

# Traceability

**Its Importance in the Analytical Process**

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# What is Traceability?

ISO-9000-2015

2016 ANSI / NELAC Standard

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identification data.

# Measurement Traceability

- Measurement Traceability  $\approx$  Confidence
  - Chain of Comparison to a certified standard
    - With Stated Uncertainty
      - Bias, precision and accuracy
  - Confirmation of Project meeting DQOs

# The Expanding Reach of Traceability

- Metrology
- Qualitative Attributes
  - Chronology
  - Product Quality
  - Certifications
  - Trades Licenses
  - Industrial Processes

# From Data Production to Product Traceability

- Software Development, Electronics, Food/Pharm
  - Schedule
  - Product Specifications
  - Regulatory Requirements
  - Reliability
  - Recycling / Responsible Disposal

# Traceable Aspects of Laboratory Operations

Lab Ownership

Lab Representations

Lab Licenses

Lab Certifications

Analyst Training

Waste Handling

Completed Contracts

Facility Security

Sample Receipt

Sample Security

Sample Custody

Instrument Performance

Calibrations

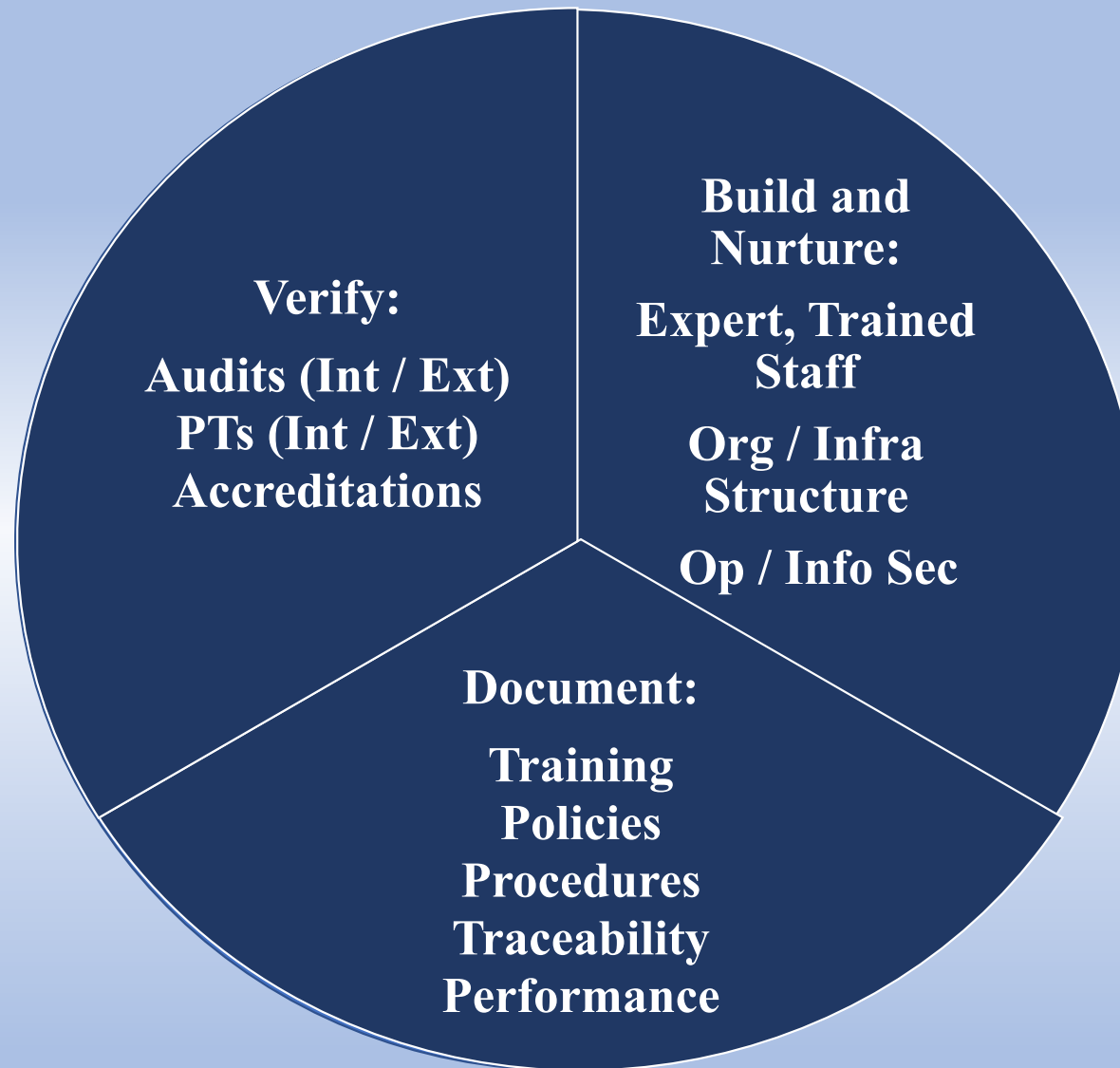
QC Performance

Sample Processing

Sample Results

Business Performance

# Circle of Success



# Jessica



Pet Hippo Jessica –  
Bing Images



# Case Study: Traceability Interrupted

## Full-service laboratory:

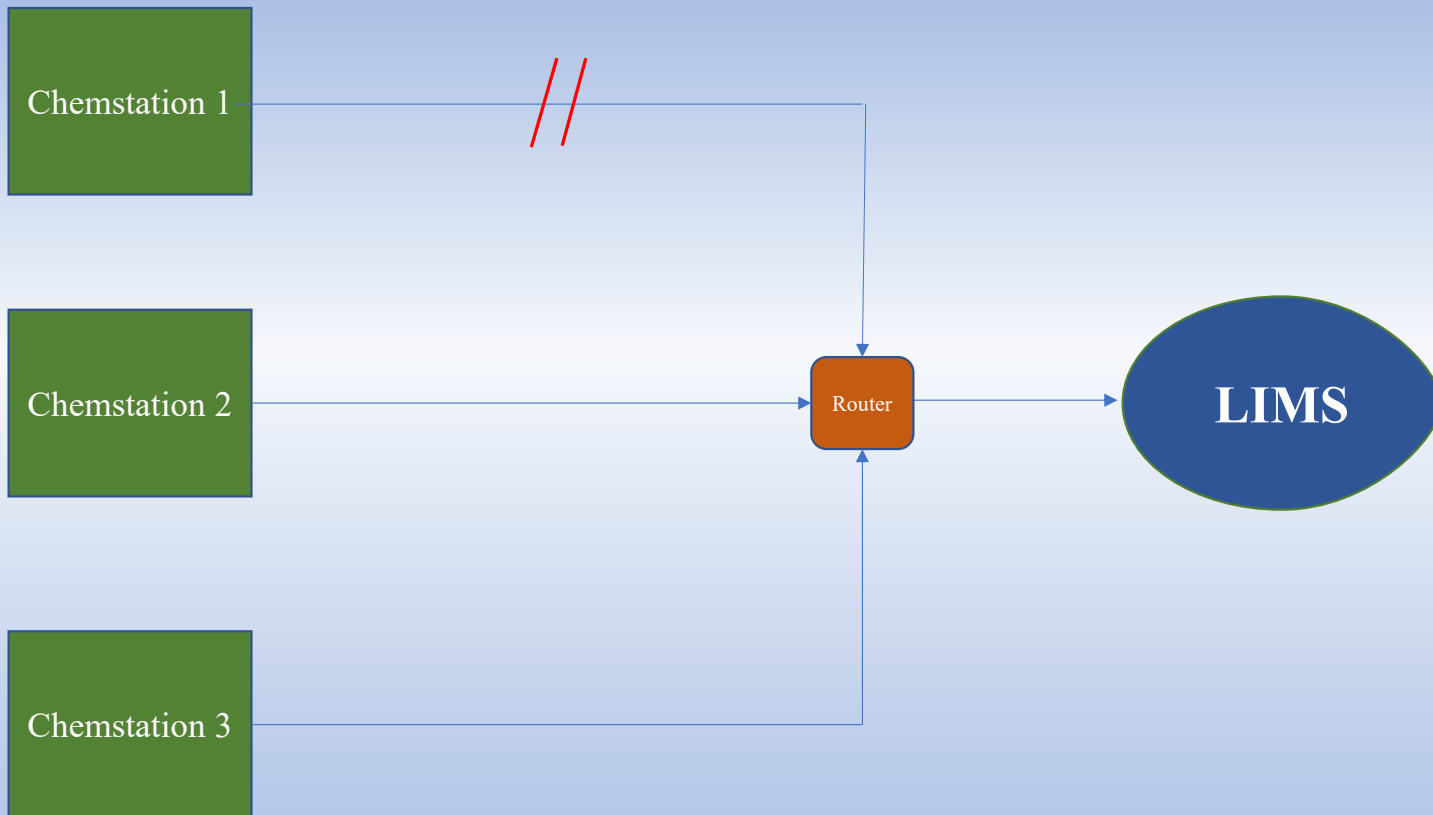
- LIMS with a state-of-the-art operating system
- Implemented SEDD
- Volatile Organics Department with two technicians and three instruments for Trace VOA

# Case Study: Traceability Interrupted, Findings

## Electronic Media Audit:

- Manual Integration status flag (in xml file) should be “yes” or “no”
- Status set to “null”
- Evidence found of improper manual integration in QC samples

# Case Study: Traceability Interrupted!



# Case Study Follow-up

## Traceability of Laboratory Results to

- lab, instrument, analyst, and peer reviewer
- manual integrations during data processing
- instrument performance data
- relevant initial and continuing calibrations
- lab systems integrity
- sample preparation method, materials, reagents, staff, storage
- log-in information and initial storage

# Benefits of Traceability in the Laboratory

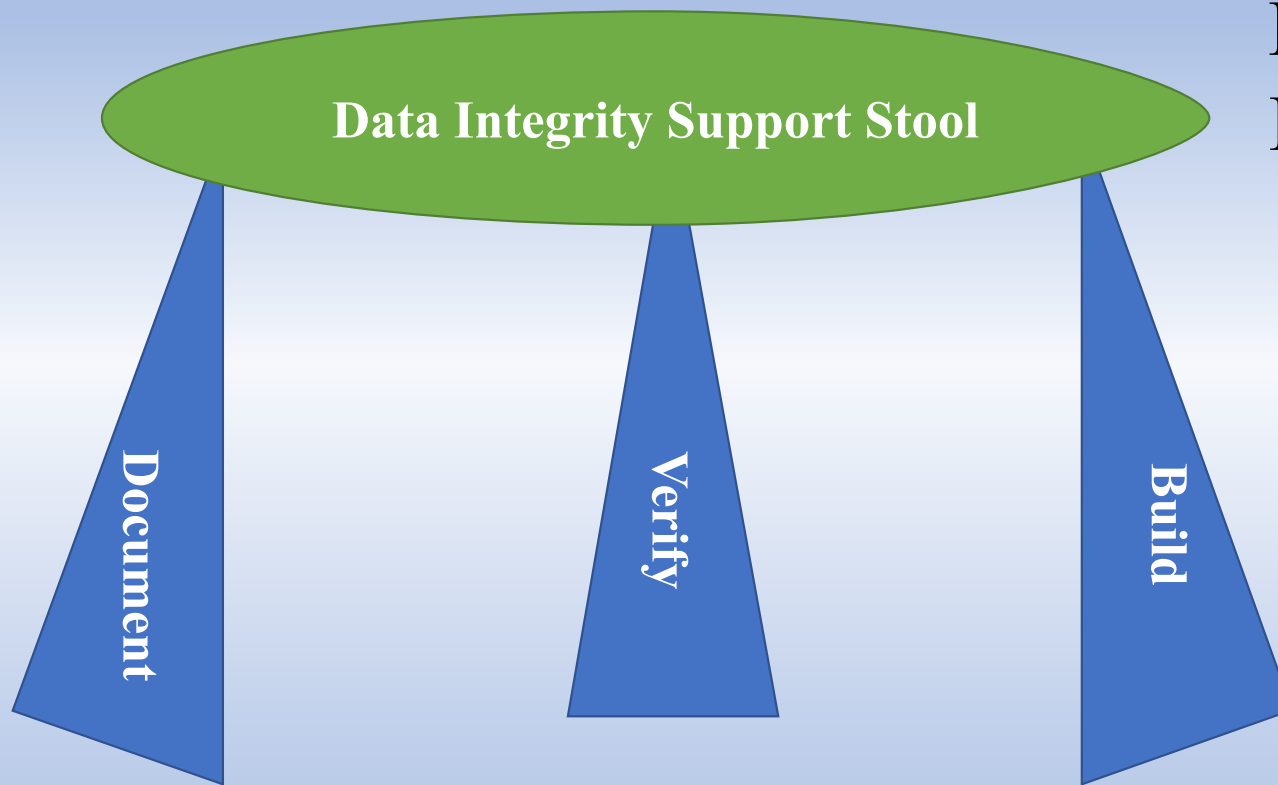
## A More Enhanced Quality System

- Metrologic and Qualitative Traceability
- A what, where, and who perspective on quality
- Integrity of each data set documented and reliable

## Sample Processing Throughout the Laboratory

- Automated tracking of location of each sample
- Time, place, and identity of staff for each step performed
- Less incentive for inappropriate practices

# Supporting Data with Integrity



# Traceability

# Questions?

Thanks for your attention and interest!

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# Traceability, References

1. ISO-9000-2015
2. ANSI / NELAC Standard, 2016 §5.6
3. ISO/IEC Guide 99, §6.5.1, Note 1 of ISO-17025:2017(E)
4. NIST Policy on Metrological Traceability, created 2/12/2010, updated 4/20/2021
5. Keyence, (search for Keyence article on traceability)
6. Senneset, Foras, Fremme; Challenges regarding implementation of electronic chain traceability; British Food Journal, 2007 – emerald.com