AUDITING THE ENVIRONMENTAL LABORATORY:

A PRACTICAL CHECKLIST & FIELD GUIDE

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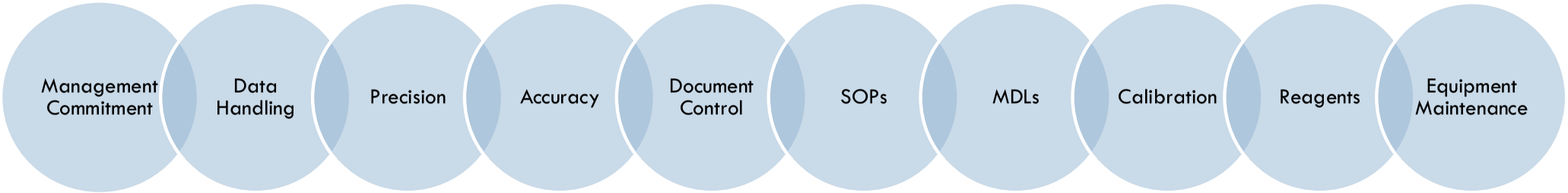
Your Resource for Defensible Data

Quality Assurance

Quality Assurance

- The system by which the laboratory can assure outside investigators that data are of known quality.
- Quality control is only one part of quality assurance.
- Quality is not free.
- Quality is everyone's business!

Data Quality – like a chain – is only as strong as its weakest link.



Auditing Your Environmental Lab

A Practical Checklist

1. Management Responsibility

Management Commitment

- ☑ Has management defined, developed, and implemented the Quality Management (QM) system?
- ☑ Has management ensured that all employees understand the goals and objectives of the QM system?
- ☑ Are meetings conducted to discuss important changes?

Quality Policy

- ☑ Is the quality policy issued and available?
- ☑ Does the quality policy include the company's goals and customer expectations?
- ☑ Is the quality policy understood, implemented, and maintained at all levels of the company?

Organization

- ☑ Does the company have an organization chart?
- ☑ Does the organization chart list all positions and departments?
- ☑ Does the company have job descriptions for personnel whose work affects quality?

Quality Planning

- When evaluating a new project, do staff members meet to define and document how requirements for quality will be met?
- Are assessments made as to what impact projects or contracts will have on resources?

Management Review

- Are the following records examined during management reviews?
  - Customer complaints
  - Service report trends (i.e. turnaround time)
  - Internal quality audit trends
  - Non-conforming QC activities
  - Corrective and preventive action trends

2. Quality System

Quality System

- ☑ Is a quality management (QM) system established and maintained?
- ☑ Is a QM system structure described?
- ☑ Is a quality manual issued and maintained?
- ☑ Does the manual contain a table of contents, date of issue, and revision level?
- ☑ Does the manual contain or refer to procedures?
- ☑ Are requirements defined and described, and how are they met for all services, equipment testing, labeling, and quality records?

3. Sample Receiving and Handling

Sample Receiving and Handling

- ☑ Are standard operating procedures (SOPs) in place?
- ☑ Is there a log system for tracking samples?
- ☑ Is there a clear, simple acceptance policy and are protocols in place?
- ☑ Are chain of custody protocols defensible?
- ☑ Is there a sample disposal policy?
- ☑ Are guidelines established for proper storage of samples?
- ☑ Do sample identification procedures prevent samples from being confused?

4. Document Control

Document Control

- ☑ Are SOPs established and maintained to control all documents and data?
- ☑ Are documents reviewed and approved for accuracy prior to issue?
- ☑ Does a master list of all established documents exist to prevent use of invalid documents?
- ☑ Are forms, logs, SOPs, training records, data sheets, etc. all controlled?

Document Control

- ☑ Are copies of approved documents available at workstations?
- ☑ Are obsolete documents removed from workstations?
- ☑ Are obsolete documents clearly labeled and maintained for historical purposes?
- ☑ Is the procedure for review and approval of revisions the same procedure used to review and approve the original document?

5. Control of Quality Records

Control of Quality Records

- ☑ Are procedures established and maintained for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records?
- ☑ Are record retention times established?
- ☑ Are quality records available for review (i.e. management review records, contracts, supplier lists, batch records, equipment calibration records, data review records, corrective action records, training records, audits, etc.)?

6. Quality Control

Quality Control

- ☑ Are QC activities and protocols clearly established for each analyte?
- ☑ Are QC activities being performed?
- ☑ Are “decision trees” in place?
- ☑ Is a method blank run with each batch?
- ☑ Is a Laboratory Control Standard (LCS) run with each batch, and is it prepared from a separate lot number than the calibration?

Quality Control

- ☑ Is the Analytical Balance(s) verified for accuracy at least once each day of use?
- ☑ Are NIST Class S or ASTM/ANSI Class I weights used?
- ☑ Does the lab maintain copies of the original certificate of traceability for each weight?
- ☑ Are the Class S or Class I weights verified at least once every 5 years for accuracy by qualified service?

Quality Control

- ☑ Is the balance serviced and verified for accuracy annually by an external provider?
- ☑ Is the balance labeled with date of annual service?
- ☑ Does lab maintain copies of Certificate of Traceability for annual service?
- ☑ Is the balance clean?
- ☑ Is the balance located in an area free of air movement and free from vibrations?

Quality Control

Form 110-0

WWTP Laboratory Balance Calibration

Month/Year: _____

Reference Weight ID's or Serial Numbers _____

Balance	Mettler AB104S			Initials
Mass	1.0000 g wt.	10.0000 g wt.	100 g wt.	
	Limit	Limit	Limit	
Date	0.9950-1.0050	9.9500-1.0050	99.50-100.50	

Instructions:

1 Verify the balance is level. The inner circle should be within the outer circle. If not, adjust until inner circle is within the outer circle. Generally the legs of the balance are turned to balance.
2 Using a balance brush, brush the pan and inside of balance to ensure it is clean.
3 Press the tare or zero button on the balance to obtain a reading of 0.0000 g.
4 Transfer the lowest mass using supplied tweezers or a cotton glove and place in the center of the balance pan.
5 Allow the reading to stabilize and record the result in the appropriate column.
6 Repeat steps 3 - 5 until all three weights have been measured and documented.

Quality Control

Quality Control

Quality Control

- Does the lab maintain the manufacturer's instruction manual for each balance?
  - Why is this Important?

Quality Control

- ☑ Does the lab perform verifications of working thermometer accuracy?
- ☑ Does the lab have a NIST traceable thermometer verified once every 5 years for accuracy?
- ☑ Is the NIST thermometer verified at the temperatures of use?
- ☑ Does the lab maintain copy of the original thermometer certificate from the manufacturer?
- ☑ Is the thermometer labeled with verification date and correction factors?

Quality Control

Quality Control

- If the laboratory verifies its own working thermometers, does the lab maintain copies of every verification performed?
- Does the lab reference which NIST thermometer is used to perform the verification?
- Is every working thermometer labeled with calibration date and correction factor?
- If the lab subcontracts the working thermometer verification does the lab obtain a copy of the raw data associated with the verification from the provider?

Quality Control

WWTP Laboratory

Calibration of Thermometers

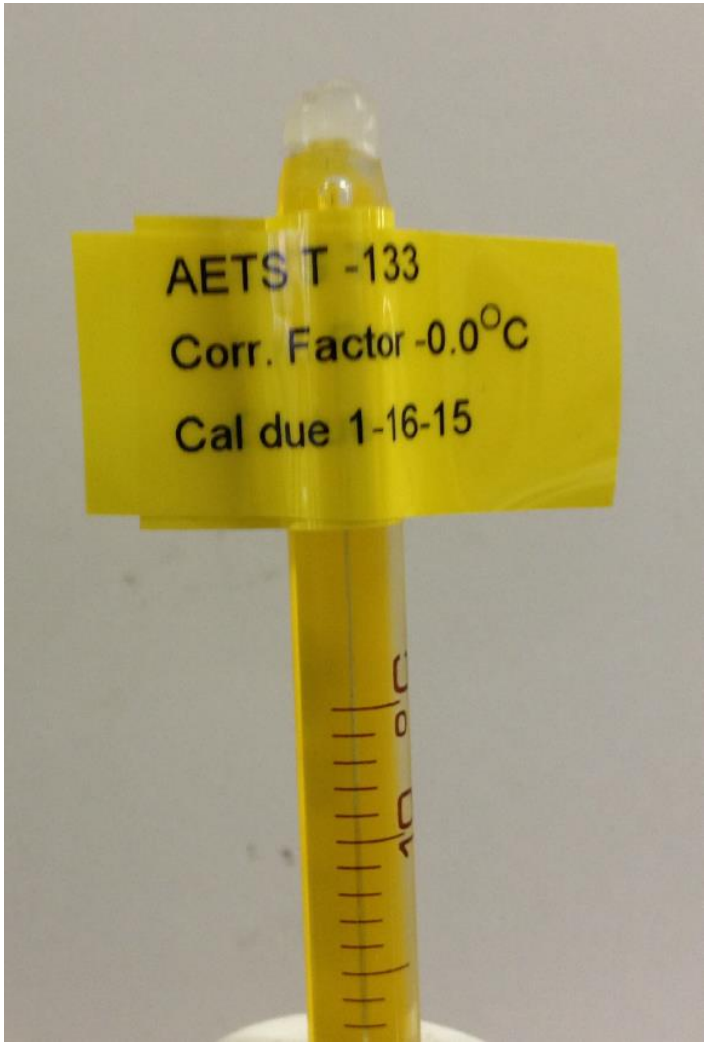
Form 107-0

NBS Reference Thermometer Serial Number: ABC4321

Thermometer	Ser. No.	NIST Reading	Test Reading	Correction °C
Ertco - lab refrigerator	11223	5.0	6.0	-1.0
Ertco - Solids Oven	446689	103.0	103.0	0.0

Performed By: _____ Date: _____

Quality Control



Quality Control

- ☑ Does the lab document temperatures of equipment and incubators once per day for non microbiological tests?
- ☑ Does the lab document temperatures of equipment and incubators twice per day at least 4 hours apart for microbiological tests (fecal, E. coli, etc.)?
- ☑ Are the recorded temperatures within the required range?

Form 111-0

WWTP
Chemistry Equipment Temperature Check

Month/Year _____

Equipment	Time	Drying Oven	BOD Incubator	Sample Refrigerator	Reagent Refrigerator	Initials
Range °C	Checked	103 - 105	19.0 - 21.0	0 - 6	0 - 6	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
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31						

Quality Control

- ☑ Does the lab calibrate the pH meter daily?
- ☑ Is the slope of the calibration documented?
- ☑ Is the date & time & analyst of calibration documented?
- ☑ Are the buffers used for calibration documented?
- ☑ Does the lab verify the pH meter calibration every 12 hours or after 10 or more sample measurements?
- ☑ Is the calibration and verifications documented and maintained?

Determination of pH

WWTP

	Reagent Numbers
pH 7	
pH 4	
pH 10	
Second Source pH 7	

Analyst	Date Calibrated	Time Calibrated (hh:mm)	Slope (92-102)	pH 7 check (6.90-7.10)

Sample ID	Analyst	Date Analyzed	Time Analyzed (hh:mm)	pH Result

Quality Control

- Do the pH results of all samples fall between the lowest and highest buffer concentrations used for calibration?
- Example: If using pH 7 and pH 10 buffers – do all sample results fall between 7.0 and 10.0?
- If not, the meter will need recalibrated either using a pH 4 and pH 7 buffer or using all three buffers (4, 7 & 10).
- Is the meter manual and electrode manual available?

7. Accuracy

Accuracy

- ☑ Are control charts in use?
- ☑ Are limits clearly established?
- ☑ Does a determination of accuracy include QC samples and spikes?

8. Precision

Precision

- ☑ Are control charts in use?
- ☑ Are limits established (either using Shewhart constants or RPDs)?
- ☑ Does a determination of precision include duplicates and/or matrix spike duplicates?

9. Methodology

Methodology

- ☑ Are methods chosen for method compliance?
- ☑ Are approved methods used and cited?
- ☑ Has the method been validated?
- ☑ Are methods being followed?
- ☑ Are SOPs in place?
- ☑ Are holding times being met and is preservation and sample pretreatment proper?

10. Method-Specific and General SOPs

Method-Specific and General SOPs

- ☑ Are they in place for all analytes and protocols (sample receiving, training, corrective action, document control, etc.)?
- ☑ Do SOPs come under some type of document control?
- ☑ Can a specific SOP be cited for a prior analysis?
- ☑ Do SOPs refer to an approved method?
- ☑ Is there a standardized format for SOPs?
- ☑ Is there a master list of SOPs?
- ☑ Are revisions tracked?

11. Logbooks

Logbooks

- ☑ Are instrument logbooks in use?
- ☑ Do they contain sufficient information (i.e. calibration, maintenance, troubleshooting, etc.)?
- ☑ Are equipment logbooks in use for other key pieces of equipment (i.e. ovens, refrigerators, water baths, autoclaves, etc.)?
- ☑ Are logbooks in use for other processes (i.e. samples, reagents, waste, safety, etc.)?
- ☑ Are pages sequentially numbered and entries made in permanent ink?

12. Reagents

Reagents

- ☑ Are appropriate grades of reagents in use?
- ☑ Are reagents and solutions traceable to the manufacturer for each analytical run?
- ☑ Are reagents and solutions stored properly?
- ☑ Are reagents and solutions labeled appropriately?

Reagents

- ☑ Are procedures in place to make sure expired reagents and solutions are not used?
- ☑ Are reagent logs and tracking systems adequate?
- ☑ Are there clear and consistent instructions for preparation of solutions?
- ☑ Are lab packing and disposal procedures in place (Are regents and solutions disposed of properly)?

13. Method Detection Limits

Method Detection Limits

- ☑ Are studies being performed and are they being performed correctly?
- ☑ Is the frequency of performance appropriate (annually, new equipment, new analyst, etc.)?
- ☑ Are studies evaluated for validity (i.e. 10X rule, all data points above calculated MDL)?
- ☑ Are calculations correct?
- ☑ Are all data points included in the study?

14. Data Handling

Data Handling

- ☑ Are raw data sheets controlled documents?
- ☑ Do they contain essential information, including date of analysis, analyst, etc.?
- ☑ Can QC data be batched with a given analytical run?
- ☑ Are procedures in place to prevent alteration of data?
- ☑ Are calculations performed correctly?
- ☑ Are “decision trees” in place?
- ☑ Are corrections made appropriately?

15. Training

Training

- ☑ Is the staff adequately trained (are general analyst training guidelines specified)?
- ☑ Is training documented?
- ☑ Is there initial competency training with documentation?
- ☑ Is there on-going competency training with documentation?
- ☑ Is there specific safety training with documentation?

16. Calibrations

Calibrations

- ☑ Are thermometers tagged with date and correction factor?
- ☑ Are balances calibrated frequently enough and with appropriate weights?
- ☑ Are micro-pipettors calibrated at routine intervals?
- ☑ Are instruments tuned and calibrated properly?

Calibrations

- Are calibration curves performed at appropriate times (new analyst, new instrument, change in reagents, annually, etc.)?
- Are all points used in calibration curves?
- Are enough points used in preparing the curve?
- Is other equipment calibrated regularly (autoclave temperature dials, pH meters, DO meters, ion probes, etc.)?

17. Maintenance

Maintenance

- ☑ Are records maintained and is maintenance documented, preferably in a logbook?
- ☑ Is maintenance scheduled?
- ☑ Are maintenance contracts maintained?

18. Corrective Action

Corrective Action

- ☑ Are procedures in place to address and document corrective action?
- ☑ Is corrective action documented for out-of-control conditions?
- ☑ Does corrective action extend to broader issues than a single analytical run?

19. Ethics

Ethics

- ☑ Is there a clear ethics policy with management support?
- ☑ Is there a signed ethics agreement?
- ☑ Is training provide to employees and documented?
- ☑ Do employees know there is a direct regulatory link between testing and public health?

20. Proficiency Testing Samples

Proficiency Testing (PT) Samples

- ☑ Is proficiency testing part of the QA program?
- ☑ Does the laboratory use blind PT samples?