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TNI Assessment Forum

Traceability and Root Cause Analysis

Laboratory Perspective - Bob Di Rienzo

Assessor/Data User Perspective - Silky Labie

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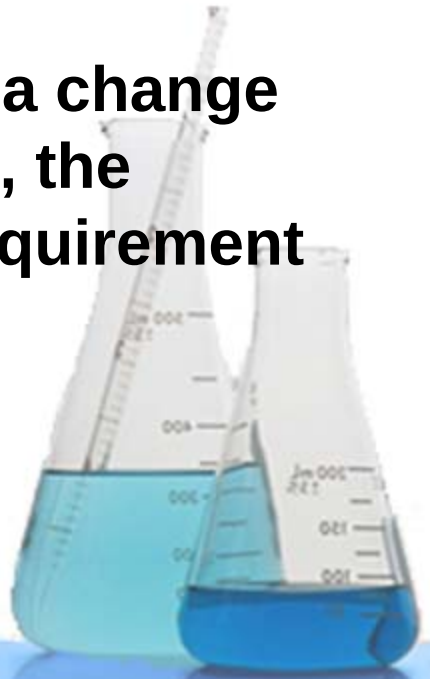

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Objectives

The understanding of Traceability and Root Cause Analysis has different perspectives. We hope to give you a look at these different perspectives in order to facilitate common understanding of these concepts.

Traceability- Laboratory Perspective

Do you have a record of what was used for testing – Includes reagents, solutions, solvents, acids, support equipment, calibration and quality control standards.

Traceability- Laboratory Perspective

- The TNI standard addresses records for:
  - Reference Standards (V1M2 5.6.3.1, 5.6.4.1a, 5.6.4.2)
  - Reference Materials (VIM2 5.6.3.2, 5.6.4.1b, 5.6.4.2)
  - Reagents (Solutions, Reagents, Solvents, Acids) (V1M2 5.6.4.2, 4.13.3.f) IX and XI)
  - Support Equipment (V1M2 5.5.13)

Traceability- Laboratory Perspective

- *Reference Standards*
  - *Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.*
  - *Where commercially available, this traceability shall be to a national standard of measurement.*

Traceability- Laboratory Perspective

- *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.*

Traceability- Laboratory Perspective

- Reagents (Solutions, Reagents, Solvents, Acids)
  - 5.6.4.2 Manufacturer, COA, Purity, Date of Receipt, Storage, Expiration, Preparation of…
  - 4.13.3 f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory.
    - standard and reagent origin, receipt, preparation, and use;

Traceability- Laboratory Perspective

- *Support Equipment (V1M2 5.5.13.1)*
  - This Standard applies to all devices…. if quantitative results are dependent on their accuracy…..
    - All Support Equipment Maintained
    - All Support Equipment Calibrated or Verified Yearly
    - Raw Data Records
    - Day of Use Verification
    - Volumetric Dispensing Calibrated or Verified Quarterly

Traceability – Assessor/Data User

- Auditor
  - Can I establish, from records, how a reported result was determined?
- Data User
  - When questioned about my results, can the laboratory provide me with information concerning the generation of the results?

Traceability – Assessor/Data User

- Traceability does not necessarily mean where the sample was 24/7, but
- **How** the sample was processed or handled
- **Who** was responsible

Traceability – Assessor/Data User

- Cradle to Grave Concept – Sample Receipt to Sample Disposal/Depletion
- Important to Have Dates (and times) of Each Event.

Traceability – Assessor/Data User

- Sample Receipt
  - Condition
  - ID & Source
  - Requested Tests
  - Holding Time Constraints

Traceability – Assessor/Data User

- Sample Storage
- Sample Prep
  - How much
  - Procedure
  - Ending Volume

Temperature

Reagents → Preparation, Lot Numbers, Expiration

Equipment → Calibration, Temperature, Sterility, ID

Traceability – Assessor/Data User

- Analysis
  - Instrument → ID, Conditions, Temperature, Column
  - Calibration → Standards → Preparation, Lot Numbers, Expiration
  - QC – LCS, Method Blank, Spikes, Continuing Calibration

Traceability – Assessor/Data User

- Sample Assessment & Reporting
  - Reviewers – What Was Reviewed?
  - Who Authorized Report?
  - How was the Report Issued?

Traceability – Assessor/Data User

- Sample Disposal
  - Authorization
  - Method

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Discussion Time

Root Cause - Laboratory

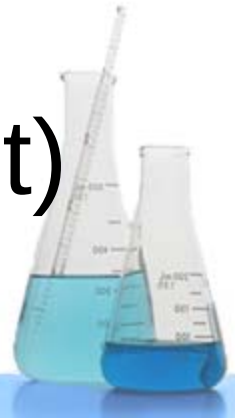
WHY?

Root Cause - Laboratory

- Root Cause is why something happened.
- How and What are symptoms.
- Root Cause can be simple or can be complex depending on the process and situation.

Root Cause - Laboratory

- Simple to Complex
  - Mis-spiked sample (1 person/1 event)
  - Mis-spiked sample (2 people/one area/2 events)
  - Mis-spiked sample (Many people/all areas/routine event)



Root Cause - Laboratory

- Techniques that are useful
  - Five Why
  - Statistical Process Control
  - Quality Circles
    - Pareto, Fishbone, etc…

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Root Cause - Laboratory

- Proper Root Cause analysis is the single biggest program in your laboratory to improve your processes.

Root Cause - Assessor/Data User

- Have you ever observed
  - A repeat deficiency
  - The same deficiency, different test?
- Have you ever received reports with:
  - A recurring QC failure on the same test
  - The same QC failure on multiple tests?

Root Cause - Assessor/Data User

- Assessor
  - The Lab's MS failed
- Data User
  - What Else is Wrong?
- Lab
  - Fixed the problem – here's our corrective measure
- Bottom Line – There may be other problems

Root Cause - Assessor/Data User

- Lab Did not Find the Root Cause
  - Stopped at symptoms rather than going on to lower level root causes.
  - Lack of support to help determine the underlying cause
  - Tendency to isolate a single root cause, when there could be many

Root Cause - Assessor/Data User

- Root Cause Analysis means getting to the bottom of the problem – The **Initiating Cause** of a Causal Chain
- 5 Whys

Root Cause - Assessor/Data User

- Root Cause Process also
  - Helps prevent similar problems from occurring – Lessons Learned
  - Promotes continuous improvement
- Win-Win Situation
  - Lab Fixes the Problem –
  - Assessor Finds no Deficiencies
  - Data user gains confidence.

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Discussion Time

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Thank You