

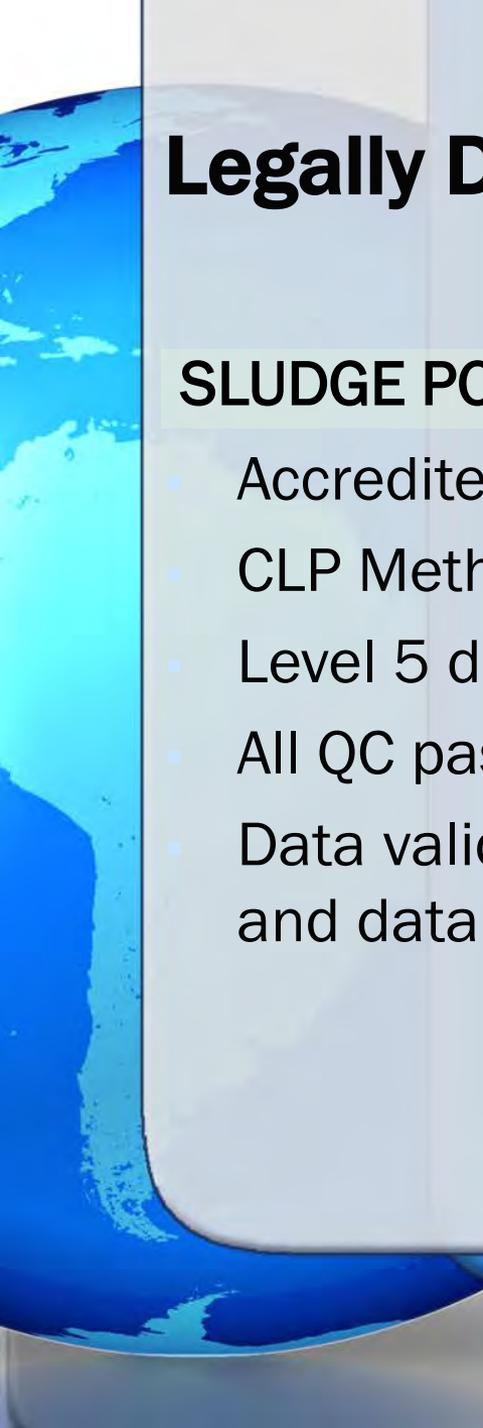
Ensuring Legal Standing

Legally defensible data
is an oxymoron.



Jerry Parr

Catalyst Information Resources



Legally Defensible?

SLUDGE POND REMEDIATION

- Accredited lab
- CLP Method used
- Level 5 data package
- All QC passed
- Data validation performed and data validated

DUMPSTER SAMPLE

- No sampling plan
- Cross contamination
- Wrong method used
- No LCS
- No MS
- No data validation
- Holding times exceeded

The Sludge Pond Sample

- Sent in for soils analysis
- Sample had 2 % solids
 - Representative 30 g sample?
- GPC correction factor not applied
- Results corrected to dry weight with multiplier of 100
- MS performed on another unrelated sample in the batch
- Results made no logical sense



The Dumpster Sample

People vs Hale (1994)

- Dumpster filled with sawdust mixed with illegal waste disposal
- Samples contained 1,1,1-TCA in concentrations ranging from 2 to 15%
- Method 8015 used instead of 8010
- Failures were harmless.

“SW-846 is not the name of some new gasoline additive”

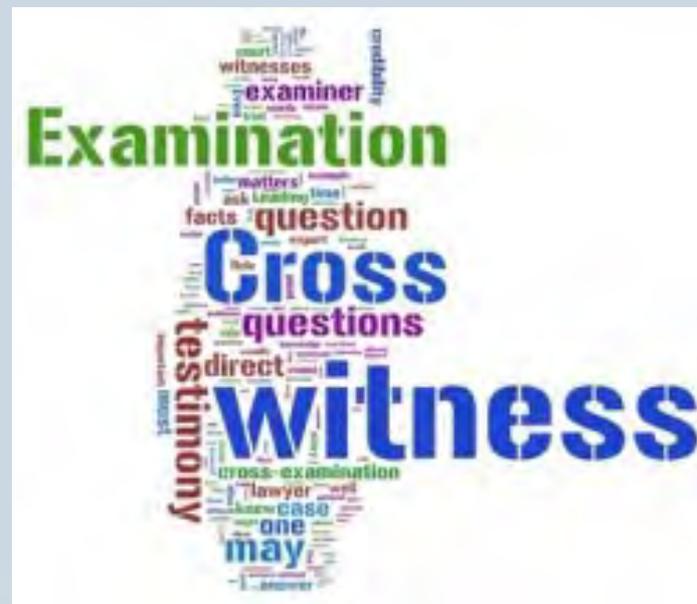
The Legal Process

- Qualified expert may provide testimony
- Judge may or may not allow testimony to be admitted as evidence
- Jury decides merits of testimony

Jurors may be swayed by skill of lawyers or experts and thus Judges do not like expert evidence to be provided.

Legal Precedence for Scientific Data

- Federal Rules of Evidence
- Case Law
- Four Supreme Court Decisions



Federal Rules of Evidence

Rule 702 Testimony by Experts (Reliable)

- If scientific knowledge will help understand a fact, a witness qualified as an expert may testify

Rule 703 Basis of Testimony (Defensible)

- Data is the type that may be reasonably relied upon by experts

Rule 901 Authenticating Evidence

- Evidence sufficient to support a finding that the item is what the proponent claims it is.

Frye vs. United States (1923)

Scientific evidence “must be sufficiently established to have gained general acceptance in the particular field in which it belongs.”



“Unlike a jury verdict, scientific consensus is not arrived at by a vote.”

Paoli Railroad Yard PCB Litigation (1992)

Data Reliability is Important (so are SOPs)

- No written SOP
- Blank results > sample results
- MS 1000 X sample concentrations
- Sample results below low standard

“every reliable laboratory has a written protocol, particularly with regard to a test as complex as congener specific analysis so that a test is performed the same way each time and so that outside scientists can review the results.”

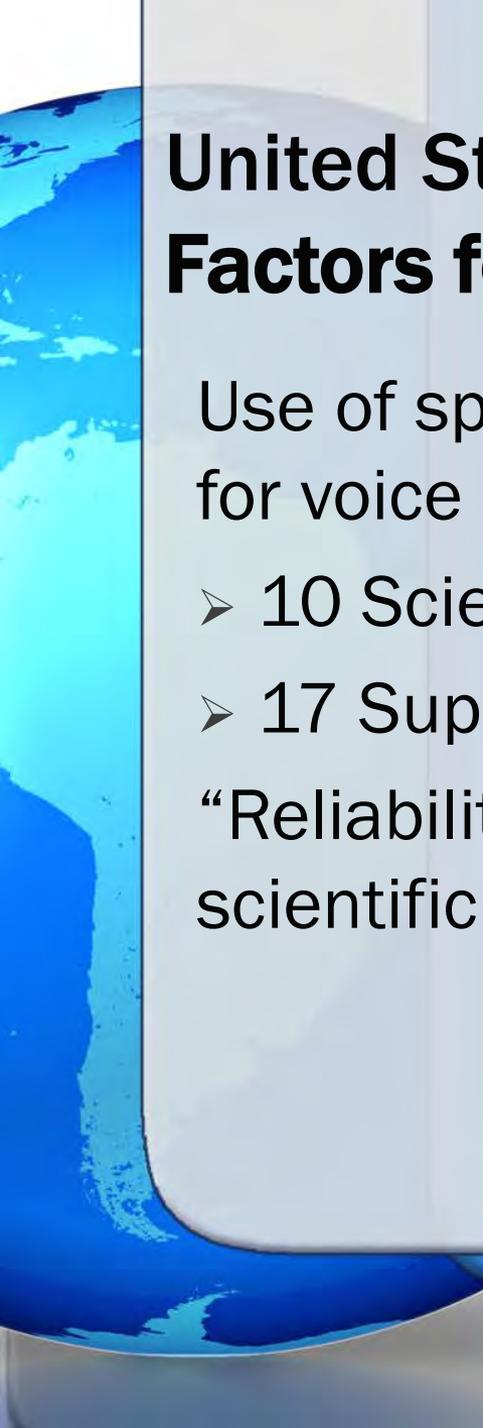
Data was **not** admissible

People vs Mobil Oil (1983)

Method Details Are Important

- ASTM Method D323-58 for Reid vapor pressure
- “Gross errors can be obtained ... if the prescribed procedure is not followed carefully.”
- Plaintiff had deviated from the procedure
- Judge ruled deviations were “substantial and meaningful”

Data was **not** admissible and judge ruled for the defendant



United States vs. Williams (1978)

Factors for Data Reliability

Use of spectrographic information as evidence for voice recognition

- 10 Scientists opposed test
- 17 Supported

“Reliability cannot rely solely on counting scientific noses”

“all of the safeguards designed to assure reliability, and to prevent a misleading of the jury, were employed.”

Williams Reliability Factors

- Potential rate of error
- Existence and maintenance of standards
- Accepted industry practice
- Certification
- Care and concern over use
- Potential for abuse
- Fail-safe characteristics

Daubert vs. Merrell Dow Pharmaceuticals (1993)

Federal Rules of Evidence, not Frye, provide the standard for admitting expert scientific testimony

“The most influential Supreme Court case you’ve never heard of.”



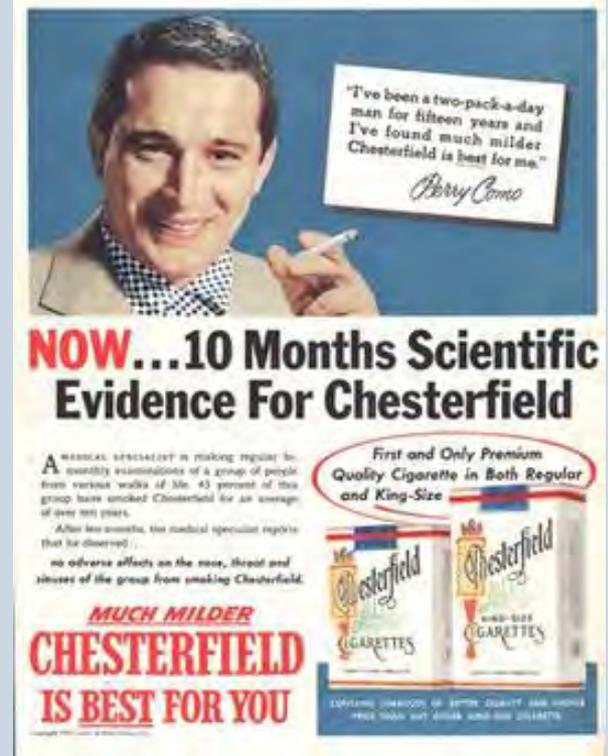
Daubert Scientific Validity Principles

- Whether a technique has been tested
- Whether the technique has been accepted within the scientific community*
- Whether there is a high known or potential rate of error
- Whether there are professional standards controlling the technique's operation

*a factor to be considered but not dispositive

Principle 1: Reliability of the Technique

- Proponent must bear the burden of demonstrating the technique's capacity to produce a reliable result.
 - Published method performance data
 - Method validation studies
 - On-going QC



"I've been a two-pack-a-day man for fifteen years and I've found much milder Chesterfield is best for me."
Berry Como

NOW...10 Months Scientific Evidence For Chesterfield

A MEDICAL SPECIALIST in making regular bi-monthly examinations of a group of people from various walks of life. 43 percent of this group have smoked Chesterfield for an average of over 100 years.

After ten months, the medical specialist reports that he observed:

no adverse effects on the nose, throat and sinuses of the group from smoking Chesterfield.

MUCH Milder
CHESTERFIELD
IS BEST FOR YOU

First and Only Premium Quality Cigarette in Both Regular and King-Size

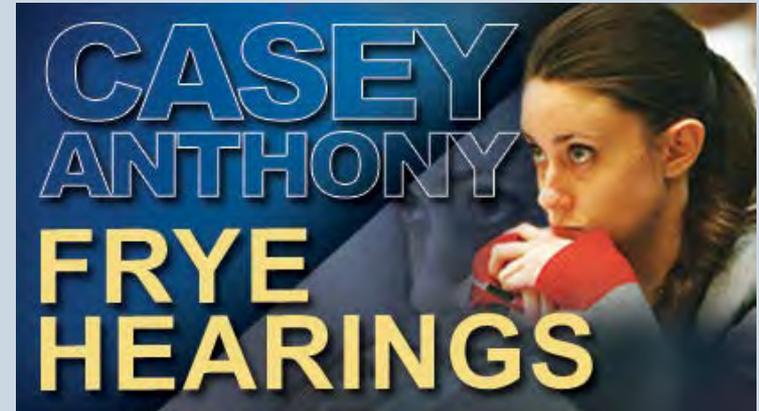
CHESTERFIELD CIGARETTES

CHESTERFIELD KING-SIZE CIGARETTES

CONTAINS 20 CIGARETTES OR 10 KING-SIZE CIGARETTES. PRICE 100% BUY 100% AND 100% CIGARETTES.

Principle 2: General Acceptance

1. Reference Methods
 - Standard Methods
 - ASTM
 - EPA
2. Literature
3. Conference Presentations
4. Vendor Applications



Principle 3: Known Error Rate

- Results from PT samples
- QC samples
- Reliable LOD and LOQ



Principle 4: Professional Standards

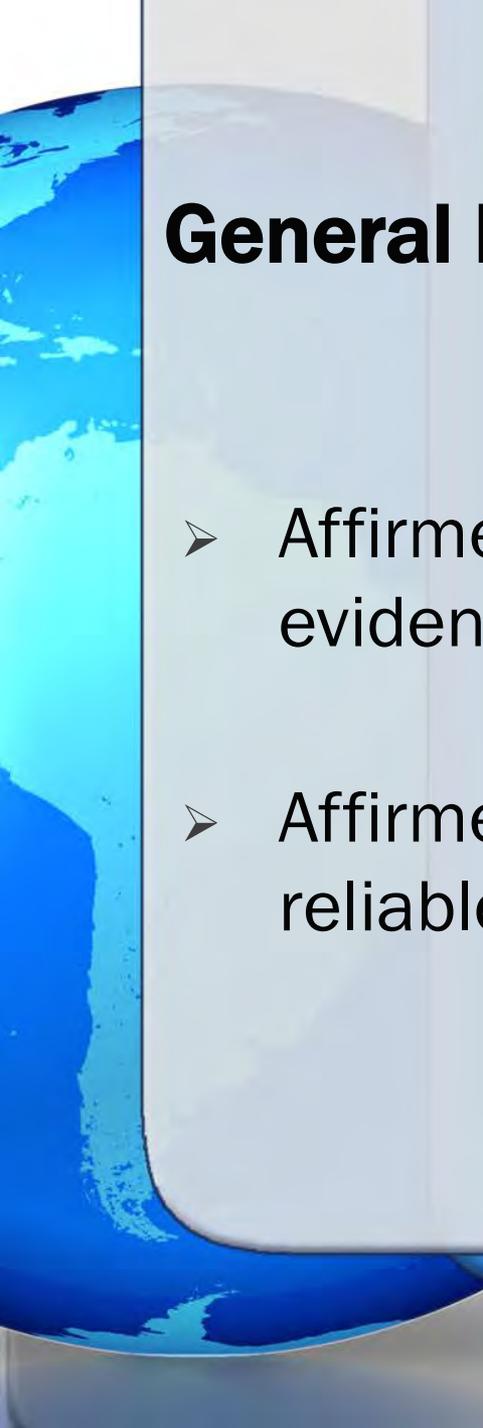
- The TNI Laboratory Standard



Daubert: Validity vs. Reliability

- Validity (does the principle support what it purports to show?)
- Reliability (does application of the principle produce consistent results?)
 - ❑ “In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.”

Affirms importance of method validation as prerequisite for reliability



General Electric vs. Joiner (1997)

- Affirmed gatekeeper role of the judge in screening evidence
- Affirmed that judge is to decide if evidence is reliable

Kumho Tire vs. Carmichael (1999)

- Daubert factors apply to engineers and other experts
- Judge may consider one or more of the specific Daubert factors.
- Daubert factors do not constitute a definitive checklist
- Highest weight to Daubert factors that are reasonable measures of reliability

Impact of Daubert

- Less scientific testimony being admitted
- Some “science” now considered less reliable
 - Many forensic tests, e.g.,
 - Ballistics
 - Expert handwriting
 - Hair analysis
 - Social sciences, e.g.,
 - Battered woman syndrome
 - Psychological profiling

Nearly one in five wrongful convictions overturned through DNA testing involved faulty hair analysis.

What is our “Hair” Test?

- Method 5030A (low-level volatiles in soil)
 - Published EPA method
 - QC passes
 - Data validation passes
 - Method super-ceded by 5030B in 1996
- Results widely recognized as meaningless
- Then why do you still run this test?
- Would this data be admissible?

MDL a close
second

Other Contenders for “Junk Science”

- “Total” cyanide
- Correlation coefficient
- Matrix Spikes (unless done on every sample)
- Hexachlorocyclopentadiene
- Holding times
- ????

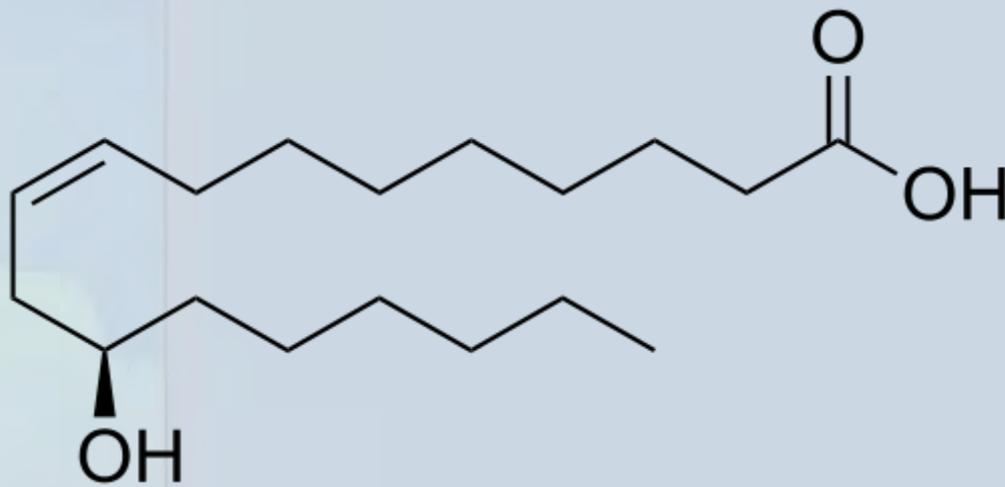
For 40 years or more, many laboratory practices met the Frye definition of reliability...
general acceptance

Admissibility of DNA Results

- Documented quality system
- Minimum education and experience
- Validated procedure
- PT sample analysis
- Sample handled properly
- Analysis conducted properly

As established in *Quality Assurance Standards for Forensic DNA Testing*

Case Study: The Motorcycle Wreck



Vegetable oils, due to their good lubricity and biodegradability are attractive alternatives to petroleum-derived lubricants. Castor oil has better low temperature viscosity properties and high temperature lubrication than most vegetable oils, making it useful as a lubricant in race car engines.

Case Study: Documentation

- Deposition stage
- 1000 plus pages of 8140 data
- Great chromatograms
- QC passed
- Probably very good data
- Could not find link to initial calibration
- Data was rejected in its entirety

Documentation Trail

- All raw data, including QC and calibration
- Method SOP in effect at the time of analysis
- QC limits in effect at the time of analysis
- SOPs for
 - **sample tracking,**
 - subsampling,
 - spiking, and
 - sample storage.

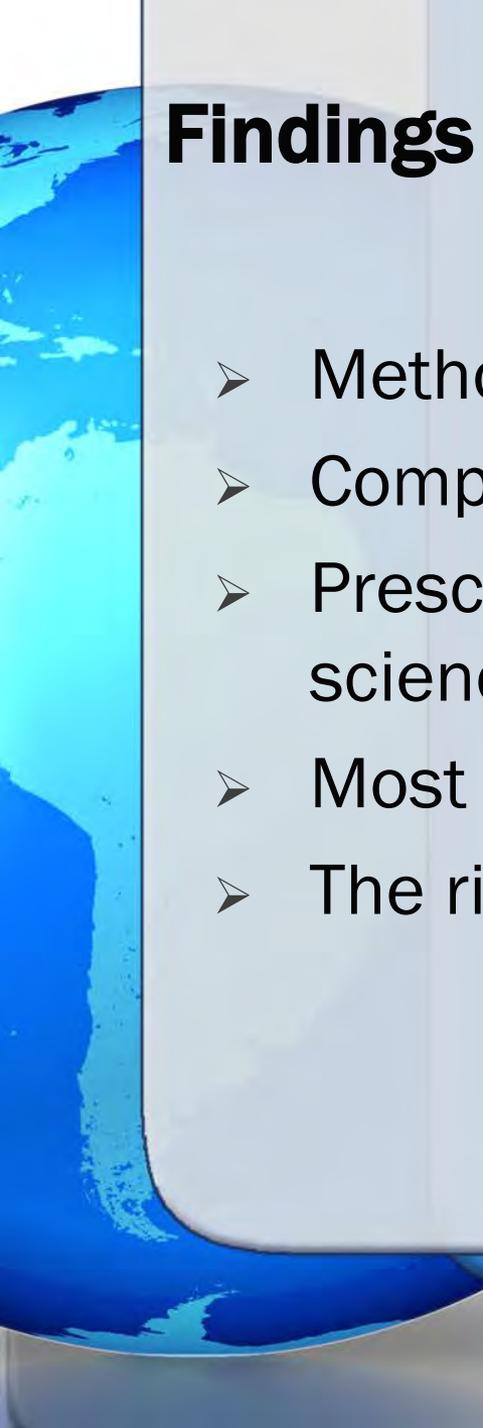


To show
accordance with
accepted
practices

Case Study: Is the pH > 12.5

- Rail car spill of lime in California
- pH measured to be 12.5 and thus spill is a hazardous waste by corrosivity
- Lime is pH 12 buffer
- pH at 25 C is 12.454
- Lab should have used temperature correction and expanded readout

This episode led to a revision of Method 9045: If an accurate pH reading is required, the analyst should control sample temperature at 25 ± 1 C when sample pH approaches the alkaline end of the scale (e.g., a pH of 11 or above).



Findings

- Method details are important
- Complete documentation is important
- Prescriptive methods sometimes constrain the science and common sense
- Most QC has little real value
- The right answer generally wins

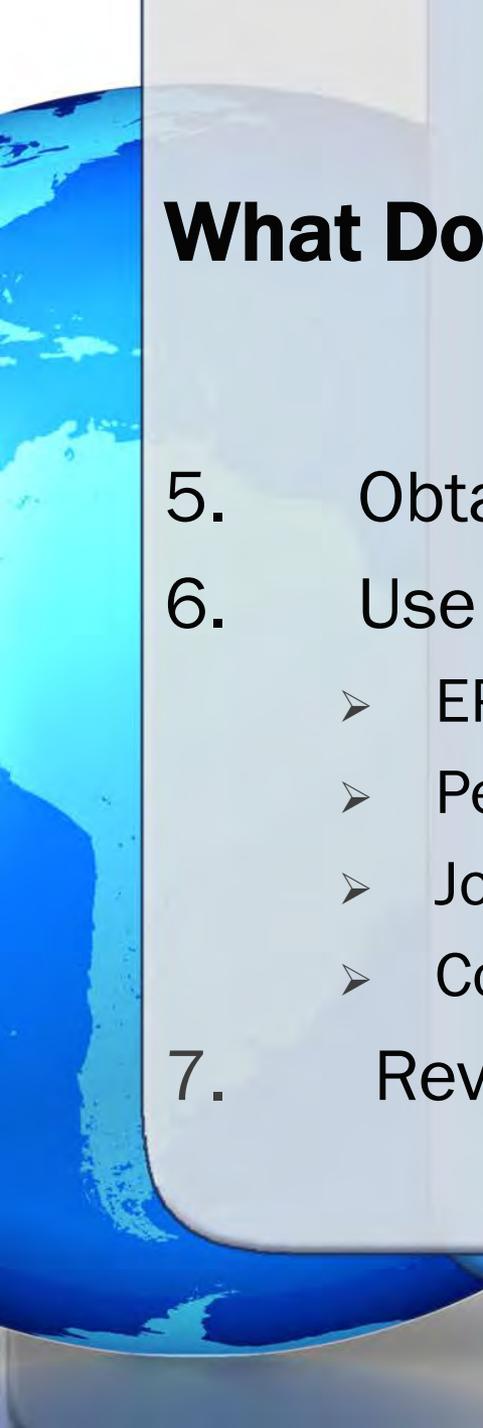
Focus of Opposing Attorneys

- Qualifications as an expert
 - Education and experience
 - Publications
 - Presentations
- Chain of custody
 - Link result to sample
- Customary and standard practice
- OK to not meet QC limits
 - Trick question

What Does This Mean For Labs?

Critical

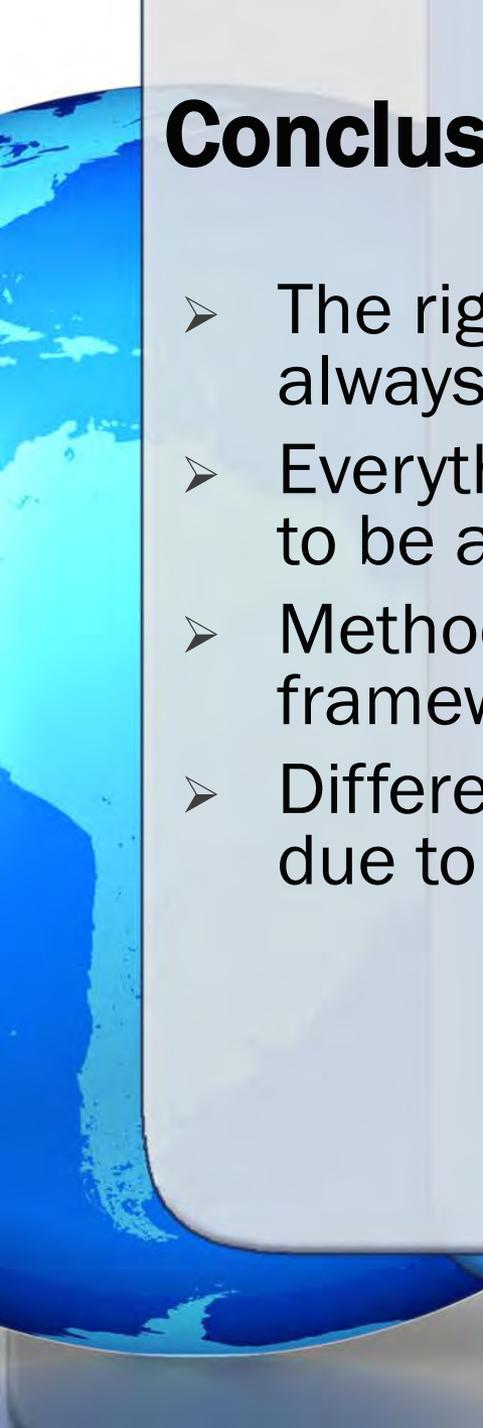
1. Validate method and document in SOP before use
2. Know and document error rate
 - Participate in PT programs
 - Appropriate and relevant QC
 - Corrective action and data qualifiers
3. Use professional standards of the industry
 - The TNI accreditation standards
4. Maintain complete documentation
 - Fully reconstruct result



What Does This Mean For Labs?

Important

5. Obtain reliable certification (e.g. NELAP)
6. Use generally recognized techniques
 - EPA validated methods
 - Peer review
 - Journal publication
 - Conference presentation
7. Review data for reasonableness



Conclusions

- The right answer, “scientific validity”, should always be admissible
- Everything does not have to be perfect for data to be admissible
- Methods used within a sound quality systems framework should have strong legal standing
- Differences in data on split samples are likely due to other factors

Finally, What Is A “Defensible” Result?

- Method used is appropriate for the measurement need ★
- Method performance validated ★
- Laboratory QC demonstrated control
- Quality is known and documented
- Laboratory has a quality system
- Quality system is independently verified
- Documentation is sufficient to reconstruct result ★



THANK YOU!

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