



Bureau of Laboratories

Laws Relating to Accreditation, the use of NGABs, and Enforcement

National Environmental Monitoring Conference

New Orleans, LA

August 6, 2018

▶ Presentation Overview

- Laws and Regulations Establishing Accreditation Authority and Responsibility
- PA-DEP's Powers and Duties
- Requirements for Accreditation
- PA-DEP LAP Allocation of Resources
- Examples of Violations
- Consequences of Non-Compliance
- Resolution of Liability

► Accreditation Laws & Regulations

- USEPA National Primary DW Regulations
Implementation: 40 CFR Part 142.10
 - A State has primary enforcement responsibility, pursuant to appropriate State legal authority
 - Must adopt regulations as stringent as Federal
 - Must adopt and implement enforcement procedures of State regulations
 - Must be a State laboratory certification program

► Accreditation Laws & Regulations

- Require Applications for Accreditation
- Require Payment of Fees
- Mutual Recognition Agreements
 - Secondary NELAP applications
 - Accreditation Program deemed “equivalent”
- Additional Requirements
 - Supervisor Qualifications
 - Proficiency Testing
 - Reporting/Notification Requirements

► Accreditation Laws & Regulations

- Mutual Recognition Agreements
 - The commissioner may enter into agreements with certifying authorities of federal agencies and agencies of other states for reciprocal recognition...
 - An OOS lab with NELAP accreditation from a State that has received NELAP recognition shall be eligible for accreditation...
 - Secondary Accreditation means the accreditation ... based on primary accreditation from another State
 - An agency that is deemed to have a program that meets or exceeds the accreditation program
 - An accreditation program that is deemed equivalent

▶ Accreditation Laws & Regulations

- PA-DEP ELAA, June 29, 2002, 27 Pa C.S. § 4103(a)
 - The Department shall establish an accreditation program for environmental laboratories
 - The Program shall include a NELAP accreditation Program for those laboratories seeking this certification
 - The Program may recognize accreditations from other specific broad-based Federal or State Accreditation programs for certification

► Accreditation Laws & Regulations

- Environmental Laboratory Accreditation Regulations 25 Pa. Code Chapter 252
 - Accreditation Body (AB): A territorial, State, or Federal Agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.
 - The PA-DEP will recognize accreditations granted by other NELAP-recognized ABs and another state AB with standards for accreditation that are substantively equivalent to Chapter 252.

▶ PA-DEP Powers and Duties

- The Department may refuse to issue a certificate of accreditation to an environmental lab which has:
 - demonstrated a lack of intention or ability to comply with the Lab Act
 - engaged in unlawful conduct
 - an employee, officer, contractor, agent or other person set forth in regulation who has engaged in unlawful activity under the Lab Act
- The Department may disqualify a lab supervisor who is responsible for the submission of inaccurate test or analysis results

▶ Laboratory Responsibilities

- The lab shall have the staff, management structure, equipment, quality assurance and quality control procedures and recordkeeping procedures necessary to ensure that the lab generates valid and accurate test results.
- Testing, analysis and reporting of data by an accredited lab shall be under the direct supervision of a lab supervisor.
- The lab supervisor shall certify that each test or analysis is accurate and valid and that the test or analysis was performed in accordance with all conditions of accreditation.

▶ Laboratory Responsibilities

- It shall be unlawful for a person:
 - to violate or to cause or assist in the violation of the Lab Act,
 - to fail to comply with an order or condition of accreditation within the time specified by the Department or
 - to hinder, obstruct, prevent, or interfere with the Department in the performance of its duties under the Lab Act.
- Failure of a lab or lab supervisor to maintain adequate records or PT samples as required creates a rebuttable presumption that the test or analysis was not conducted as required.

► Evaluation of Laboratory Activities

- Assessment of Laboratory Operations
 - On-site or data review
 - SOPs, PT performance, training, recordkeeping, sample receipt and handling procedures, equipment, etc.
- Assessment of Laboratory Personnel
 - Laboratory Supervisor qualifications and capability, analyst training and competence
- Complaint Investigations
 - Complaints from other laboratories, customers, DEP personnel, NELAP accreditation bodies, etc.

▶ Allocation of Resources

- Process Applications for Accreditation
- Perform Laboratory Assessments
- Proficiency Testing Review – Accreditation Status Changes/Updates
- Evaluation of Laboratory Supervisor Qualifications
- Compliance Assistance
- Complaint Investigations
- Enforcement Activities – Denial, Suspension, Revocation, Consent Orders & Agreement, Fines & Penalties

► Findings that Lead to Enforcement

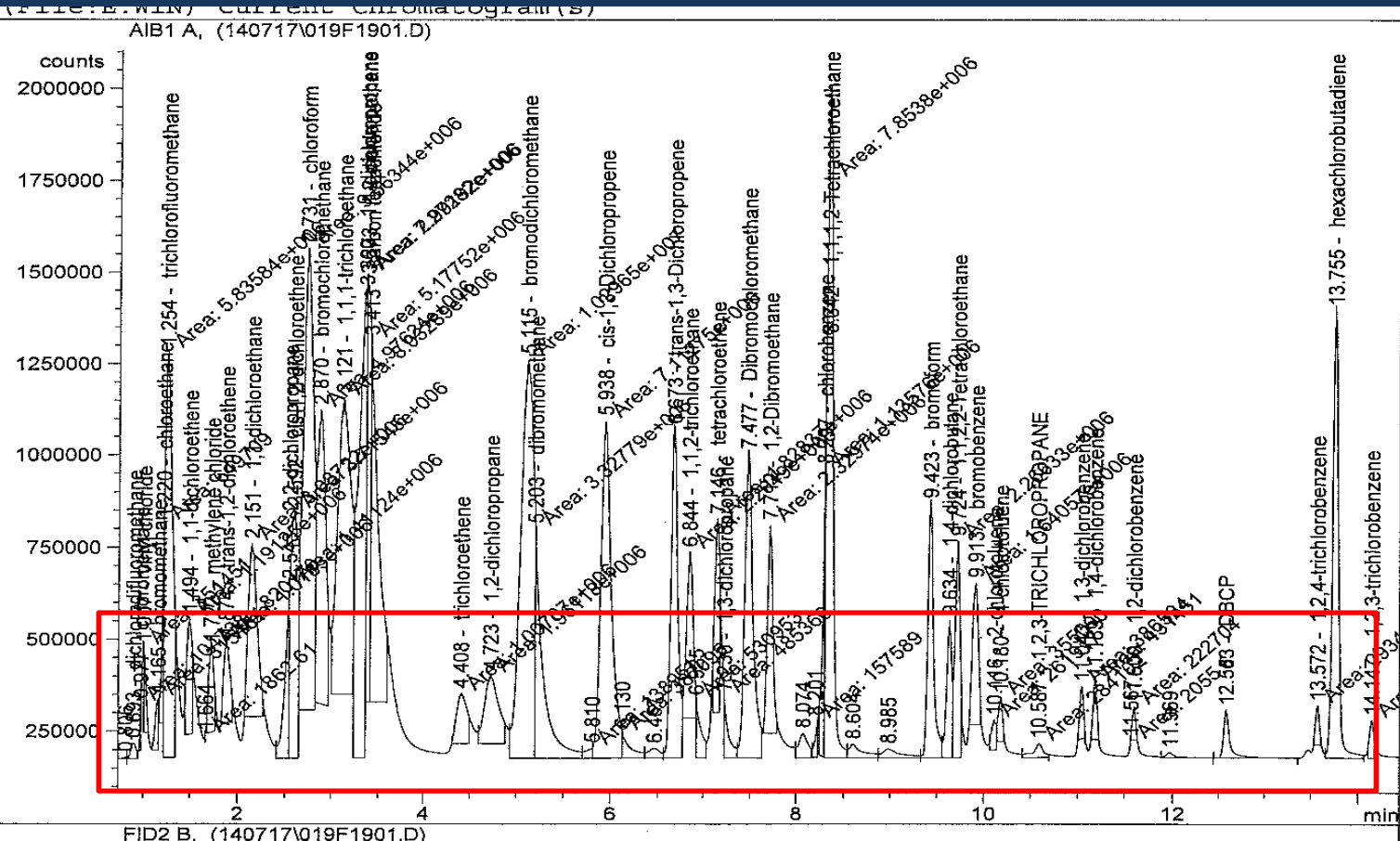
- Knowingly, willfully, or recklessly:
 - Misrepresenting that a test or a sample is accurate or was performed in accordance with all procedures authorized by the Lab Act.
 - Performing or reporting an inaccurate test result or analysis of a sample.
 - Misrepresenting that a laboratory holds a certificate of accreditation.
 - Falsifying results of testing or analysis of environmental samples for compliance purposes.

► Findings that Lead to Enforcement

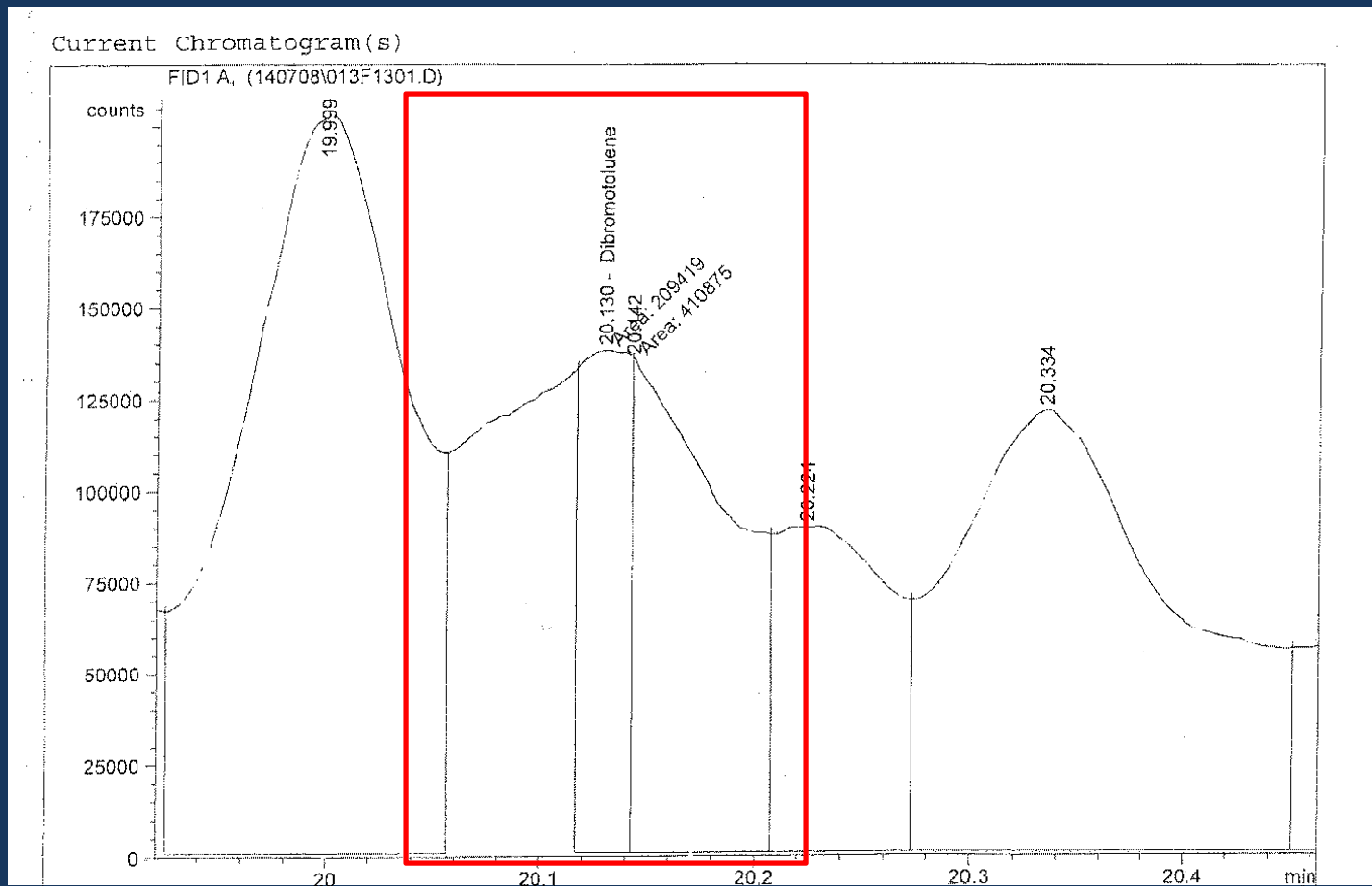
- Violation of a condition of accreditation
- Failure to comply with an order by the Department
- Lack of intention or ability to comply
- Denial of access
- Failure to provide adequate supervision or training to laboratory staff
- Repeat Violations
- Engaging in unethical or fraudulent practices
- Falsifying analyses
- Failure to properly handle, analyze, or report environmental samples and test results

▶ Examples of Violations

- Absentee/Ineffective Laboratory Management
- Failure to Report Accurate Results
- Data Approval by Untrained/Unqualified Analysts
- **Improper Manual Integrations**
- Improper Analytical Practices
- **Use of Malfunctioning Equipment**
- Analyst Failures
- Improper Handling of PT Samples
- Failure to meet DW Reporting Requirements
- **Dry-Labbing/Falsification of Data Records**



Examples of Violations



Examples of Violations

Ceriodaphnia dubia Chronic Survival/Reproduction Data Sheet



Study Number: 5336429

Day	Replicate										Percent Adults Alive	Young per Adult
	A	B	C	D	E	F	G	H	I	J		
Dose 1:	0	0	0	0	0	0	0	0	0	0		
1	0	0	0	0	0	0	0	0	0	0		
Control	2	0	0	0	0	0	0	0	0	0		
3	0	0	6	0	0	5	3	6	0	0		
4	0	6	0	0	4	3	0	0	3	0		
5	10	9	8	5	8	8	10	8	10	6		
6	X	13	9	11	17	10	9	12	10	8		
7												
8	↓											
Total	10	28	25	16	24	21	22	26	25	14	902	21.2
No. Broods	1	3	3	2	3	3	3	3	3	2	702	% 3 Broods

Ceriodaphnia dubia Chronic Survival/Reproduction Data Sheet



Study Number: 5336431-1

Day	Replicate										Percent Adults Alive	Young per Adult
	A	B	C	D	E	F	G	H	I	J		
Dose 1:	0	0	0	0	0	0	0	0	0	0		
1	0	0	0	0	0	0	0	0	0	0		
Control	2	0	0	0	0	0	0	0	0	0		
3	0	0	6	0	0	5	3	6	0	0		
4	0	6	0	0	4	3	0	0	3	0		
5	10	9	8	5	8	8	10	8	10	6		
6	X	13	9	11	17	10	9	12	10	8		
7												
8	↓											
Total	10	28	25	16	24	21	22	26	25	14	902	21.2
No. Broods	1	3	3	2	3	3	3	3	3	2	702	% 3 Broods

Examples of Violations

Transfer Date/Time									
	0	1	2	3	4	5	6	7	8
Date	12-2-14	12-3-14	12-4-14	12-5-14	12-6-14	12-7-14	12-8-14		
Time	840	830	832	830	900	850	840		
Sign.	TG	TG	TG	CBE	CBE	CBE	MM		

Transfer Date/Time									
	0	1	2	3	4	5	6	7	8
Date	12-2-14	12-3-14	12-4-14	12-5-14	12-6-14	12-7-14	12-8-14		
Time	835	800	815	805	810	840	830		
Sign.	mm	mm	mm	mm	DM	DM	mm		

► Consequences of Non-Compliance

- Report of an Assessment (Deficiency Report)
- Notice of Violation (NOV)
- Consent Order and Agreement
- Assessment of Fines and Penalties
- Disqualification of a Lab Supervisor
- Denial, Suspension, Revocation of Accreditation
- Civil Enforcement in courts
- Criminal Investigation, Prosecution, etc.

▶ Resolution of Liability

- Lab Act provides for remedies available by law
- DEP can order corrective actions
 - Designed to stop harm caused by violations
 - Administratively or in court
 - Unilaterally or with consent
- Civil Penalties
 - Deter; remove economic benefits of noncompliance
 - Unilateral or with consent
- Criminal Enforcement – PA Attorney General, EPA

In Summary

- Laws and regulations govern operations and authority of Accreditation Bodies
- PA-DEP compliance testing must be conducted by a PA-DEP accredited laboratory.
- PA-DEP allocation of resources is fluid and dependent on daily evaluation of laboratory compliance/non-compliance
- Compliance is the laboratory supervisor's responsibility
- Failure to adhere to the accreditation requirements can result in fines, penalties, loss of accreditation, and/or disqualification of lab supervisor



Bureau of Laboratories

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