electrical supply. This is a clinical continuity decision, and it drives redundancy, essential-supply distribution and plant room space.

SECTION 06

Pressure cascade *and containment.*

Direction of flow is the cheapest protection in the building — and the easiest to lose to a door, a leaky ceiling or an unbalanced extract.

Filtration cleans the air that enters a room. The pressure regime determines where air goes once it is there, and which way it moves through every doorway and gap. In containment terms, direction of flow is doing at least as much work as filtration, and it costs almost nothing to design correctly at the outset.

The two regimes

- **Positive pressure** — the room is held above its neighbours, so leakage flows outward and unfiltered air cannot enter through gaps. Used to protect what is inside: the surgical field, the sterile store, the immunosuppressed patient.
- **Negative pressure** — the room is held below its neighbours, so leakage flows inward. Used to protect what is outside: airborne infection isolation, some laboratory and dirty-utility functions.

The cascade is the arrangement of these differentials across a department so that air moves consistently from the cleanest space toward the least clean. It has to be designed as a whole. A single room's differential is meaningless without knowing what it is measured against, and a cascade that is correct on paper can be defeated by one extract fan commissioned to the wrong volume.

> WHAT TO STATE, FOR EVERY CLASSIFIED ROOM
>
> **A value in pascals, a sign, and a named reference space.** For example: "+15 Pa with respect to the sterile corridor". Differentials in the region of 10 to 15 Pa between adjacent classified spaces are commonly applied in practice, but the figure for your project must come from the governing framework and your designer, and must be consistent across the whole cascade.

The three things that defeat a cascade

1 · Room envelope leakage

A pressure differential is produced by the difference between supply and extract volumes working against the leakage of the room envelope. If the envelope leaks more than the design assumed, the differential collapses; if it leaks less, the differential overshoots and doors become difficult to open. The envelope is therefore part of the ventilation design, and it is built by other trades.

Every penetration matters — electrical containment, medical gas, data, drainage, the gaps above the ceiling line, the door undercuts. Specify the sealing requirement, allocate it clearly to a trade, and inspect it before the ceiling is closed. This is the single most common cause of a classified room that will not hold its pressure at commissioning, and by then the ceiling is in.

2 · Doors

Opening a door removes the differential for as long as it is open, and the door leaf itself displaces a volume of air as it swings. Airlocks, or lobbies, restore the cascade by ensuring that two doors are never open at once between spaces of different classification. Where interlocks are specified, they must be coordinated with fire strategy and with clinical workflow — an interlock that obstructs an emergency will be disabled within a month of handover, and the cascade goes with it.

3 · Unbalanced or drifting extract

The differential depends on both sides of the balance. Extract volumes drift as filters load, as dampers move and as adjacent systems are altered. Specify continuous monitoring of the differential in every critical room, a local indication that clinical staff can read, an alarm on deviation, and a defined response procedure. A differential that is measured once at commissioning and never again is a differential you do not have.

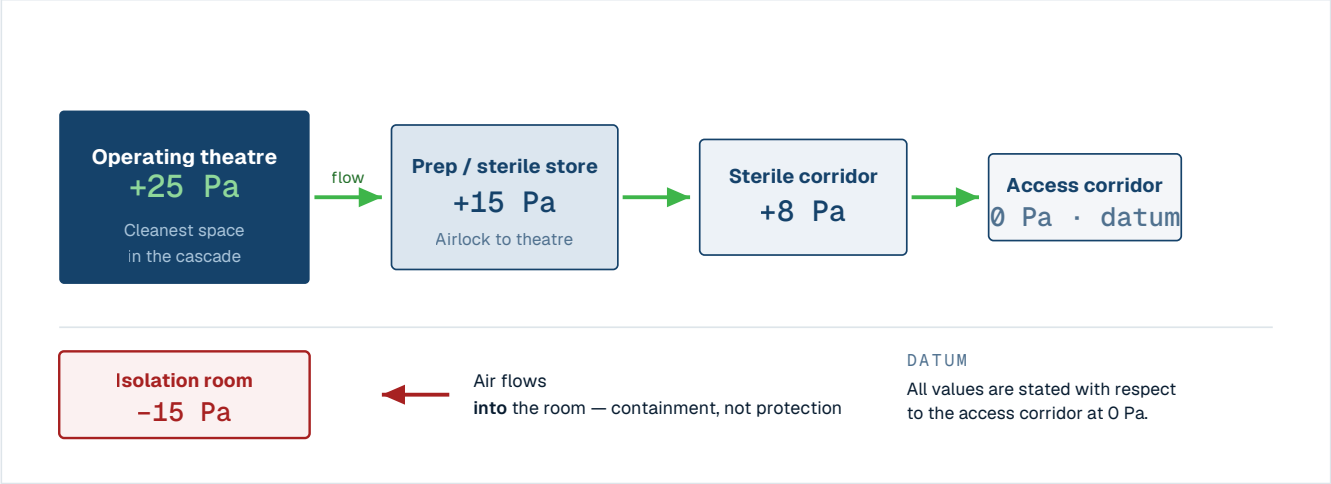


Figure 6.1 — A pressure cascade requires a stated datum. The values shown are illustrative of the structure only; the figures for any project must come from the governing framework and the designer.

> **TWO ROOMS THAT MUST NEVER SHARE A CASCADE**
>
> A protective-isolation room and an airborne-infection-isolation room look similar on a drawing and are opposites in function. One is held positive to protect a vulnerable patient from the building; the other is held negative to protect the building from an infectious patient. Confusing them, or building them as a switchable pair without a rigorous control and verification regime, is a serious clinical risk. State which is which, in the room data sheet, in words as well as in signs.

SECTION 07

Commissioning, validation *and qualification.*

Three words used interchangeably on most projects, meaning three different things, performed by three different parties.

The distinction matters because the three activities have different purposes, different competences and — critically — different signatories. A project that treats them as one activity performed by the installing contractor has no independent verification at all.

TABLE 7.1 — THREE ACTIVITIES, THREE PURPOSES

Activity	Asks	Normally performed by
Commissioning	Does the installation work as designed? Are volumes set, controls functional, plant balanced?	The installing contractor, witnessed by the client's engineer
Validation	Does the finished room meet its stated classification criteria, measured by a defined method?	An independent testing body, competent and — where required — accredited
Qualification	Is there documented evidence, across design, installation, operation and performance, that the system does what it was specified to do and will keep doing it?	The operator's quality function, assembling evidence from both of the above

NAME THE INDEPENDENT TESTER IN THE CONTRACT

Validation should not be performed by the party whose payment depends on the result. State in the tender documents who appoints the testing body, what competence or accreditation it must hold, who pays for the first test, and — importantly — who pays for the retest after a failure. That last clause prevents more argument at handover than any other single sentence.

Prerequisites — the room must be finished first

Classification testing on an unfinished room produces a number that means nothing and will have to be repeated. Before any validation test is booked, confirm all of the following, and make them a formal hold point:

- All construction work complete; no open ceiling, no ongoing dusty trades in the zone
- Every envelope penetration sealed and inspected; door sets hung, adjusted and closing
- Full clean-down completed to the operator's method, and the room released as clean
- Ventilation running continuously for a stated stabilisation period before testing
- Terminal filters installed and their in-place leak tests passed
- Controls commissioned, set points loaded, monitoring and alarms live
- Room data sheet issued, agreed and available to the testing body on the day

The test schedule

Which tests apply depends on the governing framework and the room class. The following is the set encountered in healthcare work; take the applicable list and the test methods from the governing framework in its current edition.

TABLE 7.2 — VALIDATION TESTS IN A HEALTHCARE CLASSIFIED AREA

Test	Demonstrates	Typical reference
Supply and extract air volumes	Design volumes and air change rates achieved	Commissioning codes; governing framework
Installed filter leak test	Terminal filters, frames and seals are intact in place	ISO 14644-3 test methods
Airborne particle count and classification	The room achieves its ISO class in the stated occupancy state	ISO 14644-1
Pressure differential	Cascade achieved, in the correct direction, against the stated datum	Governing framework; room data sheet
Recovery performance	The room returns to class within a stated time after a contamination event	ISO 14644-3 test methods
Airflow visualisation	The air distribution pattern behaves as designed, with no reverse flow into the protective zone	ISO 14644-3 test methods
Protection degree in the protective zone	For DIN 1946-4 class Ia rooms, the protective effect over the operating table	DIN 1946-4 test method
Containment leak	For negative-pressure rooms, that contamination does not escape	Governing framework
Temperature, relative humidity, noise	Design conditions achieved within the stated ranges	Room data sheet
Microbiological sampling	Where the operator's infection-control policy or a GMP regime requires it	Operator policy; EU GMP Annex 1 where applicable

> TEST IN THE STATE YOU SPECIFIED, AND ONLY IN THAT STATE
>
> A room specified as ISO 7 in operation must be tested in operation, with the stated number of people present, the stated equipment running and the process simulated. Testing an in-operation requirement at rest produces a comfortable number and proves nothing. If the specification did not state the occupancy state — see Section 02 — this argument happens on the day of the test, in front of the client.

Hold points

Four points in the programme should be formal hold points, at which work does not proceed until an inspection is signed. They cost nothing to impose and are almost impossible to recover once passed.

1. **Before ceiling closure** — envelope penetrations sealed, duct installation and protection inspected, access doors positioned and reachable.

2. **On terminal filter installation** — filter certificates verified against serial numbers, in-place leak test performed and passed.
3. **Before validation** — the prerequisite list above, signed off.
4. **Before handover** — full documentation pack received, reviewed and accepted, and operator training completed.

The documentation pack

The pack is what the hospital will rely on for the next twenty years, in every subsequent audit, refurbishment and dispute. Specify its contents in the tender documents; it is much harder to obtain after the final account is settled.

- Room data sheets as validated, with every measured value against every stated criterion
- Filter certificates by serial number, with the in-place leak test report for each terminal filter
- Air volume and balancing records for every terminal and every plant item
- Classification test reports from the independent testing body, with method and instrument calibration records
- Pressure differential records and the as-commissioned cascade diagram
- Duct cleanliness verification to the stated class
- Control philosophy, set points as loaded, alarm schedule and response procedures
- Operation and maintenance manuals, filter schedule by position and class, spares list
- Requalification schedule with the first due date stated
- Record drawings showing every access door, damper, sensor and terminal filter position

Requalification

Classification is a state, not a property. Filters load, seals age, dampers drift, building works alter the pressure regime, and clinical use changes. Every classified area needs a periodic requalification interval, defined by the governing framework and the operator's policy, with an owner and a budget line. Where a room is altered, or a terminal filter is changed, or adjacent construction work is undertaken, the affected tests should be repeated before the room returns to clinical use.

> BUILD THE FIRST REQUALIFICATION INTO THE CONTRACT
>
> Requiring the first periodic retest to be performed and priced within the contract — typically at the end of the defects period — gives the operator a second data point, catches early drift while the contractor is still on risk, and establishes the routine before it has a chance to lapse.

SECTION 08

What the design costs *to operate.*

A theatre suite is among the most energy-intensive spaces in any building. Most of that cost is fixed by decisions taken in the specification.

Healthcare ventilation is expensive to run because it does several expensive things at once: it moves large air volumes, through high-resistance filtration, often on a high proportion of outdoor air, conditioned to a narrow temperature and humidity band, twenty-four hours a day. Each of those is a specification decision, and each has a cost that persists for the life of the installation.

The four cost drivers

TABLE 8.1 — WHERE THE OPERATING COST IS DECIDED

Driver	Decided by	What it costs over the life of the system
Air volume	Room class, air change rate, protective zone area	Fan energy, and duct, plant and plant room space. The dominant driver in almost every case.
System resistance	Filter classes, duct sizing, component selection, layout	Fan energy for the whole life of the installation, plus filter replacement cost
Outdoor air fraction	Framework requirements and the recirculation decision	Heating, cooling, humidification and dehumidification energy
Condition band	Temperature and humidity ranges in the room data sheet	Reheat and humidification energy — a narrow humidity band is very costly to hold

> WHY AIR VOLUME DOMINATES
>
> For a fixed system, the fan laws give the relationships that matter: volume flow varies with fan speed, the pressure the fan must develop varies with the square of speed, and the absorbed power varies with the cube. The practical consequence is that a specification which raises the air change rate “to be safe” buys a disproportionate and permanent increase in fan energy. Specifying the right air volume is not a cost-cutting exercise — it is the difference between a defensible design and an expensive guess.

Filters

Filter cost has three components, and the purchase price is the smallest of them.

- **The filter itself**, on a replacement cycle driven by loading rather than by the calendar — which requires the differential pressure measurement specified in Section 05.
- **The energy to push air through it** across its whole service life, which for a terminal HEPA is a substantial figure and frequently exceeds the purchase price several times over.
- **The cost of changing it in a classified area** — access, containment, room downtime, clean-down and the retest that follows. In an operating theatre, the lost clinical session may be the largest cost of the three.

A well-specified first stage is the cheapest protection available for the two stages behind it. It is also the stage most often value-engineered out.

Setback, and the limits of it

A theatre that is unused overnight does not need full design conditions overnight. A setback regime — reduced air volume, relaxed condition band, cascade maintained — can remove a substantial part of annual energy consumption. Three conditions apply:

1. **The pressure cascade must be maintained in setback**, at least in direction, or the room fills with air from the corridor and the clean-down is undone.
2. **The recovery time from setback to full specification must be defined, demonstrated at commissioning and known to clinical staff.** A theatre that takes forty minutes to return to class cannot be used for an emergency case ten minutes after being woken, and the staff must be told which it is.
3. **The regime must be agreed with infection control** and written into the operating procedures, not left as a setting in the building management system that nobody can account for three years later.

> THE RECURRING COST NOBODY BUDGETS FOR
>
> Periodic requalification of classified areas is a real annual cost — testing body fees, the clinical time lost while the room is out of use, and the remedial work that testing occasionally reveals. It is rarely in the operational budget of a new facility because it was never priced during design. Establish the interval, the scope and the cost before handover, and hand it to the operator as a budget line rather than as a surprise.

Where the savings actually are

In order of typical impact, and none of them requiring any relaxation of clinical standards:

1. Correct classification in the first place — not specifying class Ia where class Ib meets the clinical need, which is a decision for infection control and not for the engineer
2. A setback regime, properly designed, agreed and demonstrated
3. Low-resistance system design — generous duct sizing, low-loss components, filter selection on life-cycle rather than purchase cost
4. Heat recovery selected to suit the containment requirement, so that it can actually be used rather than disabled after handover
5. Condition-based filter replacement rather than fixed-interval replacement

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On energy-saving claims generally. The savings available from any of the measures above depend entirely on the existing design, the climate, the utilisation pattern and the tariff. Any figure quoted without a measured baseline for your specific facility is marketing, not engineering. Establish the baseline first.

SECTION 09

The forty-point *specification checklist.*

Take this into your own tender documents. If every box can be ticked before issue, most of what Section 01 described will not happen to you.

A · CLASSIFICATION AND GOVERNANCE

- ☐ One governing framework is named with its edition, and any other frameworks cited are marked as reference only
- ☐ The applicable national adoption has been confirmed for the project location
- ☐ The classification decision is recorded, with the date and the person who took it
- ☐ Infection control or the hospital hygienist has signed the classification schedule
- ☐ The clinical procedures intended for each classified room are documented

B · ROOM DATA

- ☐ Every classified room appears on a room data sheet
- ☐ Class or grade is stated for every room
- ☐ Occupancy state for verification is stated for every room
- ☐ Total air changes per hour stated
- ☐ Minimum outdoor air changes per hour stated separately
- ☐ Pressure differential stated as value, sign and named reference space
- ☐ Temperature range and relative humidity range stated, with adjustment authority
- ☐ Noise limit stated with the measurement position
- ☐ Air distribution pattern stated — displacement, protective zone or mixed flow
- ☐ Recovery performance requirement stated where the framework requires it
- ☐ No cell on the room data sheet is blank; “not applicable” is written where it applies

C · FILTRATION

- ☐ Number of filter stages stated
- ☐ Each stage classified to the correct standard — ISO 16890 or EN 1822
- ☐ No legacy G or F designations remain in the document
- ☐ Position of each stage stated relative to fan, coils and heat recovery
- ☐ Terminal housings specified as scan-testable, with an upstream injection point and the seal type stated
- ☐ Installed leak test required on every terminal filter, to a named method
- ☐ Differential pressure measurement required across every stage, with set points
- ☐ Filter access, change procedure and retest requirement defined for classified areas

D · AIR HANDLING UNITS AND DUCTWORK

- ☐ Hygienic execution required, with the reference standard named
- ☐ EN 1886 classes stated for casing leakage, filter bypass, strength and thermal performance
- ☐ Drainable trays and correctly sized traps required, with the sizing basis stated
- ☐ Inspection access, internal lighting and viewing ports required at every section
- ☐ Heat recovery type specified, and any carry-over accepted in writing by infection control
- ☐ Recirculation permitted or prohibited, stated explicitly per area
- ☐ Duct air-tightness class and cleanliness class both named, with verification required before handover
- ☐ Duct protection during construction required and made inspectable
- ☐ Intake position assessed against every discharge, and resilience on plant failure defined

E · ENVELOPE, PRESSURE AND CONTROLS

- ☐ Envelope sealing requirement specified and allocated to a named trade
- ☐ Airlock and door arrangement shown, with interlock strategy coordinated with fire and clinical workflow
- ☐ Continuous differential monitoring, local indication, alarm and response procedure specified

F · COMMISSIONING AND HANDOVER

- ☐ Independent testing body named, with the competence or accreditation required and the appointment route stated
- ☐ Liability for the retest after a failed test stated in the contract
- ☐ The four hold points defined — ceiling closure, filter installation, pre-validation, pre-handover
- ☐ Documentation pack contents listed, and the first requalification priced within the contract

Checklist sign-off

Complete and retain with the tender documents. A checklist that nobody signed is a checklist that nobody used.

SPECIFICATION READINESS SIGN-OFF

Item	Name and role	Date and signature
Project		
Specification document and revision		
Classification schedule prepared by		
Infection control / hygiene sign-off		
Room data sheets complete — no blank cells		
Checklist points 1–40 confirmed		
Outstanding items listed and owned		
Released for issue by		

> IF YOU CAN ONLY DO THREE THINGS
>
> **One.** Complete a room data sheet for every classified room, with no blank cells, and have infection control sign it.
> **Two.** Require an installed leak test on every terminal filter as a hold point before ceiling closure.
> **Three.** Name the independent testing body in the contract and say who pays for the retest.
>
> Those three alone remove the majority of the risk described in this guide.

REFERENCE

Standards referred to *in this guide.*

Listed by number and subject so that you can obtain and read them. Confirm the current edition, and the applicable national adoption, before citing any of them in a contract document.

STANDARDS REGISTER

Reference	Subject
ISO 14644-1	Cleanrooms and associated controlled environments — classification of air cleanliness by particle concentration
ISO 14644-2	Monitoring to provide evidence of continued cleanroom performance
ISO 14644-3	Test methods, including installed filter leak testing, recovery and airflow visualisation
ISO 14644-4	Design, construction and start-up
ISO 14644-14	Assessment of the suitability for use of equipment by airborne particle concentration
DIN 1946-4	Ventilation and air conditioning in buildings and rooms used for healthcare
VDI 6022	Ventilation and indoor air quality — hygiene requirements for ventilation and air conditioning systems
EN 1822 series	High-efficiency air filters — EPA, HEPA and ULPA classification and testing at the most penetrating particle size
EN ISO 16890 series	Air filters for general ventilation — classification by particulate matter efficiency, replacing the former EN 779 classification
EN 1886	Ventilation for buildings — air handling units, mechanical performance of the casing
EN 15780	Ventilation for buildings — cleanliness of ventilation systems
EN 1507	Ventilation for buildings — sheet metal air ducts with rectangular section, strength and leakage
EN 12237	Ventilation for buildings — ductwork, strength and leakage of circular sheet metal ducts
EN 16798-3	Energy performance of buildings — ventilation for non-residential buildings, performance requirements
ASHRAE Standard 170	Ventilation of health care facilities
EU GMP Annex 1	Manufacture of sterile medicinal products — EudraLex Volume 4
ISO 50001	Energy management systems — relevant where a facility operates a formal energy programme

HOW TO USE THIS REGISTER

Standards are revised, withdrawn and superseded. Before any reference in this list is written into a specification, a contract or a tender document, verify the current edition with the national standards body applicable to your project, confirm whether a national adoption exists, and confirm that the clause you intend to rely on still says what you think it says. Nothing in this guide should be relied upon as a statement of the content of any standard.

About APIS

APIS is an integrated engineering group founded in Kosovo, operating across the Western Balkans and into the European Union. The Group delivers mechanical, electrical, energy and infrastructure works through twenty-one delivery divisions across two strategic business units — Building Systems & Technologies, and Energy, Industry & Infrastructure — supported by four engineering excellence centres. APIS operates management systems certified to ISO 9001, ISO 14001, ISO 45001 and ISO 50001.

The **HVAC-R Division** designs, installs, commissions and maintains heating, ventilation, air conditioning and refrigeration systems, including classified and hygienic areas in healthcare, pharmaceutical and food processing facilities. Work is delivered under the Group's DBOM lifecycle model — design, build, operate and maintain — so that the party which specifies the system is accountable for what it costs to run.

Prepared by the APIS HVAC-R Division · **Document** APS-GD-01 issue v1.0 of 18 August 2026 · **Contact** apisgroup.net/contact

Planning a theatre suite, an extension *or a refurbishment?*

The specification stage is where healthcare ventilation risk is created and where it is cheapest to remove. If you are preparing tender documentation, or reviewing a bid you have already received, our HVAC-R engineers will read it against the checklist in Section 09 and tell you what is missing.

SPEAK TO THE HVAC-R DIVISION

Specification review · classification schedules · room data sheets · commissioning and validation strategy · lifecycle cost modelling

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