# **📘 HTM 03-01 Part A:**

### ***Concept, Design, Specification, Installation & Validation***

## **1. Purpose & Scope**

* Ventilation = **infection prevention + staff safety + product quality assurance**.
* Applies to **new builds/major refurbishments**.
* Focus: **theatres, isolation, endoscopy, sterile services, critical care, labs**.

## **2. Legal & Regulatory Duties**

* **Health Act 2009**: duty of care.
* **Health & Safety at Work 1974**: overarching.
* **COSHH 2002**: LEV systems statutory (14-monthly testing).
* **Building Regs**: ACH standards, Legionella control, fire regs.
* **Firecode HTM 05**: duct fire/smoke containment.

## **3. Isolation & Protective Rooms**

* **Airborne infection isolation (AIIR)**:
  + ≥ **10 ACH**.
  + Negative pressure ≥ **–5 Pa** vs corridor.
  + Self-closing doors, pressure monitors visible outside.
* **Protective isolation (immunosuppressed)**:
  + ≥ **10 ACH**.
  + Positive pressure **+10 to +15 Pa**.
  + HEPA/EPA filtration required.
* **PPVL (positive pressure ventilated lobby)** isolation:
  + Lobby **+10 Pa**, bedroom neutral, ensuite negative.
  + ACH ≥ **10 bedroom**, ≥ **12 lobby**.
  + Protects both staff and patients.

## **4. Operating Theatres**

* **Conventional theatre**:
  + ≥ **20 ACH** minimum (design standard 25 ACH).
  + Positive cascade (theatre +25 Pa).
* **UCV theatre (orthopaedics/implants)**:
  + Background ≥ **22 ACH and 25Pa**
  + Canopy airflow **0.2 - 0.3 m/s ±20% at 1 m above floor**.
  + Air cleanliness at instrument table ≤ **10 CFU/m³** during operation.
* **Support rooms**:
  + Sterile: Prep room: ≥ 35Pa for ‘lay up’
  + Clean: Anaesthetic room & scrub room: **≥ 15 Pa and 15 ACH**
  + Transitional: Recovery room: 0 Pa and 15 ACH
  + Dirty: Utility/dirty areas: negative Pa to theatre.

## **5. Environmental & Design Parameters**

* **Temperature**: 20–25 °C (theatres may allow 18–25 °C).
* **Relative Humidity**: ≤ 60%.
* **Air velocity**: must avoid turbulence in UCV canopy.
* **Filter standards**: minimum **ISO ePM10 ≥ 50%** for supply; HEPA H13/H14 for UCV.
* **Noise levels**: must comply with HTM tables. Mainly <45 Db

## **6. Validation & Commissioning**

* **Mandatory independent validation** before clinical use.
* **Tests include**:
  + ACH measurement.
  + Differential pressures (manometer/indicator).
  + Particle counts.
  + Microbiological validation (settle plates, active sampling).
* **Acceptance standards**: theatres must meet ACH, pressure, microbiology values before use.

## **7. Sustainability**

* Ventilation default: **natural → mixed → mechanical**.
* Switch off or setback when unused.
* Replace belt-driven fans with EC fans.
* Minimise carbon footprint but **infection control takes precedence**.

# **📘 HTM 03-01 Part B**

### ***Management, Operation, Maintenance & Routine Testing***

## **1. Scope**

* Applies to **all existing systems**.
* Ensures safe, efficient, compliant systems.

## **2. Governance**

* **Designated Person** – board-level.
* **AE(V)** – independent oversight.
* **AP(V)** – operational lead.
* **CP(V)** – maintenance/testing.
* **IPC Doctor/Microbiologist** – infection control assurance.
* **VSG** – Ventilation Safety Group; central governance.

## **3. Theatres – Verification**

* **Quarterly inspections**: visual fabric, seals, stabilisers.
* **Annual verification** must show:
  + Theatres: ≥ **18 ACH**.
  + Anaesthetic room: ≥ **12 ACH**.
  + Prep room: ≥ **12 ACH**.
  + ≥ **80% design flow** elsewhere.
  + **Pressure cascade** intact.
  + UCV canopy airflow: **0.38 m/s ±20% at 1 m**.
  + **UCV microbiology**: ≤ **10 CFU/m³** at instrument table.
  + **Noise, temperature, humidity** compliance.

## **4. Isolation Facilities – Ongoing Testing**

* Must maintain **–5 Pa** negative or **+10–15 Pa** protective.
* **ACH ≥10** verified annually.
* Visual pressure gauges required at room entrance.
* Records must document ACH, pressures, microbiology results.

## **5. Maintenance Standards**

* **AHUs**: labelled, secure intakes/discharges, drainage (glass traps, stainless trays).
* **Filters**: pressure differential gauges; HEPA safe replacement protocols.
* **Humidifiers**: only **steam injection** allowed.
* **Fans**: EC/direct drive only for new systems.
* **Portable AC**: discouraged; only with VSG approval, strict cleaning regime.

## **6. Records & Audit**

* **Logbooks mandatory**: ID, commissioning, verification, alterations.
* **Retention**: ≥5 years; ≥25 yrs for manufacturing pharmacies.
* Must be accessible for **CQC/HSE inspections**.

## **7. Incident Management**

* Failures → escalate to **VSG + IPC team**.
* Reportable under **RIDDOR** if safety risk.
* Theatres/isolation may be **closed until rectified**.

## **8. Lifecycle**

* **Refurbishment** at ~10 yrs (full inspection, rebalancing, recommissioning).
* **Replacement** at ~20 yrs.
* Programme overseen by **VSG**.

# **✅ Key Figures for Exam Recall**

* **Isolation (AIIR):** –5 Pa, ≥10 ACH.
* **Protective isolation:** +10–15 Pa, ≥10 ACH, HEPA.
* **PPVL isolation:** lobby +10 Pa, bedroom neutral, ensuite negative; ≥10 ACH.
* **Conventional theatre:** ≥20–25 ACH, +25 Pa cascade.
* **Anaesthetic room:** ≥12–15 ACH.
* **UCV theatre:** canopy 0.38 m/s ±20% @1 m; ≤10 CFU/m³ at instrument table.
* **Annual verification minimums:** 18 ACH theatre, 12 ACH anaesthetic room, 80% design elsewhere.
* **Temperature:** 20–25 °C. **Humidity:** ≤60%.