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Ensuring Reliable Data

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How Traceability Helps Ensure Reliable Data

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What is Traceability?

- An **unbroken chain** of comparisons or trace back the accuracy of a value to a primary standard, at SI (international standard).

What Items are Traceable?

- Reference Materials
  - Material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (TNI)
- Reference Standards
  - Standard used for the calibration of working measurement standards in a given organization or at a given location. (TNI)
- Reagent
  - A substance used (as in detecting or measuring a component, in preparing a product, because of its chemical or biological activity (Webster)

Should Samples be Traceable?

- There should be an unbroken link from:
  - Sample receipt to;
  - Sample log in to;
  - Sample preparation to;
  - Sample analysis to;
  - Reporting to;
  - Sample disposal.

Why is Traceability Important?

- Any break in the chain can create doubt in the quality of the result.
- Examples
  - Purity of a reagent
  - Mass of a weight
  - Water bath temperature
  - Composition of a calibration standard
  - Temperature of samples when received
  - Degradation of a working standard after preparation
  - Mis-labeling of a sample extract

TNI Requirements for Reference Standards

- Where possible, traceability shall be to national or international standards of measurement or to national or international standard reference materials.
- Used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.
- Calibrated before and after any adjustments.
- Checks needed to maintain confidence in the status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.
- The laboratory shall have procedures for safe handling, transport, storage and use of reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

TNI Requirements for Reference Materials

- Where possible, traceability shall be to national or international standards of measurement or to national or international standard reference materials.
- Internal reference materials shall be checked as far as is technically and economically practicable.
- Checks needed to maintain confidence in the status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.
- The laboratory shall have procedures for safe handling, transport, storage and use of reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

TNI Requirements for Reagents

- For original containers, if an expiration date is provided by the manufacturer or vendor it shall be recorded on the container. If an expiration date is not provided by the manufacturer or vendor it is not required.
- All reagent containers shall bear a unique identifier and expiration date.
- Procedures shall be in place to ensure prepared reagents meet the requirements of the method.
- Reagents shall not be used after their expiration dates unless their reliability is verified by the laboratory.

TNI Requirements for Samples

- Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the customer.
- A system for identifying samples designed and operated so as to ensure that samples cannot be confused physically or when referred to in records.
- Procedures and appropriate facilities for avoiding deterioration, loss or damage to the sample during storage, handling and preparation.
- A documented system for uniquely identifying the sample containers to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.

Documentation Requirements

- Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.
  - The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.
  - Records shall be maintained on standard, reference material, and reagent preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

Examples of Poor Traceability and the Impact

- Citation to TNI standard provided.

Method Validation

- Procedural change to method assumed to be sufficient, due to following procedures in a similar method (change of volumes utilized).
- Data reported out as N.D.
- Comparison to historical data later showed that sample site had previous low-level hits.
- When samples were reanalyzed with unaltered method low-level hits were still present.
- Client had begun shutting down cleanup of site based off N.D. data.

QMS Failure
5.4.5 – Method Validation

Incorrect Temperature

- Microbiology methods for total coliform require incubation at 35°C ±0.5 °C
- The thermometer used for the incubator had a correction factor of +0.8 °C. The correction factor was not taken into account for daily temperature readings.
- Laboratory violated requirement in 40 CFR 141 to follow the method exactly as written.
- Results were likely accurate, but not acceptable.

QMS Failure

5.9.3 – Mandated Methods

5.5.13.1 – Support Equipment

Benzidine? Really?

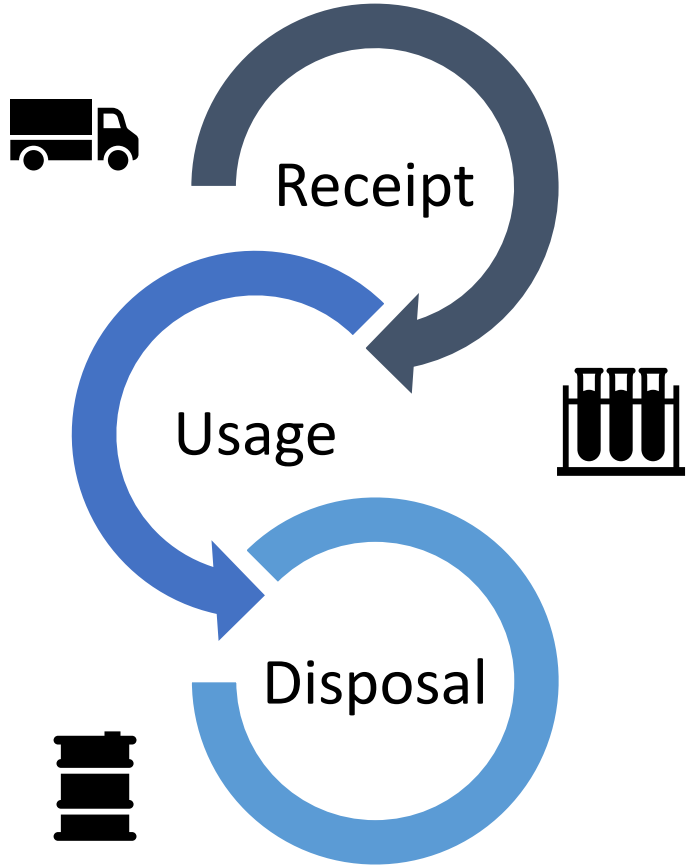
- Laboratory reported benzidine (4,4′-diaminobiphenyl) in 100's of samples from petroleum contaminated sites.
- Identification based on retention time and mass spectrum of benzidine standard purchased from a vendor.
- Upon investigation, standard was actually dibenzothiophene, a compound with the same melting point.

QMS Failures

5.6.3.2 – Reference Materials

1.7.1.1 (Module 4) – Second Source Verification

Recommended Best Practices for Ensuring Traceability of Reference Materials



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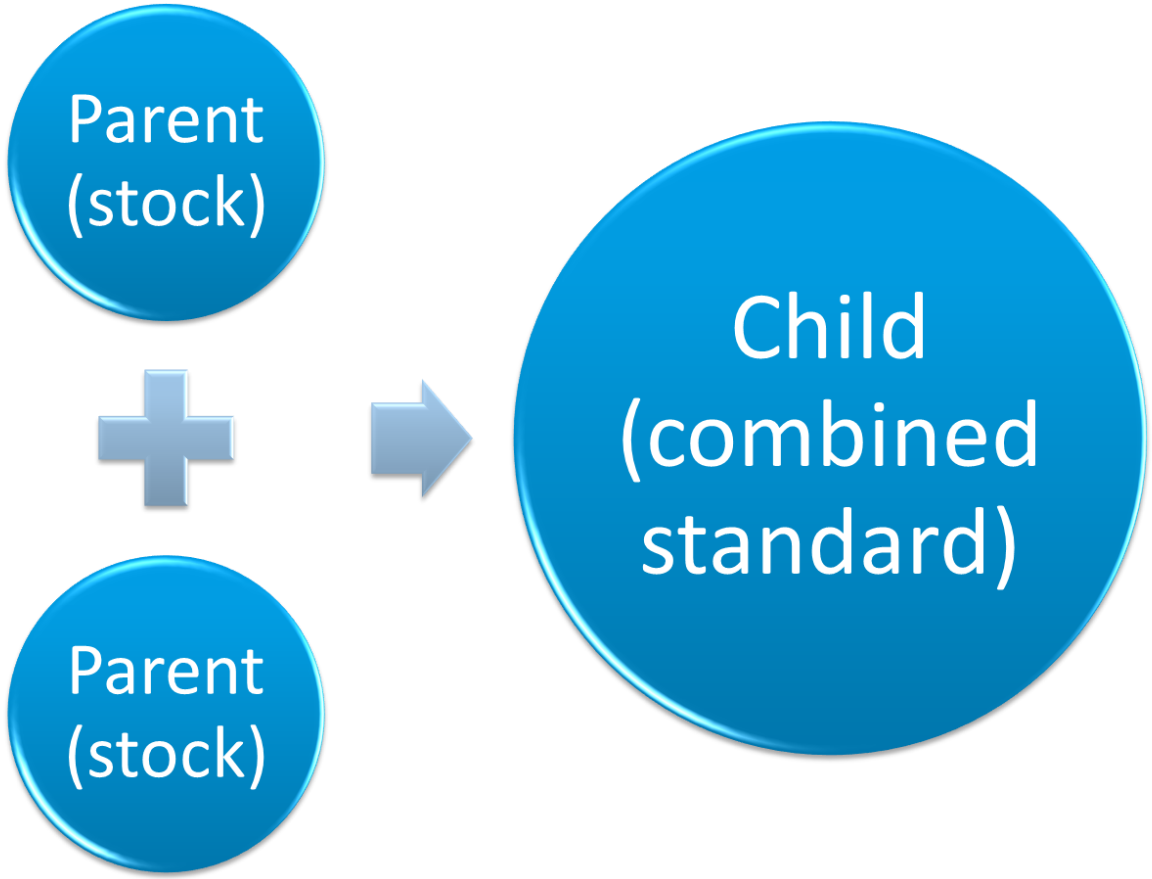
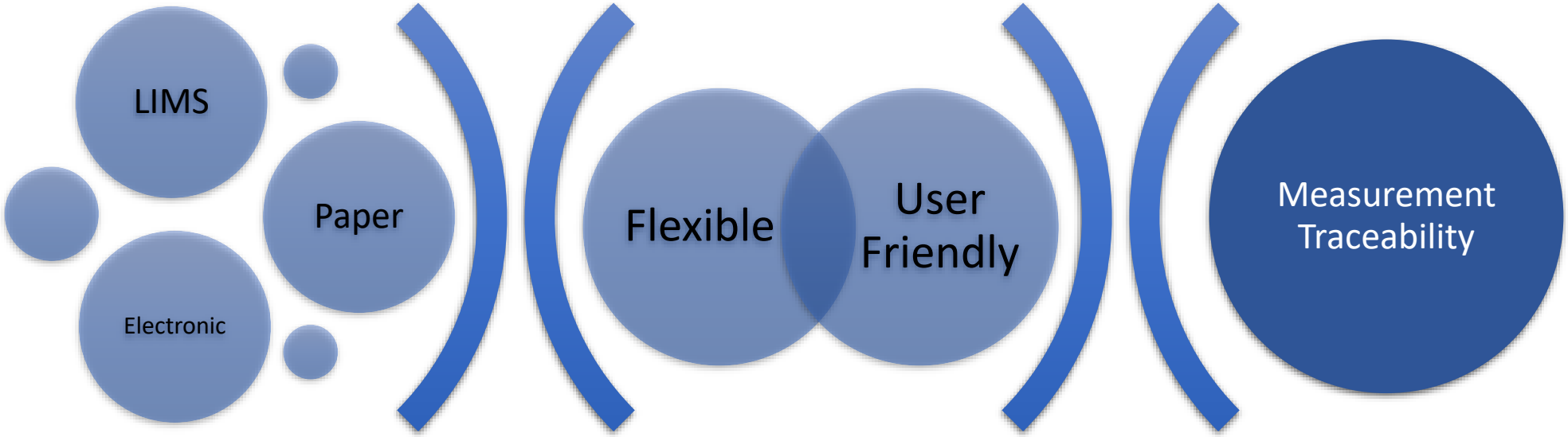
Recommended Best Practices for Ensuring Traceability of Reference Standards

Recommended Best Practices for Ensuring Traceability of Reference Reagents



Recommended Best Practices for Ensuring Traceability of Samples



Closing Thoughts

- A robust traceability effort greatly improves the reliability of the reported result by increasing confidence in the quality of the reference materials, reference standards, and reagents.
- A robust traceability effort ensures an unbroken link from the sample to the reported results.

Data you can trust.

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THANK YOU!

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