

FOR DISCUSSION PURPOSES ONLY

Sample Collection, Receipt, and Handling Concept Paper

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.307. Methodology.

(a) An environmental laboratory shall follow the requirements for testing or analysis, sample collection, sample preservation and holding times specified in this section.

(f) When an environmental laboratory collects a sample to be analyzed, the sample collection method required by applicable State and Federal laws, regulations or permit conditions shall be followed.

(g) An environmental laboratory shall follow the sample container, preservation procedures and holding times required by State and Federal regulations. If the sample container, preservation procedures and holding times are not required by State or Federal regulations, an environmental laboratory shall follow the sample container, sample preservation procedures and holding time established in the method.

(j) An environmental laboratory shall maintain instructions for sample collection and preservation that meet the requirements of subsections (f) and (g).

(1) The environmental laboratory's instructions must accurately reflect all aspects of the sample collection and preservation requirements for the particular analyses, including the following:

- (i) Container type, size and number of containers or bottles.
- (ii) Sample collection method, amount of sample required and explanation of other specific requirements for sample collection such as "zero headspace" and "first draw."
- (iii) Chemical preservation, including type of preservation and the procedure used to preserve the sample.
- (iv) Thermal preservation, including the temperature requirements and procedure used to preserve the sample.
- (v) Field blank requirements.
- (vi) Holding time.

(2) The environmental laboratory shall make the sample collection and preservation instructions available to all laboratory sample collection personnel and to customers and clients that collect samples.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

(f) An environmental laboratory shall establish procedures for handling environmental samples.

(1) The environmental laboratory shall implement procedures for checking and verifying the condition of the sample. The results of these checks shall be recorded. The environmental laboratory shall check:

- (i) The sample container and the sample preservation, both thermal and chemical, of each sample.
- (ii) The sample pH for all samples to be analyzed for whole effluent toxicity and safe drinking water chemistry fields of accreditation, unless the sample is collected by the environmental laboratory performing the analysis.

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- (iii) The sample for the presence of residual chlorine when the presence of residual chlorine will compromise the validity of the test.
- (2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:
 - (i) The client/project name.
 - (ii) The date, time and location of sample collection, name of sample collector and field identification code.
 - (iii) The date and time of laboratory receipt and identification of the individual receiving the sample at the laboratory.
- (g) An environmental laboratory shall have a sample acceptance policy that clearly outlines the circumstances under which environmental samples will be accepted or rejected. The environmental sample acceptance policy must include the following areas:
 - (1) Sample identification, location, date and time of collection, collector's name, preservation type and sample type.
 - (2) Sample labeling.
 - (3) Use of appropriate containers and sample preservation method.
 - (4) Adherence to holding times specified in the regulation and when not specified by the regulation, adherence to the holding times specified by the method.
 - (5) Sufficient sample volume shall be available to perform the necessary testing and analysis, including any required quality control testing or analysis.
 - (6) Procedures to be used when samples show signs of damage, contamination or inadequate preservation.

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.706. Recordkeeping.

- (a) An environmental laboratory shall maintain records in an organized manner accessible by the Department.
- (b) An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, proficiency test studies, initial demonstration of capability or demonstration of continued proficiency. These records include the following:
 - (1) Start and end dates and times of incubations, drying cycles, digestion, distillations, and the like, when a minimum or maximum time is specified by method, regulation or permit.
 - (2) Unequivocal link between the laboratory's sample identification number to the results of all associated quality control.
 - (3) Instrument identification.
 - (4) Identification of, or reference to, the standards, reagents, media, supplies, and the like, used during sample preparation or analysis, or both.
 - (5) The results of chemical or thermal preservation verifications or adjustments, or both.
 - (6) Date of sample preparation or analysis, or both.
 - (7) Time of sample preparation or analysis, or both, if the holding time for either activity is less than or equal to 72 hours.
 - (8) Manual calculations.
 - (9) Test results.

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- (c) All records, except records generated by automated collection systems, shall be recorded promptly and legibly in permanent ink or in an electronic format.
- (1) The individual generating the record must be identified by initials or name and the individual making the observation must be identified by initials or name if different from the individual generating the record.
 - (2) Changes to records shall be made so that the original entry remains visible. The individual making the change shall be identified by name or initials, date the correction and include the reason for the change unless correcting a typographical error. These criteria also apply to electronically maintained records.
- (d) Records required under this chapter shall be maintained for a minimum of 5 years unless otherwise specified.
- (e) An environmental laboratory shall have a written plan that specifies how records will be maintained or transferred if the laboratory transfers ownership or terminates operations.

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DISCLAIMER: This document is for discussion purposes only. The concepts contained within this document do not amend, change, remove or add to the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa. Code Chapter 252.

For the purposes of this document, the term “sample collection personnel” refers to an individual employed by an accredited environmental laboratory.

Sample Collection, Preservation, and Transport Instructions: § 252.307

1. The laboratory must maintain instructions for sample collection and preservation that meet the requirements of 252.307(f) and (g). The laboratory may develop their own or they may be obtained/copied from another source. Options for laboratories:
 - a. Use EPA or other publications
 - b. Use current laboratory SOPs
 - c. Develop new documents
2. Must cover all fields of accreditation for compliance testing to be sampled. The laboratory that provides sample bottles to customers for their own collection, or sends staff out to collect the samples, must ensure that the sample collection instructions are applicable to the analysis types to be collected.
3. The instructions must meet any Federal, State, method, or permit requirements
 - a. 40 CFR Parts 136, 141, 143, 503, etc.
4. Must include requirements for sample container, sample preservation procedures, and holding times. A table format that outlines the requirements for each type of sample would be recommended. Another option would be to have different collection instructions for different sample types.
5. Must include collection techniques, preservation techniques, and transport requirements.
 - a. Number of containers, type, size
 - b. Amount of sample
 - c. Specific collection requirements, such as “zero headspace” or “first draw” and specific definitions and instructions that explain these terms.
 - d. Preservation Requirements:

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- i. Amount of preservation for chemical preservation or specific endpoint (such as a final pH)
 - ii. Type of preservation (sulfuric acid, sodium hydroxide, sodium thiosulfate, etc.)
 - iii. Does the bottle already contain the preservation? And specific instructions on what to do with the preservation, such as “do not rinse the bottle”, etc.
 - iv. Thermal preservation (temperature specific requirements, ice, etc.)
 - v. Packing requirements (are Bac-T bottles treated differently, such as bagged before placed in ice, amount of ice, cooler type, etc.)
 - vi. Alternative preservation routines for some samples (if applicable or necessary), such as metals samples can be collected without preservation.
- e. Any specific transport requirements
- i. Transport time to ensure holding times are met
 - ii. Requirements for field blanks or trip blanks

Training Documentation for Laboratory Employees – sample collection personnel § 252.304 and 252.401(d) and (e)

1. The lab management must define the minimal level of qualification, experience and skills necessary for all laboratory employees, including sample collection personnel.
2. The lab management must ensure and document that each employee has read, understood, and is using the latest version of the SOP and QM (as it relates to the employee’s job duties).
3. The management must also ensure and document that the sample collection personnel have demonstrated capability and have been trained in the proper sample collection and preservation requirements for the specific sampling undertaken.
4. Sample collection personnel must participate in ethics training, including training regarding the potential liability for improper, unethical or illegal actions. They must also read, understand, and acknowledge their personal ethical and legal responsibilities including punishments and penalties. Ethical and legal responsibilities training must occur within 2 months of employment and at least once every 14 months thereafter.
5. Lab management must maintain records of all sample collection personnel, including dates of employment, signatures, and initials.

Sample Receipt and Handling Procedures § 252.401(f) and (g)

1. Laboratories must implement procedures for checking and verifying and documenting the condition of the sample, to include, but not limited to container, preservation (both thermal and chemical) of each sample.
 - a. Must document the condition of the sample upon receipt and specifically note any anomalies or questions.
 - b. Establish procedures for how and when sample temperatures are taken. Temperatures of sample is also part of the ‘condition of the sample’ and must be taken and documented at the time of receipt. Laboratories must establish how to choose which sample bottle(s) will be checked. Considerations include:
 - i. Sample type (different sample types might yield different temperatures even if taken at the same location)
 - ii. Sample collection time (different sample sources taken from the same client/customer site within a short time period, with the same contact time with the ice, should have the same or similar sample temperature and might not require individual sample temperatures)

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- iii. Sample collection date (samples that are not received by the laboratory on the same day as collection are probably all going to have the same temperature within the same cooler)
 - iv. Subcontracted samples (same as item iii above)
 - v. Use of Temperature Blanks – Might be acceptable for samples that are removed from a refrigerator, already all at the same temperature, and packed at a laboratory and shipped to another location under the exact same conditions; such as when subcontracting samples that are shipped to another laboratory for analysis. Temperature blanks would not be appropriate for documenting a temperature of samples collected from different sites when the temperature blank does not represent was not held under the same conditions as all of the samples.
2. Requirement to check pH for all SDWA samples, WETT samples, and any other sample that requires specific preservation requirements. The DEP has not established an acceptance criteria for the pH check for compliance with this subsection, only that the laboratory take and document the pH. The sample acceptance policy must explain what to do if the sample does not meet the expectations.
 - a. Specify where, when, and who performs and documents these checks. Such as: upon receipt, in the laboratory, the analyst, after analysis (such as VOCs), etc. Laboratories can establish procedures within their own laboratory to meet this requirement.
 - b. Noted Exceptions: Samples that do not require pH preservation may not require pH check at the laboratory if the sample was collected by a laboratory employee who has documented training on the sample collection procedures maintained by the laboratory.
3. Laboratories must check the sample for the presence of residual chlorine when its presence will compromise the validity of the test.
 - a. Laboratories must establish a procedure for determining if the presence of residual chlorine will compromise the validity of the test. Some considerations would be:
 - i. Does the method require a check for the presence of residual chlorine?
 - ii. Does the method require chemical treatment of samples for residual chlorine?
 - iii. Do the sample preservation requirements indicate that residual chlorine changes the validity of the test or affect the measurement of the analyte/analyte of interest?
 - b. Establish which tests/samples require a residual chlorine check.
 - c. Establish procedures for how and when the residual chlorine is checked. The check does not need to occur at the time of receipt. Laboratories can establish procedures within their own laboratory to meet this requirement. The documentation of the check, the result of the check, and any actions that resulted must be maintained.
4. Establish procedures for a recordkeeping system to document the receipt of all sample containers.
 - a. The procedures must explain what to do if any of the required information is not provided or available. The laboratory may establish procedures for obtaining this information after receipt. At a minimum, the system must include procedures for recording/maintaining:
 - i. The client/project name
 - ii. The date, time, location of sample collection
 - iii. Name of sample collector
 - iv. Field ID code

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- v. Date and time of laboratory receipt and identification of the individual receiving the sample at the laboratory.
 - b. The procedures should include ways to identify how the sample was transported/received. Such as:
 - i. Shipped via courier or directly received from the customer
 - ii. Identification of who is making every entry and the affiliation of that person to explain why they are making the entry and to enable that person to be contacted to provide additional information if necessary.
 5. The laboratory may choose to use specific Chain of Custody forms or may document the information in various log books, LIMS system, or other recordkeeping procedures provided they meet all Chapter 252 requirements for recordkeeping and record retention.

Sample Acceptance/Rejection Policy § 252.401(g)

1. The sample acceptance/rejection policy must explain the laboratory's policies related to what is acceptable and what is cause for rejection. The policy must provide specific instructions for handling samples that do not meet the sample acceptance policy.
2. The sample acceptance policy would directly relate to the sample receipt and handling procedures where the laboratory staff observe and document the condition of the sample and compare that observation to the specific requirements of the test. Any anomalies or deviations from the requirements observed during sample receipt, analysis and reporting would result in a sample that might need to be rejected, qualified, or additional information gathered before a final decision can be made.
3. The sample acceptance policy must include review and evaluation of the compliance with any specific sample collection, handling, preservation, and documentation requirements.
4. The laboratory's procedures for accepting and rejecting a sample for analysis can include instructions to reject any sample that does not meet the specific acceptance criteria for a particular analysis or can be instructions to seek further guidance from a project manager or supervisor. All decisions must be documented.
5. The sample acceptance policy must specify how to handle samples that are checked for pH, as required by 252.401(f)(1)(ii) but do not meet expectations.
 - a. The laboratory is responsible for defining what the expectations for sample acceptance would be based on sample type, client history, or other information specifically related to the sample.
 - b. For example, SDWA samples collected for nitrate and nitrite analysis require an unpreserved bottle in order to obtain a valid result for nitrite. If the laboratory checks the sample bottle and the pH is <2, then the sample is invalid for compliance and the sample acceptance policy must explain how this situation is handled.
 - c. Another example would be cyanide samples received at the laboratory that are not pH >12. The samples must be preserved with sodium hydroxide at the time of collection.
6. The sample acceptance policy must specify how to handle samples that must be dechlorinated and are checked for residual chlorine, as required by 252.401(f)(iii) and it is present. NOTE that some SDWA samples are obtained from chlorinated sources and the presence of chlorine in these samples, when the sample collection requirements do not specify dichlorination, might not invalidate the sample. The laboratory's sample acceptance policy would need to address these types of samples too.
7. The Department strongly recommends that any SDWA compliance sample should be automatically rejected if ALL sample acceptance criteria are not met. Justification/Rationale:

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- a. Analysis of non-compliant microbiology samples that yield a positive result would require check samples and 1-hr notification to the PWS and 24-hr written notification to the Department regardless of condition of sample.
- b. Analysis of non-compliant microbiology samples that yield a negative result would require specific approval to be reported and will often be rejected by the DEP for compliance purposes and a replacement sample would likely be required.
- c. Analysis of non-compliant chemistry samples would require specific approval to be reported, and will often be rejected for compliance purposes and would likely require collection of replacement samples.
- d. All of the above unnecessarily cost time and money, for the laboratory, the PWS, and the DEP.