Quality Management Structure
In a Large Multi-Purpose Laboratory:

What Model Works Best?

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Objectives

1. Keep our new director out of jail

2. Provide an overview of the Wisconsin State Laboratory of Hygiene (WSLH)

3. Review the strategies used to ensure quality management in our large public health laboratory

4. Compare and contrast strategies and provide a vision for the future

Speaker disclosures: None.
WSLH Overview

- Located in Madison, WI
- Affiliated with the University of Wisconsin-Madison since 1903
- Attached to the School of Medicine and Public Health
- Mission of Service, Education, Research, and Outreach
- About 300 employees
Organizational Layout

- **Testing Divisions**
  - Communicable Disease
  - Disease Prevention
    - Newborn Screening
    - Cytology
    - Cytogenetics
    - Biochemical Genetics
  - Environmental Health
  - Occupational Health
  - Laboratory Improvement
    - Proficiency Testing Service

- **Administrative Offices**
  - Administration
    - Facilities Management
    - Quality Management
    - Medical Director (CLIA)
    - Public Affairs
  - Finance
    - Billing
    - Purchasing
    - Accounting
  - Information Systems
  - Human Resources
Revenue Streams

45% Lab Fees and Grants
5% State Driver Surcharge
25% State GPR
25% State/Federal Contracts

100%
## Services and Certifications/Accreditations

### Medical
- Chemistry, Toxicology, Microbiology, Immunology, Histopathology, Cytology, Cytogenetics
  - CAP (CLIA)
- Select Agents
  - CDC and UW
- Proficiency Testing
  - CMS

### Environmental
- SDWA
  - EPA, NELAC (ISO17025)
  - WI Dept. of Agriculture
  - WI Dept. of Natural Resources
  - MT Dept. of Health (radiochem)
- Non-potable water, solids
  - NELAC, WI DNR
- Air (EPA NATTS)
- Radon (NRPP-AARST)
- Cryptosporidium PT (ANAB-ISO17043)
- Occupational (AIHA-ISO17025)

### Forensic
- Urine, Blood Alcohol, Drugs
  - ABFT
Quality Management Coordination Duties

1. Preparation and response for accredits inspections
2. Occurrence management
3. Document control for SOPs and QA manuals
4. QA metrics and QSE management reports
5. LIMS administration
6. Training and competency documentation
7. Quality improvement projects (Lean/Six Sigma)
8. HIPAA and CMS compliance
9. Human subjects compliance

- Equipment
- Purchasing, inventory
- Customer service
- Facilities and safety
QMS Models: Past

1. Quality Management Teams
   - Decentralized QA staff
   - Delegated authority
   - No one person in charge

2. Office of Quality Assurance
   - Medical and environmental co-directors
   - Coordinating council and subcommittees
   - Centralized environmental QA staff (dedicated staff)
   - Decentralized medical QA staff (managers/lead workers)
   - Authority not delegated
   - Duties not clearly defined
QMS Model: Future

3. Quality Assurance Cross-Cutting Team
   - One delegated overall QM Officer
     - Team Chair in Director’s Office
     - Business analysis coordinator
     - LIMS administration coordinator
   - One delegated medical QA Coordinator
     - Shared between medical divisions for CAP/CLIA
   - Delegated environmental QA Coordinators
     - Shared between relevant accreditations
     - Centralized and shared unit
   - One Training Coordinator
     - Director’s Office
     - Internal staff training
Questions/Discussion

1. Is the hybrid model of one overall coordinator with a team of QA staff from all diagnostic areas the best model?

2. Is the model of dedicated environmental QA staff feasible for the medical side?

3. If so, should these dedicated QA staff be centralized or decentralized?