CALAMBA WATER DISTRICT

TITLE: OPERATION OF REXMED AUTOMATIC AUTOCLAVE

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1.0 PURPOSE

1.1 The objective of this documented information is to provide standard instruction for the operation of Rexmed Automatic Autoclave LS – 2D.

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.

1.3 To use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

1.4 To identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

1.5 To control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

2.0 SCOPE

2.1 The scope applies to the safe operation of the autoclave by the authorized laboratory personnel.

3.0 RESPONSIBILITY

3.1 The Head of Laboratory shall manage the administrative and technical operations of the laboratory.
3.2 The Laboratory Analyst must control and maintain the equipment.

4.0 DEFINITION OF TERMS

4.1 Sterilization – the removal of all microorganism and pathogens from an object or surface by treating it with chemicals by subjecting it to high heat or radiation.

5.0 PROCESS FLOW STEPS

STEP	INPUT	PROCESS FLOW	OUTPUT	RESPONSIBLE
		START		
1	Sterilization of glassware or media	Open the lid and remove the bottom plate		Laboratory Personnel
2		Return the bottom plate		Laboratory Personnel
3		Place the item to be sterilized inside the chamber accuracy.		Laboratory Personnel
4		Put the selector switch to "Ster" position		Laboratory Personnel
5		Set timer for sterilization		Laboratory Personnel
6		Put master switch "On", green pilot lamp glows		Laboratory Personnel
7		The red pilot indicates timer countdown		Laboratory Personnel
8		The buzzer will sound after the sterilization cycle		Laboratory Personnel
9		Turn Master Switch to "off"		Laboratory Personnel
10		Open the exhaust knob valve for steam exhaustion until 0 pressure	Equipment Monitoring Form	Laboratory Personnel
		END		

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6.0 PROCESS DETAILS

6.1Preparation

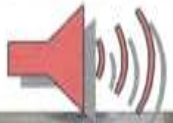
Open the lid and remove the bottom plate. Fill the pressure vessel with distilled water about 1.5 liters, the level must cover the top of heating element.	
Return the bottom plate.	
Place the item to be sterilized inside the chamber. Close the lid securely and tightly.	

6.2 Program Setting

Put the selector switch to "Ster" position	

Set timer for sterilization 15 mins – media 30 mins - glassware	
Put master switch "On", green pilot lamp glows	
The red pilot indicates timer countdown	

6.3 After sterilization

The buzzer will sound after the sterilization cycle	
Turn Master Switch to "off"	

Open the exhaust knob valve for steam exhaustion until 0 pressure	

6.4 HEALTH AND SAFETY

6.4.1 Personal Protective Equipment (Apron, Goggles and Heat resistant gloves) must worn when removing the sterilized items

6.4.2 The handle should only be gripped at the experiment end and step back when opening the sterilizer

6.4.3 Autoclavable bags should be partially opened to prevent it from bursting.

6.4.4 Do not sterilize pressure – sealed vessels the bath, as corrosion of the stainless steel may result.

7.0 RECORDS RETENTION

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

8.0 REFERENCE

8.1 ISO 9001:2015 QMS Standard

8.2 Rexmed Automatic Autoclave Operation Manual

8.3 WHO Biosafety Manual 2004

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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