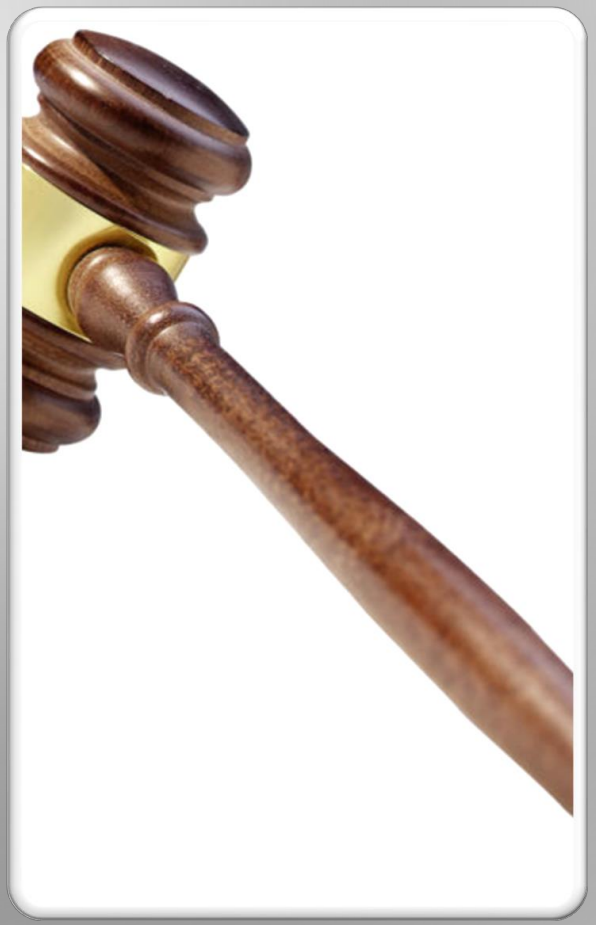
# DEFENSIBLE DATA – WHAT IS IT?

PRESENTED BY: MARCY BOLEK

# DEFENSIBLE DATA DEFINITION

DATA OF KNOWN QUALITY GENERATED BY A LABORATORY PERFORMING ANALYSIS WITHIN A DEFINED SET OF PROCEDURES, CONTROLLED DOCUMENTS AND BY ANALYSTS WHO HAVE DEMONSTRATED CAPABILITY OF PERFORMING THE TESTS WITHIN DISTINCT ACCEPTANCE CRITERIA.



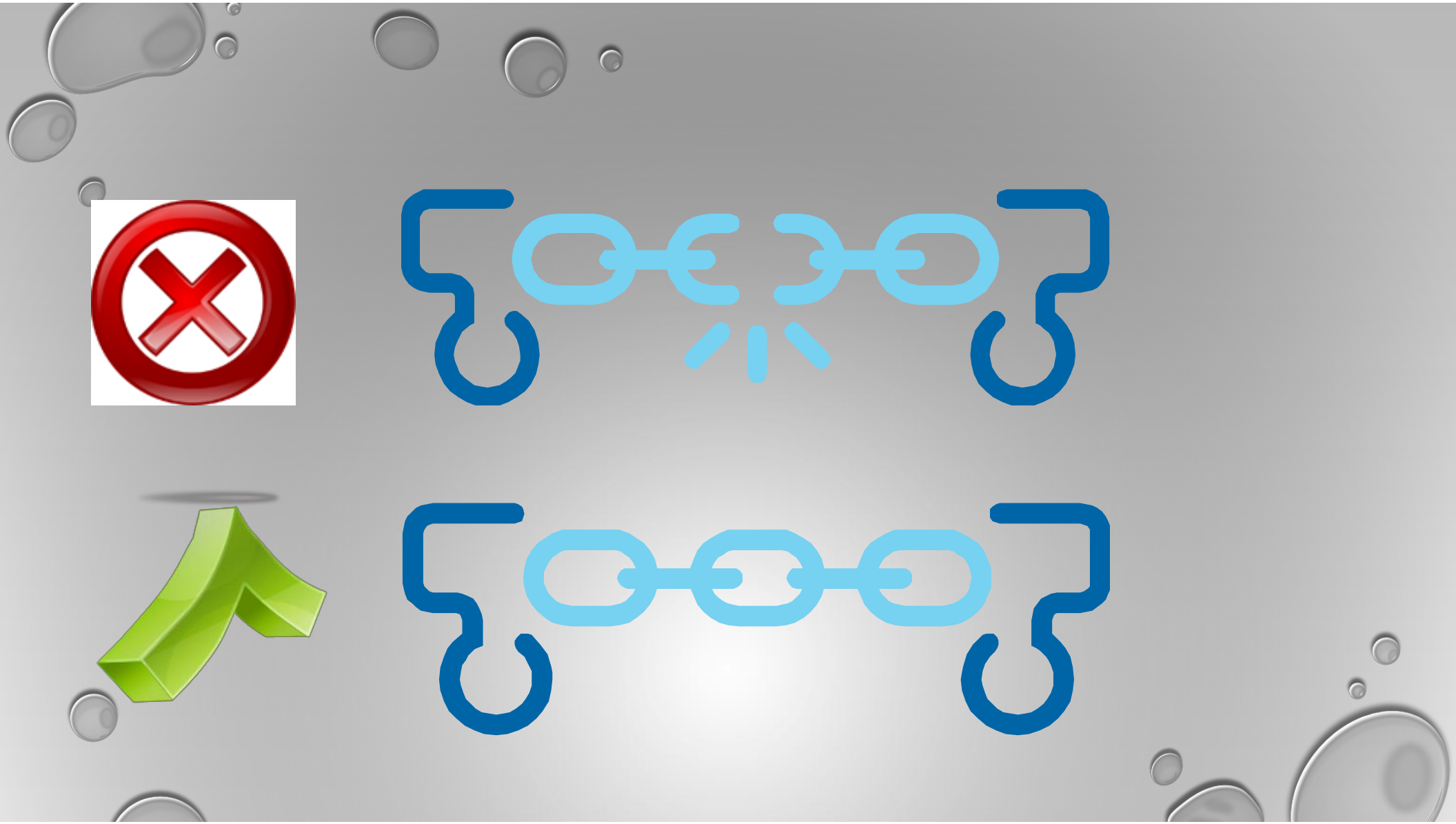
# WHAT PERTAINS TO DEFENSIBLE DATA IN A WATER LABORATORY?

SYSTEM

# QA MANUAL

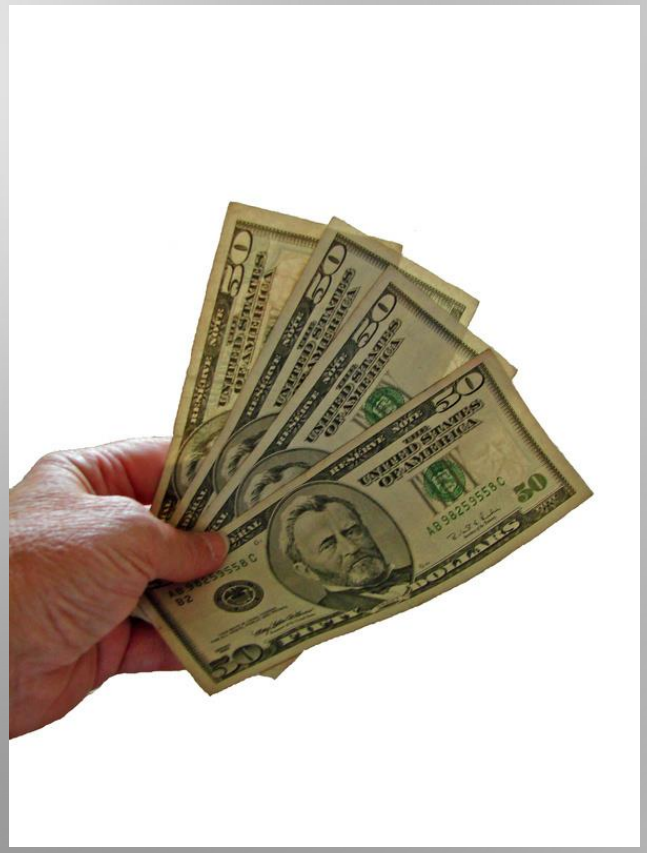
## DATA OF KNOWN QUALITY

STATEMENT



# QUALITY IS NOT FREE!

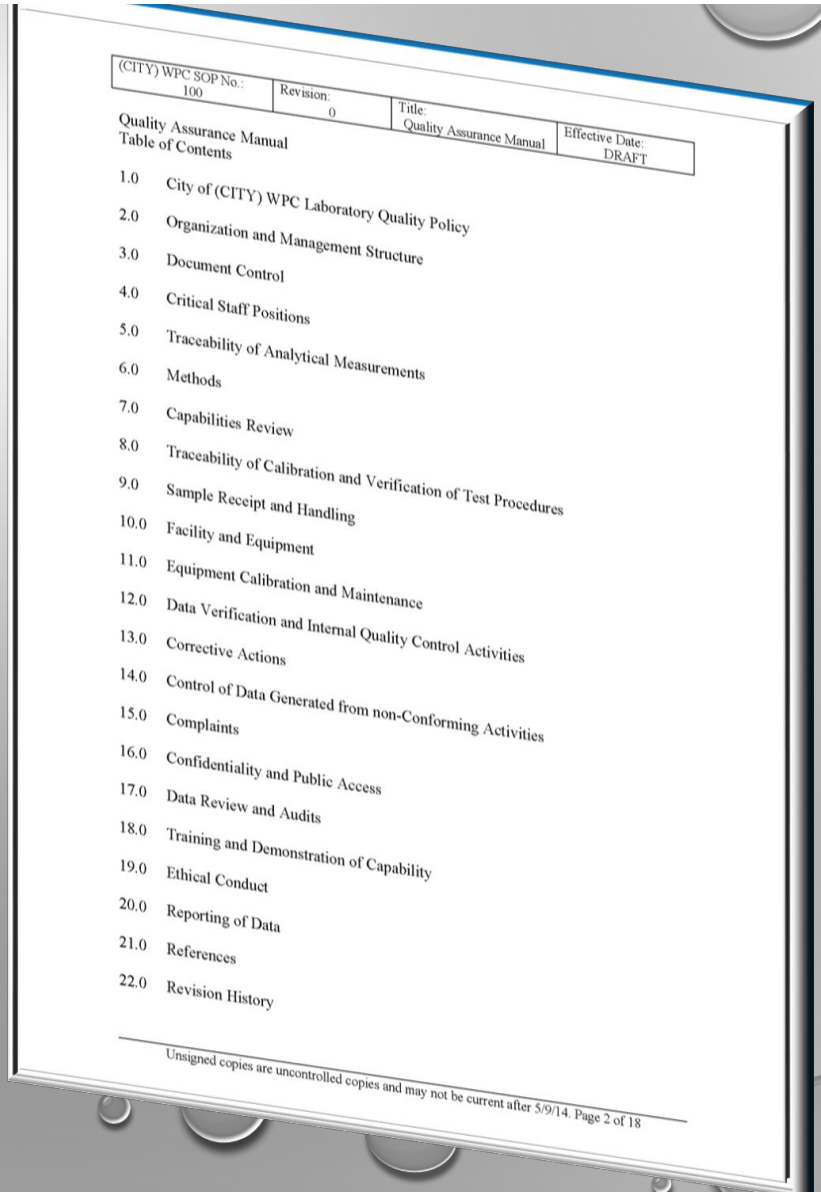
- COSTS ASSOCIATED WITH QA OFFICER SALARY
- PROFICIENCY TESTING
- ANALYSIS OF QUALITY CONTROL STANDARDS
- ANALYSIS OF PRECISION & ACCURACY SAMPLES
- PERFORMING METHOD DETECTION LIMIT STUDIES
- TIME INVOLVED TO PERFORM INITIAL AND ONGOING DEMONSTRATION OF CAPABILITY
- TIME INVOLVED TO AUDIT LABORATORY



# QUALITY INVOLVES THE ENTIRE STAFF

- MANAGEMENT COMMITMENT
  - DEFINES THE PROCESS
  - INSPECTS WHAT IS EXPECTED
    - PERFORM DATA REVIEWS
    - PERFORM LABORATORY AUDITS
    - REVIEW ANALYST DURING ANALYSIS
- EMPLOYEE COMMITMENT
  - UNDERSTAND EXPECTATIONS
  - PERFORM ANALYSIS IN ACCORDANCE TO CURRENT SOPS
  - PERFORM ANNUAL CAPABILITY STUDIES
  - ANALYZE PT STANDARDS

- ORGANIZATIONAL CHART
- DOCUMENT CONTROL
- TRACEABILITY
- METHODS
- SAMPLE RECEIPT & HANDLING
- FACILITY & EQUIPMENT
- VERIFICATION OF DATA
- CORRECTIVE ACTIONS
- ETHICS
- TRAINING
- REPORTING OF DATA



| (CITY) WPC SOP No.: 100 | Revision: 0 | Title: Quality Assurance Manual | Effective Date: DRAFT |
|---|---|---|---|

Quality Assurance Manual
Table of Contents

# CONTROLLED DOCUMENTS

STANDARD OPERATING PROCEDURES

AND FORMS

SOP

FORMS

WHO

WHAT

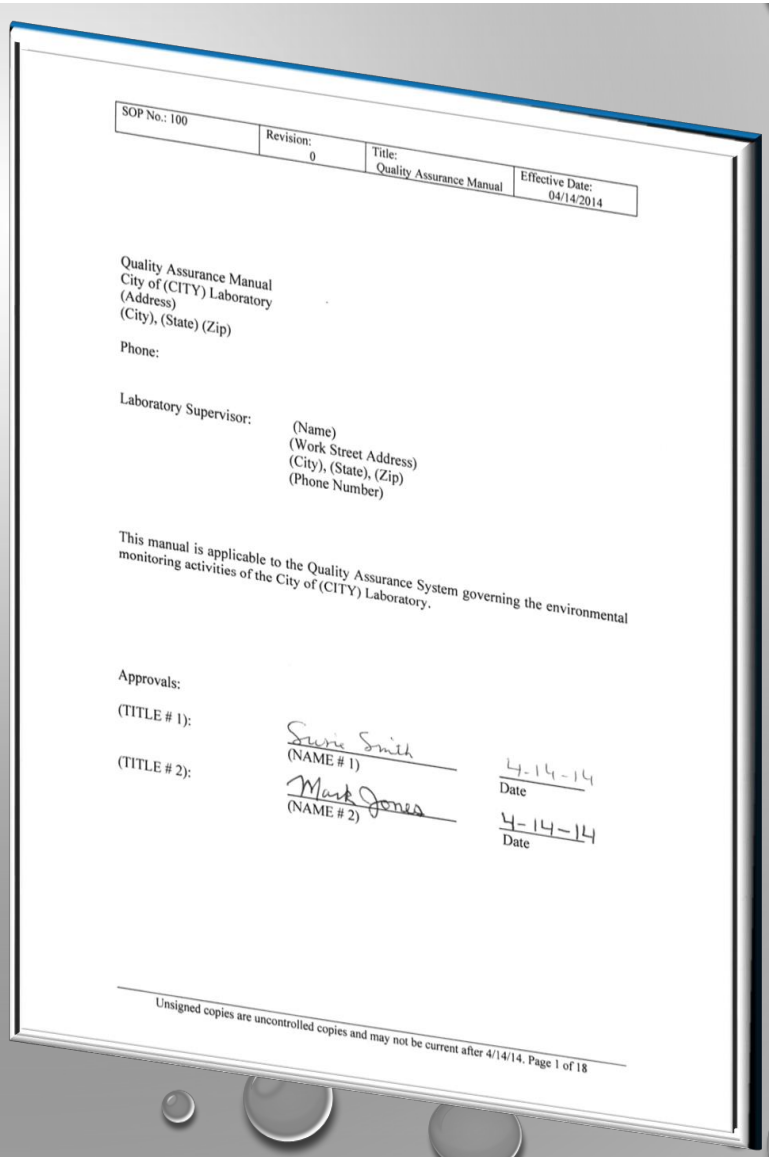
HOW

WHEN

WHERE

# DOCUMENT APPROVAL

- ARE ALL DOCUMENTS REVIEWED AND APPROVED FOR ACCURACY PRIOR TO USE?
- IS THERE AN SOP ON HOW TO WRITE SOPS?
  - DEFINES FORMAT
  - NUMBERING
  - REVISIONS
  - SECTIONS
  - REVISION HISTORY



| SOP No.: 100 | Revision: 0 | Title: Quality Assurance Manual | Effective Date: 04/14/2014 |
|---|---|---|---|

Quality Assurance Manual
City of (CITY) Laboratory
(Address)
(City), (State) (Zip)

Phone:

Laboratory Supervisor: (Name)
(Work Street Address)
(City), (State), (Zip)
(Phone Number)

This manual is applicable to the Quality Assurance System governing the environmental monitoring activities of the City of (CITY) Laboratory.

Approvals:

(TITLE # 1): Sara Smith (NAME # 1) 4-14-14 Date

(TITLE # 2): Mark Jones (NAME # 2) 4-14-14 Date

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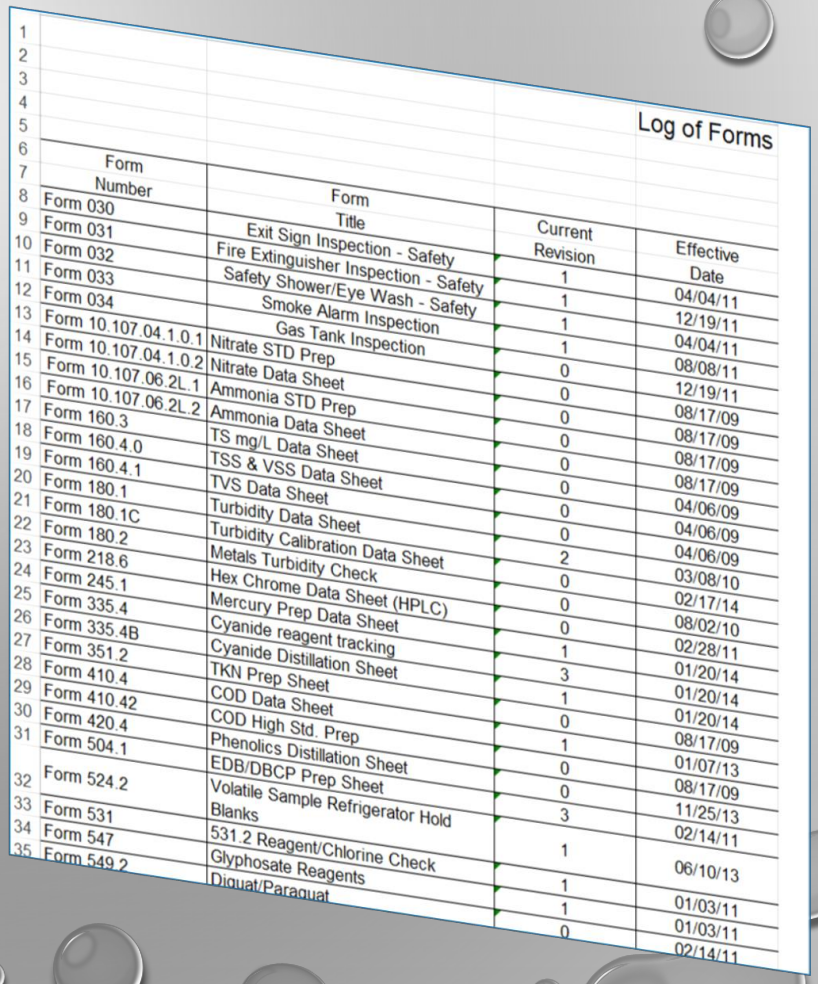
# CONTROLLED DOCUMENTS

- DOES A MASTER LIST OF ALL ESTABLISHED DOCUMENTS EXIST TO PREVENT USE OF INVALID DOCUMENTS?
  - SOPS
  - FORMS

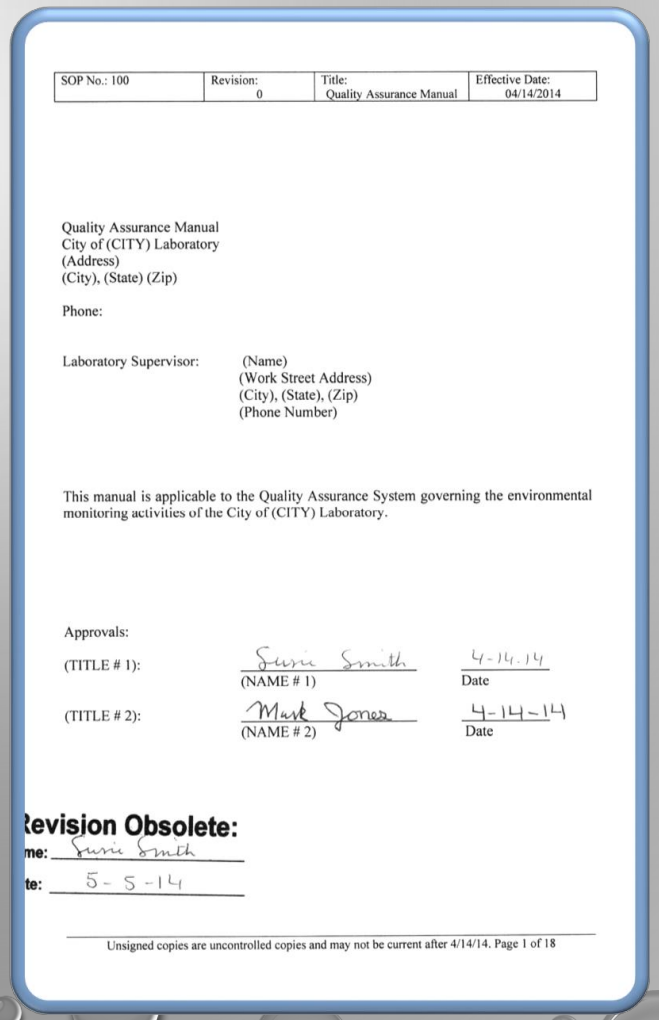


Log of Forms

| Form Number | Form Title | Current Revision | Effective Date |
|---|---|---|---|
| Form 030 | Exit Sign Inspection - Safety | 1 | 04/04/11 |
| Form 031 | Fire Extinguisher Inspection - Safety | 1 | 12/19/11 |
| Form 032 | Safety Shower/Eye Wash - Safety | 1 | 04/04/11 |
| Form 033 | Smoke Alarm Inspection | 0 | 08/08/11 |
| Form 034 | Gas Tank Inspection | 0 | 12/19/11 |
| Form 10.107.04.1.0.1 | Nitrate STD Prep | 0 | 08/17/09 |
| Form 10.107.04.1.0.2 | Nitrate Data Sheet | 0 | 08/17/09 |
| Form 10.107.06.2L.1 | Ammonia STD Prep | 0 | 08/17/09 |
| Form 10.107.06.2L.2 | Ammonia Data Sheet | 0 | 08/17/09 |
| Form 160.3 | TS mg/L Data Sheet | 0 | 04/06/09 |
| Form 160.4.0 | TSS & VSS Data Sheet | 0 | 04/06/09 |
| Form 160.4.1 | TVS Data Sheet | 2 | 04/06/09 |
| Form 180.1 | Turbidity Data Sheet | 0 | 03/08/10 |
| Form 180.1C | Turbidity Calibration Data Sheet | 0 | 02/17/14 |
| Form 180.2 | Metals Turbidity Check | 0 | 08/02/10 |
| Form 218.6 | Hex Chrome Data Sheet (HPLC) | 1 | 02/28/11 |
| Form 245.1 | Mercury Prep Data Sheet | 3 | 01/20/14 |
| Form 335.4 | Cyanide reagent tracking | 1 | 01/20/14 |
| Form 335.4B | Cyanide Distillation Sheet | 0 | 01/20/14 |
| Form 351.2 | TKN Prep Sheet | 1 | 08/17/09 |
| Form 410.4 | COD Data Sheet | 0 | 01/07/13 |
| Form 410.42 | COD High Std. Prep | 0 | 08/17/09 |
| Form 420.4 | Phenolics Distillation Sheet | 3 | 11/25/13 |
| Form 504.1 | EDB/DBCP Prep Sheet | 1 | 02/14/11 |
| Form 524.2 | Volatile Sample Refrigerator Hold Blanks | 1 | 06/10/13 |
| Form 531 | 531.2 Reagent/Chlorine Check | 1 | 01/03/11 |
| Form 547 | Glyphosate Reagents | 1 | 01/03/11 |
| Form 549.2 | Diquat/Paraquat | 0 | 02/14/11 |

# APPROVED & OBSOLETE DOCUMENTS

- ARE COPIES OF APPROVED DOCUMENTS AVAILABLE AT WORKSTATIONS AND TO ALL LABORATORY PERSONNEL?
- HOW ARE DOCUMENTS ISSUED?
- DO PERSONNEL SIGN FORMS INDICATING ACKNOWLEDGEMENT OF NEW REVISIONS?
- ARE OBSOLETE DOCUMENTS CLEARLY LABELED AND MAINTAINED FOR HISTORICAL PURPOSES?



| SOP No.: 100 | Revision: 0 | Title: Quality Assurance Manual | Effective Date: 04/14/2014 |
|---|---|---|---|

Quality Assurance Manual
City of (CITY) Laboratory
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This manual is applicable to the Quality Assurance System governing the environmental monitoring activities of the City of (CITY) Laboratory.

Approvals:

(TITLE # 1): Susie Smith (NAME # 1) 4-14-14 Date

(TITLE # 2): Mark Jones (NAME # 2) 4-14-14 Date

**Revision Obsolete:**
me: Susie Smith
te: 5-5-14

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- QUALITY ASSURANCE OFFICER
  - MAINTAINS QUALITY SYSTEM
  - PERFORMS INTERNAL AUDITS
  - SIGNS OFF ON FORMS
  - FILES ORIGINAL DOCUMENTS
  - KEEPS CURRENT REVISIONS ACCESSIBLE TO ALL PERSONNEL
  - REPORTS DIRECTLY TO UPPER MANAGEMENT

- EMPLOYEE RESPONSIBILITY
  - KNOW WHERE TO ACCESS CURRENT REVISIONS OF SOPS AND FORMS
  - COMPLIANCE TO ISSUED DOCUMENTS AND FORMS
  - PERFORMING ON-GOING DEMONSTRATION OF CAPABILITY
  - NOTIFYING QUALITY ASSURANCE OFFICER OF ALL ISSUES

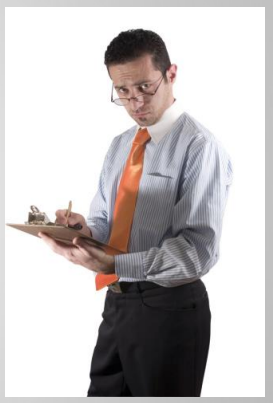
CHARTS

SHIFTS

# QUALITY CONTROL

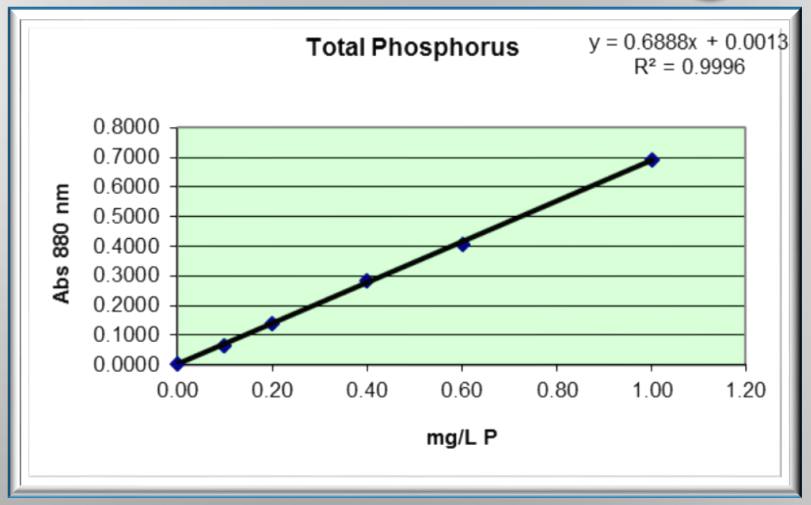
## ACCURACY & PRECISION

- QUALITY CONTROL
  - OPERATIONS TAKEN TO ENSURE DATA ARE WITHIN KNOWN LIMITS
  - METHOD BLANKS
  - LABORATORY FORTIFIED BLANKS
  - DUPLICATES
  - MATRIX SPIKE / MATRIX SPIKE DUPLICATE



- QUALITY ASSURANCE
  - IS THE OVERALL PROCESS OR SYSTEM BY WHICH THE LABORATORY CAN ASSURE OUTSIDE INVESTIGATORS THAT THE DATA IS OF KNOWN QUALITY
- THE QA MANUAL DEFINES THE LABORATORY PROCESSES

- 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 FORTIFIED BLANK ANALYZED WITH EACH BATCH?
- ARE THE CALIBRATION CURVE ACCEPTANCE CRITERIA DEFINED?
- ARE CONTINUING CALIBRATION VERIFICATION STANDARDS ANALYZED AND IS THE FREQUENCY DEFINED?

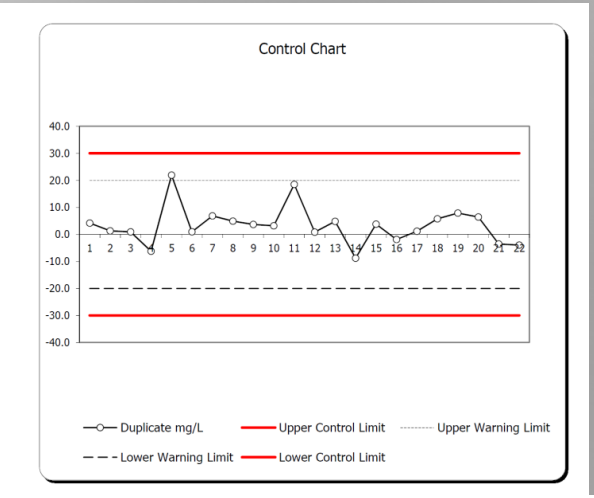


☑ARE CONTROL CHARTS IN USE?

☑ARE LIMITS CLEARLY ESTABLISHED?

☑DOES A DETERMINATION OF ACCURACY INCLUDE QC SAMPLES AND SPIKES?

☑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?

CUSTODY

# SAMPLING

## RECEIPT & HANDLING

STORAGE

# SOP, PRESERVATION & HOLD TIME

| (City)<br>SOP No.: 107 | Revision:<br>0 | Title: Drinking Water Sampling | Effective Date:<br>DRAFT |
|---|---|---|---|

Approvals:

| | | |
|---|---|---|
| (Title # 1) | | Date: |
| (Title # 2) | | Date: |
| (Title # 3) | | |

1.0 Sampling for The Determination of Following Analyte(s)

1.1 This method is NOT intended to supply directions for sampling in high hazard situations. It is intended to be a guide for sampling in a confined space nor involves explosive or flammable conditions.
1.2 Metals in wastewater
1.3 Nutrients such as phosphorus
1.4 General water characteristics
1.5 Organics

2.0 Applicable Matrix (s)

2.1 Drinking Water
2.2 Ground Water
2.3 Well Water
2.4 Surface water

3.0 Objective

3.1 The objective of sampling is to collect a portion of material small enough in volume to be transported conveniently and large enough for analytical purposes while accurately representing the material being sampled.
3.2 It is also the objective of sampling to preserve the concentration of all pertinent components in the sample in the same concentration as they were in the material being samples.
3.3 It is also necessary to handle the samples in such a way that no significant changes in composition occur before the test(s) are completed.
3.4 This procedure addresses the collection and preservation of water and wastewater samples.



| Contaminant | Preservative[1] | Container[2] | Time[3] |
|---|---|---|---|
| Antimony | $HNO^3$ | P or G | 6 months |
| Arsenic | Conc $HNO_3$ to pH <2 | P or G | 6 months |
| Asbestos | 4 °C | P or G | 48 hours[4] |
| Barium | $HNO^3$ | P or G | 6 months |
| Beryllium | $HNO^3$ | P or G | 6 months |
| Cadmium | $HNO^3$ | P or G | 6 months |
| Chromium | $HNO^3$ | P or G | 6 months |
| Cyanide | 4 °C, NaOH | P or G | 14 days |
| Fluoride | None | P or G | 1 month |
| Mercury | $HNO^3$ | P or G | 28 days |
| Nickel | $HNO^3$ | P or G | 6 months |
| Nitrate | 4 °C | P or G | 48 hours[5] |
| Nitrate-Nitrite[6] | $H^2SO^4$ | P or G | 28 days |
| Nitrite | 4 °C | P or G | 48 hours |
| Selenium | $HNO^3$ | P or G | 6 months |
| Thallium | $HNO^3$ | P or G | 6 months |

[1]For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4 °C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2]P = plastic, hard or soft; G=glass, hard or soft.

[3]In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

[4]Instructions for containers, preservation procedures and holding times as specified in Method 100.2 must be adhered to for all compliance analyses including those conducted with Method 100.1.

[5]If the sample is chlorinated, the holding time for an unacidified sample kept at 4 °C is extended to 14 days.

[6]Nitrate-Nitrite refers to a measurement of total nitrate.

(3) Analysis under this section shall only be conducted by laboratories that have been certified by EPA or the State. Laboratories may conduct sample analysis under provisional certification until January 1, 1996. To receive certification to conduct analyses for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite and selenium and thallium, the laboratory must:

SAMPLING INSTRUCTIONS
SYNTHETIC ORGANIC COMPOUNDS (SOCs)

**NOTE:** Flush out the piping between the tap and water main. The sample to be collected is intended to be representative of the water in the main. The tap must be opened fully and the water allowed to run for at least 3-5 minutes to provide adequate flushing of the piping between the tap and the water main.

Method 504.1 – Analytes of interest: Dibromochloropropane (DBCP) and Ethylene Dibromide (EDB). Fill three 40-mL vials containing sodium thiosulfate to the top, leaving NO HEADSPACE.

Method 508 – Analytes of interest: Aldrin, Chlordane, Dieldrin, Endrin, Heptachlor, Heptachlor Epoxide, Hexachlorbenzene, Hexachlorocyclopentadiene, Lindane, Methoxychlor, and Toxaphene. Fill two amber quarts containing sodium thiosulfate.

Method 515.1 – Analytes of interest: Dalapon, Dicamba, 2, 4-D, Dinoseb, Pentachlorophenol, Picloram, and 2,4, 5-TP (Silvex). Fill two amber quart bottles containing sodium thiosulfate.

Method 525.2 – Analytes of interest: Alachlor, Atrazine, Butachlor, Metolachlor, Metribuzin, Propachlor, Simazine, Benzo-a-pyrene, DI(2-ethyhexyl)adipate and DI(2-ethyhexyl)phthalate. Fill two amber quarts containing sodium sulfite. Add 3 mL of 1:1 HCl after filling container with sample.

Method 531.2 – Analytes of interest: Aldicarb, Aldicarb Sulfone, Aldicarb Sulfoxide, Carbaryl, Carbofuran, 3-Hydroxycarbofuran, Methomyl and Oxamyl (Vydate). Fill one 240-mL amber bottle containing sodium thiosulfate, potassium, and dihydrogen citrate.

Method 547 – Analyte of interest: Glyphosate. Fill three 40-mL vials containing sodium thiosulfate, leaving NO HEADSPACE.

Method 548.1 – Analyte of interest is Endothall. Fill one un-preserved 240-mL amber bottle.

Method 549.2 – Analyte of interest is Diquat. Fill one amber plastic quart containing sodium thiosulfate. Add 5-mL of 1:1 Sulfuric Acid after filling the container with the sample.

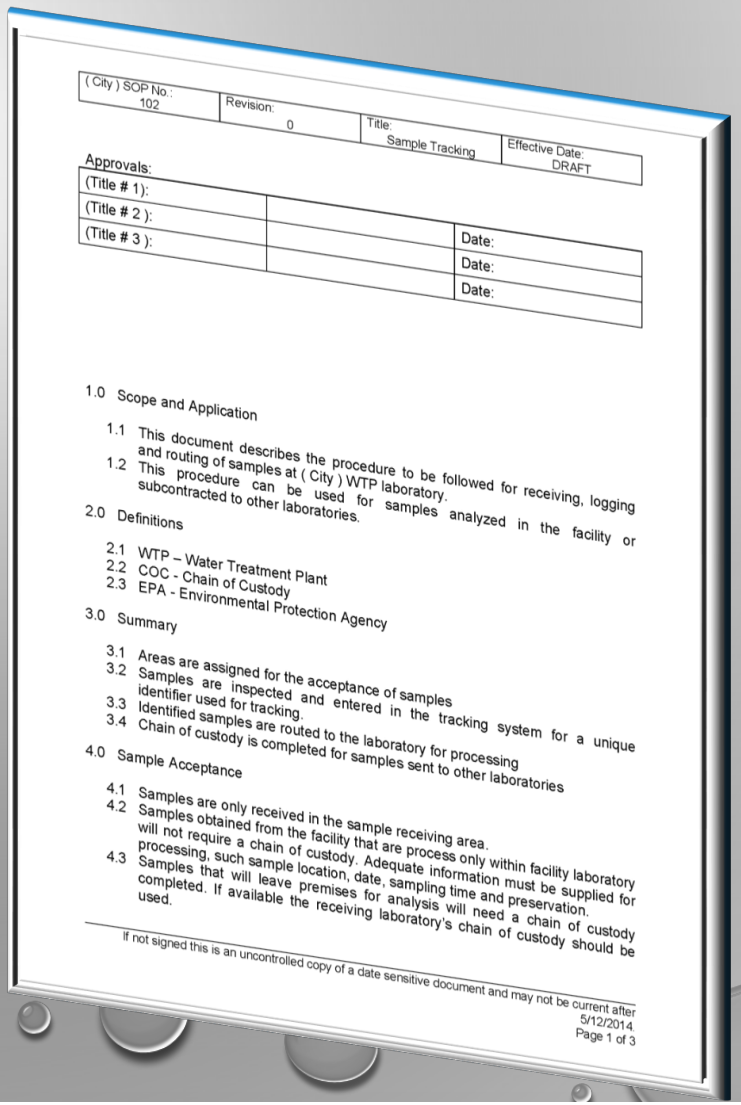
SAMPLES MUST BE KEPT COLD. PLEASE PLACE SAMPLES IN COOLER. FILL ZIPLOC STORAGE BAGS WITH ICE AND PLACE UPRIGHT IN COOLER WITH SAMPLES. SEND TO LAB VIA NEXT-DAY DELIVERY.

Samples for any SOC method MUST be received at the lab at or below 6° C. We recommend that you collect the sample, then place it in the refrigerator overnight. Ship the sample the next day using an overnight/next-day delivery service. Make sure you pack the sample in plenty of ice. Ziploc bags filled with actual ice work better than ice packs. Please cushion the samples with plenty of bubble wrap, newspaper, or another material. Place samples upright in cooler.

- SAMPLING PROCEDURES
  - WHAT TYPE OF BOTTLE
    - GLASS
    - PLASTIC
  - WHAT PRESERVATIVE
    - HCl
    - SODIUM THIOSULFATE
  - HOW MUCH VOLUME
  - WHERE TO COLLECT
  - IDENTIFY TESTS REQUIRED
  - GRAB SAMPLE
  - COMPOSITE SAMPLE
  - HOLDING TIME
  - IS COOLING REQUIRED

# SAMPLE HANDLING

- DEFINE PROCEDURES FOR HANDLING
  - TRANSPORTATION
  - RECEIPT
  - PROTECTION
  - TRACKING
  - STORAGE
  - RETENTION
  - DISPOSAL



| ( City ) SOP No.: 102 | Revision: 0 | Title: Sample Tracking | Effective Date: DRAFT |
|---|---|---|---|

Approvals:

| | | |
|---|---|---|
| (Title # 1): | | Date: |
| (Title # 2 ): | | Date: |
| (Title # 3 ): | | Date: |

1.0 Scope and Application

1.1 This document describes the procedure to be followed for receiving, logging and routing of samples at ( City ) WTP laboratory.
1.2 This procedure can be used for samples analyzed in the facility or subcontracted to other laboratories.

2.0 Definitions

2.1 WTP – Water Treatment Plant
2.2 COC - Chain of Custody
2.3 EPA - Environmental Protection Agency

3.0 Summary

3.1 Areas are assigned for the acceptance of samples
3.2 Samples are inspected and entered in the tracking system for a unique identifier used for tracking.
3.3 Identified samples are routed to the laboratory for processing
3.4 Chain of custody is completed for samples sent to other laboratories

4.0 Sample Acceptance

4.1 Samples are only received in the sample receiving area.
4.2 Samples obtained from the facility that are process only within facility laboratory will not require a chain of custody. Adequate information must be supplied for processing, such sample location, date, sampling time and preservation.
4.3 Samples that will leave premises for analysis will need a chain of custody completed. If available the receiving laboratory's chain of custody should be used.

If not signed this is an uncontrolled copy of a date sensitive document and may not be current after 5/12/2014.
Page 1 of 3

# SAMPLE HANDLING

## SAMPLE RECEIPT

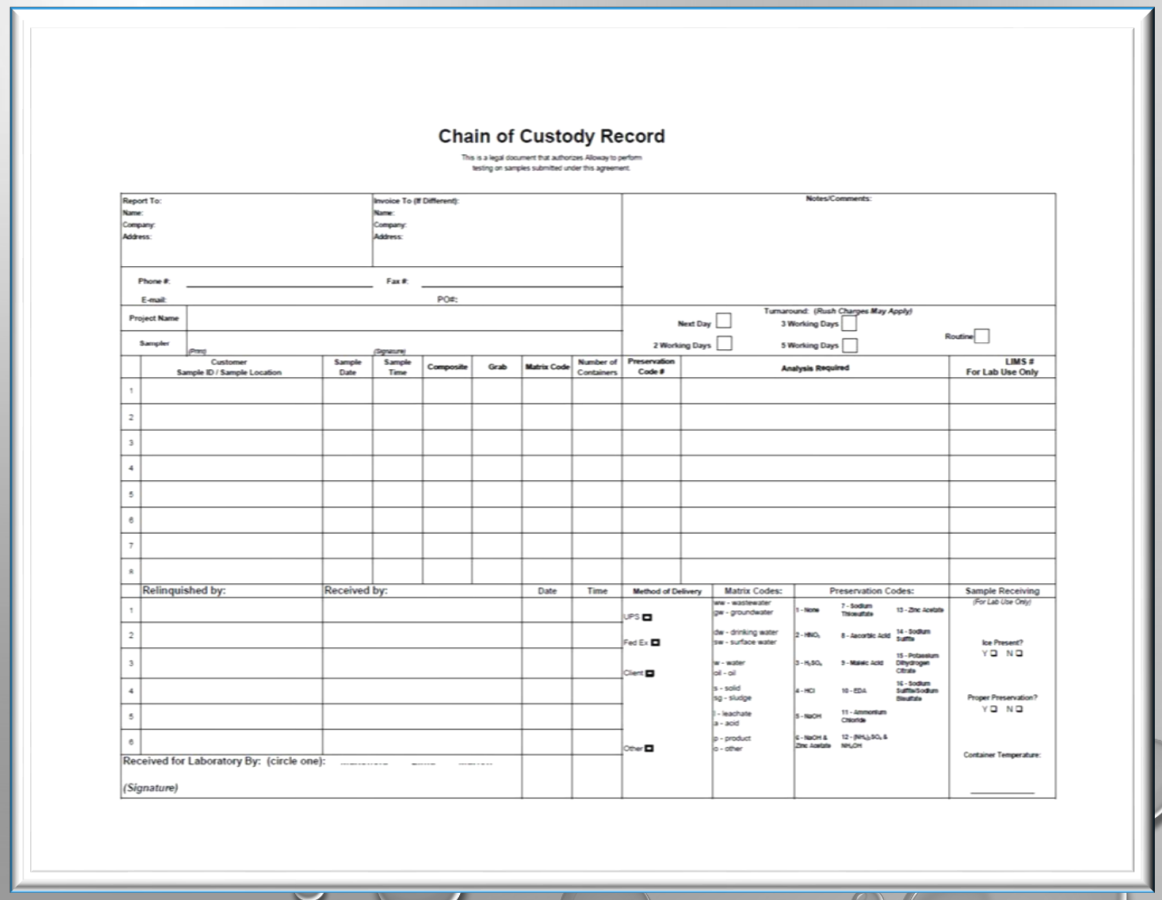
- DEFINE PROCESS TO:
  - DOCUMENT SAMPLE CONDITION
  - DOCUMENT ABNORMALITIES
  - NOTIFICATION OF NON-CONFORMANCE
- CREATE SAMPLE RECEIPT CHECKLIST
- USE CHAIN OF CUSTODY

## SAMPLE ACCEPTANCE

- DESCRIBE PROCESS OF ACCEPTANCE AND REJECTION OF SAMPLES
- IDENTIFY INFORMATION REQUIRED TO DESCRIBE THE SAMPLE
  - SAMPLE IDENTIFICATION
  - LOCATION
  - DATE & TIME COLLECTED
  - SAMPLER'S NAME
  - PRESERVATION TYPE
  - MATRIX
  - RECEIVED WITHIN HOLDING TIME
  - SUFFICIENT VOLUME FOR ANALYSIS REQUIRED

# CHAIN OF CUSTODY REVIEW

- ESTABLISH PROCEDURES TO REVIEW FOR:
- SAMPLE IDENTIFICATION
- PROJECT IDENTIFICATION
- SAMPLE LOCATION
- DATE & TIME OF COLLECTION
- SAMPLER NAME
- PRESERVATIONS USED
- DATE AND TIME RECEIVED
- RELINQUISH AND RECEIVE BY SIGNATURES



**Chain of Custody Record**

This is a legal document that authorizes Alloway to perform testing on samples submitted under this agreement.

| Report To: Name: Company: Address: | Invoice To (If Different): Name: Company: Address: | Notes/Comments: |
|---|---|---|
| Phone #: _____ Fax #: _____ E-mail: | PO#: | |
| Project Name | | Turnaround: (Rush Charges May Apply) Next Day ☐ 2 Working Days ☐ 3 Working Days ☐ 5 Working Days ☐ Routine ☐ |
| Sampler (Print) (Signature) | | |

| | Customer Sample ID / Sample Location | Sample Date | Sample Time | Composite | Grab | Matrix Code | Number of Containers | Preservation Code # | Analysis Required | LIMS # For Lab Use Only |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | |
| 2 | | | | | | | | | | |
| 3 | | | | | | | | | | |
| 4 | | | | | | | | | | |
| 5 | | | | | | | | | | |
| 6 | | | | | | | | | | |
| 7 | | | | | | | | | | |
| 8 | | | | | | | | | | |

| | Relinquished by: | Received by: | Date | Time |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| Received for Laboratory By: (circle one): _____ _____ _____ (Signature) | | | | |

| Method of Delivery | Matrix Codes: | Preservation Codes: | Sample Receiving (For Lab Use Only) |
|---|---|---|---|
| UPS ☐ Fed Ex ☐ Client ☐ Other ☐ | ww - wastewater gw - groundwater dw - drinking water sw - surface water w - water oil - oil s - solid sg - sludge l - leachate a - acid p - product o - other | 1 - None 2 - $HNO_3$ 3 - $H_2SO_4$ 4 - HCl 5 - NaOH 6 - NaOH & Zinc Acetate 7 - Sodium Thiosulfate 8 - Ascorbic Acid 9 - Maleic Acid 10 - EDA 11 - Ammonium Chloride 12 - $(NH_4)_2SO_4$ & $NH_4OH$ 13 - Zinc Acetate 14 - Sodium Sulfite 15 - Potassium Dihydrogen Citrate 16 - Sodium Sulfite/Sodium Bisulfate | Ice Present? Y ☐ N ☐ Proper Preservation? Y ☐ N ☐ Container Temperature: _____ |

IDOC

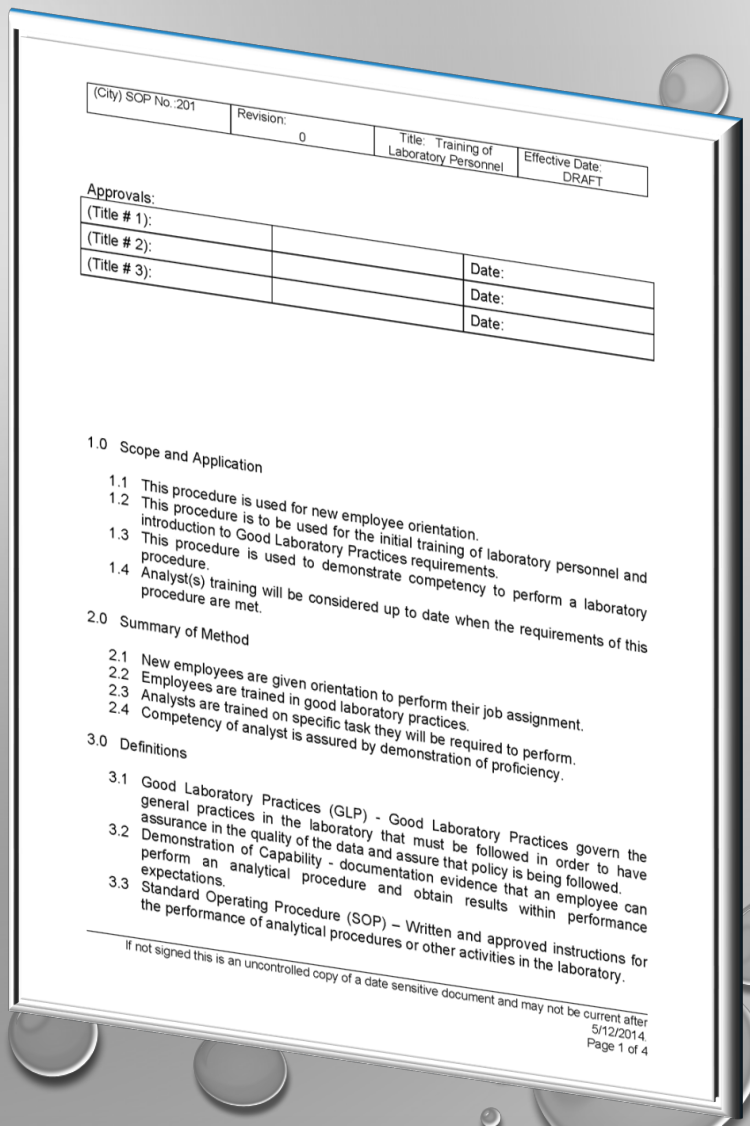
# TRAINING

IS ANALYST CAPABLE OF MEETING METHOD QC REQUIREMENTS?

IDOC

# TRAINING SOP

- SOP ON HOW TO TRAIN
  - KEEPS TRAINING CONSISTENT
  - IDENTIFIES FORMS USED IN TRAINING PROCESS
  - IDENTIFIES GENERAL TRAINING REQUIREMENTS
  - IDENTIFIES ANALYTICAL TRAINING REQUIREMENTS



| (City) SOP No.:201 | Revision: 0 | Title: Training of Laboratory Personnel | Effective Date: DRAFT |
|---|---|---|---|

Approvals:

| | | |
|---|---|---|
| (Title # 1): | | Date: |
| (Title # 2): | | Date: |
| (Title # 3): | | Date: |

1.0 Scope and Application

1.1 This procedure is used for new employee orientation.
1.2 This procedure is to be used for the initial training of laboratory personnel and introduction to Good Laboratory Practices requirements.
1.3 This procedure is used to demonstrate competency to perform a laboratory procedure.
1.4 Analyst(s) training will be considered up to date when the requirements of this procedure are met.

2.0 Summary of Method

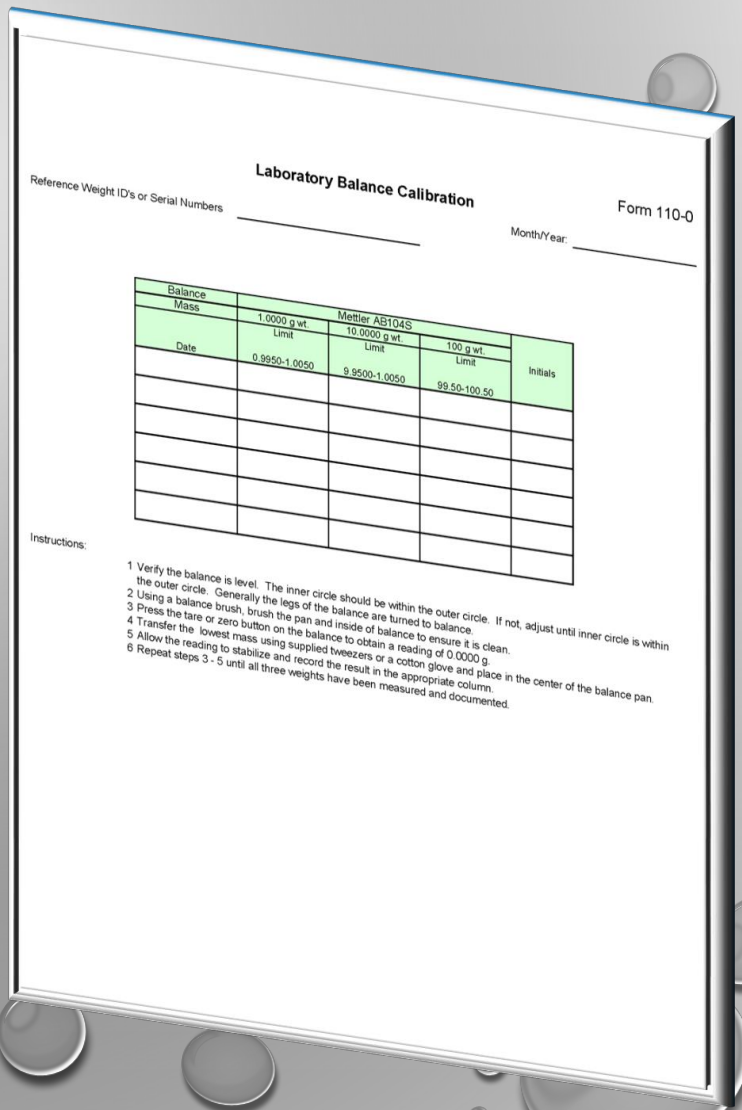
2.1 New employees are given orientation to perform their job assignment.
2.2 Employees are trained in good laboratory practices.
2.3 Analysts are trained on specific task they will be required to perform.
2.4 Competency of analyst is assured by demonstration of proficiency.

3.0 Definitions

3.1 Good Laboratory Practices (GLP) - Good Laboratory Practices govern the general practices in the laboratory that must be followed in order to have assurance in the quality of the data and assure that policy is being followed.
3.2 Demonstration of Capability - documentation evidence that an employee can perform an analytical procedure and obtain results within performance expectations.
3.3 Standard Operating Procedure (SOP) – Written and approved instructions for the performance of analytical procedures or other activities in the laboratory.

# GLP TRAINING

- GOOD LABORATORY PRACTICES TRAINING
  - READ QA MANUAL, ETHICS SOP
  - BALANCE VERIFICATION
    - FREQUENCY
    - WEIGHTS TO USE
  - MECHANICAL PIPET VERIFICATIONS
  - THERMOMETER VERIFICATIONS
    - CORRECTION FACTOR
      - PARTIAL VERSUS TOTAL IMMERSION



**Laboratory Balance Calibration** Form 110-0

Reference Weight ID's or Serial Numbers _____ Month/Year: _____

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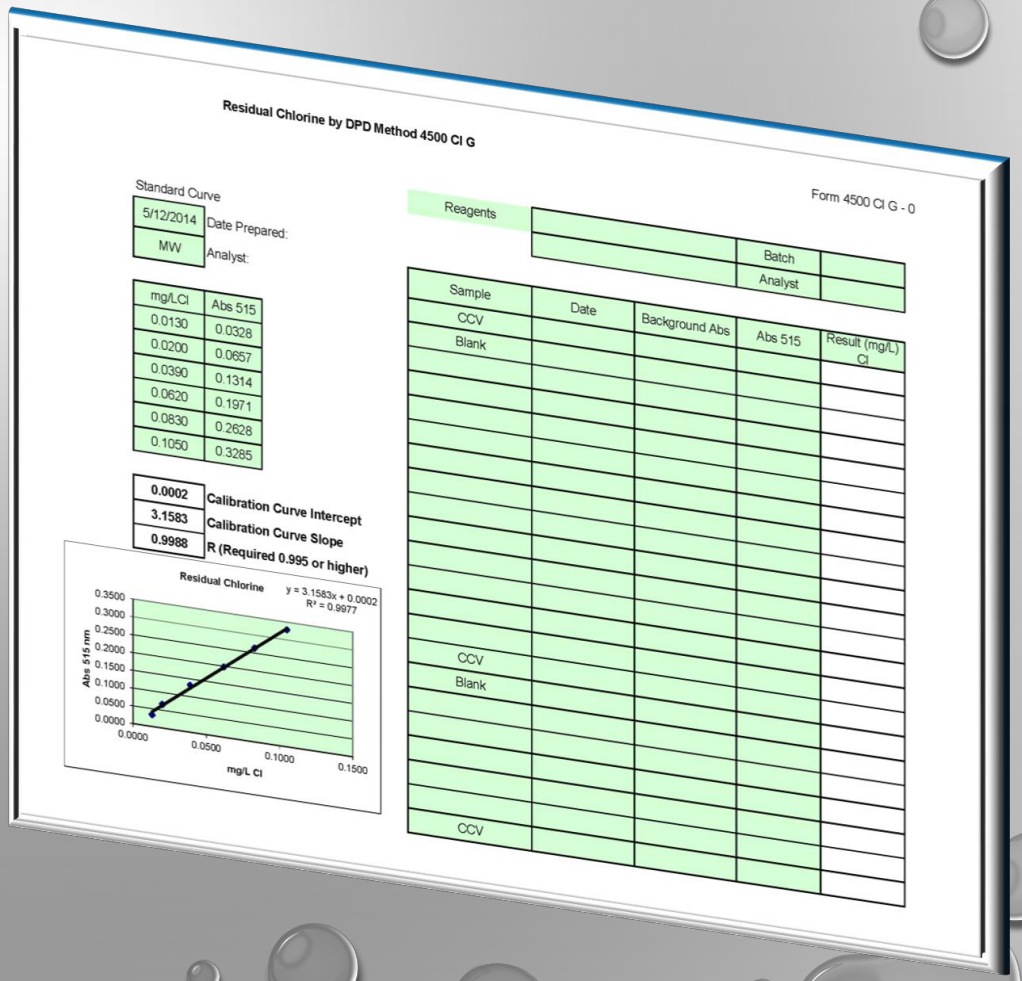
Instructions:

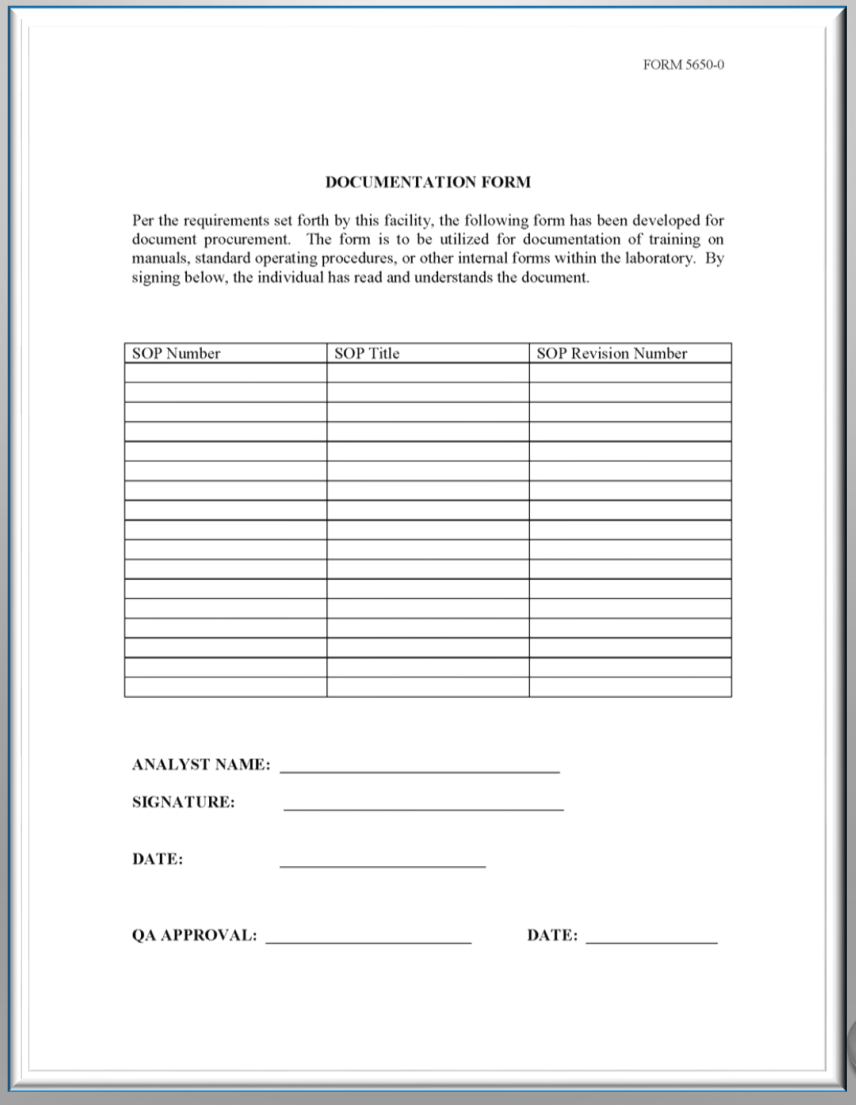
1 Verify the balance is level. The inner circle should be within the outer circle. If not, adjust until inner circle is within the outer circle. Generally the legs of the balance are turned to balance.
2 Using a balance brush, brush the pan and inside of balance to ensure it is clean.
3 Press the tare 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.

# METHOD SPECIFIC TRAINING

- USE SOP TO TRAIN ANALYST
- ANALYST TO READ SOP AND SIGN FORM INDICATING THEY READ AND UNDERSTAND THE SOP
- TRAINING TO INCLUDE
  - INSTRUMENTATION TRAINING AND MAINTENANCE
  - CALIBRATION CURVE PREPARATION IF APPLICABLE
  - MDL STUDY
  - COMPLETION OF IDOC



# READ & UNDERSTAND FORM



FORM 5650-0

**DOCUMENTATION FORM**

Per the requirements set forth by this facility, the following form has been developed for document procurement. The form is to be utilized for documentation of training on manuals, standard operating procedures, or other internal forms within the laboratory. By signing below, the individual has read and understands the document.

| SOP Number | SOP Title | SOP Revision Number |
|---|---|---|
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**ANALYST NAME:** _____

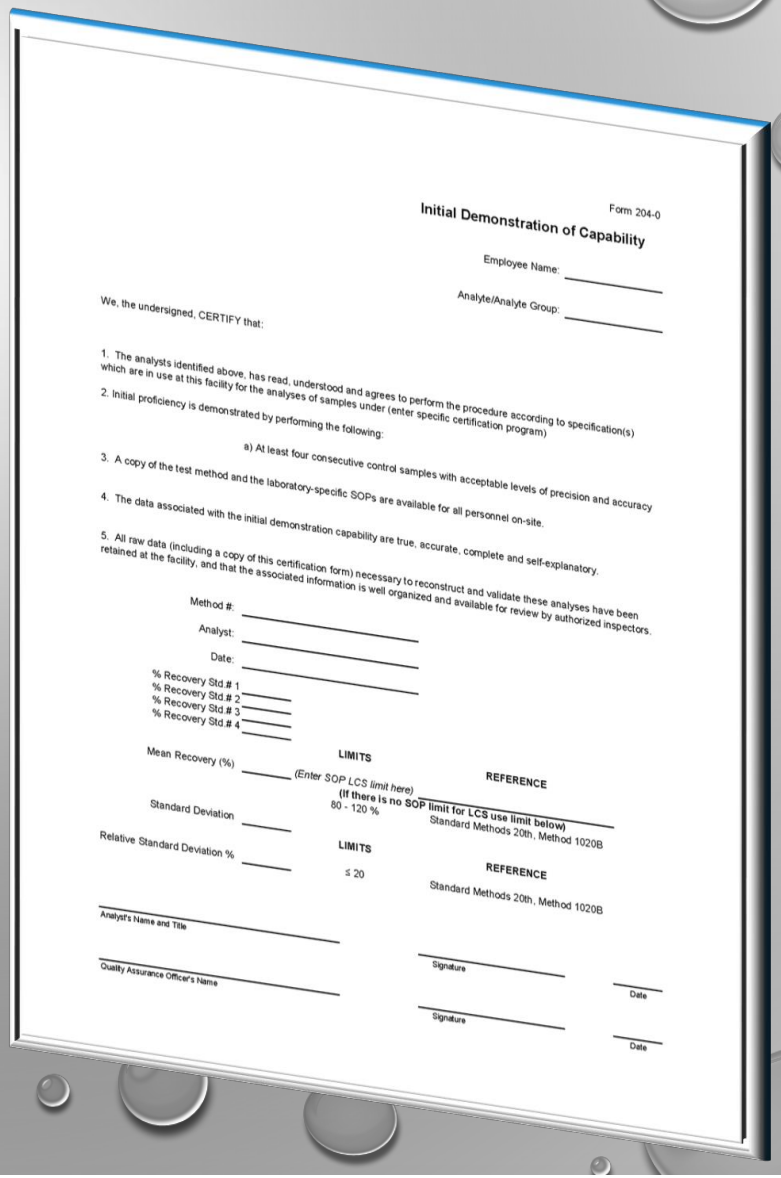
**SIGNATURE:** _____

**DATE:** _____

**QA APPROVAL:** _____ **DATE:** _____

# IDOC

- IDOC – INITIAL DEMONSTRATION OF CAPABILITY
- ANALYZE A LABORATORY FORTIFIED BLANK 4 TIMES
- CALCULATE PRECISION & ACCURACY
- ARE RESULTS WITHIN METHOD SPECIFIED LIMITS?



Form 204-0

**Initial Demonstration of Capability**

Employee Name: _____

Analyte/Analyte Group: _____

We, the undersigned, CERTIFY that:

1. The analysts identified above, has read, understood and agrees to perform the procedure according to specification(s) which are in use at this facility for the analyses of samples under (enter specific certification program)
2. Initial proficiency is demonstrated by performing the following:
   a) At least four consecutive control samples with acceptable levels of precision and accuracy
3. A copy of the test method and the laboratory-specific SOPs are available for all personnel on-site.
4. The data associated with the initial demonstration capability are true, accurate, complete and self-explanatory.
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors.

Method #: _____

Analyst: _____

Date: _____

% Recovery Std.# 1 _____

% Recovery Std.# 2 _____

% Recovery Std.# 3 _____

% Recovery Std.# 4 _____

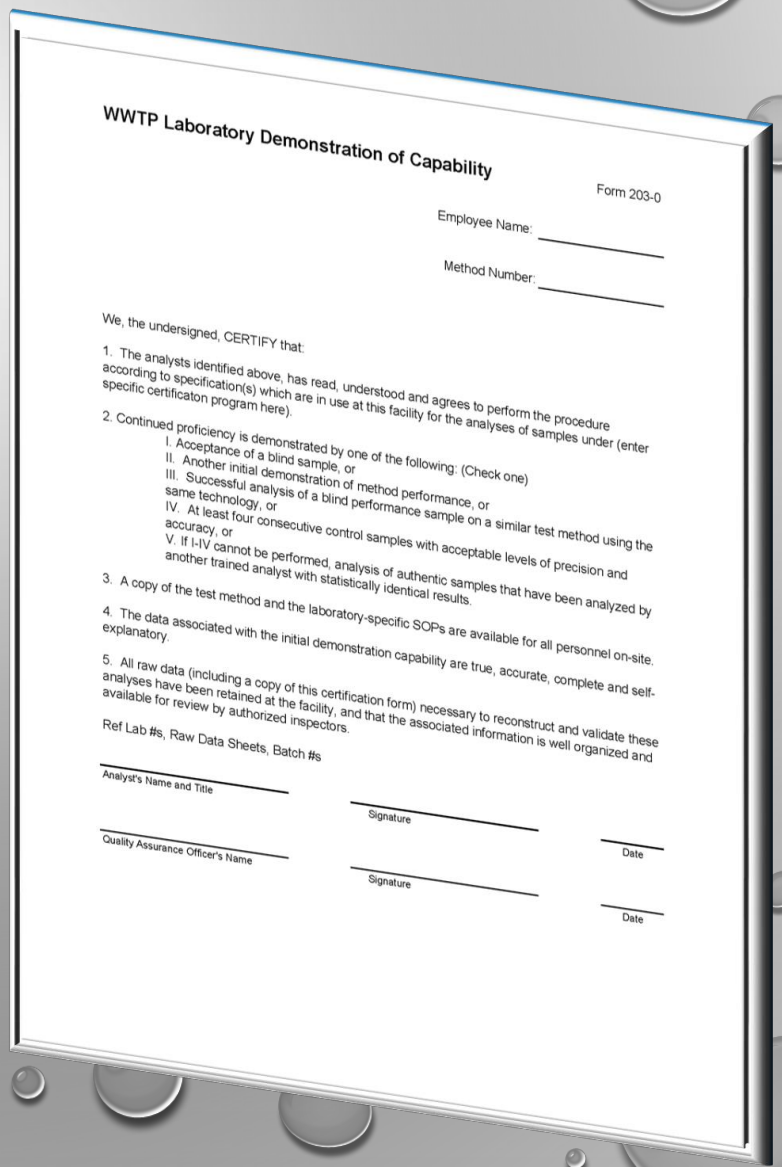
| | | | |
|---|---|---|---|
| | **LIMITS** | | **REFERENCE** |
| Mean Recovery (%) _____ | *(Enter SOP LCS limit here)* **(If there is no SOP limit for LCS use limit below)** 80 - 120 % | | Standard Methods 20th, Method 1020B |
| Standard Deviation _____ | | | |
| | **LIMITS** | | **REFERENCE** |
| Relative Standard Deviation % _____ | ≤ 20 | | Standard Methods 20th, Method 1020B |

Analyst's Name and Title _____ Signature _____ Date _____

Quality Assurance Officer's Name _____ Signature _____ Date _____

# DOC

- ANNUALLY DEMONSTRATE CONTINUED CAPABILITY TO MEET METHOD REQUIREMENTS
  - PT STUDY
  - 4 FORTIFIED BLANKS
  - BLIND SAMPLE ANALYSIS
  - PERFORM ANOTHER IDOC



**WWTP Laboratory Demonstration of Capability**

Form 203-0

Employee Name: _____

Method Number: _____

We, the undersigned, CERTIFY that:

1. The analysts identified above, has read, understood and agrees to perform the procedure according to specification(s) which are in use at this facility for the analyses of samples under (enter specific certificaton program here).
2. Continued proficiency is demonstrated by one of the following: (Check one)
   - I. Acceptance of a blind sample, or
   - II. Another initial demonstration of method performance, or
   - III. Successful analysis of a blind performance sample on a similar test method using the same technology, or
   - IV. At least four consecutive control samples with acceptable levels of precision and accuracy, or
   - V. If I-IV cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically identical results.
3. A copy of the test method and the laboratory-specific SOPs are available for all personnel on-site.
4. The data associated with the initial demonstration capability are true, accurate, complete and self-explanatory.
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors.

Ref Lab #s, Raw Data Sheets, Batch #s

Analyst's Name and Title _____ Signature _____ Date _____

Quality Assurance Officer's Name _____ Signature _____ Date _____

# TRAINING FILES

- TRAINING DOCUMENTS TO BE FILED IN EACH PERSON'S TRAINING FOLDER
  - PAPER COPIES
  - PDF DOCUMENTS
- TRAINING FOLDERS TO BE SEPARATE FROM PERSONNEL FILES
- EACH ANALYST RESPONSIBLE TO ENSURE TRAINING FILES ARE UP TO DATE AND CONTAIN ALL TRAINING RECORDS
  - PERFORMANCE BASED

RIGHTS

WRONGS

# ETHICS

## ANNUAL TRAINING

# ETHICS SOP

| SOP No.:200 | Revision: 0 | Title: Training-Ethical Conduct | Effective Date: |
|---|---|---|---|

Approvals:

| Lab Supervisor: | | Date: |
|---|---|---|

1.0 Scope and Application

1.1 This procedure defines basic requirements for ethical conduct but does not list or limit the all actions that are violations of ethical conduct. It is used as a training tool in order to instill the commitment to operate the laboratory in an ethical manner.
1.2 This procedure is applicable to all services and analysis supplied by the laboratory.
1.3 Ethical conduct applies to data generation and interaction with our customers
1.4 Ethical conduct applies to our interaction with fellow employees.
1.5 This procedure is used to train employees.

2.0 Ethics Policy

2.1 It shall be the policy of the management of the WTP laboratory to conduct business with integrity and in an ethical manner. It is the responsibility of each staff member to hold to the highest ethical standard of professional conduct in the performance of duties.

3.0 Equipment and Supplies

3.1 Ethical Training Form

4.0 Procedure

4.1 Employees will be trained using this SOP. Reading and agreement to comply will be documented.
4.2 Each employee is responsible to comply with the requirements of this procedure. This procedure is NOT an exhaustive list of all unethical behavior



FORM 5650-0

**DOCUMENTATION FORM**

Per the requirements set forth by this facility, the following form has been developed for document procurement. The form is to be utilized for documentation of training on manuals, standard operating procedures, or other internal forms within the laboratory. By signing below, the individual has read and understands the document.

| SOP Number | SOP Title | SOP Revision Number |
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**ANALYST NAME:** _____

**SIGNATURE:** _____

**DATE:** _____

**QA APPROVAL:** _____ **DATE:** _____

# WHAT IS ETHICS?

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**E**NCOURAGES GOODNESS

**T**EACHES EMPLOYEES TO BE COGNITIVE TO ETHICAL ISSUES

**H**ONORABLE BEHAVIOR

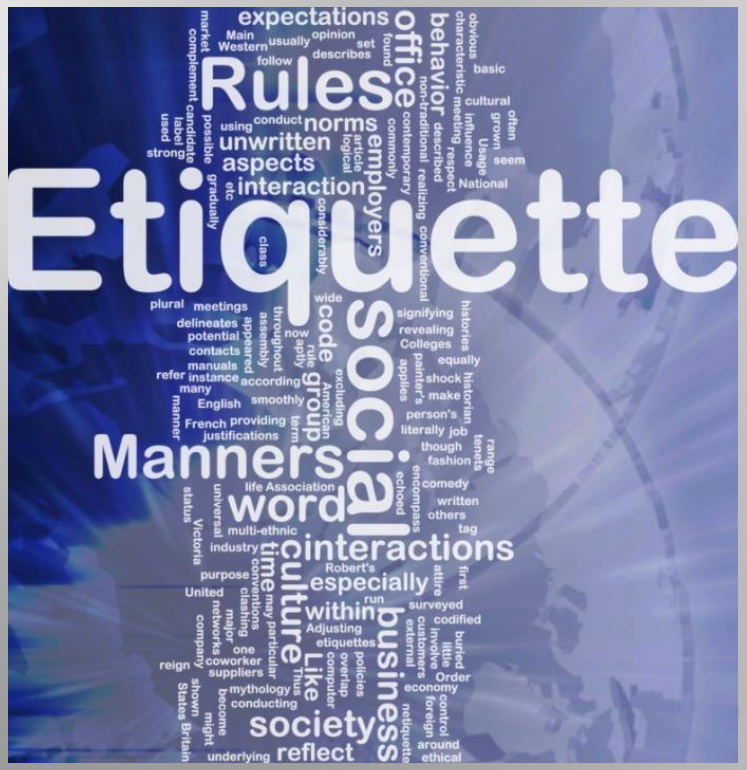
**I**NVOLVES RIGHTS AND WRONGS

**C**ONSCIENCE OF INDIVIDUALS

**S**TANDARDS OF SOCIETY

# ENCOURAGES GOODNESS

- WHAT IS "GOODNESS"?
  - DECENCY
    - EXHIBITING GOOD MANNERS AS JUDGED BY SOCIETY
    - FOLLOWING PROPER ETIQUETTE
    - ACTIONS AND BEHAVIOR DEEMED RESPECTABLE BY OTHERS
  - RIGHTEOUSNESS
    - FAIRNESS
    - JUSTNESS
    - HONOR



# TEACHES EMPLOYEES TO BE COGNITIVE TO ETHICAL ISSUES

- COGNITIVE TO ETHICAL ISSUES?
  - ANNUAL TRAINING PROVIDES A MEANS TO REMIND US OF OUR MORAL BELIEFS
  - REITERATES EXPECTATIONS OF EMPLOYEES AND MANAGEMENT
  - EXPLAINS THE PROCESS OF REPORTING BREECHES IN ETHICAL CONDUCT
  - IDENTIFIES POSSIBLE PUNISHMENT

# HONORABLE BEHAVIOR

- THE ACT OF PERFORMING IN ACCORDANCE TO SOCIETY'S NORM ("PERFORMING A GOOD DEED")
  - A PERSON IN THE GROCERY LINE AHEAD OF YOU DROPS A $20 BILL
    - DO YOU PICK IT UP AND GIVE IT TO THEM OR ALERT THEM OR:
    - DO YOU WAIT UNTIL THEY LEAVE AND PICK IT UP AND PUT IT IN YOUR POCKET
- SPEAK THE TRUTH
- BE LOYAL
- BE EMPATHETIC

# INVOLVES RIGHTS AND WRONGS


- IS IT RIGHT TO:
  - PICK UP LOOSE CHANGE FROM SOMEONE'S DESK WITHOUT ASKING?
  - USE STEROIDS TO ENHANCE ATHLETIC PERFORMANCE?
  - DOCUMENT EQUIPMENT CHECKS THAT WERE NEVER PERFORMED?
  - LOOK THE OTHER WAY AND NOT REPORT AN OBSERVED UNETHICAL ACT?

# CONSCIENCE OF INDIVIDUALS


- SENSITIVITY TO OTHERS
  - PUT YOURSELF IN SOMEONE ELSE'S SHOES
  - IDENTIFY WITH SOMEONE'S EXPERIENCE
  - UNDERSTAND HOW YOUR ACTIONS AFFECT SOMEONE ELSE
- DECIDE WHAT ACTION IS THE BEST BASED UPON MORAL BELIEFS

# STANDARDS OF SOCIETY

- CODE OF CONDUCT
  - GOLDEN RULE
    - TREAT OTHERS AS YOU WOULD LIKE TO BE TREATED
  - TEN COMMANDMENTS
    - THOU SHALL NOT KILL
    - THOU SHALL NOT STEAL
  - CODE OF THE INTERNATIONAL RED CROSS
    - CODE #2: "AID IS GIVEN REGARDLESS OF THE RACE, CREED OR NATIONALITY OF THE RECIPIENTS AND WITHOUT ADVERSE DISTINCTION OF ANY KIND".

# OUR MORAL DECISIONS

Who or what is affected by our daily work decisions?

- WATER SUPPLY USERS
  - INDUSTRY
    - BEVERAGE COMPANIES
      - COCA-COLA
      - PEPSI
    - RESTAURANTS
  - RESIDENTIAL

# HOW OFTEN IS ETHICS TRAINING REQUIRED?

- NEW EMPLOYEES
- MINIMUM OF ONCE PER YEAR
- TRAINING CAN BE PERFORMED INTERNALLY
  - DOCUMENT MATERIALS TRAINED
  - SIGNATURE LOG OF THOSE ATTENDING TRAINING

# WHAT IS GOOD DATA?

## GOOD DATA IS DEFENSIBLE

- RESULTS THAT ARE TECHNICALLY VALID
  - SAMPLES COLLECTED USING CONTROLLED PROCEDURES
  - SAMPLES PRESERVED PROPERLY
  - SAMPLES ANALYZED WITHIN HOLDING TIMES
  - QUALITY CONTROL WITHIN LIMITS
  - QUALITY OBJECTIVES MET
  - METHOD DETECTION LIMIT STUDIES PERFORMED.
  - REPORTING LIMITS VERIFIED WITH EVERY ANALYTICAL RUN
- RESULTS THAT ARE WELL DOCUMENTED
  - QUALITY MANUAL
  - SOPS
  - TRAINING
  - TRACEABILITY
    - REAGENTS
    - INSTRUMENTATION
  - ANALYTICAL DATA DOCUMENTATION
    - WHO, WHAT, WHERE, WHEN & HOW
  - CALIBRATION DATA