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