

The Benefits of PHIN for Laboratory Certification Programs

Susan Wyatt

Supervisor, Environmental Laboratory Certification Program
Minnesota Dept. of Health

Gary Jones

IS Manager
Minnesota Dept. of Health

Current LIM Issues for Laboratory Certification Programs

- ★ No common application used by PHLs for laboratory certification programs
- ★ Information exchange between PHL certification programs is difficult and non-uniform
- ★ Information received from PT vendors is difficult to use or upload to current application

LIMS Collaborative

- ★ PHLs, APHL, Public Health Informatics Institute
- ★ Identified work flow areas and business process requirements for PHLs
- ★ Includes requirements for laboratory certification/licensing programs

Identified Work Flow Areas for Laboratory Certification Programs

- ★ Proficiency Testing
- ★ Initial Licensing
- ★ Annual Licensing (renewals)
- ★ QA Specifications
- ★ System Output requirements

Proficiency Testing Requirements

- ★ Records of PTs supplied by the PHL and results reported by laboratories
- ★ Records of PTs supplied by other vendors/suppliers and results reported by laboratories
- ★ Records associated with out-of-state laboratories performing work within PHL jurisdiction

Initial Licensing/Certification Requirements

- ★ Ability to create a master file for new applicants
- ★ Ability to track capabilities of laboratories for testing requested
- ★ Schedule and check initial inspection visit and record findings
- ★ Ability to track initial inspection deficiencies, re-inspection scheduling, and re-inspection results
- ★ Issuance of license/certificate

Annual (Renewal) Licensing Requirements

- ★ Annual inspection schedule
- ★ Record of deficiencies
- ★ Re-inspection process and recording of deficiency resolution
- ★ Issuance of annual license
- ★ Master record of each laboratory's testing capabilities and qualifications

Quality Assurance Requirements

- ★ Ability to perform internal audits of quality system within certification program
- ★ Ability to track corrective actions taken or policies developed to prevent further deviations from occurring
- ★ Monitor turnaround time for application processing and inspections
- ★ Assess consistency in laboratory inspections
- ★ Ability to maintain historical records of laboratory participation and performance

System Output Requirements

- ★ Data sets for entry into regulatory reporting system (NELAP- National Database)
- ★ Production of variety of regulatory reports (CLIA, NELAC)
- ★ Reports of laboratory participation in PT studies
- ★ PT distribution schedule
- ★ Oversight inspection schedule
- ★ History reports by laboratory
- ★ Inspection and oversight reports for government agencies

Current Certification Application: Minnesota's Program

- ★ PT tracking indicating laboratory participation, analytical results, and corrective actions received
- ★ Initial and renewal information for each laboratory indicating current capability and historical record of certification
- ★ Date of last inspection and assigned certification officer

Current Certification Application: Minnesota's Needs Assessment

- ★ Include collection of inspection information
- ★ Track laboratory inspection deficiencies for historical record
- ★ Build data for consistent report language relating to identified deficiencies
- ★ Automate the inspection report-writing process
- ★ Generate QA reports to track laboratory compliance and program consistency
- ★ Receive data from PT vendors in consistent format and standardized coding to enable accurate and reliable electronic exchange

New Certification Application: Minnesota's Proposed Re-Design

- ★ Decision made to re-design, not patch
- ★ Incorporate Business Requirements from the LIMS Collaborative document
- ★ Incorporate PHIN Standards for data encryption/decryption and data exchange.
- ★ Incorporate NELAC and CLIA standards

New Certification Application: A Collaborative Opportunity

- ★ Consult with the LIMS Collaborative Team
- ★ Design with intentions of compatibility with the Collaborative Requirements
- ★ Partner with other states on design and development

For More Information

Susan Wyatt

Supervisor, Environmental Laboratory Certification Program

Minnesota Dept. of Health

susan.wyatt@health.state.mn.us

612-676-5674

Gary Jones

IS Manager

Minnesota Dept. of Health

gary.L.jones@health.state.mn.us

612-676-5242