DCLS TIP: **SEE page 5 & page 6 FOR THE TEXT OF THE FINDINGS ASSOCIATED WITH THIS 'SAMPLE CORRECTIVE ACTION PLAN'.**

ON-SITE ASSESSMENT

LABORATORY NAME: Sample Wastewater Laboratory (Chapter 45)

CORRECTIVE ACTION PLAN (CAP)

VELAP ID: 450001 SITE VISIT DATE(S): April 1-2, 2016

LABORATORY RESPONSE:

DCLS USE ONLY:

Checklist ID / Issue #	Lab's Corrective Action Plan	Expected Completion Date	Documentation to be submitted to DCLS to demonstrate implementation*	Plan Approval [Yes/No]	Description of Documentation Received	Doc Accepted [Date]
98 – Issue 1 (TSS)	1. Quality Manager will revise TSS SOP to include change in procedure to include cycle of redry/reweigh to constant weight and the evaluation criteria which must be met. 2. Quality Manager will revise TSS bench sheet to hold reweigh data and the evaluation data. 3. Lab Manager will train analysts on updates to procedure and documentation of training will be kept by lab.	6/1/2016	1. Updated SOP-TSS-002 2. Example of TSS bench sheet for recent sample, with redry/reweigh data and evidence of evaluation against stated criteria 3. Copy of sign-off sheet showing TSS analysts have read and understood changes to SOP			
98 – Issue 2 (CBOD)	1. Quality Manager will revise CBOD SOP to reflect the requirement	6/1/2016	1. Updated SOP-CBOD-003 2. Example CBOD bench sheet showing duplicate analysis and			

DCLS TIP: Corrective Action (CA) **almost always** requires an update to the SOP or Quality Manual **and** evidence that the action has been implemented in day-to-day work. (An exception would be when the SOP indicates the required action but at the time of the assessment, it was not being followed as stated in the SOP.)

Adding procedural changes to the SOP or Quality Manual provides documentation to current staff for immediate use and makes the job of training new staff much easier.

	for sample duplicates at a rate of 5% of samples, or one per batch, whichever is more frequent, and will include the evaluation criteria for duplicates. 2. Quality Manager will review data to assure duplicate analysis is done at required rate 3. Lab Manager will train analysts on updates to procedure and documentation of training will be kept by lab.		data review 3. Copy of sign-off sheet showing CBOD analysts have read and understood changes to SOP			
738	1. A documented corrective action (CA) will be done for failed PT study due to nonparticipation 2. The Quality Manager will update the Quality Manual to specify that all failed PT studies require a corrective action 3. The Quality Manager will make a month-by-month list of things that must be done periodically and include dates and reminders about ordering	6/1/2016	1. Copy of corrective action 2. Updated Quality Manual 3. Copy of sign-off sheet showing staff members have read and understood changes to QM 4. Copy of month-by-month list			

DCLS TIP: When planning Corrective Actions, think about covering POLICY AND PRACTICE, and then TRAINING staff on changes. Generally more than one action is required to complete a corrective action plan for a finding.

After you list the 'steps' to the Corrective Action, think about how you will document that each step was implemented. This DOCUMENT is what you send to DCLS in order to show that implementation is complete, so that the finding can be 'closed'. Sometimes a verbal instruction or 're-training' is required. In this case, meeting minutes, memorandum to staff, or demonstration of competency forms will be sufficient.

	PTs. 4. All staff will review and sign the revised QM					
18	1. The Quality Manager will make a month-by-month list of things that must be done periodically and include annual Quality Manual Review	6/1/2016	1. Copy of month-by-month list 2. Quality Manual showing current review status			
361	1. Sterility checks for new lots of sample containers for Colilert testing will be described in the Colilert SOP. 2. Supplies such as sample containers that require per-lot validation will be logged into the Reagent log so that notations about sterility testing can be recorded. The Reagent Log will become the "Reagent and Supplies Log" 3. Lab Manager will train analysts on updates to procedure and documentation of training will be kept by lab.	6/1/2016	1. Updated SOP-Colilert-007 2. Example of Reagent/Supply log showing sterility check done on current lot of sample containers (to include lot # of media used) 3. Copy of sign-off sheet showing Colilert analysts have read and understood changes to SOP			

DCLS TIP: Sometimes CAs will address multiple issues at once. Note the overlap in #738 and #18 and #122. **Be sure to label documentation that is submitted for 'overlapping' CA's with all applicable finding numbers.**

122	1. The Quality Manager will add the quarterly verification of dispensing devices to the month-by-month list of things that will be done periodically [See #18]. 2. The Quality Manager will create a list of all dispensing devices to assure that none are omitted in future quarterly checks.	6/1/2016	1. Copy of month-by-month list 2. Copy of list of dispensing devices 3. Copy of most recent calibrations done for dispensing devices			
101	1. A DOC has been done for all testing performed by our new analyst. This DOC is filed in the analyst's training file. 2. The Quality Manual has been updated to state that an analyst must have completed Demonstrations of Capability prior to being authorized to perform customer samples. 3. All staff will review and sign the revised QM.	6/1/2016	1. Copy of DOCs for new employee 2. Updated Quality Manual 3. Copy of sign-off sheet showing all staff members have read and understood changes to QM			

* Include Quality Manual, SOPs, bench sheets, training records, meeting notes, etc. as relevant to demonstrate full implementation of corrective action. Typical corrective actions require updates to POLICY/PROCEDURE + PRACTICE, accompanied by STAFF TRAINING, for full implementation.

DCLS expects to see evidence of implementation of corrective action plans. **For certification under 1VAC30-45, refer to 1VAC30-45-390 D and 1VAC30-45-100 B regarding the laboratory's responsibility for corrective actions. For accreditation under 1VAC30-46, refer to NELAC 2003 4.1.3 and 1VAC30-46-100 B.**

PLEASE NUMBER INDIVIDUAL ACTION ITEMS AND DOCUMENTATION ITEMS WITHIN A CORRECTIVE ACTION, as shown in the example.
See the Corrective Action section of the VELAP web page (www.dgs.virginia.gov/dcls) for additional information and CAP examples.

RELATED "SAMPLE FINDINGS":

98. 1VAC30-45-730 D 2: Test methods. The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample handling, transport and storage, preparation and analysis). The method and procedures shall be consistent with the accuracy required and with any standard specifications relevant to the calibrations or tests concerned.

OBSERVATION: The following test procedures were inconsistent with reference method specifications:

ISSUE #1: Total Suspended Solids: -The cycle of drying, cooling, desiccating, and weighing was not repeated for filter preparation until a constant weight was obtained or until the weight change was less than 4 percent of the previous weight or 0.5 mg, whichever is less (SM 18th Ed. 2540D 3.a.).

ISSUE #2: BOD/CBOD: -For the analyses of Biochemical Oxygen Demand (BOD) and Carbonaceous Biochemical Oxygen Demand (CBOD), the laboratory did not demonstrate that sample duplicates were analyzed at a frequency of 5% or more of samples as indicated by the reference method (SM 18th 1020B 6).

738. 1VAC30-45-520 D 1: Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document the investigation and action taken in its own records.

OBSERVATION: The laboratory could not provide records demonstrating that an investigation and corrective actions had been performed for the failed proficiency testing (PT) results obtained due to failure to participate in a PT study within the required six month timeframe.

18. 1VAC30-45-610 C 2: The quality assurance manual shall be reviewed and approved by the quality assurance officer, the laboratory manager, and the responsible official at least annually.

OBSERVATION: The Quality Manual had not been reviewed and approved since originally issued in September 2009.

361. 1VAC30-45-791 A 4: Microbiological sterility checks and blanks. Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers.

OBSERVATION: The laboratory did not demonstrate that a sterility check using a nonselective growth medium such as tryptic soy, trypticase soy, or tryptone broth was analyzed on one container for each lot of purchased sample containers.

122. 1VAC30-45-740 D 1 E: Calibration - Support Equipment. Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.

OBSERVATION: The laboratory could not provide documentation that the mechanical pipettors had been checked for accuracy on a quarterly basis.

101 1VAC30-45-730 E 1: Demonstration of capability. Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required. This demonstration does not test the performance of the method in real world samples, but in an applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking water, solids, biological tissue and air. Laboratories shall follow the procedure in subsection F (1VAC30-45-730 F) of this section to demonstrate capability.

OBSERVATION: The laboratory did not provide evidence that initial demonstrations of capability (DOCs) were performed by all analysts for certified analyses.

NOTE: Per 1VAC30 45 730 E 4, the laboratory shall complete and retain a certification statement for each DOC performed, and all associated supporting data shall be retained. A copy of the Demonstration of Capability Certification Statement Form may be obtained from the VELAP website.