

Laboratory Ethics and Data Integrity
“Train-the-Trainer” Presentation

Oregon Technical Advisory Committee (OTAC)

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Disclaimer

The following information is provided to assist Oregon laboratories with Laboratory Ethics and Data Integrity Training in their facilities.

The information is for guidance only.

TNI Standard

2009 TNI (NELAC) Standard 5.2.7

“Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis”

Case Study

The following is a theoretical event:

Max is scheduled to read some Collilert results in the afternoon, he gets very busy with an emergency in the plant which makes him late for his son's big game and he totally forgets about the micro samples.

The next morning Max looks at the samples and they are all yellow. The yellow color indicates a negative result.

Sure the 24 hour window has past but they are still negative why not write down yesterday's date and move on.

What would you do and why?

Case Study

You saw Max taking readings in the morning and know they should have been done yesterday

What should you do and why?

Is this an improper practice? Is this fraud?

Ethics and Data Integrity Training

Program Overview

Define Ethics

Why is Ethical Behaviour Important

Define Laboratory Fraud and Improper Laboratory Practice

Clearly identify what constitutes unethical behaviour and the penalties that accompany such behaviour.

Consequences of Improper Practices

Identify the employees' responsibility

Identify the employers' responsibility

Examples of Improper Practices

Review correct integration procedures

Ethics Defined

A system of moral principles governing the appropriate conduct for a person or group

Doing the right thing

Being honest and straightforward not lying or cheating

A code of conduct

- ACS web page "The Chemist's Code of Conduct"
- www.acs.org/careers search Code of Conduct
- ACIL web page Code of Conduct for Laboratories
- www.acil.org look under About Us

Why Act Ethically

Your personal reputation and the reputation of your organization or business depends upon it

Decisions we make as chemists and environmental professionals affect the environment and the lives of others

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

Definition of Improper Practice

A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.

Definition of Laboratory Fraud

The deliberate falsification of analytical or quality assurance results, where failed method requirements are made to appear acceptable during reporting.

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.

What is the Difference Between Fraud and an Improper Practice?

Fraud is purposeful and intentional

Fraud is not a mistake.

Fraud is an intentional misrepresentation of lab data to hide known or potential problems.

Fraud makes data look better than it really is, with the intent to deceive.

Sometimes the difference between fraud, improper practice and honest mistake is simply lack of proper documentation.

Examples

You're in a hurry because it's a short week. You started up the autoclave and forgot to check the pressure and temperature during the sterilization cycle as required by the SOP. Why not just check off the column in the log book. We have that positive bottle in there to determine sterility, right? It's just this one time.

This practice is:

A. An improper lab practice

B. Lab fraud

Back to Max

Max is scheduled to read some Collilert results in the afternoon, he gets very busy with an emergency in the plant which makes him late for his son's big game and he totally forgets about the micro samples.

The next morning Max looks at the samples and they are all yellow. The yellow color indicates a negative result.

Sure the 24 hour window has past but they are still negative why not write down yesterday's date and move on.

Is this Fraud or Improper Practice?

Examples

An analyst knows that the response to VOCs degrades over time on their GC/MS. The lab is slammed with VOCs and analyses will be going out of hold if they have to stop to recalibrate.

When they prepare the samples they put just a little more standard into the LCS sample to make sure they get good results

The results are almost always ND it really won't make a difference.

This practice is:

A. An improper lab practice

B. Lab fraud

Examples

Julie is being pressured by her supervisor to get more metals digestions done in a shorter time due to rush turnaround times. She decides that she could turn up the temperature and digest in half the time to solve her dilemma.

This practice is:

A. An improper lab practice

B. Lab fraud

Ethics Scenario - Possible Solutions

Discuss the situation with the supervisor (and possibly Quality Manager) and clearly define how many samples can be done correctly.

Coordinate with the supervisor the possibility of extra shift work or weekend work to complete all the samples on time.

If this is not possible, inform supervisor and Project Manager which clients need to be informed that their samples will not be completed on time.

Document all actions taken on prep log.

Propose her method performance improvements to management who may decide that the changes are method compliant and the SOP can be modified.

Why Talk about Improper Laboratory Practices and Fraud

The EPA Office of the Inspector General (OIG) has shown continued interest in the investigation of laboratory misconduct in the last decade.

- Arizona – 20 cases of severe improper procedures, including fraud, during audits of over 140 laboratories seeking certification from the State (about 1 in 7 laboratories)

- EPA OIG Report, September 21, 2006

Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks

<http://www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf>

What Are the Penalties for Fraud

Some Possible Legal Actions

- ◆ Suspension or Debarment
- ◆ Civil Prosecution
- ◆ Criminal Prosecution

Regulations or Statues that may be used for Fraud Prosecution

- ◆ False Claims - 18 U.S.C. 287
- ◆ False Statements - 18 U.S.C. 1001
- ◆ Mail Fraud - 18 U.S.C. 1341
- ◆ Wire Fraud - 18 U.S.C. 1343
- ◆ Conspiracy - 18 U.S.C. 371
- ◆ Misprision (Concealment) of Felony - 18 U.S.C. 4
- ◆ Obstruction of Justice - 18 U.S.C 1505

What Are the Penalties for Fraud

Penalties for Conviction of Fraud

- ◆ False Claims – up to 5 Years prison and/or \$500,000 fine
- ◆ False Statements - up to 5 Years prison and/or \$500,000 fine
- ◆ Mail Fraud - up to 5 Years prison and/or \$500,000 fine
- ◆ Wire Fraud - up to 5 Years prison and/or \$500,000 fine
- ◆ Conspiracy - up to 5 Years prison and/or \$500,000 fine
- ◆ Concealment of Felony - up to 3 Years and/or \$500,000 fine
- ◆ Obstruction of Justice - up to 5 Years prison and/or \$500,000 fine

OIG – Areas of Concern

- Data manipulation
- Failure to follow SOPs/reference methods
- Falsifying existing data
- Improper calibration
- Inappropriate manual integrations
- Overwriting files: peak shaving, juicing/peak enhancing, deleting
- Inadequate training
- Inappropriate collection process
- Incomplete record keeping

OIG – Areas of Concern

- Mislabeled sample
- No demonstration of competency
- No requirement for collector
- Reporting data for samples not analyzed ("dry labbing")
- Retention times not assured
- Sample integrity unknown
- Selective use of QC data
- Spiking samples after preparation
- Time travel (changing times and dates)

Source: EPA OIG expert panel

Fraud Prevention

Create effective policies:

Zero Tolerance – fraud is grounds for immediate dismissal

Be Proactive:

Develop a Laboratory Data Integrity Program Plan

Develop a Code of Conduct and/or Ethics Agreement

Write SOPs (manual integration, use of electronic audit functions, data review criteria)

Laboratory Responsibilities

Continuously monitor data on a periodic but random basis – data audits

Provide clear guidance and policies for ethical behaviour - code of conduct statement signed yearly

Provide ongoing training to employees

Perform confidential investigations if a problem is detected.

Notify clients and reissue reports if data is negatively impacted.

Eliminate undue pressure on analysts – quality ahead of TAT

Provide mechanism for confidential reporting of abuse without recrimination – whistle blower policy

Employee Responsibilities

- Uphold the ethics policy and practices as demonstrated in their daily conduct.
- Seek help when the proper course of action is unclear or unknown to them.
- Remain alert and sensitive to situations that could result in actions by any employee that are improper, illegal, unethical, or otherwise in violation of the ethics policy and practices.
- Counsel fellow employees when it appears that they are in danger of violating the ethics policy and practices.
- Report violations of the ethics policy and practices to their supervisor.

How Do I Know a Practice is Improper

Does it violate policy or procedure, SOP or QAPP

Mom Test – would mom approve

Would an auditor approve

Gut check – Do I really feel this is right

Would my son or daughter be proud

Am I doing this so I can leave early

Would my supervisor, lab director or

QA manager disapprove



Why do Improper Practices Occur?

TO MAKE QC PASS!

* (this is WRONG!)

Bench Reasons:

- to avoid re-running sample
- to avoid instrument maintenance
- to avoid missing sample holding times
- to avoid getting in trouble with boss

Management Reasons:

- to avoid looking bad to upper management
- to avoid financial penalties on contract
- please client

An Ounce of PREVENTION:

If you miss a holding time or make a mistake, be honest about it. Covering it up can take it from honest mistake to fraud.

Don't be clever be smart, in the long run it takes less effort to just follow policy than to find clever ways to circumvent it .

QC is used to determine sample, equipment, or method issues, not how good you are at your job.

Whatever the problem, it is not worth losing your job or going to jail!

Talk with your Supervisor or QA Officer if you have questions

An Ounce of PREVENTION:

DOCUMENT, DOCUMENT, DOCUMENT!!- An 'outsider' should be able to re-create the entire analytical process, including data review decisions

Talk with your Supervisor, QAO or Lab Chief if you have doubts or questions

Follow the method / SOP as written- (or revise the SOP as necessary)

Quick Review

Lab Fraud / Scientific Misconduct

Has intent behind it

Is not an accident or mistake

Is not acceptable for any reason

Can destroy careers

Prevention

DOCUMENT / Communicate problems immediately

Take time to do it right!

Don't take short cuts

Follow the SOP / Method

Expect some QC to fail on occasion

To Be Clear...

It is **OK** to make a mistake

- It is **NOT** OK to hide that mistake

It is **OK** to have QC out of limits

- It is **NOT** OK to hide QC that is out of limits or make it appear to be within limits when it is not.

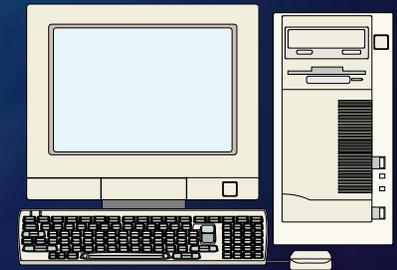
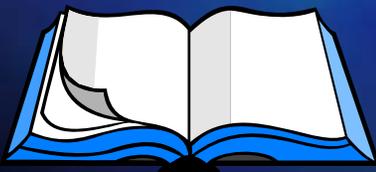
There are potentially **severe** consequences for scientific misconduct that can affect you and your lab.

Good **communication** can be key to prevention of these problems!



Examples of Improper Lab Practices

Not a "How To" but a 'How Not To'



Improper Preparation Practices

Not prepping a PT sample before analysis (direct injection)

Not prepping calibration standards when required by method

Not adding surrogates or spikes until after prep – post spike

Leaving out hydrolysis step in Herbicide analysis

Not digesting samples for metal analysis when required by the method

- organo-metalics give low or no reading

Treating Batch QC Different than Samples

Not treating batch QC samples in the same way as the rest of the batch

- Not extracting or digesting method blank or laboratory control sample (LCS).
- Must use same clean-up techniques on QC samples as regular samples

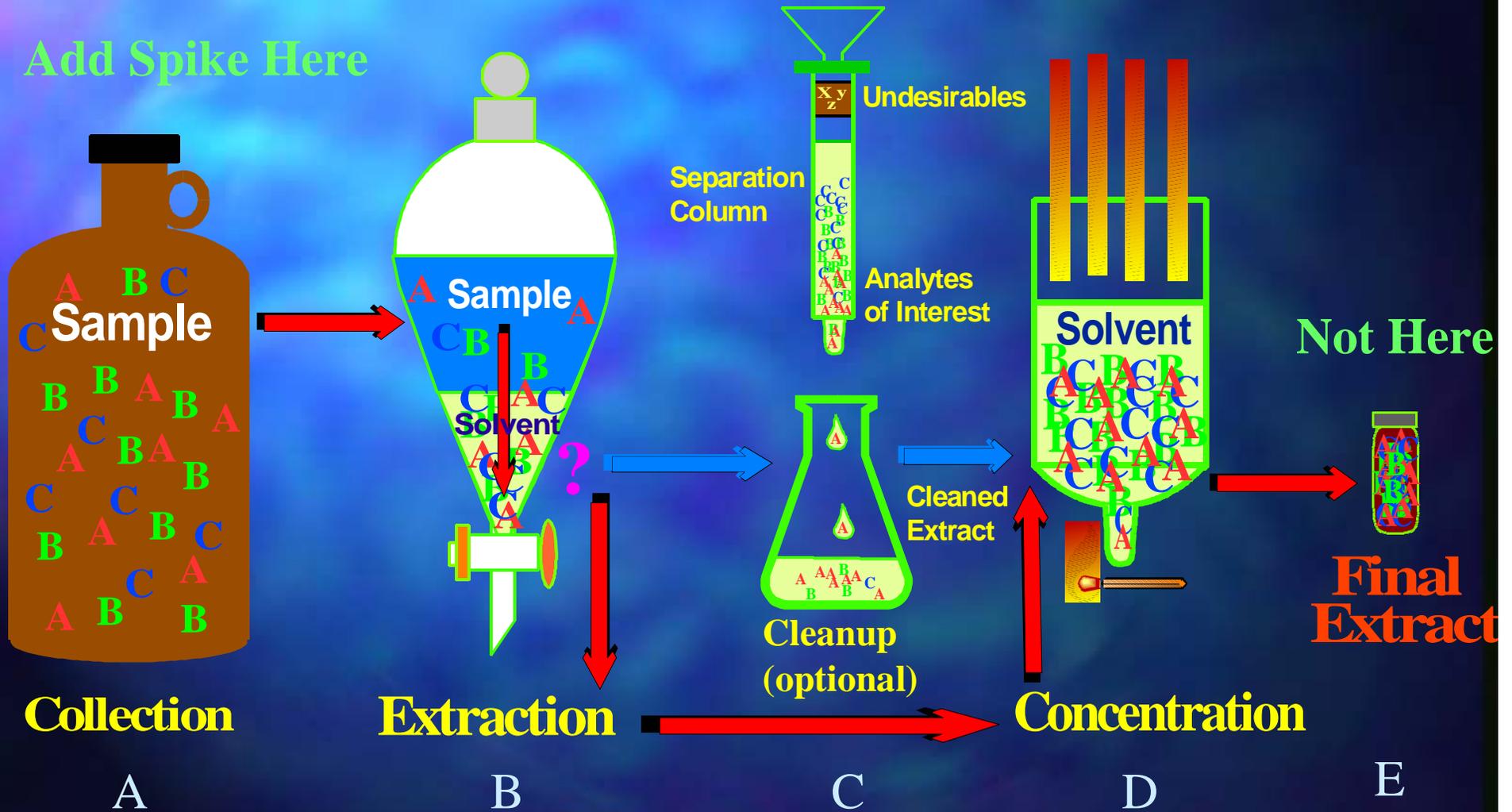
Reserving special glassware for blanks

- blank may appear cleaner than samples would
- may report sample results that are blank related

Improper Spiking Procedure

Testing for Analytes A, B, and C

Add Spike Here



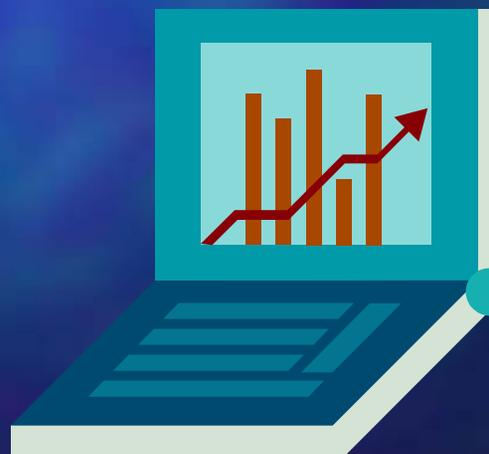
Improper Calibration Procedures

Using calibration procedures that are not allowed by the required method

- Second order curves

Selective removal of bad points to avoid re-running standards

sometimes allowed (upper, lower, statistical cause)



Data Deletion

Removal of existing data to give the appearance of non-detect results

- e.g. You run this station every week and it always is non-detect....

Selective removal of MDL data points

- e.g. Analyze eight and choose the best seven

Raw data packages not containing all data, should include failed data.

Improper Use of QC Data

Selective use of QC data

- Running extra QC in case some results don't 'work out' and not using the 'bad' data
- Running QC samples without documented evaluation criteria

This can lead to inconsistent evaluation of the results.

Improper Analytical Procedures

Data Modification / Manipulation / Selection

- modification of existing data to represent values different from actual
- Dry labbing of data
- time travel
- Improper manual integration

Examples of Dry Labbing (fabrication)

Changing a computer generated report to represent sample results which were never generated

Using the result from one sample and applying it to others as an accurate determined value for each sample

Manually entering random values for results never determined through analysis

- e.g. pH of this station is always 7.5.....

GC Peak Integration

Determines area or height of a chromatographic peak

Necessary to quantitate chromatographic analytes

Currently major focus of abuse in lab fraud cases

Two basic types of integration: auto and manual

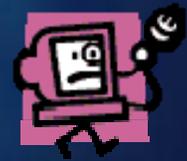
Auto Integration

Computer decides:

- proper technique (drop, tangent, valley)
- where baseline is
- the beginning and end of each peak

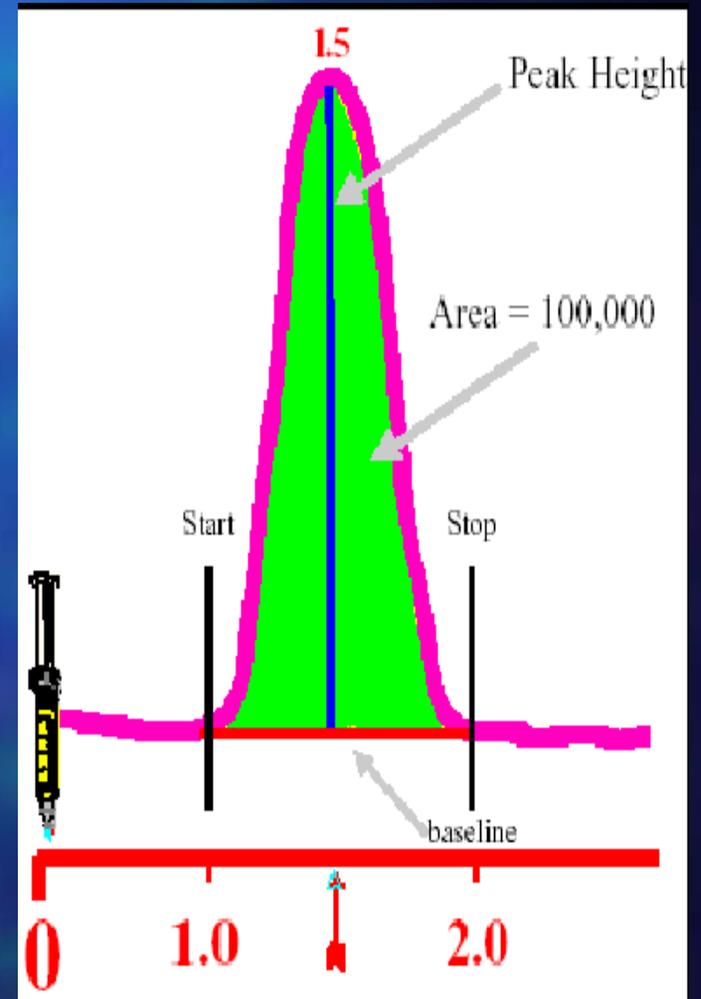
Difficult to show intent of fraud.

- ◆ BUT -- Computers can make mistakes, especially with a noisy detector. Need manual check.



Normal Peak Integration

<u>Name</u>	<u>RT</u>	<u>Area</u>	<u>Amount</u>
8) 2-Chlorophenol	7.12	128 634775	67.57 ug/L
10) 1,4-Dichlorophenol	7.33	146 250996	24.25 ug/L
17) N-Nitroso-di-propylamine	7.87	70 253477	38.19 ug/L



Manual Integration (MI)

Operator decides everything. Big potential for fraud. Big **RED** flag.

Sometimes very necessary to use MI for accurate results, not always wrong.

Can be very difficult to determine proper integration method.

- Co-elutions
- Bad baselines



- ◆ **Protect yourself:** always document how and why MI done!

Reasons for Improper Manual Integration

Biggest reason: **TO MAKE QC PASS!**

Curve does not pass response criteria

- minimum response or linearity

Continuing Calibration response does not match curve (% difference >)

Internal Standard areas out

Surrogates out

Matrix spikes out

Results of Poor Integration

Sample results too high (calibration or ISTD area)

Sample results too low (calibration or ISTD area)

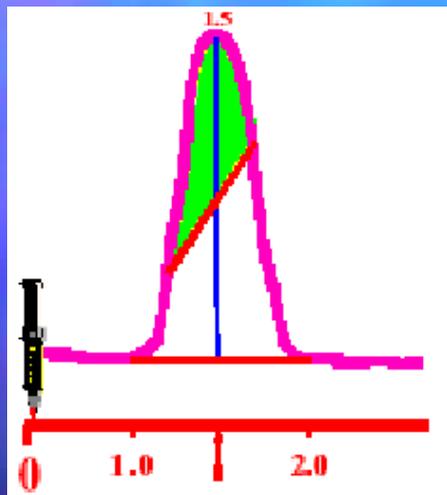
Data appears better than it is:

- Curve looks good, when should not
- Continuing Cal passes, when should not
- Internal Standards match, when should not
- Surrogates appear ok, when should not
- Spikes appear to ok, when should not

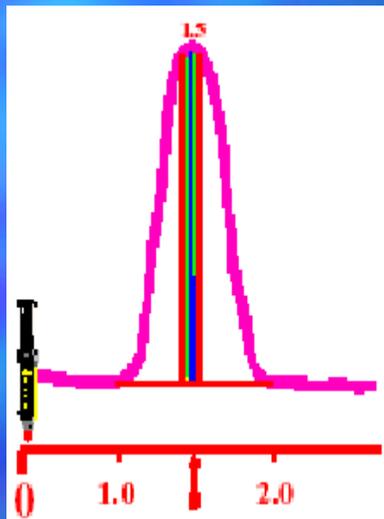


Peak Shaving: Less Area

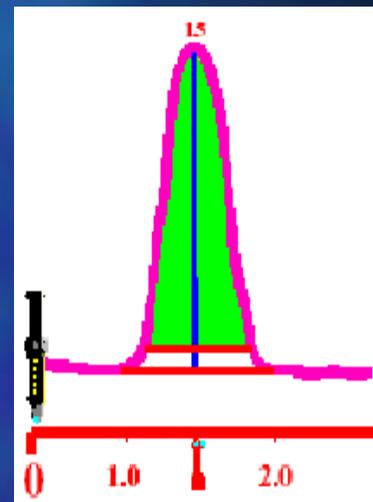
Std Area = 100,000
 Sample Result = 1,000 ug/Kg



Std Area = 40,000
 Sample Result = 2,500 ug/Kg



Std Area = 5,000
 Sample Result = 20,000 ug/Kg

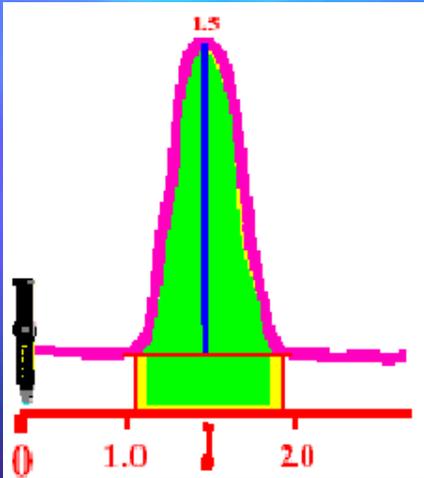


Std Area = 90,000
 Sample Result = 1,111 ug/Kg

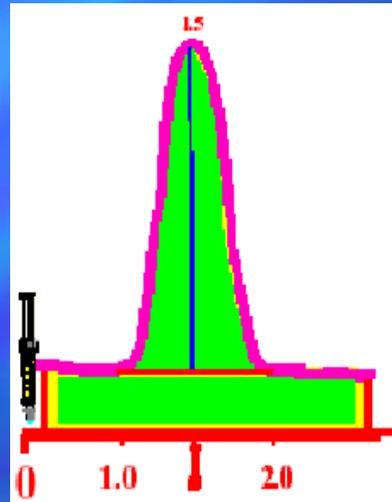
Name	RT	Area	Amount
Target Compounds			
5) Phenol	7.02	94 79878m	62.71 ug/L

Peak Addition: More Area

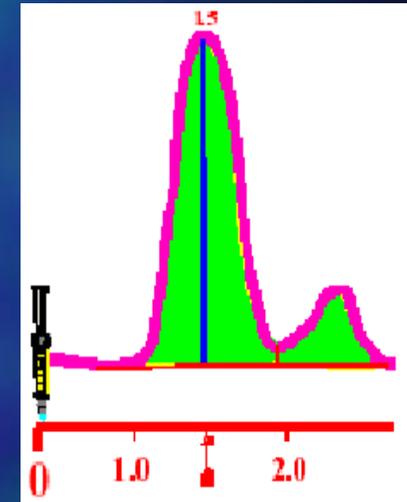
Std Area = 100,000
 Sample Result = 1,000 ug/Kg



Std Area = 130,000
 Sample Result = 769 ug/Kg



Std Area = 200,000
 Sample Result = 500 ug/Kg



Std Area = 130,000
 Sample Result = 769 ug/Kg

Name	RT	Area	Amount
Target Compounds			
5) Phenol	7.02	94 79878m	62.71 ug/L

Acknowledgements

USEPA Office of Inspector General (OIG) –
Laboratory Fraud

State of South Carolina DHEC – Improper Practices

City of Portland, OR and City of Keene, NH – Ethics
Training

Laboratory Fraud Detection and Deterrence

Rick McMillin and David Stockton, USEPA Region 6

Certificate of Completion

This Certificate is presented to:

On this ____ day of _____

For completion of

OTAC Train the Trainer
Laboratory Ethics and Data Integrity