

# Ethics/Data Integrity Training

By  
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# Gary Ward - Background

- ORELAP Administrator – retired
- Ranked in Top 20 Cannabis Analytical Scientists in the country
- Columbia Analytical Services – VP – 9 labs
- ITS-Director of Labs -257 labs world-wide
- Underwriters DW Laboratory – Lab Dir.
- Enseco Laboratories - VP- QA, Technology
- US EPA – Manager, Superfund CLP >100 labs , authored EPA methods & QA/QC

# History of Lab Ethics Programs

How did we get to the ethics programs of today

What happened to labs, analysts, samplers in the past  
– personally involved

Seeming small actions can have devastating effects

# History of Ethics Issues

- First - 1983 – RTP lab, NC
- Second – Seattle lab
- Third – NY lab
- Fourth– large PA lab
- Fifth - 1999 – ITS labs – Dallas, TX
- 2000 – Caleb Brett - Americas



# Recent Ethics Issues

- 2016 – Accutest Laboratories
- 2017 – Las Vegas NV Cannabis Labs
- 2018 – Berkeley CA Cannabis Lab
- 2019 – Sacramento CA Cannabis Lab

# Recent Sampling Ethics Issues

- Coos Bay Water
- Maui Hawaii Water
- Oakland CA Cannabis Lab - 2018

# History of Ethics Issues

- First - 1983 – Lab in RTP, NC – “Creative Integrations” – caught by data review
- Tunes for GC/MS
- CCVs
- Result – suspend CLP contract, lost work
- Eventually closed

# History of Ethics Issues

- 2nd – Seattle lab - Disgruntled employee
- Improper integrations
- “Juicing” CCVs
- IG investigation – undercover analyst
- Result – lab lost CLP contract, lost work
- Lab closed



# History of Ethics Issues

- 3<sup>rd</sup> – NY lab – data review
- Single passing LCS for multiple batches
- Unannounced audit
- Result – lab lost CLP and other contracts
- Eventually closed

# History of Ethics Issues

- NY lab – caught by data review
- Time travel to meet holding times
- Result – Lab president went to jail
  - He lost family (wife divorced and kids moved away)
  - Had heart attack and died in prison
- And lab closed

# History of Ethics Issues

- 4th – large PA lab – caught by audit
- “Time Travel” - change computer dates to meet holding times – actually in SOP
- Result - \$4 million penalty fee
- “Debarred” – cannot perform ANY government work for 2 years (not just environmental)
- Eventually closed

# History of Ethics Issues

- 5th – ITS Dallas
- 250 people in huge lab
- AFCEE “QA Lab” – one of every 10 samples went to lab
- Parent company (London) - \$1 billion



# ITS Dallas

- Caught by new QA officer, self disclosed
- “Time Travel” - change computer dates to meet holding times
- Improper integrations – “juicing” (boat anchors), shaving peaks, adding peaks
- Dry lab monitoring samples
- Fake monitor sampling

# ITS Dallas

- Make up calibrations from past calibrations
- Bad Manual integration of IS – affect all QC
- Spiking in additional amounts
- Copy files to other runs
- Lab Director threatened with cattle prod (first definition of “undue pressure” to produce)

# ITS - Dallas

- “Raided lab” with 40 armed agents and DOJ
- Put everyone against walls
- Seized all computers, entire LIMS, 1200 boxes data
- Stored in Federal warehouse across from the “bookstore” (site of JFK assassination)
- Interviewed each person with 3 agents
- Indicted 13 people – supervisors, analysts, lab director

# ITS - Dallas

- Within 6 months – everyone laid off
- Each of 13 indicted received letter -stating they owed the Federal government the sum of \$2 million (send check or money order)
- Initial Company Result
  - proposed \$400 million fine from gov't
  - \$600 million in lawsuits from clients



# ITS - Dallas

Parent company (London) took action

- Shut down all environmental labs worldwide
- Hired objective consultant approved by EPA
- Hired 60 new people to re-process data for over 100,000 samples using extensive, exact Manual Integration SOPs and data processing SOPs (calibration, QC, etc)
- Cost \$16 million & 2 years (1999-2000)

# ITS - Dallas

- Re-Process Results – presented in meeting with CID from EPA and DoD, IG, DOJ, US Attorney General (Janet Reno)
- All analysts were tried in court
- Each one needed own lawyers at a cost of over \$100,000 each
- Each person officially “debarred”
- Debarment check is boilerplate for almost all contracts – civil and government

# ITS - Dallas

Re-Process Results – very little effects on data and data decisions but....

- Charges were mail fraud and false claims against the government regardless of data usability
- Mailed/emailed reports with fraudulent data
- False claim – invoiced for fraudulent work
- EACH data report was a separate charge for \$5000 fine and 5 years in jail

# ITS - Dallas

- Parent company spent \$16 million on re-processing data
- Estimated court costs \$6 million
- Ended up with EPA fine of \$22 million
- Luckily, EPA reduced fine to \$6 million by allowing credit for \$16 M for re-processing
- Civil lawsuits – \$0 since re-processed data usable



# ITS – Caleb Brett

- 254 labs world-wide
- Analyzed gasoline and oil in ships in harbors
- Clients needed certain values for high test gas
- Clients would go to other labs if not satisfied
- New Jersey lab - investigated

# ITS – Caleb Brett

## Fraudulent Actions

- Repeated analysis until got answer client wanted
- Since method was  $\pm 30\%$ , used that uncertainty and applied to results to get values acceptable to client
- Adjusted integrations to get desired results
- Just change results to get desired results

# ITS – Caleb Brett

How caught

- People client sold to found out

Others

- Disgruntled employee
- Government audit
- Inter-lab comparisons
- Independent data reviewers
- Private citizen/reporter investigations

# ITS – Caleb Brett

## Results

- Lab Manager and Organic Supervisor went to jail and were fined \$200,000
- Guilty analysts fired and fined \$100,000
- Lawyer fees were \$75,000 to \$150,000
- Mail fraud – mailed, email, fax
- False invoices
- Each report is separate charge (\$5000 + 5 yrs in jail)



# Accutest

2016 – headquartered in NJ

- One of largest lab networks
- DOJ investigation
- \$ 3 million fine
- Altered GC/MS to make QC pass
- Did not follow calibration protocols
- Altered QC samples to make QC pass

# ITS - Dallas

Mis-conceptions – Its OK if...

- If its in the SOP
- If lab is audited and problem is not found
- Data manipulation had very little if any effect on data results
- Never find analyte in samples, so QC not important
- Monitoring sample with nothing before so why analyze (rationalization for fraud)

# EPA Response

- Based on Dallas and other cases, there was widespread distrust of non-EPA labs
- EPA proposed moving funds into EPA labs and not sending samples to other labs
- Setup “ESATs”, support assistance team contracts bringing in analysts into EPA labs

# History of Ethics Program

- ACIL – American Council of Independent Laboratories - 2000
  - 80% of lab industry (by revenue)
- ACIL (lab trade association) set up meeting with Nikki Tinsley, EPA Inspector General



# History of Ethics Program

- Meeting in Washington DC with myself and Charlie Carter (VP TestAmerica) – now deceased
- Presented “fixes” for labs to re-establish confidence in private labs
- Ensure lab management is doing all it can to prevent data integrity issues

# Lab Fixes

- Lab Management put program in place to ensure employees know what the company wants and what will not be tolerated

# Lab Fixes

- Manual integration – before & after, date, who, why – reviewer can check & validate
- MI (Manual Integration) SOP
- Ethics (Data Integrity) signed statement describing company policy
- Termination of offending employees
- Termination of person who saw fraud done (ie., data reviewer) and didn't report

# Lab Fixes

- Management to encourage open door policy and anonymous reporting system
- Initial ethics training as orientation
- Annual refresher ethics training
- Annual audit
- Personnel free from undue pressure to perform & compromise technical judgement



# EPA Agreement

- If labs implement “fixes”, DOJ will not prosecute lab management or close lab company
- Single “rogue” analyst will not initiate investigation
- EPA will continue to use private labs

# But...in Chicago, IL

- In EPA Region 5 laboratory
- Analysts were found to be committing many of the same unethical actions
- Investigation showed it had been going on for 5 years
- Problem – there were no “profit gains” to drive fraudulent actions

# EPA Region 5 Lab – Results

- All analysts terminated
- All analysts on debarment list
- EPA had to throw out years of data
- Had to go back and review all decisions
- Decided to have laboratories receive a 3<sup>rd</sup> party evaluation
- Went overboard and required that no manual integrations were acceptable

# EPA Region 5 Lab – Why?

- Lot of samples to analyze
- Analysts did not appreciate the impact of their actions
- Analysts had not received clear training on expectations
- Not interested in results, just wanted to get analyses done
- Poor technical training



# Coos Bay Sampling Fraud

- Sampler for Coos Bay Water Plant
- Sampling was to be done at various points around plant and environment
- Sampling was to be at 10 sample points
- Sampler took all 10 samples at a single point, then went to lunch

# Coos Bay Sampling Fraud

- Caught when supervisor saw lack of mileage on vehicle
- Followed her around
- Result – sampler was sentenced to prison
- Coos Bay had to implement immediate and frequent sampling and testing

# Maui Hawaii Sampling Problems

- Lab sampler was sampling from a spigot on tank
- Problems discover on an audit
- Sample spigot was not under cover so rain dripped down into sample while sampling
- Sample was taken in sampling “bucket” then poured into sample bottles
- No QC or cleaning of sampling bucket

# Maui Hawaii Sampling Issues

- Result – State threw out all monitoring data
- System had to undergo rigorous re-sampling and re-analyses
- Sampler and supervisor were fired
- Lab developed and implemented detailed sampling SOP



# Oakland Sampling Mess -2018

- Lab Sampler for cannabis did not follow sampling requirements on a large client batch
- Sampling increments and weights were short cutted
- State found out and threw out all the test results

# Oakland Sampling Mess -2018

- Client had to recall 50 lb batch
- Client had to re-sample and re-test
- Laboratory reputation was ruined
- Clients bailed
- Laboratory had to shut down

# NV Labs – 2017

## Cannabis Labs suspended

- “Lab was not following proper procedures”
- Four NV labs suspended for improper procedures
- Three corrected issues
- One still suspended

# Berkeley CA Lab – 2018

## Cannabis Lab suspended

- Fraudulently, changed results to meet customer request
- Applied pressure on clients (higher fees) to give desirable results
- One of a national network of labs
- Suspended laboratory



# Sacramento CA Lab – 2019

## Cannabis Lab suspended

- Fraudulently reported pesticides
- For 4 months, lab had been “faking pesticide results”
- For 22 pesticides they were reporting, the lab did not even have standards for calibration
- Lab Director knew and admitted it

# Lab Industry Implementation

TNI (The NELAC Institute) formed

- Integrated the ethics/data integrity concepts into the standard
- Enforced data integrity through assessments

# Government Investigations

- Government can/will suspend a lab for up to 18 months while it investigates
- Agency – can't trust data for decisions so must suspend lab to see if it is true.
- IG report - 58 labs under investigation (1/3 were drinking water labs)

# Some IG Issues Found

- Time travel – holding times
- Time travel - QC
- Dry lab results
- False spiking
- Fraudulent manual integrations – juicing, shaving
- False blanks – Qdelete, isolated equipment
- False reporting
- Cheating on PTs
- Fake sampling



# Ethics

- Bottom Line – any ethically lapses and the following could occur
- Results – devastating personally
- Results – destruction of lab and those who work there

# Actions

- Suspension/debarment
- Civil action, penalties
- Criminal action – company and/or individuals
  - prison & fines
  - mail fraud, false claims
  - obstruction of justice

# How to Sleep At Night

- Have systems in place to check for improper actions
- Make sure people know you are checking
- Show management responsibility
- NELAP Accreditation (ORELAP)
- Ethics program – statement, on going training  
“Ethics becomes a problem in most companies, not because of ethical differences, but rather because it is not part of the conversation.”

# How to Sleep At Night

- Data integrity statements
- Print out before and after integrations, sign & dated
- Employee handbook
- Ombudsman program
- Open door policy
- Define company policy, use examples
- “Zero tolerance” policy



# How to Sleep At Night

- Make sure every single person knows their actions can take down the company
- Make sure every single person knows they personally can go to jail
- Keep reminding them of it
- Very specific SOPS, particularly integrations & actions for out of control QC
- Very specific policies, checklists
- Technical training with SOPs

# Ethics/Data Integrity

- Bottom Line – no client, no project are worth the possibility of
  - Prison
  - Financial catastrophe
  - Loss of job
  - Health Issues or death