Installation Qualification and Operation Qualification

Prepared by
The Baker Company, Inc.

For

Biosafety Cabinet

Serial Number

Configured and manufactured for:

PROTOCOL APPROVAL SIGNATURES				
These signatures indicate that the protocol, prior to execution, has been reviewed and found to be acceptable for this Biosafety Cabinet qualification.				
TITLE	**DEPARTMENT**	**SIGNATORY NAME**	**SIGNATURE**	**DATE**
>				
>				
>				

EXECUTED PROTOCOL APPROVAL SIGNATURES				
These signatures indicate that the protocol execution has been reviewed and found to be acceptable.				
TITLE	**DEPARTMENT**	**SIGNATORY NAME**	**SIGNATURE**	**DATE**
>				
>				
>				

TABLE OF CONTENTS

TEST SUMMARIES

The Test Summaries table lists all the Installation Qualification and Operation Qualification tests, execution dates and tests results. This table is completed with data from the executed protocol sections. All acceptable results show the Biosafety Cabinet has successfully completed the Installation Qualification and Operation Qualification and complies.

Tests Summaries	Completion Date	Results Acceptable		
		Yes	No	Info Only
Installation Qualification				
Utilities				
Electrical Service Requirements				
Location of Cabinet in the Room				
Environmental Conditions				
Component Specifications				
SterilGARD SG604 Biosafety Cabinet				
Plumbing Orientation, Cable Ports, and Petcocks				
Channel Base Stand				
Documentation Requirements				
Equipment Standard Operating Procedures				
Manuals				
Operation Qualification				
General Operations and Alarms				
Field Airflow Balance Tests				
Field Airflow Smoke Pattern Tests				
Field HEPA Filter Leak Tests				
Field Site Installation Assessment Tests				
Field Light, Vibration, and Noise Tests				

Summary Populated By:	Date:

DOCUMENT INTRODUCTION

This document is the qualification protocol package for the SG604 Biosafety Cabinet specified above. All results must be acceptable for the Biosafety Cabinet to pass the Installation Qualification (IQ) and Operation Qualification (OQ).

The qualification of the Biosafety Cabinet consists of an Installation Qualification and an Operational Qualification. The following descriptions detail the testing/checks to be performed for each section if they are to be included in the qualification of the unit.

Installation Qualification

1) The Biosafety Cabinet specified in the purchase order, design specifications or other purchasing documentation, with applicable features, matches the Biosafety Cabinet delivered and installed.

2) Any utility required by the Biosafety Cabinet has been supplied with correct parameters (pressure, flow rate, amperage, etc.) as specified by manufacturer specifications, design specifications or nameplate data.

3) Any Biosafety Cabinet instrumentation used, either automatically or manually, to maintain proper operation and control or to make permanent record of operation will be in current calibration (Calibrated Instrumentation). All other Biosafety Cabinet instrumentation will be recorded as reference instrumentation (Non-Calibrated Instrumentation).

4) Standard operating procedures for the operation, maintenance, cleaning and calibration of the Biosafety Cabinet exist and are in a draft form at a minimum.

Operation Qualification

1) Operation Qualification functional testing of all major features to verify that:

   a) The Biosafety Cabinet operation meets all predetermined process specifications.
   b) All applicable operation features have been tested and meet manufacturer and NSF/ANSI International Standard 49 -2018 Revision requirements. (It is NSF policy to test cabinets to the standard revision under which they were certified.)

METHODS:

The Biosafety Cabinet Installation Qualification and Operation Qualification testing shall be conducted in accordance with the respective sections of this protocol. Wherever possible, "Specified" information or expected results are compared to "As-Found" information or results. A Yes/No prompt follows all comparisons and is intended to be answered Yes, if testing is found acceptable. A summary table is located at the beginning of the protocol to summarize the test results from each section.

DESCRIPTION:

The SterilGARD SG604 is a Class II Type A2 (as defined by NSF/ANSI Standard International 49 – 2018) biosafety cabinet of original design. A Type A2 cabinet has a minimum of 100 FPM intake air velocity and biologically contaminated ducts and plenums that are under negative pressure or surrounded by negative pressure.

The unit is designed to protect not only the environment and the people using the cabinet, but also the product within from airborne contaminants. With proper work practices it also provides a workspace that can help prevent the spread of contamination by contact.

This cabinet may be used with agents assigned to biosafety levels 1, 2 and 3, or BSL 4 when a positive pressure suit is used in a high containment laboratory. Minute amounts of toxic volatile chemicals or radionuclides may be used in a Class II Type A2 cabinet that is properly vented outside via a properly functioning canopy exhaust connection to a building exhaust system.

DOCUMENTATION REQUIREMENTS AND RESPONSIBILITIES

Prior to the initiation of qualification procedures, this protocol will be reviewed and approved by the appropriate personnel. The validation testing specified in the approved protocol will be conducted in strict accordance with the instructions detailed in the approved protocol. Specific documentation requirements are as follows:

1) The "Conducted By" line at the bottom of each data entry page of the protocol will be signed and dated by the individual(s) performing the tests. It will be signed and dated on the day testing is conducted.
2) Any blank entry space or box must have a line drawn through it, initialized and dated.
3) All crossed out data will have one line drawn through it, initialized and dated.
4) The "Performed By" line at the bottom of the Test Summary page is signed and dated by all individuals who performed testing.
5) The completed protocol is reviewed and approved by the appropriate personnel and their signatures appear on the "Executed Document Reviewed By" line (not to be signed by individuals performing the testing).

If it is not possible to complete the testing as specified in the protocol a **Deficiency and Corrective Action Report (DCA)** must be completed. The following information must be included in the DCA.

1) A description of the deficiency that is signed and dated by the initiator of the DCA.
2) The deficiency is assessed for its impact on the overall equipment qualification.
3) A corrective action plan and/or disposition of the deficiency is noted on the DCA.
4) The DCA is signed and dated by the appropriate personnel. The DCA must be attached to the protocol.
5) Any re-testing, because of a deficiency, is documented in an exhibit.

EQUIPMENT/MATERIALS:

The following list of equipment is needed to perform the testing as detailed in this protocol. As applicable, test equipment will be in current calibration and calibration will be traceable to the National Institute of Standards and Technology (NIST). Place a copy of the certificate of calibration for each instrument used after the "Exhibit: Calibration Certificates" page. All instruments are to meet NSF/ANSI International Standard 49 – 2018 requirements.

Test Equipment and Materials Required

-INSTALLATION QUALIFICATION-

The Installation Qualification is the process used to ensure the specified Biosafety Cabinet was delivered as ordered and has been properly installed.

The Installation Review may include some or all the following:

o Utility Check
o Component Verification
o Additional Checks as Required

UTILITIES

Utility pages are used to verify that the supplied utilities meet the Biosafety Cabinet requirements. The utility check is not intended to serve as a check of the performance of the utility, only to verify that the utility meets the Biosafety Cabinet requirements. To use the utility pages, record the Specified parameters for each utility as they are given on the nameplate of the Biosafety Cabinet, the design specifications, or the operator's manual before protocol execution. During protocol execution, record the actual utility parameters present and verify that the As-Found parameters meet the Specified parameters. When specifications are not available, record As Found parameters for reference.

Record the identification number and calibration due date of all test instruments and gauges used to make measurements. Record any pertinent observations in the comment section of each page.

Electrical Service Requirements

Function: To provide proper electrical power to the cabinet

Source: Customer facility electrical mains

Origin of Specifications: Manufacturer and UL

Parameter	Specified	As Found	Meets Specified (Y/N)
Phase	Single		
Voltage	115V		
Hertz	60		
Amps	16.0 Total Load		
Socket/Plug Type	NEMA 5-20 Plug		

Test Instruments and Gauges:

Description:	ID#	Calibration Due Date	In Cal.(Y/N)

Comments and Observation:

Conducted By: Date:

Location of Cabinet in the Room

Function: To allow for proper cabinet function and performance

Origin of specifications: Manufacturer and industry guidelines

Parameter	Specified	Meets Specified (Y/N)
In quiet corner	Out of traffic	
Away from doors or windows	No cross drafts	
No influence of air supplies	No cross drafts	

Test Instruments and Gauges:

Description:	ID#	Calibration Due Date	In Cal.(Y/N)

Comments and Observation:

Conducted By: Date:

COMPONENT SPECIFICATIONS

The component pages are used to verify that the Biosafety Cabinet specified in purchase order is what was delivered and installed. Specified parameters for each component have been populated during the creation of this protocol. During protocol execution, record the actual component parameters found and verify that the As-Found parameters meet the Specified parameters.

Biosafety Cabinet

Manufacturer: The Baker Company, Inc.

Origin of Specifications: Customer / Manufacturer

Parameter	Specified	As Found	Meets Specified (Y/N)
Correct Model Delivered			
Sash Height			
Pressure Gauge			
Duplex outlets (1 left side wall/1 right side wall)			
IV Bar			

Comments and Observation:

Conducted By: Date:

Plumbing Orientation, Cable Ports, and Petcocks

Manufacturer: The Baker Company. Inc.

Parameter	Specified	As Found	Meets Specified (Y/N)
Plumbing (Left Position 1)			
Plumbing (left Position 2)			
Plumbing (Right position 1)			
Plumbing (Right position 2)			
Cable Port Location (1)			
Plumbing Piping Location			

Comments and Observation:

Conducted By: Date:

Channel Base Stand

Manufacturer: The Baker Company, Inc.

Parameter	Specified	As Found	Meets Specified (Y/N)
Stand Configuration			

Comments and Observation:

Conducted By: Date:

INSTRUMENTATION

The instrumentation pages, calibrated and non-calibrated, are used to document all Biosafety Cabinet associated instruments and to assure calibrated instruments are in current calibration. During protocol execution, record the As-Found characteristics identified for all calibrated instruments on the Calibrated Instruments pages and all As-Found characteristics for the non-calibrated instruments on the Non-Calibrated pages. After all instrumentation has been recorded, verify that all calibrated instruments are in current calibration.

Record any pertinent observations in the comments section of each page.

Calibrated Instruments

Record all information for all calibrated instruments associated with the equipment. Obtain a copy of each instrument calibration certificate and include it in the calibration certificate exhibit.

Instrument Description	ID#	Cal Due Date

Results

All instrumentation in current calibration: (Yes/No) _____

Non-Calibrated Instruments

Record all information for all non-calibrated instruments associated with the equipment. These instruments are set up using calibrated instruments.

Instrument Description	ID#	Location

Recorded By:	Date:

IQ DOCUMENTATION CHECKS

The following section includes the IQ Documentation verification records. This check ensures that all procedures and supporting documentation required for the user to maintain and operate the Biosafety Cabinet is present and at least in draft form.

Standard Operating Procedures (SOPs)

Record all SOPs instructing the use and maintenance of the Biosafety Cabinet. Prior to IQ/OQ final approval, there must be, in at least draft form, an SOP for certification, operation, use, spill response, cleaning and maintenance.

SOP TITLE	CODE	REVISION

Verify that required SOPs have been located and recorded: (Yes/No) _____

Comments:

Manuals on File

All available manuals for the Biosafety Cabinet will be recorded here and is intended for information only.

Manual Title: Operator's Manual and Factory Test Report
Verify electronic location via QR code located on cabinet

Confirmed By:	Date:

OPERATION QUALIFICATION

Operation Qualification is the process used to ensure that the Biosafety Cabinet operates according to specifications. The operation qualification tests are designed to ensure proper Biosafety Cabinet function when run on the customer's utilities at the customer's location. The Operation Qualification tests must test all aspects of the Biosafety Cabinet that are critical to the process.

General Operation and Alarms

Perform the following tests with the Biosafety Cabinet operating under normal conditions and in accordance with the current revision of the Standard Operating Procedure.

Purpose

The purpose of this test section is to demonstrate that the Biosafety Cabinet operates according to the manufacturer specifications and process requirements.

Test Methods and Results

Test methods used to verify options will be documented in the space provided below each option.

Option	Acceptance Criteria	Meets Criteria (Yes/No)
Drain Valve Installed and Closed	The drain valve must be installed on the unit and closed before the cabinet is used.	
Test Method: Install the drain valve on the unit before the cabinet is placed on the stand. Make certain the drain valve is closed before operating the cabinet.		
Cleaning and Disinfecting	The cabinet must be thoroughly cleaned and disinfected before use.	
Test Method: Thoroughly clean the interior of the cabinet with an appropriate detergent. Thoroughly decontaminate the interior surfaces of the cabinet with a disinfectant that is known to kill the microorganisms that might be present or worked with. Make sure to allow the kill time recommended by the disinfectant manufacturer. After kill time, clean up the disinfectant with sterile water and/or with alcohol to protect the stainless steel.		
Start-up Checks	All switches must cause the appropriate response and none other. Indicators, interlocks and alarms must function.	
Test Method: Turn all switches on and off to check the response caused by each switch. With the cabinet running, check that all indicators (e.g. pressure monitor), interlocks (e.g. sash closed) and alarms (e.g. sash height alarm) behave as described in the operator's manual.		
Plumbing assembly and testing.	Plumbing connection and testing must meet local codes.	
Test Method: Connect the plumbing according to local codes. Leak test the installed plumbing to local codes.		

FIELD AIRFLOW BALANCE TEST PROTOCOL FOR THE STERILGARD SG604

I. SUPPORTING DOCUMENTATION

A. NSF/ANSI International Standard 49 - 2018 Annex F

II. DESCRIPTION

A. This test is to verify that the intake and down flow airflows, as well as the balance of the cabinet, are within specifications.

III. SCOPE

A. Baker will run these tests on all cabinets prior to shipment from the factory.
B. The cabinet certifier shall perform these tests on-site.

IV. MATERIALS AND METHODS

A. **Materials:** Instruments must meet NSF specifications.
1. Microprocessor-controlled micromanometer with flow hood
2. Thermal anemometer with ring stand

B. **Methods**:
3. Check that instruments meet calibration requirements:
a) Check for current calibration tag.
b) Do not use if out of calibration.
c) Fill out instrument calibration information on the "Equipment / Materials" form.
d) Perform any setup on the instrument that is recommended by the manufacturer.
e) Place OUT OF SERVICE tag on any instrument that does not set up properly.
4. Choose which method to use:
a) INTAKE VELOCITY-PRIMARY METHOD—Direct intake measuring device (DIM) i.e. Microprocessor controlled micromanometer with flow hood
(1) Reference Direct Inflow Measurement Method in NSF/ANSI International Standard 49-2018- Annex F.3.3.2
(2) Reference cabinet data plate located on front of cabinet for airflow setpoint values
b) INTAKE VELOCITY-SECONDARY METHOD—Restricted 3-inch sash opening measuring intake readings per instructions on the cabinet data plate using a thermal anemometer with ring stand
(1) Reference Alternate Inflow Measurement Method using constricted access opening in NSF/ANSI International Standard 49-2018- Annex F.3.3.3.2
(2) Reference cabinet data plate located on front of cabinet for airflow setpoint values
c) DOWNFLOW VELOCITY- Follow data plate label instructions and record the results obtained in the "Airflow Balance Test Data - Downflow Velocity" exhibit form at the back of this document.

V. ACCEPTANCE:

A. All final test results will meet the cabinet data plate airflow setpoint values.

--END OF DOCUMENT--

FIELD AIRFLOW SMOKE PATTERN TEST PROTOCOL FOR THE STERILGARD SG604

I. SUPPORTING DOCUMENTATION

A. NSF/ANSI International Standard 49 - 2018 and Annex F

II. DESCRIPTION

A. These tests are to visually verify that cabinet airflows are behaving properly.

III. SCOPE

A. Baker will run these tests on all cabinets prior to shipment from the factory.
B. The cabinet certifier shall perform these tests on-site.

IV. MATERIALS AND METHODS

A. Materials:

1. Smoke tubes

B. **Methods**:

1. Perform the following tests according to NSF/ANSI International Standard 49-2018 Annex F.4:
   a) F.4.3.1 Downflow Test
   b) F.4.3.2 View Screen Retention Test
   c) F.4.3.3 Work Access Opening Retention Test
   d) F.4.3.4 Sash and Window Seal Test
   e) Record the results obtained in the "Airflow Pattern Tests Data" exhibit form at the back of this document

V. ACCEPTANCE

A. All final test results will meet the NSF acceptance statements in F.4.4.

--END OF DOCUMENT--

FIELD HEPA FILTER LEAK TEST PROTOCOL FOR THE STERILGARD SG604

I. SUPPORTING DOCUMENTATION

A. NSF/ANSI International Standard 49 – 2018 Annex F

II. DESCRIPTION

A. This test is to verify that there are no unacceptable leaks in the HEPA filter medium, adhesive area, gasket or filter frame.

III. SCOPE

A. Baker will run these tests on all cabinets prior to shipment from the factory.
B. The cabinet certifier shall perform these tests on-site.

IV. MATERIALS AND METHODS

A. **Materials**: All instruments must meet NSF specifications.
1. Aerosol generator
2. Aerosol photometer
3. Compressed air adequate to operate the generator
4. Pressure gauge DOP or alternate oil such as PAO

B. **Methods:**
5. Check that instruments meet calibration requirements:
a) Check for current calibration tag.
b) Do not use if out of calibration.
c) Fill out instrument calibration information on the "Equipment / Materials" form.
d) Perform any setup on the instrument that is recommended by the manufacturer.
e) Place OUT OF SERVICE tag on any instrument that does not set up properly.

6. Perform the following tests according to NSF/ANSI International Standard 49-2018 Annex F.5:
a) Test the supply and the exhaust HEPAs according to F.5.3
b) Record the results obtained in the "HEPA Filter Leak Test Data" exhibit form at the back of this document.

V. ACCEPTANCE

A. All final test results will meet the NSF acceptance statements per F.5.4.

--END OF DOCUMENT--

FIELD SITE INSTALLATION ASSESSMENT TEST PROTOCOL FOR THE STERILGARD SG604

I. SUPPORTING DOCUMENTATION

A. Baker Company test procedures
B. NSF/ANSI International Standard 49 – 2018 Annex F.7

II. DESCRIPTION

A. These tests are performed to verify that the biosafety cabinet is integrated properly into the facility.

III. SCOPE

A. Baker will run these tests on all cabinets prior to shipment from the factory to verify alarm functionality.
B. The cabinet certifier shall perform these tests on-site.

IV. MATERIALS AND METHODS

A. Materials:

1. Thermal anemometer with ring stand
2. Smoke Tubes

B. **Methods**: Instruments must meet NSF specifications.

1. Check that instruments meet calibration requirements:
   a) Check for current calibration tag.
   b) Do not use if out of calibration.
   c) Fill out instrument calibration information on the "Equipment / Materials" form.
   d) Perform any setup on the instrument that is recommended by the manufacturer.
   e) Place OUT OF SERVICE tag on any instrument that does not set up properly.

2. Perform the following tests according to NSF/ANSI International Standard 49-2018 Annex F.7:
   a) F.7.3.1.1 Sash Alarm

3. Record the results obtained in the "Site Installation Assessment Test Data" exhibit form at the back of this document.

ACCEPTANCE:
All final test results will meet the NSF acceptance statements per F.7

--END OF DOCUMENT—

FIELD LIGHT, VIBRATION, & NOISE TEST PROTOCOL FOR THE STERILGARD SG604

I. SUPPORTING DOCUMENTATION

A. NSF/ANSI International Standard 49 – 2018 Annex F

II. DESCRIPTION

A. This protocol is for noise, lighting and vibration testing of the SterilGARD SG604 to ensure proper functioning and a comfortable work station.

III. SCOPE

A. The customer may or may not choose to perform these tests on-site; it is not a requirement to perform these tests in the field as noted in NSF/ANSI International Standard 49 – 2018 Annex F.1.2.

IV. MATERIALS AND METHODS

A. **Materials:** Instruments must meet NSF specifications.

1. Sound meter and noise generator if required.
2. Light meter
3. Vibration meter

B. **Methods**: (From NSF/ANSI International Standard 49 – 2018)

1. Check that instruments meet calibration requirements:
   a) Check for current calibration tag.
   b) Do not use if out of calibration.
   c) Fill out instrument calibration information on the "Equipment / Materials" form.
   d) Perform any setup on the instrument that is recommended by the manufacturer.
   e) Place OUT OF SERVICE tag on any instrument that does not set up properly.

2. Perform the following tests according to NSF/ANSI International Standard 49-2018 Annex F.:
   a) F.9 Lighting Intensity Test:
   b) F.10 Vibration Test:
   c) F.11 Noise Test:
   d) Record the results obtained from all three tests in the "Noise, Light & Vibration Test Data" exhibit form at the back of this document.

V. ACCEPTANCE:

A. All final test results will meet the NSF acceptance statements in F.9.4, F.10.4 and F.11.4.

--END OF DOCUMENT--

Appendix 1 – IQ/OQ Deviation Form

DEFICIENCY NUMBER:
TEST SECTION:
DETAILS OF DEFICIENCY FOUND:
IDENTIFIED BY: DATE:
RESPONSE
The deficiency is: CRITICAL ☐ NON-CRITICAL ☐
If the deficiency is Critical (operational status is affected) describe the impact:
Is corrective action required (Yes/No): _____ (If Yes, describe below)
ACTION PLAN:
BY: DATE:
ACTION PLAN APPROVED BY: DATE:
DATE OF PLANNED IMPLEMENTATION:
PERSON RESPONSIBLE FOR PLANNED IMPLEMENTATION:
IMPLEMENTED PLAN:
CORRECTIVE PLAN IMPLEMENTATION DATE:
COMPLETED CORRECTIVE ACTION MEETS PROTOCOL ACCEPTANCE CRITERIA (YES/NO): _____

Note: This page may be copied independent of the rest of the protocol if multiple deviations are identified

Exhibit: Deficiencies and Corrective Actions

(Attach ALL Deviation Forms Created)

EXHIBIT: CALIBRATION CERTIFICATES

Exhibit: Airflow Balance Test Data

TEST		REQUIRED	FOUND	PASS?
Intake Velocity		100 – 110 FPM		Y / N
		389 to 428 CFM Average at 8" Sash Opening		Y / N
Downflow Velocity	Zone 1	Back & Middle rows: 48 to 58 FPM		Y / N
	Zone 2	Front row: 42 to 52 FPM		Y / N
Downflow Uniformity		Individual readings within ± 25% or 16 FPM, whichever is greater, from the average downflow velocity of each zone.		Y / N

Signature	Date

Exhibit: Airflow Smoke Patterns Test Data

TEST	REQUIRED	FOUND	PASS?
Downflow Test	Smoothly downward		Y / N
	No dead spots or reflux		Y / N
	No escapes from cabinet		Y / N
View Screen Retention Test	Smoothly downward		Y / N
	No dead spots or reflux		Y / N
	No escapes from cabinet		Y / N
Work Opening Edge Retention Test	No smoke out once in		Y / N
	No smoke onto the work surface		Y / N
Sash Seal Test	No upward refluxing		Y / N
	No escapes from cabinet		Y / N

Signature	Date

Exhibit: HEPA Filter Leak Test Data

TEST	REQUIRED	FOUND	PASS?
Measure Upstream Concentration	$\geq$ 10 μg/l		Y / N
Supply HEPA filter	$\leq$ 0.01% of upstream concentration		Y / N
Exhaust HEPA filter	$\leq$ 0.01% of upstream concentration		Y / N

Signature	Date

Exhibit: Site Installation Assessment Test Data

TEST	REQUIRED	FOUND	PASS?
Sash Alarm	Alarm triggers when window is raised 1” above and 1” below 8” indicator arrows.		Y / N

Signature	Date

Exhibit: Light, Vibration, & Noise Test Data

TEST	REQUIRED	FOUND	PASS?
Lighting Test	Total Average ≥ 45 ft. candles	fc	Y / N
	Background to be no greater than 15 ft candles	fc	Y / N
Vibration Test	Net displacement ≤ 0.002 in. RMS	µm disp. RMS	Y / N
Noise Test	≤ 70 dbA Total	dbA	Y / N
	With ≤ 60 dbA Background	dbA	Y / N
	Corrected dbA reading if necessary	dbA	Y / N

Signature	Date