NMISA Building 4W Clean room site assessment and recommendation report

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Abbreviations

Unless elsewhere specified the following abbreviations will be used in the report:

HEPA – High-Efficiency Particulate Air

UPS – Uninterrupted Power Supply

SAG – Supply air grille

RAG – Return air grille

RH – Relative Humidity

AHU – Air handling unit

ACH - Air changes per hour

ISO – International Organization for Standards

1 INTRODUCTION

Cleanrooms and associated controlled environments are designed to manage and control airborne contamination, ensuring conditions suitable for conducting contamination-sensitive operations. Effective contamination control is essential for maintaining product and process integrity across various industries, including aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, and food production.
Following initial **assessment,** it is required to verify continued compliance and environmental sterility, in accordance with **ISO 14644** and, where applicable, **Good Manufacturing Practice (GMP)** standards.

This report provides a summary of the **findings, and recommendations** arising from the assessment of the controlled environment.

Steps taken for assessment

- Assessed the overall condition of the cleanroom and laboratory, including the integrity of finishes, seals, penetrations, and services.
- Inspected the air handling unit (AHU) system to evaluate operational condition, airflow performance, filtration integrity, and control functionality.
- Inspected the extraction system, including fume hoods and exhaust ductwork, to assess airflow rates, control capability, and system condition.
- Investigated potential causes of the cleanroom experiencing unintended negative pressure, including supply and exhaust airflow balance and envelope leakage.
- Checked and measured supply and return airflow rates at selected measurement locations to verify actual system performance.
- Measured and verified room pressure differentials between adjacent spaces to assess pressure cascade stability.
- Verified fume hood exhaust airflow rates and corresponding air change rates under various operating scenarios.
- Collected laboratory equipment data to support the heat load analysis and assess its impact on HVAC system performance.

2. FINDINGS

2.1. Assessing the condition of the cleanroom and laboratory

- The overall condition of the cleanroom and laboratory was found to be unsatisfactory. Water was observed on the laboratory floor, particularly behind equipment, as well as on the supply diffuser plates. In addition, water staining on the walls indicates ongoing or historical leakage within the laboratory space.
- Visible water marks on both walls and ceiling surfaces further confirm the presence of leakage affecting the laboratory environment.
- Seals at panel joints, particularly within the ceiling areas, were observed to be worn and degraded, compromising the integrity of the cleanroom envelope.
- Light fittings were found to be inadequately sealed, with visible evidence of air leakage around their perimeters.
- Several ceiling trap doors within the cleanroom were observed to be poorly sealed, allowing air leakage to the ceiling void.
- The cleanroom floor finishes were not in acceptable condition and exhibited multiple visible cracks, creating potential contamination traps and limiting effective cleaning.
- Drainage and plumbing installations were found to be in poor condition, with visible signs of air leakage around the pipework.

Figure 1: Air leakage on the electrical trunking

Figure 2: Seal around the lights not in good condition

Figure 3: Seal on the supply air grilles showing signs of leakage

Figure 4: Electric trunk not in good condition

Figure 5: Supply grill inside cleanroom showing air leakage on the sides

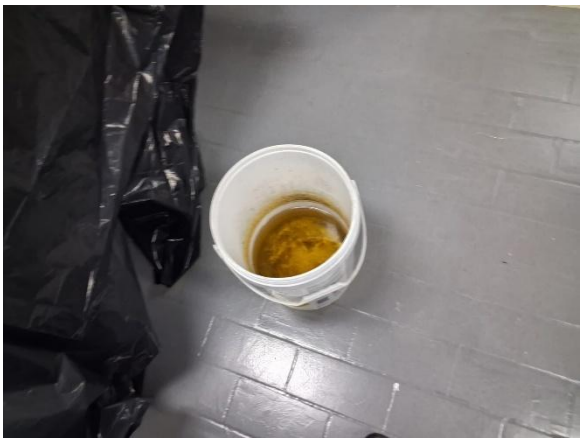


Figure 6: Water leaking into cleanroom from the supply air grilles

Figure 7: Water leaks on the lab floor leaking from the supply air diffuser

Figure 8: Water on the supply diffuser from the AHU

Figure 9: Wall not in good condition for cleanroom standard

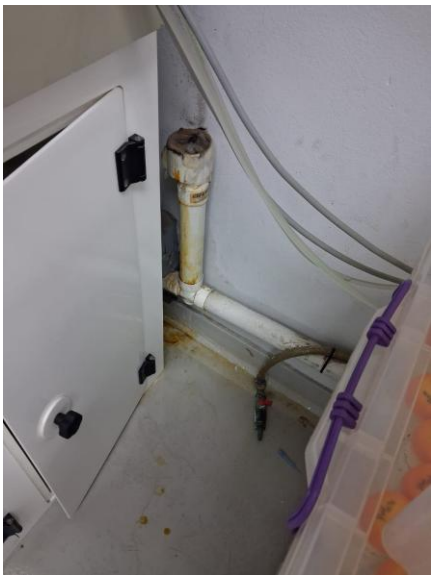


Figure 10: Plumbing not in good condition

Figure 11: Water leakage marks on the wall

Figure 12: Pipes not sealed

Figure 13: Electrical conduit not sealed properly

Figure 14: The trap door inside laboratory does not seal properly

Figure 15: Poorly installed electrical trunking

Figure 16: Air leakage on the trap doors to the ceiling void

Figure 17: The wall not sealed

Figure 18: Floor has visible cracks

Figure 1: Air leakage on electrical trunking
Electrical trunking within a cleanroom must be airtight and flush with adjacent surfaces. Visible air leakage indicates a loss of pressure integrity, which compromises the controlled airflow regime required by ISO 14644. This condition also presents a contamination risk due to unfiltered air ingress and particulate accumulation.

Figure 2: Seal around light fittings not in acceptable condition
Light fittings in cleanrooms must be fully sealed and flush mounted. Deteriorated or incomplete sealing creates crevices where contaminants may accumulate and allows air leakage into the cleanroom envelope, violating GMP requirements for cleanable, sealed surfaces.

Figure 3: Seal on supply air grilles showing signs of leakage
Supply air grilles must be airtight to maintain unidirectional airflow and pressure cascades. Leakage at the perimeter of the grilles disrupts airflow patterns, reduces filtration effectiveness, and compromises ISO 14644 airflow performance criteria.

Figure 4 & 15: Electrical trunking not in acceptable condition
Poorly installed or damaged electrical trunking introduces gaps, sharp edges, and unsealed joints. This condition prevents effective cleaning and creates contamination traps, which is not compliant with GMP cleanroom construction principles.

Figure 5: Supply grille inside cleanroom showing air leakage on sides
Air leakage around supply grilles indicates improper sealing and installation. This results in uncontrolled airflow paths, turbulence, and potential particulate ingress, undermining cleanroom classification and pressure control requirements.

Figure 6, 7 & 8: Water leaking into cleanroom from supply air grilles
Standing water on the cleanroom floor presents a severe contamination and safety risk. Floors must remain dry, smooth, and cleanable. This condition indicates HVAC system deficiencies, likely due to condensation or poor sealing around the AHU as shown on figure 31.

Water ingress within a cleanroom is a critical non-conformance. Moisture promotes microbial growth, damages finishes, and compromises GMP hygiene requirements. Supply air systems must not introduce condensate or water into controlled areas.

Figure 9: Wall finishes not compliant with cleanroom standards
Cleanroom walls must be smooth, impervious, non-shedding, and easy to clean. Damaged or uneven wall surfaces create contamination traps and are not compliant with ISO 14644 and GMP facility design requirements.

Figure 10: Plumbing installation not in acceptable condition
Exposed or poorly installed plumbing introduces unsealed penetrations and irregular surfaces. All services within cleanrooms must be neatly routed, sealed, and designed to allow effective cleaning and maintenance without contamination risk.

Figure 11: Water leakage marks on wall
Visible water staining indicates historical or ongoing moisture intrusion. This compromises surface integrity and increases the risk of microbial contamination, which is unacceptable under GMP environmental control requirements.

Figure 12: Pipes not sealed at wall penetrations
All service penetrations through cleanroom walls must be fully sealed and flush. Unsealed pipe penetrations allow air leakage and particulate migration, compromising pressure integrity and cleanroom classification.

Figure 13: Electrical conduit not sealed properly
Improperly sealed electrical conduits create air leakage paths and contamination risks. GMP requires all conduits to be sealed to maintain pressure differentials and prevent dust accumulation.

Figure 14 & 16: Trap door inside laboratory does not seal properly
Trap doors must maintain the same airtightness and surface integrity as surrounding ceilings. Poor sealing allows uncontrolled air leakage to the ceiling void, disrupting airflow control and pressure regimes.

Figure 17: Wall not sealed
Unsealed wall joints and interfaces allow air leakage and particulate ingress. Cleanroom walls must be continuous, sealed, and impervious to ensure environmental control and compliance with GMP standards.

Figure 18: Floor with visible cracks
Cleanroom floors must be seamless, crack-free, and easy to clean. Cracks act as contamination traps and may harbour microorganisms, making this condition non-compliant with both ISO 14644 and GMP flooring requirements.

2.2. Inspection on the air handling unit system for performance.

The cleanroom supply air system is designed to provide filtered, conditioned air to the controlled areas in order to maintain the required air change rates, pressure differentials, temperature, humidity, and particulate cleanliness in accordance with ISO 14644 and GMP requirements. Air is supplied via the Air Handling Unit (AHU), where it is conditioned and filtered through a multi-stage filtration arrangement consisting of primary, secondary, and terminal HEPA filtration.

The AHU draws return and fresh air through the primary filters, followed by secondary filters and HEPA filters to remove progressively finer particulates before air is delivered to the supply fan.

Airflow volume and pressure are controlled via a Variable Speed Drive (VSD) on the supply fan, allowing adjustment of airflow to achieve the required air change rates and to maintain pressure cascades between adjacent spaces. Differential pressure monitoring across filter stages and between rooms is required to verify correct system operation and to ensure ongoing compliance.

All supply ducting, diffusers, penetrations, and interfaces forming part of the cleanroom envelope are required to be airtight, smooth, sealed, and constructed from materials suitable for cleanroom applications. This ensures that unfiltered air bypass, leakage, and particulate ingress are prevented, and that the system can be effectively cleaned, maintained, and validated in accordance with GMP principles.

Below are the findings related to the supply air system, together with our assessment of the observed deficiencies and the technical basis for concluding that these conditions represent errors or non-compliances.

Figure 19: Supply air ducting disconnected from the main HVAC system

Figure 20: Wires in the ceiling void are unsafe

Figure 21: Unclear primary filter gauge

Figure 22: Unclear secondary and HEPA filter gauges

Figure 23: AHU distribution board

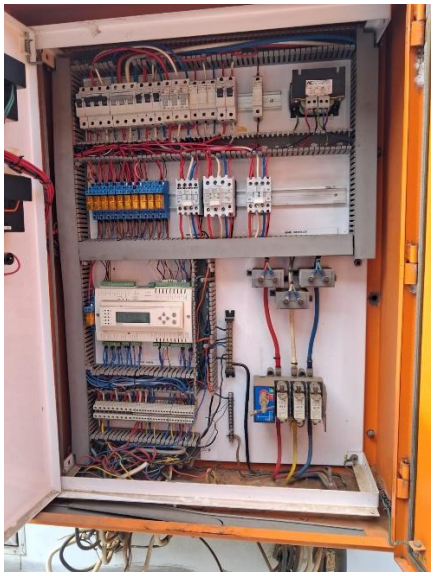


Figure 24: Control panel

Figure 25: VSD is running on manual

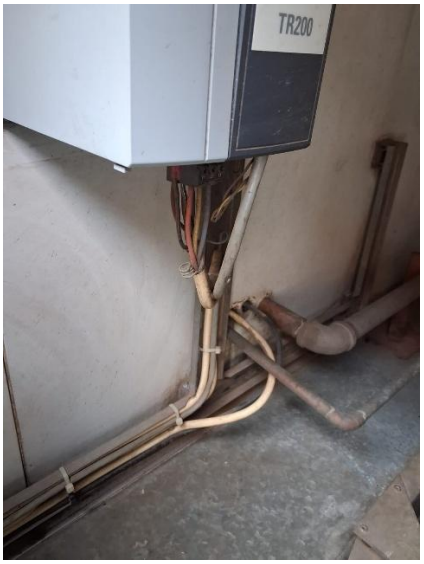


Figure 26: Unsafe and exposed wiring inside the AHU

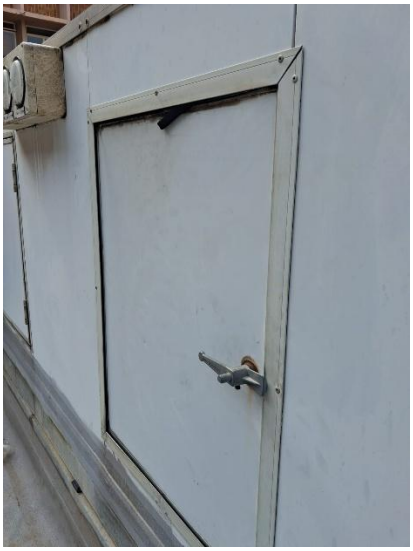


Figure 27: AHU doors showing leakage

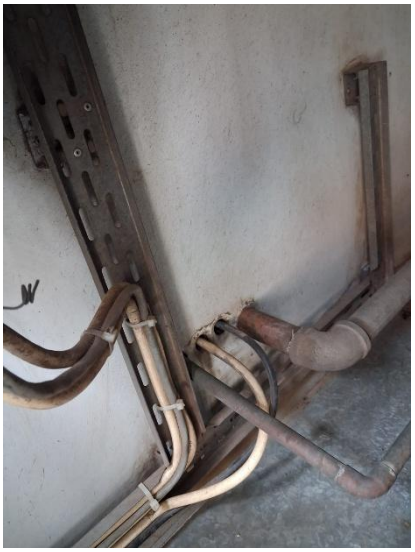


Figure 28: AHU inside penetrations not sealed

Figure 29: Return damper inside the AHU shows signs of rust

Figure 30: Worn out gasket around the Primary filter frame

Figure 31: Water mark leakages in the AHU

Figure 19: Flexible supply air ducting disconnected from the main HVAC system
During the site inspection, it was observed that a section of the supply air ducting was disconnected from the main HVAC system, this is due to the material of the duct (flexible). This condition resulted in uncontrolled air delivery and reduced airflow to the cleanroom, adversely affecting air change rates, pressure differentials, and overall filtration performance, with direct implications for cleanroom classification and compliance with ISO 14644. On the final day of the assessment, the disconnected duct section was reconnected by our technician to improve airflow distribution. Following this intervention, a slight increase in the measured air change rates and airflows was observed.

Figure 20: Unsafe wiring in the ceiling void
Exposed and unsecured wiring presents both a safety hazard and a contamination risk. GMP requires

services to be safely installed, protected, and routed to prevent dust accumulation and accidental damage.

Figure 21 & 22: Primary, secondary and HEPA filter pressure gauge unclear
Filter pressure gauges must be clearly readable to allow proper monitoring of filter loading and performance. An unclear gauge prevents effective maintenance and compromises filtration control. HEPA filter performance is critical in cleanroom environments. Unclear or unreadable gauges prevent verification of pressure drop across filters, increasing the risk of operating with compromised filtration without detection

Figure 23 & 24: AHU control panel

Control panels are required to provide clear operational status indication and functional alarms to ensure effective control of cleanroom environmental conditions in accordance with ISO 14644. During the inspection, the control panel was found to be non-functional. The associated distribution box was observed to be in poor condition, with unsafe and poorly arranged wiring, presenting both operational and safety concerns. In addition, the voltage and amperage meters were not functioning, preventing effective monitoring of electrical and system performance. These deficiencies significantly reduce the ability to maintain and verify controlled environmental conditions within the cleanroom.

Figure 25: Variable Speed Drive (VSD) operating in manual mode
Operation of the Variable Speed Drive (VSD) in manual mode prevents automatic control of airflow, pressure differentials, and air change rates. GMP and ISO 14644 require stable, controlled operation with monitored and validated setpoints. At the time of inspection, the VSD was operating in manual mode at approximately 30% output, limiting the system's ability to maintain consistent airflow performance and controlled environmental conditions within the cleanroom.

Figure 26: Unsafe and exposed wiring inside the AHU
Exposed wiring within the AHU presents a risk of electrical failure, contamination, and maintenance-related damage. All internal wiring must be secured, enclosed, and protected in accordance with good engineering practice.

Figure 27 and 28: AHU doors showing air leakage
AHU casings are required to be airtight to prevent bypass air and to maintain filtration integrity. Air leakage was observed at the AHU access doors, reducing system efficiency and allowing unfiltered air to enter the supply air stream. In addition, unsealed penetrations were identified within the AHU casing, providing further pathways for air leakage and contamination. These conditions compromise pressure control and filtration effectiveness, in violation of ISO 14644 system integrity requirements. Furthermore, visible water marks were noted on and around the access doors, indicating previous or ongoing water ingress, which presents a risk of corrosion, microbial growth, and degradation of internal components, further impacting HVAC performance and cleanroom compliance.

Figure 29: Return air damper inside AHU showing signs of rust
Rust indicates corrosion and material degradation. Corroded components can shed particulates into the air stream and are not acceptable for GMP-controlled environments where cleanable, corrosion-resistant materials are required.

Figure 30: Worn gasket around primary filter frame
A damaged or worn gasket allows air bypass around the filter, reducing filtration efficiency. This directly compromises HEPA filtration integrity and cleanroom air quality.

Figure 31: PVC ducting
PVC ducting is generally not suitable for GMP cleanroom HVAC systems due to its potential to degrade, accumulate static, and be difficult to clean. Ductwork should be constructed from smooth, durable, cleanroom-compatible materials.

Figure 32: Fan housing and electrical wiring
Poorly installed fan housing and exposed wiring increase the risk of mechanical failure and contamination. All components must be securely mounted, enclosed, and designed for cleanroom service conditions.

2.3. Inspection on the extraction system.

Figure 32: PVC ducting

Figure 33: fan housing and electrical wiring

Figure 34: Exhaust system for the fume hoods

Figure 31: PVC ducting used for extraction

Extraction ducting within or connected to cleanroom systems must meet the same material and cleanability standards as supply systems. PVC ducting may not provide adequate durability, sealing, or cleanability for GMP compliance.

Figure 32: Extraction fan housing and electrical wiring
Unsafe wiring and inadequately protected fan components present safety risks and increase contamination potential. Extraction systems must be robust, sealed, and compliant with good engineering and GMP practices.

Figure 34: Exhaust airflow measurement

The image illustrates the assessment team conducting airflow measurements on the exhaust air system as part of the HVAC performance evaluation. Airflow measurements were taken at the exhaust stack discharge points, as these locations provided sufficiently long and straight duct sections to allow accurate and representative airflow measurements in accordance with good engineering practice. A total of five airflow readings were recorded at each exhaust point, including measurements associated with the facility's air extraction equipment as well as the general return air points. The multiple readings were used to improve measurement reliability and to account for any short-term fluctuations in airflow. These results are shown in detailing section 4 of this report.

Following completion of the airflow measurements, air change rates were calculated using the measured airflow volumes in conjunction with the verified room dimensions for each space assessed. These calculated air change rates were then used to evaluate the performance of the exhaust system and its impact on room pressurisation and overall compliance with ISO 14644 and GMP cleanroom ventilation requirements.

2.4. Potential cause of why clean room experiencing negative pressure.

The negative pressure observed within the cleanroom is considered to be the result of several contributing factors identified during the site assessment.

- The fume hood exhaust system is extracting air at a rate that exceeds the supply airflow delivered by the air handling unit (AHU). This imbalance results in a net loss of air within the cleanroom and laboratory spaces, leading to unintended depressurisation.
- A section of the supply air ducting was found to be disconnected during the assessment, which reduced the effective supply airflow to the cleanroom and further contributed to the pressure imbalance.
- Air leakage was identified from the AHU casing, including at access doors and unsealed penetrations, allowing conditioned supply air to escape before reaching the cleanroom.
- Leakage from the laboratory and cleanroom envelope, including unsealed penetrations, degraded seals, and poorly sealed doors and panels, provides additional uncontrolled airflow paths, exacerbating pressure instability.

In a cleanroom laboratory containing fume hoods, negative pressure conditions typically arise when the exhaust airflow rate exceeds the supplied airflow. While fume hoods are designed to safely remove hazardous substances by extracting significant volumes of air, the cleanroom HVAC system must be appropriately balanced to compensate for this exhaust demand. Failure to adequately match supply airflow to exhaust requirements results in excessive negative pressure, loss of pressure cascade control, and instability of the cleanroom environment.

The inspections of the AHU and extraction systems identified significant deficiencies affecting airflow control, filtration integrity, system safety, and material suitability. Collectively, these issues represent **major non-conformances** with ISO 14644 and GMP requirements and will adversely impact cleanroom performance, validation, and ongoing regulatory compliance unless appropriate corrective actions are implemented.

3. HEAT LOAD ANALYSIS

Heat Load Survey for Laboratory Equipment

BoQ Item:
Survey instruments in laboratory to prepare an inventory of equipment to determine heat load in instrument laboratory.

This section forms part of the overall assessment of the Instrument Laboratory HVAC performance. In addition to the evaluation of pressure cascades, air change rates, and airflow measurements, a heat load assessment was undertaken to quantify internal heat gains within the laboratory space.

The objective of the heat load assessment was to establish the thermal contribution of laboratory equipment, occupants, internal services, and ventilation air, in order to support the evaluation and verification of the laboratory cooling capacity requirements. The assessment is based on an inventory of installed equipment, measured ventilation parameters, and standard engineering assumptions for internal heat gains.

The heat load calculation was carried out using an equipment-based approach in accordance with standard HVAC engineering practice. The following methodology was applied:

- An on-site survey was conducted to identify all major laboratory instruments and ancillary equipment.
- Electrical nameplate data was used where available; where not available, typical industry values were applied.
- Appropriate load factors were applied to account for intermittent operation.
- All electrical input power was assumed to be converted to sensible heat within the space.
- Internal loads from occupants, lighting, small plug loads, and office equipment were included.

Equipment Load Assessment

Equipment heat loads were calculated based on the rated electrical input power of laboratory instruments, adjusted by operational load factors to reflect typical usage.

The total calculated equipment heat load for the Instrument Laboratory is:

Equipment Heat Load: 16.44 kW

Internal Loads Assessment

Internal loads were calculated to account for heat gains from occupants, lighting, computers, monitors, printers, and miscellaneous plug loads. Standard laboratory design values were applied.

The total internal heat load is:

Internal Heat Load: 4.34 kW

Summary of Heat Load Results

Load Category	Heat Load (kW)
Equipment Load	16.44
Internal Loads	4.34
TOTAL LAB LOAD	**21.64**

The total calculated sensible heat load for the Instrument Laboratory is **21.64 kW**.

Design Considerations & Assumptions

The following assumptions were applied in the assessment:

- Equipment was assumed to operate at typical load factors rather than continuous full load.
- Heat losses through the building envelope were considered negligible due to the laboratory's internal location.
- No allowance has been made for future equipment unless otherwise stated.

4. AIR CHANGE RATE

4.1. AHU AIR CHANGE RATE

Project #	M029	Country:	South Africa	Town:		Original ?:	Y/N	

DATE	TIME
21 January 2026	
AHU	
ROOM PRESSURE	REF TO

1. Please only use the required table(s) pertaining to the relevant ducting / reading required per room.
2. Only insert info in yellow areas.

ROOM VOLUME m^3	LENGTH m	BREATH m	HEIGHT m	SUPPLY ACH	EXH. ACH	OFFSET	TOTAL SUPPLY VOLUME $m^{3/h}$	TOTAL EXH VOLUME $m^{3/h}$
0.000	0.000	0.000	0.000	0.000	0.00	-2761.80	4454.80	1693.00

AIR SUPPLY CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SLAVE D1	4455.00	4295.00	4528.00	4490.00	4506.00	4454.8000	4454.80

RETURN AIR CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SLAVE D1	1154.00	1816.00	1833.00	1825.00	1837.00	1693.0000	1693.00

FRESH AIR CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SLAVE D1	1810.00	1772.00	1789.00	1895.00	1872.00	1827.6000	1827.60

Table 1: AHU air change rate

4.2. CLEANROOM AIR CHANGE RATE

Project #	M029	Country:	South Africa	Town:	Pretoria	Original ?:	Y/N	

DATE	TIME
21 January 2026	
ROOM	
CLEANROOM	
ROOM PRESSURE	REF TO
-23.3	Ambient

1. Please only use the required table(s) pertaining to the relevant ducting / reading required per room. 2. Only insert info in yellow areas.

ROOM VOLUME m^3	LENGTH m	BREATH m	HEIGHT m	SUPPLY ACH	EXH. ACH	OFFSET	TOTAL SUPPLY VOLUME $m^{3/h}$	TOTAL EXH VOLUME $m^{3/h}$
85.092	7.480	4.740	2.400	11.383	77.41	5618.60	968.60	6587.20

AIR SUPPLY CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SLAVE A1	72.00	58.00	50.00	44.00	48.00	54.4000	
SLAVE A2	235.00	239.00	244.00	242.00	243.00	240.6000	968.60
SLAVE A3	250.00	252.00	257.00	254.00	254.00	253.4000	
MASTER A	413.00	416.00	428.00	421.00	423.00	420.2000	

EXHAUST AIR CALCULATIONS

PITOT TUBE READINGS IN $m^{3/H}$

EAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
FH1	1616.00	1601.00	1532.00	1505.00	1444.00	1539.6000	
FH2	1222.00	1632.00	1557.00	1611.00	1593.00	1523.0000	6587.20
FH3	1495.00	1477.00	1484.00	1362.00	1400.00	1443.6000	
FH4	1825.00	2146.00	2176.00	2138.00	2120.00	2081.0000	

Table 2: Cleanroom air change rate

4.3. LABORATORY AIR CHANGE RATE

Project #	M029	Country:	South Africa	Town:	Pretoria	Original ?:	Y/N	

DATE	TIME
21 January 2026	
ROOM	
Laboratory	
ROOM PRESSURE	REF TO
-24.4	Ambient

1. Please only use the required table(s) pertaining to the relevant ducting / reading required per room. 2. Only insert info in yellow areas.

ROOM VOLUME m^3	LENGTH m	BREATH m	HEIGHT m	SUPPLY ACH	EXH. ACH	OFFSET	TOTAL SUPPLY VOLUME $m^{3/h}$	TOTAL EXH VOLUME $m^{3/h}$
121.704	10.480	4.900	2.370	27.983	36.84	1078.00	3405.60	4483.60

AIR SUPPLY CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SAG01	914.00	920.00	928.00	904.00	906.00	914.4000	
SAG02	862.00	889.00	883.00	855.00	885.00	874.8000	3405.60
SAG03	683.00	695.00	690.00	675.00	682.00	685.0000	
SAG04	932.00	936.00	921.00	924.00	944.00	931.4000	

EXHAUST AIR CALCULATIONS

PITOT TUBE & BALOMETER READINGS IN $m^{3/H}$

EAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
RAG01	324.00	293.00	294.00	295.00	285.00	298.2000	
RAG02	895.00	900.00	880.00	897.00	916.00	897.6000	4483.60
RAG03	381.00	370.00	375.00	376.00	396.00	379.6000	
E01 (IPS 1A)	959.00	936.00	1000.00	1029.00	1012.00	987.2000	
E02 (IPS65)	422.00	393.00	370.00	328.00	344.00	371.4000	
E03 (IPS59 &58)	845.00	838.00	830.00	759.00	822.00	818.8000	
E04 (IPS48)	506.00	704.00	773.00	835.00	836.00	730.8000	

Table 3: Laboratory air change rate

4.4. ANTE ROOM AIR CHANGE RATE

Project #	M029	Country:	South Africa	Town:	Pretoria	Original ?:	Y/N	

DATE	TIME
21 January 2026	
ROOM	
Anteroom	
ROOM PRESSURE	REF TO
-7.2	Ambient

1. Please only use the required table(s) pertaining to the relevant ducting / reading required per room. 2. Only insert info in yellow areas.

ROOM VOLUME m^3	LENGTH m	BREATH m	HEIGHT m	SUPPLY ACH	EXH. ACH	OFFSET	TOTAL SUPPLY VOLUME $m^{3/h}$	TOTAL EXH VOLUME $m^{3/h}$
5.928	1.790	1.380	2.400	19.533	45.37	153.20	115.80	269.00

AIR SUPPLY CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SAG05	120.00	115.00	117.00	112.00	115.00	115.8000	
							115.80

EXHAUST AIR CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

EAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
EAG04	270.00	265.00	266.00	267.00	277.00	269.0000	
							269.00

Table 4: Ante room air change rate

4.5. ENTRY ROOM AIR CHANGE RATE

Project #	M029	Country:	South Africa	Town:	Pretoria	Original ?:	Y/N	

DATE	TIME
21 January 2026	
ROOM	
Entry Room	
ROOM PRESSURE	REF TO
1.9	Ambient

1. Please only use the required table(s) pertaining to the relevant ducting / reading required per room. 2. Only insert info in yellow areas.

ROOM VOLUME m^3	LENGTH m	BREATH m	HEIGHT m	SUPPLY ACH	EXH. ACH	OFFSET	TOTAL SUPPLY VOLUME $m^{3/h}$	TOTAL EXH VOLUME $m^{3/h}$
13.491	1.790	2.910	2.590	21.451	0.00	0.00	289.40	0.00

AIR SUPPLY CALCULATIONS

BALOMETER READINGS IN $m^{3/H}$

SAD LABEL	READING 1	READING 2	READING 3	READING 4	READING 5	VOLUME	TOTAL HOOD VOLUME $m^{3/h}$
SAG09	294.00	284.00	285.00	291.00	293.00	289.4000	
							289.40

Table 5: Entry room air change rate

5. ROOM PRESSURES

The pressure trend illustrates the relative pressure relationships between the Entry Room, Ante Room, Cleanroom (W5), and Laboratory over the monitoring period. Under normal operating conditions, the Entry Room remains at the highest pressure, followed by the Ante Room, with the Cleanroom and Laboratory maintained at progressively lower pressures to support the intended pressure cascade and containment strategy. The below graphs indicates the different scenarios relating to the fume hoods.

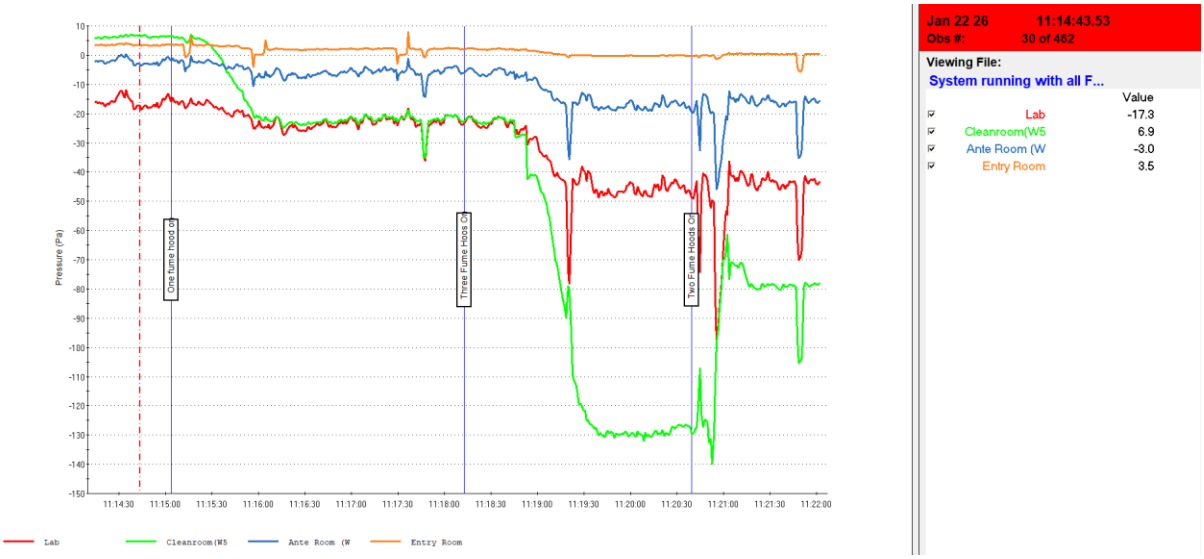


Figure 35: Graph showing the pressures with all fume hoods not I operation

At the start of the monitoring period, all the fume hoods were switched off, with the Entry Room remaining slightly positive, the Ante Room operating at a moderate negative pressure, and the Cleanroom and Laboratory operating at more negative pressures relative to adjacent spaces. Minor fluctuations are observed, consistent with normal operational variability.

Figure 36: Graph showing the pressures with one fume hood running

When a single fume hood is switched on, a small but noticeable change in room pressures is observed. The Laboratory experiences an increase in negative pressure, while the Cleanroom shows a negative pressure. The Ante Room pressure also decreases slightly, indicating that the additional exhaust demand is being drawn from adjacent spaces. Although the general pressure cascade direction is largely maintained, the reduction in cleanroom pressurisation indicates a weakening of pressure control rather than an acceptable operating condition.

Figure 37: Graph showing the pressures with two fume hoods running

The most severe pressure fluctuations were observed when three fume hoods were operated simultaneously. During this condition, rapid pressure drops and recoveries occurred, indicating instability within the HVAC control system and a limited ability to respond dynamically to increased exhaust demand.

Figure 38: Graph showing the pressures with three fume hoods running

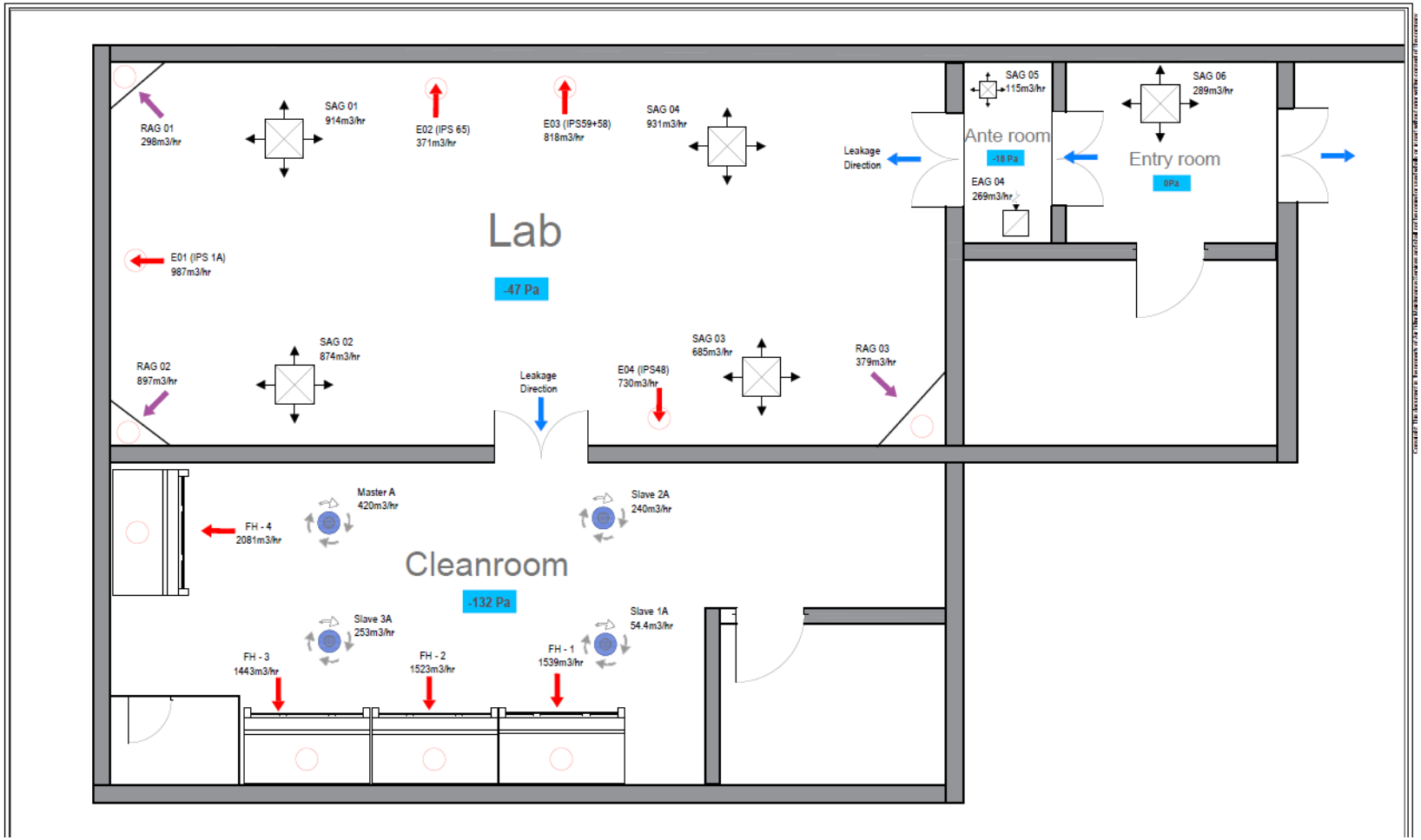
After observing the pressures when the 3 fume hoods are running, it was noted that this scenario resulted in a significant drop in pressure in the cleanroom, we therefore switched off one fume hood to observe the impact this would have on the system. After switching off one fume hood to have 2 fume hoods running, we noted a slight increase in pressure which still results in a negative pressure state of the cleanroom. This behaviour indicates that the combined exhaust demand from the fume hoods exceeds the available supply air capacity, resulting in excessive depressurisation of the controlled spaces. The Cleanroom becoming increasingly negative represents a deviation from the

intended pressure cascade and poses a risk to contamination control and ISO 14644 and GMP compliance

Overall, the pressure trend demonstrates that the existing balance between supply and exhaust air is insufficient to maintain stable pressure differentials during fume hood operation. This results in loss of pressure cascade control and the development of excessive negative pressures within both the Cleanroom and the Laboratory, increasing the risk of contamination ingress and loss of containment. These conditions are not compliant with ISO 14644 and GMP cleanroom pressure control requirements.

As illustrated in the pressure trend above, not all four fume hoods were operated simultaneously during testing. This decision was taken due to the rooms becoming increasingly negative, and to avoid potential compromise to the building structure and the integrity of the cleanroom envelope during the assessment.

6. Airflow Schematic -Current Operating Condition



Airflow Schematic Current Operating Condition

The above airflow schematic illustrates the current operating condition of the cleanroom, laboratory, ante room, and entry room as assessed during the site inspection and performance testing. The schematic presents the measured supply, return, and exhaust airflow rates, together with the corresponding room pressures recorded **while fume hoods FH-1, FH-3, and FH-4 were in operation**.

As shown on the schematic, the Entry Room is maintained at approximately 0 Pa, while the Ante Room operates at approximately –18 Pa. The Laboratory and Cleanroom, however, are operating at significantly negative pressures of approximately –47 Pa and –132 Pa respectively under this operating scenario. This pressure regime indicates a loss of the intended pressure cascade, with the Cleanroom being the most negatively pressurised space, which is not aligned with ISO 14644 and GMP cleanroom design principles.

The Cleanroom is served by multiple fume hoods, and the combined exhaust demand from **fume hoods FH-1, FH-3, and FH-4** exceeds the supply air delivered to the space. This results in severe depressurisation of the Cleanroom, as evidenced by the measured room pressure and the airflow leakage paths indicated at door interfaces and envelope penetrations. Airflow arrows on the schematic confirm that air is being drawn from adjacent areas, including the Laboratory and Ante Room, into the Cleanroom to compensate for the shortfall in supply air.

The Laboratory is similarly affected, operating under negative pressure due to a combination of exhaust airflows and insufficient supply compensation. Although supply and return air grilles are present, the measured airflow rates are inadequate to counterbalance the exhaust demand and envelope leakage, resulting in uncontrolled airflow paths and pressure instability.

The Ante Room, intended to function as a pressure buffer between the Entry Room and the controlled spaces, is unable to maintain effective pressure stabilisation due to the magnitude of the negative pressures generated downstream during fume hood operation. This increases the risk of airflow reversal and compromises contamination control.

Overall, the airflow schematic demonstrates that, under the tested operating condition with fume hoods FH-1, FH-3, and FH-4 in operation, the existing HVAC system is unable to maintain stable airflow balance and pressure differentials. This finding directly supports the conclusions drawn from the pressure trend analysis and confirms the need for system upgrades to achieve compliance with ISO 14644 and GMP requirements.

7. RECOMMENDATIONS FOR COMPLIANCE AND CORRECTIVE ACTIONS

Based on the findings from the site assessment, airflow measurements, AHU and extraction system inspections, and the observed room pressure trends during fume hood operation, the following corrective actions are recommended to restore cleanroom performance and achieve compliance with ISO 14644 and GMP requirements.

Restore and Stabilise Room Pressure Cascade

The supply airflow delivered by the existing Air Handling Unit (AHU) is insufficient to offset the exhaust demand generated by the fume hoods. Worst-case operating conditions, including the simultaneous operation of multiple fume hoods, were tested during the assessment and resulted in

excessive depressurisation of both the Cleanroom and Laboratory. This confirms that the current AHU does not have adequate capacity or control capability to maintain the required airflow balance and pressure cascade.

Based on the results of the worst-case testing, it is recommended that the existing AHU be replaced with a suitably sized and controlled unit designed to meet the full supply air demand under maximum exhaust loading. The replacement AHU shall be capable of maintaining stable airflow rates and pressure differentials in accordance with ISO 14644 and GMP requirements during all operating conditions.

The replacement AHU should be designed to:

- Provide sufficient supply airflow to maintain the intended pressure cascade during full fume hood operation
- Incorporate appropriate multi-stage filtration suitable for cleanroom applications
- Feature an airtight casing construction to prevent air leakage and bypass
- Operate with automatic airflow and pressure control via VSDs and differential pressure monitoring
- Support commissioning, testing, and validation in line with ISO 14644 and GMP requirements

This approach ensures that the cleanroom pressure regime can be reliably maintained during all operating scenarios, including peak fume hood usage, and supports long-term compliance and validation.

7.1. Automated Pressure Control

Room pressure control should be automated using differential pressure sensors linked to the Building Management System (BMS) or AHU controls. This will allow dynamic adjustment of supply airflow in response to changes in exhaust demand, preventing the rapid pressure drops observed during testing.

7.2. Magnehelic Gauges

It is recommended that Magnehelic differential pressure gauges be installed across all cleanroom and laboratory spaces, including the Cleanroom, Laboratory, Ante Room, and Entry Room. These gauges shall be installed to continuously indicate pressure differentials between adjacent rooms and between controlled spaces and surrounding areas.

7.3. Replace Flexible Duct In the supply air system

It is recommended that all flexible ducting installed within the supply air system be removed and replaced with rigid, cleanroom-appropriate ductwork. Flexible ducting is prone to air leakage, pressure losses, internal contamination, and difficulty in effective cleaning, which can adversely affect airflow distribution, filtration performance, and pressure control.

Replacement ductwork should be constructed from smooth, airtight, and durable materials suitable for cleanroom applications, with all joints properly sealed and supported in accordance with good engineering practice. Implementing rigid ducting will improve airflow consistency, reduce leakage, enhance cleanability, and support stable pressure cascade control, thereby contributing to compliance with ISO 14644 and GMP cleanroom requirements.

Improve Fume Hood and Exhaust System Integration

7.3.1. **Install Variable Exhaust Control**

It is recommended that variable exhaust control be implemented on the fume hood exhaust system to regulate extraction airflow in response to actual demand. The pressure trend observed during the assessment demonstrated that fixed exhaust volumes, particularly during simultaneous operation of multiple fume hoods, result in excessive depressurisation of the Cleanroom and Laboratory, indicating a lack of dynamic control.

Variable exhaust control, achieved through the installation of Variable Speed Drives (VSDs), modulating dampers, or airflow control valves, will allow exhaust airflow to be adjusted based on fume hood usage, sash position, or real-time pressure feedback. This will reduce unnecessary extraction when fume hoods are partially or not in use, helping to stabilise room pressures and maintain the intended pressure cascade.

The variable exhaust system should be integrated with the supply air system and room pressure monitoring to ensure coordinated control of airflow rates. This approach will improve system responsiveness, reduce pressure fluctuations, enhance energy efficiency, and support ongoing compliance with ISO 14644 and GMP cleanroom pressure control requirements.

7.4. Restore Cleanroom Envelope Integrity

7.4.1. **Seal All Penetrations and Joints**

All wall, ceiling, and service penetrations must be sealed flush using cleanroom-compatible sealants. Panel joints, especially in the ceiling, must be resealed to eliminate air leakage paths.

7.4.2. **Repair or Replace Trap Doors**

All trap doors within the cleanroom ceiling must be fitted with proper gaskets and sealed to the same standard as the surrounding ceiling to prevent air leakage into the ceiling void. These must be installed with proper clamps for effective air tightness.

7.4.3. **Seal Light Fittings**

Light fixtures must be resealed to ensure they are airtight and flush with ceiling panels, eliminating air leakage and contamination traps.

7.5. Address Water Ingress and Moisture Control

7.5.1. **Investigate and Eliminate Water Sources**

All sources of water ingress identified at supply diffusers, AHU components, walls, and floors must be investigated and rectified. This may include correcting condensation issues, improve drainage, or repair leaking services. Alternatively, replacing the entire AHU will eliminate this water ingress into the facility.

7.5.2. **Repair Affected Surfaces**

Walls, ceilings, and floors showing water damage must be repaired or replaced using materials suitable for cleanroom environments to prevent microbial growth and surface degradation.

7.6. **Repair or Replace Cracked Flooring**

Cleanroom floors must be seamless, crack-free, and cleanable. All cracks must be repaired

using approved cleanroom flooring systems or the floor replaced where damage is extensive.

7.7. Electrical and Control System Improvements

7.7.1. **Reconfigure VSD Operation**

The supply fan VSD should be removed from manual operation and configured for automatic control with validated setpoints. This will enable stable airflow delivery and pressure control in response to system demands. This will be integrated to the BMS.

7.7.2. **Secure and Enclose All Wiring**

Unsafe and exposed wiring identified in the AHU, ceiling void, and extraction systems must be properly enclosed, secured, and labelled in accordance with good engineering and GMP practices.

7.8. Verification, Testing, and Validation

7.8.1. **Recommission the HVAC System**

Following completion of corrective actions, the HVAC system must be recommissioned, including airflow balancing, pressure cascade verification, and functional testing under worst-case operating conditions.

7.8.2. **Repeat Pressure Trend Analysis**

Room pressure monitoring should be repeated with all fume hoods operating simultaneously to confirm that stable pressure differentials are maintained and that the cleanroom does not enter unintended negative pressure.

7.8.3. **Conduct ISO 14644 Performance Testing**

Final compliance testing, including air change rates, pressure differentials, and airflow patterns, should be conducted in accordance with ISO 14644-3 to support cleanroom reclassification and GMP compliance.

7.9. Replacement of Existing Wooden Doors

- The pressure trend analysis demonstrated significant pressure differentials during fume hood operation, increasing the risk of air leakage at door interfaces. The existing wooden doors do not provide an airtight seal and therefore contribute to loss of pressure cascade control and uncontrolled air movement between adjacent spaces. These wooden doors are porous, difficult to clean effectively, and susceptible to degradation from moisture, which was evidenced by air leakage and pressure instability observed during the assessment. It is recommended that these doors be replaced with cleanroom-rated doors constructed from non-porous, smooth, and cleanable materials suitable for GMP environments, fitted with continuous perimeter seals and appropriate door hardware to ensure airtight closure. The interlocks shall be integrated with the Building Management System (BMS) to ensure controlled door operation, maintain pressure differentials, and support stable pressure cascade control in accordance with ISO 14644 and GMP requirements.

7.10. Labelling of Fume Hoods

It is recommended that the labelling of all fume hoods be reviewed and corrected, as the current numbering was found to be inaccurate. Incorrect labelling can lead to confusion during operation, testing, maintenance, and airflow balancing activities, increasing the risk

of operational errors. All fume hoods shall be clearly and permanently labelled in accordance with the airflow schematic on this report.