

The Iliad – Quarrel between Achilles & Agamemnon

Book I – Most Recent Audit
Findings

Achilles

- King of the Myrmidons
- Great Greek Warrior in the Trojan War
- Handsome
- Invincible except for one fatal flaw
 - “Achilles’ Heel”
- Died in battle by arrow struck in you-know-where

Agamemnon

- King of Mycenae (or Argos?)
- Leader of the Greeks in the Trojan War
- Was willing to sacrifice his daughter Iphigenia to sail for Troy & start the war
- Was heroic but was overwhelmingly haughty in demeanor
- Was killed by his wife or her lover

The Quarrel

- Achilles angry at Agamemnon's arrogance
- Agamemnon took attractive slave Briseis from Achilles
- Achilles withdraws his forces from the Trojan campaign
- This quarrel overshadowed by quarrels among Zeus and the gods

NELAC

- The battle between emotion and reason
- The battle between specificity and flexibility

So What Are the FL-DOH Assessors Observing at Laboratories?

- Findings (Deficiencies) Cited Since March 1, 2009
- In this talk, only the findings observed on at least 15 occurrences (laboratories) are reported

Samples are not checked for adequate chemical preservation

- NELAC 5.5.8.3.1(a)(2)
- pH < 2 in Metals, TOC, Nutrients, O&G, Rad-Chem. Samples
- Absence of Cl₂ in Microbiology, BOD/CBOD, Organics samples
 - Field chlorine measurements required for the “Microbiology exemption” to be applicable
- 15 occurrences, 2 REPEATS

Support Equipment not Checked with NIST-Traceable References on Each Day of Use

- NELAC 5.5.5.2.1(d)
- Thermometers in incubators & waterbaths on weekends when samples are tested
- Balances
 - Don't forget the pan balances for weighing soil samples & Microbiology media
 - NELAC supersedes any DW cert. manual recommendations for monthly calibrations
- 15 occurrences, 1 REPEAT

Sample Matrix Spikes aren't performed as required by the test method

- App. D.1.1.3.1(b) to Chapter 5
- LCS/LCSD's don't substitute for MS/MSD's if insufficient sample supplied
 - LCS/LCSD's don't assess sample matrix effects
- To meet NELAC Standards, data qualifiers must appear several places:
 - Review of requests, tenders, contracts (records that clients do not need MS/MSD's or test method compliance)
 - Sample receipt records note violation of NELAC sample acceptance policy since insufficient sample volume provided
 - Departure from test method requirements noted on sample preparation & analysis records
 - Test report notes departures from method requirements for the results reported (applies to ALL samples from the relevant prep. batch)
 - Authorized lab. representative permits & takes responsibility for departure from documented policies & procedures
- 15 occurrences, 3 REPEATS

Test Method SOP's Scope & Application section does not list ALL components to be analyzed

- NELAC 5.5.4.1.2(b)(4)
- If applying for additional analytes to an already-accredited test method, the SOP must be updated to include the new analytes
- Don't forget Data Assessment & Acceptance Criteria, Method Performance, Validation Data, etc. for the new analytes
- 16 occurrences, 3 REPEATS

Lab. does not have SOPs that reflect all phases of current activities & all test methods

- NELAC 5.5.4.1.1 & 5.5.4.1.2(b)
- 16 occurrences, 2 REPEATS
- What else can I say?

Microbiology Incubators & Waterbaths

- App. D.3.8(b)(6)(i) to Chapter 5
- Not evaluated for uniformity of temperature distribution and time to achieve thermal equilibrium conditions after test sample additions
- 16 occurrences, 4 REPEATS

Microbiology Reagent Water

- App. D.3.6(c) to Chapter 5
- Problems observed cover ALL of the required water quality parameters
- Problems cover frequency of monitoring & achieving acceptance criteria
- Commercially purchased DI water & dilution rinse water subject to water quality requirements
- 17 occurrences, 3 REPEATS

Purchased Ready-to-Use Media

- App. D.3.6(d) to Chapter 5
- pH of lot not measured & documented
- Manufacturer's certificates are not adequate (see NELAC 5.4.6.2)
- 17 occurrences, 4 REPEATS

Limits of Detection & Limits of Quantitation

- App. D.1.2.1(c) & D.1.2.1(d) to Chapter 5
- Must have established procedures to relate LOD's with LOQ's
- The LOD determination is NOT ENOUGH, must VERIFY the LOD
 - Required for each quality system matrix, method, and analyte
 - Florida regulations may require LOD determination even if NELAC doesn't
 - A quality system matrix is not the same as a field of accreditation matrix
- 20 occurrences, 4 REPEATS

Method Numbers not documented on analytical data

- NELAC 5.4.12.2.5.2(b)
- If the calibration or analysis data is applicable to more than one method, then all applicable methods must be documented
- If methods added per the MUR and the original method kept, both methods need to be documented
- 19 occurrences, 3 REPEATS

- Are any patterns becoming apparent yet?

The Forgotten Art of Conducting Internal Audits

- NELAC 5.4.1.5(i)(6) & 5.4.13.1
 - Internal audits inadequately performed or not at all
 - Not all technical operations, quality system activities, & environmental testing of the laboratory covered
 - 22 occurrences, 5 REPEATS
- NELAC 5.4.14.2
 - No follow-ups by lab. mgmt. to ensure that corrective actions are implemented
 - 18 occurrences, 1 REPEAT

Laboratory personnel are not being trained

- No certifications that personnel are using the latest version of the Quality Manual & other applicable SOP's (NELAC 5.5.2.6(c)(1))
- No certifications that personnel agree to follow the latest versions of the test methods (NELAC 5.5.2.6(c)(3))
- No annual refresher data integrity training (NELAC 5.5.2.7)
- 40 occurrences, 13 REPEATS

Records not clear & do not document critical information

- Cannot reconstruct sample history that produced the resultant test data (NELAC 5.4.12.1.5)
- Information not documented on analytical test methods & related laboratory activities (NELAC 5.4.12.1.5(b))
- Information available cannot historically reconstruct the data (NELAC 5.4.12.2.4(b))
- Laboratory does not document all analytical & operational activities (NELAC 5.5.2.6(d))
- 45 occurrences, 6 REPEATS

Traceability Lost

- Equipment used in a test is incorrectly identified or not identified in records
 - NELAC 5.4.12.2.5.3(c)
 - 33 occurrences, 7 REPEATS
- Standards & reagents not identified, incorrectly identified, or not traceable to standard materials
 - NELAC 5.4.12.2.5.3(i)
 - 30 occurrences, 4 REPEATS

Labs. not following the methods they are accredited for

- Not following calibration requirements stipulated in the test method (NELAC 5.5.5.2.2)
- Not following quality control or procedural requirements stipulated in the test method (NELAC 5.1.1)
- Not following its own requirements documented in the SOP's (NELAC 5.5.9.2(d))
- 65 occurrences, 6 REPEATS

The Saga Continues....

- After The Iliad ends, The Odyssey begins
- NELAC becomes self-sufficient
 - The NELAC Institute (TNI)
- FL Dept. of Health Rule Development Workshops to adopt the TNI Standards
 - Mon. Nov. 2 Tallahassee
 - Tues. Nov. 3 Clearwater
 - Thurs. Nov. 5 Lantana
 - Fri. Nov. 6 Jacksonville