

# Traceability

What is it and how to achieve it

*Helping you make a better measurement.*

## Webinar Presenters & Humidity Experts



Bruce McDuffee

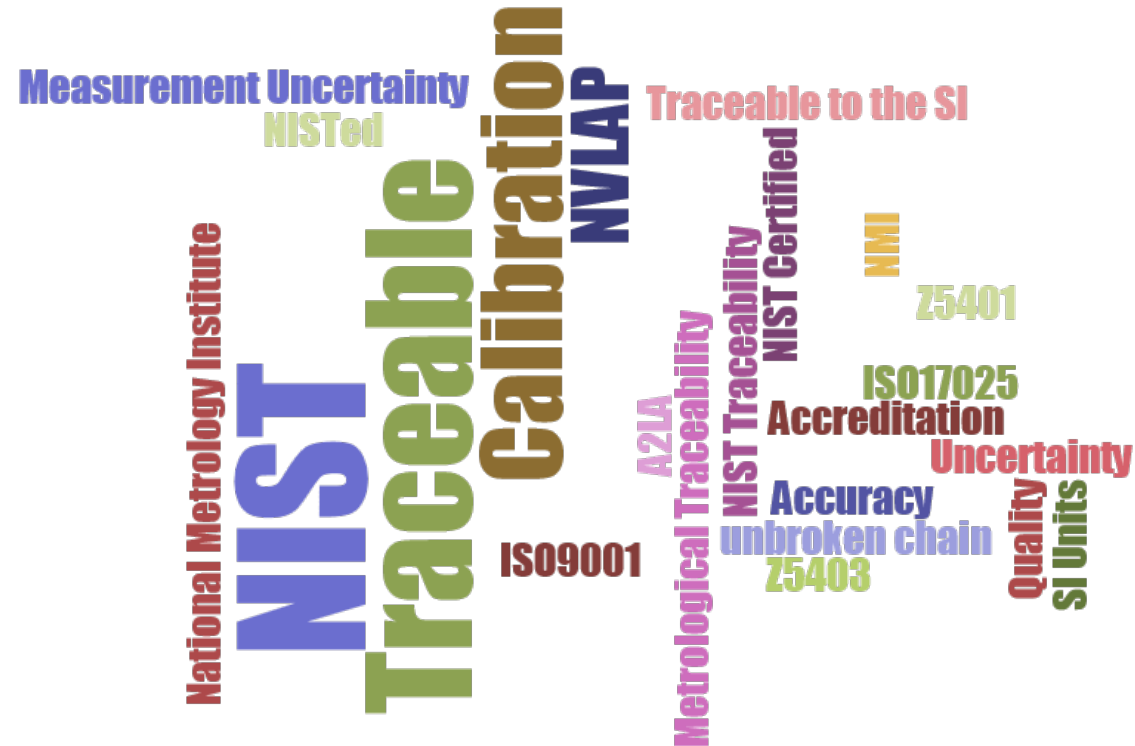


Michael Boetzkes

# Agenda & Learning Objectives

- Definition of Traceability
- Why is it Important
- Responsibilities for Traceability
- Components to prove Traceability
- Ensuring traceability of Calibrations

# Common Terms



# Requirement for Traceability

- Regulatory or International Standards
  - FDA
  - ISO9001
  - ISO17025
- Best Practice Documents
  - NCSLi
    - RP6 Calibration Quality Systems for the Healthcare Industry (2015)
  - NIST
    - <http://www.nist.gov/traceability/>

# What is “NIST Traceable”?

- Metrologically traceable to NIST's practical realization of the definition of a measurement unit



# Definition – Metrological Traceability

- *Property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty.*



*Bureau international des poids et mesures*

Source: BIPM, JCGM200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

# Why is Metrological Traceability Important?

- Every standard requires traceability
- Promotes consistency in measurement
- Relates measurements back to a single source








# Comments & Questions



If we don't get to your question today, we'll respond via email after the webinar.

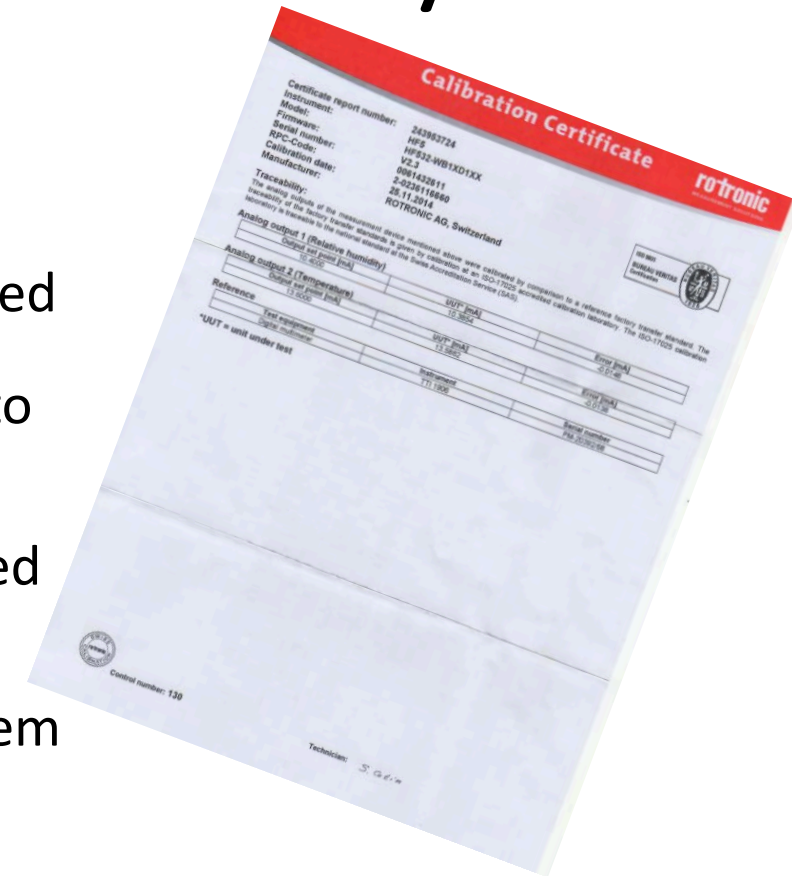
# Who is Responsible for Traceability?

- NIST? 
- Calibration Provider? 
- User of Instrument? 

# Evidence to Prove Metrological Traceability

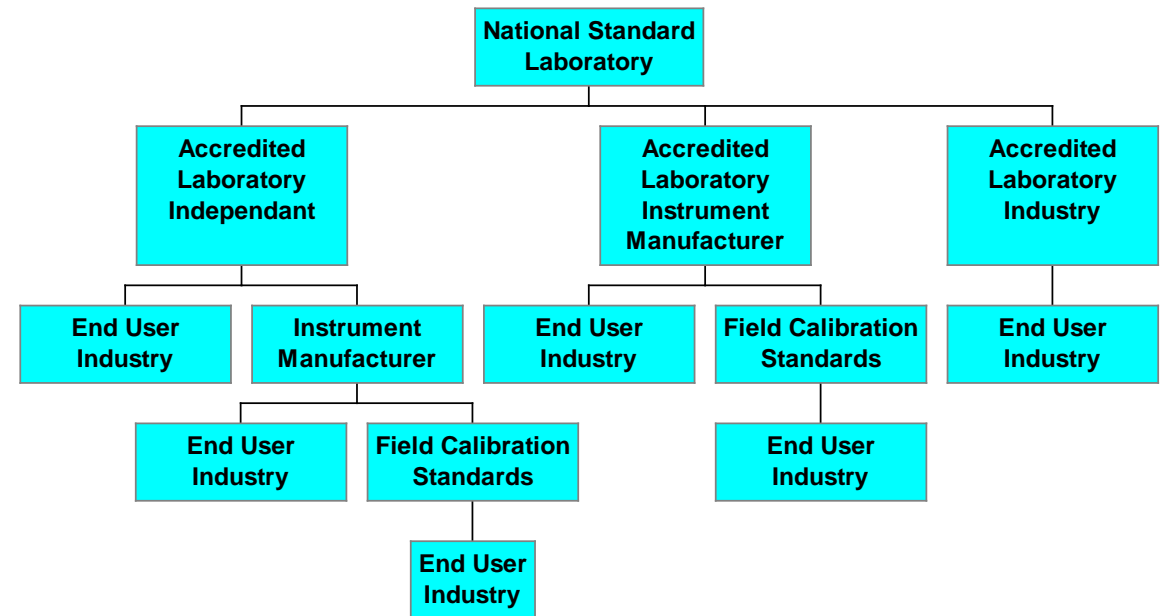
## Calibration Certificate

- a clearly defined reference quantity that has been measured
- a complete description of the instrument or system used to perform the measurement
- a stated measurement result, which includes a documented uncertainty
- a complete specification of the reference standard or system
- An internal measurement assurance program for establishing the status of the reference standard



# The Importance of Uncertainty

- Strength of the traceability chain
- Accuracy alone does not provide full picture of instrument performance.



# Ensuring Metrological Traceability

## The Hard Way

- Audit your vendor
- Traceability program in place
- Relevant data on calibration certificates



# Ensuring Metrological Traceability

## The Easy Way

- Use Accredited Calibration Labs!
- Accreditation body has ensured the lab has the competence to complete the work and required documentation in place.
- ILAC or APLAC MRA signatory



# Takeaways

- Metrological Traceability is a property of a measurement.
- Traceability provides consistency of measurements.
- Calibration does not guarantee Metrological Traceability.
- Measurement Uncertainty is a key part of Metrological Traceability.

# Comments & Questions



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# 8 Questions to Assess your Calibration Lab.

We'll include this in the follow up email as a thank you for attending the live broadcast.

ROTRONIC APPLICATION NOTE

## Is Your Humidity Calibration Lab Competent?

Find out by asking these 8 critical straight forward questions.

**Question 1 – Is the lab accredited to the ISO 17025 standard?**

Accreditation to the ISO/IEC 17025 standard for competency and testing calibration is a really good place to start. In general, accreditation does not specifically say how the calibration should be performed, but rather it speaks to a set of guidance principles and results that the approved procedures should provide. ISO/IEC 17025 accreditation confirms that the calibration laboratory has successfully addressed five major areas within the calibration process; Scope of Competencies, Properly Defined Procedures, Demonstrated Control of the Process, Demonstrated Understanding of the Measurement Uncertainty, Demonstrated Proficiency in the Measurement. The ISO 17025 accreditation ensures that your calibration vendor has given serious management and



technical attention to their capabilities and can repeatedly perform calibrations to that same level of competence. Although accreditation is a strong indicator that the lab is competent, accreditation or lack thereof should not be the sole indicator of competence.

**Question 2 – May I see the uncertainty budgets for the humidity calibration process?**

Ask the calibration lab vendor for the details on the uncertainty study. When considering the uncertainty of the calibration for humidity, the lab should have examined the following sources: the reference

instrument uncertainty, repeatability and drift of both the temperature and humidity reference instrument, the temperature and humidity gradients that are occurring inside the humidity chamber, the temperature and humidity stability within the chamber where the devices will be placed and the resolution of the unit under test (UUT). The lab should be capable and willing to explain their calculations on uncertainty and what assumptions went into the calculations. If they are unwilling or unable to do so, you should probably ask why and maybe start looking for another lab.

*continued*

ROTRONIC UNCERTAINTY BUDGET		
Measured Parameter or Device Calibrated	Range	Uncertainty (k=2)
<b>THERMODYNAMIC</b>		
<b>HUMIDITY UNCERTAINTY</b>		
Humidity Measurement Relative Humidity	0.1 % RH to 0.8 % RH	0.21 % RH
	10.5 % RH to 11.5 % RH	0.22 % RH
	34 % RH to 36 % RH	0.29 % RH
	79 % RH to 81 % RH	0.49 % RH
<b>TEMPERATURE UNCERTAINTY</b>		
Thermometer Probe	21 °C to 27 °C	0.065 °C

# Humidity Academy

- Resources for making a better measurement
  - Psychrometric charts
  - Technical notes
  - Humidity calculator
  - Application notes
  - more



[www.rotronic-usa.com/humidity-academy](http://www.rotronic-usa.com/humidity-academy)

## Helping you make a better humidity measurement – and more.

Transmitters, portable meters and loggers for:

- Humidity
- Carbon Dioxide
- Low Dew Point
- Water Activity
- Differential Pressure
- Monitoring systems for cGMP
- ISO 17025 accredited calibrations (humidity and temperature)



# Post webinar survey

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