

ANALYTICAL TEST METHOD REQUIREMENTS

An Enforcement Perspective

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Analytical Test Methods and Enforcement

- Clean Water Act (CWA) and Safe
 Drinking Water Act (SDWA) establish national regulatory programs
- States may administer subject to EPA oversight
- EPA has developed mandatory methods for sampling and analysis of water and waste streams



Analytical Test Methods and Enforcement

- Methods are codified at 40 C.F.R. §136
 (CWA) and 40 C.F.R. §141 (SDWA)
- Methods apply to federal and state administered programs
- Alternative test methods (ATP) require formal EPA approval



Analytical Test Methods and Enforcement

 EPA receiving reports of use of improper test method for wastewater and drinking water analyses

- Reports include accounts of outright fraud
 - Allegations of fraud are reported to EPA's Criminal Investigation Division (CID)



Analytical Test Methods and Enforcement

- Analytical methods not compliant with CWA and SDWA requirements
 - Improper substitution of test methods
 - Improper modification of test methods



Improper Substitution of Test Methods

- Use of Resource Conservation and Recovery Act (RCRA) test methods (SW 846) for analysis of wastewater samples
 - SW 846 not authorized for wastewater
 - SW 846 lacks QA/QC rigor of Part 136 test methods
 - Failure to report substitution to EPA can expose lab to enforcement action



Improper Modification of Test Methods

- E. coli holding times
 - Substitution of drinking water e. coli 30 hour holding time (Part 141) for wastewater 6 hour holding time (Part 136)
 - Presence/absence versus enumeration different test, different purposes
- Reports of rural water systems exceeding 30 hour holding times for drinking water analyses
 - Potential adverse human health impacts are serious concern



Enforcement Response to Improper Testing

- Improper testing (to include fraud) places individuals and labs at risk of enforcement action
- Knowingly and willfully reporting false data to regulatory authorities can lead to felony criminal charges under Title 18 of the U.S. Code
- Title 18 charges may include:
 - Mail fraud (18 U.S.C. §1341)
 - Wire fraud (18 U.S.C. §1343)
 - False statements (18 U.S.C. §1001)
- Potential for significant fines and incarceration



Recent Lab Fraud Enforcement Actions

Upstate Laboratories

Blue Marsh Laboratories/Michael McKenna

Martha Hebert



Upstate Laboratories

- Syracuse, NY certified lab performing water and soil analyses for public and private clients
- Charged premium for expedited analyses to meet specified holding times
- Falsified holding times for over 3,300 samples and told clients analyses were performed per required methods
- Submitted false invoices through U.S. mail
- Pled guilty to mail fraud
- Fined \$150,000 and placed on 5 years probation



Blue Marsh Laboratories and Michael McKenna

- Blue Marsh/McKenna analyzed water, wastewater, and food for pesticides residues
- BM/McKenna mailed analytical results to customers falsely stating proper EPA methods were followed
- Falsified and mailed fraudulent pesticide test results to the FDA
- Defendants pled guilty to fraud, CWA crimes, and false statements to the FDA
- McKenna received five months in prison, Blue Marsh five years probation, and ordered to pay \$14,114 in restitution



Martha Hebert

- Hebert was co-owner of Laboratory Technology (LT) which performed toxicity tests on produced water for oil and gas industry
- Hebert knew LT's lab supervisor was signing reports certifying accuracy of toxicity tests despite not following required protocols
- Hebert allowed this practice to continue for years but did not report it to authorities
- Hebert pled guilty to 18 U.S.C. §4 misprision of a felony
- Sentenced to two years probation, fined \$10,000, and not allowed to perform produced water toxicity tests for five years



Lab Fraud: Collateral Consequences

- Suspension and debarment
 - Keeps individuals, organizations, or government entity from receiving future federal grants or contracts
 - Has government-wide effect
 - Automatic for CWA violations
- Loss of business/reputation
 - 1,400 1,500 GLP labs pleased to take business from convicted labs or labs suspected of improper practices