# AUDIT AFTERMATH –

## …helping you solve the audit puzzle

*Rick Mealy*
*Wisconsin DNR*
*Lab Certification*

1

The donuts have been eaten,
the coffee is burnt grounds.
Audit's over… but
What do you do now?

2

## MELTDOWN: CONFIRMED

3


# You CAN do this
# WE can help…

4

## But first.... a little housekeeping

Disclaimer & Caution

*Any reference to product or company names does not constitute endorsement by the Department of Natural Resources*.

5

# What do we take away from an audit?

6

## We see some really nice things…


courtesy of the Village of Bloomfield

Really nice hood set up

7

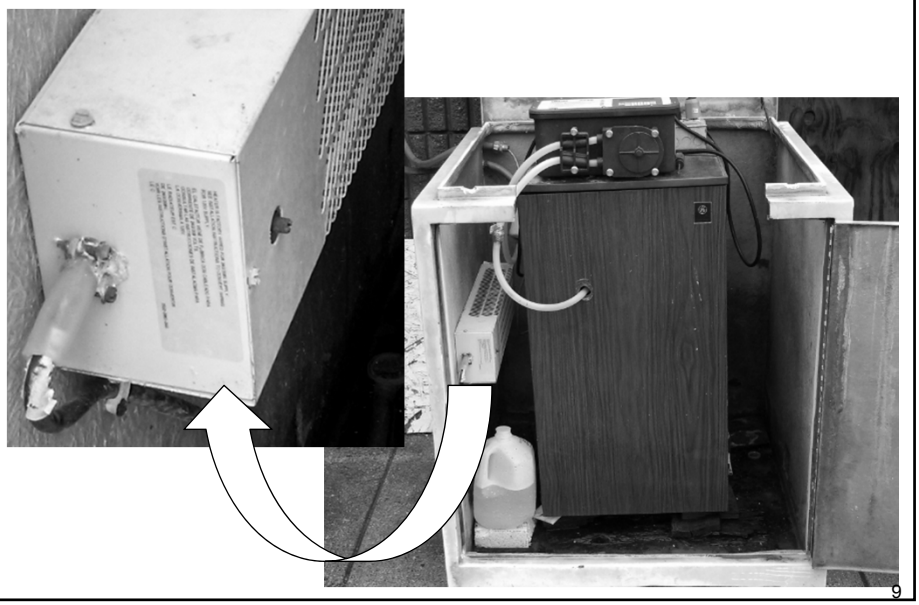
## We see some really ingenious innovations


courtesy of the Brodhead WWTP

Ingenuity – a timer alert system

8

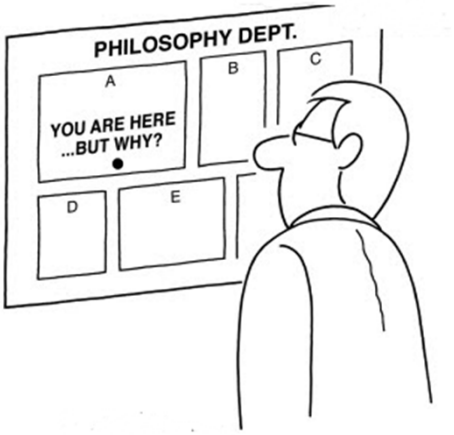
## …and we see some really crazy stuff



9

## But that's not why we're here today…

**…although some of it matters…especially when things like the heated autosampler are eventually what YOU'RE trying to address after the audit**




10

## Why are we here?

- Get a better understanding of what happens after the audit is over.
- Review program data for audit closures.
- Learn what some of the most common deficiencies we find are.
- Share some of the DOs and DON'Ts of responding to an audit report.
- Help you craft a successful audit response.

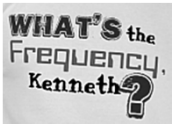
11

## Audits are taking a long time to close. But why? What's the root cause of delayed audit closures? …and what corrective action is needed?

12

## What's the frequency, Kenneth?

1. **Lack of response**….. period – taking a long time to respond (3 – 6 months) or until we need to initiate drastic measures.
2. **Partial response** – ignore responding to one or more deficiency or bullet item.
3. Response provided **piecemeal** (vs. 1 complete package).
4. Response is **unorganized** (what are you responding to?)
5. Response **does not addresses the deficiency** in full.
6. Response includes **no documentation** of the fix.
7. Response contains **indeterminate documentation**
   - is it in practice for real samples?
   - Those new columns on that benchsheet look great…but are they being used?



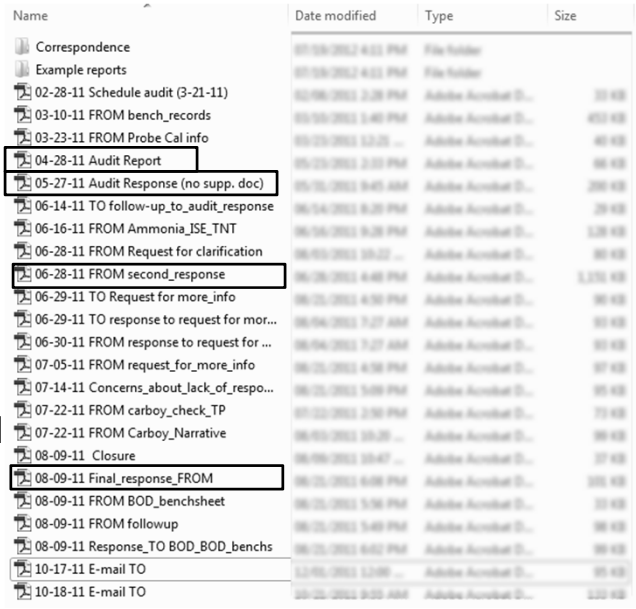

13

# Examples of responses that don't cut it

14

# This is just too much like work

Granted there were 9 deficiencies…. But….this seems like a little too much back and forth. This lab narrowly averted an NON




15

# If you're going to submit data, you might want it to be good data

Deficiency: ***Critical sample pre-treatment is not performed before BOD analysis.***

Response: We are following your recommendations on solving this issue. We will first raise the sample temperature up to 17-23. Then prior to the BOD test, the sample will be shaken vigorously and allowed to sit for a minimum of three minutes. The dilution water will also be shaken vigorously prior to use. If the BOD blank or the sample reading does not fall within 0.4 mg/L of the theoretical DO saturation point, they will have to shaked again or the meter recalibrated or troubleshooted. If the DO measurement is greater than 9 mg/L, the samples or dilution water will have to be shaked again. The SOP is being revised to reflect this. The SOP will be sent to you with the quality control manual.

The "proof"

**BOD**

In Date: 11-4-11 Out Date: 11-9-11
Operator/Time: JR 806 Operator/Time:

| Sample Type | BLANK | BLANK | SEED | SEED | | Jug 1 |
|---|---|---|---|---|---|---|
| Bottle Number | | | | | | 483 |
| Mls of Sample | | | | | | 300 |
| DO - IN (mg/L) | | | | | | 9.96 |
| ~~DO - OUT (mg/L)~~ | | | | | | |
| Depletion (mg/L) | | | | | | |
| Seed Correction | | | | | | |
| BOD (mg/L) | | | | | | |
| Avg. BOD (mg/L) | | | | | | |

| | |
|---|---|
| GGA lot # | |
| Seed lot # | |

16

## …and another!

**BOD Benchsheet** (12/4/11) Facility:

| Method Number: | SM 5210B | Edition: | 21st |
|---|---|---|---|

| Composite Sample Checks | | | Read In Calibration | | Read Out Calibration | | Quality Control |
|---|---|---|---|---|---|---|---|
| Sample ID + sample date | pH | Temp (°C) | Analyst | DS | Analyst | DS | Blanks ≤ 0.24 mg/L |
| 130423 Inf | 6 | 23 | Room Temp. (°C) | 20 | Room Temp. (°C) | 20 | GGA = 167.5 - 228.5 |
| 130423 Eff | 6 | 23 | Local pressure (in Hg) | 29.5 | Local pressure (in Hg) | 29.2 | Residual DO ≥ 1.0 mg/L |
| | | | DO Sat Chart (mg/L) | 8.87 | DO Sat Chart (mg/L) | 8.55 | DO depletion ≥ 2.0 mg/L |
| | | | DO Meter (mg/L) | 8.85 | DO Meter (mg/L) | 8.59 | |
| | | | Date bottles in | 4/2/13 | Date bottles out | 4/28/13 | Code Defintions |
| | | | Time bottles in | 5:00pm | Time bottles out | 4:00pm | N = Extra Nutrients added to sample |

Traceability Lot # or Lab ID Information — I = Inhibitor added to sample

| | | | | | | P = Sample pre-diluted per SOP (≤ 3 mL) |
|---|---|---|---|---|---|---|
| Dilution water nutrient pillow | A2023 | synthetic commercial seed | 94351 | GGA | B12D130207B2 | |
| Sample bottle nutrient pillow | | | | | | |

| Sample ID (include sample date) | Bottle ID | Sample Volume Used (mL) | Nutrient or Inhibitor added | Seed Volume added (mL) | Initial DO (mg/L) | Final DO (mg/L) | DO Depletion (mg/L) | Do due to Seed (mg/L) | Final Sample DO (mg/L) | Dilution Factor | BOD (mg/L) | Average BOD (mg/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 130423 Eff Bottle | 127 | 300 | Y | | 11.5 | 10.7 | | | | | | |
| 130423 Inf Bottle | 132 | 300 | Y | | 11.4 | 11.0 | | | | | | |

Documentation provided that to show that bottle blanks are analyzed

**11.5 mg/L initial DO?????**

17

## We appreciate it…but an ASTM traceable CLOCK?

ilac-MRA ACCREDITED Calibration Certificate No. 1750.01

**Calibration complies with ISO 9001**
**ISO/IEC 17025 AND ANSI/NCSL Z540-1**

**Cert. No.: 1072-5046472**

**Traceable® Certificate of Calibration for LCD Wall Clock**

**Instrument Identification:**

Model: 1072 S/N: 130221667 Manufacturer: Control Company

**Standards/Equipment:**

| Description | Serial Number | Due Date | NIST Traceable Reference |
|---|---|---|---|
| Non-contact Frequency Counter | 26.6 2025 | 3/08/14 | 1000333504 |

**Certificate Information:**

Technician: 67 Procedure: CAL-01 Cal Date: 4/18/13 **Cal Due: 4/18/15**

Test Conditions: 21.5°C 51.0 %RH 1008 mBar

**Calibration Data: (New Instrument)**

| Unit(s) | Nominal | As Found | In Tol | Nominal | As Left | In Tol | Min | Max | ±U | TUR |
|---|---|---|---|---|---|---|---|---|---|---|
| Sec/24hr | | N.A. | | 0.000 | 0.100 | Y | -8.640 | 8.640 | 0.130 | >4:1 |

**This Instrument was calibrated using Instruments Traceable to National Institute of Standards and Technology.**

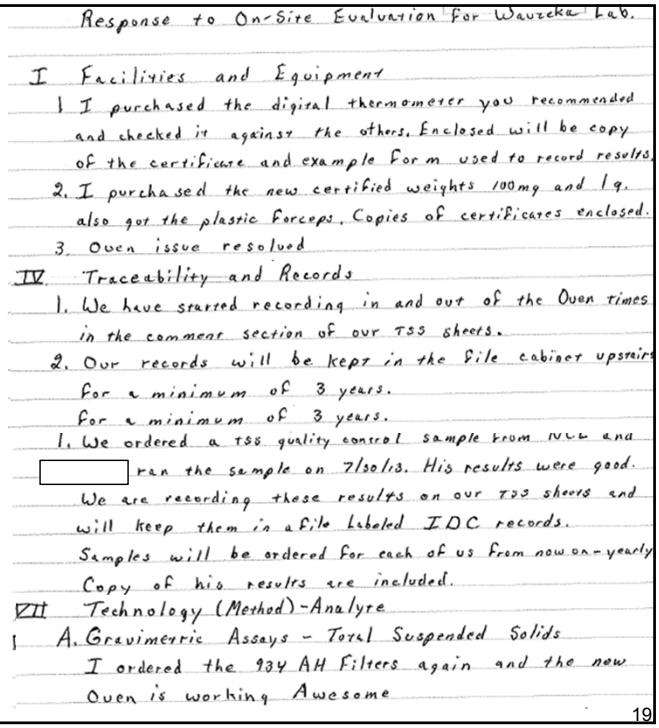
A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. In tolerance conditions are based on test results falling within specified limits with no reduction by the uncertainty of the measurement. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading; As Left=Instrument's Reading; In Tol=In Tolerance; Min/Max=Acceptance Range; ±U=Expanded Measurement Uncertainty; TUR=Test Uncertainty Ratio; Accuracy=±(Max-Min)/2; Min = Nominal(Rounded) - Tolerance; Max = Nominal(Rounded) + Tolerance; Date=MM/DD/YY

18

A pretty good response. No…points aren't deducted for being handwritten.

The problem is no documentation was submitted



Response to On-Site Evaluation for Waueka Lab.

I Facilities and Equipment
1. I purchased the digital thermometer you recommended and checked it against the others. Enclosed will be copy of the certificate and example form used to record results.
2. I purchased the new certified weights 100mg and 1g. also got the plastic forceps. Copies of certificates enclosed.
3. Oven issue resolved

IV. Traceability and Records
1. We have started recording in and out of the Oven times in the comment section of our TSS sheets.
2. Our records will be kept in the file cabinet upstairs for a minimum of 3 years.
for a minimum of 3 years.
1. We ordered a tss quality control sample from NCL and [redacted] ran the sample on 7/30/13. His results were good. We are recording these results on our TSS sheets and will keep them in a file labeled IDC records. Samples will be ordered for each of us from now on - yearly Copy of his results are included.

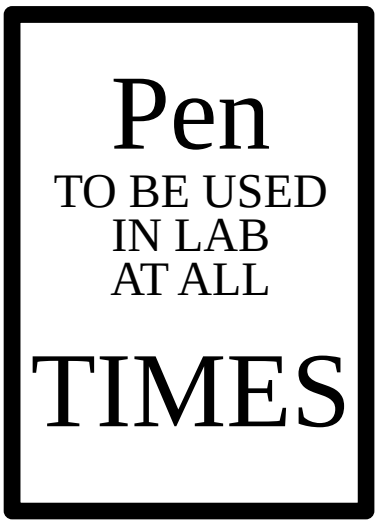
VII Technology (Method) - Analyte
1 A. Gravimetric Assays - Total Suspended Solids
I ordered the 934 AH Filters again and the new Oven is working Awesome

19

## Sincere effort…will it work?

This lab was cited---for the 2nd consecutive audit--- for having (and using) whiteout in the lab.

They went to the effort of creating this nice 8.5 x11 sign to be posted in the lab.




20

## Is this what EVERY Primary Analyst must do for IDC?

[redacted] is the Primary Analyst for the [redacted] Laboratory, and has been for the last four years. He has 13 years of Municipal laboratory experience, and 30 years of over all industrial and municipal wastewater experience. He has run the WSLH Proficiency tests and the Blind Standards for 13 years. He is a WDNR Grade 4 Certified Operator in almost all categories including Laboratory. The Analyst attends all WDNR and WWOA lab seminars that are offered and attended 3 NR 149 review of changes classes, to keep himself and the laboratory current on any changes or training that are needed. His Demonstration of Capability besides all daily testing and QC can be found in the WLSH Proficiency Testing binder that has all Proficiency tests and blind standards that he has run.

**IDCs are not a list of credentials.**
**They are what YOU require for a specific function**

21

## Is this what EVERY secondary analyst and "weekend guy" must do for IDC?

[redacted], is the secondary analyst for the city of [redacted] laboratory. [redacted] has been a water and Operator for 18 years. He is a grade four certified Operator in plant required classifications including The lab. He has 8 years of lab experience in [redacted] lab. He ran WLSH blind samples for Sus Solids and BOD and a GGA in March of 2007 and Passed all three tests which are on file. He would Run the BOD and Sus Solids when the primary Analyst is off. He preserves the ammonia and phos, Samples for the primary analyst to run when he Returns. He has attended some lab classes offered Through the WWOA and State lab of Hygiene in When they were offered.

[redacted] do weekend analysis only for P.H. And Dissolved Oxygen. They both received training On calibration procedures for the PH, and DO Meters from the primary analyst. Both operators Will read out one BOD analysis per month on the Weekend of the month that they work. Both were Trained on calibration of the BOD meter and were Able to calibrate and read out a GGA set up by the Primary analyst and pass before being allowed to Read out weekend BOD,s.

22

# Repeat deficiency. Better…but not fixed

**Deficiencies** – Supplemental Information

1. **Lab temperature stability is not maintained. REPEAT DEFICIENCY**
   - NR 149.43 (1) (b) & (2) -

In order to maintain samples at the required temperature of 20 ± 3 °C during DO measurements for BOD analysis, the room temperature must also be maintained at 20 ± 3 °C. DO measurements are sensitive to temperature (a 0.5 °C change translates to a 0.1 mg/L dissolved oxygen change). Room temperature records indicated that temperatures above 23 °C occur frequently. Better laboratory temperature control is required.

*Let me know what the laboratory has done to correct this problem.*

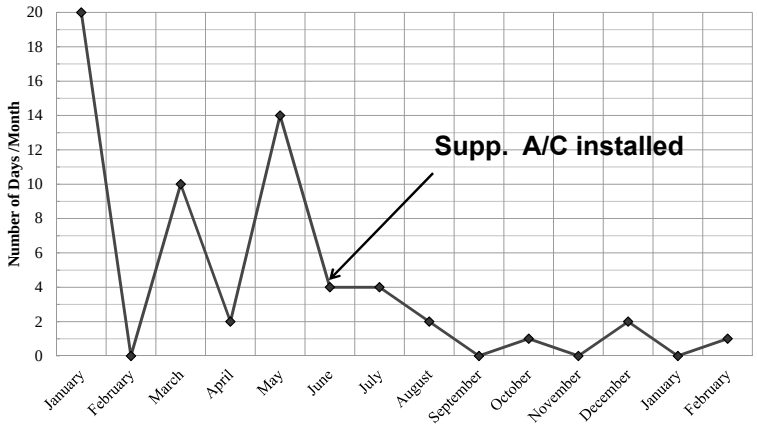
In response to the deficiency sited on our Laboratory Temperature:

Attached is a graph showing our Lab (room) Temperature that was out of tolerance for 2012 and Jan. - Feb. 2013. A supplemental air conditioning unit was installed on June 6th, 2012 to aid in temperature control of the BOD area. Since August 2012, we had between 0 - 2 days of out of the required Temperature Range. A new heating and air conditioning unit is scheduled for installation prior to October 2013 which should provide further improvement in temperature.

Sincerely,

**NOTE: 2 days out of 30 = 6% exceedance**

**2012 Room Temp. Out of Compliance** (outside 20 +/- 3 C)

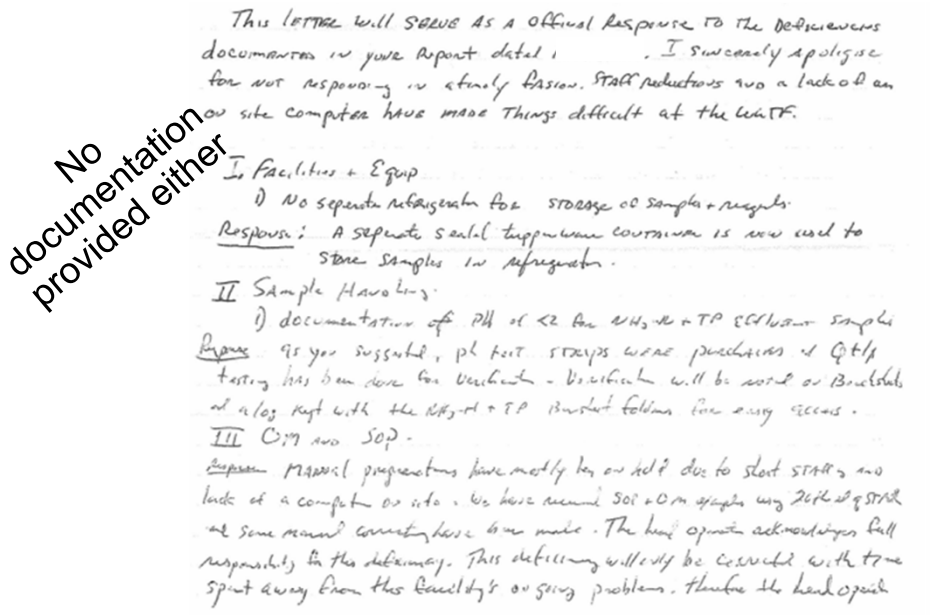



Did the new A/C unit fix the problem???

24

# Handwritten is OK…if it's legible

No documentation provided either



This letter will serve as a official Response to the deficiencies documented in your report dated . I sincerely apologize for not responding in a timely fashion. Staff reductions and a lack of an on site computer have made Things difficult at the unit.

I. Facilities + Equip

1) No separate refrigerator for storage of samples + reagents

Response: A separate sealed tupperware container is now used to store samples in refrigerator.

II Sample Handling.

1) documentation of PH of <2 for $NH_3$-N + TP preservation samples

Response as you suggested, pH test strips were purchased + QA/QC testing has been done for verification. Verification will be noted on Bench sheets or a log kept with the $NH_3$-N + TP Bench sheet folders for easy access.

III C/M and SOP.

Response manual preparations have mostly been on hold due to short staffing and lack of a computer on site. We have reviewed SOP + QM examples using Profs of staff and some minor corrections have been made. The lead operator acknowledges full responsibility in the deficiency. This deficiency will only be corrected with time spent away from the laundry's ongoing problems. Therefore the lead operator

25

# The repeat deficiency, the NON, and cutting some slack

I conducted an on-site evaluation of your laboratory on to determine compliance with Chapter NR 149, Laboratory Certification and Registration, Wisconsin Administrative Code. Enclosed is a report that summarizes the observations I made while at your laboratory.

This report also serves as a formal Notice of Non-Compliance (NON). This NON is being issued to your laboratory for the use of correction fluid to alter and obscure changes in bench records and for the lack of acceptable Initial Demonstrations of Capability for backup analysts. This is the second time your laboratory has been cited for the use of correction fluid. The Laboratory Certification Code (NR 149.39(1)g(3)) states that corrections or other alterations made to entries in records or documents may not obscure the original entry. The correction fluid obscured a large portion of TSS records. In regards to the IDC, NR 149.36 (3)(b) states that "*…the laboratory shall establish demonstration of capability criteria for determining that each person who performs testing on compliance samples using the method has demonstrated the necessary skills and expertise required to generate quality analytical results. The laboratory shall retain documentation that each person performing a given test on compliance samples has satisfied the demonstration of capability criteria established by the laboratory*". These issues are likely linked to the lack of credible commitment to training of backup analysts in the laboratory. Your laboratory must take steps to provide training to ensure these issues are resolved.

**The evaluation process necessitates that the following report focus on deficiencies and recommended improvements. The NON should in no way reflect on the competency of [redacted] the primary analyst and operator. He is very knowledgeable and a competent analysts. The use of correction fluid and IDC issues that led to the NON are linked to backup analysts that were not fully trained. The Village needs to make a credible commitment to provide fully trained backup analysts for the laboratory.**

26


27

What's the…

28

## How big an issue is this?

Since July 2011, 157 WWTP labs have been audited, received their report, and the case has subsequently been closed out.

In a sample of 51 audit reports…

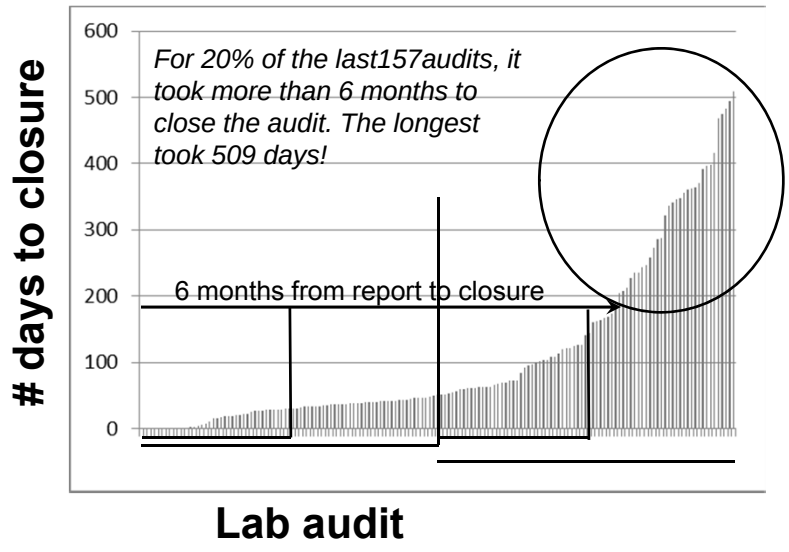
- an average of 5-6 deficiencies are cited per lab
- The largest number of citations was 17

The average time it took for the report was 23 days
The average time to closure was 132 days

132 days (4.5 months) is not too shabby.
But the standard deviation ***is*** pretty shabby: 129 days.
If we set control limits, that would mean that 99% of audits are closed between 0 days and 1.5 YEARS.

29

## It doesn't need to be this difficult




30

# Always start with the code. What does the NR 149 say?

31

Day 0 to Day 30

**NR 149.31 Evaluation reports. (1)** The department shall document the deficiencies of an on−site evaluation in reports issued to the evaluated laboratory.

**(2)** The report of an on−site evaluation shall be issued to a laboratory within 30 days of the conclusion of the on−site visit. ***We're doing it in 23 days on average***
When the department finds it necessary to issue an evaluation report at a date **later than 30 days** after the conclusion of an on−site visit, **the department shall notify the laboratory within 10 days** after the conclusion of the 30−day period about the delay. The notice shall include an expected delivery date for the report.

***Only 18 of 157 reports exceeded 30 d***

32

## Day 31 to Day 60

**NR 149.32 Evaluation corrective action. (1)** A laboratory shall take corrective action to address any deficiencies discovered during an on−site evaluation.
**(2) A laboratory shall submit to the department within 30 days from the evaluation report's date a plan of corrective action to address <u>all</u> the deficiencies noted in the report.** When a laboratory finds it necessary to submit a corrective action plan at a date **<u>later than 30 days</u>** after the evaluation report's date*, the laboratory shall notify the department about the delay* and provide an expected delivery date in consultation with the department.

33

**We're shooting to close out audits in 6 months (180 days) or less…**

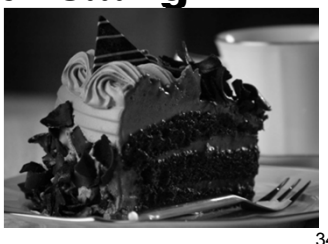
- **23 days on average to write report**
- **30 days to receive a response**

---

**= 127 days to review your response**

**This should be a piece of cake…right?**

**If we both do our parts**



34

## What comes after Day 60?

Review the response.

Let the lab know if additional materials are needed.

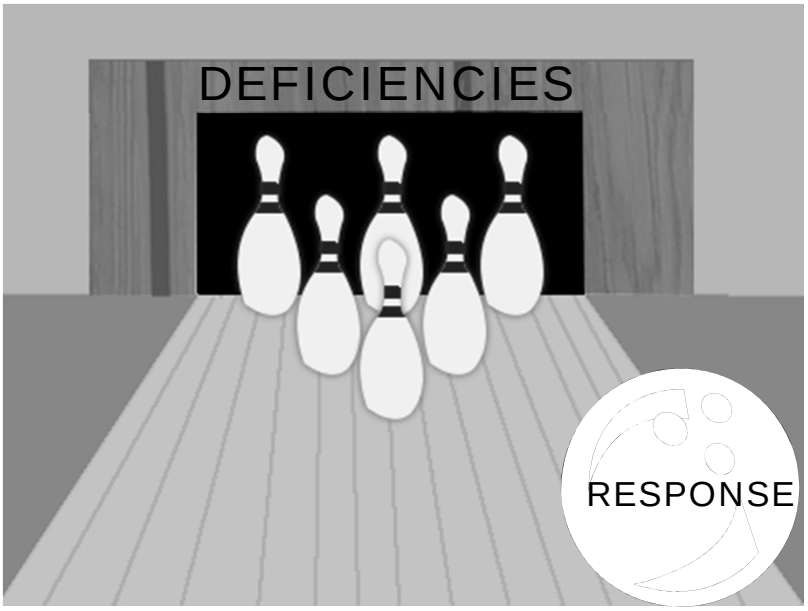
If all is complete within 180 days,

Close out the audit.

**OK…so the audit needs to be closed within 6 months if your response "gets it in one"**

35

## It's like bowling…




36

## What if you don't roll that strike?

(b) When the department determines that additional action or documentation is needed to evaluate compliance with this chapter, the department shall agree on a date for a **second corrective action plan** to be submitted in consultation with the laboratory.

**It's like bowling…you only get two shots.**

**But you need to pick up that spare !**

37

## What comes after Day 60?

1. When the department determines that *the second corrective action plan addresses all noted deficiencies satisfactorily*, the department shall inform the laboratory in writing that the evaluation process has concluded.
2. **When the department determines that the second corrective action plan does not address all the noted deficiencies** satisfactorily, the department may
   - schedule another on−site evaluation,
   - terminate any outstanding application that led to the audit or
   - direct enforcement to the laboratory.
3. When a second on−site evaluation is scheduled as a follow−up to a second corrective action plan, **the department shall establish deadlines that resolve any remaining unresolved deficiencies expeditiously, but no later than 90 days after the conclusion of the follow−up visit.**

38

# We don't want to re-audit or initiate enforcement action any more than you!

## So let's take corrective action

39

## Section VIII of the audit report is designed to help you respond

**VIII. SUPPORTING DATA**

For each of the deficiencies listed in this report, the laboratory must provide data that demonstrates that the corrective taken has resolved the deficiency. At a minimum, the following supporting data is to be sent with the audit response for the auditor to review.

If the deficiency requires a change in procedure that impacts the Quality Manual then a copy of the section in the Quality Manual that was updated must be sent.

If the deficiency requires a change in procedure that impacts the way that the laboratory performs their method procedure then a copy of the section in the Method SOP that was updated must be sent.

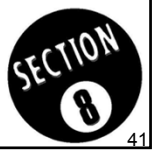

40

## Section VIII of the audit report is designed to help you respond

If the deficiency requires that **missing documentation be recorded then a copy of a benchsheet, analytical run, or *other record needs to be sent***. This data is provided to demonstrate that the appropriate records are now kept. When compiling the audit response make sure to include all of the supporting data that will demonstrate that the corrective actions taken have **resolved the cited deficiencies.**

One way to help speed up the review of your audit response and the audit closure is to organize the submittal as follows

- Indicate the corrective action that the laboratory has taken to resolve each deficiency listed in this report
- Provide that information in the order that the deficiencies are listed in this report
- Make sure that the supporting data that demonstrates the corrective action has been implemented is included for each deficiency
- Label the supporting data with the section and number of the deficiency




41

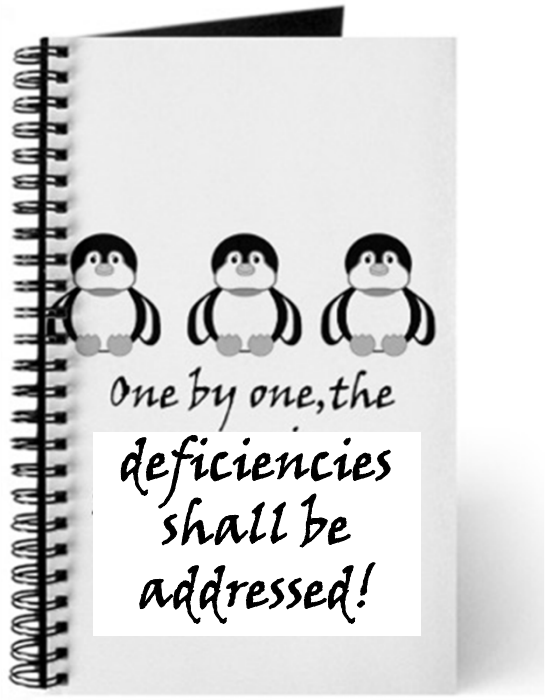
# Let's review and try to address common deficiencies

42

## Common deficiencies 51 Audits)

| | | |
|---|---|---|
| **Sample containers** | **36 of 53** | **(71%)** |
| **Thermometers** | **26** | **(51%)** |
| **Traceability records** | **25** | **(49%)** |
| **SOP issues** | **22** | **(43%)** |
| **Quality Manual issues** | **19** | **(37%)** |
| **BOD: super-saturation** | **19** | **(37%)** |
| Corrective action issues | 16 | (31%) |
| IDC issues | 11 | (22%) |
| Record permanence | 9 | (18%) |
| Barometer calibration | 9 | (18%) |
| Analytical balance checks | 6 | (12%) |
| Pipet verification | 4 | ( 8%) |
| Weight re-certification | 3 | ( 6%) |


43




44

# The laboratory does not have a procedure for verifying cleanliness of sample carboys and containers.

**II. SAMPLE HANDLING**

Samples are collected from 7 am to 7 am. Samples from other facilities are received without any preservation. With very rare exception, TSS, BOD, and TP analysis are performed on the same day that samples are collected.

**Deficiencies** – Supplemental Information – *Suggested Lab Response*

2. **The laboratory has not verified that the sample collection containers used do not contribute to the contamination of samples.**
   - NR 149.46 (1) (b) -

   Laboratories must have a standard operating procedure in place which addresses the concerns that the containers used to house samples are adequately cleaned and not contributing to the contamination of samples at levels which will affect sample determinations.

   The laboratory will need to address this requirement with the composite sampler containers used to collect samples that will be analyzed for TSS, BOD, $NH_3$-N, and TP. In addition, the laboratory will need to address this requirement with the bottles that are sent out to external clients for collecting samples. Data (from the bottle blanks) must be available to demonstrate that the containers used are of adequate cleanliness. See the handout I provided during the evaluation for further details on one way to address this issue.

   *Send me the results of your verification studies and the SOP or section of your Quality Manual that indicates how your laboratory is addressing this issue.*

45

# The laboratory does not have a procedure for verifying cleanliness of sample carboys and containers.

**II. Sample Handling**

2. (see sheet C)

C

**On a annual basis, Sample containers and Lab sample bottles are filled with reagent water (distilled water). The containers and bottles are filled for at least 24 hours. A aliquot of that water (sample) is then labeled Sample container / bottle blank.**

NOTE: Determination of BOD use 300ml
Determination of Total Suspended Solids use 500ml
Determination of Total Phosphorus use same volume as Method Blank.
Determination of Ammonia Nitrogen use same volume as Method Blank.

**Final results for Sample containers and Lab sample bottles to be acceptable must have a concentration of less than 2.0 mg/1 for BOD and TSS.** For **Total Phosphorus and Ammonia Nitrogen** the results **must be below the current LOD**

46

## The laboratory does not have a procedure for verifying cleanliness of sample carboys and containers.

**BOD Benchsheet** Facility

| Composite Sample Checks | | | Read In Calibration | |
|---|---|---|---|---|
| Sample ID + sample date | pH | Temp (°C) | Analyst | DS |
| 130416 Inf | 7 | 2.4 | Room Temp. (°C) | 20 |
| 130416 Eff | 7 | 2.6 | Local pressure (in Hg) | 29.6 |
| | | | DO Sat Chart (mg/L) | 8.75 |
| | | | DO Meter (mg/L) | 8.76 |
| | | | Date bottles in | 4/16/13 |
| | | | Time bottles in | 5:30pm |

| Method Number: | SM 5210B | Edition: | 21st |
|---|---|---|---|
| Read Out Calibration | | | |
| Analyst | DS | | |
| Room Temp. (°C) | 20 | | |
| Local pressure (in Hg) | 29.8 | | |
| DO Sat Chart (mg/L) | 9.01 | | |
| DO Meter (mg/L) | 9.10 | | |
| Date bottles out | 4/21/13 | | |
| Time bottles out | 5:21pm | | |

| Quality Control |
|---|
| Blanks ≤ 0.24 mg/L |
| GGA = 167.5 - 228.5 |
| Residual DO ≥ 1.0 mg/L |
| DO depletion ≥ 2.0 mg/L |

| Code Defintions |
|---|
| N = Extra nutrients added to sample |
| I = Inhibitor added to sample |
| P = Sample pre-diluted per SOP (≤ 3 mL) |

Traceability Lot # or Lab ID Information

| | | | | | |
|---|---|---|---|---|---|
| Dilution water nutrient pillow | A2023 | synthetic commercial seed | 84351 | GGA | B12D130207B2 |
| Sample bottle nutrient pillow | A2270 | | | | |

| Sample ID (include sample date) | Bottle ID | Sample Volume Used (mL) | Nutrient or Inhibitor added | Seed Volume added (mL) | Initial DO (mg/L) | Final DO (mg/L) | DO Depletion (mg/L) | Do due to Seed (mg/L) | Final Sample DO (mg/L) | Dilution Factor | BOD (mg/L) | Average BOD (mg/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 130416 Eff Bottle | 127 | 300 | Y | | 8.7 | 8.6 | | | | | | |
| 130416 Inf Bottle | 139 | 300 | Y | | 8.5 | 8.5 | | | | | | |

90 Days after Cleaning Bottles

C

47

## The laboratory does not calibrate all of its thermometers/ not currently calibrated.

I. **Facilities and Equipment**

1. We have added four NIST traceable thermometers for verifying room temperature influent and effluent BOD as well as for suspended solids, and another thermometer for the COD reactor and suspended solids oven. Invoice attached (see sheet A)

North Central Laboratories
1-800-648-7836
Fax: (715) 449-2454
www.nclabs.com
Email: nclabs@nclabs.com

NCLABS
FED ID: 39-1538387

A
*Lab Supplies since 1985*

INVOICE

INVOICE NO.

| QUANTITY | DESCRIPTION |
|---|---|
| 1 | ea TC-414, Digital Themom, 8"stem, -50 to 280C, NIST |
| 1 | Serial number for above: 68907 |
| 4 | 3.8 liter H-18, Hydrochloric Acid, 10%(v/v) |
| 1 | ea TC-452A, Digital thermom,8"stem 0.2C accuracy, NIST |
| 1 | Serial number for above: 111943599 |
| 1 | ea TC-452A, Digital thermom,8"stem 0.2C accuracy, NIST |
| 1 | Serial number for above: 111943695 |
| 1 | ea TC-452A, Digital thermom,8"stem 0.2C accuracy, NIST |
| 1 | Serial number for above: 122009970 |
| 1 | rl TM-94, pH paper, 1-14 |
| 1 | pk(100/pk) EM-9590, EM pH test strips, 0-14 |

48

## The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met.

**Deficiencies** – Supplemental Information – *Suggested Lab Response*
**1. The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met.** - NR 149.39 (3) –

Below I have listed areas that need to be corrected:
**a.** A policy that governs the permanence of records has not been created.
**b.** The sample date reported is not the date that the majority of the sample is collected.
**c.** The order in which samples are analyzed must be unequivocally clear for all tests.
**d.** Newly received chemicals are not documented at the time of receipt – they are only documented once they are opened for use.
**e.** NR 149 requires that the laboratory ensure that results of analyses be linked to all of the standards and reagents used to derive the results.
**f.** There is no documentation to support the preparation of lab prepared chemicals (reagents and standards).
**g.** Containers that house chemicals are sometimes insufficiently labeled.
**h.** The temperature of the COD reactor for each TP digestion is not documented.
**i.** Currently some dates are pre-filled out on benchsheets before they occur.
**j.** The theoretical DO content must be determined and documented on each day that the DO meter is calibrated.

49

## The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met.

Below I have listed areas that need to be corrected:

a. A policy that governs the permanence of records has not been created.

**a. (see sheet D)**

**b.** The sample date reported is not the date that the majority of the sample is collected.

**b. Sample date has been changed to reflect the date the majority of the sample is drawn. (see sheet M and R)**

**c.** The order in which samples are analyzed must be unequivocally clear for all tests.

**c. (see sheets N,O,P, and S,)**

.

50

**The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met.**

**b. The sample date reported is not the date that the majority of the sample is collected**

**b. Sample date has been changed to reflect the date the majority of the sample is drawn. (see sheet M and R)**

R

**Determination of Biochemical Oxygen Demand (BOD5)**
5-DAY BOD Technique
Reference: Standard Methods, 18th edition, Procedure 5210 B

For the Plant Lab
2/19/02
Revised March 19, 2012

**TESTING**

1) Turn on YSI 5100 Dissolved Oxygen Meter with 5010 BOD Probe.
2) Turn on the NIST Traceable thermometer located on top of the YSI 5100 Meter.
3) Turn on VWR Scientific Inc. Model 1230 (Shel-lab) Water Bath Incubator.
4) Retrieve Influent and Effluent Samples storage bottles from the Samplers.

10) Record all required data pertaining to that test date on the BOD5 bench sheet. Set up the Lab according to the Bench Sheet. (NOTE: Sample date and flow date are the same)

51

**The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met. - NR 149.39 (3) –**

Below I have listed areas that need to be corrected:

**d.** Newly received chemicals are not documented at the time of receipt – they are only documented once they are opened for use.

**d. (see sheet E and right margin of sheet F)**

**e.** NR 149 requires that the laboratory ensure that results of analyses be linked to all of the standards and reagents used to derive the results.

**e. Staff has started using a traceability binder that will show the analysis start and end dates.**

**f.** There is no documentation to support the preparation of lab prepared chemicals (reagents and standards).

**f. (see sheet G and H)**

52

d. Newly received chemicals are not documented at the time of receipt – they are only documented once they are opened for use.

**d. (see sheet E and right margin of sheet F)**

E

WWTP
Chemical / Reagent Traceability
for Total Phosphorus

NCL # P35A Phosphate Standard (1.00 ml = 5ug)(5ppm as P)
Lot # _____
Expiration Date _____
Received By _____
Date Received _____
Opened _____
End Date _____

F

WWTP
pH Calibtation Log

**Note: CHANGE pH REFERENCE BUFFERS DAILY.**
**CHECK ELECTRODE SLOPE DAILY (Slope should be in the 92 - 102 % Range)**

| ANALYST | DATE | TIME | BUFFERS USED | BUFFER TEMP. | SAMPLE TEMP. | pH | COMMENTS | NCL # B-47 Buffer Solution pH 7.00 |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Lot # _____ |
| | | | | | | | | Expiration Date _____ |
| | | | | | | | | Received By _____ |
| | | | | | | | | Date Received _____ |
| | | | | | | | | Opened _____ |
| | | | | | | | | End Date _____ |
| | | | | | | | | |

53

**The laboratory does not consistently document all of the records to ensure that method and code traceability requirements are met. - NR 149.39 (3) –**

Below I have listed areas that need to be corrected:

**g.** Containers that house chemicals are sometimes insufficiently labeled.

**g. (see picture on sheet I)**

**h.** The temperature of the COD reactor for each TP digestion is not documented

**h. (see sheets J and K)**

i. Currently some dates are pre-filled out on benchsheets before they occur.

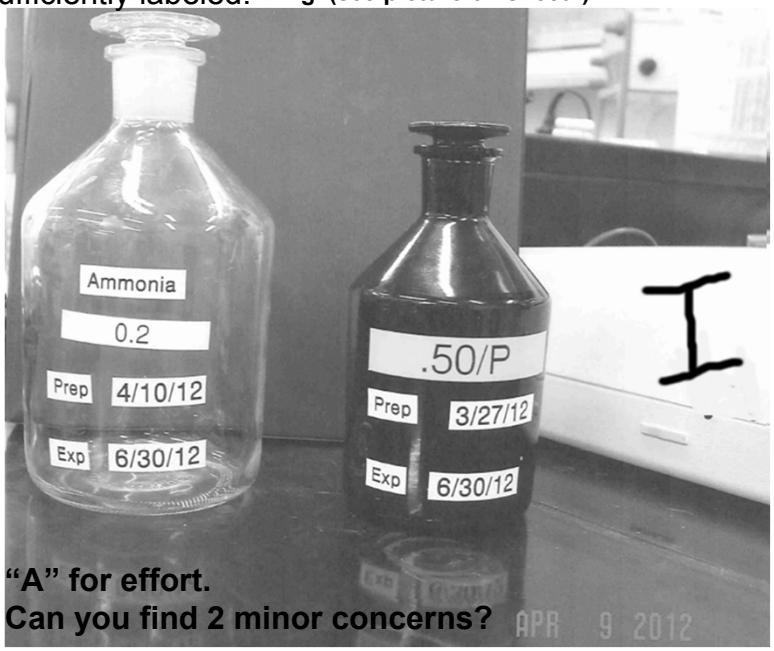
**i. Staff is now filling in dates on the day of analysis.**

**j.** The theoretical DO content must be determined and documented on each day that the DO meter is calibrated.

**j. (see sheets Land M)**

54

g. Containers that house chemicals are sometimes insufficiently labeled. **g. (see picture on sheet I)**




**"A" for effort.**
**Can you find 2 minor concerns?**

55

## The laboratory's SOPs do not address all of the required elements.

**2. The method SOPs do not address all of the required elements.**
- NR 149.40 (2) -
Method SOPs (TSS, BOD, NH3-N, and TP) need to address each of the elements required in NR 149 section 149.40 (2) (d). It is best if the methods are written in a recipe format so that anyone could perform the method following the instructions in the SOP. The missing items can be added at the end of your SOP. See the method SOP checklist I handed out during the audit.
*Send me a copy of your method SOPs when they are completed.*

3. **The quality manual does not address all of the required elements. The method SOPs do not address all of the required elements.**
I am in the process of re-writing my quality manual. I will send you a copy of the manual when I am finished.

Let's review what the required elements are

56

# SOPs (149.40)

**NR 149.40 SOPs. (1)** General requirements.

(a) Labs shall maintain written SOPs that document or reference activities needed to maintain their quality systems and that enable performing or reproducing an analysis in its entirety as performed at the lab.

(b) SOPs may be documents written by lab personnel or may consist entirely of copies of published documents, manuals or procedures **if the lab follows the chosen source exactly**.

(c) SOPs may consist in part of copies of published documents, manuals or procedures if**:**

1. Modifications to the published source are described in writing in additional documents.

2. Clarifications, changes or choices are completely described in additional documents, when methods offer multiple options, ambiguous directives or insufficient detail to perform or reproduce an analysis.

(d) SOPs shall indicate their dates of issue or revision.

57

Solids, residue at 105°C, suspended, gravimetric

Parameter and Code:
Solids, residue at 105°C, suspended, I-3765-85 (mg/L): 00530

**1. Application**
This method may be used to determine the suspended-solids concentration of any natural or treated water or industrial waste.

**2. Summary of method**
2.1 Suspended solids are those that are retained on a glass-fiber filter. The determined value is fairly representative of the sample but does not accurately represent the suspended sediment concentration of a stream; suspended solids values should not be confused with sediment concentration, which is the more accurate measure of material in suspension.
2.2 The unfiltered sample is mixed thoroughly and an appropriate volume is rapidly poured into a graduated cylinder. The suspended solids are collected on a glass-fiber filter, and the insoluble residue is dried and weighed.

**3. Interferences**
Precipitation in the sample during storage, such as iron, will produce erroneously high results.

**4. Apparatus**
4.1 *Desiccator,* charged with indicating silica gel or other efficient desiccant.
4.2 *Filtration apparatus,* consisting of suction flask, gooch crucible, glass-fiber filter disk, and suitable holder.
4.3 *Oven,* 105°C, uniform temperature throughout.

**6. Procedure**
6.1 Shake the sample bottle vigorously and rapidly pour a suitable volume into a graduated cylinder. Record the volume.
6.2 Quantitatively collect the suspended material from the sample on a tared glass-fiber filter disk. A blank should be determined with each set of samples.
6.3 Wash the suspended material on the filter sparingly with demineralized water.
6.4 Dry the residue and filter disk overnight at 105°C.
6.5 Cool in a desiccator and weigh the filter disk containing the dry residue to the nearest 0.1 mg. Record the weight.

**7. Calculations**
7.1 Apply a correction for any loss shown by the blank.
7.2 Determine suspended solids in milligrams per liter as follows:

$$\text{Suspended solids, mg/L} = \frac{1000}{\text{mL sample}} \times \text{mg residue}$$

**8. Report**
Report solids, residue at 105°C, suspended (00530), concentrations as follows: less than 1,000 mg/L, whole numbers; 1,000 mg/L and above, three significant figures.

**9. Precision**
Precision data are not available for this method.

Reference

Guy, H. P., 1969, Laboratory theory and methods for sediment analysis: Techniques of Water-Resources Investigations of the U.S. Geological Survey, book 5, chapter C1, 58 p.

# SOPs: How to use a referenced method

This is your SOP ONLY if you are following this method precisely. In addition, if the method offers any flexibility in options, you must specify what specific course of action you follow.

**Add an SOP Addendum to your SOP.**

58

## Example: SOP Modifications addendum

**ACME SOP # TSS- I-3765-85**

**Revision Date:** _____

ACME Lab follows USGS method I-3765-85 for the analysis of TSS with the exception of the following modifications or clarifications where the method presents flexibility or options.

- 4.2 – Do not use Gooch crucibles, use Millipore filter funnel, 45 mm filters.
- 4.3, 6.4 - Oven temperature is allowed to be 103-105 ºC (104 ± 1 ºC).
- 6.1 - Generally use 500 mL for effluent, 25 mL for influent. Sample is stirred continuously with magnetic stir bar until sample aliquot is removed.
- 6.2 - Blanks are not analyzed, an exemption allowed in ch. NR 149.14(3)(d)
- 6.4- Samples are dried overnight (at least 8 hours). The laboratory performs a verification of drying effectiveness quarterly as per DNR letter (May 2001).
- 7.1- No correction for blank results is allowed by NR 149.
- NOTE 1. Sample preservation is not to exceed 6 ºC and not to be frozen.
- NOTE 2. Filters from NCL, deemed to be equivalent to method specs.
- NOTE 3. Use 3 x 25-mL portions of reagent water to wash filters.
- NOTE 4. Filters undergo 3X final wash of 20, 20, and 10 mL of reagent water.

59

## Methods Manual- if you write your own SOPs

NR 149.40 Standard operating procedures.

**(2) Analytical methods manual**. (a) The **lab shall have and maintain a list describing analytical test methods performed for programs covered by this chapter**.

(b) The analytical methods manual **may consist of published or referenced test methods**, or SOPs written by the lab as allowed in this section.

(c) The essential elements of test methods required in par. (d) may be presented in narrative, tabular, schematic or graphical form. The analytical methods manual shall be an identifiable document in hard copy or electronic format traceable to the lab.

(d) **When the analytical methods manual consists of SOPs written by the laboratory, each SOP <u>shall include, address</u> <u>or refer to, at a minimum</u>**, the following elements:

1. Identification of the test method.
2. Applicable analytes.
3. Applicable matrices.
4. Method sensitivity.
5. Potential interferences.
6. Equipment and analytical instruments.
7. Consumable supplies, reagents and standards.
8. Sample preservation, storage and hold time.
9. QC samples and frequency of their analysis.
10. Calibration and standardization.
11. Procedure for analysis.
12. Data assessment and acceptance criteria for QC measures.
13. Corrective actions and contingencies for handling out of control or unacceptable data.

60

**The laboratory's Quality Manual does not address all of the required elements.**

Let's review what the critical elements are

61

## Quality Manual

**NR 149.37 Quality manual. (1)** Purpose and general provisions. The lab's quality system shall be defined in a **quality manual**, **however named**. All policies and procedures governing the lab's quality system shall be documented or referenced in the quality manual. **All lab personnel shall follow the policies and procedures established by the quality manual**.

**(2)** Format. The quality manual **shall have a format**, however conceived, **that addresses the content elements specified in this section**. Content elements may be presented in narrative, tabular, schematic or graphical form. The manual shall be in hard copy or electronic format traceable to the lab.

62

# Quality Manual must include:

**NR 149.37 (3)** Content. The quality manual shall include, address or refer to, at a minimum, the following elements:

(a) Organization and management structure of the lab.

(b) Procedures for retention, control and maintenance of documents used in or associated with analyses.

(c) Procedures for achieving traceability of standards, reagents and reference materials used to derive any results or measurements.

(d) Procedures for handling samples.

(e)Lists of major analytical instruments and support equipment.

(f) Procedures for calibration, verification and maintenance of major analytical instruments and support equipment.

61

# Quality Manual must include:

(g) Procedures for evaluating quality control samples, including, but not limited to, method blanks, LCS, MS/MSD, and replicates.

(h) Procedures for initiating, following up on and documenting corrective action addressing QA and QC failures, discrepancies or nonconformance.

(i) Procedures for reviewing analytical data and reporting analytical results.

**(4)** Revisions. **The quality manual shall be kept current by the responsible party**, however named, for maintaining the lab's quality system. **All** editions or **versions of the quality manual shall indicate the dates in which they were issued or revised.**

64

# Critical sample pre-treatment is not performed as required for BOD analysis .

**VII. ANALYTICAL TECHNOLOGY**

**A. Oxygen Demand Assays: SM 5210B**

**Deficiencies** – Supplemental Information

1. **Samples are not treated properly for DO supersaturation.**
   - SM 5210B (4) (b) -

Samples must be properly treated for DO saturation. Proper DO saturation is a saturation that is very close to the saturation point. It is easier to remove DO from samples when they are warmed to 22.0 – 23.0 °C. Shaking them vigorously, sometimes multiple times, is often required to remove supersaturated DO from the samples. Currently, the laboratory reports many initial dissolved oxygen values that are greater than 9.

65

# Critical sample pre-treatment is not performed as required for BOD analysis .

**VII. ANALYTICAL TECHNOLOGY**

**A. Oxygen Demand Assays: SM 5210B**

1. **Samples are not treated properly for DO supersaturation.**

The BOD method has been changed to reflect treatment of final effluent samples to remove supersaturation. Attached bench sheets confirm that DO values are below 9.0. The attached SOP emphasizes requirements for proper room temperature, treatment for DO supersaturation (and addresses that analysis be completed in 30 minutes as found in the supplemental letter.)

4) Samples supersaturated with DO are brought to about 20°C, and the sample is shaken vigorously for 1 minute. **Final effluent is always shaken for 1 minute**. To properly treat for DO saturation, especially during winter months, the final effluent sample is warmed to 22.0-23.0 °C. The sample is poured into a 2 liter bottle and shaken vigorously, allowed to sit with the cap off; the process is repeated at least once to remove supersaturated DO.
5) Sample temperature adjustment – Just before analysis, all samples are brought to 20±3°C by placing them in a warm water bath. Samples needing dilution should be brought to 20±3°C before dilution. The room temperature is controlled to meet test requirements of 20±3°C. The room temperature is recorded on the bench sheet and QC book daily. Any deviation beyond the acceptable limits will result in corrective action of having the room temperature controller raised or lowered electronically to bring the lab into the correct temperature range.

****The temperature requirement of 20±3°C is used by the DNR for audit evaluation, and to clear confusion regarding temperature requirements found in different versions of Standard Methods.**

6) Nitrification inhibition: 0.16 grams Hach 2533 is added to the inhibited final

66

**Critical sample pre-treatment is not performed as required for BOD analysis .**

IN Baro.Read(in.Hg) 27.47 IN H2O Temp C 21.3 IN Cal Value 8.70 *** OU

UV DISINFECTION USED. CHECK HERE IF EQUALIZATION TANK IS IN SERVICE FOR

| Set Code: | Sample Date | Seed Name | Seed Volume | Setup |
|---|---|---|---|---|
| *PLT | 02/27/13 to 02/28/13 | DS1 | 5 | 11:16 02/28/13 |

| Bottle | Seed | Vol | Type | Set | QA | Sample Name | Sample Date | DO Initial | DO Final |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | 300 | B | PLT | 1 | Blank | 02/28/13 | 8.73 | |
| 2 | | 300 | B | PLT | 1 | Blank | 02/28/13 | 8.71 | |
| 3 | | 300 | B | PLT | 1 | Blank other | 02/28/13 | 8.70 | |
| 4 | DS1 | 15 | B | PLT | 0 | Seed | 02/28/13 | 8.60 | |
| 5 | DS1 | 20 | B | PLT | 0 | Seed | 02/28/13 | 8.50 | |
| 6 | DS1 | 25 | B | PLT | 0 | Seed | 02/28/13 | 8.42 | |
| 7 | S1 | 6 | B | PLT | 3 | GGA | 02/28/13 | 8.68 | |
| 8 | S1 | 6 | B | PLT | 3 | GGA inhibited | 02/28/13 | 8.72 | |
| 9 | | 5 | B | PLT | 0 | RAW | 02/27/13 | 8.58 | |
| 10 | | 10 | B | PLT | 0 | RAW | 02/27/13 | 8.53 | |
| 11 | | 15 | B | PLT | 0 | RAW | 02/27/13 | 8.41 | |
| 12 | | 5 | B | PLT | 0 | PI | 02/27/13 | 8.66 | |
| 13 | | 7 | B | PLT | 0 | PI | 02/27/13 | 8.63 | |
| 14 | | 10 | B | PLT | 0 | PI | 02/27/13 | 8.63 | |
| 15 | | 15 | B | PLT | 0 | PE | 02/27/13 | 8.52 | |
| 16 | | 20 | B | PLT | 0 | PE | 02/27/13 | 8.44 | |
| 17 | | 25 | B | PLT | 0 | PE | 02/27/13 | 8.34 | |
| 18 | S1 | 50 | B | PLT | 0 | FIN | 02/27/13 | 8.73 | |
| 19 | S1 | 70 | B | PLT | 0 | FIN | 02/27/13 | 8.70 | |
| 20 | S1 | 100 | B | PLT | 0 | FIN | 02/27/13 | 8.68 | |
| 21 | S1 | 120 | B | PLT | 0 | FIN | 02/27/13 | 8.62 | |
| 22 | S1 | 150 | B | PLT | 0 | FIN | 02/27/13 | 8.69 | |

BOD WORKSHEET -bod02-28.bod

67

## Corrective actions are not consistently documented as required.

IV. **Traceability and Records**

**2. Corrective actions are not documented as required**

Corrective actions are now kept in a separate binder and documented on the corrective action logbook form (sheet X). Page 17 (sheet W) should be placed in the _____ Quality Assurance document. This sheet details the procedures for corrective actions. Corrective actions will be documented using the Corrective Action sheet (sheet Y). Maintenance actions will be documented on a separate form. These forms have been included (sheet Z1,Z2, Z3, Z4).

68

# Corrective actions are not consistently documented as required.

**Corrective Action Logbook Form** [version (5/1/03)]

Instructions: Complete this form and save it. If you need more than one line you can just continue on the next line. Include as much detail as you can. You do not have to limit yourself to one line per entry. Use as much space as you need to explain the situation clearly.

*Example QC failures (there are others)*

| | | | |
|---|---|---|---|
| Method blank | LCS | Replicate (duplicate) | Matrix spike |
| QCS samples | Proficiency Testing samples | Calibration | Lab policy or procedure not followed |

| Date | Test | What was the problem (or what failed)? | What was done to try and fix the problem? | Did the fix work? (Y/N) | Qualify data (Y/N) | How do you know the fix worked? | Analyst Initials |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

This form is just one example of how to document corrective actions. There are many ways that corrective actions can be documented. If you have any questions on this form contact the Laboratory Certification and Registration Program.

69

# Corrective actions are not consistently documented as required.

9. **PROCEDURES FOR INITIATING, FOLLOWING UP ON AND DOCUMENTING CORRECTIVE ACTION ADDRESSING QUALITY ASSURANCE AND QUALITY CONTROL FAILURES, DISCREPANCIES OR NONCONFORMANCE**

a. Corrective action is initiated when any situation becomes apparent which may affect data quality (i.e., consistent QC parameter failure, or failure of a PT sample). When it has been determined that a corrective action is needed the analyst accurately documents all the required information on a Corrective Action Log that is kept in the Corrective Action Logbook Binder. All documented Corrective Actions must be reported on the DMR.

b. Lab analysis bench sheets or computer programs have built-in Quality Control measures to help identify documental Corrective Actions.

c. Data affected over time by the corrective action are referenced in the log. The situation is monitored for improvement and noted are made in the corrective action logbook. If the situation does not improve as expected, a new corrective action is undertaken and documented in the same manner as the initial attempt. This cycle continues until the situation has reached a state of acceptability.

| | |
|---|---|
| PLAN | Design or revise laboratory process components to improve results. |
| DO | Implement the plan and measure its performance. |
| CHECK | Assess the affect of the improvements |
| ACT | Decide on changes needed to improve the process. |

70

# Corrective actions are not consistently documented as required.

21

Year _____

| DATE | ANALYST | BOD MAINTENANCE ACTIONS |
|---|---|---|
| | | |
| | | |
| | | |

TOTAL SUSPENDED SOLIDS MAINTENANCE ACTIONS

24

Year _____

| Analyst | Date | Description |
|---|---|---|
| | | |
| | | |

NITROGEN AMMONIA MAINTENANCE ACTIONS

22

Year _____

| Analyst | Date | Description |
|---|---|---|
| | | |
| | | |
| | | |

TOTAL PHOSPHORUS MAINTENANCE ACTIONS

23

Year _____

| Analyst | Date | Description |
|---|---|---|
| | | |
| | | |
| | | |

71

# Initial Demonstrations of Capability (IDCs) have not been completed.

[redacted] Treatment Plant [redacted]

**NR 149 Compliance Evaluation** [redacted] **page 5**

**V. QUALITY CONTROL**

**Deficiencies** – Supplemental Information – *Suggested Lab Response*

1. **Initial demonstrations of capability (IDCs) have not been completed as required.**
   - NR 149.36 (3) -

   The laboratory must document what their IDC criteria are for each test (BOD, TSS, $NH_3$-N, and TP). The Laboratory Manager must decide what the criterion is that all analysts must pass for each test the laboratory is accredited for. A supervisor cannot just grant an analyst approval without any data to support that the analyst is proficient to analyze a test – that is not an acceptable IDC. An analyst is only qualified to analyze samples for each method they have passed an IDC for. The laboratory must also maintain the documentation for each analyst's IDC in an organized fashion. Records must be available to show which analysts have passed an IDC and for which tests. It is critical that all analysts complete the IDC before they perform sample analysis.

   *Send me what the laboratory has defined as the IDC requirements for each test. Also let me know how the laboratory is organizing the IDC records for each analyst and send me those results.*

5. **Initial demonstrations of capability (IDCs) have not been completed as required.**
   I have established requirements for each test for each operator [redacted] superintendent) has promised me that he will make available every one of the operators who do not have an IDC. The first thing that each operator has to do is read the SOP

72

# Initial Demonstrations of Capability (IDCs) have not been completed.

[redacted] TREATMENT PLANT Initial Demonstrations of Capability

Revised October 10, 2012

The capability of the operators to do the various laboratory tests in the absence of the lab tech is determined by the Laboratory manager. The criteria for the IDC is for the operators to realize that the SOPs for each test are not guides but the way the test is to be run.

The rest of the requirements are that the BOD is to be set up with the G/GA and then reading it five days later having not failed the G/GA or the blank.

The requirement for the ammonia is to set up the test (after successfully calibrated the machine and gotten a good slope) and pass the LCS.

The successful candidate for the TSS IDC has to analyze the final and the raw samples for a day and prepare the empty filters.

The successful candidate must also run a total phosphorus and pass the CCV.

The operators also have to be able to set up and read a total coliform test, run the pH, and set up a Total Solids test.

These tests have to be done in my presence.

[redacted] have passed all these tests and I feel confident that they can do the work. They have truly demonstrated their capability in the lab.

73

# Records are not maintained in a manner that ensures their permanence and security.

**IV. TRACEABILITY and RECORDS**

**Deficiencies** – Supplemental Information – *Suggested Lab Response*

2. **In some cases corrections to records or documents obscure the original entry.**
   NR 149.39(1)g(3) --

   Handwritten records must be written in ink. Correction fluid (e.g., "white-out") must not be used because it obscures the original entry. Any errors should be corrected by drawing a single line through the erroneous result rather than completely scratching out the mistake. The correct information should then be written near the old value along with your initials.

   *Let me know your plan for resolving this issue.*

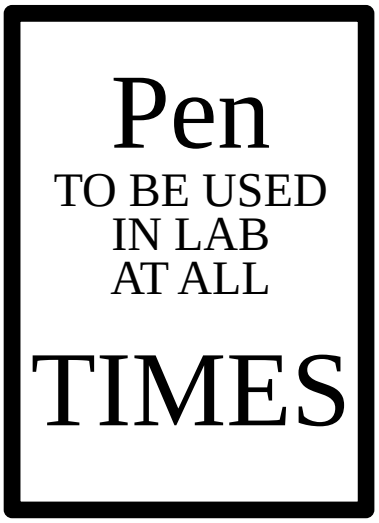
IV. Traceability and Records.
2) Corrections. white-out is not normally used to make corrections. Lead operator reviewed Bench sheets with remaining operators and proper correction procedures were also discussed.

74

## Is this enough?


**Bet you saw a few of these on your way here.**
**Did you follow those?**

**Lab response to a deficiency related to record permanence**




75

## Does this have a little more meat?

I acknowledge my understanding that the use of pencil or correction fluid/materials of any kind is strictly prohibited in the laboratory. I understand that indelible ink is required for all laboratory records and that errors shall be corrected by drawing a single line through the error, writing the correction above it and adding my initials and the date. My supervisor has discussed this with me including any sanctions for failure to comply.

*Print Employee Name*:

_____

*Employee Signature:*

_____*(date)* _____

76

# The room barometer is not verified for accuracy.

2. Repeat: **The barometer used to measure atmospheric pressure is not verified for accuracy.**
   - NR 149.44 (3) (a) -

   The laboratory must ensure that pressure measurements are accurate. Room aneroid barometers must be checked for accuracy at a minimum each year and I would recommend each six months.

   *Let me know the plan for checking the accuracy of the barometer. Send me the records that show the barometer has been verified as required. Update this requirement in the Quality Manual or BOD SOP.*

**Enclose please find the corrections the Laboratory has made to clear up deficiencies:**

**I. Facilities and Equipment, 1. & 2.**

**2. The room barometer is not verified for accuracy.**

**We are now using the spreadsheet to record our barometer readings monthly, and a barometer reading is measured and recorded on each BOD analysis day bench sheet.**

77

# The room barometer is not verified for accuracy.

**Monthly DO Meter Barometric Pressure Verification Log**

**Laboratory or Facility Name** r Treatment Plant Laboratory

**Facility Elevatation** 856 feet

**Meter or barometer model:** YSI Model 5100 DO meter

BP=Barometeric Pressure

**Note: Facility should fill in the highlighted fields only.**

| Month | Date | Initials | Official BP (mm Hg) | Official source that current local pressure was taken from | Local Elevation Correction Factor | Official elevation corrected BP (mm Hg) | Measured BP at facility (mm Hg) | Difference between facility and official BP (mm Hg) | Facility BP adjustment Required? (*adjust if >5 mm Hg difference*) |
|---|---|---|---|---|---|---|---|---|---|
| JAN | 1-23-13 | KML | 741.2 | | 0.972 | 737.8 | 737 | -2.3 | NO |
| FEB | | | | | 0.972 | | | | |

Facility Elevation (ft) 856

$$\text{Local Elevation Correction Factor} = CF = \frac{760 \text{ mm Hg} - (\text{facility elevation, ft} \times 0.026)}{760 \text{ mm Hg}} = \frac{760 \text{ mm Hg} - (856 \times 0.026)}{760 \text{ mm Hg}} = \frac{737.7}{760} = 0.97066$$

Note: To convert "in Hg" to "mm Hg" multiply by 25.4

Example: 29.2 in Hg x 25.4 = 742 mm Hg

78

## The accuracy of volumetric dispensing devices is not verified at least quarterly.

**Deficiencies** – Supplemental Information – *Suggested Response*
**1. Mechanical pipette verifications are not performed. --NR 149.44(3)(i)—**
**The laboratory has not checked their mechanical pipettes for accuracy**. NR149.44(3)(i) require mechanical pipettes to be checked for accuracy quarterly. Verification must be evaluated statistically. A link to a video demonstration and a written procedure were sent to the facility after the on-site evaluation to provide guidance on how to complete and document this task. Since the laboratory's pipettes are variable volume models, they should be tested for accuracy at 2-3 volumes (e.g., low, middle and high volumes). The volumes selected for testing should correspond to the volumes typically used in sample analysis.

*The laboratory must send a copy of the results from their pipette verification along with their response to show this deficiency has been resolved. The laboratory may wish to use the form and video from the link sent to them after the on-site evaluation to perform and document the pipette checks.*

79

## The accuracy of volumetric dispensing devices is not verified at least quarterly.

**Enclose please find the corrections the Laboratory has made to clear up deficiencies:**

**I. Facilities and Equipment, 1. & 2.**

**1. Mechanical pipette verifications are not performed.**

**Enclosed please find a copy of the results from our pipette verification, indicating that our pipettes are now acceptable for accuracy in our laboratory testing. The video was of great help.**

80

## The accuracy of volumetric dispensing devices is not verified at least quarterly.

**Quarterly Pipette Calibration (gravimetric)***

| | | | | | |
|---|---|---|---|---|---|
| Date | 1/29/13 | Analyst | KML | Balance | VO 214 |
| Temp. (C) | 21 | Z-Factor | 1.0031 | Serial # | O11120307 |

| Pipette # | Tensette 1ml |
|---|---|
| VOLUME (ml) | WEIGHT (g) |
| 0.50 | 0.497 |
| 0.50 | 0.498 |
| 0.50 | 0.497 |
| 0.50 | 0.495 |
| MEAN | 0.49675 |
| CORR. MEAN | 0.49829 |
| STD DEV | 0.00126 |
| % CV | 0.252524821 |
| % INACC. | 0.342015 |
| PASS / FAIL ? | PASS |

| Pipette # | Tensette 10ml |
|---|---|
| VOLUME (ml) | WEIGHT (g) |
| 1.00 | 0.989 |
| 1.00 | 0.986 |
| 1.00 | 0.990 |
| 1.00 | 0.985 |
| MEAN | 0.98750 |
| CORR. MEAN | 0.99056 |
| STD DEV | 0.00238 |
| % CV | 0.240315896 |
| % INACC. | 0.943875 |
| PASS / FAIL ? | PASS |

81

## Weights used for analytical balance verifications are not properly certified.

2. **The laboratory does not adequately perform monthly balance accuracy checks.**
   **--NR 149.44 (3) (g)--**

   The laboratory uses various sized Class S weights ranging from 5 mg to the gram size to perform balance accuracy checks monthly. The laboratory only checks one weight per month, not one in the mg and gram size as required by code. The QA Officer acknowledged the weights were old and none had valid certificates. Multiple weights were stored loose in plastic bottles and showed noticeable discoloration from age and poor storage conditions. Analytical balances must be checked at least monthly with at least 2 certified Class-1 weights, one weight in the gram range and one weight in the milligram range (e.g., 50 mg and 1 g). This check must be documented and the weights need to be recalibrated by an outside metrology company every five years.

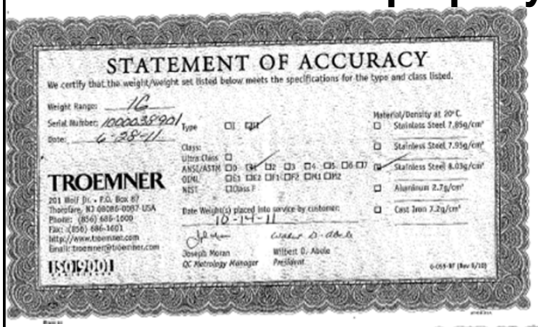
*The laboratory must order replacement weights or have the current weights recertified. The laboratory needs to send copies of the weight certificates to confirm this deficiency has been resolved.*

Deficiency: ***The laboratory does not adequately perform monthly balance accuracy checks.***

Response: On October 10, we replaced the current weights. We ordered from NCL a 1 g and 50 mg certified weights. Copies of the weight certificates are included. We added to our computerized maintenance program the task of recalibrating or replacing these weights every five years.

82

## Weights used for analytical balance verifications are not properly certified.



STATEMENT OF ACCURACY

We certify that the weight/weight set listed below meets the specifications for the type and class listed.

Weight Range: 1g
Serial Number: 1000038901
Type: ☐1 ☑2
Date: 6-28-11

Class:
Ultra Class ☐
ANSI/ASTM ☐0 ☐1 ☑2 ☐3 ☐4 ☐5 ☐6 ☐7
OIML ☐E1 ☐E2 ☐F1 ☐F2 ☐M1 ☐M2
NIST ☐Class F

Material/Density at 20°C.
☐ Stainless Steel 7.85g/cm³
☐ Stainless Steel 7.95g/cm³
☑ Stainless Steel 8.03g/cm³
☐ Aluminum 2.7g/cm³
☐ Cast Iron 7.2g/cm³

Date Weight(s) placed into service by customer: 10-14-11

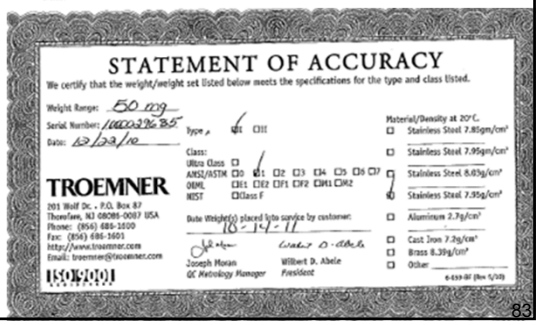
TROEMNER
201 Wolf Dr. • P.O. Box 87
Thorofare, NJ 08086-0087 USA
Phone: (856) 686-1600
Fax: (856) 686-1601
http://www.troemner.com
Email: troemner@troemner.com

ISO 9001

Joseph Moran
QC Metrology Manager

Wilbert D. Abele
President

G-033-W (Rev 5/10)



STATEMENT OF ACCURACY

We certify that the weight/weight set listed below meets the specifications for the type and class listed.

Weight Range: 50 mg
Serial Number: 1000038635
Type: ☐1 ☑2
Date: 12/22/10

Class:
Ultra Class ☐
ANSI/ASTM ☐0 ☑1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
OIML ☐E1 ☐E2 ☐F1 ☐F2 ☐M1 ☐M2
NIST ☐Class F

Material/Density at 20°C.
☐ Stainless Steel 7.85gm/cm³
☐ Stainless Steel 7.95gm/cm³
☑ Stainless Steel 8.03g/cm³
☐ Stainless Steel 7.95g/cm³
☐ Aluminum 2.7g/cm³
☐ Cast Iron 7.2g/cm³
☐ Brass 8.39g/cm³
☐ Other

Date Weight(s) placed into service by customer: 10-14-11

TROEMNER
201 Wolf Dr. • P.O. Box 87
Thorofare, NJ 08086-0087 USA
Phone: (856) 686-1600
Fax: (856) 686-1601
http://www.troemner.com
Email: troemner@troemner.com

ISO 9001

Joseph Moran
QC Metrology Manager

Wilbert D. Abele
President

G-033-W (Rev 5/10)

83

84

## Remember the Pickle Pledge?

# I've Taken The Pickle* Pledge

**"I will turn every complaint into either a blessing or a constructive suggestion."**

**By taking *The Pickle Pledge*, I am promising myself that I will no longer waste my time and energy on blaming, complaining, and gossiping, nor will I commiserate with those who steal my energy with their blaming, complaining, and gossiping.**

** So-called because chronic complainers look like they were born with a dill pickle stuck in their mouths.*



85

## Now comes the Deficiency Declaration

**I will do _____ faithfully.**

**This is how I will do _____.**

**Here is proof that I am doing it.**

**…and I will prepare my response in the same sequence as deficiencies appear in the report and label all attachments with the deficiency number**


86

# This is your quest….the Perfect Game

This is what you're all shooting for!

: Laboratory
**NR 149 Compliance Evaluation** page 4

**I. FACILITIES and EQUIPMENT**

No significant deficiencies were identified.

**II. SAMPLE HANDLING**

No significant deficiencies were identified.

**III. QUALITY MANUAL and SOPs**

No significant deficiencies were identified.

**IV. TRACEABILITY and RECORDS**

No significant deficiencies were identified.

**V. QUALITY CONTROL**

No significant deficiencies were identified.

**VI. TEST REPORTS**

No significant deficiencies were identified.

**VII. TECHNOLOGY - ANALYTE**

**A. OXYGEN DEMAND ASSAYS – BOD**

No significant deficiencies were identified.

**B. COLORIMETRIC TECHNOLOGY – TOTAL PHOSPHOURUS**

No significant deficiencies were identified.

**C. GRAVIMETRIC ASSAYS – TSS**

No significant deficiencies were identified.

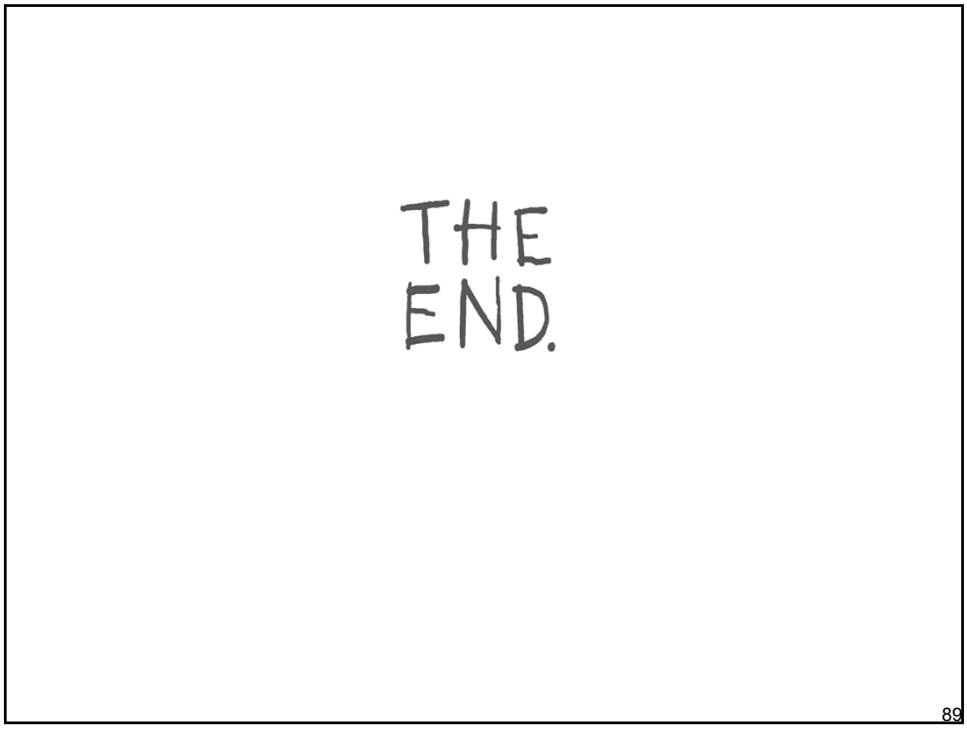
87

# That was then…….this is now


**7:00 AM...the audit begins**


**3:00 PM…ball's in YOUR court now**

88


THE
END.
89