On-site Assessment Guidance

Disclaimer: The information in this guidance document does not supplant the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252 or the TNI Standard. This document is a tool to help laboratories comply with Chapter 252 and the TNI Standard. If there is any disagreement between the contents of this document and Chapter 252 and the TNI Standard, the regulations or standard shall prevail. The examples given in this document are for illustrative purposes only, meant to aid individuals in visualizing applications of the regulatory requirements. These examples do not represent all method or regulatory requirements.

1. General – On-site Assessment (§ 252.601):

   The on-site assessment is the evaluation process used to measure or establish the performance, effectiveness, and conformance of the laboratory and the laboratory's procedures to the regulatory requirements of 25 PA Code Chapter 252 and/or the TNI Standard. The on-site assessment is an integral and requisite part of the accreditation process and is one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team collects and evaluates information and makes observations which are used to determine the laboratory's conformance with Chapter 252 and/or the TNI Standard.

   This guidance document describes the typical procedures and requirements for the on-site assessment and provides guidance to laboratories regarding the on-site assessment process. This guidance document also provides examples of an on-site assessment report and examples of a laboratory's response to the on-site assessment report.

   Chapter 252 requires an initial on-site assessment of each facility before the PA-DEP Laboratory Accreditation Program (LAP) may grant accreditation to an environmental laboratory. The LAP generally performs on-site assessments every two to three years after the initial on-site assessment. Additional on-site assessments may be performed at the Department's discretion. The LAP may perform announced or unannounced on-site assessments.

2. Pre-on-site assessment planning:

   Prior to an announced on-site assessment, the lead assessor contacts the laboratory to verify the date of the on-site assessment. The purpose of the verification is to ensure that the laboratory's key personnel, such as the laboratory supervisor(s) and quality assurance officer(s) are available.

   The lead assessor sends a confirmation letter to the laboratory prior to the announced assessment. The confirmation letter will identify the date of the assessment, the estimated time of arrival of the team, and the composition of the assessment team. The confirmation letter will also provide specific instructions and outline documentation that must be provided to the LAP prior the on-site assessment.

   2.1 Documents that are requested prior to the on-site assessment may be provided in hard copy or printed format or electronically unless otherwise specified in the notification letter provided by the Department. If the laboratory provides the documentation in an electronic format, it is the responsibility of the laboratory to ensure that the Department will not require specialized instrumentation/software to view the data. Any data should be provided in .PDF format. The lead assessor will describe the required format for the documentation in the pre-on-site letter. This documentation may include:

2.1.1 Copies of the laboratory's current Quality Manual and related quality SOPs.

2.1.2 Copies of the laboratory's analytical SOPs for all applied methods.

2.1.3 A listing of laboratory personnel and their assigned laboratory duties. This list should include all personnel responsible for supervision of the laboratory, sample receipt, sample preparation, sample analysis and reporting, and any other key laboratory personnel such as information technology personnel, project managers, and client services personnel. Any non-standard schedules for the laboratory personnel should be identified on the personnel listing. The laboratory may also provide an organization chart.

2.1.4 Copies of requested laboratory data and sample reports. The assessment team may review any data from the previous five years. The assessment team may request selected data and sample reports to be provided prior to the on-site or to be gathered and available for review during the on-site assessment. The data may be selected from laboratory sample reports or from data submitted to the Department for drinking water supply systems. Generally, the assessment team will select a period of time for which the data is requested. If the laboratory has not analyzed any samples during that period of time, then the laboratory should choose a sample analyzed as close to that date as possible.

The laboratory must supply all appropriate supporting documentation for the requested sample data (NOTE: The lead assessor may specify that the laboratory should have the documentation available on-site rather than sending it to the LAP):

- Calibration Curve used for the requested samples,
- All batch QC associated with each sample (e.g. Laboratory Fortified Blank, Laboratory Reagent Blank, Continuing Calibration Checks, Matrix Spikes),
- Copy of the Chain of Custody(s) for the referenced samples,
- Copy of the final reports provided to the client for the referenced samples,
- Any digestion, extraction, distillation, and/or other sample preparation logs for the reference samples,
- All reagent and standard preparation logs for the QC associated with the referenced samples, and
- Any additional supporting documentation that you feel may be necessary to reconstruct the analysis of the referenced samples.

Data should be separated into folders or clearly separated by tabs/clips/or other separation for each data package. If data will be submitted electronically, the laboratory should provide a minimum of two copies of the disks containing the data in .PDF format and a table of contents which clearly identifies the contents of the disk. The documentation contained on the disk(s) must be separated into individual files for each data package, at a minimum.

2.1.5 Instructions for any necessary clearances and/or admittance instructions to the laboratory. If the assessment team must park in a special area, must go to a guard station, or is required to provide specific identification, these instructions must be provided prior to the date of the assessment.

2.1.6 Directions to the laboratory. Special instructions and key landmarks to the laboratory are helpful to the assessment team.

2.1.7 For NELAP accredited laboratories only: completed NELAP Assessment Checklist. This checklist must be completed with appropriate citations documenting the location of each requirement within your laboratory's Quality System (Quality Manual and/or supporting quality system documents). If a specific person will need to be interviewed in reference to any of the questions on the checklist(s) you should indicate the individual to whom the assessor should speak. Provide the most complete list of references possible to fulfill the individual NELAP Quality Systems Checklist requirements. If the assessor is unable to find any of the documentation or procedures, it may be a deviation in the assessment report. An example of a completed NELAP Quality Systems Checklist is provided in **Appendix A**.

The NELAP Assessment Checklist is available to laboratories by request to the LAP. The checklist may be used to assist the laboratory with their internal audits and quality system reviews. Laboratories may complete the checklist at any time prior to the on-site assessment process. Completion of the checklist prior to the on-site will reduce some of the work required during the pre-on-site planning period.

Copies of all quality documents referenced in the NELAP Assessment Checklist must be provided to the assessment team. These copies will be retained by the Department for use when reviewing your laboratory's corrective action response.

2.1.8 Copies of selected proficiency testing ("PT") data and PT records. The assessment team will identify the PT studies that will be reviewed during the on-site. All of the study raw data (e.g. digestion/distillation/extraction logs, calibrations, chromatograms, instrument printouts, calculations, logs, etc.) and the associated QC raw data must be available for review at the time of the on-site assessment.

2.1.9 Copies of Limit of Detection ("LOD") or Method Detection Limit ("MDL") studies, Limit of Quantitation studies (NELAP only), Initial Demonstration of Capability, and Continuing Demonstration of Capability or Demonstration of Continued Proficiency study raw data. All of the sample and study raw data (e.g. digestion/distillation/extraction logs, calibrations, chromatograms, instrument printouts, calculations, logs, etc.) and the associated QC raw data must be available for review for these samples at the time of the on-site assessment.

2.1.10 Any changes or additions to the laboratory's application or Scope of Accreditation. Any changes to your accreditation and/or most recent application must be supplied to the Department along with the appropriate "Addition of Fields of Accreditation" fee of $250 and any appropriate category fee in accordance with Chapter 252, § 252.204(a).

NOTE: The pre-on-site planning period is not the appropriate time to begin to review and revise SOPs and laboratory procedures and to correct deficiencies. Laboratories must be in compliance at all times and review of laboratory procedures should routinely occur throughout the year. Recurring deficiencies that are corrected just prior to the on-site assessment may still be deviations in the on-site assessment report. The pre-on-site planning time is limited and should be used to prepare the pre-onsite package containing laboratory records and SOPs for submission to the Department.

3. On-site assessment:

Applicant laboratories are required to allow the Department and its representatives access to the laboratory. If the laboratory does not allow access to a member of the LAP who arrives to perform an announced or unannounced assessment during regular business hours, the LAP may revoke the laboratory's accreditation in accordance with Chapter 252, § 252.702(b)(14).

3.1 Opening Meeting

Prior to the beginning of the assessment, the assessment team will conduct an informal opening meeting with the laboratory's representative(s). The laboratory may have any laboratory personnel attend the opening meeting. It is recommended that at least the laboratory supervisor(s) and quality assurance officer(s) attend the opening meeting.

The opening meeting is conducted to explain the purpose and scope of the on-site assessment, procedures for the on-site assessment, and estimated length of the assessment. This meeting allows an opportunity for laboratory personnel to ask any questions they may have about the assessment process and review any procedures for safety, evacuation, and access to the laboratory.

3.2 General Laboratory Assessment

During the laboratory assessment, the assessment team will review the laboratory's documentation, equipment, supplies, procedures, facilities, and laboratory operations. The assessment team will appraise the laboratory through staff interviews, observations, and data and record reviews. The assessment team will be evaluating the laboratory's conformance to federal regulations, State regulations including 25 PA Code Chapter 252, the TNI Standard as applicable, and method requirements.

3.3.1. Records Review – The assessment team will review laboratory records for accuracy, completeness, and the use of proper methodology for each field of accreditation. These laboratory records must be on-site and available for review by the assessment team at the beginning of the on-site assessment. Records that are not available for review during the on-site assessment may be deviations in the assessment report.

3.3.2. Interviews – The assessment team will interview laboratory personnel for the applied fields of accreditation and laboratory procedures. The interviews with the staff include a discussion of laboratory procedures and documentation, training, compliance with laboratory standard operating procedures and regulatory requirements, and equipment and instrument maintenance and handling.

NOTE: The assessment team does not expect every analyst to be familiar with all aspects of the laboratory or analysis. Many laboratories have divisions of labor in which one analyst may prepare samples for analysis and another may analyze and report samples. The interview with the analyst will be performed to review the laboratory's procedures and to determine the analyst's compliance with his or her own individual responsibilities in the laboratory.

3.3 Closing Meeting

Prior to the completion of the assessment, the assessment team will meet with the laboratory's representative(s) in a closing meeting. The laboratory may have any laboratory

personnel attend the closing meeting. It is recommended that at least the laboratory supervisor(s) and quality assurance officer(s) attend the closing meeting.

The closing meeting is conducted to provide an informal debriefing and discussion of the assessment findings. The assessment team will review the findings from the assessment. The laboratory may discuss any of the findings with the assessment team and ask any questions about the assessment findings. Any disagreement that the laboratory has regarding the findings from the assessment should be discussed at this time.

The laboratory should take notes during the closing meeting. Deviations will be discussed during the meeting, and the laboratory should begin developing and implementing the corrective actions before receipt of the on-site assessment report. If the laboratory begins the corrective action process before the receipt of the report, it will have approximately 30 additional days to prepare the corrective action report than a laboratory that waits until the receipt of the report.

At the close of the meeting, the lead assessor will review the report and response procedures with the laboratory and answer any questions that the laboratory may have.

4. Reporting and Corrective Action Response:

After the conclusion of the on-site assessment, the assessment team will prepare an on-site assessment report outlining the deficiencies that were observed during the on-site assessment. Laboratories must prepare and submit corrective action reports ("CARs") in response to the on-site assessment report to the Department. These CARs must be a detailed explanation of the corrective actions implemented in the laboratory to correct the deficiencies in the on-site assessment report. The procedures and timelines for the on-site assessment report and CARs are detailed below.

4.1 On-site Assessment Report

The on-site assessment report is prepared by the assessment team and documents the deficiencies and recommendations discussed during the closing meeting. The on-site assessment report is the official record of the deviations found by the Department during the assessment and is titled "Report of an On-Site Assessment". The assessment report will be issued to the laboratory approximately 30 to 45 days following the completion of the on-site assessment visit.

4.1.1. Report of an On-site Assessment

The written on-site assessment report, "Report of an On-site Assessment," is prepared by the assessment team and documents the method deficiencies, any detailed Chapter 252 or TNI Standard deficiencies, and recommendations. An example of an On-site Assessment Report is provided in **Appendix B**.

4.1.1.1. List of Deviations – The list of deviations comprises the main body of the assessment report and identifies the deficiencies observed during the on-site assessment. The deviations cited may include general deviations from Chapter 252 and/or the TNI Standard and technical deviations related to specific methods or federal regulations. The laboratory must provide a corrective action response to all deviations cited in the on-site assessment report.

The report will also identify any repeat deviations in the report. Repeat deviations are deviations observed during the assessment that were cited during a previous assessment. Repeat deviations demonstrate that the laboratory did not correct deficiencies or implement the corrective actions from the previous assessment. Failure to correct deficiencies and/or failure to implement corrective actions are causes for revocation of accreditation.

4.1.1.2. Comments and Recommendations – Any comments or recommendations that the assessment team has for the laboratory are documented in the comments and recommendations section. The laboratory is not required to implement the recommendations. The laboratory may be required to respond to the comments, depending on the nature of the comment.

4.1.1.3. Corrective Action Required – The corrective action required section provides instructions for the corrective action report and identifies the documentation that must be submitted to the assessment team to demonstrate correction of the deviations. This documentation may include copies of laboratory SOPs, copies of laboratory data, and copies of other laboratory documentation or procedures. The laboratory is required to provide all requested documentation. If this documentation is not provided, or unsatisfactory, the Department may suspend or revoke accreditation.

4.1.2. Out-of-State Reimbursement (Out-of-State Laboratories only)

Applicant laboratories located outside the borders of the Commonwealth of Pennsylvania are required to reimburse the LAP for all on-site related expenses. The LAP provides an invoice outlining the required payment. If the laboratory does not pay the cost of the on-site assessment, the LAP will deny the applicant's application or revoke a currently accredited laboratory's certificate.

4.2 Corrective Action Report (CAR)

Laboratories must prepare and submit corrective action reports (CARs) to the Department. These CARs must:

- Include a detailed explanation of the corrective actions that the laboratory has either implemented or plans to implement. This should be in the form of a cover letter. If the laboratory intends to submit a plan for corrective action, then a timeline for completion of the corrective actions must also be included.
- Address each individual deviation itemized in the assessment report.
- Ensure that the corrective action for the deviations ensures that they do not recur and are appropriate to the cited deficiencies.
- Include a summary of investigations taken to identify and correct any similar deviations not listed as examples in the assessment report.
- Include all requested documentation outlined in the "Corrective Action Required" section of the assessment report.

The laboratory must identify each corrective action according to the sub-section label assignment outlined in the assessment report or the number in the first column of the deviation number. An example of a laboratory CAR is provided in **Appendix C**. The CAR in Appendix C corresponds to the Report of an On-site Assessment in Appendix B.

When preparing the CAR, the laboratory must make sure that the corrective actions address the entire deviation, not just the examples of the deviation that were identified in the assessment report. For example, the deviation is:

> *"The laboratory does not ensure that all working thermometers have been calibrated against the certified NIST thermometer annually. 'Working thermometers may be glass, dial or electronic and shall be calibrated against a certified NIST reference thermometer as follows: Glass, liquid filled thermometers shall be calibrated every 12 months at the temperature used [252.306(f)(2)(ii)(A)].' For example, the thermometer for the microbiology incubator and the thermometer for the total suspended solids oven have not been calibrated against the NIST thermometer."*

The following is an example of an unacceptable CAR:

> *"We now calibrate the thermometers in the microbiology incubator and the TSS oven."*

The laboratory must calibrate the thermometers for the incubator and oven against the NIST thermometer. But the example above does not respond to the actual deviation, just the examples of the deviation. How will the assessment team know that the laboratory is ensuring that all working thermometers have been verified against the NIST thermometer? The laboratory must submit documentation of the investigations taken to identify and correct any similar deviations that were not provided as examples in the report. The laboratory will need to search the laboratory and identify all working thermometers and make sure that all thermometers have been calibrated against the NIST thermometer. Therefore, an appropriate response to the deviation is:

> *"We investigated the laboratory and identified all working thermometers that have not been calibrated against the certified NIST thermometer. We assigned identification numbers to all thermometers in the laboratory and created a tracking sheet for the thermometer calibrations. Any new thermometers will be logged on the tracking sheet. All thermometers will be calibrated against our certified NIST reference thermometer every 12 months at the temperature used. As part of our investigation we identified three other thermometers that were not calibrated: the sample receiving refrigerator, the TKN digestion block, and the oil and grease oven. Attached is a copy of the thermometer calibrations for the incubator, solids oven, oil and grease oven, sample receiving refrigerator, and the TKN digestion block. "*

This response to the Department clearly responds to the entire deviation. The Department will know that the laboratory will ensure that all thermometers are calibrated against the NIST thermometer annually. In fact, as part of the investigation, three other thermometers that were not calibrated against the NIST thermometer were identified. An additional benefit to this investigation is that the laboratory will be less likely to have a repeat deviation during the next on-site assessment due to this pro-active corrective action.

When developing the corrective action plan and writing the CAR, the laboratory should think about how to correct the entire deviation and ensure that the deviation will not recur. **If the laboratory does not understand a deviation or has any questions about how to develop a corrective action for the deviation, the laboratory should contact the accreditation officer or a member of the assessment team.** If the laboratory has

questions, it must be sure to contact the accreditation officer before the response deadline and before submission of the response. The report deadlines must be met, and the CAR must identify the corrective actions. The CAR is not the appropriate place to challenge deviations or ask questions. If a laboratory fails to respond with an appropriate corrective action, the response will not be acceptable. If the laboratory believes the assessment team made a mistake or misunderstood something that resulted in a deviation, the laboratory should contact the lead assessor and express the concern immediately. Do not wait to respond in the CAR.

Laboratories are not required to correct all deficiencies by the deadline for the submission of the CAR, unless clearly instructed to do so by the Department. Rather, laboratories must provide a corrective action plan and timeline for implementation of the corrective actions. **NOTE:** All deficiencies must be corrected within 120 days of receipt of the assessment report. The laboratory may choose to establish its own deadlines for correction of deficiencies as long as that timeframe does not exceed 120 days. Timelines and deadlines outlined in the laboratory's CAR must be met. The Department may grant extensions to the laboratory-established deadlines to submit supporting documentation, provided a written request is received at least ten (10) calendar-days before the original deadline.

The Department will not extend the timeline for submission of the CAR (see section 4.3 for specific requirements). The Department would only allow the laboratory to request an extension to provide documentation evidencing the implementation of the corrective actions. Requests may be filed via e-mail to **eplabaccredit@pa.gov**. Please do not e-mail your accreditation officer directly. The general e-mail account is monitored daily and will ensure a prompt response to your request.

4.3 Report and Response Timelines

Laboratories have timelines to respond to an on-site assessment report. These timelines vary depending on whether the laboratory holds State (Chapter 252) or NELAP accreditation. All laboratories must respond to the on-site assessment report with a written CAR that documents the corrective actions taken to correct each deficiency. Unless otherwise approved by the Department, all deficiencies must be corrected within 120 calendar days of the receipt of the on-site assessment report. The Department does not offer extensions for deadlines outlined in Chapter 252, § 252.601.

4.3.1. State (Chapter 252) Accreditation

State Accredited laboratories must respond to an on-site assessment report within 60 calendar days of the receipt of the on-site assessment report. The Department will review and respond in writing to the written CAR. If any portion of the CAR is not acceptable, but does not warrant enforcement action such as suspension or revocation, the laboratory must submit a revised CAR within 30 calendar days of receipt of the Department's response. Failure to respond to the assessment findings or failure to submit an acceptable CAR within timeframes indicated may result in revocation of the laboratory's accreditation as a State accredited laboratory.

4.3.2. NELAP Accreditation

NELAP Accredited laboratories must respond to an on-site assessment report within 30 calendar days of the receipt of the report. The Department will review and respond in writing to the written CAR. If any portion of the CAR is not acceptable, the laboratory

must submit a revised CAR within 30 calendar days of receipt of the Department's response. Failure to respond to the assessment findings or failure to submit an acceptable CAR within timeframes indicated may result in revocation of the laboratory's accreditation as a NELAP accredited laboratory.

NOTE: The Department is not required to grant a laboratory the "corrective action report" process outlined in § 252.601 of Chapter 252 if the laboratory's violations are such that denial, suspension, or revocation is warranted. Please refer to Subchapter G—Miscellaneous Provisions of Chapter 252 for reasons for denial, suspension, and revocation.

5. On-site Assessment Closure:

After the LAP reviews the completed corrective actions reported by the laboratory, the Chief of the LAP makes the final determination of the accreditation status for the laboratory and notifies the laboratory of that determination in writing. The determination based on the on-site assessment may include one or more of the following: granting of accreditation, denial of application, revocation of accreditation, and suspension of accreditation.

5.1 Granting of Accreditation

If the final determination of the assessment indicates that the laboratory meets the minimum requirements for the Department to grant or continue accreditation, the laboratory will receive or retain a Certificate of Accreditation awarded by the Department. The Certificate of Accreditation will contain a Scope of Accreditation, as an attachment, listing the specific fields of accreditation for which the laboratory has obtained or maintains accreditation.

For those fields of accreditation for which the laboratory has successfully completed an on-site assessment and has met the PT study requirements, the accreditation status will be listed as Accredited on the Laboratory Scope of Accreditation. A new and revised Scope of Accreditation will be issued with each change in Accreditation status. The laboratory may only perform the testing identified on the laboratory's Scope of Accreditation.

In accordance with Chapter 252 § 252.702(b)(2) and (3), failure to implement and maintain the corrective action plan may result in revocation of accreditation for fields of testing, specific methods, or analytes within those fields of testing. The LAP may perform follow-up on-site assessments to confirm compliance with Department regulations. These follow-up assessments may be unannounced.

5.2 Denial of Application

If the final determination of the assessment indicates that the laboratory does not meet the minimum requirements for the Department to grant accreditation, the laboratory's application for accreditation may be denied in accordance with Chapter 252 § 252.701.

5.3 Revocation of Accreditation

If the final determination of the assessment indicates that the laboratory does not meet the minimum requirements for the Department to continue accreditation, the laboratory's accreditation may be revoked in part or in total in accordance with Chapter 252 § 252.702.

5.4 Suspension of Accreditation

If the final determination of the assessment indicates that the laboratory does not meet the minimum requirements for the Department to continue accreditation, the laboratory's accreditation may be suspended in part or in total in accordance with Chapter 252 § 252.703.

Appendix A. Example Completed NELAP Assessment Checklist

Item		Reference	STANDARD REQUIREMENT	Y/N	Comments
		V1M2: 4	**MANAGEMENT REQUIREMENTS**		
		V1M2: 5.8.5	**Additional Requirements - Documentation**		
QS	163	V1M2: 5.8.5	The following are essential to ensure the validity of the laboratory's data:		
QS	164	V1M2: 5.8.5.a	The laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time.	Y	Sample Receiving SOP (#21), Section 2.0
QS	165	V1M2: 5.8.5.a	This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.	Y	Sample Receiving SOP (#21), Section 2.0
QS	166	V1M2: 5.8.5.b	This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample.	Y	Sample Receiving SOP (#21), Section 2.0
QS	167	V1M2: 5.8.5.c	The laboratory ID code shall be placed as a durable mark on the sample container.	Y	Sample Receiving SOP (#21), Section 2.0
QS	168	V1M2: 5.8.5.d	The laboratory ID code shall be entered into the laboratory records.	Y	Sample Receiving SOP (#21), Section 2.0
QS	169	V1M2: 5.8.5.d	The laboratory ID code shall be the link that associates the sample with related laboratory activities such as sample preparation.	Y	Sample Receiving SOP (#21), Section 2.0
QS	170	V1M2: 5.8.5.e	In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.	Y	Sample Receiving SOP (#21), Section 2.0
		V1M2: 5.8.6	**Additional Requirements - Sample Acceptance Policy**		
QS	171	V1M2: 5.8.6	The laboratory shall have a written sample acceptance policy that includes the following:	Y	Sample Receiving SOP (#21), Section 4.0
			a) proper, full, and complete documentation, which shall include:	Y	Sample Receiving SOP (#21), Section 4.1
			--Sample Identification	Y	
			--Location	Y	
			--Date and Time of Collection	Y	
			--Collector's Name	Y	
			--Preservation Type	Y	
			--Sample Type	Y	
			--Any special remarks concerning the sample	Y	
			b) proper sample labeling to include:	Y	Sample Receiving SOP (#21), Section 4.2
			--Unique Identification	Y	
			--A labeling system for the sample with requirements concerning the durability of labels (water resistant) and the use of indelible ink	Y	
			c) use of appropriate sample containers;	Y	Sample Receiving SOP (#21), Section 4.3
			d) adherence to specified holding times;	Y	Sample Receiving SOP (#21), Section 4.4
			e) sufficient sample volume to perform the necessary tests;	Y	Sample Receiving SOP (#21), Section 4.5
			f) procedures to be used when samples show signs of damage, contamination or inadequate preservation; and	Y	Sample Receiving SOP (#21), Section 4.6
			g) qualification of any data that do not meet the above requirements.	Y	Sample Receiving SOP (#21), Section 4.7 Reporting SOP (#10), Section 2.0

Appendix B. Example On-site Assessment Report

REPORT OF AN ON-SITE ASSESSMENT
ASSESSMENT SUMMARY

DEP ID # 99-99999
Example Laboratory
123 Example Road
Harrisburg, PA 17105
March 1, 2014

Laboratory Accreditation Program
Commonwealth of Pennsylvania
Department of Environmental Protection
Bureau of Laboratories
P.O. Box 1467
Harrisburg, Pennsylvania 17105-1467

INTRODUCTION

The equipment and procedures employed in the analyses of environmental samples by this laboratory were examined for conformance with the provisions of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with environmental laboratory accreditation) (27 Pa C.S. Sections 4101 – 4113) and 25 Pa Code Chapter 252. Those items cited under the following sections are contrary to the regulations and must be changed to comply with the regulations and promulgated methods in order for this laboratory to maintain status as an accredited laboratory.

CORRECTIVE ACTION REQUIRED

In order to demonstrate that the laboratory has corrected the deviations identified in the List of Deviations, the laboratory shall provide a detailed explanation of the corrective actions implemented in the laboratory to assure that these deviations do not recur. The laboratory must also submit documentation of the investigations taken to identify and correct any similar deviations not provided as examples in the List of Deviations. The laboratory shall identify each corrective action according to the Deviation number. For example: Deviation G10.

Standard Operating Procedures Required
The laboratory shall provide copies of the following Standard Operating Procedures (SOPs) to the Department. The laboratory must also provide documentation that the analyst has read, understands, and is performing the method as written in the SOP.

1. SM 2540D
2. SM 5210B
3. HACH 8038

Data and Supporting Documentation Required
The laboratory shall provide data for the following test methods as indicated. The data shall include all necessary supporting documents to reconstruct the test results.

1. 2 days for SM 2540D
2. 2 days for SM 5210B
3. 2 days for HACH 8038

Additional Information and Other Documentation Required
The laboratory shall provide the following documentation to the Department:

1. Documentation that each employee has read, understood, and is using the correct versions of SOPs and QM
2. Distillation Records for Ammonia
3. Thermometer calibration records for the microbiology incubator thermometer

4. Sample Acceptance Policy
5. Membrane filter records
6. Detection Limit Studies for Ammonia and Total Phosphorus

ANALYTICAL METHODOLOGY REVIEWED

SM 9222D	SM 2540D	HACH 8038	HACH 8048
SM 2540G	EPA 160.4	SM 5210B	HACH 8190

LABORATORY SUPERVISORS AND QA

1. Jane Doe - Laboratory Supervisor
2. John Smith - Laboratory Supervisor
3. Mary Lou Miller - QA/QC Officer

PERSONNEL INTERVIEWED:

1. Jane Doe
2. John Smith
3. Mary Lou Miller
4. Dave Dunne
5. Betty Jones
6. Marvin Stone

ASSESSORS:

1. Lead Assessor
2. Assessor 2

_____
Lead Assessor
Laboratory Accreditation Officer
Department of Environmental Protection

REPORT OF AN ON-SITE ASSESSMENT

LIST OF DEVIATIONS

Example Laboratory, ID# 99-99999

Assessment Date(s): March 1, 2014

Deviation RM 1 Method-Specific Requirements **252.402, 403, 404, 405(b)**

Requirement:

When a method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

Example(s) of deviations to this requirement found during the assessment include:

1. See Deviation RM2

Deviation RM 2 Total Suspended Solids **SM 2540 D 19th Ed.**

Requirement:

Wash with three successive 10-mL volumes of reagent-grade water, allowing complete drainage between washings, and continue suction for about 3 min after filtration is complete [SM 2540 D.3.c].

Example(s) of deviations to this requirement found during the assessment include:

1. The laboratory only washes the filter one time.

Deviation G 11 Personnel Requirements **252.304(b)(3)(ii)**

Requirement:

The environmental laboratory management shall be responsible for ensuring and documenting that each employee has read, understood and is using the latest version of the laboratory's standard operating procedures that relate to each employee's job responsibilities.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory has documentation from March 2008 that laboratory personnel have read, understood and are using the quality manual and SOPs, however the quality manual and SOPs have been revised in August 2008 or later.

Deviation G 45 Working Thermometers **252.306(f)(2)(ii)(A)**

Requirement:

Glass, liquid filled thermometers shall be calibrated every 12 months at the temperature used.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The thermometer for the microbiology incubator and the thermometer for the total suspended solids oven have not been calibrated against the NIST thermometer.

Deviation G 56 Analytical or Pan Balances **252.306(f)(4)(i4)**

Requirement:

Balance calibration shall be verified using a minimum of three ASTM class 1, 2 or 3 (Class S or S-1) certified reference weights that bracket the effective range of the balance's use.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory does not calibrate the balance with a minimum of three weights that bracket the weighing needs of the balance.

Deviation G 101 **Standard Operating Procedures** **252.307(d)(1)**

Requirement:

The environmental laboratory's standard operating procedures must accurately reflect all aspects of the testing or analysis for the fields of accreditation, including the following:

(x) Reporting of results.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory's SOPs do not include or reference a procedure for the reporting of results.

Deviation G 118 Sample Acceptance Policy **252.401(g)**

Requirement:

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 areas required by 252.401(g)(1)-(6).

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The sample acceptance policy does not outline the circumstances under which the laboratory will accept of reject samples.

Deviation C 36 Laboratory Control Samples **252.402(h)(1)**

Requirement:

A laboratory control sample must be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory does not analyze a glucose/glutamic acid (GGA) standard with nitrification inhibitor for CBOD analysis when samples are analyzed for CBOD.

Deviation C 38 Laboratory Control Samples **252.402(h)(3)**

Requirement:

An environmental laboratory shall analyze a laboratory control sample at a minimum of one per preparation batch. When no separate preparation method is used, for example volatile in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together with the same method, personnel and lots of reagents.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. See Deviation C36.

Deviation C 44 Sample Duplicates **252.402(j)(2)**

Requirement:

A sample duplicate or matrix spike duplicate shall be analyzed at a minimum of one per preparation batch. When no separate preparation batch method is used, for example volatiles in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory does not distill sample duplicates or matrix spike duplicates for ammonia analysis by HACH 8038. The laboratory runs a second aliquot of the distilled sample for the sample duplicate.

Deviation C 53 Detection Limits **252.402(k)(3)**

Requirement:

A detection limit shall be initially determine for the compounds of interest in each method in matrix in which neither the target analyte nor interferences are at a concentration that would impact the results. The detection limit shall be determined in the matrix of interest.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory has not determined the detection limits for total phosphorus or ammonia.

Deviation M27 Culture Dishes **252.404(c)(1)(iii)**

Requirement:

An environmental laboratory shall verify the sterilization capability of each autoclave by utilizing appropriate biological indicators (for examples, spore strips or ampoules) once a month. Records of biological indicator tests shall be maintained in a laboratory notebook and include:

Autoclave identification,
Date,
Incubation time and temperature,
Results, and
Initials of the responsible individual.

Example(s) of deviations to this requirement found during the assessment include, but are not limited to the following:

1. The laboratory does not retain the documentation of the monthly autoclave sterilization.

Appendix C. Example Laboratory Corrective Action Report (CAR)

June 1, 2014

Chief - Laboratory Accreditation Program
Bureau of Laboratories
PO Box 1467
Harrisburg, PA 17105-1467

Re: Corrective Action Report
DEP Lab # 99-99999

Dear Chief:

On April 2, 2014, Example Laboratory received the Report of an On-Site Assessment from the Department's March 1, 2014 on-site inspection of our laboratory. We have investigated the deviations and have outlined the implemented and proposed corrective actions that we believe will correct the deviations. Additionally, for those deviations that have already been corrected, we have included the requested documents outlined in the "Corrective Action Required" section of the on-site report. For those deviations that we have not yet corrected, we have outlined a timeframe for completion. For those instances where examples were included in the Report of an On-Site Assessment, we have included our investigations to prove that other areas of the laboratory have been reviewed and similar deviations corrected.

LIST OF CORRECTIVE ACTIONS

RM1 & RM2: We have revised our TSS procedure to ensure that the filters are rinsed at least three times. (See Attachment #1 – SOP for TSS and Attachment #2 – two days of TSS data.) We will ensure that we review all SOPs on a regular basis and interview analysts to make sure that we are compliant with all method and program requirements.

G11: We have documentation for the training of each member of Example Laboratory. Each employee has read, understood and is using the latest versions of the SOPs and quality manual and has signed the SOP and Quality Manual review sheets. We have attached copies of the SOP and Quality Manual review sheets for your review. We have also reviewed each employee's training file and have developed a tracking spreadsheet to make sure our records are up-to-date. Anytime a new document or SOP is issued, we will make sure each employee signs-off for the document. We also plan to review each employee's training file every six months to ensure that we have the proper training records and that each employee's training is up-to-date. (See Attachment # 3 – Employee training records.)

G45: We investigated the laboratory and identified all working thermometers that have not been calibrated against the certified NIST thermometer. We assigned identification numbers to all thermometers in the laboratory and created a tracking sheet for the thermometer calibrations. Any new thermometers will be logged on the tracking sheet. All thermometers will be calibrated against our certified NIST reference thermometer every 12 months at the temperature used. As part of our investigation we identified three other thermometers that were not calibrated: the sample receiving refrigerator, the TKN digestion block, and the oil and grease oven. Attached is a copy of the thermometer calibrations for the incubator, solids oven, oil and grease oven, sample receiving refrigerator, and the TKN digestion block. (See Attachment # 4 – Thermometer Calibration.)

G56: We investigated all balance calibrations and identified two balances that were not calibrated with three weights. We now calibrate all balances in the lab with a minimum of three weights that bracket the weighing needs of the balance. Each balance has been numbered and a separate monthly calibration sheet is located next to each balance. Whoever is the first to use the balance each day must check the balance with three weights that encompass the weights used on the balance. We keep documentation of the calibration weights used, weight read on the balance, and the range of the reagent or sample weights determined to make sure the weights bracket the weighing needs. We also ordered one new set of weights so each balance has its own

weight set. We will review the sheets at the end of each month to make sure the correct weights are used. (See Attachment # 5 – Balance calibrations for May 2014.)

G101: We have reviewed all the chemistry SOPs (total suspended solids and volatile solids, ammonia, total phosphorus, and BOD) and have updated the procedures to include the reporting of results sections. We will review the microbiology SOP for membrane filtration by June 29, 2014 and update the SOP to include reporting of results. We will also review all SOPs annually to ensure that the SOPs accurately reflect lab procedures and meet the requirements of Chapter 252. (See Attachment 3 – SOPs for TSS, ammonia and BOD and Attachment 6 – Employee training records. The other SOPs are available upon request.)

G118: We are currently revising our sample acceptance polity to make sure that it clearly outlines the circumstances under which environmental samples will be accepted or rejected. We are comparing our acceptance SOP against the sample preservation and hold time table from 40 CFR Part 136. We will have this procedure completed by June 29, 2014. Upon completion, we will send you the updated SOP with the appropriate training records by July 3, 2014.

C36 & C38: We now run a glucose/glutamic acid (GGA) standard with nitrification inhibitor for the CBOD analysis when samples are analyzed for CBOD. We checked the other chemistry analyses in the laboratory and we were running the laboratory control samples (where appropriate) through all steps of the procedure. We updated the BOD SOP and revised our data sheets for BOD and CBOD. (See Attachment 7 – SOP for BOD and Attachment 8 – two days of BOD and CBOD data.)

C44: We now run a sample duplicate or matrix spike duplicate with each preparation batch of samples through all steps of the procedure. We are running duplicates for BOD, TSS, and volatile solids and running matrix spike duplicates for ammonia and total phosphorus. The duplicates are prepared in exactly the same manner as routine samples including preparation such as distillation or digestion. We are also ordering two additional distillation units for ammonia for the additional QC samples. (See attachment 9 – SOP for ammonia and Attachment 10 – ammonia distillation log and two days of data.)

C53: We have run the MDL studies for total phosphorus and ammonia. We will repeat the MDL studies for total phosphorus and ammonia anytime there is a change in the procedure. We do not need to perform MDLs for BOD, membrane filter, TSS and volatile solids because spiking solutions are not available for these analyses. (See Attachment 11 – MDLs for total phosphorus and ammonia.)

M27: We are now retaining complete documentation of the monthly autoclave sterilization verification. (See Attachment 12 – Copy of autoclave sterilization verification records for two months.)

In conclusion, we have done our best to correct the deviations found in our laboratory. We look forward to hearing from you. Feel free to drop in any time.

Sincerely,

Jane Doe
Laboratory Supervisor

Enclosures