



Lessons Learned from Initiating a *Cryptosporidium* Drinking Water Laboratory Certification Programs

Carrie Miller

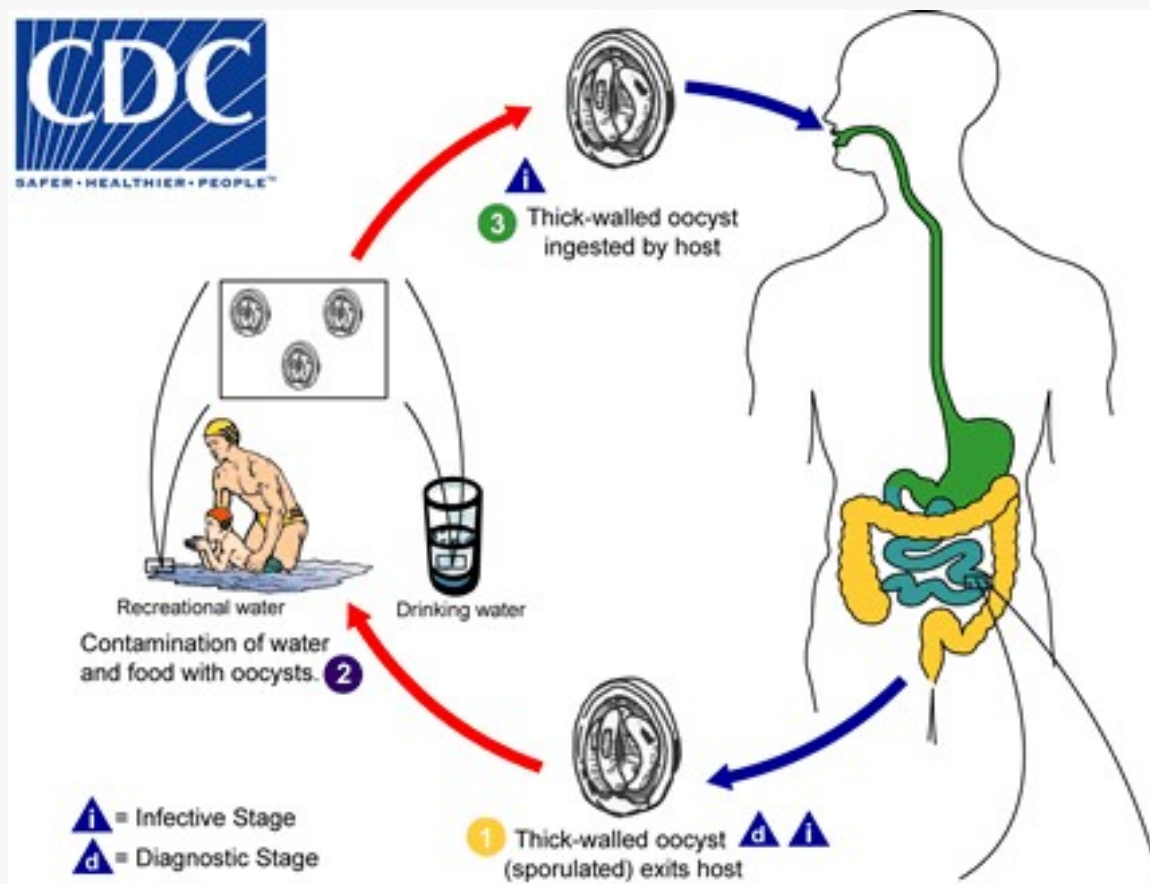
Drinking Water Lab Certification Team
Office of Ground Water and Drinking Water
Standards and Risk Management Division
Technical Support Center



Before Drinking Water Laboratory Certification

- Reference Standards
- Method Validation
 - Criteria for Quality Control
- Proficiency Testing
 - Provider Accreditation
 - Acceptance Criteria
- Certification Officers

Reference Standards May Not Be Easy to Produce





Method Validation

Is the method complete?

Sample Collection



Processing



Determinative Assay

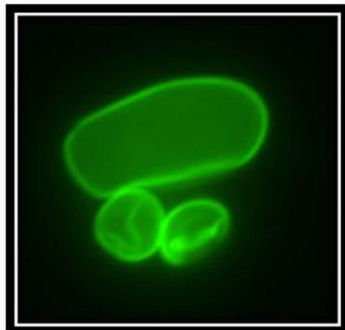
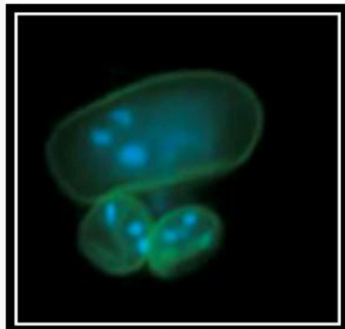


Units of Measurement



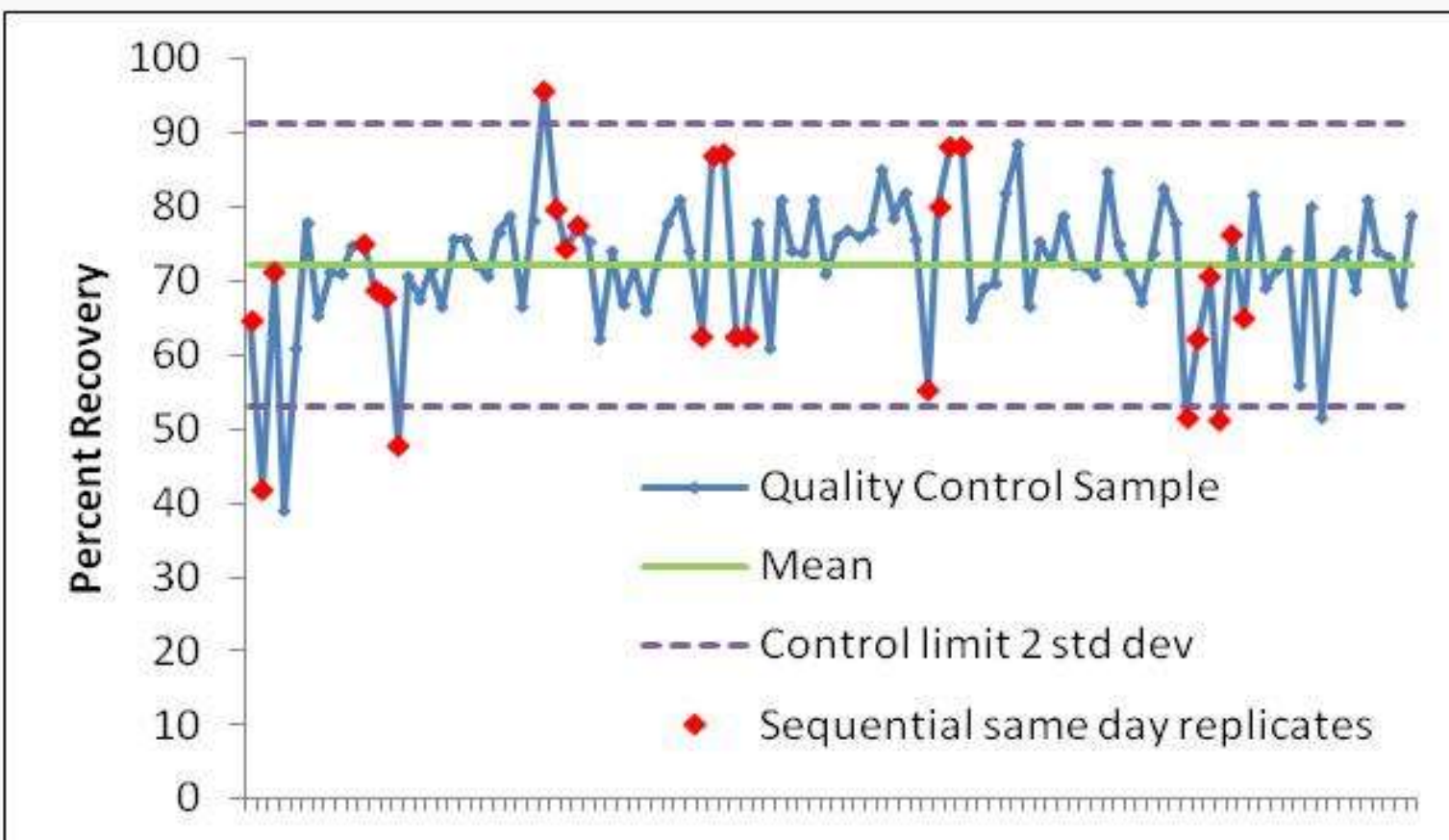
Inter-laboratory Method Validation Study

**Office of Water (MS 140)
EPA 816-R-12-002
February 2012
<http://water.epa.gov/drink>**



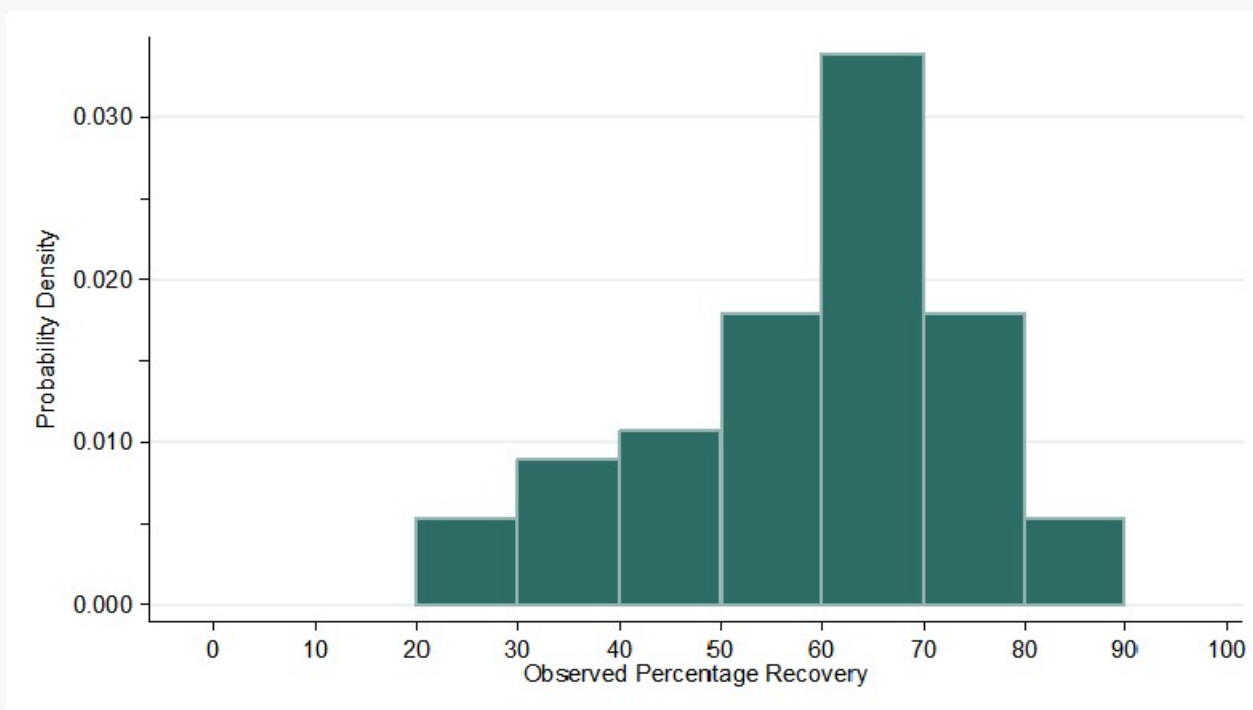


Validation in One Lab, N=100



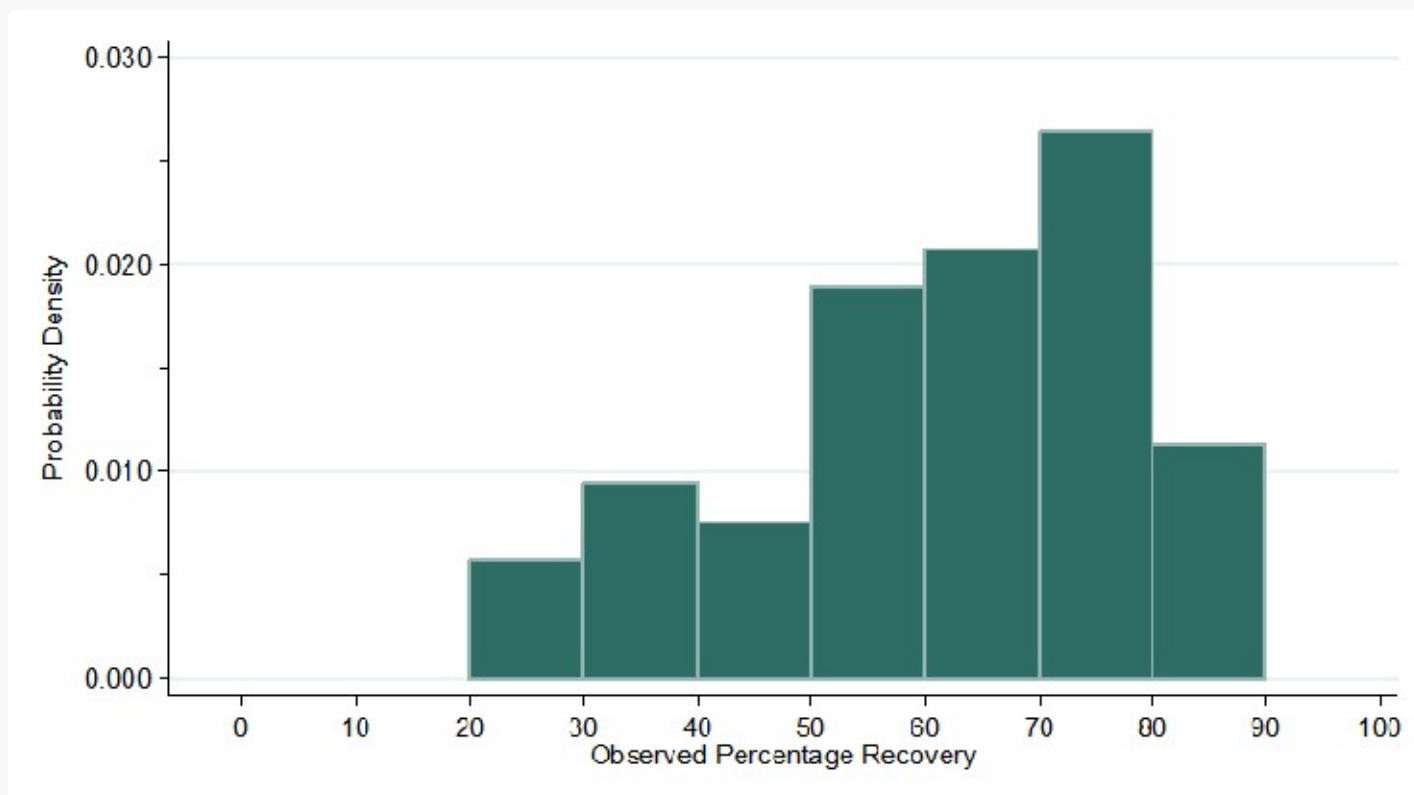


Validation Data for 14 Laboratories, Reagent Water; N=56





Validation Data for 14 Laboratories, Source Water; N = 53



10/20/2015

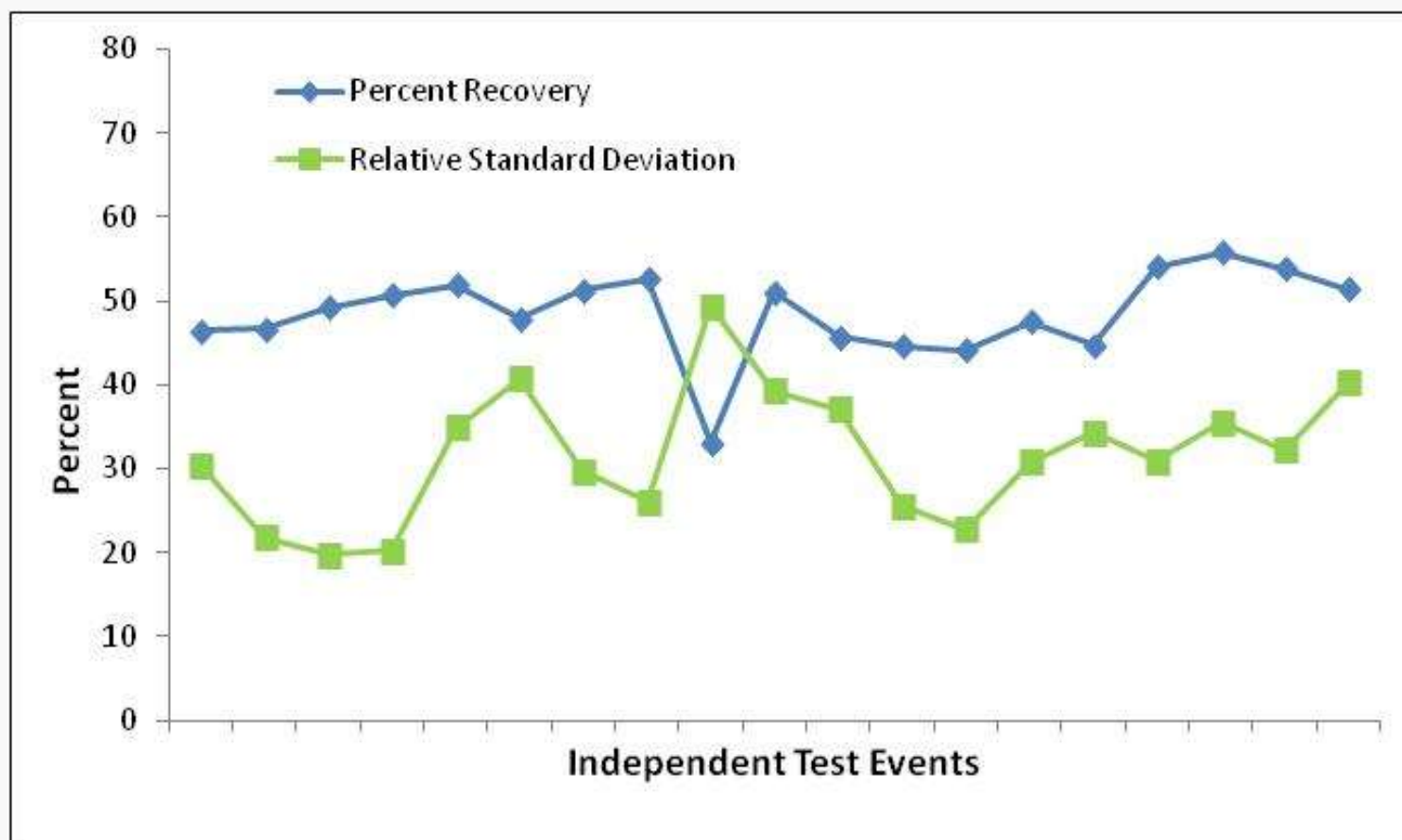


Method Criteria for Ongoing QC

- Lab comparability
 - Data gathered from proficiency tests
- Statistical approach
 - To develop and analyze criteria
- Lab performance over time
 - Improvement measurements



Comparability of 50 Laboratories





Statistical Approaches to Develop QC Criteria

- Analysis of variance (ANOVA)
 - recovery scale
 - Log transformation scale
- Bayesian Markov Chain Monte Carlo



Method Criteria Over Time

	11% In 2005	22% In 2009	33% In 2013
Data Source	Lab QC Known Spike Values	2 PT events Blind Spike Values	5 PT events Blind Spike Values
Labs Participated	6	58	56
Samples Analyzed	293	333	753



Criteria Update in 2009 and 2013

- **2009 update Federal Register Vol. 74, No. 36**
 - **60 day comment period**
- **2013 update Federal Register Vol. 78, No. 172**
 - **60 day comment period**
- **No laboratory comments regarding criteria update were received.**



Quality Control Frequency

Every 20 samples, the lab must recover 33% of the oocysts spiked into reagent water before analyzing field samples.



Proficiency Test Provider

- Only one
- Accredited to ISO/IEC 17043
- TNI posted Protozoan FoPT Table



Developing PT criteria

- **30 to 50 Labs per event**
- **10 tri-annual events**
- **1500 data points**



Analysis of Variance (ANOVA) Results

- **More variation between events than between labs**
- **Criteria better developed between labs than within labs in a given event**
 - **More strict**
 - **Better addressed problematic labs**



The acceptance limits are laboratory mean recovery between ± 2 standard deviations of the mean recovery for all approved labs in a given test event.

Federal Register Vol. 74, No. 36 2/25/2009



Lab Certification Officer Responsibilities



- Evaluate lab capability
- Monitor PT results
- Perform on-site audits

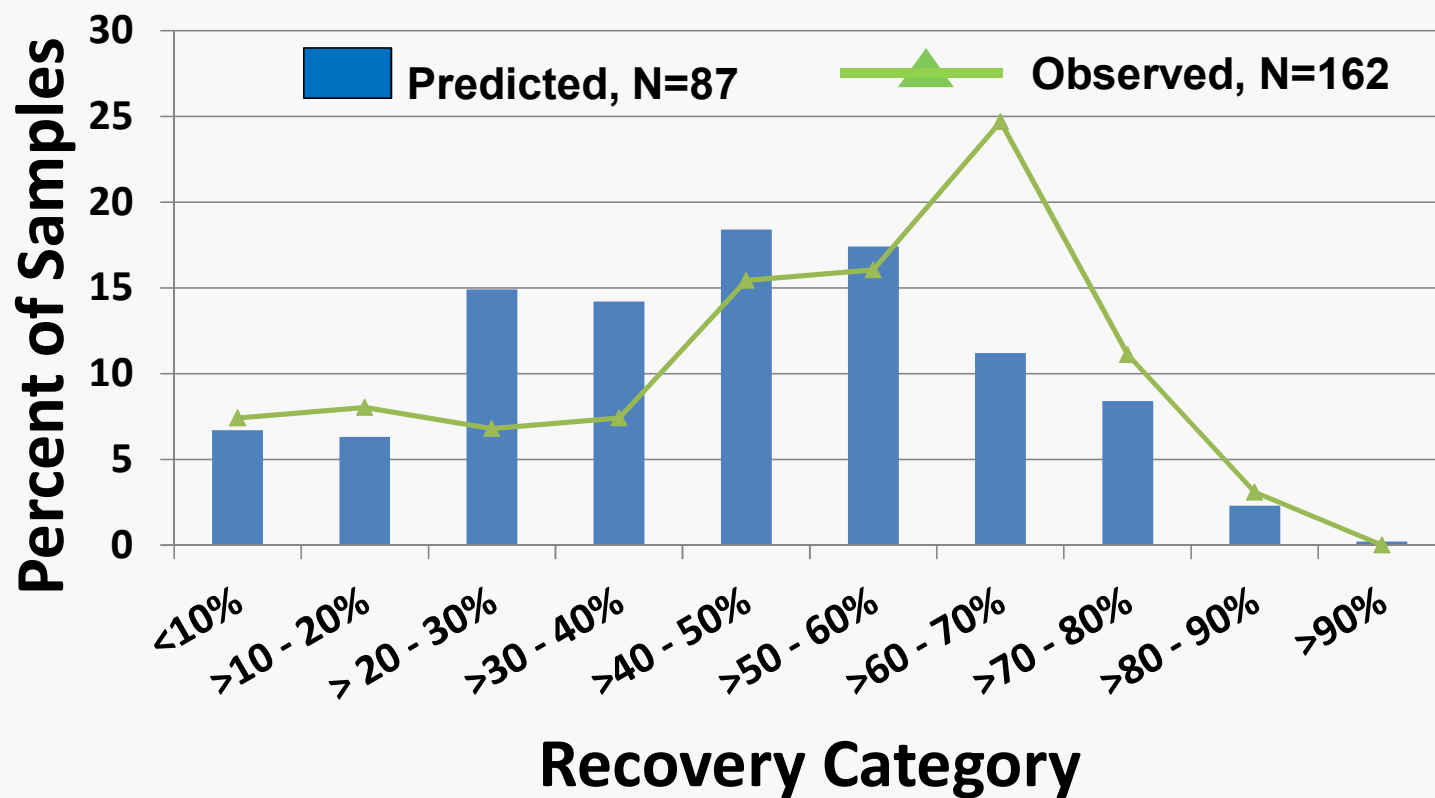


Training for Certification Officers

- **Classroom Courses initiated in 2010**
- **Online Courses initiated in 2014**
- **Online References**
 - **Training modules**
 - **Videos**



Compliance Monitoring: QC Predicted and Observed





For more information:

Miller.carrie@epa.gov