# Welcome

#### **Data Integrity** ...Beyond Bytes and Signatures



Paul Daniel Senior Regulatory Compliance Expert

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#### Vaisala team





#### Speaker:

Paul Daniel Sr. Regulatory Compliance Expert

Chat operator:

Janice Bennett-Livingston Marketing Manager



#### Vaisala in Brief

- We serve customers in weather and controlled environment markets
- 80 years of experience in providing a comprehensive range of innovative observation and measurement products and services





### Vaisala - Life Science

#### **Our Offering**

Provides measurement instrumentation, continuous monitoring systems and validation systems for regulated or highly controlled life science environments.

#### **Our Goal is to help customers**

- Reduce their risk of lost or adulterated product
- Reduce their risk of failing to meet
   GxP regulations and/or guidelines





#### **Data Integrity** ...Beyond Bytes and Signatures



#### Goals

#### History

- How did we get here?
- What is Data Integrity?
- New Guidance
  - Recent Publications
- Data Integrity Practices
  - as recommended by PIC/S
  - for a Monitoring System Application









Page 8 / 2017 / Data Integrity

### **POLL 1 Q: Years of GMP Experience**

- I just started
- 1 to 3 years.
- 4 to 10 years.
- 10 to 20 years.
- More than 20 years...



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## PASS



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Page 10 / 2017 / Data Integrity

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Page 11 / 2017 / Data Integrity

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Page 12 / 2017 / Data Integrity











Page 13 / 2017 / Data Integrity











Page 14 / 2017 / Data Integrity











Page 15 / 2017 / Data Integrity









Page 16 / 2017 / Data Integrity

#### **Sociological Mores**

#### Mores

the customs, values, and behaviors that are accepted by a particular group, culture, etc.

- www.merriam-webster.com







Page 18 / 2017 / Data Integrity





Page 19 / 2017 / Data Integrity





Page 20 / 2017 / Data Integrity

#### **Mobile Phones**







Page 21 / 2017 / Data Integrity





Page 22 / 2017 / Data Integrity



1. Quality Culture teaches the unspoken GxP Rules.



- 1. Quality Culture teaches the unspoken GxP Rules.
- 2. Learning the GxP Rules takes time.



- 1. Quality Culture teaches the unspoken GxP Rules.
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- **3**. Established Quality Culture is most effective at teaching GxP Rules.



- 1. Quality Culture teaches the unspoken GxP Rules.
- 2. Learning the GxP Rules takes time.
- 3. Established Quality Culture is most effective at teaching GxP Rules.
- 4. Quality Culture adapts slowly to new technologies.



- 1. Quality Culture teaches the unspoken GxP Rules.
- 2. Learning the GxP Rules takes time.
- 3. Established Quality Culture is most effective at teaching GxP Rules.
- 4. Quality Culture adapts slowly to new technologies.

- "Recipe for disaster":
- Immature quality culture at young companies.
- New technology with computerized systems.



#### The Big Bang of Data Integrity



Page 28 / 2017 / Data Integrity

#### The Big Bang of Data Integrity





Page 29 / 2017 / Data Integrity

#### The Big Bang of Data Integrity





Page 30 / 2017 / Data Integrity







Page 31 / 2017 / Data Integrity

#### **Data Integrity: What is it?**





Page 32 / 2017 / Data Integrity











### **Making Money**















#### **Checks/Cheques**

- Bank Name
- Routing Number
- Account Number
- Check Number
- Recipient
- Date
- Amount
- Authorized Signature







Page 36 / 2017 / Data Integrity

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#### **The Core of Data Integrity**



	CALIE	BRATION
I.D.	1-	4032412
BY_	PCD	DATE 28-FEB-16
DUE.	28-	FEB-17

YOUR NAME Your Address Your City, Your State ,Your Zip Code	DATE
PAY TO THE ORDER OF	S DOLLARS
AUTHORIZED SIGNATURE	56780-0876543

"Ensuring that our data are sufficiently reliable that we may trust it as a basis for making GxP decisions."

- Paul Daniel



### What is Data Integrity? "ALCOA +"

#### Data must be

- Accurate
- Legible
- Contemporaneous
- Original
- Attributable
- Plus "+"
  - Complete, Consistent, Enduring, Available



### **Latest Publications**

- MHRA March 2015
  - "GMP Data Integrity Definitions and Guidance for Industry"
- PIC/S August 2016 (Draft)
  - "Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments"
- WHO May 2016
  - "Guidance on Good Data and Record Management Practices"
- **FDA** April 2016 (Draft)
  - "Data Integrity and Compliance with cGMP Guidance for Industry"











## **PIC/S Data Integrity**



#### Section 2.4

 Data Integrity "...is fundamental in a pharmaceutical quality system which ensures that medicines are of the required quality. Poor data integrity practices and vulnerabilities undermine the quality of records and evidence, and may ultimately undermine the quality of medicinal products."

#### Section 3.4

 "This guide is not intended to impose additional regulatory burden upon regulated entities, rather it is intended to provide guidance on the interpretation of existing PIC/S GMP/GDP requirements relating to current industry practice."



### **PIC/S Table of Contents**



9. Specific data integrity considerations for computerised systems

- 9.1 Structure of QMS and control of computerised systems
- 9.2 Qualification and validation of computerised systems
- 9.3 System security for computerised systems
- 9.4 Audit trails for computerised systems
- 9.5 Data capture/entry for computerised systems
- 9.6 Review of data within computerised systems
- 9.7 Storage, archival and disposal of electronic data



### **PIC/S Simplified**



- 1. Quality Management System
- 2. Validation
- 3. Security
- 4. Audit Trail
- 5. Data Capture
- 6. Data Review
- 7. Data Storage



### **PIC/S Simplified**





- 2. Validation
- 3. Security
- 4. Audit Trail
- 5. Data Capture
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- 7. Data Storage



#### **PIC/S Simplified**





- **O** Malidation
  - 3. Security
  - 4. Audit Trail
  - 5. Data Capture
  - 6. Data Review
  - 7. Data Storage







2 Validation

Data Protection

- 3. Security
- 4. Audit Trail
- 5. Data Capture
- 6. Data Review
- 7. Data Storage

Data Capture























#### **Data Integrity** for Enterprise Monitoring Systems

#### Data Capture

- Sensor Location
- Sensor Calibration
- Review of Data
- **Data Protection** 
  - Software Functions
  - Security Procedures
  - IT Procedures





### **Data Capture 1: Location Verification**

- Is the correct sensor installed?
  - Model
  - Serial Number
- Is the sensor in the correct location?
- Is the sensor fixed in place?





#### Verifications:

#### VAISALA

1 (1) Certificate report no. H45-12500149

#### **CALIBRATION CERTIFICATE**

Instrument Order code Serial number Manufacturer Calibration date Humidity and Temperature Transmitter HMT331 HMT330 180A101BCAB146A5CAABAA1 H5020110 Vaisala Oyj, Finland 13th December 2012

The above instrument was calibrated by comparing the readings of the instrument to working standards of the manufacturer. The reference humidity was calculated from dewooint temperature and temperature readings with the exception of the driest condition that was measured as reliative humidity. Dewojnit temperature was measured with a 372 LHX dewojnit mether. Temperature and relative humidity user measured with two factory working standards. At the time of shipment, the instrument described above met its operating specifications.

The 373 LHX devpoint meter has been calibrated at Centre for metrology and accreditation (MIKES) by using a MIKES working standard moceble to National institute of Standards and Technology (NIST). The temperature readings of the factory working standards have been calibrated at an ISO/LEC 1702 Societide calibration iberatory (FMAS), visitabi Masumenni Standards Laboratory (MSL) by using MSL working standards traceable to NIST. The relative humidity readings of the factory working standards have been calibrated at the Vasiabi factory burging as 72 LHX devpoint meter.

Reference	Reference temperature	Observed humidity	Observed probe	Additional probe	Humidity difference	Permissible
%RH	*c	%RH	*C	°C	%RH	%RH
+0.1	+ 21.84	0.0	+ 21.87		- 0.1	±1.0
+ 12.8	+ 21.86	+ 13.1	+ 21.88		+ 0.3	± 1.0
+ 33.7	+ 21.86	+ 34.0	+ 21.87		+ 0.3	± 1.0
+ 54.9	+ 21.86	+ 55.2	+ 21.87		+ 0.3	± 1.0
+ 75.9	+ 21.86	+ 76.0	+ 21.87		+ 0.1	± 1.0
+ 95.5	+ 21.87	+ 96.4	+ 21.87		+ 0.9	± 1.7

Reference temperature	Observed probe temperature	Temperature difference	Additional probe temperature	Temperature difference	Permissible difference
°C	*C	*C	*c	*C	*C
+ 21.86	+ 21.87	+ 0.01			± 0.10

Equipment used in	alibration		
Type	Serial number	Calibration date	Certificate numbe
MBW 373 LHX	08-1204	2012-09-13	M-12H050
PTU303 / T	H0730001	2012-02-25	K008-V00376
HMT337 / T	E4420206	2012-04-18	K008-V00701
PTU303 / RH	H0730001	2012-11-22	H45-12471001
HMT337 / RH	E4420206	2012-11-22	H45-12471002

Uncertainties ( 95 % confidence level, k=2) Humidity ± 0.6%RH @ 0...40%RH, ± 1.0%RH @ 40...97%RH

Temperature ± 0.10 °C. Ambient conditions / Humidity 46 ± 5% RH, Temperature + 23 ± 1 °C, Pressure 1014 ± 1 hPa.

COPY

Technician

![](_page_52_Picture_17.jpeg)

- Calibration Management SOP
  - SOP approved?
  - SOP applies to CMS sensors?

					Certificate reg	port no. H45-12
		BRATI		ERTIFI	CATE	
Instrument Order code Serial number Manufacturer Calibration data	Humidity and HMT330 180 H5020110 Vaisala Oyj, I 1315 Decemb	Temperature Tra A101BCAB146A5 Finland	nsmitter HMT331 CAABAA1			
The above instrum The reference hur condition that was Temperature and i described above m The 373 LHX dew standard traceable standard have be Laboratory (MSL).	ent was calibrated nidity was calculat a measured as re- relative humidity w tet its operating sp point meter has be to National Institu- en calibrated at an by using MSL wo on calibrated at the	by comparing the ed from devocint lative humidity. D ere measured wit ecifications. en calibrated at C te of Standards a ISO/IEC 17025 a rking standards b Visited factors h	readings of the in temperature and bewpoint tempera- h two factory wor entre for metrolog and Technology (tecredited calibrati- raceable to NIST weare a 373 LH	strument to working 1 temperature read ture was measure king standards. At 29 and accreditation INST). The tempera- ion laboratory (FINA . The relative hum 2 devenoir meter	g standards of the ings with the exci d with a 373 LH the time of shipm a (MIKES) by using thre readings of t (S), Vaisala Meas idty readings of t	manufacturer, eption of the dri X dewpoint me ent, the instrum g a MIKES work the factory work urement Standa the factory work
Humidity calibrati	on results	e valsala lactory o	y using a srs cro	<ul> <li>dewpoint meter.</li> </ul>		
Reference	Reference	Observed humidity	Observed probe temperature	Additional probe temperature	difference	difference
%RH	*C	%RH	*C	°C	%RH	%RH
+ 0.1	+ 21.84	0.0	+ 21.87		- 0.1	±1.0
+ 12.8	+ 21.86	+ 13.1	+ 21.88		+ 0.3	± 1.0
+ 33.7	+ 21.86	+ 34.0	+ 21.87		+ 0.3	± 1.0
+ 54.9	+ 21.86	+ 55.2	+ 21.87	· ·	+0.3	± 1.0
+ 75.9	+ 21.86	+ /6.0	+ 21.87		+0.1	1.0
+ 90.0	+ 21.67	+ 90.4	+ 21.07		+0.8	1 1.7
Reference	Observed	Temperature	1	Additional	Temperature	Permissible
temperature	probe	difference		probe	difference	difference
	temperature			temperature		
*C	*C	*C		*C	*C	*C
+ 21.86 Equipment used i	+ 21.87	+ 0.01	1			± 0.10
Туре	Serial num	ber Ca	libration date	Certificate number	pr -	
MBW 3/3 LHA	08-1204	20	12-09-13	NH120000		
HMT337 / T	E4420206	20	12-02-25	K008-V003701		
PTU303 / RH	H0730001	20	12-11-22	H45-12471001		
HMT337 / RH	E4420206	20	12-11-22	H45-12471002		
Uncertainties ( 95	% confidence lev H @ 040%RH, ±	rel, k=2) 1.0%RH @ 409	7%RH			

![](_page_53_Picture_6.jpeg)

- Calibration Management SOP
  - SOP approved?
  - SOP applies to CMS sensors?
- Calibration Certificate
  - Passed calibration?
  - Shows valid calibration dates?
  - Stored appropriately?

					Certificate rep	ort no. H45-1250
	CALIE	BRATI	ON CE	ERTIFI	CATE	
nstrument Order code ierial number Manufacturer Calibration date	Humidity and HMT330 180 H5020110 Vaisala Oyj, 13th Decemb	Temperature Tra A101BCAB146A5 Finland er 2012	nsmitter HMT331 CAABAA1			
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he 373 LHX dew tandard traceable tandards have be aboratory (MSL) tandards have be	point meter has be to National Institu- en calibrated at an by using MSL wo ren calibrated at the	en calibrated at C ite of Standards a ISO/IEC 17025 a rking standards to Vaisala factory b	entre for metrolog ind Technology (N ccredited calibrati raceable to NIST. y using a 373 LHX	y and accreditation NIST). The tempera on laboratory (FINA . The relative humi 4 dewpoint meter.	(MIKES) by using ture readings of t S), Vaisala Measu dity readings of th	a MIKES working the factory working rement Standard he factory working
Reference humidity	Reference temperature	Observed humidity	Observed probe	Additional probe temperature	Humidity difference	Permissible difference
%RH	*c	%RH	*C	°C	%RH	%RH
+ 0.1	+ 21.84	0.0	+ 21.87		- 0.1	±1.0
+ 0.1 + 12.8	+ 21.84 + 21.86	0.0 + 13.1	+ 21.87 + 21.88	:	+ 0.1	±1.0 ± 1.0
+ 0.1 + 12.8 + 33.7	+ 21.84 + 21.86 + 21.86	0.0 + 13.1 + 34.0	+ 21.87 + 21.88 + 21.87		- 0.1 + 0.3 + 0.3	±1.0 ± 1.0 ± 1.0
+ 0.1 + 12.8 + 33.7 + 54.9	+ 21.84 + 21.86 + 21.86 + 21.86	0.0 + 13.1 + 34.0 + 55.2	+ 21.87 + 21.88 + 21.87 + 21.87	· ·	- 0.1 + 0.3 + 0.3 + 0.3	±1.0 ± 1.0 ± 1.0 ± 1.0
+ 0.1 + 12.8 + 33.7 + 54.9 + 75.9	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.86	0.0 + 13.1 + 34.0 + 55.2 + 76.0	+ 21.87 + 21.88 + 21.87 + 21.87 + 21.87 + 21.87	· · ·	- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9	±1.0 ±1.0 ±1.0 ±1.0 ±1.0
+ 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87	0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4	+ 21.87 + 21.88 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87	· · ·	- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9	±1.0 ± 1.0 ± 1.0 ± 1.0 ± 1.0 ± 1.7
+ 0,1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5 emperature cali	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 bration results	0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4	+ 21.87 + 21.88 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87		- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9	±1.0 ±1.0 ±1.0 ±1.0 ±1.7
+ 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5 emperature calil Reference	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 bration results Observed	0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4 Temperature	+ 21.87 + 21.88 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87	Additional	- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9	±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible
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+ 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5 * emperature calil Reference temperature temperature * 21.86 * 21.86	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 + 21.87 + 21.87 bration results Observed probe temperature *C + 21.87 in calibration Serial num 08.1204 H0730001 E4420206	0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 98.4 Temperature difference *C + 0.01 ber Ca 20 20 20	+ 21.87 + 21.88 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87		- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.1 + 0.9 Temperature difference *C -	1.0 ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
+ 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5 emperature call Reference temperature * 21.86 Type MGW 373 LHX PTU303 / RH HMT337 / RH HMT337 / RH HMT337 / RH	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.87 bration results Observed probe temporature C + 21.87 in calibration Serial num 08-1204 H0730001 E4420205	0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 70.0 +	+ 21.87 + 21.88 + 21.87 + 21.8	Additional probe temperature *C Certificate number M-12H050 K008-V003701 K008-V003701 H45-12471001	- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9 Temperature difference *C -	±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
+ 0.1 + 12.8 + 13.8 + 12.8 + 15.9 + 15.5 + 1	+ 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 bration results Observed prober temposterre temposterre temposterre Serial num 08.1204 H0730001 E4420208 5 % confidence let 4 ©	0.0 • 13.1 • 34.0 • 55.2 • 76.0 • 76.0 • 66.4 • 0.01 •	+ 21.87 + 2		- 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9 Temperature difference *C - *	1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0

![](_page_54_Picture_10.jpeg)

- Calibration Management SOP
  - SOP approved?
  - SOP applies to CMS sensors?
- Calibration Certificate
  - Passed calibration?
  - Shows valid calibration dates?
  - Stored appropriately?
- Sensor
  - Calibration sticker present?

					Certificate rep	ort no. H45-1250
	CALIE	BRATI	ON CI	ERTIFI	CATE	
strument rder code erial number anufacturer alibration date	Humidity and HMT330 180 H5020110 Vaisala Oyj, I 13th Decemb	Temperature Tra A101BCAB146A5 Finland xer 2012	nsmitter HMT331 iCAABAA1			
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Reference humidity	Reference temperature	Observed humidity	Observed probe temperature	Additional probe temperature	Humidity difference	Permissible difference
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unidity calibrat Reference humidity %RH + 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 75.9 + 95.5	C         C           + 21.84         + 21.86           + 21.86         + 21.86           + 21.86         + 21.86           + 21.86         + 21.86           + 21.86         + 21.86	Observed humidity %RH 0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4	Observed probe temperature *C + 21.87 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87	Additional probe temperature - - - - - - - - - - - -	Humidity difference %RH + 0.3 + 0.3 + 0.3 + 0.1 + 0.9	Permissible difference ±1.0 ±1.0 ±1.0 ±1.0 ±1.0 ±1.7
umidity calibrat Reference humidity %RH * 0,1 * 12,8 * 33,7 * 54,9 * 75,9 * 75,9 * 95,5 mperature calibrat Reference temperature	ion results Reference temperature *C + 21.84 + 21.86 + 21.86 + 21.86 + 21.86 trainer * 21.86 trainer * 21.86 * 21.86	Observed humidity %RH 0.0 + 13.1 + 54.0 + 55.2 + 76.0 + 96.4 Temperature difference	Observed probe           temperature           *C           + 21.87           + 21.87           * 21.87           * 21.87           * 21.87	Additional probe temperature *C - - - - - - - - - - - - - - - - - -	Humidity difference %RH -0.1 +0.3 +0.3 +0.3 +0.1 +0.9 Temperature difference	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference
<u>umidity calibrat</u> Reference humidity %RH + 0.1 + 12.8 + 33.7 + 54.9 + 54.9 + 55.5 symperature calil Reference temperature *C	ion results Reference temperature *C +21.84 +21.86 +21.86 +21.86 +21.86 +21.87 Observed probe temperature *C *C *C *C *C *C *C *C *C *C	Observed humidity %RH 0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4 Temperature difference *C	Observed probe temperature *C         */>*C           + 21.87         * 21.87           * 21.87         * 21.87	Additional probe temperature *C - - - - - - - - - - - - - - - - - -	Humidity difference %RH - 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9 Temperature difference *C	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C
umidity calibrat Reference humidity %RH + 0.1 + 12.8 + 33.7 + 54.9 + 54.9 + 55.5 emperature cali Reference temperature * 21.86 automatical and a second * 21.86	ion results Reference temperature *C + 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 Observed probe temperature *C * 21.87 in calibration	Observed humidity 5(RH 0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4 Temperature difference * C + 0.01	Observed probe           temperature           *C           + 21.87           + 21.87           + 21.87           + 21.87           + 21.87	Additional probe temperature c - - - - - - - - - - - - - - - - - -	Humidity difference 5%RH -0.1 +0.3 +0.3 +0.1 +0.1 +0.9 Temperature difference *C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
umidity calibrat Reference humidity %RH + 0.1 + 12.8 + 33.7 + 54.9 + 75.9 + 95.5 mperature calii Reference temperature * 21.86 quipment used iype	ion results Reference temperature * 21.84 + 21.86 + 21.86 + 21.86 + 21.86 + 21.86 temperature temperature * 21.87 bration results bration results	Observed humidity           %RH           0.0           +13.1           +55.2           +76.0           +56.4           Temperature difference           *C           *0.01	Observed probe           temperature           *C           + 21.87           + 21.87           + 21.87           + 21.87           + 21.87           + 21.87           + 21.87           + 21.87           ibitration date	Additional probe temperature *C - - - - - - - - - - - - - - - - - -	Humidity difference %RH -0.1 +0.3 +0.3 +0.1 +0.9 Temperature difference *C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
umidity calibrat Reference humidity 5.RH + 0.1 + 12.8 + 33.7 + 54.9 + 54.9 + 55.5 + 95.5 mperature calibrative Reference temperature * 21.86 quipment used i type (BW) 373 LHX	ion results Reference temperature * C * 21.86 * 21.86 * 21.86 * 21.86 * 21.86 * 21.86 * 21.87 braion results Doserved probe temperature * C * 21.87 in calibration Serial num 08.1204	Observed humidity           %RH           0.0           + 13.1           + 34.0           + 55.2           + 76.0           + 96.4           Temperature difference           * 0.01           ber         C 20	Observed probe temperature *C         */>>*C           *21.87         *21.87         *21.87           *21.87         *21.87         *21.87           bibration date         *2.09-13         *20-13	Additional probe temperature c - - - - - - - - - - - - - - - - - -	Humidity difference %RH -0.1 +0.3 +0.3 +0.1 +0.9 Temperature difference *C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
science           Normality           SRH           + 12.8           + 12.8           + 33.7           + 54.9           + 75.9           + 55.5           Importure call           Reference           temporature call           reget           + 21.86           quipment used           TU330.7 T	ion results Reference temperature *C +21.84 +21.86 +21.86 +21.86 +21.86 *21.86 probe temperature *C *C *1.87 bration results Observed probe temperature *C *C *C *C *C *C *C *C *C *C	Observed humidity %RH 0.0 + 13.1 + 34.0 + 55.2 + 76.0 + 96.4 Temperature difference *C + 0.01	Observed probe temperature *C         */*           *21.87         *21.87           *21.87         *21.87           *21.87         *21.87           *21.87         *21.87           *21.87         *21.87	Additional probe temperature 	Humidity difference %RH -0.1 +0.3 +0.3 +0.1 +0.9 Temperature difference *C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
umidity calibrat Reference humidity KRH • 0.1 + 12.8 + 33.7 + 55.9 + 95.5 + 95.5 + 95.5 Reference temperature calibration Reference * C + 21.86 autopment used (type & W333 / T * M333 / T	ion results Reference temperature *C +21.84 +21.86 +21.86 +21.86 +21.86 +21.87 braison results Doserved probe temperature *C serial num 08.1204 H0730001 E4420205	Observed humidity           %RH           0.0           + 13.1           + 54.0           + 55.2           + 76.0           + 95.4           Temperature difference           *C           + 0.01           Call           20           20           20	Observed probe temperature *C         */>>*C           + 21.87         * 21.87           * 21.87         * 21.87           * 21.87         * 21.87           # 21.87         * 21.87           # 21.87         * 21.87           # 21.87         * 21.87           # 21.87         * 21.87	Additional probe c c - - - - - - - - - - - - - - - - -	Humidity difference %RH - 0,1 + 0,3 + 0,3 + 0,3 + 0,1 + 0,9 Temperature difference *C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10
unidity calibrat Reference humidity KRH + 0.1 + 0.1 + 0.2 + 0.1 + 0.2 + 0.1 + 0.2 + 0.1 + 0.2 + 0.1 + 0.2 +	ion results Reference temperature *C + 21.86 + 21.86 + 21.86 + 21.86 + 21.87 + 21.87 + 21.87 + 21.87 + 21.87 in calibration Serial num 08-1204 H0730001 E4920205	Observed humidity 56.8H • 0.1 • 55.2 • 76.0 • 76.0 • 76.4 • 76.4	Observed probe temperature 	Additional probe temperature *C - - - - - - - - - - - - - - - - - -	Humidity difference %RH - 0.1 + 0.3 + 0.3 + 0.3 + 0.1 + 0.9 Temperature difference • C -	Permissible difference %RH ±1.0 ±1.0 ±1.0 ±1.0 ±1.7 Permissible difference *C ±0.10

![](_page_55_Picture_12.jpeg)

### **Data Capture 3: Data Review Verification**

- Data Review SOP approved?
- SOP includes the following:
  - Responsibilities for Data Review.
  - Clear definitions of acceptable data.
  - Actions to take for unacceptable data.

![](_page_56_Figure_7.jpeg)

![](_page_56_Picture_8.jpeg)

### **Data Capture: Additional Thoughts**

Monitoring systems can capture data directly from sensors.

![](_page_57_Picture_2.jpeg)

 To apply "Data Capture" to other types of computerized systems, you may need additional verification activities.

![](_page_57_Picture_4.jpeg)

Software Function Verifications

![](_page_58_Picture_2.jpeg)

![](_page_58_Picture_3.jpeg)

Page 59 / 2017 / Data Integrity

#### Software Function Verifications

- Access Control Features
  - Uniquely identifies user Example: username
  - Controls entry to program Example: password
  - Controls access within program Example: user profile

![](_page_59_Figure_6.jpeg)

#### Software Function Verifications

- Access Control Features
  - Uniquely identifies user Example: username
  - Controls entry to program Example: password
  - Controls access within program Example: user profile
- Audit Trail
  - Records all changes to data.

![](_page_60_Picture_8.jpeg)

![](_page_60_Picture_9.jpeg)

#### Software Function Verifications

- Access Control Features
  - Uniquely identifies user Example: username
  - Controls entry to program Example: password
  - Controls access within program Example: user profile
- Audit Trail
  - Records all changes to data.
- Secure Reporting Format
  - Provides data in format that cannot be edited.
    - Example: .PDF File

![](_page_61_Picture_11.jpeg)

![](_page_61_Picture_12.jpeg)

### **Data Protection 2: Security SOPs**

#### Verifications

- Site Physical Security SOP
- Password Management SOP
- Periodic User Review SOP
- Audit Trail Review SOP

#### All SOPs must be:

- Approved?
- Include the monitoring system?

![](_page_62_Picture_9.jpeg)

![](_page_62_Picture_10.jpeg)

### **Data Protection 3: IT SOPs**

Verifications

- Change Management SOP
- Disaster Recovery SOP
- Data Back-Up SOP
  - Daily (Local)
  - Weekly (Protected Local)
  - Monthly (Protected Off-Site)

All SOPs must be:

- Approved?
- Include the monitoring system?

![](_page_63_Picture_11.jpeg)

![](_page_63_Picture_12.jpeg)

#### **Data Integrity** for Enterprise Monitoring Systems

#### Data Capture

- Sensor Location
- Sensor Calibration
- Review of Data
- **Data Protection** 
  - Software Functions
  - Security Procedures
  - IT Procedures

![](_page_64_Picture_9.jpeg)

![](_page_64_Picture_10.jpeg)

### **Recent FDA Warning Letter – May 2016**

- "Failure to exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data, and to provide controls to prevent omission of data."
  - "The computerized system lacked access controls and audit trail capabilities."
  - "All employees had administrator rights and shared one user name."
  - "Electronic data could have been manipulated or deleted without traceability."

![](_page_65_Picture_5.jpeg)

![](_page_65_Picture_6.jpeg)

#### Review

#### History

- How did we get here?
- What is Data Integrity?
- New Guidance
  - Recent Publications
- Data Integrity Practices
  - as recommended by PIC/S
  - for a Monitoring System Application

![](_page_66_Picture_9.jpeg)

![](_page_66_Picture_10.jpeg)

#### POLL: Question Do you want Vaisala to contact you?

- Yes, I'm interested in... Loggers
- Yes, I'm interested in... Validation Mapping Kit
- Yes, I'm interested in... Mapping Services
- Yes, I'm interested in... Continuous Monitoring System
- Yes, I'm interested in... Process Instrumentation
- Yes, I'm interested in... Handheld devices
- Yes, I'm interested in... Other
- Not at this time, thanks.

Page 68 / 2017 / Data Integrity

![](_page_67_Picture_9.jpeg)

#### **Thanks for Attending!**

![](_page_68_Picture_1.jpeg)

Paul Daniel Senior Regulatory Compliance Expert Vaisala, Inc.

Email: paul.daniel@vaisala.com

![](_page_68_Picture_4.jpeg)