

Ethics Training for Environmental Laboratories

2024



Learning Objectives

Understand what the term ethics means to the environmental laboratory

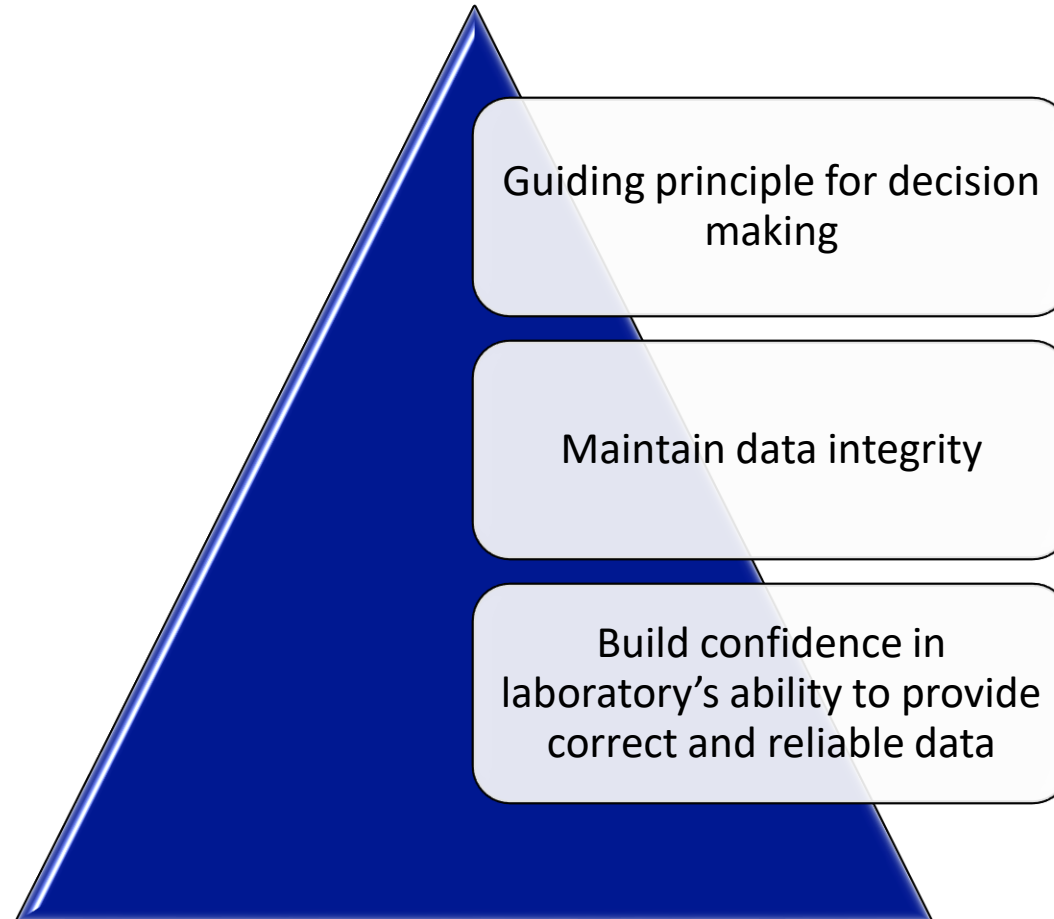
Understand the importance of data integrity

Learn ramifications of unethical conduct

Identify basic detection and prevention mechanisms



Why Attend Ethics Training?



What is Ethics?

Guidelines for conduct that help people in making a judgment about what is right or wrong

Moral principles that govern a person's behavior or the conducting of an activity

Rules of conduct recognized in respect to a particular group

Moral principles that control or influence a person's behavior

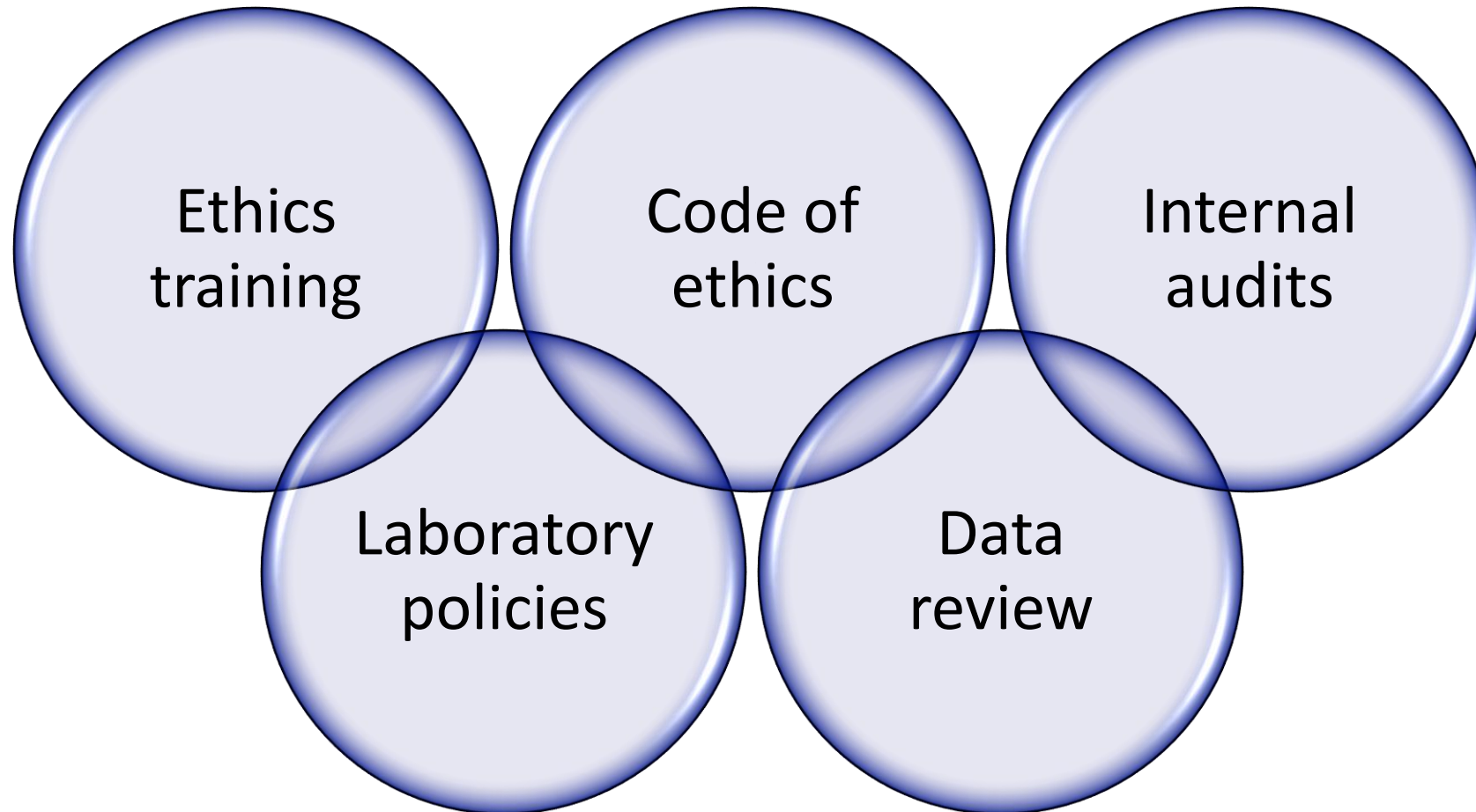


Code of Ethics

Document that describes the characteristics of a set of moral principles dealing with accepted standards of conduct by, within and among laboratory personnel



Ensure Ethical Laboratory Practices



Laboratory Policy

Relationship of organizational mission to critical need for honesty and full disclosure in all aspects of laboratory operations, including reporting data

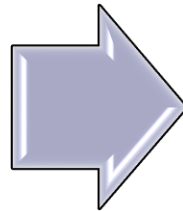
Address laboratory's exact position on ethics, integrity and code of conduct

Zero-tolerance philosophy established by management to detect and deter improper, unethical or illegal actions



What is Data Integrity?

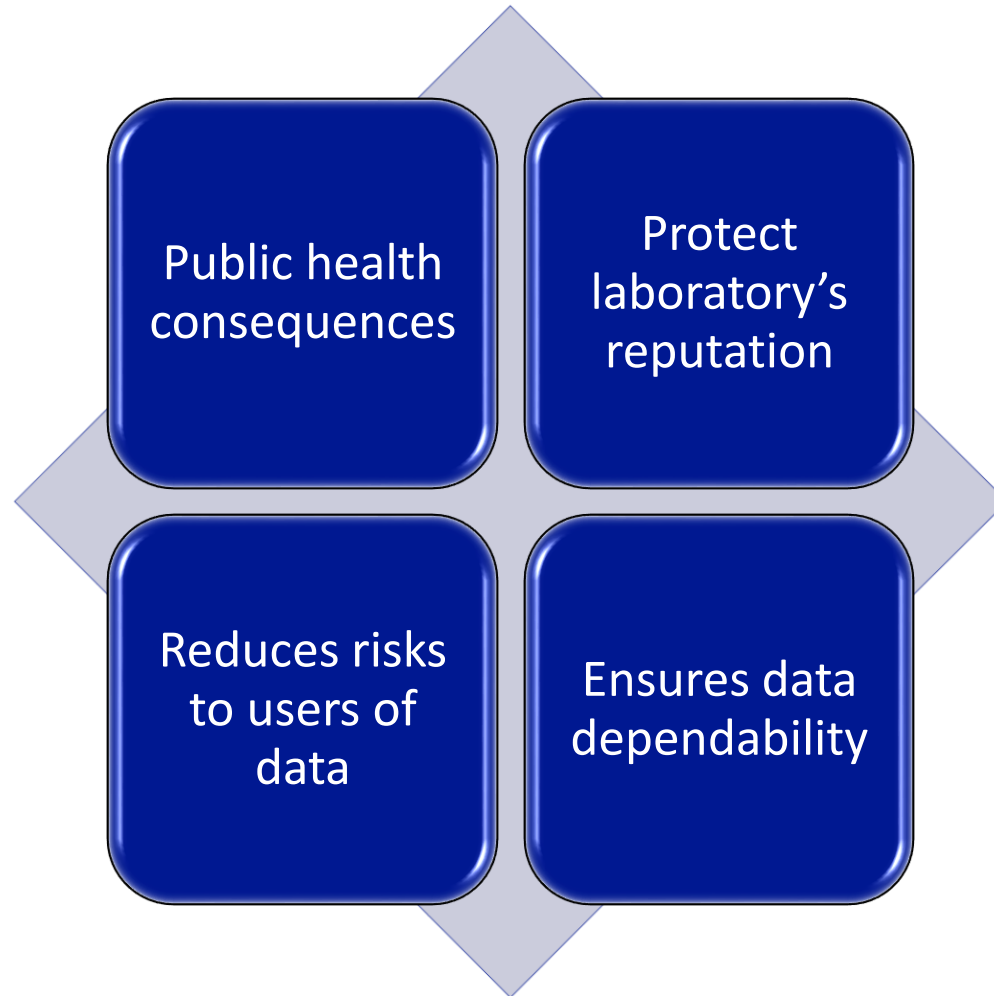
Complete,
consistent and
accurate data



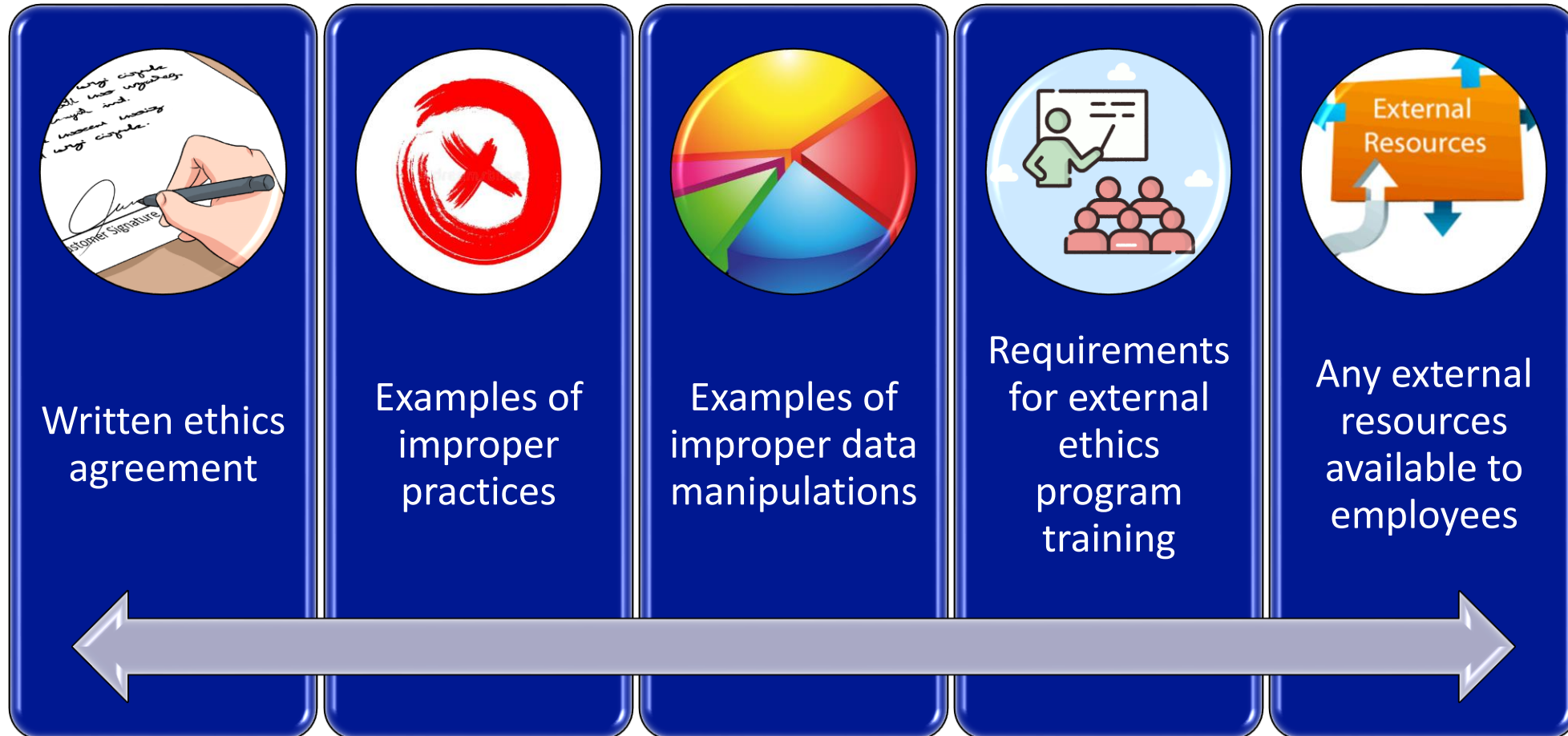
Data is precise,
accurate and of
known and
documented quality



Why is Data Integrity Important?



Ethics Program



Fraud vs Improper Practice

Fraud

- Purposeful
- Intentional
- Not mistake

Improper practice

- Mistake
- No intent to deceive
- Disclosed



Unethical or Illegal Actions (Fraud)

Deliberate falsification of analytical or quality control results, where failed method or contractual requirements are made to appear acceptable



Improper Actions

Intentional or
unintentional
deviation from
contract-specified
or method-specified
analytical practices
not authorized



Fraud vs Improper Practice

Difference
between fraud and
improper practice
may be as simple
as lack of proper
documentation



10 Elements of an Ethics Program

Define improper and unethical or illegal actions

Outline elements of detection/deterrence programs

Provide examples of improper laboratory practices

Require ethics policy to be read and signed by all personnel



10 Elements of an Ethics Program

Have in a place a “no-fault” reporting policy that encourages laboratory personnel to report suspected improper, unethical or illegal activities, without fear of retribution

Have a designated data integrity officer whom personnel may confidentially report suspected instances of improper, unethical or illegal activities



10 Elements of an Ethics Program

Require initial and annual ethic training

Be included as part of the internal audit program

Require an explanation and sign-off on all manual changes to data

Where available in instrument software, enable all electronic tracking and audit functions



Unethical, Improper or Illegal Actions

Concealing known problems

Concealing known improper or unethical behaviors or actions

Failing to report occurrence of prohibited practice or known improper or unethical act to appropriate laboratory or contract representative

Misrepresenting or misreporting equipment quality control or verification of data



Unethical, Improper or Illegal Actions

Fabrication, falsification or misrepresentation of data

- Creating data for test that was not performed
- Creating information for sample that was not collected
- Using external analysts, equipment and/or laboratories to perform analyses when not allowed by contract



Unethical, Improper or Illegal Actions

Improper clock setting (time traveling) or improper date/time recording

- Resetting internal clock on an instrument to make it appear that sample was analyzed within holding time when in fact it was not
- Changing actual time or recording a false time to make it appear that specified times were met
- Changing times for a step to make it appear that specifications were met



Unethical, Improper or Illegal Actions

Unwarranted manipulation of samples or test conditions

Unwarranted manipulation of computer software

Turning off, or otherwise disabling, electronic instrument audit/tracking functions



Unethical, Improper or Illegal Actions

Procedural
changes

Unauthorized
deviations from
laboratory's
approved SOP



Detection and Deterrence

Zero-
tolerance
philosophy
established
by
management

- Acknowledge support by upholding spirit and intent of ethics and integrity procedures
- Effectively implement specific requirements, including surveillance protocols



Ethical Practices

Document all
work
performed

Admit to
mistakes

Identify and
communicate
issues

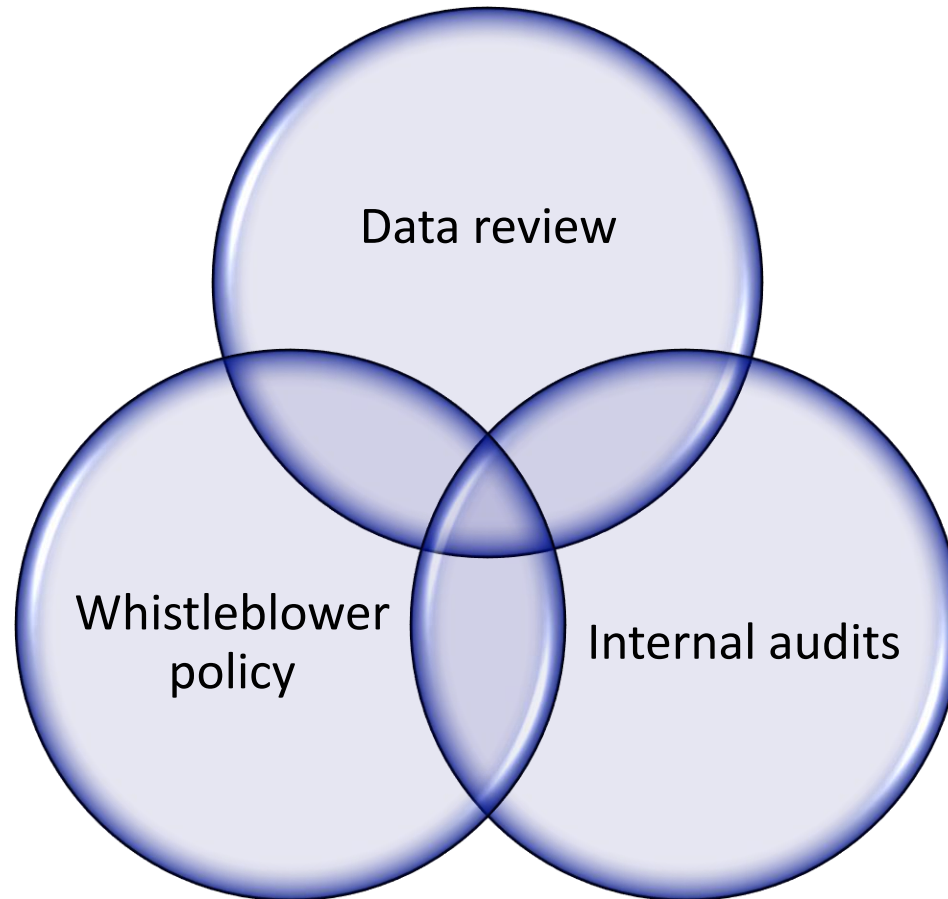
Update
procedures

Perform
proper quality
control

Document
failed controls



Basic Detection Mechanisms



Data Review

Raw data differs from final report

Work performed not documented

Missing signatures, initials or dates

Missing process steps

Procedure not followed

QC not performed with samples



Internal Audits

Types of audits

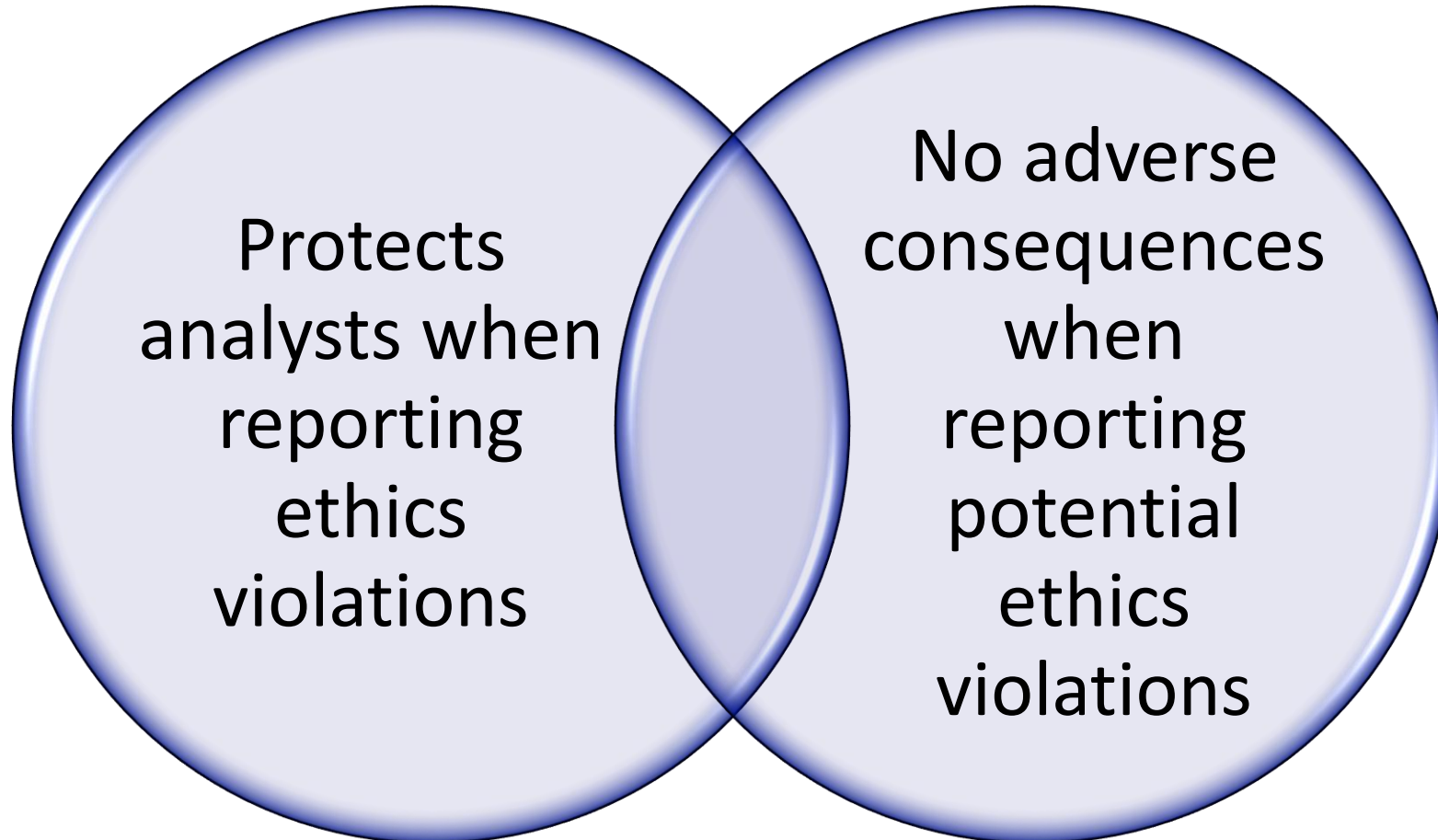
- Horizontal
- Vertical

Impartiality of auditors

- Not auditing own work
- Knowledgeable of processes performed



Whistleblower Policy



Basic Prevention Mechanisms

Ethics training at all levels

Communication of whistleblower policy

Management support and commitment

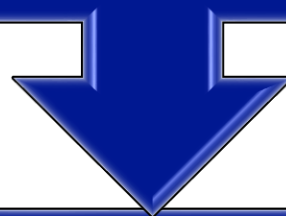
Laboratory accreditation

Up-to-date information systems and procedures



Consequences for Infractions

Detailed investigation



Very serious consequences

Immediate
termination

Debarment

Civil/criminal
prosecution



Ramifications of Unethical Conduct

Public health
consequences

Environmental
pollution

Indefensible
data

Compliance
issues

Loss of
accreditation

Legal
consequences



Real World Ramifications

Falsifying water sampling

- Lab director imprisoned for falsifying water sampling
- Convicted for misrepresenting testing of water samples from municipalities and other customers throughout Mississippi Delta
- Victim impact statements sent to over 150 clients

<https://www.bakerdonelson.com/lab-director-imprisoned-for-falsifying-water-sampling>



Real World Ramifications

Falsifying sample data

- Environmental laboratory analyst enters guilty plea for falsifying test results
- Took steps to make it appear samples had passed when in fact the samples failed by manipulating tune and calibration portions of quality control process
- Did so to increase productivity



<https://www.justice.gov/usao-ndoh/pr/environmental-lab-analyst-enters-guilty-plea-falsifying-test-results-charge>

Real World Ramifications

Falsifying results of tests

- False data reported for environmental tests used for decision making at superfund sites, DoD facilities and hazardous waste sites
- Fined \$9 million



Real World Ramifications

Falsifying results of tests

- Falsified test results to elevate THC potency results in more than 1200 samples in an attempt to deceive consumers
- Attempted to destroy evidence of falsified data
- Lab shut down



Ultimately

Importance of proper written narration by laboratory personnel in all work performed

Follow ethical guidelines

Report potential ethics violations



Conclusion

Monitor data through data reviews

Provide clear policies and procedures for ethical behavior

Train employees

Uphold a whistleblower policy

Ensure no undue pressure on analysts

Ask for assistance when unsure how to proceed

Report potential violations



Thank you!

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ANSI National Accreditation Board