OPERATIONS DIVISION.

Specification

Title: Specification for the Maintenance of Microbiological Safety Cabinets, Fume Cupboards, Laminar Airflow Booths, and AFOS Tables

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Purpose

To provide a specification to be used for the maintenance, service, repair and any emergency call out agreement to the following systems:

- Microbiological Safety Cabinets
- Isolators
- Fume Cupboards
- Laminar Airflow Booths
- AFOS and Perfusion Tables.
- LEV for Operator Protection to include Welding Bay and Carpenter Work Equipment

The 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 entire system, and a current equipment list will be attached to this specification if applicable. (Equipment List attached YES/NO, delete as necessary)

General Requirements

The Services required are:

- **Scheduled site/service visits** - to carry out routine and planned preventative maintenance (PPM). (Completed certificates/service sheets of examination to confirm this, denoting it's compliance to the relevant standard). It will also include any works required by current regulations.
- **Emergency Call Outs** – Attendance on site for emergency repairs/fault diagnosis should be within 48 hours of notification of emergency, on a Monday to Friday basis.

Associated Documents

Workbench Document General Requirements for External Contractors Attending Site at NIBSC. SN 6598.
Workbench Document UKSCB Class II Cabinet Specification SN1467
Workbench Document General Permit-to Work SN3204
Workbench Document Decontamination Certificate SN3205
Workbench Document Access Authorisation Form –V1 SN 6979
Workbench Document QA/Form:QM098 Change Proposal Form SN 1509
Workbench Document OPS/SSS/SOP 03. Operation of SSS SEC Autoclave SN 2709
Workbench Document OPS/Maint/SOP0016 Replacement of HEPA Filters SN6696
BS EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinet.

British Standard BS EN 1822 Part 1:2009 High Efficiency Air Filters (EPA, HEPA, and ULPA).
British Standard BS 7989:2001 Specification for Re-circulatory Filtration Fume Cupboard.
BE EN 14175-2:2003 Fume Cupboards. Safety and performance requirements.
BS EN 14175-3:2003 Fume Cupboards. Type test methods.
BS EN 14175-4:2004 Fume Cupboards. On-site test methods.
BS EN 14175-5:2006 Recommendations for installation and maintenance.
British Standard BS EN 14644-1:1999 Cleanrooms and associated controlled environments.
HSG258 Controlling airborne contaminants at work: A guide to local exhaust ventilation (LEV).
HSE Publication - Guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents.
BS EN 12741:1999 Biotechnology - Laboratories for research, development, and analysis - Guidance for biotechnology laboratory operations, Annex A (informative) Guidance on the use of isolators.

Health and Safety

Before any servicing can commence on any Safety Cabinet, Isolator, Laminar Air Flow unit, Fume Cupboard and AFOS/Perfusion Table, the end users or responsible person should ensure that the equipment is cleaned and/or decontaminated in the appropriate manner, and the relevant permit-to-work and de-contamination documentation displayed on the equipment.
Filter Changing:
When filters are removed and changed by the contractor, in accordance with the standard procedure they will be immediately, in situ, placed in two autoclave bags (supplied by the Institute) by the contractor, to await collection by NIBSC Staff. An email to SSS staff from Maintenance will detail how many filters require autoclaving, and where they are required to be moved to in order for SSS staff to process.
Filters will then be disposed of according to the Scientific Support Services protocol SN 2709.

Manufacturers Instruction Compliance

- Operator protection systems used within the institute are sourced from a wide range of manufactures, and are of considerably differing ages. It is therefore difficult to consolidate information from all of these sources into a single procedure for servicing. In many cases information is not now available.
- The manufactures information available from recently installed equipment from Walker and Scanlaf both suggest MSC's should be tested and serviced to BS EN 12469.
- This specification details how MSC's are serviced and tested in accordance with BS EN 12469, Fume Cupboards are serviced and tested in accordance with BS EN 14175.
- LAF and AFOS are serviced and tested to Manufacturer's Instructions and LEV regulations HSG258.

Planned Maintenance and Service

There will be no reduction in the service visits intervals detailed in this specification, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager. Any deviations from the test procedures and pass criteria

detailed in this document will require full justification from the user, and will require a Change Request SN1509 to the Maintenance Manager.

The following checks should be carried out as a minimum.

Class I Microbiological Safety Cabinets

Class I Microbiological Safety Cabinets are serviced and tested ANNUALLY in CL2 laboratories and 6 MONTHLY in CL3 and CL4 laboratories.
There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager
Service of Class I Microbiological Safety Cabinets must be performed in accordance with BS EN 12469:2000 to include the items listed below.
A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Filter Integrity Check - Exhaust and Bypass (if Applicable)	<0.01% Penetration	Value and Pass/fail	Test criteria and methods described in BS EN 1822
Airflow Visualisation Check	Ensure airflow around aperture is in towards MSC.	Pass/fail	Smoke pencil test to observe air movement around MSC face aperture.
Check function of airflow indicator	Functions correctly, is correctly calibrated and is in green 'safe' zone when operating.	Pass/fail	
Check function of audible alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of visual alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of anti-blow back device	Function correctly	Pass/fail	Tested by observation with and without MSC running.
Check function of fans	Function correctly	Pass/fail	
Check function of internal lighting	Function correctly and adequate	Pass/fail	
Check function of UV light (If fitted)	Function correctly	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of interior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of work surface	No surface defects, cracks or other damage	Pass/fail	

	visible		
Check condition of viewing panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of closure panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of all seals	Present and intact	Pass/fail	
Check condition of duct work connections	No defects or cracks in connection	Pass/fail	
Measure air inflow	All measured values >0.7m/s – 1m/s	Value	Measured at points defined in BS EN 12469
Perform Operator Protection Test	<62 spots on each filter membrane at each position	Value and Pass/fail	MSC's up to 1.5m wide = 5 duplicate KI Discuss Tests at 4 fixed external positions (X, Y, X1, Y1). MSC's 1.5m to 2m wide = 15 Duplicate KI Discuss Tests at 4 fixed external positions (X, Y, X1, Y1). MSC's above 2m wide consult BS EN 12469 for test criteria
Ensure all cabinet and duct work test ports have suitable bungs present	All test port bungs in place, are suitable and in good condition	Comment	

The Service label on Class I MSC's should be updated with the following information:

- Validation Date.
- Certificate Number.
- NIBSC Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail
- Filters Pass or Fail
- Operator Protection Test Result Pass or Fail.

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

If the night door has a UV lamp fitted this must be checked to confirm it is operational

Class II Microbiological Safety Cabinets

Class II Microbiological Safety Cabinets are serviced and tested ANNUALLY in CL2 laboratories and 6 MONTHLY is CL3 and CL4 laboratories.

There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager.
All Safety Cabinets with motorised sashes must have an additional thorough check on all parts of the driving system, and sash fixings, with findings and observations noted on the service report.

Service of Class II Microbiological Safety Cabinets must be performed in accordance with BS EN 12469:2000 and/or GMP as required to include the item listed below.
A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Filter Integrity Check Exhaust, Downflow and Bypass (If applicable)	<0.01% Penetration	Value and Pass/fail	Test criteria and methods described in BS EN 1822
Airflow Visualisation Check	Ensure airflow around aperture is in towards MSC.	Pass/fail	Smoke pencil test to observe air movement around MSC face aperture.
Check function of airflow indicator	Functions correctly, is correctly calibrated and is in green 'safe' zone when operating.	Pass/fail	
Check function of audible alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of visual alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of anti-blow back device	Function correctly	Pass/fail	Tested by observation with and without MSC running.
Check function of fans	Function correctly	Pass/fail	
Check function of internal lighting	Function correctly and adequate	Pass/fail	
Check function of UV light (If fitted)	Function correctly	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of interior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of work surface	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of viewing panel	No surface defects, cracks or other damage	Pass/fail	

	visible		
Check condition of closure panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of all seals	Present and intact	Pass/fail	
Check condition of duct work connections	No defects or cracks in connection	Pass/fail	
Measure air inflow	Average value ≥0.4m/s BS EN 12469 Average value ≥0.4m/s GMP	Value	Measured at points defined in BS EN 12469
Measure air downflow	All measured values 0.25m/s – 0.5m/s BS EN 12469 All measured values 0.36m/s – 0.54m/s GMP	Value	Measured at points defined in BS EN 12469
Perform Operator Protection Test	<62 spots on each filter membrane at each position	Value and Pass/fail	MSC's up to 1.5m wide = 5 duplicate KI Discuss Tests at 4 fixed external positions (X, Y, X1, Y1). MSC's 1.5m to 2m wide = 15 Duplicate KI Discuss Tests at 4 fixed external positions (X, Y, X1, Y1). MSC's above 2m wide consult BS EN 12469 for test criteria
Ensure all cabinet and duct work test ports have suitable bungs present	All test port bungs in place, are suitable and in good condition	Comment	

The Service label on Class II MSC's should be updated with the following information:

- Validation Date.
- Certificate Number.
- NIBSC Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail
- Filters Pass or Fail
- Operator Protection Test Result Pass or Fail.

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

If the night door has a UV lamp fitted this must be checked to confirm it is operational

Class III Microbiological Safety Cabinets

Class III Microbiological Safety Cabinets are serviced and tested ANNUALLY in CL2 laboratories and 6 MONTHLY is CL3 and CL4 laboratories.
There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager
Service of Class III Microbiological Safety Cabinets must be performed in accordance with BS EN 12469:2000 to include the item listed below.
A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Filter Integrity Check Exhaust and Inlet/Supply	<0.01% Penetration	Value and Pass/fail	Test criteria and methods described in BS EN 1822
Check function of airflow indicators	Functions correctly, is correctly calibrated and is in green 'safe' zone when operating.	Pass/fail	
Check function of audible alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of visual alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of anti-blow back device	Function correctly	Pass/fail	Tested by observation with and without MSC running.
Check function of fans	Function correctly	Pass/fail	
Check function of internal lighting	Function correctly and adequate	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of interior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of work surface	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of viewing panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of closure panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of all seals	Present and intact	Pass/fail	
Check condition of duct	No defects or cracks in	Pass/fail	

work connections	connection		
Measure air inflow (Glove Breach)	Measured value ≥0.7m/s	Value	Measured through 1 open glove port as defined in BS EN 12469
Determine average air flow volume through inlet HEPA	>0.05 m3/s per m3 of internal cabinet volume	Value	As per BS EN 12469, gives an ACH rate of 180.
Measure internal negative operating pressure	-200pa or lower when compared to resident laboratory	Value	
Pressure hold test (leak tightness test)	Not greater than 10% loss over 30 mins.	Value	Pumped to a minimum starting pressure of +500pa, No greater than +550pa
Ensure all cabinet and duct work test ports have suitable bungs present	All test port bungs in place, are suitable and in good condition	Comment	

The Service label on Class III MSC's should be updated with the following information:

- Validation Date.
- Certificate Number.
- NIBSC Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail
- Filters Pass or Fail
- Pressure Hold Test Result Pass or Fail.

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

Isolators

Isolators are serviced and tested ANNUALLY in CL2 laboratories and 6 MONTHLY in CL3 and CL4 laboratories.
There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager
Service of Isolators for the containment of biological agents must be performed in accordance with, HSE Publication - Guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents and BS EN 12741:1999 Biotechnology - Laboratories for research, development and analysis - Guidance for biotechnology laboratory operations, Annex A (informative) Guidance on the use of isolators, to include the item listed below.
A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Filter Integrity Check Exhaust and Inlet/Supply	<0.01% Penetration	Value and Pass/fail	Test criteria and methods described in BS EN 1822
Check function of airflow indicators	Functions correctly, is correctly calibrated and is in green 'safe' zone when operating.	Pass/fail	
Check function of audible alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of visual alarm	Functions correctly and is correctly calibrated	Pass/fail	
Check function of anti-blow back device	Function correctly	Pass/fail	Tested by observation with and without MSC running.
Check function of fans	Function correctly	Pass/fail	
Check function of internal lighting	Function correctly and adequate	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of interior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of work surface	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of viewing panel	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of closure panel/Doors	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of all seals	Present and intact	Pass/fail	
Check condition of duct work connections	No defects or cracks in connection	Pass/fail	
Calculate air change rate	13 air changes or greater	Value	Calculation based on measured supply volume and isolator volume
Measure isolator internal negative operating pressure	-30pa or lower when compared to resident laboratory	Value	
Pressure hold test (leak tightness test)	Not greater than 10% loss over 30 mins.	Value	Pumped to a minimum starting pressure of +150pa
Leak detection	Visual test to detect air leaks at gloves/ports, seals, carcass seams and filter housings.	Pass/fail	Conducted during pressure hold test using visual indicators (bubbles, smoke etc.)

			A test method is defined in BS EN 12469
Ensure all Isolator cable ports and duct work test ports have suitable bungs present	All test port bungs in place, are suitable and in good condition	Comment	
The HEPA Filter must be replaced in Isolator Nebuliser Chamber (Carousel Filter 205mm x 205mm x 66mm) on TB003B at every service interval	Replaced Filter	Comment	This has been recommended by the manufacturer to prevent formaldehyde leakage occurring after fumigation

Additionally the following nominal operating and test values should be noted with regard to specific equipment.

Equipment	Operating Pressure	Air Change Rate	Leak Tightness Test Pressure
TB003 B	-80pa	52	+150pa
TB003 C	-70pa	43	+150pa
CAS014	-220pa	180	+500pa

Note. CAS014 is a CLIII MSC, therefore it must be tested as such and NOT as an Isolator. The gloves on this equipment must be changed at each 6 monthly visit and the sleeves changed every other visit (Annually).
CAS014 has a local alarm sounder which sounds on pressure alarm only. No other parameters (including Air Change Rate) activate the local sounder.
Due to an overchallenge of Dispersed Oil Particulate (DOP) during a routine service visit, which resulted in the incorrect failing of 5 of the 6 HEPA filters, the service contractor must ensure the correct DOP testing machine is used, with fine control for testing the small HEPA filters associated with the TB equipment.

The Service label on Isolators should be updated with the following information:

- Validation Date.
- Certificate Number.
- Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail
- Filters Pass or Fail
- Pressure Hold Test Result Pass or Fail.

Fume Cupboards

Fume Cupboards are serviced and tested ANNUALLY.

There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager

Service of Fume Cupboards & Filtered Extraction Units Cabinets must be performed in accordance with BS EN 14175 to include the item listed below.

A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Measurement of air inflow	Average reading ≥0.3m/s	Value	BS EN 14175 does not define inflow values, its predecessor standard BS 7258 suggests (but does not mandate) a reading < 0.3m/s is unlikely to be adequate. A lower average reading would not necessarily be a failure but would require further investigation.
Check safe working aperture	Aperture size is in limits defined by BS EN 14175	Pass/fail	
Check function of sash mechanism	Functions correctly	Pass/fail	
Check function of inflow gauge	Functions correctly and is correctly calibrated	Pass/fail	
Check function of fans	Function correctly	Pass/fail	
Check function of internal lighting	Function correctly and adequate	Pass/fail	
Check function of audible alarm	Functions correctly and is correctly calibrated	Pass/fail	
Perform visual smoke test	Air flow around aperture is in towards the Fume Cupboard	Pass/fail	A test method is defined in BS EN 14175

The Service label on Fume Cupboards should be updated with the following information:

- Validation Date.
- Certificate Number.
- Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

Laminar Air Flow Booths (LAF) and AFOS/Perfusion Tables

Laminar Air Flow Booths and AFOS/Perfusion Tables are serviced and tested ANNUALLY.
There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager
Service of Laminar Air Flow Booths and AFOS/Perfusion Tables must be performed as per Manufacturer's Instructions, and OPS/Maint/SOP.007 SN 1281, and LEV regulations HSG258 to include the item listed below.

A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Measurement of air downflow	LAF – 0.36m/s = 0.54m/s AFOS/Perfusion = ≥0.28m/s, >0.5m/s not detrimental to protection but may effect specimen	Value	Pass criteria defined by manufacturers
Check function of fans	Functions correctly	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of interior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Check condition of work surface	No surface defects, cracks or other damage visible	Pass/fail	
Perform visual smoke test	Air flow around aperture or table surface is inwards.	Pass/fail	A test method is defined in HSG258

The Service label on LAF Booths and AFOS/Perfusion tables should be updated with the following information:

- Validation Date.
- Certificate Number.

- Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

Local Exhaust Ventilation systems (LEV)

LEV systems are serviced and tested 6 MONTHLY.
There will be no reduction in the service visits above, however if users feel additional service visits are justified, it must be submitted via the Change Request Process SN1509 to the Maintenance Manager
Service of LEV systems must be performed as per Manufacturer's Instructions and LEV regulations HSG258 to include the item listed below.

A service report for each unit, evidencing the completion of these tests/checks, signed by the service engineer and detailing the date completed and the next test date, must be presented to the responsible person, or their deputy upon the completion of the service visit.

Procedure	Pass Criteria	Expressed in Report	Additional Information
Measurement of air inflow	Manufacturers and/or commissioning documentation must be consulted to determine desired air flow speeds.	Value	Pass criteria defined by manufacturers
Check function of fans	Functions correctly	Pass/fail	
Check condition of exterior surfaces	No surface defects, cracks or other damage visible	Pass/fail	
Perform visual smoke test	Air flow around aperture or table surface is inwards.	Pass/fail	A test method is defined in HSG258

The Service label on LEV Systems should be updated with the following information:

- Validation Date.
- Certificate Number.
- Equipment ID
- Next Validation Date Due.
- Airflow Pass or Fail

Service certification must be provided for each cabinet giving final airflow readings and details of any repairs.

Instrument Calibration Certificates

Authorised calibration certificates for instruments used in the service of any type of equipment are to be received by NIBSC within one week of the calibration being performed. Certificate is required to show:

- Date of calibration and service.
- The make, model, and serial number of instruments used in calibration.

Contractor Requirements

All servicing is to comply with the manufacturer's recommendations and any relevant standards and certifications.

Administration Process

The procedure used to administer the service and documentation is detailed in a workbench document SN6721

END.