Ethics and Improper Laboratory Practices

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GOALS

It's important to stay on top of them.

Goals for This Presentation

- Discuss why this training is necessary.
- Define Ethics, Data Integrity and Fraud.
- Discuss Improper Laboratory Practices
- Provide examples and answer questions.

USEPA's "Mission"

- EPA's mission is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends.

- P.S. We take our mission VERY seriously!

Why We are Having this Chat

- The EPA Office of the Inspector General (OIG) has shown increased interest in the investigation of field and laboratory misconduct.
- The number of fraud cases investigated by OIG has increased each year.

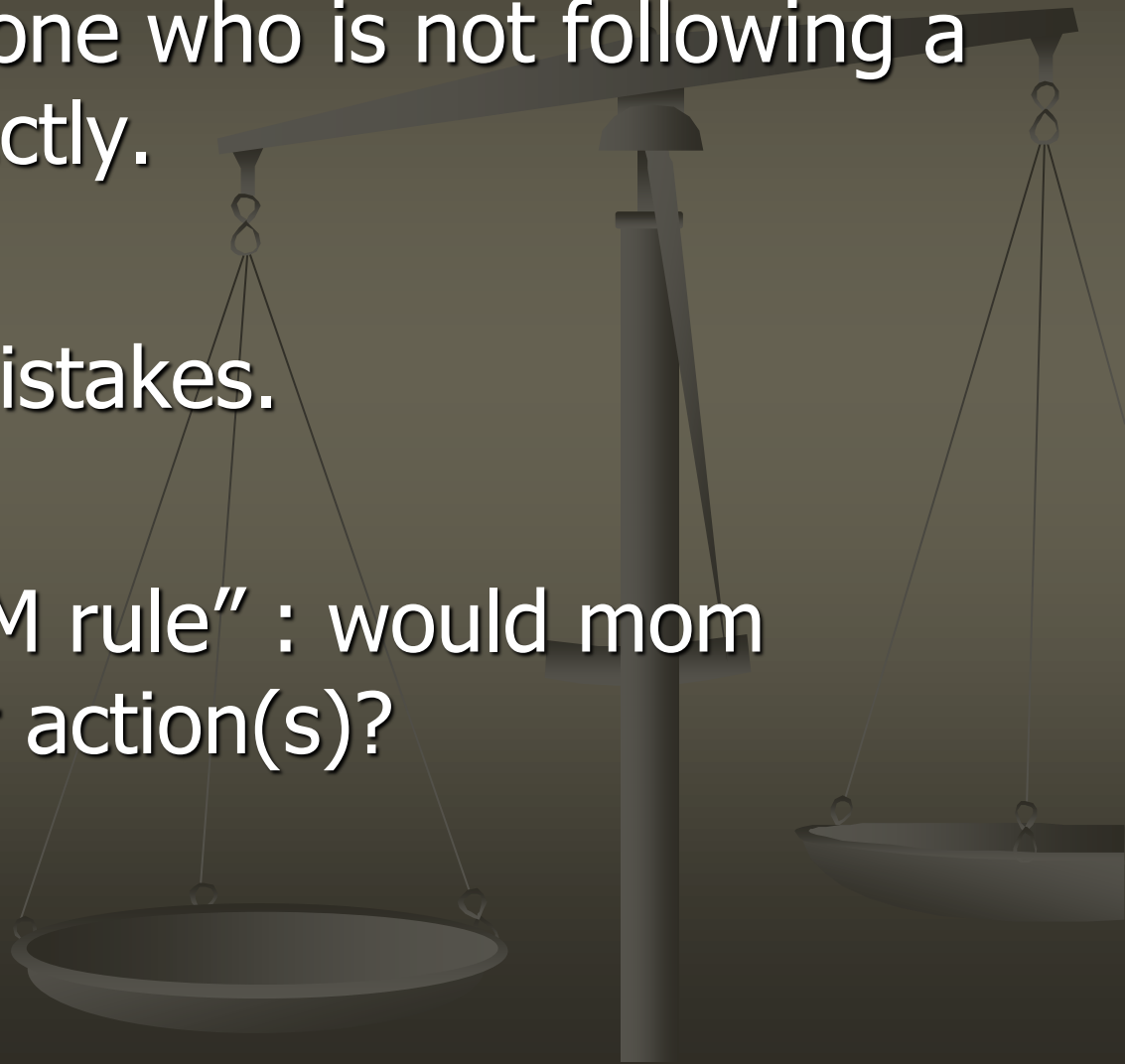
What is “Ethics”?

Ethics:

- **Webster's online dictionary defines ethics as:**
- the discipline dealing with what is good and bad and with moral duty and obligation
  - a set of moral principles
  - a theory or system of moral values
  - the principles of conduct governing an individual or a group
  - a guiding philosophy
  - a consciousness of moral importance
  - a set of moral issues or aspects (as rightness)

Examples of Good Ethics

- "Helping" someone who is not following a procedure correctly.
- Documenting mistakes.
- Follow the "MOM rule" : would mom approve of your action(s)?



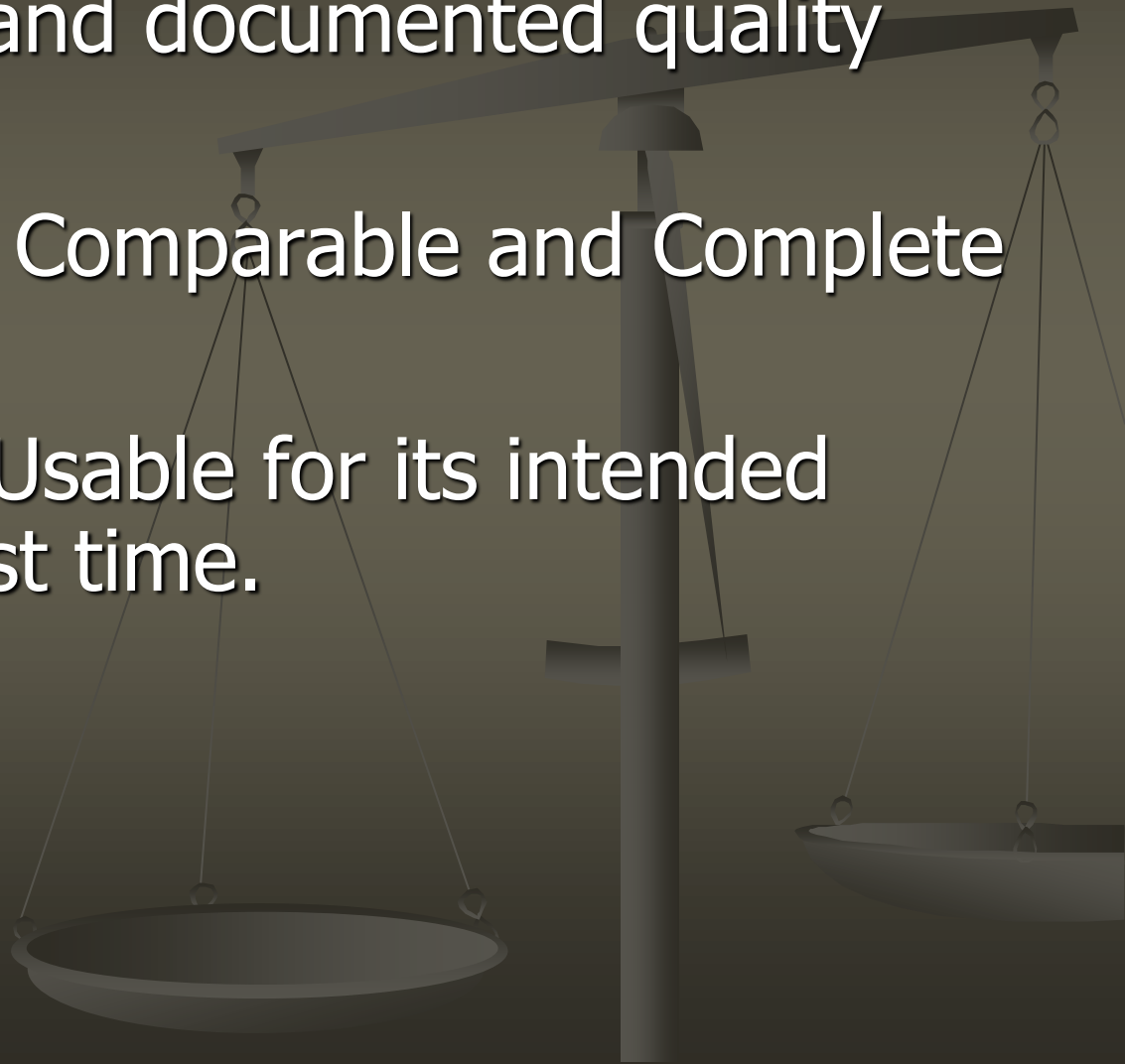
Why Act Ethically?

- Your personal reputation and the reputation of your organization or business depends upon it.
- Acting ethically can enrich your work life as well as your home life.
- The penalties for misconduct for you and your organization can be substantial.

Data Integrity

What is Data Integrity?

- Data of known and documented quality
- Representative, Comparable and Complete
- Defensible and Usable for its intended purpose, the first time.

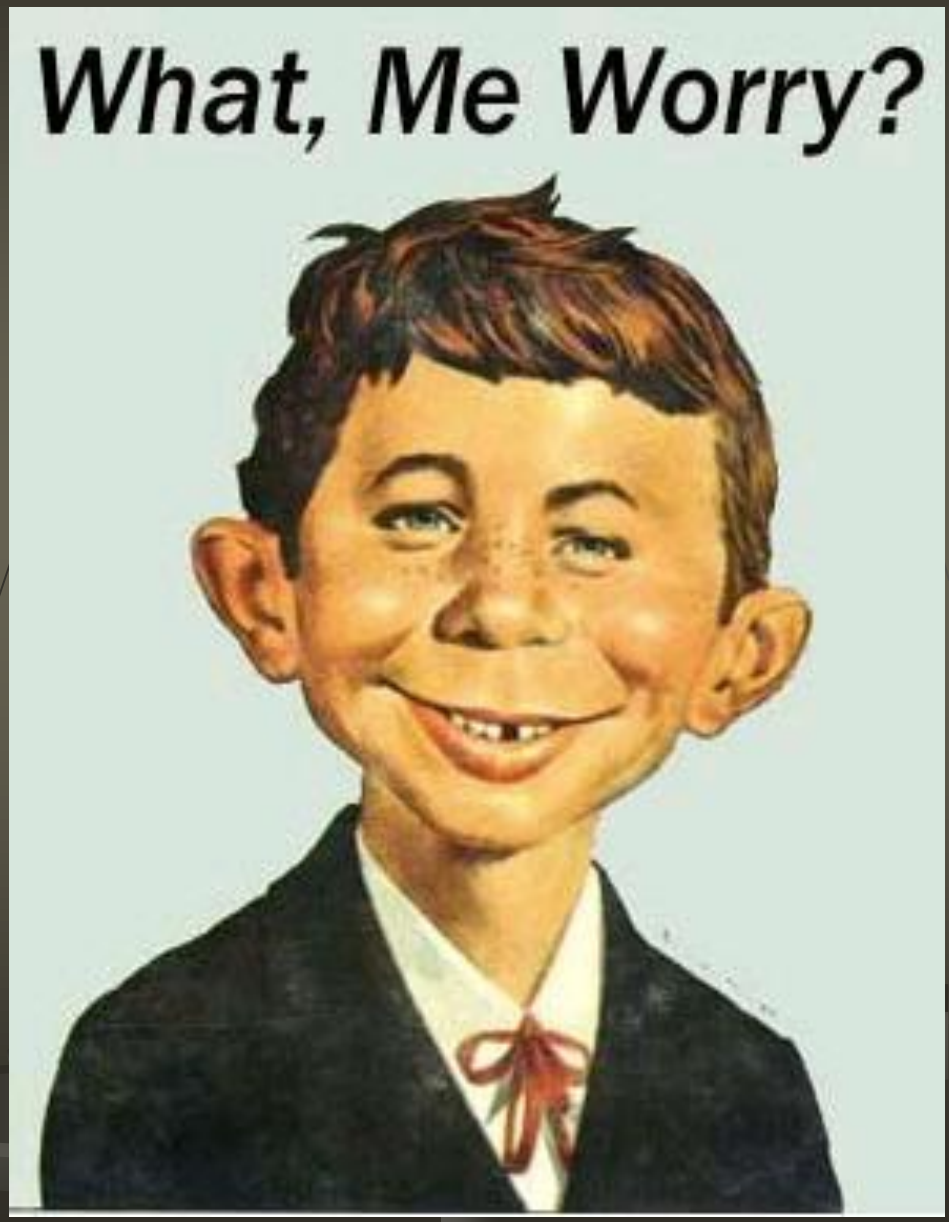


Environmental “Fraud”

What is “Fraud?”

- The Intentional misrepresentation of lab data to hide known or potential problems.
- The Intentional recording or reporting of incorrect information
- An Intentional gross deviation from method specified analytical practices, combined with the intent to conceal the deviation.

Why Should I Care?



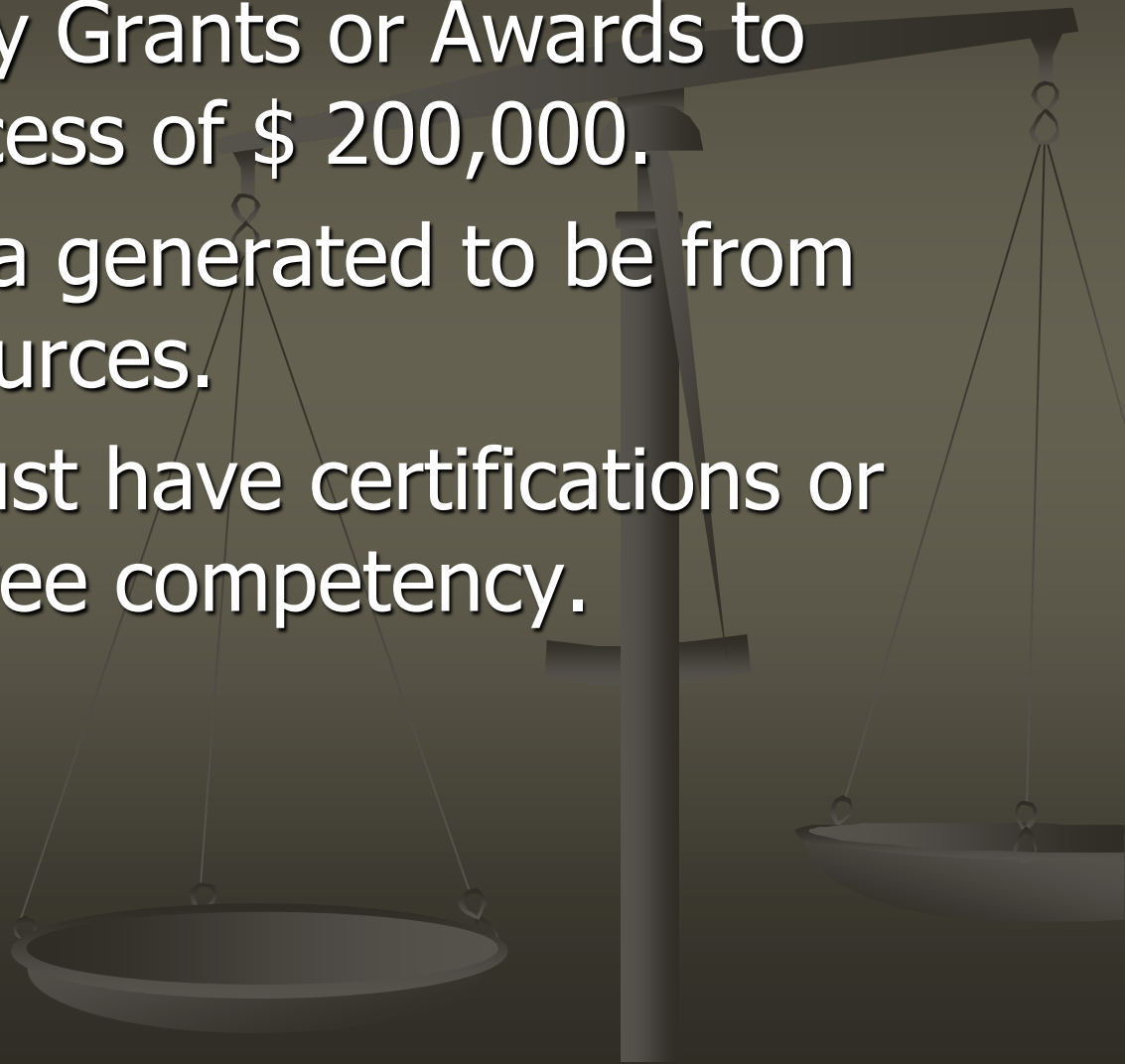
Be the Solution, NOT the Problem

- Fraudulent data puts public health at risk (including you and your family).
- Others watch your fraudulent procedures and will imitate your techniques.
- Regulatory agencies ALSO watch your fraudulent procedures will be happy to give you free room and board for about 5 years.

Changing the Subject with an Axe!

EPA Competency Policy

- Required for any Grants or Awards to Programs in excess of $ 200,000.
- Requires all data generated to be from COMPETENT sources.
- Laboratories must have certifications or proof of employee competency.



EPA Competency Policy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 28 2011

OFFICE OF THE
SCIENCE ADVISOR

MEMORANDUM

SUBJECT: Policy to Assure Competency of Laboratories, Field Sampling, and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions

FROM: Paul T. Anastas
EPA Science Advisor

TO: Assistant Administrators
Regional Administrators

Attached is a new Agency Policy Directive titled, *Policy to Assure Competency of Laboratories, Field Sampling, and Other Organizations Generating Environment Measurement Data under Agency-Funded Acquisitions*. This Policy Directive was developed by the Forum on Environmental Measurements (FEM) in consultation with the Office of Acquisition Management and the Office of General Counsel, and has cleared intra-agency review under the auspices of the FEM.

The purpose of this memorandum is to convey EPA policy requiring that organizations (e.g., laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency, which may include participation in applicable certification and/or accreditation programs. All organizations performing environmental analysis for the Agency shall demonstrate their qualifications in the field(s) of analyses to be conducted, prior to performing such analyses.

This policy will be available on the FEM website at, http://www.epa.gov/.../fem. Please disseminate this information to your respective staff for immediate use. If you have any questions, please contact me or have your staff contact Lara Autry, FEM Executive Director, at (919) 541-9544.

cc: STPC Members

Competency Continued

- Not much of an issue for State Labs in Drinking Water. Wastewater more problematic.

- For more information go to:
  - http://www2.epa.gov/sites/production/files/2015-03/documents/competency-policy-aaia-new.pdf

Back on Track!

Improper Practices in the Laboratory

Bad Lab Technique

Bad Sampling

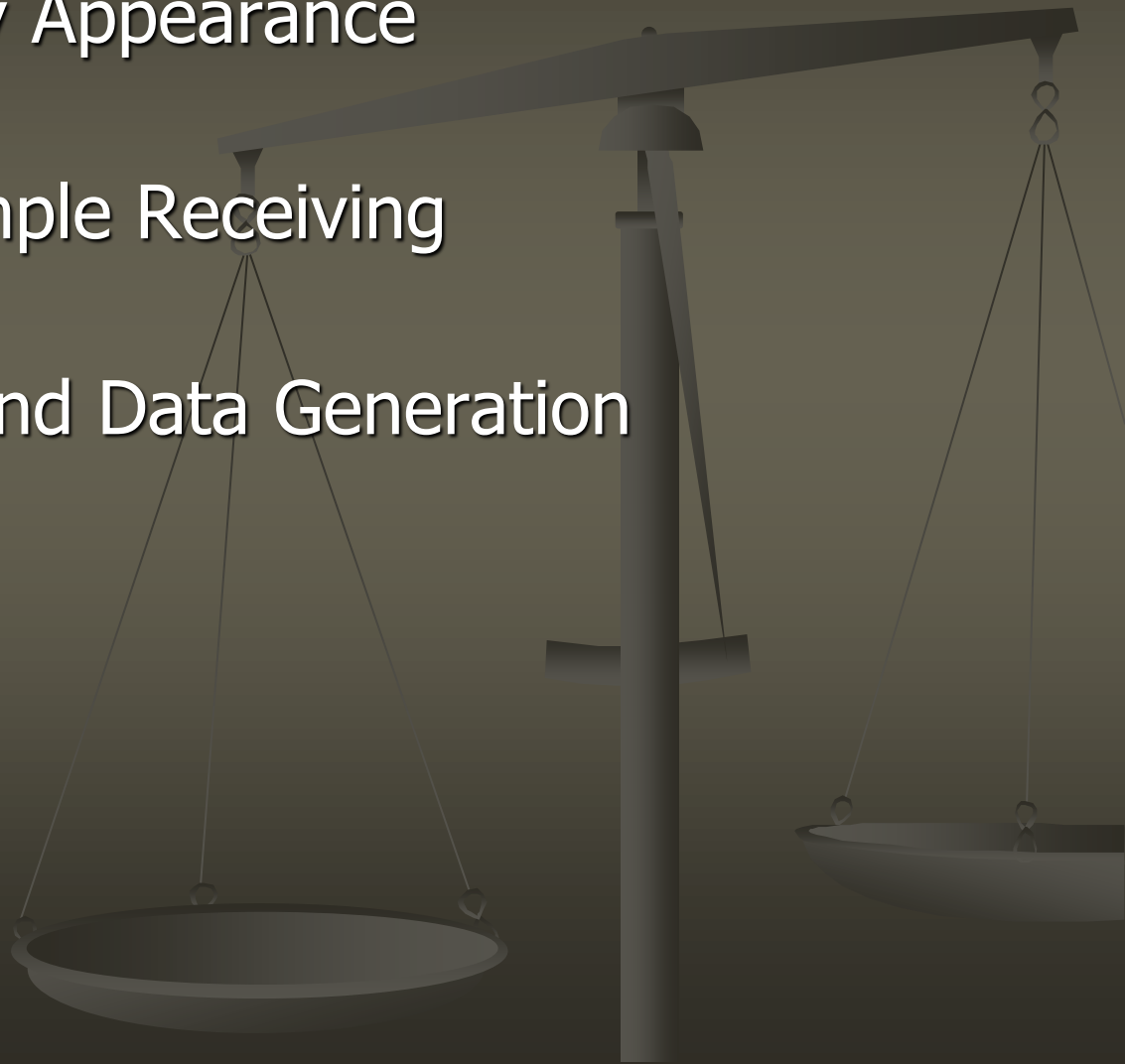
Just Plain BAD

Types of Improper Laboratory Practices

- Unintentional, through ignorance or lack of communication.
- Intentional, but with minor impact on public health or environment
- Intentional, which jeopardizes public health.

Lab Areas and their Problems

- Overall Laboratory Appearance
- Sampling and Sample Receiving
- Sample Analysis and Data Generation
- Quality Control
- Data Reporting



Overall Laboratory Appearance

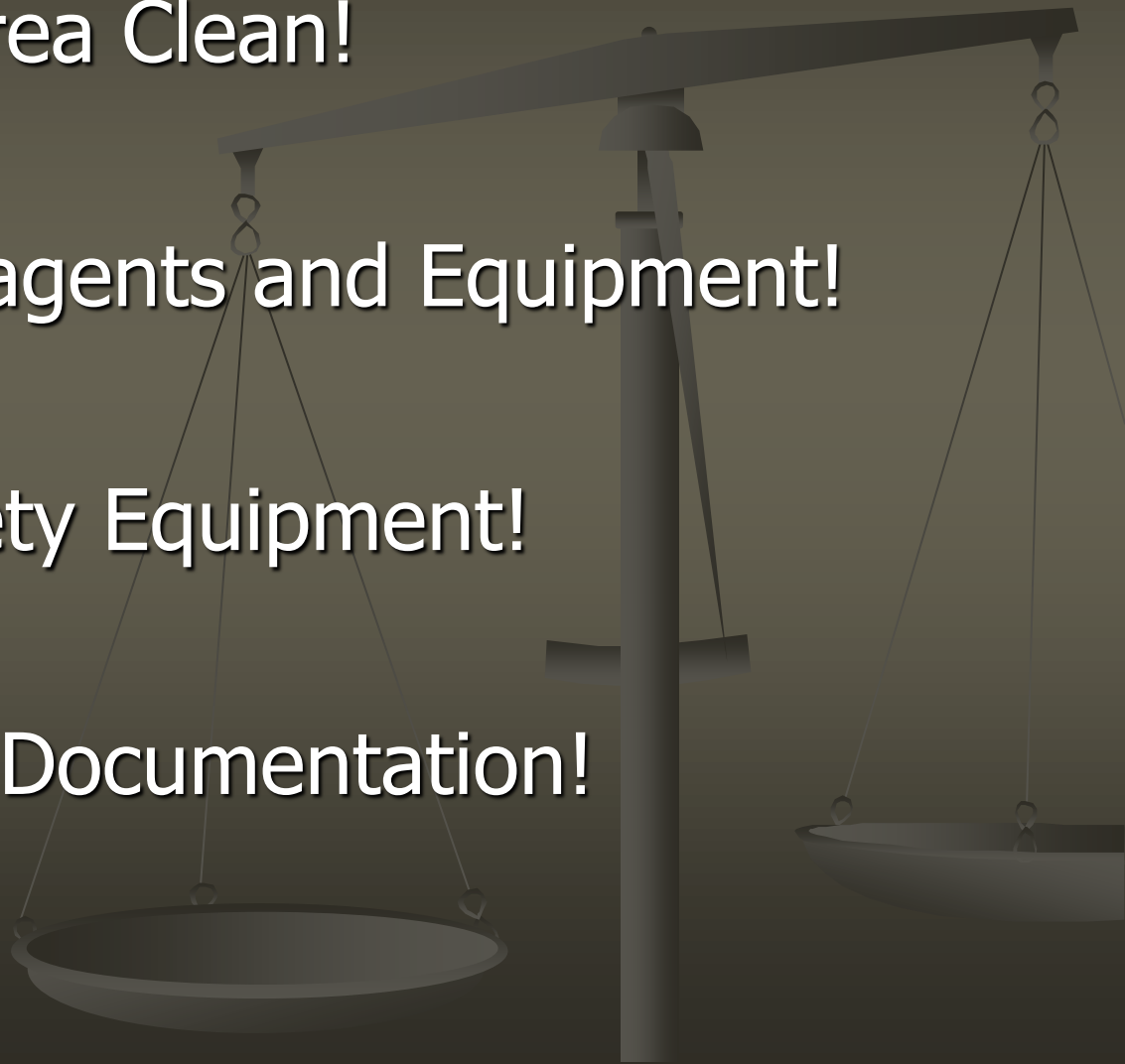
A “Laboratory” in Region 4

This is a REALLY bad sign!

A “Methy” Laboratory!

Cleanliness and Safety Broadcast Pride in a Lab's Work

- Keep the Lab Area Clean!
- Organize All Reagents and Equipment!
- Use Proper Safety Equipment!
- Keep Adequate Documentation!



What We Have Seen

- Ether extractions and Metals digestions without a fume hood.
- Strong Acids stored in overhead cabinets.
- Solvents stored under ovens.
- Lead poisoning symptoms in analysts/workers.

Properly Equipped Laboratory

Should See This!

Not This!

Sample Receiving Issues

Good Sample Receiving Practices

- Only receive samples in the proper containers!
- Make sure the paperwork is correct. Especially Chain of Custody documents, if used.
- Check preservation (temperature, pH, chlorine, etc.) and WRITE IT DOWN.

Sample Receiving continued

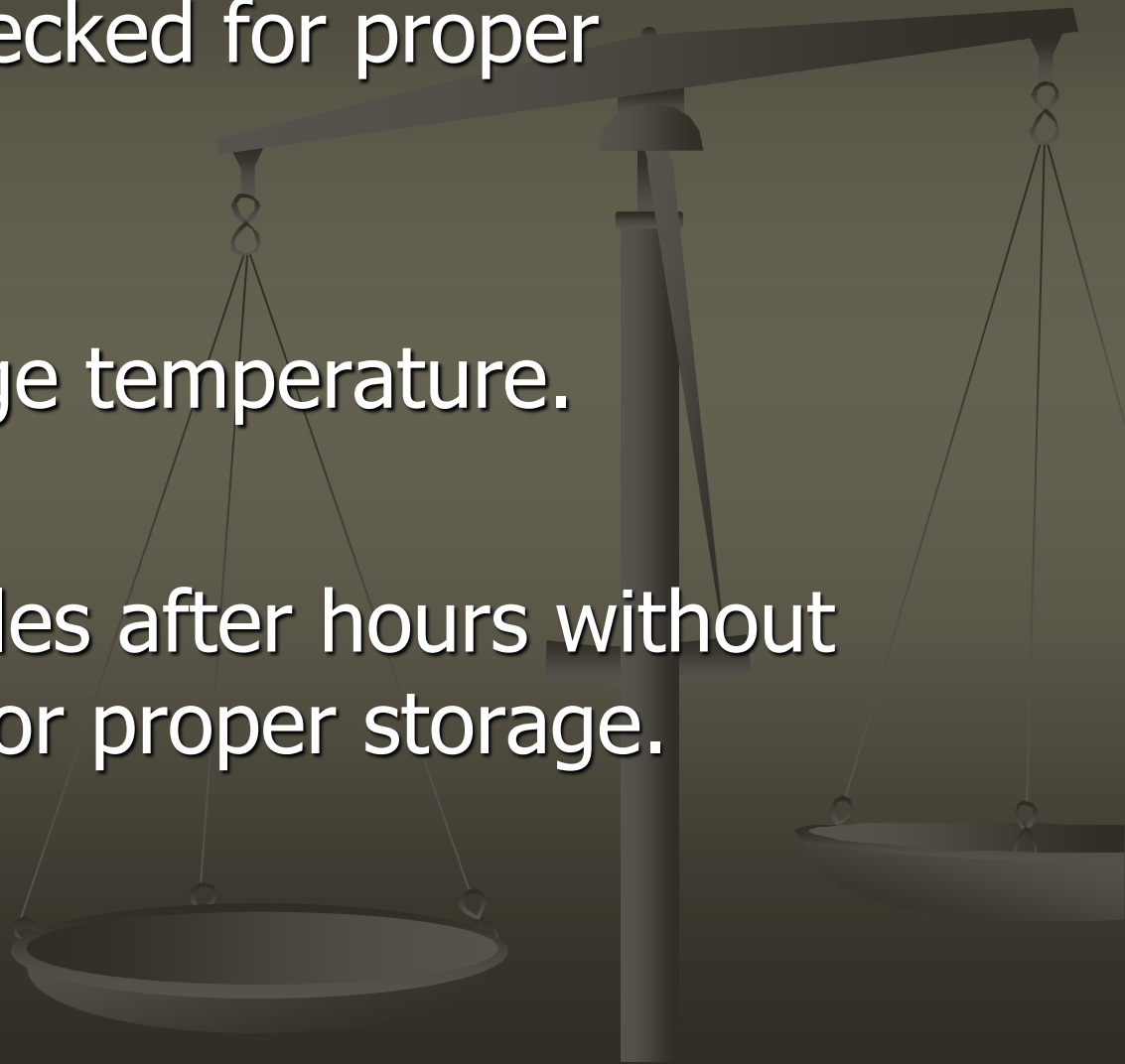
- Store the samples in a monitored refrigerator or incubator.
- Notify the Client immediately if there is a problem. DOCUMENT IT!
- Check Temperatures Correctly.

Common Problems Noted in Sample Receiving

- Out of date preservation reagents.
- No sample paperwork.
- Thermometers not calibrated (expired).

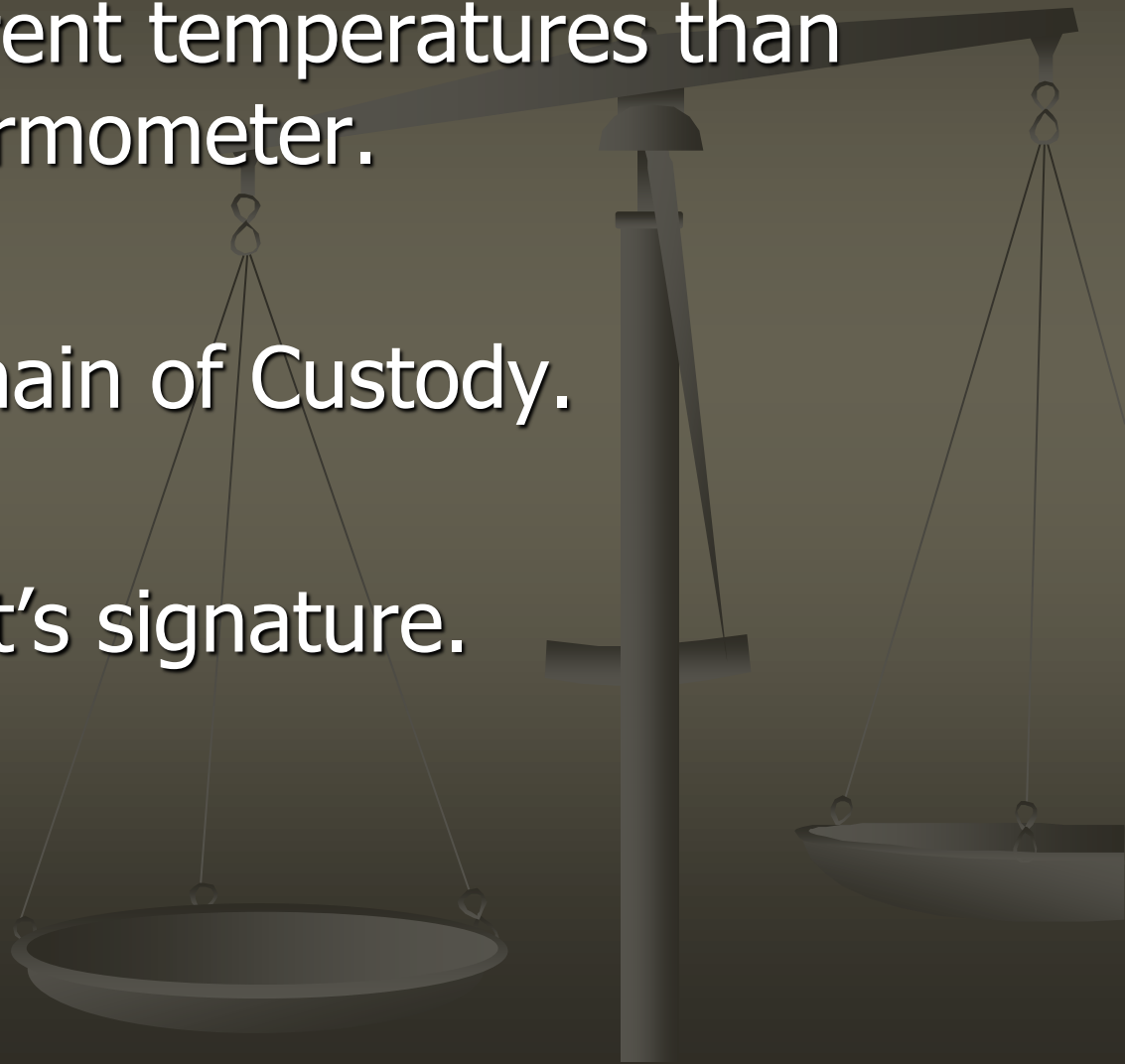
Common Problems, continued

- Samples not checked for proper preservation.
- Improper storage temperature.
- Receiving samples after hours without signatures and/or proper storage.



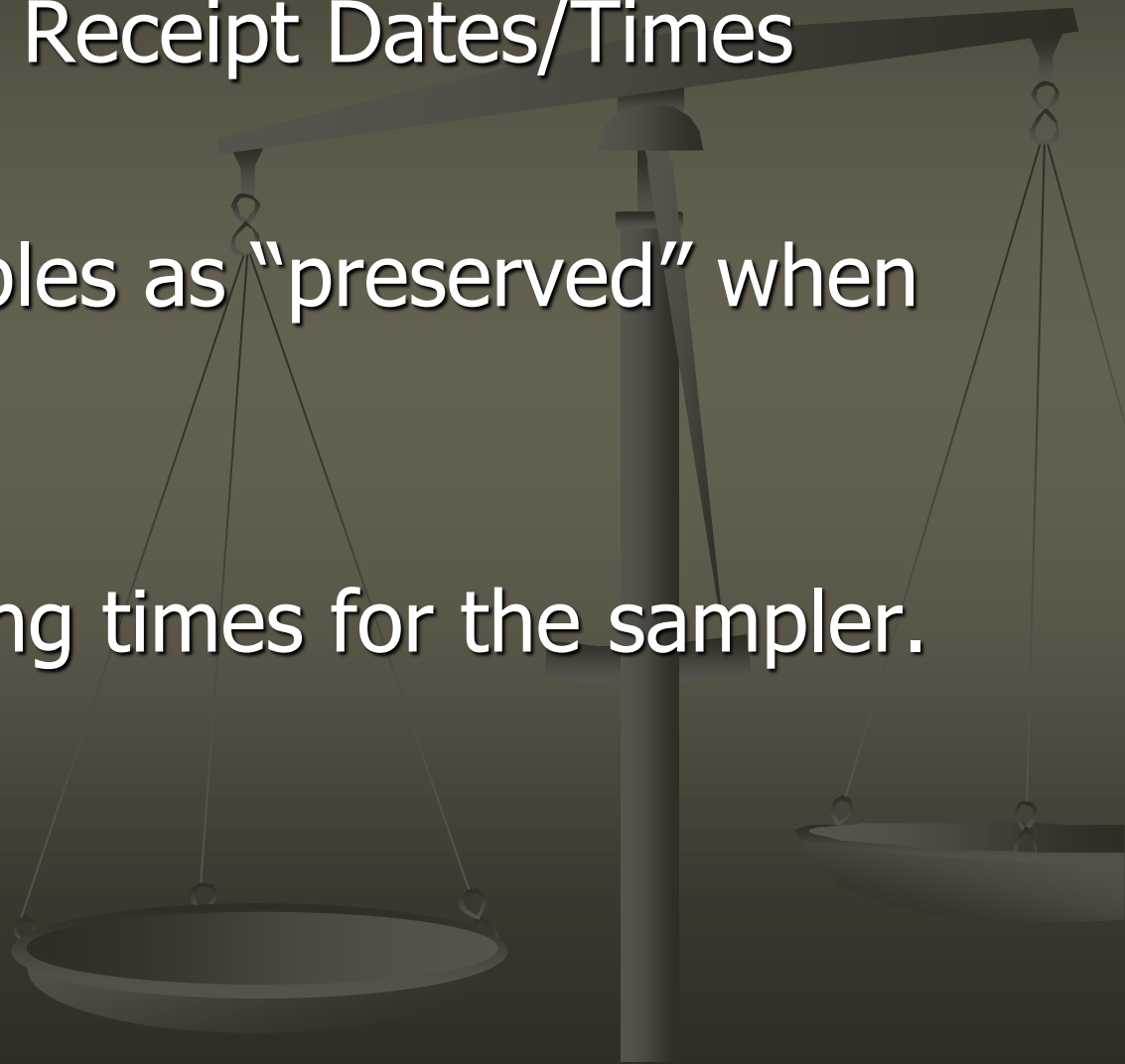
When It Might Be Fraud

- Recording different temperatures than read on the thermometer.
- Fabricating a Chain of Custody.
- "Faking" a client's signature.



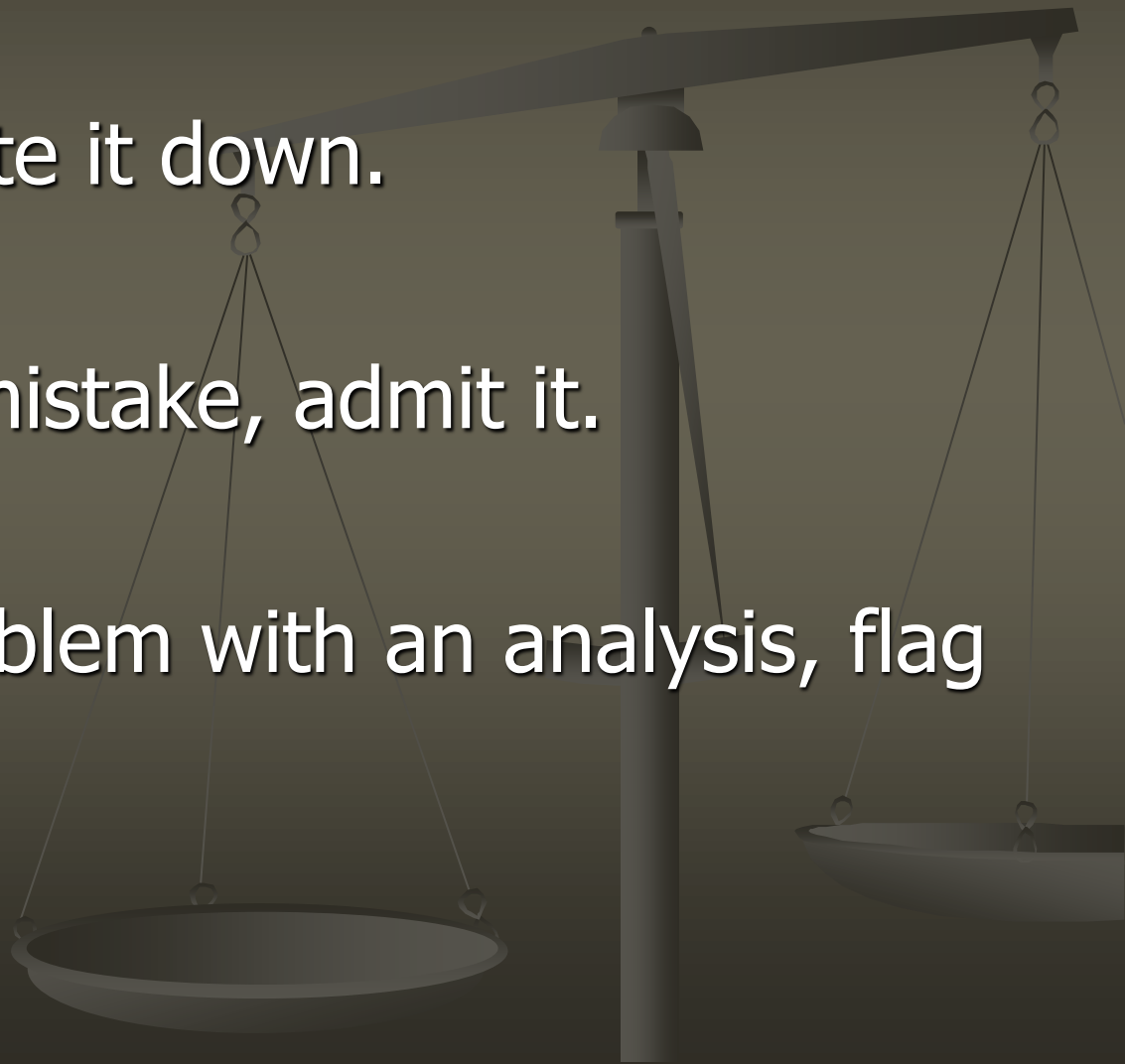
More “Might be Fraud”

- Recording False Receipt Dates/Times
- Recording Samples as “preserved” when they are not.
- Filling in sampling times for the sampler.



Laboratory Analysis Issues

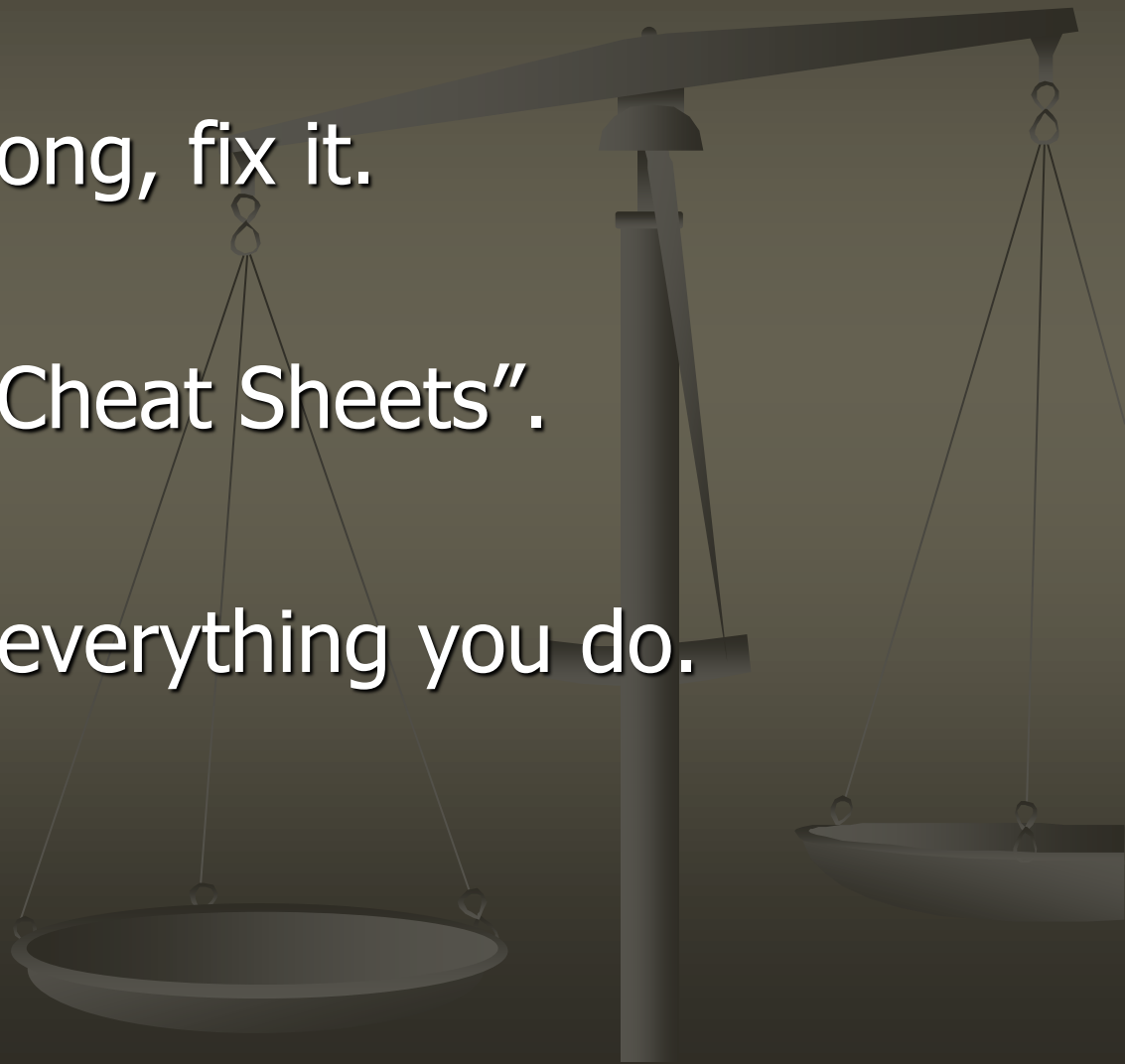
Good Laboratory Practices



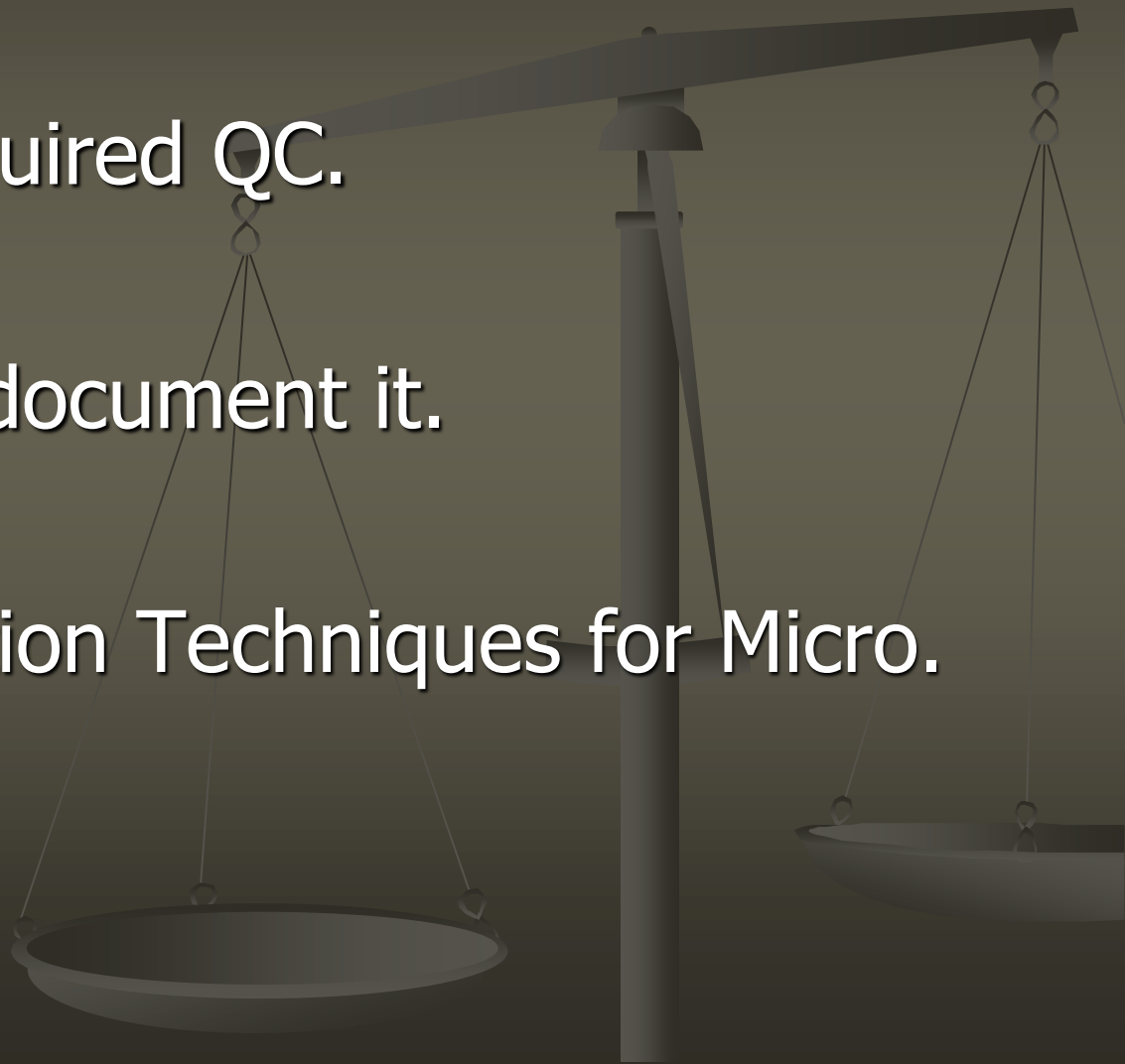
- If you do it, write it down.
- If you make a mistake, admit it.
- If there is a problem with an analysis, flag it.

More Stuff You Should Do

- If the SOP is wrong, fix it.
- If possible, no “Cheat Sheets”.
- Date and initial everything you do.



Still More Good Lab Stuff



- Perform the required QC.
- If the QC fails, document it.
- Proper Sterilization Techniques for Micro.

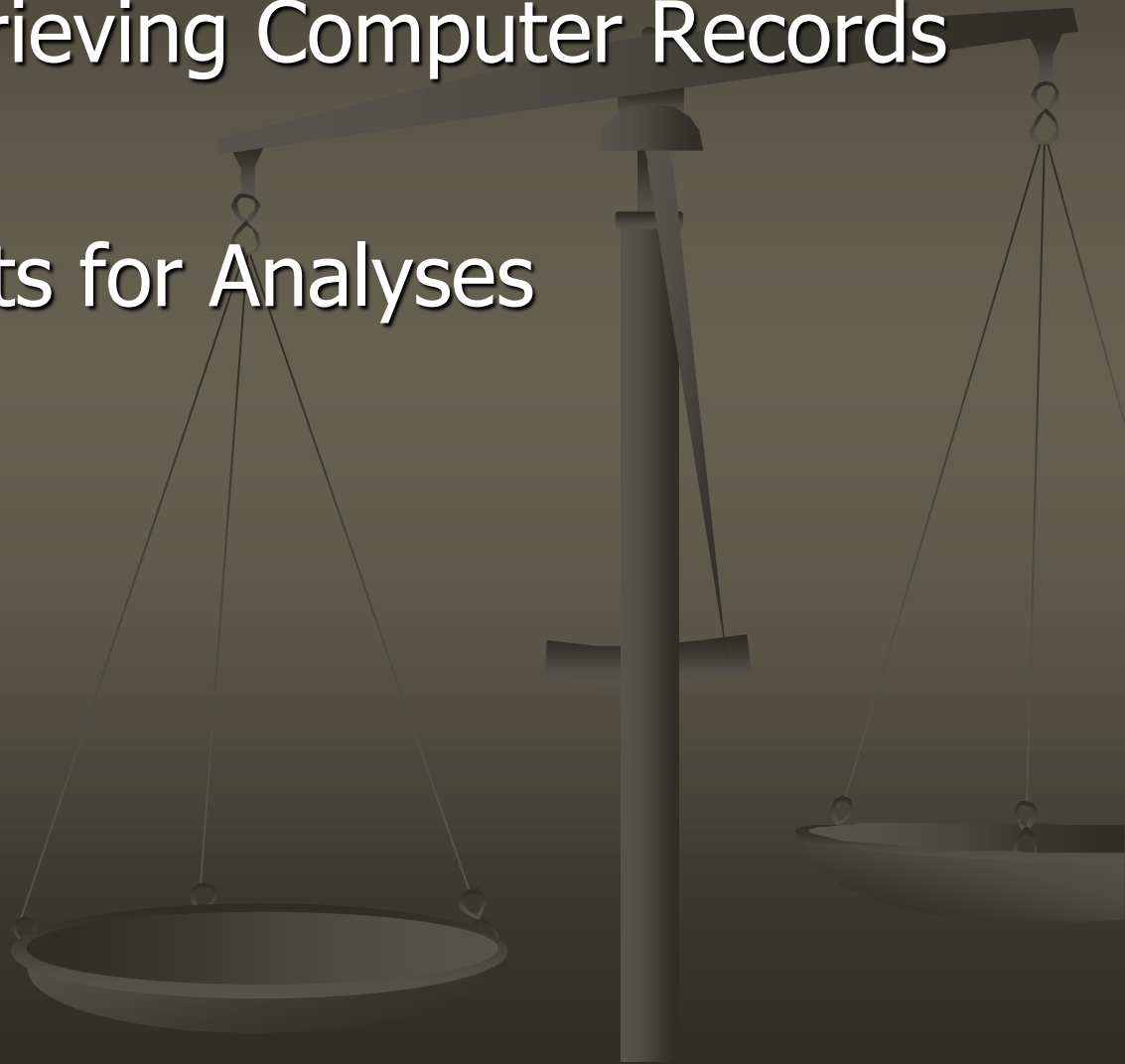
Possible Fraud

Possible Indications of Lab Fraud

- No Instrument Available for the Analysis.
- Instrument Isn't in Operating Condition.
- Equipment is Dirty, Corroded, etc.
- No Bench Sheets or Log Books.

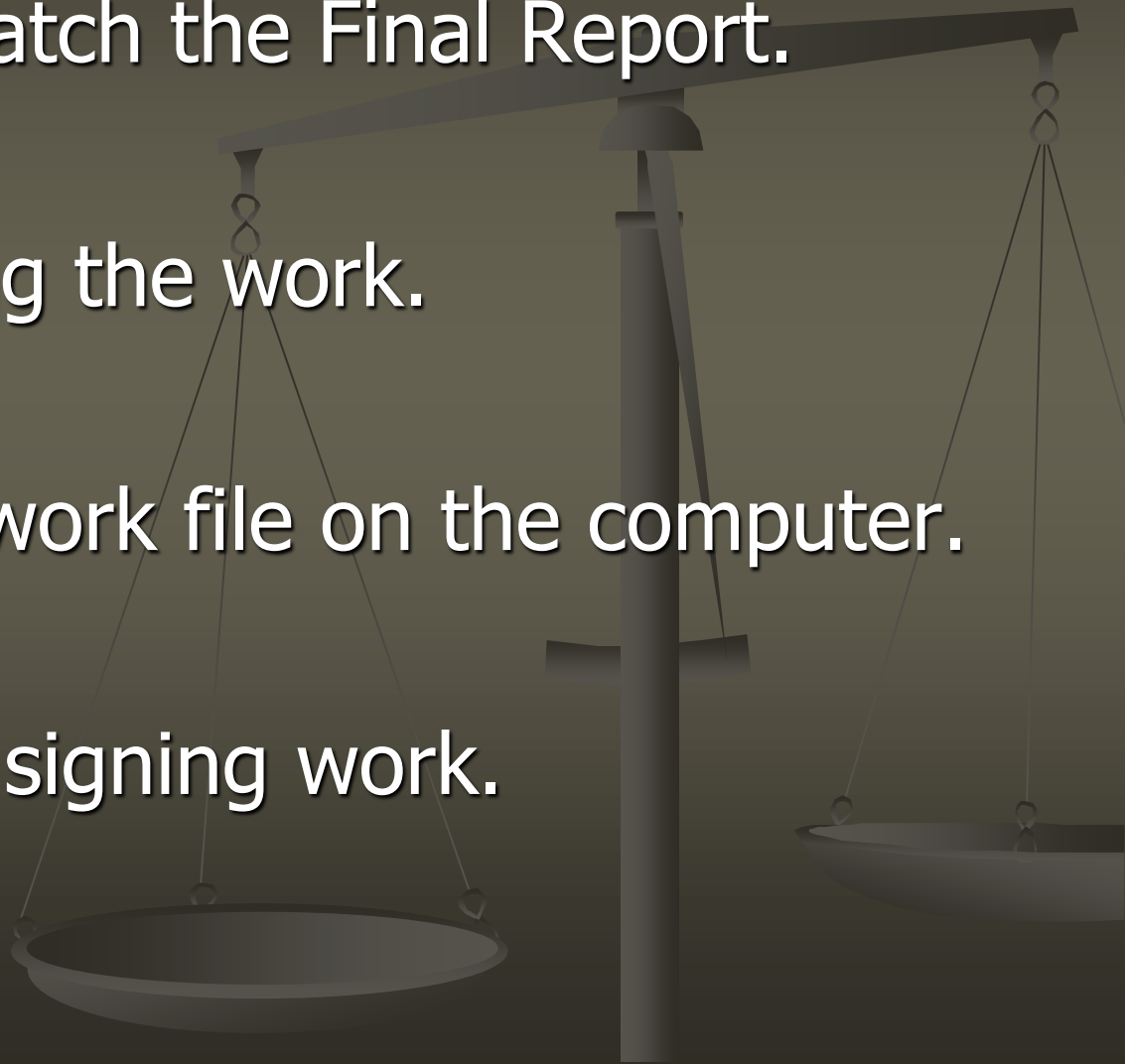
More Possibilities

- Difficulty in Retrieving Computer Records
- Missing Reagents for Analyses
- Poor Safety



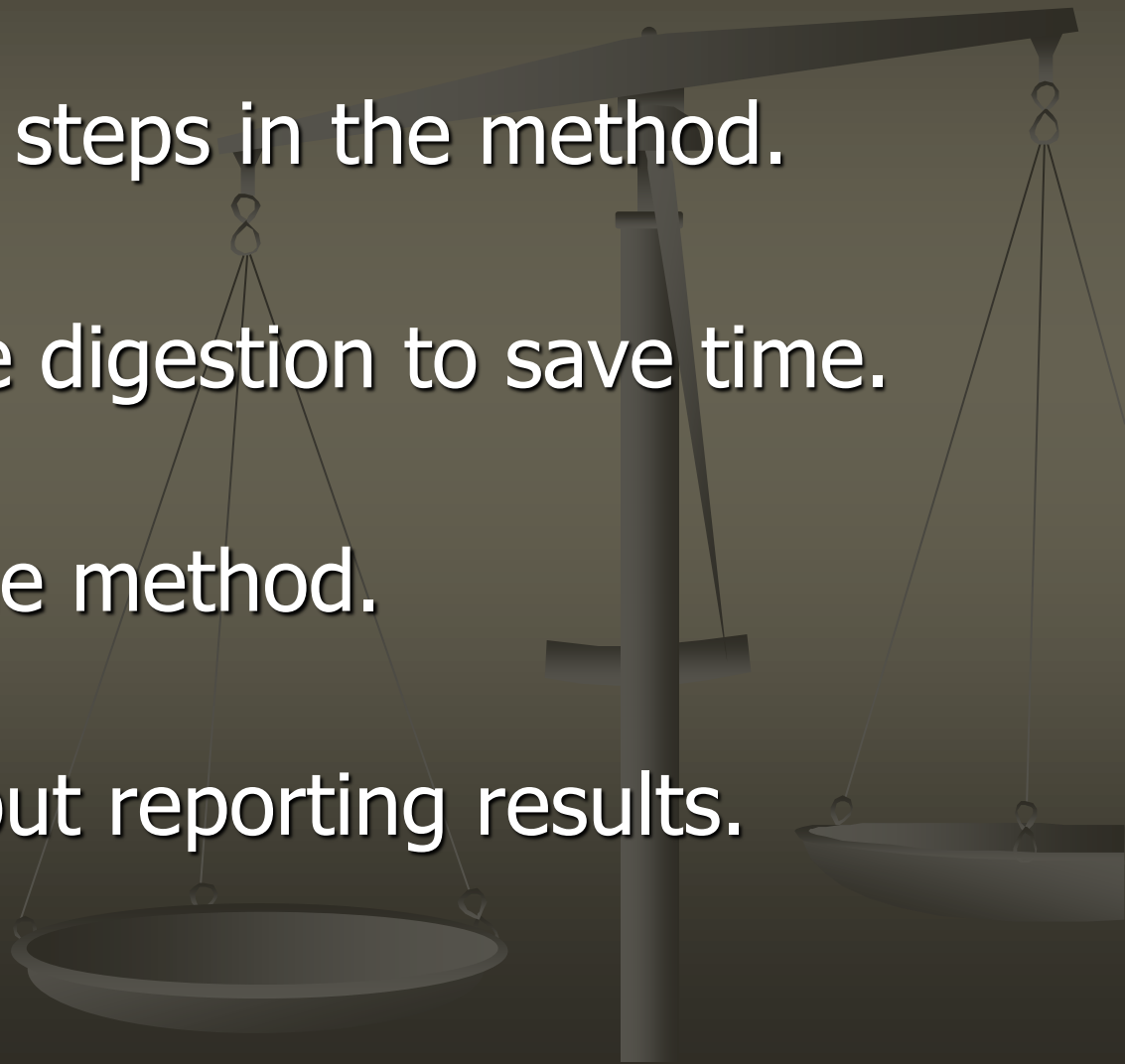
Good Indicators of Bad Data

- Results don't match the Final Report.
- Not documenting the work.
- Not saving the work file on the computer.
- Not initialing or signing work.



More Indicators of Bad Data

- Skipping critical steps in the method.
- Skipping sample digestion to save time.
- Not following the method.
- No equipment but reporting results.



Violations We Have Actually Witnessed

- Reporting results for fecal coliforms with no equipment and no purchase orders for supplies.
- Fecal results on DMRs for dates with empty incubators (we wrote down the date and time during the inspection).
- QC results for a standard but no standard in house or ever ordered.

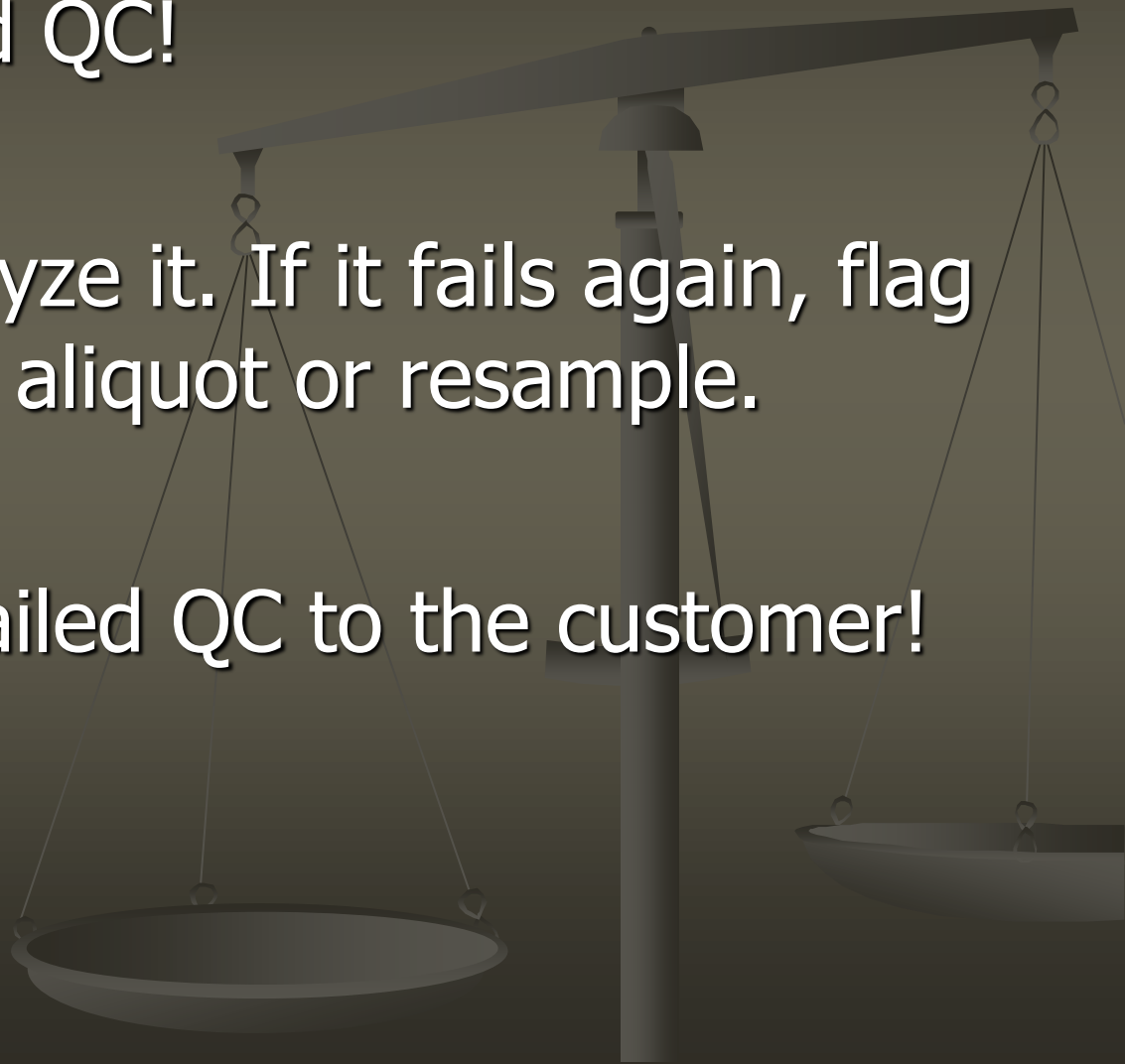
More Violations

- Lab analyzed for compound, but PE samples (DMR-QA) analyzed at another lab and claimed to be conducted here.
- Reporting TSS but no drying oven in lab.
- Falsified Certifications: State Lab, TNI (NELAC), and/or A2LA Certifications.

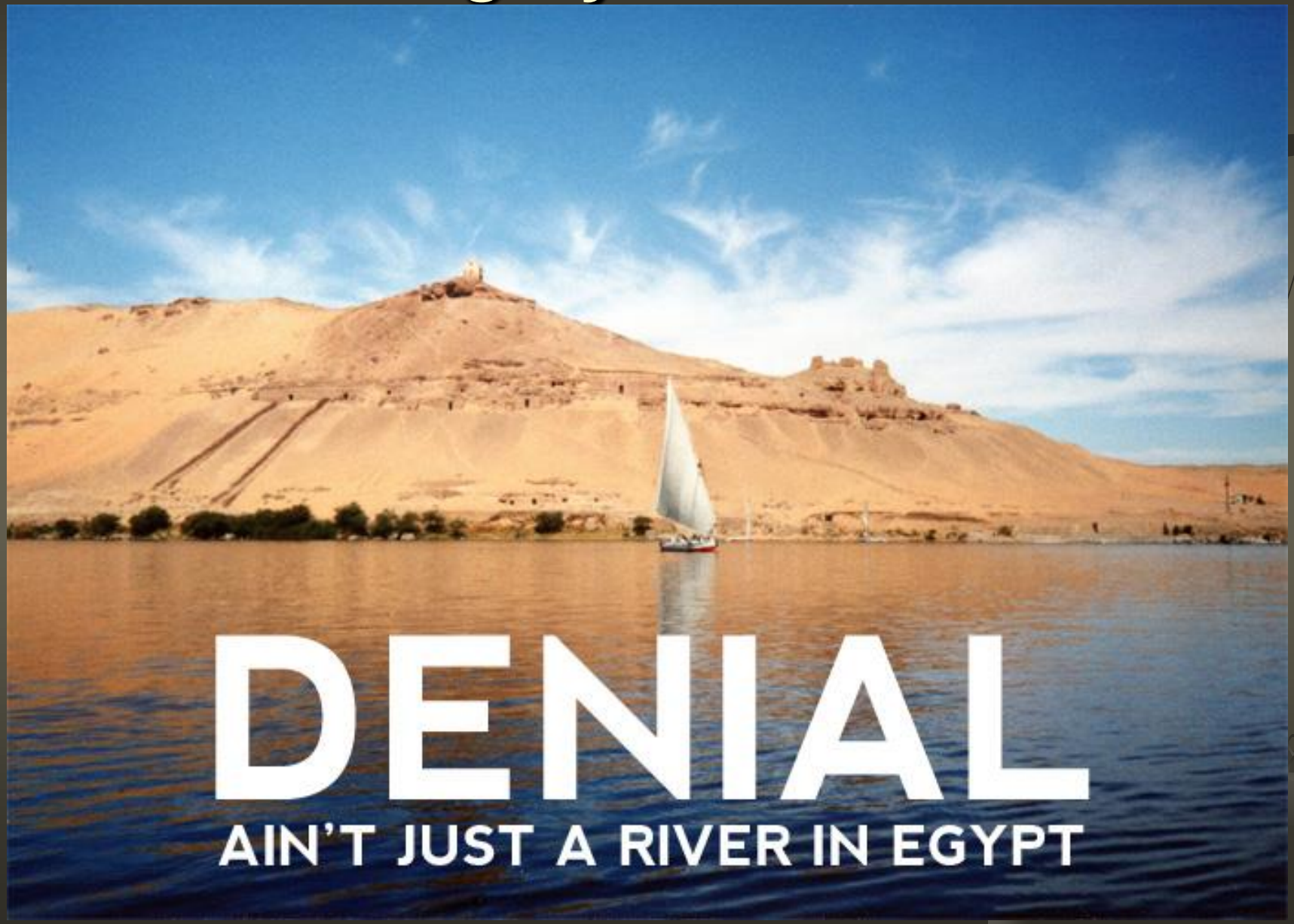
Quality Control Issues

Good QC Practices

- Do the Required QC!
- If it fails, reanalyze it. If it fails again, flag it, prep another aliquot or resample.
- Always report failed QC to the customer!



Naughty Behavior



Naughty QC or Lab Behavior We Have Encountered

- "Fudging" the numbers by a couple of percent so LCS/LFB and MS samples can pass.
- Using another Batch's QC as a substitute.
- Biasing the QC samples by using special glassware or techniques (very common).

More NO-NOs We Have Found

- Adding more standard spike to "boost" the results.
- Using a different calibration curve for the QC samples than for regular samples.
- Running a lot of standards and picking the good ones (cherry picking).
- Biasing Method Detection Limits (MDLs).

More Stuff We Have Found

- Have QC results but no standards in the lab.
- Excel macro calculates the QC and always generates a passing number.
- Using a vendor demonstration VOA GC/MS Calibration Curve for 2 years.

Still More “Stuff”

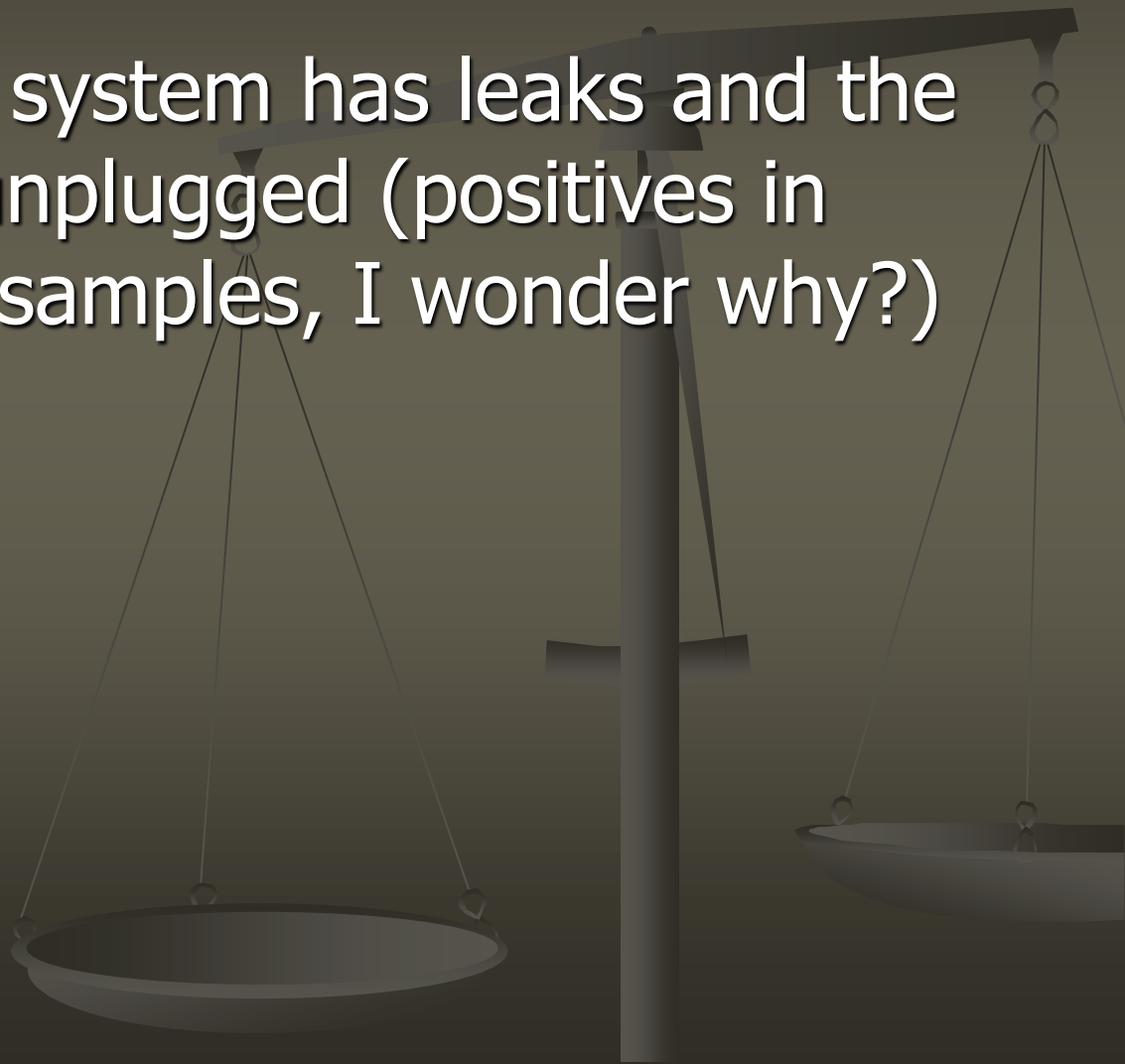
- Re-injecting the same sample / extract / digestate and calling it the duplicate. Usually VERY low RPD!
- “Accurate” counts of 210 and 270 fecal colonies with no dilution for plate counts.
- TSS results in grams/Liter (think about it)

More “Bad” Stuff

- Four Composite Samples and only two times (8:00am and 2:00pm)
- Lots of Data but no Lab
- pH probe is bone dry but reporting daily readings (always seems to be 7, hummm).

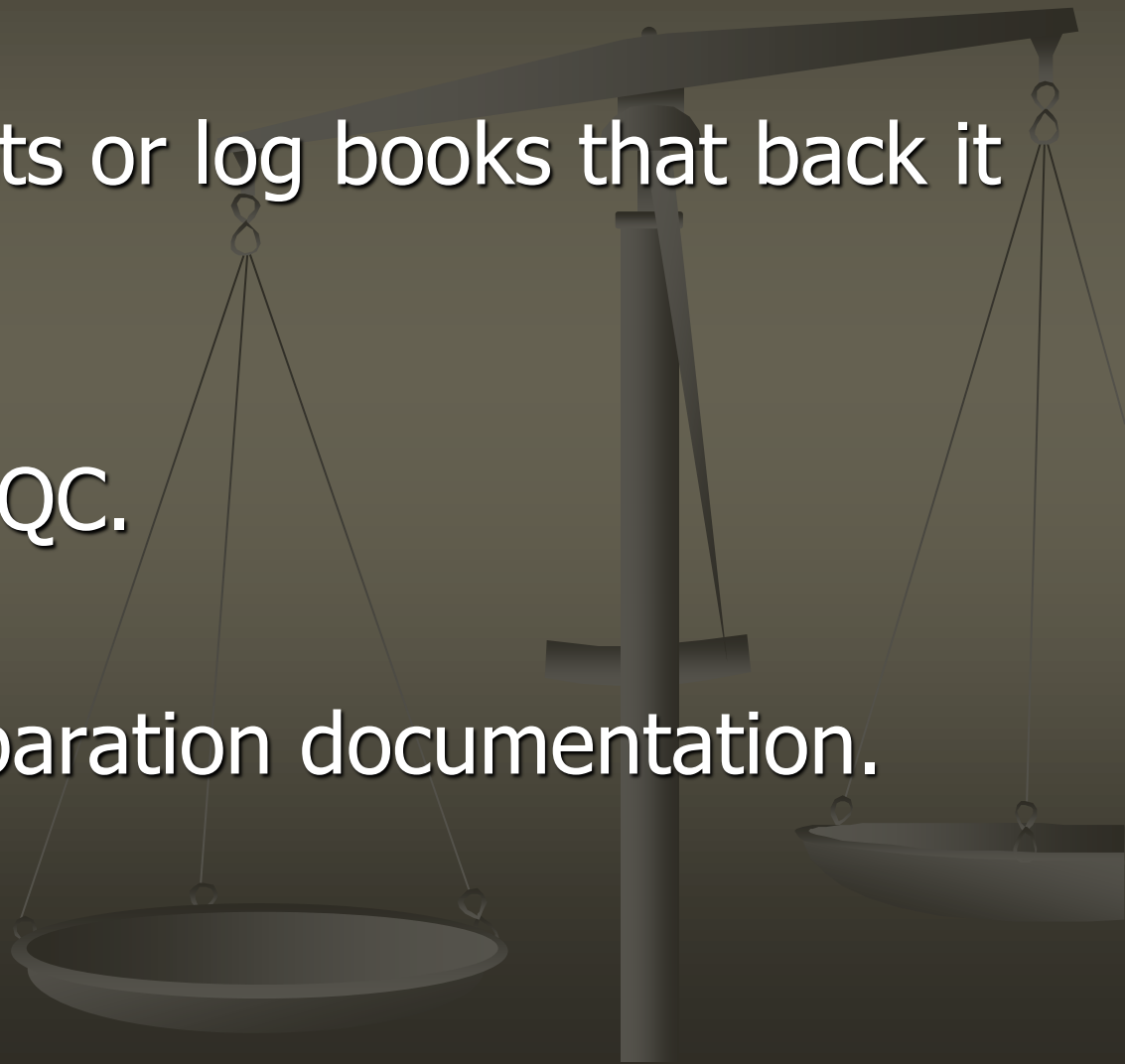
Still More “Bad” Stuff

- “Type II” water system has leaks and the UV sanitizer is unplugged (positives in BOD and micro samples, I wonder why?)



Data Reporting

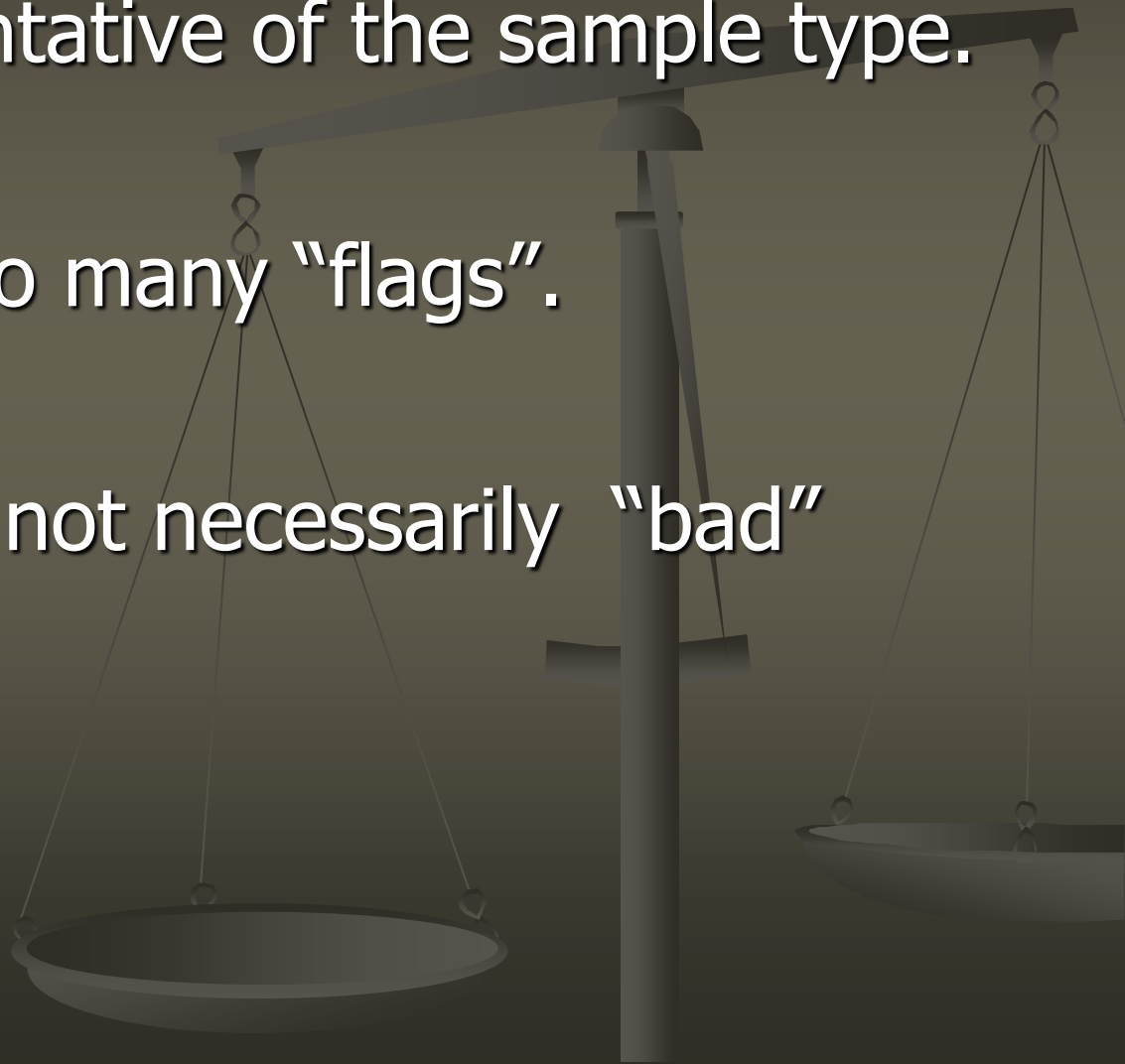
“Indications of Good Data”



- Has bench sheets or log books that back it up.
- Has acceptable QC.
- Has proper preparation documentation.

More Possibly “Good Data”

- Data is representative of the sample type.
- Doesn’t have too many “flags”.
- “Ugly” data but not necessarily “bad” data.

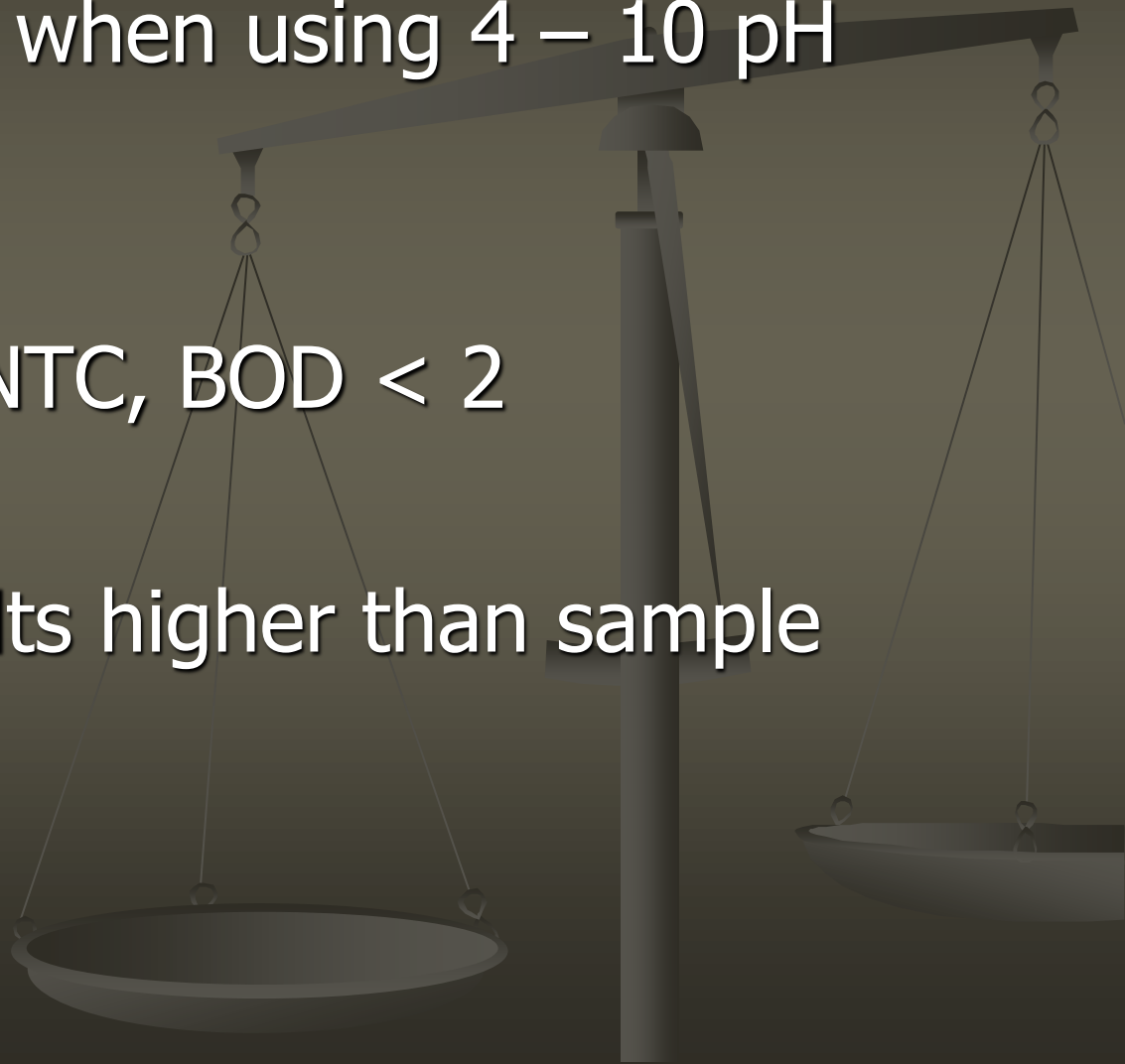


“Bad” Data

- Only a Final Report, no supporting documentation (logbooks, printouts, etc.)
- No QC results traceable to the Data (no lot numbers).
- Final report results don’t match bench sheet results.

“Bad” Data we have found

- pH readings <2 when using 4 – 10 pH paper.
- Fecal Results TNTC, BOD < 2
- BOD blank results higher than sample results



And STILL More “Stuff”

- Reporting results below your lowest calibration standard concentration, without a flag (very common).
- Reporting results above your highest calibration standard concentration, without a dilution or a flag.

Summing Up

USEPA's Expectations

- Use Approved Methods.
- Follow the Method Procedures.
- Preserve, Prepare and Analyze Samples as Required in the Method.
- Perform the Required Quality Control.
- Document, document, document.
- Note any "problems" associated with the results.

Be BRAVE!

COURAGE

Do one brave thing today... then run like hell.

Questions?

Thank You, VERY Much!

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