



State Hygienic  
Laboratory

# Preparing for an On-Site Audit

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SHL Lab Symposium  
September 27, 2018

*Iowa's Environmental & Public Health Laboratory*

# The Auditor is Coming



# Common Thoughts on Activities that are Better than an Audit



# How You Should Feel Before an Audit



# Think Long Term

- Don't Wait till the last minute
- Use the Tools You have available
- Make sure your documents are up to date
- Ask Questions between audits if they come up

# Update Quality Plan

## Critical Elements of QA Plan

- Sampling procedures
- Sample handling procedures--specify procedures used to maintain integrity of all samples. Samples likely to be the basis for an enforcement action may require Chain-of-Custody procedures

# Critical Elements of QA Plan (cont.)

- Instrument or equipment calibration procedures and frequency of their use
- Analytical procedures
- Data reduction, validation and reporting  
data reduction: conversion of raw data to final concentrations.
- Validation: includes insuring accuracy of data transcription and calculations

# Critical Elements of QA Plan (cont.)

- Reporting: includes procedures and format for reporting data to clients and IDNR
- Types of quality control (QC) checks and frequency of their use. This may include preparation of calibration curves, instrument calibrations, replicate analyses, use of external QC check samples, and use of QC charts



# Critical Elements of QA Plan (cont.)

- Preventive maintenance procedures and schedules
- Specific routine procedures used to determine data precision and accuracy for each contaminant measured. Precision is based on the results of replicate analyses. Accuracy is normally determined by comparison of results with “known” concentrations in spiked media

# Critical Elements of QA Plan (cont.)

- Corrective action contingencies. Laboratory response after obtaining unacceptable results from analysis of PE samples and from internal QC checks
- Laboratory organization and responsibility. Include a chart or table showing the laboratory organization and line of authority.

# Tools to Use

- Review Checklists from Previous Audits
- Internal Audits – Use Checklist to review yourself
- Review Report from Last On-site – Have Deficiencies been addressed and Recommendations considered

# Typical Items That Cause Issues

- QA Plan – no signature page or evidence of review
- QA Plan – no corrective action section or detailed account of how to deal with non-conformities
- SOP – not following procedure as written
- SOP – outdated reference – method name not correct
- Equipment: Oven out of specification for TSS

# Typical Items That Cause Issues

- Temperature logs have no acceptance ranges
- Temperature logs have no correction factor or correction factor not being applied to recorded temperature
- Certified thermometer out of compliance
- No updated QC charts or tables
- Ammonia: distillation waiver not available
- Ammonia: ammonia-free water not being used

# Typical Items That Cause Issues

- Ammonia: distillation apparatus not being steamed out before use.
- Water quality not being checked
- TSS: Desiccant needs to be changed
- TSS: Oven not keeping constant temperature
- BOD: Dilution water blanks too high
- BOD: Not following the 2/1 rule
- CBOD: Samples not being seeded
- BOD: G&G not being performed on daily basis

# Typical Items That Cause Issues

- TNT: Not performing all QC parameters as defined in the 2017 MUR
- pH: Not bracketing samples with calibrated buffers
- Not performing PT's with required frequency.
- Incorrect method reported to PT vendor.
- Incomplete traceability – e.g., no standard log book
- Composite samples not being kept at  $<6^{\circ}\text{C}$

# Typical Items That Cause Issues

- Compositing sampler temperature not being recorded before and after compositing cycle.
- All required information not available on final report
- Pipettes not calibrated
- Balance not checked annually
- Balance weights not checked annually



# Typical Items That Cause Issues

- QC: No sample spike available
- QC: No duplicate available
- QC: Samples not bracketed by QC



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Questions?

# Thank you

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