CWA Analytical Method Program Requirements: Analytical Method Approval and Implementation, Roles and Responsibilities

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Clean Water Act Analytical Methods

http://water.epa.gov/scitech/methods/cwa/index.cfm

Presentation Overview

- Clean Water Act (CWA) Requirements
- Overview of Rulemaking Process
- Source of CWA Methods
- Process for Approving Methods
- Implementation of Methods

Methods Approved for use in CWA Compliance Monitoring

- Clean Water Act (CWA) Section 304(h) requires USEPA to promulgate test procedures (analytical methods) for the analysis of pollutants.

- All methods approved at the federal level are approved by the Administrator and promulgated through the rulemaking process.

- Approved methods are required in applications for National Pollutant Discharge Elimination System (NPDES) permits and for continuing use to demonstrate compliance with those permits.

Rulemaking Process

- EPA proposes a rule to add a method(s) to the list of approved methods at Title 40 of the Code of Federal Regulations (40 CFR) Part 136.
- The public is provided an opportunity to submit comments on the proposal.
- EPA publishes a final rule promulgating the method(s) for use in compliance monitoring required under the CWA

Where Do Methods Come From?

- These methods originate from one of the following three general sources:
  - Methods developed, validated and published by EPA for a specific regulatory purpose.
  - Methods developed, validated and published by voluntary consensus standards bodies (VCSBs) and submitted for approval under the National Technology Transfer Advancement Act (NTTAA) or those developed by other Government Agencies.
  - Methods developed, validated and published by other organizations and submitted for review as alternate test procedures (ATPs).

Methods from EPA

- EPA has developed many methods for CWA compliance monitoring, including those from:
  - Office of Research and Development (ORD)
  - Office of Ground Water and Drinking Water (OGWDW) that also may be applicable to wastewater
  - Office of Water's Engineering and Analysis Division (EAD)

Commonalities

- The EPA Science Advisory Board (SAB) recommended that all CWA methods use a common set of QC operations, although the terminology may differ among Offices
- Similar method structure, based on 1990s EMMC format
- Same goal – to generate data of known quality and legally defensible

How are EPA Methods Evaluated for Inclusion at 40 CFR Part 136?

- Basic tenets resemble those set forth with the advent of the Priority Pollutant List:

http://water.epa.gov/scitech/methods/cwa/pollutants-background.cfm

  - One or more analytes must either be regulated already, or must be needed for an upcoming regulation of some industrial category or water quality criteria
    http://water.epa.gov/scitech/wastetech/guide/industry.cfm

  - Appropriate analytical standards and reference matrices and materials must be available

Other Considerations

- Method must be sensitive enough to meet regulatory need
- Minimize false positive risks (i.e., technique needs to be sufficiently selective and free of other interferences)
- Method steps must be well documented so that a knowledgeable analyst can perform it without being an expert (e.g., no hidden tricks)
- Method must be rugged and can be transferred to routine production laboratory setting

Documentation

- Methods developed by EPA must be supported by extensive documentation, including:
  - Formal study planning documentation (e.g., QAPP and/or study plan)
  - Availability of all raw data supporting the testing
  - Clear discussion of the data evaluation procedures and any statistical analyses

Methods from Sources Other Than EPA

- These include methods developed and validated and submitted by the following sources:
  - VCSBs such as the Standard Methods Committee, ASTM International and AOAC International.
  - Government Agencies other than EPA such as the United States Geological Survey (USGS).
  - Methods developed, validated by other sources and submitted for consideration as ATPs.

Considerations When Evaluating Methods From Sources Other Than EPA

All Methods:

- Is it justified (e.g., update to previously approved method, less costly than existing methods, other benefits)?
- Does it address all required elements (scope, summary, definitions, interferences, data reporting, etc.)?
- Are appropriate QC elements addressed?
- Does it include specific QC acceptance criteria that are equal to or better than the method currently approved at 40 CFR 136?
- Does it have a unique method number & date/revision date?

Considerations When Evaluating Methods Developed by VCSBs or Other Government Agencies

- Does it contain a revision date or date of approval?
- Would use be practical and comply with NTTAA requirements?
  - **Applies to VCSB methods only**
- Is the method in its final form?
- Has it been approved/published by the VCSB or Government Agency

- **For Modified/Revised Versions of Approved Methods**
  - Is a copy of the currently approved method enclosed, with redline/strikeouts and additions noted?

CWA ATP Program

- EPA's regulations at 40 CFR §§ 136.4, and 136.5 establish procedures for EPA to review and approve the use of an alternate test procedure (ATP) in place of an EPA-approved method for use in CWA compliance monitoring.

- 40 CFR. § 136.4 describes the procedures for application and approval of ATPs for nationwide use in all laboratories

- 40 CFR. § 136.5 describes the procedures for application and approval of ATPs for limited-use.

CWA ATP Program (cont.)

- Under EPA's CWA ATP program, a method developer (other than EPA, VCSBs or other government agencies) may apply for approval for the use of an ATP for measurement of a specific regulated constituent.

- Applicants conduct validation studies to generate comparability data for the performance of the ATP relative to the performance of the approved Part 136 method for which it is a proposed alternative.

- Protocols have been developed to provide guidance for submission, validation, and EPA review of these methods for chemical and microbiological contaminants.

- These protocols are available on our web page at: http://water.epa.gov/scitech/methods/cwa/index.cfm

Roles and Responsibilities for CWA Nationwide Use ATPs

- ATP applications for nationwide use are submitted to the National ATP Coordinator at EPA Headquarters.
- EPA's Engineering and Analysis Division (EAD) staff review all nationwide use ATP applications. EAD may be assisted in its technical review by contractor personnel.
- The EPA National ATP Coordinator notifies the applicant of EPA's recommendation for or against approval of the ATP.
- For ATPs recommended for approval for nationwide use, EPA will initiate the rulemaking process through which methods are formally approved by the EPA Administrator.

Roles and Responsibilities for Limited Use ATPs

- Limited use ATP applications are submitted to the State authority that issues the NPDES permit (in most cases), or directly to EPA Regional staff in States that do not have the authority to administer their own NPDES permit programs.

- States will review limited use ATP applications and forward them to EPA Regional staff with a recommendation for or against approval.

- The EPA Regional ATP Coordinator issues the formal approval or rejection of the ATP.

- Approval may be limited to a specific discharger and their facility or, at the discretion of the Regional ATP Coordinator, to multiple dischargers and their facilities as specified in the approval by the Region.

Considerations When Evaluating Validation Study Plans

- Was EPA consulted/did EPA participate in development of the original study plan for validating the method?
  - Applies to New Methods, Methods involving Method-defined Parameters, and other ATP applications that go beyond explicitly allowed modifications
  - Does the application include written documentation of EPA's participation?
  - Were all EPA recommendations incorporated into the original study plan
- Does application include a copy of the validation study plan, validation study report, and data requirements?
  - Not required for updates of previously approved methods that do not affect the chemistry of the method, determinative technique or QC acceptance criteria

Considerations when Evaluating Validation Study Reports/ Supporting Documentation

- Do data show the MDL was determined as part of the study?
- Did the validation study include real world samples?
- Do data demonstrate compliance with the currently approved method for the following:
  - existing analyte concentration ranges,
  - sample collection,
  - preservation,
  - preparation and
  - holding time requirements?
- Are data that support quantitation range and QC limits included?
- Do supporting data address instrument calibration?

Note: Above not required for updates to previously approved methods and revisions that do not affect the chemistry of the method, determinative technique, or QC acceptance criteria

Validation Study Report/Supporting Documentation Considerations (cont.)

- Do data address:
  - Bias/Trueness
  - Precision
  - Method selectivity
  - Ruggedness?

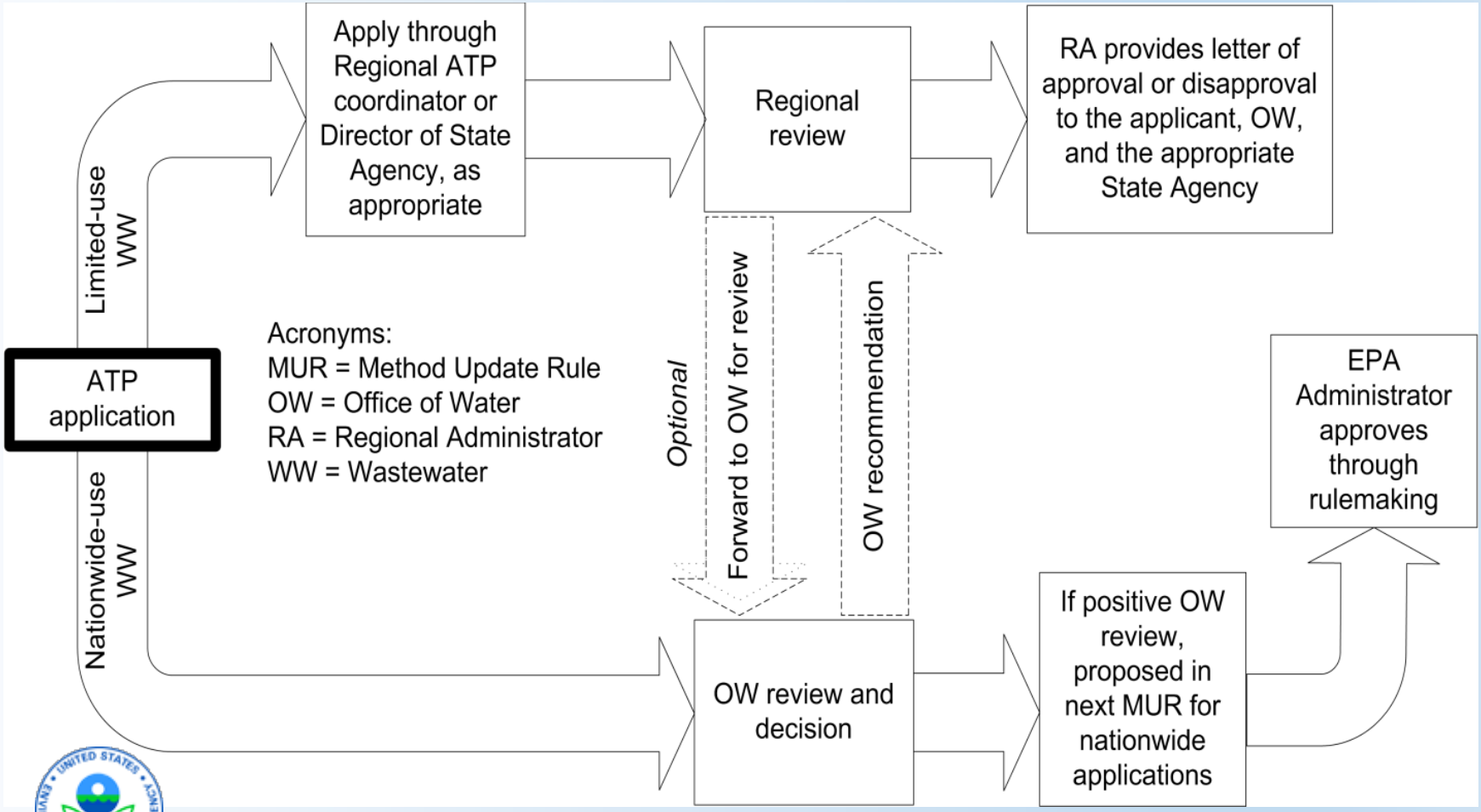
- Are interlaboratory study data provided?
  - Should be submitted in tabular form; raw data should be available for review
  - Should include discussion of/rationale for any changes method to the method resulting from study

Note: Above not required for updates to previously approved methods and revisions that do not affect the chemistry of the method, determinative technique, or QC acceptance criteria

Considerations Unique to Method-Defined Parameters (MDPs)

- **For well-defined MDPs already listed at 40 CFR Part 136:**
  - Does application include:
    - data from side-by-side samples
    - performed in triplicate
    - using both the new and approved methods
    - in 9 distinct real-world matrices?
  - Is the chemistry or determinative step the same as the approved method? If not:
    - are the chemistry and determinative step used to identify and measure the MDP well-explained and
    - clearly defined, along with any potential interferences or difficulties?
- Does the study include appropriate calibration data?
- Do data demonstrate comparable performance of the new method to the approved method?
  - **Will the new and approved methods measure the same forms and species?**

Overview of The ATP Approval Process



Implementing Methods into CWA Permits

- National Pollutant Discharge Elimination Permit System (NPDES) Permits
  - Required for any discharge of pollutants from a point source
  - Establish monitoring requirements for discharge of pollutants
  - Issued by Permitting Authority which can be either an EPA Regional Office or a Delegated State
  - Require monitoring the discharge to demonstrate compliance
- Pollutant discharges from an industrial point source are also subject to monitoring requirements and limits on the discharge of pollutants
  - Referred to as the Pretreatment Program

Key Regulatory Requirements – Monitoring

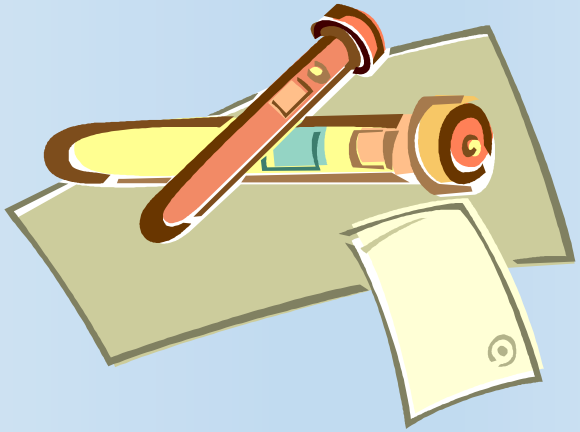
- Permits must specify the type, intervals, and frequency of monitoring sufficient to yield data representative of the monitored activity [§ 122.48(b)]
- Monitoring required [§ 122.44(i)(1)]
  - the mass or other measurement specified in the permit for each pollutant limited in the permit
  - the volume of effluent discharged from each outfall
  - other measurements as appropriate (e.g., internal waste streams and determination of compliance with narrative requirements)

Approaches to Monitoring

- Self-monitoring
  - permittee performs sampling and analysis
- Compliance monitoring
  - permitting authority monitors effluent (during a compliance inspection)

Frequency of Monitoring Considerations

- Size and design of facility
- Type of treatment
- Location of discharge
- Frequency of discharge (batch, continuous)
- Compliance history
- Nature of pollutants
- Number of monthly samples used in developing permit limit
- Cost

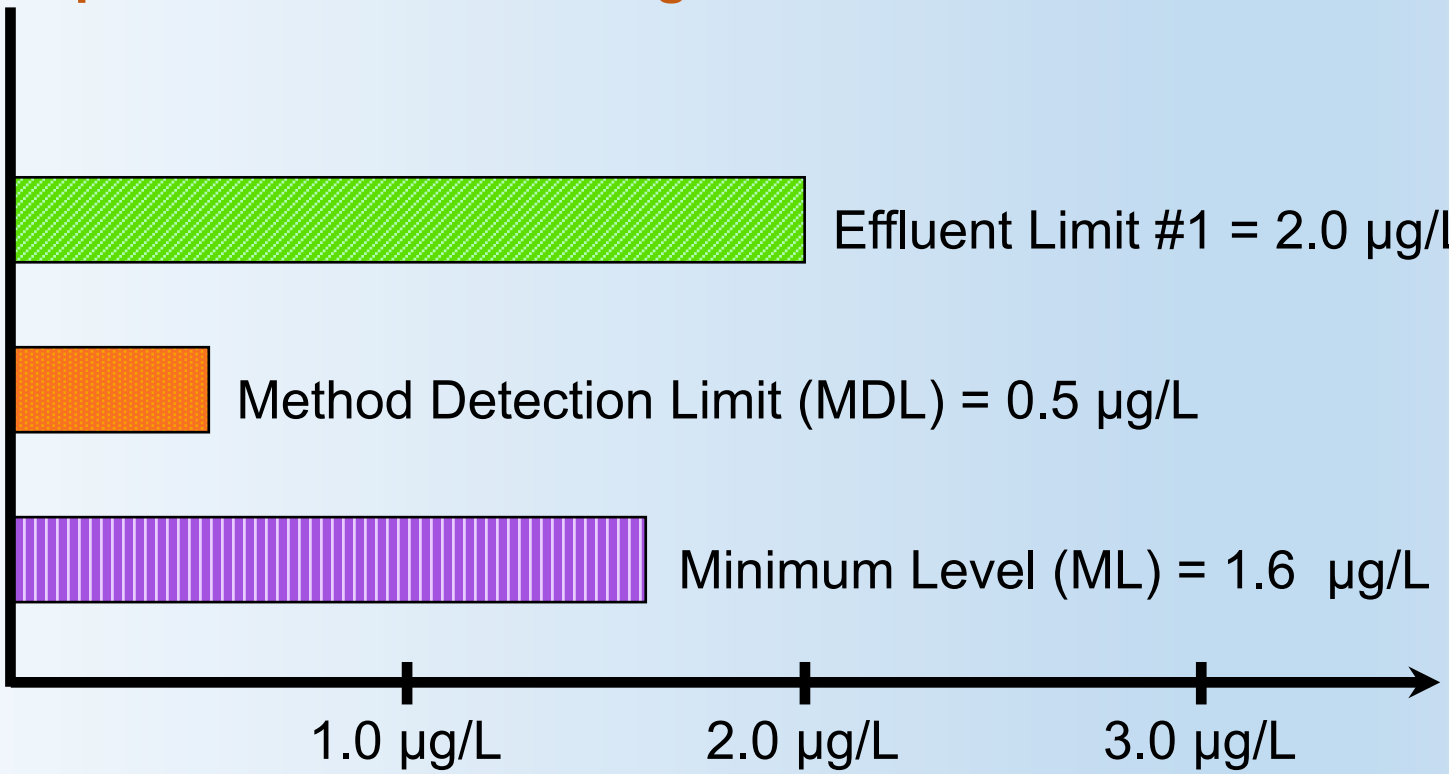


Analytical Considerations in Establishing Monitoring Requirements

- ***Method Detection Limit* (MDL):** the minimum concentration of analyte that can be measured and reported with 99% confidence that the analyte concentration is greater than zero [§ 136.2(f)]
- ***Minimum Level* (ML):** concentration at which the entire analytical system gives a recognizable signal and acceptable calibration point
  - ***Sufficiently Sensitive Methods (*SSM):** Regulations at §122.44(i) and Part 136 require the permitting authority to establish in the permit a sufficiently sensitive method for analysis [79 FR 49001, August 19, 2014]

Analytical Considerations in Establishing Monitoring Requirements

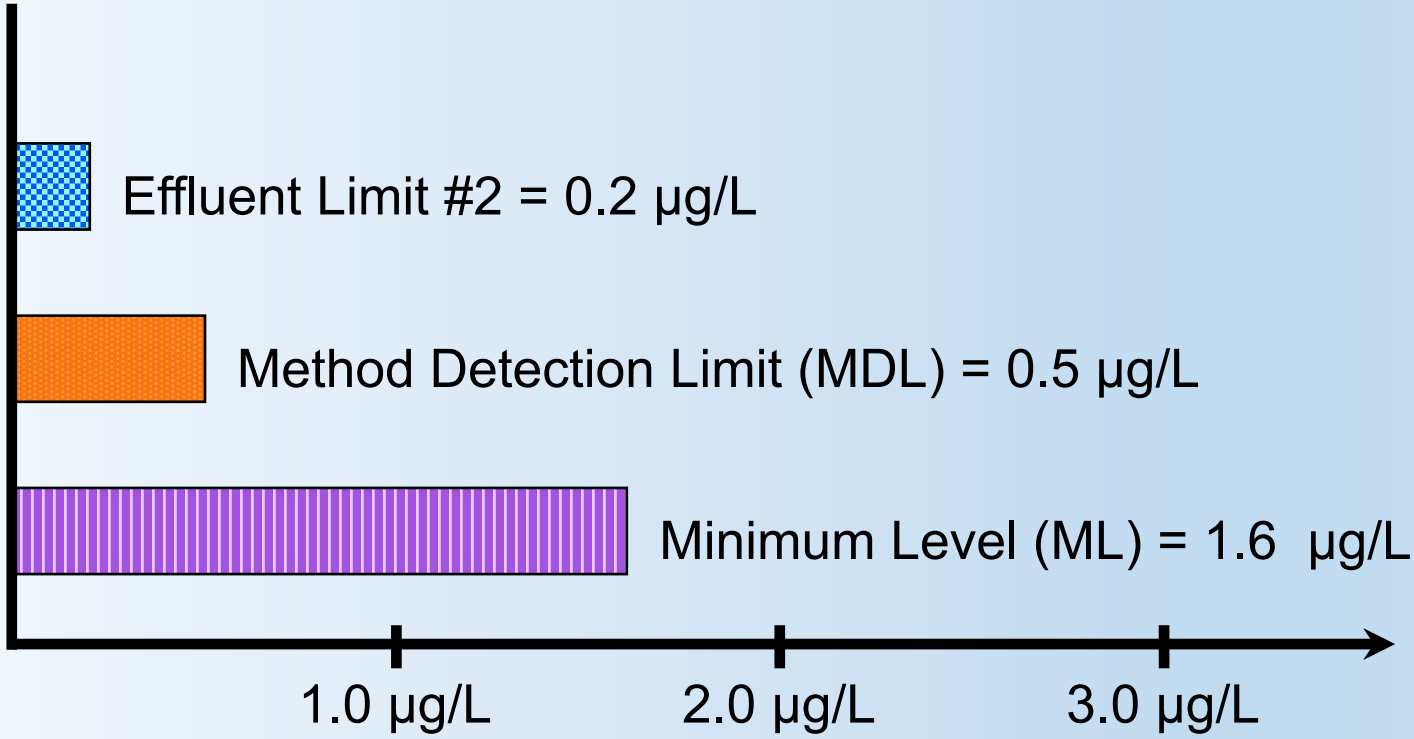
Example #1: Effluent limit is greater than both the MDL and ML



Determine compliance using results from Part 136 method

Analytical Considerations in Establishing Monitoring Requirements

Example #2: Effluent limit is below both the MDL and ML



Determine compliance using results from ??

Key Regulatory Requirements – Reporting

- What is reported?
  - monitoring results as required in permit [§ 122.41(l)(4)]
  - data for pollutants monitored more frequently than required using approved methods [§ 122.41(l)(4)(ii)]
- When is information reported?
  - reporting requirements must be established on a case-by-case basis with the frequency dependent on the nature and effect of the discharge, but in no case less than once a year [§ 122.44(i)(2)]

Key Regulatory Requirements – Reporting (continued)

- Who is responsible for reporting?
  - the permittee [§ 122.22(b)]
- What format is used for reporting?
  - Discharge Monitoring Reports (DMR) [§ 122.41(l)(4)(i)]
    - state, territory, or tribe with NPDES authority may modify DMR to substitute state agency name, address, and logo in place of EPA's
    - state, territory, or tribe may also require additional reporting
  - Increasing number of states use electronic reporting (eDMR)

Enforcement Tools for CWA Compliance Monitoring Laboratory Testing

- ✓ Must use CWA Part 136 Approved Methods
- ✓Must use Validated Equipment, Methods, Analytical Systems, Data, Trained Personnel and Reference Standards
- ✓Must follow Good Laboratory Practice (GLP) Guidelines
- ✓Signed Ethic Forms in the ATP and New Method protocols to Certify all Lab Results
- ✓Must follow QAPP
- ✓Lab SOPs must be written and performed with sufficient QA/QC
- ✓Data must be of Known Quality and Legally Defensible (Security, Integrity and Traceability)