STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Operation, Calibration and Cleaning procedure of Cooling Cabinet	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE:

To lay down the procedure for Operation, Calibration and Cleaning of Cooling Cabinet.

2.0 SCOPE:

This Standard Operating Procedure is applicable at Microbiology section of Quality Control department of .....

3.0 REFERENCES:

3.1 Users Manual (Cooling Cabinet)

4.0 RESPONSIBILITY:

4.1 Microbiologist/Executive-Quality control shall be responsible for the Operation, Calibration and Cleaning of the Cooling Cabinet.

4.2 Quality Control (QC) Head shall be responsible to ensure proper control and compliance of the SOP.

4.3 Quality Assurance (QA) Department shall be responsible to review the SOP and to ensure the implementation of SOP.

4.4 Regulatory Affairs, Quality Head and Plant Head shall be responsible for reviewing and approval of SOP.

5.0 ABBREVIATIONS:

5.1 CC : Change Control

5.2 IPA : Iso Propyl Alcohol

5.3 No. : Number

5.4 PID : Proportional Band, Integral Time, Derivative time

5.7 RTD : Resistance Temperature Detectors

5.8 SOP : Standard Operating Procedure

5.9 % : Percentage

6.0 DEFINITION:

6.1 Standard Operating Procedure (SOP): A written authorized procedure, which gives instructions for performing operations.

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7.0 PROCEDURE:

7.1 Operation of Cooling Cabinets:

7.1.1 As main supply is switched on, the controller display will show following window set the parameters by using Controller.

7.1.2 Operation of Controller

= SET Key (Press to enter or exit set-up)

= MUTE /SCROLL KEY (This is Multi-functional key)

- Press to Scroll through various graphic screen to view various process information.
- Press to Acknowledge any pending alarm(s) and mute (switch off) the Buzzer.

= INCREMENT KEY(Press to increase the parameter value)

=DECREMEMT KEY (Press to decrease the parameter value)

= ENTER KEY (Press to store the Set Parameter and to scroll to the next parameter on the page)

7.1.3 Set-up Mode: Access and Operation

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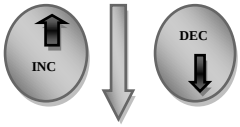
7.1.3.1 The various parameters are arranged in different groups, called PAGES, the parameter name appearing on the upper text line and its value appearing on the lower text line. Follow the steps below for setting the parameter values:

MAIN Display Mode

Press **SET** key to
enter Set-up mode

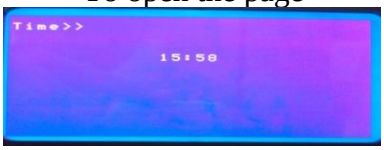
Default Page



Use INC/DEC keys to
set the page Number

Page Number

Press **ENTER** key
To open the page



First Parameter
On PAGE-17

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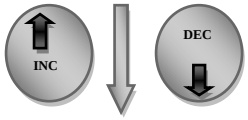
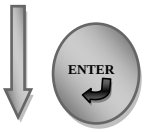


Use INC/DEC keys
to change the value



Press **ENTER** key to store the value& move the next parameter.

Next Parameter on PAGE-17

- Press and release SET Key. The Upper Text Line shows PAGE>> and the Lower Text Line shows page number 0.
- Use **INC/DEC** keys to set the desired **PAGE NUMBER.**
- Press and release ENTER Key. The Upper Text Line shows the name for the first parameter listed in the set PAGE and the lower Text Line Shows its current value.if the entered PAGE NUMBER is Invalid (contains no parameter or any assosiated function),the controller reverts to the main display mode.
- Press and release ENTER Key untill the name for required parameter appears on the upper Text Line.
- Use **INC/DEC** keys to adjust the parameter value.
- Press and release ENTER Key. The new value gets stored in the controller's non-volatile memory and the next parameter in the list is displayed.

PAGE SETTINGS:

PAGE NUMBERS	PARAMETER DESCRIPTION
PAGE-0	To check set point.

PAGE-12	To select temperature measurement units in ˚C or ˚F
PAGE-13	To Edit Set Point Value.
PAGE-17	For settings ie. Time, Date, Month Year etc.

7.1.4 To acknowledge an alarm push the MUTE /SCROLL KEY

7.1.5 Cooling Cabinet shall run through software REMI Datasoft.

7.1.6 Click on the **REMI Datasoft** and enter Login name and Password.

7.1.7 Check all details i.e. Real Time display, Real Time summary, Inputs & Outputs, Alarm Log, Report, Equipment setting and Equipment Data Log Report.

7.1.8 All alarms shall be acknowledged after checking of reason(s) of alarm (Mains fail, etc.) regularly.

7.1.9 Take printout of Data log of Temperature on daily basis.

7.1.10 If the temperature recorded is out of specification inform engineering department to take the corrective action.

7.1.11 Only authorized person shall be allowed to open the chambers as per annexure-2

7.1.12 Details of Cooling Cabinet–

INSTRUMENT ID No.	SET TEMPERATURE	ACCEPTANCE TEMPERATURE
Q199	5^0C	2^0C to 8^0C

NOTE: If any drift in acceptance temperature is observed during cleaning or any other activity (due to prolonged opening), it should be mentioned/remarked with justification on the daily temperature monitoring data of equipment.

7.2 **Loading and Unloading of Samples in Cooling Cabinets**

7.2.1 Unlatch the door of the Cooling Cabinet, locate the place to keep/remove the sample and load/unload the samples and close the door. Make sure that the door is properly latched, otherwise temperature will leak and accuracy will not be maintained.

7.2.2 Lock the door.

7.2.3 During sample placement while loading or unloading, the following should be observed.

- Sample has to stay in the confined area of tray.
- Free space on the side of the trays should not be blocked by the sample.
- Air circulation holes should not be blocked.
- Sensor should not be covered with samples.

7.3 Shutdown of Cooling Cabinets.

7.3.1 In case a Cooling Cabinet to be shutdown, the main switch of the Cooling Cabinets to be switched 'OFF'. Nothing else is necessary. When the temperature will fall below low alarm limit, it will generate an alarm. Acknowledge the alarm.

7.4 Cleaning of Cooling Cabinets.

7.4.1 For cleaning of inside the Cooling Cabinet, shift the stored items placed on the tray on half portion of the tray.

7.4.2 Clean the walls of Cooling Cabinets and surface of the tray with wiping of IPA 70 %.

7.4.3 Shift the items on the cleaned portion of tray and then clean the remaining portion of tray and walls with IPA 70%.

7.4.4 Clean all the trays following the procedure mentioned in 7.4.1 to 7.4.3.

7.4.5 Record the cleaning activities as per the Annexure-1.

7.4.6 Frequency: Once in a Week.

7.5 Calibration/Validation of Cooling Cabinets.

Note: Executive/ Officer- Microbiology shall inform the out side agency selected for calibration/Validation as per the schedule for performing the calibration as per the plan mentioned below.

7.5.1 Take one calibrated certified thermocouple Dataloger.

7.5.2 Place eight calibrated thermocouple sensors in Cooling Cabinet per the location Diagram attached as Annexure-3.

7.5.3 Operate the Cooling Cabinets per the above operating procedure.

7.5.4 Take the readings from each thermocouple at an interval of 10 minutes and record the results up to 24 hours.

7.5.5 Attach the printouts of temperature readings with the report of calibration.

7.5.6 Calibrate the sensor of Cooling Cabinet with a calibrator.

7.5.7 After successfully completion of activity paste the calibration status label as per Annexure-4.

7.6 Frequency of calibration:

7.6.1 Yearly

8.0 DISTRIBUTION:

8.1 Quality Assurance

8.2 Quality Control

9.0 ANNEXURES:

9.1 Annexure 1 : Cleaning Record Of Cooling Cabinet.

9.2 Annexure 2 : List Of Authorized Person.

9.3 Annexure 3 : Diagram For Location Of Thermocouple In Cooling Cabinet

9.4 Annexure 4 : Calibration Status Label.

9.5 Annexure 5 : List of Cooling Cabinet Contents.

10.0 REVISION HISTORY:

Version Number	Revision Details	Effective Date	Ref. Change Control Number
00	New SOP		