

## Vaisala Veriteq Continuous Monitoring System

### Installation and Operational Qualification Protocol

For Vaisala Veriteq viewLinc Software

Version 3.6

Vaisala Canada Inc.

Document #: M211375EN-B

Date Prepared: May 11, 2011

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\_\_\_\_\_

## PROTOCOL PRE-APPROVAL

The Installation / Operational Qualification Protocol for the Vaisala Veriteq Continuous Monitoring System and its viewLinc software Version 3.6 has been reviewed and approved by the following for execution. Signing this protocol indicates that the contents of this document have been reviewed, all test procedures are accurate, and the acceptance criteria are applicable for the intended purpose of this study. The following responsible functional areas have approved this Installation / Operational protocol:

**Approved By:**

_____	_____
Information Technology	Date
_____	_____
Operations	Date
_____	_____
Quality Assurance	Date

DRAFT

*Disclaimers:*

1. *Prior to execution of this protocol, the following conditions must be met:*
  - a. *Loggers and transmitters have been attached to the system either directly via a cable connection or indirectly via a vNet or Digi PortServer device.*
  - b. *All cables being used that require drivers have been properly installed on the viewLinc Server.*
  - c. *All vNet and Digi PortServer devices being used have been setup with static IP addresses and correct network information, and have had their drivers installed on the viewLinc Server.*
  - d. *All computers used in the Continuous Monitoring System must meet the minimum requirements as specified in the viewLinc documentation.*
  - e. *The Vaisala Veriteq vLog software has been installed on the viewLinc Server used in this validation. vLog 4.3 or newer is recommended. Using older versions may result in deviations.*
2. *The procedures in this protocol assume that the default templates have not been changed. If the installation of this software is an upgrade and previous settings are imported, deviations from expected results may occur because of changes made to templates in previous versions.*
3. *Administrative permissions to the computer are required to complete some sections of this protocol.*
4. *Unless otherwise specified, the procedures in this protocol assume that the default 5 minute sample interval in the Vaisala Veriteq loggers has not been changed. Deviations from expected results may occur if different sample intervals are used.*
5. *The logger data cable must not become disconnected during transmission and the logger in test must contain an adequate amount of data.*
6. *Some logger channel types have non-editable descriptions. Procedures requiring the alteration of channel descriptions may not succeed when performed on a logger with these channel types. The Logger and Channel Descriptions of the 300 Series Transmitters are non-editable.*
7. *Loggers used in this protocol must not be linked to vLog audit trails unless specifically required in a test, as deviations relating to logger and channel description modifications may occur.*
8. *Events may not be written to the Event Log immediately. If an expected event does not appear in the log, wait a few minutes then advance the log's end time and refresh the event list.*
9. *When representations of data appear in this protocol, text surrounded by <angled brackets> will be replaced by data specific to your installation.*
10. *The procedures in this protocol may not leave the system in an ideal configuration for your particular application, especially in the case of an upgrade from a previous version. Review and modification of the system configuration, settings, and templates is highly recommended following validation.*

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## 1 Purpose

The purpose of this IQ/OQ protocol is to provide assurance that the Vaisala Veriteq Continuous Monitoring System has been set up properly, is functional, and operates with a high degree of integrity, security, and reliability.

The Installation Qualification (IQ) protocol was written, executed, and approved to ensure that the system, composed of both the hardware and the software, has been installed correctly at the point of use.

The Operation Qualification (OQ) protocol was written, executed, and approved to ensure that each component of the system performs as intended.

This document is provided in Microsoft Word document format for customization, and is located on *Qualification Protocol CD* in the directory \Qualification Protocol\.

## 2 Responsibilities

### 2.1 Vendor Responsibilities

Vaisala Canada Inc. is responsible for the following:

- IQ/OQ Protocol Template Creation
- Initial Logger Calibration
- Protocol Preparation

### 2.2 User Responsibilities

User ( \_\_\_\_\_ ) is responsible for the following:

- Equipment Maintenance
- Ensuring Calibrated Status of Unit(s)
- Protocol Pre-Approval
- Protocol Implementation and Reporting of Results
- Protocol Execution Deviations, Assessment, and Corrective Measures
- Protocol and Report Review
- Protocol and Report Approval

## 3 System Description

The Vaisala Veriteq Continuous Monitoring System is a PC-based, real-time environmental monitoring, alarming, reporting, and data collection system. The system consists of discrete, battery-operated, microprocessor-based data collection devices (data loggers) and a PC software reporting system for monitoring and recording temperature and relative humidity in regulated environments.

The system is comprised of Vaisala Veriteq viewLinc 3.6 software; Microsoft Windows® 2000, XP, Vista, or 7, and Windows Server® 2003 or 2008 based PCs with an approved web browser; Vaisala Veriteq data loggers; and connectivity cabling.

The Vaisala Veriteq viewLinc 3.6 software package is a commercial off-the-shelf program compatible with VL data loggers, offering monitoring, alarming, and reporting functions. Multiple data loggers can be monitored locally on a PC or across a network in a supported Internet Explorer or Firefox Internet browser.

The Vaisala Veriteq Continuous Monitoring System consists of Server and client components. For the purposes of the protocol, a Server is any computer on which the viewLinc software is installed. The Server

component is the core of the Continuous Monitoring System. It controls the central database, web server, system configuration, alarming, and other functions. In the viewLinc software, the clients are standard web browsers, such as Microsoft Internet Explorer or Mozilla Firefox, which connect to the Server in order to see real-time conditions at the points being monitored or to make configuration changes.

The Vaisala Veriteq data loggers are self-contained electronic recording instruments that include on-board sensors (may also include one or more external sensors), non-volatile EEPROM memory, a 10-year lithium battery, and a clock. The system is driven by an on-board microprocessor operating under Vaisala Veriteq firmware – an unalterable factory-supplied program.

The Vaisala Veriteq data loggers work by sampling and storing sensor readings at regular user-programmed sample intervals. In the Vaisala Veriteq VL-2000, both temperature and relative humidity readings are taken simultaneously and stored as a set because the response of the RH sensor is temperature-dependent. When the logger data is downloaded to a PC, the Vaisala Veriteq viewLinc software automatically processes the raw data and creates an encrypted file for display, analysis, reporting, and historical archiving.

The data loggers will connect to the Continuous Monitoring System using one or a combination of the following four methods: Vaisala Veriteq serial port interface cables, Vaisala Veriteq USB interface cables, Vaisala Veriteq vNet Ethernet devices, or one of the approved models of Digi Ethernet devices.

The Vaisala Veriteq Continuous Monitoring System also includes user-based security and unique file identifiers for data integrity. The Vaisala Veriteq Continuous Monitoring System allows the end user to set alarm thresholds and notifies the end user(s) visually and via email to computer, phone, pager, or other mobile messaging devices, when an alarm condition is triggered, acknowledged, or when a logger communication problem exists. The software has built in trending and reporting, and can schedule downloads of logger data (historical data) for later review, graphing, and filing.

This protocol applies to Vaisala Veriteq viewLinc software and the Vaisala Veriteq VL series data loggers.

## 4 Objective

The objective of this protocol is to qualify the installation and operation of the Vaisala Veriteq Continuous Monitoring System at \_\_\_\_\_.

This protocol will verify the installation, correct functionality and operation of the Vaisala Veriteq Continuous Monitoring System according to manufacturer's specifications and the requirements of \_\_\_\_\_.

## 5 Documentation Procedures

- 5.1 Data generated during the execution of this protocol will be collected and recorded on the data sheets provided. All supplemental information documents will be attached in "Attached Exhibits" section of this protocol.
- 5.2 During the execution, the executor's initials and date will be provided at the time of completion for each activity.
- 5.3 Handwritten data is to be neatly printed using a black or blue ball point pen. Corrections are to be crossed out with a single line, initialed, and dated, with an explanation for the correction.
- 5.4 Charts, printout, notes etc. generated during the execution will be dated, signed, and attached to the completed protocol document.
- 5.5 All pages will be reviewed and signed by appropriate \_\_\_\_\_ personnel to verify document completeness.
- 5.6 Unless specifically required, tests and operational steps may be performed in sequences other than indicated.

- 5.7 Throughout this document, the use of N/A and U/A shall be interpreted as “not applicable” and “unavailable”, respectively. A written explanation must be provided whenever U/A is used.
- 5.8 Pages may be photocopied as needed in order to complete additional testing or perform testing required to resolve deviations/discrepancies. Additional pages must be numbered appropriately to identify them as extra pages and to identify the order in which they appear. Identification shall be applied using alphabetical characters next to the page number and a numeric group annotation to the right of the page number as it appears in the header. For example, if three (3) additional copies of page seven (7) of a forty-one (41) page document are required, the page numbering shall be annotated to read as follows: “Page 7A of 41, Additional page 1 of 3”.
- 5.9 OPTIONAL: Throughout the document **(SS)** indicates that a screenshot should be taken and attached to the protocol.
- 5.10 Protocol Definitions

A discrepancy is defined as:

- A difference between the expected results and the actual results

An exception is defined as:

- A difference between the approved protocol procedure and the procedure followed in testing.

A deviation is defined as:

- A discrepancy or exception that prevents meeting the acceptance criteria.

Discrepancies, exceptions, and deviations to approved protocols may occur. It is the responsibility of the qualification group to document each deviation, exception, or discrepancy and to provide an explanation of the circumstances that led to said deviation, exception, or discrepancy. They should be documented in the space provided in each test section.

Deviations, exceptions, and discrepancies must be approved by the Quality Assurance group according to current standard operating procedures, prior to any further execution of the protocol.

## 6 INSTALLATION QUALIFICATION

### 6.1 Test Plan

Testing will be performed to verify that the installation of the Vaisala Veriteq Continuous Monitoring System is in conformance with manufacturer's specifications and customer requirements. The test plan consists of five sections. These are:

#### 6.1.1 Documentation

This section will verify the presence of all documentation necessary to qualify, maintain, and operate the system properly.

#### 6.1.2 Logger / Transmitter Information

This section will verify that all Data Loggers and 300 Series Transmitters are properly cataloged and that all configuration information for each logger and transmitter is recorded.

#### 6.1.3 Connectivity Information for Vaisala Veriteq Data Loggers

This section will record the connection types for the loggers used.

#### 6.1.4 Connectivity Information for 300 Series Transmitters

This section will verify that all required equipment is present and properly documented, and that it meets the hardware requirements of the Vaisala Veriteq Continuous Monitoring System.

#### 6.1.5 Computer Hardware Requirements and Configuration

This section will verify that all required equipment is present and properly documented, and that it meets the hardware requirements of the Vaisala Veriteq Continuous Monitoring System.

#### 6.1.6 Software Installation Verification

This section will verify that the correct version of the Vaisala Veriteq viewLinc software is present and properly installed on the PC(s).

## 6.2 Documentation

Record the following information for the system. Fill in all applicable information.

Document	Criteria	Storage Location (attach copies as necessary)	Meets Criteria Yes / No Initials/Date
Purchase Order / Packing Lists	PO matches items received? Yes / No		
viewLinc installable disks	Back up disks available? Yes / No Location _____		
Calibration Program	Calibration Program has been documented		
Drawings	<i>Showing installation locations.</i>		
Manuals	Document # / Description	Storage Location (attach copies as necessary)	Meets Criteria Yes / No Initials/Date
Vaisala Veriteq viewLinc Software Quick-Start Guide			
Vaisala Veriteq viewLinc User's Guide			
Vaisala Veriteq viewLinc Administrator's Guide			

Comments/Deviations: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Acceptance Criteria:** Sufficient documentation is in place to allow the user to properly install, operate, and maintain the system. All documentation is correct, current, and has been filed.

Acceptance Criteria Met? Pass/Fail: \_\_\_\_\_ Initials/Date: \_\_\_\_\_/\_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_



## 6.4 Connectivity Information for Vaisala Veriteq Data Loggers

Record the following connectivity information for all Vaisala Veriteq Data Loggers on your system. Fill in all information that is applicable. The first row has been filled out with sample data in gray text; please replace this data with your own.

If your system does not include any Vaisala Veriteq Data Loggers, please skip to Section 6.5.

*This form may be duplicated as needed to complete this section.*

Server Computer:					
Connection Type	Network Info (vNet and Digi Only)	Port # / COM Port	Data Logger Serial #	Location	Meets Criteria Yes / No Initials/Date
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> vNet <input checked="" type="checkbox"/> Digi Model: PortServer TS4	MAC: 07f613a99c39 IP: 192.168.140.5 Subnet Mask: 255.255.255.0 Gateway: 192.168.140.1	Port 1 / COM 10 Port 2 / COM 11 Port 3 / COM 12 Port 4 / COM 13	0648921 0617938 0583630 0617823	Incubator 1 Incubator 2 Freezer 1 Refrigerator1	
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> vNet <input type="checkbox"/> Digi Model: _____	MAC: IP: Subnet Mask: Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> vNet <input type="checkbox"/> Digi Model: _____	MAC: IP: Subnet Mask: Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> vNet <input type="checkbox"/> Digi Model: _____	MAC: IP: Subnet Mask: Gateway:	Port 1 / COM ____			

<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			

<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			
<input type="checkbox"/> USB cable  <input type="checkbox"/> Serial cable  <input type="checkbox"/> vNet  <input type="checkbox"/> Digi Model: _____	MAC:  IP:  Subnet Mask:  Gateway:	Port 1 / COM ____			

Comments/Deviations: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Acceptance Criteria:** For each Server computer, the type of connection used, the network information (if a vNet or Digi PortServer device is used), the associated COM port, logger serial number, and logger location must be recorded.

Acceptance Criteria Met? Pass/Fail: \_\_\_\_\_      Initials/Date: \_\_\_\_\_/\_\_\_\_\_

Reviewed by: \_\_\_\_\_      Date: \_\_\_\_\_

## 6.5 Connectivity Information for 300 Series Transmitters

Record the following connectivity information for all 300 Series Transmitters on your system. Fill in all information that is applicable. The first row has been filled out with sample data in gray text; please replace this data with your own.

If your system does not include any Vaisala 300 Series Transmitters, please skip to Section 6.6.

*This form may be duplicated as needed to complete this section.*

Server Computer:						
Connection Type	Info for Network connected Transmitters	Info for COM Port connected Transmitters	Port # / COM Port	Transmitter Serial #	Location	Meets Criteria Yes / No Initials/Date
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input checked="" type="checkbox"/> Digi Model: <u>PortServer TS4</u> <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC: 07f613a99c39  IP: 192.168.140.5  Subnet Mask: 255.255.255.0  Gateway: 192.168.140.1  TCP Port: 23	Baud Rate: 19200  Data Bits: 8  Stop bits: 1  Parity: None	Port 1 / COM 10  Port 2 / COM 11  Port 3 / COM 12  Port 4 / COM 13	G0648921  G0617938  G0583630  G0617823	Incubator 1  Incubator 2  Freezer 1  Refrigerator1	
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: _____ <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port: 	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: _____ <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port:	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			

<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: <hr/> <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port:	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: <hr/> <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port:	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: <hr/> <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port:	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			
<input type="checkbox"/> USB cable <input type="checkbox"/> Serial cable <input type="checkbox"/> Digi Model: <hr/> <input type="checkbox"/> LAN <input type="checkbox"/> WLAN	MAC:  IP:  Subnet Mask:  Gateway:  TCP Port:	Baud Rate:  Data Bits:  Stop bits:  Parity:	Port 1 / COM ____			

Comments/Deviations: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Acceptance Criteria:** For each Server computer, the type of connection used, the network information (LAN, WLAN, or Digi PortServer device) or the COM Port settings, the associated COM port, transmitter serial number, and transmitter location must be recorded.

Acceptance Criteria Met? Pass/Fail: \_\_\_\_\_ Initials/Date: \_\_\_\_\_/\_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

DRAFT

## 6.6 Computer Hardware Requirements and Configuration

Record the following information for each computer to be used as a Server in the Vaisala Veriteq Continuous Monitoring System. Fill in all information that is applicable. If the Server Port is not yet known, this field may be completed later.

*This form may be duplicated as needed to complete this section.*

PC ID / Location	PC Model #	Operating System/ Web Browser	Meets Hardware Requirements	PC Network Info	Meets Criteria Yes / No Initials/Date
				Server Port: _____ MAC address: _____ IP address: _____	
				Server Port: _____ MAC address: _____ IP address: _____	
				Server Port: _____ MAC address: _____ IP address: _____	

Comments/Deviations: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Acceptance Criteria:** Each computer (Server and Clients) must meet the requirements as outlined in the "Getting Started | Requirements" section of the viewLinc Help file. Each Server computer must be able to communicate with the loggers to be hosted either through direct serial or USB connections, or by using a serial-to-Ethernet converter, such as a vNet or Digi PortServer. The Server machines must be running: MS Windows XP, Vista, 7, Server 2003, or Server 2008 and operating 24/7. Each computer on the network that will access the Continuous Monitoring System must be running Internet Explorer version 6.0 and higher or Firefox version 2.0 and higher browsers with pop-ups enabled for the viewLinc software application.

Acceptance Criteria Met? Pass/Fail: \_\_\_\_\_ Initials/Date: \_\_\_\_\_/\_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

## 6.7 Software Installation Verification

Follow the steps below to confirm installation of the Vaisala Veriteq viewLinc 3.6 software.

**Note:** The software must only be installed on a PC that has passed the Computer Hardware Requirements and Configuration qualification (Section 6.6 of the viewLinc IQ/OQ Protocol).

**Note:** If you are upgrading from a version of viewLinc 3.4 or later, you must **STOP** the **viewLinc Watchdog**, **viewLinc POS Display**, and **viewLinc Enterprise Server** services **PRIOR** to inserting the viewLinc 3.6 software CD in the computer's CD drive.

Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.7.1	Enter the PC ID for computer used: _____	The PC ID is recorded.	
6.7.2	Insert the Vaisala Veriteq viewLinc 3.6 software CD into the computer's CD drive.	The software installation manager starts and the <b>Select Setup Language</b> dialog box appears. (SS)	
6.7.3	Select <b>English</b> from the dropdown menu and click the <b>OK</b> button.	The <b>Welcome to the Vaisala Veriteq viewLinc Setup Wizard</b> dialog box appears. (SS)	
6.7.4	Click the <b>Next &gt;</b> button.	The <b>License Agreement</b> appears. (SS)	
6.7.5	Select the <b>I accept the agreement</b> radio button and click the <b>Next &gt;</b> button.	If you are upgrading from viewLinc 3.4 or later, go to the Expected Results for Step 6.7.9.  If you are upgrading from an older version, or if this is a fresh installation, the <b>Select Destination Location</b> screen appears. (SS)	
6.7.6	Accept the default location (or browse to select a different folder) by clicking the <b>Next &gt;</b> button.	The <b>Select Components</b> screen appears. (SS)	
6.7.7	Select <b>Enterprise Server</b> from the dropdown menu and click the <b>Next &gt;</b> button.	If you have a version of viewLinc 3.x prior to 3.4 installed, the <b>Import Settings</b> dialog box appears (go to Step 6.7.8). (SS)  If you do not have a previous version of viewLinc 3.x installed but the default HTTP Server port (80) is in use by another application then the <b>Port Number for viewLinc HTTP Server</b> dialog box appears (go to Step 6.7.9). (SS)  If port 80 is not in use, go to the Expected Results for Step 6.7.9.	
6.7.8	Check the <b>Import Settings</b> box and click the <b>Next</b> button.	Go to the Expected Results for Step 6.7.9.	

Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.7.9	Select an alternate port for the HTTP Server to use and click the <b>Next</b> button.  Port Number used: _____	The <b>Ready to Install</b> dialog box appears. <b>(SS)</b>	
6.7.10	Confirm that the installation information is correct and click the <b>Install</b> button.  (If you are using a software firewall that prompts you to block or unblock the application, select unblock.)	The installation runs and the <b>Completing the Vaisala Veriteq viewLinc Setup Wizard</b> dialog box appears once it is finished. <b>(SS)</b>	
6.7.11	Click the <b>Yes, restart the computer now</b> radio button and click the <b>Finish</b> button.	The <b>Vaisala Veriteq viewLinc Setup Wizard</b> closes and your computer restarts.	

Comments/Deviations: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Acceptance Criteria:** All Acceptance Criteria have been met and the Vaisala Veriteq viewLinc Version 3.6 software is installed successfully.

Acceptance Criteria Met? Pass/Fail: \_\_\_\_\_ Initials/Date: \_\_\_\_\_/\_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

## 6.8 IQ Final Approval

The procedures in this section have been implemented, reviewed, and approved by the individuals listed below. All results have been documented and all deviations have been identified, documented, reviewed, and approved.

**Note:** *The Final "Approvers" should be the same as the original protocol approvers, when available.*

Implemented by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

QA Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

## 7 OPERATIONAL QUALIFICATION

### 7.1 Test Plan

Testing will be performed to verify that the operation of the Vaisala Veriteq Continuous Monitoring System is in conformance with manufacturer's specifications and customer requirements. The Acceptance Criteria for all sections are derived from Vaisala Canada's recommendations. The test plan will consist of thirty-one areas of functionality as defined below.

#### 7.1.1 viewLinc Service

The Continuous Monitoring System runs as a service on a workstation or server. This test will ensure that the installation of the service was successful, and that the viewLinc service is correctly configured for automatic startup operation.

#### 7.1.2 System Clock Security

The system clock is used to correctly define the time stamps of the historical and live data, as such; the system clock shall be tested for security settings.

#### 7.1.3 Email System Setup

The viewLinc alarm functions rely on notification via Simple Mail Transfer Protocol (SMTP). This test will ensure that the alarm email system is correctly configured to allow emails to be relayed through the company SMTP mail server.

#### 7.1.4 Email Template Setup

All alarms and notifications can be emailed to a list of users. The setup of templates, to define the information to be included in these notifications, is tested within this section.

#### 7.1.5 System Events Log Validation

All system and user actions are recorded within the Events section of the Continuous Monitoring System. All sections of the validation will have generated their respective Events that will have been recorded within the Events section. Any alterations to this Event log will be tested for complete validated status.

#### 7.1.6 Logger Discovery

The operation of the Vaisala Veriteq loggers relies on a plug and play function. All communication ports installed on the computer, real or virtual, will be tested for connection to a Vaisala Veriteq logger. This test ensures that all loggers attached to the Continuous Monitoring System can be discovered and displayed in the viewLinc software interface.

#### 7.1.7 Adding 300 Series Transmitters

This test ensures that all Vaisala 300 series transmitters attached to the Continuous Monitoring System can be added, either one at a time or by batch, and displayed in the viewLinc software interface.

#### 7.1.8 Zone Setup

Chambers, Rooms, Departments, etc, can be set up to as Zones, to allow the logical grouping of sensors and simplify the selection of relevant information. This test ensures that loggers associated with locations or groups, etc. can be allocated to Zones and filtered for viewing.

#### 7.1.9 Selectable Units of Display for Temperature

The viewLinc software's default settings for temperature display Celsius or Fahrenheit can be overridden at the channel level. E.g. Chambers can be displayed as Celsius, and ambient room temperature can be displayed as Fahrenheit.

#### 7.1.10 Logger and Channel Descriptions

The Logger and Channel Descriptions of Data Loggers can be edited.

## 7.1.11 Logger and Channel Aliases

Loggers and channels can be assigned both short descriptions and longer aliases. The user can configure the viewLinc software to display one, or both, of these identifiers.

## 7.1.12 Pre-configured Comments

Each operation that requires user input can have a selectable drop down for pre-configured comments. These can be used as part of text input, or as standalone comments.

## 7.1.13 Contact Schedules

Notification schedules can be created, which will define the times that the system can send alarm notifications to users, as specified by the administrator.

## 7.1.14 User Creation

System users can be created and assigned various authentication types, security levels, notification schedules, and channel view permissions, depending on their needs.

## 7.1.15 Changing Passwords

System users can change their viewLinc password or authentication type depending on their security level.

## 7.1.16 Logger Transfers

The Vaisala Veriteq loggers are able to store data locally and send the data to a pre-defined storage location. The periodic download of secure data ensures that all readings used within the viewLinc software's historical reports, can be restored should catastrophic failure of the Continuous Monitoring System's server occur.

## 7.1.17 Logger Transfers Disruption

As per logger Transfer, this test validates that any interruption of the data transfer does NOT corrupt the data download.

## 7.1.18 Alarm Templates

The viewLinc software allows the use of Alarm Templates which contain common alarm settings that can be used in multiple situations. Parameters include color codes, messages, delays, notifications and comments.

## 7.1.19 Threshold Templates

Additional Threshold Templates can be used to specify Alarm limits for similar environmental conditions.

## 7.1.20 High Alarm Testing

This test will verify the Vaisala Veriteq Continuous Monitoring System's High Threshold Alarm functionality. Each alarm state can have a specific time delay before the alarm is considered real. Each alarm can have any number of user email alerts to allow specific users to respond depending on alarm criticality. All active alarms are shown.

## 7.1.21 Low Alarm Testing

This test will verify the Vaisala Veriteq Continuous Monitoring System's Low Threshold Alarm functionality. Each alarm state can have a specific time delay before the alarm is considered real. Each alarm can have any number of user email alerts to allow specific users to respond depending on alarm criticality. All active alarms are shown.

## 7.1.22 Threshold Deactivation and Reactivation

This test will verify that threshold alarms can be deactivated and reactivated.

## **7.1.23 Alarm Template Modification**

This test will verify that selecting a new alarm template for an existing threshold template will update the settings for thresholds on individual channels.

## **7.1.24 Communication Alarm Testing**

This test will verify the Vaisala Veriteq Continuous Monitoring System's Communication Alarm functionality. Each alarm state can have a specific time delay before the alarm is considered real. Each alarm can have any number of user email alerts to allow specific users to respond depending on alarm criticality. All active alarms are shown.

## **7.1.25 Threshold Alarm Pause - Channel**

This test allows a User to pause threshold alarming on a particular Channel, for a specific period. After the period has elapsed, the alarm function will automatically resume.

## **7.1.26 Threshold Alarm Pause – Logger and Zone**

This test allows a User to pause threshold alarming on a particular Logger or Zone for a specific period. After the period has elapsed, the alarm function will automatically resume.

## **7.1.27 Reports – Alarm Reports**

This test will verify historical Alarm logs, analysis and report generation. Each alarm report can be automatically generated and emailed to an email list of users. The alarm log is secured and cannot be modified without corrupting the reports. The reports will indicate that modification has been attempted. These tests include: Report generation for selectable channels – this shall test the current number of alarms, the durations and any associated comments from the logged-on User. The reports shall then be tested for automatic archiving, scheduled email, and template creation.

## **7.1.28 Reports – Channel History Reports**

The object of the Historical Data Report testing is to confirm the correct translation of logger data, to the viewLinc software's historical database. Once the data is validated, the tests prove the correctness on the Statistical and Excursion reports, with a section for data tampering. All, or individual channels can be used within the reports. The reports shall then be tested for automatic archiving, scheduled email, and template creation.

## **7.1.29 Channel History Statistical Validation**

This test will validate the statistical information from the reports.

## **7.1.30 Logger Swapping with Vaisala Veriteq Data Loggers**

This test ensures that when swapping a logger associated with a particular point being monitored (i.e. a chamber or freezer), any alarm settings, data transfer locations and schedules migrate to the new logger. This test ensures that data regarding serial numbers and comments are captured correctly within the Audit Trail, during the logger swap.

## **7.1.31 Logger Swapping with 300 Series Transmitters**

This test ensures that when swapping a transmitter associated with a particular point being monitored, any alarm settings and aliases are migrated to the new transmitter. This test also ensures that data regarding serial numbers is captured during the logger swap.

## **7.1.32 viewLinc System Security**

This test ensures that users created for the validation can access the specific areas designated within the viewLinc Account Permissions.

## **7.1.33 Logger Deactivation and Reactivation**

The loggers that have, at any time, been discovered within the Vaisala Veriteq Continuous Monitoring System, can be deactivated from monitoring and alarming. The data collected by loggers prior to being deactivated shall be held within the historical database and will remain accessible in reports

### 7.1.34 **Logger Configuration Alarms**

This test validates that the Logger is actively collecting historical data within its on-board memory. Each logger transmits both internally recorded and live readings to the system on each update, allowing for multiple sample points per update. Should the Historical logging fail internally, a configuration alarm will be generated for that Logger, and sent to the Administrator for system alert.

### 7.1.35 **System Watchdog**

This test validates the auto-recovery features of the viewLinc software application. The viewLinc watchdog service monitors the viewLinc application and restarts it in the event of a problem. A problem with the viewLinc application will be simulated by stopping the viewLinc service.

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### 7.37 OQ Final Approval

The procedures in this section have been implemented, reviewed, and approved by the individuals listed below. All results have been documented and all deviations have been identified, documented, reviewed, and approved. NOTE: The Final "Approvers" should be the same as the original protocol approvers, when available.

Implemented by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

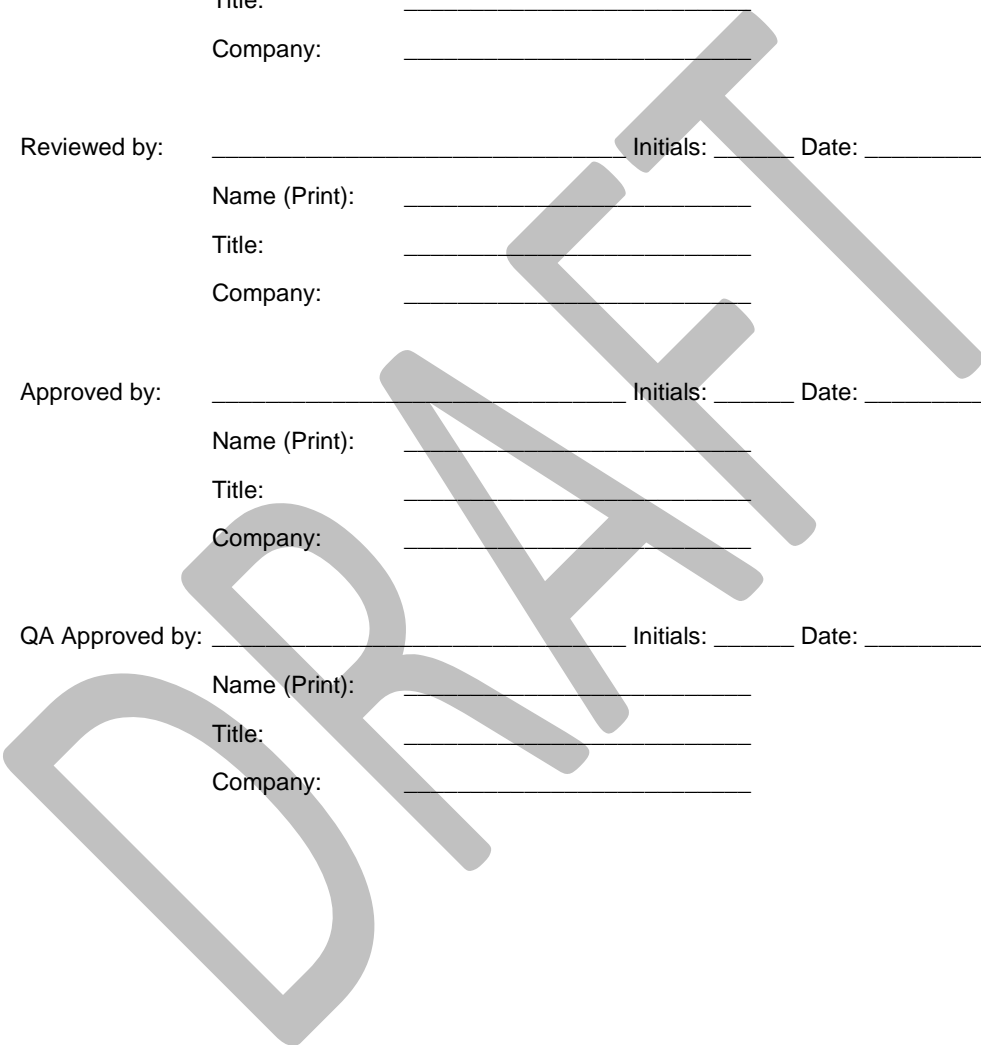
Company: \_\_\_\_\_

QA Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_



## 8 Signature Identification Form

All personnel assigned to execute or review this executed protocol, attached deviations, modifications, and/or supporting documentation must sign and initial in the space provided below. **Signature also indicates the individual has read and understands the protocol prior to task execution.** In the affiliation and title column fill in company name and designated title.

Printed Name	Signature	Title/Affiliation	Initials/Date

Comments/Deviations: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Implemented by: \_\_\_\_\_ Date: \_\_\_\_\_  
Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

## 9 IQ/OQ DOCUMENT FINAL APPROVAL

The Vaisala Veriteq Continuous Monitoring System has passed all tests, and as such, is qualified to be used in the \_\_\_\_\_ environment:

Pass/Fail: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

QA Approved by: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

## 10 DOCUMENT HISTORY

**Note:** This section is for internal tracking purposes and may be omitted depending on your procedure for validation document revisions, SOP #\_\_\_\_\_.

Document #	Description of changes	Date	By

DRAFT