^ Infrastructure and Operations Division (IOPS)

Specification

Title: **Specification for Environmental Performance and Filter Integrity Testing**

Purpose: To provide a specification that is to be used as the basis for the service agreement to all the HEPA filter systems and Environmental performance testing within NIBSC.

Associated Documents

Work bench Document Serial No 6598 for contractor general requirements
Work bench Document Serial No 6696 Replacement of HEPA Filters
Work bench Document Serial No 2709 Procedure for SSS Autoclave
Work Bench Document Serial No 1571 Maintenance, Testing, Validation and Cleaning of the UKSCB Cleanroom Suites
CBRM Folder with the title 'CBRM Clean Room Validation Summary' kept in room 1.24
CBRM Drawing for Pressure Cascade M:\Drawings\Site wide PDF\M-CBRM-Air Flow-M5241.pdf
HPA/RA/02472 Maintenance and terminal HEPA filter change
HPA/RA/00601 Replacing Extract Filter HEPA CL4
BS EN ISO 14644-^ 1:2015 specifies the classification of the related performance requirements for nine classes of environmental cleanliness.
BS EN ISO 14644-^ 2:2015 specifies procedures for the monitoring of cleanroom performance related to air cleanliness by particle concentration.
BS EN ISO 14644-3:2019^ Cleanrooms and associated controlled environments. Test methods. This British Standard has recently been updated and due to its length and complexity advice will be sought from our specialist contractor to see if and how it impacts this document. A change request will be raised once the full implications are known.
^ BS EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinets
BS EN ISO 14698 -1:2003 Cleanrooms and associated controlled environments. Biocontamination control. General principles and methods
BSRIA Application Guide AG 3/89.3 'Commissioning Air Systems, Application procedures for buildings'

This specification should be used as a minimum requirement, and any additional recommended works should be agreed between NIBSC and the service provider.
The specification will cover the filter part of the system, and a current equipment list will be attached to this specification if applicable (Equipment List attached YES/NO, delete as necessary)

The Services required are:
Scheduled site/service visits and tests - to carry out routine and planned preventative maintenance (PPM), and testing schedule. (Completed certificates/service sheets of examination to confirm this)
The service will be carried out to the appropriate British Standard for each area.

Health and Safety

The correct PPE must be worn when removing installed HEPA filters, and NIBSC policy adhered to for the bagging and preparation for autoclaving, prior to disposal.
Care must be taken when working at height, the most suitable access equipment must be used, as well as taking all other precautions associated with working at height. The service supplier must ensure that Health and Safety is adhered to, and to implement safe working practices at all times when working within The Institute. The service supplier is required to keep up to date with any changes of legislation within the industry that may affect their responsibilities to carry out the Service Level Agreement. The service supplier must ensure that any service engineers attending site are fully trained and competent to carry out their duties in a safe and controlled manner.

Planned Maintenance, Service, and Testing

Cleanroom:

BS EN ISO 14644-1:2015 specifies the method of classification for nine classes of environmental cleanliness by the use of discrete particle counters.

BS EN ISO 14644-3:2019^ specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational.

EU GMP, Amendment to Annex 1 (March 09) specifies the acceptance criteria for the four cleanliness grades which are equivalent to four cleanliness classes within ISO 14644-1. The airborne cleanliness testing (particle counting) results for the UKSCB facility must be specified as a GMP grade.

The Service Supplier is required to carry out the following **HEPA** Filter and **Environmental Performance** testing procedures for Cleanrooms as part of the service agreement. The testing procedures required will be determined by the laboratory environment and its purpose of use and must be tested in accordance with BS EN ISO 14644-3:2019^ (please refer to asset list).

HEPA Filters:

Verify the installed efficiency of each HEPA filter including its housing has a leakage penetration not exceeding 0.01%. Test method to be in accordance with BS EN ISO 14644-3:2019^ section B.6.2 and to include:

- Measurement of flow rate through the filter – the airflow velocity test should be done prior to performing this test.
- Measurement of pressure difference across the installed filter.
- Installed filter system leakage test (referred to as scan test method)

The procedure for filters installed in ducts or air-handling units where the downstream face does not have adequate access for scanning should be modified to be in accordance with BS EN ISO 14644:3-3 section B.6.4 (referred to as volumetric test method)

Environmental Performance Testing:

To assess the cleanrooms environmental performance is within specified design criterion and stipulated industry standards the following tests and calculations where required are to be carried out:

- Airborne particle count – classification test
- Airflow test - measurement of air supply and extract flow rates
- Air pressure difference test – measurement of room pressures with respect to surrounding areas
- Airflow direction test and visualisation – to confirm either the direction or airflow pattern or both meets the design specification
- Temperature test – to confirm the temperature is within the design specification at the time of visit
- Humidity test (if controlled) – to confirm the temperature is within the design specification at the time of the visit.
- Recovery test – to verify if the installation is capable of returning to a specified cleanliness level within a finite time. (to be carried out following a filter change or as deemed appropriate).
- Light level test – to confirm light level at the working height (1m above FFL unless otherwise specified)
- Noise level test - to confirm the noise level at the time of visit with all plant running in a balanced state
- Three-point Testing and Calibration of Magnehelic Gauges.

Containment suite/room:

Service provider will supply fully trained engineers with calibrated test equipment to test HEPA filters in accordance with the Advisory Committee on Dangerous Pathogens (ACDP) and COSHH regulation adopted by the HSE for Animal Containment (Level 3 & 4). These standards state that extracted air is HEPA filtered before being discharged to the atmosphere. Intervals between testing are to be no greater than 14 months, and that the room is maintained at a negative pressure.
In order to comply with Industry practice, NIBSC requires that extracted and supply HEPA filters installed in Containment facilities are tested in accordance with BS EN ISO 14644-3:2019^ .

The Service Supplier is required to carry out the following **HEPA** Filter and **Environmental Performance** testing procedures for containment suite/rooms as part of the service agreement. The testing procedures required will be determined by the laboratory environment and its purpose of use (please refer to asset list). In order to comply with Industry practice, NIBSC requires that extracted and supply HEPA filters installed in Containment facilities are tested in accordance with BS EN 12469:2000.

HEPA Filters:

Verify the installed efficiency of each HEPA filter including its housing has a leakage penetration not exceeding 0.01%. Test method to be in accordance with BS EN ISO 14644-3:2019^ section B.6.2 (scan test - preferred) or section B.6.4 (volumetric test – where no access to the clean face is available) and to include:

- Measurement of flow rate through the filter – the airflow velocity test should be done prior to performing this test.
- Measurement of pressure difference across the installed filter.
- Installed filter system leakage test

Environmental Performance Testing:

To assess the Containment suite/room **Environmental Performance** is within specified design criterion and stipulated industry standards the following tests and calculations where required are to be carried out.

- Calculation of Air Change Rates
- Measurement of Light & Sound Levels (where applicable)
- Three point Testing and Calibration of Magnehelic Gauges
- Temperature and Humidity testing
- Filter Velocity Measurement
- Air Flow Direction
- Nominal Air Flow Volume Rate
- Room Differential Pressure Testing
- Rip-out Door Leak Test (CL4 areas only). The seal will be replaced every five years.

Additional Requirements

- The service supplier must be flexible and adaptable to work with and meet the needs of the institute.
- The service supplier must provide a robust Service Level Agreement that includes a well organised/structure Planned Preventative Maintenance program.
- ⊥ To minimise any downtime of associated plant and equipment during an unforeseen breakdown the service supplier must have access to a prompt supply of parts/spares through a trusted supplier and to provide the NIBSC a prompt turnaround of any remedial works required. ^
- The Service supplier will need to have previous experience working within the clean rooms and associated controlled environment areas or similar.
- As part of the service contract the supplier is required to provide a detailed asset list that will detail the location, size, and quantity of all existing HEPA and non HEPA filters within the institute and to provide an electronic report that will be held on file for NIBSC reference.

Work is normally carried out during planned shutdown periods, being part of a service level agreement (SLA).
The service provider must produce a legible report sheet for each supply and or extract system inspected/tested /revalidated, which shows the work carried out, and noting any outstanding issues, and or recommendations for improvements, or parts/spares which may be required.
All additional repairs over and above the requirements of planned preventative maintenance must be authorised by a NIBSC representative. The Contractor should organise for quotes to be raised for all proposed work, and emailed to the Maintenance Administrator and ^ Responsible Person, within 72 hours of the initial site visit.

Contractor/service engineer must report to the Maintenance Department ^ Responsible Person or their deputy at the end of each working day, and provide feedback on progress to date.
A signed off report sheet is to be left on completion of the task with a copy of any raw data available.
The service provider will supply a current test certificate, traceable to an accredited UKAS test facility for all calibrated test instruments used. The final report must be submitted, no later than 10 working days after the completed works.
All servicing is to comply with the manufacturer's recommendations, and any relevant standards and certifications.
Any HEPA filters which are taken out, should be double bagged immediately after removal from the terminal housing, and labelled by the contractor, and left in the area in a safe and tidy manner. The Maintenance Supervisor or Administrator must then be informed, to allow them to arrange disposal using NIBSC protocol.

NIBSC Requirements and Responsibilities

Specifications and operating parameters will be issued for individual areas.
NIBSC will provide a signed permit to work, and / or a decontamination certificate to confirm that the area is decontaminated, and can be worked on.
NIBSC plan all scheduled works, and the service provider is contacted to arrange attendance dates.
NIBSC will provide a clean and safe area for the engineers to work.
NIBSC will provide bags for putting replaced filters into prior to disposal.
NIBSC will brief the service report for the SLA to the responsible Lab Staff, who will then sign the document to agree this action has taken place.
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