Installation/Operational Qualification Benchtop Water Activity Meters for Volatile Samples

1.1 Equipment identification

Fill out this section after unpacking the AQUALAB 4 instrument and corresponding accessories.

| Manufacturer METER Group, Inc. USA | | | | | | |
|------------------------------------|-----------------------|-----------------------|--|--|--|--|
| Model | Serial Number | Serial Number | | | | |
| Company Information | | | | | | |
| Company | | | | | | |
| Department | Room | Contact | | | | |
| Calibration SOP | Calibration Frequence | Calibration Frequency | | | | |

2. Installation Qualification (IQ)

Installation of AQUALAB[®] TDL includes placing the instrument on a level surface in a location where the temperature remains fairly stable. This location should be well away from any air conditioners, heaters, vents, open windows, outside doors, or other items that may cause rapid temperature fluctuation. After finding a good location for the TDL, plug the power cord to the back of the unit and standard AC outlet. The ON/OFF switch is located on the lower right corner of the AQUALAB meter's back panel.

The AQUALAB[®] TDL is properly installed at the facility

| Qualified by: Signature | Date | | |
|----------------------------|----------|--|--|
| Name/Title | Initials | | |

3. Operational Qualification (OQ)

The TDL instrument utilizes a tunable diode laser to determine water activity. The performance of the laser is verified by measuring specially prepared calibration standards that have a specific molality and water activity. Performance Verification Standards in four water activity levels are used for qualification: 0.250, 0.500, 0.760, 1.000 aw. The TDL will read each standard with \pm 0.005 aw of the stated value. To measure the water activity of the standards follow the instructions in the User's Manual for taking a reading.

| Standard @ 25 °C | | Lot | | a _w ± 0.005 | | Tunable Diode Laser °C | | 2 | | | |
|--------------------------------------|--|-----------------|----------------|------------------------|--------------|------------------------|------------|-----|---|----------|----|
| 13.41m LiCl | 0.250 | | | | | | | | | | |
| | 0.250 | | | | | | | | | | |
| 8.57m LiCl | 0.500 | | | | | | | | | | |
| | 0.500 | | | | | | | | | | |
| 6.0m NaCl | 0.760 | | | | | | | | | | |
| | 0.760 | | | | | | | | | | |
| Steam Distilled H_20 | 1.000 | | | | | | | | | | |
| | 1.000 | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | _ | | | _ | | |
| | AQUALAB meter measured Verification Standards within specification Qualification met the vendor acceptance criteria | | | | ation | | Yes Yes | | | No No | |
| qualification met i | ine venuo | i acceptance ci | itena | | | | Tes | | | NO | |
| | | | | | | | | | | | |
| Complete the fo | llowing if | f "No" has hee | n checked | otherwise | enter "N/A | ,, | | | | | |
| | - | | | | | | | | | | |
| Explanation of v | vny accep | Stance criteria | was not m | let | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| Action Plan to m | leet acce | ptance criteria | a | | | | | | | | |
| | | <u>.</u> | | | | | | | | | |
| | | | | | | | | | | | |
| Observation | | | | | | | | | | | |
| Check after com Qualification mee | | | e criteria aft | er completi | on of action | plan | | Yes | | | No |
| | | | | | | • | | | | | |
| Notes & remarks f | rom check | king contents. | | | | | | | | | |
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| Signature | Date |
|------------|----------|
| Name/Title | Initials |