Maintenance of HVAC
HVAC Design Requirements
Air Flow Diagram

Horizontal unidirectional flow, vertical unidirectional flow and turbulent flow

UDAF, unidirectional airflow; HEPA, high-efficiency particulate air.
Air Flow Diagram แบบ Once Through

Full fresh air system

Supply air-handling unit

Production facility

Exhaust air-handling unit

Optional filtration depending on exhaust air contaminants
Definition Of Conditions

As built

At rest

In operation
Maintenance GMP Requirements

- There should be a planned preventive maintenance programme, procedures and records for the HVAC system.

- In order to maintaining the various environmental parameters such as temperature, humidity, air quality, air flow, and pressurization. Various maintenance activities should be done.

- Records should be kept.

- Maintenance personnel should receive appropriate training.
Operating and maintenance (O&M) manuals, schematic drawings, protocols and reports should be maintained as reference documents for any future changes and upgrades to the system.

These documents should be kept up to date, containing any system revisions made.
HEPA filters should be changed either by a specialist or a trained person, and then followed by installed filter leakage testing.

Any maintenance activity should be assessed critically to determine any impact on product quality including possible contamination.
Maintenance GMP Requirements

- Maintenance activities should normally be scheduled to take place outside production hours, and any system stoppage should be assessed with a view to the possible need for requalification of an area as a result of an interruption of the service.
### Part A: schedule of tests to demonstrate compliance (for reference purposes only)

<table>
<thead>
<tr>
<th>Test parameter</th>
<th>Clean room class</th>
<th>Max. time interval</th>
<th>Test procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Particle count test</strong> (Verification of cleanliness)</td>
<td>All classes</td>
<td>6 months</td>
<td>Dust particle counts to be carried out and printouts of results produced. No. of readings and positions of tests to be in accordance with ISO 14644-1 Annex B</td>
</tr>
<tr>
<td><strong>Air pressure difference</strong> (To verify absence of cross-contamination)</td>
<td>All classes</td>
<td>12 months</td>
<td>Log of pressure differential readings to be produced or critical plants should be logged daily, preferably continuously. A 15 Pa pressure differential between different zones is recommended. In accordance with ISO 14644-3 Annex B5*</td>
</tr>
<tr>
<td><strong>Airflow volume</strong> (To verify air change rates)</td>
<td>All classes</td>
<td>12 months</td>
<td>Airflow readings for supply air and return air grilles to be measured and air change rates to be calculated. In accordance with ISO 14644-3 Annex B13*</td>
</tr>
<tr>
<td><strong>Airflow velocity</strong> (To verify laminar flow or containment conditions)</td>
<td>All Classes</td>
<td>12 Months</td>
<td>Air velocities for containment systems and laminar flow protection systems to be measured. In accordance with ISO 14644-3 Annex B4*</td>
</tr>
</tbody>
</table>

**Part B: recommended optional strategic tests (ISO 14644)**

<table>
<thead>
<tr>
<th>Test parameter</th>
<th>Clean room class</th>
<th>Max. time interval</th>
<th>Test procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter leakage tests <em>(To verify filter integrity)</em></td>
<td>All classes</td>
<td>24 months</td>
<td>Filter penetration tests to be carried out by a recognized authority to demonstrate filter media and filter seal integrity. Only required on HEPA filters. In accordance with ISO 14644-3 Annex B6*</td>
</tr>
<tr>
<td>Containment leakage <em>(To verify absence of cross-contamination)</em></td>
<td>All classes</td>
<td>24 months</td>
<td>Demonstrate that contaminant is maintained within a room by means of: • airflow direction smoke tests • room air pressures. In accordance with ISO 14644-3 Annex B4*</td>
</tr>
<tr>
<td>Recovery <em>(To verify clean-up time)</em></td>
<td>All classes</td>
<td>24 months</td>
<td>Test to establish time that a clean room takes to return from a contaminated condition to the specified clean room condition. This should not take more than 15 min. In accordance with ISO 14644-3 Annex B13*</td>
</tr>
<tr>
<td>Airflow visualization <em>(To verify required airflow patterns)</em></td>
<td>All classes</td>
<td>24 months</td>
<td>Tests to demonstrate airflows: • from clean to dirty areas • do not cause cross-contamination uniformly from laminar flow units. Demonstrated by actual or videotaped smoke tests. In accordance with ISO 14644-3 Annex B7*</td>
</tr>
</tbody>
</table>
Table 3 gives various tests that can be carried out. The required tests and intervals between testing should be determined through risk assessment.
Maintaining clean HVAC systems is important.

- Contaminants in HVAC systems can take many forms. Common contaminants include:
  - Dust particles
  - Active bacterial or fungal growth
  - Debris from HVAC components (rust, belt shedding, grease)
  - Loose duct lining
  - Mold spores
The AHU should be inspected periodically for air leaks, rusting, condensate drainage problems, and dirt accumulation,

And to verify the proper operation of doors, drives, dampers and actuators, and lighting and switches.
Single Skin AHU
Double Skin AHU

- Damper
  - With Motorize
- Manual

Robatherm
Double Skin

Flush Interior Smooth Surface

Round Corner

Round Edge

ตัวอย่างการผนวกภายใน

ตัวอย่างภายใน
Air Handling Units

Periodic cleaning of the unit’s interior is recommended, particularly for units serving classified spaces, such as aseptic operation.

- A cleanliness inspection should consider the components within the unit, such as:
  - filters
  - heating and cooling coils
  - condensate pans
  - condensate drain lines
  - humidification systems
  - acoustic insulation
  - fans
  - fan compartments
  - dampers
  - door gaskets
  - general unit integrity
Cleaning AHU

- Prefilters do not remove all air contaminants inside an AHU. Dirt accumulation over time can lead to microbial growth.
- Typically, the units are washed down with a solution that will kill microorganisms, while at the same time, eliminating grease and oil that may have been dispersed from bearings and other lubricated joints.
General House Keeping

- Pools of standing water in condensate drain pans can lead to microbial growth and rusting of ferrous parts. Drainage should be checked during hot and humid periods when condensate generation is high.

- It is recommended that visible rust is removed and surfaces repainted to return their appearance to new.
**Single Skin**

**Casing**
Single wall skin, light-weighted, quiet and superior thermal resistance.

**Coil Module**
High efficient aluminium fin available in 2, 4, 6 & 8 rows with 108, 144 & 168 fin per foot.

**General Construction**
Bolted frame & panel with modular and compact construction.

**Fan Module**
Each unit fully tested & balanced at the factory, ensures quality & reliability.

**Drain Pan**
Sloped, insulated and coated for proper condensate removal, thermal isolation and corrosion protection.
Single Skin

รูป เครื่องสั่งลมเย็นแบบ Single Skin ที่มีกำลังลมต่ำ

ภายใน AHU เป็นฉนวนซึ่งสามารถหลุดออกมาได้และเป็นหลังเก็บเชื้อ,ผุน
Components

- Defective electrical switches and receptacles can lead to electrical hazards, poor operation of the components they serve, and increased maintenance.

- Door maintenance is significant to the air tightness of a space. Gaskets, frames, hinges and latching handles tend to loosen and wear, leading to lower air delivery from the unit, energy loss, sweating, and infiltration of dirt.
Inspection Door
We provide
- Doors, not hatches
- In order to ease cleaning
- Easy to replace filter

BAD
Good
Maintaining desired fan airflow is critical to providing adequate conditioned supply air into a space. If not appropriately maintained, fan components can lead to diminished airflow and eventual failure; components include:

- fan housings
- wheels
- bearings
- belts
- guards
- motor
**Fans**

- The fan wheel should be checked periodically for accumulation of dirt, mechanical fatigue, and imbalance that can result in increased vibration and noise, and ultimately catastrophic failure with life threatening potential (i.e., broken blades and housings).

- If these problems are not corrected, desired airflow volume may not be achieved.
Fans

- Bearing failure is common, because of over- or under-lubrication and the use of lubricants that are not intended for the airstream environment. Personnel should have appropriate training from bearing manufacturers and lubrication suppliers.

- Vibration and temperature monitoring can assist in trending analysis to identify impending bearing failure.
Belt Drive

Fan

Belt-Driven Ventilator
Speed control alternatives:
• Belt-pulley ratio
Fans

- Belt drives need extensive care and procedures for removing, installing, and starting-up equipment with belt drives.

- Improper belt tension is one of the most common root causes of premature failure; steps which should be followed include:
  - Check belt tension
  - Start the drive, looking and listening for any unusual noise or vibration
**Direct Drive**

**Fan**

**Freewheeling Ventilator**
- Easy to clean
- Easy to maintain
- Reliable
- Precise flow rate control
Motors

- Dirty motors run hot when thick dirt insulates the frame and clogs cooling air passages.
  - Motor exterior should be periodically cleaned to remove contaminants that can affect heat dissipation from the motor.
- Check for signs of corrosion.
- Lubricate the bearings only when scheduled or if they are noisy or running hot. Do not over-lubricate. Excessive grease and oil captures dirt and can damage bearings.
- Feel the motor frame and bearings for excessive heat or vibration. Listen for abnormal noise that may indicate a potential motor failure. Promptly identify and eliminate the source of the heat, noise, or vibration.
- Verify that belt and motor drive guards are securely fastened so as not to cause vibration and noise and possible damage to equipment and personnel.
Heating and Cooling Coils

- Coils, whether for heating, cooling, or dehumidifying, should be clean both internally and externally, and the fins for heat transfer should be intact and undamaged.
  - Typically, coils (especially cooling coils) are externally cleaned once a year, as this side of the coil receives the most dirt (from the air stream).
  - Internal cleaning typically is performed only when DPs of the heat transfer fluid (inlet versus outlet) increase beyond manufacturer recommendations for that which is acceptable for a particular operation.
**Heating and Cooling Coils**

- Coils may be periodically pressure tested for leaks.
- Control valves wear out over time due to constant modulation. These valves should be included in a regularly scheduled maintenance program.
- By treating heating steam and heat transfer water, tubes of coils should remain clean, and heat transfer capability should remain high for a number of years.
Air Filtration

- Ideally, filters should be replaced based on a predetermined DP drop.
- Filters should be correctly installed to prevent air bypassing them.
- ASHRAE type filters should be replaced after no more than two years of service, even if pressure differential change out limits have not yet been reached. This eliminates potential microbial growth and filter degradation.
- Filters should be inspected twice per year as a minimum.
- ASHRAE type filters (non-HEPA) should not be repaired nor require leak testing.
Filter Section

HEPA Filter

Medium Filter

Pre-Filter
## Filter Specifications

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<tr>
<th>EU Class</th>
<th>Percentage (average)</th>
<th>EN 779 &amp; EN 1822</th>
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<tr>
<th>AMperance (%)</th>
<th>Dust spot efficiency</th>
<th>EN/TC-185 Aerosol EN1822</th>
<th>CEN/TC/185 WG1-G1-T9 WG2-H10-10</th>
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</table>
HEPA/ULPA

- Depending on the testing method and product/process, leakage of the upstream aerosol concentration above an acceptable limit when tested in-situ may require that HEPA/ULPA filters be replaced or patched.

- More specific details regarding acceptance limits for localized leak rates in different applications can be found in ISO 14644-3, IEST-RP-CC034.2, and EN 1822, Parts 1 through 5.
HEPA/ULPA

- In-situ leak testing normally is performed once a year for GMP operations, but aseptic manufacturing normally requires testing every six months for some areas.

- Leaks also may occur along the interface where the medium is sealed to the frame. The adhesive material can sometimes crack or separate its bond from the frame.

- Another major leak source is at silicone gel seals, where the filter housing meets the knife-edge of the filter grid system. Over time, the gel can deteriorate because of exposure to aerosols used in the testing of filters.
When leaks are detected, the filter may be replaced or repaired.

The size and area of a patch over the leak is significant. If there is no owner’s standard for filter repair, HEPA filters should be replaced when the patched area is more than 3 to 5% of the net face area of the filter as furnished from the factory or when a single patch has a lesser linear dimension exceeding 1.5 inches (3.8 cm).

Patching material should be RTV silicone sealant caulk,

(It is not recommended to attempt to caulk a leak between silicone gel and the filter frame knife-edge, nor to repair a filter leak in a Grade 5 – Grade A hood where airflow patterns need to be uniform.)
Ductwork

- Periodic inspection of HVAC ductwork can identify potential problems (dirt, debris, leaks, and corrosion) to be corrected before unexpected failure and extensive repairs are needed.
- Ductwork can lose its seal over time and can be a source of excessive leakage that can affect room pressurization.
- Ductwork that has been crushed leads to insufficient airflow, increased noise, and poor airflow control.
- Damaged or lost duct insulation should be quickly replaced so as to not cause sweating with the potential of condensation getting into work areas, surface rusting, and surface mold growth.
Ductwork
Dampers, Louvers and Diffusers

- These should be checked for dirt accumulation and free movement without binding of the linkages over the full range of operation (full open to close).
- If these units are allowed to accumulate dirt or do not operate correctly, insufficient air distribution can result.
- Dampers, Louvers and Diffusers should be inspected and cleaned periodically.
Diffusers

Figure 9
Induction diffuser

Figure 10
Perforated plate diffuser

Figure 11
Swirl diffuser
Air Balancing

- Testing, Adjusting, and Balancing (TAB) for HVAC systems should be performed at regular intervals to ensure system compliance.
- When changes to the room configurations or HVAC equipment occur, TAB should be performed.
- At least, recalibration of monitoring instruments, verifying supply airflow to process spaces and recalculating air changes per hour (ACPH), and adjusting pressure relationships should occur at least annually for GMP spaces, or when terminal HEPA filters are tested.
Air Balancing

- Full rebalancing should be considered every five years as a minimum and seven years for non-GMP spaces. A total rebalancing can uncover unsuspected increases in energy consumption and potential equipment failures.
- There is a risk in performing partial re-balancing; as a change in airflow to one zone may cause the opposite change in other zones (increasing air flow to one room may reduce airflow to all other rooms).
# Suggested Maintenance Frequency

ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning

## Table 5.6: Suggested Maintenance Frequency

<table>
<thead>
<tr>
<th>Room Type</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic Operation (Grades 5-7) – re-calibration of instruments, check ACPH and airflow; test HEPA filters</td>
<td>6 months</td>
</tr>
<tr>
<td>GMP Classified Operation (Grade 8) – re-calibration of instruments, check ACPH and airflow; test HEPA filters</td>
<td>1 year</td>
</tr>
<tr>
<td>Other GMP Spaces, Pilot Plants, Animal Facilities, Laboratory Space, R&amp;D Space – full rebalancing</td>
<td>5 years</td>
</tr>
<tr>
<td>Non-GMP Spaces including electrical and mechanical rooms, auditoriums, utility spaces, central plant ventilation, kitchens and offices – full rebalancing</td>
<td>7 years</td>
</tr>
</tbody>
</table>