

Vaisala Veriteq vLog

Installation and Operational Qualification Protocol

For Vaisala Veriteq vLog

Version 4.5

Vaisala Canada Inc.

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Date Prepared: July 22, 2011

Prepared by: Katie Lowe

Reviewed by:

Michael Boetzkes

PROTOCOL PRE-APPROVAL

The Installation / Operational Qualification Protocol for the Vaisala Veriteq vLog Software Version 4.5 has been reviewed and approved for execution by the following. 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 Qualification Protocol:

Approved By:

_____	_____
Information Technology (Signature)	Date
_____	_____
Operations (Signature)	Date
_____	_____
Quality Assurance (Signature)	Date

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Disclaimers:

1. Prior to the execution of this protocol, the following conditions must be met:
 - a. Loggers 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 vLog 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 vLog Server.
 - d. All computers used in the vLog system must meet the minimum requirements as specified in the vLog documentation.
2. The logger data cable must not become disconnected during transmission unless specified in the procedure and the logger in test must contain an adequate amount of data.
3. 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 is highly recommended following validation.
4. When representations of data appear in this protocol, text surrounded by <angled brackets> will be replaced by data specific to your installation.

Vaisala Canada Inc.

Unit 100 – 13775 Commerce Parkway
Richmond, BC Canada V6V 2V4
Tel: (604) 273-6850
Fax: (604) 273-2874
Toll Free: 1-800-683-8374
Email: veriteqsupport@vaisala.com
Web Site: <http://www.vaisala.com>

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1 Purpose

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

The Installation Qualification (IQ) protocol template has been designed 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 template has been designed to ensure that each component of the system performs as intended.

Vaisala Veriteq loggers use Coordinated Universal Time (UTC) to create a base time in every logger file. This provides an absolute reference that the Vaisala Veriteq vLog software uses to display the logger information using the computer's local time zone. Sample files using the Eastern Time Zone have been included on the *Vaisala Veriteq vLog Qualification Protocol CD* in the \Samples\ directory. When implementing this protocol, it is essential that the time zone within the software be set to the Eastern Time Zone for particular sections.

The appendices contain printouts of both sample graph files and tabular data listings.

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

_____ 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 vLog Validatable Data Logging System is a battery-operated, microprocessor-based data collection and PC reporting system for monitoring and recording temperature and relative humidity in FDA-regulated environments.

The system consists of one or more VL-1000, VL-1016, VL-1000LT, VL-1000VLT, (hereafter referred to collectively as VL-1000); V-1400, VL-1416 (hereafter referred to collectively as VL-1400), VL-1700 (thermocouples), VL-4000 and/or VL-2000 data loggers; and the Vaisala Veriteq vLog Windows-based software. The data loggers are connected to the vLog System using Vaisala Veriteq serial cables, Vaisala Veriteq USB cables, Vaisala Veriteq vNet devices, and/or approved models of Digi PortServer Ethernet devices. The system also comprises a PC with print capability. Each VL-1000 data logger, except the VLT, can optionally include one or more external temperature probes.

The VL data loggers are self-contained electronic recording instruments that include on-board 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 temperature sensor used in the VL loggers and in the external temperature probes is a NTC thermistor that varies its resistance in relation to temperature. The relative humidity sensor used in the VL-2000 is a capacitive sensor. It works by varying its capacitance in relation to changes in RH. Each VL data logger is factory-calibrated against NIST traceable standards and all calibration information is encrypted and stored digitally in the logger's memory. The onboard sensors are located just inside the lower left corner of the plastic enclosure and are exposed to the ambient environment through ventilation openings in the enclosure.

The external temperature probe for the VL-1000 and VL-1400 data loggers consists of a short length of two-conductor, shielded twisted pair cable, with a plug-in connector at one end, and a thermistor, epoxy-encapsulated in a stainless steel tip or waterproof Teflon tip, at the other end. The probe can be used to provide an additional measurement channel and to allow monitoring in areas not suitable for data loggers.

The VL-1700 series of data loggers, allows thermocouples to be used, particularly in extreme temperature ranges. Completing the series, the VL-4000 series allows external devices, using Voltage or Current analog outputs, to be read and stored.

The VL data loggers work by sampling and storing sensor readings at regular user-programmed sample intervals. In the 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 vLog software package automatically processes the raw data and creates an encrypted file for display, analysis, and reporting.

The Vaisala Veriteq vLog software package is a commercial off-the-shelf program compatible with Vaisala Veriteq VL and SP data loggers, offering data logger setup, graphing, and reporting functions. The Vaisala Veriteq vLog software also includes unique file identifiers and password protection for data integrity.

4 Objective

The objective of this protocol is to qualify the installation and operation of the Vaisala Veriteq vLog software at _____.

This protocol will verify the installation, correct functionality and operation of the Vaisala Veriteq vLog software 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 to the 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 lined 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 discrepancy, exception, or deviation and to provide an explanation of the circumstances that led to said discrepancy, exception, or deviation. They should be documented in the space provided in each test section.

Discrepancies, exceptions, and deviations 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 installation of the Vaisala Veriteq vLog software 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 Information

This section will verify that all data loggers are properly catalogued.

6.1.3 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 vLog system.

6.1.4 Software Installation Verification

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

6.1.5 Test User Security Level Information

This section will add users with varying levels of security clearance to the system for use in testing.

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		
vLog 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 vLog Software Quick-Start Guide			
Vaisala Veriteq vLog User'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: _____

6.5 Software Installation Verification

Follow the steps below to confirm installation of the Vaisala Veriteq vLog 4.5 software. All Vaisala Veriteq USB cables should be unplugged prior to beginning the software installation process.

Note: *The software must only be installed on a PC that has passed the Hardware Requirements and Configuration qualification (Section 6.4 of the vLog IQ/OQ Protocol).*

Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.5.1	Enter the PC ID for the computer used: _____	The PC ID is recorded.	
6.5.2	Insert the Vaisala Veriteq vLog 4.5 software CD into the computer's CD drive.	The software installation manager starts and the Select Setup Language dialog box appears.	
6.5.3	Select English from the dropdown menu and click the OK button.	The Welcome to the Vaisala Veriteq vLog Setup Wizard dialog box appears.	
6.5.4	Click the Next button.	The License Agreement appears.	
6.5.5	Select the I accept the agreement radio button.	You have accepted the terms of the license agreement.	
6.5.6	Click the Next button.	You are asked to enter the vLog Security Key.	
6.5.7	Enter the vLog Security Key (as found on a label on the CD case).	The security key has been entered. The code should be kept confidential.	
6.5.8	Click the Next button.	The Select Destination Location screen appears.	
6.5.9	Accept the default location (or click the Browse button to select a different folder) by clicking the Next button.	The installation location is set. The Select Start Menu Folder screen appears.	
6.5.10	Accept the default folder (or click the Browse button to select a different folder) by clicking the Next button.	The Start menu folder is set. The Select Additional Tasks screen appears.	
6.5.11	If desired, check the Create a desktop icon box. Click the Next button.	The Ready to Install screen appears. (SS)	
6.5.12	Confirm that the installation information is correct. Click the Install button. Be sure to unplug any Vaisala Veriteq USB cables from the computer. A message will pop up advising you to do so before proceeding. Unplug the cables and click the OK button to proceed.	If you have a previous version of vLog installed, a box asking Would you like to uninstall vLog <version number> now? will appear. Proceed to Step 6.5.13. If this is a fresh installation, skip to the Expected Results for Step 6.5.15.	

Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.5.13	Click the Yes button to uninstall the previous version of vLog.	The vLog – InstallShield Wizard asks if you wish to completely remove the application and its features.	
6.5.14	Click the Yes button.	The vLog – InstallShield Wizard confirms that the program has been uninstalled.	
6.5.15	Click the Finish button.	The Completing the Vaisala Veriteq vLog Setup Wizard screen appears.	
6.5.16	Click the Finish button.	vLog is unable to find the security file and asks if you would like to create one.	
6.5.17	Click the Yes button.	The vLog Security Wizard opens.	
6.5.18	Click the Next button.	The vLog Security Wizard page is shown, prompting the user to enter the CD security key.	
6.5.19	Enter the CD security key, and click the Next button. (The security key is found on a label on the CD case.)	Upon successful security key entry, the vLog Security Wizard administrator account setup page is shown.	
6.5.20	Enter a User name and Password for an existing valid Windows account, and the Full name by which the user is identified. Click the Next button. Note: This user will be granted vLog ADMINISTRATOR status.	Upon successful entry of administrator's details, the wizard prompts the user to specify the audit trail folder location.	
6.5.21	Accept the default location (or click the ... button to select a different folder) by clicking the Next button.	The Security Level page is shown.	
6.5.22	Select the High security radio button.	High security is selected.	
6.5.23	Click the Finish button.	The vLog program starts.	
6.5.24	Click Help > About Veriteq vLog from the menu bar.	The Veriteq vLog box appears, displaying the software version that was installed. (SS)	
6.5.25	Click the Veriteq vLog box.	The Veriteq vLog box disappears.	
6.5.26	Click File > Exit .	vLog closes.	

If the CD Autorun feature is disabled on your system, the installation must be manually started by double-clicking on the file D:\SETUP.EXE, where D: is the letter of your CD-ROM drive.

Comments/Deviations: _____

Acceptance Criteria: All Expected Results have been met and the Vaisala Veriteq vLog Version 4.5 software is installed successfully.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____/_____

Reviewed by: _____ Date: _____

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6.6 Test User Security Level Information

Using the Administrator account set up in Step 6.5.20, create the local vLog accounts as listed below. If the vLog Administrator account created during software installation is not the “administrator” account you wish to use during the protocol execution, create a second “Admin” account. These accounts will be used during the Operation Qualification testing. All accounts use Windows authentication.

Note: The User and Guest accounts must be either 2 existing Domain accounts, or new Local accounts created in advance by the Local Administrator.

Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.6.1.1	Log in to vLog using the administrator’s User Name and Password .	The software opens.	
6.6.1.2	Click Tools > Administrator Options .	The Administrator Options window opens.	
6.6.1.3	On the Security tab, click the Add button.	The Add User window opens.	
6.6.1.4	Configure the new user with the following settings: User Name: User1 Log on to: <Local> Full Name: User1 User Role: User	The new user, User1 , is configured as per the instructions.	
6.6.1.5	Click the OK button.	The Add User window closes. User1 appears in the User name column.	
6.6.1.6	Select User1 and click the Test button.	The Test User Account window opens.	
6.6.1.7	Enter the Windows Authentication password and click the OK button.	The message The specified user credentials were successfully authenticated in Windows (SS) appears.	
6.6.1.8	Click the OK button.	The message closes.	
6.6.1.9	Click the Add button.	The Add User window opens.	
6.6.1.10	Configure the new user with the following settings: User Name: Guest1 Log on to: <Local> Full Name: Guest1 User Role: Guest	The new user, Guest1 , is configured as per the instructions.	
6.6.1.11	Click the OK button.	The Add User window closes. Guest1 appears in the User name column.	
6.6.1.12	Select Guest1 and click the Test button.	The Test User Account window opens.	

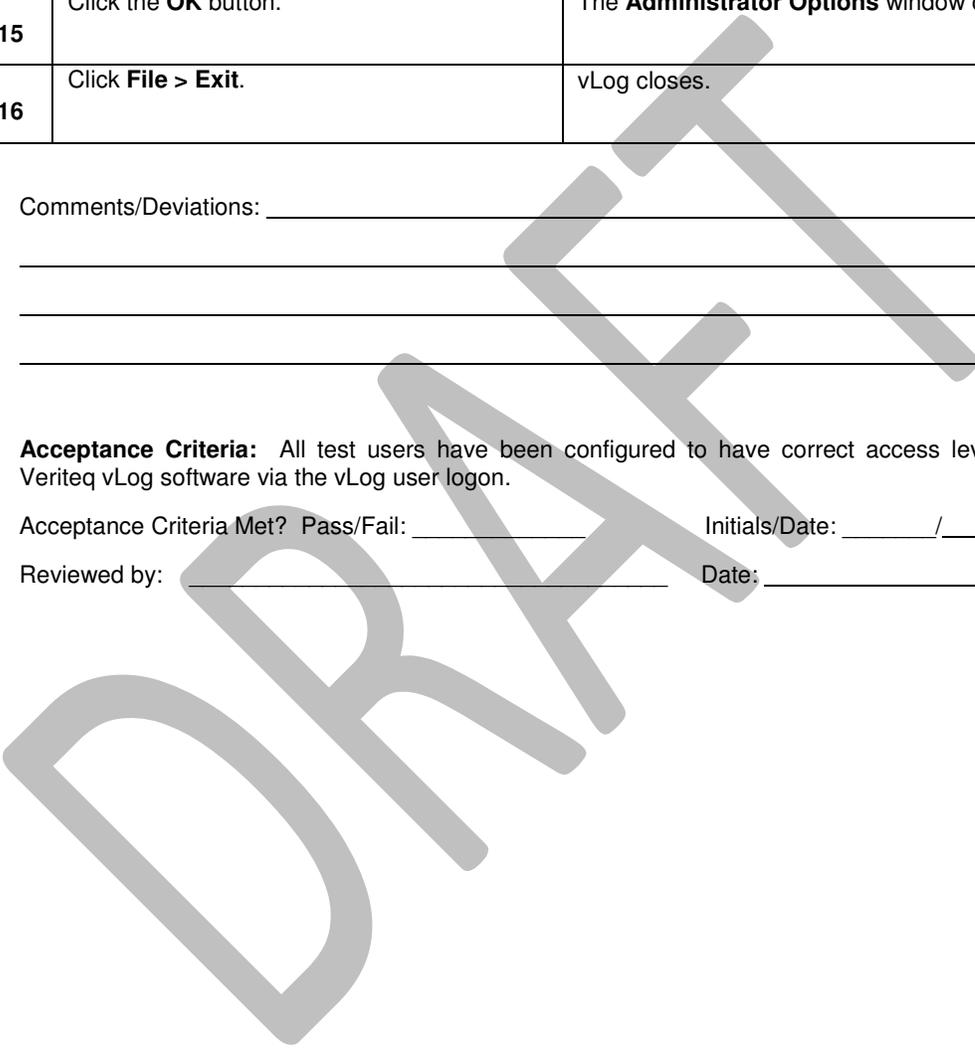
Step	Procedure	Expected Results	Are actual results as expected? Initials/Date
6.6.1.13	Enter the Windows Authentication password and click the OK button.	The message The specified user credentials were successfully authenticated in Windows (SS) appears.	
6.6.1.14	Click the OK button.	The message closes.	
6.6.1.15	Click the OK button.	The Administrator Options window closes.	
6.6.1.16	Click File > Exit .	vLog closes.	

Comments/Deviations: _____

Acceptance Criteria: All test users have been configured to have correct access level to the Vaisala Veriteq vLog software via the vLog user logon.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____/_____

Reviewed by: _____ Date: _____



6.7 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.*

Upon final approval, OQ testing may commence.

Implemented by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Reviewed by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

QA Approved by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

7 Operational Qualification Methodology

7.1 Test Plan

Testing will be performed to verify that the operation of the Vaisala Veriteq vLog 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 four main sections, as defined below.

7.1.1 Functional Testing

Functional testing will verify the following capabilities of the Vaisala Veriteq vLog software:

- Vaisala Veriteq vLog Software Setup
- Logger Communication
- Batch Transfers
- Graph Files
- Graph Titles
- Time Axis Settings
- Scrolling and Zooming
- Logger Files and the Cursor
- Multiple Logger Files
- Axis Units and Range
- Printing of Secure and Non-Secure Logger Files
- Data Integrity and Security

7.1.2 Statistical Testing

Statistical testing will ensure that the data within the files is correctly displayed, and calculated to provide validated results.

- Instantaneous Value Reports
- Channel Minimum, Maximum, and Average Reports
- Channel Statistical Deviation Reports
- Group Minimum, Maximum, and Average Reports
- Group Statistical Reports
- Channel and Group Mean Kinetic Temperatures
- Lethality

7.1.3 Audit Testing

Uneventful testing will test the Auditing of Vaisala Veriteq vLog System interaction as a whole, and will consist of the following parts:

- Linking Loggers to an Audit Trail
- Single Logger Processing
- Batch Logger Processing

- User Account Privileges
- Account Security
- Audit File Integrity
- Security File Integrity
- Batch File Integrity

7.1.4 Eventful Testing

Eventful testing is concerned with testing unexpected events. The tests will verify that the Vaisala Veriteq vLog System can handle these unexpected events with no loss or corruption of data. These events are:

- Logger Disconnection During Transfer
- System Power Loss During Transfer

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7.2 OQ FINAL APPROVAL

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

Implemented by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Reviewed by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

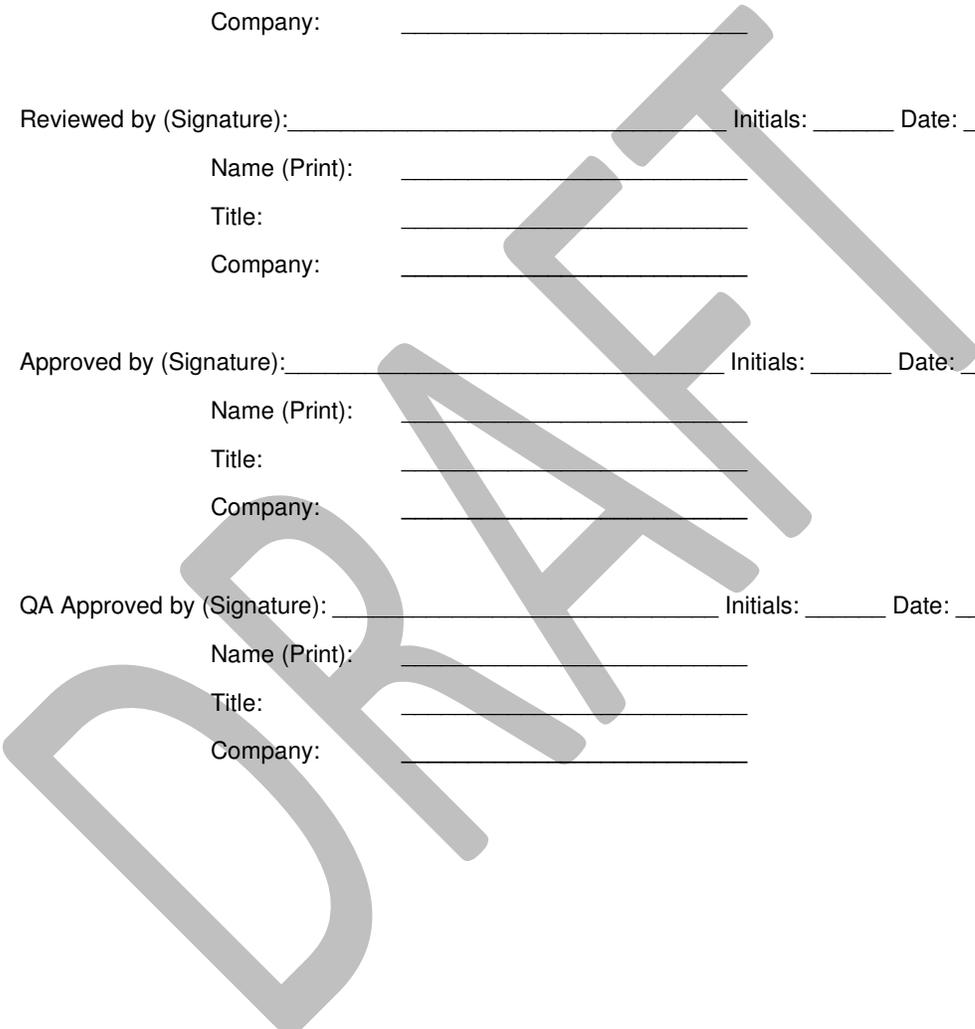
Company: _____

QA Approved by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____



9 IQ/OQ DOCUMENT FINAL APPROVAL

The Vaisala Veriteq vLog System has passed all tests, and as such, is qualified to be used in the _____ environment:

Reviewed by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by (Signature): _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

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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