Writing a Quality Manual for PA State (Chapter 252) Accreditation

Disclaimer: The information in this guidance document does not supplant the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252 ("Chapter 252"). This document is a tool to help laboratories to comply with Chapter 252. If there is any discrepancy between the contents of this document and Chapter 252, the regulations shall prevail. The examples given in this document are for illustrative purposes only, meant to aide individuals in visualizing applications of the regulatory requirements. These examples do not represent all regulatory requirements. This document contains both the Department's requirements and recommendations for quality manuals.

Quality Manual ("QM") (§252.401(a)): Laboratories accredited under Chapter 252 must develop and maintain a quality manual. A quality manual is a written document that states the policies, objectives and principles for ensuring the quality of the testing performed by a laboratory. The QM states or makes reference to the methods performed by the laboratory and describes the laboratory's quality assurance ("QA") and quality control ("QC") plans. It also identifies the individuals responsible for implementing the policies of the lab, reviewing data, and ensuring that the laboratory generates legally defensible data of known quality. The QM is the document that all lab personnel reference when a situation arises that will impact data quality, and where the individuals involved are unsure of how to proceed. The QM must be available to and used by all laboratory personnel.

Note: If a particular item in this document is not relevant or not applicable to the lab's operations, the QM should state this and provide a brief explanation. The quality manual should be responsive to all required items while remaining brief and easy to follow. The intended goals are producing data of known and documented quality and minimizing paperwork, while increasing the efficiency of the lab's operations and transfer of knowledge.

1. **Cover Page:** The quality manual should begin with a cover page. The quality manual must contain at least the following information:

   1.1. The full name and physical address of the laboratory (§252.401(a)(1)) The lab should also include the telephone number of laboratory.

   1.2. The name, address (if different from section 1.1) and telephone number of the laboratory supervisor(s) (§252.401(a)(2)). For example, a small laboratory has hired a consultant to supervise the laboratory, but the consultant only works at the lab a few hours a day and spends most of the day in a different office across town. The quality manual must have the address of the supervisor's office. NOTE: The laboratory does not have to identify the address of the supervisor if the supervisor is permanently assigned to the laboratory's address. (Do not include the supervisor's home address if they work nearly every day at the lab.)

   1.3. Revision number and Effective Date (§252.401(a)(3)): Chapter 252 requires a revision number and effective date on all lab procedures and manuals. Effective dates allow anyone who views the laboratory's QM to see the time period during which a particular revision was effective and being used in the laboratory and the revision numbers ensure that all laboratory personnel are using the most recent version of the QM. Each time changes are made to the QM, a new revision number and effective date must be assigned. NOTE: Labs must retain copies of past versions of each document for at least five years from the date of retire.

1.4. A table of contents, and applicable list of references, glossaries and appendices (§252.401(a)(4)): The QM must contain a Table of Contents. The table of contents may make the document easy to use and make important sections easy to find.

The quality manual should contain the following information:

1.5. Approving Signatures: Laboratory management should review the QM. By signing the QM, laboratory personnel know that it has been reviewed and is approved for use.

2. **Revision History:** The laboratory should create a revision history record. The revision history section describes the changes made to the QM at each revision. The descriptions should be brief, yet accurately and completely describe how the document changed with each revision.

3. **Distribution List:** Distribution lists help laboratory management track the number of copies of the QM that are in circulation, and identify the individuals or sections of the lab that have been given copies of the QM. By creating a distribution list, laboratory management can easily recall all of the old documents when new revisions are made, and thereby ensure that all of the necessary personnel are using the most recently updated revision of the QM. A distribution list is not a requirement of Chapter 252.

4. **Ethics Training Procedure (§252.401(b)(1), §252.401(d), and §252.304(b)(3)(iv)):** The laboratory must implement ethics training procedures. The ethics training procedures must include procedures for educating and training lab personnel in their ethical and legal responsibilities, including the potential punishments and penalties for improper, unethical and illegal actions. It may summarize conflicts of interest, activities considered to be misrepresentations of analytical data, improper practices in the laboratory, and any conduct the lab deems to be unacceptable for its employees. Ethics training must be provided to all employees within two months of employment to the laboratory and at least every 14 months thereafter (§252.401(d)(2)). The laboratory management must document the employees' participation in training courses in ethical and legal responsibilities. Lab management may choose to develop their own ethics training course or may use a course developed by another organization as long at it meets the requirements of Chapter 252. Currently, DEP does not approve specific courses.

4.1. **Example Ethics Training Procedure:**

The QA Officer or Laboratory Supervisor is responsible for providing ethics training to laboratory personnel. All Laboratory personnel must receive ethics training, including samplers, sample receipt personnel, laboratory technicians and analysts, laboratory management, interns, data reporters, and client service managers. Employees must be trained within two months of hire, and annually thereafter not to exceed 14 months from previous training. Training will be given to groups of personnel, not to exceed 20 people. The training will be given on multiple days to ensure that all employees are able to attend.

Ethics training will be documented through the use of the Ethics training sign-in sheet. A copy of the training sheet will be placed in each employees training file. The training will be presented with the use of slides, handouts and worksheets. The presentation handouts and worksheets will be maintained on file for review by regulators. A test will be given at the end of the training. The test will be placed in each employees' training file.

Topics covered during the ethics training must include:

- Organizational mission
- Management support
- Emphasis on honesty, full disclosure, and written narration
- Realistic expectations for the laboratory

- Procedures for reporting of ethical issues
- Procedures for response to reported ethical issues
- Consequences of infractions
- Ethics Agreements
- Conflict of Interest
- Periodic data review
- Investigation and root cause analysis
- Proper and improper practices
- Legal Defensibility
- Documentation of training
- Current Events – News Stories
- Discussion / Questions

5. **Ethics Policy (§252.401(b)(1) §252.401(d) and §252.304(b)(3)(v)):** The laboratory must develop and maintain an ethics policy statement. The ethics policy statement describes the code of conduct for the laboratory and its staff. This statement may be signed by each employee or by the laboratory management after review with employees to document that each employee has read, understood and acknowledged his or her personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical, or illegal actions. The ethics policy statement should include an agreement that employees will not participate in such activities, and will disclose any information concerning such activities. It may summarize conflicts of interest, activities considered to be misrepresentations of analytical data, and any conduct the lab deems to be unacceptable for its employees. The policy should describe how the signed statements are maintained.

5.1. **Example Ethics Policy Statement**:

XYZ Laboratory is committed to the highest level of honesty and integrity in all of its testing services. XYZ laboratory does not tolerate unethical or improper lab practices that may taint or compromise the integrity of analytical results, or give the appearance that analytical results are compromised. XYZ laboratory ensures that all lab personnel are trained in their ethical responsibilities prior to performing analytical work by reviewing with a supervisor the following ethics policy and consequences for unethical behavior. After reviewing the following Ethics Policy, each member of the technical staff must sign a copy of the policy, and the signed and dated policy is retained in the employee's training file:

Conflict of interest: No employee may have any interest, financial or otherwise, direct or indirect, or engage in any business, transaction or professional activity, or incur any obligation, which is in substantial conflict with the proper discharge of his/her duties in the public interest.

No employee may accept employment, engage in business with or professional activity, which would require him/her to disclose confidential information, which was gained by reason of his/her official position or authority. No employee may disclose confidential information acquired in the course of official duty nor use such information to further personal interests.

No employee may use or attempt to use his/her official position to secure unwarranted privileges or exemptions for him/herself or others.

No employee may by his/her conduct give reasonable basis for the impression that any person can improperly influence him/her or unduly enjoy his/her favor in the performance of his/her official duties, or that he/she is affected by kinship, rank, position, or influence of any party or person.

An employee must abstain from making personal investments in enterprises which he/she has reason to believe may be directly involved in decisions to be made by him/her or which will otherwise create substantial conflict between his/her duty in the public interest and his/her private interest.

An employee must pursue a course of conduct, which will not raise suspicion among the public that he/she is likely to engage in acts that are in violation of his/her trust.

If any employee has a financial interest, direct or indirect, having a value of ten thousand dollars or more, in any activity which is subject to the jurisdiction of a regulatory agency, he/she must file a written statement, which shall be open to public inspection.

Improper, unethical and illegal actions: No employee shall mishandle data or the reporting of data for any reason. These activities include but are not limited to:

- Deliberately mislabeling a sample bottle or sampling location,
- Deliberately diluting samples before analysis without recording or accounting for such dilutions in the calculation of final reportable sample results,
- Falsifying dates or times on raw data records, logbooks or log sheets,
- Falsifying results of analysis,
- Manipulating standard solutions to create the appearance of passing quality control,
- Deliberately recording false data, or data not actually generated by XYZ Laboratory, in order to create the appearance of compliance with regulations or a regulatory permit,
- Knowingly taking shortcuts in the analysis,
- Knowingly using a method other than the approved method for a particular analysis or not following said method, and
- Knowingly performing a procedure incorrectly.

All improper, unethical or illegal actions observed by the technical staff must be reported to the QA Officer or laboratory supervisor, fully investigated and documented using corrective action forms.

Violations: In addition to any penalty contained in any other provision of law, any such employee who knowingly and intentionally violates any provision of XYZ Laboratory's Ethics Policy may be fined, suspended or removed from employment in the manner provided by law. Punishments for violating the Ethics Policy will be evaluated by the laboratory management on a case-by-case basis and administered according to the severity of the violation.

6. **Document Control System (§ 252.401(b)(2) and §252.401(c)):** The laboratory must develop and maintain a document control system. The document control system is a written procedure for the control and maintenance of all laboratory documents. The document control system describes how the lab protects and controls documents from unauthorized manipulations, and thereby ensures that the information contained therein is current and accurately reflects the practices of the lab. The system must also ensure that Standard Operating Procedures ("SOP"), reference methods, manuals, and all other lab procedures have an effective date, indicating the time period during which the procedure or document was being used by the lab. NOTE: All records generated by the laboratory must be maintained for a minimum of 5 years from the date of the last entry (for logbooks) or date of retire (for SOPs, QA manual, etc.).

6.1. Recordkeeping (§252.401(b)(3) and §252.706): The QM must describe the procedure for storing laboratory records and making changes to documents. All data generated by the lab

must be recorded promptly and legibly in permanent ink or in an electronic format. In addition, when changes are made to laboratory records, the original entry must remain visible by drawing a single line through the original entry and entering the new information beside it. The individual making the change must initial and date the correction. Labs may choose to include some or all of the recordkeeping procedures in the document control policy or elsewhere in the QM. See Section 15, of this document for additional information on recordkeeping.

6.2. Termination of Operation (§252.401(b)(4) and §252.706(e)): The laboratory must have a written plan that describes how records will be maintained or transferred if the lab terminates operations, or ownership of the lab is transferred.

6.3. **Example Document Control Policy**:

XYZ Laboratory ensures that the quality manual, the analytical and general SOPs, the raw data sheets, the temperature logs, the instrument calibration logs, the equipment logbooks and operator manuals, the final data reports, and other policy documents are properly controlled. The purpose of the document control system is to protect and maintain the accuracy of lab documents. The document control policy ensures that only the most recent revisions of all documents are used by and available to lab personnel, that revisions are timely and made by authorized persons, and that documents receive the required approvals. The individual polices that follow delineate the procedure for handling and maintaining lab documents based on the document type.

Document Control for Procedures & Manuals (QM, SOPs, etc.):
All internal regulatory documentation, including the SOPs, the Quality Manual, written work instructions, service manuals, and product instructions are subject to the document control procedure described in this section. This procedure does not apply to equipment and reagent logbooks or raw data records. Controlled documents subject to this procedure are assigned a unique document number and are stamped on each page in red ink with the following:

CONTROLLED DOCUMENT
DO NOT DUPLICATE
If this stamp is not colored red, this is not a controlled copy

The Quality Assurance Officer controls the stamp and ink in a secure location.

The Quality Assurance Officer is responsible for administering and implementing the document control system and maintains a master list of all controlled documents with their location and current revision number. The Laboratory Supervisor and the Quality Assurance Officer approve all newly released documents, including SOP revisions, Quality Manual revisions, and new and revised work instructions. Approval is indicated by the signatures of the Laboratory Supervisor and the Quality Assurance Officer on the cover page of each controlled document. The effective date, revision number, document number, and document title are located on each page of controlled documents in the document's header. The revision history and distribution list are located on the reverse side of the cover page.

All operating instructions, service manuals or product instructions providing specific information on the operation and maintenance of lab equipment are given unique document numbers and effective dates, which are written on the first page of the material and accompanied by the QA Officer's initials. The QA Officer tracks the locations of each uniquely identified manual. Operating instructions, service manuals and product instructions are also

stamped in red on each page with the stamp referenced above. Product instructions associated with consumable laboratory supplies are not included.

Changes: Any employee may request to change or revise a document. Changes made to the laboratory's written policies and procedures, including but not limited to the QM and the laboratory's SOPs, shall be approved by the laboratory's QA Officer. Initially, changes may be made by drawing a single line through the text and writing the substituting material directly on the document. Such changes must be accompanied by the date of the change (indicating the date the change was made effective) and the QA Officers initials (approving the change). Changes made in this fashion are only appropriate initially, until the document is formally revised. Where necessary, obsolete documents may be retained for legal reasons or for knowledge preservation. The Quality Assurance Officer retains all obsolete documents.

Reagent Preparation Logbooks:
See the "Equipment Listing" section of the quality manual (Section 16 of *Writing a Quality Manual for PA State (Chapter 252) Accreditation*) for information on document control policies for equipment logbooks.

XYZ Laboratory maintains records of all reagent and standard preparation in bound laboratory notebooks for each analytical method performed. There is a separate logbook for each analytical method. The logbooks are stored in each analytical section of the lab where the associated methods are performed. When the logbooks are filled, they are archived and stored by the QA Officer according to analytical method and date. Each logbook is uniquely identified by the method name and number, followed by a logbook number. For example, pH by SM 4500-H^+ B – 001, indicates that the book is for pH analysis by Standard Methods 4500-H^+ B, and it is the first logbook used to document the preparation of standards and reagents associated with pH analysis. All logbooks are numbered in sequential order, such that the next logbook in the above example would be pH by SM 4500-H^+ B – 002. Instructions for preparing the reagents and standards are located within each analytical SOP.

Each standard and reagent logbook must contain at least the following information:

1. Identification of the compound or solution
2. Concentration of the final solution
3. Date of preparation
4. Initials of individual preparing the solution
5. Date of expiration

Changes: Changes to standard and reagent preparation logs must be made by a drawing a single line through the original entry, such that it remains legible. XYZ Laboratory does not permit the obliteration of original entries or the use of obliterating materials, such as correction fluid. All changes made to raw data records must be accompanied by the initials of the individual making the change and the date.

Raw Data Records:
XYZ Laboratory maintains all laboratory documents such as SOPs and the quality manual, raw data records, instrument calibration sheets, corrective actions forms, and temperature logs, etc., that are associated with the generation of sample results. All documents and data, including original observations, calculations and derived data, calibration records, QC records, and copies of final sample reports are kept for a minimum of five years in accordance with the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252, unless a longer period of time is otherwise specified by permit, regulation, or other authority. The QA

Officer tracks, maintains and stores all raw data sheets, calibration sheets, corrective actions forms, and temperature logs, according to analytical method and date.

Changes: Changes to raw data records must be made by a drawing a single line through the original entry, such that it remains legible. XYZ Laboratory does not permit the obliteration of original entries or the use of obliterating materials, such as correction fluid. All changes made to raw data records must be accompanied by the initials of the individual making the change and the date.

Termination of Operations: In the event that XYZ Laboratory terminates operations, XYZ Laboratory will ensure that all laboratory documents and records, including laboratory data, are maintained for a minimum of five years. If XYZ laboratory transfers ownership, the new owner shall ensure that all laboratory records are maintained for a minimum of five years. The requirements for record maintenance shall be part of the sales agreement. If XYZ terminates operations, the records shall be maintained by the primary shareholder(s) for a minimum of five years from the last day of laboratory operation.

7. **Personnel Records (§252.401(e) and §252.304(b)):** Laboratories must document the training and competency of lab employees through personnel records. The QM should explain how the training and competency of each employee is documented, describing the contents of the personnel records and where and how the records are maintained. The following information must be maintained for each laboratory employee. Many laboratories choose to create a separate file for each employee that contains the following information:

7.1. Information required for each lab employee:

7.1.1. Resumes, transcripts, etc., demonstrating that the employee meets the qualification requirements for his/her position.

NOTE: The laboratory management establishes the minimum qualifications, education and experience requirements for all analytical positions in the lab. The only position with State-mandated education and experience requirements is the laboratory supervisor. See Chapter 252, §252.302, for lab supervisor qualification requirements.

7.1.2. A signed statement indicating that the employee has read, understood and is using the latest version of the QM (§252.304(b)(3)(i)).

7.1.3. A signed statement indicated that the employee has read, understood and is using the latest version of the analytical SOPs (§252.304(b)(3)(ii)).

7.1.4. Documentation of the employee's technical and analytical training and training on lab procedures. Documentation of technical training does not require labs to send personnel to formal training sessions. This documentation may simply be a summary of training provided in-house and on the job. Such documentation should include the dates of training and material covered during each training date (§252.304(b)(3)(iii)).

7.1.5. Documentation of the employee's training in Lab Ethics and legal responsibility. Documentation of ethics training does not require labs to send personnel to formal training sessions. This training may be provided in-house, as long as the employee's ethical and legal responsibilities are clearly outlined (§252.304(b)(3)(iv)).

7.1.6. A signed statement indicating that the employee acknowledges and understands his/her personal ethical and legal responsibilities, including potential punishments for unlawful or unethical behavior (§252.304(b)(3)(v)).

7.1.7. An Initial Demonstration of Capability ("IDC") (§252.304(vi)): Every analyst must perform an IDC for each analysis they perform. The IDC must be performed initially, before a new analyst begins to process real environmental samples, and the IDC must be repeated when changes are made to the method, instrument used or personnel performing the method. Labs must retain all raw data associated with the IDC so that the entire procedure and all associated lab activities can be reconstructed from the lab's records. See *Required Documentation for PA State (Chapter 252) Accreditation* for additional information.

7.1.8. Annual Continued Demonstration of Capability ("DOC") (§252.304(vii)): Every analyst must perform a DOC for each analysis they perform. The DOC must be performed every 12 months for each analysis. Labs can choose to fulfill the annual DOC requirement by performing any one of the options listed in Chapter 252, §252.304.b.3.vii.A-E. Labs must retain all raw data associated with the DOC so that the entire procedure and all associated lab activities can be reconstructed from the lab's records. See *Required Documentation for PA State (Chapter 252) Accreditation* for additional information.

7.1.9. Labs must also keep a list of the dates of employment for each lab employee, an example of each lab employee's signature and initials, and a list of which persons are authorized to approved or release data. The lab may choose to keep this information in each employee's training file along with the required documentation listed above. However, some laboratories find it more convenient to have this information in a single list stored separately from the information specified above. The Department does not mandate the format in which these records are kept. The Department only requires that the information be maintained such that it is easily retrieved upon request (§252.304(e)).

7.2. **Example Personnel Files Maintenance Procedure:**

XYZ Laboratory maintains an employee file for each member of the technical staff. When hiring new employees, the lab management reviews an applicant's level of qualification, experience, and skills against the requirements identified by the job description before assigning an employee to the laboratory. Thereby, XYZ Laboratory ensures that each analyst has adequate experience and education to demonstrate specific knowledge of his/her function and a general knowledge of laboratory operations, test methods, QC procedures, and records management.

Personnel Records

The lab management maintains a file for each member of the technical staff to demonstrate and document their training and competency. The employee file contains the following:

1. A copy of the employee's job description;
2. A copy of the employee's resume, education history and transcripts;
3. A signed and dated statement indicating that the employee has read, understood and is using the latest version of the QM and applicable SOPs;
4. A signed and dated statement indicating that the employee has read, acknowledged and understood XYZ Laboratory's Ethics Policy and his/her ethical

and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions;
5. The employee's IDC data packages for each method the employee performs;
6. Documentation of any technical training the employee received (courses, seminars, or workshops), including the employee's initial in-house training;
7. Documentation of training received in lab ethics;
8. The employee's DOC data packages for the past 5 years for each analytical method the employee performs.

See XYZ Laboratory's *SOP for Initial Demonstration of Capability* and *SOP for Annual Continued Demonstration of Capability* for more information on completing each of these items. An IDC/DOC Certification Statement containing the date, the analyst's name, the matrix, the analytical method (i.e., SOP number and revision), the analyte measured, and text certifying that the test was performed by the analyst indicated, must be signed and dated by the QA officer and attached to the IDC data package.

The Lab Supervisor maintains a list of all technical personnel, which includes their dates of employment, signatures, initials, and identifies the persons authorized to approve or release data. This list is subject to XYZ Laboratory's document control policy.

8. **Permitting Departures from Established Lab Procedures (§ 252.401(b)(5), §252.401(h), §252.304(b)(5)):** Laboratories must have a procedure for permitting departures from documented policies and procedures (contained in the QM, SOPs, reference methods, etc.) when such departures are necessary.

Example: The lab protocol or regulation requires a 24-hour composite sample to be collected from an automatic sampler. The sampler malfunctions, and the sample is not collected properly, or not enough sample is collected. What action does the laboratory take in such situations? How does the lab document what happened?

The policy for permitting departures from lab procedures does not have to be specific for every conceivable situation where the lab may have to deviate from its procedures. However, the policy must be detailed enough to describe a course of action taken by lab personnel, including how the occurrence is documented.

Whenever a departure from lab procedures occurs (permitted or otherwise), the cause of the departure must be identified and the corrective action taken to prevent future occurrences must be documented. One way to document departures and corrective actions is with a corrective action form. A corrective action form details the nature of the occurrence, how the lab's polices were modified, the investigation conducted, the cause of the occurrence, and the action taken by the lab to avoid recurrences. Corrective action forms contain all the necessary information in a concise format, allowing lab management to easily track recurring problems. An example Corrective Action Form is located in **Appendix A** of this document.

Chapter 252 requires laboratories to initiate corrective actions if the lab fails a Proficiency Testing ("PT") sample and when QC measures (i.e. blank, LCS, DUPs) do not meet the required acceptance criteria (§252.501(k), §252.402-405).

8.1. Example Policy for Permitting Departures from Lab Procedures

When deviations from XYZ Laboratory's quality manual or SOPs are necessary, the analytical staff must inform and receive the approval of the Laboratory Supervisor or QA Officer before proceeding with the test method. The Laboratory Supervisor or the QA Officer ensures that a

corrective action form is completed. The analyst must ensure that adequate notes describing the occurrence and deviation from lab procedures, the course of action taken, and the approving manager's initials, are made in the raw data records and the final sample report form. If the analyst is not authorized to approve or release data, then the analyst must inform the individual that will be approving the affected data of the notations that must be made on the final sample report.

If the Laboratory Supervisor or QA Officer is not available to give approval and the analyst must proceed with the test method, the analyst may mimic a previous action taken for a similar occurrence, or use his/her best judgment and knowledge of laboratory ethics to determine a course of action. However, the analyst must keep detailed notes on the occurrence, including all of the information specified above, and notify the lab manager immediately upon the manager's return.

All departures from lab procedures must be documented on corrective action forms. Copies of the corrective action forms are maintained by the QA Officer and stored with the affected data packages. Corrective action forms are subject to the "Raw Data Records" section of the Document Control Policy. A copy of XYZ Laboratory's corrective action form is found in Appendix A of the Quality Manual.

9. **Detecting Departures from Established Procedures (§252.401(b)(5), §252.401(i)):** In addition to departures that are permitted and approved by the laboratory, non-permitted, unrealized, and unintentional departures from laboratory policies and procedures are likely to occur. Laboratories must establish procedures for detecting when departures from the lab's procedures have occurred.

   Quality control samples processed along with sample analysis are one way to detect departures from established procedures. Other examples are secondary review procedures, where a supervisor or senior analyst reviews data and calculations before the final results are reported. Labs may also conduct internal audits or participate in double blind PT studies.

   9.1. The procedures for detecting departures must include at least the following:

      9.1.1. Identity of the individual responsible for assessing each quality control type: Does each analyst review the QC results? Is there a secondary data review to check the analyst's work?

      9.1.2. Identity of the individual(s) responsible for initiating and/or recommending corrective actions: Does the analyst initiate or recommend corrective action when a problem is identified during sample analysis? Does lab management initiate or recommend corrective action after completion of an internal audit?

      9.1.3. Procedure for handling of sample results if the associated QC fails to meet the requirements of the method: Do the results get reported with a data qualifier? Are the samples re-prepared and re-analyzed?

      9.1.4. Procedure for documenting corrective actions: How does the lab handle "out-of-control" data, and how are corrective actions documented and implemented?

      9.1.5. Procedure for review of corrective action reports: Is there a timeline for correcting problems identified in the corrective action reports? How are the reports handled, filed and stored? How are they linked back to the affected data? Are corrective action forms periodically reviewed to identify recurring problems in the lab?

9.2. **Example Policy for Detecting Departures from Lab Procedures**

XYZ Laboratory has several procedures that enable the laboratory management to detect when departures from the laboratory's procedures occur. These procedures include the following:

1. Review of analysis quality control data such as method blanks, laboratory control samples, matrix spikes, duplicates, and calibration verifications.
2. Second level review of laboratory data.
3. Internal audits
4. Internal proficiency testing.

Each analyst is responsible for reviewing the quality control data from their analyses prior to reporting the data. In addition, a second level review will occur once a week. The laboratory supervisor or QA officer will select random data from each analyst and review all quality control and calculations.

All laboratory personnel are responsible for initiating or recommending corrective actions. The laboratory supervisor and/or QA officer are responsible for reviewing all corrective actions for appropriateness and completeness. These corrective actions will be documented on the Corrective Action forms. Copies of the corrective action forms are maintained by the QA Officer and stored with the affected data packages. Corrective action forms will be reviewed by laboratory management within a week of the initiation of the corrective action. Corrective actions will be reviewed quarterly to ensure that the corrective action has been implemented and to determine if recurring problems exist. Corrective action forms are subject to the "Raw Data Records" section of the Document Control Policy. A copy of XYZ Laboratory's corrective action form is found in Appendix A of the Quality Manual.

If laboratory samples are not associated with acceptable quality control data or if samples fail to meet the requirements of the laboratory's procedures, the laboratory will attempt to reanalyze the sample if it is within the appropriate hold-times and sufficient sample is available. If it is not possible to reanalyze the sample, then the client may be notified and a resample may be ordered. If the data is to be reported, then the data must be reported with a qualifier. The laboratory may use standard defined qualifiers where appropriate. If a standard defined qualifier is not appropriate to the data, then the laboratory will provide a text comment on the final report that describes the non-conformance in appropriate detail.

10. **Prevention & Detection of Improper Practices (§252.401(b)(6) and §252.304(b)(7)):** The laboratory must develop and implement procedures to detect and prevent improper, unethical or illegal actions. These procedures must be proactive, focusing on preventing improper practices, instead of simply correcting them after they have occurred. Examples of such practices are:

10.1. Internal proficiency testing: PT samples or QC samples analyzed by a lab may be single blind or double blind to the analyst. Single blind means that the analyst knows the sample is a PT study, but the true value or concentration of the sample is unknown to the analyst. Double blind means that the PT study is disguised so that the analyst is unaware that the sample is a PT study, and the true concentration of the sample is unknown. Chapter 252 requires that labs successfully perform one single blind PT every 12 months for each Field of Accreditation ("FOA") (§252.501(d)).

10.2. Post analysis electronic data and magnetic tape audits or reviews: If data is stored in an electronic format or on magnetic tape (i.e., floppy discs), the lab ensures that the data can

be retrieved from that format and remains intact (i.e., chromatograms or scanned calibration curves appears properly).

10.3. SOPs: Labs can develop SOPs for identifying appropriate and inappropriate lab practices and instrumentation manipulations to prevent improper practices.

10.4. Internal audits: Laboratory management performs an internal audit similar to an audit performed by a regulatory agency, reviewing the reference methods, SOPs, QM, and data to ensure compliance with the reference method and all applicable regulations.

10.5. Corrective Actions: Chapter 252 requires laboratories to initiate and document corrective actions if improper, unethical or illegal practices are detected. Corrective actions are also used to prevent the recurrence of problems. See Section 8, of this document for additional information.

10.6. **Example Prevention of Improper, Unethical or Illegal Actions Policy**

XYZ Laboratory prevents improper, unethical and illegal lab practices through the following mechanisms:

Ethics Policy: XYZ Laboratory trains all analysts in their ethical and legal responsibilities. All new analysts must review XYZ Laboratory's Ethics Policy with a supervisor. See the Ethics Policy section of the quality manual for additional information.

Internal Proficiency Testing: Each analyst must successfully perform at least one single blind PT study every 12 months for each test method the analyst performs. PT studies must be prepared and diluted according to the manufacturer's instructions, and then carried through all preparatory and analytical steps of the method. PT samples must be handled exactly like routine samples, using the same personnel, standards and reagents, and prepared and analyzed along with regular, routine samples. PT samples must be analyzed with the same frequency, and processed with the same amount of QC as routine samples. The lab initiates corrective actions for all PT failures, and the failure is documented using corrective action forms.

Each analyst must also analyze one double blind PT study every 12 months. The analysts are not given knowledge of when double blind PTs are in-house. The double blind PTs are used to detect analytical problems that may otherwise remain unnoticed through the analysis of regular QC measures and single blind PT samples. The lab initiates corrective actions for all PT failures, and the failure is documented using corrective action forms.

Post-analysis Data Review: For raw data and sample information that are transcribed into a spreadsheet. The spreadsheet is printed and checked for transcription errors by the analyst that entered the data and again by the QA Officer. The QA Officer initials and dates the data to show that it has been reviewed. The bench sheets and spreadsheet are filed together. The QA Officer reviews a representative sampling of the calculations generated by the spreadsheet for accuracy before the data is reported. The QA Officer rotates which calculations are checked each day, such that over a one-month time period all the calculations have been checked for accuracy.

A sampling of data permanently stored on floppy discs is retrieved annually and checked for accuracy. Records of these checks are retained by the QA Officer. When transcription errors, formatting or other errors are detected in the data, the cause is investigated, corrrected, and documented using corrective action forms.

Inappropriate Instrument Manipulations: Inappropriate, unethical and illegal instrument manipulations are detailed in XYZ Laboratory's *SOP on Improper Lab Practices*. When any inappropriate instrument manipulations are detected, the incident is investigated, documented on corrective action forms, and the QA Officer shall assess the effect on previously reported data. All data associated with inappropriate instrument manipulations must be recalled and re-reported with appropriate qualifiers.

Internal Audits: The QA Officer performs an internal audit of the laboratory procedures and Quality System bi-annually, including a review of the QM, SOPs, and a sampling of reported data for conformance with reference methods and applicable regulations. The QA Officer ensures that the lab's procedures are accurate, appropriate, effective, and followed by lab personnel. The SOPs are reviewed for conformance to the reference method, and lab personnel are interviewed to ensure that the SOPs are followed and reflect current lab practices. A representative sampling of reported data are chosen and traced through the entire analytical process to check for sampling or sample handling errors, reporting, calculation and transcription errors and appropriate documentation of corrective actions. All findings of the internal audit are fully documented. The Laboratory Supervisor and the QA Officer ensure that all findings are corrected in a timely manner.

11. **Sample Handling Procedures (§ 252.401(b)(7) §252.401(f), §252.401(g), §252.307(f), §252.307(g)):** Labs must develop procedures for handling environmental samples properly and in accordance with method-specific and regulatory requirements. Labs can choose to keep sample handling information in the analytical SOPs, the QM, or both. Many labs include general lab procedures and policies that apply to all analytical methods in the QM only, and keep method-specific information in the analytical SOPs. By placing the method-specific sample handling requirements in the analytical SOPs, the Quality Manual must only contain general, laboratory-wide sample handling procedures. Labs are not required to duplicate the information on sample handling in the QM and analytical SOPs. The QM may reference the analytical SOPs for more information on sample handling for specific analyses. Likewise, the analytical SOPs can reference the QM for general procedures on sample handling. Sample handling procedures may include:

    11.1. Sampling procedures (§252.307(f), §252.401(g)(3), §252.401(g)(5)): The lab's sampling procedures should give instructions for collecting each type of sample (composite, grab, water, soil, etc.) and describe the equipment and containers used for collecting samples. Sample containers must comply with Federal or method specific requirements. Since some analyses require the use of different sample containers, many labs choose to keep information on collection containers in the analytical SOPs. The lab's procedures must describe the amount of sample to collect for each type of analysis, allowing for any required quality control testing. The sampling procedures should also indicate whether the lab collects its own samples or if samples collected by non-laboratory personnel are accepted.

    11.2. Sample Collection, Preservation & Hold Time (§252.307(g), §252.401(g)(3)-(4): Samples must be collected, preserved and analyzed within the time constraints mandated in the applicable Federal, State or method specific requirements. The Code of Federal Regulations ("CFR") lists required collection, preservation and hold times for the analysis of many analytes (40 CFR 136, 40 CFR 141). Requirements may also be listed in Federal or State issued permits (i.e., NPDES permits). If there is no information listed in the permits or the CFR, the collection containers, preservation techniques and holding times specified in the reference method may be followed. Since sample collection, preservation and holding time may be different for each test method, many labs choose to keep information regarding these requirements in the analytical SOPs. Preservation procedures must include chemical and thermal (refrigeration) preservation techniques. Both chemical and thermal preservation

must be verified and documented prior to sample analysis. Labs must record the time and date of collection and analysis to document that the mandated holding times are satisfied.

11.3. Sample Handling Documentation and Chain of Custody Procedures (§252.304(b)(6)): Labs must have procedures for accepting and handling samples. Documentation of sample collection and sample receipt must be maintained and may include the use of Chain of Custody forms. Chain of Custody forms ensure documentation of sample collection, handling and transfer in accordance with all applicable regulations. Chains of Custody are important for the legal defensibility of samples accepted by the laboratory. At a minimum, labs must document the condition of samples at the time of receipt to the lab. If this is not done by use of a Chain of Custody, the lab must document these observations in another form such as a logbook.

The laboratory must maintain the following documentation of sample acceptance and handling (§252.401(f)), see **Appendix B** for example of sample receipt documentation:

11.3.1. Temperature of the received samples. Labs must take and document the temperature of at least one bottle from each sample location.

11.3.2. Chemical preservation of received samples for each sample bottle (such as pH).

11.3.3. Number, type, and volume of sample containers (e.g. 3-40mL VOC vials, 1-100mL nitric acid preserved bottle for metals, 1-500mL sulfuric acid preserved bottle for ammonia and phosphorus, 2-500mL un-preserved bottles, etc.)

11.3.4. The client /project name

11.3.5. The date, time and location of sample collection, name of sample collector and field identification code (e.g. Collected 5/5/10 at 8:38am, by Bob Smith, outfall 001).

11.3.6. The date and time of sample receipt at the laboratory.

11.3.7. A unique laboratory ID code that corresponds to the information required by Chapter 252. (This is the laboratory sample ID number or code. For example: Sample #01254B)

11.3.8. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code. (For example, Sample #01254B sulfuric acid bottle not preserved to pH < 2.)

11.3.9. An identification of the person making the entries (such as sample receipt personnel, sample collector, etc.)

11.4. Acceptance/rejection criteria (§252.401.g.5-6): A sample acceptance/rejection policy describes the action taken by the lab if a received sample is not properly preserved or shows signs of damage or degradation. Does the laboratory still analyze the sample? If so, how does the lab document on the final sample report that the sample was improperly handled? See Section 12, of this document for more information on sample acceptance policies.

11.5. Sample Acceptance Policy (§252.401(g), §252.304(b)(6)): Labs must develop a Sample Acceptance Policy, and some of the information above may be addressed there. See Section 12, of this document for information on sample acceptance policies.

12. **Sample Acceptance Policy (§ 252.401.b.7, §252.401(g), §252.304(b)(6)):** The laboratory must have a Sample Acceptance Policy to describe the circumstances under which samples are rejected or accepted for analysis or when a sample does not meet the criteria given in the policy. For example, if an automatic sampler programmed to collect a composite sample, collects an insufficient volume of sample, the sampling personnel will collect a grab effluent sample and add it to the amount of sample collected by the automatic sampler and document the occurrence on the raw data sheet. Some of the information described in Section 11, above may overlap with the requirements listed below for the lab's Sample Acceptance Policy.

    12.1. The laboratory's Sample Acceptance Policy must include the following:

        12.1.1. Sample Information: The Sample Acceptance Policy must describe how general information about the sample is documented. Labs must document the identification if each sample, the location of sample collection, the date and time of collection, the collector's name, the preservation type used (i.e. preserved with 0.5mL H_2SO_4 or chilled to 4ºC), and sample type (i.e. drinking water, wastewater, surface water, grab, composite). For samples received by the laboratory, this information may be contained on a Chain of Custody form. In-house labs may document this information on running clipboards or daily bench sheets. Please see section 11.3 for a detailed list of required information.

        12.1.2. Collection Containers, Preservation & Holding Time: The Sample Acceptance Policy must ensure that samples are collected and stored in appropriate containers, properly preserved, and analyzed within the time constraints mandated by the Federal, State or method-specific requirements. See Section 11.2, of this document for more information.

        12.1.3. Sufficient sample size: The Sample Acceptance Policy must ensure that sample collectors are educated on the volume of sample required for each analysis. The volume of sample needed to perform required QC measures must be included in the volume of sample collected.

        12.1.4. Failures: The Sample Acceptance Policy must describe the procedures followed when samples do not meet the criteria established for items 12.1.1 – 12.1.3 or Section 11 above, or show signs of damage, contamination or inadequate preservation. Does the lab properly re-collect the sample before the analysis will be performed? Does the lab analyze the sample, and qualify the data?

13. **Reporting Data (§252.401(b)(8), §252.401(j), §252.402, §252.403, §252.404, §252.405):** The laboratory must develop written procedures used to report data and identifying the individuals authorized to approve and report data. The data reporting procedure must describe the information contained on the final sample report. The lab may also reference and attach a copy of a final sample report to the QM to indicate the information that is contained on final sample reports.

    13.1. Each test report must include at least the following information, except as specified in Section 13.2:

        13.1.1. The name and address of the laboratory.

        13.1.2. The total number of pages in the report, including any addendums, in the format of Page x of y.

13.1.3. The name and address of the client.

13.1.4. An identification of the test method used.

13.1.5. An identification of the sample(s) including the client identification code.

13.1.6. The date and time of sample collection.

13.1.7. The date of sample analysis.

13.1.8. The time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.

13.1.9. The test results and units of measurement.

13.1.10. The quantitation limit.

13.1.11. The names, functions, and signatures of the persons authorizing the test report.

13.1.12. An identification of results reported on a basis other than as received (e.g., dry weight).

13.1.13. An identification of testing or analysis results not covered by the laboratory's scope of accreditation.

13.1.14. An identification of results that do not meet the requirements of this Chapter (See Section 13.3).

13.1.15. An identification of subcontracted results.

13.2. Tests performed by an environmental laboratory operated by a facility that provides results to the facility management for compliance purposes do not need to be reported with all information required in Section 13.1, provided the information required by Section 13.1 is maintained according to the recordkeeping requirements §252.706.

13.3. The data reporting section must also describe how the lab flags or qualifies data (See Section 13.1.14). Data flags and qualifiers are the mechanism used to note when a sample is associated with failing batch QC, improper collection/preservation methods, or any special circumstance causing the sample to be considered in violation of the method specifications or applicable regulations. If samples deviate from method specifications or regulatory requirements, they must be reported with some indicator or qualifying statement describing the reason(s) why the sample does not conform to the standard protocol.

Reporting data with a qualifier does not necessarily mean that the data is not usable for compliance purposes. Qualifiers or flags only indicate that the data may be suspect or less reliable. Chapter 252 requires labs to report data with appropriate qualifiers if batch QC and continuing calibration verifications fail to meet the established acceptance criteria, or if samples are analyzed out of holding time, or improperly collected and preserved. Therefore, reporting data with appropriate qualifiers is an accepted and appropriate practice. Conversely, knowingly reporting data without a qualifier when a qualifier is appropriate is unethical and a violation of Chapter 252, and such actions may result in denial, suspension or revocation of the lab's accreditation.

14. **Monitoring the Quality of Analysis (§252.401(b)(9) and §252.401(l)):** Labs must develop and implement procedures for monitoring the quality of analysis. The QM may reference the analytical SOPs for this information, provided the type and frequency with which quality is monitored is addressed in the SOPs. More likely, some information will be contained in the analytical SOPs (QC specific to the analytical method) and some information (general practices that apply to all analyses) will be contained in the QM. Chapter 252 and many analytical methods specify the frequencies for QC to be performed. However, a lab may define its own frequency for performing QC, when there is no frequency required by method or regulation. The frequency should be documented in the analytical SOPs or the QM. Chapter 252 requires many of the quality control measures in the examples below, while others are recommendations.

    14.1. Examples of Quality Monitoring include:

        14.1.1. Batch QC (§252.402, §252.403, §252.404, §252.405): Chapter 252 requires the use of QC techniques with each batch of samples to monitor the quality of analysis. See Chapter 252, §252.402 for more information on required QC for Chemistry methods. Similar requirements are listed for Microbiological (§252.404), Toxicity (§252.403), and Radiochemistry testing (§252.405). The QM may reference the analytical SOPs for QC measures to be performed with each batch of samples. If the information is contained in the QM only (not in the analytical SOPs), the SOP must reference the QM for batch QC requirements, and the QM must be readily available to all lab personnel at all times. Corrective actions must be initiated and documented for all QC failures.

        Example Policy:

        Batch QC Samples for Chemistry Testing: XYZ Laboratory analyzes the following QC samples with each batch of samples prepared and analyzed. A batch is defined as one to 20 samples of the same matrix prepared and analyzed, using the same methods, personnel and lot(s) of reagents, and with a maximum elapsed time of 24 hours between the start of processing of the first and last sample, unless a more stringent requirement is contained in the reference method. See the individual analytical SOPs for more specific information.

        Blank: A sample of similar matrix to the associated samples that is free from the analyte(s) of interest. The blank is processed simultaneously with, and under the same conditions as the environmental samples, through all steps of the analytical procedure. The blank is used to detect the presence of contamination in the analytical environment. Analysis of the blank must indicate that no target analyte(s) or interferences are present at concentrations above the reporting limit for the method or that impact the analytical results for sample analyses.

        Laboratory Control Sample ("LCS") (aka Laboratory Fortified Blank ("LFB")): A blank matrix, free from the analyte(s) of interest, spiked with a verified, known amount of method analyte(s). The LCS is analyzed simultaneously with, and under the same conditions as the environmental samples, through all steps of the analytical procedure. The LCS is used to determine that the methodology is in control, that the laboratory is capable of making accurate and precise measurements, and that the laboratory is able to recover the analyte(s) using the analytical method. The results of the LCS are evaluated for percent recovery. A LCS with a percent recovery of ±15% is considered acceptable, unless otherwise specified in the analytical SOP.

        Duplicate: Two aliquots of the same sample analyzed by an identical procedure. The duplicate samples measure the precision associated with laboratory procedures, but

not with sample collection, preservation, or storage procedures. The duplicate sample is analyzed simultaneously with, and under the same conditions as the environmental samples, through all steps of the analytical procedure. The duplicate samples are evaluated for relative percent difference ("RPD"), and a duplicate is considered acceptable when a RPD of 10% or less is obtained, unless otherwise specified in the analytical SOP.

Matrix Spike ("MS"): Two aliquots of the same sample analyzed by an identical procedure, where a known quantity of the method analyte(s) is added to one of the aliquots. The MS is analyzed simultaneously with, and under the same conditions as the environmental samples, through all steps of the procedure. The MS is used to determine whether the sample matrix contributes bias to the analytical results. The background concentration of the analyte(s) in the sample matrix must be determined in the unspiked aliquot, and the measured values in the MS must be corrected for any background concentration found in the unspiked sample aliquot. The results of the MS are evaluated for percent recovery. A MS sample with a percent recovery of ±15% is considered acceptable, unless otherwise specified in the analytical SOP.

Failures: Should any batch QC measure fail the established acceptance criteria, the cause of the failure shall be investigated, documented on corrective actions forms, and the samples shall be reprocessed and reanalyzed, if possible. If reanalysis is not possible, due to exceeded holding times, etc., the data must be reported with an appropriate data qualifier.

14.1.2. PT Studies: Participation in PT studies, other inter-laboratory comparisons or round robin testing may also be used to monitor the quality of laboratory analysis. Labs are required to successfully analyze one single blind PT sample for each accredited test method/analyte that appears on the PA Fields of Proficiency Testing Tables every 12 months (§252.501). Labs are free to participate in additional PT studies, internal QC samples, double blind PT samples, inter-laboratory comparisons or round robin testing in addition to the annual PT requirement.

14.1.3. Split samples: Samples may be split and analyzed by different labs, and the results compared to monitor the quality of analysis. However, it is unethical to split a sample with another lab and then choose which sample result to report for compliance purposes. Splitting samples should only be used as a means to monitor the quality of analysis.

14.1.4. Secondary Source Standards: Secondary reference materials or standards are standards purchased from a different manufacturer or different lot number than the standards used to calibrate instruments. Analysis of a secondary source standard ("QCS") ensures the accuracy of the calibration standards and is required after each initial instrument calibration (§252.402.c.5). The use of certified reference materials or QC samples are another method for monitoring the quality of analysis. QC samples are purchased samples with known concentrations, much like PT samples, except these samples are typically less expensive and the true value of the sample is given to the lab while the lab has possession of the sample.

14.1.5. Replicate Testing: Labs may test replicate samples using the same or different test methods to monitor analytical quality. Replicate testing is performed by analyzing duplicate sample aliquots through different, same or similar test methods to compare results and measure accuracy and precision. Chapter 252 requires labs performing

Chemistry testing to prepare and analyze one duplicate sample through the same test method for each batch of samples. See Section 14.1.1, of this document.

14.1.6. Retesting: Labs may retest samples using the same or different personnel to compare the results and measure accuracy. Retesting samples should only be used as a means to monitor the quality of analysis. It is unethical to retest samples using different methods or personnel to selectively report data for compliance purposes.

14.1.7. Correlation of Results: Labs may evaluate the results from different but related analyses, correlating the results to ensure quality. For example, total phosphorus results should be greater than or equal to orthophosphate results.

15. **Recordkeeping (§252.706):** The laboratory must have a written procedure describing how and where records are to be maintained. The recordkeeping policy should include records necessary to document compliance with the requirements of Chapter 252, including the records necessary to reconstruct lab activities associated with sample analysis and records maintained on technical personnel. This policy must address how corrections are made to raw data records and how the lab ensures that records are kept securely from unauthorized manipulation, loss or damage during storage. The policy must also describe how the records will be transferred or maintained should the lab terminate operations or transfer ownership, and the length of time that records are kept. Labs are required to keep all documents for compliance with Chapter 252 for at least 5 years, unless a longer period of time is specified by permit or regulation. Labs are also required to maintain records in a manner accessible by the Department. The recordkeeping policy may be contained as a separate section of the lab's QM or within the lab's document control policy. See Sections 6 and 7, of this document for additional information and examples.

16. **Equipment Listing:** Labs may choose to include an equipment listing in their QM. The listing is accompanied by routine and preventive maintenance procedures, as well as how to troubleshoot problems. An equipment listing is not required to be in the laboratory's QM, however Chapter 252 does mandate that laboratories must maintain records of each item of equipment significant to the testing or analysis performed and does specify the manner in which certain pieces of equipment must be maintained (§252.306, §252.404(c)). Some labs choose to reference the location(s) of the equipment maintenance logbook(s) and provide general procedures for equipment maintenance in the QM. For example, the QM may list the information that must be recorded in the instrument logbooks, the information required in the autoclave run log, the frequency that required checks are performed on the autoclave, and how the performance of these checks are recorded. The equipment section of the QM may also describe the actions taken when instruments cannot be repaired.

16.1. **Example Laboratory Equipment Listing**

XYZ Laboratory maintains records for each item of equipment in bound laboratory notebooks. Each piece of equipment has a separate logbook. The logbooks are stored in the same area as the corresponding piece of equipment. When the logbooks filled, they are archived by the QA Officer. All equipment logbooks are subject to XYZ Laboratory's Document Control Policy. Each equipment logbook is uniquely identified with the equipment name, followed by a notebook number. For example, pH#1-001 indicates that the logbook is for pH meter #1, and it is the first logbook used to document maintenance of the meter. All logbooks are numbered in sequential order, such that the next notebook in the example above would be pH#1-002. If an instrument malfunctions, analysts should refer to the manufacturer's instructions and the logbook's maintenance history for guidance. If the instrument continues to malfunction, the analyst must inform the QA Officer, and the

instrument will be taken out of service. The item will be clearly marked "Out-of-service", and the QA Officer will ensure that the item is repaired or replaced.

Each equipment logbook must contain the following information:

1. The name of the item
2. The manufacturer's name, type identification and serial number or other unique identifier
3. The date received and place into service, if the information is available
4. The equipment's location in the laboratory
5. The equipment's condition when received, if the information is available (i.e. new, used, reconditioned)
6. The location of the manufacturer's instructions
7. The date and details of maintenance performed
8. A history of any damage, malfunction, modification, or repair
9. The dates of calibration, concentrations of calibration standards, lot numbers of stock standards used, responses or instrument readings, and all other pertinent information from instrument calibrations and calibration verifications.
10. All entries into the laboratory notebooks must be initialed and dated by the individual making the entry

Certain pieces of equipment require specialized information. If more documentation is required by regulation for certain equipment, specific instructions will be given on the first page of the equipment logbook. For example, additional records must be maintained for autoclaves, and the instructions for recording information are located on the first page of the autoclave logbook.

The laboratory maintains the following pieces of equipment:

- Autoclave
- Water Bath Incubator
- 35ºC Hot Air Incubator
- pH Meter – #1
- pH Meter – #2
- Ammonia Meter
- D.O. Meter – stationary
- D.O. Meter – field meter
- 20ºC BOD Incubator – #1
- 20ºC BOD Incubator – #2
- Top-loading pan balance
- Analytical balance
- 105ºC Drying oven
- Muffle furnace
- COD Spectrophotometer
- 4ºC Sample Refrigerator – #1
- 4ºC Standard Refrigerator – #2
- -10ºC Standard Freezer

Appendix A:

Corrective Action Report Form

Corrective Action # _____

Section 1: Origination

Sample ID #:_____ Date Analyzed:_____

Analyte/Result:_____ Analyst:_____

Data Reviewer/Approver:_____ Date Reviewed:_____

Target Date for completion of corrective action:_____

Type of Failure or Departure from Standard Procedures (Check all that apply):

[ ] Chain of Custody [ ] Data Inquiry [ ] Customer Complaint [ ] SOP (SOP#____) [ ] QC Failure [ ] PT Failure (PT#_____) [ ] Sample Receipt

[ ] Analytical Observation [ ] Permissible Departure (QA Initials_____)

[ ] Other _____

Description of Occurrence: _____

_____

Policy Modification Required:_____

_____

Section 2: Action

Action Taken (Check all that apply):

[ ] Data Reviewed [ ] Data Recalled [ ] Data User Notified

[ ] Sample Reanalyzed [ ] Analyst Training [ ] Equipment Service

[ ] Other _____

Reanalyzed Result:_____ Date:_____

Comments:_____

_____

_____

Completed by:_____ Date:_____

Signature:_____

Section 3: QA

QA Comments:_____

_____

_____

Attachments: [ ] Yes [ ] No # of pages:_____ [ ] Data User Contacted [ ] Data Amended

Corrective Action Classification: [ ] Analytical Confirmation – Confirmed [ ] Yes [ ] No

[ ] Reporting Error [ ] Calculation Error [ ] QC Exceeded limits [ ] Documentation

[ ] Timeliness of analysis [ ] Materials [ ] Training need [ ] SOP [ ] Equipment

[ ] Other _____

QA Officer Signature:_____ Completion Date:_____

Appendix B: Example Sample Receipt Log/Chain of Custody

Client/Project Information:

Name: Good Client
Address: 123 Quality Lane
Harrisburg, PA 17110
Phone #: 717-555-1234

Sample Condition Information:

Sample Temp: 4 °C
Ice Present?: Y N N/A
Legal Seal?: Y N
Bottles intact?: Y N

XYZ Laboratory Sample Receipt Form

- Form to be completed by laboratory staff upon receipt of sample to lab.
- A separate form is required for each client and each cooler.
- All observations must be noted on this form in blue or black ink.
- For samples that do not meet sample acceptance criteria, contact the Lab Supervisor for further instructions

Sample Information:

NOTE: Information in this category is taken directly from the sample bottle or from the sample collector.

PWSID# is required for all DW samples.
PWSID#: _____

Lab ID Code	Sample Description	Collector	Date	Time	Sample Type: Drinking Water	Sample Type: Wastewater	Sample Type: Soil	Sample Type: Other	# of Containers	Volume (mL)	Preservation: Unpreserved	Preservation: H_2SO_4	Preservation: HNO_3	Preservation: HCl	Preservation: NaOH	Preservation: $Na_2S_2O_3$	Preservation: Other	pH Check: <2	pH Check: >12	pH Check: N/A	Comments:
1254A	Outfall 001-grab	John Smith	5/5/10	8:36am		x			1	500	X									x	Sample split in lab*
1254B	Outfall 001-grab	JS	5/5/10	8:37am		X			2	100						X					Fecal Coliform—short hold
1255	Outfall 002—comp.	JS	5/5/10	9:01am		X			2	1000		X						N			preserved in sample receiving**

Sample Receipt Information:

Received In Lab By: Mary Jane Jones (Name) 5/5/10 (Date) 11:05am (Time)

Form completed by: Mary Jane Jones

Other Comments:

* 1234A-sample split for metals and inorganics, metals sample preserved in metals laboratory (see log in metals lab)

** 1255 was not properly preserved, both bottles preserved in sample receiving using H_2SO_4 lot# 25789B to pH<2