CALAMBA WATER DISTRICT

TITLE: OPERATION OF BIOLOGICAL SAFETY CABINET

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1.0 PURPOSE

1.1 The objective of this documented information is to provide standard instruction for the operation of Biological Safety Cabinet Type II

1.2 CWD shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:
1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
2) the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implantation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities.

2.0 SCOPE

2.1 The scope applies to the safe operation of the Biological Safety Cabinet by the authorized laboratory personnel.

2.2 The CWD shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

3.0 RESPONSIBILITY

3.1 The Headof the Laboratory shall manage the administrative and technical operations of the laboratory.

3.2 The Laboratory Analyst must control and maintain the equipment.

4.0 DEFINITIONS

4.1 biological safety cabinet – is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level.

4.2 biological safety level – i s a **level** of the biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The **levels** of containment range from the lowest **biosafety level** 1 (**BSL**-1) to the highest at **level**4 (**BSL**-4).

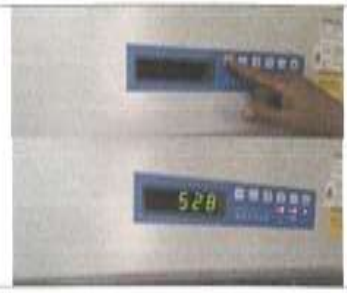
5.0 PROCESS FLOW STEPS

STEP	INPUT	PROCESS FLOW	OUTPUT	RESPONSIBLE
		1. Start Up		
		START		
1	Equipment Monitoring Form	Press and hold the ON key until the blower start (audible blower operation), status indicators (LEDs) illuminate		Laboratory Personnel
2		Move the window to the work position		Laboratory Personnel
3		Wait until the green LED "airflow is steady" illuminates		Laboratory Personnel
		END		
		2. Operating Mode		
		START		
1		Off mode – the unit is in an idle state		Laboratory Personnel
2		Window open mode		Laboratory Personnel
3		Working mode		Laboratory Personnel
4		Standby mode		Laboratory Personnel
5		UV Mode		Laboratory Personnel
		END		

STEP	INPUT	PROCESS FLOW	OUTPUT	RESPONSIBLE
		3. Loading the Chamber		
		START		
1		Move the front window in maximum opening position		Laboratory Personnel
2		Avoid blocking the front intake grille		Laboratory Personnel
3		Move the front window to work position and wait until the airflow is stabilized		Laboratory Personnel
		END		
		4. Shut down		
		START		
1		Remove samples from the sample chamber		Laboratory Personnel
2		Press and hold the ON key for five seconds until all LEDs are off.	Equipment Monitoring Form	Laboratory Personnel
		END		

6.0 PROCESS DETAILS:

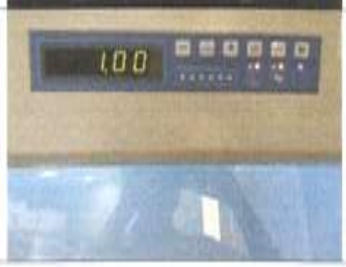
6.1 Start Up

Press and hold the ON key until the blower start (audible blower operation), status indicators (LEDs) illuminate, and an audible tone sound	

Move the window to the work position. The side guide rails have markings that define the lower edge of the front window	
Wait until the green LED "airflow is steady" illuminates	

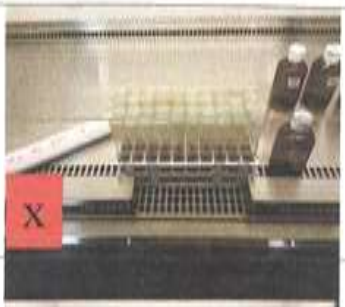
6.2 Operating Modes

Off mode – the unit is in an idle state	
Window open mode – the state in which the window is opened and position outside the working position	

Working mode – active when the front window is in the working position and the air system is operating steadily.	
Standby mode – state in which the window is closed with the blower velocity reduced.	
UV mode – means the UV light is on with a set timer running. The window must be in the closed position to protect against UV radiation. The light will not turn on with the window open	

6.3 Loading the chamber

Move the front window in maximum opening position. Install needed work materials within the sample chamber work area.	

Avoid blocking the front intake grille.	
Move the front window to work position and wait until the airflow is stabilized	

6.4 Shut – down

Remove samples from the sample chamber. Clean and disinfect the sample chamber surfaces including the drain pan.	
Press and hold the ON key for five seconds until all LEDs are off.	

6.5 HEALTH AND SAFETY

6.5.1 Before starting a procedure, take off all jewelry, put on required personal protective equipment (Laboratory gown and gloves).

6.5.2 Do not cause air turbulence by quick hand, arm or body movements in the sample chamber or in front of the work opening.

6.5.3 A height adjustable working chair with an adjustable seat back should be used during extended work periods at the cabinet.

6.5.4 Do not place accessories into the sample chamber that cause air turbulence or emit excessive heat.

7.0 RECORDS RETENTION

7.1 Active Retention – indefinite retention period for current or active documents for both electronic and hardcopy/Controlled Copy.

7.2 Inactive/Archival Retention – shall be kept for active three (3) years or may request for an extension as deemed necessary (hardcopy); for electronic/soft file, it shall be kept in a separate folder named "Obsolete Copy".

8.0 REFERENCE DOCUMENTS

8.1 ISO 9001:2015 QMS Standard
8.2 QMS Manual
8.3 Statutory and Regulatory Requirements
8.4 Biological Safety Manual Class II Operation Manual

9.0 ATTACHMENTS

9.1 Equipment Monitoring Form

10.0 DISTRIBUTION LIST

Note 1: Select Relevant Recipient to Appear in below List.

COPY HOLDER NO.	DEPT/SEC./COPY HOLDER
1b	General manager
8	Laboratory (Quality Control Division)

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