

# **A NELAP Accreditation Body's First-Year Experience Using Contract Assessors**

## ***Lessons Learned in Florida***



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**Environmental Measurement  
Symposium/NEMC  
August 4, 2014**

# No-Cost Contracts



- Providers qualified by the State
- Certified laboratories select providers based on self-identified criteria
  - Price
  - Scope
  - Availability
  - Etc...
- Labs pay providers directly

# Provider Responsibilities



- Lab assessments according to the Rules and adopted NELAC standards with corresponding review of the TNI standards
- Comprehensive assessments
  - Quality/Management Systems
  - FOA specifics
- Qualified assessors
- Ethical conduct
  - Ensure no Conflict of Interest exists
- Reporting
- Corrective Action review

# DOH Responsibilities



- Select qualified and competent providers
- Oversight
  - “Evaluation” assessments
  - Ongoing review of assessor qualifications
  - Review of assessment reports
  - Surveillance assessments
- Enforcement
  - Follow-up assessments
  - Extraordinary assessments
- PT tracking, review and enforcement
- Consultation and assistance
- All certification decisions



# Laboratory Responsibilities



- Obtain compliant assessment within 6 months of due date
- Pay provider fees and expenses
- Think “PTs”

# **Florida Contract Assessment Providers**



- Analytical Excellence, Inc.
- ANSI-ASQ National Accreditation Board (ACLASS)
- Dade Moeller & Associates
- Laboratory Accreditation Bureau (L-A-B) a division of A-S-B
- Shepherd Technical Services
- Wade Consulting and Solutions

# How About Some Stats?



- Certified labs (primary): 334
- Contract assessments conducted so far: 117
- Assessments scheduled: 17 (as of July 18)
- Backlog remaining: Cleared by month's end!

# The Sky Is Not Falling



- Provider fees are reasonable(?) and might be decreasing
- The assessors are not bad guys (they are not making things up)
- Assessors are able to provide guidance and assistance (short of consultancy)
- The quality is there!



# Has the Assessment Process Changed?



- “The DOH assessors never did it this way.”
- “The last assessor didn’t cite that.”
- They have to be blunt, but not horrible.
- Less method, more systems?
- Root Cause Analysis (RCA)
  - We never pressed it
  - It was always needed
  - There is RCA in labs’ future

# What Should Not Have Changed



- Opening conference
- Assessment
  - Interviews
  - Document review
  - Prior deficiencies check
  - Witnessing as needed
- Closing conference
- Report within 30 days
- Corrective Action (CA) review within 30 days (contracts actually only allow 20)

# **Report and Corrective Action Review**



- Assessors recommend, but do not decide
- We audit, we do not edit
- Still thinking about the “After-the-Fact” approach

# Almost Like Starting Over



- Communication
- Education
- Revelation

# A Fundamental Concept



- What needs to be covered during a biennial “full” on-site assessment?
- “The Provider shall conduct comprehensive on-site laboratory assessments to determine compliance with the applicable provisions of Florida Administrative Code Chapter 64E-1 and the 2003 NELAC standards adopted by reference therein. The assessments shall encompass all Fields of Accreditation for which the laboratory seeks initial or recertification.”
- Fields of Accreditation (FOAs) are defined as Matrix-Method-Analyte combinations. This means each and every FOA must be reviewed.



# Things That Have Come Up



- Assessment reports recommending or reporting a change in a lab's current certification need to explicitly list the FOAs
- Documentation regarding a lab's corrective action plans needs to include the date (or dates if there are revised plans required from the lab) of receipt
- We need to know when a lab pays the bill

# Things That Have Come Up



- We need a notice directly from labs for relinquishments (i.e., drops)
- We need to know when a lab does not submit CAs within 30 days
- Labs do need to perform and document corrective action for failed proficiency tests

# Things That Have Come Up



- Applications from labs with assessments scheduled
- Assessments scheduled for labs with applications

# Some More Things That Have Come Up



- Method blanks and duplicates not required for qualitative (P/A) chromofluorogenic microbiology tests
- Linear Calibration Range checks not needed for allowed non-linear calibrations (SOP needs to include this “modification”)
- Documentation of thermometer correction factors
- Definition of “reagent”

# And Some More Things That Have Come Up



- Verifications for EPA 1600 (Enterococci)
- Luminescent Dissolved Oxygen sensors for BOD/CBOD
- Quality Manual review (periodic, not annual)
- Procedures (documented or not?)
- Certification ID on reports
- Certified labs lookup: <http://appprod.dep.state.fl.us/labs/cgi-bin/aams/index.asp>



# Friendly Advice for Laboratories



- Get quotes from all providers
- Band together if possible (save on travel)
- Use the tools we provide
- Do not wait until the last minute
  - Assessment scheduling
  - Scope changes
- Don't be afraid to “push back”
- Use us as a resource
- (But first use the provider's assessors)

# **The Jury is Still Out**



- Contract specifications
- Capacity
- Oversight
- Compliance

# Is Contracting Working?



*The laboratories and the  
assessment providers are  
making it work!*

# Thank You!

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