

Assessment of Vaisala Veriteq viewLinc Continuous Monitoring System Compliance to 21 CFR Part 11 Requirements

The 21 CFR Part 11 rule states that the FDA view is that the risks of falsification, misinterpretation, and change (without leaving evidence) within the GMP environment are higher with electronic records than paper records, and therefore specific controls are required.

The Vaisala system is a hybrid continuous monitoring system that employs the use of both electronic records and signed paper records. The electronic records in the Vaisala system are controlled such that, once created, they cannot be modified. This unmodifiable nature of the electronic records allows them to be printed and signed with full assurance that they represent a true representation of collected data.

This white paper is a clause-by-clause analysis of the requirements of 21 CFR Part 11 and how the Vaisala system responds to and helps users meet these requirements.

Subpart A - General Provisions

Section 11.1 Scope

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and written signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.	Note that although the Vaisala system complies with 21 CFR Part 11 requirements where applicable, ultimate responsibility for 21 CFR Part 11 rests with persons responsible for electronic record content, just as the responsibility for compliance with paper records requirements generally lies with those responsible for the record's content.

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.	The electronic records created by the Vaisala system are used to create signed paper records. The electronic records are not intended to form part of an FDA submission but, rather, must be archived to back up submitted data.
(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.	Not applicable.
(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with Sec. 11.2, unless paper records are specifically required.	The Vaisala system does not employ electronic signatures and, consequently, signed paper records are required.
(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.	The electronic records generated by the Vaisala system must be backed up and maintained by the user. Vaisala maintains backward compatibility in its viewLinc software. Records created by older versions of viewLinc can be read by newer versions of the software. However, users may want to archive a copy of the version used to create the electronic records as a backup reference.

Section 11.2 Implementation

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(a) For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.	Users may decide to archive the Vaisala system's printed records using a PDF (Adobe Acrobat) printer system and, under such circumstances, the responsibility for maintaining the electronic signature system is the responsibility of the user.
(b) For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that:	The Vaisala system is a hybrid system that does not employ electronic signatures and, consequently, relies on printed records that must be signed. However, the Vaisala system can print signed electronic records using a "PDF printer" (Adobe Acrobat) and, under such circumstances, the user is responsible for setting up and maintaining such a printing system.
(1) The requirements of this part are met and;	No comment.

Section 11.2 Implementation - continued

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(2) The document or parts of a document to be submitted have been identified in public docket No.92S-0251 as being the type of submission the agency accepts in electronic form.This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g.,specific center,office,division,branch) to which such submissions may be made. Documents sent to the agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records.Persons are expected to consult with the intended agency receiving unit for details on how (e.g.,method of transmission,media,file formats,and technical protocols) and whether to proceed with the electronic submission.	No comment.

Section 11.3 Definitions

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.	No comment.
(b) The following definitions of terms also apply to this part:	No comment.
(1) Act means the Federal Food, Drug, and Cosmetic Act (secs.201-903 (21 U.S.C.321-393)).	No comment.
(2) Agency means the Food and Drug Administration.	No comment.
(3) Biometrics means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.	Not applicable.
(4) Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.	The Vaisala system is closed in that no access is permitted to alter the data on electronic records.
(5) Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.	The Vaisala system is a hybrid system that does not employ electronic or digital signatures. Rather,the system outputs printed records which must be signed.
(6) Electronic record means any combination of text,graphics,data, audio,pictorial,or other information representation in digital form that is created,modified,maintained,archived,retrieved, or distributed by a computer system.	The Vaisala system is a hybrid system that does not employ electronic or digital signatures. Rather,the system outputs printed records which must be signed.

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(7) Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.	The Vaisala system is a hybrid system that does not employ electronic signatures. Rather, the system outputs printed records which must be signed.
(8) Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.	The Vaisala system requires that users employ handwritten signatures on printed graphs and documents.
(9) Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.	Vaisala's system is a closed system due to required security levels using Windows authentication. An audit trail documents all interactions with the Vaisala system.

Subpart B - Electronic Records

Section 11.10 Controls for closed systems

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	Although validation is a customer responsibility, Vaisala offers validation assistance in the form of Installation (IQ) and Operation Qualification (OQ) protocols. Computer files generated by the Vaisala system are in a proprietary (to Vaisala only) format using a checksum technique to detect invalid or altered records.

Section 11.10 Controls for closed systems - continued

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	Complete and accurate electronic copies of records are available by copying the raw data files or by setting up a "PDF printer" (requires Adobe Acrobat or similar) in order to export graphs in PDF format. Note that the Vaisala system is a hybrid system that generates electronic records that must be printed and signed.
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	On the data logger, electronic data is held internally in non-volatile EEPROM memory. Once data has left the data logger, the media it is stored on, the backup strategy, and retrieval procedures are the responsibility of the user. Note that the data on the logger is considered to be "transient data" and is thus excluded from 21 CFR Part 11. This is because although the data logger initially acquires the data, it only temporarily stores it before passing it onto a PC and a printer to complete the task. For reference, refer to "Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; Appendix 4; Key Areas for Guidance; Section 4.5 Transient Data" (published by ISPE and PDA, 2001).
(d) Limiting system access to authorized individuals.	The Vaisala system provides access control using Windows authentication.
(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	The Vaisala system is based on the creation of secure database files that cannot be modified (without rendering the database completely unusable). Because of the unmodifiable files, there are no operations that are possible to be performed on the electronic data logger record after, or during, file creation. A complete "audit trail" is available with a Vaisala Veriteq viewLinc/VL data logger files. All data associated with the electronic data logging record is captured in the data logger file. Users cannot disable or modify the content or the way data is written to the electronic record nor can the information be edited or deleted any time during or after the record is created. In addition, any changes made to data logger operating parameters in the middle of a recording session results in the creation of a completely new electronic record. Data in the logger is cleared.

Section 11.10 Controls for closed systems - continued

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	The Vaisala system does not allow modification of electronic records under any circumstances or sequence of steps taken by the user.
(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	The Vaisala system provides access control using Windows authentication. The Vaisala system does not allow modification of original electronic records by any individual, authorized or not.
(h) Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	The Vaisala system follows a proprietary protocol for communicating with its data logger devices that serves to positively identify each device and determine whether the data from that device is valid or invalid.
(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	The Vaisala system is a hybrid system that does not employ electronic signatures. However, the system can print signed electronic records using a "PDF printer" (Adobe Acrobat) and, under such circumstances, the responsibility for maintaining the electronic signature system is the responsibility of the user.
(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	The Vaisala system is a hybrid system that does not employ electronic signatures. However, the user can print signed electronic records using a "PDF printer" (Adobe Acrobat) and, under such circumstances, the responsibility for managing and controlling such a system is the responsibility of the user.
(k) Use of appropriate controls over systems documentation including:	Operational procedures are the responsibility of the user. wThe audit trail captures all interactions with the Vaisala system including the clearing of a data logger.
(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.	
(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	



Section 11.30 Controls for open systems

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in Sec. 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.	The Vaisala system is a closed system in that data files, once created, cannot be modified under any circumstances. The audit trail captures all interactions with the Vaisala system including the clearing of a data logger.

Section 11.70 Signature / Record linking

No. 21 CFR Part 11 Clause	Vaisala Comment/Response
Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	Historical database is encrypted with 128-bit encryption key. It is impractical to break it by brute force within a human lifetime. Any alteration of the electronic record (historical database) renders the file completely unusable. Any alteration of the electronic record (Event log files) is detected and identified when a report over that time range is done. Every log record has a unique ID number and a checksum. The ID number is a 64-bit integer, so there's a 1 in 2^{64} chance that the number will be repeated ¹ . The checksum ensures integrity of the record. All interaction with the Vaisala system is tracked in the audit trail.

¹ The Calibration data has a separate 96 bit key ($7.92E+28$ combinations) stored in the loggers itself. Also, the data is stored in the logger files and graph files as raw binary values - not in a human readable format. All of the keys must be correct before vLog will display "VERIFIED" and "SECURE". See www.vaisala.com/veriteq for more information.



Subpart C - Electronic Signatures

The Vaisala system is a hybrid system that incorporates both electronic and paper records. Data is measured and recorded in electronic form then printed onto paper to form the permanent record. The electronic records cannot be modified without rendering the files completely unusable. Once a paper record has been generated, it would be subject to the audit trail requirements for equivalent paper records.



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