

Hybrid Accreditation Standards: Wisconsin's Laboratory Accreditation

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Consult these links for official information:

<http://dnr.wi.gov/regulations/labcert/>

<http://www.mmsd.com/>

Program Profile

- * Chemistry and Whole Effluent Toxicity
- * SDWA, NPDES, RCRA, CERCLA
- * Commercial, Municipal, Public Health, Industrial
- * In and Out of State
- * Fee Supported
- * Registration for Non-Commercials
- * Certification for Commercials

Hybrid Program

- * Certification vs. registration
- * NELAP elements vs. state requirements
- * Drinking water vs. all other matrices
- * Attempt to merge the best of several systems
- * Follows already established tradition

NELAP Technical Advisory Committee (TAC)

- * In 1998 recommended becoming a NELAP AA
- * Two-tiered system:
 - * Commercials NELAP
 - * Others covered by State program
- * Needed a change in the Statute
- * Required legislative sponsorship

Green Bay Packers Rule



- * Had a strong sponsor in House of Representatives.
- * However, Senate leader focused on funding alternatives for GBP stadium renovation.
 - * Would not consider any rule changes until GBP stadium renovation satisfied party's concern.
- * Stadium renovation funding mechanism approved.
- * WI NELAP statute changed approved by House, not considered by Senate.
 - * Rule change died in session.

Aftermath

- * Agency got cold feet.
 - * Commercials objected to two-tiered system.
 - * Municipals did not want to be part of NELAP.
 - * Both groups essentially lobbied against a NELAP compromise.
- * No sponsor in next legislative session.
- * No substantial internal or external support to become a NELAP AA (AB).

Other Reasons for 1998 Outcome

- * Wisconsin's Program predated NELAP by more than a decade.
- * Lack of local control over the accreditation standard.
- * Perceived by some as a costly alternative that did not add significant value to what already was in place.
- * Suspicion from the not-for-profit sector that commercials would take over.
- * Commercials insistence on a single accreditation tier.

Regroup

- * Realization that NR 149 needed change.
 - * The Code had not undergone a major revision since it was created in 1986.
- * Formed NR 149 Rule Advisory Committee to:
 - * Use the NELAC Standards as the basis for NR 149 revision.
 - * Take what was best and sensible from the NELAC Standards.
 - * Retain some Wisconsin-specific provisions.

The Product

- * Extensive compromising and negotiation.
- * Process took approximately six years.
- * Revised NR 149 published in April 2008.
- * Revision became effective September 2008.
- * Process for revising the 2008 version has started.
 - * New rule process would take at least three years to complete.

NELAP Items that Made It

- * Tiers of Accreditation
 - * Technology – Matrix – Analyte
 - * Method – Matrix – Analyte
- * Quality Systems Approach
- * Majority of the provisions of the Quality Systems Standard

NELAP Items that Did NOT Make It

- * Two PTs per year
 - * NR 149 requires one PT in combination with either three quality control standards or a second source verification program.
- * Internal audits
- * Annual management system reviews
- * Personnel qualifications
- * Unannounced assessments
- * Five-years for records retention

Items Unique to NR 149

- * Extensive and “particular” calibration section for analytical instruments.
- * Exclusion of PTs for AA flame analysis and colorimetric procedures.
 - * Must analyze three quality control standards evenly spaced in a year.
- * Program does not accept solid PT sample results.

Observations

- * NELAP has raised the bar.
- * Systems approach has worked.
- * Documentation has improved dramatically.
- * Laboratories certified under NR 149 have been able to transition to NELAP relatively easily.

On the Other Hand...

- * Have lost all reciprocal agreements previously in place with non-NELAP states.
- * Easy for out-of-state laboratories to miss Wisconsin specific requirements.
- * Remain in partial isolation.
- * Have not lessened assessment load.

My Laboratory

- * Certified for chemistry by WDNR under NR 149.
- * Certified for microbiology by WDATCP under ATCP 77.
- * Accredited to 2009 TNI Standards by Florida.
- * Not that difficult to maintain certifications and accreditations.
 - * Similar to complying with special client requirements.
- * NELAP accreditation improves credibility of results.
 - * Needed or useful to market Milorganite®

Editorials

- * Have uniformity as a principal goal.
- * Shun preferences that buy you little and that are obstacles to uniformity.
- * If you must have a two-tiered program, make demarcation clear and provide incentives that favor joining NELAP.
- * Avoid incorporating provisions in statute.
- * Try to incorporate as much as possible by reference.

And...

- * Know that adopting a standard in whole has advantages:
 - * Do not have to argue over selection.
 - * Do not have to re-invent content.
 - * Gives reason to justify all requirements.

Contact



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