

# Calibration in Life Science & ISO/IEC 17025:2017

New technologies mean an updated standard for  
calibration laboratories

**VAISALA**

# 80 Years of Measurement Leadership

- We serve customers in weather and controlled environment markets
- Over 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
- Ensure their products meet or exceed all quality guidelines and standards



# Your Hosts

**Daniel Soave – Presenter**

**Paul Daniel – Presenter**

**Jennifer Clay – Chat Question Support**

**Janice Bennett-Livingston – Q&A**

# Changes to: ISO/IEC 17025:2017

Daniel Soave, Service Manager, Vaisala Inc.  
Calibration and Repair Services

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# Webinar Goals

- Review of changes in ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories.”
- Discussion of changes that will impact environmental monitoring, measurement and validation.
- Key points – pitfalls to watch for!

# Poll

- We have had ISO 17025 come up during an audit or inspection.
- We have not had ISO 17025 come up during an audit or inspection, and we want to keep it that way.

# ISO/IEC 17025 Purpose & Scope

- The ISO/IEC 17025 standard requires calibrations to meet criteria for personnel competencies in the maintenance of equipment and processes that create data.
- ISO/IEC 17025:2017 is applicable to all organizations performing laboratory activities, regardless of the number of personnel.
- The standard is of interest to customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use ISO/IEC 17025:2017 in confirming or recognizing the competence of laboratories.



# What's New?

- The scope has been revised to cover testing, calibration and sampling associated with subsequent calibration and testing.
- The process approach now matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies).
- The standard has now a stronger focus on information technologies and incorporates the use of computer systems, electronic records and the production of electronic results and reports. It is now more aligned with daily operations and modern technologies, with better guidance on conformity and reporting.
- A new chapter introduces the concept of risk-based thinking.
- So... let's look at how this affects YOU.

# What's New for you?

17025:2017 7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

Out Of Tolerance As Received: YES

Temperature, °C				
Reference Mean	Unit Under Test Mean	Error	± Tolerance	± Uncertainty
-70.00	-71.36	-1.36	0.50	0.06
-39.99	-40.92	-0.93	0.40	0.05
0.00	-0.42	-0.42	0.27	0.05

# Conformance Decisions

- When receiving an accredited calibration, you may start to be asked about conformance decisions. You will need to decide:
  - If you want a conformance decision?
  - If you want a specific decision rule?
  - If a proposed decision rule is acceptable?



# Decision Rule

- What's your Decision Rule based on?
  - Manufacturer Spec?
  - Uncertainty of the Measurement?
  - Your own Quality System?



# Do I need ISO 17025 calibration, or is ISO 9001 calibration sufficient?

- ISO 9001 certification applies to an Organization and their Management System.
  - Does not have the same requirements for test/inspection/calibration data that ISO 17025 requires.
- ISO 17025 calibrations minimize risk
  - More stringent requirements for technical content when it comes to calibration data.
  - How crucial is the item being calibrated to your Quality System?
  - How much risk is acceptable?



# Things to Think about...

- Do I want a Conformance Decision on my certificate or do I just need the data?
- What is my Decision rule based on?
- Do I need ISO 17025 calibration?



# Risk Assessment

A quick tutorial.

Paul Daniel  
Sr. Regulatory Compliance Expert  
[paul.daniel@vaisala.com](mailto:paul.daniel@vaisala.com)

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# Poll

- Who has extra...?
  - Budget
  - Time
  - Labor



# Definitions: Risk

- Noun - The possibility that something bad or unpleasant (such as an injury or a loss) will happen.

merriam-webster.com

- Two Parts
  - Possibility.
  - Unpleasantness.



# Break it down...



- **Severity** – How we measure **unpleasantness**.
  - How much could this impact product quality?
- **Probability** – How we measure **possibility**.
  - How likely is it that the unpleasant event will come to pass?



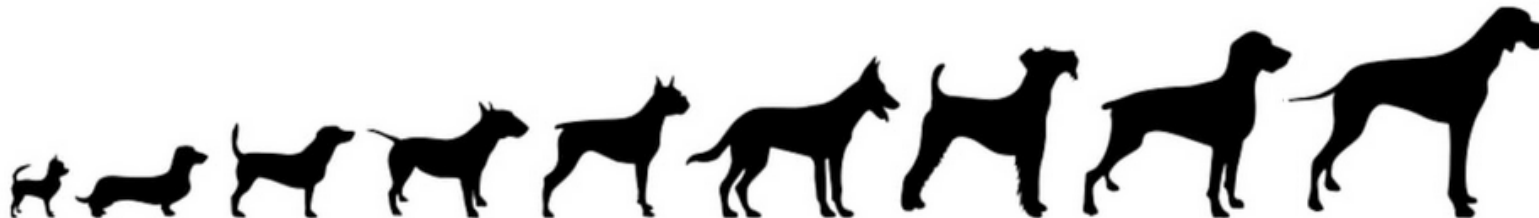
# Assessment Process

- Two Part Process
  - Part 1: Declare General Assumptions
  - Part 2: Make Clear Scoring Rules
- Allows
  - Clear Rationale
  - Repeatable Process



# Sorting Dogs with no Scale

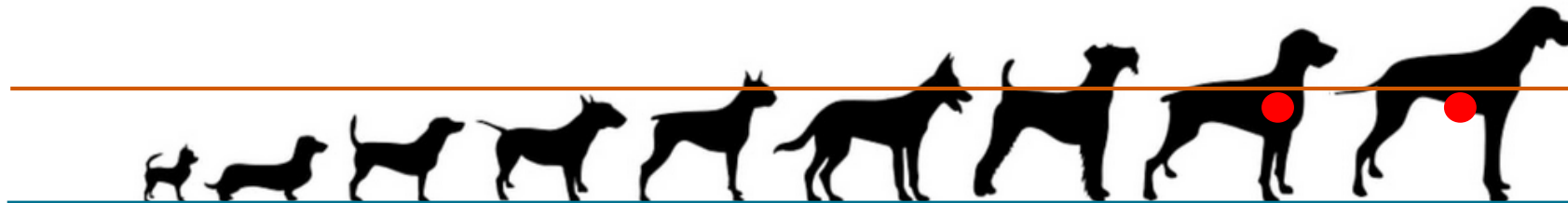
- Assumptions
  - Tall dogs tend to be heavier.
  - Long dogs tend to be heavier
- Rules
  - Small : Both  $<50\text{cm}$  tall AND  $<50\text{cm}$  long
  - Medium: Either  $<50\text{cm}$  tall OR  $<50\text{cm}$  long
  - Large: Both  $>50\text{cm}$  tall AND  $>50\text{cm}$  long



# Sorting Dogs with no Scale

- How Tall?

● > 50cm tall

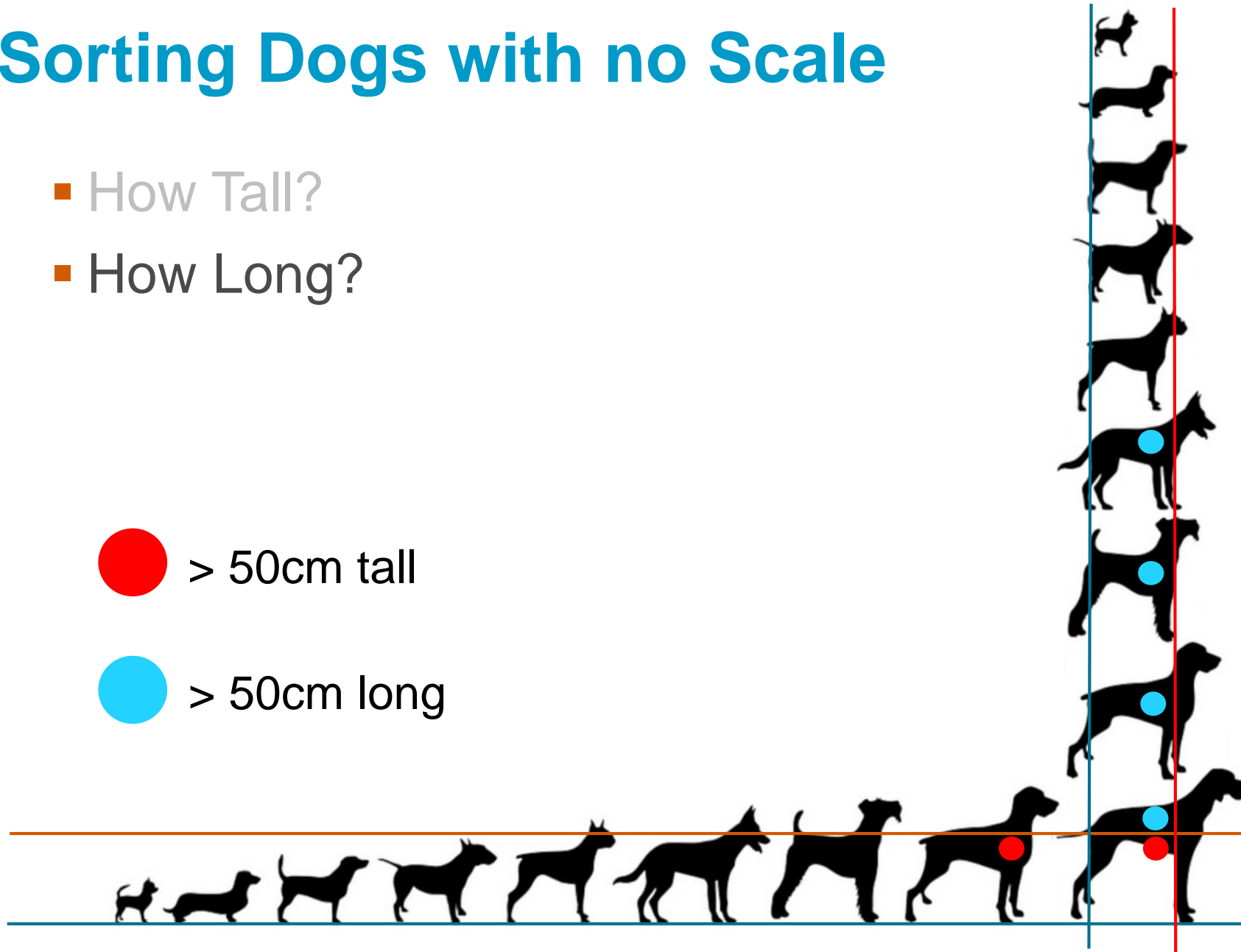


# Sorting Dogs with no Scale

- How Tall?
- How Long?

● > 50cm tall

● > 50cm long

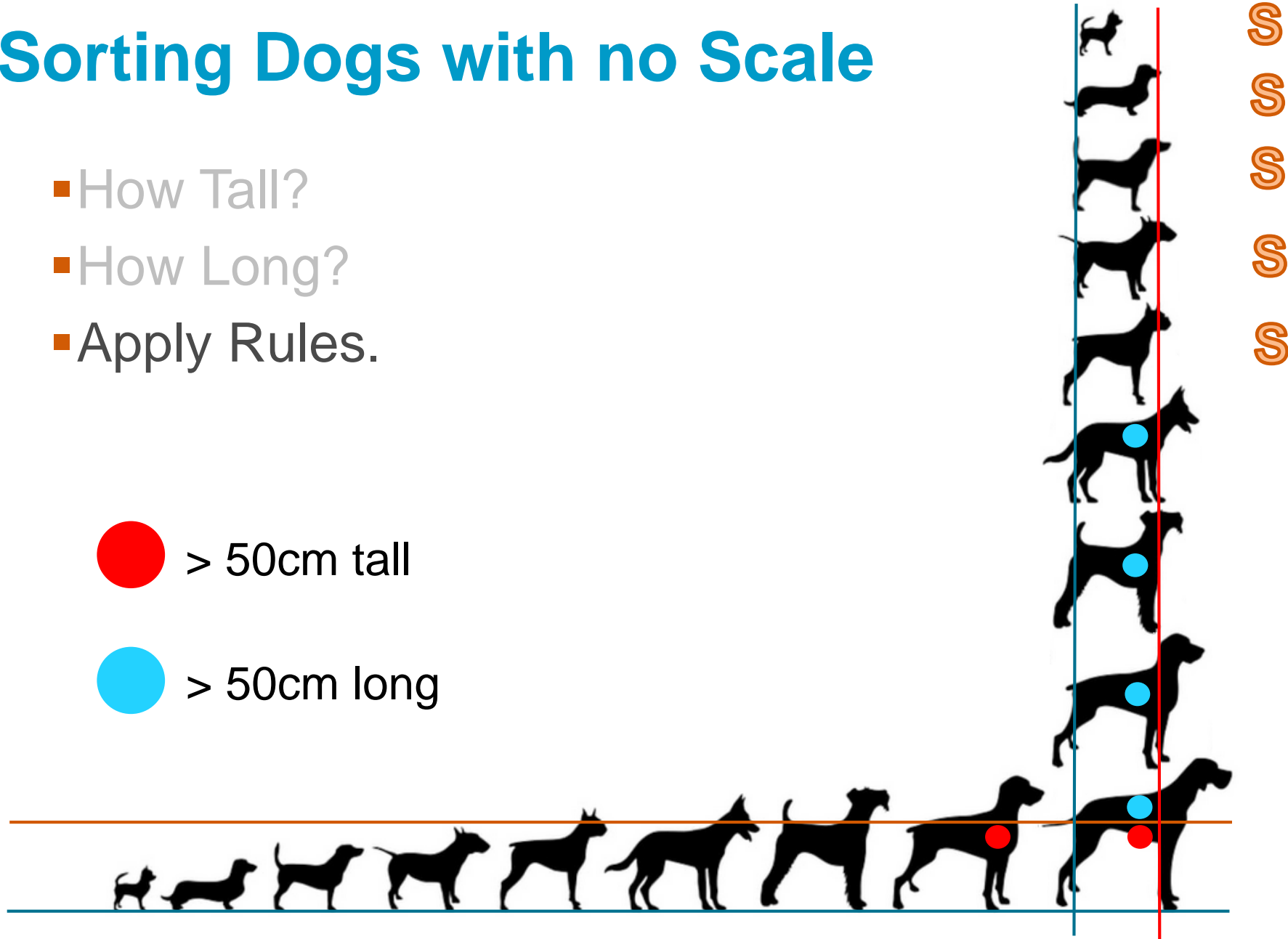


# Sorting Dogs with no Scale

- How Tall?
- How Long?
- Apply Rules.

● > 50cm tall

● > 50cm long

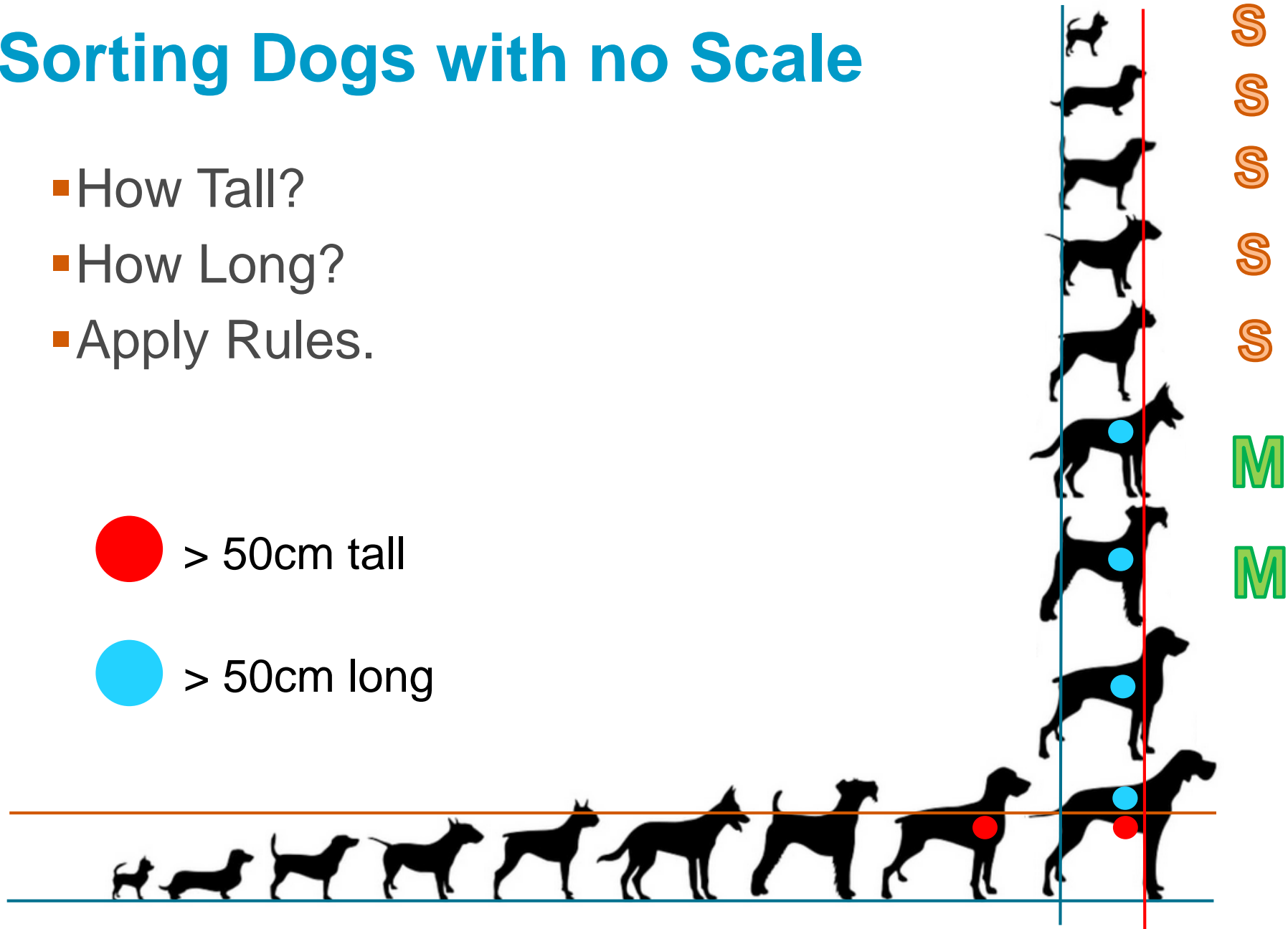


# Sorting Dogs with no Scale

- How Tall?
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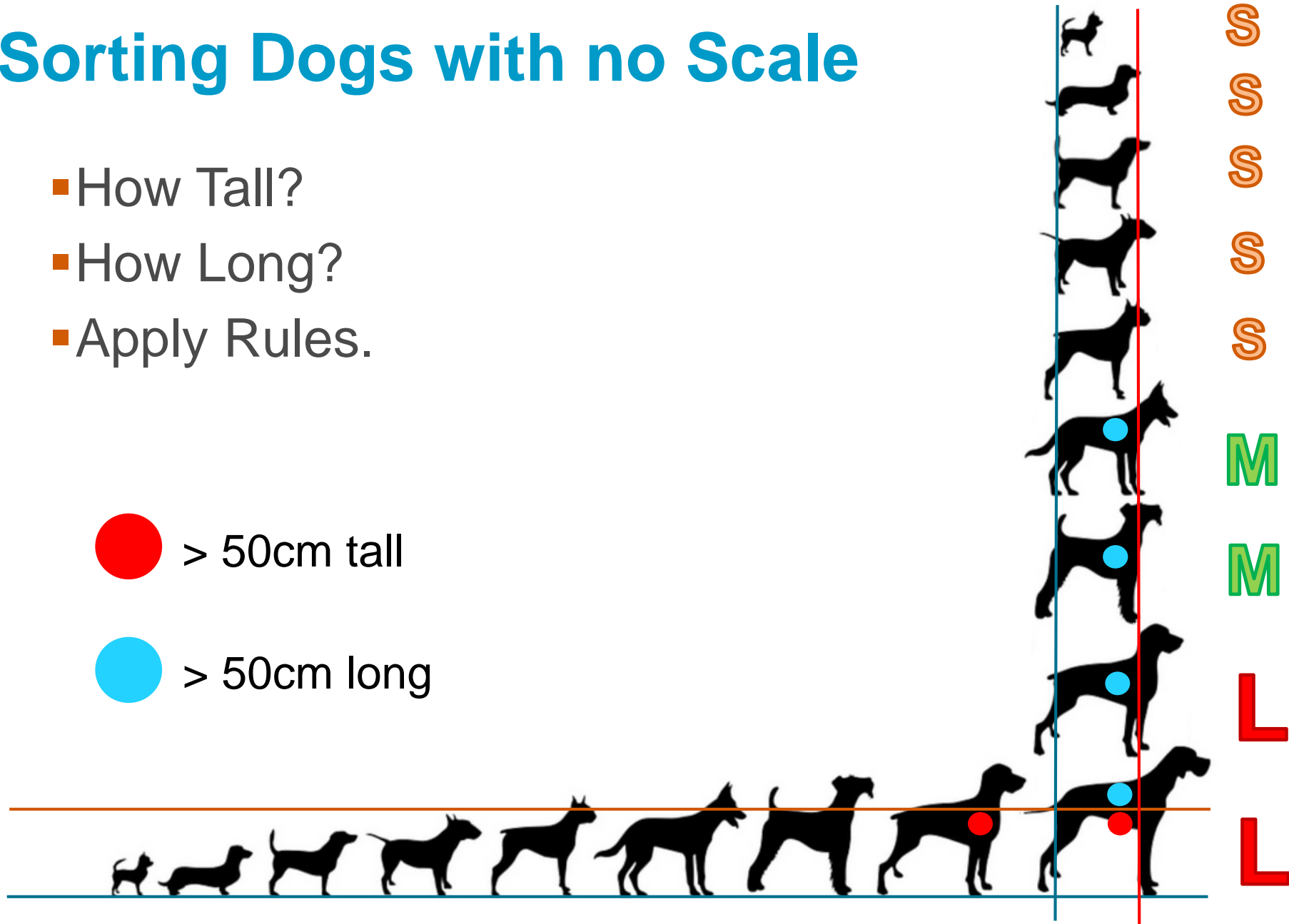


# Sorting Dogs with no Scale

- How Tall?
- How Long?
- Apply Rules.

● > 50cm tall

● > 50cm long



# Severity Part 1: GMP Assumptions

- Assumption 1
  - An out of tolerance instrument can impact product quality.
- Assumption 2
  - The impact will be greatest in sensitive processes.



# Severity Part 2: Make Scoring Rules

- Low Impact: 1
  - Failure does not affect product quality.
- Moderate Impact: 2
  - Failure has potential or reversible impact on product quality.
- High Impact: 3
  - Failure will cause product quality failure.



# Probability Part 1: Metrology Assumptions

- Assumption 1
  - An instrument is less likely to be found out of tolerance when intermediate checks are performed between calibration events.
- Assumption 2
  - A product issue is less likely if the process tolerance is larger than the instrument tolerance.



# Probability Part 2: Make Scoring Rules

- Low Probability: 1
  - Intermediate checks are performed
    - AND
  - Process tolerance is greater than instrument tolerance.
- Moderate Probability: 2
  - Intermediate checks are performed
    - OR
  - Process tolerance is greater than instrument tolerance.
- High Probability: 3
  - Intermediate checks are NOT performed
    - AND
  - Process tolerance is NOT greater than instrument tolerance.

# Instrument List

ID	Description
1	Warehouse Humidity
2	Dryer Humidity
3	Stability Chamber Temp

# Instrument List

- Determine Severity Scores

ID	Description	Severity
1	Warehouse Humidity	1
2	Dryer Humidity	2
3	Stability Chamber Temp	3

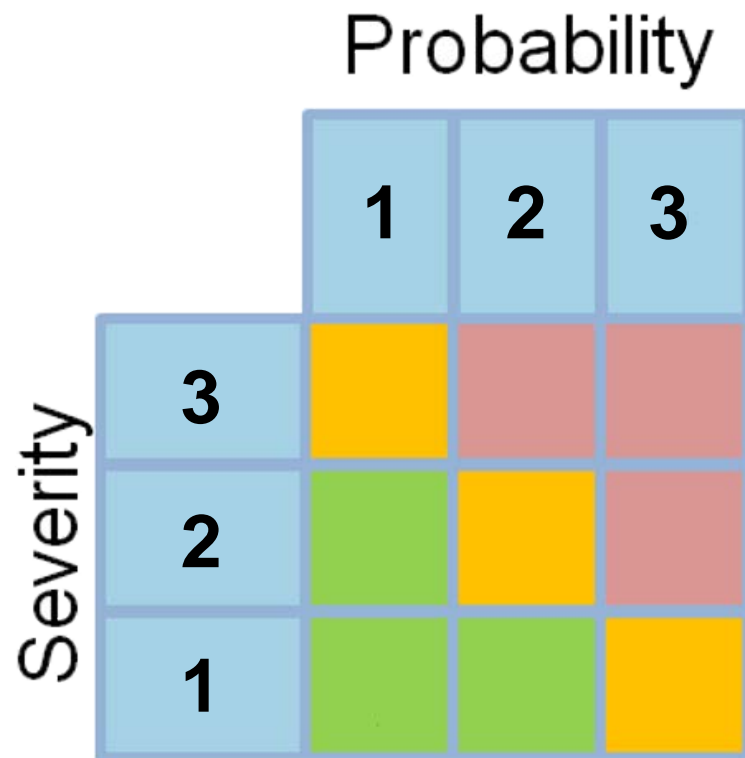
# Instrument List

- Determine Severity Scores
- Determine Probability Scores

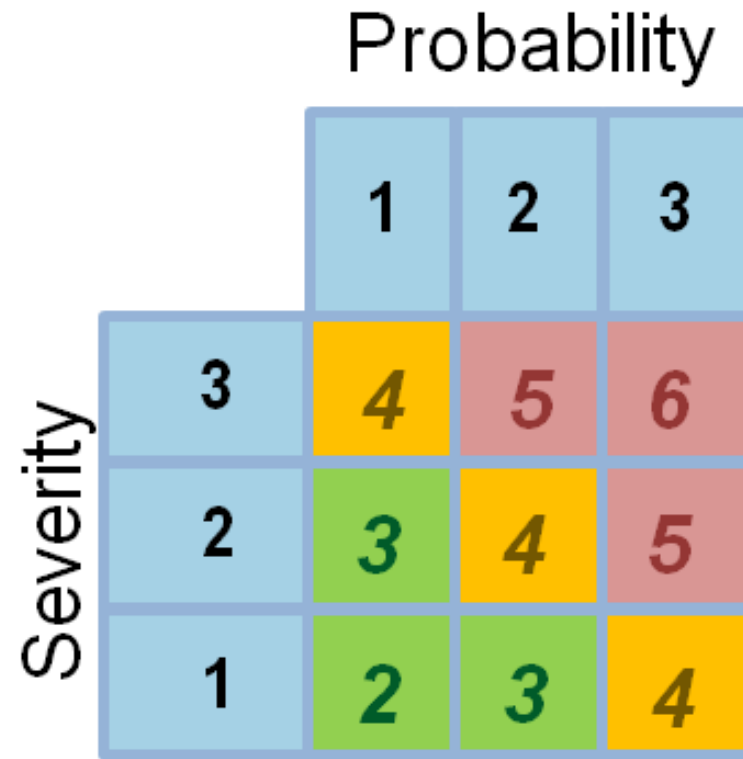
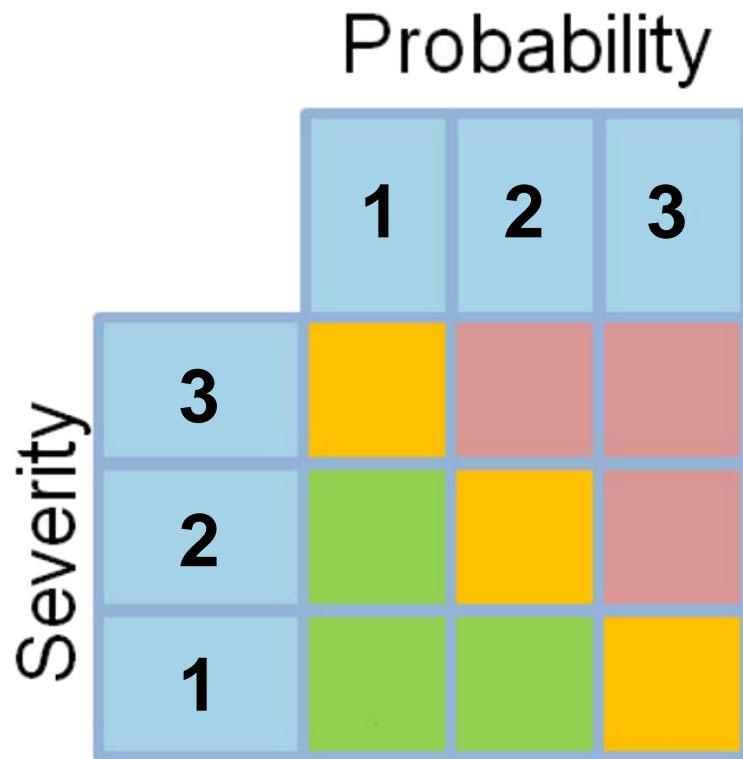
ID	Description	Severity	Probability
1	Warehouse Humidity	1	1
2	Dryer Humidity	2	2
3	Stability Chamber Temp	3	3



# Risk Matrix



# Risk Matrix



# Instrument List

- Determine Severity Scores
- Determine Probability Scores
- Add Scores to determine Risk Class

		Probability		
		1	2	3
Severity	3	4	5	6
	2	3	4	5
	1	2	3	4

ID	Description	Severity	Probability	Risk Class
1	Warehouse Humidity	1	1	2
2	Dryer Humidity	2	2	4
3	Stability Chamber Temp	3	3	6

# What next?

- Use risk assessment as a basis for decision making to guide use of limited resources.
  - Time
  - Budget
  - Labor

		Probability		
		1	2	3
Severity	3	4	5	6
	2	3	4	5
	1	2	3	4

- Stop intermediate checks in Warehouse?
- Buy more reliable sensor for Stability Chamber?

ID	Description	Risk Class
1	Warehouse Humidity	2
2	Dryer Humidity	4
3	Stability Chamber Temp	6

# In Review

- Risk Assessment Exercise
  - Two Part Process
    - Use General Assumptions to make Clear Scoring Rules
    - Add Scores in Risk Matrix to Identify Highest Risk Items
  - Use it as a tool to guide decision making.
- New revision of ISO 17025
  - Alignment with ISO 9001
  - Computerized Systems
  - Decision Rules and Statements of Conformity
  - Instrument Tolerance vs Process Tolerance
  - Risk Assessment



# Questions?



Daniel Soave  
Calibration Service Manager  
Daniel.soave@vaisala.com

Paul Daniel  
Sr. Regulatory Compliance Expert  
paul.daniel@vaisala.com

# Thank you for your time!

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Daniel Soave  
Calibration Service Manager  
Daniel.soave@vaisala.com

Paul Daniel  
Sr. Regulatory Compliance Expert  
paul.daniel@vaisala.com

