IPP ANNUAL SEMINAR 2016

LEGALLY DEFENSIBLE LABORATORY DATA

EAGLE EYE BANQUET FACILITY

EAST LANSING, MICHIGAN
OCTOBER 6, 2016

WHY DEFENSIBLE DATA IMPORTANT?

Laws and Regs Require

Michigan Part 23 Rules

Sample taking/analysis shall be performed with sufficient care to produce evidence admissible in enforcement proceedings or in judicial actions. (R 323.2306(c)(vi).)

WHY DEFENSIBLE DATA IMPORTANT?

Part 23 Rules require all monitoring and analysis to comply with the procedures established in 40 CFR Part 136 or other test procedures approved by EPA.

WHY DEFENSIBLE DATA IMPORTANT?

Integrity of IPP Requires.

If data ≠ admissible evidence, enforcement action thrown out of court.

If date ≠ defensible, lose credibility with users/regulators.

WHAT IS LEGALLY DEFENSIBLE DATA?

Bright line test? Sorry, no.

What is sufficient varies from case to case.

Depends on what trying to prove.

Data good for one purpose, not necessarily good for another.

WHAT IS LEGALLY DEFENSIBLE DATA?

US EPA Guidance:

Follows graded approach.

Level of detail and stringency of data verification and validation efforts needed will depend on the needs of the sampling project and program in question.

WHAT IS LEGALLY DEFENSIBLE DATA?

Bottom line:

Data sought to be introduced in court is "evidence" subject to rules of evidence established by law.

For evidence to be admitted, must be relevant, authentic, reliable, and trustworthy.

Can the evidence properly be applied to the facts of the case?

DETERMINING DEFENSIBILITY.

Is the quality of the data suitable for the purpose?

Documentation available to verify the suitability?

DETERMINING DEFENSIBILITY.

Is the data technically valid?

Analytical procedures used adequate to identify/measure pollutants of interest with necessary accuracy and precision?

DETERMINING DEFENSIBILITY.

Procedures: sample collection; transport; storage; preservation; analytical method.

Conducted by personnel with sufficient expertise/experience?

Technically invalid?: e.g., could not see POI; false negative results; not required level of precise/accuracy.

ATTRIBUTES OF SUITABLE DATA QUALITY

The purposes of the measurement are clearly stated, including:

Chemical compounds to be analyzed;

Sample matrices to be submitted;

Intended use of the data; and

Associated detection limits, accuracy, and precision required.

ATTRIBUTES OF SUITABLE DATA QUALITY

Appropriate data management is used, such as sample tracking (chain-of-custody) and associated activities that guarantee the laboratory results are associated with the correct sample.

ATTRIBUTES OF SUITABLE DATA QUALITY

A technically valid sampling plan is used that is correctly implemented to properly collect, identify, preserve, store and prepare samples for analysis.

The chosen method of analysis has sufficient selectivity, detection limits, accuracy and precision to be technically valid.

ATTRIBUTES OF SUITABLE DATA QUALITY

The quality control samples sufficient to allow the necessary statements of accuracy, precision, and detection limits. These include blanks (field, trip, laboratory, reagent), duplicate measurements, matrix spikes, laboratory control samples, and performance evaluation samples.

ATTRIBUTES OF SUITABLE DATA QUALITY

Clearly stated acceptable limits for quality control samples such as allowable blank contamination; precision of duplicate samples; and accuracy of matrix spikes, performance evaluation samples and laboratory control samples. Calibration frequency and linearity may also be included.

ATTRIBUTES OF SUITABLE DATA QUALITY

Documentation is sufficient to allow third party evaluator to verify the suitability of the sample data.

ATTRIBUTES OF SUITABLE DATA QUALITY

Routine sampling using known methods for sampling/analysis (EPA or ASTM)

vs.

Non-standard situations where standard methods not applicable or expert testimony may be required.

CRITERIA FOR NON-STANDARD SITUATIONS

Criteria developed by courts to determine whether data evidence is admissible.

Daubert v. Merrell-Dow Pharmaceuticals, 509 US 597 (1993).

CRITERIA FOR NON-STANDARD SITUATIONS

Daubert Factors:

Does the theory or technique involve testable hypotheses?

Has the theory or technique been subject to peer review and publication?

Are there known or potential error rates and are there standards controlling the technique's operation?

Is the method or technique generally accepted in the scientific community?

CRITERIA FOR NON-STANDARD SITUATIONS

<u>Additional Criteria Developed By Courts</u>:

Planning criteria

Implementation criteria

Result and assessment criteria

Sample authenticity criteria

Data integrity criteria

(See handout for additional details.)

FACTORS WEAKENING DEFENSIBILITY

The more deviation from specific applicable procedures and methods or in-house SOPs, the resulting data will be less legally defensible.

In all cases, it will be a question of degree and depend on goal of data sampling/analysis.

FACTORS WEAKENING DEFENSIBILITY

Common data quality failures:

Holding time exceedences; calibration issues: retention time issues; issues regarding the accuracy and precision of spiked quality control samples; mislabeled sample containers; documentation problems (incomplete or incorrect); and data that cannot be verified.

STRATEGIES WHERE DATA QUESTIONABLE

If data problems pervasive: forgo enforcement until resampling (until you can "get it right").

If only some samples bad, or deviations are not substantial/significant, evaluate whether remaining samples are sufficient and effect of deviations on overall data quality.

STRATEGIES WHERE DATA QUESTIONABLE

Where some data bad and other data is just fine, consider just dropping problematical violations and proceed with violations where you know your data is good.

Involves exercise of professional judgment.

QUESTIONS?

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