

APHL Quality Manager Exchange

Host Laboratory: New Hampshire Public Health Laboratories

4/20/2023

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Quality Manager Exchange Top Three Takeaways

1. Clinical Test System Change Process

- Test Method Implementation Checklist Form
- Test Method Discontinuation Form

2. Qualtrax Compliance Software

- Documents & Workflows
- CLIA & ISO/IEC 17025 Quality Manual

3. New Employee Onboarding Process

- New Hampshire PHL New Employee Onboarding Form

Incorporating Learning at our Laboratory

- Louisiana will be creating a Qualtrax workflow for clinical test system changes that incorporates the details shared by New Hampshire.
- Louisiana will implement an improvement of the new employee onboarding processes in the future.

THANK YOU

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The Big Aha Moments in Little Rock

Michael Carpinona

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Pictured left to right: Gene Davis (AR), Ryan Berry (AR), Rachael Yeskey (AZ), Michael Carpinona (NJ)



Bridging the Gap

1. Excellent QA and testing staff relationships!
 - QA staff at Arkansas have built a great relationship with testing staff and the laboratory director
 - Routinely rotating through units for bite size internal audits and meeting with directors

How can New Jersey incorporate this?

- Implement system to spend more time observing data and testing while ensuring familiarity with staff
- Identify monthly check in items for QA to focus on
- Continue extensive internal audits in off inspection years
- Keep building ties in the QA community as well



Dirty Hands

2. Arkansas QA is actively involved in PT tracking and training/competency tracking!

 - QA developed a PT logging and tracking electronic system with their LIMS team and maintain personnel training and competency records for all testing staff

How can New Jersey incorporate this?

- Incorporate PT tracking from receipt of the specimen/sample rather than current result review tracking
- Find a competency tracking software that enables completion to be tracked by QA and units
- Be more routinely present as mentioned in prior aha moment



Feeling Validated



3. Arkansas QA worked with their LIMS team to create validation checklists for LIMS changes!

- Includes aspects of functionality, requests, interfacing, and reporting to ensure all aspects of the system have been validated
- Outlines steps for LIMS validation, and includes creation of performance reports where required

How can New Jersey incorporate this?

- Develop similar checklist for QA to use during LIMS validation reviews to uncross mental wires
- Continue to build upon process revamping efforts recently taken to improve LIMS validation consistency and completeness



WY-SD Quality Manager Exchange

Marie Gosselin

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April 20, 2023



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Walk Throughs

- Expiration dates
- Completion of forms

Weekly Huddles

- Regular Check-Ins
- Two way communication
- Issue Spotting

AH-HA!

Words Matter

- Bacteriology plate reading
- Day 1 or 24 Hours



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Walk Throughs

- More management lab visibility
- Creative problem-solving for issues like storage

Huddles!

- Divided weekly meetings by job duties
- Meeting times are shortened

SOP Review

- Add in flexibility where appropriate
- Scientific expertise



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APHL Quality Manager Exchange Program: Dallas County PHL and NH PHL Visit MN PHL

Bonita Bryant (MN PHL), David Silva (Dallas County PHL), Michael Stevenson (NH PHL)
March 14-15, 2023

Participants:

Bonita Bryant, MT (ASCP)

Quality Improvement Specialist, Principal | Infectious Disease Laboratory Section
SharePoint Site Owner | Public Health Laboratory Division
Quality Council Chair | Minnesota Department of Health Agency
St. Paul, MN

David Alejandro Silva, M.S.

Quality Manager, Public Health Laboratory
Dallas County Health and Human Services
Dallas, TX

Michael J Stevenson, PhD

Microbiologist V | Deputy Lab Director
NH Public Health Laboratories
Concord, NH



MN Agriculture and Health Laboratory, St. Paul, MN

Agenda Day 1: March 14, 2023

8:30 – 10:00

Arrive at MN PHL. Introductions. Safety Overview. MN PHL overview presentation. Site tour.

10:00 – 12:00

- Quality Management System (QMS) Overview
 - Roles and responsibilities of Quality Management (QM) staff
 - CLIA certificate of conformance requirements and responsibilities of QM staff
 - Training and competency assessment process
 - Validation and Verification process
 - Proficiency Testing (PT) and intra/intra laboratory challenges overview
 - Corrective and Preventative Action (CAPA) process
 - IQCP
 - QA reviews (monthly report, tracking/trending of quality matters)

1:00 – 5:00

- Safety and Quality united
 - Infectious Disease Laboratory Safety Task Force (STF) initiatives
 - Risk Assessments
- Audit program
- Laboratory Information System
- Document Control

Agenda Day 2: March 15, 2023

8:30 – 12:00

- MDH and PHL Quality Meeting Overview
- Quality Assurance Manual Initiatives
- Lessons learned from last MN PHL CLIA Inspection (September 2022)
- Open Discussion



Feedback:

- A great experience for David and Michael to visit MN PHL and Bonita!
- Excellent value having three PHL quality managers in a room together to compare notes and experiences.
- Suggest a 2 day event instead of 1.5 days to allow three different PHL experiences to be shared.

THANK YOU – Bertina Su and APHL, and to Bonita Bryant!



A happy Quality Manager is
a happy public health lab!!