



SIGNS OF A WELL MANAGED LABORATORY, AN ASSESSOR'S VIEWPOINT

*Mitzi Miller, Miller Quality Consulting (MQC)
Charles Newton, NV5/Dade Moeller*

Miller Quality
Consulting &
(MQC)

NV5
DADE MOELLER

OVERVIEW

- Role of the Assessor
- Laboratory Cultures
- Red flags for Assessors
- Opportunities for Improvement
- Lessons Learned

ROLE OF THE ASSESSOR

- Role: Independent and impartial review of the laboratory's activities for compliance with the standard requirements.
- Qualifications: Relevant laboratory experience with an understanding of methods, quality systems, regulations and accreditation criteria. Documented competence with assessment techniques and applicable Quality System Standards (TNI, ISO 17025, QSM, etc.) and approved by the accrediting body to conduct assessment activities.

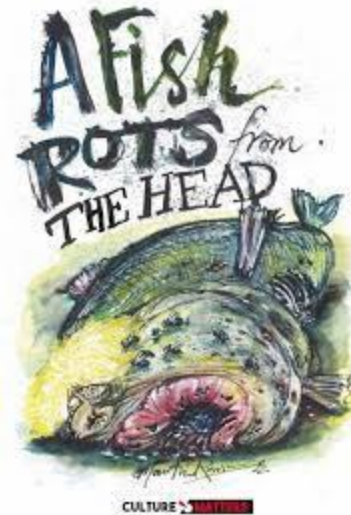
Assessor opinions are not findings and should be critically reviewed by the laboratory. Only when a lack of compliance with a standard requirement is documented does it become a finding.

LABORATORY CULTURES

- Black Box vs Open Communications
- Active engagement by the leadership
- Production vs Quality Driven
- Innovative vs Status quo
- Should vs Shall

THE FISH ROTS FROM THE HEAD

- Management sets the tone for the laboratory staff. If something is important (QUALITY) to the management, it will be important to the staff.
- Visible leadership in the facility
- Provides consistent messaging to the staff of the importance of quality
- Understands what the staff are doing and the requirements for the test being conducted.
- Actively seeks input from the staff



MANAGEMENT PITFALLS

- Lack of delegation and authorizing the staff to make decisions
- Punitive actions when employees point out problems
- Insufficient staff to accomplish the scope
- Covering up or ignoring client complaints
- Make the numbers (profit) no matter the quality

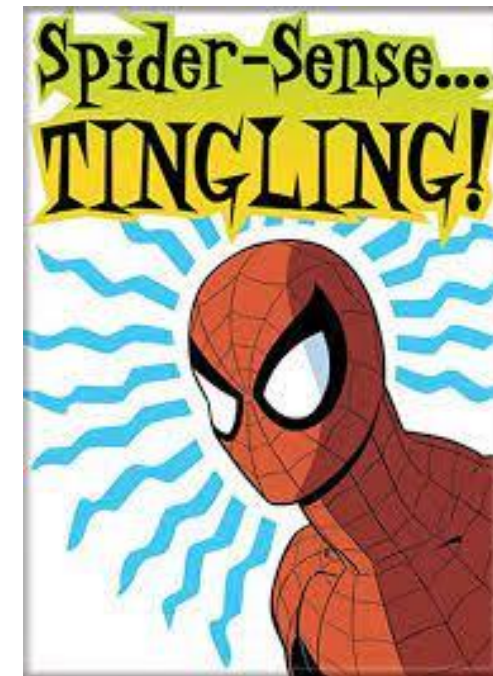
THE FUTURE IS NOW!

- Laboratories with high employee attrition are susceptible to quality issues. “You only know what you know.”
- Recruiting and retaining skilled analysts is critical. Make it a career, not just a job!
- Motivating, stimulating and retaining staff can be difficult. Understand the staff motivations: salary, flexible schedules, achievement, recognition, feeling good about the job.



MY SPIDER SENSES ARE TINGLING

- Facility maintenance
- Staff turn-over and analyst experience level...some labs report >25% staff attrition
- Currency of Quality System documents...reviewed just prior to an assessment.
- Equipment Maintenance



MY SPIDER SENSES ARE TINGLING (CONT)

- Engagement of Management and Quality Management in Day-to-day Operations
- Lack of root cause investigations and follow-up on corrective actions
- Are records organized, easy to follow, and readily available?
- “Say what you do and DO what you say!”

OPPORTUNITIES FOR IMPROVEMENT

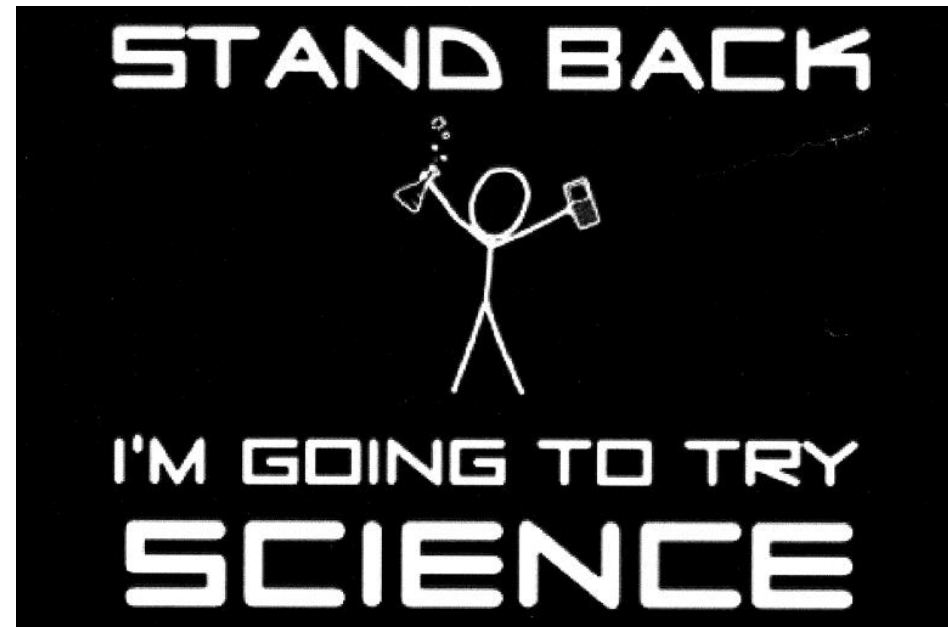
- Strategic staff plans
- Re-invest in people and instrumentation
- Regular and clear communications to staff of quality expectation
- Employee retention



- IT solutions for compiling and tracking quality data...and use that data!
- Laboratory Automation
- Budget for quality...price should not be the only motivation.
- Internal audits with a technical component, not just quality system requirements

ARE WE STILL SCIENTISTS?

- Stay current on technology and new regulatory requirements
- Validate all new software and automated processes
- Map the analytical process to identify opportunity for improvement
- Evaluate method performance data to spot trends and potential issues
- Question why we do what we do!
“Because I said so” is never an acceptable response.



- Quality starts with the leadership...aka Quality MANAGEMENT System!
- Stay current – regulations, technology and people!
- We're scientists, not number generators!
- Budget for quality!

QUESTIONS??

Miller Quality
Consulting &
(MQC)

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DADE MOELLER



THANK YOU

Miller Quality
Consulting &
(MQC)

NV5
DADE MOELLER

Charles Newton, NV5/Dade Moeller
251.243.3631, Charles.Newton@nv5.com

Mitzi Miller, MQC
509.531.0255, Mitzi.MQC@gmail.com