



Annual Inspection and  
Verification Requirements  
**HTM 03-01**

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# The Requirement for Inspection & Verification

## HTM 03-01 – Annual Inspection and Verification Requirements

**Every ventilation system must undergo a basic yearly visual examination. The extent of the examination is determined by the usage of the location served by the system.**

Essential ventilation systems must undergo a quarterly inspection and be validated once a year at the minimum. There may be cases where validation needs to be conducted more often.

The quarterly inspection is simple, and on-site maintenance personnel should receive training to execute it and maintain an inspection record.

**The aim of the yearly validation of critical systems necessitates an elevated degree of skill and education to ensure that:**

- The application-specific minimum standards are upheld.
- The system is functioning at an acceptable performance level.
- The system continues to be suitable for its intended purpose.





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**A critical ventilation system refers to a ventilation system whose failure would significantly diminish the ability of a facility to deliver optimal healthcare. According to HTM 03-01 Part B Section 4.8, critical systems include:**

- Operating theatres and interventional investigation rooms
- Patient isolation facilities
- Critical care, intensive treatment or high dependency units
- Neonatal units
- Category 3 or 4 containment laboratories or rooms
- Pharmacy aseptic suites
- Inspection and packing rooms in sterile services departments
- MRI, CAT and other emerging imaging technologies that require stable environmental conditions to remain within calibration
- Any system classified as an LEV system under the COSHH Regulations
- Any other system that clearly meets the definition.





## Critical Theatres

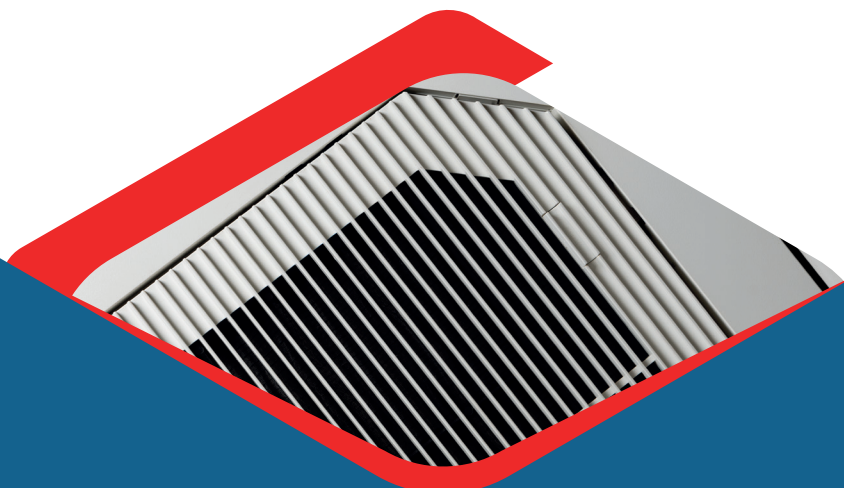
Among all the critical systems identified in HTM 03-01, operating theatres are the most delicate and demand a high level of proficiency to validate compliance and troubleshoot performance defects.

HTM 03-01 provides comprehensive guidelines on the necessary performance and inspection standards that must be upheld in operating theatres to ensure the continual maintenance of optimal performance levels.

## Key Requirements

Some of the key requirements for maintaining optimal performance levels in an operating theatre, as stipulated in HTM 03-01, are:

- Air volumes and air change rates must be at least 75% of the design
- Room pressure differential must ensure a flow from clean to less clean areas
- Supply and extract diffusers must be kept clean
- Pressure stabilisers must be clean and function properly
- The surgeons panel must be free of faults
- The fabric of the suite should not have any significant visible defects
- Doors must be able to close completely.



## Isolation facilities

In terms of infection control, isolation rooms are used to protect

- A patient with a susceptibility to infection from other sources – source isolation
- From a patient that presents an infection risk to others – protective isolation

## HBN 4 identifies two types of isolation

### 1 Enhanced Single Room with En-Suite Facilities:

This type of isolation facility is a cost-effective solution that includes a single room with en-suite sanitary facilities, which has extract ventilation. It is designed to provide protective isolation for patients on general wards.

### 2 Isolation Suite – Enhanced Single Room with En-Suite Facilities and Ventilated Lobby:

This isolation facility includes a single room with a positive pressure ventilated entry lobby and en-suite facilities with extract ventilation. It offers both source and protective isolation, with the positive pressure lobby preventing air from the corridor entering the isolation room, and vice versa. The design eliminates the need for switchable ventilation or special training for staff, and allows for safe isolation of patients with an unknown condition. It also complies with COSHH regulations and is classified as a Local Exhaust Ventilation (LEV) System that requires specialist testing and comprehensive service records.

## **Air Handling Plant Serving a Critical System**

According to Part B of HTM 03-01, air handling plants that serve critical systems must undergo a comprehensive inspection annually, and a detailed record must be maintained that answers all the questions listed in the guidelines. The inspection must be thorough, and it must comply with the standards specified in HTM 03-01 Part B.

## **The Theatre Sterile Services Units (TSSU) and Hospital Sterilisation Service Units (HSSU)**

**These facilities have specific airflow performance requirements to control airborne contamination. The design and operational principles for these departments are outlined in HBN 13: 'Sterile Services Departments.'**

The environmental control standard for these facilities is BS EN ISO 14644, with particular attention paid to particle contamination levels. The inspection, assembly, and packing (IAP) room standards are set at Class 8 (ISO 14644). Routine monitoring of microbial contamination levels is essential to ensure they remain within defined levels.

## **Other critical environmental specifications include:**

- Temperature and humidity levels
- Room pressure differentials
- Air change rates
- Lighting levels