Sufficient Documentation to Reconstruct the Results is a Key Component of Reliable Data

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Laboratory Products

- Level 1 Report
  - Basically, just the data
- Level 2 Report
  - The data with some quality control information
- Level 3 Report
  - Usually, a customized report
  - Data with more detailed QC information and summary
  - Calibration or other requested materials
- Level 4 Report
  - Full data package
  - “CLP” like report
  - Frequently customer defined

Data/Report Reconstruction?

- You never know when it will be required.
- You may not know why it is required.
- Can be required on any project or program regardless of what reporting level was originally provided.
- Understood that not all "requirements" of Level 4 reporting may be able to be produced. Generally, not a defensibility concern unless they were required by SOP or QSM
  - Examples: GPC performance check, Florisil checks, TIC, etc.

Why are laboratories asked for Level 4 Reports or Reconstruction of Data for Evaluation?

- Contract Compliance
- Regulatory Compliance
- Dispute Resolution
- Pending Litigation or Fear of Future Litigation

The Typical Level 4 Report

- Sample ID Summary
- Analytical Results
- Surrogate Recovery
- Matrix Spike (MS)/MS Duplicate Summary
- Laboratory Control Samples (LCS)/LCS Duplicate Summary
- Method Blank Summary
- QC Batch Summary
- Instrument Performance Check
- Internal Standard Area and Retention Time Summary
- Calibration Data, including Initial, Second Source, and Continuing
- Holding Time Summary
- Linear Range Standard Summary
- Interference Check Samples
- Tuning and Response Factor Summary
- Spike Sample Summary
- Serial Dilution
- Raw Data

Volatile Data Review

- Preservation and Holding Times
- Gas Chromatograph/Mass Spectrometer Instrument Performance Check
- Calibration
- Initial Calibration Verification
- Continuing Calibration Verification
- Blanks
- Surrogate
- Matrix Spike/Matrix Spike Duplicate
- Internal Standard
- Target Analyte Identification
- Target Analyte Quantitation
- Tentatively Identified Compounds

Semivolatiles Data Review

- Preservation and Holding Times
- Gas Chromatograph/Mass Spectrometer Instrument Performance Check
- Initial Calibration
- Initial Calibration Verification
- Continuing Calibration Verification
- Blanks
- Surrogate
- Matrix Spike/Matrix Spike Duplicate
- Laboratory Control Sample
- Gel Permeation Chromatography Performance Check
- Internal Standard
- Target Analyte Identification
- Target Analyte Quantitation
- Tentatively Identified Compounds

Pesticides Data Review

- Preservation and Holding Times
- Gas Chromatograph/Electron Capture Detector Instrument Performance Check
- Initial Calibration
- Continuing Calibration Verification
- Blanks
- Surrogate
- Matrix Spike/Matrix Spike Duplicate
- Laboratory Control Sample
- Florisil Cartridge Performance Check
- Gel Permeation Chromatography Performance Check
- Target Analyte Identification
- Gas Chromatograph/Mass Spectrometer Confirmation
- Target Analyte Quantitation

Aroclor Data Review

- Preservation and Holding Times
- Initial Calibration
- Continuing Calibration Verification
- Blanks
- Surrogate
- Matrix Spike/Matrix Spike Duplicate
- Laboratory Control Sample
- Gel Permeation Chromatography Performance Check
- Target Analyte Identification
- Gas Chromatograph/Mass Spectrometer Confirmation
- Target Analyte Quantitation

Inorganic Data Review (ICP/OES-AES)

- Preservation and Holding Times
- Calibration
- Blanks Interference Check Sample
- Laboratory Control Sample
- Duplicate Sample Analysis.
- Spike Sample Analysis
- Serial Dilution
- Target Analyte Quantitation

Inorganic Data Review (ICP-MS)

- Preservation and Holding Times
- Tune Analysis
- Calibration
- Blanks
- Interference Check Sample
- Laboratory Control Sample
- Duplicate Sample Analysis
- Spike Sample Analysis
- Serial Dilution
- Internal Standards
- Target Analyte Quantitation

Inorganic Data Review (Mercury, Anions and Cyanide)

- Preservation and Holding Times
- Calibration
- Blanks
- Laboratory Control Sample
- Duplicate Sample Analysis
- Spike Sample Analysis
- Target Analyte Quantitation

EPA National Functional Guidelines

- NATIONAL FUNCTIONAL GUIDELINES
  for Inorganic Superfund Methods Data Review
  - OLEM 9240.1-66 EPA 542-R-20-006 November 2020

- NATIONALFUNCTIONALGUIDELINES
  for Organic Superfund Methods Data Review
  - OLEM 9240.0-51 EPA 540-R-20-005 November 2020

Some Difficult Experiences

In almost 50 years in the analytical environmental services business as a provider of testing data and as a consultant, I have experienced, despite best efforts of laboratories to the contrary, serious “pitfalls” that have significantly jeopardized testing data.

Many of the Pitfalls

Some of the more frequent and yet difficult to defend situations are failures due to inadequate, inappropriate or the lack of any documentation of a non-compliance, or quality control exceedance!

So Let's Walk through the Lab

- Where does the process actually begin?
- Does the process begin in receiving?
- Not really! Some avoidable pitfalls can be seen in proper documentation in the field sampling efforts.
- Even before you send out the sampling related supplies, has the project been properly initiated, have all the client requirements been understood and communicated. Have any discrepancies been documented?

Project Management

- Proper initiation of the project
- Correct parameter list
  - Special/added analytes
- Known detection limits
- Special quality assurance criteria, if any
- Reporting requirements
- Due dates/special timing requirements
- Data retention

Sample Management

- Sample collection and receipt information
  - Proper chain of custody
  - Shipping issues
- Temperature
- Appropriate bottles and preservation
- Appropriate filtration, if required
- Sample screening , if required
- Sample storage and management during analysis
- Appropriate sample/extract/digestate disposal and/or archiving

Frequent Analytical Failures in Documentation

- Preservation and Holding Times
- Sample/Extract Storage and Handling
- Calibration Deficiencies
  - Range
  - Standard (number and/or removal)
  - Marginal exceedances
  - CCV frequency and acceptance criteria
- Blank Results and Sequence of Analysis
- Manual Integrations

Frequent Analytical Failures in Documentation

- Internal Standards and Surrogate Recoveries
- Dilutions and Data Reporting
- Analyte Identification
  - Aroclors
  - Coeluting compounds
- Laboratory Control Samples/2nd Sources
- Interference Check Samples

Frequent Difficulties in Defensibility

- Procedural Non-Compliance
  - Methods
  - Contract
  - Laboratory Requirements

- Failure to Provide Adequate Documentation
  - Knowingly or unknowingly
  - Any step in the entire process
  - Failures in notification

Providing Data Defensibility

- Ensure you adhere to every step in the method!
  - Method Compliance
- Ensure you adhere to all laboratory defined requirements
  - Compliance with your Quality Systems Manual
- Embrace the fact that many methods have different requirements
  - "One size doesn't fit all"

Bottom Line

- In the best cases defending your data is a stressful process
- Data is rarely perfect
- Must be of known and documented quality
- Lawyers are intelligent and savvy
- Lawyers generally know the methods and even your laboratory processes better than most analysts
- One of the simplest ways to see your data discredited is to realize documentation errors and/or deficiencies

Providing Data Defensibility

DOCUMENT

DOCUMENT

DOCUMENT

DOCUMENT

Reliable Data?

While method compliance and a robust Quality Management System can provide for reliable data of known and documented quality, there are numerous pitfalls that can still “sneak” into the process and put data defensibility into question.

Legal Defensibility is a Challenge

- As we all know, methods are complex, inconsistent in regard to control requirements and acceptance criteria
- Many methods have requirements and process steps beyond those normally seen
- Laboratory specific requirements can often add additional requirements.
- Remaining compliant requires serious diligence

Legal Defensibility

- Experienced environmental lawyers working on behalf of their clients and examining our data are:
  - Intelligent,
  - Intuitive,
  - Perceptive
  - Knowledgeable
    - Frequently an effective lawyer will know the requirements of the method or even a lab quality manual better than the analysts

Legal Defensibility

- Even with most diligent and robust systems, data is rarely without some quality issues or procedural exceptions.
- But imperfect data can still be defensible
- All exceptions, at each and every step in the entire process, must be fully and accurately documented.

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Conclusions

- The abstract for this presentation said I would “describe all the documentation required to ensure that the results can be accepted by the courts”.
- The complexity of what we do in the laboratory prevents me in the time allotted to “describe all the documentation”.
- My recommendation:

Document any and all, minor or major deviations or inconsistencies with or from method requirements, accreditation requirements, or requirements in the laboratory's SOPs and/or QSM requirements

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Document everything regardless of how trivial it may seem at the time!

Thank you!

Questions

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