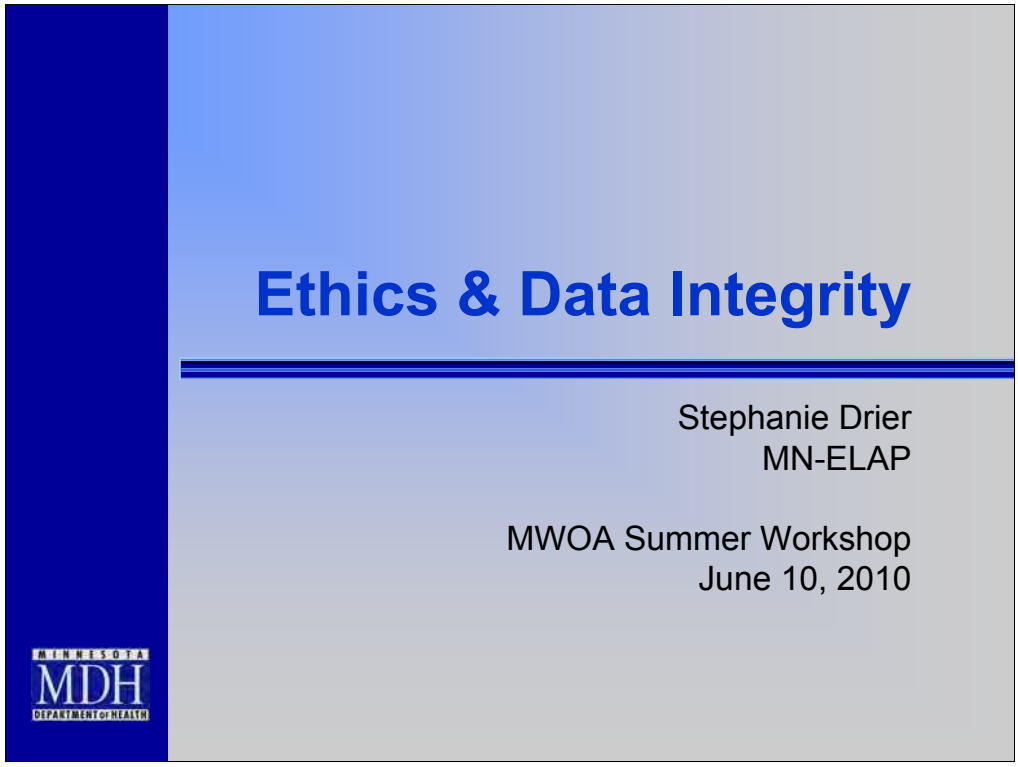


The Minnesota Environmental Laboratory Accreditation Program (MN-ELAP) presented the 2003 NELAC Standard ethics and data integrity requirements for implementation within accredited environmental laboratories. The information was presented at the MWOA Summer Workshop on June 10, 2010, and the session satisfied the annual ethics and data integrity training for environmental laboratory personnel in attendance. Certificates of completion were awarded by the Minnesota Wastewater Operator's Association and Central States Water Environment Association.

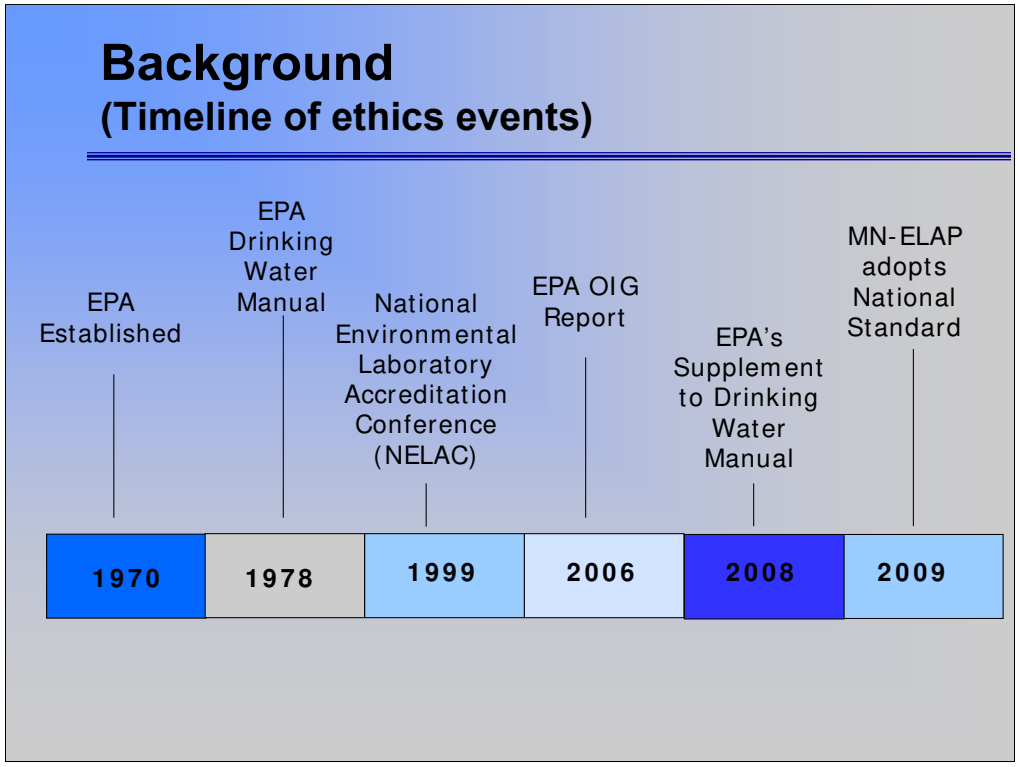
There four main target topics reviewed and summarized within this presentation were:

•The background in the development of ethics requirements within the laboratory community and the necessary definitions,

•secondly, the NELAC Standard required components of a laboratory's data integrity and ethics program were reviewed to ensure the building or maintenance of ethical organizations,

•next, the potential consequences of not incorporating or implementing a quality ethics and data integrity program into your laboratory were outlined, and

•finally, resources and next steps were provided for building or enhancing an ethics and data integrity programs within laboratories.



Timeline of Ethics and Data Integrity Requirements Incorporation:

•The Environmental Protection Agency was formed on December 2, 1970 to protect human health and to safeguard the natural environment (air, water, and land) upon which life depends.

•1978- The U.S. Environmental Protection Agency's (EPA's) Office of Ground Water and Drinking Water, prepared the first manual for the certification of laboratories analyzing drinking water.

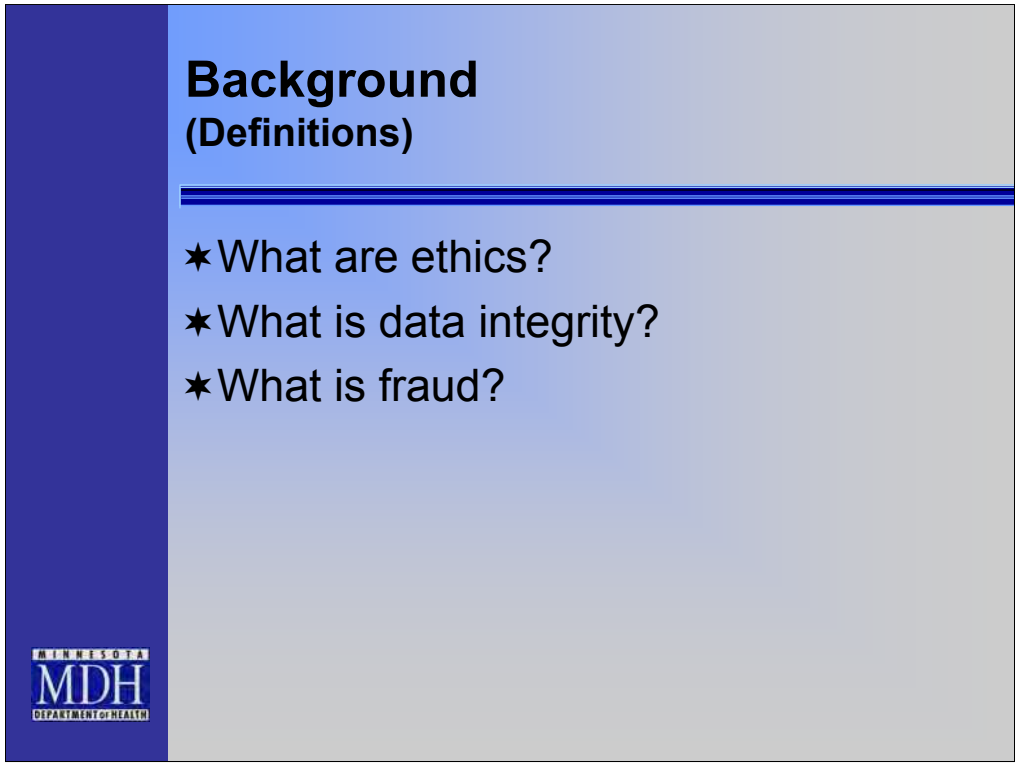
•During the 1980's the incidences of fraud cases increased and more than 25% of the laboratories in the contract lab program (CLP) were under investigation for fraudulent activities to meet time demands and cut costs (Ann Rosecrance).

•The National Environmental Laboratory Accreditation Conference (NELAC) in 1999, was the first to include ethic and data integrity requirements and training standards.

•The Office of Inspector General (Act of 1978 to conduct audits and investigations into fraud, waste and abuse within EPA) issued a report in 2006 that outlined the assessment, evaluation and provided advice to improve laboratory integrity.

•In 2008, the Drinking Water Certification Manual's Supplement to the 5th Edition encouraged certification officers to participate in fraud detection and ethics training. The supplement also encouraged labs to have ethics policies and implement fraud detection and deterrence policies and programs.

•As of July 1, 2009, Minnesota Statute 144.98 requires the Environmental Laboratory Program (MN-ELAP) to accredit laboratories according to the most current environmental laboratory standard recognized by the National Environmental Laboratory Accreditation Program of the NELAC Institute (TNI). Section 5.1.7 of the 2003 NELAC Standard is the roadmap for data integrity and training requirements.



It is essential to define “ethics”, “data integrity” and “fraud” to be clear about the references to these terms throughout the presentation.

Background
(Defining "Ethics")

-Veruca Salt- Charlie and the Chocolate Factory

Webster's Dictionary defines ethics as the discipline of dealing with what is good and bad and with moral duty and obligation. It is important to note that morals define personal character, while ethics are defined by the community or societal system in which individuals apply their morals.

While Veruca Salt was adored and spoiled by her father, Willy Wonka determined that both of their actions caused them to be rejected as "bad eggs" and plummeted them both down a garbage chute as a consequence. Everyone has differing values, which is why it is important that we clearly define what the values will be for our own community. In the environmental testing community, the U.S. EPA and the National Standards set the minimum expectations for appropriate laboratory practices that will result in data of a known and documented quality.

Background
(Defining "Data Integrity")

Data integrity policies and procedures need to be incorporated into:

- all levels of responsibility
- training
- documenting, and
- controlling and reporting results

-NELAC 5.1.7

The data integrity procedures provide assurance that a highly ethical approach to testing is a key component of all the laboratory planning, training and implementation of methods.

Data integrity and data integrity procedures are an essential part of a laboratory's quality system. Laboratories need to establish and maintain data integrity procedures, and the procedures need to be defined within the quality manual. Data integrity polices and procedure need to incorporated into the areas outlined in NELAC 5.1.7.

Background
(Defining "Fraud")

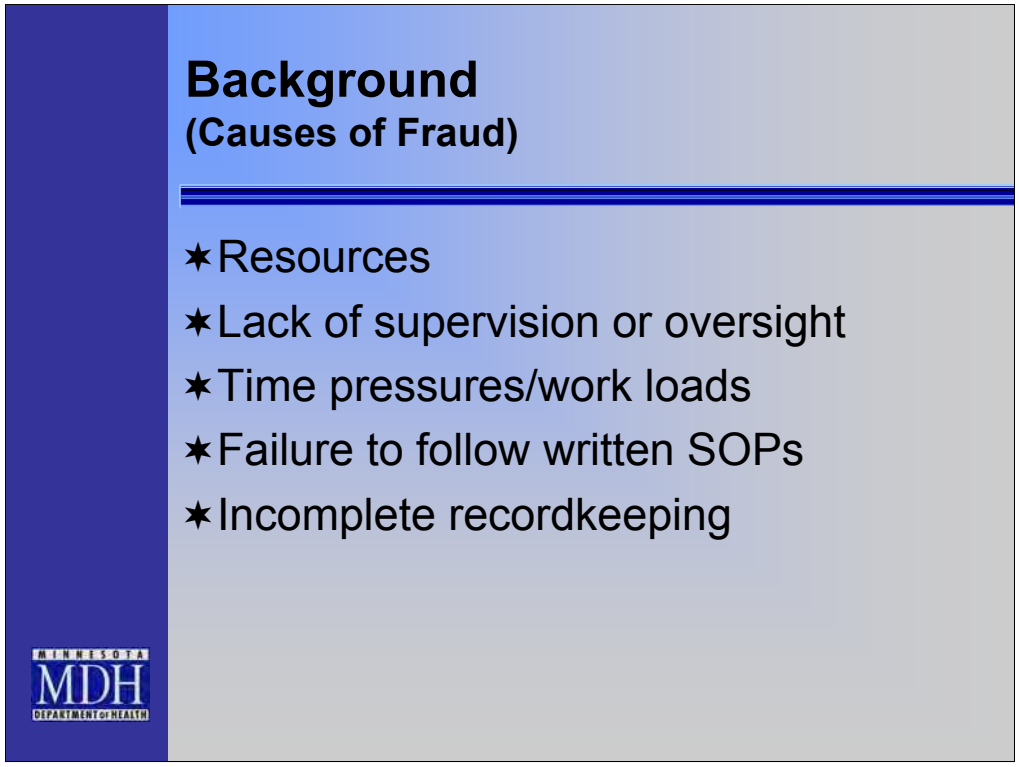
Types of Laboratory Fraud:

- Falsification
- Fabrication (dry-labbing)
- Failure to follow procedures

- Ethics Education and Practices in the Laboratory

MINNESOTA MDH DEPARTMENT OF HEALTH

The EPA (OIG) defines fraud as the deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable during reporting. Falsification, fabrication or dry labbing, and the failure to follow procedures are examples of lying, cheating, and stealing. Fraudulent activities are completely against the mission of the EPA and the laboratory community's standard. Lying, cheating, and stealing within the laboratory could lead to criminal, civil, and administrative actions against the laboratory or an employee of the laboratory.

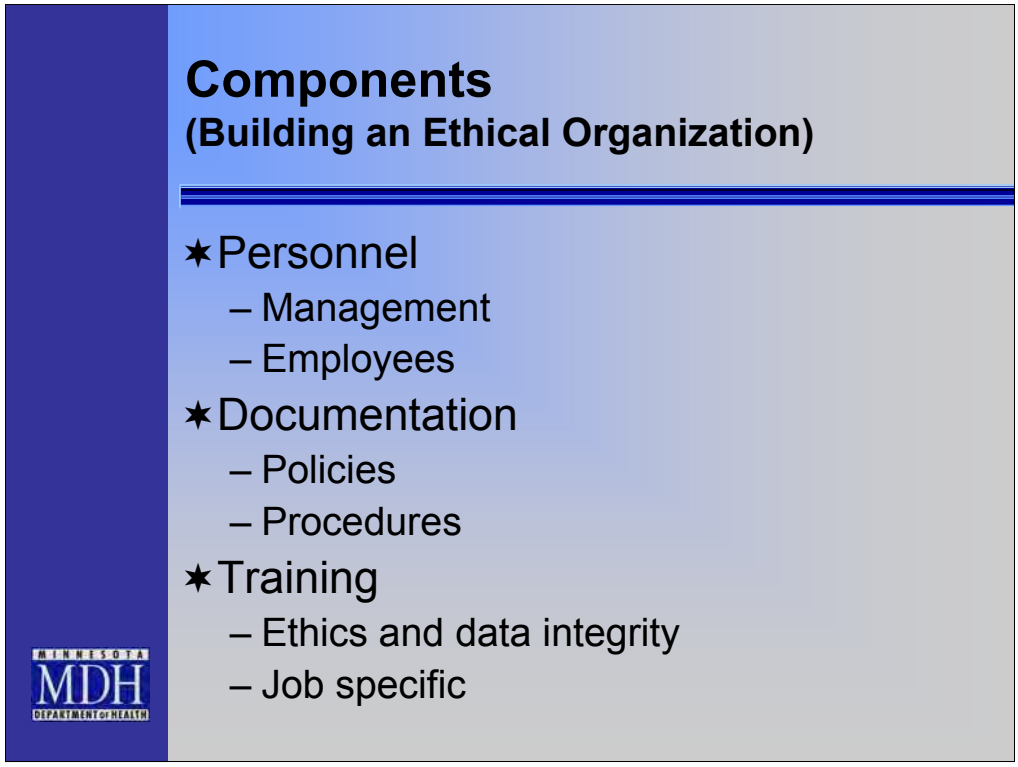


Vulnerabilities exist in all laboratory activities. For this reason, it is important for laboratories to proactively manage risk. Knowing a few factors that may contribute or be the root cause of laboratory fraud will help laboratories set up an ethics program that accomplishes effective management of risk. The factors include:

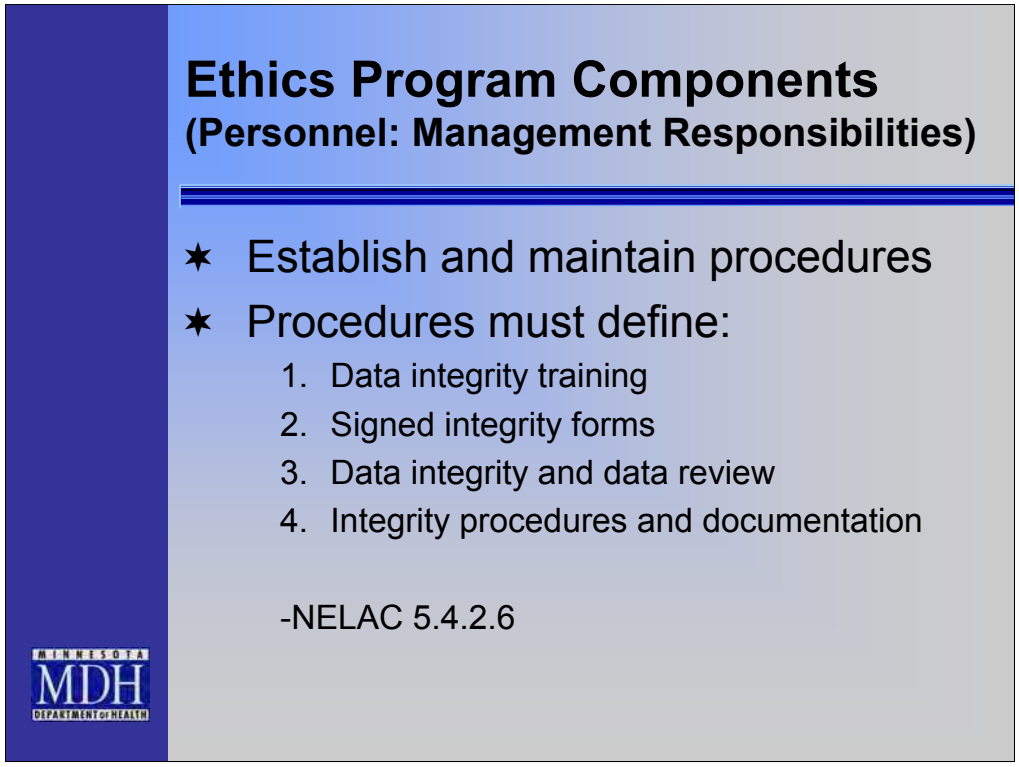
- The laboratory's limited resources. For example, the lack of laboratory equipment and supplies, limited trained personnel, access to laboratory training and documentation may lead to fraud.
- Fraud is more prevalent in laboratories with the lack of supervision or with oversight by poor ethical leadership.
- Time pressures caused by heavy workloads, hold times, contractual agreements, and loss of trained personnel may lead or contribute to fraud.
- Fraud is caused by the failure to follow written procedures, which might be caused by poor training in both job specific and data quality/integrity or intentional deliberate fraudulent acts.

Additional cause of fraud are:

- A lab's ineffective or lack of an ethics training program
- Efforts to cut cost and drive profit margin
- Human factors



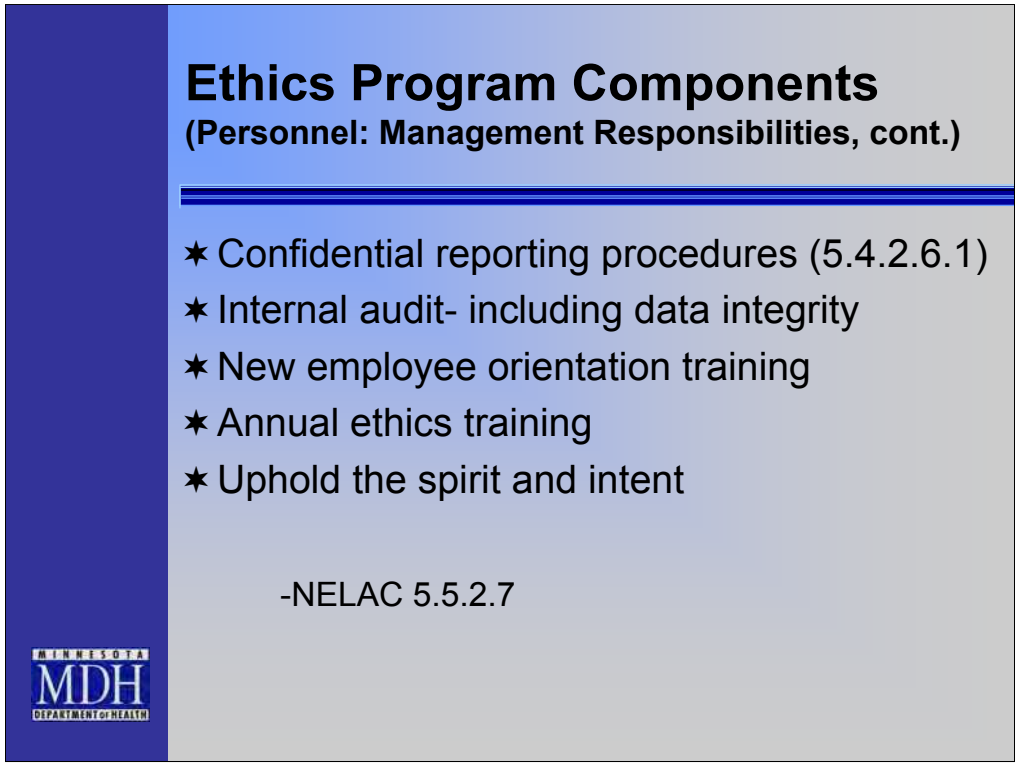
Ethics and data integrity standards must be built both individually and collectively into the laboratory's organization, and the components of an organization must be built from the ground up and vice versa. Laboratory management and employees must uphold the spirit and intent of the quality system, which include data integrity and ethical polices and procedures. The laboratory must document its policies, and procedures to ensure quality environmental testing results. The lab's quality, data integrity and ethical policies and procedures need to be communicated, made available, and understood by appropriate laboratory personnel (NELAC 5.4.2.1). It is also essential that the laboratory enforce its ethics and data integrity policies and procedures at all levels.



The 2003 NELAC Standard outlines a series of responsibilities that require managerial leadership to set the tone for the data integrity training procedures. Management must incorporate the polices and procedures into the laboratory's system and these procedures must be signed and dated by senior management. Data integrity policies and procedures must be implemented, made available for assessor review, and annually reviewed by management.

The four required elements within the data integrity system are:

1. the data integrity training (annual and initially for new employees),
2. integrity forms that are completed and signed by each employee,
3. periodic in-depth monitoring of data integrity, and
4. data integrity procedures and documentation.



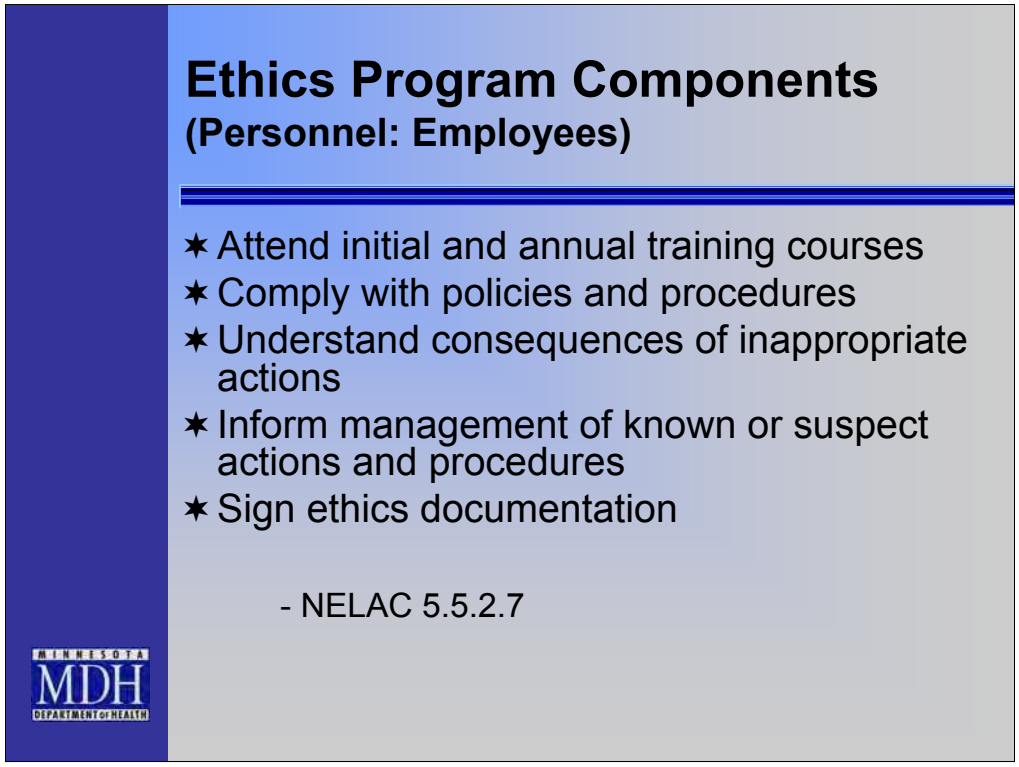
The data integrity procedures must also include:

•Confidential reporting procedures for employees to report data integrity issues while assuring confidentiality and a receptive environment to discuss and report ethical issues.

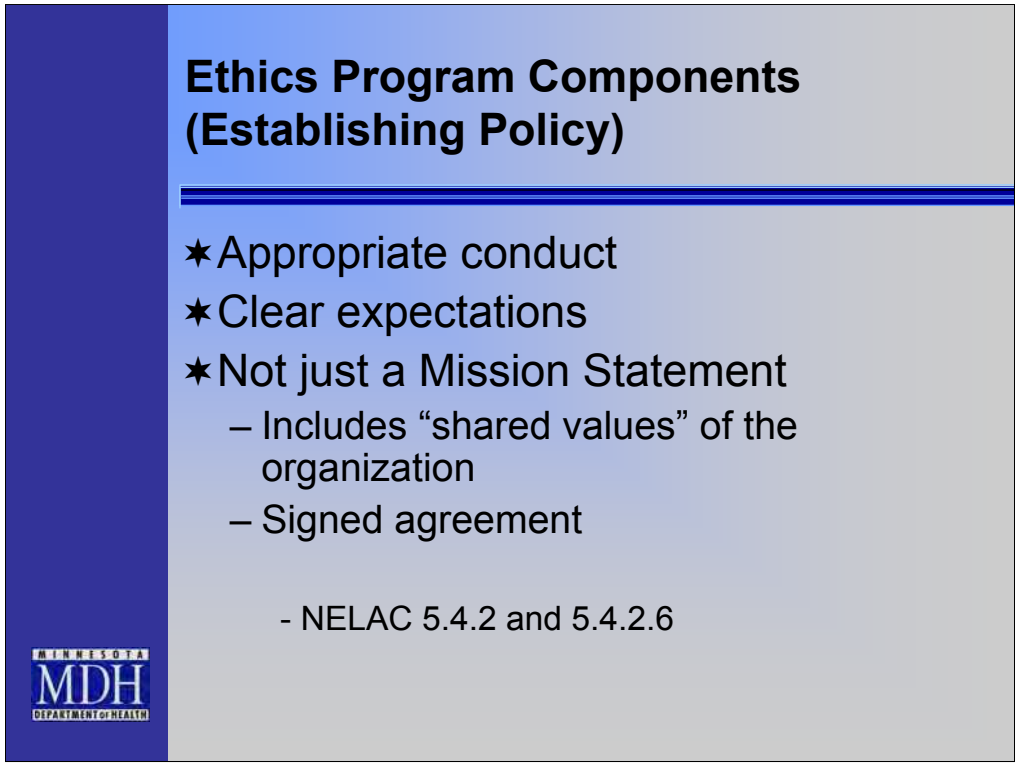
•The quality manager must plan and conduct an internal assessment of their laboratory on an annual basis (NELAC 5.4.13.1) and ensure that a review is conducted into any evidence of inappropriate actions and ensure that the review evaluates vulnerabilities to data integrity.

•The management of the laboratory must provide data integrity training to new employees during a formal orientation and must also be provide ethics and data integrity training on an annual basis.

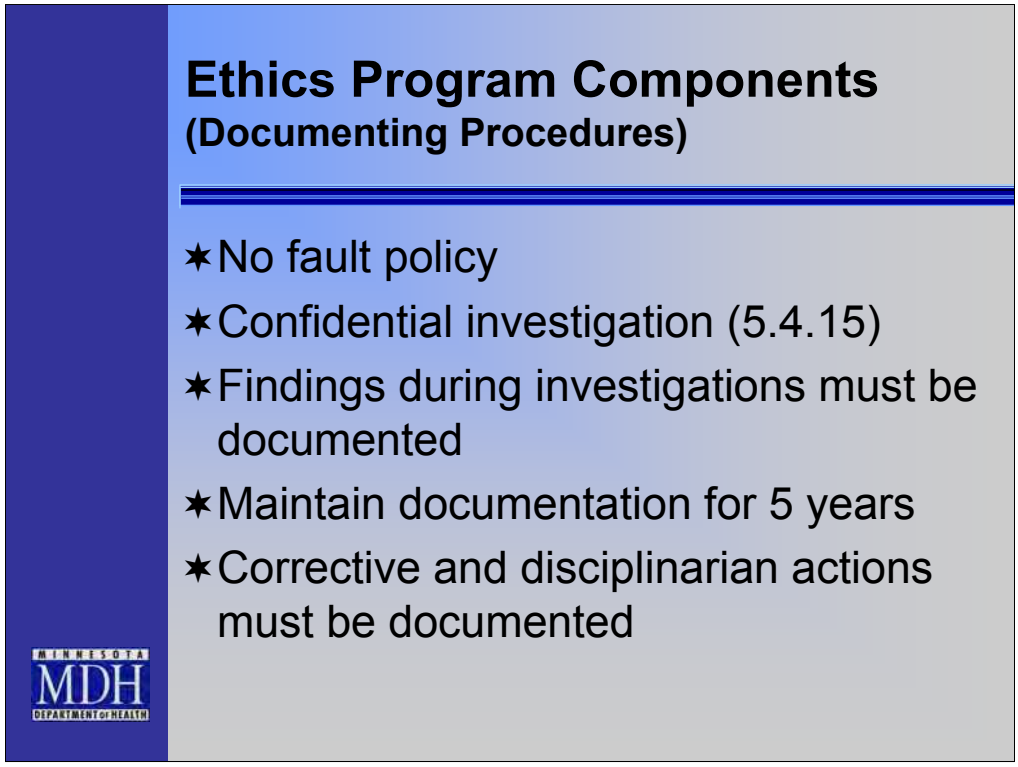
•Management must uphold the spirit and intent of the data integrity procedures by leading by example, and implementing these specific requirements within their laboratory's quality system.



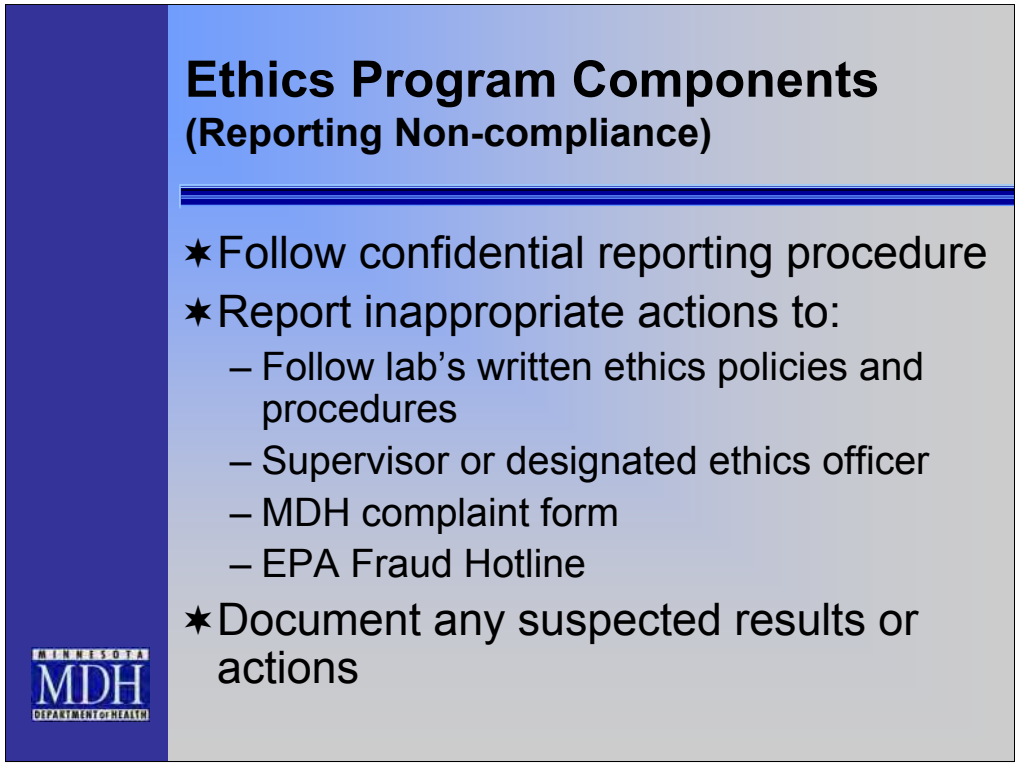
Laboratory employees must understand and comply with the data integrity and ethics policies and procedures. They must also recognize that any serious and detailed investigations into their practices could result in termination, debarment or civil and criminal prosecution. Employees must be familiar how and when to use the laboratory's data integrity policies and procedure for reporting or informing management of known or suspected unethical actions and procedures. The employee must sign the laboratory's ethics documentation attesting to the fact they have participated in initial or annual data integrity training, and that they understand their obligations related to data integrity.



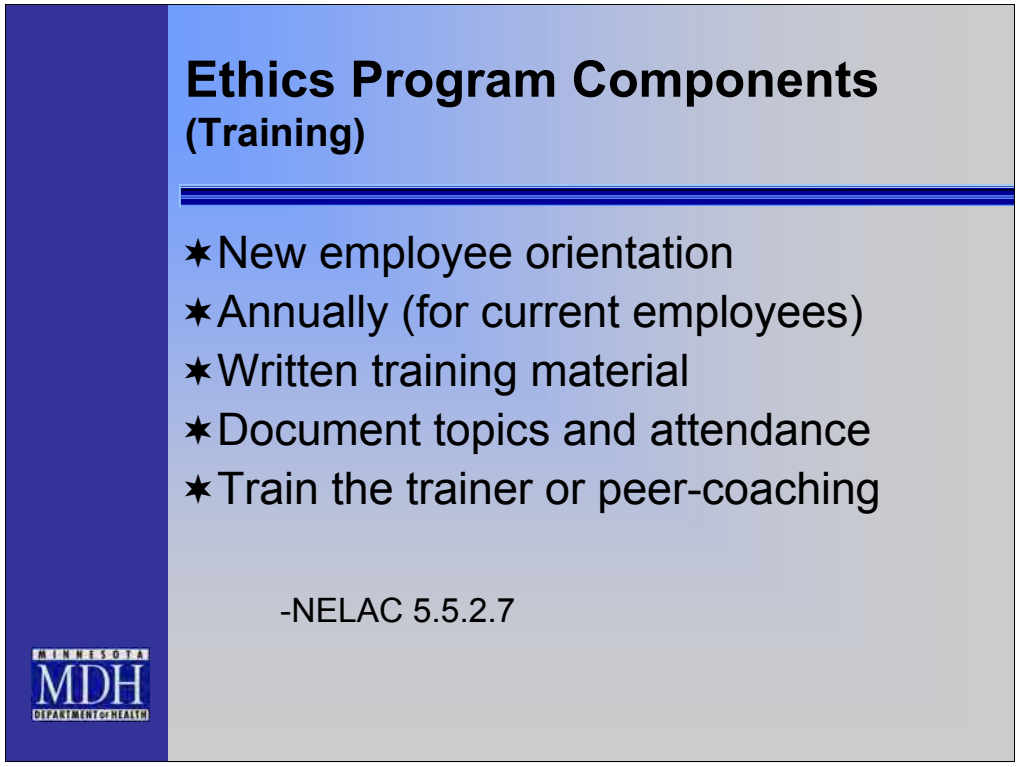
It is essential that laboratories establish a policy on ethics and data integrity. The policy must establish and outlined the appropriate conduct required. The policy should clearly state what is expected of employees. For example, “employees must conduct themselves in an honest and ethical manner at all times.”. The policy must also outline and provide clear consequences and procedures for unethical or suspect conduct. The laboratory’s ethics policy is NOT just a lab’s mission statement, but more of a ‘shared value’ statement of the organization. The established ethics policy should be a signed agreement by all employees to reinforce their commitment to ethical conduct.



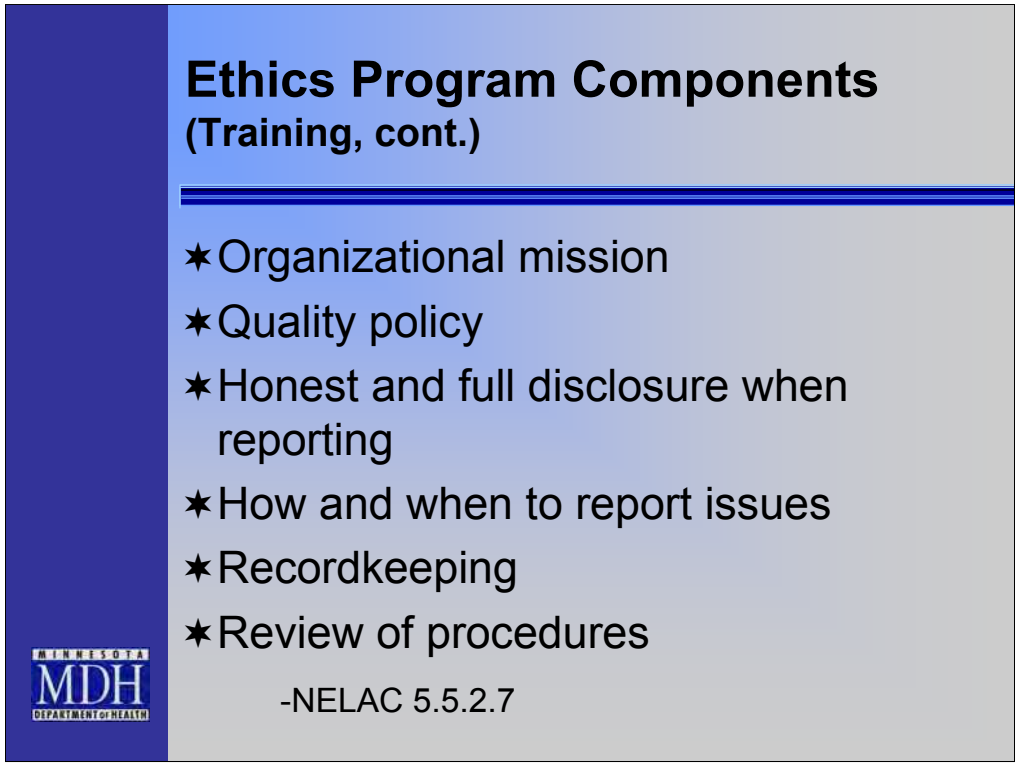
The laboratory must implement a no-fault management policy regarding inappropriate action reporting and ensure that employees do not face retribution for data integrity and ethical misconduct reporting. The discovery of potential issues shall be handled in a confidential manner until follow-up and investigations have been completed and the issues clarified. All procedures and investigations that result in findings and any corrective or disciplinarian actions must be documented. The documentation must be maintained for at least five years.



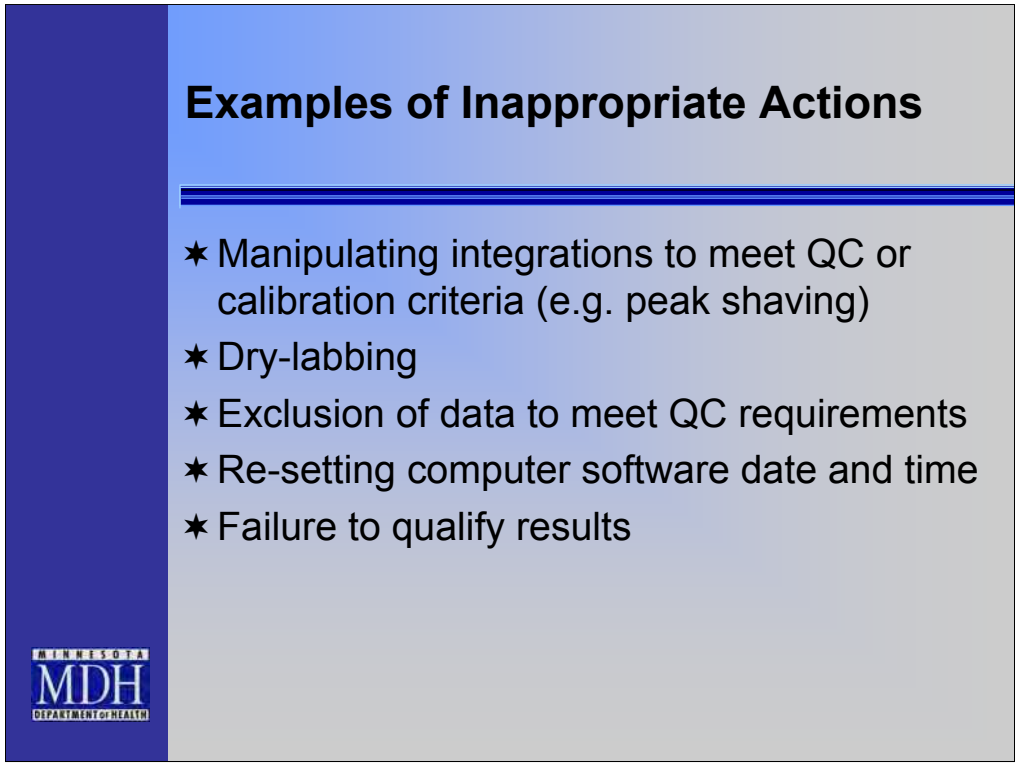
Inappropriate activity or fraudulent findings must be documented (NELAC 5.4.15) and shall include any disciplinary actions involved, corrective actions taken and client notifications. The laboratory employees shall also be informed of the laboratory's written ethics policies and procedures. In addition, the employees should be provided with a mechanism for confidential reporting mechanism for data integrity and ethical concerns within their laboratory (NELAC 5.4.2.6.1). Any inappropriate activities, investigations, suspected results or actions (e.g. corrective or disciplinarian) shall be document and maintained for at least five years (NELAC 5.4.15).



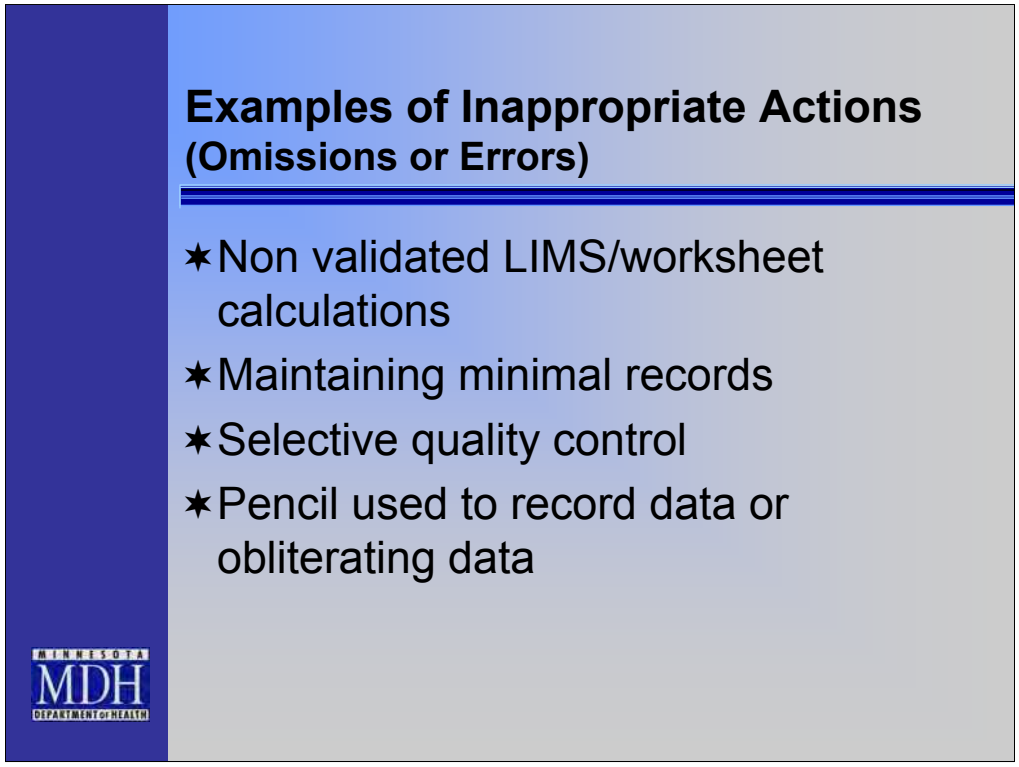
The NELAC Standard requires accredited laboratories to provide formal initial data integrity training upon hire and an annual refresher thereafter. The data integrity training (either internal or external) must be written training material that outlines the topics discussed, and attendance must be documented. No two laboratory ethics and data integrity programs will be developed or look the same. It may be useful for the data integrity training to include written ethics agreements, examples of improper practices, examples of improper actions or inappropriate changes, and requirements for attendance at external ethics training events. The laboratory might use the concept of peer coaching groups to internally provide specific examples of ethical behavior and improper data manipulations, instrument adjustments (e.g. time travel) and inappropriate changes to calibration curves, quality control, standard concentration, improper chromatographic manipulations or results.



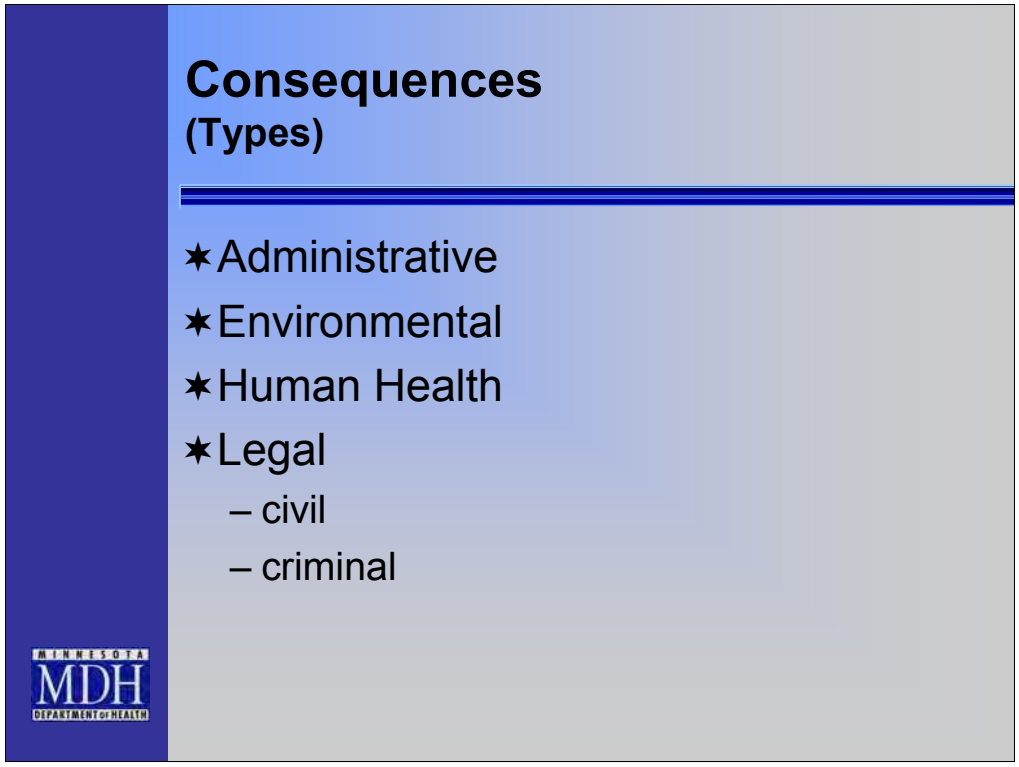
Training shall include discussion regarding all data integrity policies and procedures, data integrity training documentation, in-depth data monitoring and data integrity procedures documentation. Specifically, the training shall address and include the organizational mission, quality policy, the need for honest and full disclosure reporting, procedures for reporting suspect issues and recordkeeping.



It might be essential to have ethics and data integrity training that include specific examples of inappropriate actions within a laboratory.



Sometimes the difference between fraud, improper practice and an honest mistake is simply the lack of proper documentation. Maintaining minimal records is an inappropriate action, because recording only those results that 'work' within the laboratory notebook is an incomplete record and may increase 'dry labbing' suspicions. Along with selecting only the 'passing' results, selectively choosing to run quality control on particular samples or particular days when you know that the quality control may pass is also an example of inappropriate activity. Using non-permanent recordkeeping allows easier changes to data and make inappropriate actions easier to conduct and harder to detect.



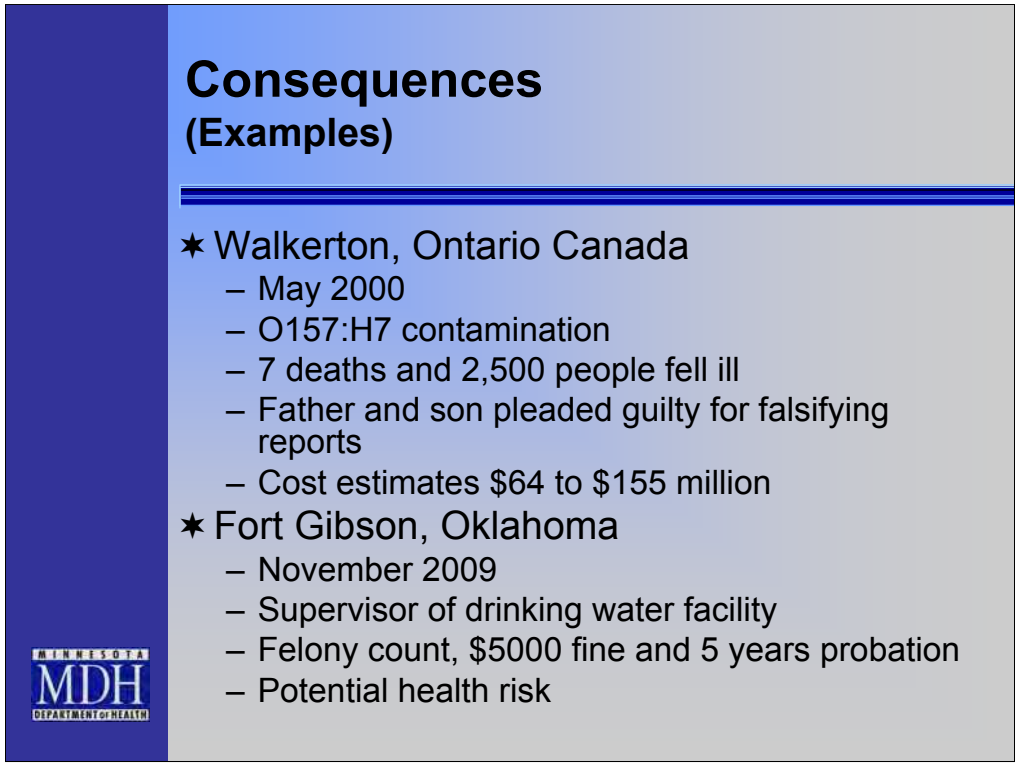
Types of consequences for breaches in an ethics and data integrity policy and procedures are:

•Administrative- consequences mean one could lose his/her job or the laboratory could lose clients or contracts,

•Environmental- pollution of the streams, fish kills, and degradation of the overall quality of the environment (land, air and water),

•Human health – the health of the citizens within the community, including one's own health and well being, and

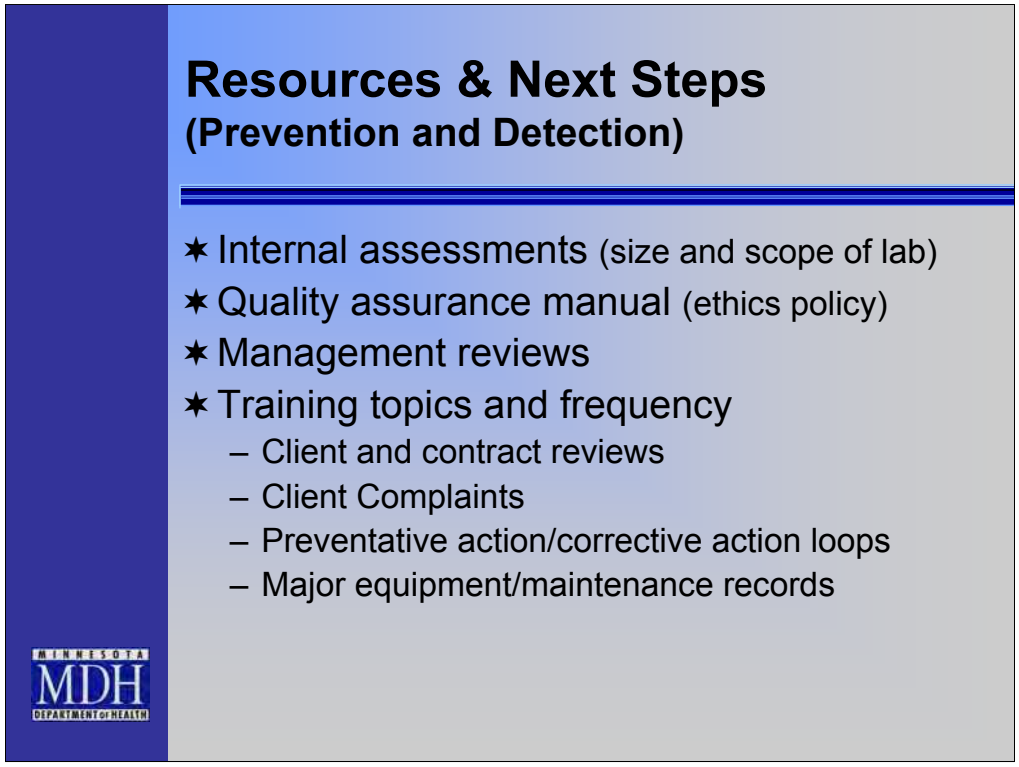
•Legal- the laboratory or the employee engaging in inappropriate actions may be liable for civil suits, regulatory fines, loss of accreditation, or criminal prosecution.



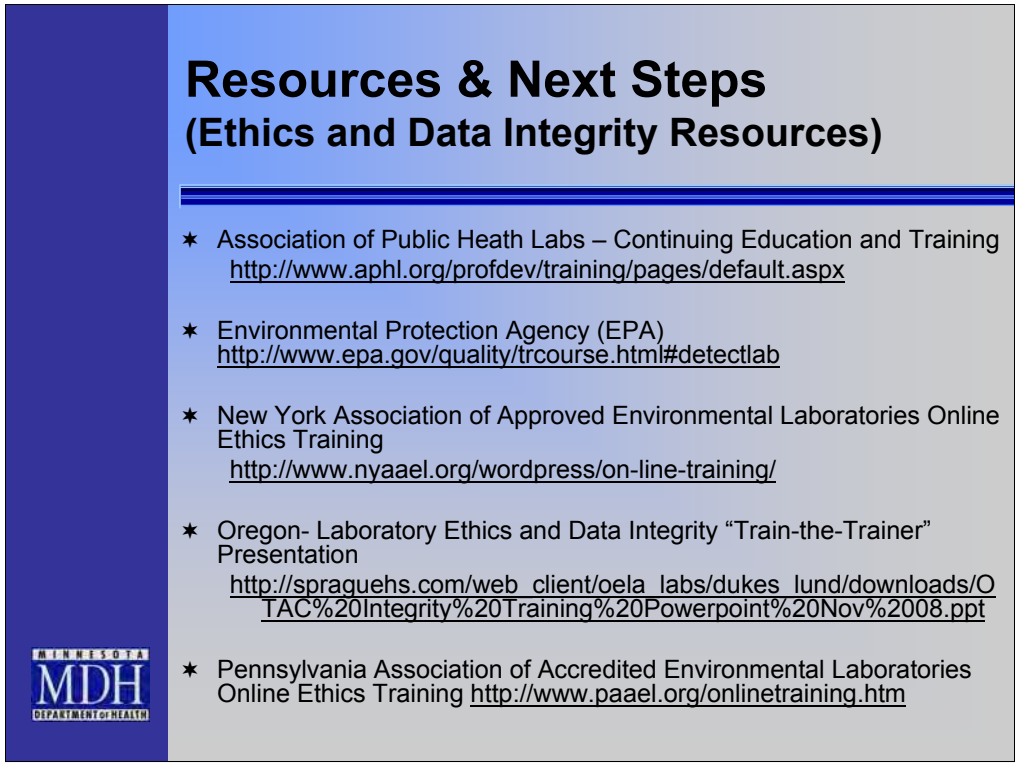
The consequences of unethical or inappropriate actions or inactions are represented through these two case examples:

- Walkerton, Ontario Canada, Stan Kobel (manager) and Frank Kobel (water foreman), father and son, were sentenced for a series of events in May 2000 that lead to e.coli contamination that caused half of the town's population to fall ill and cause 7 deaths. The two operators had no formal training other than on the job-training and were found guilty to falsifying water quality reports. In this case, familial pressures may also have caused or contributed to fraud.

- Fort Gibson, Oklahoma, Christopher Gauntt, the former water treatment manager pleaded guilty to making false statements in a monthly operational reports submitted in Oklahoma. He was fined and sentenced to probation for submitting operational reports with false entries for turbidity and residual chlorine. He was sentenced for his actions, because of the potential health risk associated with the presence of microorganisms in the drinking water.



For the detection and prevention of improper practices with the laboratory, the laboratory's management should plan and conduct internal assessments and management reviews in a timely manner (NELAC 5.4.13 and 5.4.14). The internal assessments should assess the entire size and scope of the laboratory. With that said, the laboratory should assess the lab's entire system from project management, contract review, regulatory compliance, data integrity/ethics policies and training, and the quality assurance manual and procedures (NELAC 5.4.2.6). Management reviews are also necessary to review the entire system for effectiveness, identify vulnerabilities and ensure there are not undo pressures within the lab's systems. It is also essential to review the training topics with regular frequency and use the lab's systems and records (e.g. client complaints, client and contract reviews/feedback and etc) as tools to possibly identify vulnerabilities or inappropriate actions.



There are several online resources that may assist laboratories in the development of their own ethics/data integrity training, as well as offer training sessions for free or a small fee. This is a list of resources that may provide training programs or provide example ethics and data integrity programs (please note this is not meant to be an endorsement of any product or service).

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- Walkerton Tragedy: http://en.wikipedia.org/wiki/Walkerton_Tragedy

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