QUALIFICATION PROTOCOL OF TOC ANALYSER

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EQUIPMENT NAME	TOC ANALYSER
EQUIPMENT ID. NO.	
LOCATION	

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Qualification protocol no. ……. Indicates agreement with the qualification approach described in this document. This Qualification protocol has been reviewed and approved by the following persons:

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		PROJECTS / ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		

QUALIFICATION PROTOCOL OF TOC ANALYSER

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to qualify the TOC analyzer due to transfer from other location and installation in purified water storage and distribution system.

2.2 PURPOSE:

The purpose of this protocol is to provide the documented evidence that the functions of the equipment, which affect the product quality, and safety, are integrated.

2.3 SCOPE:

The protocol shall define the test procedures, documentation and acceptance criteria to establish that the Installation and operational parameters of TOC analyzer are satisfactory and all the functional parameter lies within acceptance criteria.

The Scope of this protocol is limited to the Qualification of TOC. After successful qualification of the equipment, it can be taken for routine use.

2.4 RESPONSIBILITY:

The following persons shall be responsible;

Quality Assurance – Officer/Executive- Preparation of protocol/execution

Projects / Engineering officer/Executive – Execution of activity

Production officer/Executive – For execution support

Projects / Engineering Head – For execution support and protocol approval

Production Head – For execution support and protocol approval

Quality Assurance Head – For verification of adequacy and final approval

2.5 EXECUTION TEAM:

The satisfactory operation of the TOC Analyzer shall be verified by executing the Qualification studies described in this protocol. The successfully executed protocol documents that the TOC Analyzer is operational and is satisfactorily working.

Execution team is responsible for the execution of qualification of the TOC Analyzer. Execution team comprises of:

DEPARTMENT	DESIGNATION	NAME	SIGNATURE	DATE
ENGINEERING				
PRODUCTION				
QUALITY ASSURANCE				

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3.0 ACCEPTANCE CRITERIA:

3.1 All Standard Operating Procedure shall be verified.

3.2 All the measuring parameters shall be verified.

3.3 All the functional checks shall be carried out.

3.4 All the challenge tests shall be verified.

3.5 The availability of utilities for the equipment shall be verified.

3.6 All the measuring gauges should be verified for its validity of calibration.

4.0 QUALIFICATION CRITERIA:

The machine shall be qualified if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.

5.0 INSTRUCTION FOR FILLING THE CHECKLIST:

5.1 Write down the actual observation in observation column.

5.2 Give the detailed information in the summary and conclusion part of the qualification protocol.

5.3 Whichever column is blank or not used 'NA' shall be used.

6.0 QUALIFICATION PROCEDURE

6.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	TOC Analyzer
Supplier / Manufacturer	:	GE Power and Water
Model	:	…..
Location	:	Purified Water Storage and Distribution System

Inference: ----------

Reviewed by

(Sign/Date)

6.2 QUALIFICATION CHECKLIST:

Qualification checklist is as follows:

Following checks shall be carried out during the qualification of TOC analyzer

1. Checklist
2. Identification and verification of major components
3. Identification of supporting utilities
4. Verification of functional checks
5. Verification of operational sequence
6. Verification of challenge tests for TOC
7. Verification of calibration of the measuring components:
8. Test instrument details
9. Verification of standard operating procedure (sop)
10. Training Record of Personnel (S):

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6.2.1 Checklist:

S.No.	Statement	Method of verification	Observation	Verified by (sign/date)
1.	Verify that major components are securely anchored and shock proof.	Verified by Visually.		
2.	Verify that there is no observable physical damage.	Verified by Visually.		
3.	Verify that there is sufficient room provided for servicing.	Verified by Visually.		
4.	Verify that all piping and electrical connections are done according to the drawings.	Verified by Visually.		
5.	All access ports are examined and cleared of any debris.	Verified by Visually.		
6.	Safe electrical connections.	Verified by Visually.		
7.	Wiring diagram affixed to inside section of control panel.	Verified by Visually.		
8.	Equipment identification nameplate visible.	Verified by Visually.		
9.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Verified by Visually.		
10.	Verify the proper leveling of equipment.	Verified with sprit level indicator.		

Inference: ----------

Reviewed by

(Sign/Date)

6.2.2 IDENTIFICATION & VERIFICATION OF MAJOR COMPONENTS:

System Components	Design Specification		Method Of Verification	Observation	Verified by Sign/Date
Description	Make	GE power and water	Shall be verified with tag		
	Model	Sievers 500 RL	Shall be verified with tag		
	Sr. No.	To be recorded	Shall be verified with tag		
Printer	Make	EPSON	Shall be verified with tag		
	Model	LX-310	Shall be verified with tag		
	Qty.	01	Shall be verified visually		

Inference: ----------

Reviewed by

(Sign/Date)

6.2.3 Identification & Verification of Supporting Utilities:

Utility	Required	Method of Verification	Observation	Checked by (Sign & Date)
Electricity	1 Phase,220±10 %	With Multimeter.		

Inference: ----------

Reviewed by

(Sign/Date)

6.2.4 VERIFICATION OF FUNCTIONAL CHECKS:

Name of system component	Method of Verification	Acceptance criteria	Observation	Verified By Sign/Date
Main instruments	Check the main instrument for any kind of the damage	Instruments should be damage free		
Printer	Connect the printer and press the print button	Paper should printout		
Water connection	Connect the pipeline supply to the TOC	Water supply should connect properly without any leakages		
	Connect the outlet water from the TOC to drain	Outlet should connect properly without any leakages		

Inference: ----------

Reviewed by

(Sign/Date)

6.2.5 VERIFICATION OF OPERATIONAL SEQUENCE:

Component of control panel	Method of verification	Acceptance criteria	Observation	Verified by (sign/date)
Power supply to the equipment	Turn the switch to ON position and observe	Power supply to the TOC analyzer should start.		
	Turn the switch to OFF position and observe	Power supply to the TOC analyzer should Stop.		
Power supply to the printer	Turn the switch to ON position and observe	Power supply to the printer should start.		
	Turn the switch to OFF position and observe	Power supply to the printer should Stop.		

Inference: ----------

Reviewed by

(Sign/Date)

6.2.6 VERIFICATION OF CHALLENGE TEST FOR TOC:

Purpose: To verify the operation and proper working of TOC analyzer

Safety features description	Method of verification	Acceptance criteria	Observation	Verified by (Sign/Date)
High TOC	Operate the Purified Water Storage & Distribution System as per the standard operating procedure and reset the TOC set point below the actual observed value.	The Flow Diverter Valve – FDV-..... should open immediately & dump the water. The TOC High should be indicated on the panel. **"TOC HIGH"** After the TOC value is changed to the original present value. (After 30 seconds of consistent low value below the set point the control value FDV will automatically close.		
TOC HIGH HIGH	Set the TOC Value below the actual observed value on HMI and observe for 5 minutes	After 300 seconds of consistent dumping it will trip the system with alarm and indication on the panel. The HMI should indicate the message **"TOC High High"** and Hooter should ON.		

Inference: ----------

Reviewed by

(Sign/Date)

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7.0 VERIFICATION OF CALIBRATION OF THE MEASURING COMPONENTS:

Name of Components	Identification Number	Calibration Done On	Calibration Due On	Checked By Sign/Date

Inference: ----------

Reviewed by

(Sign/Date)

8.0 TEST INSTRUMENT DETAILS:

Objective: This test is intended to describe the test instruments used for the verification of the Calibration of measuring components of TOC Analyzer.

S.No.	Inst. Name	Inst. ID. No.	Calibration Valid Upto	Checked By Sign/Date

Inference: ----------

Reviewed by

(Sign/Date)

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9.0 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures for operation has been verified.

SOP TITLE	SOP NUMBER	VERIFIED BY	DATE

Inference: ----------

Reviewed by (Sign/Date)

10.0 TRAINING RECORD OF PERSONNEL (S):

Following person has been trained during operation qualification about machine operation and setting parameter.

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Inference: ----------

Reviewed by

(Sign/Date)

11.0 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was identified and corrective actions taken in consultation with the validation team.

Description of deficiency:

Corrective action(s) taken: ----------

Reviewed By:

Date

12.0 ANNEXURE (S):

S.No.	Annexure No.	Title of Annexure

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13.0 QUALIFICATION FINAL REPORT:

13.1 SUMMARY ----------

13.2 CONCLUSION: ----------

Reviewed By

Date

13.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this report are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol (If applicable).

Signature in the block below indicates that all items in this qualification report of TOC analyzer have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. The equipment can be taken for routine production purposes.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PROJECTS / ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		