Ethics and Data Integrity in the Microbiology Laboratory

To Protect and Enhance Kentucky's Environment

Definition

- **Laboratory Integrity**: The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

  (Data is legally defensible.)

Ensure Quality Data

- Document all work performed!!
- Be able to “reconstruct” work from readily available records
- Proper Training
- Current SOPs
- Oversight (internal and external audits)

Ethics Policy

- Laboratory should establish a set of ethical standards and procedures. They should be documented and reviewed annually.
- The Ethics Policy should describe laboratory's expectations regarding workplace integrity, ethics, and compliance concerns.
- A critical part of new employee training.

Proper Documentation

- Bench sheets and sampling forms – filled out completely with accurate information.
- Logbooks – bound with numbered pages.
- SOPs - should be current, accurate, and reviewed frequently. SOPs should reflect exactly what you do.
- Corrective Action Books – document any mistakes, deviations, or accidents.

Definition

- **Laboratory fraud**: The deliberate falsification of analytical and quality assurance results, where failed method requirements are made to appear acceptable during reporting.

Definition

- **Inappropriate procedure**: 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.

  (Even the appearance of an impropriety may challenge the integrity of the data.)

Types of Lab Fraud

- Intentional misrepresentation of lab data to hide existing or potential problems.
- Intent to deceive – making data look better than it really is.
- Dry Labbing – Reporting data for samples or procedures not actually analyzed or performed.
- Data deletion – removal of bad/undesirable data.

Areas of Lab Deception

- Deviations from SOPs. This could result in the data not being representative because it was produced in a way inconsistent with correct lab procedures.
- Elimination or modification of critical steps of sample prep or analysis that change results or the interpretation of data.

Areas of Lab Deception

- Data Deception
- QC Deception
- Time Travelling
- PT Deception

Data Deception

- Data Modification – changing results to desirable ones
- Data Deletion – Removal of “Hits” (Positives) in samples or blanks
- Data Creation – Missing data/Dry labbing
- Data Ignoring – Ignoring bad QC results and reporting results anyway

QC Deception

- Falsification of QC results to meet method requirements
- Failure to prepare and analyze all required QC samples
- QC samples not analyzed with batch samples
- Reporting results without flags when QC fails
- Not following proper lab protocols when QC fails

Time Travelling

- Log book dates and times modified to show media prep, sample prep or analysis within holding times
- Resetting of clocks (i.e. sample receipt daters or autoclave clocks) to make appear date stamped is within acceptance criteria
- Times of sample collection changed to seem as though within holding times

PT Deception

- Reporting PT results from another lab as their own (Subcontract PT samples)
- Calling another lab who uses the same PT provider, to get their results
- Analysis of PT sample by a method other than reported
- Analyze PT sample differently than client sample

Examples

- Records “too good” (Perfect)
- Leaving out sodium thiosulfate in sample bottles
- Samples “analyzed” before they were collected
- Altering test conditions (not incubating at correct temp or time, not adding media, etc.)
- Reporting results as negative without analyzing samples
- Creating calibration or temperature records

Detection

- Data Review (notice incomplete/missing/ altered records)
- Random spot checks at the bench
- Perform internal audits
- Check maintenance records of equipment
- Review inventory of laboratory supplies
- Deviations from the SOP
- Lab reports manipulated or altered

Deterrence

- Training – Adequate to demonstrate capability
- SOP – annual review
- Implement Lab Ethics Program
- Discuss employee pressure to out-perform, make deadlines and cut costs
- Quality Assurance (public health) vs. Profit (dry labbing)

Strive for EXCELLENCE!!

- Encourage all staff to perform according to documented, approved procedures and policies.
- Ensure staff are NOT pressured to or allowed to take short cuts or deviate from approved method or SOP.
- Suspicion of misconduct should be investigated immediately and dealt with appropriately.

Avoid Unethical Behavior

- Don’t deviate from the SOP or method.
- Don’t fabricate data.
- If a mistake happens: write Corrective Action, tell supervisor, ask for sample replacement, etc.
- Don’t hide error, mistake or fact.
- Maintain a code of ethics: honesty, integrity and reliability

What Do You Do if You Suspect Fraud?

- You should contact your immediate supervisor or manager
- Contact your QA manager
- Contact your State point-of-contact
- Contact Regional EPA office
- Contact Office of Inspector General (OIG) fraud hotline toll-free at 1-888-546-8740
  - Note: OIG Hotline is the only option for anonymous fraud reporting

Possible Consequences

- Criminal Conviction - mail fraud, wire fraud, conspiracy to defraud, false statements (imprisonment and fines)
- Civil Conviction
- Administrative Action – suspension or dismissal
- Laboratory de-certified

Reference

- OIG Final Report :

  "Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks" September 21, 2006

- Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks (epa.gov)

Additional Sources

- "Best Practices for the Detection and Deterrence of Laboratory Fraud"

  March 1997 labfraud.pdf (epa.gov)
- "Department of Defense (DoD) Policy and Guidelines for Acquisitions Involving Environmental Sampling or Testing"

  November 2007 Scan157, December 06, 2007 (osd.mil)

For Additional Information

(502) 564-3410
dowlabcertification@ky.gov

Laboratory Certification Webpages

- All DEP website addresses have changed
- Search engine links might not work (have to look for ones that start with eec instead of water.ky)
- New general address:
  - Welcome - Kentucky Energy and Environment Cabinet

Laboratory Certification Webpages

Main Page:

Laboratory Certification - Kentucky Energy and Environment Cabinet

Drinking Water:

Drinking Water Lab Certification Program - Kentucky Energy and Environment Cabinet

Wastewater:

Wastewater Lab Certification Program - Kentucky Energy and Environment Cabinet

Laboratory Pure Water – Daily Requirements

- Monitor daily conductivity of laboratory produced pure water and record results (ASTM Type I or II – see attached specification sheet) using a reliable device.

- Record daily results – develop a system such that all analysts using laboratory pure water are aware that daily monitoring has verified its' acceptability for drinking water analysis.

Laboratory Pure Water – Monthly Requirements

- Verify laboratory pure water monthly using an EPA approved reference method for conductivity utilizing a low level conductivity standard (2–10 uS/cm) to validate the bench conductivity meter reading and record results.
- Additionally, when performing the monthly verification of laboratory pure water, also analyze the same water using the daily monitoring device. This will ensure that the daily measurements are within acceptable range of use.
- Document monthly results using the conductivity bench meter and the device used for daily monitoring of the laboratory pure water.