Laboratory Ethics and Data Integrity

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Learning Objectives

• Understand the definitions relating to ethics and integrity
• Understand the various roles and responsibilities relating to work ethic, ethical conduct and producing data with unquestionable integrity
• Be able to recognize data integrity vulnerabilities in the laboratory
• Know how and when to report potential data or ethical breaches
Introduction

Definitions

**Ethics**: Principles of conduct governing an individual or profession*

**Ethical Behavior**: Acting in a way that displays integrity, honesty and morally good behavior

**Work Ethic**: Demonstrating ethical behavior at work; a set of values centered on the importance of doing work and working hard*

**Integrity**: Firm adherence to a moral code* or set of values; the quality of being honest and consistent

**Data Integrity**: Maintaining the accuracy and consistency of data over its entire life-cycle

*Merriam Webster

Laboratory Ethics and Data Integrity

*Takes Commitment “At all levels”*
Administrative Priority

• Most laboratories have policies, procedures, and trainings to highlight the importance of ethics, integrity and expectations of honesty

• Examples can include:
  • Employee Code of Ethics
  • Mission or Vision Statements
  • Quality Policy Statements
  • Standards of Conduct
  • Conflicts of Interest Disclosures

Employee Code of Ethics (Virginia)

• I am committed to the highest ideals of professionalism and the stewardship of public resources.
• I will not hold financial interests that conflict with the conscientious performance of duty.
• I will act impartially and not give preferential treatment to any private organization or individual.
• I will disclose waste, fraud, abuse, and corruption to appropriate authorities.
• I will uphold these principles, demonstrating professional integrity and conscious that public office is a public trust.
• I will conduct myself at work in a manner that is consistent with the Commonwealth's Standards of Conduct for Employees, applicable agency regulations and policies, and the policies of the Department of Human Resource Management.
Data Integrity and Ethics Training

Regulatory Requirement

2009 The NELAC Institute (TNI) Standard:
- Section 5.2.7 (2009 TNI V1M2 & 2016 TNI V1M2 Rev.2.1)
- “Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees”.
- “Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in detailed investigation that could lead to very serious consequences including immediate termination, debarment, or civil/criminal prosecution”.

Clinical Laboratory Improvement Amendments (CLIA):
- 42 CFR 493 Subpart M Personnel for Non-waived Testing

ISO/IEC 17025:
- “…policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.”

What is “GOOD” Work Ethic?
“GOOD” Work Ethic

Reliable
- Showing up to work on time and when scheduled
- Completing assigned tasks, independently and on time
- Managing one’s time and emotions effectively
- Attending meetings fully prepared and following up on action items in a timely manner

Dependable

Helpful

Focused

Mature

Honest

Dedicated

Accountable

Responsible

Characteristics of Good Work Ethic

Reliable
- Doing more than the bare minimum
- Caring about your job performance (giving your best effort)
- Helping co-workers with tasks when asked or when help is needed

Committed

Trusted

Truthful

Hard-working

Focused

Dedicated

Responsible
Characteristics of Good Work Ethic

Dependable
• Working together to meet laboratory/group goals
• Striving to always deliver quality work
• Respecting EVERYONE at every level; including working with difficult people

Integrity and Honesty
• Always being truthful
• Striving for high moral standards
• Aiming for accuracy in everything you do
• Asking questions or speaking up when things are questionable

Why Behave Ethically at Work? “It is just the RIGHT thing to do!!”

• Our laboratory data and laboratory decisions impact lives, impact our communities, the environment, the safety of our food supply, etc.
• Your personal reputation and the reputation of your laboratory depends upon it (“Customer trust”)
• Demonstrating good work ethic and a positive attitude impacts morale and provides a positive example for all employees
• The penalties for misconduct for you, your laboratory, and your leadership can be substantial
So what’s the big deal?

• Scientifically sound decisions are not always clear
• Scientific troubleshooting and interpretation of data can be tricky
• Producing reliable/defensible data

What is an improper practice?
• Scientifically unsound or technically unjustified practice that makes results appear acceptable
• Decisions can often seem like no big deal
Reasons why improper practices occur?

- Production or deadline pressures
- To avoid having to re-run samples
- To avoid having to perform instrument maintenance
- Poor communication and/or training
- Misinterpretation of method requirements
- Personality and attitude, not really necessary
- Fear of authority; intimidating work environment
- Lack of attention to detail
- Misguided trust

Unethical Work Behavior

*Examples*

- Entering data or results for work you did not perform
  - “Dry-labbing”
  - Entering freezer temperatures or QC data when not performed
  - Initialing results for co-worker
- Failure to run proper controls or cherry-picking control data
- Not following laboratory protocols
  - Sending out results without proper review
  - Omitting steps in a SOP
  - Improper calibration or NO calibration
Unethical Work Behavior

**Examples**

- Changing run dates or accessioning dates/times to make samples appear to meet holding times (“Time Travel”)
- Deleting data that doesn’t meet customers needs or at the request of a customer
- Sharing information about laboratory testing or testing results with family or friends (breaches in confidentiality)

*If you are EVER UNSURE if your actions are unethical ask yourself....would you do it if someone was watching you?*

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When it **“Crosses the Line” = FRAUD**

- EPA definition of FRAUD*
  
  “The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements”

- Fraud is purposeful
- Fraud is **not** a mistake or an accident
- Fraud is an intentional misrepresentation of lab data in order to **hide** known or potential problems
- Fraud makes data look better than it really is, with the **intent to deceive**

* EPA 2006 Evaluation Report
Penalties for Fraud

- Civil Prosecution
- Criminal Prosecution
- Penalties can be up to 5 years in prison and/or a $500,000 fine
- Suspension or loss of accreditation
- Loss of customers and work
- Violation of standards of conduct and grounds for immediate termination

Impacts not only YOU but your co-workers, the Lab, and the Director

Ways to tell if an improper practice or unethical work behavior is FRAUD?

- Was it done intentionally to misrepresent data?
- Did you know that the action specifically violated a policy or procedure?
- Were you told NOT to do it and you did it anyway?
- When asked about what happened, did you tell a lie?
- Gut check – Do you feel as if your actions were wrong?
Ethics and Data Integrity

*Laboratory Program Key Elements*

- Employee Assessment
- Confidentiality
- Documentation
- Data Monitoring and Review
- Training
- Policies and Procedures

So who is responsible for what?
Employee Responsibilities

- Uphold ethical practices and data integrity each and every day
- Ask for help when you are unsure of the proper action to take
- Be sensitive and alert to situations that could result in actions by ANYONE that are improper, illegal, or unethical
- Talk to co-workers when they appear to be in danger of violating ethics and data integrity policies or procedures; help them get help
- Report ethical or data integrity violations (or suspicions) to your manager (or above)
  - Remember your actions speak louder than words

QA Staff Responsibilities

- Develop and maintain a robust quality management system focused on ethics and data integrity
- Perform continuous data review, always looking for red flags or warning signs
- Conduct internal audits, monitoring and blind sample challenges as required or necessary
- Ensure an open door policy for all employees
- Promote a culture where employees feel safe reporting concerns or issues in confidence
Management Responsibilities

• Promote the importance of ethics and data integrity at all levels
• Minimize “undue” pressure throughout the lab especially on staff
• Promptly notify customers when data integrity is compromised; re-issue reports as necessary
• Ensure all employees know that there are SEVERE consequences not only for themselves but for the entire laboratory for actions involving scientific misconduct and fraud
• Provide an environment where employees can report concerns without retribution; make available multiple reporting channels including anonymous reporting

How to Report Issues?

• Report to your manager/supervisor, QA Department or Laboratory Director
• In circumstances requiring reporting of fraudulent activities at the State level or higher

Contact:
• State Fraud, Waste, and Abuse Hotline (if available)
• US EPA Fraud Waste and Abuse Hotline: 1-888-546-8740; e-mail: OIG_Hotline@epa.gov
REMEMBER: Mistakes happen!

Reporting mistakes is an important and vital component of a strong quality management system

“The aim of leadership should be to improve the performance of man and machine, to improve quality, to increase output, and simultaneously to bring pride of workmanship to people, [...], the aim of leadership is not merely to find and record failures of men, but to remove the causes of failure; to help people to do a better job with less effort”

- W. Edwards Deming

Summary

- Always be honest and ethical
- Ask questions if you don’t understand
- It’s OK to make a mistake, it is NOT OK to hide the mistake
- Good COMMUNICATION is key to preventing ethical and data integrity issues
  - See something – Say something
  - Question something - ASK
- Remember: Fraud and ethical breaches can result in serious consequences – it’s NOT worth your job or going to jail over
Contact Information

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