Commonwealth of Virginia
Department of General Services
Division of Consolidated Laboratory Services
Richmond, Virginia

Onsite Assessment Corrective Action Plan (CAP) Form

DCLS TIP: SEE page 4 & page 5 FOR THE TEXT OF THE FINDINGS ASSOCIATED WITH THIS 'SAMPLE CORRECTIVE ACTION PLAN'.

LABORATORY NAME: Sample Wastewater Laboratory (Chapter 45) VELAP ID: 450001 Site Visit Date(s): April 3-4, 2018

Checklist ID / Issue #	Lab's Corrective Action Plan – *include sufficient detail to communicate the plan has addressed the non-conformity observed in a manner to prevent recurrence**	Expected Completion Date	Documentation to be submitted to DCLS [IF REQUESTED] to demonstrate implementation**	VELAP USE ONLY			
				Plan Approval [Yes/No]	Documen-tation requested? [Yes/No]	Description of Docs Received recorded in PROD? [Yes/No]	Doc Accepted [Date]
930 – 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.	08/01/2018	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.				
930 – Issue 2 (CBOD)	1. . Quality Manager will revise CBOD SOP to reflect the requirement for sample duplicates at a rate of every 20 samples, or one per batch, whichever is more	08/01/2018	1. Updated SOP-CBOD-003. 2. Example CBOD bench sheet showing duplicate analysis and data review. 3. Copy of sign-off sheet				

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.

	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 kept by lab.		showing CBOD analysts have read and understood changes to SOP.	
1207	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 PTs. 4. All staff will review and sign the revised QM.	08/01/2018	1. Copy of corrective action. 2. Updated Quality Manual. 2. Copy of sign-off sheet showing all staff members have read and understood changes to QM. 3. Copy of month-by-month list.	
856	1. The Quality Manager will make a month-by-month list of things that must be done periodically and include annual Quality Manual Review.	08/01/2018	1. Copy of month-by-month list. 2. Quality Manual showing current review status.	
1100	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	08/01/2018	1. Updated SOP-Colilert-007. 2. Example of Reagent/Supply log showing sterility check done on current lot of sample containers (to	

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.

DCLS TIP: Sometimes CAs will address multiple issues at once. Note the overlap in #1207 and #856 and #973. **Be sure** to label documentation that is submitted for 'overlapping' CA's with **all applicable finding numbers.**

	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.		include lot # of media used). 3. Copy of sign-off sheet showing Colilert analysts have read and understood changes to SOP				
973	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 #856]. 2. The Quality Manager will create a list of all dispensing devices to assure that none are omitted in future quarterly checks.	08/01/2018	1. Copy of month-by-month list. 2. Copy of list of dispensing devices. 3. Copy of most recent calibrations done for dispensing devices.				
933	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.	08/01/2018	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 description of updates to Quality Manual, SOPs, bench sheets, training records, 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.

** **IF VELAP REQUESTS SUBMISSION OF DOCUMENTATION AFTER REVIEW OF THE SUBMITTED PLAN, PLEASE LABEL ALL DOCUMENTS SUBMITTED TO CORRESPOND WITH THE CHECKLIST ID / ISSUE #. Please do not submit documentation unless requested. Documentation not submitted will be reviewed at the next on-site assessment.** **See the Corrective Action section of the VELAP web page (www.dgs.virginia.gov/dcls) for additional information and CAP examples.**

RELATED "SAMPLE FINDINGS":

930. 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.

THE FOLLOWING DEVIATIONS FROM THE REFERENCE METHODS AND/OR LABORATORY'S STANDARD OPERATING PROCEDURES (SOPs) WERE OBSERVED:

Residue-Nonfilterable Total Suspended Solids (TSS) by SM 2540 D-2011 in Non-Potable Water:

ISSUE 1: Section 3.c. of SM 2540 D-2011 states, "Repeat the cycle of drying, cooling, desiccating, and weighing until a constant weight is obtained or until the weight change is less than 4% of the previous weighing or 0.5 mg, whichever is less." At the time of the assessment, the analyst interviewed stated that when weighing sample filters for analysis, the cycle of drying, cooling, desiccating, and weighing was performed two times and then the larger filter weight was used to calculate the TSS.

Carbonaceous Biochemical Oxygen Demand (CBOD) by SM 5210 B-2011 in Non-Potable Water

ISSUE #2: Section 2.f of SM 5020 B-2010 states, "Include at least one duplicate for each matrix type daily or with each batch of 20 or fewer samples." 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 each batch of 20 or fewer or more of samples as indicated by the reference method.

1207. 1VAC30-45-520 C 1: When a laboratory receives a PT study result of "not acceptable,", the laboratory shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request.

OBSERVATION: The laboratory did not consistently perform a corrective action when proficiency test (PT) results were not acceptable. For example, at the time of the assessment, the laboratory could not provide corrective action documentation associated with the Non-Participation study for Carbonaceous Biochemical Oxygen Demand by SM5210B-2011 in Non-Potable Water which closed 02/18/18.

856. 1VAC30-45-610 D 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 laboratory did not demonstrate that the Quality Assurance Manual was reviewed and approved by the laboratory's management at least annually. Laboratory documentation indicated that the Quality Manual was reviewed by the Responsible Official, the Quality Assurance Officer, and the Laboratory Manager on 05/26/2016 and the next review was performed on 08/10/2018.

1100. 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, pre-sterilized containers with nonselective growth media.

The laboratory was not performing sterility checks on each lot of disposable sample collection bottles used for E. Coli by Colilert MPN prior to first use. For example, at the time of the assessment the laboratory could not provide documentation that a sterility check had been performed on the disposable sample collection bottles from lot # AN010 using a nonselective growth medium such as tryptic soy, trypticase soy, or tryptone broth.

973. 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 did not demonstrate that mechanical volumetric dispensing devices had been checked for accuracy on at least a quarterly basis. For example, laboratory documentation indicated that three pipettors in use in the laboratory had not been verified since October 2017. The laboratory staff interviewed indicated that the laboratory did not have plans to verify the dispensing accuracy of these pipettors until October 2018.

933 1VAC30-45-730 E 1: Demonstration of capability. Prior to acceptance and institution of any test method, satisfactory initial 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), for example, 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.