QUALITY ASSURANCE OVERVIEW

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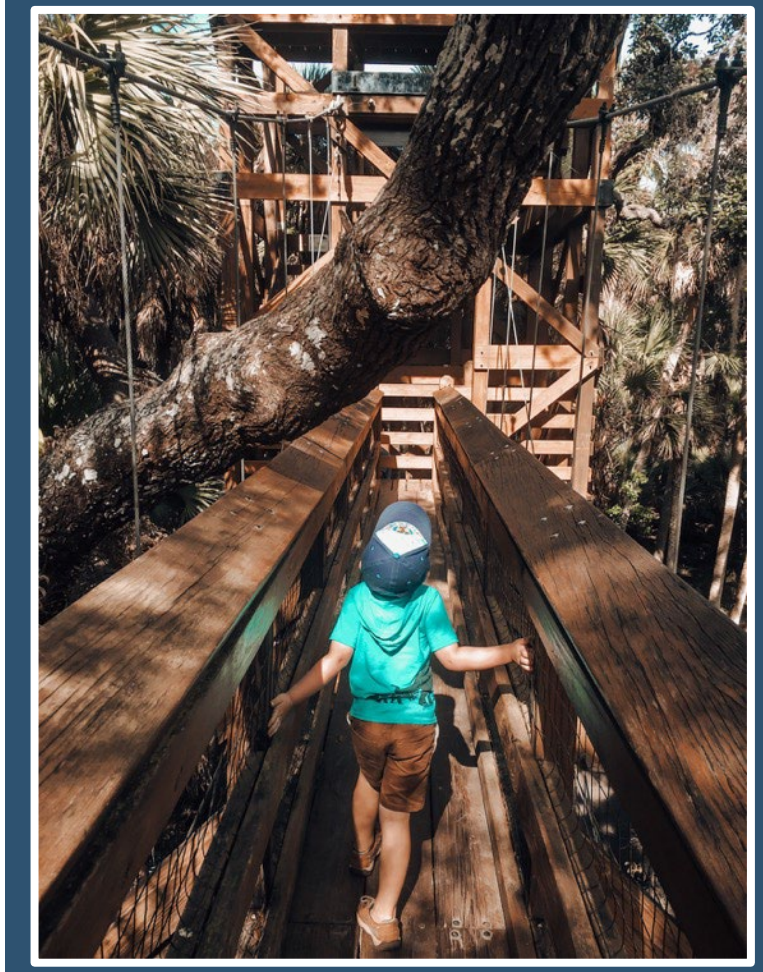
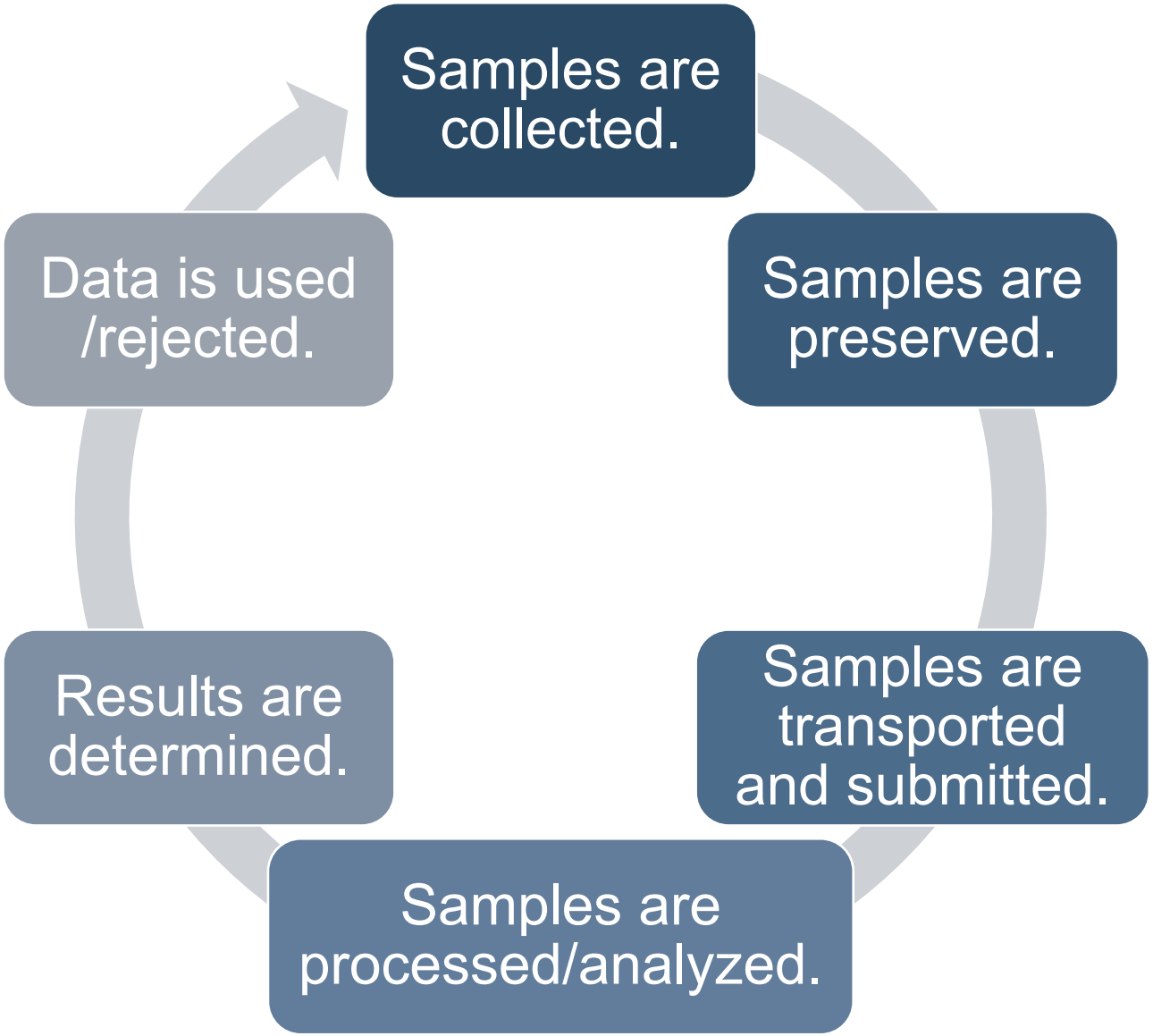
QUALITY ASSURANCE OVERVIEW

OUTLINE

- Basics of Quality Assurance (QA).
- Chapter 62-160, Florida Administrative Code (F.A.C.); the QA Rule.
- Common Department of Environmental Protection (DEP) Standard Operating Procedures (SOP).
- Groundwater Sampling SOP Variances.
- Data Review Basics.



LIFE OF SAMPLE



DATA QUALITY AND DEP

- Possible consequences of poor data quality:
  - Create or use erroneous data.
  - Reach unsupported decisions.
    - If “real” result is higher than reported.
      - Environment is not protected.
    - If “real” result is lower than reported.
      - Costly, unnecessary response actions.
  - In either case:
    - Legal challenges.
    - Adverse publicity and doubt.
  - Ultimately results in more staff time and wasted $$ based on poor data quality.

DATA QUALITY OBJECTIVES AND PROGRAM REQUIREMENTS

- DEP must verify that data is useable.
- Consistent with Data Quality Objectives and program requirements.
- We have statutory authority to reject data.

QUALITY ASSURANCE AND THE DEPARTMENT

AUTHORITY AND OBLIGATION

Section 403.0623, Florida Statutes (F.S.)

- Directs DEP to "establish, by rule, appropriate quality assurance requirements for environmental data submitted to the department and the criteria by which environmental data may be rejected by the department."

Chapter 62-160, Florida Administrative Code (F.A.C.)

- DEP's "QA Rule" contains requirements for field and lab data submitted to DEP.

Chapter 62-160, F.A.C., the QA Rule

CHAPTER 62-160, F.A.C. RULES

62-160.110	Purpose, Scope and Applicability
62-160.120	Definitions and Standards
62-160.210	Approved Field Procedures
62-160.220	Approval of Alternative and Modified Field Procedures
62.160.240	Record Keeping and Reporting Requirements for Field Procedures
62-160.300	Laboratory Certification
62-160.320	Approved Laboratory Methods
62-160.330	Approval of Alternative and Modified Laboratory Methods

CHAPTER 62-160, F.A.C. RULES

62-160.400	Sample Preservation and Holding Times
62-160.405	Electronic Signatures
62-160.600	Research Field and Laboratory Procedures
62-160.650	Field and Laboratory Audits
62-160.670	Data Validation by the Department
62-160.700	Tables (Data Qualifier Codes)
62-160.800	Documents Incorporated by Reference

QA RULE: WHAT YOU SHOULD KNOW

- The QA rule applies to all entities involved with sampling, field testing, lab analysis, data review and presentation and vending services for sampling supplies (kits) or instrument calibration.
- More stringent requirements can be imposed by contracts, orders permits or other DEP rules.
- Most sampling and field testing is routine and must follow the DEP Standard Operating Procedures (SOPs).
- There are minimum documentation and reporting requirements for both field and lab records.
  - DEP can ask for any required records at any time.
  - DEP can specify the format of data reports sent to DEP.

QA RULE: WHAT YOU SHOULD KNOW

- Most lab analyses must be performed by certified labs.
- Most lab methods are routine, are “recognized” as approved by DEP, and may be specified in DEP rules, contracts, orders or permits where required.
- Alternative or modified field and lab procedures and methods must be pre-approved by DEP.
- Most sample preservation and holding time procedures are standard and required as listed in the DEP SOPs (FS 1000 tables).
- Research field and lab procedures must be pre-approved via work plans, sampling and analysis plans or contracts that provide required minimum information.

QA RULE: WHAT YOU SHOULD KNOW

- DEP can audit samplers, field records and lab records at any time.
  - Can include on-site audits by DEP auditors.
- There are minimum criteria for validating data submitted to (or generated by) DEP.
  - The Data Usability document (DEP-EA-001/07) explains the process of determining whether data is usable for a specific purpose.
- Specific Data Qualifier Codes must be used for reported data associated with quality control failures (Rule 62-160.700, F.A.C.).

RULE 62-160.700 TABLES (DATA QUALIFIER CODES)

Codes in Table 1 must be used by lab and field organizations (or other data reviewers) when submitting data to DEP, according to code definitions.

Common Lab Qualifiers	
I	The reported value is greater than or equal to the lab Method Detection Limit (MDL) but less than the Practical Quantitation Limit (PQL).
V	Indicates the analyte was detected at or above the MDL in both the sample and the associated method blank and the blank value was greater than 10% of the associated sample value.
Q	Samples analyzed beyond the required holding time (hours or days, for prep or analysis)

Common Field Qualifiers	
G	Indicates that the analyte was detected at or above the MDL in both the sample and the associated field blank, equipment blank, or trip blank, and the blank value was greater than 10% of the associated sample value.
S	Secchi disk was visible to bottom of waterbody.

RULE 62-160.700 TABLES (DATA QUALIFIER CODES)

Codes in Table 1 must be used by lab and field organizations (or other data reviewers) when submitting data to DEP, according to code definitions.

Common Lab Qualifiers	
U	Indicates the compound was analyzed for but not detected.
Y	Improperly preserved sample (thermal or chemical preservation, either preserved too late or insufficiently)
J	Estimated value. Narrative explanation must be provided in comment (Ex. No Quality Control (QC) measures performed, QC failure, matrix interference, improper lab or field procedures, lab or field calibration failure)

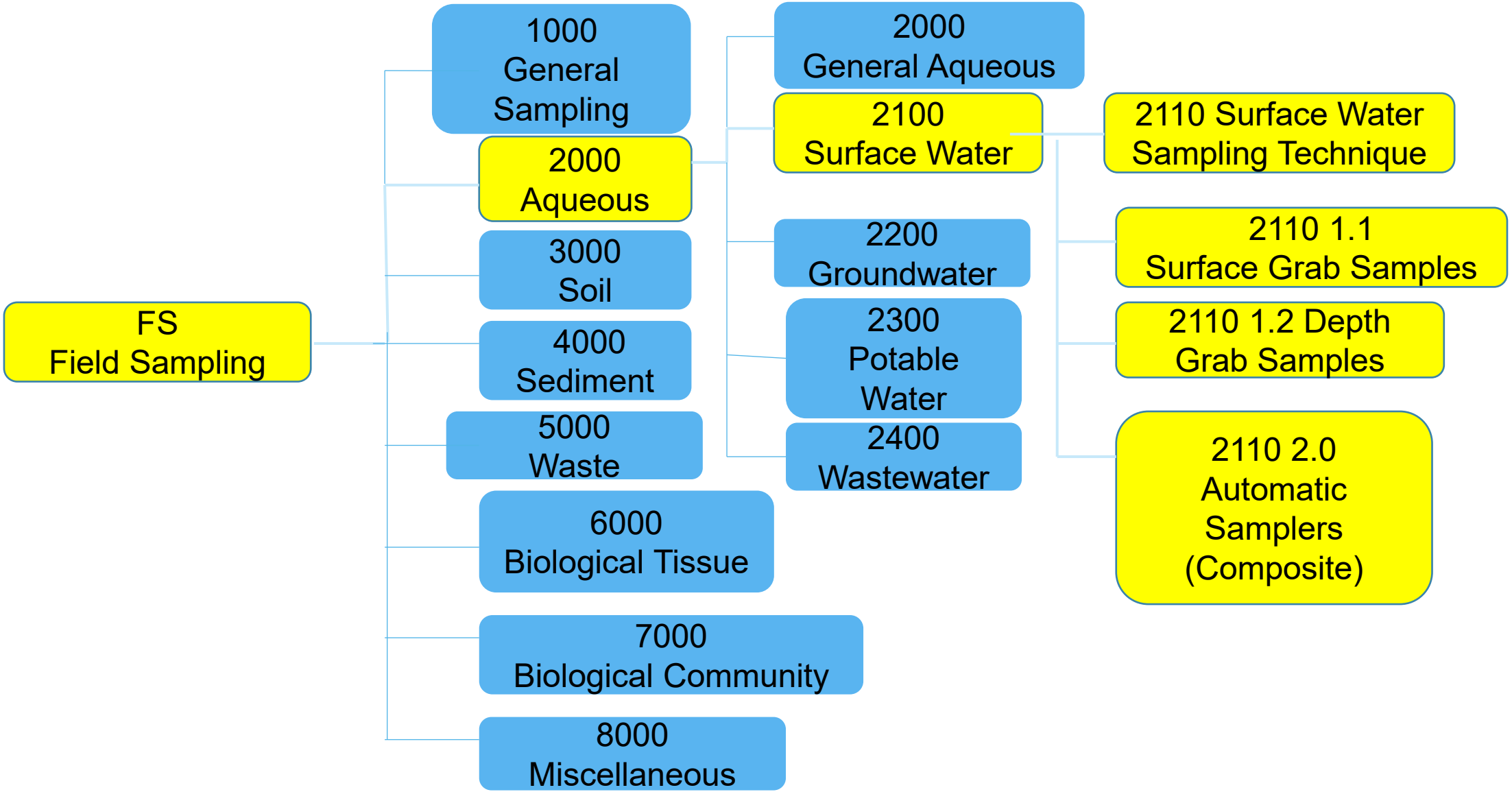
Common Field Qualifiers	
R	Significant rain in the past 48 hours. (Significant rain typically involves rain in excess of ½ inch within past 48 hours.)
J	Estimated value. Narrative explanation must be provided in comment (Ex. No QC measures performed, QC failure, matrix interference, improper lab or field procedures, lab or field calibration failure)

Common DEP Standard Operating Procedures (SOP)

NAMING CONVENTIONS FOR FIELD SOP

- FA Field Administrative and Quality Systems.
- FC Field Cleaning.
- FD Field Documentation.
- FM Field Mobilization and Laboratory.
- FQ Field Quality Control.
- FS Field Sampling Procedures.
- FT Field Testing.

SOP DESIGN


FS
Field Sampling
1000
General
Sampling
2000
Aqueous
3000
Soil
4000
Sediment
5000
Waste
6000
Biological Tissue
7000
Biological Community
8000
Miscellaneous
2000
General Aqueous
2100
Surface Water
2200
Groundwater
2300
Potable
Water
2400
Wastewater
2110 Surface Water
Sampling Technique
2110 1.1
Surface Grab Samples
2110 1.2 Depth
Grab Samples
2110 2.0
Automatic
Samplers
(Composite)

FIELD ADMINISTRATIVE PROCEDURES

- Instructions for using the SOPs and roadmap.
  - “Shall” and “must” vs. “should” and “may.”
- Instructions for how to request an alternative field procedure.
- Quality System requirements:
  - Expectations for QA officers and other staff.
  - Quality Manual Requirements.
- Audit procedures.
- Glossary of terms in the SOPs.
- Definitions for matrices and analyte groups.

QUALITY MANUAL

A quality manual includes, but is not limited to, the following items:

- Organizational structure and key personnel.
- Organization's capabilities.
- QA polices and procedures specific to the organization.
- Equipment lists.
- Routine maintenance activities.
- Discussion of or reference to procedures used in review and assessment of raw data.
- Criteria for determining when corrective actions must be initiated.

See all requirements in FA 3300.

AUDITING

You may be audited by DEP!

Find Example Checklists for Selected SOPs:

- FA 1000 Appendix and QA audit webpage: https://floridadep.gov/dear/quality-assurance/content/data-review-and-audits
- DEP SOPs are audit criteria:
  - Basis for checklists for performance and documentation.

SOME UNIVERSAL DOCUMENTATION REQUIREMENTS

- Sign or initial all documentation.
- Record enough information so that interpretations are not required.
- Do not erase or obliterate errors on records. Make corrections with a line through the error so that it is still legible. Initial the marked error and its correction.
- Clearly link documentation with the associated sample or measurement.
- Keep electronic or hard copies of all documentation for a minimum of five years after the date of generation or completion of the records.
- Keep records of original and reduced or manipulated data.
- Electronic records are equivalent to paper records.
  - Electronic copies intended to replace original records must contain the same information as the original records.

‘PERFORMANCE-BASED’ CLEANING

- Demonstrate effective cleaning with blanks.
- See Table FC 1000-1.

Cleaning to meet a performance specification (no detections in field-QC blanks) rather than following a rigid, required procedure.

WHY USE BLANKS?

- Monitor sampling environment, container/equipment cleaning, preservatives, analyte-free water, and storage and transport conditions.
- Show that samples have not been contaminated by the sampling process.
- Ensure that samples are representative of the sampling source and not biased by a contamination error.

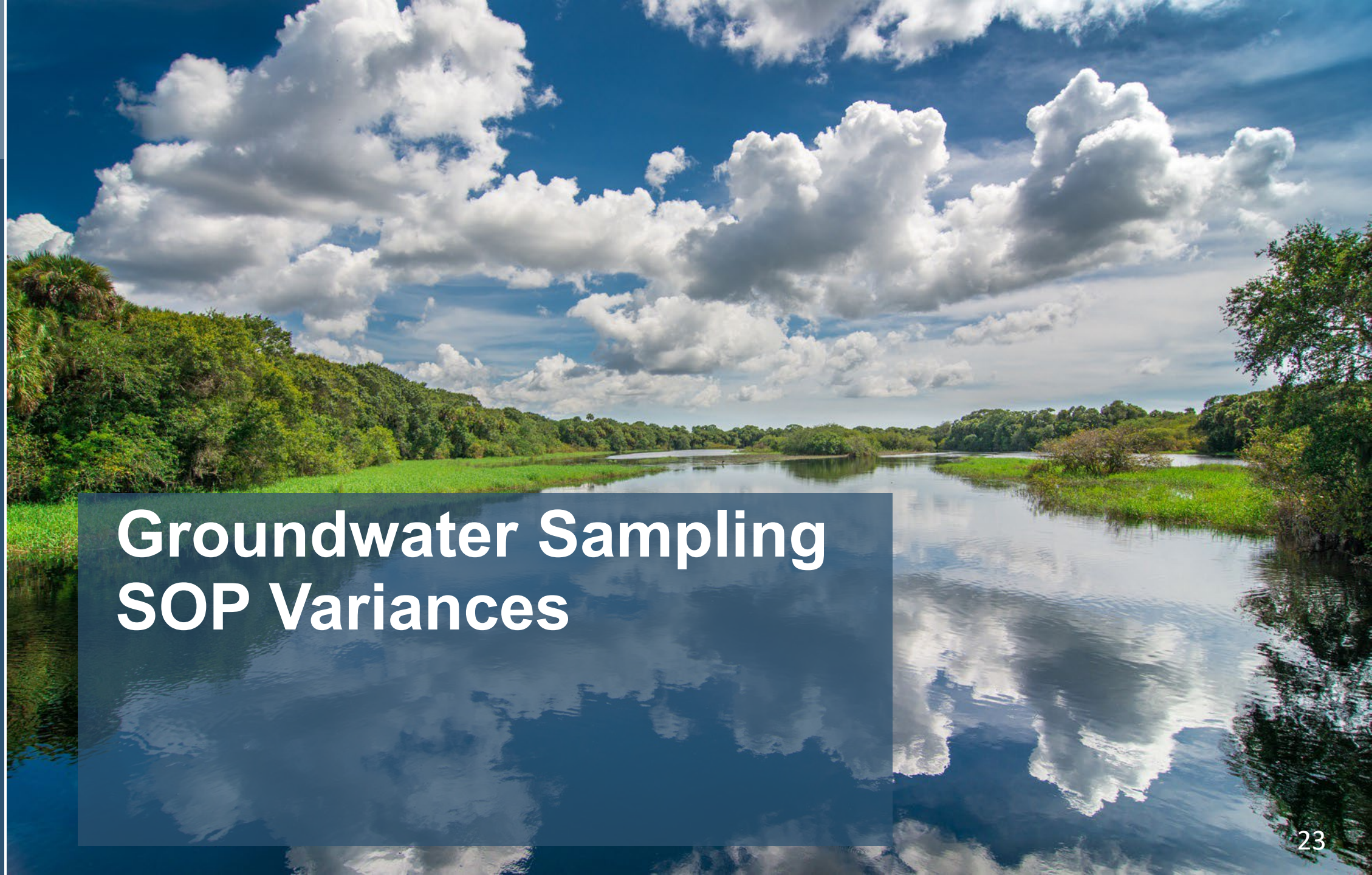
GENERAL SAMPLING PROCEDURES

Important information for all types of sampling.

Useful tables in FS 1000 Appendix:

- Sample Preservation, Holding Times and Container Types.
- Construction Materials and Approved Sampling Equipment.

Be Familiar with and understand the basic requirements in these tables.



Groundwater Sampling SOP Variances

GENERAL SAMPLING PROCEDURE VARIANCES AND CLARIFICATIONS

https://floridadep.gov/sites/default/files/BPSSVariances-Final-May02-2005.pdf

Variances

- Allows for continuing purging if stabilization parameters are not within limits.
- For shallow wells, pump or tubing must be within top two feet of the water column and not in the saturated portion of the screened interval.

GENERAL SAMPLING PROCEDURE VARIANCES AND CLARIFICATIONS

Clarifications

- Minimize drawdown. Drawdown cannot be eliminated.
- For vertical extent wells that are deep, use equipment volume purge instead of well volume purge.
- A well with a partially submerged well screen is considered a water-table (or “shallow”) well, and a well with a fully submerged well screen is considered a vertical extent (or “deep”) well.

Data Review Basics

DEP RULES

Data submitted for regulatory use requires analytical methods approved by DEP

- Programs specify in rules or quality plans which qualified data can be used.
- Methods or method lists (sources) specified in rules.
  - References and tables in waste management rules (see 62-780, F.A.C., Tables C, D, E).
- Verify certification for the reported method.
  - Department of Health (DOH) certified labs query.

DEP Biological and Audit Report Search | Florida Department of Environmental Protection

DATA QUALITY OBJECTIVE AND DATA QUALITY INDICATOR

Data Quality Objective (DQO): Specifications (descriptive and/or prescriptive) established for an intended use of a set of data. A target or goal describing a level of expected data quality.

Data Quality Indicator (DQI): A specified, numerical or qualitative criterion used to evaluate data for conformance with a Data Quality Objective.

DQO AND DQI EXAMPLES

- **DQO: Use DEP SOPs for sampling.**
  - DQI: Collected groundwater samples per DEP SOP FS 2200.
- **DQO: Use DEP SOPs for field measurements.**
  - DQI: Determined stream flow per DEP SOP FT 1800.
- **DQO: Use certified lab for analyses (DOH / Environmental Laboratory Certification Program).**
  - DQI: Lab was certified for reported method number and matrix.
- **DQO: Use approved method for lab analysis.**
  - DQI: Measured corrected chlorophyll a by EPA method 446.0.
- **DQO: Achieve detection levels lower than water quality standards.**
  - DQI: Lab reported MDL of 0.05 µg/L for silver.

EASY CHECKS FOR DATA REVIEW

- Completeness:
  - Report of sample data and relevant Quality Control (QC) data.
    - Sampling and analysis dates and times.
    - Report of relevant field information.
  - Other Contract Deliverables (if applicable).
- Lab certification:
  - Analytical Methods Used.
  - See the Site Manager Guide section 9.2 (Site Manager Guide).

EASY CHECKS FOR DATA REVIEW

- Reported MDL and PQL values.
- Data Qualifiers:
  - Holding Time and Preservation.
  - Blanks.
  - Precision and Spike Recovery.
  - MDL and PQL.

DATA USE AND CONTEXT

- Project management goals.
- Quality Control Results for Data Quality Indicators.
- Action or compliance levels.
- Corroborating Data.
- Consider sampling and analysis issues.

DEP DATA QUALIFIERS

- **What do they do?** Qualifiers Provide Quality Control Information.
- **What do they NOT do?** Automatically Signify Unusable Data.
  - For example: A spike failure or a method blank hit must be interpreted in the context of data use.
- **Where to find them?** Rule 62-160.700, F.A.C.

DEP DATA QUALIFIERS
Rule 62-160.700, F.A.C.

1st table: (primarily) Lab Qualifiers:

- Shall be used by labs and/or field orgs when reporting values that meet specified descriptions or do not meet the QC criteria.
- A, B, F, H, I, J, K, L, M, N, O, Q, T, U, V, X, Y and Z.

2nd table: Field Qualifiers:

- Shall be added by organization that collects the samples if they apply.
  - D, E, G, R, S and !

BLANK EVALUATION

Data Qualifier Codes:

- Samples receive data qualifier codes per “10%” rule.
- If Blank Concentration > 10% of Sample Concentration:
  - “G” – analyte found in **field-QC blank.**
  - “V” – analyte found in **Lab Method Blank.**
  - “J” – analyte found in any other type of lab QC Blank.
    - Code comment required.
- Blank values are not typically subtracted from sample results.

PRESERVATION (Y)

Proper Preservation?

- Temperature control.
- Chemical treatment.
- pH adjustment.

Improper Preservation: “Y”.

- If Exceeded:
  - +/- Estimations Based on Chemical/Biological Properties.
    - Chemical Results may be biased high or low.

HOLDING TIME (Q)

Were Required Holding Times Met?

- Hours or days?
- Sample Preparation (including extracts) or Analysis?
  - Separate holding times may be required for sample prep vs. analysis (e.g., EPA 8270 for semi-volatile compounds).

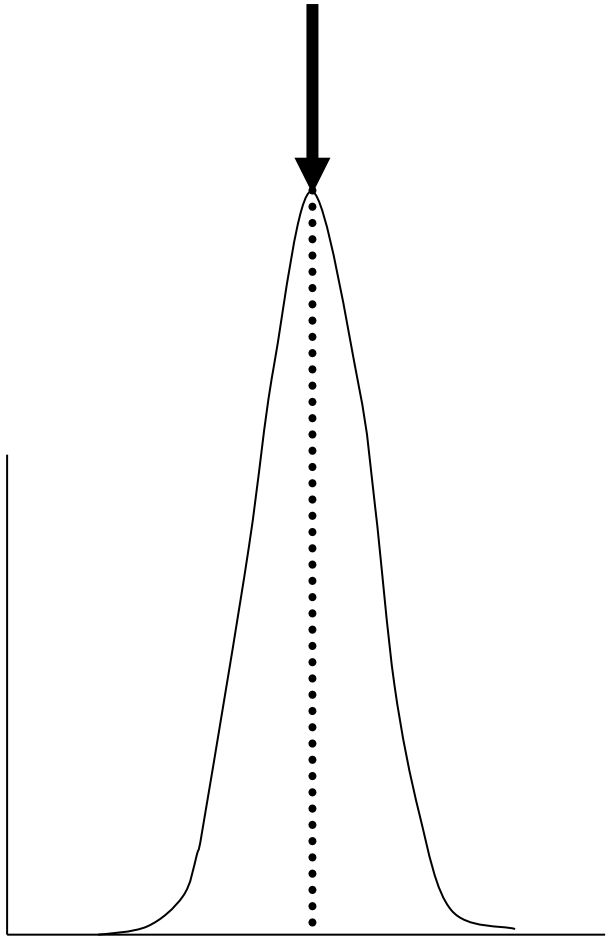
Exceeded Holding Time: "Q".

- If Exceeded:
  - +/- Estimations Based on Chemical/Biological Properties.

PRECISION AND ACCURACY

- **Accuracy**: The ability to measure the “true” value. Overall agreement of a measurement to a known value - includes a combination of random error (precision) and systematic error (bias) in both sampling and analysis operations.
- **Bias**: Systematic or persistent distortion of a measurement process that causes errors in one direction.
- **Precision**: Consistency of measurements. Agreement among repeated measurements under identical, or substantially similar conditions.

ACCURACY
SPIKES – ALL TYPES

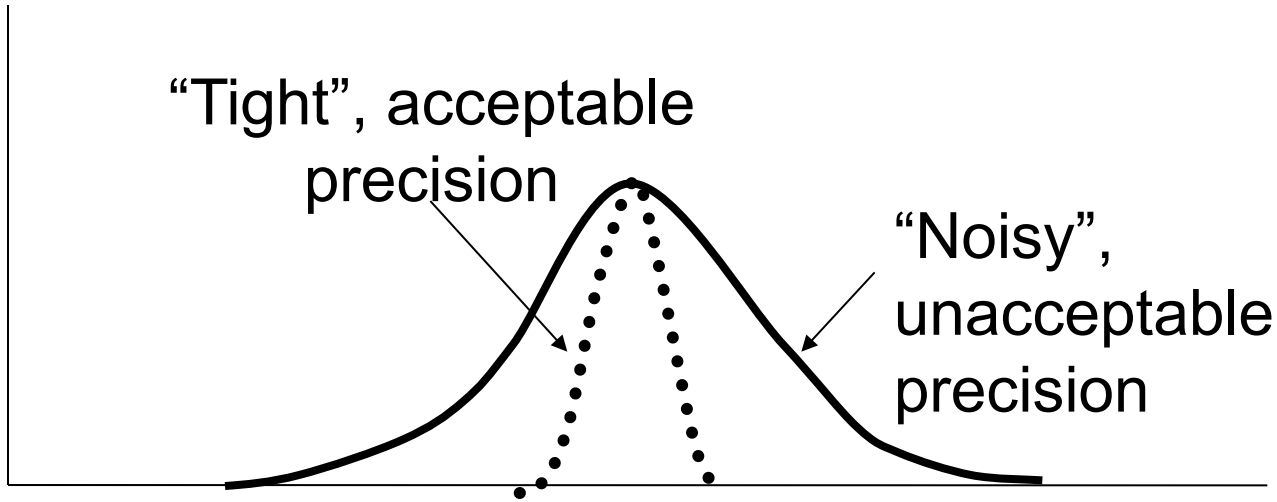


The true or standard value is based on the central tendency of measurements involving multiple high quality testing laboratories, using exacting National Institute of Standards and Technology procedures (used to establish reference standards).

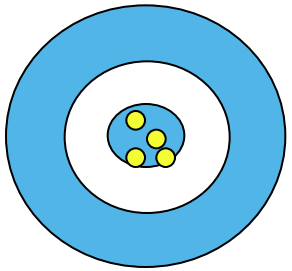
Most laboratories purchase reference standards for calibration and QC (e.g. for spikes).

PRECISION
DUPLICATES OR REPLICATES

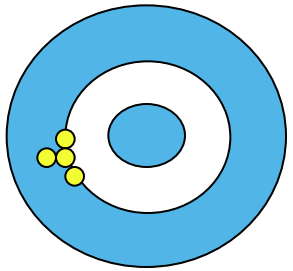
The relative agreement in values from repeated measures of the same sample (e.g., relative standard deviation) during routine testing runs (measurement repeatability).



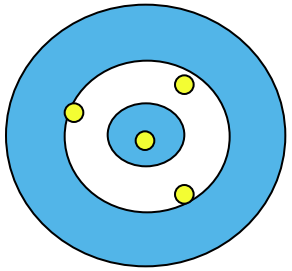
PRECISION AND ACCURACY DUPLICATES AND SPIKES



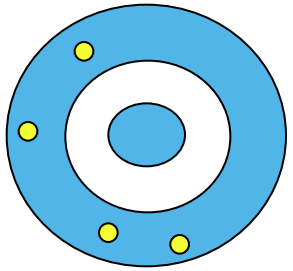
Good precision,
Good accuracy



Good precision,
Poor accuracy



Poor precision,
Good accuracy



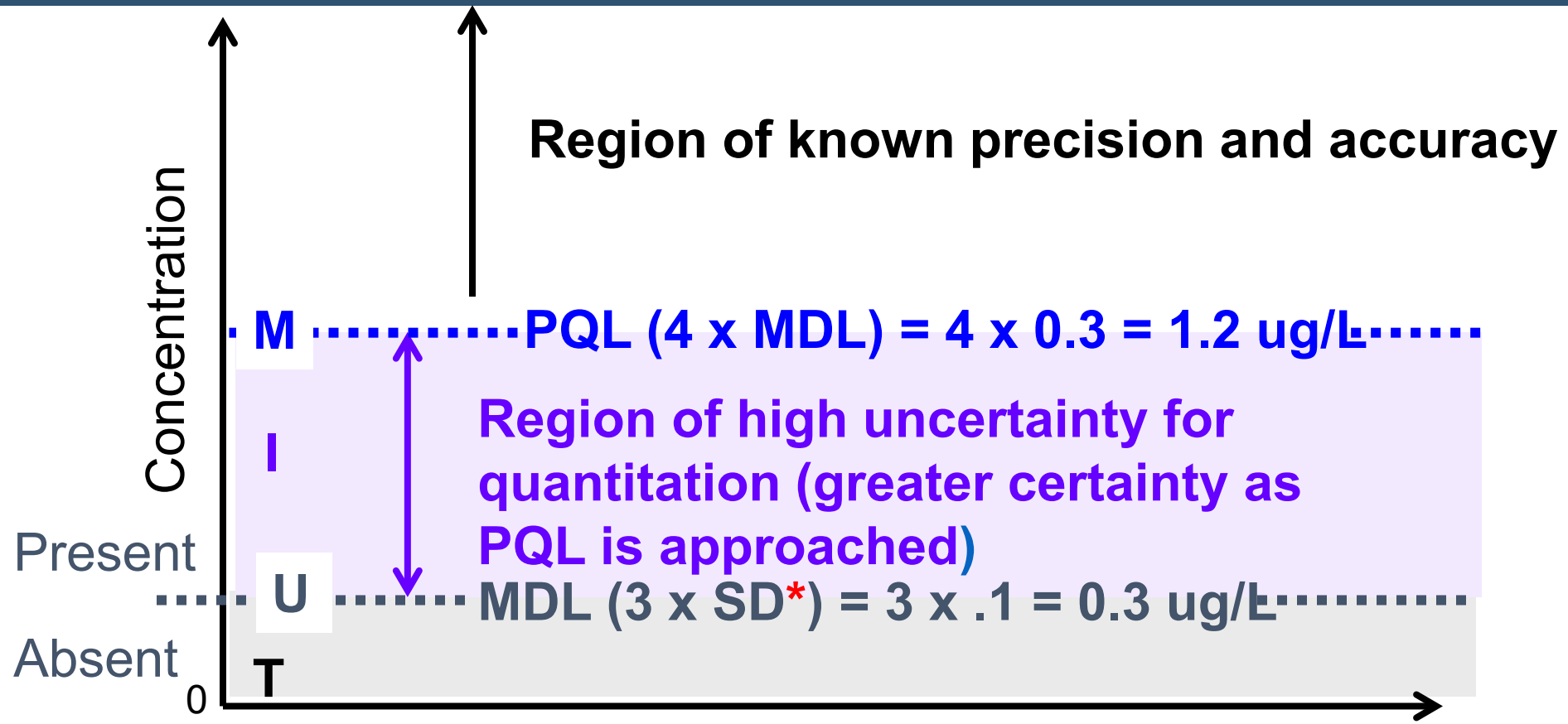
Poor precision,
Poor accuracy

MDL AND PQL*

- **Method Detection Limit (MDL)**: An estimate of the minimum amount of a substance that an analytical process can reliably detect and/or distinguish from a blank. Note: per 62-160, Limit of Detection (LOD) = MDL for data usability purposes.
- **Practical Quantitation Limit (PQL)**: The lowest level of measurement that can be reliably achieved during routine laboratory operating conditions within specified limits of precision and accuracy. Note: per 62-160, Limit of Quantitation (LOQ) = PQL for data usability purposes.
- MDLs and PQLs are analyte-and matrix-specific and are laboratory-dependent, determined from the preparation and analysis of a sample in a given matrix containing the analyte.

* **“Reporting Limits“ can be either of the above... Or something else. Be careful!**

MDL / PQL RELATIONSHIP



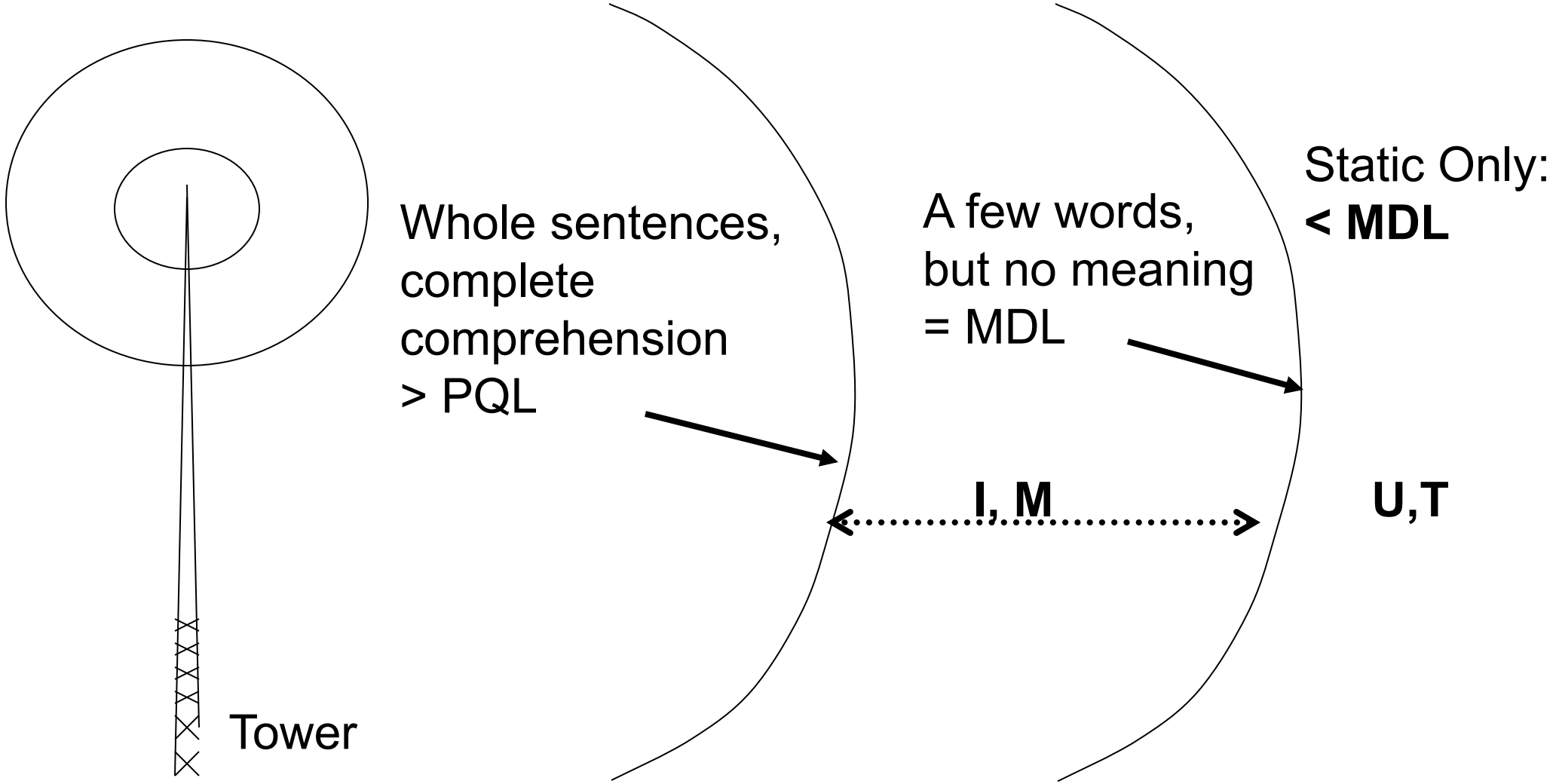
*Standard Deviation from MDL replicate study (Example: SD=0.1 ug/L)

MDL is an Estimate of a Lab's Ability to Detect (not quantitate) at the MDL concentration

DETECTION AND QUANTIFICATION QUALIFIERS

- U: **Analyte Not Detected in Sample** (MDL value reported).
- I : **Sample Value is between MDL and PQL** (sample value reported).
- M: **Sample Value is between MDL and PQL** (PQL value reported).
- T: **Sample Value is less than MDL** (sample result reported).
  - “T” rarely used and should be explained, since these values are generally not applicable for regulatory purposes.

MDL AND PQL RADIO RECEPTION ANALOGY



MDLS AND PQLS PROBLEMS

- Lab MDL or PQL is too high for intended use.
  - Sensitivity not usable for non-detect samples.
    - Reported MDL or PQL doesn't meet target.
    - Elevated MDL / PQL from unnecessary sample dilutions not usable (may require explanation from lab).
- Estimated values for sample results <PQL are potentially problematic.
  - Values are less reliable.

MDLS AND PQLS
SPECIFICS FOR PRP AND PAH DATA

- Issued May 14, 2007, Quality Assurance Related Issues Memo available at https://floridadep.gov/waste/petroleum-restoration/documents/quality-assurance-and-related-issues.
- The groundwater Contaminant Target Levels (CTLs) for the four carcinogenic Polycyclic Aromatic Hydrocarbons (PAHs) listed below, may be lower than their respected PQLs.
    - Benzo(a)anthracene.
    - Benzo(b)fluoranthene.
    - Dibenz(a,h)anthracene.
    - Indeno(1,2,3-cd)pyrene.

MDLS AND PQLS
SPECIFICS FOR PRP AND PAH DATA

- If one or more PAHs above are detected but their concentrations do not exceed their respective PQLs, it is considered that the alternative groundwater CTLs are met even if the risk-based groundwater CTLs referenced in Table I of Chapter 62-777, F.A.C. are lower than the PQL.
- When the risk-based CTL is lower than the PQL, the PQL becomes the alternative CTL completion, if it is the **best achievable detection limit** for these four PAHs.
- However, in order to achieve site rehabilitation completion, it must be demonstrated that no CTLs are exceeded.

INTERPRETING QUALIFIERS

"J" – Estimated Values

- Narrative Explanation Must be Provided.
  - Lab should estimate bias if possible.
- Evaluate Based on Explanation.

Examples

- No QC Measures Performed.
- QC Failure (e.g., Accuracy, Precision).
- Matrix Interference.
- Improper Lab or Field Procedures.
- Lab or field calibration failure.

REPLICATE PRECISION (J)

- Lab Replicates (e.g., Duplicates): Lab Precision Criteria.
- Field Replicates: Use Lab Precision Criteria as Starting Point for Evaluation.
- Unacceptable Precision: “J” (estimated value).
  - Evaluate lab replicates based on required criteria.
    - Analytical method, project DQO or lab precision limit.
  - Evaluate Field Replicates:
    - Does precision exceed lab precision criterion?
    - Site or sampling event issues.
      - Sampling Error - Improper Sampling Techniques?
      - Indication that Samples are not Representative.

REVIEW DATA

- Does it Make Sense?
  - Different from Expected?
  - Consistently the Same Value?
  - Do Parts Add up to Total (e.g., dissolved vs. total)?
- Are Non-Detects Reported Correctly (“U”)?
- What QC Problems are Reported?
  - Spikes (all types), duplicates, blanks, calibrations.
  - Detection and quantitation limit issues.

REVIEW DATA

Possible Warning Flags

- No QC Problems – **Ever!**
- Always in Compliance.
- All MDLs or PQLs are at the Regulatory Limit.

ASK QUESTIONS

- You have the authority to ask questions:
  - Data report issues.
  - Sampling procedures.
  - Laboratory procedures.
- Be persistent.
- Ask for documentation (QA rule).
- Seek other DEP resources:
  - Other division subject matter experts.
  - Aquatic Ecology and Quality Assurance Section.
  - Tallahassee laboratories (expert staff for chemistry and biology).

DATA REVIEW RESOURCES

- DEP-EA-001/07 Process for Assessing Data Usability.
- Chapter 62-160, F.A.C. (QA Rules).
- DEP SOPs.
- MDL and PQL target lists:
  - Chapter 62-777, F.A.C., PQL target lists.
  - Memorandum about PAH PQLs- https://floridadep.gov/sites/default/files/Quality-Assurance_14May07.pdf

DATA REVIEW RESOURCES

- Chapter 62-780, F.A.C.
- General Technical Guidance website. General Technical Guidance | Florida Department of Environmental Protection.
- Permits.
- Agreements.
- Experienced Staff!
- Quality_Assurance@FloridaDEP.gov

THANK YOU

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Florida Department of Environmental Protection

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