

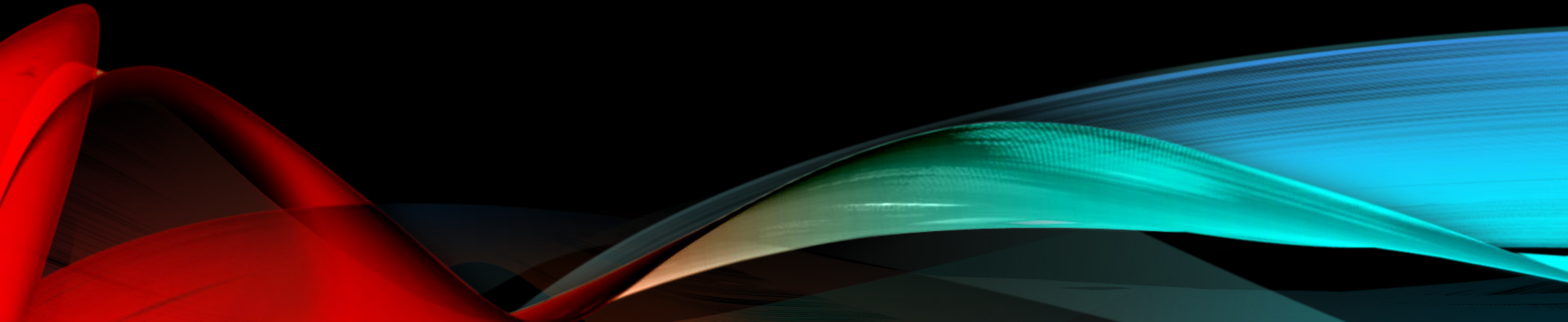
DATA INTEGRITY AND ETHICS

APHL QUALITY IMPROVEMENT FORUM

Kathryn Wangsness, Arizona State Public Health Laboratory

Shane Olund, Minnesota State Public Health Laboratory

OVERVIEW OF DATA INTEGRITY AND ETHICS



WHAT IS ETHICS?

- Generally defined, it ties into the moral principles that guide an individual's actions
 - Shaped by culture which includes accepted practices, religious morality
- Professionally it is a set of standards generally agreed upon by which individuals conduct their work
 - Code of Conduct or Code of Ethics – listed below are some examples
 - American Public Health Association (APHA) Public Health Code of Ethics:
 - https://www.apha.org/-/media/files/pdf/membergroups/ethics/code_of_ethics.ashx
 - American Society for Clinical Laboratory Science (ASCLS) Code of Ethics
 - <https://ascls.org/code-of-ethics/>
 - American Chemical Society (ACS) The Chemical Professional's Code of Conduct
 - <https://www.acs.org/content/acs/en/careers/career-services/ethics/the-chemical-professionals-code-of-conduct.html>

DIFFERENT NAMES

- There are different names in different industries beyond ethics that get to the same general concept of standard acceptable practice:
 - Impartiality
 - Data Integrity
 - Confidentiality
 - Laboratory Integrity
 - Data Quality
- These are seen not only in the laboratory industry but in many other industries throughout the world



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WHY IMPORTANT

- Codes of conduct build trust within the profession and with the public, and when individuals or laboratories do not follow this it can hurt the entire industry
- Falsification
 - The intentional act of destroying, altering, mutilating or changing any original information
 - Civil
- Fraud
 - The wrongful or criminal intent to falsify information for gain
 - Deliberate falsification or intentional recording/reporting of incorrect information to make it appear acceptable
 - Criminal

SLIPPERY SLOPE

- Analysts are relied on to follow the procedures (SOPs), methods and other documents in their laboratory
 - Yet, there are still instances where they may need to use their best judgement when performing measurements
 - Armed with knowledge, analysts can learn to avoid the slippery slope of unethical practice



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PRESSURES

- Laboratories are expensive and there can be pressure to ensure costs are managed and clients are happy
- If you ever feel forced to complete a test that is not working or that there is not enough time to complete due to internal or external pressures
 - Such as feeling you are letting the team down
 - Afraid to ask for help
 - Team members or supervisors
 - Customers/clients
 - Outside events – family, friends
 - Resources - believing not available
- Do not be afraid to reach out
 - Contact a supervisor/manager
 - Contact quality

TO BE CLEAR...

- It is **OK** to make a mistake
 - It is **NOT** OK to hide that mistake
- It is **OK** to have QC out of limits
 - It is **NOT** OK to hide QC that is out of limits or make it appear to be within limits when it is not.
- There are potentially **severe** consequences for scientific misconduct that can affect you and your lab.
- Good **communication** can be key to prevention of these problems!

LABORATORY RESPONSIBILITIES

- Continuously monitor data on a periodic but random basis – data audits
- Provide ongoing training to employees
- Perform confidential investigations if a problem is detected
- Notify clients and reissue reports when impacted
- Eliminate undue pressure on analysts – quality ahead of TAT



EMPLOYEE RESPONSIBILITIES



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Uphold the ethics policy and practices as demonstrated in their daily conduct.

Seek help when the proper course of action is unclear or unknown to them.

Remain alert and sensitive to situations that could result in actions by any employee that are improper, illegal, unethical, or otherwise in violation of the ethics policy and practices.

Counsel fellow employees when it appears that they are in danger of violating the ethics policy and practices.

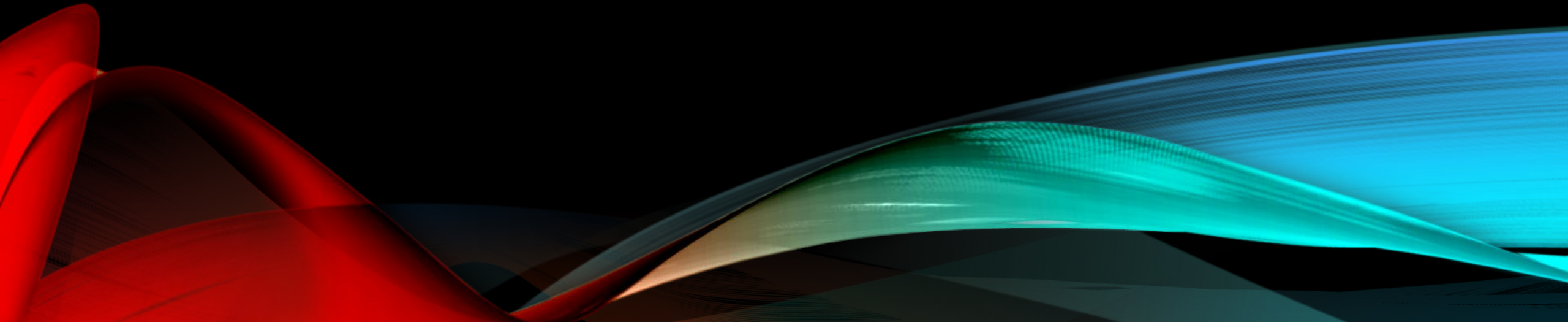
Report violations of the ethics policy and practices to their supervisor.



POLL QUESTION 1

- Managers are the only ones responsible for ensuring data integrity and ethics:
 - True
 - False

EXAMPLES



Coronavirus

UKHSA considers legal action against privately run Immensa lab

Peter Walker *Political correspondent*

🐦 @peterwalker99

Wed 8 Dec 2021 01:00 EST

A government health watchdog is considering legal action against a private health company whose laboratory gave at least 43,000 people potentially false negative Covid-19 test results.

➤ [Water Sci Technol. 2003;47\(3\):1-6.](#)

Drinking water contamination in Walkerton, Ontario: positive resolutions from a tragic event

R Holme ¹

Affiliations + expand

PMID: 12638997

Abstract

In May 2000, *Escherichia coli* O157:H7 and *Campylobacter jejuni* contaminated the drinking water supply in Walkerton, Ontario. **Seven people died** and over 2,000 were ill as a result. The Ontario Provincial Government set up a judicial Inquiry into the circumstances surrounding the outbreak and also moved quickly to introduce a new Drinking Water Regulation that incorporated some significant

U.S. NEWS

Epic Drug Lab Scandal Results in More Than 20,000 Convictions Dropped

Five years ago, Massachusetts drug lab chemist Annie Dookhan was caught faking results. That led to Tuesday's dismissal of over 21,000 convictions.



— Former state chemist Annie Dookhan sits in Suffolk Superior Court in Boston before entering a guilty plea on charges of obstruction of justice, perjury and tampering with evidence on Nov. 22, 2013.

David L. Ryan / Boston Globe via AP, file

FOR IMMEDIATE RELEASE

Tuesday, May 4, 2021

Owner Of A Consumer Products Testing Company Pleads Guilty To \$46 Million Fraud Scheme Involving Fabricated Test Results

Defendant Admitted to Sending Customers Fraudulent Reports for Laboratory Tests That Were Not Fully Performed

Audrey Strauss, United States Attorney for the Southern District of New York, announced that GABRIEL LETIZIA Jr., the owner and executive director of AMA Laboratories, Inc. ("AMA"), a consumer products testing company in New City, pled guilty today to defrauding customers by reporting laboratory test results

THE UNITED STATES ATTORNEY'S OFFICE NORTHERN DISTRICT *of* OHIO

[U.S. Attorneys](#) » [Northern District of Ohio](#) » [News](#)

Department of Justice

U.S. Attorney's Office

Northern District of Ohio

FOR IMMEDIATE RELEASE

Tuesday, March 9, 2021

Lab analyst sentenced for falsifying test results

A former environmental laboratory analyst was sentenced by U.S. District Court Judge Pamela A. Barker to two years of probation and ordered to pay a \$2,500 fine for falsifying laboratory test results.

Andrew K. Ecklund, age 58, of Tallmadge, Ohio, pleaded guilty in November of 2020 to nine counts of wire fraud stemming from a scheme to falsify laboratory analysis reports in order to improve work efficiency.

RECURRING CLINICAL LAB FRAUD CASES

In October 2015, California-based [Millennium Health \(https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic\)](https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic) paid \$256 million to settle the qui tam allegations leveled against it. The company was accused of paying kickbacks to doctors and billing the government for unnecessary testing, including unwarranted genetic testing.

Millennium has hardly been the only one to face clinical lab fraud allegations. In April 2015, after a three-year investigation, two other clinical labs reached a \$48.5 million settlement with the U.S. government. As seen in the Millennium case, the [hefty sum \(https://www.fbi.gov/columbia/press-releases/2015/two-cardiovascular-disease-testing-laboratories-to-pay-48.5-million-to-settle-claims-of-paying-kickbacks-and-conducting-unnecessary-testing\)](https://www.fbi.gov/columbia/press-releases/2015/two-cardiovascular-disease-testing-laboratories-to-pay-48.5-million-to-settle-claims-of-paying-kickbacks-and-conducting-unnecessary-testing) pertained to allegations that the labs had orchestrated a kickback scheme and billed federal healthcare programs for unnecessary lab procedures.

One of the most widely publicized clinical lab fraud cases in U.S. history saw almost 40 healthcare providers pleading guilty to participation in a bribery scheme. Biodiagnostic Laboratory Services LLC, based in Parsippany, New Jersey, was the subject of the 2013 case and its considerable fallout. According to the allegations, [hundreds of doctors \(http://www.nbcnewyork.com/news/local/NJ-Lab-Workers-Plead-Guilty-Medical-Testing-Firm-Medicare-Insurance-Fraud-Billing-](http://www.nbcnewyork.com/news/local/NJ-Lab-Workers-Plead-Guilty-Medical-Testing-Firm-Medicare-Insurance-Fraud-Billing-)

Theranos

'People wanted to believe': reporter who exposed Theranos on Elizabeth Holmes' trial

Karl Paul in San Francisco

Sun 29 Aug 2021 01:00 EDT



As blood testing startup founder's fraud trial looms, John Carreyrou says hero worship is still a problem in Silicon Valley

The unraveling of Theranos began with a 2015 [article](#) in the Wall Street Journal that revealed how the revolutionary technology promoted by the blood testing startup wasn't exactly what it seemed.

Over the proceeding months, the reporter John Carreyrou exposed how the testing devices the [Silicon Valley](#) darling said could perform a variety of medical tests with just a drop of blood were not actually being used to perform most of the analyses. Investors and consumers, Carreyrou found, were being fooled.

Theranos dissolved in 2018 and its star founder, Elizabeth Holmes, will face trial in a San Jose courtroom next week.

Loss of Scientific Integrity Finding at USGS National Water Quality Lab

Release Date: MARCH 16, 2021

Background Information

The USGS National Water Quality Laboratory (NWQL) is an environmental analysis and research facility specializing in chemical analyses of water, sediment and tissue, and the taxonomic identification and quantification of benthic invertebrates. The NWQL Analytical Services (AS) Section carries out analyses of 800+ inorganic and organic constituents in more than one million samples of groundwater, surface water, wastewater, sediment, atmospheric precipitation and biological tissues. Each year, the NWQL analyzes tens of thousands of water samples. The lab's work helps understand the health of aquatic systems and pinpoint potential sources of contamination such as agricultural runoff.

On July 8, 2020, NWQL's quality assurance/quality control processes revealed that data values of some samples had been altered without required explanatory notation. USGS immediately launched an investigation and has determined that from March 2019 through June 2020, a single AS Section analyst significantly departed from accepted practices and standards, violating the USGS's fundamental science practices and resulting in a loss of scientific integrity. Evidence shows the analyst acted alone and intentionally to falsify data for the nutrients nitrogen and phosphorus in approximately 2,300 water samples.

The USGS has taken appropriate measures to notify users of the affected analyses

Contacts

Department of the Interior,
U.S. Geological Survey

Office of
Communications and
Publishing
12201 Sunrise Valley
Drive
Reston, VA 20192
United States
Phone: 703-648-4460

[David Ozman](#)

Central
Communications Chief
Email:
dozman@usgs.gov
Phone: 303-202-4744

Lab test owner indicted in \$100M fraudulent billing scheme

Alia Paavola - Thursday, November 4th, 2021 [Print](#) | [Email](#)

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An Arkansas man who owned and managed several diagnostic testing laboratories was indicted in an alleged \$100 million fraudulent billing scheme, the Justice Department said Nov. 3.

Prosecutors allege Billy Joe Taylor and his laboratory testing sites submitted claims for urine drug testing, COVID-19 testing and other clinical tests that were not medically necessary, not ordered by a medical provider or not provided as represented. Further, prosecutors allege Mr. Taylor also obtained medical information for Medicare beneficiaries and misused the information to continually submit claims to Medicare for tests that were not performed by the labs. The alleged scheme took place between February 2017 and May 2021.

Prosecutors claim that as a result of the scheme, the labs owned or managed by Mr. Taylor submitted \$100 million in false and fraudulent claims to Medicare.

Mr. Taylor is charged with 16 counts of healthcare fraud and one count of engaging in a monetary transaction in criminally-derived property.

LABORATORY FRAUD



Laboratories are used to analyze soil, water, and other media to determine their chemical composition, to assess whether such chemicals pose human health risks, and to determine whether such media are contaminated and in need of remedial treatment. In light of this role, maintenance of the integrity of laboratory sample tests, results, and reports is critical. A Lab Fraud Task Force and Lab Fraud Initiative were established to survey the problem of fraudulent laboratory testing and to determine how best to tackle it. ECS attorneys prosecuted several nationally significant cases associated with the Initiative.

ECS also prosecuted lab fraud prior to setting up the Task Force. In one case a lab and its owner pled guilty to one count of conspiracy to commit mail fraud and one count of making false statements to EPA relating to the pesticide residue tests. The president of the lab was sentenced to serve 48 months incarceration and pay a \$50,000 fine stemming from concealing and falsifying pesticide residue tests used by EPA to determine whether levels of pesticide residues in foods are safe and for the protection of public health. The lab was sentenced to pay a \$15.4 million fine. The president and the company also each paid \$3.7 million in restitution to defrauded pesticide manufacturers and EPA. The defendants falsified the results of their tests in order to save time and money that would have been necessary to repeat tests that did not meet calibration or quality control requirements. Numerous other co-defendants were sentenced to various fines and, for two co-defendants, terms of imprisonment.

In the News United States Department of Justice and United States Environmental Protection Agency Joint Press Release "Owner Sentenced to Prison for Falsifying Pesticide Test." 25 Feb. 1994. (PDF)

Metallurgist Admits She Falsified Test Results for Steel Used in Navy Submarines

For more than 30 years, Elaine Thomas altered test results for more than 240 steel productions while working for a foundry that provides metal for U.S. Navy submarines.



A former metallurgist at Bradken Inc., a foundry in Tacoma, Wash., pleaded guilty on Monday to falsifying test results that measured the strength and toughness of steel used for U.S. Navy submarines. Ted S. Warren/Associated Press



By Jesus Jiménez

Published Nov. 8, 2021 Updated Nov. 10, 2021

A former metallurgist at a foundry that provides steel used to make U.S. Navy submarines pleaded guilty in federal court in Tacoma, Wash., on Monday to falsifying test results that measured the strength and toughness of the metal — a practice that prosecutors said she continued for more than three decades.

The former metallurgist, Elaine Thomas, 67, of Auburn, Wash., who pleaded guilty to major fraud, falsified test results for more than 240 steel productions, the U.S. Attorney's Office for the Western District of Washington said in a statement. She could face up to 10 years in prison and a \$1 million fine when she is sentenced on Feb. 14.

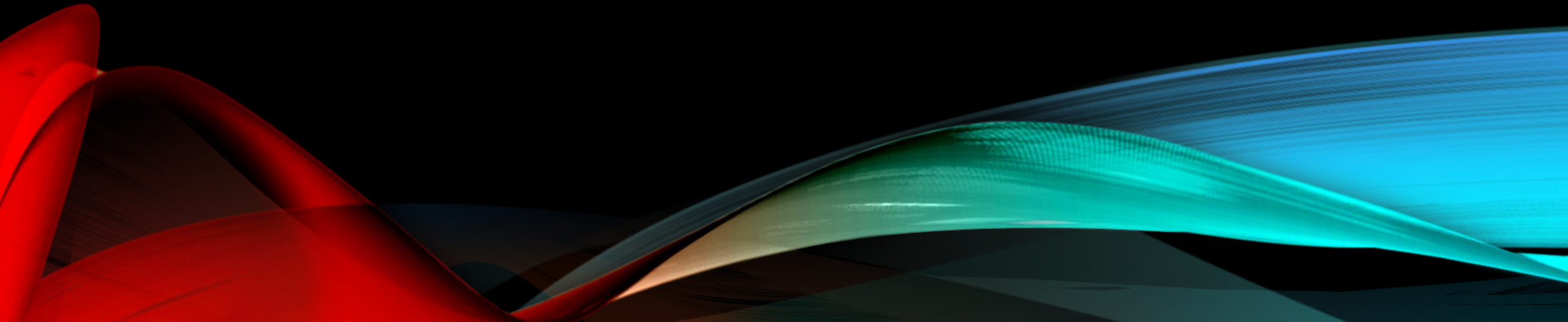
Between 1977 and 2017, Ms. Thomas worked as a metallurgist at a steel foundry in Tacoma, Wash., owned by Atlas Castings & Technology and acquired by [Bradken Inc.](#), in 2008, according to the indictment in the case. Ms. Thomas was named director of metallurgy for the company in 2009.

Bradken produces steel castings as a subcontractor or supplier for companies that contract with the Navy, according to the indictment. The company is the Navy's leading supplier of "cast high-yield" steel used for naval submarines, prosecutors said, adding that the productions whose tests were falsified make up "a

POLL QUESTION 2

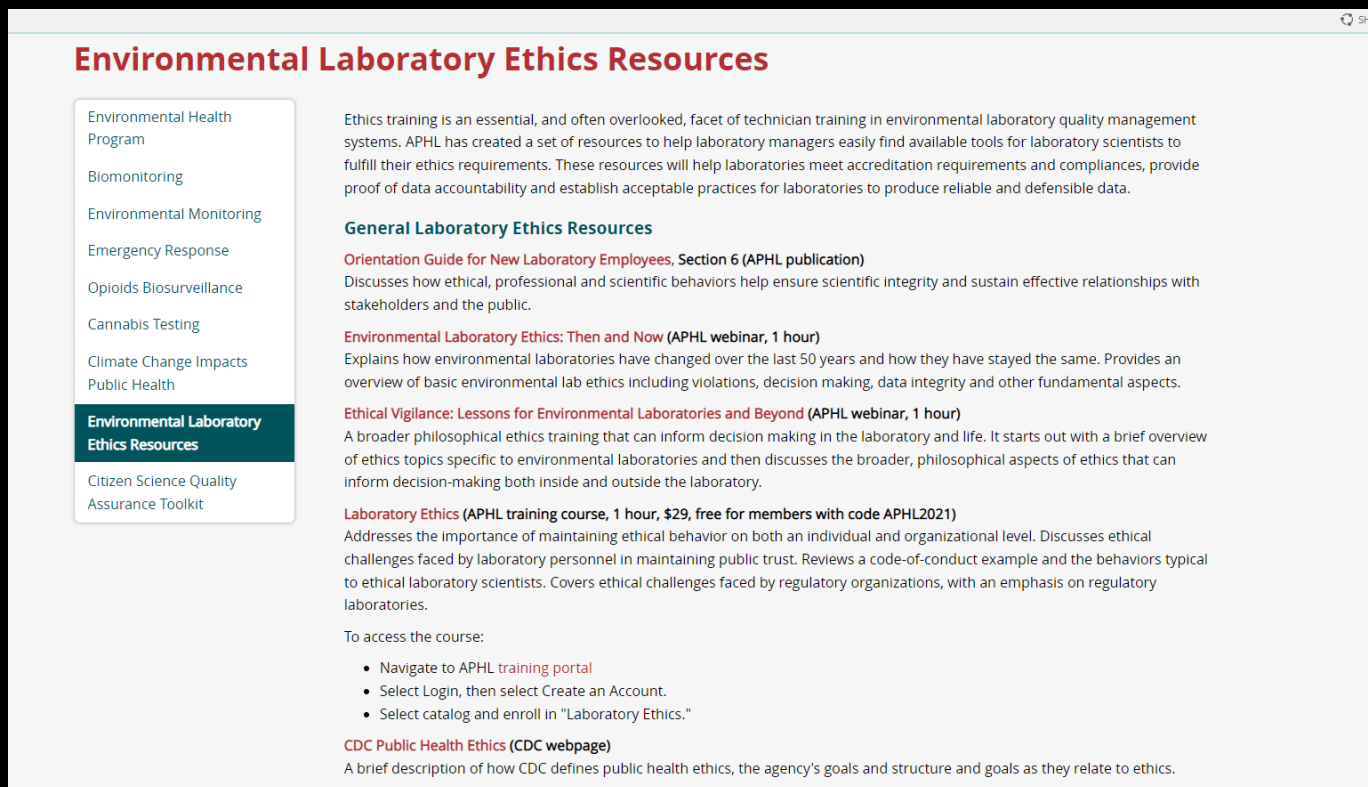
- Individuals convicted of fraud involving laboratory data can have all but what happen:
 1. Debarment
 2. Jailed
 3. Promotion
 4. Fines
 5. Business Closure

TOOLS AND RESOURCES



APHL ENVIRONMENTAL LABORATORY ETHICS RESOURCES

- https://www.aphl.org/programs/environmental_health/Pages/Environmental-Laboratory-Ethic-Resources.aspx



The screenshot shows the 'Environmental Laboratory Ethics Resources' page on the APHL website. On the left is a sidebar with a menu of topics: Environmental Health Program, Biomonitoring, Environmental Monitoring, Emergency Response, Opioids Biosurveillance, Cannabis Testing, Climate Change Impacts Public Health, Environmental Laboratory Ethics Resources (highlighted), and Citizen Science Quality Assurance Toolkit. The main content area has a title 'Environmental Laboratory Ethics Resources' and a paragraph explaining that ethics training is essential and often overlooked, with APHL providing resources for accreditation and compliance. Below this is a section titled 'General Laboratory Ethics Resources' containing three items: 'Orientation Guide for New Laboratory Employees, Section 6 (APHL publication)' which discusses ethical behaviors; 'Environmental Laboratory Ethics: Then and Now (APHL webinar, 1 hour)' which provides an overview of lab ethics; and 'Ethical Vigilance: Lessons for Environmental Laboratories and Beyond (APHL webinar, 1 hour)' which discusses philosophical aspects of ethics. A 'Laboratory Ethics (APHL training course, 1 hour, \$29, free for members with code APHL2021)' section follows, addressing the importance of ethical behavior and providing steps to access the course. At the bottom, there is a 'CDC Public Health Ethics (CDC webpage)' section with a brief description.

Environmental Laboratory Ethics Resources

Environmental Health Program

Biomonitoring

Environmental Monitoring

Emergency Response

Opioids Biosurveillance

Cannabis Testing

Climate Change Impacts Public Health

Environmental Laboratory Ethics Resources

Citizen Science Quality Assurance Toolkit

Ethics training is an essential, and often overlooked, facet of technician training in environmental laboratory quality management systems. APHL has created a set of resources to help laboratory managers easily find available tools for laboratory scientists to fulfill their ethics requirements. These resources will help laboratories meet accreditation requirements and compliances, provide proof of data accountability and establish acceptable practices for laboratories to produce reliable and defensible data.

General Laboratory Ethics Resources

Orientation Guide for New Laboratory Employees, Section 6 (APHL publication)
Discusses how ethical, professional and scientific behaviors help ensure scientific integrity and sustain effective relationships with stakeholders and the public.

Environmental Laboratory Ethics: Then and Now (APHL webinar, 1 hour)
Explains how environmental laboratories have changed over the last 50 years and how they have stayed the same. Provides an overview of basic environmental lab ethics including violations, decision making, data integrity and other fundamental aspects.

Ethical Vigilance: Lessons for Environmental Laboratories and Beyond (APHL webinar, 1 hour)
A broader philosophical ethics training that can inform decision making in the laboratory and life. It starts out with a brief overview of ethics topics specific to environmental laboratories and then discusses the broader, philosophical aspects of ethics that can inform decision-making both inside and outside the laboratory.

Laboratory Ethics (APHL training course, 1 hour, \$29, free for members with code APHL2021)
Addresses the importance of maintaining ethical behavior on both an individual and organizational level. Discusses ethical challenges faced by laboratory personnel in maintaining public trust. Reviews a code-of-conduct example and the behaviors typical to ethical laboratory scientists. Covers ethical challenges faced by regulatory organizations, with an emphasis on regulatory laboratories.

To access the course:

- Navigate to APHL [training portal](#)
- Select Login, then select Create an Account.
- Select catalog and enroll in "Laboratory Ethics."

CDC Public Health Ethics (CDC webpage)
A brief description of how CDC defines public health ethics, the agency's goals and structure and goals as they relate to ethics.

APHL MEMBER RESOURCE CENTER

- <https://www.aphl.org/MRC/Pages/default.aspx>
 - Using search words such as “Data Integrity” or “Ethics”
 - Resources such as new employee orientation or previous presentations

Member Resource Center (MRC) Search

[Clear Search](#)

Type in the search bar below and press “Enter” to find a resource. You can also filter documents by topic, published year or document type by checking the specific filter(s) you would like to use and then pressing “apply”.

Topic

☐ Communications, Marketing, and Outreach

☐ Emergency Preparedness, Biosafety, and Biosecurity

☐ Environmental Health (biomonitoring, LRN-C, etc.)

☐ Environmental Testing

☐ Food Safety and Agriculture

☐ Infectious Diseases

Ethics

Results

Orientation Guide for New Laboratory Employees

Description: In this workbook, you will have the opportunity to learn more about some of the competency dc integral to work in the public health laboratory environment. The activities will also help you prepare for a me supervisor following each section to assess your learning.

Topic(s): Infectious Diseases; Training and Workforce Development

Document Type: pdf

Laboratory Ethics and Data Integrity Presentation

Description: Narrated Training and Quiz on Laboratory Ethics and Data Integrity by the Houston Health Department for non-commercial use by Public Health Departments

Topic(s): Training and Workforce Development

Document Type: pdf

QIF Presentation- Laboratory Challenges with TNI Implementation and Laboratory Audits, December 2017

Description: This presentation was given on December 14, 2017. Drs. Donna Ferguson and Martina McGarvey, laboratory directors of the Monterey County and Pennsylvania Department of Environmental Protection Laboratories, respectively, presented. Topics included the California Local Public Health Laboratories and Pennsylvania State Laboratory experiences, challenges and lessons learned.

Topic(s): Environmental Health (biomonitoring, LRN-C, etc.)

RESOURCES

- Online Dictionary
- EPA Region 9, *Laboratory Fraud: Detection & Deterrence*, 2005
- EPA OIG Report, *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*, September 21, 2006, <https://www.epa.gov/office-inspector-general/report-promising-techniques-identified-improve-drinking-water-laboratory>
- Oregon Technical Advisory Committee, *Laboratory Ethics and Data Integrity "Train-the-Trainer" Presentation*, 2008
- Publication: [*Ethics Training is Essential in Environmental Laboratory Testing*](#), coauthored by members of AWWA, WEF, and APHL



OPEN DISCUSSION

- What questions do you have about data integrity and ethics?
- What should you do if you are uncertain about what is being done?



SCENARIO A

- When you're checking the morning temperatures, you realize that you forgot to record yesterday afternoon's temp in the log book. You know you read it and that it was fine. Can you fill in the data now?

SCENARIO B

- You're in a hurry because it's a short week. You started up the autoclave and forgot to check the pressure and temperature during the sterilization cycle. Why not just check off the column in the log book that we have that positive bottle in there to determine sterility? It's been fine for the past six months, always at the right temp and pressure, and besides, don't we always set up a blank? It's just this one time.