



What's New at ORELAP and TNI?

By
Gary K. Ward

OELA Annual Environmental Laboratory Workshop

May 21, 2015

Gary Ward

- **ORELAP Administrator - June 1, 2011**
- **Background**
 - **BS Chemistry, Loyola ; MS & PhD studies – University of Miami, Chemical Oceanography**
 - **NOAA, Washington DC – Lab Director**
 - **EPA, Washington DC – Superfund Contract Lab Program – CLP Program Manager, SW-846 Task Group**
 - **Enseco/Quanterra/STL/TestAmerica, Denver – Corporate Director – QA, Technology (R&D), EH&S**

Gary Ward

- **Background**

- **Eurofins Lab/ UL /EHL South Bend, IN**
 - **Lab Director**
- **Intertek Testing Service, London – Director, Laboratories, World-Wide (257 labs)**
- **ALS Environmental-Kelso (Columbia Analytical Services, Kelso) Washington – Vice-President – QA, EH&S, IT, Business Development, Marketing, Ethics Officer**
- **Retired 2008 – Heart Attack**
- **Unretired - ORELAP Administrator - 2011**

Experience Highlights

- **Over 135 Publications/Presentations**
- **Wrote a number of EPA methods (CLP, SW 846) ie., 6020, 1613, 8290**
- **Wrote National Guidelines for Data Review – for both Organics & Inorganics**
- **EPA Drinking Water Certification Officer – Microbiology, Radiochemistry, Organic Chemistry, Inorganic Chemistry, Cryptosporidium/Giardia**
- **Also Air Analyses; WET (Whole Effluent Toxicity – Bioassay)**

ORELAP News

Shannon Swantek

- **Hired full time in OSPHL for ORELAP**
- **EPA Drinking Water Certification Officer – Microbiology, Organic Chemistry, Inorganic Chemistry**
- **Also Air Analyses assessment**
- **Heading up Cannabis Labs accreditation**

Shannon Swantek

- **Background**

- **BS in Chemistry from St. Joseph's University**
- **Post-Doc Research Assistant focused on Environmental Remediation**
- **Background in both Private Industry and Government laboratories, including Drinking Water**
- **Lead Analyst in Development of ICP-MS methods in nutraceutical field**
- **Experience in Organic, Inorganic and Microbiology analyses**

Shannon Swantek

- Sample Coordinator for >5 years at DEQ**
 - Lead project review on over 1600 events/year**
 - Spearheaded Training and Outreach efforts with small municipalities and DEQ permit writers**
 - Participated in multiple process improvement forums in the permit process, DEQ Kaizen, and PHL LEAN**
- Certified TNI Assessor (2003 and 2009 Standards) for Quality Systems**
- Lead ORELAP Assessor**
- ISO Trained Assessor**

ORELAP Organization

- **Oregon Environmental Laboratory Accreditation Program (ORELAP)**
- **ORELAP is in OSPHL (Oregon State Public Health Laboratory)**
- **Lab Compliance Section**
- **Section Chief is Stephanie Ringsage (replaced Rita Youell who retired)**
- **Assessors (except Shannon & Gary) are from DEQ (Department of Environmental Quality)**

What's New at ORELAP

- **Program, Policy, and Procedure Manual (QAM) – revised, on-line**
 - **Part I – Program description**
 - **Part II – Quality Manual**
 - **Part III – SOPs**
- **2009 TNI Standard – August 1, 2011**
- **Cannabis Laboratory Accreditation**

What's New at ORELAP

- **All electronic files**
- **Electronic Accreditation Certificates & Scopes**
- **Electronic invoicing**
- **Unannounced assessments**
- **Assessment philosophy**
- **Cryptosporidium/Giardia accreditation**

Assessment Philosophy

- **Assessment Purpose :**
 - Help labs improve analyses using our experience, point out areas for improvement
 - Allow me to stand behind lab data
- **Goal: “0” findings**

NELAP vs NELAC

- **NELAP – National Environmental Laboratory Program**
- **Oregon’s ORELAP is part of NELAP**
- **NELAC was the National Environmental Laboratory Accreditation Committee**
- **NELAC was dissolved in 2006 and NELAP/TNI replaced it**
- **Confusing since TNI is “The NELAC Institute”**

NELAP vs NELAC

- **All ORELAP labs are accredited in/through NELAP**
- **Please make sure all websites, documents, etc are using NELAP, not NELAC**

OVERSIGHT of ORELAP

- **EPA Region 10 Drinking Water program triennial audit – May 2012**

- One finding:

Verify positive hits are reported to DW office within 24 hrs

OVERSIGHT of ORELAP

- **EPA Region 10 Drinking Water program audit – comments:**

“Oregon has in place an effective Certification Drinking Water Program that is being conducted by a dedicated team of scientists.”

OVERSIGHT of ORELAP

- **NELAP AB (Accrediting Body) triennial assessment**
 - results - minor documentation findings
 - comments:
 - **Assessors demonstrated excellent knowledge of their fields and established a friendly and comfortable rapport with the staff being interviewed.**
 - **The assessment was thorough and covered all methods. The team used ORELAP checklists as a support tool for their interview questions.**
 - **The assessment was well-organized and minimized the time required of laboratory staff.**

Past Program Issues

- **Assessment Timeliness**
- **Assessment Invoicing**
- **Initial Report Turnaround**
- **CAP Review Response Time**
- **Late Accreditations**
- **Assessment Inconsistency**

Assessment Timeliness

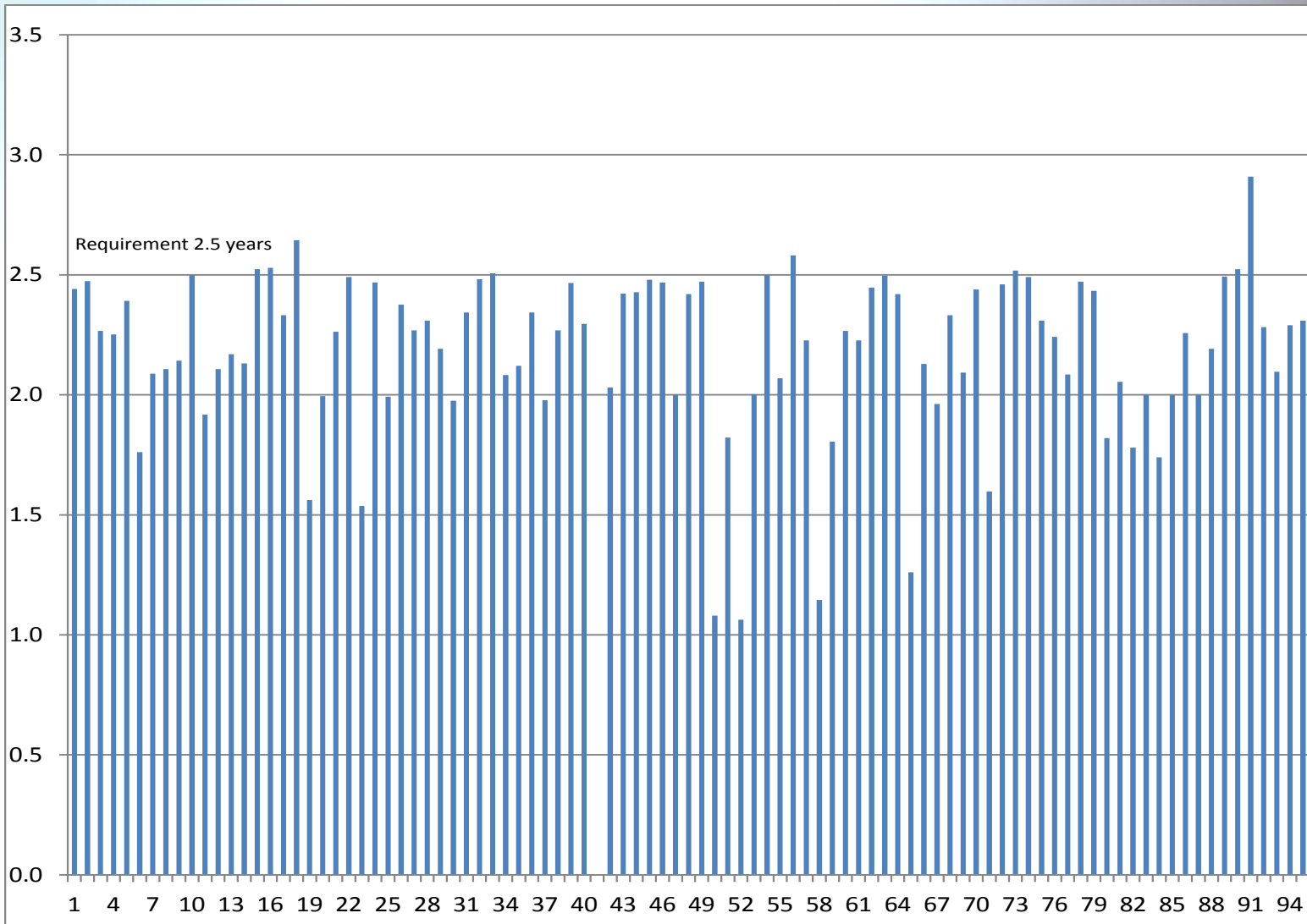
May 2011

- **Labs with past due assessments (greater than 2.5 years) = 12**
- **Labs with past due assessment greater than 3 years = 4**

May 2015

- **All assessments scheduled within 2.5 years or less**

Assessment Timeliness- Years Between Assessments



Invoicing - Assessments

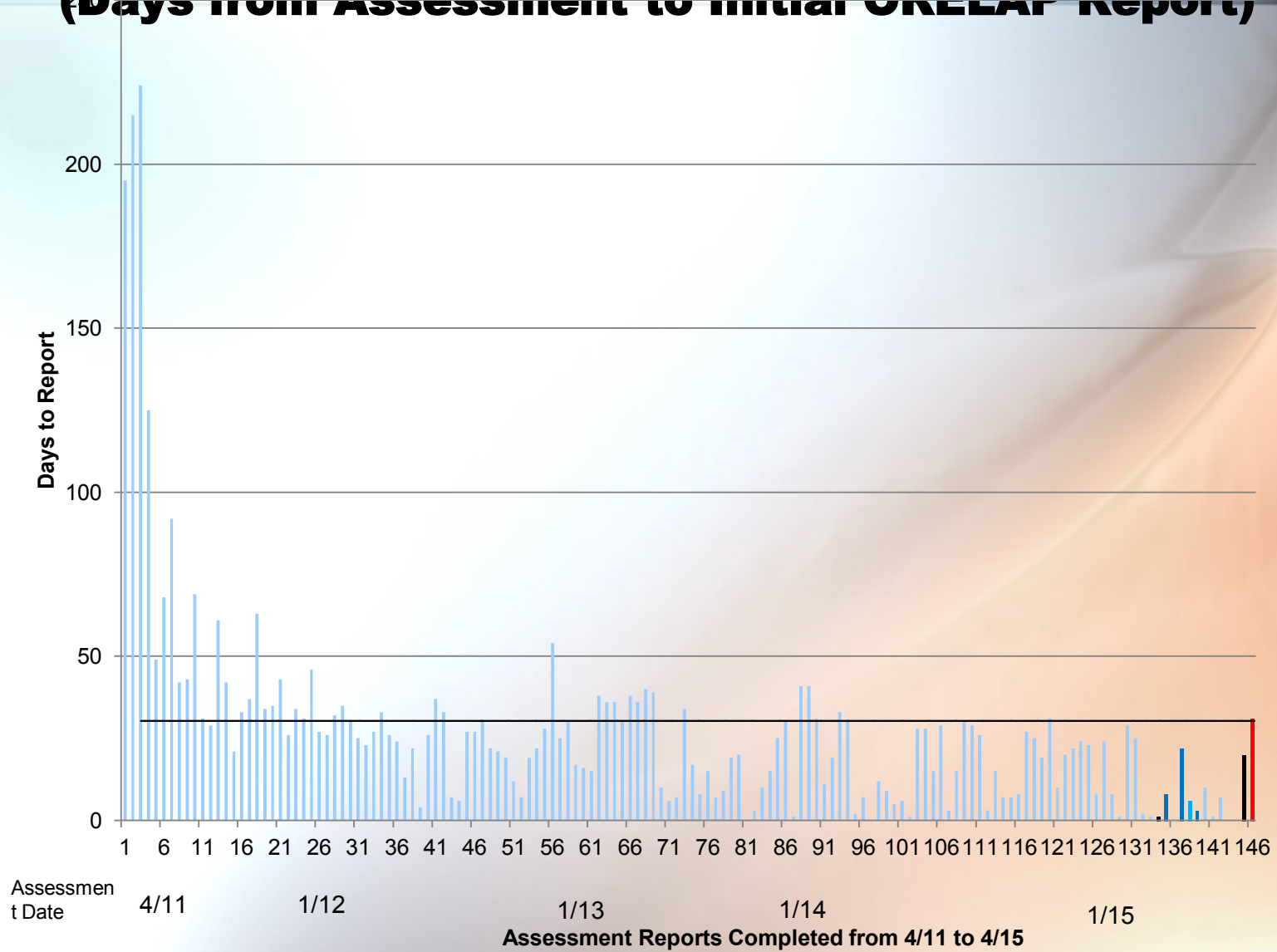
Past

- **Late invoices - paper**
- **Fee vs assessment not tracked**

Current

- **Invoices on time – 2 mos before expiration**
- **Electronic–tracked to assessment**

Report Turnaround Time Improvement (Days from Assessment to Initial ORELAP Report)



ORELAP CAP Review

- **Goal – 30 days**
- **Shannon has set up tracking system**
- **Implemented in March 2015**

ORELAP Late Accreditations

- **June 2011 – 17 labs with expired certificates**
- **June 2015 – all labs certs expiring in June were accredited by May 9**
- **Email out electronic pdfs of: Accreditation Certificate & Scope of Accreditation (FOAs)**
- **Mail out hard copies with Accreditation Letter**

ORELAP Late Accreditations

- **Process:**
 - **Application - four months before expiration**
 - **Invoice - two months before expiration**
 - **Review performance (PTs), documents, correct application**
 - **Complete certificate and scope documents - one month before expiration – email & hardcopy**

Assessment Inconsistency

- **Microbiology**
 - **standardized over the last 2 years**
- **Chemistry**
 - **Standard checklists**
 - **each Method & Version**
 - **Document "grey areas" with ORELAP interpretations**

ORELAP Program at a Glance

- **Number of labs in the program**
2012 - 103 labs
2015 - 133 labs
- **Labs In Oregon**
2012 - 40 labs
2015 - 40 labs
- **Labs in CA – 25 labs**

ORELAP Program at a Glance

- **Oregon Primary**
2012 - 71 labs
2015 - 101 labs (includes 4 EPA Regional Laboratories, US Army Corps-Korea, UT & IA Public Health Labs, WSMR)
- **Oregon Secondary (accredited in another state)**
2012 - 32 labs
2015 - 32 labs

Helpful Hint

“J” Flag – footnote/description

J-value is equivalent to DNQ (Detected, not quantified) which is a trace value. A trace value is an analyte detected between the MDL and the laboratory reporting limit. This result is of an unknown data quality and is only qualitative (estimated). Baseline noise, calibration curve extrapolation below the lowest calibrator, method blank detections, and integration artifacts can all produce apparent DNQ values, which contribute to the un-reliability of these values.

Questions

1. When does the reporting clock for MCL violations start? When the sample result is "validated" and ready to leave the lab? At end of QC review?

Or

When report is printed and signed?

Answer: The clock starts when the QC signoff is completed and data is validated.

Questions

2. Should reports be held up if a manager/or regular signee is out of the office (vacation, sick leave for a few days, etc.) How do you want the labs to handle that? Particularly MCL violations for Coliforms, Arsenic, Nitrates.

Answer: Procedures should be in place to always have backup to handle MCL violation reporting as soon as they occur.

Reports – up to lab to hold up reports.

Recommend a signee or designee be available to sign reports.

What's New – TNI (The NELAC Institute)

- **Number of State ABs: 14**
- **Number of States applying: 3**
- **Number of States requiring TNI Standard: 34**

What's New - TNI

- **2009 TNI Standard Implementation
– July 1, 2011 – still in process**
- **NEFAP - Field Sampling &
Analysis Program**
- **National Environmental Monitoring
Conference/ TNI Mtg – Chicago –
July 13 - 17, 2015**
- **Working on 2015 Standard**

What's New – TNI

- **New Calibration Module**
- **New MDL/LOD method**
 - **Matches EPA's MUR proposal**

What's New – TNI

- **TNI LAMS – implemented**
 - **requires standardized method & analyte codes**
- **LAMS – Oregon uploads monthly updates**
- **Good to check, sometimes upload issues**

Thanks – Group effort

- **Stephanie Ringsage – Lab Compliance Mgr, Rita Youell ret.**
- **Pam Swanson –Website, Support**
- **Jimmy (Thavorn Tatiyatrairong) – IT**
- **Scott Hoatson – QA Officer**
- **Lead Assessor – Shannon Swantek**
- **Lizbeth Garcia, Heather Cayton, Chris Redman – DEQ Assessors**

ODIE – ORELAP Data Input & Edit

Common problems – renewal

- **Click on “Apply” for Lab status**
- **Click on “Save Analyte Changes”**
- **Then “Continue to Fees”**
- **Then click on “Submit to PHL”**

- **Analytes not showing up for method**
- **Methods not in database**

ODIE – ORELAP Data Input & Edit

ODIE Re-Write

- **Top 2 problems to fix in rewrite**
- **Send to me at**
Gary.K.Ward@state.or.us

ODIE – ORELAP Data Input & Edit

ODIE Demonstration