
Ensuring Data Quality

A Laboratory Management System

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Are data from all accredited laboratories of known and documented quality?

Are data from all accredited laboratories defensible?

No

“The EPA Office of Inspector General (EPA-OIG) has seen an increase in the number of allegations that environmental laboratories inappropriately manipulate laboratory data.”

An Open letter to the environmental analytical community from Nikki L. Tinsley ,
Inspector General , 9/5/01

“In recent years, what has come to our attention is that outside (non-governmental) labs are often times in bed with the people who hired them, and conspired to commit environmental crime”

David Uhlmann, Department of Justice Environmental Crimes
Section as reported by Larry Margasak in The Seattle Times, January
22, 2003

There were 12 laboratory fraud cases filed by the EPA-OIG office in 2000. In 2004 this number has almost quadrupled to 42.

Presentation by Michael Dagett, 8/23/04 NELAC Annual Meeting

Why has the number of laboratory fraud cases increased, even though state accreditation programs are in place and NELAC is active?

- Technology- An increase in technology has made it easier for laboratories to produce fraudulent reports.
- System audits- Laboratory audits are primarily quality system audits and little data is reviewed.
- Laboratory profits have fallen from 7% to under 1% since 1998. This has resulted in poor training and short cuts in laboratory procedures.
- Accreditation systems do not provide effective oversight.

Accreditation in the United States

- There is no single national environmental laboratory accreditation.
- The federal government only mandates that drinking water laboratories be accredited. This accreditation process is the responsibility of the states.
- Several states have accreditation systems for wastewater and solid waste. The requirements vary significantly state to state.

NELAP / NELAC

- The National Environmental Laboratory Accreditation Program implements standards set forth by the National Environmental Accreditation Conference.
- This association represents 12 accreditation authorities in 11 states. Reciprocity is maintained between these authorities.
- Approximately 1300 laboratories are accredited to the NELAC standard in 47 states. Laboratories are accredited based on the state where data are submitted, not the location of the laboratory.
- The NELAC standard is based on laboratories passing a biennial audit to ISO 17025 and semi-annual proficiency testing.
- It is the most comprehensive accreditation program available but still does not provide sufficient oversight to ensure quality laboratory data.

NELAC Shortfalls

- Organization

- It is a classic bureaucratic organization which prevents timely solutions to emerging problems. There generally is a minimum two year implementation cycle. This long implementation cycle leads to an organization not able to react to leading edge issues in the environmental community.

- Audits

- Audits are generally coordinated with laboratories, this allows laboratories to properly or improperly prepare. NELAC audits measure capabilities and do not define day to day competencies.

- Proficiency Testing

- The proficiency testing program should ensure that capability and competence is maintained over time. The current system does not accomplish this goal.

NELAC Proficiency Testing

The current program requires laboratories to perform PT testing on each analyte/matrix/method twice per year. In order to maintain accreditation a laboratory must pass two out of three of their most recent PTs.

This means that on a known performance sample a laboratory must only pass 66% of the time to remain accredited.

NELAC Proficiency Testing

The mathematical regressions to determine acceptable laboratory performance are too broad to be meaningful. Passing a PT does not ensure the laboratory is competent or that the data they produce are defensible.

Analyte	At the Given Concentration	
	Lowest Acceptable Recovery	Greatest Acceptable Recovery
Hg	75 %	124 %
Benzene	72 %	128 %
Toluene	72 %	126 %
Chlordane	51 %	149 %

NELAC'S IMPACT

- NELAC has leveled the playing field for environmental laboratories. It has created an industry that is concerned with obtaining accreditation and not improving the quality of data.
- Laboratories do not compete against each other on the basis of quality but only on the basis of price. Competitive pressures have not eliminated laboratories with poor quality.
- Corporate, engineering and consulting firms are at great risk of receiving data that is not defensible and of poor quality.

Consequences of “Bad” Data

- Retesting of all analytical work completed at the laboratory.
- Premature termination of remediation.
- Excessive cost of clean up to levels below action limits.
- Loss of your client’s confidence.
- Continued operation out of compliance.

An Effective Laboratory Management Program

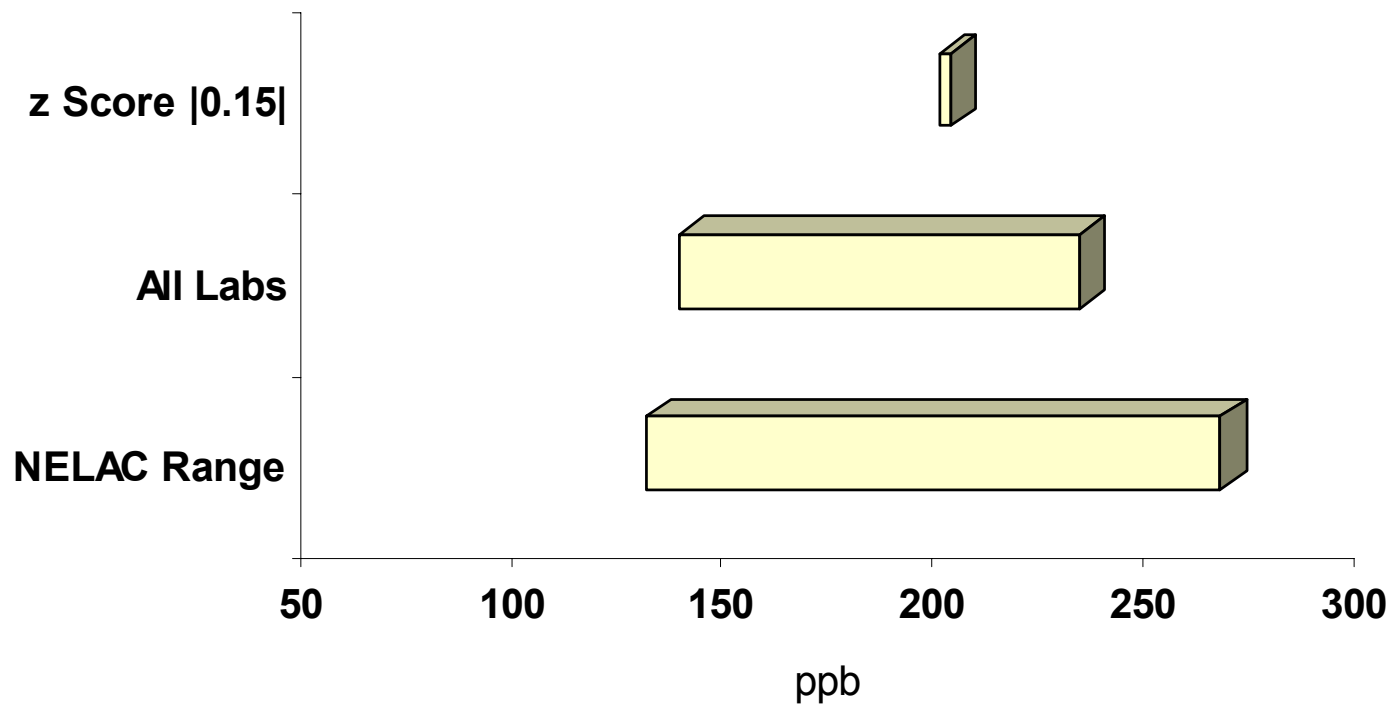
A laboratory management program is essential to any comprehensive environmental management system. The critical components of such a program are:

- Requiring NELAC accreditation of all laboratories. This establishes a baseline.
- Benchmarking laboratories using a routine single blind proficiency testing program based on z Scores.
- Challenging laboratories with frequent double blind testing.

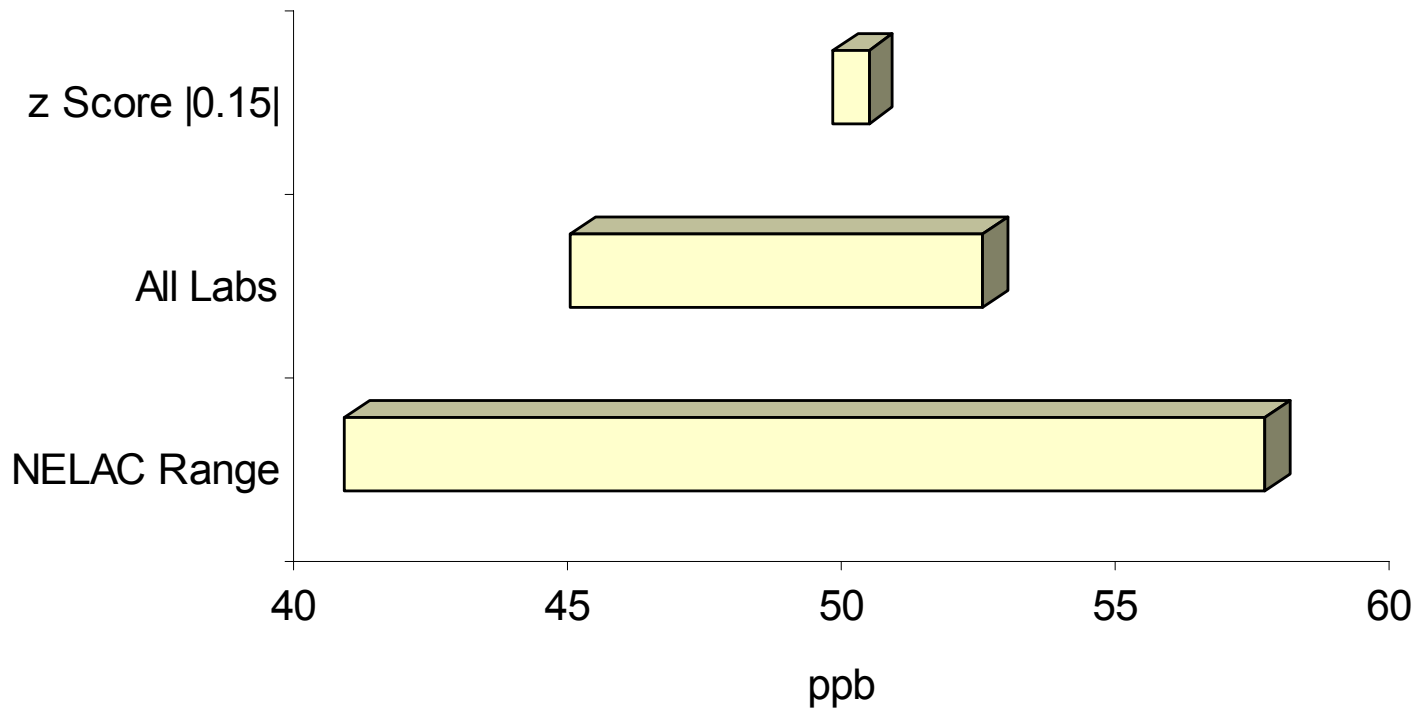
Single Blind Proficiency Testing

- Use a PT service that provides z Scores for performance. A z Score is a number derived from the interlaboratory mean and standard deviation of data which indicates data defensibility.
- The lower the absolute value of the z Score the more defensible the data.
- By evaluating z Scores over time you can determine both the quality and defensibility of your laboratory.

1,1,1 Trichloroethane 200 ppb Sample



Hex Chrome 50 ppb Sample



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A laboratory management program which incorporates accreditation, routine single blind testing and frequent double blind testing by a third party can help ensure you select a suitable laboratory and demonstrates your due diligence.

Thank You

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