

Data Integrity for Cannabis Sampling

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Gary Ward - Background

- ORELAP Administrator - retired
- 2020 -Top 20 Scientists in Cannabis Science
- CCIA – CA Quality Control Committee
- Columbia Analytical Services – VP – 9 labs
- Intertek Testing Services – Director of Laboratories – 257 labs world-wide
- Enseco Laboratories - VP- QA, Technology
- US EPA – Manager, Superfund CLP >100 labs , authored EPA methods for metals, organics, developed QA/QC program

Cannabis Sampling

- OR Sampling Protocols
- Sample size ($>0.5\%$ of batch weight)_
- Maximum batch size (50lbs)
- Sampling Plan
- Equipment and cleaning specifics
- Balance Verification
- Sampling Report Form

Sampling Plan

- Size, shape, # containers
- Number of increments to be collected_
- Minimum weight of each increment
- Locations where increments will be taken
- Random selection of locations

Sampling Report Form

- Name & address of producer with license#
- Product type_
- Total batch weight
- Lab batch ID
- # Containers sampled
- # sample increments from each container
- Weight & location of each increment
- Total weight sampled

Sampling Report Form

- Sampling Plan ID & revision date
- Sampling procedure ID & revision date_
- Description of tools & equipment used
- Address where sampled
- Date Sampled

Data Integrity Concerns

Why do we need ethics/data integrity programs .

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

Seeming small actions can have devastating effects

Good people can do bad things . . .

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but are less likely to do so when:

- *There is a culture of honesty, quality and integrity.*
- *There are clear policies and procedures in place.*
- *They understand the “big picture” and the value of the work that they do.*

Threats to Data Integrity

- Improper practice
 - A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters or sampling processes, making the results appear acceptable.
- Fraud
 - The **deliberate** falsification of process or analytical results, where failed sample requirements are made to appear acceptable.
 - The **intentional** recording or reporting of incorrect information
 - An **intentional** gross deviation from required practices, combined with the intent to conceal the deviation.

Recent Sampling Issues

Sampling issues in environmental testing and cannabis sampling

Bad sampling = Bad data

- Oakland CA Cannabis Lab
- CA Cannabis Labs
- Other cannabis incidents

Oakland Sampling Mess

- 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

- 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

CA Sampling Issues

- R&D samples - client sampled
- Compliance samples – lab sampled
- Results from R&D very different from Compliance testing
- Client blamed lab for bad results
- Client applied pressure to report R&D data

Other State Labs

Cannabis Labs suspended

- “Lab was not following proper procedures”
- One half labs were suspended for improper procedures
- Most corrected issues
- One still suspended

CA Lab A

Cannabis Lab suspended

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

CA Lab B

Cannabis Lab suspended

- Fraudulently reported pesticides data
- **Sampled only plants isolated from pesticides**
- For 4 months, lab had been “faking pesticide results”
- For 22 pesticides they were reporting, the lab did not even have calibration standards

Another State

Cannabis Lab suspended

- Fraudulently reported fake results
- Lab had been reporting non-detects when results were above action limits
- Grower claimed it was No-Pest strips for DDVP (Dichlorvos) **sampling contamination** so shouldn't be reported

Recent Sampling Issues

- Sampling part of buds with higher THC
- Find plant with high THC during R&D, then sample it
- Isolate plants from pesticides – sample only those
- Edibles – sample only part of product (ie., jam on top of cookies)

Recent Ethics Issues

- Shop labs for high results – analysis and sampling
- Food – “good”: batch sampled had CBD, rest little if any CBD
- Extracts – use highest number from multiple, duplicate or replicate samples
- Excessive inflated THC , forced State to shutdown one of their large labs.

Recent Data Integrity Issues

- In one state, 10.6% cannabis flowers, 20.4% inhalable oils, 32.9% edibles, tinctures, lotions had labels more than 10% difference from the true value.
- In another state, random sampling found significant yeast and mold on products declared contamination free. Recall affected over 100 dispensaries

Recent Data Integrity Issues

- Take duplicate samples from the same plant
- Take “Duplicate samples” from same homogenized sample
- Contamination from inadequate cleaning sampling equipment

Preventing Data Integrity Issues

- Follow policies and procedures
- Ask for help
- Help others
- Report violations
- Self survey:
 - I am an ethical person.
 - I will do the right thing even if no one knows
 - I will do the right thing even if under pressure
 - I want other people to think I'm honest and ethical.
 - I will do the right thing even if no one else is doing it.



Fraud Prevention

- Ethics/data integrity program

“Ethics becomes a problem in most companies, not because of ethical differences, but rather because it is not part of the conversation.”

Lab Fixes

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

Lab Fixes

- Ethics (Data Integrity) signed statement describing company policy
- Termination of offending employees
- Termination of person who saw fraud done and didn't report
- Document sampling with video
- Detailed sampling forms with specified increments and weights.

Lab Fixes

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

Ethics/Data Integrity

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